Rosemary M. Rivas (State Bar No. 209147)
Email: rrivas@finkelsteinthompson.com
FINKELSTEIN THOMPSON LLP
505 Montgomery Street, Suite 300
San Francisco, California 94111
Telephone: (415) 398-8700
Toll-free: (877) 800-1450
Facsimile: (415) 398-8704

[Additional Counsel on Signature Page]

Attorneys for Plaintiffs Ben Martin, Carrie Martin, and Kryssa Cable

PSG

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CV 14 0429

BEN MARTIN, CARRIE MARTIN, and KRYSSA CABLE, on Behalf of Themselves and All Other Persons Similarly Situated,

Plaintiffs,

v.

23ANDME, INC.,

Defendant.

CASE NO.

CLASS ACTION COMPLAINT FOR DAMAGES, EQUITABLE, DECLARATORY AND INJUNCTIVE RELIEF

JURY TRIAL DEMANDED

Plaintiffs Ben Martin, Carrie Martin and Kryssa Cable ("Plaintiffs"), by and through their attorneys, allege as follows upon personal knowledge as to their own acts, and as to all other matters upon information and belief based upon, *inter alia,* the investigation made by and through their attorneys.

INTRODUCTION

1. Plaintiffs bring this consumer class action on behalf of themselves and those who purchased 23andMe, Inc.'s ("Defendant," "23andMe," or the "Company") DNA Saliva Collection Kit and Personal Genome Service (defined by the U.S. Food and Drug Administration ("FDA" or "Agency") as the "PGS") from November 2007 through the present (hereinafter the "Class").

2. Among other things, 23andMe claimed that for a cost of $99.00 and the submission of a saliva sample, the PGS could provide consumers with health reports on over 240 conditions and traits, a subject's carrier status concerning certain genetic traits, health risks, and information concerning an individual's potential responses to certaindrugs.

3. Unfortunately for the consuming public, Defendant made these and other representations without ever substantiating the accuracy of the PGS. As a result, since the Company has failed to obtain proper authorization from the FDA, the Agency ordered the Company to cease marketing health-related genetic test information based on the PGS until 23andMe can substantiate its methodology for providing such information. Additionally, numerous sources have commented that the real value for the Company concerning consumers' DNA submissions is not in the information it provides to consumers, but rather the massive database it has created based on the collection of its customers' DNA. Through this database, which has been compiled from hundreds of thousands of consumers' DNA, the Company now has the means to market this information to various sources for substantial profit.

4. For these reasons, and those discussed in greater detail below, Plaintiffs and the Class have been harmed by 23andMe's false and misleading marketing concerning the

use of the PGS. Therefore, on behalf of themselves and the Class, Plaintiffs allege statutory violations of the Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* ("UCL" or "Section 17200"), the False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.* (the "FAL" or "Section 17500"), the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* (the "CLRA"), and common law claims for breach of express warranty, breach of contract, intentional misrepresentation, negligent misrepresentation, and unjust enrichment.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because the matter in controversy, upon information and belief, exceeds $5,000,000, exclusive of interests and costs, and this matter is a class action in which at least one Class member is a citizen of a different state than Defendant.

6. This Court has personal jurisdiction over 23andMe because Defendant is located in California, does substantial business in California, has sufficient minimum contacts with California or otherwise intentionally avails itself of the markets within California through sales and marketing to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because Defendant's acts occurred in this Judicial District. Moreover, the misconduct at issue had effects in this County. Venue is also proper in this County because Defendant is located in this County.

THE PARTIES

8. Plaintiff Ben Martin purchased the PGS and was damaged by Defendant's improper marketing of the health-related genetic test information derived from the PGS as alleged herein. Plaintiff is currently a citizen and resident of San Diego, California and purchased the PGS for personal use. Plaintiff read Defendant's representations on its website about the PGS at www.23andme.com and purchased this product/service in reliance on those

claims. Moreover, 23andMe's representations concerning the PGS were a material and substantial factor which influenced his decision to purchase the PGS. He would not have purchased the PGS had he known that it did not provide accurate information concerning the health-related genetic test information as represented. As such, Plaintiff suffered injury in fact and lost money as a result of Defendant's practices.

9. Plaintiff Carrie Martin purchased the PGS and was damaged by Defendant's improper marketing of the health-related genetic test information derived from the PGS as alleged herein. Plaintiff is currently a citizen and resident of San Diego, California and purchased the PGS for personal use. Plaintiff read Defendant's representations on its website about the PGS at www.23andme.com and purchased this product/service in reliance on those claims. Moreover, 23andMe's representations concerning the PGS were a material and substantial factor which influenced her decision to purchase the PGS. She would not have purchased the PGS had she known that it did not provide accurate information concerning the health-related genetic test information as represented. As such, Plaintiff suffered injury in fact and lost money as a result of Defendant's practices.

10. Plaintiff Kryssa Cable purchased the PGS and was damaged by Defendant's improper marketing of the health-related genetic test information derived from the PGS as alleged herein. Plaintiff is currently a citizen and resident of Los Angeles, California and purchased the PGS for personal use. Plaintiff read Defendant's representations on its website about the PGS at www.23andme.com and purchased this product/service in reliance on those claims. Moreover, 23andMe's representations concerning the PGS were a material and substantial factor which influenced her decision to purchase the PGS. She would not have purchased the PGS had she known that it did not provide accurate information concerning the health-related genetic test information as represented. As such, Plaintiff suffered injury in fact and lost money as a result of Defendant's practices.

11. Defendant 23andMe was founded in April of 2006 and is a privately held personal genomics and biotechnology company with headquarters located at 1390 Shorebird

Way, Mountain View, California 94043. The Company provides what has been described as rapid genetic testing. 23andMe is named for the twenty-three (23) pairs of chromosomes in a normal human cell. The Company's personal genome test kit was named Invention of the Year by *Time* magazine in 2008. 23andMe was founded by Linda Avey ("Avey"), Paul Cusenza ("Cusenza"), and Anne Wojcicki ("Wojcicki") to provide genetic "testing" and "interpretation" to individual consumers. Cusenza and Avey are no longer with the Company, having left 23andMe in 2007 and 2009, respectively.

CLASS ACTION ALLEGATIONS

12. Plaintiffs bring this lawsuit, both individually and as a class action on behalf of similarly situated customers of 23andMe, pursuant to Federal Rule of Civil Procedure 23. The proposed Class is initially defined as:

> All individuals who purchased the PGS from November 2007 through the present. Excluded from the proposed Class is Defendant, its respective officers, directors, and employees, and any entity that has a controlling interest in Defendant. Plaintiffs reserve the right to amend the Class definition as necessary.

13. **Numerosity**: Upon information and belief, the Class comprises thousands of consumers and is so numerous that joinder of all members of the Class is impracticable. While the exact number of Class members is presently unknown and can only be ascertained through discovery, Plaintiffs reasonably believe that there may be hundreds of thousands of Class members.

14. **Common Questions of Law and Fact Predominate:** There are questions of law and fact common to the Class, which predominate over any individual issues, including, but not limited to:

(A) Whether Defendant engaged in the conduct alleged herein;

(B) Whether Defendant's practices were deceptive, unfair, improper and/or misleading;

(C) Whether Defendant made intentional misrepresentations;

(D) Whether Defendant made negligent misrepresentations;

(E) Whether Defendant's conduct as alleged herein constitutes breach of contract;

(F) Whether Defendant's conduct as alleged herein constitutes and resulted in unjust enrichment;

(G) Whether Defendant's conduct as alleged herein violated the UCL, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

(H) Whether Defendant's conduct as alleged herein violated the FAL, Cal. Bus. & Prof. Code §§17500, *et seq.*;

(I) Whether Defendant's conduct as alleged herein violated the CLRA, Cal. Civ. Code § 1750, *et seq.*;

(J) Whether Plaintiffs and Class members have sustained monetary loss and the proper measure of that loss; and

(K) Whether Plaintiffs and Class members are entitled to declaratory and injunctive relief.

