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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RACHAEL MAHER, JASMIN AMARO, MARINA GOMEZ, REBECCA TORRES GLORIA URIBE, CAROLYN GILL, MARY JO BARNES, BRITTANY BONDS, TERESA FAUGHNAN, LUZ VARGAS EBONY ODOMMORRIS, JENNIFER MALTESE, and LISA BRADY individually and on behalf of others similarly situated,	:	**Case No. 2:20-cv-00152-JMV-SCM**
Plaintiffs,	:	**PLAINTIFFS' SECOND CONSOLIDATED AMENDED CLASS ACTION COMPLAINT AND JURY DEMAND**
v.	:	
AMAG PHARMACEUTICALS, INC.,	:	
Defendant.	:	

Plaintiffs Rachael Maher, Jasmin Amaro, Marina Gomez, Rebecca Torres, Carolyn Gill, Mary Jo Barnes, Brittany Bonds, Teresa Faughnan, Luz Vargas, Ebony Odommorris, Jennifer Maltese and Lisa Brady bring this case on behalf of themselves and all others similarly situated against defendant AMAG Pharmaceuticals, Inc., and in support thereof state:

NATURE OF THE CASE

1. This case arises from Defendant's marketing and sale of the prescription drug Makena, a hydroxyprogesterone caproate. Defendant purchased the exclusive marketing rights to Makena, raised the price to outrageous levels when it sold Makena, and continued marketing and selling Makena under the false guise that it was safe and would help prevent premature births even when it knew those claims to be untrue.

PARTIES AND BACKGROUND

2. Plaintiff Rachael Maher, a New Jersey citizen, resides in Neptune, Monmouth County, New Jersey. During the class period, Ms. Maher was prescribed, injected with, and purchased Makena.

3. Plaintiff Rachael Maher began Makena treatment in April 2019 at Hackensack Meridian Medical Group in Hackensack, New Jersey. Ms. Maher received approximately twenty weekly injections—and ended treatment in July 2019. Ms. Maher delivered on July 16, 2019.

4. Plaintiff Rachael Maher paid out of pocket for Makena.

5. Plaintiff Jasmin Amaro, a California citizen, resides in Los Angeles, Los Angeles County, California. During the class period, Ms. Amaro was prescribed, injected with, and purchased Makena during three pregnancies.

6. Plaintiff Jasmine Amaro began Makena treatment for the first time on April 8, 2011, at Kaiser Los Angeles Medical Center in Los Angeles, California. Ms. Amaro received approximately twenty weeks of injections—and ended her treatment on or around September 1, 2011. Ms. Amaro delivered September 7, 2011, at 35 weeks.

7. Plaintiff Jasmine Amaro began Makena treatment for the second time in December 2015, at White Memorial Medical Center in Los Angeles, California. Ms. Amaro received approximately twenty weeks of injections—and ended treatment in May 2016. Ms. Amaro delivered on May 25, 2016.

8. Plaintiff Jasmine Amaro received began Makena treatment for a third time on December 6, 2017, at Kaiser Permanente-Baldwin Park Medical Center in Baldwin Park, California. Plaintiff Amaro approximately twenty weekly injections—and ended treatment in May 2018. Ms. Amaro delivered on May 11, 2018.

9. Marina Gomez, a California citizen, resides in Davis, Yolo County, California. During the class period, Ms. Gomez was prescribed, injected with, and purchased Makena.

10. Plaintiff Marina Gomez began Makena treatment on May 17, 2019, at Women's Health-Roseville Medical Center in Roseville, California. Ms. Gomez received approximately 17 weekly injections and ended treatment in or around September 2019. Ms. Gomez delivered on October 23, 2019, at 38 weeks.

11. Plaintiff Rebecca Torres, a California citizen, resides in Riverside, Riverside County, California. During the class period, Ms. Torres was prescribed, injected with, and purchased Makena during two pregnancies.

12. Plaintiff Rebecca Torres began Makena treatment for the first time in December 2011 at Magnolia Women's Medical Center in Riverside, California. Ms. Torres received approximately twenty weeks of injections—and ended treatment in May 2012. Ms. Torres delivered on May 21, 2012.

13. Plaintiff Rebecca Torres began Makena treatment for the second time in October 2019 at Magnolia Women's Medical Center in Riverside, California. Ms. Torres received approximately twenty weeks of injections—and ended treatment in February 2020. Ms. Torres delivered on February 28, 2020, at 38 weeks.

14. Plaintiff Gloria Uribe, a California citizen, resides in Orange, Orange County, California. During the class period, Ms. Uribe was prescribed, injected with, and purchased Makena.

15. Plaintiff Gloria Uribe began Makena treatment in or around November 2017, at AkermanMed OBGYN & Midwifery in Orange, California. Ms. Uribe received

approximately fifteen weekly injections—and ended treatment in or around March 2018. Ms. Uribe delivered on March 29, 2018, at 38 weeks. During the course of this treatment, Ms. Uribe received Makena marketing materials in each shipment of Makena that was mailed to her home.

16. In or around November 2017, Plaintiff Gloria Uribe spoke to a representative from AMAG on the phone who explained the administration instructions and benefits of Makena.

17. Plaintiff Gloria Uribe became pregnant again in or around mid-2019. Ms. Uribe's insurance company refused to pay cost for Makena, and she was placed on a less expensive compounded version of hydroxyprogesterone caproate.

18. Plaintiff Carolyn Gill, a Kansas citizen, resides in Leawood, Johnson County, Kansas. During the class period, Ms. Gill was prescribed, injected with, and purchased Makena.

19. Plaintiff Carolyn Gill began Makena treatment in February 2017 at Women's Healthcare Group in Overland Park, Kansas. Ms. Gill received approximately twenty weekly injections—and ended treatment in July 2017. Ms. Gill delivered on July 21, 2017, at 37 weeks.

20. Plaintiff Carolyn Gill paid out of pocket for Makena.

21. Plaintiff Mary Jo Barnes, a Missouri citizen, resides in Miller, Lawrence County, Missouri. During the class period, Ms. Barnes was prescribed, injected with, and purchased Makena.

22. Plaintiff Mary Jo Barnes began taking Makena in May 2017 at Mercy Clinic Women's Health in Joplin, Missouri and ended treatment in late June 2017 at 26 weeks. In or around May 2017, Ms. Barnes received marketing materials/pamphlets about Makena in her doctor's office.

23. Plaintiff Mary Jo Barnes paid out of pocket for Makena.

24. Plaintiff Brittany Bonds, a Missouri citizen, resides in Imperial, Jefferson County, Missouri. During the class period, Ms. Bonds was prescribed, injected with, and purchased Makena for three pregnancies.

25. Plaintiff Brittany Bonds began her first course of treatment in or around October 2012 at Mercy Hospital St. Louis in St. Louis, Missouri. Ms. Bonds received approximately seventeen weekly injections—and ended treatment in March 2013. Ms. Bonds delivered on March 25, 2013, at 36 weeks. During the course of this treatment, Ms. Bonds received Makena marketing materials/pamphlets in each shipment of Makena to her home.

26. Plaintiff Brittany Bonds began her second course of treatment in or around May 2017 at Mercy Clinic OB/GYN in Fenton, Missouri, Ms. Bonds received approximately twenty weekly injections—and ended treatment in September 2017.

Ms. Bonds delivered on September 16, 2017, at 36 weeks. During the course of this treatment, Ms. Bonds received Makena marketing materials/pamphlets in each shipment of Makena to her home.

27. Plaintiff Brittany Bonds began her third course of treatment in or around July 2019 at Mercy Birthing Center Midwifery Care – St. Louis in St. Louis, Missouri. Ms. Bonds received approximately fifteen weekly injections—and ended treatment in November 2019. Ms. Bonds delivered on November 23, 2019, at 30 weeks. During the course of this treatment, Ms. Bonds received Makena marketing materials/pamphlets in each shipment of Makena to her home. Ms. Bonds reviewed the Makena website during this pregnancy.

28. Plaintiff Brittany Bonds paid out of pocket for Makena.

29. Plaintiff Teresa Faughnan, a New York citizen, resides in Apalachin, Tioga County, New York. During the class period, Ms. Faughnan was prescribed, injected with, and purchased Makena during two pregnancies.

30. Plaintiff Teresa Faughnan began Makena treatment for the first time in June 2016 at Sante Comprehensive Women's Clinic in Johnson City, New York. Ms. Faughnan received approximately twenty weekly injections—and ended treatment in November 2016. Ms. Faughnan delivered on November 28, 2016, at 36 weeks.

31. Plaintiff Teresa Faughnan began Makena treatment for the second time in March 2019 at Sante Comprehensive Women's Clinic in Johnson City, New York.

Ms. Faughnan received approximately twenty weekly injections—and ended treatment in July 2019. Ms. Faughnan delivered on August 8, 2019, at 37 weeks.

32. Plaintiff Teresa Faughnan paid out of pocket for Makena.

33. Plaintiff Luz Vargas, a New York citizen, resides in Bronx, Bronx County, New York. During the class period, Ms. Vargas was prescribed, injected with, and purchased Makena.

34. Plaintiff Luz Vargas began Makena treatment in August 2018 at NYC Health + Hospitals/Metropolitan in New York, New York. Ms. Vargas received approximately 17 weekly injections—and ended treatment in December 2018. Ms. Vargas delivered on December 31, 2018, at 37 weeks. During the course of this treatment, Ms. Vargas received Makena marketing materials/pamphlets in each shipment of Makena that was mailed to her home. Ms. Vargas also had several telephone conversations with a "Vanessa" from Makena Care Connection during this course of treatment.

35. Plaintiff Ebony Odommorris, a New York citizen, resides in Brooklyn, King County, New York. During the class period, Ms. Odommorris was prescribed, injected with, and purchased Makena.

36. Plaintiff Ebony Odommorris began Makena treatment in or around May 2020 at SUNY Downstate in Brooklyn, New York. Ms. Odommorris received

approximately 12 weekly injections—and ended treatment in or around August 2020. Ms. Odommorris delivered on August 12, 2020, at 28 weeks.

37. Jennifer Maltese, a New York citizen, resides in East Northport, Suffolk County, New York. During the class period, Ms. Maltese, was prescribed, injected with, and purchased Makena during two pregnancies.

38. Plaintiff Jennifer Maltese began Makena treatment for the first time in or around June 2013 at South Bay OB/GYN in West Islip, New York. Ms. Maltese received approximately 20 weekly injections—and ended her treatment in or around October 2013. Ms. Maltese delivered on October 19, 2013, at 32 weeks.

