standard of care for a few genes (e.g., analysis of *BRCA1* and *BRCA2* in assessing the risk of breast and ovarian cancer in individuals with a strong family history of these disorders). As sequencing technologies become less expensive, they can be expected to be more commonly used for both identifying mutations in patients with genetic disorders and screening asymptomatic individuals at risk of genetic disease.

Another unique aspect of genetic testing is the concern that genetic information about individuals may be used to discriminate against them by employers or by insurance companies. In the United States, the Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits the use of genetic information by employers in making decisions related to employment and by health insurance companies in issuing insurance policies or setting premium rates based on knowledge of the applicant's genetic status. GINA does not cover disability insurance, long-term care insurance, or life insurance policies.

Although public attention has been most closely focused on DNA testing, other clinical laboratory investigations that are not usually thought of as genetic may provide important genetic information about the person being tested. For example, serum protein electrophoresis may reveal α-1 antitrypsin deficiency. Depending on the clinical laboratory technology used, measurement of hemoglobin A_{1C}, commonly used for monitoring diabetes control, may reveal a hemoglobin variant such as HbS (sickle cell). Measurement of cholesterol and triglyceride levels may reveal any of a number of hereditary disorders. All of these results are types of genetic information.

REGULATION OF THE CLINICAL LABORATORY

In the United States, all clinical laboratory testing performed for clinical purposes (but not for research purposes) is regulated by the federal Clinical Laboratory Improvement Amendments Act of 1988 (CLIA). Home monitoring by patients who are testing their own specimens is not covered by CLIA. The statute and the regulations, which are administered by the Centers for Medicare and Medicaid Services, apply to all laboratories, whether located in a physician's office, a large hospital, or a reference laboratory; and all laboratories are required to hold a valid CLIA certificate that is appropriate for the highest complexity level of the tests they perform. The U.S. Food and Drug Administration is responsible for assigning the complexity level of commercial tests. The lowest category of complexity is the "waived" category, which is followed (in order of increasing complexity) by the categories of "provider-performed microscopy," "moderate-complexity testing," and "high-complexity testing." The category of provider-performed microscopy is used to cover tests such as the use of potassium hydroxide preparations on skin scrapings to examine for fungi, fern tests, and sperm motility tests; it does not encompass histopathology that falls into the high-complexity category. Even if a clinical laboratory is performing only testing in the "waived" category, it must still hold a valid CLIA certificate. Laboratories that hold certificates for nonwaived tests are required to participate in proficiency testing and are regularly inspected to monitor their performance.