15. **Typicality**: Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class have been similarly affected by Defendant's common course of conduct and were exposed to the same misrepresentations made by Defendant.

16. **Adequacy of Representation**: Plaintiffs will fairly and adequately represent and protect the interest of the Class. Plaintiffs have retained counsel with substantial experience in handling complex class action litigation. Plaintiffs and their counsel are committed to prosecuting this action vigorously on behalf of the Class and have the financial resources to do so.

17. **Superiority of the Class Action**: A class action is superior to all other available methods for the fair and efficient adjudication of this lawsuit, because individual litigation of the claims of all Class members is economically unfeasible and procedurally impracticable. While the aggregate damages sustained by the Class are likely in the millions

of dollars, the individual damages incurred by each Class member resulting from Defendant's wrongful conduct are too small to warrant the expense of individual suits. The likelihood of individual Class members prosecuting their own separate claims is remote, and even if every Class member could afford individual litigation, the court system would be unduly burdened by individual litigation of such cases. Individual members of the Class do not have a significant interest in individually controlling the prosecution of separate actions, and individualized litigation would also present the potential for varying, inconsistent, or contradictory judgments, and would magnify the delay and expense to all of the parties and to the court system because of multiple trials of the same factual and legal issues. Plaintiffs know of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action. In addition, Defendant has acted or refused to act on grounds generally applicable to the Class and, as such, final injunctive relief or corresponding declaratory relief with regard to the members of the Class as a whole is appropriate.

18. Unless a class is certified, Defendant will retain monies it took from Plaintiffs and the proposed Class by means of its unlawful conduct. Unless an injunction is issued, Defendant will continue to commit the alleged violations, and the members of the Class and the general public will continue to be misled.

FACTUAL ALLEGATIONS

19. Genetic testing is a multi-billion dollar industry. In fact, it is projected that genetic tests may become a $25 billion annual market in the U.S. within a decade.

20. Founded in April 2006, 23andMe began offering its direct-to-consumer ("DTC") DNA testing service in November 2007. As of December 2013, customers were charged $99.00 (plus shipping and handling) for the PGS which required them to provide a saliva sample which was then genotyped. The customer's results were then posted online, along with an assessment of inherited traits, genealogy, and possible congenital risk factors.

21. 23andMe has aggressively advertised, marketed and sold the PGS to the consuming public and purports to be a leader in the genetic testing industry. According to the Company's website, it has approximately 500,000 customers and approximately 90% of its customers have opted-in to participate in Defendant's research database. 23andMe also claims to have collected "more than 200 million phenotypic data points (individual survey responses)" and "on an average week the company collects approximately two million new survey responses from our active online research community." *See* http://mediacenter.23andme.com/fact-sheet. Based on this compilation of confidential datasets provided by its customers, 23andMe has the ability to provide testing for certain research initiatives and to share this information with third parties.

22. 23andMe is backed by Google and has raised funding from other sources as well. CEO Wojcicki married Google co-founder Sergey Brin ("Brin") in early May 2007. In 2007, Google invested $3,900,000 in 23andMe, along with other investors such as Genentech. In 2012, the Company raised $50 million which almost doubled its existing capital of $52.6 million.

23. During the relevant time period, 23andMe made numerous representations through various forms of advertising, including its website, concerning the PGS. For example, during the relevant period the Company noted the following on its website:

(a) "Learn hundreds of things about your health. Using your DNA information, 23andMe helps you know more about your health so you can take an active role in managing it. With reports on over 240+ health conditions and traits, here are a few of the things you'll learn about you;"

(b) "Plan for the future. Find out if your children are at risk for inherited conditions, so you can plan for the health of your family;"

(c) "Living well starts with knowing your DNA;"

(d) "Health tools – Document your family health history, track inherited conditions, and share the knowledge;"

(e) "Drug response – Arm your doctor with information on how you might respond to certain medications;" and

(f) "Below are a few examples [diabetes, arthritis, coronary heart disease, breast cancer, plavix, lactose intolerance] where we can help you learn more. And when you know more, you can make better lifestyle choices, look out for common conditions and take steps toward mitigating serious diseases."

24. In addition to the foregoing, 23andMe also made the following statements concerning the health benefits associated with its DNA testing:

> 23andMe is a DNA analysis service providing information and tools for individuals to learn about and explore their DNA. We use the Illumina HumanOmniExpress-24 format chip[.] Our chip consists of a fully custom panel of probes for detecting single nucleotide polymorphisms (SNPs) selected by our researchers. The selection was made to maximize the number of actionable health and ancestry features available to customers as well as offer flexibility for future research.

25. Unfortunately for consumers, despite the foregoing representations, 23andMe never substantiated the accuracy of the PGS and has utterly failed to gain authorization from the FDA to market the PGS as to health-related genetic test information. As noted in a Warning Letter from the FDA to CEO Wojcicki and 23andMe dated November 22, 2013 ("FDA Warning Letter"), after years of dialogue with 23andMe, which included fourteen (14) face to face meetings and hundreds of emails exchanged to no avail, the Agency stated in pertinent part:

> ***The Food and Drug Administration (FDA) is sending you this letter because you are marketing the 23andMe Saliva Collection Kit and Personal Genome Service (PGS) without marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act).***[1]
>
> This product is a device within the meaning of section 201(h) of the FD&C Act, 21 U.S.C. 321(h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. For example, your

[1] At all times, emphasis is added unless otherwise indicated.

company's website at www.23andme.com/health (most recently viewed on November 6, 2013) markets the PGS for providing ***"health reports on 254 diseases and conditions,"*** including categories such as ***"carrier status," "health risks,"*** and ***"drug response,"*** and specifically as a ***"first step in prevention" that enables users to "take steps toward mitigating serious diseases" such as diabetes, coronary heart disease, and breast cancer.*** Most of the intended uses for PGS listed on your website, a list that has grown over time, are medical device uses under section 201(h) of the FD&C Act. Most of these uses have not been classified and thus require premarket approval or de novo classification, as FDA has explained to you on numerous occasions.

