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11 **UNITED STATES DISTRICT COURT**
12 **SOUTHERN DISTRICT OF CALIFORNIA**

13 KYLE DILGER, on behalf of himself and
14 all other similarly situated,

15 Plaintiff,

16 vs.

17 23ANDME, INC., a Delaware
18 corporation,

19 Defendant.

Case No.: '14CV0296 MMABGS

COMPLAINT (CLASS ACTION)

For Violations Of:

- 1) Business and Professions Code
§§17200 *et seq.*
- 2) Consumer Legal Remedies Act,
Civil Code §§1750 *et seq.*

(Jury Trial Demanded)

20
21 Plaintiff Kyle Dilger (“Plaintiff”) brings this action, by and through his
22 undersigned counsel, on behalf of himself and all others similarly situated, based on
23 information and belief and the investigation of counsel, except for information based
24 on personal knowledge, and hereby alleges as follows:

25 **I. NATURE OF ACTION**

26 1. This is a consumer protection and false advertising class action.
27 Defendant 23andMe, Inc. (“Defendant” or “23andMe”) markets, advertises, sells,
28 distributes, and processes a 23andMe Saliva Collection Kit and Personal Genome

1 Service (collectively, its “Product”). Specifically, Defendant mails a “DNA Spit
2 Kit” to consumers across the United States that is to be returned to Defendant for
3 DNA processing and analysis.

4 2. Through this class action, Plaintiff challenges Defendant’s unlawful and
5 unfair business practice of distributing its Product to the public without disclosing
6 that the products are not-FDA approved, misbranded, adulterated, and not known to
7 be accurate.

8 3. Such untrue, deceptive and misleading practices violate California’s
9 consumer protection laws and gives rise to claims under the Unfair Competition Law
10 (Cal. Bus. & Prof. Code §§ 17200 *et seq.*, hereinafter referred to as the “UCL”), and
11 the Consumer Legal Remedies Act (Cal. Civ. Code §§ 1750 *et seq.*, hereinafter
12 referred to as the “CLRA”). This Complaint alleges violations of California’s
13 Sherman Food, Drug and Cosmetic Act (California Health and Safety Code §§
14 110100, *et seq.* (“Sherman Law”) as predicate acts of a violation of Cal. Bus. &
15 Prof. Code § 17200.

16 4. At relevant times during the Class Period, Plaintiff purchased
17 Defendant’s Product online at Defendant’s website, www.23andme.com.

18 5. At the time of Plaintiff’s initial purchase, Defendant did not disclose
19 that the Product (1) was not approved by any governmental regulatory body,
20 including, but not limited to, the Food and Drug Administration (“FDA”) and the
21 California Department of Health Services (“DHS”); (2) was misbranded under
22 applicable law; (3) was adulterated under applicable law; and (4) that Defendant did
23 not have analytical or clinical data to support the Products efficacy, making the
24 Product’s accuracy questionable due to lack of proper testing (the “Material
25 Omissions”).

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1 **III. THE PARTIES**

2 13. Plaintiff Kyle Dilger is an adult individual who resides in Orange
3 County, California. He appears individually and on behalf of all those similarly
4 situated as described herein. He asserts all claims in this case on behalf of the Class
5 defined below.

6 14. Defendant 23andMe, Inc. is, and at all times mentioned herein was, a
7 Delaware corporation, with its headquarters, principal place of business and nerve
8 center at 1390 Shorebird Way, Mountain View, California 94043. Defendant’s
9 agent for service of process in the State of California is Anne Wojcicki whose
10 registered business address is also 1390 Shorebird Way, Mountain View, California
11 94043. Defendant distributes the Products to consumers throughout California and
12 throughout the United States.

13 **IV. FACTUAL ALLEGATIONS**

14 **A. Defendant’s Product**

15 15. Throughout the Class Period, Defendant has marketed, advertised,
16 sold, distributed, and processed its Product – the 23andMe Saliva Collection Kit
17 and Personal Genome Service. Defendant describes its Product as follows:

18 The 23andMe Personal Genome Service is a comprehensive genetic
19 scan of a subset of the SNPs (single nucleotide polymorphisms) in
20 your genome which correspond to the SNP data being studied by the
21 research community. Individuals provide saliva samples which are
22 analyzed by our CLIA-certified laboratory, and the results are
23 returned to your online account in approximately 6-8 weeks.
24 23andMe provides both health and ancestry information in a single
25 service for a single price. In addition to the features below, you also
26 have the ability to browse and download your raw genotyped data.

