

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i>	§	
Marsha Fontanive and Lindsey Vitez,	§	
	§	
Plaintiffs/Relators,	§	
	§	
VS.	§	CIVIL ACTION NO.
	§	
CARIS LIFE SCIENCES, INC., <i>et al.</i> ,	§	3:10-CV-02237-P
	§	
Defendants.	§	

**DEFENDANTS’ ANSWER TO
RELATORS’ SECOND AMENDED COMPLAINT**

Defendants Caris Life Sciences, Inc., Caris Diagnostics, Inc., Miraca Life Sciences, Inc., and Caris MPI, Inc. (collectively, “Defendants”), through their undersigned attorneys, hereby respond to the Second Amended Complaint (“Complaint”), filed by Relators Marsha Fontanive and Lindsey Vitez, upon knowledge as to their own actions and upon information and belief as to all other matters, and assert defenses based upon information currently available to them.

All allegations in the Second Amended Complaint (including allegations contained in headings, footnotes, and exhibits) that are not expressly admitted in this Answer are denied.

* * * * *

The unnumbered opening paragraph of the Second Amended Complaint describes Relators’ claims and requires no response. Insofar as a response is required, Defendants deny the allegations in the unnumbered opening paragraph.

1. Paragraph 1 describes Relators’ claims and requires no response. Insofar as a response is required, Defendants deny the allegations in Paragraph 1.

2. Defendants admit that Relator Vitez has filed suit pursuant to 31 U.S.C. § 3730(h), but Defendants deny that Relator Vitez has brought (or can bring) an actionable claim under that statute.

3. Defendants admit that Relators brought this action pursuant to 31 U.S.C. § 3729 *et seq.*, but Defendants deny that Relators have brought (or can bring) an actionable claim under those statutes.

4. Defendants lack knowledge or information sufficient to form a belief about Relator Fontanive's residency and therefore deny the same. Defendants deny the remaining allegations in Paragraph 4.

5. Defendants lack knowledge or information sufficient to form a belief about Relator Vitez's residency and therefore deny the same. Defendants deny the remaining allegations in Paragraph 5.

6. Defendants admit that Caris Life Sciences, Inc., may be served with process by serving its registered agent CT Corporation System at 350 N. St. Paul St., Suite 2900, Dallas, Texas 75201. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 6.

7. Defendants deny the allegations in Paragraph 7.

8. Defendants admit that Miraca Life Sciences, Inc. is a Delaware corporation and may be served with process by serving its registered agent CT Corporation System at 350 N. St. Paul St., Suite 2900, Dallas, Texas 75201. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 8.

9. Defendants admit that Caris MPI, Inc. is a Delaware corporation and may be served with process by serving its registered agent CT Corporation System at 1999 Bryan St.,

Suite 900, Dallas, Texas 75201. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 9.

10. Paragraph 10 asserts a legal conclusion to which no response is required. Insofar as a response is necessary, Defendants deny that the Court possesses subject matter jurisdiction over this action.

11. Paragraph 11 asserts a legal conclusion to which no response is required. Insofar as a response is necessary, Defendants deny that the Complaint is timely filed.

12. Defendants deny that they committed any acts proscribed by the False Claims Act. The remainder of Paragraph 12 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the remaining allegations of Paragraph 12.

13. Paragraph 13 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 13 and refer to the cited statutes for their true meaning and effect.

14. Paragraph 14 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 14 and refer to the cited statute for its true meaning and effect.

15. Paragraph 15 asserts legal conclusions to which no response is required. Insofar as a response is required, Defendants deny the allegations in Paragraph 15, and refer to the cited statute for its true meaning and effect.

16. Paragraph 16 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 16, and refer to the cited statute for its correct text, true meaning and effect.

17. Paragraph 17 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 17, and refer to the statute for its true meaning and effect.

18. Paragraph 18 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 18, and refer to the statutes for their true meaning and effect.

19. Paragraph 19 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 19, and refer to the referenced CMS Form for its true meaning and effect.

