

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director

LISA K. HSIAO
Senior Deputy Director, Civil Litigation

HILARY K. PERKINS
Assistant Director

NOAH T. KATZEN (D.C. Bar No. 1006053)
ISAAC C. BELFER (D.C. Bar No. 1014909)
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice
450 Fifth St., N.W.
Washington, DC 20530
Tele: 202-305-2428 (Katzen)/202-305-7134 (Belfer)
Fax: 202-514-8742
Noah.T.Katzen@usdoj.gov
Isaac.C.Belfer@usdoj.gov

Attorneys for Defendants (see signature page for complete list)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, M.D., FACOG, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

CIV. NO. 1:17-00493-JAO-RT

**ANSWER TO CORRECTED
SECOND AMENDED AND
SUPPLEMENTAL COMPLAINT**

Defendants now respond to Plaintiffs' Corrected Second Amended and Supplemental Complaint. ECF No. 212. Defendants admit, deny, or otherwise answer the numbered paragraphs in the Corrected Second Amended and Supplemental Complaint as follows:

1. Defendants admit that mifepristone was approved by the U.S. Food and Drug Administration ("FDA") in 2000 for use in a regimen with misoprostol for medical termination of early intrauterine pregnancy, and is subject to approved conditions of use, including the Mifepristone Risk Evaluation and Mitigation Strategy ("REMS") Program. Defendants deny that Mifeprex and generic mifepristone are subject to "identical regulations." As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

2. This paragraph characterizes the cited document. Defendants deny the allegations for lack of knowledge or information sufficient to form a belief as to the allegations' truth, as the allegations are vague and use undefined terminology. Defendants further deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

3. This paragraph characterizes the cited documents. Defendants deny the allegations in the first sentence of paragraph 3 for lack of knowledge or information sufficient to form a belief as to the allegations' truth, as the allegations are vague and use undefined terminology. As to the second sentence, Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. As to the third sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

4. Deny, except Defendants admit that mifepristone is approved by FDA in a regimen with misoprostol for medical termination of early intrauterine pregnancy, and is subject to approved conditions of use, including the Mifepristone REMS Program.

5. Defendants admit that the cited statutes contain the quoted text, with the clarification that the statute cited in the first sentence refers to "the drug," not "a drug." Defendants deny any characterization of the cited statutes, which speak for themselves, and respectfully refer the Court to the cited statutes for a full and complete statement of their contents.

6. Regarding the allegations up to footnote 6, Defendants deny any characterization of the Parties' Joint Stipulation of Facts, ECF No. 85, that is inconsistent with the contents of that document, which were accurate as of the November 27, 2019 date of filing. Regarding the allegations after footnote 6, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

7. Defendants admit that Plaintiffs filed this litigation in 2017. The remainder of this paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

8. Defendants admit that the text quoted in the third sentence is contained in the cited opinion. Defendants deny any characterization of the proceedings in the case discussed in this paragraph, which speak for themselves, and respectfully refer the Court to the opinions cited in this paragraph for a full and complete statement of their contents.

9. This paragraph characterizes the cited documents. Defendants deny any characterization of the cited documents, which speak for themselves, and

respectfully refer the Court to those documents for a full and complete statement of their contents.

10. Admit, with the clarification that Plaintiffs' motion for summary judgment was filed in April 2021, ECF No. 141.

11. This paragraph characterizes the cited documents. Defendants admit that The Society of Family Planning sent a letter to FDA on August 11, 2021, and that Dr. Graham Chelius, The Society of Family Planning, and The California Academy of Family Physicians sent a letter to FDA on September 29, 2021. Defendants deny that "the mifepristone REMS is medically unjustified and burdens patients and the health care system." Defendants further deny any characterization of the cited documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

12. Defendants deny the allegation that certain medications "pose risks greater than or comparable to that of mifepristone" for lack of knowledge or information sufficient to form a belief as to its truth, as it is vague and uses undefined terminology. Defendants further deny the allegations about how Jeuveau "is used," for lack of knowledge or information sufficient to form a belief as to their truth. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document or of the referenced

Jeuveau labeling, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

13. Defendants admit that on January 3, 2023, FDA approved supplemental applications that modified the Mifepristone REMS Program. Defendants further admit that the cited documents contain the quoted text. Defendants deny any characterization of the cited documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

14. Defendants admit that the cited statute contains the quoted text. Defendants deny any characterization of the cited documents and statute, which speak for themselves, and respectfully refer the Court to the cited documents and statute for a full and complete statement of their contents. Defendants deny that FDA did not consider statutorily required factors and “never grappled with facts critical to the mifepristone REMS analysis.”

