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GUARDANT HEALTH, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GUARDANT HEALTH, INC., a Delaware corporation, Plaintiff, vs. NATERA, INC., a Delaware corporation, Defendant.	Case No. 3:21-cv-04062 **ORIGINAL COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Guardant Health, Inc. ("Guardant" or "Plaintiff") files this Original Complaint against Defendant Natera, Inc. ("Natera" or "Defendant") and in support thereof, alleges as follows:

I. INTRODUCTION

1. This case concerns Plaintiff's Guardant Reveal™ ("Reveal") liquid biopsy cancer assay for early-stage colorectal cancer (CRC) patients, and Defendant Natera's campaign of false and misleading advertising directed at this important and innovative diagnostic product. As the world's leading provider of comprehensive circulating tumor DNA (ctDNA) assays for clinical use, Guardant's oncology platform—including its gold-standard Guardant360®, Guardant360® CDx, and GuardantOMNI® assays—have helped improve clinical outcomes, while lowering healthcare costs, for advanced stage cancer patients around the world.

2. Leveraging its patented technology, vast data sets, and advanced analytics, Guardant recently launched Reveal, a plasma-only liquid biopsy test that detects residual and recurrent CRC in about 7 days from a simple blood draw. For oncologists, Reveal improves the management of early-stage CRC patients by detecting ctDNA in plasma after surgery, enabling doctors to identify patients with residual CRC who may benefit from post-surgery chemotherapy (adjuvant chemotherapy), months earlier than current standard-of-care tests permit. Reveal is the first test for minimal residual disease (MRD) detection that detects ctDNA in the plasma of CRC patients following treatment ***without the need for a tissue sample and sequencing*** to determine the particular mutations that were present in the patient's tumor. Reveal achieves outstanding sensitivity (91%) for predicting recurrence of CRC disease.

3. With little or no concern for the CRC patients who could be harmed, Natera has undertaken a campaign of misinformation to convince customers and potential customers, including oncologists and other physicians, cancer researchers, health care institutions, biopharmaceutical companies, and genetic laboratories, to avoid using Reveal in favor of Natera's own Signatera™ ("Signatera"), a tumor-dependent assay. In its commercial advertising and promotion, Natera makes literally false and misleading statements that disparage Guardant's new assay, and falsely asserts that Signatera is superior to Reveal across a variety of metrics, including sensitivity,[1] failure rate,[2] negative predictive value (NPV),[3] and Hazard Ratio,[4] among other categories. These claims are false. Natera combines outright misrepresentations with scientifically unfounded comparisons based on cherry-picked metrics, data artifacts, and

[1] "Sensitivity" refers to the assay's ability to identify which patients will develop recurrences based on MRD detection by ctDNA assay. A higher percentage indicates a test is more sensitive.

[2] "Failure rate" refers to the percentage of time a ctDNA assay fails to provide a result at all, whether positive or negative. For any test, a lower failure rate is more desirable.

[3] "NPV" refers to the assay's ability to correctly predict which patients will subsequently not develop a recurrence of CRC (i.e., a "negative" test result means CRC will not recur).

[4] The "Hazard Ratio" refers to a comparison between the recurrence rate over time in CRC patients who tested positive for MRD by ctDNA assay, to the recurrence rate in CRC patients who tested negative for MRD by ctDNA. A larger hazard ratio suggests that the assay is potentially more useful in successfully distinguishing CRC patients whose cancers will or will not recur.

noncomparable clinical studies to exaggerate the purported benefits of Signatera while inaccurately denigrating Reveal. In truth, Reveal has important clinical advantages over Signatera—including its superior landmark sensitivity, its availability for patients from whom tumor samples are unavailable, and its faster initial turnaround time from sample collection to assay results—all of which Natera ignores.

4. Guardant seeks to enjoin Natera from continuing to make or disseminate false and misleading statements about the performance of Reveal and Signatera; to require Natera to retract, remove, and correct these false and misleading advertising claims; and to recover damages and other relief for the harm that Natera has inflicted on Guardant.

II. PARTIES

5. Plaintiff Guardant is a Delaware corporation having its principal place of business at 505 Penobscot Dr., Redwood City, California 94063.

6. Guardant was founded in 2012 by pioneers in DNA sequencing and cancer diagnostics. Since its inception, Guardant has focused its expertise on the development of liquid biopsy assays for cancer. It was the first company to develop and commercialize a comprehensive liquid biopsy assay to identify genomic biomarkers for advanced solid tumors using cell-free ctDNA, from simple, non-invasive blood draws.