Some of the uses for which PGS is intended are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses (e.g., warfarin sensitivity, clopidogrel response, and 5-fluorouracil toxicity) because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these. For instance, if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist. Assessments for drug responses carry the risks that patients relying on such tests may begin to self-manage their treatments through dose changes or even abandon certain therapies depending on the outcome of the assessment. ***For example, false genotype results for your warfarin drug response test could have significant unreasonable risk of illness, injury, or death to the patient due to thrombosis or bleeding events that occur from treatment with a drug at a dose that does not provide the appropriately calibrated anticoagulant effect.*** These risks are typically mitigated by International Normalized Ratio (INR) management under a physician's care. ***The risk of serious injury or death is known to be high when patients are either non-compliant or not properly dosed; combined with the risk that a direct-to-consumer test result may be used by a patient to self-manage, serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported.***

Your company submitted 510(k)s for PGS on July 2, 2012 and September 4, 2012, for several of these indications for use. However, to date, your company has failed to address the issues described during previous interactions with the Agency or provide the additional information identified in our September 13, 2012 letter for (b)(4) and in our November 20, 2012 letter for (b)(4), as required under 21 CFR 807.87(1). Consequently, the 510(k)s are considered withdrawn, *see* 21 C.F.R. 807.87(1), as we explained in our letters to you on March 12, 2013 and May 21, 2013. ***To date, 23andMe has failed to provide adequate information to support a determination that the PGS is substantially equivalent to a legally marketed predicate for any of the uses for which you are marketing it; no other submission for the PGS device that you are marketing has been provided under section 510(k) of the Act, 21 U.S.C. § 360(k).***

The Office of In Vitro Diagnostics and Radiological Health (OIR) has a long history of working with companies to help them come into compliance with the FD&C Act. ***Since July of 2009, we have been diligently working to help you comply with regulatory requirements regarding safety and effectiveness and obtain marketing authorization for your PGS device.*** FDA has spent significant time evaluating the intended uses of the PGS to determine whether certain uses might be appropriately classified into class II, thus requiring only 510(k) clearance or de novo classification and not PMA approval, and we have proposed modifications to the device's labeling that could mitigate risks and render certain intended uses appropriate for de novo classification. Further, we provided ample detailed feedback to 23andMe regarding the types of data it needs to submit for the intended uses of the PGS. ***As part of our interactions with you, including more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications, we provided you with specific feedback on study protocols and clinical and analytical validation requirements, discussed potential classifications and regulatory pathways (including reasonable submission timelines), provided statistical advice, and discussed potential risk mitigation strategies. As discussed above, FDA is concerned about the public health consequences of inaccurate results from the PGS device; the main purpose of compliance with FDA's regulatory requirements is to ensure that the tests work.***

However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses, which have expanded from the uses that the firm identified in its submissions. In your letter dated January 9, 2013, you stated that the firm is "completing the additional analytical and clinical validations for the tests that have been submitted" and is "planning extensive labeling studies that will take several months to complete." Thus, ***months after you submitted your 510(k)s and more than 5 years after you began marketing, you still had not completed some of the studies and had not even started other studies necessary to support a marketing submission for the PGS.*** It is now eleven months later, and you have yet to provide FDA with any new information about these tests. You have not worked with us toward de novo classification, did not provide the additional information we requested necessary to complete review of your 510(k)s, and FDA has not received any communication from 23andMe since May. Instead, we have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA.

Therefore, 23andMe must immediately discontinue marketing the PGS until such time as it receives FDA marketing authorization for the device. The PGS is in class III under section 513(f) of the FD&C Act, 21 U.S.C. 360c(f). Because there is no approved application for premarket approval in effect pursuant to

> section 515(a) of the FD&C Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the FD&C Act, 21 U.S.C. 360j(g), the PGS is adulterated under section 501(f)(1)(B) of the FD&C Act, 21 U.S.C. 351(f)(1)(B). Additionally, the PGS is misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because notice or other information respecting the device was not provided to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k).
>
> Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific actions you have taken to address all issues noted above. Include documentation of the corrective actions you have taken. If your actions will occur over time, please include a timetable for implementation of those actions. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the actions will be completed. ***Failure to take adequate corrective action may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.***

See Exhibit A attached hereto.

26. As of the filing of this Complaint, 23andMe has not provided the FDA with any of the information requested. Moreover, without acknowledging the seriousness of the FDA's concerns, the Company's website currently states:

> Welcome to 23andMe.
>
> ***At this time, we have suspended our health-related genetic tests to comply with the U.S. Food and Drug Administration's directive to discontinue new consumer access during our regulatory review process.***
>
> We are continuing to provide you with both ancestry-related genetic tests and raw genetic data, without 23andMe's interpretation.
>
> If you are an existing customer please click the button below and then go to the health page for additional information, including information about refunds.
>
> We remain firmly committed to fulfilling our long-term mission to help people everywhere have access to their own genetic data and have the ability to use that information to improve their lives.
>
> Upon entering the site, please confirm you understand the new changes in our services.

27. Interestingly, even though the Company no longer provides health-related genetic test information as part of the PGS, there has been no reduction in the price of the overall service which remains at $99.00 according to 23andMe's website. *See* https://www.23andme.com/.. This begs the question of whether the Company attributed ***any*** value to the health-related genetic test information it was providing to consumers or if Defendant's primary goal was to simply garner as much information for its genetic database as possible. Also, Defendant has limited refunds to consumers who bought the PGS from November 22, 2013 to December 5, 2013.

28. It is also important to note that numerous sources have challenged the accuracy and reliability of 23andMe's health-related genetic test information. For example, on May 14, 2008, in response to questions from Senator Hillary Rodham Clinton concerning the future of Alzheimer's Disease, Dr. Rudolph Tanzi stated the following:

> As an aside, it should be noted that companies like 23andMe, Navigenics, Knome, and DeCode are already charging considerable sums of money for anyone who wishes to pay to be tested for the "unconfirmed" genetic risk factors for Alzheimer's and other common diseases, *e.g.* cardiovascular disease, cancer, and stroke. ***In my view, it is highly premature and both medically and commercially irresponsible to be conducting these tests.*** To reliably predict disease risk, we will first need to establish the full set of "confirmed" risk factors and then determine how they work together to influence risk in a "multigenic" manner. As these companies become more popular, the public will need to be increasingly informed and educated about the fact these tests are not yet accurate, reliable, or scientifically sound. ***I am concerned that these tests may increasingly lead to unwarranted anxiety or a false sense of security about one's genetic destiny as these companies services become more "trendy."***

See http://curealz.org/2008/06/more-tanzi-testimony-senate-hearing-alzheimers?page=83.

29. Numerous other sources have expressed similar concern regarding the genetic testing industry as well as 23andMe's dissemination of health-related genetic test information to the consuming public. For example, in an article entitled "FDA to 23andMe: Stop Selling Spit Kits," posted on *MedCityNews.com* and dated November 25, 2013, it was noted that "UnitedHealth Group Inc. (UNH), the largest publicly traded U.S. health insurer, raised concern in a March 2012 report about the ***accuracy*** and affordability of the tests. Such types

of genetic tests may become a $25 billion annual market in the U.S. within a decade, highlighting the need to identify which work best, the insurer said at the time."

30. In an article entitled "Why the FDA is Targeting 23andMe: Unnecessary MRIs, Mastectomies," posted on *VentureBeat* and dated November 26, 2013, the publication stated in pertinent part:

> ***[T]he majority of geneticists and medical professionals I've spoke with have sided with the Food and Drug Administration, arguing that many patients require genetic counseling after receiving DNA test results that point to a high risk of cancer and other life-threatening conditions.***
>
> One San Francisco-based neurologist, who asked to remain anonymous, told me that some of her healthiest patients — all 23andMe customers — have begun demanding unnecessary and expensive MRI tests for Alzheimer's Disease. ***"23andMe's test is creating chaos with people in their 20s and 30s," she said. "They generate havoc and walk away."***
>
> * * * * *
>
> The agency may have decided to take public action now, given that 23andMe has begun testing various mutations of genes that indicate a woman might have a high risk of getting breast or ovarian cancer. ***A false positive on that test could cause a woman to undergo a needless mastectomy. And a growing number of women are requesting this test after hearing the news about Angelina Jolie's surgery.***
>
> * * * * *
>
> ***In this particular case, the FDA may have taken issue with 23andMe's aggressive marketing tactics.*** The company recently hired a former Gilt Groupe exec as its president; since then, it has been advertising its test to consumers on social media and various television networks.
>
> Consumers may not understand that the test is serious — not just a bit of fun — and that the results can indicate incurable or life threatening disease.
>
> "When I started Navigenics (a 23andMe rival that was acquired by Life Technologies for an unspecified sum), we spent an enormous amount of time communicating shades of grey — and we did all this alongside regular meetings with the FDA," said human geneticist and entrepreneur Dietrich Stephan in an interview.
>
> "Engaging the FDA as a partner to bring the most robust and safe new type of test to market is "diagnostics 101," he added.
>
> ***Stephan told me about a family friend who ordered a 23andMe test on a whim. His mother felt compelled to take the test, after discovering that her son carried a genetic variant called BRCA, which indicates a high risk of breast and ovarian cancer. After the mother received a positive result, she ordered a double mastectomy despite protestations from friends and family.***

