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Director

State of California—Health and Human Services Agency  
Department of Public Health



ARNOLD SCHWARZENEGGER  
Governor

June 9, 2008

Kari Stefansson, CEO  
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NOTICE TO CEASE AND DESIST  
PERFORMING GENETIC TESTING WITHOUT LICENSURE  
OR PHYSICIAN ORDER

Dear Ms. Stefansson,

It has come to the attention of the California Department of Public Health (Department), Laboratory Field Services, that deCODEme Genetics is in violation of California law. Business and Professions (B&P) Code Section 1241 requires that all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, possess a clinical laboratory license or registration<sup>1</sup>.

deCODEme Genetics is also in violation of B&P Code Section 1288 which prohibits the offering of a clinical laboratory test directly to the consumer without a physician order, unless specifically exempt. Genetics tests are NOT exempt. As such, the test must be ordered by a physician or surgeon.

In order to be granted a California clinical laboratory license, in addition to meeting all other licensure requirements, deCODEme Genetics must provide satisfactory validation documentation to verify the test performance specifications of all genetic tests.

Specifically, B&P Code 1265 (a) (1) states, in part,  
“A clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a clinical laboratory license pursuant to this chapter. The department shall issue a clinical laboratory license to any person who has applied for the license on forms provided by the department and who is found to be in compliance with this chapter and the regulations pertaining thereto. No clinical laboratory license shall be issued by the department unless the clinical laboratory and its personnel meet the CLIA requirements for laboratories performing tests or examinations classified as of moderate or high complexity, or both.”

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<sup>1</sup>See also B&P Code Section 1287 and 1288.5

Clinical laboratory tests or examinations are defined at B&P Code 1206 (a) (4) as, "Clinical laboratory test or examination" means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of non diagnostic tests for assessing the health of an individual."

California state law at B&P Code Section 1220 (d) (2) (B) has incorporated federal quality control requirements for moderate and high complexity tests. Federal law at 42 Code of Federal Regulations 493.1253 states the following,

*"Establishment of performance specifications.* Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures, or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results and reference interval."

Finally, California state law at B&P Code Section 1246.5 limits the tests that can be ordered without a physician, as follows,

"Notwithstanding any other provision of law, any person may request, and any licensed clinical laboratory or public health laboratory may perform, the laboratory tests specified in this section.....The tests that may be conducted pursuant to this section are: pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit. A test approved only as an over-the-counter collection device may not be conducted pursuant to this section."

deCODEme Genetics must immediately Cease and Desist offering genetic tests to citizens of California until a license has been issued by the Department. Any advertising for genetic services, whether it be in written word or by internet, must clearly state that this testing is prohibited for California residents. deCODEme Genetics shall not take any unsolicited requests for genetic tests from California residents.

B&P Code Section 1281 states, in part,

"It is unlawful for any person to own, operate, maintain, direct, or engage in the business of operating a clinical laboratory, as defined this chapter, unless she or she possesses a valid clinical laboratory licensed issued by the department..."

B&P Code Section 1287 (b) (3) further states,

"The enforcement remedies provided under this section are not exclusive, and shall not preclude the use of any other criminal or civil remedy."

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You are directed to submit a plan to this office by June 23, 2008 which will show how you will prevent further violation of California state laboratory law. Failure to comply with this order may subject deCODEme Genetics to civil and/or criminal sanctions as provided by law. If you have any questions, you may contact me at [karen.nickel@cdph.ca.gov](mailto:karen.nickel@cdph.ca.gov).

Sincerely,



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