39. Plaintiff Jennifer Maltese began Makena treatment for a second time in or around November 2018 at South Bay OB/GYN in West Islip, New York. Ms. Maltese received approximately 20 weeks of injections—and ended her treatment in or around February 2019. Ms. Maltese delivered on February 25, 2019, at 32 weeks.

40. Plaintiff Lisa Brady, a Wisconsin citizen, resides in Pewaukee, Waukesha County, Wisconsin. During the class period, Ms. Brady was prescribed, injected with, and purchased Makena.

41. Plaintiff Lisa Brady began Makena treatment in April 2017 at Moreland OB-GYN Associates in Waukesha, Wisconsin. Ms. Brady received approximately twenty weeklyinjections—and ended her treatment in or around September 2017. Ms. Brady delivered on September 15, 2017, at 38 weeks. In or around April 2017,

Ms. Brady received Makena marketing materials/pamphlets at her doctor's office. Ms. Brady also spoke on the phone with a representative of AMAG about Makena on approximately three separate occasions during this course of treatment.

42. Defendant AMAG Pharmaceuticals, Inc. ("AMAG") is a Delaware corporation headquartered in Waltham, Massachusetts. AMAG currently holds the exclusive marketing rights to Makena.

JURISDICTION AND VENUE

43. Venue is proper in this District under 28 U.S.C. § 1391(b) because at all times relevant to the Complaint: (a) AMAG transacted business, was found, or acted through subsidiaries or agents present in this District; and (b) a substantial part of the events giving rise to Plaintiffs' claims occurred in this District. Alternatively, venue lies under 28 U.S.C. § 1391(c) because AMAG is subject to the Court's personal jurisdiction.

44. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d) because the case is a class action, the class members are diverse from AMAG, and the amount in controversy exceeds $5,000,000.

45. This Court has personal jurisdiction over AMAG because AMAG transacted business in this District.

FACTUAL ALLEGATIONS

I. History of Hydroxyprogesterone Caproate

46. The hormonal medication hydroxyprogesterone caproate has been in the U.S. marketplace since 1956. Over time, the pharmaceutical companies who have marketed and sold hydroxyprogesterone caproate have not added anything new to this drug—failing to make the drug a viable product for mothers at risk of premature births and failing to mitigate the potential adverse consequences of taking hydroxyprogesterone caproate. The only real addition by the pharmaceutical companies has been enormous price increases.

47. Schering AG developed hydroxyprogesterone caproate in 1953 and reported its medical effects in 1954.[1] The drug was first marketed in Japan in 1954-55 before it was introduced in the United States in 1956 by Bristol-Myers Squibb, having acquired the license to the patent, under the brand name Delalutin, to manage abnormal bleeding in patients with uterine cancer.[2]

48. In the 1960s, Delalutin began to be used to treat pregnant women who had

[1] Ralph I. Dorfman, *Methods in Hormone Research*, Academic Press (1966).

[2] Lippincott, *New and Nonofficial Drugs*, Council on Drugs (1964); *see also* Tom Morrow, MD, *Resurrection of Preterm Labor Drug Evokes Questions of Fairness,* Biotechnol. Healthc. 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3138388/.

tumorous ovaries removed.[3]

49. In the 1990s, Delalutin (and thus hydroxyprogesterone caproate) had become a drug to treat an imminent premature birth threat during pregnancy after studies focused on its potential to reduce preterm births.[4]

50. Bristol-Myers Squibb voluntarily withdrew the drug from the market in 1999.[5]

51. Interest in hydroxyprogesterone caproate or 17P resurfaced after a single clinical trial published in 2003[6] by the National Institute of Child Health and Human Development (the "Meis study") appeared to find that it might reduce the risk of preterm births in at-risk mothers.[7]

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[3] Macintyre, *Ovarian surgery with loss of corpus luteum in early pregnancy. Report of two cases brought to term with progestin (Delautin) therapy*, Can. Med. Assoc. J. (1961), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1848126/pdf/canmedaj00899-0006.pdf.

[4] Keirse, Progestogen administration in pregnancy may prevent preterm delivery, Obstet. Gynaecol. (Feb. 1990); *see also* Morrow, *Resurrection of Preterm Labor Drug Evokes Questions of Fairness.*

[5] *Determination that Delalutin Injection, 125 mg/ mL and 25 mg/ mL, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness*, FDA (June 25, 2010), https://www.federalregister.gov/documents/2010/06/25/2010-15416/determination-that-delalutin-hydroxyprogesterone-caproate-injection-125-milligramsmilliliter-and-250.

[6] In Plaintiffs' Consolidated Amended Class Action Complaint, a typo identified this study as having occurred in 2013 and not 2003.

[7] Meis PJ, *et al*, *Prevention of Recurrent Preterm Delivery By 17 Alpha-Hydroxyprogesterone Caproate*, New England Journal of Medicine (June 2003), 348(24):2379-2385, https://www.nejm.org/doi/full/10.1056/NEJMoa035140.

52. On the heels of the results from the Meis study, Adeza Biomedical Corporation ("Adeza") submitted a New Drug Application ("NDA") for Gestiva, the name that Adeza gave to 17P in Adeza's NDA, in May 2006.

53. Adeza became part of Hologic, Inc. ("Hologic") in October of 2007.

54. On January 22, 2008, KV Pharmaceuticals ("KV") entered into an agreement with Hologic, whereby Hologic agreed to sell worldwide rights to Gestiva to KV for $82.5 million in cash upon approval of the pending Gestiva NDA. [8]

55. KV attempted to corner the market for 17P by rebranding the drug as Makena and then applying for exclusive sales rights under the Orphan Drug Act ("ODA").

56. The Orphan Drug Act, 21 U.S.C. § 360aa, was intended to attract pharmaceutical companies to develop drugs designed to treat rare but serious conditions like ALS, Tourette syndrome and muscular dystrophy.[9] Under the Orphan Drug Act, an "orphan drug" is a drug used to treat a disease or condition that affects fewer than 200,000 people in the United States or lacks commercial viability.

57. Section 360cc of the Orphan Drug Act grants drug companies exclusive

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[8] Lisa Brown, *KV Pharmaceutical, hologic Settle Makena Dispute*, St. Louis Post-Dispatch (Dec. 13, 2012), https://www.stltoday.com/business/local/kv-pharmaceutical-hologic-settle-makena-dispute/article_79fd8d56-bd16-51fe-9225-a6ac33d8ba8a.html.

[9] Richard Knox, *Premeire Prevention Drug Costs 53 Times More Than Generic, But Researches Find it's No Better,* WBUR 90.9 (Oct. 3, 2017), https://www.wbur.org/commonhealth/2017/10/03/preterm-birth-prevention-drug-costs.

marketing rights for a drug that treats a rare disease or condition for up to seven years. Makena was designated as an "orphan drug" under the Act in 2007.[10]

58. The FDA granted KV's request for Orphan Drug Act protection on February 4, 2011, but did not grant KV patent rights covering 17P. [11]

59. The data used to support Makena's fast-track application and subsequent approval, however, was insufficient to assess Makena's efficacy.[12]

60. In seeking approval, KV relied heavily on the Meis study. The FDA's Statistical Review and Evaluation, however, found that reliance solely on the 2003 National Institute of Child Health and Human Development study was insufficient to establish the efficacy of the drug in preventing preterm births.[13]

61. Analysis of the Meis study found that: 1) the study failed to identify the optimal time to start taking Makena; 2) one study center accounted for nearly half

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[10] *Id.*

[11] FDA, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf .

[12] Jim Doyle, *FDA's Fast-Track Approval of Makena Could Backfire on KV*, St. Louis Post-Dispatch (Mar. 13, 2011), https://www.stltoday.com/business/local/fda-s-fast-track-approval-of-makena-could-backfire-on/article_e4472916-0646-539d-b04a-520756765418.html.

[13] Statistical Review and Evaluation: Clinical Studies (21-945 Makena), FDA (July 13, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021945Orig1s000StatR.pdf.

of the subjects, calling into question the effectiveness of the study's randomizations; and 3) women treated with Makena experienced fetal and neonatal deaths earlier than women who were taking the placebo.[14]

62. The statistical review concluded that Makena's medical benefits in reducing preterm births were "**not convincing** when considering that only one study was submitted to support the claim of effectiveness" for hydroxyprogesterone caproate.[15]

63. Despite the FDA's own statisticians' misgivings about the effectiveness of Makena, the FDA approved it on a fast-track basis, allowing the drug to hit the U.S. market in early 2011.[16]

64. After frantic and dubious efforts to save its bottom line with Makena failed, KV Pharmaceutical was forced to file for chapter 11 bankruptcy and re-emerged under the name Lumara Health ("Lumara") in 2013.[17]

65. Thereafter, Lumara continued to manufacture, market, and sell Makena.

66. In 2014, despite Lumara/KV's checkered history, AMAG bought Lumara

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[14] *Id*. at 6.

[15] *Id*. at 39 (emphasis added).

[16] FDA, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf .

[17] Angela Mueller, *Former KV Pharmaceutical to be Acquired*, St. Louis Business Journal (2014), https://www.bizjournals.com/stlouis/blog/health-care/2014/09/former-kv-pharmaceutical-to-be-acquired.html.

and its drug portfolio for $675 million and an additional $350 million contingent on sales milestones.[18] The flagship product in the acquisition was Makena.