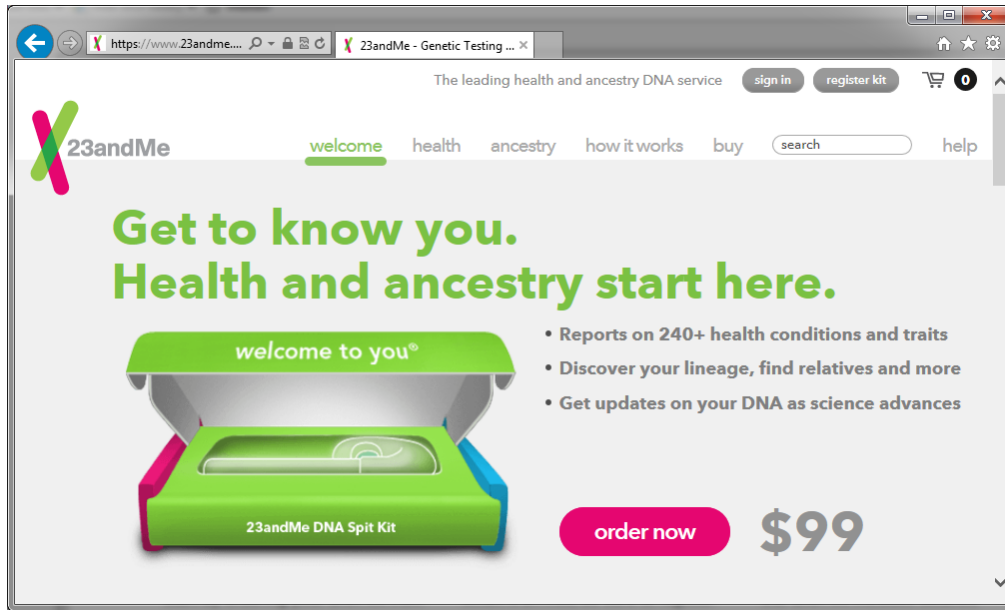
27 “FAQ: About the 23andMe Personal Genome Service” available online at
28 <[https://customercare.23andme.com/entries/22591668-About-the-23andMe-
Personal-Genome-Service](https://customercare.23andme.com/entries/22591668-About-the-23andMe-Personal-Genome-Service)> (last accessed on December 4, 2013).

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1 16. Upon information and belief, Defendant’s Product is sold exclusively
2 on its www.23andme.com website:



14 17. Currently, the Product is sold at a price of \$99.00, but was previously
15 sold at significantly higher prices.

16 18. Defendant’s website states that “[g]etting started is simple” and
17 outlines the process: (1) order the DNA spit kit; (2) register the DNA spit kit’s bar
18 code online; and (3) return the DNA spit kit to Defendant. “How It Works”
19 available online at <<https://www.23andme.com/howitworks>> (last accessed on
20 December 4, 2013).

21 19. Defendant states that based on a consumer’s DNA, it will “provide
22 specific health recommendations” such as whether is a person is at risk of celiac
23 disease (gluten sensitivity), whether you are a carrier for certain mutations that are
24 passed on to children, or at risk for certain drug reactions. *Id.*

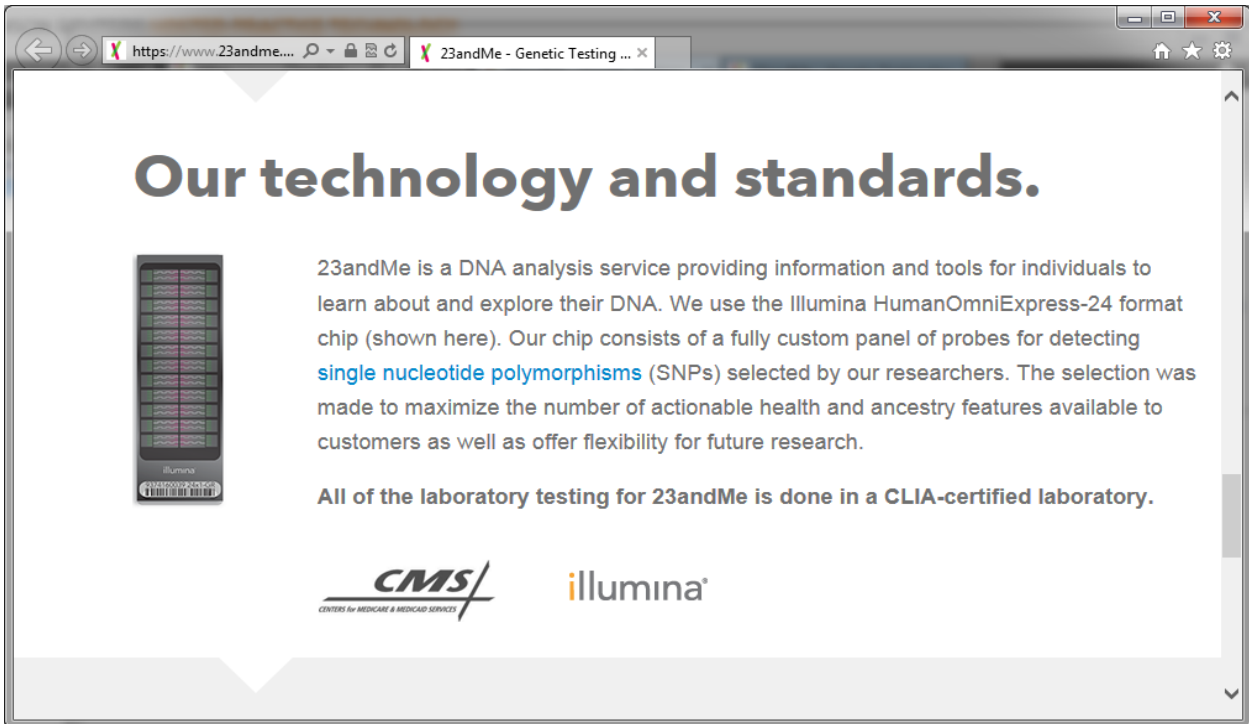
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1 20. Under the heading “Our technology and standards”, Defendant states
2 the following:



15
16 *Id.* Notably, Defendant displays the logo of the Centers for Medicare and Medicaid
17 Services in the technology and standards section on its website.

18 21. The Centers for Medicare & Medicaid Services (“CMS”), is a federal
19 agency within the United States Department of Health and Human Services that
20 administers the Medicare program and works in partnership with state
21 governments to administer Medicaid. In addition, CMS has other responsibilities,
22 including the administering clinical laboratory quality standards.

23 22. Defendant states the following with regards to the quality of the
24 Product:

25 How well does the technology work?

26 The vast majority of the variants on our chip, especially those associated
27 with our Health and specific Ancestry features, have a 98% or greater call
28 rate, meaning that the chip can provide accurate data for more than 98% of
those variants in any particular person. Variants for which a confident
determination cannot be made are reported as "no calls." A small portion of
variants, including those on the sex chromosomes (X and Y) and the

1 mitochondrial DNA, are difficult to analyze because of biological issues
2 (e.g. pseudogenes, DNA structure, and highly variable regions). These
3 variants will typically have a lower call rate.

4 While we do not include genetic markers with low call rates in our Health
5 reports, they are still valuable in our ongoing research efforts and so you
6 may see information for some of them in your raw data.

7 “FAQ: About the 23andMe Personal Genome Service” available online at
8 <[https://customercare.23andme.com/entries/22591668-About-the-23andMe-](https://customercare.23andme.com/entries/22591668-About-the-23andMe-Personal-Genome-Service)
9 [Personal-Genome-Service](https://customercare.23andme.com/entries/22591668-About-the-23andMe-Personal-Genome-Service)> (last accessed on December 4, 2013).

10 23. On information and belief, the actual DNA Spit Kit packaging is
11 standard packaging that Defendant has distributed and continues to distribute for
12 sale to the public throughout the State of California and the United States during
13 the Class Period. Plaintiff received the standard DNA Spit Kit after placing his
14 order in March 2012.

15 B. Defendant’s Product is a Medical Device Requiring Premarket
16 Approval

17 24. Under both the FDCA and the Sherman Law, Defendant’s Product is a
18 “device” because it is intended for use in the diagnosis of disease or other
19 conditions or in the cure, mitigation, treatment, or prevention of disease, or is
20 intended to affect the structure or function of the body. *See* 21 U.S.C. §321(h) and
21 California Health and Safety Code § 109920.

22 25. Additionally, upon information and belief, Defendant’s Product has
23 been categorized by the FDA a Class III medical device.¹

24 26. As such, Defendant’s Product is subject to premarket approval by
25 FDA before the Product can be marketed in the U.S.

26 ¹ *See* 21 U.S.C. §360c(a)(1)(C); *see also* FDA Warning Letter dated November 22,
27 2013, *available online at* <[http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm37629](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm)
28 [6.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm)> (last accessed December 4, 2013) (“Most of the intended uses for PGS
listed on your website...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...”).

1 27. The premarket approval (“PMA”) is the FDA process of scientific and
2 regulatory review to evaluate the safety and effectiveness of Class III medical
3 devices, such as Defendant’s Product.

4 28. Due to the level of risk associated with Class III devices, the FDA
5 has determined that general and special controls alone are insufficient to assure the
6 safety and effectiveness of Class III devices.

7 29. Therefore, new Class III devices must clear FDA premarket review by
8 either PMA² or through the “510(k) process.”³

9 30. PMA is the most stringent type of device marketing application
10 required by the FDA. The applicant must receive FDA approval of its PMA
11 application prior to marketing the device. PMA approval is based on a
12 determination by the FDA that the PMA contains sufficient valid scientific
13 evidence to assure that the device is safe and effective for its intended use(s). An
14 approved PMA is, in effect, a private license granting the applicant (or owner)
15 permission to market the device.

16 31. The regulation governing premarket approval is located in Title 21
17 Code of Federal Regulations (CFR) Part 814, Premarket Approval.

18 32. A Class III device that fails to meet PMA requirements is considered
19 to be adulterated under section 501(f) of the FDCA and cannot be marketed.

20 33. In addition to the PMA process, medical devices can receive FDA
21 clearance through the premarket notification, or “510(k)” process.

22 34. Pursuant to the 510(k) process, FDA approval to market a device can
23 be secured by submitting a premarket notification application which establishes
24 that the device is “substantially equivalent” to a Class I or II device already on the
25 market or a Class III device on the market prior to May 28, 1976.⁴

26 ² 21 U.S.C. §§ 360c(a)(1)(C), 306e.