15. Defendants admit that the cited statute contains the quoted text. Defendants deny any characterization of the cited statute and of FDA’s REMS review memoranda referenced in paragraph 14, which speak for themselves, and respectfully refer the Court to the cited statute and memoranda for a full and complete statement of their contents. Defendants deny that “FDA does not impose

similar restrictions on other, riskier drugs” for lack of knowledge or information sufficient to form a belief as to its truth.

16. Defendants admit that the cited statute contains the quoted text. Defendants deny that “the mifepristone REMS is not supported by science and harms patients and the health care system” and that “the mifepristone [Elements To Assure Safe Use (‘ETASU’)] are ‘unduly burdensome on patient access to the drug,’ particularly for ‘patients in rural or medically underserved areas’ who struggle to obtain abortion care.” Defendants further deny any characterization of the cited statute and of FDA’s REMS review memoranda referenced in paragraph 14, which speak for themselves, and respectfully refer the Court to that statute and those memoranda for a full and complete statement of their contents.

17. Deny.

18. Deny.

19. Deny.

20. Defendants deny the allegations in the first sentence for lack of knowledge or information sufficient to form a belief as to their truth. Defendants deny the allegations in the second sentence.

21. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

22. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

23. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

24. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

25. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

26. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

27. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

28. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

29. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

30. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

31. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

32. Admit, with the clarification that Xavier Becerra is the Secretary of the Department of Health and Human Services.

33. Admit.

34. Admit.

35. Defendants admit the allegations in the first sentence to the extent they refer to new drugs but deny that a new drug application ("NDA") is required for all drugs. Defendants deny the allegations in the second sentence and note that the safety and efficacy of a drug product are not the only criteria FDA evaluates to determine the drug product's approvability.

36. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

37. This paragraph appears to characterize the document cited in paragraph 36. Defendants deny any characterization of the cited document, which

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

38. Admit, except Defendants deny that supplemental NDAs are submitted only to seek approval for “changes to the labeling” of an approved drug or “to market the drug for a new indication.”

39. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of the cited document, statute, or regulations, which speak for themselves, and respectfully refer the Court to the cited document, statute, and regulations for a full and complete statement of their contents.

40. This paragraph characterizes the cited statutes and regulations. Defendants deny any characterization of the cited statutes and regulations, which speak for themselves, and respectfully refer the Court to those statutes and regulations for a full and complete statement of their contents.

41. This paragraph characterizes the cited statute. Defendants deny any characterization of the statute, which speaks for itself, and respectfully refer the Court to that statute for a full and complete statement of its contents.

42. Defendants admit that the cited statute contains the quoted text, with the clarification that the cited statute refers to “the drug,” not “a drug.” Defendants deny any characterization of the cited statute, which speaks for itself, and

respectfully refer the Court to the cited statute for a full and complete statement of its contents.

43. Defendants admit that the cited statute contains the quoted text. Defendants deny any characterization of the cited statute, which speaks for itself, and respectfully refer the Court to the cited statute for a full and complete statement of its contents.

44. This paragraph characterizes the cited statute. Defendants deny any characterization of the statute, which speaks for itself, and respectfully refer the Court to that statute for a full and complete statement of its contents.

45. Defendants admit that the cited statutes contain the quoted text. Defendants deny any characterization of the cited statutes, which speak for themselves, and respectfully refer the Court to the cited statutes for a full and complete statement of their contents. Defendants specifically deny that ETASU are “restrictive and burdensome.”

46. Defendants admit that the cited statutes contain the quoted text. Defendants deny any characterization of the cited statutes, which speak for themselves, and respectfully refer the Court to the cited statutes for a full and complete statement of their contents.

47. Defendants admit that the cited statutes contain the quoted text. Defendants deny any characterization of the cited statutes, which speak for

themselves, and respectfully refer the Court to the cited statutes for a full and complete statement of their contents.

48. Defendants admit that the cited statutes contain the quoted text. Defendants deny any characterization of the cited statutes, which speak for themselves, and respectfully refer the Court to the cited statutes for a full and complete statement of their contents.

49. Defendants admit that the cited statutes contain the quoted text. Defendants deny any characterization of the cited statutes, which speak for themselves, and respectfully refer the Court to the cited statutes for a full and complete statement of their contents.

50. This paragraph characterizes the labeling for Mifeprex, generic mifepristone, Cytotec, and generic misoprostol. Defendants deny any characterization of that labeling, which speaks for itself, and respectfully refer the Court to the labeling for a full and complete statement of its contents.

51. This paragraph characterizes the cited document and the labeling for Mifeprex and generic mifepristone. Defendants deny any characterization of the cited document or of that labeling, which speak for themselves, and respectfully refer the Court to the document and the labeling for a full and complete statement of their contents.

52. This paragraph characterizes the labeling for Mifeprex and generic mifepristone. Defendants deny any characterization of that labeling, which speaks for itself, and respectfully refer the Court to the labeling for a full and complete statement of its contents.

53. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

54. Defendants admit that the cited documents contain the quoted text. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

55. The first four sentences characterize the Korlym labeling and reviews. Defendants deny any characterization of the Korlym labeling and reviews, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents. Regarding the last sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

56. As to the first two sentences, Defendants deny the allegations for lack of knowledge or information sufficient to form a belief as to their truth. As to the third sentence, Defendants admit that the cited document contains the quoted text, but deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

57. Admit.

58. Admit.

59. This paragraph characterizes the cited document, the Mifeprex NDA, and the Mifeprex NDA review documents. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of the cited document, the Mifeprex NDA, or the Mifeprex NDA review documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

60. Admit.

61. This paragraph characterizes the referenced clinical trials. Defendants deny any characterization of the referenced clinical trials, which speak for themselves, and respectfully refer the Court to reports of the referenced clinical trials for a full and complete statement of their contents. Defendants further deny the allegations for lack of knowledge or information sufficient to form a belief as

to their truth to the extent they relate to the undefined term “European post-market experience.” Defendants admit that FDA’s approval of mifepristone did not involve an accelerated review, deny that FDA “imposed ETASU,” and admit that Mifeprex was approved with a restricted distribution system under the Subpart H regulations.

62. This paragraph characterizes the referenced ETASU. Defendants deny any characterization of the referenced ETASU, which speak for themselves, and respectfully refer the Court to those ETASU for a full and complete statement of their contents. Defendants specifically deny that “ETASU [were] imposed at the time of Mifeprex’s original approval.”

63. This paragraph characterizes the cited document. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

64. Defendants deny the allegations in the first sentence and deny that ETASU were imposed at the time of approval. The second and third sentences characterize the cited documents. Defendants deny any characterization of the cited documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

65. Admit, except Defendants deny the allegation regarding the Population Council “noting its objections” for lack of knowledge or information sufficient to form a belief as to its truth.

66. The first sentence characterizes the referenced document. Defendants deny any characterization of the referenced document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants deny the allegations in the second sentence for lack of knowledge or information sufficient to form a belief as to their truth.

67. This paragraph characterizes the referenced Mifeprex REMS. Defendants admit that, in 2011, in response to a submission by the sponsor, FDA approved the Mifeprex REMS after determining that it was necessary to ensure the benefits of mifepristone outweigh the risks. Defendants deny any characterization of the referenced Mifeprex REMS, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

68. This paragraph characterizes the referenced Mifeprex REMS. Defendants deny any characterization of the referenced Mifeprex REMS, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

69. This paragraph characterizes the referenced Mifeprex REMS. Defendants deny any characterization of the referenced Mifeprex REMS, which

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

70. This paragraph characterizes the referenced Mifeprex REMS. Defendants deny any characterization of the referenced Mifeprex REMS, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

71. This paragraph characterizes the referenced Mifeprex REMS. Defendants admit that the referenced Mifeprex REMS contains the quoted text. Defendants further admit that 21 U.S.C. § 355-1 provides for periodic assessments to be submitted by the sponsor to FDA. Defendants deny any characterization of the referenced Mifeprex REMS, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

72. Defendants deny the allegations in the first three sentences for lack of knowledge or information sufficient to form a belief as to their truth, except admit that FDA approved Mifeprex in 2000 and that Danco submitted a supplemental NDA to FDA in May 2015 that included proposed labeling changes. Defendants deny the allegations in the last sentence.