68. In November 2020, AMAG was acquired by Covis Group S.à r.l. ("Covis") for $647 million.[20]

II. Makena Is Exorbitantly Priced and Doesn't Work

69. Makena hit the market with a breathtaking sticker price: $1,500 per injection, up from the generic $10-$20 price. Women who were taking the generic drug were understandably shocked: "I'm ready to have a heart attack," Janice Watkins, who had been taking the compounded drug known as 17P, said in 2011 after she learned of the price increase from her doctor's office.[21] "I'm nervous now because I have to

[18] Grogan, *AMAG $1 Billion Deal to Buy Preterm Birth Drug Makena*, http://www.pharmatimes.com/news/amag_$1_billion_deal_to_buy_preterm_birth_drug_makena_1002541.
[19] *See* Ex. 1, AMAG00099670 at 9670.
[20] Covis Pharma., *Covis Group Completes Acquisition of AMAG Pharmaceuticals*, (Nov. 16, 2020), https://www.prnewswire.com/news-releases/covis-group-completes-acquisition-of-amag-pharmaceuticals-301173667.html.
[21] Sean Hamill, *Pregnancy drug's sharp price hike called 'greed'*, Pittsburg Post-Gazette, (March 11, 2011), https://www.post-gazette.com/news/health/2011/03/11/Pregnancy-drug-s-sharp-price-hike-called-greed/stories/201103110343.

go home and call my insurance company to see if they'll cover me."[22]

70. Due to public outrage over KV Pharmaceutical's price hike, the FDA allowed compounding pharmacies to make the generic drug 17P in their pharmacies to allow a more affordable option for expecting mothers.[23]

71. Eventually, in large part due to competition from compounded 17P, KV Pharmaceutical reduced the price to $690 per Makena injection.[24]

72. Since acquiring Lumara, AMAG has continued price-gouging its customers.

73. As one woman reported in 2019: "Insanely expensive - did not find this out until halfway through my amount of injections that they were charging my insurance $1500 per shot! Insurance 'covered' half leaving me with $750ish a shot. No one told me they would be this expensive. Hopefully I can save someone the surprise."[25]

74. A 2017 Harvard study, which analyzed a database of insurance claims for Makena, noted Makena costs 100 times more than compounded 17P. The study

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[22] David Whelan, Forbes, "Is KV Pharmaceutical A Flat-Out Evil Company?" available at https://www.forbes.com/sites/davidwhelan/2011/03/11/is-kv-pharmaceutical-a-flat-out-evil-company/#11da813831b5.

[23] Alexander Gaffney, *FDA Maintains Compounding Exemption for KV Pharmaceutical's Makena*, Regulatory Focus (June 18, 2012), https://www.raps.org/regulatory-focus/news-articles/2012/6/fda-maintains-compounding-exemption-for-kv-pharmaceuticals-makena.

[24] *Id; see also* Senator Sherrod Brown Statement on Makena Repricing.

[25] Comment posted Sept. 18, 2019, https://www.drugs.com/comments/hydroxyprogesterone/makena.html (accessed Oct. 30, 2019).

found that the average cost per pregnancy of Makena was $10,917, compared to $206 per pregnancy for the compounded version.[26]

75. The same study found no statistically significant difference in the rate of preterm births between the women who received Makena and the women receiving compounded 17P.[27]

76. The same study further concluded that despite purported concerns regarding compounded drugs, the frequency of infections during treatment regimens was equally low among the women receiving compounded 17P and the women receiving Makena.[28]

77. This study concluded that the "analysis raises concerns about the value of hydroxyprogesterone caproate."[29]

78. Each of the named Plaintiffs paid at least hundreds of dollars for each shot of Makena.

III. AMAG Misleadingly Markets Makena as Safer and More Effective than Compounded 17P

[26] *See* "Utilization, Cost, and Outcome of Branded vs Compounded 17-Alpha Hydroxyprogesterone Caproate in Prevention of Preterm Birth" available at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2655241.

[27] *See id.*

[28] *Id.*

[29] *Id.*

79. AMAG and its predecessors, who – again, did not discover a novel drug or invent 17P and instead relied on an NICHD-funded Meis study to receive orphan drug status, have aggressively attacked compounded versions of 17P, engaging in a sophisticated campaign of misinformation and dubious litigation. AMAG and its predecessors made these attacks to protect their scandalous pricing regime over an ineffective drug.

80. Due to AMAG and its predecessors' relentless marketing, physicians and pharmacy directors now fear the repercussions of prescribing a compounded hydroxyprogesterone caproate. AMAG and its predecessors have used proxies (as well as their own direct marketing) to argue that compounded 17P is impure or ineffective and therefore any unforeseen side effect due to compounded 17P could result in liability for the medical professional or pharmacist.

81. AMAG, its predecessors, and third parties contracted by AMAG, have consistently and aggressively sowed such concerns throughout the commercial life of Makena.

82. And while AMAG, its predecessors, and third parties contracted by AMAG have couched these attacks as concerns for safety and efficacy, these unfounded attacks are simply an excuse for charging outrageous prices and reaping the profits.

83. In 2012, after lawmakers and insurers complained that KV was engaged in price gouging, the FDA refused to stop compounding pharmacies from making 17P.

Despite evidence to the contrary, KV argued that compounded versions of 17P were not as effective or as safe as Makena and should therefore be taken off the market by the FDA. In response to KV's pressure, the FDA tested 16 samples of compounded 17P. While the FDA noted in its conclusions that approved products may generally provide assurance of safety and efficacy, the FDA concluded that the 16 tested samples of generic 17P posed no major safety risks. [30]

84. Around the same time, the FDA also noted that KV was expressly misrepresenting the FDA's position on compounded 17P. The FDA noted in a press release that KV was attempting to stop compounding pharmacies by sending compounding pharmacies misleading letters and threatening to sue for continuing to sell compounded 17P at a fraction of the cost of Makena.[31]

85. In these letters to prescribing physicians and pharmacies, KV falsely claimed that the FDA would not exercise enforcement discretion regarding compounding of generic 17P. The FDA responded that, "FDA understands that the manufacturer of Makena, KV Pharmaceuticals has sent letters to pharmacists indicating that FDA

[30] *K-V sues FDA over Makena in Fight for Survival,* Anna Yukhanano, Reuters, July 5, 2012, available at https://www.reuters.com/article/us-fda-makena/k-v-sues-fda-over-makena-in-fight-for-survival-idUSBRE86502T20120706.
[31] *Id.*

will no longer exercise enforcement discretion with regard to compounded versions of Makena. **This is not correct**."[32]

86. In 2012, after the FDA refused to bow to KV's pressure campaign and initiate enforcement against compounding pharmacies, KV sued the FDA to stop compounding of generic 17P.

87. KV's suit against the FDA was dismissed by the district court in short order, roughly two months after KV filed suit.[33]

88. AMAG and Lumara have followed KV's attempts to cast compounding pharmacies as unsafe and lower quality. In a briefing document submitted to the FDA to persuade the FDA to keep Makena on the market, AMAG raised the specter of impure, contaminated compounded drugs as a reason to allow AMAG to continue to market Makena.[34]

89. In a press release to its investors dated April 4, 2016, announcing the release of "preservative-free Makena," AMAG acknowledged it was monitoring the market share of compounded 17p: "[a]ccording to our latest estimates, we believe that 38%

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[32] *See KV Pharmaceutical Company, et al., v. United States Food and Drug Administration, et al.* Doc. 23 at 4-5, Case No. 12-cv-01105 (D.D.C. Sept. 6, 2012) (emphasis added).

[33] *See id.* The case was eventually vacated and remanded for further consideration by the D.C. Circuit Court. KV dismissed its case against the FDA with prejudice on July 3, 2014. *See id.* (Docs. 27, 34).

[34] Makena NDA 021945/S-023, Advisory Comm. Briefing Document (Oct. 29, 2019), pp. 34-35.

of pregnant women at risk for recurrent preterm birth are treated with compounded product."[35]

90. Since prior efforts to stop compounding pharmacies (via forced prosecution by the FDA) from producing 17P were unsuccessful, AMAG set its sight on convincing physicians to prescribe only the brand name Makena injection and convincing patients to take only the brand name Makena.

91. These efforts include providing prescribers talking points to use when dealing with insurance companies refusing to pay for Makena over compounded versions. Examples of talking points AMAG and its predecessors provided to healthcare providers in marketing materials include:

a. "I want my patient to have an FDA- approved drug."

b. "I don't have the appropriate assurance that a compounded drug is going to be the labeled potency, free of impurities and sterile."

c. "From a liability perspective, I am not comfortable prescribing a compounded product when an FDA-approved product is available,

[35] *AMAG Pharmaceuticals Announces the U.S. Commercial Launch of New Single-Dose, Preservative-Free Makena® (hydroxyprogesterone caproate injection)*, AMAG Newsroom (April 4, 2016), https://www.amagpharma.com/news/amag-pharmaceuticals-announces-the-u-s-commercial-launch-of-new-single-dose-preservative-free-makena-hydroxyprogesterone-caproate-injection/.

particularly in light of the New England Compounding Center fungal meningitis outbreak due to contaminated vials of a steroid injectable."[36]

92. To further scare prescribers to prescribe Makena over compounded 17P, Lumara funded an Astroturf opinion article entitled "Pharmacy Compounding Primer for Physicians." The article, funded by Ther-Rx, a wholly-owned subsidiary of Lumara/KV, warns that: "[p]hysicans should also be aware that the liability based on inappropriate use of a non-FDA-approved drug can be significant, and possible negative consequences can include the invalidation of their malpractice insurance, personal liability and possible criminal prosecution. This is a situation beyond buyer beware that really is "prescriber beware'."[37]

93. In the fine print at the very end of the article, the authors Sarah Sellers and Wulf H. Utian disclose that they are "current or previous consultants to Ther-Rx Corporation." This "disclosure" (really a misleading half-truth) artfully avoids disclosing that Ther-Rx was a wholly owned subsidiary of KV Pharmaceuticals, AMAG's predecessor and (of course) a company with an enormous financial motive to discourage the use of compounded 17P.[38]

94. In fact, the main study author received compensation for drafting the manuscript. In other words, AMAG's predecessor commissioned the opinion piece,

[36] Ex. 2, AMAG00001068 at 1179.
[37] Ex. 3, AMAG00009000 at 9004.
[38] *Id.* at 9005.

so that it could be used to scare prescribing physicians' into avoiding compounded 17P and only prescribing Makena.[39]

96. Lumara also used video advertisements engaging in similar scare tactics in or around Fall 2014 to at least as late as February 2015.[41]

97. When prescribers encounter push back from insurance companies and pharmacies about substituting compounded 17P for Makena, AMAG advises providers to "stand firm in their prescribing decisions to help ensure patients receive Makena + support when pharmacists ask about generic substitution."[42]

98. Lumara and KV's efforts were not limited to intimidating physicians. AMAG's predecessors also developed videos directly targeting patients. These marketing pieces engaged in the same scare tactics, encouraging potential Makena patients to ask their doctors if they were receiving Makena or a compounded 17P, and encouraging patients to insist on Makena over a compounded 17P.[43]

[39] *Id.*
[40] Ex. 4, AMAG00014668 at 14680.
[41] Ex. 22, AMAG00132209.
[42] Ex. 5, AMAG00089636 at 640.
[43] Ex. 6, AMAG00024946.