27 ³ 21 U.S.C. § 360c(f)(1); 360c(b)(1).

28 ⁴ *See* 21 U.S.C. § 360(i)(1)(A); 21 C.F.R. §§ 807.81, 807.87.

1 35. Upon information and belief, Defendant submitted its first 510(k)
2 applications for basic FDA approval on July 2, 2012 and September 4, 2012, but
3 has yet to receive any clearance, approval, or certification from the FDA.

4 36. On November 22, 2013, the Director of the FDA's Public Health
5 Service issued a Warning Letter to Defendant, which stated, in relevant parts, as
6 follows:

7 "The [FDA] is sending you this letter because you are marketing the
8 [Product] without marketing clearance or approval in violation of the
9 [FDCA]

10 ...

11 Most of the intended uses for [the Product] listed on your website...
12 are medical device uses under section 201(h) of the [FDCA]. Most of
13 these uses have not been classified and thus require premarket
14 approval or de novo classification, as FDA has explained to you on
15 numerous occasions.

16 FDA Warning Letter dated November 22, 2013, *available online at*
17 [http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm37629](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm)
18 [6.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm)> (last accessed December 4, 2013).

19 37. The Warning Letter further noted that:

20 Some of the uses for which PGS is intended are particularly
21 concerning, such as assessments for BRCA-related genetic risk and
22 drug responses (e.g., warfarin sensitivity, clopidogrel response, and 5-
23 fluorouracil toxicity) because of the potential health consequences that
24 could result from false positive or false negative assessments for high-
25 risk indications such as these. For instance, if the BRCA-related risk
26 assessment for breast or ovarian cancer reports a false positive, it
27 could lead a patient to undergo prophylactic surgery,
28 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.

Id.

38. In addition, the Warning Letter noted that after years of exchanges,
the FDA still has no "assurance that [Defendant] has analytically or clinically
validated the [Product] for its intended uses, which have expanded from the uses
that the firm identified in its submissions." *Id.*

1 39. Rather, as of January 9, 2013, Defendant was ““completing the
2 additional analytical and clinical validations for the tests that have been submitted’
3 and [was] ‘planning extensive labeling studies that will take several months to
4 complete.’” *Id.*

5 40. Upon information and belief, to date, Defendant has not satisfied any
6 of the Premarket approval requirements for its Product, as Defendant’s 510(k)
7 applications are currently considered withdrawn and Defendant has failed to
8 provide adequate information to support a determination that the Product is
9 substantially equivalent to a legally marketed predicate device for any of the uses
10 for which the Product is currently marketed.

11 41. In all, Defendant has been marketing, selling, and distributing the
12 Product to Plaintiff and Class members for a number of years without the required
13 Premarket approval.

14 42. Defendant omits the following from its website, 23andMe.com, and
15 the packaging of its DNA spit kit:

- 16 a. that Defendant’s Product is a medical device, which is not
17 approved by any governmental regulatory body, including, but not
18 limited to, the CMS, the FDA, and DHS;
- 19 b. that Defendant’s product is misbranded under applicable law,
20 including, but not limited to, 21 U.S.C. § 352(o), and California
21 Health and Safety Code §§ 111330;
- 22 c. that Defendant’s product is adulterated under applicable law,
23 including, but not limited to, 21 U.S.C. § 351(f)(1)(B);
- 24 d. that Defendant’s Product is not known to be accurate;
- 25 e. that Defendant’s Product may report inaccurate results;
- 26 f. that Defendant’s Product may report false positives or false
27 negatives; and
28

1 g. that Defendant's Product was subject to an on-going governmental
2 investigation.

3 43. On information and belief, the 23andMe website described in the
4 paragraphs has been materially consistent throughout the Class Period.

5 44. Plaintiff reviewed the www.23andMe.com website before placing his
6 purchase in March 2012.

7 45. As a result, Plaintiff and other Class members were unaware of the
8 material omissions identified in Paragraph 5 above.

9 C. Plaintiff's Claims Are Predicated On Violations of California's
10 Sherman Food, Drug, and Cosmetic Law

11 46. The FDCA includes an explicitly preemption provision in the form of
12 section 360k(a), which provides:

13 [N]o State or political subdivision of a State may establish or continue
14 in effect with respect to a device intended for human use any
15 requirement- 1) which is different from, or in addition to, any
16 requirement applicable under this chapter to the device, and 2) which
relates to the safety or effectiveness of the device or to any other
matter included in a requirement applicable to the device under this
chapter.

17 47. Although section 360k speaks in terms of what states may *not* do, by
18 negative implication, section 360k also expresses what state *may* do, i.e., states
19 *may* establish their own requirements pertaining to a requirement for a medical
20 device so long as the state's requirements are identical to the requirements of the
21 FDCA.

22 48. As provided below, Plaintiff's claims are predicated on, among other
23 things, Defendant's violations of California's Sherman Food, Drug, and Cosmetic
24 Law.

