

**UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF NORTH CAROLINA
1:17-cv-00276-CCE-JLW**

THE UNITED STATES OF)
AMERICA, ex rel. JOSEPH M.)
THOMAS, bringing this Action on)
Behalf of the United States of America,)

Plaintiff,)

DUKE UNIVERSITY, DUKE)
UNIVERSITY HEALTH SYSTEM,)
INC., WILLIAM M. FOSTER, Ph.D.,)
and ERIN N. POTTS-KANT,)

Defendants.)

DEFENDANT WILLIAM M. FOSTER,
Ph.D.’s ANSWER TO AMENDED
COMPLAINT

Defendant William M. Foster, Ph.D. (“Foster”), through counsel, hereby answers Plaintiff’s Amended Complaint as follows:

1. The allegations in Paragraph 1 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

I. Introduction

2. The allegations in Paragraph 2 require no response. To the extent a response is required, the allegations are denied.

3. Foster denies the allegations in Paragraph 3.

4. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations that Duke University made certifications of accuracy and completeness of grant documents and certifications of compliance with Duke University’s policies and federal regulations governing research misconduct and therefore denies the same. Except as expressly admitted, Foster denies the remaining allegations in Paragraph 4.

5. Foster admits that during the time period relevant to the allegations in the Amended Complaint, he was involved in operating a laboratory for research at Duke University

and researchers at other institutions. Except as expressly admitted, Foster denies the allegations in Paragraph 5.

6. Foster denies the allegations in Paragraph 6.

7. Foster denies the allegations in Paragraph 7.

8. Foster denies the allegations in Paragraph 8.

9. Foster denies the allegations in Paragraph 9.

10. Foster denies the allegations in Paragraph 10.

II. Jurisdiction and Venue

11. Foster admits that this Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 and 31 U.S.C. §§ 3732 and 3730(b).

12. Foster admits that this Court has personal jurisdiction over Foster under 31 U.S.C. § 3732(a).

13. Foster admits venue is proper in this Court under 31 U.S.C. § 3732(a).

14. The allegations in Paragraph 14 call for legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

15. The allegations in Paragraph 15 call for legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

III. Parties and Other Key Players

A. Joseph M. Thomas

16. Foster admits the allegations in Paragraph 16 upon information and belief.

17. Foster admits the allegations in Paragraph 17 upon information and belief.

18. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 18 and therefore denies the same.

B. Duke University

19. Foster admits the allegations in Paragraph 19 upon information and belief.

C. DUHS

20. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 20 and therefore denies the same.

21. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 21 and therefore denies the same.

D. Erin N. Potts-Kant

22. Foster admits that Defendant Erin N. Potts-Kant (“Potts-Kant”) was an employee of Duke University. Foster admits that Potts-Kant was approximately 25 years old when she began working for Duke University. Foster further admits that Potts-Kant worked with him at the Airway Physiology Laboratory. Except as expressly admitted, Foster denies the allegations in Paragraph 22.

23. Foster admits that Potts-Kant subsequently served as the Clinical Research Coordinator II in the Pulmonary, Asthma and Critical Care Division (“Pulmonary Division”). Foster admits that what purports to be a true and accurate copy of the Job Description for Clinical Research Coordinator II at the Pulmonary Division is attached as **Exhibit A** to the Amended Complaint.

- a. Foster states that **Exhibit A** is in writing and speaks for itself. To the extent that the allegations of this subparagraph vary from the content of Exhibit A, they are denied.
- b. Foster states that **Exhibit A** is in writing and speaks for itself. To the extent that the allegations of this subparagraph vary from the content of Exhibit A, they are denied.

c. Foster states that **Exhibit A** is in writing and speaks for itself. To the extent that the allegations of this subparagraph vary from the content of Exhibit A, they are denied.

d. Foster states that **Exhibit A** is in writing and speaks for itself. To the extent that the allegations of this subparagraph vary from the content of Exhibit A, they are denied.

E. William Michael Foster, Ph.D.

24. Foster admits that he was a Research Professor of Medicine in the Pulmonary Division. Foster admits that Foster was an employee of Duke University. Foster admits that he was Potts-Kant's direct supervisor for certain work that she performed. Except as expressly admitted, Foster denies the allegations in Paragraph 24.

25. Foster denies the allegations in Paragraph 25.

F. Other Key Players

(i) The Foster Lab

26. Foster admits that the Pulmonary Department is within the Department of Medicine and includes researchers possessing advanced degrees.. Except as expressly admitted, Foster denies the allegations in Paragraph 26.

27. Foster admits that other researchers would submit experiments to the Foster Lab to be conducted. Expressly as expressly admitted, Foster denies the allegations in Paragraph 27.

28. Foster denies the allegations in Paragraph 28.

(ii) The Pulmonary Division

29. Foster admits that the Pulmonary Division is within Duke University's Department of Medicine and is made up of several researchers who possess advanced degrees and are sometimes referred to as "Principal Investigators" in the context of the research for

which they are responsible. Except as expressly admitted, the allegations of paragraph 29 are denied.

30. Foster admits that the institutional chart attached as **Exhibit A-1** sets out the relationships among Duke University, DUHS, and the relevant employees within the Pulmonary Divisions. Except as expressly admitted, Foster denies the allegations in Paragraph 30.

31. Foster admits that he was worked in the Pulmonary Division until his retirement in May 2015 and served as a Principal Investigator with regard to certain research projects. Except as expressly admitted, Foster denies the allegations in Paragraph 31.

32. Foster admits the allegations in Paragraph 32 upon information and belief.

33. Foster admits the allegations in Paragraph 33 upon information and belief.

34. Foster admits that Dr. Hollingsworth served as a Principal Investigator on certain research projects. Foster also admits that Dr. Hollingsworth supervised Potts-Kant on certain research projects. Except as expressly admitted, Foster denies the allegations in Paragraph 34.

35. Foster admits that Dr. Que served as a Principal Investigator on certain research projects. Except as expressly admitted, Foster denies the allegations in Paragraph 35.

36. Foster admits the allegations in Paragraph 36 upon information and belief.

37. Foster admits the allegations in Paragraph 37 upon information and belief.

38. Foster admits the allegations in Paragraph 38 upon information and belief .

39. Foster admits that Ms. Ingram worked at one time with Dr. Kraft. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 39 and denies the same.

40. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 40 and therefore denies the same.

41. Foster admits that Ms. Theriot worked in Dr. Walker's laboratory. Except as expressly admitted, Foster denies the remaining allegations of Paragraph 41.

