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AMERICAN ARBITRATION ASSOCIATION

KAREN DAVIS-HUDSON and SARAH DIAZ, Claimants, vs. 23ANDME, INC., Respondent.	AAA No.: 74-20-1400-0032 **RESPONSE TO FIRST AMENDED COMPLAINT FOR CLASS ACTION ARBITRATION**

Respondent 23andMe, Inc. ("23andMe" or the "Company") responds to the First Amended Demand for Class Arbitration filed by Claimants Karen Davis-Hudson and Sarah Diaz (the "Complaint") as follows.

GENERAL DENIAL

23andMe generally denies each and every of the Complaint's material allegations and implications, specifically including:

- That 23andMe's personal genome service (the "PGS") failed to provide information that is useful and valuable to consumers;
- That the manner in which 23andMe marketed the PGS was in any way deceptive, inaccurate, untrue, unfair, fraudulent or unlawful;
- That the PGS failed to perform the functions described in the Terms of Service and other website descriptions pursuant to which the PGS was sold to customers;
- That the PGS was marketed or described as providing diagnoses;
- That 23andMe stated or implied that the PGS had received FDA approval, or that the PGS "had been approved by the government for sale and purchase";
- That 23andMe concealed the fact that the PGS was being marketed, advertised and sold from the FDA, or that the FDA was not fully aware of the details of the marketing, advertising and sale of the PGS at any time during the alleged class period;
- That the November 22, 2013 FDA "warning letter asserted that any statement made by 23andMe in the course of marketing, advertising or selling the PGS was false or materially misleading;
- That the PGS was worth less than the purchase price paid by Claimants or members of the alleged class;
- That 23andMe counseled, purported to provide, medical advice or diagnoses;
- That 23andMe counseled, advised or encouraged customers to self-manage their medical treatment, or make medical decisions without consulting a physician;
- That the information provided to PGS customers was unsupported by scientific studies and data;
- That 23andMe committed any other violation of law, or breached any duty, as alleged in the Complaint or otherwise;

- That 23andMe earned profits on the PGS at any time during the alleged class period;
- That the "health component" of the PGS to which Claimants and members of the alleged class continue to have access (without updates) lacks substantial value;
- That the health component of the PGS is worth less than the "ancestry" and "raw data" components of the PGS, which were unaffected by the November 22, 2013 FDA Warning Letter and are not covered by the claims asserted in the Complaint;
- That Claimants are entitled to recover disgorgement, restitution or damages from 23andMe;
- That Claimants are entitled to injunctive relief;
- That 23andMe violated the Federal Food, Drug and Cosmetic Act;
- That 23andMe violated any portion or prong of Sections 17200 *et seq.* of the California Business & Professions Code;
- That 23andMe violated Sections 17500 *et seq.* of the California Business & Professions Code;
- That 23andMe breached the implied warranty of merchantability under Section 2314 of the California Commercial Code;
- That 23andMe breached the implied warranty of fitness for a particular purpose under Section 2315 of the California Commercial Code;
- That 23andMe violated the California Legal Remedies Act, Section 1750 *et seq.* of the California Civil Code;
- That 23andMe negligently misrepresented materials facts regarding the PGS;
- That 23andMe was unjustly enriched by the sale of the PGS; and
- That Claimants are legally entitled to certify a national class on the claims asserted in the Complaint.

OVERVIEW OF 23ANDME AND ITS BUSINESS

23andMe is a small privately held personal genetics company dedicated to helping individuals access and understand their personal genetic data. The Company was founded in 2006 with backing from prominent health science companies. It employs a staff of scientists and other professionals, as well as an outside scientific advisory board composed of recognized

experts in human genetics, bioinformatics and computer science. 23andMe also participates in a variety of medical school and research programs that advance the rapidly evolving understanding of genetics.

During the class period alleged in the Complaint 23andMe provided heavily subsidized "direct to consumer" genetic testing and services that leveraged findings from the Human Genome Project, and a platform through which individuals could participate in ongoing genetic research. The Personal Genome Service, or PGS, consisted of three components -- "health," "ancestry" and "raw data" -- only one of which (health) is the subject of Claimants' claims asserted in the "Complaint.

The PGS was named Invention Of The Year by *Time* Magazine in 2008. 23andMe thereafter raised additional money from investors to subsidize and lower the PGS price to $99 and further genetic research. It has sold the PGS at a loss since it was launched in 2007, while maintaining an A-plus rating from the Better Business Bureau. Because 23andMe sold the PGS well below cost, during the alleged class period the Company incurred a loss of approximately $89 million on sales of approximately $80 million.

