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August 2, 2010

NIH GTR RFI Comments
National Institutes of Health
Office of Science Policy
6705 Rockledge Drive
Room 750
Bethesda, MD 20892

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

Re: Request for Information (RFI) on the National Institutes of Health Plan to Develop the Genetic Testing Registry, 75 Fed. Reg. 33317 (June 11, 2010)

To Whom It May Concern:

On behalf of AdvaMed, the Advanced Medical Technology Association, we respectfully submit these comments in response to “Request for Information (RFI) on the National Institutes of Health (NIH) Plan to Develop the Genetic Testing Registry”. AdvaMed appreciates the opportunity to offer input and feedback in response to NIH’s plans in this area.

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed’s members produce nearly 90 percent of the health care technology products purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than \$30 million in domestic sales annually. Our members produce advanced diagnostic laboratory tests that are facilitating evidence-based medicine, improving quality of patient care, and enabling early detection of disease and reduction of overall health care costs.

AdvaMed has provided comments below in the following three subject areas:

- The nature of the NIH initiative;
- The accuracy and reliability of the information submitted; and



- The scope and audience for the data collection.

I. The Nature of the NIH Initiative

AdvaMed is committed to the principles of evidence-based medicine. Patients, providers, manufacturers and other stakeholders share an interest in taking steps to ensure that there is adequate and accurate information to guide health decision-making concerning the effectiveness of medical interventions. Registries are one mechanism that may be appropriate for gaining additional information about the safety and/or effectiveness of medical interventions. When designed and executed properly, registries can provide useful information about legitimate, pre-defined scientific questions.

The Agency for Healthcare Research and Quality (AHRQ) defines a registry as:

[A]n organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serves one or more pre-determined scientific, clinical, or policy purposes.¹

As described in the NIH notice and on the NIH web site, the planned “Genetic Testing Registry” (GTR) is not an AHRQ-defined registry because it does not evaluate specified outcomes for a specified population, defined by a particular disease, condition or exposure. Rather, it appears that NIH’s plans are more accurately described as a data collection or database initiative, seeking to collect information on a voluntary basis for a wide range of genetic tests that may relate to any disease, condition or exposure.

AdvaMed therefore recommends that NIH re-name this project a genetic testing *database*, rather than a registry. This will clarify for the public and researchers alike that they can find basic information that has been submitted about tests in the database, but that the initiative is not employing study methods to evaluate specific outcomes for particular diseases or conditions.

II. Accuracy and Reliability of Information

As described in the information provided on NIH’s initiative, the information provided in the database will be collected on a voluntary basis. Based on the “Questions and Answers” portion of the NIH GTR website, submitters will be solely responsible for the content and quality of the data provided to the GTR. The operation of the GTR will be subject to oversight by an NIH Steering Group and Scientific Group; however, these groups do not

¹ Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes: A User’s Guide. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHS A290200500351 TO1.) AHRQ Publication No. 07-EHC001-1. Rockville, MD: Agency for Healthcare Research and Quality. April 2007.

appear to serve the function of validation as would be typically conducted by the data governance committee of a registry. While there will be mechanisms in place to help address inadvertent submitter error and provide general oversight of the GTR, neither validation nor other review appears to be planned for the data submitted to GTR.

If information is to be provided and relied upon by various parties – most significantly, patients and their physicians in making health care decisions – then it is necessary to put in place processes to verify the accuracy of the voluntarily entered information. Without verification, the information submitted may be unreliable and inaccurate, misleading patients and their physicians, thereby potentially leading to poor patient care management and inappropriate treatment or counseling. Until appropriate systems and safeguards are in place to ensure verification of the data submitted to GTR, AdvaMed recommends that NIH only collect the following information: test name; manufacturer/institution name and contact information; regulatory status (whether or not the product is FDA cleared/approved); and an option to link to data specific to that product/test that has already been appropriately reviewed and verified (e.g., FDA product summaries for cleared/approved products, clinical test results available via ClinicalTrials.gov).

Only after appropriate safeguards are in place to verify the accuracy and reliability of the data entered into the database should data be accessible for use. After such systems and safeguards are in place, AdvaMed would recommend that the additional relevant data fields to include would be: indications for use; warnings and limitations; specimen requirements; availability; and accessibility. AdvaMed welcomes additional dialogue and is willing to assist in working with NIH to clarify the type of information that is needed for each of the data fields.

III. Scope and Audience for the Data Collection

Based on the information provided to date, AdvaMed recommends that NIH clarify the scope and audience for the data collection. This is an important step to identifying the appropriate data elements for inclusion in the database.

First, AdvaMed is concerned that the scope of the data collection is overly broad. Rather than encompassing every “genetic” test that involves enzymes, proteins and metabolites, AdvaMed recommends that NIH limit the scope of the database to tests that involve analysis of human chromosomes, deoxyribonucleic acid, ribonucleic acid, and genes. Limiting the scope in this fashion will enable NIH to establish the database and ensure that the information provided is accurate, reliable, useful and relevant to end users. Once the database is established as an accurate and reliable resource of information, then expansion to a larger scope can be considered.

Second, it is unclear who the audience is for the data collection. The notice states that the database will be a “resource for health care providers and patients interested in learning about

the tests and easily locating laboratories offering particular genetic tests.”² In questions 2 and 3, however, there is a wide array of audiences or targets enumerated, including payers, clinical laboratory professionals, and policymakers.³ Clarifying the identity of the intended end users of the information is critical to making the information understandable and relevant to those audiences. For example, the way one would present the database information so that patients will understand the data would be very different from the way one would present the information to researchers and clinical laboratory professionals. AdvaMed is concerned about the complexity that may result in targeting the information for use among so many different parties.

Furthermore once the audience is better defined, the end uses of this data collection effort will be better understood. Importantly, we believe the database cannot be a substitute for an appropriate and meaningful regulatory framework for all diagnostic tests.

AdvaMed appreciates the opportunity to comment. We would like to discuss the initiative further with you and answer any questions you may have. Please contact me (202-434-7267 or kcalleja@advamed.org) to schedule the meeting.

Sincerely,



Khatereh Calleja
Vice President
Technology and Regulatory Affairs

cc: Kathy Hudson, NIH Chief of Staff

² 75 Fed. Reg. at 33317.

³ 75 Fed. Reg. at 33318.