42. Foster admits the allegations in Paragraph 42 upon information and belief.

43. Foster admits the allegations in Paragraph 43 upon information and belief.

(iii) Other Researchers

44. Foster admits the allegations in Paragraph 44.

45. Foster denies the allegations in Paragraph 45.

46. Foster admits that Dr. Soman Abraham (Department of Immunology, Pathology, and Molecular Genetics and Microbiology); Dr. Jo Rae Wright (Department of Cell Biology); Dr. Mary Sunday (Department of Pathology); Dr. Michael "Dee" Gunn (Department of Medicine, Cardiology); and Dr. Richard L. Auten (Department of Pediatrics) were Principal Investigators. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 46 and therefore denies the same.

IV. Legal Framework

A. The FCA

47. The allegations in Paragraph 47 call for legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

48. The allegations in Paragraph 48 call for legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

49. The allegations in Paragraph 49 call for legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

50. The allegations in Paragraph 50 call for legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

51. The allegations in Paragraph 51 call for legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

B. NIH Grants

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

52. Foster admits the allegations in Paragraph 52 upon information and belief.

53. Foster admits the allegations in Paragraph 53 upon information and belief.

54. Foster admits the allegations in Paragraph 54 upon information and belief.

(ii) The purpose of NIH grants.

55. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 55 and therefore denies the same.

56. Foster admits the allegations in Paragraph 56.

57. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 57 and therefore denies the same.

58. The allegations in Paragraph 58 require no response. To the extent a response is required, the allegations are denied.

59. The allegations in Paragraph 59 require no response. To the extent a response is required, the allegations are denied.

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

60. The NIH Grants Policy Statement is in writing and speaks for itself. The allegations in Paragraph 60 require no response. To the extent a response is required or the allegations in Paragraph 60 vary from the written terms of the NIH Grants Policy Statement, the allegations are denied.

61. The NIH Grants Policy Statement is in writing and speaks for itself. The allegations in Paragraph 61 require no response. To the extent a response is required or the

allegations in Paragraph 61 vary from the written terms of the NIH Grants Policy Statement, the allegations are denied.

62. The NIH Grants Policy Statement is in writing and speaks for itself. The allegations in Paragraph 62 require no response. To the extent a response is required or the allegations in Paragraph 62 vary from the written terms of the NIH Grants Policy Statement, the allegations are denied.

63. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 63 require no response. To the extent a response is required or the allegations in Paragraph 63 vary from the written terms of 42 C.F.R. Part 93, the allegations are denied.

64. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 64 require no response. To the extent a response is required or the allegations in Paragraph 64 vary from the written terms of 42 C.F.R. Part 93, the allegations are denied.

65. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 65 require no response. To the extent a response is required or the allegations in Paragraph 65 vary from the written terms of 42 C.F.R. Part 93, the allegations are denied.

66. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 66 require no response. To the extent a response is required or the allegations in Paragraph 66 vary from the written terms of 42 C.F.R. Part 93, the allegations are denied.

67. 42 C.F.R. Part 93 and 70 Fed. Reg. 28378 are in writing and speak for themselves. The allegations in Paragraph 67 require no response. To the extent a response is required or the allegations in Paragraph 67 vary from the written terms of 42 C.F.R. Part 93 or 70 Fed. Reg. 28378, the allegations are denied.

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

68. The allegations in Paragraph 68 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

69. The allegations in Paragraph 69 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

70. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 70 are legal conclusions to which no response is required. To the extent a response is required or the allegations in Paragraph 70 vary from the written terms of 42 C.F.R. Part 93, the allegations are denied.

71. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 71 are legal conclusions to which no response is required. To the extent a response is required or the allegations in Paragraph 71 vary from the written terms of 42 C.F.R. Part 93, the allegations are denied.

72. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 72 are legal conclusions to which no response is required. To the extent a response is required or the allegations in Paragraph 72 vary from the written terms of 42 C.F.R. Part 93, the allegations are denied.

73. The allegations in Paragraph 73 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

74. The allegations in Paragraph 74 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

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

75. The allegations in Paragraph 75 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

76. The allegations in Paragraph 76 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

77. The allegations in Paragraph 77 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

78. The allegations in Paragraph 78 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

79. The allegations in Paragraph 79 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

80. The allegations in Paragraph 80 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

81. The allegations in Paragraph 81 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

82. The allegations in Paragraph 82 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

83. The allegations in Paragraph 83 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

84. The allegations in Paragraph 84 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

85. The allegations in Paragraph 85 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

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

86. The allegations in Paragraph 86 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

87. The allegations in Paragraph 87 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

(vii) Institutional certifications relating to grant awards.

88. The allegations in Paragraph 88 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

89. The allegations in Paragraph 89 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

90. The allegations in Paragraph 90 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

91. The NIH grant application form (PHS 398) is in writing and speaks for itself. The allegations in Paragraph 91 require no response. To the extent a response is required or the allegations of Paragraph 91 vary from the terms of NIH grant application form (PHS 398), the allegations are denied.

92. The SF 424 (R&R) Grant Application Form is in writing and speaks for itself. The allegations in Paragraph 92 require no response. To the extent a response is required or the allegations of Paragraph 92 vary from the terms of SF 424 (R&R) Grant Application Form, the allegations are denied.

93. The Supplemental Grant Instructions For All Competing Applications and Progress Reports (the “Supplemental Grant Instructions”) are in writing and speak for themselves. The allegations in Paragraph 93 require no response. To the extent a response is required or the allegations of Paragraph 93 vary from the terms of the Supplemental Grant Instructions, the allegations are denied.

94. The allegations in Paragraph 94 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

95. The NIH Grants Policy Statement is in writing and speaks for itself. The allegations in Paragraph 95 require no response. To the extent a response is required or the allegations of Paragraph 95 vary from the terms of the NIH Grants Policy Statement, the allegations are denied.

96. The allegations in Paragraph 96 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

97. The allegations in Paragraph 97 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

98. The allegations in Paragraph 98 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

99. The grant progress report (PHS 2590) is in writing and speaks for itself. The allegations in Paragraph 99 require no response. To the extent a response is required or the allegations of Paragraph 99 vary from the terms of the grant progress report, the allegations are denied.

100. The allegations in Paragraph 100 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

101. The allegations in Paragraph 101 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

(vii) 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. The allegations in Paragraph 102 require no response. To the extent a response is required, the allegations are denied.

103. The allegations in Paragraph 103 require no response. To the extent a response is required, the allegations are denied.

104. The allegations in Paragraph 104 require no response. To the extent a response is required, the allegations are denied.

105. The allegations in Paragraph 105 require no response. To the extent a response is required, the allegations are denied.

106. The allegations in Paragraph 106 require no response. To the extent a response is required, the allegations are denied.

