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November 12, 2010

Cathy Fomous, Ph.D.
Office of Biotechnology Activities
National Institutes of Health
Office of Science Policy
6705 Rockledge Drive
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Bethesda, MD 20892

Submitted via e-mail to cfomous@od.nih.gov

Re: Request for Comments; Plan to Develop a Genetic Testing Registry at the National Institutes of Health, 75 Fed. Reg. 62406 (October 8, 2010)

Dear Dr. Fomous:

On behalf of AdvaMed Dx, a Division of the Advanced Medical Technology Association (AdvaMed), we provide these comments in response to "Request for Comments on the Plan to Develop a Genetic Testing Registry (GTR) at the National Institutes of Health (NIH)." AdvaMed Dx appreciates the opportunity to offer additional feedback regarding specific aspects of NIH's plans in this area.

AdvaMed Dx member companies produce advanced, *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMed Dx is the only multi-faceted, policy organization that deals exclusively with issues facing *in vitro* diagnostic companies both domestically in the United States and abroad.

We appreciate the efforts of NIH to hold the November 2 public meeting and solicit further stakeholder input on specific questions in implementation of the GTR. We believe a database of genetic tests, as called for by the Secretary's Advisory Committee for Genetics Health and Society, can be a useful tool to provide transparent information to the public regarding the growing number of genetic tests available today. Assuring the accuracy and usefulness of such information will be critical for its public utility. We recommend NIH continue to coordinate with the Food and Drug Administration (FDA) to draw on information from its current manufacturer registration and listing database, which will help encourage participation in the GTR.

We recognize both the immensity and the potential value of this undertaking and appreciate the importance of the questions NIH raises for the design of this database.

1. Tests for Inclusion in the Database

AdvaMed Dx supports the inclusion of tests that involve analysis of human chromosomes, deoxyribonucleic acid, and genes. We believe this scope is appropriate and will enable NIH to establish the database and ensure that the information provided is accurate, reliable, and relevant to end users. Once the database is established as an accurate and reliable resource of information, expansion to a larger scope can be considered.

With respect to information that will be made available by NIH, we believe that appropriate safeguards must be applied to verify the accuracy and reliability of the information entered before any information is accessible for use. Until such appropriate systems and safeguards are in place to ensure verification of the information submitted to GTR, AdvaMed Dx recommends that NIH should focus its collection to the following information: test name; manufacturer/institution name and contact information; premarket review regulatory status (indicating whether the test has been cleared or approved by the Food and Drug Administration) and an option to link to test data that has already been appropriately reviewed, such as FDA decision summaries or clinical test results available via ClinicalTrials.gov (on which NIH has been collaborating with the FDA).

Once processes have been put in place to verify the accuracy of the voluntarily entered information in the database, additional data fields that could be added later might include indications for use, warnings and limitations, specimen requirements, availability, and accessibility. These processes are needed to assure that information provided to the public, most significantly patients and their physicians, is trustworthy, as it is likely to be relied upon by these parties in shaping health care decisions. Accordingly, we urge a judiciously phased approach in implementing the database.

Based on NIH's presentation at the November 3 meeting, we understand that FDA regulatory status will be indicated in the database and that the database will allow for population of information from FDA's registration and listing database as well as FDA decision summaries for tests. We appreciate NIH's effort to coordinate with FDA to avoid redundancy and encourage participation in the database while supporting access to existing facility and test information as well as verified and independently reviewed test information. All information in the database should be similarly accurate, verified, and standardized prior to inclusion in the database. While a multitude of test information sources may be available, verification of the specific test data elements is needed to assure accurate and reliable genetic test information for the public.

2. *Clinical Utility Information*

AdvaMed Dx supports the principles of evidence-based medicine. Patients, providers, manufacturers and other stakeholders share an interest in ensuring that adequate and accurate empirical information is available to guide health care decision-making.

AdvaMed Dx supports the posting of published, peer-reviewed studies that contain information about clinical utility. Studies or data that are not published and subject to peer review should not be included in the database. If the information is limited to published, peer-reviewed studies, then a test developer should be able to post such information in the database; however, adequate systems should be in place to prevent third parties from posting studies or data to entries of test developers, who could be held responsible for such content.

3. *Test Cost as a Data Element*

AdvaMed Dx does not support the inclusion of cost as an element in the database. The core purpose of NIH's initiative should be to provide accurate, timely and robust *clinical* information that will inform patients and their physicians in making clinical decisions. Cost information is outside the scope of this purpose.

If the NIH includes cost as a data element, the question is what information would be provided in the database and to what end. Whose costs would be recorded in the database and who is the audience for this information?

Cost can be defined in many different ways, and any cost variable is likely to reflect substantial variation. If one is looking at the rates paid by insurers (or payers) to laboratories for a given test, those rates typically vary by payer and often vary geographically (even for a single test within the Medicare program). If one is looking at the underlying costs to a laboratory of providing a given test, those costs vary significantly from laboratory to laboratory. This variation is caused by differences in technology, platform, and geographic differences in wage rates and supply costs. If the audience for the database is patients, those who have insurance coverage would most likely be interested in their out-of-pocket costs. If covered by health insurance, the patient's coinsurance varies depending on the patient's health plan. For this reason, information that might be accurate and useful for one patient is not likely to be helpful for others in different circumstances. Further, any of the cost information mentioned above is likely to change relatively rapidly as economic variables change, leading to a significant burden of keeping the information up to date.

As mentioned previously, AdvaMed Dx does not think that cost should be included as an element because the database should be focused on clinical information that is useful to inform patients and physicians. We believe providing cost information would present insurmountable difficulties for NIH, and we do not believe that this role is an appropriate one for NIH to attempt to undertake.

4. *Safeguards for Accuracy and Reliability*

As mentioned at the outset, AdvaMed Dx believes that safeguards are essential to verify the accuracy and reliability of information in the database. NIH is looked to as a trusted scientific resource for the public and the database will be relied upon in potential health care decisions and outcomes. Thus, we believe that mechanisms should be in place to assure validation and review of data voluntarily submitted to GTR. Adequate quality control of the content of the database will allow it to become a valuable resource for patients and physicians. In contrast, without such verification, the information submitted may be unreliable and inaccurate, misleading those facing difficult health care decisions and potentially damaging the public health. If verification is not possible, then the contents of the database should be limited to the information previously described, with an option for linkage to test data such as FDA's registration and listing databases or product summaries of cleared or approved tests.

If such safeguards are not put into place, we urge that a prominent disclaimer be placed on all pages of the website, including the individual test entries, stating that the information contained cannot be verified and no endorsement is made of the test nor the accuracy of the information submitted. We note that intended use claims and other key elements proposed for the database are reviewed by FDA as part of its premarket review process and are subject to promotional and labeling regulations, but not all the tests in the database will have been subject to this scrutiny. Thus, wide-ranging and possibly false claims could be included in the database.

Although we cannot anticipate all uses of the database, we are concerned about the potential for use of the database as a marketing resource rather than scientific resource. Thus, clear understanding by patients and providers of the reliability of the data is a critical aspect.

5. *User Comprehensibility*

AdvaMed Dx and other stakeholders would benefit from a better understanding of the audience for the information in the database to address this topic. Clarifying the intended users of the information is essential for determining how to make the information understandable and relevant. Obviously, to the extent that non-clinicians, specifically patients and their families, are expected to access and use the database, the standards for comprehensibility would be much different than if the database is envisioned principally as a tool for clinicians. Lay people are likely to access the database in any case, and care must be taken with the content and presentation of information to avoid the risk that it could be inadvertently misleading.

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AdvaMed Dx is committed to ensuring advances in genomic sciences and patient timely access to safe and effective diagnostic tests. We appreciate the work undertaken by NIH to increase understanding of genetic tests available today, and we recognize the complexity of this undertaking. Thank you for the opportunity to share our comments in the development of the framework for this new initiative. We look forward to continued discussion with NIH on the database, including development of an initial pilot, and stand ready to assist in any way we can.

Best Regards,

A handwritten signature in black ink that reads "Khatereh Calleja". The signature is written in a cursive, flowing style.

Khatereh Calleja
Vice President, Technology and Regulatory Affairs