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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RALICA ZAMFIROVA, individually and on behalf of others similarly situated,	)	
Plaintiff,	)	**Case No.**
v.	)	
AMAG PHARMACEUTICALS, Inc.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

CLASS ACTION COMPLAINT

Plaintiff Ralica Zamfirova brings this case on behalf of herself and all others similarly situated (the "Class," defined below) against defendant AMAG Pharmaceuticals, Inc., and in support thereof states:

NATURE OF THE CASE

1. This case arises from Defendant's marketing, sale, and manufacturing of the drug Makena, a hydroxyprogesterone caproate.

PARTIES AND BACKGROUND

2. Plaintiff Ralica Zamfirova resides in Northvale, Bergen County, New Jersey. During the class period (as defined below), Ms. Zamfirova was prescribed, injected with, and purchased Makena. Ms. Zamfirova paid out of pocket for Makena. The Makena shots cost at lease hundreds of dollars per shot.

3. Defendant AMAG Pharmaceuticals, Inc. ("AMAG") is a Delaware corporation headquartered in Waltham, Massachusetts. AMAG is a publicly traded company. (Nasdaq: AMAG). AMAG currently holds the exclusive rights to Makena.

4. Hologic, Inc. is a Delaware corporation, headquartered in Marlborough, Massachusetts. Hologic (NASDAQ: HOLX) is a multinational, publicly-traded corporation. Hologic developed and originally held the exclusive rights to Makena. Hologic sold the exclusive rights to Makena to KV Pharmaceutical shortly after Hologic obtained FDA approval in early 2011.

5. Lumara Health, Inc., f/k/a KV Pharmaceutical Co. ("Lumara") was a Missouri corporation, headquartered in St. Louis, Missouri. KV Pharmaceutical purchased the rights to Makena from Hologic Inc. KV Pharmaceutical and subsequently Lumara manufactured and sold Makena during the class period. AMAG acquired Lumara in 2014, including the exclusive rights to manufacture and sell Makena.

6. KV Pharmaceutical came under fire in 2009 when the Justice Department filed lawsuits against KV Pharmaceutical and several of its executives for violating the Food,

Drug and Cosmetic Act by manufacturing and selling oversized morphine tablets that contained more morphine than the label stated.[1]

7. In March 2011, KV Pharmaceutical CEO Mark Hermelin pled guilty to misbranding and received thirty days in jail, along with a fine of $1,000,000 and a forfeiture of $900,000.[2] However, Hermelin fled to Israel once a federal investigation was opened into the company's practices. The charging U.S. attorney stated that felony charges would have been brought against Hermelin but for the fact that Israel may not have extradited Hermelin unless the charges were reduced.[3]

8. After this debacle, KV Pharmaceutical was forced to file for chapter 11 bankruptcy and re-emerged under the name Lumara Health in 2013.[4]

9. Lumara Health continued to manufacture, market, and sell Makena.

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[1] Dept. of Justice, *Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case* (Mar. 10, 2011), https://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case.

[2] *Id.*

[3] Jim Doyle, *Ex-chief of KV Pharmaceutical gets month or less in jail*, St. Louis Post Dispatch (Mar. 11, 2011), https://www.stltoday.com/business/local/ex-chief-of-kv-pharmaceutical-gets-month-or-less-in/article_693616ab-1af6-5d34-a763-6fd01683aa5c.html.

[4] 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.

10. In 2014, AMAG bought Lumara for $675 million and an additional $350 million contingent on sales milestones.[5] The flagship product in the acquisition was Makena.

JURISDICTION AND VENUE

11. 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 Plaintiff's 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.

12. 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.

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

FACTUAL ALLEGATIONS

I. History of Hydroxyprogesterone Caproate and Makena

14. The hormonal medication hydroxyprogesterone caproate has been in the U.S. marketplace since 1956. Over time, the pharmaceutical companies have not added

[5] Kevin Grogan, *AMAG $1 Billion Deal to Buy Preterm Birth Drug Makena*, PharmaTimes online (Sept. 29, 2014), http://www.pharmatimes.com/news/amag_$1_billion_deal_to_buy_preterm_birth_drug_makena_1002541.

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 manufacturers has been an enormous price increase.

15. Shering AG developed hydroxyprogesterone caproate in 1953 and reported its medical effects in 1954.[6] The drug was first marketed in Japan in 1954 and 1955 before it was introduced in the United States in 1956 by Squib, having acquired the license to the patent, under the brand name Delalutin to manage abnormal bleeding in patients with uterine cancer.[7]

16. In the 1960s, Delalutin began to be used to treat pregnant women who had tumorous ovaries removed.[8]

17. In the 1990s, Delalutin (and thus hydroxyprogesterone caproate) had become a leading drug to treat an imminent premature birth threat during pregnancy after studies

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

[7] J.B. Lippincott Co., *New and Nonofficial Drugs Evaluated by A.M.A. Council on 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/.