20. Paragraph 20 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 20, and refer to the statutes and regulations for their true meaning and effect.

21. Paragraph 21 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 21.

22. Paragraph 22 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 22, and refer to the referenced billing procedure codes for their true meaning and effect.

23. Paragraph 23 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 23, and refer to the referenced Medicare Claims Processing Manual provisions for their true meaning and effect.

24. Paragraph 24 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 24, and refer to the referenced provisions for their true meaning and effect.

25. Paragraph 25 asserts medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 25, and refer to the referenced Medicare Claims Processing Manual provisions for their true meaning and effect.

26. Paragraph 26 asserts medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 26, and refer to the referenced Medicare Claims Processing Manual provisions for their true meaning and effect.

27. Paragraph 27 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 27, and refer to the cited provision for its true meaning and effect.

28. Paragraph 28 asserts medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 28, and refer to the cited Medicare Claims Processing Manual provisions for their true meaning and effect.

29. Defendants deny the allegations in Paragraph 29.

30. Defendants admit the allegations in Paragraph 30.

31. Defendants deny the allegations in Paragraph 31.

32. Defendants deny the allegations in Paragraph 32.

33. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33, and therefore deny the same.

34. Defendants admit that Ms. Fontanive began working at Caris Diagnostics, Inc. in April 2008 as a Director of Business Development. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 34.

35. Defendants admit that Ms. Fontanive left her employment with Caris Diagnostics, Inc. in April 2010. Defendants lack knowledge or information sufficient to form a belief about what Ms. Fontanive allegedly told others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 35.

36. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36, and therefore deny the same.

37. Defendants admit that Ms. Vitez began working at Caris Diagnostics, Inc. in December 2008 in Garland, Texas, as a billing specialist – data entry. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 37.

38. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly told others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 38.

39. Defendants admit that “Target Now” was the trade name for a range of individual molecular testing services. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 39, including the allegations in footnote 1.

40. Paragraph 40 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 40.

41. Paragraph 41 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 41.

42. Paragraph 42 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 42.

43. Defendants admit that Ms. Fontanive received the instruction and training necessary to fulfill her duties during her employment. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 43.

44. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 44, and therefore deny the same.

45. Defendants lack knowledge or information sufficient to form a belief about what Ms. Fontanive allegedly told others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 45.

46. Defendants lack knowledge or information sufficient to form a belief about what Florida Hospital allegedly told Ms. Fontanive, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 46.

47. Defendants admit that sales team members received the necessary training to carry out their duties. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 47.

48. Defendants admit that all necessary materials were distributed to employees to carry out their duties. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 48.

49. Defendants admit that all necessary forms were distributed to providers. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 49.

50. Defendants deny the allegations in Paragraph 50, including the allegations in footnote 2 and the accuracy and truthfulness of Exhibit A.

51. Defendants refer to the cited document for its contents, which speak for themselves. To the extent any further response is required, Defendants deny the allegations in Paragraph 51.

52. Defendants admit that sales team members and other key employees were properly instructed regarding billing and related issues. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 52.

53. Defendants admit that sales team members and other key employees were properly instructed regarding billing and related issues. Defendants lack knowledge or information sufficient to form a belief about the last sentence in Paragraph 53, and therefore deny the same. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 53.

54. Defendants lack knowledge or information sufficient to form a belief about who participated in the alleged conference call, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 54.

55. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 55, and therefore deny the same.

56. Defendants deny the allegations in Paragraph 56.

57. Defendants lack knowledge or information sufficient to form a belief about what information Ms. Fontanive reviewed, and therefore deny the same. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 57.

58. Defendants deny the allegations in Paragraph 58.

59. Defendants deny the allegations in Paragraph 59.

60. Defendants admit that Daniel Von Hoff, M.D., was the principal investigator on a study that is generally referred to as the “Bisgrove Study,” the results of which were published in the Journal of Clinical Oncology in 2010. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 60.

