# UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF GEORGIA ATHENS DIVISION

UNITED STATES OF AMERICA, ex rel. : ELIZABETH PETERS YOUNG, :

.

Plaintiffs, : CIVIL ACTION NO. 3:17-CV-00094-CDL

:

:

BTW SOLUTIONS, LLC,

v.

:

Defendant.

#### BTW SOLUTIONS, LLC'S ORIGINAL ANSWER

BTW Solutions, LLC, hereby answers and pleads the following defenses to the Complaint in Intervention ("Complaint") filed by the United States of America on behalf of Elizabeth Peters Young ("Relator"). BTW denies each allegation in the Complaint not expressly admitted herein. Any factual allegation admitted herein is admitted only as to the specific facts alleged and not as to any conclusions, characterization, or other implications.

BTW responds to each of the numbered paragraphs as follows:

#### **SUMMARY OF ACTION**

- Defendant admits the United States of America brings this action under the federal
   False Claims Act. Defendant denies the remaining allegations contained in paragraph 1 of the
   Complaint.
  - 2. Defendant denies the allegations contained in paragraph 2 of the Complaint.
- 3. Paragraph 3 does not make an allegation about Defendant and thus no response is required.
  - 4. Defendant denies the allegations contained in paragraph 4 of the Complaint.

- 5. Defendant admits the allegations contained in paragraph 5 of the Complaint.
- 6. Defendant denies the allegations contained in paragraph 6 of the Complaint.
- 7. Defendant denies the allegations contained in paragraph 7 of the Complaint.
- 8. Defendant pleads that the Distribution Agreement speaks for itself and denies any characterization of the same. To the extent a response is further required, Defendant denies any remaining allegations in paragraph 8.
  - 9. Defendant denies the allegations contained in paragraph 9 of the Complaint.
  - 10. Defendant denies the allegations contained in paragraph 10 of the Complaint.
  - 11. Defendant denies the allegations contained in paragraph 11 of the Complaint.
  - 12. Defendant denies the allegations contained in paragraph 12 of the Complaint.
- Defendant pleads that the marketing materials in paragraph 13 speak for themselves 13. and denies any characterization of the same. To the extent a response is further required, Defendant denies any remaining allegations in paragraph 13.
  - 14. Defendant denies the allegations contained in paragraph 14 of the Complaint.
  - 15. Defendant denies the allegations contained in paragraph 15 of the Complaint.
  - 16. Defendant denies the allegations contained in paragraph 16 of the Complaint.
  - 17. Defendant denies the allegations contained in paragraph 17 of the Complaint.
  - 18. Defendant denies the allegations contained in paragraph 18 of the Complaint.
  - 19. Defendant denies the allegations contained in paragraph 19 of the Complaint.
  - 20. Defendant denies the allegations contained in paragraph 20 of the Complaint.
- 21. Defendant pleads that the letter referenced in paragraph 21 speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 21.

- 22. Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies any remaining allegations in paragraph 22.
  - 23. Defendant denies the allegations contained in paragraph 23 of the Complaint.
  - 24. Defendant denies the allegations contained in paragraph 24 of the Complaint.
  - 25. Defendant denies the allegations contained in paragraph 25 of the Complaint.
  - 26. Defendant denies the allegations contained in paragraph 26 of the Complaint.
- 27. Defendant pleads that it billed LidoPro in accordance with all the requirements of the OWCP fee schedule and guidance. Specifically, OWCP regulations require a name brand drug to be billed at AWP. The AWP is set by the manufacturer and BTW reasonably relied on OWCP's guidance and the manufacturer's AWP. Defendant denies the remaining allegations contained in paragraph 27 of the Complaint.
  - 28. Defendant denies the allegations contained in paragraph 28 of the Complaint.
  - 29. Defendant denies the allegations contained in paragraph 29 of the Complaint.
  - 30. Defendant denies the allegations contained in paragraph 30 of the Complaint.
  - 31. Defendant denies the allegations contained in paragraph 31 of the Complaint.
  - 32. Defendant denies the allegations contained in paragraph 32 of the Complaint.
  - 33. Defendant denies the allegations contained in paragraph 33 of the Complaint.
  - 34. Defendant denies the allegations contained in paragraph 34 of the Complaint.
- Paragraph 35 contains legal conclusions to which no response is required. To the 35. extent a response is required, Defendant denies the allegations in paragraph 35.

#### **JURISDICTION AND VENUE**

- 36. Defendant admits the Court has subject matter jurisdiction.
- 37. Defendant admits the Court has personal jurisdiction.

