



Association for Molecular Pathology

Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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Association for Molecular Pathology (AMP) Comments Regarding the DHHS SACGT Draft Report on Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease

June 22, 2006

Reed V. Tuckson, MD
SACGHS Chair
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Dr. Tuckson and Members of the Secretary's Advisory Committee on Genetics, Health, and Society:

The Association for Molecular Pathology (AMP) is an international medical professional association representing over 1,400 physicians, doctoral scientists, and medical technologists who perform genetic testing, as well as other testing, based on knowledge derived from molecular biology, genetics, and genomics. AMP members practice their specialty in academic medical centers, community hospitals, independent clinical laboratories, and federal and state health facilities.

On behalf of our membership, The Executive Council and Professional Relations Committee of AMP have reviewed the SACGT document entitled *Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease*.¹ We would like to take this opportunity to applaud the Committee's efforts in defining the scope, issues, benefits, and implications of such an important undertaking.

AMP supports the concept for this project. We anticipate debate about many of the issues identified in the Committee's report, but are hopeful that the information derived from a large population study will facilitate clinical applications. We believe that the policy and process issues identified must be thoughtfully and actively pursued. We will provide detailed written comments before July 31, which will include our concerns regarding scientific and technical issues of the project. However, today we would like to focus our comments on two facets of this report of great concern to our membership: clinical validation of research findings and patient safety.

As molecular pathology laboratory professionals, our members will undoubtedly serve as the interface between the public and the scientists in any such endeavor. It is through clinical laboratories that specimens (tissue, blood, cellular material) will be collected, processed, stored, archived, catalogued, and shared among the various participants of this study. In addition, it is certain that much of the clinical data essential to this work will be obtained from laboratory information systems. Consequently, policy decisions regarding this study that touch on the HIPAA Privacy Rule and the Clinical Laboratory Improvement Act of 1988 (CLIA) are of great concern to us. While the draft report (p.41, line 1679) states that "an investigator...has no therapeutic relationship with the subject", there is no doubt that our members do have a relationship with their patients, with all the attendant clinical, legal and ethical responsibilities. Furthermore, we direct CLIA-certified clinical laboratories that would be the appropriate

locations for clinical validation of research results prior to reporting to subjects. The members of AMP are prepared to engage in substantive discussions to define the clinically-relevant information which should be returned to individual subjects and in what manner. As the primary interface between scientists and the public for this high-profile study, we believe much of the data communication will be our responsibility, which we willingly accept.

In addition, we also recognize our obligation to pursue the best interests of our patients. In the clinical implementation of research findings, we anticipate that our members will frequently provide the public face for this effort, a role we are quite willing to accept. We note that the draft report focuses heavily on the scientific aspects of this project, but our experience as clinicians and scientists leaves no doubt that the clinical importance and applicability could be immediate. Recognizing the very significant role our members will play in this effort, AMP strongly recommends that processes and policies relevant to clinical implementation and, importantly, patient safety must be specifically addressed now, rather than later.

AMP appreciates the opportunity to address the Committee on this very important endeavor. We reiterate our commitment to participate not only in pursuing the success of this project, but in translating the results of this effort for the betterment of the public's health and well being. Please contact Wayne W. Grody, MD, PhD, Chair of the AMP Professional Relations Committee at wgrody@mednet.ucla.edu if we can provide further information.

Respectfully yours,



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President
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1. Draft Report on Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease, Draft Report, SACGHS, May 2006.