> Indeed, physicians I interviewed stressed that patients should not order a DNA test without regard to the consequences. Dr. Malcolm Thaler, a primary care provider at One Medical, said he would prefer to have a conversation with a patient before they order a test "to put the results in context" and explain the numbers in detail.
>
> ***In the short term, we may see 23andMe under pressure to more readily link consumers with genetic counselors and adapt its marketing campaigns to reflect the life-changing and potentially very serious nature of the results.***

31. On the same day, in a *San Jose Mercury News* article entitled "FDA Issues Cease Warning to 23andMe - Agency Orders Company to Stop Sales of Widely Used Personal Genetic Tests," it was noted:

> It's likely that 23andMe will try to resolve the dispute through further negotiations with the FDA, said Colleen Heisey, a lawyer specializing in FDA regulations. But if it fails to satisfy the agency, she added, the FDA might seek an injunction to halt 23andMe's business.
>
> "This is serious," Heisey said of the warning letter. "It's intended by the FDA to be a wake-up call."
>
> Marcy Darnovsky, executive director of the Berkeley-based Center for Genetics and Society, said the FDA may have let 23andMe stay in business as long as it has because genetic tests sold directly to consumers are relatively new, and the agency wants to be careful how it regulates them. ***But she said it's crucial such companies are closely monitored.***
>
> ***"If they are giving health information, there has to be some oversight," she said. "Otherwise, we're back to the snake-oil era."***
>
> DNA tests sold directly to consumers have been criticized as having limited value because they typically examine only a small sample of a person's genetic makeup.
>
> ***In 2010, investigators from the U.S. Government Accountability Office concluded that 23andMe and Navigenics of Foster City were offering information that was "misleading and of little or no practical use." Although both companies defended their products, the agency blasted them for drawing unsupportable conclusions and making health predictions that didn't always jibe with their customers' actual medical conditions.***
>
> Navigenics has since been bought by Life Technologies of Carlsbad, which only does genetic tests for research service and has no problem with the FDA, according to Life Technologies spokeswoman Suzanne Hatcher.
>
> ***DNA tests such as those offered by 23andMe also have aroused the concern of California health authorities. In 2008, they launched an investigation into the marketing of such tests, saying some companies lacked proper state licenses.***
>
> ***That same year, a study in the American Journal of Human Genetics concluded that "there is insufficient scientific evidence" to prove the tests "are useful in***

> ***measuring genetic risk for common diseases."*** Also in 2008, a U.S. Department of Health and Human Services advisory committee found "significant gaps in the U.S. system of oversight of genetic testing that can lead to harm."

32. Similarly, in a *Houston Chronicle* article, entitled "FDA Halts Sales of Home DNA Testing Kit," dated November 26, 2013, concerns of numerous geneticists and doctors regarding the validity and reliability of 23andMe's PGS were highlighted as follows:

> "(The agency) is concerned about the public health consequences of inaccurate results," the FDA writes in the letter, which is dated Nov. 22 and was posted online Monday. It called some of the tests "particularly concerning...because of potential consequences that could result from false positive or false negative assessments for high-risk indications."
>
> ***The move was applauded by Houston geneticists and doctors, who said questions remain about the validity of tests being marketed for medical diagnoses. They also said the information returned to consumers is difficult to understand and easily misinterpreted without accompanying genetic counseling.***
>
> ***Dr. Jennifer Litton, an M.D. Anderson Cancer Center breast oncologist, said she routinely sees patients who have ordered the home genetic testing and think they've had "full testing for a hereditary cancer syndrome when in fact they've only had a tiny snippet." She noted that such snippets of information can give false information.***
>
> Alana Cecchi, a genetic counselor at the University of Texas Health Science Center who recently took the 23andMe testing, said the results were complex and confusing enough that she had to "go above and beyond, do additional research" just to understand them.
>
> * * * * *
>
> ***Dr. Sharon Plon, a Baylor College of Medicine professor of molecular and human genetics, said if a patient came to her with 23andMe test results, she'd seek new testing at a certified laboratory because she'd want to be confident of the standard of testing provided.*** She compared it to a patient coming in with an MRI scan from a commercial company.
>
> Misleading info
>
> Amy McGuire, director of Baylor's Center for Medical Ethics and Health Policy, said that though it's true that many interventions suggested by a 23andMe test would require a doctor who would prevent the procedure if it wasn't indicated, ***consumers could still be harmed by wrong or misleading information in other ways that do not involve licensed health care professionals.***
>
> ***She noted certain results could cause depression or anxiety, or lead to taking of unnecessary supplements or unproven alternative therapies.***

> McGuire called the FDA move part of a clear signal it plans to regulate the home genetic testing industry, something she said she actually expects its leaders to welcome, "The worst thing for a market is regulatory uncertainty," she said.

33. Thereafter, in an article dated December 4, 2013 in *The Tennesean*, entitled "23andMe DNA Kits under Fire," the following observations were made:

> The product in question is a $99 test that, the company claims, can unlock the secrets of customers' genomes. "Understand your genetic health risks. Change what you can, manage what you can't," 23andMe says on the home page of its website.
>
> California-based 23andMe has been cruising for regulatory action for some time, according to local experts.
>
> "We've actually been expecting that for a while," said Mark Harris, CEO of Nashville company NextGxDx, which aims to create a genetic testing marketplace. That's because, as the FDA mentions in its letter, it had been trying to work with 23andMe for years to no avail.
>
> "It's pretty clear that the FDA has really wanted to be involved in this process and 23andMe has just ignored it," said Meredith Edwards Collins, a health care attorney at Bass Berry & Sims.
>
> * * * * *
>
> 23andMe has marketed its product under the premise that every person deserves a right to know his or her own genome, without having that information pass through the hands of a medical professional. ***But that kind of genetic revolutionary mindset is misleading for two reasons, experts say. First, 23andMe's test does not give people the kind of genetic information that many people think it does.***
>
> ***"Most people assume that 23andMe is actually sequencing genes, but they're not; their technology just looks for very specific mutations," Harris said. In other words, he added, "It's not fully comprehensive — the results have to be taken with a grain of salt."***
>
> ***Second, it's not entirely clear what that genetic information tells people once they get it. 23andMe sells a direct-to-patient product that may be less useful than promised, even in the hands of a medical professional, according to Harris.*** "I've talked to a lot of doctors who have had patients bring in their 23andMe results to visits, and that drives them crazy," Harris said. "Even if you go in and hand your results to a doctor, it doesn't mean they know what to do with it or that it will change your treatment at all."