[8] ID 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.

focused on its potential to reduce preterm births.[9]

18. Bristol Meyer Squibb voluntarily withdrew the drug from the market in 1999.[10]

19. Interest in hydroxyprogesterone caproate resurged after a taxpayer-funded study appeared to find that the drug reduced the risk of preterm births in at-risk mothers.[11] After this study was published, KV Pharmaceutical acquired hydroxyprogesterone caproate (via the drug Makena) and its exclusive marketing rights.[12]

II. Makena Receives FDA Fast-Track Approval

20. FDA fast-track approval was created to expedite the development and review of drugs that treat serious conditions and fill an unmet medical need.[13]

21. The "New Drug Application" or NDA seeking accelerated approval for Makena

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[9] MJ 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.*

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

[11] Meis PJ, Klebanoff M, Thom E, Dombrowski MP, Sibai B, Moawad AH, et al., *Prevention of Recurrent Preterm Delivery By 17 Alpha-Hydroxyprogesterone Caproate*, N. Engl. J. Med. 348(24):2379-2385 (Jun. 2003), https://www.nejm.org/doi/full/10.1056/NEJMoa035140.

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

[13] FDA, *Fast Track* (current as of Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

was approved by the FDA on February 3, 2011.[14]

22. The data used to support Makena's fast-track application and subsequent approval, though, was insufficient to make a proper determination of Makena's efficacy.[15]

23. The FDA relied heavily on a single clinical trial published in 2003 by the National Institute of Child Health and Human Development ("NICHD").[16] However, the government's Statistical Review and Evaluation found that reliance solely on the 2003 NICHD study was insufficient to establish the efficacy of the drug in preventing preterm births.[17]

24. Analysis of the NICHD trial found that: 1) the study failed to identify the optimal time to start taking Makena; 2) one study center accounted for nearly half 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.[18]

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

[15] Jim Doyle, *FDA's Fast-Track Approval of Makena Could Backfire on KC*, 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.

[16] Meis PJ, Klebanoff M, Thom E, et al., *Prevention of Recurrent Preterm Delivery By 17 Alpha-Hydroxyprogesterone Caprote*, N. Eng. J. Med. 348(24):2379-2385 (Jun. 2013), https://www.nejm.org/doi/full/10.1056/NEJMoa035140.

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

[18] *Id*. at 6.

25. 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.[19]

26. 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 shortly thereafter.[20]

27. The fast-track approval was conditioned on a follow-up, long-term clinical trial to confirm the efficacy of hydroxyprogesterone caproate in preventing preterm births.[21]

28. On March 8, 2019, after 8 years of Makena sales at absurdly-high prices, AMAG announced the results of that FDA-mandated follow-up trial, known as the PROLONG (Progestin's Role in Optimizing Neonatal Gestation) study ("PROLONG Study").

29. According to AMAG, 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 or neonatal mortality or

[19] *Id*. at 39.

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

[21] *Id*.

morbidity. [22] In other words, the PROLONG Study showed that Makena, is no more effective than a placebo.

30. 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.[23]

31. On information and belief, AMAG knew far earlier than finalization of the PROLONG Study that Makena was ineffective.

32. 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. [24]

33. According to AMAG, 11% of the women in the study who took Makena delivered

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

[23] 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/.

[24] AMAG Pharmaceuticals, *AMAG Pharmaceuticals Announces Topline Results from the Prolong Trial Evaluating Makena*, (Mar. 8, 2019).

their babies at 35 weeks or earlier; whereas 11.5% of women who took the placebo delivered their babies at 35 weeks or earlier. There were also no statistically significant differences concerning miscarriages and stillbirths (adverse events) between Makena and the placebo treatment.[25]

34. The PROLONG Study showed Makena was essentially as effective as a placebo.

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

36. AMAG reported 2018 revenue for operations of approximately $474 million, with Makena contributing the lion's share of AMAG's annual revenue at $323 million.[26]

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

37. Makena was and is marketed as an effective hormonal medication that reduces the risks for pregnant mothers of giving birth before term. Makena's website explicitly states: "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 support." [27]

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[25] *Id*.