38. Defendant admits venue is proper.

#### **PARTIES**

- 39. Defendant admits the United States of America brings this action on behalf of DOL and OWCP.
- 40. Defendant admits that Relator filed an action alleging violations of the FCA. Defendant denies that Relator was, at any time, contracted with the Defendant to sell its products in the State of Georgia. Defendant is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 40 of the Complaint, and therefore denies the same.
  - 41. Defendant denies the allegations contained in paragraph 41 of the Complaint.
- 42. Defendant admits that BTW is a registered wholesale distributor of drugs and medical devices in the State of Arkansas. Defendant admits BTW provides billing services. Defendant denies the remaining allegations contained in paragraph 42 of the Complaint.

#### LEGAL AND REGULATORY FRAMEWORK

- 43. Paragraph 43 does not make an allegation about Defendant and thus no response is required.
- 44. Paragraph 44 does not make an allegation about Defendant and thus no response is required.
- 45. Paragraph 45 does not make an allegation about Defendant and thus no response is required.
- 46. Paragraph 46 does not make an allegation about Defendant and thus no response is required.

- 47. Paragraph 47 does not make an allegation about Defendant and thus no response is required.
- 48. Paragraph 48 does not make an allegation about Defendant and thus no response is required.
- 49. Paragraph 49 does not make an allegation about Defendant and thus no response is required.
- 50. Paragraph 50 does not make an allegation about Defendant and thus no response is required.
- 51. Paragraph 51 does not make an allegation about Defendant and thus no response is required.
- 52. Paragraph 52 does not make an allegation about Defendant and thus no response is required.
- 53. Paragraph 53 does not make an allegation about Defendant and thus no response is required.
- 54. Paragraph 54 does not make an allegation about Defendant and thus no response is required.
- 55. Paragraph 55 does not make an allegation about Defendant and thus no response is required.
- Paragraph 56 does not make an allegation about Defendant and thus no response is 56. required.
- 57. Paragraph 57 does not make an allegation about Defendant and thus no response is required.

- 58. Paragraph 58 does not make an allegation about Defendant and thus no response is required.
- 59. Paragraph 59 does not make an allegation about Defendant and thus no response is required.
- 60. Paragraph 60 does not make an allegation about Defendant and thus no response is required.
- 61. Paragraph 61 does not make an allegation about Defendant and thus no response is required.
- 62. Paragraph 62 does not make an allegation about Defendant and thus no response is required.
- 63. Paragraph 63 does not make an allegation about Defendant and thus no response is required.
- 64. Paragraph 64 does not make an allegation about Defendant and thus no response is required.
- 65. Paragraph 65 does not make an allegation about Defendant and thus no response is required.
- 66. Paragraph 66 does not make an allegation about Defendant and thus no response is required.
- Paragraph 67 does not make an allegation about Defendant and thus no response is 67. required.
- 68. Paragraph 68 does not make an allegation about Defendant and thus no response is required.

- 69. Paragraph 69 does not make an allegation about Defendant and thus no response is required.
- 70. Paragraph 70 does not make an allegation about Defendant and thus no response is required.
- 71. Paragraph 71 does not make an allegation about Defendant and thus no response is required.
- 72. Paragraph 72 does not make an allegation about Defendant and thus no response is required.
- 73. Paragraph 73 does not make an allegation about Defendant and thus no response is required.
- 74. Paragraph 74 does not make an allegation about Defendant and thus no response is required.
- 75. Paragraph 75 does not make an allegation about Defendant and thus no response is required.
- 76. Paragraph 76 does not make an allegation about Defendant and thus no response is required.
- 77. Paragraph 77 does not make an allegation about Defendant and thus no response is required.
- Paragraph 78 does not make an allegation about Defendant and thus no response is 78. required.
- 79. Paragraph 79 does not make an allegation about Defendant and thus no response is required.

- 80. Paragraph 80 does not make an allegation about Defendant and thus no response is
- required.
- 81. Paragraph 81 does not make an allegation about Defendant and thus no response is
- required.
- 82. Paragraph 82 does not make an allegation about Defendant and thus no response is
- required.
- 83. Paragraph 83 does not make an allegation about Defendant and thus no response is
- required.
  - 84. Paragraph 84 does not make an allegation about Defendant and thus no response is
- required.
  - 85. Paragraph 85 does not make an allegation about Defendant and thus no response is
- required.
  - 86. Paragraph 86 does not make an allegation about Defendant and thus no response is
- required.
  - 87. Paragraph 87 does not make an allegation about Defendant and thus no response is
- required.
  - 88. Paragraph 88 does not make an allegation about Defendant and thus no response is
- required.
  - 89. Paragraph 89 does not make an allegation about Defendant and thus no response is
- required.
  - 90. Paragraph 90 does not make an allegation about Defendant and thus no response is
- required.

