

TAKING RESPONSIBILITY: REGULATIONS AND PROTECTIONS IN DIRECT-TO-CONSUMER GENETIC TESTING

By Andrew S. Robertson

Starting in November 2007, the New York State Department of Health mailed “cease and desist” letters to thirty-one companies, ordering them to stop providing genetic tests directly to consumers without the involvement of a licensed physician.¹ In June 2008, the California Department of Public Health sent similar letters to thirteen genetic testing companies, also involved in direct-to-consumer (DTC) genetic testing services.² These cease-and-desist letters echo public concern regarding laboratory testing standards, the need for physician involvement, and the use of misleading advertising.³ California has since granted licenses to a number of these companies,⁴ but discussions regarding the concerns of DTC testing continue. Among these concerns are the lack of standards used to demonstrate the validity of different genetic tests, uncertainty as to whether healthcare professionals must always be involved in the ordering of such tests to protect patients, and lack of consumer understanding regarding the use of genetic testing.⁵

This Note aims to address the debate surrounding genetic testing within the context of the DTC market. Part I describes the potential for genetic testing in the clinical setting as a result of recent scientific advances. Part II provides an introduction to the DTC genetic testing industry, including the business models being employed by various firms. Part II also pro-

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1. Sarah Lynch, *Should Genetic Testing be Regulated?*, TIME, July 22, 2008, available at <http://www.time.com/time/health/article/0,8599,1825539,00.html>.

2. *Id.*

3. *Id.*

4. See e.g., Andrew Pollack, *California Licenses 2 Companies to Offer Gene Services*, N.Y. TIMES, Aug. 19, 2008, at C3.

5. Andrew Pollack, *Gene Testing Questioned by Regulators*, N.Y. TIMES, June 26, 2008, at C1.