(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. The allegations in Paragraph 107 require no response. To the extent a response is required, the allegations are denied.

108. The allegations in Paragraph 108 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

109. The allegations in Paragraph 109 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

110. The allegations in Paragraph 110 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

111. 42 C.F.R. Part 93 is in writing and speaks for itself. The allegations in Paragraph 111 require no response. To the extent a response is required or the allegations of Paragraph 111 vary from the terms of 42 C.F.R. Part 93, the allegations are denied.

112. The allegations in Paragraph 112 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

113. The allegations in Paragraph 113 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

C. EPA Grants

114. The allegations in Paragraph 114 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

(i) Certifications Relating to EPA Grant Awards

115. The allegations in Paragraph 115 require no response. To the extent a response is required, the allegations are denied.

116. EPA Form SF 424 is in writing and speaks for itself. The allegations in Paragraph 116 require no response. To the extent a response is required or the allegations of Paragraph 116 vary from the terms of EPA Form SF 424, the allegations are denied.

117. The allegations in Paragraph 117 require no response. To the extent a response is required, the allegations are denied.

118. The allegations in Paragraph 118 require no response. To the extent a response is required, the allegations are denied.

119. The allegations in Paragraph 119 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

120. The allegations in Paragraph 120 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

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

121. The allegations in Paragraph 121 require no response. To the extent a response is required, the allegations are denied.

122. The allegations in Paragraph 122 require no response. To the extent a response is required, the allegations are denied.

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

123. The allegations in Paragraph 123 require no response. To the extent a response is required, the allegations are denied.

124. The EPA Research Misconduct Policy is in writing and speaks for itself. The allegations in Paragraph 124 require no response. To the extent a response is required or the allegations of Paragraph 124 vary from the terms of the EPA Research Misconduct Policy, the allegations are denied.

125. The EPA Research Misconduct Policy is in writing and speaks for itself. The allegations in Paragraph 125 require no response. To the extent a response is required or the allegations of Paragraph 125 vary from the terms of the EPA Research Misconduct Policy, the allegations are denied.

126. The EPA Research Misconduct Policy is in writing and speaks for itself. The allegations in Paragraph 126 require no response. To the extent a response is required or the allegations of Paragraph 126 vary from the terms of the EPA Research Misconduct Policy, the allegations are denied.

127. The EPA Research Misconduct Policy is in writing and speaks for itself. The allegations in Paragraph 127 require no response. To the extent a response is required or the allegations of Paragraph 127 vary from the terms of the EPA Research Misconduct Policy, the allegations are denied.

128. The allegations in Paragraph 128 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

129. The allegations in Paragraph 129 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

130. The allegations in Paragraph 130 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

V. Factual Allegations

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

131. The allegations in Paragraph 131 require no response. To the extent a response is required, the allegations are denied.

132. The allegations in Paragraph 132 require no response. To the extent a response is required, the allegations are denied.

133. The allegations in Paragraph 133 require no response. To the extent a response is required, the allegations are denied.

134. The allegations in Paragraph 134 require no response. To the extent a response is required, the allegations are denied.

135. The allegations in Paragraph 135 require no response. To the extent a response is required, the allegations are denied.

136. The allegations in Paragraph 136 require no response. To the extent a response is required, the allegations are denied.

137. The allegations in Paragraph 137 require no response. To the extent a response is required, the allegations are denied.

138. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 138 and therefore denies the same.

B. Duke University's Policy

139. Foster admits that research institutions have policies and procedures directed towards preventing research misconduct, partly because of the requirements to receive grant funds. Except as expressly admitted, Foster denies the allegations in Paragraph 139.

140. Foster admits the allegations in Paragraph 140 upon information and belief.

141. The Duke University Policy and Procedures Governing Misconduct in Research (the “Duke Policy”) is in writing and speaks for itself. The allegations in Paragraph 141 require no response. To the extent a response is required or the allegations vary from the written terms of the Duke Policy, the allegations are denied.

142. The Duke University Policy and Procedures Governing Misconduct in Research (the “Duke Policy”) is in writing and speaks for itself. The allegations in Paragraph 142 require no response. To the extent a response is required or the allegations vary from the written terms of the Duke Policy, the allegations are denied.

143. The Duke University Policy and Procedures Governing Misconduct in Research (the “Duke Policy”) is in writing and speaks for itself. The allegations in Paragraph 143 require no response. To the extent a response is required or the allegations vary from the written terms of the Duke Policy, the allegations are denied.

144. The Duke University Policy and Procedures Governing Misconduct in Research (the “Duke Policy”) is in writing and speaks for itself. The allegations in Paragraph 144 require no response. To the extent a response is required or the allegations vary from the written terms of the Duke Policy, the allegations are denied.

145. The Duke University Policy and Procedures Governing Misconduct in Research (the “Duke Policy”) is in writing and speaks for itself. The allegations in Paragraph 145 require no response. To the extent a response is required or the allegations vary from the written terms of the Duke Policy, the allegations are denied.

146. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 146 and therefore denies the same.

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

147. Foster admits the allegations in Paragraph 147.

148. Foster admits the allegations in Paragraph 148.

149. Foster admits the allegations in Paragraph 149.

150. Foster admits that the airway physiology and inflammation data resulting from experiments performed on the *flexiVent* and multiplex machines is fundamental in current pulmonary research studies. Except as expressly admitted, Foster denies the allegations in Paragraph 150.

151. Foster admits the allegations in Paragraph 151.

152. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 152 and therefore denies the same.

153. Foster denies the allegations in Paragraph 153.

154. Foster denies the allegations in Paragraph 154.

155. Foster denies the allegations in Paragraph 155.

156. Foster denies the allegations in Paragraph 156.

157. Foster denies the allegations in Paragraph 157.

158. Foster denies the allegations in Paragraph 158.

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

159. Foster admits that approximately 38 scientific papers and journal articles in which Potts-Kant co-authored with a variety of Duke University Faculty, DUHS appointees, and others, between 2007 and 2013 are attached as **Exhibit B** to the Amended Complaint. Except as expressly admitted, Foster denies the allegations in Paragraph 159.

160. Foster denies the allegations in Paragraph 160.

161. Foster denies the allegations in Paragraph 161.

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

162. Foster admits that Potts-Kant performed experiments that contributed to the paper entitled *Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47 Subunit of NAD(P)H Oxidase*. Except as expressly admitted, Foster denies the allegations in Paragraph 162.

163. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 163 and therefore denies the same.

164. Foster admits the allegations in Paragraph 164.

165. Foster states that the publication entitled *Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47 Subunit of NAD(P)H Oxidase* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 165.

