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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

ALEX M. AZAR, II, *in his official capacity as*
SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-DKW-KSC

ANSWER

Judge: Hon. Derrick K. Watson
Related Documents:

DEFENDANTS' ANSWER TO PLAINTIFFS' COMPLAINT

Defendants, by and through their undersigned attorneys, as their answer to plaintiffs' complaint, states as follows:

1. Defendants admit the allegations in the first sentence of paragraph 1. Defendants admit that Mifeprex is the only drug approved in the United States for use in non-surgical termination of an early pregnancy but Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the second sentence of paragraph 1.

Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence of paragraph 1. The allegations in fourth sentence of paragraph 1 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents. Defendants deny the allegations in the fifth sentence of paragraph 1 because "miscarriage" is an undefined term.

Defendants are without knowledge or information sufficient to form a belief as to the allegations in the last sentence of paragraph 1 except to admit that Mifeprex is approved, in a regimen with Misoprostol, to end a pregnancy through 70 days gestation.

2. The allegations in paragraph 2 are plaintiffs' summary of its complaint to which no answer is required. To the extent that an answer is required, Defendants deny the allegations in paragraph 2.

3. The allegations in paragraph 3 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

4. With respect to the first sentence of paragraph 4, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations because the allegations are vague and use undefined terminology (in particular, it is unclear what is meant by the term "risks"). With respect to the second sentence of paragraph 4, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations because the allegations

are vague and use undefined terminology, except that Defendants admit that there are risks, including of fatality, for a woman who carries a pregnancy to term.

5. Defendants admit that there is no known risk of a patient developing a dependency on Mifeprex, but are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5.

6. The allegations preceding footnote 3 in paragraph 6 contain plaintiffs' characterization of, and quotations from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents. Defendants deny the remainder of the allegations in paragraph 6 except that Defendants admit that Mifeprex is subject to a Risk Evaluation and Mitigation Strategy ("REMS")

7. The allegations in paragraph 7 contain plaintiffs' characterization of, and quotations from, the cited statutory provisions and Defendants respectfully refer the Court to those provisions for full and complete statements of their contents.

8. The allegations in paragraph 8 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

9. Defendants deny the allegations in paragraph 9 except that Defendants admit that Mifeprex is subject to a REMS with ETASU.

10. The allegations in paragraph 10 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

11. The allegations in the first sentence of paragraph 11 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and

complete statement of its contents. Defendants admit that a healthcare provider can write a prescription for misoprostol but are without knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 11.

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12.

13. Defendants deny the allegations in the first and second sentences of paragraph 13. The allegations in the third sentence of paragraph 13 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

14. The allegations in paragraph 14 contain plaintiffs' characterization of, and quotations from, the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

15. The allegations in paragraph 15 contain plaintiffs' characterization of, and quotations from, the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

16. Defendants deny the allegations in the first and second sentences of paragraph 16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences of paragraph 16.

17. Defendants deny the allegations in paragraph 17.

18. Defendants deny the allegations in the first sentence of paragraph 18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentences of paragraph 18.

19. Defendants are without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 19.

20. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20, except that Defendants deny that “the Mifeprex REMS makes health care less safe.”

21. The allegations in the first sentence of paragraph 21 contain plaintiffs’ characterization of the cited case and Defendants respectfully refer the Court to that case for a full and complete statement of its contents. The allegations in the second sentence of paragraph 21 are legal conclusions to which no answer is required. Defendants deny the allegations in the third sentence of paragraph 21.

22. The allegations in paragraph 22 are legal conclusions to which no answer is required.

23. The allegations in paragraph 23 are legal conclusions to which no answer is required.

24. The allegations in paragraph 24 are legal conclusions to which no answer is required.

25. The allegations in paragraph 25 are legal conclusions to which no answer is required.

26. The allegations in paragraph 26 are legal conclusions to which no answer is required.

27. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27.

28. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28.

29. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29.

30. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30.

31. Defendants are without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 31.

32. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 32.

33. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33.

34. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 34.

35. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35.

36. Defendants aver that Don J. Wright is no longer the Acting Secretary of the United States Department of Health and Human Services (“HHS”), as Alex M. Azar is the current Secretary of HHS. Defendants admit the remaining allegations in paragraph 36.