25 49. The sections of the Sherman Law Plaintiff claims Defendant violated
26 as predicates violations of the UCL parallel the federal requirements under the
27 FDCA.

28

1 50. Plaintiff is not seeking to enforce, or to restrain violations of the
2 FDCA. Rather, Plaintiff's claims are predicated on California state laws
3 establishing independent state requirements identical to the requirements imposed
4 by the FDCA, something Congress explicitly approved in section 360k of the
5 FDCA.

6 51. As such, Plaintiff's claims are not preempted by federal law.

7 **V. INJURY AND DAMAGE**

8 52. By selling the Product exclusively through its own website, Defendant
9 ensured that Plaintiff and all Class members would be subject to the same material
10 representations and omissions.

11 53. Plaintiff and the members of the Class suffered actual and direct
12 injury, incurred damage and financial loss as a result of Defendant's conduct
13 complained of herein. Among other things, Plaintiff and the Class paid a premium
14 price for the 23andMe Product purchased the Product unaware of the material
15 omissions identified in Paragraph 5.

16 54. Had Plaintiff known of the material omissions identified in Paragraph
17 5, he would not have paid the premium price that he paid. Rather, he would have
18 paid less money for the Product and/or purchased a substitute Product. By
19 omitting said information, Defendant injured Plaintiff and the members of the
20 Class, caused them damage and caused them to incur out-of-pocket financial loss.

21 **VI. CLASS ACTION ALLEGATIONS**

22 55. Plaintiff seeks relief in his individual capacity and seeks to represent
23 a class consisting of all others who are similarly situated. Pursuant to Fed. R. Civ.
24 P. 23(a) and (b)(2) and/or (b)(3), Plaintiff seeks certification of a class initially
25 defined as follows:

26 All persons residing in the United States who purchased Defendant's
27 23andMe Saliva Collection Kit and Personal Genome Service from
28 the *www.23andMe.com* website at any time during the Class Period
(hereinafter, the "Class").

1 The “Class Period” dates back four years (or the length of the longest applicable
2 statute of limitations for any claim asserted) from the date this action was
3 commenced and continues through the present and the date of judgment.
4 Specifically excluded from the Class are: (a) any officers, directors or employees of
5 the Defendant; (b) any judge assigned to hear this case (or spouse or immediate
6 family member of any assigned judge); (c) any employee of the Court; (d) any juror
7 selected to hear this case; and (e) any attorneys’ of record and their employees.

8 **56. Numerosity of the Class.** Members of the Class are so
9 numerous that their individual joinder herein is impracticable. The precise
10 number of members of the Class and their addresses are presently unknown
11 to Plaintiff, but is believed to exceed 1,000 people.

12 **57. Ascertainable Class.** The proposed Class is ascertainable from
13 objective criteria.

14 **58. Common Questions of Fact and Law Exist and Predominate**
15 **over Individual Issues.** There is a well-defined community of interest in
16 the questions of law and fact involved affecting the parties to be
17 represented. These common questions of law and fact exist as to all
18 members of the Class and predominate over the questions affecting only
19 individual members of the Class. These common legal and factual
20 questions include without limitation:

- 21 a) Whether Defendant’s failure to inform Plaintiff and Class
22 members that the Product is adulterated under applicable law
23 constitutes a material omission likely to deceive a consumer;
24 b) Whether Defendant’s failure to inform Plaintiff and Class
25 members that the Product is misbranded under applicable law
26 constitutes a material omission likely to deceive a consumer;
27 c) Whether Defendant’s failure to inform Plaintiff and Class
28 members that the Product is not known to be accurate and/or may

1 report false positives or false negatives constitutes a material
2 omission likely to deceive a consumer;

3 d) Whether Defendant violated California Civil Code §§ 1750, *et*
4 *seq.* by omitting that the Product did not have the previously
5 specified sponsorship, approval, characteristics, uses, or benefits.

6 e) Whether Defendant violated California Business and Professions
7 Code §§ 17200, *et seq.*; and

8 f) Whether Plaintiff and Class members sustained injury and
9 damages resulting from Defendant's conduct and, if so, the
10 proper measure of damages, restitution, equitable, or other relief,
11 and the amount and nature of such relief.

12 59. **Typicality.** Plaintiff's claims are typical of the claims of
13 members of the Class. Typical of other class members, Plaintiff purchased
14 Defendant's Product using Defendant's www.23andMe.com website.
15 Plaintiff and the Class members each sustained damages arising from
16 Defendant's common course of wrongful conduct, as alleged more fully
17 herein. Plaintiff's claims are founded on the same legal theories as those of
18 the Class. The effort Plaintiff undertakes to pursue his own claim will
19 significantly benefit the Class members because of the identical nature of
20 the issues across the Class.

21 60. **Adequacy of Representation.** Plaintiff will fairly and adequately
22 represent and protect the interest of the members of the Class. Plaintiff shares a
23 common interest with the Plaintiff Class members, with respect to the conduct of
24 the Defendant herein and redress of injury. Plaintiff has suffered an injury-in-fact
25 as a result of the conduct of the Defendant, as alleged herein. Plaintiff has retained
26 counsel who are competent and experienced in the prosecution of complex
27 consumer fraud, mass tort and class actions. Plaintiff and his counsel intend to
28 prosecute this action vigorously and faithfully for the benefit of the Class

1 members. Plaintiff has no interests contrary to the class members, and will fairly
2 and adequately protect the interests of the Class.

3 **61. Community of Interest.** The proposed Class has a well defined
4 community of interest in the questions of fact and law to be litigated. The common
5 questions of law and fact are predominant with respect to the liability issues, relief
6 issues and anticipated affirmative defenses. The named Plaintiff has claims typical
7 of the Class members. Without limitation, as a result of Defendant's conduct
8 alleged herein, Plaintiff was: (a) injured; (b) deprived of the value of the products
9 that he bargained for; and (c) sustained pecuniary loss in an ascertainable amount
10 to be proven at the time of trial.

11 **62. Superiority of Class Adjudication.** The certification of a class in this
12 action is superior to the litigation of a multitude of cases by members of the
13 putative class. Class adjudication will conserve judicial resources and will avoid
14 the possibility of inconsistent rulings. Moreover, there are Class members who are
15 unlikely to join or bring an action due to, among other reasons, their reluctance to
16 spend large sums of time and money to recover what may be a relatively modest
17 individual recovery. Equity dictates that all persons who stand to benefit from the
18 relief sought herein should be subject to the lawsuit and hence subject to an order
19 spreading the costs of the litigation among the class members in relationship to the
20 benefits received. The damages, restitution and other potential recovery for
21 each individual member of the Class are modest given the low-purchase
22 price of the consumer products at issue, relative to the substantial burden
23 and expense of individual prosecution of these claims. Given the amount of
24 the individual Class members' claims, few, if any, Class members could or
25 would afford to seek legal redress individually for the wrongs complained of
26 herein. Even if the members of the Class themselves could afford individual
27 litigation, the court system could not. Individualized litigation presents a
28 potential for inconsistent or contradictory judgments. Individualized

1 litigation increases the delay and expense to all parties and the court system
2 presented by the complex legal and factual issues of the case. By contrast,
3 the class action device presents far fewer management difficulties, and
4 provides the benefits of single adjudication, economy of scale, and
5 comprehensive supervision by a single court.

6 63. In the alternative, the above-referenced Class may be certified
7 because:

- 8 a) The prosecution of separate actions by the individual members of
9 the Class would create a risk of inconsistent or varying
10 adjudication with respect to individual Class members' claims
11 which would establish incompatible standards of conduct for
12 Defendant;
- 13 b) The prosecution of separate actions by individual members of the
14 Class would create a risk of adjudications which would as a
15 practical matter be dispositive of the interests of other members of
16 the Class who are not parties to the adjudications, or which would
17 substantially impair or impede the ability of other Class members
18 to protect their interests; and,
- 19 c) Defendant has acted or refused to act on grounds generally
20 applicable to the Class, thereby making appropriate final and
21 injunctive relief with respect to the Class.

22 **VII. CLAIMS FOR RELIEF**

23 **COUNT I - UNFAIR AND DECEPTIVE PRACTICES**

24 **(Violation of the California Consumers Legal Remedies Act)**

25 64. Plaintiff fully incorporates by reference herein all of the above
26 paragraphs, as though fully set forth herein.

27 65. This cause of action is brought pursuant to the California Consumers
28 Legal Remedies Act, Cal. Civ. Code §§1750, *et seq.* (the "CLRA").

1 66. Defendant's actions, representations, and conduct have and continue
2 to be subject to the CLRA because they extend to transactions that are intended to
3 result, or that have resulted, in the sale of goods to consumers.

4 67. Plaintiff and the proposed Class members are "consumers" within the
5 meaning of Cal. Civ. Code §1761(d).

6 68. Defendants are "persons" as defined by Cal. Civ. Code §1761(c).

7 69. Defendants sold to Plaintiff and other Class members its Product
8 which is a good within the meaning of California Civil Code §1761(a). The goods
9 at issue were purchased by Plaintiff and the Class for personal and/or household
10 use.

11 70. By engaging in the deceptive acts and practices set forth in this
12 complaint, Defendant violated, and continues to violate Sections 1770(a)(5) and(9)
13 of the CLRA, which expressly prohibit:

14 (5) Representing that goods or services have sponsorship, approval,
15 characteristics, ingredients, uses, benefits, or quantities which
16 they do not have or that a person has a sponsorship, approval,
status, affiliation, or connection which he or she does not have;
and

17 (9) Advertising goods or services with intent not to sell them as
18 advertised.

19 71. Specifically, Defendant violated, and continues to violate, Section
20 1770(a)(5) of the CLRA by omitting Defendant's failure to obtain FDA approval
21 of the device at the time of purchase and the other material omissions identified in
22 Paragraph 5.

