Secretary's Advisory Committee on Genetics, Health, and Society
Summary of the Fifth Meeting
Bethesda, Maryland
October 18-19, 2004

Committee Members Present:

Edward McCabe, M.D., Ph.D., Chair
Cynthia Berry, J.D.
Barbara Willis Harrison, M.S.
C. Christopher Hook, M.D.
Debra G.B. Leonard, M.D., Ph.D.
Brad Margus
Agnes Masny, R.N., M.P.H., M.S.N.
Joan Reede, M.D., M.P.H., M.S.
Huntington Willard, Ph.D.
Emily Winn-Deen, Ph.D.
Kimberly Zellmer, J.D.

Ex Officios/Alternates Present:

Hratch Semerjian, M.Sc., Ph.D. (DOC)
Martha Turner, Ph.D. (DOD)
Cari Dominguez, M.A. (EEOC)
Peter Gray, J.D. (EEOC)
Matthew Daynard, J.D. (FTC)
Martin Dannenfelser (HHS/ACF)
Francis D. Chesley, Jr., M.D. (HHS/AHRQ)
Muin Khoury, M.D., Ph.D. (HHS/CDC)
Terrence Kay, M.D. (HHS/CMS)
James Rollins, M.D. (HHS/CMS)
Suzanne Feetham, Ph.D., R.N. (HHS/HRSA)
Michael Carome, M.D. (HHS/OHRP)
Steven Gutman, M.D., M.B.A. (HHS/FDA)
Francis Collins, M.D. (HHS/NIH)
Alan Guttmacher, M.D. (HHS/NIH)
Howard Zucker, M.D. (HHS/OASH)
Robinsue Frohboese, J.D., Ph.D. (HHS/OCR)
Amy Turner, J.D. (DOL)
Ellen Fox, M.D. (DVA)
Sherrie Hans, Ph.D. (DVA)

Sarah Carr, Executive Secretary

Monday, October 18, 2004

Welcome and Opening Remarks
Raynard Kington, M.D., Ph.D., Deputy Director, National Institutes of Health

Dr. Raynard Kington, Deputy Director of the National Institutes of Health (NIH), welcomed participants and informed the Committee of several important changes in its membership and leadership:

- The term of Dr. Edward McCabe, the first Chair of the Committee, is ending, although his membership on the Committee will continue for another year.
- Dr. Reed Tuckson has been appointed to succeed Dr. McCabe as the new Chair.
- The service of Committee members' Kim Zellmer and Brad Margus, who were appointed for their knowledge of consumer issues, also is ending.

Remarks of the New SACGHS Chair
Reed V. Tuckson, M.D.

Dr. Tuckson noted that the public was made aware of the Committee's meeting through notices in the *Federal Register* and through announcements on the SACGHS website and listserv. He stated that the Committee has been rechartered through August 2006.

Dr. Tuckson thanked the ex-officio members present and welcomed Ms. Cari Dominguez, Chair of the Equal Employment Opportunity Commission (EEOC), who was there to serve as that agency's ex-officio, and Dr. Francis Chesley, Director of the Agency for Healthcare Research and Quality's (AHRQ) Office of Extramural Research, Education, and Priority Populations, who was introduced as AHRQ's new ex-officio member. He also welcomed Mr. Richard Campanelli, Director of the Department of Health and Human Services' (DHHS) Office for Civil Rights, and noted that he would be participating in the meeting as an observer.

Dr. Tuckson provided an overview of the Committee's work since June. He remarked that the Resolution on Genetics Education and Training of Health Professionals was transmitted to the Secretary in August and that copies were available on site. He said the Roadmap for the Iintegration of Genetics and Genomics in Society and the letter to the Secretary on direct-to-consumer marketing of genetic tests and technologies will be transmitted to the Secretary in the near future. Dr. Tuckson concluded his remarks by outlining the meeting's agenda.

The Importance of Family History in Health
Alan Guttmacher, M.D.
Deputy Director, National Human Genome Research Institute (NHGRI)

Dr. Guttmacher stated that, at first glance, family history might not seem like an important component of genomics. However, since most diseases result from an interaction of multiple genes and environmental factors, family history has become a critical diagnostic tool. Family history will become even more useful in the years to come for such varied health concerns as heart disease, colorectal cancer, breast cancer, ovarian cancer, osteoporosis, asthma, diabetes, and suicide. Family history can contribute to our understanding of many common diseases with significant morbidity and mortality rates and can play an important role in clinicians' care of to individual patients. This kind of family information can also be used to conduct population screening for many different kinds of conditions.