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

166. Foster admits the allegations in Paragraph 166.

167. Foster admits that in contributing to *The Role of the Extracellular Matrix Protein Mindin in Airway Response to Environmental Airways Injury* that Potts-Kant performed experiments on the *flexiVent* machine. Except as expressly admitted, Foster denies the allegations in Paragraph 167.

168. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 168 and therefore denies the same.

169. Foster admits the allegations in Paragraph 169.

170. Foster admits that the publication entitled *The Role of the Extracellular Matrix Protein Mindin in Airway Response to Environmental Airways Injury* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 170.

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

171. Foster admits the allegations in Paragraph 171.

172. Foster admits that in contributing to *Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide* that Potts-Kant performed experiments on the *flexiVent* machine. Except as expressly admitted, Foster denies the allegations in Paragraph 172.

173. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 173 and therefore denies the same.

174. Foster denies the allegations in Paragraph 174.

175. Foster admits the allegations in Paragraph 175.

176. Foster admits that the publication entitled *Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide* is in writing and speaks for itself. Except as expressly admitted, the allegations of paragraph 176 are denied.

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

177. Foster admits the allegations in Paragraph 177.

178. Foster admits that in contributing to *SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice* that Potts-Kant performed experiments on the *flexiVent* machine and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 178.

179. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 179 and therefore denies the same.

180. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 180 and therefore denies the same.

181. Foster admits the allegations in Paragraph 181.

182. Foster admits that the publication entitled *SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 182.

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

183. Foster admits the allegations in Paragraph 183.

184. Foster admits that in contributing to *The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace* that Potts-Kant performed experiments on the *flexiVent* machine, as well as OVA exposures, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 184.

185. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 185 and therefore denies the same.

186. Foster admits the allegations in Paragraph 186.

187. Foster admits that the publication entitled *The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 187.

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

188. Foster admits the allegations in Paragraph 188.

189. Foster admits that in contributing to *Ambient Ozone Primes Pulmonary Innate Immunity in Mice* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 189.

190. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 190 and therefore denies the same.

191. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 191 and therefore denies the same.

192. Foster admits the allegations in Paragraph 192.

193. Foster admits that the publication entitled *Ambient Ozone Primes Pulmonary Innate Immunity in Mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 193.

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

194. Foster admits the allegations in Paragraph 194.

195. Foster admits that in contributing to *Hyaluronan Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 195.

196. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 196 and therefore denies the same.

197. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 197 and therefore denies the same.

198. Foster admits the allegations in Paragraph 198.

199. Foster admits that the publication entitled *Hyaluronan Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 199.

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

200. Foster admits the allegations in Paragraph 200.

201. Foster admits that *Alveolar Macrophages from Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 201.

202. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 202 and therefore denies the same.

203. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 203 and therefore denies the same.

204. Foster admits the allegations in Paragraph 204.

205. Foster admits that *Alveolar Macrophages from Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 205.

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

206. Foster admits the allegations in Paragraph 206.

207. Foster admits that in contributing to *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)-/- mice* that Potts-Kant performed experiments on the *flexiVent* machine and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 207.

208. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 208 and therefore denies the same.

209. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 209 and therefore denies the same.

210. Foster admits the allegations in Paragraph 210.

211. Foster admits that *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)-/- mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 211.

(x) Additional Publications

212. Foster admits that additional publications co-authored by Foster and/or Potts-Kant are attached as **Exhibit E** to the Amended Complaint. Except as expressly admitted, Foster denies the allegations in Paragraph 212.

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

213. Foster denies the 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. Foster denies the allegations in Paragraph 214.

215. The allegations in Paragraph 215 require no response. To the extent a response is required, the allegations are denied.

216. The allegations in Paragraph 216 require no response. To the extent a response is required, the allegations are denied.

217. The allegations in Paragraph 217 require no response. To the extent a response is required, the allegations are denied.

218. Foster denies the allegations in Paragraph 218.

219. Foster denies the allegations in Paragraph 219.

220. Foster denies the allegations in Paragraph 220.

221. Foster denies the allegations in Paragraph 221.

222. Foster denies the allegations in Paragraph 222.

223. Foster denies the allegations in Paragraph 223.

F. Duke University made false certifications.

224. Foster denies the allegations in Paragraph 224.

225. Foster denies the allegations in Paragraph 225.

226. Foster denies the allegations 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. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 227 and therefore denies the same.

228. Foster admits the allegations in Paragraph 228 on information and belief.

229. Foster admits the allegations of Paragraph 229 on information and belief.

230. Foster admits the allegations in Paragraph 230 upon information and belief.

231. Foster admits the allegations in Paragraph 231 upon information and belief.

232. Foster admits the allegations in Paragraph 232.

233. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 233 and therefore denies the same.

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

234. Foster denies the allegations in Paragraph 234.

235. Foster denies the allegations in Paragraph 235.

236. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 236 and therefore denies the same.

237. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 237 and therefore denies the same.

238. Foster denies the allegations in Paragraph 238.

239. Foster states that publications PMID 21930959, PMID 22073274, PMID 22773729, PMID 21684833, PMID 21037098, PMID 17993584, and PMID 17878331 are in

writing and speak for themselves. Except as expressly admitted, Foster denies the allegations in Paragraph 239.

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

240. Foster denies the allegations in Paragraph 240.

241. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 241 and therefore denies the same.

242. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 242 and therefore denies the same.

243. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 243 and therefore denies the same.

244. Foster denies the allegations in Paragraph 244.

245. Foster admits that publications PMID 22773729 and PMID 20543006 are in writing and speak for themselves. Except as expressly admitted, Foster denies the allegations in Paragraph 245.

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

246. Foster denies the allegations in Paragraph 246.

247. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 247 and therefore denies the same.

248. Foster denies the allegations in Paragraph 248.

249. Foster denies the allegations in Paragraph 249.

250. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 250 and therefore denies the same.

251. Foster denies the allegations in Paragraph 251.

252. Foster admits that publications PMID 22073274, PMID 21930959, PMID 21684833, PMID 21037098, PMID 17878331, and PMID 19494306 are in writing and speak for themselves. Except as expressly admitted, Foster denies the allegations in Paragraph 252.

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

253. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 253 and therefore denies the same.

254. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 254 and therefore denies the same.

255. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 255 and therefore denies the same.

256. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 256 and therefore denies the same.

257. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 257 and therefore denies the same.

258. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 258 and therefore denies the same.

259. Foster denies the allegations in Paragraph 259.

260. Foster admits that publications PMID 1976254, PMID 22052876, PMID 22773729, PMID 20543006, and PMID 20348208 are in writing and speak for themselves. Except as expressly admitted, Foster denies the allegations in Paragraph 260.

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

261. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 261 and therefore denies the same.

262. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 262 and therefore denies the same.

263. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 263 that relate to Dr. Hollingsworth's experiments, and therefore denies the same. Foster denies the remaining allegations of Paragraph 263.

264. Foster lacks knowledge or information as to the allegations contained in Paragraph 264, and therefore denies the same.

265. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 265 and therefore denies the same.

266. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 266 and therefore denies the same.

267. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 267 and therefore denies the same.

268. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 268 and therefore denies the same.

269. Foster denies the allegations in Paragraph 269.

270. Foster states that publications PMID 22773729, PMID 17878331, PMID 20007931, PMID 20348208, PMID 23560245, PMID 21684833, PMID 18818374, and PMID 23010656 are in writing and speak for themselves. Except as expressly admitted, Foster denies the allegations in Paragraph 270.

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

271. Foster admits examples of data created by Potts-Kant and the Airway Physiology Laboratory (the "Foster Lab") are contained in the documents attached as **Exhibit D**

(Relator_000114 – 000119) to the Amended Complaint. Except as expressly admitted, Foster denies the allegations in Paragraph 271.

272. Foster admits that the experiments referenced in **Exhibit D** were conducted to understand the interaction between TNF- α , a cytokine involved in lung inflammation, and mast cells, myeloid-derived cells involved in the immune system. Except as expressly admitted, Foster denies the allegations in Paragraph 272.

273. Foster states that the referenced Exhibit D is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 273.

274. Foster states that publication PMID 22502799 is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 274.

275. Foster states that the referenced Exhibit D is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 275.

276. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 276 and therefore denies the same.

277. Foster denies the allegations in Paragraph 277.

278. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 278 and therefore denies the same.

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

279. Foster denies the allegations in Paragraph 279.

280. Foster denies the allegations in Paragraph 280.

281. Foster denies the allegations in Paragraph 281.

282. Foster denies the allegations in Paragraph 282.

283. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 283 and therefore denies the same.

284. Foster denies the allegations in Paragraph 284.

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

285. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 285 and therefore denies the same.

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

286. Foster denies the allegations in Paragraph 286.

287. Foster denies the allegations 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. Foster admits the allegations in Paragraph 288.

289. Foster admits the allegations in Paragraph 289.

290. Foster admits the allegations in Paragraph 290.

291. Foster states that the referenced publications are in writing and speak for themselves. Except as expressly admitted, Foster denies the allegations in Paragraph 291.

292. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 292 and therefore denies the same.

293. Foster admits the allegations in Paragraph 293.

294. Foster admits the allegations in Paragraph 294.

295. Foster admits that the application for renewed funding of the SP-A project included research results based on certain raw data produced by Potts-Kant. Except as expressly admitted, the allegations in Paragraph 295 are denied.

296. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 296 and therefore denies the same.

(iii) Duke’s primary interest – in particular the Pulmonary Division – has been self-preservation.

297. Foster denies the allegations in Paragraph 297.

298. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 298 and therefore denies the same.

299. Foster admits the allegations in Paragraph 299.

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

300. Foster denies the allegations in Paragraph 300.

301. Foster admits the allegations in Paragraph 301.

302. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 302 and therefore denies the same.

303. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 303 and therefore denies the same.

304. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 304 and therefore denies the same.

305. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 305 and therefore denies the same.

306. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 306 and therefore denies the same.

307. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 307 and therefore denies the same.

308. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 308 and therefore denies the same.

309. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 309 and therefore denies the same.

310. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 310 and therefore denies the same.

311. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 311 and therefore denies the same.

312. The allegations in Paragraph 312 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

J. The Defendants' acts and omissions occurred knowingly.

313. The allegations in Paragraph 313 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

314. The allegations in Paragraph 314 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

315. Foster denies the allegations in Paragraph 315.

316. Foster denies the allegations in Paragraph 316.

317. Foster denies the allegations in Paragraph 317.

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

318. Foster denies the allegations in Paragraph 318.

319. Foster denies the allegations in Paragraph 319.

320. Foster denies the allegations in Paragraph 320.

321. Foster denies the allegations in Paragraph 321.

322. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 322 and therefore denies the same.

323. Foster denies the allegations in Paragraph 323.

324. Foster denies the allegations in Paragraph 324.

325. Foster denies the allegations in Paragraph 325.

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

326. Foster denies the allegations in Paragraph 326.

327. Foster denies the allegations in Paragraph 327.

328. Foster admits that Ms. Theriot operated the *flexiVent* machine in Dr. Walker's

lab. Except as expressly admitted, Foster denies the allegations in Paragraph 328.

329. Foster denies the allegations in Paragraph 329.

330. Foster denies the allegations in Paragraph 330.

331. Foster denies the allegations in Paragraph 331.

332. Foster denies the allegations in Paragraph 332.

333. Foster denies the allegations in Paragraph 333.

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

334. Foster denies the allegations in Paragraph 334.

335. Foster denies the allegations in Paragraph 335.

336. Foster denies the allegations in Paragraph 336.

337. Foster denies the allegations in Paragraph 337.

338. Foster denies the allegations in Paragraph 338.

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

339. Foster denies the allegations in Paragraph 339.

a. Foster admits the allegations of Paragraph 339(a) to the extent that they relate to research that Foster conducted and/or was responsible for. Except as expressly admitted, Foster denies the allegations of Paragraph 339(a).

b. Foster denies the allegations in Paragraph 339(b).

c. Foster denies the allegations in Paragraph 339(c).

d. Foster denies the allegations in Paragraph 339(d).

- e. Foster denies the allegations in Paragraph 339(e).
- f. Foster denies the allegations in Paragraph 339(f).
- g. Foster denies the allegations in Paragraph 339(g).
- h. Foster denies the allegations in Paragraph 339(h).
- i. Foster denies the allegations in Paragraph 339(i).
- j. Foster denies the allegations in Paragraph 339(j).

340. Foster denies the allegations in Paragraph 340.

341. Foster denies the allegations in Paragraph 341.

- a. Foster denies the allegations in Paragraph 341(a).
- b. Foster denies the allegations in Paragraph 341(b).
- c. Foster denies the allegations in Paragraph 341(c).
- d. Foster denies the allegations in Paragraph 341(d).
- e. Foster denies the allegations in Paragraph 341(e).
- f. Foster denies the allegations in Paragraph 341(f).
- g. Foster denies the allegations in Paragraph 341(g).
- h. Foster denies the allegations in Paragraph 341(h).
- i. Foster denies the allegations in Paragraph 341(i).
- j. Foster denies the allegations in Paragraph 341(j).