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- 91. Paragraph 91 does not make an allegation about Defendant and thus no response is required.
- 92. Paragraph 92 does not make an allegation about Defendant and thus no response is required.
- 93. Paragraph 93 does not make an allegation about Defendant and thus no response is required.
- 94. Paragraph 94 does not make an allegation about Defendant and thus no response is required.
- 95. Paragraph 95 does not make an allegation about Defendant and thus no response is required.
- 96. Paragraph 96 does not make an allegation about Defendant and thus no response is required.

### FACTUAL ALLEGATIONS<sup>1</sup>

- 97. Defendant admits the allegations contained in paragraph 97 of the Complaint.
- 98. Defendant denies the allegations contained in paragraph 98 of the Complaint.
- 99. Defendant admits the allegations contained in paragraph 99 of the Complaint.
- 100. Defendant admits the allegations contained in paragraph 100 of the Complaint.
- 101. Defendant pleads that the Distribution Agreement speaks for itself and denies any characterization of the same. To the extent that a response is further required. Defendant denies any remaining allegations in paragraph 101.
  - Defendant admits the allegations contained in paragraph 102 of the Complaint. 102.

<sup>&</sup>lt;sup>1</sup> Defendant does not repeat the Government's headings from its Complaint. Those headings are not allegations to which a response is required. To the extent the Court decides otherwise, Defendant denies all allegations within the Government's headings.

- 103. Defendant admits the allegations contained in paragraph 103 of the Complaint.
- 104. Defendant denies the allegations contained in paragraph 104 of the Complaint.
- 105. Defendant denies the allegations contained in paragraph 105 of the Complaint.
- 106. Defendant admits the allegations contained in paragraph 106 of the Complaint.
- 107. Defendant denies the allegations contained in paragraph 107 of the Complaint.
- 108. Paragraph 108 does not make an allegation about Defendant and thus no response is required.
  - 109. Defendant denies the allegations contained in paragraph 109 of the Complaint.
  - 110. Defendant admits the allegations contained in paragraph 110 of the Complaint.
- 111. Defendant admits Patrick Booth, Rick Rioles, Chad Montgomery, Clark Mohar, and Michael LaFauve worked for BTW and Infinity. Defendant denies the remaining allegations in paragraph 111 of the Complaint.
  - 112. Defendant denies the allegations contained in paragraph 112 of the Complaint.
  - 113. Defendant denies the allegations contained in paragraph 113 of the Complaint.
  - 114. Defendant admits the allegations contained in paragraph 114 of the Complaint.
- 115. Defendant denies BTW restricted the patients to whom its products could be sold. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations.
  - 116. Defendant admits the allegations contained in paragraph 116 of the Complaint.
- 117. Paragraph 117 does not make an allegation about Defendant and thus no response is required.
  - 118. Defendant admits the allegations contained in paragraph 118 of the Complaint.

- 119. Paragraph 119 does not make an allegation about Defendant and thus no response is required.
- 120. Paragraph 120 does not make an allegation about Defendant and thus no response is required.
  - 121. Defendant denies the allegations contained in paragraph 121 of the Complaint.
  - 122. Defendant denies the allegations contained in paragraph 122 of the Complaint.
  - 123. Defendant denies the allegations contained in paragraph 123 of the Complaint.
- 124. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 124 of the Complaint.
  - 125. Defendant denies the allegations contained in paragraph 125 of the Complaint.
  - 126. Defendant denies the allegations contained in paragraph 126 of the Complaint.
- 127. Defendant pleads that any agreements between it and Terrain speak for themselves and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 127.
  - 128. Defendant denies the allegations contained in paragraph 128 of the Complaint.
- 129. Defendant pleads that the distribution agreement speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 129.
- 130. Defendant pleads that the distribution agreement speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 130.
- 131. Defendant pleads that the distribution agreement speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 131.
- 132. Defendant pleads that the distribution agreement speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 132.

- 133. Defendant pleads that the distribution agreement speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 133.
- 134. Defendant pleads that the distribution agreement speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 134.
- 135. Defendant pleads that the distribution agreement speaks for itself and denies any characterization of the same. Defendant denies the remaining allegations in paragraph 135.
  - 136. Defendant admits the allegations contained in paragraph 136 of the Complaint.
  - 137. Defendant denies the allegations contained in paragraph 137 of the Complaint.
- 138. Defendant admits that physician-customers received the products. Defendant is without knowledge or information sufficient to form a belief as to the truth of the generalized statement regarding the distribution of products directly to patients.
- 139. Defendant affirmatively admits that this billing amount was used in accordance with OWCP's regulations and relevant guidance, specifically that the billing of name brand products be billed based on AWP.
  - 140. Defendant denies the allegations contained in paragraph 140 of the Complaint.
- 141. Defendant admits that Michael LaFauve created the BTW Worksheets. Defendant denies the remaining allegations contained in paragraph 141 of the Complaint.
  - 142. Defendant denies the allegations contained in paragraph 142 of the Complaint.
  - 143. Defendant denies the allegations contained in paragraph 143 of the Complaint.
  - 144. Defendant denies the allegations contained in paragraph 144 of the Complaint.
  - 145. Defendant denies the allegations contained in paragraph 145 of the Complaint.
  - 146. Defendant denies the allegations contained in paragraph 146 of the Complaint.

- 147. Defendant admits that sales representatives were trained to respond to objections raised by potential customers. Defendant denies the remaining allegations contained in paragraph 147.
  - 148. Defendant denies the allegations contained in paragraph 148 of the Complaint.
  - 149. Defendant denies the allegations contained in paragraph 149 of the Complaint.
  - 150. Defendant denies the allegations contained in paragraph 150 of the Complaint.
- 151. Defendant denies the allegations contained in paragraph 151 of the Complaint.

  Defendant pleads that any marketing materials speak for themselves and further denies any characterization of the same.
- 152. Defendant denies the allegations contained in paragraph 152 of the Complaint.

  Defendant pleads that any documents referred to speak for themselves and denies any characterization of the same.
- 153. Defendant denies the allegations contained in paragraph 153 of the Complaint. Defendant pleads that any documents referred to speak for themselves and denies any characterization of the same.
  - 154. Defendant denies the allegations contained in paragraph 154 of the Complaint.
  - 155. Defendant denies the allegations contained in paragraph 155 of the Complaint.
  - 156. Defendant denies the allegations contained in paragraph 156 of the Complaint.
- 157. Defendant lacks sufficient information to form a belief as to the truthfulness of what former owner Laurie Morris knows about BTW and, therefore, denies the allegations in paragraph 157.

- 158. Defendant admits it distributed marketing materials that promoted the effectiveness and benefits of the products for patients. Defendant denies the remaining allegations in paragraph 158 of the Complaint.
  - 159. Defendant denies the allegations contained in paragraph 159 of the Complaint.
  - 160. Defendant denies the allegations contained in paragraph 160 of the Complaint.
- 161. Paragraph 161 contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 161 of the Complaint.
  - 162. Defendant denies the allegations contained in paragraph 162 of the Complaint.
  - 163. Defendant denies the allegations contained in paragraph 163 of the Complaint.
  - 164. Defendant denies the allegations contained in paragraph 164 of the Complaint.
  - 165. Defendant denies the allegations contained in paragraph 165 of the Complaint.
  - 166. Defendant denies the allegations contained in paragraph 166 of the Complaint.
  - 167. Defendant denies the allegations contained in paragraph 167 of the Complaint.
  - 168. Defendant admits the allegations contained in paragraph 168 of the Complaint.
  - 169. Defendant admits the allegations contained in paragraph 169 of the Complaint.
- 170. Paragraph 170 does not make an allegation about Defendant and thus no response is required. To the extent a response is required, BTW lacks sufficient information to form a belief as to the truthfulness of the allegations in paragraph 170 and denies the same.
  - 171. Defendant denies the allegations contained in paragraph 171 of the Complaint.
  - 172. Defendant denies the allegations contained in paragraph 172 of the Complaint.
  - 173. Defendant denies the allegations contained in paragraph 173 of the Complaint.
  - 174. Defendant denies the allegations contained in paragraph 174 of the Complaint.
  - 175. Defendant denies the allegations contained in paragraph 175 of the Complaint.

- 176. Defendant denies the allegations contained in paragraph 176 of the Complaint.
- 177. Defendant denies the allegations contained in paragraph 177 of the Complaint.
- 178. The allegations in paragraph 178 state legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 178.
- 179. The allegations in paragraph 179 state legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 179.
  - 180. Defendant denies the allegations contained in paragraph 180 of the Complaint.
  - 181. Defendant denies the allegations contained in paragraph 181 of the Complaint.
- 182. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 182 of the Complaint.
  - 183. Defendant denies the allegations contained in paragraph 183 of the Complaint.
  - 184. Defendant denies the allegations contained in paragraph 184 of the Complaint.
- 185. Defendant pleads that the referenced document speaks for itself and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 185.
  - 186. Defendant denies the allegations contained in paragraph 186 of the Complaint.
  - 187. Defendant admits the allegations contained in paragraph 187 of the Complaint.
- 188. Defendant pleads that any written communication speaks for itself and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 188.
- 189. Defendant pleads that any written communication speaks for itself and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 189.

- 190. Defendant denies the allegations contained in paragraph 190 of the Complaint.
- 191. Defendant denies the allegations contained in paragraph 191 of the Complaint.
- 192. The allegations in paragraph 192 state legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 192.
- 193. Defendant admits that Dr. Yusufuji entered into an agreement with Defendant. Defendant pleads that the Distribution Agreement speaks for itself and denies any characterization of the same. To the extent a response is further required, Defendant denies any remaining allegations in paragraph 193.
- 194. Defendant pleads that any claim speaks for itself and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 194.
- 195. Defendant pleads that the distribution agreement and any claims speak for themselves and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 195.
  - 196. Defendant denies the allegations contained in paragraph 196 of the Complaint.
  - 197. Defendant denies the allegations contained in paragraph 197 of the Complaint.
- 198. The allegations in paragraph 198 state legal conclusions to which no response is required. To the extent a response is required, paragraph 198 does not make an allegation about Defendant and thus no response is required.
- 199. Defendant admits that Dr. Nicholson entered into an agreement with Defendant. Defendant pleads that the Distribution Agreement speaks for itself and denies any characterization of the same. To the extent a response is further required, Defendant denies any remaining allegations in paragraph 199.

- 200. Defendant pleads that any claim speaks for itself and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 200.
- 201. Defendant pleads that the distribution agreement and any claim speak for themselves and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 201.
  - 202. Defendant denies the allegations contained in paragraph 202 of the Complaint.
  - 203. Defendant denies the allegations contained in paragraph 203 of the Complaint.
- 204. The allegations in paragraph 204 state legal conclusions to which no response is required. To the extent a response is required, paragraph 204 does not make an allegation about Defendant and thus no response is required.
- 205. Defendant admits that Dr. Dorris entered into an agreement with Defendant. Defendant pleads that the Distribution Agreement speaks for itself and denies any characterization of the same. To the extent that a response is further required, Defendant denies any remaining allegations contained in paragraph 205.
- 206. Defendant pleads that any claim speaks for itself and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 206.
- 207. Defendant pleads that the distribution agreement and any claim speak for themselves and denies any characterization of the same. To the extent a further response is required, BTW denies the allegations in paragraph 207.
  - 208. Defendant denies the allegations contained in paragraph 208 of the Complaint.
  - 209. Defendant denies the allegations contained in paragraph 209 of the Complaint.

- 210. Defendant denies the allegations contained in paragraph 210 of the Complaint.
- 211. The allegations in paragraph 211 state legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 211.
- 212. The allegations in paragraph 212 state legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 212.
  - 213. Defendant denies the allegations contained in paragraph 213 of the Complaint.
  - 214. Defendant admits the allegations contained in paragraph 214 of the Complaint.
  - 215. Defendant denies the allegations contained in paragraph 215 of the Complaint.
  - 216. Defendant denies the allegations contained in paragraph 216 of the Complaint.
  - 217. Defendant denies the allegations contained in paragraph 217 of the Complaint.
  - 218. Defendant admits the allegations contained in paragraph 218 of the Complaint.
  - 219. Defendant denies the allegations contained in paragraph 219 of the Complaint.
- 220. Defendant admits that during Laurie Morris's employment she maintained responsibilities pertaining to BTW's performance of billing services.
  - 221. Defendant denies the allegations contained in paragraph 221 of the Complaint.
  - 222. Defendant denies the allegations contained in paragraph 222 of the Complaint.
  - 223. Defendant denies the allegations contained in paragraph 223 of the Complaint.
  - 224. Defendant denies the allegations contained in paragraph 224 of the Complaint.
  - 225. Defendant denies the allegations contained in paragraph 225 of the Complaint.
- 226. Defendant admits that it listed the AWP for the charge of the service in accordance with OWCP billing guidelines and requirements.
  - 227. Defendant denies the allegations contained in paragraph 227 of the Complaint.
  - 228. Defendant denies the allegations contained in paragraph 228 of the Complaint.

- 229. Defendant denies the allegations contained in paragraph 229 of the Complaint.
- 230. Defendant denies the allegations contained in paragraph 230 of the Complaint.
- 231. Defendant denies the allegations contained in paragraph 231 of the Complaint.
- 232. Paragraph 232 contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations contained in paragraph 232.
  - 233. Defendant denies the allegations contained in paragraph 233 of the Complaint.
  - 234. Defendant denies the allegations contained in paragraph 234 of the Complaint.
  - 235. Defendant denies the allegations contained in paragraph 235 of the Complaint.
  - 236. Defendant denies the allegations contained in paragraph 236 of the Complaint.
- 237. Paragraph 237 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 237.
- 238. Paragraph 238 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 238.
- 239. Paragraph 239 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 239.
  - 240. Defendant denies the allegations contained in paragraph 240 of the Complaint.
- 241. Defendant contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 241.
- 242. Paragraph 242 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 242.

# COUNT I FCA: Presentation of False Claims (31 U.S.C. § 3729(a)(1)(A))

- 243. Defendant repeats and denies by reference the responses to the allegations contained in paragraph 1 through 242 as if fully set forth herein.
- 244. Paragraph 244 does not make an allegation about Defendant and thus no response is required.
- 245. Paragraph 245 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 245.
  - 246. Defendant denies the allegations contained in paragraph 246 of the Complaint.
- 247. Defendant is without knowledge or sufficient information to form a belief as to the truth of the allegations contained in paragraph 247 of the Complaint.
- 248. Paragraph 248 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 248.

#### **COUNT II**

## FCA: Making or Using False Statements to Get False Claims Paid (31 U.S.C. § 3729(a)(1)(B))

- 249. Defendant repeats and denies by reference the responses to the allegations contained in paragraph 1 through 248 as if fully set forth herein.
- 250. Paragraph 250 does not make an allegation about Defendant and thus no response is required.
- 251. Paragraph 251 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 251.
- 252. Paragraph 252 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 252.

- 253. Defendant is without knowledge or sufficient information to form a belief as to the truth of the allegations contained in paragraph 253 of the Complaint.
- 254. Paragraph 254 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 254.
- 255. Paragraph 255 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 255.

### COUNT III

## FCA: False Record Material to Obligation to Pay (31 U.S.C. § 3729(a)(1)(G))

- 256. Defendant repeats and denies by reference the responses to the allegations contained in paragraph 1 through 255 as if fully set forth herein.
- 257. Paragraph 257 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 257.
- 258. Paragraph 258 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 258.
- 259. Paragraph 259 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 259.

### **COUNT IV Payment by Mistake**

- 260. Defendant repeats and denies by reference the responses to the allegations contained in paragraph 1 through 259 as if fully set forth herein.
- 261. Paragraph 261 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary. Defendant denies the remaining allegations contained in paragraph 261 of the Complaint.

- 262. Defendant is without knowledge or sufficient information to form a belief as to the truth of the allegations contained in paragraph 262 of the Complaint and therefore denies the same.
- 263. Defendant is without knowledge or sufficient information to form a belief as to the truth of the allegations contained in paragraph 263 of the Complaint and therefore denies the same.
- 264. Paragraph 264 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 264.

#### COUNT V Unjust Enrichment

- 265. Defendant repeats and denies by reference the responses to the allegations contained in paragraph 1 through 264 as if fully set forth herein.
  - 266. Defendant denies the allegations contained in paragraph 266 of the Complaint.
- 267. Paragraph 267 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 267.
- 268. Paragraph 268 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 268.

### COUNT VI Common Law Fraud

- 269. Defendant repeats and denies by reference the responses to the allegations contained in paragraph 1 through 268 as if fully set forth herein.
  - 270. Defendant denies the allegations contained in paragraph 270 of the Complaint.
- 271. Paragraph 271 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 271.
- 272. Paragraph 272 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 272.

- 273. Defendant denies the allegations contained in paragraph 273 of the Complaint.
- 274. Defendant is without knowledge or sufficient information to form a belief as to the truth of the allegations contained in paragraph 274 of the Complaint and therefore denies the same.
- 275. Paragraph 275 contains legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 275.

#### **PRAYER FOR RELIEF**

WHEREFORE, BTW denies the United States and Relator have any right to any of the relief requested under any legal theory. Defendant prays:

- 1. That the Court enter judgement in favor of Defendant;
- 2. That the Court dismiss the Complaint upon the following affirmative defenses;
- 3. Defendant be awarded its costs and expenses; and
- 4. Such other and further relief to which Defendant may be justly entitled.

#### **JURY DEMAND**

Defendant requests a trial by jury on all claims in this action.

#### **ADDITIONAL AND AFFIRMATIVE DEFENSES**

BTW pleads the following defenses with respect to each and every claim pleaded against it in the Complaint. By virtue of asserting these defenses, BTW does not assume any burden of proof or persuasion not otherwise legally assigned to it. BTW reserves the right to assert other defenses as appropriate or were learned through the discovery process given the early juncture of this litigation.