99. AMAG also used Makena Care Connection to directly discourage patients from using compounded 17P. At least through 2018 (and likely continuing through today) AMAG instructs Makena patients to:

- REQUEST branded Makena so that Makena Care Connection may continue to provide you support
- VERIFY with your pharmacist that Makena is being dispensed before paying your out-of-pocket expense and/or approving the shipment
- TALK with your healthcare provider or Makena Care Connection if the product you received does not state Makena on the packaging[44]

100. AMAG and Lumara have employed the same scare tactics on their website to misrepresent the safety and efficacy of compounded 17P throughout the commercial life of Makena. At least through May 2014 (and likely continuing thereafter) AMAG and Lumara warned patients and physicians – in a series of half-truths and flat-out misrepresentations – that the active ingredient in compounded 17P is "unknown" and "varie[d]"[45] and further misleadingly insinuated that the Meis study concluded that branded 17P like Makena was more effective than compounded 17P.

[44] Ex. 7, AMAG00089403.
[45] Ex. 8, AMAG00010284 at 300-301.

101. None of these marketing pieces disclosed the FDA's investigation and conclusions that sampled compounded 17P met potency and purity standards and identified no major safety problems.[46]

102. None of these marketing pieces disclosed Lumara and KV's own violations of good manufacturing practices, culminating in huge fines and prison time for key executives, shortly before Makena was commercialized.[47]

103. None of these marketing pieces disclosed that KV had $24 million of its inventory seized in connection with the manufacture of unapproved drugs, again shortly before the commercialization of Makena.

104. None of these marketing pieces directed at compounding were approved by the FDA, and in fact many of AMAG and its predecessors' claims regarding compounded 17P have been expressly repudiated by the FDA.

105. This history of pushing the envelope and flat-out misconduct is not limited to KV/Lumara.

106. On October 18, 2010, the FDA sent AMAG a "Warning Letter" alleging that "[b]oth the GastroMARK and Feraheme webpages omit risks associated with the drug products; in addition, the GastroMARK webpage omits important information about the approved indication for GastroMARK, and both webpages

[46] Ex. 9, AMAG00025147.
[47] *See U.S. v. KV Pharm. Co., et al.*, No. 4:09-CV-334 (RWS)

misleadingly suggest unapproved new uses for the drugs. Thus the webpages misbrand the drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(a), (f)(1) & (n); 321(n), and FDA's implementing regulations."[48]

107. The letter further went on to state that "[t]hese violations are concerning from a public health perspective because they suggest that GastroMARK is useful in a broader range of patients and conditions than has been demonstrated by substantial evidence or substantial clinical experience, and that GastroMARK and Feraheme are safer than has been demonstrated by substantial evidence or substantial clinical experience."[49]

108. Two months after the FDA's "Warning Letter," a whistleblower complaint was filed against AMAG by the Attorneys General of twenty-seven states and The District of Columbia alleging that AMAG was "engaged in an illegal marketing scheme for, among other things, the purpose of increasing the sale of its drug Feraheme."[50]

109. Specifically, the complaint alleged:

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[48] U.S. Food and Drug Administration, Inspections, Compliance, Enforcement, and Criminal Investigations, WARNING LETTER TO AMAG PHARMACEUTICALS (December 10, 2010) https://www.fdanews.com/ext/resources/files/archives/a/AMAG_Pharma_WL.pdf.

[49] *Id.*

[50] *United States of America et al v. Amag Pharmaceuticals, Inc. et al*, No. 1:10-CV-11980 (D. Mass).

a. Violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A);

b. Violations of the Anti-Kickback Statute, 42 U.S.C. § 3729(b)(4);

c. Violations of the Stark Law – The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn, *et seq*.;

d. Violations of the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*.; and

e. Violations of each Plaintiff State's False Claims Act. [51]

110. As with Feraheme, AMAG has engaged in the same dubious conduct to drive sales of Makena. Among other tactics, AMAG has enlisted an army of doctors to extol the virtues of its Makena at conferences and speaking engagements. In 2018 alone, AMAG made Makena-related payments to 5,800 physicians and 16 hospitals totaling $498,000.[52]

IV. AMAG Knew Before Release of PROLONG that Makena Does Not Work

111. The fast-track approval of Makena was conditioned on a follow-up, long-term clinical trial to confirm the efficacy of hydroxyprogesterone caproate in preventing preterm births.[53]

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[51] *Id*.

[52] *Dollars for Docs Makena*, ProPublica (2018), https://projects.propublica.org/docdollars/products/9346.

[53] *Accelerated Approval Letter for New Drug Application 21945*, FDA (Feb. 3, 2011),

112. That study, Progestin's Role in Optimizing Neonatal Gestation ("PROLONG"), would ultimately take the better part of a decade to complete. But AMAG knew far earlier than public release of the top line results from the PROLONG study, in March 2019, that Makena was ineffective.

113. The FDA requires a sponsor of a clinical investigation that involves an investigational new drug to submit an Investigational New Drug ("IND") Application.[54]

114. Part of an IND Application includes a study protocol.[55]

115. PROLONG was designated as a phase 3 study. Phase 3 studies, sometimes known as pivotal studies, are designed to demonstrate whether a product offers a treatment benefit to a specific population.

116. Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling."[56]

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https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf .

[54] 21 C.F.R. § 312.20(a).
[55] 21 C.F.R. § 312.23(6).
[56] 21 C.F.R. § 312.21(c)

117. As a phase three study, a study protocol was required to describe all aspects of the study in detail, including:

a. A statement of the object and purpose of the study.

b. The name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each subinvestigator (e.g., research fellow, resident) working under the supervision of the investigator; the name and address of the research facilities to be used; and the name and address of each reviewing Institutional Review Board.

c. The criteria for patient selection and for exclusion of patients and an estimate of the number of patients to be studied.

d. A description of the design of the study, including the kind of control group to be used, if any, and a description of methods to be used to minimized bias on the parts of subjects, investigators, and analysts.

e. The method for determining the dose(s) to be administered, the planned maximum dosage, and the duration of individual patient exposure to the drug.

f. A description of the observation and measurements to be made to fulfill the objectives of the study.

118. A description of clinical procedures, laboratory tests, or other measures to

be taken to monitor the effects of the drug in human subjects and to minimize risk.[57]

119. On December 11, 2014, AMAG became listed as a Collaborator on the PROLONG study.[58]

120. According to the U.S. National Library of Medicine, a Collaborator is an "organization other than the Sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, **data analysis**, or reporting."[59]

121. On April 6, 2016, the Study Protocol for the PROLONG study was updated. This updated version, Version 6.0, listed AMAG as the Sponsor of the PROLONG study; the Sponsor Contact/Project Manager was Robert Birch, AMAG's Director of Clinical Affairs.[60]

122. A "sponsor" is "the organization or person who initiates the study and who

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[57] § 312.23(6)(ii), (iii).

[58] Study NCT01004029 version 26, Confirmatory Study of 17P Versus Vehicle for the Prevention of Preterm Birth in Women With a Previous Singleton Spontaneous Preterm Delivery (December 11, 2014), https://clinicaltrials.gov/ct2/history/NCT01004029?V_26=View#StudyPageTop.

[59] Glossary of Common Site Terms, CLINICALTRIAL.GOV, https://clinicaltrials.gov/ct2/about-studies/glossary (last visited June 2, 2021) (emphasis added).

[60] *A Phase 3B, Multi-Center, Randomized, Double-Blind Study of Hydroxyprogesterone Caproate Injection, 250 MG/ML, Versus Vehicle for the Prevention of Preterm Birth in Women with a Previous Singleton Spontaneous Preterm Delivery*, CLINICALTRIALS.GOV, 1 (April 6, 2016), https://clinicaltrials.gov/ProvidedDocs/29/NCT01004029/Prot_000.pdf.

has authority and control over the study."[61]

123. Section 10.2 of Version 6.0 of the Study Protocol provided, "All aspects of the study will be carefully monitored, by the sponsor or its designee, for compliance with applicable government regulations with respect to current GCP and current standard operating procedures. The monitor will visit the investigator and study facility at periodic intervals, in addition to maintaining necessary telephone and letter contact. The monitor will maintain a current personal knowledge of the study through observation, **review of study records** and source documentation, and discussion of the conduct of the study with the investigator and staff."[62]

124. Section 10.3 of Version 6.0 of the Study Protocol provides, in relevant part, "In the event of an audit, the investigator agrees to allow the sponsor, representatives of the sponsor and applicable regulatory authorities **access to all study records**."[63]

125. Section 11.2 of Version 6.0 of the Study Protocol provides, in relevant part, "The investigator is responsible for obtaining continued review of the clinical

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[61] Glossary of Common Site Terms, CLINICALTRIAL.GOV, https://clinicaltrials.gov/ct2/about-studies/glossary (last visited June 2, 2021) (emphasis added).

[62] *Study Protocol: A Phase 3B, Multi-Center, Randomized, Double-Blind Study of Hydroxyprogesterone Caproate Injection, 250 MG/ML, Versus Vehicle for the Prevention of Preterm Birth in Women with a Previous Singleton Spontaneous Preterm Delivery*, CLINICALTRIALS.GOV, § 10.2, at 44-45 (April 6, 2016), https://clinicaltrials.gov/ProvidedDocs/29/NCT01004029/Prot_000.pdf (emphasis added).

[63] *Id.* § 10.3 at 45 (emphasis added).

research at intervals not exceeding 1 year or otherwise specified by the IRB/IEC [Institutional Review Board/Independent Ethics Committee]. **The investigator must supply the sponsor or its designee with written documentation of continued review of the clinical research**."[64]

126. In addition to the requirements set forth in the Study Protocol, AMAG was legally obligated to monitor the progress of the PROLONG study.[65]

127. 21 C.F.R. § 312.56 states that "[t]he sponsor shall review and evaluate the evidence relating to the safety **and effectiveness** of the drug as it is obtained from the investigator. The sponsors shall make such reports to FDA regarding information relevant to the safety of the drug as are required under § 312.32. The sponsor shall make annual reports on the progress of the investigation in accordance with § 312.33." (emphasis added).

[redacted]

[64] *Id.* § 11.2 at 46 (emphasis added).
[65] 21 C.F.R. § 312.56(a).
[66] Ex. 10, AMAG00101220 at 221.