34. On the same day, an article entitled "Genetic Testing Could Endanger Your Health" was published in the *Chicago Tribune*. The article provides insightful analysis concerning the "quality," or lack thereof, concerning the health-related information provided by 23andMe as well as the value of the genetic database being amassed by the Company:

A small proportion of this information -- as it relates to breast cancer mutations, for example -- may be medically useful. ***For the most part, however, studies have shown that direct-to-consumer test results are inconsistent. For example, Craig Venter, a pioneer in genetics, found that for five patients, the results obtained by 23andMe and a competitor were in disagreement at least half the time on seven of 13 illnesses analyzed.***

Measuring risk

A doctor who diagnosed patients correctly only 50 percent of the time wouldn't practice medicine for very long. ***We don't want doctors to give patients ineffective or harmful drugs or false and inaccurate information. The same standard should apply to other health care providers and organizations.***

The risk with companies such as 23andMe is that in telling people they have very high odds of getting a particular disease, they may unnecessarily cause anguish or encourage invasive procedures. Or a false negative result could lead a complacent patient to forgo screening or useful preventive action.

The FDA says it has tried to work with 23andMe, holding 14 face-to-face meetings and sending hundreds of emails, to press the company for evidence of claims about the tests' validity.

Certainly, individuals have a right to their own genetic information. But whether direct-to-consumer genetic test kits should be allowed despite their flaws misses a larger point. ***The problem with these test kits is scientific. Only part of a person's DNA is tested, and scientists are still unsure how to interpret most of the information.***

Human DNA consists of a sequence of four molecules (so-called letters) that form a 3 billion-letter sequence -- 99.9 percent of which are shared by all humans. Individual DNA sequences, genomes, differ by about 3 million letters.

Several years ago, many scientists believed they would find highly predictive genetic mutations for many if not most diseases. ***But for the vast majority of patients, the causes of common diseases, such as heart disease, diabetes and most inherited forms of cancer, remain unknown; most of these afflictions can probably be ascribed to a combination of multiple genes and various environmental factors.***

The test from 23andMe, which looks at only about 1 of every 3,000 letters, misses many genes that may be involved in a disease and thus faces even more limitations. The FDA is arguing that the company is offering less complete information than it advertises. At the same time, the price of whole genome testing is falling. Although it costs about $3,000 today, it may soon be available for only a few hundred dollars more than ***23andMe's partial and not fully reliable test.*** Full genome testing doesn't solve the major scientific obstacles associated with genetic testing and disease prevention but at least it has the potential to consider more genes that could be involved in diagnosis.

Securing patents

> In some ways, 23andMe's test kit distracts attention from the company's larger presumed objectives. ***Much of 23andMe's value is in the hundreds of thousands of genetic samples it has collected from its customers. Such a collection can aid medical research, but, more important, the data will probably be very useful in securing patents.*** This year, the U.S. Supreme Court ruled that human genes can't be patented, but the court appeared to permit other kinds of patents within the field of genetics -- such as for synthetic DNA.
>
> ***Executives at 23andMe may have been gambling that the company could continue to offer its inexpensive product and accumulate samples before the FDA acted more forcefully to stop sales of its test (some companies battle with government agencies for years). By then, the company would have created a valuable product: a huge bio-bank.***
>
> Given the stakes involved, the FDA should take stronger action to protect consumers from the risks associated with direct-to-consumer testing -- ***especially overpromises about partial testing.*** In coming years, scientists will learn more about the causes of diseases. At the same time, patients, doctors and policymakers need to understand the complexities involved. When it comes to understanding the disease, $99 doesn't get you much.

35. An editorial in the *Sacramento Bee* entitled "FDA is Right to Pull Plug on 23andMe Genetic Tests," dated December 7, 2013, also raised similar concerns as those in the article above:

> The U.S. Food and Drug Administration for the last five years rightly has been pushing the company to provide studies on the accuracy of its DNA test results and to back up its health claims. To no avail.
>
> Finally, after the company embarked on a major advertising campaign with the goal of reaching 1 million customers by year's end, the FDA pulled the plug in a harsh Nov. 22 letter, telling 23andMe to "immediately discontinue marketing" the tests. ***The FDA action is warranted.***
>
> We should all be concerned about false positive results or false negative results and claims that certain markers can predict disease. Because 23andMe's tests might be used to make medical decisions, the FDA must insist on accuracy. ***The company must prove that the tests work and stop inflating claims about what the tests show.***
>
> ***Scott Diehl, director of the Center for Pharmacogenomics and Complex Disease Research at the Rutgers School of Dental Medicine, told the online publication Medical XPress that using results from one or two genetic markers to inform people they have an increased risk for getting a disease is useless,*** like "predicting whether your car will break down during a long journey after you've only checked whether a couple of lug nuts on one of the wheels are sufficiently tight."
>
> ***Hank Greely at Stanford's Center for Law and the Biosciences supports the FDA crackdown on 23andMe: "Because tests of unknown accuracy are no better than no tests at all, I applaud the FDA for taking seriously its mandate to protect public health."***

> ***23andMe's genetic testing method, Greely writes, "never was very good at providing useful genetic information" and already is obsolete.***
>
> The future, it seems, lies with so-called "next generation" sequencing. For example, the FDA approved San Diego-based Illumina's sequencing device for genetic testing of cystic fibrosis three days before its letter to 23andMe. That, Greely believes, is the future.
>
> ***The FDA kerfuffle misses what 23andMe really is about. While the company markets its genetic tests as a way for individuals to take charge of their health, it's really a way to create a giant genetic database that 23andMe can sell to drug companies and researchers to develop cures that can be patented: a biobank.***
>
> Fast Company magazine's November issue points out that "if 23andMe amasses 75,000 Crohn's disease patients, or diabetes patients, or heart disease patients, there are giant ways to monetize that data as new treatment options emerge." That is the real issue.
>
> "Why should 23andMe have my health information so they can sell it?" a genetics counselor asked in the Fast Company piece. That is the right question. The issue of the National Security Agency's warrantless surveillance of Americans' phone records has become an important national issue. ***But private companies collecting our genetic data to sell or give to pharmaceutical companies and researchers has not yet become a major issue. It should be.***

36. On December 11, 2013, an article entitled "The Future of Testing Your Genetic Future," which was published in the *Huffington Post*, concurred in the assessment provided by other sources that 23andMe's health-related genetic information is of little value to consumers and that the Company's priority is creating a biobank which can be exploited for profit:

> ***23andMe has examined not the whole genome, but only one out of every 3,000 letters. The results are even thus more limited. But the company continued to hype the benefits - though for the vast majority of customers, these have been nil. The company has now admitted, however, that its business model focuses on building a database of 1 million samples, which could then yield insights into disease, and also valuable patents, and profits for the company.***
>
> The company's new plan to offer raw data, however, poses other major concerns of how the company will market these tests. These data are essentially uninterpretable by the vast majority of people. DTC companies themselves have been found to disagree in how they interpret the same raw information. Some company supporters say the physicians can do the interpretation. But research I recently published in the Journal of Genetic Counseling found that 74 percent of internists feel their knowledge of genetic is poor, and 77 percent felt they needed more training on how to interpret results. Patients are even more bewildered. Still, the company may now claim to consumers that it is providing health information -- even if it is incomprehensible to most physicians and patients.