23 72. Defendant also violated, and continues to violate, Section 1770(a)(5)
24 of the CLRA by representing that its Product has sponsorship, approval or is
25 otherwise endorsed by the CMS, FDA and/or DHS when, in fact, it does not.

26 73. In addition, Defendant violated, and continues to violate Section
27 1770(a)(9) of the CLRA by advertising the Product on its website and product
28 packaging without the intent to sell it as advertised.

1 74. Plaintiff justifiably relied on Defendant's conduct, causing him injury.
2 Plaintiff paid a premium price for the Product that he purchased without any
3 knowledge of the material omissions identified in Paragraph 5. Plaintiff was
4 injured in fact and lost money as a result of Defendant's conduct of improperly
5 advertising the Product through misleading packaging.

6 75. Defendant has engaged and continues to engage in the above-
7 described conduct that is prohibited by the CLRA. Plaintiff and the Class members
8 have suffered, and continue to suffer, harm and actual and direct injury as a
9 proximate result of the violations of law and wrongful conduct of Defendant as
10 alleged herein.

11 76. Pursuant to CLRA §1782, Plaintiff provided written notice to
12 Defendant of the asserted violations of CLRA §1770 and demanded that
13 Defendants rectify the conduct described above. Plaintiff mailed said notice to
14 Defendant via certified mail, return receipt requested, on January 23, 2014. This
15 notice and demand notified Defendant of its above mentioned violations of the
16 CLRA that harmed Plaintiff and the members of the Class of consumers that
17 Plaintiff represents, and demanded that Defendant cease engaging in and remedy
18 the violations.

19 77. As of today, Defendant continues to violate the CLRA as specified
20 above.

21 **COUNT II - UNFAIR AND DECEPTIVE PRACTICES**

22 **Violation of California Business & Professions Code §§17200, *et seq.***

23 78. Plaintiff fully incorporates by reference all of the above-stated
24 paragraphs, as though fully set forth herein.

25 79. The Unfair Competition Law, Bus. & Prof. Code §§17200, *et seq.*
26 prohibits unfair competition, defined as "any unlawful, unfair *or* fraudulent
27 business act or practice." Under the statute there are three varieties of unfair
28 competition: practices that are unlawful, unfair or fraudulent, each of which is

1 separately and independently actionable. Here, Plaintiff's UCL claims are only
2 predicated solely on Defendant's "unlawful" conduct. Plaintiff's UCL claim is not
3 based on the fraudulent or unfair prong of the UCL.

4 80. Defendant has engaged in unlawful business acts and practices in
5 violation of Section 17200 of the Business and Professions Code, and which
6 included, but are not limited to:

7 a. Defendant made, or caused to be made, untrue and misleading material
8 omissions regarding its Product as more fully described above, in
9 violation of Civil Code 1770(a)(5); and

10 b. Defendant made, or caused to be made, untrue and misleading material
11 omissions regarding its Product as more fully described above, in
12 violation of Civil Code 1770(a)(9).

13 81. Defendant has further engaged in unlawful business acts and practices
14 in violation of Section 17200 of the Business and Professions Code by violating
15 sections of California's Sherman Act, California Health & Safety Code §§110100
16 *et seq.*, which protects consumers against the misbranding, adulteration, and
17 mislabeling of, among other things, drugs and devices.

18 82. Specifically, Defendant's actions described above violated sections of
19 the Sherman Act, which include, but are not limited to:

20 a. Defendant made, or caused to be made, untrue and misleading
21 representations regarding its Product in its marketing and advertising in
22 violation of California Health & Safety Code §§110390, 110395, and
23 110398;

24 b. Defendant made, or caused to be made, untrue and misleading
25 representations regarding its Product in its marketing and labeling in
26 violation of California Health & Safety Code §§111330, 111440, and
27 111445;

1 c. Defendant marketed, sold, advertised, or otherwise placed into the
2 stream of commerce, a new device, as that term is defined by both the
3 FDCA and the Sherman Law, which required premarket approval
4 before being marketed or sold in the US, in violation of California
5 Health & Safety Code §111550.

6 83. The conduct of Defendant as set forth above demonstrates the
7 necessity for granting injunctive relief restraining such and similar acts of unfair
8 competition pursuant to California Business and Professions Code Section 17203
9 and 17535. Unless enjoined and restrained by Order of this Court, Defendant will
10 retain the ability to, and may engage in, said acts of unfair competition and
11 misleading packaging.

12 84. As a result of the above-stated conduct, on behalf of the Class,
13 Plaintiff seeks injunctive relief, restitution, disgorgement of ill-gotten gains,
14 attorneys' fees, and all other remedies and relief that may be permitted by law and
15 equity.

