

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOHN D. DINGELL, MICHIGAN
CHAIRMAN EMERITUS
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
FRANK PALLONE, JR., NEW JERSEY
BART GORDON, TENNESSEE
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
GENE GREEN, TEXAS
DIANA DEGETTE, COLORADO
VICE CHAIRMAN
LOIS CAPPS, CALIFORNIA
MIKE DOYLE, PENNSYLVANIA
JANE HARMAN, CALIFORNIA
JAN SCHAKOWSKY, ILLINOIS
CHARLES A. GONZALEZ, TEXAS
JAY INSLEE, WASHINGTON
TAMMY BALDWIN, WISCONSIN
MIKE ROSS, ARKANSAS
ANTHONY D. WEINER, NEW YORK
JIM MATHESON, UTAH
G.K. BUTTERFIELD, NORTH CAROLINA
CHARLIE MELANCON, LOUISIANA
JOHN BARROW, GEORGIA
BARON P. HILL, INDIANA
DORIS O. MATSUI, CALIFORNIA
DONNA CHRISTENSEN, VIRGIN ISLANDS
KATHY CASTOR, FLORIDA
JOHN SARBANES, MARYLAND
CHRISTOPHER MURPHY, CONNECTICUT
ZACHARY T. SPACE, OHIO
JERRY McNERNEY, CALIFORNIA
BETTY SUTTON, OHIO
BRUCE BRALEY, IOWA
PETER WELCH, VERMONT

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

MAJORITY (202) 225-2927

FACSIMILE (202) 225-2525

MINORITY (202) 225-3641

energycommerce.house.gov

JOE BARTON, TEXAS
RANKING MEMBER

ROY BLUNT, MISSOURI
DEPUTY RANKING MEMBER
RALPH M. HALL, TEXAS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
ED WHITFIELD, KENTUCKY
JOHN SHIMKUS, ILLINOIS
JOHN B. SHADEGG, ARIZONA
STEVE BUYER, INDIANA
GEORGE RADANOVICH, CALIFORNIA
JOSEPH R. PITTS, PENNSYLVANIA
MARY BONO MACK, CALIFORNIA
LEE TERRY, NEBRASKA
MIKE ROGERS, MICHIGAN
SUE WILKINS MYRICK, NORTH CAROLINA
JOHN SULLIVAN, OKLAHOMA
TIM MURPHY, PENNSYLVANIA
MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE
PHIL GINGREY, GEORGIA
STEVE SCALISE, LOUISIANA
PARKER GRIFFITH, ALABAMA
ROBERT E. LATTA, OHIO

May 19, 2010

Dr. Vance Vanier
President and Chief Executive Officer
Navigenics, Inc.
1001 East Hillsdale Blvd.
Suite 550
Foster City, CA 94404

Dear Dr. Vanier:

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;

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.

Dr. Vance Vanier
May 19, 2010
Page 3

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.

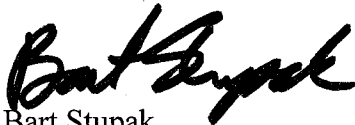
Sincerely,



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