DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Secretary's Advisory Committee on
Genetics, Health, and Society
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The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

On behalf of the entire Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), I am writing to thank you for taking time from your busy schedule to attend our meeting in July. We were delighted to have a chance to hear firsthand your vision of the future of personalized health care and to learn more about your personal outlook on the promises and challenges associated with this approach to medicine.

We heard both a sense of optimism about our capacity to stay ahead of the associated policy issues as well as an honest pragmatism about the magnitude of the challenges that lie ahead. We were extremely gratified as well by your willingness to engage with us on a more specific level and to consider our questions and comments on several topics.

We also want to take this opportunity to thank you for the high priority you have given to the policy challenges associated with the development of genetic technologies and for the progress you have made in effecting innovative policy strategies that harness public and private sector solutions and resources. As you know, during the course of your tenure, SACGHS has issued a number of reports and recommendations that identify critical gaps in the policy frameworks needed to realize the promise of personalized medicine. We recognize that many of our recommendations involve significant policy, procedural, and even statutory issues as well as substantial fiscal and administrative resources, and that they necessitate long-term analysis and planning.

We know, however, that you are committed to making every day of your tenure count, and, in that spirit, we ask you to take urgent action in three issue areas. We believe that these actions are critically important and will lay a solid foundation for the future.

Issue 1: Begin to address practical and legal questions about a national registry of laboratory tests and, for the immediate future, take steps to create incentives for laboratories to make their test menus and analytic and clinical validity data for these tests publicly available through GeneTests or, at least, post them on their own web-sites.

In our April 2008 report on the *U.S. System of Oversight of Genetic Testing*, we provided a comprehensive picture of the current state of the oversight of genetic testing and the roles of governmental agencies and private sector organizations involved in this complex system. While many components of the system are working well, we found a number of significant gaps in oversight relating to: (1) clinical laboratory quality; (2) the clinical validity and utility of genetic tests; (3) the integration of genetic information into electronic and personal health records; (4) the education and training of health professionals to improve the application of genetic testing and the interpretation of genetic tests results; and, finally, (5) the level of consumer understanding of genetics and genetic tests.

We appreciate the significant efforts that you and your team have made thus far to assess the feasibility of the 15 recommendations we made in that report and to organize a coordinated effort across HHS to begin to address the gaps. We believe that progress will be needed in all of the areas we outlined, but at this juncture we are highlighting the need for quick action on the development of a national registry of laboratory tests.

A national registry will address a significant gap that currently exists in the availability of information about genetic tests and the laboratories performing them. Currently, there is no authoritative source for information about genetic tests or their quality, validity, and utility. Consequently, to address this need, we recommended that HHS appoint and fund a lead agency to develop and maintain a mandatory, publicly available, web-based registry for laboratory tests.

Not only would a registry empower both consumers and providers by arming them with reliable information about what is known and not known about the quality and validity of tests, it would also provide a foundation for fulfilling other critical needs in the oversight of genetic tests. Specifically, such a registry would support the conduct of research on the clinical utility of genetic tests, the collection of post-market outcome data, and the development of decision-support tools for the electronic health record.

In our report, we acknowledged that there are practical and legal questions that require further analysis before a final decision can be made about how and where to implement the registry, and that stakeholder input is needed to determine the associated data elements that should be included in the test registry as well as the cost and burden of collecting them. We would like you to expedite the effort to resolve the practical and legal questions in defining the registry's data elements and the feasibility of their collection.

While this work is proceeding, we would also like to see HHS take steps to create incentives for laboratories to make their test menus and analytic and clinical validity data for these tests publicly available through GeneTests or, at least, post them on their own web-sites. Access to high quality, reliable information is an imperative in an ever-more consumer-driven testing market. The growing availability of personal genomic information—the implications of which we began to explore at our meeting in July—only heightens the importance of such information.

Issue 2: Publish FDA draft guidance on the co-development of pharmacogenomics drugs and diagnostics.

We also are highlighting the need for further progress in (1) the development and implementation of guidance on the co-development of pharmacogenomic drugs and diagnostics and (2) the coordination of review of such products within the Food and Drug Administration (FDA). We made this recommendation in our May 2008 report on *Realizing the Potential of Pharmacogenomics: Opportunities and Challenges*.

In the course of examining this issue, we learned that FDA can significantly encourage the development of pharmacogenomics by providing a coordinated review process, which promotes collaboration between drug and diagnostic developers. We appreciate that the FDA recently published a table of biomarkers and associated drugs with guidance about how pharmacogenomic tests should be used.

However, guidance from FDA is a critical policy tool to promote co-development, and we would like to see the agency issue draft guidance before the end of the year. Drug and test developers need additional incentives to assume the additional economic costs associated with development of a pharmacogenomic test.

The co-development guidance document and coordinated review process would provide a transparent and predictable pathway for both small and large diagnostic and drug developers as well as a clear signal that they will not be disadvantaged in the product review process. In the longer run, it is also important for FDA to promote more research and partnerships—as it has through the Critical Path Initiative and the Biomarkers Consortium.

Issue 3: Incorporate family history in Medicare coverage policy and clarify Medicare billing options now available to genetic counselors.

We also urge you to take action on two recommendations related to the Committee's 2006 report, *Coverage and Reimbursement of Genetic Tests and Services.* We highlighted these issues in a February 13, 2008, letter.

The Medicare program's current coverage policy impedes the integration of genetic technologies for the care of patients with a family history of disease. One way you could address this problem is to direct the Centers for Medicare & Medicaid Services (CMS) to begin to develop evidence-based criteria defining when a family history should be considered a personal history of disease. Such a change would make it possible for a Medicare beneficiary with a family history of disease to meet the "reasonable and necessary" standard for Medicare coverage of a genetic test or other indicated course of treatment. If the test showed that the patient was at high risk of developing the disease, steps could be taken to try to prevent or delay its onset. This is the essence of personalized medicine, and the Medicare program should embrace it.

As the importance of genomics in health care accelerates, ensuring an adequate genetics workforce becomes an even more daunting challenge. One way to begin to address this challenge is by clarifying the billing options available to certified genetic counselors. Currently, there is no clear guidance from CMS about which Current Procedural Terminology (CPT) code(s) genetic counselors are allowed to use when billing for services. As a starting point, we urge you to direct CMS to clarify the billing options now available to genetic counselors. If it becomes clear that genetic counselors are allowed to use only

one CPT code, the Medicare statute should be amended. Enabling genetic counselors to use the full range of CPT Evaluation and Management (E&M) codes can enhance patient accessibility to genetic counseling services and informed decision-making before and after genetic testing. Addressing this issue is one clear and straightforward step that could help the Nation meet the urgent and growing need for an adequate genetics workforce.

Finally, we applaud you for recognizing that value-driven health care depends in part on national standards. Making progress in the three areas we outline in this letter would advance your goal for such a system by increasing the strength of the value signals needed to guide both consumers and providers of genetically based health care.

As always, we appreciate the opportunity to provide advice on the issues associated with the development and use of genetic technologies. We thank you again for taking time to meet with us in July and commend your exceptional leadership as Secretary of Health and Human Services.

Sincerely yours,

Steven Teutsch, M.D., M.P.H.
SACGHS Chair