ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

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MINORITY (202) 225–3641

energycommerce.house.gov

May 19, 2010

Ms. Anne Wojcicki
President
23andMe, Inc.
1390 Shorebird Way
Mountain View, CA 94043

Dear Ms. Wojcicki:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are examining personal genetic tests sold to consumers over the Internet. Recent press reports suggest that at least one genetic testing company is now seeking to sell these tests in retail locations, despite concern from the scientific community regarding the accuracy of test results.[1]

In order to assist the Committee with its examination of this issue, we ask that you provide the Committee with the following information and documents for the period from January 1, 2007, to the present:

1. A chart listing the conditions, diseases, consumer drug responses, and adverse reactions for which you test;

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[1] *Start-Up May Sell Genetic Tests in Stores*, The New York Times (May 10, 2010); *Walgreens Delays Selling Genetic Testing Kit*, The New York Times (May 13, 2010).

2. All policy documents, training materials, or written guidance materials regarding genetic counseling and physician consultations, including documents regarding what conditions, diseases, drug responses, or adverse reactions trigger the need for genetic counseling or physician consultation, and documents governing communications with consumers regarding individual genetic testing results;

3. All documents relating to the ability of your genetic testing products to accurately identify consumer risk, including:

   a. internal and external communications regarding the accuracy of your testing;

   b. documents describing how your analysis of individual test results controls for scientific factors such as age, race, gender, and geographic location;

   c. third party communications validating the association between the scientific data your company uses for analyzing test results and the consumer's risk for each condition, disease, drug response, or adverse reaction as identified by the results of an individual test; and

   d. documents relating to proficiency testing conducted by your clinical laboratories.

4. All documents regarding your policies for processing and use of individual DNA samples collected from consumers, including:

   a. policy documents and protocols regarding collection, storage, and processing of individual DNA samples;

   b. policy documents and protocols relating to protection of consumer privacy; and

   c. documents regarding collected DNA sample uses other than to provide individual genetic counseling to a consumer, including documents relating to third-party use of collected DNA samples.

5. All documents regarding compliance with the Federal Food, Drug, and Cosmetic Act and U.S. Food and Drug Administration (FDA) regulations.

Please produce the requested information by June 4, 2010. Please include the requested information for all units, divisions, affiliates, or subsidiaries controlled or owned in whole or in part by your company.

An attachment to this letter provides additional information on how to respond to the Committee's request. If you have questions regarding this request, please contact Tiffany Benjamin of the Committee staff at (202) 226-2424. The Republican staff contact, Alan Slobodin, may be reached at (202) 225-3641.

Sincerely,

Henry A. Waxman
Chairman

Joe Barton
Ranking Member

Bart Stupak
Chairman
Subcommittee on Oversight
and Investigations

Michael C. Burgess
Ranking Member
Subcommittee on Oversight
and Investigations

Enclosure