DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Secretary's Advisory Committee on
Genetics, Health, and Society
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September 2, 2009

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

On behalf of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), I am writing to highlight four critical priorities in the area of genetics that will support effective health care reform. These priorities were identified through an exploration of how health care reforms can best harness the rapid innovation occurring in genetics and genomics to improve public health and health care. The potential for these innovations to improve health care—including the need for translational research that can turn genetic and genomic discoveries into effective clinical interventions—has been a focus of our Committee's work since its inception.

As part of our exploration of the contribution genetics could make to health care reform efforts, we held two information sessions this year on genetics and future health care system changes to learn about the concerns and views of payers, providers, patients, and industry. The four priorities outlined here support the main goals of health care reform; that is, they will expand access to quality care, lower health care costs, and improve health care quality. Moreover, effecting these changes does not depend on the achievement of comprehensive health care reform; they can be implemented through the Department's existing programs.

First, we wish to encourage the development of health information systems that are capable of storing data from genetic and genomic testing, family history, and newborn screening in standardized formats and securely transmitting and receiving this data. The storage of this information in electronic health records will enable future research to link health outcomes to particular genetic variants, specific family history circumstances, and certain conditions present at birth. This deeper understanding of disease risk factors in turn should help future clinicians and public health programs more effectively manage strategies for disease prevention and treatment. The development of clinical decision support tools capable of analyzing and interpreting this data is critical as well. We have also communicated our perspectives in this area to the National Coordinator for Health Information Technology.

Second, comparative effectiveness studies should recognize that the effectiveness of treatments and preventive interventions may vary among different genetic subpopulations. In other words, an intervention that is ineffective for the general population may be effective for a subpopulation with a particular genotype and vice versa. Therefore, whenever possible depending on the study design, federally funded comparative effectiveness studies should take account of the genetic profiles of the study

participants so that any guidelines disseminated after a study can be made specific to particular genetic subpopulations. Incorporating genetic profiles into comparative effectiveness studies will ensure that particular groups are not denied access to clinical and preventive health services that are effective for them but not others. In addition, all studies involving genetic profiling should have safeguards in place to prevent genetic discrimination, such as denial of life insurance, long-term care insurance, or disability insurance.

Third, the Centers for Medicare & Medicaid Services (CMS) should adopt a transparent, consistent, and evidence-based process for coverage, coding, billing, and payment of genetic tests under established benefits for testing. CMS processes should support patient access to accurate, reliable, and timely genomic testing; ensure continued investment and innovation in genetic and genomic technologies; reward value; account for rapid scientific and technical advances; and, most importantly, incentivize providers to use these important tools effectively to improve patient treatment outcomes.

Fourth, as changes are considered to remunerate primary care and cognitive services, the value of genetic services should also be recognized. With more and more genetic tests being developed, such as tests that guide the selection and dose of drug therapies, and with clinical whole-genome sequencing on the horizon, genetic services, particularly genetic counseling, are becoming increasingly important to preventive care. The Department should establish policies that enable genetic counselors and genetics-focused clinicians to be part of coordinated care, that enable medical geneticists to lead medical homes for patients with rare diseases, and that promote the education of practitioners in all fields about genetic tests, services, and therapies. Payment policies designed to reward the use of clinical decision support tools would also promote the use of genetic information in primary care. The integration of genetic services into primary care should help promote a shift toward preventive care that will lower costs and improve public health.

Thank you for taking the time to consider these priorities. We would welcome the opportunity to meet with you and/or your staff to discuss these matters in more depth as well as how we can, looking ahead, frame the Committee's work to help address your health goals for the Nation. We would also be honored if you or your representative could attend one of our meetings in the future. An opportunity to engage with you and demonstrate firsthand our commitment to be of service would be most welcome. SACGHS meets again October 8-9, 2009, and in 2010 our meetings are scheduled for February 4-5, June 15-16, and October 5-6.

As always, we appreciate the opportunity to be of service to you and the Department.

Sincerely,

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