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

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

38. AMAG's marketing targets mothers with testimonials of how effective its product was for other moms, including one mother stating 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."[28]

39. Makena's patient education brochure extols Makena as an effective drug for mothers who had a previous preterm birth and are at risk for another preterm delivery. The front of the brochure reads "HELP GIVE YOUR BABY MORE TIME TO DEVLEOP." The brochure tells mothers that "Makena…helps give bab[ies] more time to develop" and ends by reminding mothers that "Every week counts when you're pregnant." [29]

40. But for such statements and but for AMAG's material omissions, Plaintiff and class members would not have purchased and been injected with Makena.

IV. Makena Is Exorbitantly Priced

41. In 2008, Hologic, who owned the rights to Makena, and KV Pharmaceutical entered into an agreement giving KV Pharmaceutical worldwide rights to manufacture,

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[28] *Id*.

[29] Makena (hydroxyprogesterone caproate injection), *Makena Patient Education Brochure* (English) (2018), https://makena.com/wp-content/themes/MakenaDTP/file/Makena_Auto-Injector_Patient_Education_Brochure_-_English.pdf.

market, and sell Makena.[30]

42. KV Pharmaceutical abused its rights under the Orphan Drug Act, 21 U.S.C. § 360cc, a law designed to attract pharmaceutical companies to develop drugs designed to treat rare but serious conditions like ALS, Tourette syndrome, muscular dystrophy, etc.[31]

43. The Orphan Drug Act allows drug companies, like KV pharmaceutical, exclusive marketing rights for a drug that treats a rare disease or condition for up to seven years.[32] Makena was designated as an "orphan drug" under the Act in 2007, thereby granting KV Pharmaceutical the ability to sell Makena at expensive prices.[33]

44. 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 generic drug known as 17P, said in 2011 after she learned of the price

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[30] 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.

[31] 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 (Knox Report).

[32] 21 U.S.C.A. § 360cc (Orphan Drug Act).

[33] Richard Knox, *Premeire Prevention Drug Costs 53 Times More Than Generic, But Researches Find it's No Better*, WBUR 90.9 (Oct. 3, 2017).

increase from her doctor's office.[34] "I'm nervous now because I have to go home and call my insurance company to see if they'll cover me." [35]

45. Due to public outrage over KV Pharmaceutical's expected price hike, the FDA allowed compounding pharmacies to make the drug in their pharmacies in order to allow a more affordable option for mothers.[36]

46. As reported at the time, KV Pharmaceutical was only the manufacturer and did nothing to discover Makena or research the drug.[37]

47. Eventually, KV Pharmaceutical reduced the price to $690 per Makena injection.[38]

48. Although compounding pharmacies may offer hydroxyprogesterone caproate at a lower price than AMAG, these specialized pharmacies do not offer a viable alternative for at-risk pregnant women.

49. Compounding pharmacies are less regulated and there is a greater potential for

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[34]Sean D. Hamill, *Pregnancy drug's sharp price hike called 'greed'*, Pittsburgh Post-Gazetta (Mar. 11, 2011), https://www.post-gazette.com/news/health/2011/03/11/Pregnancy-drug-s-sharp-price-hike-called-greed/stories/201103110343.

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

[36] 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.

[37] David Whelan, *Is KV Pharmaceutical A Flat-Out Evil Company?*, Forbes (Mar. 11, 2011).

[38] *Id; see also* Senator Sherrod Brown, *Brown Statement on Makena Pricing*, Sherrod Brown Senator for Ohio (Apr. 1, 2011), https://www.brown.senate.gov/newsroom/press/release/brown-statement-on-makena-repricing.

error when creating compounded formulations of drugs in these pharmacies.[39]

50. In fact, the FDA cited a compounding pharmacy in 2014 for making tainted batches of hydroxyprogesterone caproate due to unsanitary conditions.[40]

51. Further, doctors and pharmacy directors often fear the repercussions of prescribing a compounded hydroxyprogesterone caproate over an FDA-approved product, because any unforeseen side effect due to the compounded drug could result in liability for the medical professional or pharmacist.[41]

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

53. As one woman recently reported: "Insanely expensive - did not find this out until half way 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. I get them in the hip alternating sides each time. Some days it hurts others it doesn't I think it really depends on who is administering."[42]

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[39] Yesha Patel, PharmD, *Makena or Compounded 17P?*, National Center for Biotechnology Information, Pharmacy and Therapeutics (Sept. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3462605/.

[40] Eric Palmer, *FDA Cites Compounder for Making Tainted Version of KV's Makena*, FiercePharma (Mar. 14, 2014), https://www.fiercepharma.com/regulatory/fda-cites-compounder-for-making-tainted-version-of-kv-s-makena.

[41] *Id*.

[42] Reviews for Makena, Drugs.com (Posted Sept. 18, 2019), https://www.drugs.com/comments/hydroxyprogesterone/makena.html (accessed Oct. 30, 2019).