37. Defendants admit the allegations in paragraph 37.

38. Defendants admit the allegations in paragraph 38.

39. Defendants admit the allegations in the first sentence of paragraph 39 to the extent plaintiffs are referring to new drugs, but deny that a new drug application (“NDA”) is required for all drugs. Defendants deny the allegations in the second sentence of paragraph 39 as the safety and efficacy of a drug product are not the only criteria FDA evaluates to determine approvability of a drug product.

40. The allegations in paragraph 40 contain plaintiffs’ characterization of, and quotations from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

41. The allegations in paragraph 41 contain plaintiffs’ characterization of the document cited

in paragraph 40 and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

42. Defendants admit the allegations in paragraph 42 except that Defendants deny that supplemental NDAs are only submitted to seek approval for “changes to the label” of an approved drug or “to market the drug for a new indication.”

43. The allegations in paragraph 43 contain plaintiffs’ characterization of, and quotations from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

44. The allegations in paragraph 44 contain plaintiffs’ characterization of the cited statute and regulations and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

45. The allegations in paragraph 45 contain plaintiffs’ characterization of the cited statute and Defendants respectfully refer the Court to that statute for a full and complete statement of its contents.

46. The allegations in paragraph 46 contain plaintiffs’ characterization of, and a quotation from, the cited statute and Defendants respectfully refer the Court to that statute for a full and complete statement of its contents.

47. The allegations in paragraph 47 contain plaintiffs’ characterization of, and quotations from, the cited statute and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

48. The allegations in paragraph 48 contain plaintiffs’ characterization of the cited statute and Defendants respectfully refer the Court to that statute for a full and complete statement of its contents.

49. The allegations in paragraph 49 contain plaintiffs' characterization of, and quotations from, the cited statute and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

50. The allegations in paragraph 50 contain plaintiffs' characterization of, and quotations from, the cited statute and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

51. The allegations in paragraph 51 contain plaintiffs' characterization of, and quotations from, the cited statute and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

52. The allegations in paragraph 52 contain plaintiffs' characterization of, and quotations from, the cited statute and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

53. The allegations in paragraph 53 contain plaintiffs' characterization of, and quotations from, the cited statute and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

54. The allegations in paragraph 54 contain plaintiffs' characterization of information from the Mifeprex labeling and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

55. The allegations in paragraph 55 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

56. Defendants admit that misoprostol acts has abortifacient properties but are without knowledge or information sufficient to form a belief as to whether misoprostol taken alone "is

less effective and causes more severe side effects than the Mifeprex/misoprostol regimen” because FDA has never conducted such a comparative analysis. Defendants admit the allegations in the second sentence of paragraph 56. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence of paragraph 56.

57. The allegations in paragraph 57 contain plaintiffs’ characterization of the Mifeprex labeling and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

58. The allegations in paragraph 58 contain plaintiffs’ characterization of, and a quotation from, the Mifeprex labeling and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

59. The allegations in paragraph 59 contain plaintiffs’ characterization of, and quotations from, the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

60. The allegations in the first four sentences of paragraph 60 contain plaintiffs’ characterization of the Korlym labeling and reviews, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents. The allegations in the last sentence of paragraph 60 contain plaintiffs’ characterization of, and a quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

61. Defendants admit the allegations in paragraph 61.

62. Defendants admit the allegations in paragraph 62.

63. The allegations in paragraph 63 contain plaintiffs’ characterization of the cited document

and the Mifeprex NDA review documents, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

64. Defendants admit the allegations in paragraph 64.

65. The allegations in paragraph 65 contain plaintiffs' characterization of clinical trials the undefined term European post-market experience, and Defendants respectfully refer to the Court to those documents for fully and complete statements of their contents. Defendants deny that the approval of Mifeprex was not accelerated and deny that FDA imposed ETASU as a condition of approval in 2000. Defendants otherwise admit that FDA approved Mifeprex under Subpart H.