16 **VIII. PRAYER FOR RELIEF**

17 WHEREFORE, on behalf of himself and the Class, Plaintiff prays for
18 judgment as follows:

19 A. For an order certifying that the action may be maintained as a class
20 action and appointing Plaintiff and his undersigned counsel to represent the Class in
21 this litigation;

22 B. For an order declaring that the acts and practices of Defendants
23 constitute violations of California Business & Professions Code §17200, *et seq.* and
24 California Civil Code §1750, *et seq.*

25 C. For restitution of monies wrongfully obtained and/or disgorgement of
26 ill-gotten revenues and/or profits;

1 D. For a permanent injunction enjoining Defendant from continuing to
2 harm Plaintiff and the members of the Class, and the public, and violating California
3 law in the manners described above;

4 E. For actual damages;

5 F. For reasonable attorneys' fees and the costs of the suit; and

6 G. For all such other relief as this Court may deem just and proper and
7 may be available at law or equity.

8 **IX. DEMAND FOR TRIAL BY JURY**

9 Plaintiff seeks a trial by jury for all appropriate issues on each and every cause
10 of action in this Complaint that allows for it.

11 Respectfully submitted,

12 RIDOUT LYON + OTTOSON LLP

13 Dated: February 7, 2014

By:

/s/ Christopher P. Ridout

Christopher P. Ridout (SBN 143931)

Caleb Marker (SBN 269721)

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9 (480) 348-6415 Facsimile

10 *Attorneys for the Plaintiff*

11 **UNITED STATES DISTRICT COURT**
12 **SOUTHERN DISTRICT OF CALIFORNIA**

13 KYLE DILGER, on behalf of himself and
14 all other similarly situated,

Case No.: '14CV0296 MMABGS

15 Plaintiff,

16 vs.

17 23ANDME, INC., a Delaware
18 corporation,

19 Defendant.

20 **AFFIDAVIT OF KYLE DILGER**

21 I, Kyle Dilger, submit this affidavit pursuant to California Civil Code §
22 1780(d) of the Consumers Legal Remedies Act and declare the following:

23 1. I am the named plaintiff in this action and I am a resident and a citizen
24 of the State of California. I have personal knowledge of the facts stated herein and, if
25 called as a witness, I could and would testify competently thereto.

26 2. During the last three years, I purchased the 23andMe Saliva Collection
27 Kit and Personal Genome Service which is the subject of this Complaint in Orange
28 County, California.

1 3. I did so based on information and advertising disseminated by
2 23andMe, Inc.

3 4. While living in California, I purchased 23andMe Saliva Collection Kit
4 and Personal Genome Service (the "Product") for personal consumer use. I read the
5 www.23andMe.com website. At the time of my initial purchase, 23andMe, Inc. did
6 not disclose that the Product (1) was not approved by any governmental regulatory
7 body, including, but not limited to, the Food and Drug Administration ("FDA") and
8 the California Department of Health Services ("DHS"); (2) was misbranded under
9 applicable law; (3) was adulterated under applicable law; and (4) that Defendant did
10 not have analytical or clinical data to support the Product's efficacy, making the
11 Product's accuracy questionable due to lack of proper testing.

12 5. As a result, I mistakenly believed that the Product was accurate and
13 sanctioned by all applicable governmental regulatory bodies.

14 6. Had I known of the Material Omissions, I would not have paid the
15 premium price that I paid for the Product. To wit, I paid approximately \$207.00 for
16 23andMe, Inc.'s Product at the time of my initial purchase in March 2012.

17 7. The Complaint in this action has been filed in the proper place for trial
18 under California Civil Code § 1780 (d) in that Defendant conducts a substantial
19 amount of business in this District.
20

21 I declare under the penalty of perjury that the foregoing is true and correct,
22 executed on February 7, 2014 in Orange, California.
23

24 
25 _____
26 KYLE DILGER, DECLARANT
27
28

JS 44 (Rev. 12/12)

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
 KYLE DILGER, on behalf of himself and all other similarly situated,

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

(c) Attorneys (Firm Name, Address, and Telephone Number)
 Christopher P. Ridout, Esq. (SBN 143931), Caleb Marker, Esq. (SBN 269721) Ridout Lyon + Ottoson, LLP. Add: 555 E. Ocean Blvd., Ste., 500, Long Beach, CA 90802; Tel: (562) 216-7380; Fax (562) 216-7385

DEFENDANTS
 23ANDME, INC., a Delaware corporation,

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

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

Attorneys (If Known) **'14CV0296 MMABGS**

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

1 U.S. Government Plaintiff

3 Federal Question (U.S. Government Not a Party)

2 U.S. Government Defendant

4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input checked="" type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input checked="" type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	LABOR	SOCIAL SECURITY
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))
			IMMIGRATION	FEDERAL TAX SUITS
			<input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS--Third Party 26 USC 7609
				<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 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

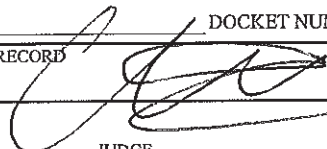
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 USC 1332 (d) - CAFA; 28:1331 - Federal Question (Personal Injury)

Brief description of cause:
Consumer protection class action

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ 5,000,000.00 CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY (See Instructions): JUDGE John A. Houston DOCKET NUMBER 13CV2847 H JMA

DATE 2/7/14 SIGNATURE OF ATTORNEY OF RECORD 

FOR OFFICE USE ONLY

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