73. Defendants deny the allegations in the first sentence. The second sentence characterizes the Mifeprex supplemental NDA review documents and the referenced letters. Defendants deny any characterization of those documents and

letters, which speak for themselves, and respectfully refer the Court to those documents and letters for a full and complete statement of their contents.

74. This paragraph characterizes the referenced letters. Defendants deny any characterization of the referenced letters, which speak for themselves, and respectfully refer the Court to those letters for a full and complete statement of their contents. Regarding the allegations describing the American College of Obstetricians and Gynecologists and the American Public Health Association, Defendants further deny the allegations for lack of knowledge or information sufficient to form a belief as to their truth.

75. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

76. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

77. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself,

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

78. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

79. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants further deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute.

80. Defendants admit that the cited documents contain the quoted text. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to the documents for a full and complete statement of their contents. Defendants specifically deny that ETASU A, the Prescriber Agreement Form, “is unnecessary for the safe dispensation of mifepristone.”

81. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself,

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

82. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

83. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants specifically deny that the Patient Agreement Form is “medically unnecessary and interferes with the clinician-patient relationship.”

84. This paragraph characterizes the referenced FDA documents. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

85. Defendants admit that FDA 0262 contains the text quoted in the second sentence and that the cited document contains the text quoted in the third and fourth sentences. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

86. The first sentence characterizes the cited document. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

87. As to the first sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. The second sentence characterizes the documents described therein. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

88. This paragraph characterizes the cited document and the referenced exhibits. Defendants admit that FDA held a meeting regarding the REMS on January 15, 2016. Defendants further admit that the cited document (specifically, FDA 0701–02) contains the quoted text. Defendants deny any characterization of that document or the referenced exhibits, which speak for themselves, and

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

89. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

90. Defendants admit that, on March 29, 2016, FDA approved a supplemental new drug application from the sponsor to alter Mifeprex's approved conditions of use, including the REMS. This paragraph otherwise contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

91. The first sentence characterizes the cited document. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

92. Defendants admit that the cited documents contain the quoted text. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

93. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

94. As to the allegations in the first sentence, Defendants admit that the Commissioner does not weigh in on every REMS assessment and that the Commissioner was a political appointee, and deny the rest of the allegations for lack of knowledge or information sufficient to form a belief as to the allegations' truth, as the allegations are vague and use undefined terminology. The second sentence contains Plaintiffs' argument and characterization of the cited court decision. Defendants admit that the cited decision contains the quoted text, deny the rest of the allegations in the second sentence, and respectfully refer the Court to the cited decision for a full and complete statement of its contents.

95. Admit.

96. As to the allegations in the first sentence, Defendants admit that FDA approved a generic version of mifepristone in 2019, deny that FDA "established" a

single, shared REMS, and deny the remaining allegations in the first sentence for lack of knowledge or information sufficient to form a belief as to the allegations' truth, as the allegations are vague and use undefined terminology. Defendants admit the allegations in the second sentence.

97. This paragraph characterizes the cited documents. Defendants deny any characterization of the cited documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

98. The first sentence characterizes the cited document. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. As to the second sentence, Defendants deny the allegations and note that the in-person dispensing requirement was preliminarily enjoined by the U.S. District Court for the District of Maryland on July 13, 2020 (*ACOG v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020)); the Supreme Court stayed the district court's order on January 12, 2021 (*FDA v. ACOG*, 141 S. Ct. 578 (2021) (mem.)); FDA announced in April 2021 that it was exercising enforcement discretion with respect to the requirement during the COVID-19 public health emergency; and FDA eliminated the requirement with the approval of supplemental applications in January 2023.

99. This paragraph characterizes the proceedings in the referenced case. Defendants deny any characterization of those proceedings, which speak for themselves, and respectfully refer the Court to the cited opinion for a full and complete statement of its contents.

100. Admit.

101. Defendants admit the allegations in the first three sentences. As to the fourth sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

102. This paragraph characterizes the cited document. Defendants admit that FDA approved a supplemental new drug application for Mifeprex in 2021. Defendants otherwise deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

103. This paragraph characterizes the cited letter from September 2021 and the appendix to that letter, as well as the referenced letter from August 2021. Defendants admit that the cited documents contain the quoted text. Defendants deny any characterization of the cited letter from September 2021 and the appendix to that letter, as well as the referenced letter from August 2021, which speak for

themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents. Defendants further deny that “the mifepristone REMS is medically unnecessary and burdensome on patients (especially patients who face difficulties accessing health care) and on the health care delivery system itself.”