CLASS ACTION ALLEGATIONS

54. Plaintiff brings this class action under Fed. R. Civ. P. 23 (the "Class"):

> All purchasers for personal, family, or household purposes of Makena in the State of New Jersey from January 1, 2011 to the present (the "Class Period").

Excluded from the Class are Defendant, its parents, subsidiaries and affiliates, its directors and officers and members of their immediate families; also excluded are any federal, state, or local governmental entities, any judicial officers presiding over this action and the members of their immediate family and judicial staff, and any juror assigned to this action.

55. Members of the Class are so numerous that their individual joinder herein is impracticable. On information and belief, Class members number at least in the hundreds, if not thousands. The precise number of Class members and their identities are unknown to Plaintiff 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 Defendant's sales records.

56. 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 was unjustly enriched by its conduct;

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

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

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

e. whether, by the misconduct set forth in this Complaint, AMAG has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sales of Makena; and

f. whether, as a result of AMAG's misconduct as alleged herein, Plaintiff and Class members are entitled to restitution, injunctive, and/or monetary relief and, if so, the amount and nature of such relief.

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

58. Plaintiff is an adequate representative of the Class because her interests do not conflict with the interests of the Class members they seek to represent. Plaintiff has retained counsel competent and experienced in prosecuting class actions. The interests of Class members will be fairly and adequately protected by Plaintiff and her counsel.

59. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of Plaintiff 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. 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.

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 and claimants are before this Court for consistent adjudication of the liability issues.

COUNT I: VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT

60. Plaintiff re-alleges the allegations contained above as if fully set forth herein.

61. Plaintiff brings this claim on behalf of herself and the Class under the New Jersey Consumer Fraud Act, codified at N.J.S.A. 56:8-2.

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

63. 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.

64. 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.

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

COUNT II: UNJUST ENRICHMENT

66. Plaintiff re-alleges the allegations contained above as if fully set forth herein.

67. Plaintiff and the Class members conferred a benefit on AMAG by purchasing Makena.

68. AMAG has benefited and knows it has benefitted at Plaintiff's and the Class members' expense by the sale of the product by collecting the price of the falsely represented product, which consumers paid because of AMAG's false and misleading advertising and representations and/or omissions.

69. AMAG's retention of the revenues from Plaintiff and Class members' purchases of Makena, under these circumstances, is unjust and inequitable because consumers were

misled by AMAG to believe that they were receiving a product effective at preventing preterm births when it was not.

70. Plaintiff and Class members were injured because they purchased a product, they otherwise would not have purchased, due to AMAG's falsities, misrepresentations, and/or omissions.

71. Because AMAG's retention of the non-gratuitous benefit conferred on it by Plaintiff and the Class members is unjust and inequitable, AMAG must pay restitution to Plaintiff and the Class members, as ordered by the Court.

PRAYER FOR RELIEF

Plaintiff, on behalf of herself and Class members, requests relief as follows:

A. That the Court determine that this action may be maintained as a class action under Rule 23(a) & (b) of the Federal Rules of Civil Procedure, that Plaintiff be named Class Representative of the Class, that the undersigned be named as Class Counsel, and 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 Plaintiff and Class members 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 against

AMAG;

E. That the Court award Plaintiff pre- and post-judgment interest;

F. That the Court award Plaintiff her 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 proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims so triable.

Dated: January 3, 2020

Respectfully submitted,

FINKELSTEIN, BLANKINSHIP, FREI-PEARSON & GARBER, LLP
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* *Pro hac forthcoming*

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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

RALICA ZAMFIROVA, individually and on behalf of others similarly situated,

(b) County of Residence of First Listed Plaintiff Bergen County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
FINKELSTEIN, BLANKINSHIP, FREI-PEARSON & GARBER, LLP, 445 Hamilton Avenue, Suite 605, White Plains, New York 10601

DEFENDANTS

AMAG PHARMACEUTICALS, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332(d)

Brief description of cause:
Defendant's deceptive marketing, sale, and manufacturing of the drug Makena.

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
01/03/2020

SIGNATURE OF ATTORNEY OF RECORD
/s/ Andrew G. Finkelstein

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

RALICA ZAMFIROVA, individually and on behalf of others similarly situated

Plaintiff

v.

AMAG PHARMACEUTICALS, Inc.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AMAG, Inc.
c/o Registered Agent
The Corporation Trust Company
1209 Orange Street
Wilmington DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Andrew G. Finkelstein
FINKELSTEIN, BLANKINSHIP,
FREI-PEARSON & GARBER, LLP
445 Hamilton Avenue, Suite 605
White Plains, New York 10601

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: