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Strengthen Federal Regulation of Laboratory-developed and Direct-To-Consumer Genetic Testing

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Executive Summary: Direct-to-consumer (DTC) genetic tests may be perceived by the public as providing both clinically valuable information, as obtained from medical devices; and general educational value, as obtained from devices for recreational purposes. DTC genetic tests, when regarded as medical devices, are problematic for several reasons (personal communication, Roundtable, July 17, 2017). First, they are often not carried out in laboratories that are held to specific standards for clinical genetic testing. Second, DTC genetic testing can exploit consumers by neglecting to disclose the true degree of clinical utility of the test and the meaning of the test results within the context of individual and familial risk factors. Third, medical testing directly to consumers can result in false-positives, unnecessary anxiety over results, as well as risks and additional costs of downstream re-testing or interventions based on false-positive testing. Lastly, privacy of individual genetic data is a concern, as for-profit testing companies may sell information, potentially resulting in discriminatory practices by insurers and others. The American Academy of Nursing (Academy) supports efforts to ensure that genomic technologies are applied through appropriate Federal Drug Administration (FDA) and Federal Trade Commission (FTC) oversight, statutory regulation of genetic testing, and legislation to prevent genetic discrimination. The Academy will work with our affiliates and consumer organizations to increase nurses' role in genetic education for patients and families and disseminate best practices for genetic testing for healthcare providers and consumers.

Background: Genetic testing has traditionally been ordered by health care providers to identify risk, diagnose, or treat an illness; however, with the advent of new technologies that greatly decrease test costs, genetic tests are increasingly being marketed to individual consumers. This presents a myriad of problems related to clinical applicability, validity, and reliability of testing, as well as potential for genetic discrimination if data are not protected. DTC testing is of concern for clinicians, consumer groups and policy makers, yet no firm legislative policy has been enacted to ensure that individuals are provided with transparent information on the limitations of genetic testing for clinical purposes, appropriate interpretation of results, potential loss of privacy, and alternative options for testing (Kaufman, Bollinger, Dvoskin, & Scott, 2012).

Genetic testing includes an array of techniques for analyzing human DNA, RNA, and protein. These services range from detecting gene variants associated with a specific disease, such as Alzheimer's and Huntington's disease, to paternity testing. Genetic tests are currently under regulatory control by the U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services (CMS), FDA and FTC. CMS is responsible for regulating all clinical laboratories performing genetic testing, ensuring the laboratory's compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The FDA's role is focused on regulating