However, clinicians and health professionals do not use family history as effectively and consistently as they could. They tend to underestimate its utility, which can be corrected in part by provider education that includes more pervasive role modeling. Another factor that influences clinicians' use of family history is the lack of time they have to obtain, organize, and analyze this type of information. Dr. Guttmacher said creative approaches for addressing these barriers are beginning to come to fruition.

He noted that data is forthcoming from the Centers for Disease Control and Prevention (CDC) indicating that although the American public is aware that family history is important, few collect health information from relatives. This suggests that people believe family history may be relevant to their health, but they rarely act on that belief. Furthermore, much of the information people have tends to be imprecise.

A number of agencies within DHHS, including the Surgeon General's Office, the Health Resources and Services Administration (HRSA), AHRQ, CDC, and various institutes of NIH, have come together to form what is now called the Surgeon General's American Family Health Initiative. The goals of the initiative are to increase the American public's awareness of the importance of family history and health; provide the American public with tools for gathering, understanding, and evaluating family history to

improve health; increase the awareness of health professionals regarding the importance of family history; provide health professionals with tools that will help them obtain, evaluate, and use the family health information of their patients; and provide clinicians with tools to communicate with their patients about their family histories. The initiative has produced the web-based tool, *My Family Health Portrait,* which will be rolled out shortly in both English and Spanish. Guidance on how to use the information gathered with this tool also will be provided.

At the conclusion of the presentation, Dr. Tuckson noted the importance of spelling out how the tool will improve genetic literacy of the public. He also recommended that the Committee follow up to determine how this tool is being incorporated into DHHS information technology efforts, especially with regard to electronic medical records. Dr. Guttmacher said he welcomed the opportunity to keep the Committee aware of the initiative's progress. He stated that pamphlets are being developed for organizations to distribute that will include a template for asking and answering questions about family history.

Dr. Tuckson summarized by suggesting three actions the Committee could take:

- Endorse the importance of family history as a tool for practitioners and clinicians;
- Report to the Secretary that Committee members are encouraged to see DHHS agencies working together on these efforts; and
- Encourage agencies that are not yet involved in the initiative to become involved.

The Committee voted unanimously to write a letter that includes these suggestions.

Session on Genetic Discrimination

Perspectives on Genetic Discrimination
Agnes Masny, R.N., M.P.H., M.S.N.
Chair, Genetic Discrimination Task Force

Dr. Tuckson opened this portion of the meeting by noting that genetic discrimination is a top priority for the Committee, which has written two letters to the Secretary urging support for the enactment of Federal genetic nondiscrimination legislation. The issue was also discussed at length at the March and June meetings. Since that time, the U.S. Senate unanimously passed a genetic nondiscrimination bill, in October 2003. The House Subcommittee on Employer/Employee Relations then held a hearing in July 2004 but did not take further action.

Dr. Tuckson explained that the Committee's Task Force on Genetic Discrimination planned this session to gather additional public perspectives on the topic. The Committee had requested public comments through the *Federal Register*, the SACGHS website, and various listservs. Forty-three sets of public comments were received: 22 from the general public, 11 from health care providers, 9 from professional organizations, and testimony from Representative Louise Slaughter, who co-sponsored the House version of the nondiscrimination bill. These written comments were compiled and distributed to Committee members at the meeting.

Dr. Tuckson introduced Agnes Masny, who chaired the Task Force and would be co-facilitating the

session with him. Ms. Masny remarked that one of the reasons for the day's public hearing was the fact that genetic discrimination is difficult to document. Some of the public comments received prior to the meeting stated that there are barriers to proving genetic discrimination in legal cases. Ms. Masny added that a lack of concrete evidence of discrimination contributed to the lack of passage of anti-discrimination legislation. She said this public hearing would provide the Committee with information that could be given to the Secretary and used to support future legislative efforts.