> ***Moreover, many customers of 23andMe do not realize that the company's main goal has been to amass a large profitable data base, rather than provide useful health information to consumers. It will be crucial that the company make this purpose far clearer to its consumers.***

37. Finally, on December 24, 2013, *VentureBeat.com* reported that six months earlier, 23andMe lost its Chief Legal Officer and General Counsel, Ashley Gould. According to an article entitled "23andMe Lost its Chief Legal Counsel Months Before FDA's legal Crackdown":

> This departure may clear up some of the confusion about why 23andMe became the target of a regulatory crackdown. ***It was a veritable legal mess.***
>
> * * * * *
>
> A combination of factors led to the Nov. 22 injunction, but the timing of Gould's departure may have played a role.
>
> * * * * *
>
> In Gould's absence, the legal team continues to report to Andy Page, a new hire who was tasked with product and engineering, marketing, finance, business development, laboratory operations, and legal and regulatory issues, according to a press release. Meanwhile, founder and chief executive Anne Wojcicki is focused on the science and research.
>
> ***Page has extensive experience in growing online businesses. Until recently, he was the president of Gilt Groupe. That explains the drastic uptick in advertising, and the slew of broadcast television ads in the past six months, which appear to have been highly troubling to the feds. For all his e-commerce expertise, Page does not seem to have much experience dealing with the complexities of medical device regulation.*** His bio on Crunchbase and the press release announcing his appointment indicates that 23andMe is his first health care company.
>
> According to sources familiar with the matter, Gould was responsible for dealing with formal processes and providing statistical evidence to ensure the testing kit is "analytically or clinically validated," according to the FDA's standards. Spokespeople from the regulatory agency claim 23andMe has failed to communicate at all since May, just a few months after Gould would accept a new job at biotech firm Hyperion Therapeutics, according to LinkedIn.

38. In light of the foregoing, 23andMe's misrepresentations and omissions concerning the purported accuracy of its PGS has caused monetary injury to Plaintiffs and the proposed Class.

FIRST CAUSE OF ACTION

(Violations of the Unfair Competition Law,

Cal. Bus. & Prof. Code §§ 17200, *et seq.*)

39. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

40. The UCL defines unfair business competition to include any "unfair," "unlawful," or "fraudulent" business or practice. Cal. Bus. & Prof. Code §§ 17200, *et seq.* Unfair competition also includes "unfair, deceptive, untrue or misleading advertising." The UCL also provides for injunctive relief and restitution for violations.

41. Defendant committed acts of unfair competition, as defined by Cal. Bus. & Prof. Code § 17200, by falsely advertising the PGS.

42. Defendant's conduct is unlawful because it violates the False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.* as alleged herein; the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* as alleged herein; and the Federal Food, Drug and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§ 301, *et seq.*, as highlighted in the FDA Warning Letter, attached as Exhibit A.

43. Defendant's conduct is unfair in that the harm to Plaintiffs and the Class arising from it outweighs the utility, if any, of those practices and because it offends established public policy and/or is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to Plaintiffs and Class members. Defendant's actions also violate the spirit of the False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*; the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*; and the FD&C Act.

44. Defendant's conduct was fraudulent and likely to deceive reasonable consumers in that Defendant misrepresented the accuracy associated with the PGS and omitted and/or failed to disclose material facts regarding the PGS. Defendant's failure to disclose the inaccuracy associated with the PGS constitutes deception by omission. Defendant had a duty to disclose these material facts.

45. The facts concealed and omitted are material facts in that a reasonable consumer would have considered them important in deciding whether or not to purchase the PGS.

46. As a result of Defendant's practices, Plaintiffs suffered injury in fact and lost money. As a direct and proximate result of the acts and practices alleged above, pursuant to Cal. Bus. & Prof. Code § 17203, Plaintiffs, on behalf of themselves and all others similarly situated, seek: (a) an Order requiring Defendant to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendant as a result of its deceptive practices, including, but not limited to, disgorgement of all profits derived from the sale of the PGS; and (c) the payment of Plaintiffs' attorneys' fees and costs pursuant to, *inter alia,* Cal. Code of Civ. Proc. § 1021.5.

SECOND CAUSE OF ACTION

(Violations of Consumers Legal Remedies Act,

Cal. Civ. Code §§ 1750, *et seq.*)

47. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

48. At all relevant times, Plaintiffs and each proposed Class member were a "consumer," as that term is defined in Cal. Civ. Code § 1761(d).

49. At all relevant times, the PGS constituted "goods," as that term is defined in Civ. Code § 1761(a).

50. At all relevant times, the PGS constituted "services," as that term is defined in Civ. Code § 1761(b).

51. At all relevant times, Defendant was a "person," as that term is defined in Civ. Code § 1761(c).

52. At all relevant times, Plaintiffs and each proposed Class Member's purchase of the PGS constituted a "transaction," as that term is defined in Civ. Code § 1761(e).

53. Defendant's practices, acts, policies, and course of conduct violated the CLRA in that Defendant represented that the PGS had characteristics, uses and benefits which it does not have, in violation of §1770(a)(5) of the CLRA.

54. Defendant's practices, acts, policies, and course of conduct violated the CLRA in that Defendant represented that the PGS was of a particular standard, quality, or grade, when it was of another, in violation of § 1770(a)(7) of the CLRA.

55. Defendant's practices, acts, policies, and course of conduct violated the CLRA in that Defendant advertised the PGS with the intent not to sell it as advertised, in violation of § 1770(a)(9) of the CLRA.

56. Defendant's practices, acts, policies, and course of conduct violated the CLRA in that Defendant represented that the subject of a transaction has been supplied in accordance with a previous representation when it has not, in violation of § 1770(a)(16) of the CLRA.

57. Plaintiffs will comply with Cal. Civ. Code § 1782(a) by serving a written letter on Defendant notifying it of the CLRA violations alleged herein. If Defendant has not rectified the issues complained of herein as set forth in the CLRA notice, Plaintiffs will amend this complaint to seek monetary relief, including restitution and damages under the CLRA. At this time, Plaintiffs seek an Order requiring Defendant to cease the acts of unfair competition alleged herein.

THIRD CAUSE OF ACTION

(Violations of Cal. Bus. & Prof. Code §§ 17500, *et seq.*)

58. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

59. Defendant disseminated untrue or misleading advertising in the public domain in violation of Cal. Bus. & Prof. Code §§ 17500, *et seq.*, by representing, among other things, the accuracy associated with the PGS.

60. Defendant committed such violations of the False Advertising Law with actual knowledge or knowledge fairly implied on the basis of objective circumstances.

61. Plaintiffs reasonably relied on Defendant's representations made in violation of Cal. Bus. & Prof. Code §§ 17500, *et seq.*

62. As a result of Defendant's violations, Plaintiffs suffered injury in fact and lost money.

63. Plaintiffs, on behalf of themselves and all others similarly situated, seek: (a) an Order requiring Defendant to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendant as a result of its deceptive practices, including, but not limited to, disgorgement of all profits derived from the sale of the PGS; and (c) the payment of Plaintiffs' attorneys' fees and costs pursuant to, *inter alia,* Cal. Code Civ. Proc. § 1021.5.

FOURTH CAUSE OF ACTION

(Breach of Contract)

64. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

65. Plaintiffs and the members of the Class entered into a contract with Defendant for the purchase of the PGS.

66. Implied in the contract between customers and Defendant was that the PGS provided accurate results.

67. Defendant breached these contracts by not providing the product as advertised and providing a product that was illegal for Defendant to sell.

68. As a direct and proximate result of Defendant's breaches of contract, Plaintiffs and Class Members have been damaged in amounts to be determined at trial.