K. The Defendants' acts and omissions were material.

342. The allegations in Paragraph 342 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

- a. Foster denies the allegations in Paragraph 342(a).
- b. Foster denies the allegations in Paragraph 342(b).
- c. Foster denies the allegations in Paragraph 342(c).

d. Foster denies the allegations in Paragraph 342(d).

e. Foster denies the allegations in Paragraph 342(e).

f. Foster denies the allegations in Paragraph 342(f).

343. The allegations in Paragraph 343 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

I. Failure to Disclose and Concealment.

344. Foster denies the allegations in Paragraph 344.

345. Foster denies the allegations 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. Foster repeats and incorporates his responses contained in the preceding paragraphs as if fully set forth herein.

347. The allegations in Paragraph 347 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

348. The allegations in Paragraph 348 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

349. The allegations in Paragraph 349 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

350. The allegations in Paragraph 350 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

351. The allegations in Paragraph 351 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

352. The allegations in Paragraph 352 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

353. The allegations in Paragraph 353 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

354. The allegations in Paragraph 354 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

355. The allegations in Paragraph 355 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

356. The allegations in Paragraph 356 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

357. The allegations in Paragraph 357 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

358. The allegations in Paragraph 358 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

359. The allegations in Paragraph 359 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

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. Foster repeats and incorporates his responses contained in the preceding paragraphs as if fully set forth herein.

361. The allegations in Paragraph 361 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

362. The allegations in Paragraph 362 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

363. The allegations in Paragraph 363 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

364. The allegations in Paragraph 364 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

365. The allegations in Paragraph 365 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

366. The allegations in Paragraph 366 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

367. The allegations in Paragraph 367 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

368. The allegations in Paragraph 368 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

369. The allegations in Paragraph 369 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

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

370. Foster repeats and incorporates his responses contained in the preceding paragraphs as if fully set forth herein.

371. The allegations in Paragraph 371 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

372. The allegations in Paragraph 372 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

373. The allegations in Paragraph 373 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

374. The allegations in Paragraph 374 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

375. The allegations in Paragraph 375 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

376. The allegations in Paragraph 376 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

377. The allegations in Paragraph 377 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

378. The allegations in Paragraph 378 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

379. The allegations in Paragraph 379 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

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. Foster repeats and incorporates his responses contained in the preceding paragraphs as if fully set forth herein.

381. The allegations in Paragraph 381 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

382. The allegations in Paragraph 381 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

383. The allegations in Paragraph 383 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

384. The allegations in Paragraph 384 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

385. The allegations in Paragraph 385 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

386. The allegations in Paragraph 386 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

387. The allegations in Paragraph 387 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

388. The allegations in Paragraph 388 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

389. The allegations in Paragraph 389 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

390. The allegations in Paragraph 390 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

391. The allegations in Paragraph 391 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

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. Foster repeats and incorporates his responses contained in the preceding paragraphs as if fully set forth herein.

393. The allegations in Paragraph 393 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

394. The allegations in Paragraph 394 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

395. The allegations in Paragraph 395 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

396. The allegations in Paragraph 396 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

397. The allegations in Paragraph 397 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

398. The allegations in Paragraph 398 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

399. The allegations in Paragraph 399 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

400. The allegations in Paragraph 400 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

401. The allegations in Paragraph 401 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

402. The allegations in Paragraph 402 are legal conclusions to which no response is required. To the extent a response is required, the allegations are denied.

**DEFENDANT FOSTER’S RESPONSES TO ALLEGATIONS CONTAINED IN
EXHIBIT E TO AMENDED COMPLAINT**

Defendant William M. Foster, Ph.D. (“Foster”), through counsel, hereby answers the allegations contained in Exhibit E to Plaintiff’s Amended Complaint as follows:

1. PMID 22052876 – *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring*

1. Foster admits the allegations in Paragraph 1.

2. Foster admits that in contributing to *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring* that Potts-Kant performed experiments on the *flexiVent* and *Luminex* machines, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 2.

3. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 3 and therefore denies the same.

4. Foster admits the allegations in Paragraph 4.

5. Foster admits that the publication entitled *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 5.

2. PMID 21960548 – *Protective Role of T-bet and Th1 Cytokines in Pulmonary Grant-verses-Host Disease and Peribronchiolar Fibrosis*

6. Foster admits the allegations in Paragraph 6.

7. Foster admits that in contributing to *Protective Role of T-bet and Th1 Cytokines in Pulmonary Grant-verses-Host Disease and Peribronchiolar Fibrosis* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 7.

8. Foster denies the allegations in Paragraph 8.

9. Foster admits the allegations in Paragraph 9.

10. Foster admits that the publication entitled *Protective Role of T-bet and Th1 Cytokines in Pulmonary Grant-verses-Host Disease and Peribronchiolar Fibrosis* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 10.

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

11. Foster admits the allegations in Paragraph 11.

12. Foster admits that in contributing to *Ozone Inhalation Promotes CX3CR1-dependent Maturation of Resident Lung Macrophages which Limit Oxidative Stress and Inflammation* that Potts-Kant performed experiments on the flexiVent machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 12.

13. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 13 and therefore denies the same.

14. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 14, and therefore denies the same.

15. Foster admits the allegations in Paragraph 15.

16. Foster admits that the publication entitled *Ozone Inhalation Promotes CX3CR1-dependent Maturation of Resident Lung Macrophages which Limit Oxidative Stress and Inflammation* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 16.

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

17. Foster admits the allegations in Paragraph 17.

18. Foster admits that in contributing to *Extracellular Matrix Protein Mindin is Required for the Complete Allergic Response to Fungal-Associated Proteinase* that Potts-Kant performed experiments on the *flexiVent* and Luminex machines, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 18.

19. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 19 and therefore denies the same.

20. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 20, and therefore denies the same.

21. Foster admits the allegations in Paragraph 21.

22. Foster admits that the publication entitled *Extracellular Matrix Protein Mindin is Required for the Complete Allergic Response to Fungal-Associated Proteinase* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 22.

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

23. Foster admits the allegations in Paragraph 23.

24. Foster admits that in contributing to *S-nitrosoglutathione supplementation to ovalbumin-sensitized and – challenged mice ameliorates methacholine-induced bronchoconstriction* that Potts-Kant performed experiments on the *flexiVent* and Luminex machines, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 24.

25. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 25 and therefore denies the same.

26. Foster admits the allegations in Paragraph 26.

27. Foster admits that the publication entitled *S-nitrosoglutathione supplementation to ovalbumin-sensitized and – challenged mice ameliorates methacholine-induced bronchoconstriction* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 27.

6. PMID 21724860 – *NOS2 regulation of LPS-induced airway inflammation via S-nitrosylation of NF-KB p65*

28. Foster admits the allegations in Paragraph 28.

29. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 29 and therefore denies the same.