7. Today, Guardant is a leading precision oncology company focused on helping conquer cancer globally through the use of its proprietary blood tests, vast data sets, and advanced analytics. The Guardant oncology platform leverages its capabilities to drive commercial adoption, improve patient clinical outcomes, and lower healthcare costs across all stages of the cancer care continuum. Guardant Health has commercially launched the liquid biopsy-based Guardant360®, Guardant360® CDx, and GuardantOMNI® tests for advanced stage cancer patients, and recently launched its Reveal test for early-stage CRC patients.

8. Defendant Natera is a Delaware corporation having its principal place of business at 13011 McCallen Pass, Building A, Suite 100 Austin, Texas 78753, and offices at 201 Industrial Rd., San Carlos, California 94070. Natera may be served with process by serving a copy of this Complaint on its Registered Agent: National Registered Agents, Inc., 1209 Orange

Street, Wilmington, Delaware 19801.

9. Natera markets and sells Signatera, a product it describes as a "personalized, tumor-informed assay optimized to detect circulating tumor DNA (ctDNA) for molecular residual disease (MRD) assessment and recurrence monitoring for patients previously diagnosed with cancer." Signatera competes with Reveal in the market for ctDNA assays that can be used after surgery on CRC patients, to detect recurrences and evaluate the need for adjuvant chemotherapy.

III. JURISDICTION AND VENUE

10. This is an action for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); for false advertising in violation of Cal. Bus. & Prof. Code § 17500 et seq.; for unlawful trade practices in violation of Cal. Bus. & Prof. Code § 17200 et seq.; and for unfair competition in violation of the common law of California and other states in which Defendant is conducting its activities.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338 and 15 U.S.C. §§ 1051, et seq.

12. This Court has jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 and the doctrine of supplemental jurisdiction.

13. The exercise of personal jurisdiction in California is proper both because of Defendant's ongoing and systematic contact with California and the Northern District of California, including its maintenance of a regular place of business in the District, and because acts giving rise to Plaintiff's causes of action have occurred in the Northern District of California. Specifically, Natera markets, promotes, advertises, offers for sale, sells, and/or distributes Signatera to customers including oncologists and other physicians, cancer researchers, health care institutions, biopharmaceutical companies, genetic laboratories, and/or others throughout the United States, including in the Northern District of California. Defendant has purposefully and voluntarily placed Signatera into the stream of commerce with the expectation that this product will be purchased by customers in the Northern District of California. Furthermore, Natera falsely and misleadingly advertises Signatera to customers, including

oncologists, pathologists, additional physicians, health care institutions, pharmaceutical companies, and/or others throughout the United States, including in the Northern District of California.

14. Venue is proper in the Northern District of California pursuant to 28 U.S.C. § 1391.

IV. FACTUAL BACKGROUND

A. Early Identification of At-Risk Patients is a Key to Preventing Recurrence of Colorectal Cancer and Prolonging Survival

15. Colorectal cancer (CRC) is the third most commonly diagnosed cancer and the second leading cause of cancer death in the United States in both men and women. While a majority of patients are diagnosed with early-stage disease, nearly a third of patients whose CRC spreads into adjacent tissues and lymph nodes will die from their disease within five years.

16. Surgery alone is often curative for early-stage CRC, and in later-stage cases, adjuvant chemotherapy after surgery can reduce the risk of recurrence. However, clinicians have had very limited means of identifying patients that require adjuvant chemotherapy. Thus, the development of effective clinical tests to identify CRC patients with MRD—i.e., a small number of CRC cells remaining in the body that can later multiply and cause recurrence of the disease—after surgery has long been recognized as a need, to help doctors both identify patients who may benefit from additional therapy, and avoid administering unnecessary and toxic treatment to patients who will not benefit from it.

17. Because residual cancer cells that remain in the body following treatment typically cause no physical signs or symptoms and are present at very low levels that are undetectable with standard techniques, detecting and monitoring MRD has required development of advanced and highly sophisticated technologies with the requisite precision and sensitivity for clinical decision-making. Reveal provides that sophisticated technology.

B. Liquid Biopsy Technology Allows Assessment of MRD by Detecting Circulating Tumor DNA in Blood

18. Human blood contains fragments of DNA that are shed into the bloodstream by

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