FIFTH CAUSE OF ACTION

(Intentional Misrepresentation)

69. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

70. During the relevant time period, Defendant made certain representations as noted herein to Plaintiffs and Class members concerning the PGS which were contained in Defendant's advertising and on its website. The representations that were made to Class members were substantially similar and uniform for the purposes of this litigation.

71. When Defendant made the subject representations, it knew they were false and made the representations with the intent to deceive and defraud Plaintiffs and Class members to induce them to act in reliance on those representations, or with the expectation that they would so act. The purpose of misrepresenting the purported benefits and accuracy associated with the PGS was to deceive Plaintiffs and Class members into purchasing the PGS. Defendant knew that if it informed the public of the true facts associated with the PGS, no one would purchase the PGS, nor would they have been permitted for sale.

72. Plaintiffs and Class members, at the time the representations were made by Defendant, and at the time they took the actions herein alleged, were ignorant of the falsity of the representations and believed them to be true. In reliance on these representations, Plaintiffs were induced to purchase the PGS. Had Plaintiffs known the actual facts, they would not have bought the PGS. Reliance on Defendant's representations was justified because it was offering the PGS through its website and offered the sale of the PGS throughout the Country. Plaintiffs had no reason to believe that Defendant would act otherwise than as represented in its advertising.

73. In the alternative, Defendant, under a duty to speak, suppressed material facts from Plaintiffs and the Class regarding the purported benefits and accuracy of the PGS, in violation of advertising laws and other State and Federal regulations.

74. As a result of Defendant's fraudulent conduct, Plaintiffs and Class members paid monies to Defendant to which it was not entitled, and have suffered monetary damages in an amount to be proven at trial.

75. The aforementioned conduct of Defendant was an intentional misrepresentation, omission, deceit, or concealment of a material fact or facts known to Defendant with the intention of Defendant to deprive Plaintiffs and Class members of property or legal rights or otherwise cause injury, and was despicable conduct that subjected Plaintiffs and Class members to a cruel and unjust hardship in conscious disregard of their rights, so as to justify an award of exemplary and punitive damages.

SIXTH CAUSE OF ACTION

(Negligent Misrepresentation)

76. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

77. During the relevant time period, Defendant made the representations to Plaintiffs and Class members, which were contained in Defendant's advertising and on its website. The representations that were made to Class members were substantially similar for the purposes of this litigation.

78. As stated herein, Defendant made certain representations concerning the purported benefits and accuracy of the PGS. The representations that Defendant made were false and material.

79. When Defendant made the representations set forth above, it knew or should have known them to be false and made the representations with the intention to deceive and defraud Plaintiffs and Class members to induce them to act in reliance upon those representations, or with the expectation that they would so act.

80. Plaintiffs and Class members, at the time the representations were made by Defendant, and at the time they took the actions herein alleged, were ignorant of the falsity of the representations and believed them to be true. In reliance on these representations,

Plaintiffs were induced to purchase the PGS. Had Plaintiffs and Class members known the actual facts, they would not have taken such action. Reliance on Defendant's representations was justified because it was offering the PGS through its website and offered the sale of the PGS throughout the Country. Plaintiffs had no reason to believe that Defendant would act otherwise than as represented in its advertising.

81. In the alternative, Defendant, under a duty to speak, suppressed material facts from Plaintiffs and the Class regarding the purported benefits and accuracy of the PGS in violation of advertising laws and other State and Federal regulations.

82. As a result of Defendant's fraudulent conduct, Plaintiffs and Class members paid monies to Defendant to which they were not entitled, and have suffered monetary damages in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION

(Unjust Enrichment)

83. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

84. By its wrongful acts and omissions, Defendant was unjustly enriched at the expense of Plaintiffs and Class members, who did not receive the service to which they were entitled, namely that the PGS did not provide the purported benefits and accuracy as represented for the payments made to Defendant, and thus Plaintiffs and the Class were unjustly deprived.

85. It would be inequitable and unconscionable for Defendant to retain the profit, benefit and/or other compensation it obtained from its deceptive, misleading, and unlawful conduct alleged herein.

86. Plaintiffs and Class members seek restitution from Defendant, and seek an order from the Court disgorging all profits, benefits, and other compensation obtained by Defendant from its wrongful conduct.

EIGHTH CAUSE OF ACTION

(Breach of Express Warranty)

87. Plaintiffs, on behalf themselves and on behalf of all others similarly situated, reallege and incorporate herein by reference each of the foregoing paragraphs.

88. Defendant made an express warranty and/or approved the use of the express warranty to Plaintiffs and members of the Class that the PGS provided certain benefits as advertised and was accurate.

89. This promise regarding the nature of the PGS marketed by Defendant specifically related to the PGS being purchased and became the basis of the bargain.

90. Plaintiffs and the Class purchased the PGS based on the belief that they conformed to the express warranties that were made on the products' packaging.

91. Defendant breached the express warranty made to Plaintiffs and members of the Class by failing to supply the PGS in a manner that conformed to the warranty made. As a result, Plaintiffs and the members of the Class suffered injury and deserve to be compensated for the damages they suffered.

92. Plaintiffs and the members of the Class paid money for the PGS. However, Plaintiffs and the members of the Class obtained the PGS which did not provide the purported benefits and accuracy as represented. If Plaintiffs and other members of the Class had known of the true nature of the PGS, they would not have purchased the PGS.

93. Plaintiffs and the Class are therefore entitled to recover damages of the amounts they paid for the PGS.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request on behalf of themselves and other members of the Class, for judgment against Defendant as follows:

1. For preliminary and permanent injunctive relief enjoining Defendant, its agents, servants and employees, and all persons acting in concert with Defendant, from

engaging in, and continuing to engage in, the unfair, unlawful and/or fraudulent business practices alleged above and that may yet be discovered in the prosecution of this action;

2. For certification of the proposed Class, appointment of Plaintiffs as Class Representatives and appointment of Plaintiffs' counsel as Class Counsel to represent the Class;

3. For damages, restitution and disgorgement of all money or property wrongfully obtained by Defendant by means of their herein-alleged unlawful, unfair, and fraudulent business practices;

4. Recovery of the amounts by which Defendant have been unjustly enriched;

5. For an accounting by Defendant for any and all profits derived by Defendant from their herein-alleged unlawful, unfair and/or fraudulent conduct and/or business practices;

6. For attorneys' fees and expenses pursuant to all applicable laws including, without limitation, Cal. Code of Civil Procedure § 1021.5 and the common law private attorney general doctrine; and

7. For costs of suit; and for such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: January 28, 2014

FINKELSTEIN THOMPSON LLP

By: Rosemary M. Rivas

Rosemary M. Rivas
505 Montgomery Street, Suite 300
San Francisco, CA 94111
Telephone: (415) 398-8700
Facsimile: (415) 398-8704
E-Mail: rrivas@finkelsteinthompson.com

Vahn Alexander (#167373)
THE ALEXANDER FIRM P.C.

A PROFESSIONAL LAW CORP.
1875 Century Park East, Suite 700
Los Angeles, CA 90067
Telephone: (310) 407-5335
Facsimile: (310) 407-5338
E-mail: info@alexanderfirmpc.com

Amir S. Salehi
SALEHI & ASSOCIATES
12400 Wilshire Blvd., Suite 1300
Los Angeles, CA 90025
Tel: (310)820-3366
Fax: (310)820-3361
E-Mail: salehiassoc@lawyer.com

Attorneys for Plaintiffs Ben Martin Carrie Martin and Kryssa Cable

EXHIBIT A

Inspections, Compliance, Enforcement, and Criminal Investigations

23andMe, Inc. 11/22/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Nov 22, 2013
Ann Wojcicki
CEO
23andMe, Inc.
1390 Shoreline Way
Mountain View, CA 94043

Document Number: GEN1300666
Re: Personal Genome Service (PGS)

WARNING LETTER

Dear Ms. Wojcicki,

The Food and Drug Administration (FDA) is sending you this letter because you are marketing the 23andMe Saliva Collection Kit and Personal Genome Service (PGS) without marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act).

This product is a device within the meaning of section 201(h) of the FD&C Act, 21 U.S.C. 321(h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. For example, your company's website at www.23andme.com/health (most recently viewed on November 6, 2013) markets the PGS for providing "health reports on 254 diseases and conditions," including categories such as "carrier status," "health risks," and "drug response," and specifically as a "first step in prevention" that enables users to "take steps toward mitigating serious diseases" such as diabetes, coronary heart disease, and breast cancer. Most of the intended uses for PGS listed on your website, a list that has grown over time, are medical device uses under section 201(h) of the FD&C Act. Most of these uses have not been classified and thus require premarket approval or de novo classification, as FDA has explained to you on numerous occasions.

Some of the uses for which PGS is intended are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses (e.g., warfarin sensitivity, clopidogrel response, and 5-fluorouracil toxicity) because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these. For instance, if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist. Assessments for drug responses carry the risks that patients relying on such tests may begin to self-manage their treatments through dose changes or even abandon certain therapies

depending on the outcome of the assessment. For example, false genotype results for your warfarin drug response test could have significant unreasonable risk of illness, injury, or death to the patient due to thrombosis or bleeding events that occur from treatment with a drug at a dose that does not provide the appropriately calibrated anticoagulant effect. These risks are typically mitigated by International Normalized Ratio (INR) management under a physician's care. The risk of serious injury or death is known to be high when patients are either non-compliant or not properly dosed; combined with the risk that a direct-to-consumer test result may be used by a patient to self-manage, serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported.

Your company submitted 510(k)s for PGS on July 2, 2012 and September 4, 2012, for several of these indications for use. However, to date, your company has failed to address the issues described during previous interactions with the Agency or provide the additional information identified in our September 13, 2012 letter for **(b)(4)** and in our November 20, 2012 letter for **(b)(4)**, as required under 21 CFR 807.87(1). Consequently, the 510(k)s are considered withdrawn, *see* 21 C.F.R. 807.87(1), as we explained in our letters to you on March 12, 2013 and May 21, 2013. To date, 23andMe has failed to provide adequate information to support a determination that the PGS is substantially equivalent to a legally marketed predicate for any of the uses for which you are marketing it; no other submission for the PGS device that you are marketing has been provided under section 510(k) of the Act, 21 U.S.C. § 360(k).

The Office of In Vitro Diagnostics and Radiological Health (OIR) has a long history of working with companies to help them come into compliance with the FD&C Act. Since July of 2009, we have been diligently working to help you comply with regulatory requirements regarding safety and effectiveness and obtain marketing authorization for your PGS device. FDA has spent significant time evaluating the intended uses of the PGS to determine whether certain uses might be appropriately classified into class II, thus requiring only 510(k) clearance or de novo classification and not PMA approval, and we have proposed modifications to the device's labeling that could mitigate risks and render certain intended uses appropriate for de novo classification. Further, we provided ample detailed feedback to 23andMe regarding the types of data it needs to submit for the intended uses of the PGS. As part of our interactions with you, including more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications, we provided you with specific feedback on study protocols and clinical and analytical validation requirements, discussed potential classifications and regulatory pathways (including reasonable submission timelines), provided statistical advice, and discussed potential risk mitigation strategies. As discussed above, FDA is concerned about the public health consequences of inaccurate results from the PGS device; the main purpose of compliance with FDA's regulatory requirements is to ensure that the tests work.

However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses, which have expanded from the uses that the firm identified in its submissions. In your letter dated January 9, 2013, you stated that the firm is "completing the additional analytical and clinical validations for the tests that have been submitted" and is "planning extensive labeling studies that will take several months to complete." Thus, months after you submitted your 510(k)s and more than 5 years after you began marketing, you still had not completed some of the studies and had not even started other studies necessary to support a marketing submission for the PGS. It is now eleven months later, and you have yet to provide FDA with any new information about these tests. You have not worked with us toward de novo classification, did not provide the additional information we requested necessary to complete review of your 510(k)s, and FDA has not received any communication from 23andMe since May. Instead, we have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA.

Therefore, 23andMe must immediately discontinue marketing the PGS until such time as it receives

FDA marketing authorization for the device. The PGS is in class III under section 513(f) of the FD&C Act, 21 U.S.C. 360c(f). Because there is no approved application for premarket approval in effect pursuant to section 515(a) of the FD&C Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the FD&C Act, 21 U.S.C. 360j (g), the PGS is adulterated under section 501(f)(1)(B) of the FD&C Act, 21 U.S.C. 351(f)(1)(B). Additionally, the PGS is misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because notice or other information respecting the device was not provided to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific actions you have taken to address all issues noted above. Include documentation of the corrective actions you have taken. If your actions will occur over time, please include a timetable for implementation of those actions. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the actions will be completed. Failure to take adequate corrective action may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

James L. Woods, WO66-5688
Deputy Director
Patient Safety and Product Quality
Office of In vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, please feel free to call Courtney Lias, Ph.D. at 301-796-5458, or log onto our web site at www.fda.gov[1] for general information relating to FDA device requirements.

Sincerely yours,
/S/
Alberto Gutierrez
Director
Office of In vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Page Last Updated: 11/25/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. http://www.fda.gov

Exhibit B

AFFIDAVIT OF ROSEMARY M. RIVAS

I, Rosemary M. Rivas, declare as follows:

1. I am a partner with the law firm Finkelstein Thompson LLP, counsel for Plaintiffs Ben Martin, Carrie Martin, and Kryssa Cable in this action. I am admitted to practice law in California and before this Court, and am a member in good standing of the State Bar of California. This declaration is made pursuant to California Civil Code section 1780(d). I make this declaration based on my research of public records and also upon personal knowledge and, if called upon to do so, could and would testify competently thereto.

2. Based on my research of public records and personal knowledge, Defendant 23andMe, Inc. does business within this County, as alleged in the accompanying Class Action Complaint.

I declare under penalty of perjury under the laws of the United States and State of California this 28th day of January 2014 in San Francisco, California that the foregoing is true and correct.

Rosemary M. Rivas

JS 44 (Rev. 12/12)
Cand rev (1/15/13)

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

BEN MARTIN, CARRIE MARTIN, and KRYSSA CABLE, on Behalf of Themselves and All Other Persons Similarly Situated,

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Rosemary M. Rivas
FINKELSTEIN THOMPSON LLP
505 Montgomery Street, Suite 300, San Francisco, CA 94111
Telephone: (415) 398-870

DEFENDANTS

23ANDME, INC.

County of Residence of First Listed Defendant Santa Clara County
(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
- x 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	x 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	x 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)*

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
- ☐ 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
- ☐ 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
- x 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

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) (2)

Brief description of cause:
False Advertising and unlawful, unfair and deceptive business practices.

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: x Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Lucy H. Koh DOCKET NUMBER 13-CV-05682

X. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

Place an "X" in One Box Only) ( ) SAN FRANCISCO/OAKLAND (X) SAN JOSE ( ) EUREKA

DATE 1/28/14

SIGNATURE OF ATTORNEY OF RECORD