104. Defendants admit that ACOG sent a letter to FDA on October 6, 2021. Defendants further admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

105. Defendants admit that the cited document contains the quoted text (specifically at 2021 REMS 001564). Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

106. Defendants deny the allegations in the first sentence. As to the second and third sentences, Defendants admit that the cited document and statutes contain the quoted text. Defendants deny any characterization of the cited document and statutes, which speak for themselves, and respectfully refer the Court to the cited document and statutes for a full and complete statement of their contents. Furthermore, the third sentence contains argument and conclusions of law, to

which no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

107. This paragraph characterizes the referenced FDA documents. Defendants admit that FDA completed its review of the Mifepristone REMS Program on December 16, 2021. Defendants further admit that FDA determined that the REMS continues to be necessary to ensure that the benefits of the drug outweigh the risks, but that the REMS must be modified to minimize the burden on the health care delivery system of complying with the REMS and to ensure that the benefits of the drug outweigh the risks. Defendants further admit that FDA determined that the REMS must be modified to remove the in-person dispensing requirement and add a pharmacy certification requirement. Defendants further admit that FDA sent a REMS Modification Notification letter to each of the mifepristone application holders. Defendants otherwise deny any characterization of the referenced FDA documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

108. Admit, with the clarification that the mifepristone generic drug applicant submitted a supplemental abbreviated new drug application to FDA.

109. Defendants admit that on January 3, 2023, FDA completed a Summary Review Memorandum summarizing its evaluation of the supplemental

applications and approved those supplemental applications, which modified the Mifepristone REMS Program. Defendants otherwise deny the allegations in the first sentence. The second and third sentences contain argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations in the second and third sentences.

110. As to the first sentence, Defendants admit that the cited statute contains the quoted text. Defendants deny any characterization of that statute, which speaks for itself, and respectfully refer the Court to that statute for a full and complete statement of its contents. The second sentence contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

111. As to the first sentence, Defendants admit that the cited statute and document contain the quoted text. Defendants deny any characterization of that statute and document, which speak for themselves, and respectfully refer the Court to that statute and document for a full and complete statement of their contents. The second sentence appears to characterize the document cited in footnote 3. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

112. As to the first sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. As to the second sentence, regarding the text up to footnote 76, Defendants deny any characterization of the Parties' Joint Stipulation of Facts, ECF No. 85, that is inconsistent with the contents of that document, which were accurate as of the November 27, 2019, date of filing. Regarding the text after footnote 76, Defendants deny the allegations for lack of knowledge or information sufficient to form a belief as to their truth.

113. As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants otherwise deny the allegations for lack of knowledge or information sufficient to form a belief as to their truth.

114. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

115. Defendants admit that the cited statute and document (specifically, at FDA 0859–60) contain the quoted text. Defendants deny any characterization of that statute and document, which speak for themselves, and respectfully refer the

Court to that statute and document for a full and complete statement of their contents.

116. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

117. Defendants admit that the cited statute and document contain the quoted text. Defendants deny any characterization of that statute or document, which speak for themselves, and respectfully refer the Court to that statute and document for a full and complete statement of their contents.

118. Defendants deny the allegations in the first and third sentences for lack of knowledge or information sufficient to form a belief as to their truth. As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

119. Defendants deny the allegations for lack of knowledge or information sufficient to form a belief as to their truth, except admit that mifepristone is approved as safe and effective for use in a regimen with misoprostol for termination of early pregnancy, under approved conditions of use, including a REMS.

120. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

121. As to the first sentence, Defendants admit that the cited statute contains the quoted text. Defendants deny any characterization of the cited statute, which speaks for itself, and respectfully refer the Court to the cited statute for a full and complete statement of its contents. Defendants admit that Mifeprex and its generic mifepristone product are 200 mg tablets and that the approved dose is one tablet. Defendants deny the allegation regarding what Mifeprex and its generic mifepristone product are “only prescribed for” for lack of knowledge or information sufficient to form a belief as to its truth. The remainder of the paragraph characterizes the Korlym labeling. Defendants admit that Korlym is not subject to a REMS, and deny any characterization of its labeling, which speaks for itself, and respectfully refer the Court to that labeling for a full and complete statement of its contents. Defendants specifically deny that Korlym “is an identical product” to Mifeprex and its generic mifepristone product. Defendants further deny the allegation that “the Agency trusts patients to use [Korlym] accordingly” for lack of knowledge or information sufficient to form a belief as to its truth.

122. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

123. Defendants admit that the cited statute and document contain the quoted text. Defendants deny any characterization of that statute and document, which speak for themselves, and respectfully refer the Court to that statute and document for a full and complete statement of their contents.

124. This paragraph characterizes the cited documents. Defendants admit that the cited documents contain the quoted text. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

125. Defendants admit that the cited documents contain the quoted text, with the clarification that FDA 0398 contains the text quoted in the second sentence. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

126. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself,

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

127. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

128. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

129. As to the portion of the first sentence before the colon, Defendants admit that the cited statute contains the quoted text. Defendants deny any characterization of the cited statute, which speaks for itself, and respectfully refer the Court to the cited statute for a full and complete statement of its contents. The remainder of the first sentence contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations. The second sentence characterizes the cited document. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. As to the third sentence, Defendants admit that the cited document contains the quoted text. Defendants

deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. The fourth sentence contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

130. Defendants deny the allegations in the first sentence. As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

131. Deny.

132. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth, as the allegations are vague, use undefined terminology, and refer to unspecified other drugs.

133. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

134. Deny, except Defendants admit that FDA determined in December 2021 that there did not appear to be a difference in adverse events between periods

when the in-person dispensing requirement was being enforced and periods when the in-person dispensing requirement was not being enforced.

135. This paragraph characterizes the cited documents. Defendants deny any characterization of the cited documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

136. The first sentence characterizes the cited document. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. As to the second and third sentences, Defendants admit that the cited documents contain the quoted text. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

137. The first sentence characterizes the cited document. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants admit the allegations in the second sentence.

138. Deny.

139. Deny.

140. Defendants admit that the Commissioner requested that the referenced ETASU be maintained. Defendants deny the remaining allegations in the first sentence. As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants deny the remaining allegations in the second sentence.

141. Defendants admit that the Commissioner requested that the referenced ETASU be maintained. Defendants further admit that the cited documents contain the quoted text. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents. Defendants deny any remaining allegations in this paragraph.

142. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

143. This paragraph characterizes the cited documents. As to the portion of the paragraph up to footnote 107, Defendants admit that 2021 REMS 001578 contains the following text: “removal of the in-person dispensing requirement from

the Mifepristone REMS Program (as discussed below in section 3.2.3) could significantly increase the number of providers to a larger group of practitioners.” As to the portion of the paragraph after footnote 107, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of the cited documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

144. Deny.

145. The first sentence characterizes the medication guides for Mifeprex and generic mifepristone. Defendants admit that the approved labeling for Mifeprex and generic mifepristone includes a medication guide. Defendants deny any characterization of the medication guides, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents. As to the second sentence, Defendants admit that the cited Joint Stipulation of Facts, ECF No. 85, contains the quoted text. Defendants deny any characterization of the Joint Stipulation of Facts that is inconsistent with the contents of that document, which were accurate as of the November 27, 2019 date of filing. Defendants deny the allegations in the last sentence.

146. This paragraph characterizes the Mifepristone REMS Program. Defendants deny any characterization of the Mifepristone REMS Program, which

speaks for itself, and respectfully refer the Court to the Mifepristone REMS Program for a full and complete statement of its contents.

147. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants further deny that FDA's rationale for maintaining ETASU A was "a pure tautology."

148. This paragraph characterizes the cited documents. Defendants admit that on January 3, 2023, FDA approved supplemental applications that modified the Mifepristone REMS Program. Defendants further admit that the cited documents contain the quoted text. Defendants deny any characterization of those documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

149. Deny.

150. Deny.

151. Defendants deny the allegations in the first sentence for lack of knowledge or information sufficient to form a belief as to their truth. Defendants deny the allegations in the second sentence.

152. Deny, except Defendants admit there are other drugs for which patient screening is the standard of care but that are not subject to ETASU.

153. Defendants deny the allegations in the first sentence. Defendants deny the allegations in the second sentence, except admit that a provider can assess the duration and location of a pregnancy by ordering an ultrasound.

154. Defendants admit that FDA determined on December 16, 2021, that with certain modifications, the Mifepristone REMS Program, including the Prescriber Agreement ETASU, continues to be necessary to ensure that the benefits of the drug outweigh the risks. Defendants deny the allegations in the first sentence for lack of knowledge or information sufficient to form a belief as to their truth. As to the second sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

155. Defendants deny the allegations in the first two sentences for lack of knowledge or information sufficient to form a belief as to their truth. Defendants deny the allegations in the third sentence.

156. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

157. Defendants admit that, under the Mifepristone REMS Program, mifepristone may be dispensed by certified pharmacies and that, to become certified, pharmacies must complete a Pharmacy Agreement Form. The remaining

allegations characterize the Mifepristone REMS Program. Defendants deny any characterization of the Mifepristone REMS Program, which speaks for itself, and respectfully refer the Court to the Mifepristone REMS Program for a full and complete statement of its contents. Defendants further deny that the Pharmacy Certification ETASU imposes burdens beyond what is permitted by statute.

158. As to the first sentence, Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants specifically deny that “the Pharmacy Certification ETASU is burdensome.” Defendants deny the allegations in the second sentence.

159. Defendants admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

160. Defendants deny the allegations in the first sentence. As to the second sentence, Defendants admit that by January 3, 2023, a limited number of pharmacies had been dispensing mifepristone without certification for a period of time. Defendants deny any remaining allegations in the second sentence.

161. As to the first sentence, Defendants admit that the cited statute contains the quoted text. Defendants deny any characterization of the cited statute, which speaks for itself, and respectfully refer the Court to the cited statute for a full and complete statement of its contents. Defendants deny the allegations in the second sentence for lack of knowledge or information sufficient to form a belief as to their truth, as the allegations are vague, use undefined terminology, and refer to unspecified other drugs.

162. Admit.

163. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth, as the allegations are vague, use undefined terminology, and refer to unspecified other drugs "that have higher safety risks than mifepristone."

164. The first and third sentences characterize the cited documents. Defendants admit that neither Viagra nor Tylenol has a REMS. Defendants deny any characterization of the cited documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents. Defendants deny the allegations in the second sentence for lack of knowledge or information sufficient to form a belief as to their truth.

165. This paragraph characterizes the cited documents, the referenced letter from the *Chelius* Plaintiffs to FDA, and the mifepristone REMS review documents.

Defendants admit that the cited documents contain the quoted text. Defendants further admit that anticoagulants are available by prescription without a REMS and that Mifeprex is available by prescription with a REMS. Defendants deny any characterization of the cited documents, the referenced letter from the *Chelius* Plaintiffs to FDA, and the mifepristone REMS review documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

166. This paragraph characterizes the cited document, the referenced letter from the *Chelius* Plaintiffs to FDA, and the 2021 and 2023 mifepristone REMS review documents. Defendants admit that the cited document contains the quoted text and admit that the 2021 and 2023 mifepristone REMS review documents did not address Jeuveau. Defendants deny any characterization of the cited document, the referenced letter from the *Chelius* Plaintiffs to FDA, and the 2021 and 2023 mifepristone REMS review documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

167. Deny.

168. Deny.

169. Deny.

170. Deny.

171. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

172. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

173. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

174. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

175. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

176. Defendants deny the allegations in the first sentence for lack of knowledge or information sufficient to form a belief as to their truth. As to the allegations in the second sentence, Defendants admit that the agency redacted the names of some agency employees in administrative record documents. Defendants deny the remaining allegations in the second sentence for lack of knowledge or information sufficient to form a belief as to their truth. As to the third sentence, Defendants admit that the cited Joint Stipulation of Facts, ECF No. 85, contains the quoted text. Defendants deny any characterization of the cited Joint Stipulation of

Facts that is inconsistent with the contents of that document, which were accurate as of the November 27, 2019, date of filing.

177. Defendants deny the allegations in the first sentence for lack of knowledge or information sufficient to form a belief as to their truth. The second sentence characterizes the cited statutes. Defendants deny any characterization of the cited statutes, which speak for themselves, and respectfully refer the Court to those statutes for a full and complete statement of their contents.

178. Defendants admit that the Patient Agreement Form contains the quoted text. Defendants deny any characterization of the Patient Agreement Form, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants further deny that the Patient Agreement Form “undermines informed consent” or “contain[s] fossilized science.” Additionally, this paragraph characterizes the document cited in footnote 123. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants deny the remaining allegations in paragraph 178 for lack of knowledge or information sufficient to form a belief as to their truth.