30. Foster admits that the publication entitled *NOS2 regulation of LPS-induced airway inflammation via S-nitrosylation of NF-KB p65* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 30.

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

31. Foster admits the allegations in Paragraph 31.

32. Foster admits that in contributing to *c-Kit is essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produce by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 32.

33. Foster denies the allegations in Paragraph 33.

34. Foster admits the allegations of Paragraph 34.

35. Foster admits that the publication entitled *c-Kit is essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 35.

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

36. Foster admits the allegations in Paragraph 36.

37. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 37 and therefore denies the same.

38. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 38 and therefore denies the same.

39. Foster admits the allegations in Paragraph 39.

40. Foster admits that the publication entitled *β -arrestin Deficiency Protects Against Pulmonary Fibrosis in Mice and Prevents Fibroblast Invasion of Extracellular Matrix* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 40.

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

41. Foster admits the allegations in Paragraph 41.

42. Foster admits that in contributing to *Particulate allergens potentiate allergic asthma in mice through sustained IgE-mediated mast cell activation* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 42.

43. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 43, and therefore denies the same.

44. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 44 and therefore denies the same.

45. Foster admits the allegations in Paragraph 45.

46. Foster admits that the publication entitled *Particulate allergens potentiate allergic asthma in mice through sustained IgE-mediated mast cell activation* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 46.

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

47. Foster admits the allegations in Paragraph 47.

48. Foster admits that in contributing to *Gastrin-releasing peptide blockade as a broad-spectrum anti-inflammatory therapy for asthma* that Potts-Kant performed experiments on the *flexiVent* and *Luminex* machines, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 48.

49. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 49 and therefore denies the same.

50. Foster admits the allegations in Paragraph 50.

51. Foster admits that the publication entitled *Gastrin-releasing peptide blockade as a broad-spectrum anti-inflammatory therapy for asthma* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 51.

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

52. Foster admits the allegations in Paragraph 52.

53. Foster admits that in contributing to *MARCKS-related peptide modulates in vivo the secretion of airway Muc5ac* that Potts-Kant performed experiments on the *flexiVent*, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 53.

54. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 54, and therefore denies the same.

55. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 55 and therefore denies the same.

56. Foster admits the allegations in Paragraph 56.

57. Foster admits that the publication entitled *MARCKS-related peptide modulates in vivo the secretion of airway Muc5ac* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 57.

58. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 58, and therefore denies the same.

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

59. Foster admits the allegations in Paragraph 59.

60. Foster admits that in contributing to *Mast Cells Mediate Hyperoxia-Induced Airway Hyper-reactivity in Newborn Rats* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 60.

61. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 61 and therefore denies the same.

62. Foster admits the allegations in Paragraph 62.

63. Foster admits that the publication entitled *Mast Cells Mediate Hyperoxia-Induced Airway Hyper-reactivity in Newborn Rats* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 63.

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

64. Foster admits the allegations in Paragraph 64.

65. Foster admits that in contributing to *Nitric Oxide Mediates Relative Airway Hyperresponsiveness to Lipopolysaccharide in Surfactant Protein A-Deficient Mice* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 65.

66. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 66, and therefore denies the same.

67. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 67 and therefore denies the same.

68. Foster admits the allegations in Paragraph 68.

69. Foster admits that the publication entitled *Nitric Oxide Mediates Relative Airway Hyperresponsiveness to Lipopolysaccharide in Surfactant Protein A-Deficient Mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 69.

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

70. Foster admits the allegations in Paragraph 70.

71. Foster admits that in contributing to *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 71.

72. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 72 and therefore denies the same.

73. Foster admits the allegations in Paragraph 73.

74. Foster admits that the publication entitled *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 74.

15. PMID 19581591 – *NPAS3 is a tracheales homolog critical for lung development and homeostasis*

75. Foster admits the allegations in Paragraph 75.

76. Foster admits that in contributing to *NPAS3 is a tracheales homolog critical for lung development and homeostasis* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 76.

77. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 77 and therefore denies the same.

78. Foster admits the allegations in Paragraph 78.

79. Foster admits that the publication entitled *NPAS3 is a tracheales homolog critical for lung development and homeostasis* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 79.

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

80. Foster admits the allegations in Paragraph 80.

81. Foster admits that in contributing to *Protection from Lipopolysaccharide-induced Lung Injury by Augmentation of Airway S-Nitrosothiols* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 81.

82. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 82 and therefore denies the same.

83. Foster admits the allegations in Paragraph 83.

84. Foster admits that the publication entitled *Protection from Lipopolysaccharide-induced Lung Injury by Augmentation of Airway S-Nitrosothiols* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 84.

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

85. Foster admits the allegations in Paragraph 85.

86. Foster admits that in contributing to *A Robust Protocol for Regional Evaluation of Methacholine Challenge in Mouse Models of Allergic Asthma Using Hyperpolarized 3He MRI* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 86.

87. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 87 and therefore denies the same.

88. Foster admits the allegations in Paragraph 88.

89. Foster admits that the publication entitled *A Robust Protocol for Regional Evaluation of Methacholine Challenge in Mouse Models of Allergic Asthma Using Hyperpolarized 3He MRI* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 89.

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

90. Foster admits the allegations in Paragraph 90.

91. Foster admits that in contributing to *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans* that Potts-Kant performed experiments on the *flexiVent* and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 91.

92. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 92 and therefore denies the same.

93. Foster admits the allegations in Paragraph 93.

94. Foster admits that the publication entitled *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 94.

19. PMID 18802477 – *In utero supplementation with methyl donors enhances allergic airway disease in mice*

95. Foster admits the allegations in Paragraph 95.

96. Foster admits that in contributing to *In utero supplementation with methyl donors enhances allergic airway disease in mice* that Potts-Kant performed experiments on the *flexiVent* machine, and that the data produced by those experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 96.

97. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 97 and therefore denies the same.

98. Foster admits the allegations in Paragraph 98.

99. Foster admits that the publication entitled *In utero supplementation with methyl donors enhances allergic airway disease in mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 99.

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

100. Foster admits the allegations in Paragraph 100.

101. Foster states that in contributing to *A micro-CT analysis of murine lung recruitment in bleomycin-induced lung injury* that Potts Kant assisted Scott Shofer, MD, PhD, in performing experiments on the *flexiVent* machine, and that the data produced by these experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 101.

102. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 102 and therefore denies the same.

103. Foster admits the allegations in Paragraph 103.

104. Foster admits that the publication entitled *A micro-CT analysis of murine lung recruitment in bleomycin-induced lung injury* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 104.