[redacted]

129. According to the PROLONG study Statistical Analysis Plan section 6.2, the PROLONG study utilized a Data and Safety Monitoring Board ("DSMB"), also known as a Data Monitoring Committee or a Data and Safety Monitoring Committee, to review unblinded summary safety data.[68]

130. According to section 6.3 of the Statistical Analysis Plan, "Unblinded data are reviewed by the DSMB."[69]

131. A "Statistical Analysis Plan" is "a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the [study] protocol and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data."[70]

132. The DSMB was an independent and external group that was contracted to review safety data as it was produced during the PROLONG study.[71]

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[67] *Id.* at 222.
[68] *Statistical Analysis Plan: A Phase 3B, Multi-Center, Randomized, Double-Blind Study of Hydroxyprogesterone Caproate Injection, 250 MG/ML, Versus Vehicle for the Prevention of Preterm Birth in Women with a Previous Singleton Spontaneous Preterm Delivery*, ClinicalTrials.Gov, (January 29, 2019), https://clinicaltrials.gov/ProvidedDocs/29/NCT01004029/SAP_001.pdf.
[69] *Id.*
[70] Guidance For Industry E9 Statistical Principles for Clinical Trials, 1998 WL 34327519, at 39.
[71] *Statistical Analysis Plan: A Phase 3B, Multi-Center, Randomized, Double-Blind Study of Hydroxyprogesterone Caproate Injection, 250 MG/ML, Versus Vehicle for*

133. The scope of the DSMB's review is defined in the DSMB charter.

134. On October 29, 2019, during the Bone, Reproductive, and Urologic Drugs Advisory Committee meeting, Dr. Julie Krop, AMAG's then Executive Vice President and Chief Medical Officer, after repeated follow-up questions, admitted to the committee that the DSMB "knew the overall [event] rate."[72]

135. If AMAG knew the overall rate of preterm birth, AMAG knew the incoming data showed Makena was ineffective, because the results were necessarily low across both the study and placebo arms.[73]

136. But AMAG didn't have to rely on incoming data from PROLONG, because Makena patients were directly reporting to AMAG that Makena wasn't working.

[redacted]

the Prevention of Preterm Birth in Women with a Previous Singleton Spontaneous Preterm Delivery, ClinicalTrials.Gov, (January 29, 2019), https://clinicaltrials.gov/ProvidedDocs/29/NCT01004029/SAP_001.pdf.

[72] *Transcript for the October 29, 2019 Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee*, U.S. Food & Drug Administration, at 104, 233 (October 19, 2019), https://www.fda.gov/media/136108/download.

[73] U.S. Department of Health and Human Services, *et. seq.*, *Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees*, ClinicalTrials.Gov, § 4.2.2, at 11, (March 2006), https://www.fda.gov/media/75398/download ("Even aggregate data on safety and efficacy may be informative.").

In other words, Makena Care Connection's mission was to ensure Makena patients kept taking and purchasing Makena, despite the reports from those patients that they were continuing to have preterm births.

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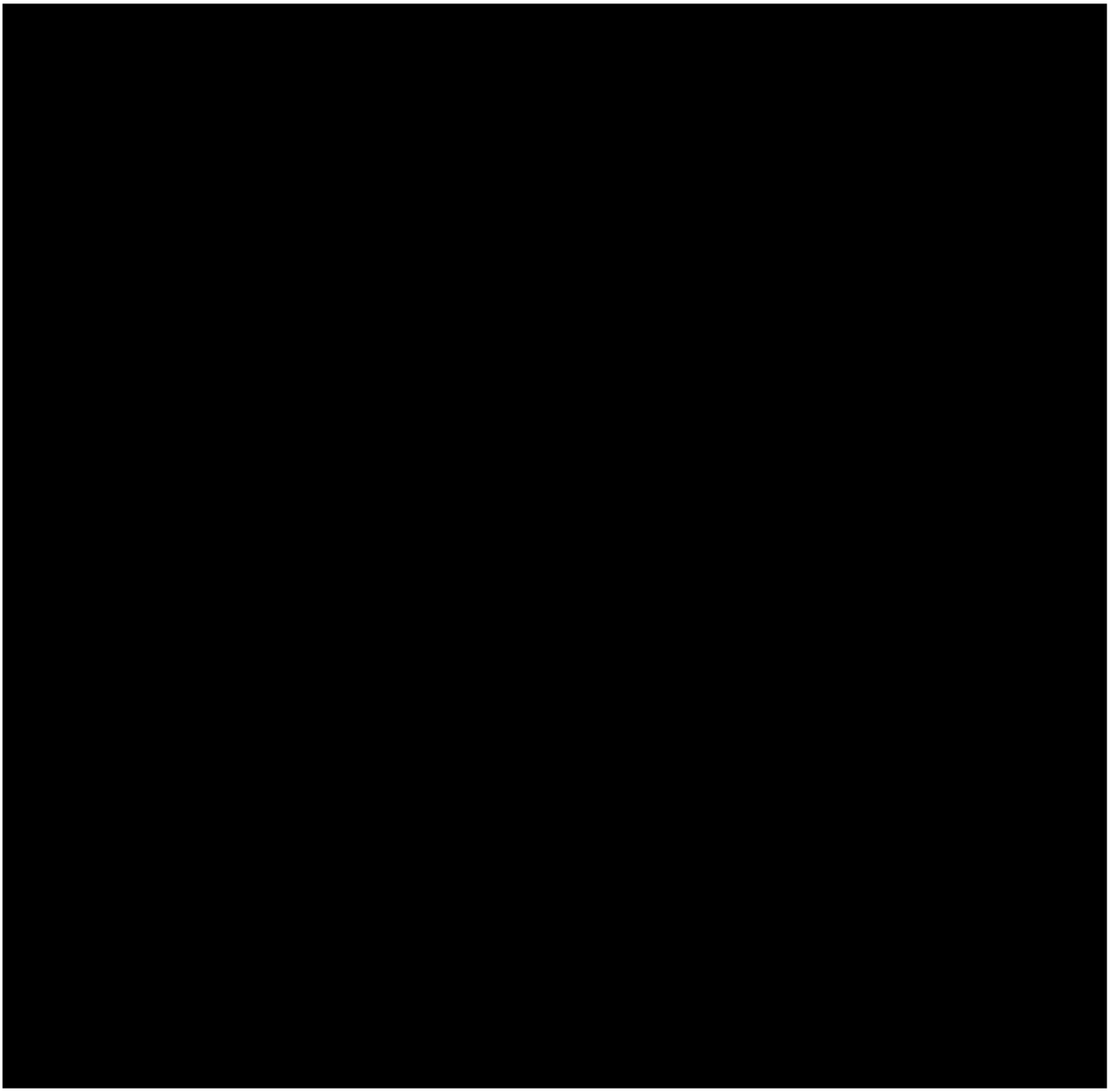
[74] *See* Ex. 11, AMAG00099141 at 151, 193 – 213.
[75] *Id.* at 193 – 213.
[76] Ex. 1, AMAG00099670 at 691 – 694 (Lumara Health, Inc. a division of AMAG Pharmaceuticals, Periodic Safety Update Report (03 Feb 2015 – 02 Feb 2016); Ex. 12 AMAG00100213 at 227 – 259.
[77] *Id.* at 147.

140. Through Makena Care Connection, AMAG communicates directly with Makena patients, with no intermediary physician. As part of the program, AMAG presents patients with HIPAA releases. The release provides AMAG sweeping access to the patient's medical treatment:



[78] Ex. 13, AMAG00089326 at 326.

[redacted]

142. When AMAG couldn't reach Makena patients, AMAG would send a standard form letter to patients, requesting such patients to establish contact. This form letter was used at least through January 2017.[80]

V. The PROLONG Study Definitively Shows that Makena Does Not Work

143. On March 8, 2019, after eight years of Makena sales at unconscionable prices, AMAG revealed the results of the FDA-mandated follow-up trial, PROLONG.

144. The PROLONG study included approximately 1,700 pregnant women and examined the efficacy of Makena versus a placebo in preventing preterm births in women who had a history of spontaneous preterm births. The study was a randomized, double-blinded, placebo-controlled clinical trial.[81]

145. According to AMAG, 11% of the women in the study who took Makena delivered their babies at 35 weeks or earlier; whereas 11.5% of women who took the placebo delivered their babies at 35 weeks or earlier. In other words, PROLONG further confirmed what the Meis study suggested and what Makena patients had

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[79] *Id.*

[80] Ex. 14, AMAG00060290.

[81] *AMAG Pharmaceuticals Announces Topline Results from the Prolong Trial Evaluating Makena*, AMAG Newsroom (Mar. 8, 2019), https://www.amagpharma.com/news/amag-pharmaceuticals-announces-topline-results-from-the-prolong-trial-evaluating-makena-hydroxyprogesterone-caproate-injection.

previously reported: Makena failed to reduce the risk of preterm birth. There were also no statistically significant differences concerning miscarriages and stillbirths between Makena and the placebo treatment.[82]

146. The PROLONG study showed that Makena was no more effective than a placebo. AMAG admitted that the PROLONG study's results showed no "statistically significant difference between the treatment [Makena] and placebo arms for the co-primary endpoints." The results also showed there was no significant difference between subjects using Makena and subjects using placebos on the rate of neonatal mortality or morbidity.[83] Put differently: the PROLONG study was further evidence that Makena does not work.

147. However, AMAG knew before the results of PROLONG that Makena was ineffective because its employees knew Makena was ineffective.

148. Jennifer Gudeman; Robert Birch; Michael J. Jozwiakowski; Monique Duncan; Laura Williams; and Julie Krop were all study authors of the PROLONG trial and were all current or former employees of AMAG at the time the topline data was published on March 8, 2019.[84]

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[82] *Id*.

[83] *Id.*

[84] Sean C. Blackwell, et al., *17-OHPC to Prevent Recurrent Preterm Birth in Singleton Gestations (PROLONG study): A Multicenter, International, Randomized Double-Blind Trial*, 37 Am. J. Perinatology 127 (2019).

149. On October 29, 2019, and based on the results of the PROLONG study, the FDA Bone, Reproductive and Urologic Drugs Advisory Committee recommended that Makena be withdrawn from the market.[85]

150. After the PROLONG trial, the health insurance industry signaled it will no longer pay claims for Makena treatment due to Makena's inefficacy. A spokesperson for America's Health Insurance Plans (AHIP), a national association representing the health insurance industry, recently confirmed that the PROLONG study definitively shows that Makena does not work. According to that spokesperson, Cathryn Donaldson, "Now it is clear it is not effective."[86]

151. On the heels of the public release of the results of PROLONG study and its failure to show that Makena was effective at preventing preterm birth, AMAG responded with substantial restructuring of its leadership and its business.

152. AMAG announced in January of 2020 that its President and CEO William

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[85] Sumanthi Reddy, *FDA Committee Recommends Withdrawing Treatment to Prevent Preterm Births From Market*, The Wall Street Journal (Oct. 29, 2019), https://www.wsj.com/articles/fda-committee-recommends-withdrawing-treatment-to-prevent-preterm-births-from-market-11572387799; *see also* Ned Pagliarulo, *FDA Panel Backs Withdrawal of AMAG Drug to Prevent Preterm Birth*, BiopharamaDive (Oct. 30, 2019), https://www.biopharmadive.com/news/amag-makena-fda-advisory-panel-vote-withdrawal-preterm-birth/566159/.

[86] Emmarie Huetteman, *Drug to Prevent Premature Birth Divides Doctors, Insurers, and FDA Experts,* NPR (January 24, 2020), https://www.npr.org/sections/health-shots/2020/01/24/798731110/drug-to-prevent-premature-birth-divides-doctors-insurers-and-fda-experts.

Heiden was stepping down.[87]

153. In April 2020, AMAG's Board of Directors appointed Scott Meyers to replace William Heiden as President and Chief Executive Officer.[88]

154. AMAG also underwent significant changes to its medical development organization. After her testimony about the results of the PROLONG study, on March 31, 2020, Dr. Julie Krop, Executive Vice President, Chief Medical Officer, and author of the PROLONG study journal article resigned.[89]

155. After the PROLONG study results were released, AMAG has also claimed that removal of Makena from the market may exacerbate inequitable outcomes in healthcare. Citing purported demographic differences between the Meis and PROLONG study, and in response to criticisms of the Meis study, AMAG opposed removing Makena from the market, stating: "Withdrawing the only FDA-approved

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[87] *AMAG Pharmaceuticals Announces Leadership Transition, Results of Strategic Review to Unlock Shareholder Value and Financial Update,* AMAG Newsroom (January 9, 2020), https://www.amagpharma.com/news/amag-pharmaceuticals-announces-leadership-transition-results-of-strategic-review-to-unlock-shareholder-value-and-financial-update/.

[88] *AMAG Pharmaceuticals Appoints Scott Myers as President and Chief Executive Officer,* AMAG Newsroom (April 28, 2020), https://www.amagpharma.com/news/amag-pharmaceuticals-appoints-scott-myers-as-president-and-chief-executive-officer/.

[89] *AMAG Pharmaceuticals Announces Changes to Medical Development Organization*, AMAG Newsroom (Mar. 4, 2020), https://www.amagpharma.com/news/amag-pharmaceuticals-announces-changes-to-medical-development-organization/ last accessed Mar. 19, 2020.

intervention could have the unintended consequence of further exacerbating existing health disparities associated with preterm birth in the most vulnerable patient populations."[90]

156. In response to the FDA's Proposal to withdraw Makena from the U.S. market, AMAG commissioned a meta-analysis study entitled Evaluating Progestogens for Preventing Preterm Birth International Collaborative ("EPPPIC study").

157. AMAG described the EPPPIC study as "a systematic review of randomized trials evaluating vaginal progesterone, intramuscular 17-alpha-hydroxycaproate (17-OHPC), and oral progesterone in women at risk of preterm birth."[91]

158. In a press release dated March 26, 2021, announcing the findings from the EPPPIC Study, AMAG stated that the "EPPPIC study reaffirms 17-OHPC for reducing early preterm birth in high-risk singleton pregnancies."[92]

159. AMAG concluded this press release by stating "[a]t this time, Makena remains approved and available and the product label remains unchanged."[93]

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[90] *AMAG Files Response to Citizen Petition*, AMAG Newsroom (January 21, 2020), https://www.amagpharma.com/news/amag-files-response-to-citizen-petition/.

[91] *EPPPIC Study Reaffirms 17-OHPC for Reducing Early Preterm Birth in High-Risk Singleton Pregnancies*, AMAG Newsroom (March 26, 2021), https://www.amagpharma.com/news/2512/.

[92] *Id.*

[93] *Id.*

160. The EPPPIC meta-analysis was supported by the US Patient-Centered Outcomes Research Institute. Two authors reported receiving research support from AMAG and another, UT Health's Sean Blackwell, MD, reported uncompensated testimony at the FDA's Makena approval hearing on behalf of the sponsor.

161. In a recent article on the EPPPIC study, the Regulatory Affairs Professionals Society noted that "[t]wo authors reported receiving research support from AMAG, and another UT Health's Sean Blackwell, MD, reported uncompensated testimony at FDA's Makena approval hearing on behalf of the sponsor."[94]

162. On the very same day that AMAG issued its press release announcing to the world that the EPPPIC study confirmed Makena's efficacy in preventing preterm birth, the FDA's Center for Drug Evaluation and Research (CDER) released its own press release in response to the EPPPIC study results. The CDER's statement stated:

> The U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) is aware of the recently published EPPPIC meta-analysis reporting the efficacy of various progestogens, with various routes of administration (vaginal progesterone, oral progesterone, intramuscular hydroxyprogesterone caproate [HPC]) to reduce the risk of pre-term birth (PTB) in at-risk women with singleton or multifetal pregnancies. CDER's recent proposal to withdraw the accelerated approval of Makena (HPC) was based upon a large randomized trial that failed to confirm the benefit of this drug to newborns or reduce the risk of PTB. In making the decision to propose Makena's withdrawal, CDER also reviewed results from prior studies of progestins (HPC and other similar drugs) for PTB, including studies relevant

[94] Kari Oakes, *FDA, unmoved by new meta-analysis, still recommends Makena withdrawal*, Regulatory Focus (March 29, 2021), https://www.raps.org/news-and-articles/news-articles/2021/3/fda-unmoved-by-new-meta-analysis-still-recommends.

to Makena that are included in the EPPPIC meta-analysis. **Therefore, the publication of the EPPPIC meta-analysis does not change CDER's proposal to withdraw the approval of Makena**.[95]

163. Currently, the FDA has not yet been removed Makena from the U.S. market.

164. AMAG has requested a hearing with the FDA prior to the FDA's withdraw of Makena. As of the date of this filing, AMAG's request has not been granted and no hearing has been set.

165. AMAG has made hundreds of millions (if not billions) of dollars in sales of Makena during the relevant time frame. In 2018, AMAG reported revenue for operations of approximately $474 million, with Makena contributing the lion's share of AMAG's annual revenue at $323 million.[96]

VI. Not Only Is Makena Exorbitantly Priced and Ineffective, It is Also Dangerous

166. In a 2015 study, scientists examined the breast cancer incidence level in women two groups of women who were receiving menopausal hormone therapy; one group received estrogen plus progesterone and the other group received estrogen alone. The study authors found that "[p]rogesterone inclusion during hormone

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[95] *CDER perspective on recently published results of EPPPIC meta-analysis*, FDA (March 26, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information (emphasis added).

[96] *AMAG 2018 Financial Results*, AMAG Newsroom (Feb. 7, 2019), https://www.amagpharma.com/news/amag-reports-fourth-quarter-and-full-year-2018-financial-results-and-provides-company-update/.

therapy intervention leads to a persistent increase in breast cancer risk after intervention and leads to the development of hormone receptor–negative tumors in addition to those that are hormone receptor positive."[97]

167. Expanding on this research, Cailin C. Murphy, PhD, MPH, and her team of scientists examined the effect of 17-OHPC (tradenames Delalutin and Proluton) exposure in utero on risk of cancer in adult offspring in the Child Health and Development Studies, a cohort of women receiving prenatal care between June 1959 and September 1966, with deliveries through June 1967. [98]

168. The researchers found that among 18,751 live births, 954 cancers were diagnosed at ages 18-58 years, offspring of women who took 17-OHPC during gestation. The results concluded that children of mothers who took 17-OHPC were two times more likely to develop cancer in their lifetime.[99]

169. In addition to the two-fold increase to cancer risk overall, the study found that infants whose mothers were treated with 17-OPHC during pregnancy were 4.78 times more likely to develop colorectal cancer and 3.83 times more likely to develop

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[97] Joshi PA, Goodwin PJ, Khokha R., *Progesterone Exposure and Breast Cancer Risk: Understanding the Biological Roots*, JAMA Oncol. 2015;1(3):283–285. doi:10.1001/jamaoncol.2015.0512.

[98] Murphy, et al., *In Utero Exposure to 17α-Hydroxyprogesterone Caproate May Contribute to Increasing Incidence Rates of Early-Onset Cancer*, Journal of the Endocrine Society, Volume 5, Issue Supplement_1, April-May 2021, Pages A496–A497, https://doi.org/10.1210/jendso/bvab048.1014.

[99] *Id*.

prostate cancer.[100]

170. Dr. Murphy concluded her paper with the following warning: "Even before mechanisms of carcinogenesis are elucidated, caution using 17-OHPC and other endocrine-active pharmaceuticals in early pregnancy is warranted, especially in the absence of a clear short-term benefit, and given the possible effect on risk of cancer in adult offspring."[101]

171. The same chemical compound that was marketed as Delalutin and Prolutin has now been rebranded as Makena. In other words, it is the exact same compound with potentially the same risks being sold under a new name.

172. Despite the overwhelming evidence that Makena does not work, and data indicating that Makena is not safe, AMAG continues to sell hundreds of millions of dollars of Makena every year.

VII. Makena Is Marketed to Women as a Drug to Prevent Preterm Births

173. AMAG's website markets Makena directly to pregnant women, saying: "Makena helps you get closer to term"; "Makena…is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past"; and "Makena gives moms an extra layer of

[100] *Id.*
[101] *Id.*

support."[102]

174. AMAG's direct to patient marketing also used testimonials describing how effective Makena was for other women who claimed that "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy," and another mother saying, "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."[103]

175. Additionally, Makena's patient education brochure extols Makena's effectiveness: "HELP GIVE YOUR BABY MORE TIME TO DEVLOPE,", "Makena…helps give bab[ies] more time to develop," and "Every week counts when you're pregnant."[104]

176. AMAG's conduct was and is unlawful in that its conduct, for example, violated the prohibition on making false or misleading statements in connection with the sale of prescription drugs found in 21 C.F.R. 202.1(e)(6-7) and 21 U.S.C. §§ 321(n), 352(a).

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[102] *Reducing Risk with Makena Auto-Injector*, Makena (hydroxyprogesterone caproate injection), https://makena.com/reducing-preterm-birth-risk-with-makena/.

[103] *Id*.

[104] Makena Patient Education Brochure (English), Makena (hydroxyprogesterone caproate injection), https://makena.com/wp-content/themes/MakenaDTP/file/Makena_Auto-Injector_Patient_Education_Brochure_-_English.pdf.

177. But for such misleading and deceptive statements and but for AMAG's material omissions – which AMAG intended Plaintiffs and class members would rely on – Plaintiffs and Class members would not have purchased and been injected with Makena.

178. At least as late as October 17, 2016, but likely continuing to today, AMAG emailed customers and doctors, encouraging patients to sign up for AMAG's "My Adherence Program," a program designed to allow AMAG and its contractors to directly communicate with Makena patients to "facilitate improved patient compliance with Makena therapy."[105]

179. Lumara also produced video advertisements for Makena from third party physicians and posted those videos to its website. These third-party physicians were paid consultants of Lumara. [106]

180. Similarly, AMAG used paid third-party physicians to promote Makena on podcasts. These podcasts were utilized at least through March 1, 2017.[107]

181. AMAG's misrepresentations and material omissions were likely to (and in fact did) mislead expecting mothers concerned about preterm birth, i.e., the Plaintiffs and class members, who acted reasonably under the circumstances. Had

[105] Ex. 15, AMAG00044975, Ex. 16, AMAG00058114, Ex. 17, AMAG00018846.
[106] Ex. 18, AMAG00132207.
[107] Ex. 19, AMAG00132220, Ex. 20, AMAG00132221, Ex. 21, AMAG00132222.

AMAG adequately disclosed to Plaintiffs and class members that Makena is not effective, Plaintiffs and class members would not have purchased Makena, and would not have undergone weekly injections of Makena, often with significant and painful side effects including bruising, skin irritation, painful rashes, and nausea. The misrepresentations and omissions by AMAG were material and were at minimum a substantial factor in influencing Plaintiffs' and class members' decisions to purchase and be injected with Makena. Accordingly, Plaintiffs and class members reasonably relied (at minimum) on AMAG's deceptive failure to disclose Makena's ineffectiveness, and would not have purchased and been injected with Makena but for AMAG's material omissions and misrepresentations.

CLASS ACTION ALLEGATIONS

182. Plaintiffs bring these consolidated class actions under Fed. R. Civ. P. 23 on behalf of the following state-wide classes:

> ***The New Jersey Class***
> All purchasers of Makena for personal, family, or household purposes in New Jersey from January 3, 2014, to the present.
>
> ***The California Class***
> All purchasers of Makena for personal, family, or household purposes in California from January 13, 2016, to the present.
>
> ***The Kansas Class***
> All purchasers of Makena for personal, family, or household purposes in Kansas from November 4, 2016, to the present.
>
> ***The Missouri Class***

All purchasers of Makena for personal, family, or household purposes in Missouri from November 1, 2014, to the present.

The New York Class
All purchasers of Makena for personal, family, or household purposes in New York from November 12, 2016, to the present.

The Wisconsin Class
All purchasers of Makena for personal, family, or household purposes in Wisconsin from February 4, 2017, to the present.

The RICO Class
All purchasers of Makena for personal, family, or household purposes from June 24, 2017, to the present who paid out of pocket for Makena.

Excluded from each Class are AMAG's employees and members of their immediate families; any federal, state, or local governmental entities; any judicial officers presiding over this action and members of their immediate family and judicial staff; and any person who timely opts out of any class consistent with the Court's order certifying a class.

183. Members of each Class are so numerous that their individual joinder herein is impracticable. On information and belief, each Class numbers at least in the hundreds, if not thousands. The precise size of each Class and the identities of their members are unknown to Plaintiffs at this time but will be determined through discovery. Class members may be notified of the pendency of this action by publication and/or mailing through AMAG's sales records.

184. For each Class, common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members.

Common legal and factual questions include, but are not limited to:

a. whether AMAG advertised or marketed Makena in a way that was false or misleading;

b. whether Makena failed to conform to the representations, which were published, disseminated, and advertised by AMAG to Plaintiffs and the Class;

c. whether AMAG concealed from Plaintiffs and the Class that Makena did not conform to its stated representations;

d. whether AMAG has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sales of Makena;

e. whether AMAG's attacks on compounded 17P were intended to coerce doctors and their patients to prescribe and purchase brand-name Makena; and

f. whether AMAG knew that Makena was not effective at preventing preterm birth prior to the public release of the PROLONG study data.

185. Plaintiffs' claims are typical of the claims of the Class members as all Class members are similarly affected by AMAG's wrongful conduct. Plaintiffs have no interests antagonistic to the interests of other Class members as Plaintiffs and all Class members have sustained economic injury arising out of AMAG's violations of law as alleged herein.

186. Plaintiffs are adequate representatives of their respective Classes because their interests do not conflict with the interests of the Class members they seek to represent. Plaintiffs have retained counsel competent and experienced in prosecuting class actions. The interests of Class members will be fairly and adequately protected by Plaintiffs and their counsel.

187. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of Plaintiffs and Class members. Each Class member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish AMAG's liability. Mass individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Mass individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of AMAG's liability. Class treatment of the liability issues will ensure that all claims can be consistently and efficiently adjudicated.

COUNT I: VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT (NEW JERSEY CLASS)

188. Plaintiff Maher re-alleges the allegations set forth throughout the complaint as if fully set forth herein.

189. Plaintiff Maher brings this claim on behalf of herself and the New Jersey Class under the New Jersey Consumer Fraud Act, codified at N.J.S.A. 56:8-1 et seq.

190. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

191. AMAG's statements that Makena was effective in reducing preterm births

constitute unconscionable commercial conduct, deception, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of a material fact with intent of reliance in connection with consumer sales of Makena in violation of the New Jersey Consumer Fraud Act.

192. These falsities include but are not limited to AMAG's statements:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

Each of these statements was false and deceptive.

193. These falsities also include AMAG's numerous statements regarding compounded 17P, detailed throughout this complaint.

194. Plaintiffs and all New Jersey Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff and New Jersey Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

195. Plaintiffs and all New Jersey Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff and New Jersey Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

COUNT II: VIOLATION OF THE CALIFORNIA BUS. & PROF. CODE § 17200 (CALIFORNIA CLASS)

196. Plaintiffs Amaro, Gomez, Torres, and Uribe re-allege the allegations throughout the complaint as if fully set forth herein.

197. Plaintiffs bring this claim on behalf of themselves and the California Class under the California Bus. & Prof. Code § 17200 *et seq.* for restitution as a result of AMAG's unlawful, unfair, or fraudulent practices.

198. AMAG misrepresented Makena's effectiveness at preventing preterm births in connection with the sale and advertisement of Makena.

199. AMAG's statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business acts or practices and unfair, deceptive, untrue or misleading advertising in violation of the California Unfair Competition Law.

200. These falsities include but are not limited to AMAG's statements that:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early

(before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

201. These falsities also include AMAG's numerous statements regarding compounded 17P, detailed throughout this complaint.

202. AMAG's conduct violated each prong of the UCL: i) it was unlawful in that it, for example, violated the prohibition on making false statements in connection with the sale of prescription drugs found in 21 C.F.R. 202.1(e)(6-7) and 21 U.S.C. §§ 321(n), 352(a); it was unfair in causing Class members to make decisions based on false information; and iii) it was fraudulent in that AMAG knew or should have known its marketing statements were not true.

203. Plaintiffs and all California Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs and California Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

204. Additionally, Plaintiffs and the California Class were injured by virtue of having to undergo and purchase weekly injections of a drug that did not work,

including all the wasted time associated with taking the injections.

205. As a result of AMAG's unlawful, unfair, or fraudulent business practices, AMAG has reaped unfair benefits and illegal revenues and profits at the expense of Plaintiffs and the California Class. As a result, AMAG should be required to disgorge its ill-gotten gains and restore those monies to Plaintiffs and the California Class.

206. Under California Business and Professions Code § 17203, Plaintiffs and class members seek those orders or judgments as may be necessary to prevent AMAG's future use of its unlawful, unfair or fraudulent practices, and to restore to Plaintiffs and the California Class any money or property that may have been acquired by means of AMAG's unfair competition.

207. AMAG's unlawful, unfair or fraudulent business practices entitle Plaintiffs to seek preliminary and permanent injunctive relief, including but not limited to an order requiring AMAG to account for, disgorge and restore to Plaintiffs and the California Class its unlawfully obtained gains.

COUNT III: VIOLATION OF THE CALIFORNIA CONSUMER'S LEGAL REMEDIES ACT (CALIFORNIA CLASS)

208. Plaintiffs Amaro, Gomez, Torres, and Uribe re-allege the allegations set forth throughout the complaint as if fully set forth herein.

209. Plaintiffs Amaro, Gomez, Nelson, and Torres bring this claim on behalf of

themselves and the California Class under the California Consumer Legal Remedies Act (CLRA), Cal. Civ. Code § 1770 *et seq.*

210. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

211. AMAG's statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising in violation of the CLRA.

212. These falsities include but are not limited to AMAG's statements that:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

Each of these statements was false and deceptive and constituted acts or practices prohibited under the CLRA.

213. These falsities also include AMAG's numerous statements regarding compounded 17P, detailed throughout this complaint.

214. Plaintiffs and all California Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs and the California Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

215. Additionally, Plaintiffs and the California Class suffered ascertainable losses of money and property caused by AMAG's misrepresentations by virtue of having to undergo weekly injections of a drug that did not work, including all the wasted time and pain associated with taking those injections.

216. As a result of AMAG's unfair business practices, AMAG has reaped unfair benefits and illegal profits at the expense of Plaintiffs and the California Class. AMAG should thus be made to disgorge its ill-gotten gains and restore those monies to Plaintiffs and the California Class.

217. Under Cal. Civ. Code § 1780, Plaintiffs and the California Class seek those orders or judgments as may be necessary to prevent AMAG's future use of its unfair and unlawful practices, for their actual damages, for an order enjoining the unlawful conduct identified herein, for restitution, attorney fees and costs, and for any other relief the court deems proper.

218. AMAG's unfair business practices entitle Plaintiffs an order requiring AMAG to account for, disgorge and restore to Plaintiffs and the California Class its unlawfully obtained gains.

COUNT IV: VIOLATION OF THE KANSAS CONSUMER PROTECTION ACT (KANSAS CLASS)

219. Plaintiff Gill re-alleges the allegations set forth throughout the complaint as if fully set forth herein.

220. Plaintiff Gill brings this claim on behalf of herself and the Kansas Class under the Kansas Consumer Protection Act, codified at Kan. Stat. Ann. § 50-623 et seq.

221. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

222. AMAG's statements that Makena was effective in reducing preterm births constitute deceptive acts and practices in violation of Kansas Consumer Protection Act.

223. These falsities include but are not limited to AMAG's statements that:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of

mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

Each of these statements was false and deceptive and constituted an unconscionable act or practice specifically proscribed under Kan. Stat. Ann. §§ 50-626 and 50-627.

224. These falsities also include AMAG's numerous statements regarding compounded 17P, detailed throughout this complaint.

225. Plaintiff Gill and all Kansas Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff Gill and Kansas Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

226. Plaintiff Gill and all Kansas Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff Gill and Kansas Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

COUNT V: VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT (MISSOURI CLASS)

227. Plaintiffs Barnes and Bonds re-allege the allegations set forth throughout the complaint as if fully set forth herein.

228. Plaintiffs Barnes and Bonds bring this claim on behalf of themselves and

the Missouri Class under the Missouri Merchandising Practices Act, RSMo §§ 407.010 et seq.

229. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

230. AMAG's statements that Makena was effective in reducing preterm births constitute "deception, fraud … false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact," in violation of the Missouri Merchandising Practices Act.

231. These falsities include but are not limited to AMAG's statements:

g. "Makena helps you get closer to term."

h. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

i. "Makena gives moms an extra layer of support."

j. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

k. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

l. "Makena … helps give bab[ies] more time to develop."

Each of these statements was false and deceptive.

232. These falsities also include AMAG's numerous statements regarding compounded 17P, detailed throughout this complaint.

233. Plaintiffs and all Missouri Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs and Missouri Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

234. Plaintiffs and all Missouri Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs Barnes and Bonds and Missouri Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

COUNT VI: VIOLATION OF NEW YORK GEN BUS. LAW SECTION 349(A) (NEW YORK CLASS)

235. Plaintiffs Faughnan, Vargas, Odommorris, and Maltese re-allege the allegations set forth throughout the complaint as if fully set forth herein.

236. Plaintiffs Faughnan, Vargas, and Maltese bring this claim on behalf of themselves and the New York Class under New York's General Business Law (GBL) §349(a).

237. AMAG's conduct as alleged herein violates § 349(a) of the GBL, which prohibits deceptive acts or practices.

238. AMAG's acts and practices were consumer-oriented, as they affected not only Plaintiffs but similarly situated consumers as well, and they had the potential to affect even more consumers.

239. In connection with the sale and advertisement of Makena, AMAG

misrepresented Makena's effectiveness at preventing preterm births.

240. AMAG's statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising in violation of the GBL.

241. These falsities include but are not limited to AMAG's statements that:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

Each of these statements was false and deceptive and constituted acts or practices prohibited by the GBL.

242. These falsities also include AMAG's numerous statements regarding compounded 17P, detailed throughout this complaint.

243. Plaintiffs and all New York Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Makena had a premium price when the product was worth zero or close to zero based on its actual attributes.

244. Additionally, Plaintiffs and the New York Class suffered ascertainable losses by virtue of having to undergo weekly injections of a drug that did not work, including all the wasted time associated with taking those injections.

245. Plaintiffs and all New York Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs Faughnan, Vargas, and Maltese and New York Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

246. Pursuant to GBL § 349(h), Plaintiffs Faughnan, Vargas, and Maltese and the New York Class seek an award of damages and/or statutory penalties, whichever is greater, injunctive relief, treble damages, and attorneys' fees.

COUNT VII: VIOLATION OF THE WISCONSIN DECEPTIVE TRADE PRACTICES ACT (WISCONSIN CLASS)

247. Plaintiff Brady re-alleges the allegations set forth throughout the complaint as if fully set forth herein.

248. Plaintiff Brady brings this claim on behalf of themselves and the Wisconsin Class under the Wisconsin Deceptive Trade Practices Act (WDTPA).

249. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

250. AMAG's statements that Makena was effective in reducing preterm births constitute deceptive acts and practices in violation of the WDTPA.

251. These falsities include but are not limited to AMAG's statements that:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

Each of these statements was a false and deceptive act or practice under the WDTPA.

252. These falsities also include AMAG's numerous statements regarding compounded 17P, detailed throughout this complaint.

253. Plaintiff Brady and all Wisconsin Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff Brady and Wisconsin Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

254. Plaintiff Brady and all Wisconsin Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff Brady and Wisconsin Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

COUNT VIII: VIOLATION OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (ALL CLASSES)

255. All Plaintiffs re-allege the allegations set forth throughout this complaint as if fully set forth herein.

256. All Plaintiffs bring this claim on behalf of themselves and all Makena customers who paid out of pocket for Makena under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), codified at 18 U.S.C. § 1961, *et seq*.

257. AMAG utilized mail (and other) marketing to falsely represent to consumers that Makena reduces the risk of pre-term birth, despite knowing that Makena was ineffective. These false representations include, but are not limited to:

a. "HELP GIVE YOUR BABY MORE TIME TO DEVLOPE,"

b. "Makena…helps give bab[ies] more time to develop," and

c. "Every week counts when you're pregnant."

258. AMAG utilized mail (and other) marketing to coerce and manipulate healthcare providers, prescribers, and/or doctors to prescribe Makena over compounded drugs and to coerce and manipulate Plaintiffs and class members to take and purchase Makena over the much less expensive compounded 17P.

259. AMAG contracted and paid other parties and companies to effectuate the enterprise described in this complaint. Among other third parties, AMAG contracted with Cardinal Health, the CDM Group, Sonexus Health, AllCare Plus Pharmacy,

LLC, and PPD Medical Communications to administer its Makena Care Connection program. These third parties effectuated (and continue to effectuate) the enterprise by (among other things) directly discouraging patients and providers from using less expensive compounded 17P and by misrepresenting the efficacy of Makena.

260. AMAG also utilized proxies to place misleading opinion pieces extolling Makena over compounded 17P.

261. The enterprise utilized numerous emails, phone calls, and mailings, all in and affecting interstate commerce, detailed throughout this complaint. This pattern of conduct consisted of marketing and correspondence to thousands and thousands of patients and doctors, spanned the entire class periods, and continue to today.

262. The enterprise shared a common and straightforward purpose: mislead physicians and patients into prescribing and taking an exorbitantly-priced drug that does not work, and mislead physicians and patients into not taking an equivalent alternative that was exponentially cheaper.

263. This conduct violated and violates 18 U.S.C. § 1962(a), (b), (c), and (d).

264. AMAG made hundreds of millions of dollars, if not billions of dollars, during the relevant time period, at least—because of their false and/or fraudulent marketing of Makena via mail and their coercive and manipulative representations to healthcare providers, prescribers, and/or doctors

265. AMAG falsely represented Makena on their website as a drug that reduces the risk of pre-term birth, despite knowing that Makena was ineffective at treating this disease. These false representations include, but are not limited to:

a. "Makena helps you get closer to term";

b. "Makena…is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past"; and

c. "Makena gives moms an extra layer of support."

266. AMAG fraudulently represented Makena on their website as a drug that reduces the risk of pre-term birth, despite knowing that Makena was ineffective at treating this disease. These fraudulent representations include, but are not limited to:

d. "Makena helps you get closer to term";

e. "Makena…is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past"; and

f. "Makena gives moms an extra layer of support."

267. AMAG utilized their website to coerce and manipulate healthcare providers, prescribers, and/or doctors to prescribe Makena over compounded drugs to Plaintiffs

[insert] and Class members. These coercive and manipulative representations include, but are not limited to:

g. Telling healthcare providers to:

i. "Help ensure your patients receive Makena plus personalized support . . . ."

ii. "DISCUSS the importance of drug + support provided only by Makena with your patients."

iii. "STAND FIRM in your prescribing decision to help ensure patients receive Makena + support when pharmacists ask about generic substitution."

h. "Help reduce the risk of recurrent preterm birth."

i. "The Makena You Know Ready to Go[:] For your patients at risk for another singleton spontaneous preterm birth (<37 weeks)."

268. AMAG obtained money and/or property from Plaintiffs and Class members because of their false and/or fraudulent marketing of Makena on their website.

269. AMAG obtained money and/or property from Plaintiffs and Class members because of their coercive and manipulative representations to healthcare providers, prescribers, and/or doctors.

270. But for AMAG's false and/or fraudulent representations of Makena by mail and on their website, Plaintiffs and Class members would not have purchased Makena.

271. But for AMAG's coercive representations by mail and on their website, healthcare providers, prescribers, and/or doctors would (have not/have been less likely) to prescribe Makena over compounded versions to Plaintiffs and Class members.

272. Plaintiffs and Class members are the intended victims of the marketing campaigns utilized by AMAG.

273. It is foreseeable that AMAG's coercive and manipulative marketing tactics directed at healthcare providers, prescribers, and/or doctors would greatly influence their decision to prescribe Makena to their patients.

274. Plaintiffs and Class members suffered a concrete and cognizable injury as a result of AMAG's coercion and misleading representations made to healthcare providers, prescribers, and/or doctors.

275. It is foreseeable that Plaintiffs and Class members would place substantial reliance upon AMAG's marketing tactics and base their purchase decisions upon AMAG's false and/or fraudulent representations. Plaintiffs and Class members suffered a concrete and cognizable injury as a result of AMAG's false and/or

fraudulent marketing tactics by mail and website, because they paid out-of-pocket for Makena, an ineffective drug that is worth zero or close to zero.

276. It is also foreseeable that Plaintiffs and Class members would place substantial reliance upon AMAG's marketing tactics and base their purchase decisions upon AMAG's false and/or fraudulent representations. Plaintiffs and Class members suffered a concrete and cognizable injury as a result of AMAG's false and/or fraudulent marketing tactics by mail and website, because they vastly overpaid for Makena as opposed to compounded 17P.

277. Because AMAG obtained Plaintiffs' and Class members' money by means of false and/or fraudulent mail and wire marketing, AMAG must pay back three times the amount received from each Plaintiff and Class member.

PRAYER FOR RELIEF

Plaintiffs, on behalf of themselves and their respective Classes, request relief as follows:

A. That the Court determine that each of the claims alleged herein may be maintained as a class action under Federal Rule of Civil Procedure 23, that Plaintiffs be named as Class Representatives of each of their respective Classes, that the undersigned be named as Class Counsel, and that the Court direct that notice of this action be given to Class members;

B. That the Court enter an order declaring that AMAG's actions, as set forth in this Complaint, violate the state laws set forth above;

C. That the Court award Plaintiffs and their respective Classes all compensatory and statutory damages, punitive damages, and/or restitution in an amount to be determined at trial;

D. That the Court issue appropriate injunctive and other equitable relief;

E. That the Court award Plaintiffs and their respective Classes pre- and post-judgment interest;

F. That the Court award Plaintiffs their costs of suit, including reasonable attorneys' fees and expenses, including costs of consulting and testifying experts; and

G. That the Court award any and all such other relief as the Court may deem just and equitable.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all claims so triable.

Dated: June 24, 2021

Respectfully submitted,

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