In November of 2013 the FDA sent 23andMe the Warning Letter that is the focal point of Claimants' claims. The Warning Letter did not assert that any statement made by 23andMe regarding the PGS was false or misleading. Nor did the FDA require 23andMe to make any change to the ancestry or raw data components, or to remove the health-related information generated before November 22, 2013 from the website. Accordingly, all members of the alleged class continued to have unrestricted access to the ancestry and raw data components, and to the health component as it existed on the date of the FDA Warning Letter (albeit without future updates).

After the Warning Letter the Company suspended inclusion of the health component in the PGS. From December 2012 through October 2015 23andMe sold the ancestry and raw data components for the same $99 price, at which the PGS had been sold when it contained the health component. From January–July 2015 sales of the PGS with the ancestry and raw data

components alone were higher than sales during the same period in 2013, when the health component was included in the PGS, despite the posting of Warning Letter information on the Company website and a much lower advertising spend. 23andMe has resumed marketing the PGS's health component, which currently includes 62 reports and will continue to expand.

THE PERSONAL GENOME SERVICE

Members of the alleged class purchased the PGS at 23andMe's online store, after reviewing the Terms of Service ("TOS") that governed the transactions. They then provided a saliva sample via a collection kit furnished by the Company. The sample was tested at a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, using state of the art equipment. The laboratory process read nearly one million specific points on each customer's genome, and generated an encrypted electronic data set. 23andMe provided the raw genetic data, analyses, comprehensive ancestry and health-related profiles based on the customer's data, along with explanatory information and navigation tools, all of which are accessed (under secure conditions) on the Company website.

The ancestry component of the PGS is the largest DNA ancestry service in the world. Using a large database and sophisticated laboratory techniques, it provides a personalized DNA analysis that enables customers to (among other things) build a family tree, locate relatives nearby or throughout the world, trace their lineage back 10,000 years, learn what parts of the world their ancestors came from, determine their percentage of Neanderthal ancestry, and identify DNA relatives.

The raw genetic data provided as part of the PGS is obtained through extensive testing performed by a certified third-party laboratory using state-of-the-art equipment. Laboratories frequently charge prices in excess of the $99 that most of the alleged class paid for the entire PGS to perform the testing required to generate such data. Consumers can send the data included in the PGS to a third party to obtain health information for as little as $5. *See, e.g.*, http://www.snpedia.com/index.php/Promethease.

The health component to which all alleged class members retained access after the FDA

Warning Letter provided a personalized overview of genetic traits and health risks, based on extensive scientific literature. As the website made clear, the information regarding specific health risks was provided for the purpose of follow-up with medical professionals, and was based on laboratory tests that accurately detect the presence of inherited mutations documented in the NIH database. The website also provided links to scientific studies, white papers and counseling services.

MARKETING OF THE PERSONAL GENOME SERVICE

The PGS is sold exclusively through the Company's website, and all customers are required to review and affirmatively accept 23andMe's TOS before the website purchase can be completed. The website makes clear that agreement to the TOS is a condition of the PGS sale and that the TOS constitute the legal contract that governs the sale.

Contrary to the allegations of the Complaint, the TOS made explicitly clear that the health information was not intended to -- and did not -- provide medical diagnoses or a diagnostic tool that could be used without consultation with medical professionals, and stated that the health component was intended for informational and educational uses. For example, the TOS emphasized:

- That the PGS is intended for research, informational and educational use only;
- That the results of 23andMe's analyses are not intended to be used by the customer for any diagnostic purpose;
- That 23andMe cannot diagnose diseases or medical conditions, provide medical advice or otherwise assess the customer's health;
- That the information provided to the customer is intended for discussion with the customer's physician;
- That the information and analyses provided are not a substitute for professional medical advice;
- That customers should not feel protected based on the health information provided by 23andMe;
- That customers should not change their health behavior solely on the basis of the information provided;

- That customers should make sure to discuss the genetic information with a physician or other health care provider before acting on it; and
- That only a trained physician can assess the customer's state of health or disease, taking into account many factors.

The TOS also further cautioned customers regarding limitations on the role that genetics play in determining health risks, the current state of scientific understanding of genetics, and the scientific literature that 23andMe used in connection with the health component, including:

- That known genes are responsible for a fraction of health risks, and that unknown genes, environmental factors and lifestyle choices are more important predictors of health risk;
- That the understanding of genetic information is incomplete and rapidly evolving; and
- That many of the genetic discoveries reported in scientific literature and on the Company's website have not been clinically validated.