#### **FIRST AFFIRMATIVE DEFENSE**

(Statute of Limitations)

This action is barred, in whole or in part, by the applicable statute of limitations and/or repose, as it relates to the actions of Defendant. 31 U.S.C. § 3731(b).

- 276. 31 U.S.C. § 3731(b)(1) provides that a civil action may not be brought more than six (6) years after the date the violation was committed.
- 277. 31 U.S.C. § 3731(c) allows the Government to intervene and amend a complaint of the relator. Once amended, and for purposes of the statute of limitations, the amendment relates back to the original filing of the relator's claim. *Id*.
- 278. In doing so, the Government must still comply with all the rules of the Federal Rules of Civil Procedure including Fed. R. Civ. P. 4(m), which requires that a defendant be served within ninety (90) days after the complaint is filed. If the Government fails to serve the defendant within the specified time frame, the court must dismiss the complaint without prejudice. *Id*.
- 279. The Government was given ample opportunity and time to elect to intervene. The Government was given thirteen (13) extensions across six (6) years starting from August 8, 2017, through April 21, 2023.
- 280. The Government finally unsealed the complaint and elected to intervene in the *qui* tam case against BTW on June 22, 2023. The Court then ordered the Government to serve the complaint on the parties within ninety (90) days from the date the complaint was unsealed.
- 281. The Complaint was unsealed on June 22, 2023, and therefore the parties would need to be served by September 20, 2023, the date the order expired.
- 282. The Government instead served the Defendant on September 21, 2023, in violation of the Court's order.
- 283. Therefore, the Government's failure to comply with the Court's order bars this action and should result in dismissal without prejudice.

- 284. The Court's dismissal of the Complaint without prejudice would require the Government to refile; thus, nullifying the tolling established by the original Complaint. 31 U.S.C. § 371(c).
- 285. The nullification of the tolling would bar the Government's claims of alleged violations before November of 2017 pursuant to the six-year statute of limitations in 31 U.S.C. § 3731(b)(1). Furthermore, the nullification would limit the subsequent complaint to alleged violations having occurred after November of 2017.
- 286. Therefore, because the Government failed to comply with the Court's order, the Court should dismiss the Complaint without prejudice and limit the subsequent complaint to alleged violations after 2017 pursuant to the six-year statute of limitations under 31 U.S.C. § 3731(b)(1).

#### SECOND AFFIRMATIVE DEFENSE

#### (Requisite Scienter)

287. Violations of the False Claims Act predicated on the Anti-Kickback Statute require proof that the defendant acted willfully. 42 U.S.C. § 1320a-7b(b). Defendant did not possess the requisite scienter for claims predicated on violations of the Anti-Kickback Statute.

#### THIRD AFFIRMATIVE DEFENSE

#### (Acts Outside of Defendant's Control or Responsibility)

288. The acts or omissions of others, over whom Defendant had no control, whose acts or omissions Defendant had no reason to anticipate, and for whom Defendant is not liable, proximately caused or contributed to the United States' damages, injuries, or loss, if any. These acts or omissions of others constituted intervening cause(s) and superseded any alleged wrongful act or omission on the part of Defendant.

#### **FOURTH AFFIRMATIVE DEFENSE**

#### (Good Faith)

289. The Complaint, and each and every purported claim, fails because the Defendant acted reasonably and in good faith and did not knowingly submit any false claim.

#### **FIFTH AFFIRMATIVE DEFENSE**

#### (Defendant's Lack of Knowledge and Intent)

- 290. Defendant did not knowingly, or with reckless disregard or deliberate ignorance, make false or materially false statements, or engage in fraudulent conduct.
- 291. Defendant did not knowingly, or with reckless disregard or deliberate ignorance, present or cause to be presented, false or fraudulent claims to the United States, or any government health care provider for payment or approval.
- 292. Defendant did not knowingly, or with reckless disregard or deliberate ignorance, offer or pay remuneration to induce a person to refer an individual to Defendant for furnishing or arranging for the furnishing of an item or service for which payment may be made in whole or in part by or under any government health care provider.
- 293. Defendant did not act with the state of knowledge or intent necessary to give rise to liability. No act or omission of Defendant was malicious, willful, wanton, reckless or made with intent to violate any statute or law.

#### SIXTH AFFIRMATIVE DEFENSE

#### (Safe Harbor)

294. Defendant invokes all safe harbors and exceptions to the statutes and laws pled by Plaintiff in this action.

#### SEVENTH AFFIRMATIVE DEFENSE

#### (Failure to State a Claim)

- 295. Relator's claims are barred, in whole or in part, because Relator failed to state a claim upon which relief can be granted.
- Relator's claims are barred, in whole or in part, because Relator failed to plead her 296. claims with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure.

#### EIGHTH AFFIRMATIVE DEFENSE

#### (Doctrine of Unclean Hands)

- 297. Relators' claims are barred, in whole or in part, under the doctrine of unclean hands, by Relator's fraud, and/or by Relator's own improper conduct.
- Relator has been convicted of fraud, conspiracy, and various violations of federal 298. statutes for her own involvement in an illegal kickback scheme.
- 299. Relator has described in the Original Complaint a scheme that does not mirror the Defendant's model but rather her own for which she was criminally convicted.
- 300. Due to Relator's own fraudulent conduct and false allegations against Defendant that are littered throughout the Complaint, Relator's claims are barred, in whole or in part, by the Relator's own negligence.

#### NINTH AFFIRMATIVE DEFENSE

#### (Excessive Fines)

301. The damages and civil fines that Relator seeks are grossly disproportionate to BTW's alleged conduct, and therefore, would violate the Excessive Fines Clause of the Eighth Amendment to the United States Constitution.

#### TENTH AFFIRMATIVE DEFENSE

#### (Violation of Due Process Clause)

302. The damages and civil fines that Relator seeks are grossly disproportionate to BTW's alleged conduct, and therefore, would violate the Due Process Clause of the Fifth Amendment of the United States Constitution.

#### **ELEVENTH AFFIRMATIVE DEFENSE**

#### (Failure to Mitigate)

- 303. Relator's claims are barred, in whole or in part, because of the failure to mitigate the United States' purported damages.
- 304. The Office of Workers' Compensation Program ("OWCP") continuously failed to properly oversee and administer the program over the past ten (10) years during which it had the opportunity to issue guidance, conduct audits, or take other reasonable action to oversee the Federal Workers' Compensation Program ("FWC"). The alleged damages would have been mitigated (or nonexistent) if the Government properly fulfilled its obligations to oversee the FWC. Instead, OWCP received, reviewed, adjusted, and knowingly paid for the services for which BTW billed on behalf of physicians. The OWCP's failure to mitigate bars its opportunity to recover damages.

#### TWELTH AFFIRMATIVE DEFENSE

#### (Relator is Barred from Filing a Qui Tam Action)

305. Relator's claims are barred, in whole or in part, because the False Claims Act bars relators from pursuing *qui tam* action when the relator has been convicted of criminal conduct. 31 USC § 3730(d)(3).

- 306. On August 6, 2020, Relator, Elizabeth Peters Young, was convicted on five (5) counts of healthcare fraud and defrauding the FWC in connection with paying and receiving illegal kickbacks in exchange for referrals of pain cream medication, including Lidopro.
- 307. From March 2015 to April 2018, Relator used her extensive knowledge of the industry to capitalize on a model to illegally deprive the FWC program of roughly \$1.5 million, which also happens to be the same model that is described and detailed in the Original Complaint.
- 308. Relator knowingly and willingly contracted with two different pharmacies to split profits for the sale of creams and patches. Relator further contracted with a medical assistant to prescribe medication for an illegal kickback for each referral.
- 309. At trial it was proven that Relator knew of the nature of her conduct and went to great lengths to conceal her conduct from Governmental authorities.
- 310. Relator was eventually convicted of criminal healthcare fraud including one count of conspiracy to pay and receive healthcare kickbacks and four counts of paying kickbacks in connection with a federal healthcare program.
- 311. Relator was further sentenced to fifty-seven (57) months in prison after the filing of this suit.
- 312. Because of Relator's proven criminal and fraudulent conduct, the Court should dismiss the Complaint in totality under 31 USC § 3730(d)(3) for false and inaccurate allegations contained therein.

#### **ADDITIONAL DEFENSES RESERVED**

BTW herein reserves the right to assert additional defenses that become known to it during the course of this action.

DATED: November 28, 2023.

Respectfully submitted,

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By: <u>/s/ Jason E. Pepe</u> Jason E. Pepe

#### ATTORNEYS FOR BTW SOLUTIONS, LLC

#### **CERTIFICATE OF SERVICE**

This is to certify that on the 28th day of November, 2023, I electronically filed the foregoing with the Clerk of Court using CM/ECF system, which automatically sends an electronic notification to all counsel of record and other CM/ECF participants.

W. Taylor McNeill USAO 300 Mulberry St. Macon, GA 31201 Via Email taylor.mcneill@usdoj.gov

#### **COUNSEL FOR PLAINTIFFS**

By: /s/ Jason E. Pepe Jason E. Pepe