66. The allegations in paragraph 66 contain plaintiffs' characterization of the referenced ETASUs and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

67. The allegations in paragraph 67 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

68. Defendants deny the allegations in the first sentence of paragraph 68. The allegations in the second and third sentences of paragraph 68 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

69. Defendants admit the allegations of paragraph 69 except that Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation regarding the Population Council "noting its objections."

70. The allegations in the first sentence of paragraph 70 contain plaintiffs' characterization of the cited Federal Register notice and Defendants respectfully refer the Court to that document for

a full and complete statement of its contents. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 70.

71. The allegations in paragraph 71 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

72. The allegations in paragraph 72 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

73. The allegations in paragraph 73 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

74. The allegations in paragraph 74 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

75. The allegations in paragraph 75 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

76. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first three sentences of paragraph 76, except that Defendants admit that Danco submitted a supplemental NDA to FDA in May 2015 that included proposed labeling changes and admit that FDA approved Mifeprex in 2000. The allegations in the last sentence of paragraph 76 contain plaintiffs' characterization of the cited document and Defendants

respectfully refer the Court to that document for a full and complete statement of its contents.

77. Defendants admit the allegations in the first sentence of paragraph 77 except that Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation “prompted a top-to-bottom review.” The allegations in the second sentence of paragraph 77 contains plaintiffs’ characterization of the Mifeprex supplemental NDA review documents and the cited letters, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

78. The allegations in paragraph 78 contain plaintiffs’ characterization of the Mifeprex supplemental NDA review documents and the cited letters, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

79. The allegations in paragraph 79 contain plaintiffs’ characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

80. The allegations in paragraph 80 contain plaintiffs’ characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

81. The allegations in paragraph 81 contain plaintiffs’ characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

82. The allegations in paragraph 82 contain plaintiffs’ characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

83. The allegations in paragraph 83 contain plaintiffs’ characterization of, and quotation

from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

84. The allegations in paragraph 84 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

85. The allegations in paragraph 85 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

86. The allegations in paragraph 86 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

87. The allegations in paragraph 87 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

88. The allegations in paragraph 88 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

89. The allegations in paragraph 89 contain plaintiffs' characterization of, and quotations from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

90. The allegations in paragraph 90 contain plaintiffs' characterization of, and quotation from, the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

91. The allegations in paragraph 91 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

92. The allegations in paragraph 92 contain plaintiffs' characterization of, and quotations from, the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

93. The allegations in paragraph 93 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

94. The allegations in paragraph 94 are legal conclusions to which no answer is required.

95. The allegations in paragraph 95 contain plaintiffs' characterization of, and quotation from, the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

96. The allegations in paragraph 96 contain plaintiffs' characterization of, and quotations from, the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

97. The allegations in paragraph 97 contain plaintiffs' characterization of, and quotations from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

98. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 98. The remaining allegations in paragraph 98 contain plaintiffs' characterization of, and quotation from, the cited case and Defendants respectfully refer the Court to that case for a full and complete statement of its

contents.

99. The allegations in the first sentence of paragraph 99 contain plaintiffs' characterization of, and quotation from, the cited statute and Defendants respectfully refer the Court to that statute for a full and complete statement of its contents. Defendants deny the remaining allegations in paragraph 99.

100. The allegations in paragraph 100 contain plaintiffs' characterization of, and quotations from, the cited statute and document, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

101. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 101. The remaining allegations in paragraph 101 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

102. The allegations in paragraph 102 are legal conclusions to which no answer is required.

103. The allegations in paragraph 103 contain plaintiffs' characterization of, and quotations from, the cited statute and document, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

104. The allegations in paragraph 104 are legal conclusions to which no answer is required.

105. The allegations in paragraph 105 contain plaintiffs' characterization of, and quotations from, the cited statute and document, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

106. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 106. The remaining allegations in

paragraph 106 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

107. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 107, including whether misoprostol "is safer and more effective in early pregnancy when used in the FDA-approved regimen with Mifeprex," except to admit that misoprostol has abortifacient properties.

108. The allegations in paragraph 108 are legal conclusions to which no answer is required.

109. Defendants deny that Korlym "is an identical product" to Mifeprex; admit that "Mifeprex is a single 200 mg tablet that is only prescribed for a single use;" are without knowledge or information sufficient to form a belief as to the truth of what Mifeprex is actually "only prescribed for;" and aver that the remaining allegations in paragraph 109 contain plaintiffs' characterization of, and quotations from, the cited statute and product labeling, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

110. The allegations in paragraph 110 are legal conclusions to which no answer is required.

111. The allegations in paragraph 111 contain plaintiffs' characterization of, and quotations from, the cited statute and document, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

112. The allegations in paragraph 112 are legal conclusions to which no answer is required.

113. The allegations in the first sentence of paragraph 113 contain plaintiffs' quotation from the cited statute and Defendants respectfully refer the Court to that documents for a full and complete statement of its contents. Defendants deny the remaining allegations in paragraph 113 except to admit that "Mifeprex had already been approved in the United States for nearly 16

years” in March 2016.

114. The allegations in paragraph 114 are legal conclusions to which no answer is required.

115. Defendants deny the allegations in the first sentence of paragraph 115. The allegations in the second sentence of paragraph 115 contain plaintiffs’ characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

116. Defendants deny the allegations in paragraph 116.

117. Because the allegations of paragraph 117 are vague, use undefined terminology, and refer to unspecified other drugs, defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations.

118. The allegations in paragraph 118 contain plaintiffs’ characterization of, and quotations from, the cited document, and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

119. The allegations in paragraph 119 contain plaintiffs’ characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

120. The allegations in paragraph 120 contain plaintiffs’ characterization of, and quotations from, the cited documents, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

121. The allegations in paragraph 121 contain plaintiffs’ characterization of, and quotation from, the cited documents, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

122. Defendants deny the allegations in paragraph 122.

123. Defendants deny the allegations in paragraph 123.

124. The allegations in paragraph 124 contain plaintiffs' characterization of, and quotation from, the cited document, and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

125. The allegations in paragraph 125 contain plaintiffs' characterization of, and quotations from, the cited document, and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

126. The allegations in paragraph 126 contain plaintiffs' characterization of, and quotations from, the cited documents, and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

127. Defendants deny the allegations in paragraph 127.

128. The allegations in the first two sentences of paragraph 128 contain plaintiffs' characterization of the cited ETASU, and Defendants respectfully refer the Court to that document for a full and complete statement of its contents. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the last sentence of paragraph 128.

129. The allegations in paragraph 129 contain plaintiffs' characterization of, and quotations from, the cited document, and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

130. Defendants deny the allegations in paragraph 130.

131. The allegations in the first sentence of paragraph 131 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents. Defendants are without knowledge

or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 131.

132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 132.

133. The allegations in paragraph 133 contain plaintiffs' characterization of the Mifeprex REMS and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

134. The allegations in paragraph 134 contain plaintiffs' characterization of, and quotation from, the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

135. Defendants deny the allegations in paragraph 135.

136. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 136. Defendants deny the allegations in the second sentence of paragraph 136.

137. Defendants deny the allegations in paragraph 137, including that Korlym is the "exact same product as Mifeprex", except to admit that there are other drugs that require patient screening but are not subject to ETASU.

138. Defendants deny the allegations in the first sentence of paragraph 138. Defendants admit the allegations in the second sentence of paragraph 138.

139. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 139.

140. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 140.

141. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 141.

142. The allegations in the first sentence of paragraph 142 contain plaintiffs' characterization of, and quotations from, the cited statute, and Defendants respectfully refer the Court to that statute for a full and complete statement of its contents. Defendants deny the allegations in the second sentence of paragraph 142.

143. The allegations in paragraph 143 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

144. The allegations in paragraph 144 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

145. Because the allegations of paragraph 145 are vague, use undefined terminology, and refer to unspecified other drugs "that have higher safety risks than Mifeprex," defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations.

146. The allegations in paragraph 146 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

147. The allegations in paragraph 147 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

148. The allegations in the first sentence of paragraph 148 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and

complete statement of its contents. Defendants admit the allegations in the second sentence of paragraph 148.

149. Defendants deny the allegations in paragraph 149.

150. Defendants deny the allegations in paragraph 150.

151. Defendants deny the allegations in paragraph 151.

152. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 152 except that Defendants deny that the Mifeprex REMS causes harms.

153. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 153.

154. The allegations in paragraph 154 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

155. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 155.

156. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 156.

157. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 157.

158. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 158.

159. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 159.

160. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 160 except that Defendants admit that the REMS add requirements that would otherwise not exist for Mifeprex.

161. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 161.

162. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 162.

163. The allegations in paragraph 163 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

164. The allegations in paragraph 164 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

165. The allegations in paragraph 165 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

166. The allegations in paragraph 166 contain plaintiffs' characterization of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents.

167. The allegations in paragraph 167 contain plaintiffs' characterization of the cited documents and Defendants respectfully refer the Court to those documents for full and complete statements of their contents.

168. The allegations in the first sentence of paragraph 168 contain plaintiffs' characterization

of the cited document and Defendants respectfully refer the Court to that document for a full and complete statement of its contents. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 168.

169. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 169.

170. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 170.

171. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 171.

172. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 172.

173. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 173.

174. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 174.

175. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 175.

176. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 176.

177. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 177.

178. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 178.

179. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 179.

180. Defendants are without knowledge or information sufficient to form a belief as to truth of the allegations in paragraph 180, except to admit that the incidence of certain medical complications to a pregnant woman resulting from abortion procedures increases as pregnancy advances.

181. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 181.

182. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 182.

183. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 183.

184. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 184.

185. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 185.

186. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 186.

187. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 187.

188. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 188.

189. Defendants are without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 189.

190. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 190.

191. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 191.

192. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 192.

193. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 193.

194. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 194.

195. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 195.

196. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 196.

197. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 197.

198. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 198.

199. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 199.

200. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 200.

201. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 201.

202. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 202.

203. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 203.

204. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 204.

205. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 205.

206. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 206.

207. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 207.

208. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 208.

209. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 209.

210. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 210.

211. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 211.

212. Defendants are without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 212.

213. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 213.

214. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 214.

215. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 215.

216. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 216.

217. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 217.

218. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 218.

219. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 219.

220. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 220.

221. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 221.

222. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 222.

223. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 223.

224. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 224.

225. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 225.

226. Defendants incorporate by reference their responses to paragraphs 1-225.

227. Defendants deny the allegations in paragraph 227.

228. Defendants incorporate by reference their responses to paragraphs 1-227.

229. Defendants deny the allegations in paragraph 229.

230. Defendants incorporate by reference their responses to paragraphs 1-229.

231. The allegations in paragraph 231 are legal conclusions to which no answer is required.

232. Defendants deny the allegations in paragraph 232.

233. Defendants incorporate by reference their responses to paragraphs 1-232.

234. The allegations in paragraph 234 are legal conclusions to which no answer is required.

235. Defendants deny the allegations in paragraph 235.

236. Defendants incorporate by reference their responses to paragraphs 1-225.

237. The allegations in paragraph 237 are legal conclusions to which no answer is required.

238. Defendants deny the allegations in paragraph 238.

239. Defendants deny the allegations in paragraph 239.

240. Defendants deny the allegations in paragraph 240.

Defendants deny each and every allegation in the complaint that has not heretofore been specifically answered or otherwise responded to.

PLAINTIFFS' PRAYERS FOR RELIEF

The remaining allegations comprise Plaintiffs' prayer for relief, to which no answer is required. To the extent that an answer is required, Defendants deny that plaintiffs are entitled to the relief requested.

DEFENSES

1. The Court lacks subject matter jurisdiction over some or all of Plaintiffs' claims.
2. Some or all of Plaintiffs lack standing to bring some or all of Plaintiffs' claims.
3. Some or all of Plaintiffs' claims are barred by the statute of limitations, 28 U.S.C. § 2401(a).
4. The actions challenged by Plaintiffs were not arbitrary and capricious and are supported by the administrative record.

WHEREFORE, having fully answered, FDA respectfully requests that the Court enter judgment in its favor, dismiss Plaintiffs' complaint with prejudice, and award FDA its costs, expenses, attorneys' fees, and such additional relief as the Court may deem appropriate.

Respectfully submitted,

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