In addition to the limitations explained in the TOS and elsewhere on the website, the health information itself noted that it was intended for educational purposes, and is not for diagnostic use. Additional cautions were included in the packaging of the saliva collection kit mailed to customers.

23ANDME'S INTERACTIONS WITH THE FOOD AND DRUG ADMINISTRATION

23andMe never stated or implied that the PGS had received FDA approval, and in fact made clear that it had merely begun the process of obtaining such approvals. Nor was anything concealed from the FDA, which was at all times fully aware that 23andMe was marketing the PGS, and of the specifics of the Company's marketing and advertising efforts.

Representatives of the Company met with the FDA before launching the PGS in 2007, and discussed the service and the Company's business plan. The FDA lodged no objections, and encouraged 23andMe to proceed. 23andMe continued to meet and communicate with the FDA regarding the PGS and the manner in which the FDA intended to regulate the PGS, if at all. In June 2010 the FDA notified the Company that it intended to regulate the PGS under the Federal

Food, Drug and Cosmetic Act. After a series of meetings and discussions regarding the appropriate regulatory path, 23andMe delivered its first round of formal documentation to the FDA in July 2012, and issued a press release announcing that it was beginning the process of pursuing FDA approval.

In November 2013, the FDA sent 23andMe a letter expressing dissatisfaction with the level of recent communication by the Company, and with the testing documentation that had been submitted to that point. The FDA letter did not state that any of the information 23andMe provided to its customers was inaccurate, or that statements made in marketing the PGS were false or misleading. Moreover, the FDA agreed that 23andMe could continue to provide everyone who had purchased the PGS prior to the date of the Warning Letter, which it obviously would not have done if it had concluded that the health information or related statements were false or misleading. The FDA also agreed that 23andMe could continue to market the ancestry and raw data components, which were unaffected by the Warning Letter.

23andMe continued to pursue FDA approval for health information, and improved the data submission and communication processes that had prompted the Warning Letter. The FDA has now cleared 62 health component reports, with more in the pipeline.

KEY DEFECTS IN ASSERTED CLAIMS

The claims asserted in the Complaint are based exclusively on the FDA Warning Letter, which does not support the premise that underlies the claims, *i.e.*, that 23andMe made false or materially misleading statements regarding health component of the PGS. The Warning Letter contains no such assertion. The fact that the FDA did not require 23andMe to remove the health information from the website, and permitted all members of the alleged class to continue to access it, underscores the fact that the FDA did not reach any such conclusion.

There is no basis for any allegation that 23andMe stated or implied that the PGS had received FDA approval. The Company never made any statement or suggestion to that effect, and issued a press release in 2012 noting that it was just beginning the lengthy process of seeking such approval.

The Complaint does not -- and cannot -- claim that 23andMe concealed the fact that it was marketing the PGS from the FDA. It is undisputed that the FDA was in the loop from the very beginning, and was aware of the specifics of the Company's marketing efforts throughout the alleged class period.

There is no basis for any claim that the PGS health component was marketed as providing medical diagnoses or medical advice. The TOS pursuant to which Claimants and members of the alleged class purchased the PGS repeatedly stated precisely the opposite.

Claimants cannot portray 23andMe as a greedy company that earned profits from the PGS. There were no profits. Rather, the PGS was sold far below cost throughout the alleged class period, and 23andMe incurred an $89 million loss on the PGS sales at issue.

The fact that the PGS was sold at a heavily subsidized cost throughout the alleged class period severely undercuts any claim that members of the alleged class suffered damages because they overpaid for it.

Claimants' attempt to establish damages is further undercut by the fact that the ancestry and raw data components of the PGS were worth more than the health component, as demonstrated by the sales data.

Claimants' ability to establish substantial damages is also blocked by the obvious value of the health component itself, and the FDA's decision to permit the members of the alleged class to have continued access to the health component notwithstanding the Warning Letter.

Claimants' inability to establish substantial damages is further reinforced by the fact that the vast majority of alleged class members purchased the PGS in part because they wanted to further the cause of genetic research. Approximately 80% of the alleged class members expressly consented to use of their genetic data for research purposes.

Claimants are legally precluded from certifying a national class on the California consumer statutes that comprise the bulk of their claims by *Mazza v. American Honda Motor Co.*, 666 Fed. 3d 581, 590-94, 596 (9th Cir. 2012). Those claims cannot be asserted on behalf non-California residents, and state law variances with respect to the remaining claims will overwhelm

common legal questions. *Id.*

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