IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, LAW DIVISION

FILED 5/11/2021 10:59 AM IRIS Y. MARTINEZ CIRCUIT CLERK COOK COUNTY, IL

KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD,))))	3277136
Plaintiffs,)	
v.) 2021L004834) No.	
ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING,))))	
Defendants.))	

COMPLAINT AT LAW

COUNT I—VIOLATION OF CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:

- 1. At all times Plaintiffs resided in the City of Roselle, County of DuPage, State of Illinois.
- 2. Plaintiffs' son, NICHOLAS BIESTERFELD, receives treatment from medical providers and therapists operating out of Cook County, Illinois.
- 3. Defendant ARIOSA DIAGNOSTICS, INC. is a corporation headquartered in the City of San Jose, County of Santa Clara, State of California.



- 4. ARIOSA DIAGNOSTICS CLINICAL LABORATORY is a division of ARISOA DIAGNOSTICS, INC. and is also located in the City of San Jose, County of Santa Clara, State of California.
- 5. Defendants engage in continuous and substantial business in Illinois including all counties.
- 6. Plaintiffs utilized Harmony Prenatal Test when Plaintiff KATHLEEN BIESTERFELD was pregnant with Plaintiffs' son, NICHOLAS BIESTERFELD.
- 7. Defendants represented that the Harmony Prenatal Test would safely and easily test the fetal DNA of NICHOLAS BIESTERFELD for Down syndrome and other genetic abnormalities.
 - 8. Harmony Prenatal Test only tests placental DNA, not fetal DNA.
- 9. Harmony Prenatal Test was aggressively and falsely sold, promoted, distributed and/or marketed by defendants as a reasonable alternative to amniocentesis and as a reliable means to detect chromosomal abnormalities including Trisomy 21. (Attached hereto as Exhibit "A" is the online advertising from Defendants' website from May 2018).
- 10. On July 23, 2017, the Defendants generated a report indicating that the chances that NICHOLAS BIESTERFELD would have a chromosomal anomaly for fetal Trisomy 21 was less than 0.1%.
- 11. Defendants did not disclose to KATHLEEN BIESTERFELD and RONALD BIESTERFELD the Harmony Prenatal Test produced T21 false negatives by only testing placental DNA.
- 12. NICHOLAS BIESTERFELD was born on February 6, 2018, and presented with clear signs of Down Syndrome.



- 13. Plaintiffs bring this cause of action pursuant to 815 ILCS 505/2, the Consumer Fraud and Deceptive Business Practices Act, in their individual capacities.
- 14. Section 2 of the Consumer Fraud and Deceptive Business Practices Act provides that it is unlawful to use "unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact."
- 15. Defendants used unfair or deceptive acts or practices in one or more of the following ways:
 - A. Misrepresenting that Harmony Prenatal Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;
 - B. Misrepresenting that Harmony Prenatal Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;
 - C. Misrepresenting the limitations of and alternatives to Harmony Prenatal Test;
 - D. Misrepresenting that Harmony Prenatal Test is more accurate than traditional first trimester screening tests;
 - E. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested;
 - F. Misrepresenting the probability and rate at which the Harmony Prenatal Test could produce false negative results; and
 - G. Using deceptive advertising to create the image, impression and belief by consumers and physicians that the use of Harmony Prenatal Test was safe, reliable, and effective for detecting fetal chromosomal abnormalities, and having no reasonable grounds to believe such representations to be true.
- 16. Defendants made the foregoing misrepresentations with the intent that Plaintiffs, and others similarly situated to Plaintiffs, would rely on such misrepresentations.



- 17. Defendants knew or had reason to know that the foregoing misrepresentations were false, unfair or deceptive to Plaintiffs and others similarly situated to Plaintiffs.
- 18. Defendants made the foregoing misrepresentations or engaged in the foregoing deceptive acts and/or practices in the course of commerce.
- 19. Due to Defendants' misrepresentations and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and concealing material information, Defendants' acts constitute unfair or deceptive acts and practices.
- 20. Defendants' actions are prohibited by the Consumer Fraud and Deceptive Business Practices Act.
- 21. As a direct and proximate result of the misrepresentations made and unfair and deceptive acts and business practices conducted by Defendants, Plaintiffs sustained injuries, harm, and economic loss for the past, present, and future.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSA DIAGNOSTICS, INC., ARIOSA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000, plus punitive damages, together with the costs of this action.

COUNT II—COMMON LAW FRAUD

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:



- 22. Plaintiffs restate and re-allege paragraphs 1-12 of Count I as their paragraphs 22 through 33 of Count II.
- 34. Defendants made false statements of material fact in one or more of the following ways:
 - A. Misrepresenting that Harmony Prenatal Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;
 - B. Misrepresenting that Harmony Prenatal Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;
 - C. Misrepresenting the limitations of and alternatives to Harmony Prenatal Test;
 - D. Misrepresenting that Harmony Prenatal Test is more accurate than traditional first trimester screening tests;
 - E. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested; and
 - F. Misrepresenting the probability and rate at which Harmony Prenatal Test could produce false negative results.
- 35. The aforesaid representations and/or statements made by Defendants regarding Harmony Prenatal Test were false.
- 36. Defendants knew or had reason to know that the aforesaid representations and/or statements were false when the Defendants made such statements and/or representations.
- 37. Plaintiffs reasonably believed Defendants' aforesaid representations and/or statements regarding Harmony Prenatal Test were true.
- 38. Defendants made the aforesaid false representations and/or statements as a means to induce Plaintiffs and others similarly situated to Plaintiffs to choose, buy, use, and order Harmony Prenatal Test.



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