61. Defendants deny the allegations in Paragraph 61.

62. Defendants admit that sales team members, including Ms. Fontanive, received the necessary training to carry out their duties. Defendants lack knowledge or information sufficient to form a belief about calls were allegedly made by Ms. Fontanive, and therefore deny the same. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 62.

63. Paragraph 63 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 63.

64. Defendants deny the allegations in Paragraph 64.

65. Defendants deny the allegations in Paragraph 65, including the accuracy and truthfulness of Exhibit B.

66. Defendants deny the allegations in Paragraph 66.

67. Paragraph 67 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants admit that hematopathology testing uses antibody-based and molecular diagnostic platforms to identify the best treatment for tumors of hematopoietic and lymphoid tissues. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 67.

68. Paragraph 68 asserts medical conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 68.

69. Defendants admit that Caris Diagnostics, Inc. worked diligently to preserve all specimens for accurate testing. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 69.

70. Defendants admit that Caris Diagnostics, Inc. worked diligently to preserve all specimens for accurate testing. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 70.

71. Defendants admit that Caris Diagnostics, Inc. worked diligently to preserve all specimens for accurate testing. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 71.

72. Defendants admit that Caris Diagnostics, Inc. worked diligently to preserve all specimens for accurate testing. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 72.

73. Defendants lack knowledge or information sufficient to form a belief about the second and third sentences of Paragraph 73, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 73.

74. Defendants admit that Caris Diagnostics, Inc. worked diligently to preserve all specimens for accurate testing. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 74.

75. Defendants deny the allegations in Paragraph 75.

76. Defendants admit that Caris Diagnostics, Inc. worked diligently to preserve all specimens for accurate testing. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 76.

77. Defendants admit that Caris Diagnostics, Inc. worked diligently to preserve all specimens for accurate testing. Defendants lack knowledge or information sufficient to form a belief about whether Ms. Fontanive participated in the referenced conference calls, and therefore deny the same. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 77.

78. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 78, including the accuracy and truthfulness of Exhibit C, and therefore deny the same.

79. Defendants deny the allegations in Paragraph 79.

80. No response is required to Paragraph 80 because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 80 solely relates. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 80.

81. No response is required to Paragraph 81 because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 81 solely relates. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 81.

82. No response is required to Paragraph 82 because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 82 solely relates. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 82.

83. No response is required to Paragraph 83, including Exhibit D, because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which

Paragraph 83 and Exhibit D solely relate. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 83 and Exhibit D.

84. No response is required to Paragraph 84 because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 84 solely relates. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 84.

85. No response is required to Paragraph 85, including Exhibit E, because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 85 and Exhibit E solely relate. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 85 and Exhibit E.

86. No response is required to Paragraph 86 because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 86 solely relates. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 86.

87. No response is required to Paragraph 87 because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 87 solely relates. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 87.

88. No response is required to Paragraph 88, including Exhibit F and the allegations in footnote 3, because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 88, Exhibit F, and footnote 3 solely relate. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 88, Exhibit F, and footnote 3.

89. No response is required to Paragraph 89 because the Court dismissed Relators' claim regarding alleged "illegal kickbacks to P4 physicians," to which Paragraph 89 solely relates. *See* October 23, 2013 Order at 26, 30 (Dkt. #47). To the extent a response is required, Defendants deny the allegations in Paragraph 89.

90. Defendants admit that pathologists often render consultations regarding test results. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 90.

91. Paragraph 91 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 91, and refer to the referenced Current Procedural Terminology codes for their true meaning and effect.

92. Paragraph 92 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 92, and refer to the referenced Current Procedural Terminology codes for their true meaning and effect.

93. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 93, and therefore deny the same.

94. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 94.

95. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly identified, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 95.

96. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 96.

97. Defendants deny the allegations in Paragraph 97, including the allegations in footnote 4.

98. Defendants deny the allegations in Paragraph 98.

99. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 99.

100. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly told others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 100.

101. Defendants deny the allegations in Paragraph 101.

102. Paragraph 102 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 102, and refer to the governing rules and regulations for their true meaning and effect.

103. Defendants deny the allegations in Paragraph 103.

104. Defendants deny the allegations in Paragraph 104.

105. Defendants deny the allegations in Paragraph 105, including the accuracy and truthfulness of Exhibit G.

106. Paragraph 106 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 106, and refer to the governing rules and regulations for their true meaning and effect.

107. Defendants deny the allegations in Paragraph 107.

108. Defendants deny the allegations in Paragraph 108.

109. Defendants deny the allegations in Paragraph 109.

110. Defendants deny the allegations in Paragraph 110.

111. Defendants deny the allegations in Paragraph 111.

112. Paragraph 112 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 112.

113. Defendants deny the allegations in Paragraph 113.

114. Paragraph 114 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 114.

115. Defendants deny the allegations in Paragraph 115.

116. Defendants deny the allegations in Paragraph 116.

117. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 117.

118. Defendants deny the allegations in Paragraph 118.

119. Defendants deny the allegations in Paragraph 119.

120. Paragraph 120 asserts medical conclusions to which no response is required. To the extent a response is necessary, Defendants deny the allegations in Paragraph 120.

121. Paragraph 121 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 121.

122. Defendants lack knowledge or information sufficient to form a belief about whether Ms. Vitez became “concerned,” and therefore deny the same. Defendants deny the remaining allegations in Paragraph 122.

123. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 123.

124. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly “felt,” and therefore deny the same. Defendants deny the remaining allegations in Paragraph 124.

125. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 125.

126. Defendants deny the allegations in Paragraph 126.

127. Defendants deny the allegations in Paragraph 127, including the accuracy and truthfulness of Exhibit G.

128. Paragraph 128 asserts various medical and legal conclusions to which no response is required. Insofar as a response is required, Defendants deny the allegations in Paragraph 128.

129. Defendants deny the allegations in Paragraph 129.

130. Paragraph 130 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 130.

131. Paragraph 131 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 131, including the allegations in footnote 5 and the truthfulness and accuracy of Exhibit H.

132. Paragraph 132 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 132.

133. Defendants lack knowledge or information sufficient to form a belief about Ms. Vitez's alleged concerns or what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 133.

134. Defendants deny the allegations in Paragraph 134.

135. Defendants deny the allegations in Paragraph 135.

136. Defendants deny the allegations in Paragraph 136.

137. Paragraph 137 asserts various medical and legal conclusions to which no response is required. To the extent a response is necessary, Defendants deny the allegations in Paragraph 137.

138. Defendants admit that Amanda Mize is not a medical doctor. The remaining allegations in Paragraph 138 assert various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the remaining allegations in Paragraph 138.

139. Defendants admit that employees worked to ensure that they had received the proper documentation and information from physicians. Except as admitted herein, Defendants deny the allegations in Paragraph 139.

140. Defendants deny the allegations in Paragraph 140.

141. Defendants deny the allegations in Paragraph 141.

142. Paragraph 142 asserts various medical and legal conclusions to which no response is required. Insofar as a response is required, Defendants deny the allegations in Paragraph 142.

143. Paragraph 143 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 143, including the accuracy and truthfulness of Exhibit G.

144. Defendants deny the allegations in Paragraph 144, including the accuracy and truthfulness of Exhibit I.

145. Defendants deny the allegations in Paragraph 145.

146. Defendants deny the allegations in Paragraph 146.

147. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly reviewed or prepared, or what others allegedly told her, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 147.

148. Paragraph 148 asserts various medical and legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 148.

149. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 149.

150. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly informed others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 150.

151. Defendants deny the allegations in Paragraph 151.

152. Defendants deny the allegations in Paragraph 152.

153. Defendants deny the allegations in Paragraph 153.

154. Defendants lack knowledge or information sufficient to form a belief about the first sentence of Paragraph 154, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 154.

155. Defendants admit that they had a zero-tolerance policy regarding retaliation and that Ms. Vitez was correctly informed that no retaliatory actions would be taken against her. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 155.

156. Defendants admit that Lorena Reyes was hired as Manager – Billing Operations in June 2010. Except as expressly admitted herein, Defendants deny the allegations in Paragraph 156.

157. Defendants deny the allegations in Paragraph 157.

158. Defendants deny the allegations in Paragraph 158.

159. Defendants deny the allegations in Paragraph 159.

160. Defendants deny the allegations in Paragraph 160.

161. Defendants lack knowledge or information sufficient to form a belief about the first sentence of Paragraph 161, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 161.

162. Defendants deny the allegations in Paragraph 162.

163. Defendants lack knowledge or information sufficient to form a belief about what Ms. Vitez allegedly told others, and therefore deny the same. Defendants deny the remaining allegations in Paragraph 163.

164. Defendants deny the allegations in Paragraph 164.

165. Defendants deny the allegations in Paragraph 165.

166. Defendants deny the allegations in Paragraph 166.

167. Defendants deny the allegations in Paragraph 167.

168. Paragraph 168 asserts a legal conclusion to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 168.

169. Defendants deny the allegations in Paragraph 169.

COUNT I

170. Defendants repeat and reallege their responses to Paragraphs 1 through 169 of the Second Amended Complaint, as if fully set forth herein.

171. Paragraph 171 asserts a legal conclusion to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 171.

172. Defendants deny the allegations in Paragraph 172.

173. Defendants deny the allegations in Paragraph 173.

174. Defendants deny the allegations in Paragraph 174.

175. Defendants deny the allegations in Paragraph 175.

176. Defendants deny the allegations in Paragraph 176.

177. Defendants deny the allegations in Paragraph 177.

178. Defendants deny the allegations in Paragraph 178.

179. Defendants deny the allegations in Paragraph 179.

180. Defendants deny the allegations in Paragraph 180.

181. Defendants deny the allegations in Paragraph 181.

PRAYER AS TO COUNT I

Defendants deny that Relators are entitled to any relief as to Count I.

COUNT II

182. Defendants repeat and reallege their responses to Paragraphs 1 through 181 of the Second Amended Complaint, as if fully set forth herein.

183. Paragraph 183 asserts a legal conclusion to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 183.

184. Defendants deny the allegations in Paragraph 184.

185. Paragraph 185 asserts legal conclusions to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 185.

186. Defendants deny the allegations in Paragraph 186.

187. Defendants deny the allegations in Paragraph 187.

PRAYER AS TO COUNT II

Defendants deny that Relators are entitled to any relief as to Count II.

COUNT III

188. Defendants repeat and reallege their responses to Paragraphs 1 through 187 of the Second Amended Complaint, as if fully set forth herein.

189. Paragraph 189 asserts a legal conclusion to which no response is required. Insofar as a response is necessary, Defendants deny the allegations in Paragraph 189.

190. Defendants deny the allegations in Paragraph 190.

191. Defendants deny the allegations in Paragraph 191.

192. Defendants deny the allegations in Paragraph 192.

PRAYER AS TO COUNT III

Defendants deny that Relators are entitled to any relief as Count III.

* * * * *

GENERAL DENIAL

Except as expressly admitted above, the allegations in the Second Amended Complaint are denied, including the allegations in all footnotes, headings, exhibits, and unnumbered paragraphs.

DEFENSES

Without assuming any burden other than that imposed by law, Defendants allege the following affirmative defenses to the Second Amended Complaint:

First Affirmative Defense

Relators' claims are barred in whole or in part because Relators have failed to state a claim upon which relief may be granted.

Second Affirmative Defense

Relators' claims are barred in whole or in part by the applicable statute of limitations, including but not limited to 31 U.S.C. §§ 3730(h) and 3731.

Third Affirmative Defense

The Court lacks subject matter jurisdiction over this action, or alternatively Relators' claims are barred in whole or in part, because Relators fail to meet the statutory requirements under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, for bringing this action, including but not limited to, the requirements under 31 U.S.C. § 3730(b)(2) and (e)(3).

Fourth Affirmative Defense

The Court lacks subject matter jurisdiction over this action under, or alternatively Relators' claims are barred in whole or in part by, the Public Disclosure Bar. *See* 31 U.S.C. § 3730(e)(4).

Fifth Affirmative Defense

Relators' claims fail in whole or in part because Defendants did not violate the False Claims Act, 31 U.S.C. § 3729, *et seq.*

Sixth Affirmative Defense

Relators' claims are barred in whole or in part because Defendants have not made, or caused to be made, any false statements or claims.

Seventh Affirmative Defense

Relators' claims fail in whole or in part because Defendants have not acted with the state of knowledge or intent necessary to give rise to liability.

Eighth Affirmative Defense

Relators' claims fail in whole or in part because any actions taken by Defendants with respect to the allegations in the Second Amended Complaint were undertaken in good faith and constitute lawful, proper, justified and/or privileged conduct.

Ninth Affirmative Defense

Relators' claims fail in whole or in part because Defendants did not knowingly present, or cause to be presented, any false or fraudulent claim for payment to the government.

Tenth Affirmative Defense

Relators' claims fail in whole or in part because any alleged false statement or claim was immaterial.

Eleventh Affirmative Defense

Relators' claims are barred in whole or in part by settlement agreement and release.

Twelfth Affirmative Defense

Relators' claims fail in whole or in part because Defendants did not violate the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, including but not limited to because the alleged conduct complied with applicable "safe harbor" regulations under the AKS, including 42 C.F.R. § 1001.952.

Thirteenth Affirmative Defense

Relators' claims are barred in whole or in part because Defendants' conduct was in compliance with, or authorized by, laws or regulations administered by a regulatory body or officer acting under state or federal statutory authority.

Fourteenth Affirmative Defense

Relators' claims are barred in whole or in part because the United States had actual or constructive knowledge of the relevant facts and therefore Relators' claims are not false and, additionally, the United States was not defrauded.

Fifteenth Affirmative Defense

Relators' claims are barred in whole or in part by the doctrine of unclean hands.

Sixteenth Affirmative Defense

Relators' claims fail in whole or in part because Defendants did not violate 31 U.S.C. § 3730(h), including but not limited to because Defendants did not take any retaliatory action against Ms. Vitez.

Seventeenth Affirmative Defense

Any damages or penalties above and beyond actual damages are unconstitutional because such damages or penalties would violate the Fifth, Sixth, and Eighth Amendments of the United States Constitution.

Eighteenth Affirmative Defense

Relators' claims fail in whole or in part because the United States has not sustained any damages.

Nineteenth Affirmative Defense

Relators' claims fail in whole or in part because they have named and served the wrong parties.

* * * * *

Defendants have not knowingly or intentionally waived any applicable affirmative defenses and reserve the right to assert and rely upon such other affirmative defenses as may become available or apparent during discovery. Defendants further reserve the right to amend their Answer and/or affirmative defenses accordingly, and/or delete affirmative defenses that Defendants determine during the course of discovery are not applicable.

JURY DEMAND

Defendants hereby request a trial by jury of issues so triable, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure.

WHEREFORE, Defendants respectfully request entry of judgment granting the following relief:

- (a) dismissing Relators' Second Amended Complaint with prejudice;
- (b) awarding the costs of defending this action, including reasonable attorneys' fees, costs, disbursements and expenses pursuant to 31 U.S.C. § 3792(d)(4) and Fed. R. Civ. P. 54(d);
- (c) entering judgment for Defendants and providing that Relators and the United States are entitled to no relief; and
- (d) granting such further relief as the Court may deem just and proper.

Respectfully submitted,

s/ Stacy L. Brainin

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CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing was served on counsel of record via ECF, in accordance with the Federal Rules of Civil Procedure on this 23rd day of April, 2014.

s/ Stacy L. Brainin

Stacy L. Brainin

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