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

105. Foster admits the allegations in Paragraph 105.

106. Foster denies the allegations in Paragraph 106.

107. Foster denies the allegations in Paragraph 107.

108. Foster admits the allegations in Paragraph 108.

109. Foster admits that the publication entitled *Chronic LPS Inhalation Causes Emphysema-Like Changes in Mouse Lung that Are Associated with Apoptosis* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 109.

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

110. Foster admits the allegations in Paragraph 110.

111. Foster admits that in contributing to *Hyaluronan Activation of the Nlrp3 Inflammasome Contributes to the Development of Airway Hyperresponsiveness* that Potts-Kant preformed experiments on the *flexiVent* machine, and that the data produced by these experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 111.

112. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 112, and therefore denies the same.

113. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 113 and therefore denies the same.

114. Foster admits the allegations in Paragraph 114.

115. Foster admits that the publication entitled *Hyaluronan Activation of the Nlrp3 Inflammasome Contributes to the Development of Airway Hyperresponsiveness* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 115.

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

116. Foster admits the allegations in Paragraph 116.

117. Foster states that in contributing to *Innate Immune Activation by Inhaled Lipopolysaccharide, Independent of Oxidative Stress, Exacerbates Silica-Induced Pulmonary Fibrosis in Mice* that Potts-Kant performed experiments on the Multiplex machine, and that the data produced by these experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 117.

118. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 118 and therefore denies the same.

119. Foster admits the allegations in Paragraph 119.

120. Foster admits that the publication entitled *Innate Immune Activation by Inhaled Lipopolysaccharide, Independent of Oxidative Stress, Exacerbates Silica-Induced Pulmonary Fibrosis in Mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 120.

24. PMID 22659878 – *NAD(P)H: Quinone Oxoreductase 1 Protects Lungs From Oxidant-Induced Empysema in Mice*

121. Foster admits the allegations in Paragraph 121.

122. Foster admits that in contributing to *NAD(P)H: Quinone Oxoreductase 1 Protects Lungs From Oxidant-Induced Empysema in Mice* that Potts-Kant performed experiments on the *flexiVent* and *Luminex* machines, and that the data produced by these experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 122.

123. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 123 and therefore denies the same.

124. Foster admits the allegations in Paragraph 124.

125. Foster admits that the publication entitled *NAD(P)H: Quinone Oxoreductase 1 Protects Lungs From Oxidant-Induced Empysema in Mice* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 125.

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

126. Foster admits the allegations in Paragraph 126.

127. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 127 and therefore denies the same.

128. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 128 and therefore denies the same.

129. Foster admits the allegations in Paragraph 129.

130. Foster admits that the publication entitled *Quinone Oxidoreductase 1 Regulates Host Susceptibility to Ozone via Isoprostane Generation* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 130.

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

131. Foster admits the allegations in Paragraph 131.

132. Foster states that in contributing to *NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia* that Potts-Kant performed experiments on the Multiplex machine, and that the data produced by these experiments are contained in the paper. Except as expressly admitted, Foster denies the allegations in Paragraph 132.

133. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 133 and therefore denies the same.

134. Foster admits the allegations in Paragraph 134.

135. Foster admits that the publication entitled *NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 135.

27. PMID 22241062 – *Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized 3He magnetic resonance imaging in an allergic mouse model*

136. Foster admits the allegations in Paragraph 136.

137. Foster admits that in contributing to *Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized 3He magnetic resonance imaging in an allergic mouse model* that Potts-Kant performed experiments on the *flexiVent* machine. Except as expressly admitted, Foster denies the allegations in Paragraph 137.

138. Foster lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 138 and therefore denies the same.

139. Foster admits the allegations in Paragraph 139.

140. Foster admits that the publication *Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized 3He magnetic resonance imaging in an allergic mouse model* is in writing and speaks for itself. Except as expressly admitted, Foster denies the allegations in Paragraph 140.

PRAYER FOR RELIEF

Defendant Foster denies that Plaintiff and/or the Relator is entitled to any relief whatsoever.

AFFIRMATIVE DEFENSES

FIRST DEFENSE

The Complaint fails to state a valid cause of action against Defendant Foster.

SECOND DEFENSE

The alleged conduct of Defendant Erin Potts-Kant constitutes a supervening and/or intervening cause that precludes a finding of liability against Defendant Foster.

THIRD DEFENSE

Plaintiff and/or Relator's claim for treble damages and statutory penalties violate the Due Process Clause and the Sixth Amendment of the United States Constitution by imposing essentially criminal penalties without affording the requisite procedural safeguards.

FOURTH DEFENSE

Plaintiff and/or Relator's claim for treble damages and statutory penalties violate the Eighth Amendment of the United States Constitution's Excessive Fines Clause.

RESERVATION AND NON WAIVER

Defendants reserve the right to assert any additional defenses as may be revealed through discovery and at trial.

WHEREFORE, having responded to Plaintiff and/or Relator's Complaint, Defendant Foster, through counsel, prays the Court for relief as follows:

1. That the Court deny each and all of Plaintiff and/or Relator's claims;
 2. That the Plaintiff otherwise have and recover nothing from Defendant Foster and that this action be dismissed with prejudice;
 3. That all issues of fact, if any, be tried before a jury;
 4. That Defendant Foster have and recover his costs to the extent allowed by law;
- and
5. That the Court grant Defendant Foster such other and further relief as it may deem just and proper.

This 19th day of June, 2017.

By: s/ Richard S. Glaser, Jr.
Richard S. Glaser, Jr.
North Carolina Bar No. 13998
Annette K. Ebright
North Carolina Bar No. 36736
Eric H. Cottrell
North Carolina Bar No. 21994
PARKER POE ADAMS & BERNSTEIN LLP
Three Wells Fargo Center, Suite 3000
401 South Tryon Street
Charlotte, NC 28202
(704) 372-9000
Fax: (704) 334-4706
rickglaser@parkerpoe.com
annetteebright@parkerpoe.com
ericcottrell@parkerpoe.com
Attorneys for Defendant William M. Foster, Ph.D.

CERTIFICATE OF SERVICE

I hereby certify that, on this 19th day of June, 2017, the foregoing was filed electronically with the Clerk of Court using the CM/ECF system, which will send a Notice of Electronic Filing to counsel of record in this matter.

s/ Richard S. Glaser, Jr.
Richard S. Glaser, Jr.
North Carolina Bar No. 13998
PARKER POE ADAMS & BERNSTEIN LLP
Three Wells Fargo Center, Suite 3000
401 South Tryon Street
Charlotte, NC 28202
(704) 372-9000
Fax: (704) 334-4706
rickglaser@parkerpoe.com
Attorneys for Defendant William M. Foster, Ph.D.