



College of American Pathologists

Comments to the
National Institutes of Health
on the proposed
Genetic Testing Registry

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The College of American Pathologists (CAP) appreciates the opportunity to provide additional comments on the proposed Genetic Testing Registry (GTR). The College of American Pathologists (CAP), celebrating 50 years as the gold standard in laboratory accreditation, is a medical society serving more than 17,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The College advocates accountable, high-quality, and cost-effective patient care. CAP Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide. Our members have extensive expertise in providing and directing laboratory services and also serve as inspectors in the CMS-deemed CAP accreditation program. CAP also provides laboratories with a wide variety of proficiency testing programs and has the responsibility to evaluate the accuracy of test performance and interpretation in more than 23,000 laboratories worldwide. CAP appreciated the opportunity to comment on the draft guidance.

The July 27, 2011 *Federal Register* Notice noted that the overarching goal of the GTR is to advance the public health and research on the genetic basis of health and disease. The Notice goes on to list the key functions of the Registry, including:

- (1) encouraging providers of genetic tests to enhance transparency by publicly sharing information about the availability and utility of their tests;
- (2) providing an information resource for the public, including health care providers, patients, and researchers, to locate laboratories that offer particular tests; and
- (3) facilitating genetic and genomic data-sharing for research and new scientific discoveries.

We are disappointed that NIH has included information about utility in the key functions as CAP and others have argued that clinical validity and clinical utility are linked to the various clinical contexts in which a test may have relevance. Any model whereby each individual lab is required to submit "clinical utility" evidence would be absolutely unworkable. Furthermore, it will be difficult, if not impossible, to capture this dynamic process in any single index or entry, and, indeed, it is critical that this process not be diminished by oversimplification. It is problematic for clinicians and genetic professionals to be the sole source of clinical utility evidence.

Response to Specific points

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

Test directories and registries can be an important tool for providers, patients and researcher, but unless these are constructed in such a manner and with sufficient safeguards, there is potential that misunderstanding, misinterpretation and misuse could compromise patient safety, or indeed, create harm. We have found that databases which may be of use to the research community are not necessarily useful to the clinical community. Information important for clinicians for clinical-decision making cannot be provided in a database with no curation or monitors. While we understand NIH's wish to make this information available to the research community, the College is not convinced that the proposed genetic testing registry can serve all the user groups listed, because the needs for each are very different.

Further, we do not think that the NIH has demonstrated that the appropriate safeguards are in place. CAP strongly recommended that NIH establish appropriate monitors to document that

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misunderstandings, misinterpretations, misuses, or other harms are not occurring through the use of this registry. Misunderstanding, misinterpretation, and misuse of any information in the GTR are of great concern to the College. The Medical Directors of clinical laboratories have responsibilities that extend from appropriate test selection for a patient's specific clinical context to correct interpretation and reporting to the ordering physician.

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

CAP members believe that NIH has underestimated the burden of the proposed collection of information. There is currently a shortage of laboratory personnel; and therefore, directing staff efforts towards entry of data into the GTR will necessarily take away from important laboratory functions that have a direct effect on the quality of patient care. The GTR would be a significant added expenditure for laboratories without obvious benefits for the reasons described above. Furthermore, much of the information being requested is duplicative of information provided to CMS and other organizations for accreditation purposes. We would ask that NIH gather information from CMS before asking laboratories with staffing challenges to devote time and energy to this project. Information should be culled from other publicly available resources as much as possible, including other government agency databases (CMS, FDA, CDC, etc.)

(3) Enhance the quality, utility, and clarity of the information to be collected;

The College supports transparency for all non-proprietary laboratory test information in order to create better understanding among healthcare providers and patients. A reference to other resources and published studies would enhance the educational value of the genetic testing registry. Centralized information could provide benefit for healthcare providers and patients, although practical value would depend on the type, accuracy, and currency of the information included in the genetic testing registry. However, a non-curated registry will have limited value to providers and may be misleading to patients.

We found it difficult to evaluate the submission form as our response would vary depending on the test being entered. While the use of the dropdown menus in the sample data submission form could help standardize the information, it is not clear how tests for example where there may be multiple potential specimen sources and multiple uses will be handled. If each use and/or specimen type had to be entered separately, the burden on laboratories willing to participate would grow.

Conclusion

CAP appreciates this opportunity to provide the College's perspectives on the proposed genetic testing registry. Pathologists and other laboratory professionals are key sources of knowledge and experience on the delivery of high quality, cost-effective laboratory services, and the CAP is willing to contribute to ongoing discussions with NIH on our common interests. CAP recommends that resources not be put into a non-curated registry as this will limit the value to the clinical community, the very group that will shoulder the greatest burden for data entry. Please don't hesitate to contact Fay Shamanski, CAP Assistant Director, Public Health and Scientific Affairs at fshaman@cap.org if you have any questions on these comments.