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August 15, 2010

Margaret Hamburg, M.D.
Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-N-0274, Oversight of Laboratory-Developed Tests: Public Meeting

Dear Dr. Hamburg:

The National Health Council (NHC) appreciates the opportunity to comment on the topic of the Food and Drug Administration's (FDA) oversight of laboratory-developed tests (LDTs). The NHC supports the FDA's decision to reconsider its policy of enforcement discretion over LDTs. Diagnostic tests play a critical role in informing treatment planning for people with chronic disease. The NHC seeks to ensure that all diagnostic tests, including LDTs, undergo an appropriate level of scientific and regulatory oversight.

The NHC is the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

As the FDA notes, clinical laboratories initially manufactured LDTs that were simple, well-characterized, low-risk pathology tests or that diagnosed rare disease and conditions for which adequate validation would not be practical. Since then, the landscape of LDTs has evolved. Complex LDTs are now informing treatment planning and, as such, the quality of information derived from the results of LDTs can directly impact the quality of care that is delivered to a patient. However, policy has not kept pace with this evolution in LDTs. Indeed, a report of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) identified several gaps in the oversight of genetic tests, including "no review of many laboratory-developed tests (LDTs) as they move from the research setting to the clinical setting due to FDA enforcement discretion."[1]

[1] Report of the Secretary's Advisory Committee on Genetics, Health, and Society, "U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services." April 2008.

In recognition of the critical role that diagnostic tests can play on treatment planning, the NHC has made the development and commercialization of advanced diagnostic tests, including genetic tests, a priority policy area. Genetic tests hold tremendous promise in driving the development of targeted therapies for disease. It is widely known that many drugs are effective in only a segment of the intended patient population and that the remaining patients are exposed to potentially harmful and toxic side effects with no commensurate benefit. We view diagnostic tests as playing a central role in eliminating this 'one-size fits all' approach to treatment.

In reconsidering the FDA's enforcement discretion of LDTs, the NHC urges the FDA to take into consideration the following:

- **The NHC concurs with the recommendations of the SACGHS report on U.S. System of Oversight of Genetic Testing (April 2008):** *"To help close the gaps in oversight related to clinical validity, which would help ensure the appropriate use of laboratory tests, the U.S. Food and Drug Administration (FDA) should address all laboratory tests, regardless of how they are produced (i.e., as a commercial test kit or laboratory-developed test), in a manner that takes advantage of its current experience."* Likewise, the NHC believes the FDA should oversee the safety and effectiveness of diagnostic tests, particularly those that are complex in nature and have a direct impact on patient care.

- **Special exemptions should be given to LDTs that diagnose or inform treatment planning for rare disease.** Rare diseases represent a unique challenge. The majority of the 6,000 to 7,000 rare diseases known today are considered genetic conditions, making genetic testing a critical component of the diagnosis and management of patients with rare disease. However, currently the development of tests for rare genetic diseases is not keeping pace with the progress of our knowledge of the genetic basis of rare diseases.[2] As noted by the SACGHS, the degree to which clinical utility can be established for genetic tests for rare disease is limited by the difficulty in conducting clinical trials to assess the impact of testing on patient outcomes due to the small numbers of patients.[3] As such, we urge the FDA to give special consideration to LDTs that focus on rare diseases, just as it does for therapies that target rare diseases.

- **The NHC supports a risk-based approach to the regulation of diagnostic tests.** Under such an approach, the FDA's regulatory requirements would vary depending on the degree of risk of the diagnostic tests. The approach should center on the risk associated with a given test as determined by several factors and any risk mitigations associated with each factor. Assessments of risk should consider the consequences of a false positive or false negative result and the usefulness of the results in treatment planning along with the availability of alternatives and the probability of illness or misdiagnosis. We believe such an approach would ensure that tests undergo rigorous validation while still promote an efficient approval process that would enable timely patient access to these important tests.

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[2] Access to Quality Testing for Rare Diseases: A National Conference Web site. See http://rarediseases.info.nih.gov/QTRD/overview.html. Accessed on July 13, 2010.

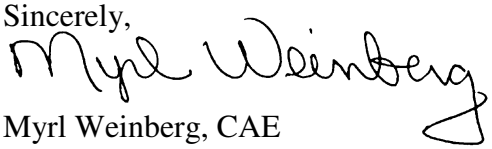
[3] Report of the Secretary's Advisory Committee on Genetics, Health, and Society, "U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services." April 2008.

- **The NHC encourages the FDA to collaborate with other HHS agencies—such as CMS and NIH—that are pursuing related initiatives.** To better leverage finite resources, we urge the FDA to coordinate with other HHS agencies on activities related to LTDs, specifically genetic tests. One area of potential collaboration is the establishment of a common lexicon in diagnostics, as too many important concepts in diagnostics are inconsistently defined.

Conclusion

We would like to thank you for this opportunity to share our comments. We look forward to working with you to ensure diagnostic tests available to patients are reliable and accurate. Please do not hesitate to contact Kevin Cain, our Assistant Vice President of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0542 or via e-mail at kcain@nhcouncil.org. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,



Myrl Weinberg, CAE
President