179. Defendants admit that the Patient Agreement Form contains the quoted text. Defendants deny any characterization of the Patient Agreement Form,

which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants deny the remaining allegations in paragraph 179 for lack of knowledge or information sufficient to form a belief as to their truth.

180. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

181. As to the first sentence, Defendants deny that the referenced ETASU “imposes significant costs and burdens” and deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth. The remainder of paragraph 181 characterizes the Mifepristone REMS Program. Defendants deny any characterization of the Mifepristone REMS Program, which speaks for itself, and respectfully refer the Court to the Mifepristone REMS Program for a full and complete statement of its contents.

182. As to the first sentence, Defendants admit that the Mifepristone REMS Program contains the quoted text. Defendants deny any characterization of the Mifepristone REMS Program, which speaks for itself, and respectfully refer the Court to the Mifepristone REMS Program for a full and complete statement of its contents. Defendants deny the allegations in the second and third sentences for lack of knowledge or information sufficient to form a belief as to their truth.

183. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

184. Defendants deny that the Mifepristone REMS Program “prohibit[s] all but certified pharmacies to dispense mifepristone” and note that certified prescribers may dispense mifepristone. Defendants deny the remaining allegations in paragraph 184 for lack of knowledge or information sufficient to form a belief as to their truth.

185. Deny.

186. This paragraph characterizes the cited documents and the mifepristone REMS review documents. Defendants admit that the cited documents contain the quoted text. Defendants deny any characterization of the cited documents and the mifepristone REMS review documents, which speak for themselves, and respectfully refer the Court to those documents for a full and complete statement of their contents.

187. As to the first sentence, Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations in the first sentence for lack of knowledge or information sufficient to form a belief as to their truth. As to the second sentence, Defendants

admit that the cited document contains the quoted text. Defendants deny any characterization of that document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents.

188. Defendants admit that the cited document contains the quoted text, with the clarification that 2021 REMS 001163–64 contains the text quoted in the last two sentences. Defendants deny any characterization of the cited document, which speaks for itself, and respectfully refer the Court to that document for a full and complete statement of its contents. Defendants further deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute.

189. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations in the first two sentences for lack of knowledge or information sufficient to form a belief as to their truth. Defendants deny the allegations in the third sentence.

190. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

191. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

192. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

193. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

194. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

195. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

196. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

197. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

198. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

199. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

200. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

201. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

202. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining

allegations for lack of knowledge or information sufficient to form a belief as to their truth.

203. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

204. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

205. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

206. Deny for lack of knowledge or information sufficient to form a belief as to the allegations' truth.

207. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

208. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining

allegations for lack of knowledge or information sufficient to form a belief as to their truth.

209. Defendants deny that the Mifepristone REMS Program imposes burdens beyond what is permitted by statute. Defendants deny the remaining allegations for lack of knowledge or information sufficient to form a belief as to their truth.

210. Defendants incorporate by reference their responses to paragraphs 1–209.

211. Deny.

212. Defendants incorporate by reference their responses to paragraphs 1–209.

213. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

214. Deny.

215. Defendants incorporate by reference their responses to paragraphs 1–209.

216. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

217. Deny.

218. Defendants incorporate by reference their responses to paragraphs 1–209.

219. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny the allegations.

220. Deny.

221. Deny.

222. Deny.

Defendants deny that Plaintiffs are entitled to any relief.

Defendants deny all allegations in the Corrected Second Amended and Supplemental Complaint, except as specifically admitted in this Answer.

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 lawful and reasonable, supported by the administrative record, and not arbitrary and capricious.

WHEREFORE, having fully answered, Defendants respectfully request that the Court enter judgment in their favor, dismiss the Corrected Second Amended and Supplemental Complaint with prejudice, and award Defendants their costs, expenses, attorneys' fees, and such additional relief as the Court may deem appropriate.

Dated: August 16, 2024

Respectfully submitted,

/s/ Isaac C. Belfer
NOAH T. KATZEN
ISAAC C. BELFER
Consumer Protection Branch
U.S. Department of Justice

Attorneys for Defendants Xavier Becerra, in his official capacity as Secretary, U.S. Department of Health and Human Services; U.S. Food and Drug Administration; and Robert M. Califf, in his official capacity as Commissioner of Food and Drugs

CERTIFICATE OF SERVICE

I hereby certify that, on August 16, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Isaac C. Belfer
ISAAC C. BELFER