The Committee heard testimony from three panels: members of the public, health care providers, and additional stakeholders. The first panel consisted of members of the public who experienced genetic discrimination or who altered their health care choices because of concerns about genetic discrimination by insurance companies and employers. The health care provider panel was composed of clinicians who have heard first-hand of their patients' experiences with genetic discrimination. The third panel was composed of stakeholders who offered other perspectives, including those of employers, health insurance companies, and society at large.

Panel One: Perspectives of Members of the Public
Heidi Williams
Phaedra Malatek
Rebecca Fisher, M.L.I.S.
Tonia Phillips
Paula Funk
Maria Carolina Hinestrosa
Phil Hardt

Ms. Heidi Williams testified that she was repeatedly denied health insurance for her children by Humana, Inc. because they are carriers of the genetic disorder alpha-1 antitrypsin (AAT) deficiency, which can affect the lungs, the liver, or both. As carriers only, Ms. Williams said her children will not experience any symptoms of the disease and Humana was given proof that the children are not at risk. However, only after Humana was approached by a reporter for a well-respected newspaper did the company reverse its decision and approve full coverage. Ms. Williams expressed her fears that her children's' genetic status will follow them into the workforce and render them unable to become employable in their chosen fields. She advocated for the Genetic Information Nondiscrimination Act (S. 1053), which was passed by the Senate but stalled in the House of Representatives. Ms. Williams concluded by emphasizing that only through legislation and education can genetic discrimination be eliminated.

Ms. Phaedra Malatek is involved at both the national and local levels as an advocate for women with breast cancer. Her father was diagnosed with and ultimately died from hemochromatosis, and two of her siblings have developed complications from the disease. She is now concerned about the welfare of her two children, but fears that genetic testing, while allowing them to receive treatment if they test positive, may also put them at risk for genetic discrimination. Ms. Malatek said genetic testing offers society the opportunity to learn more about the constitution of diseases and their potential for serious damage. She urged the Committee to use its influence to help bring S.1053 to a vote in the House.

Ms. Rebecca Fisher carries the BRCA1 mutation that is known to predispose women to breast and

ovarian cancer. She said that women with these mutations must hide their genetic information from those health care providers who would be most able to help them manage their lifelong predisposition to cancer. Hiding integral health information is the only sure way to avoid discriminatory practices, such as the loss or denial of health insurance or employment, because there is no comprehensive Federal legislation that forbids insurance or employment discrimination based on genetic information. Ms. Fisher stated that genetic information is already being used by insurance companies to prevent financial losses and there is no protection against this practice. In addition, many do not understand that the Health Insurance Portability and Accountability Act (HIPAA) does not provide a safety net for health privacy. HIPAA does not address workplace concerns, and the Employee Retirement Income Security Act (ERISA) exempts many employer-based health plans from mandatory HIPAA compliance. The Department of Labor says that 63 million Americans fall into this HIPAA gap. Ms. Fisher went on to say that people are afraid of undergoing genetic testing because of the possibility of losing health insurance or employment. She also stated that the U.S. Chamber of Commerce is the loudest voice speaking against Federal genetic information protections.

Ms. Tonia Phillips explained to the Committee that she works for a small company with a staff of four. Approximately 4 months prior, the company's group health insurance bill was increased by $13,000 annually because of the surgeries she had undergone to prevent cancer, for which she is at high risk. She was asked to switch to her husband's health insurance policy so that the company's premiums would not increase, and was promised that if she did so, her hourly rate would be increased. Because she was reluctant to switch, the company began to require that all employees pay half their of their annual premiums. She felt she was singled out and made to feel like a liability to the company.

Ms. Paula Funk has a strong family history of breast and ovarian cancer. She delayed genetic testing for 10 years because of a fear of losing health insurance. She eventually tested positive for a genetic mutation that confers a high likelihood of developing breast or ovarian cancer. When Ms. Funk and her husband started a small business, she researched individual insurance and found no protection from being denied coverage for individual insurance. She and her husband were finally able to enroll with UnitedHealthcare, but she lives in fear of her claims being rejected. She added that many of her family members are more concerned about genetic discrimination than they are about their health, and this prevents them from pursuing lifesaving testing. She emphasized that a law is needed to protect individuals from genetic discrimination.

Ms. Maria Carolina Hinestrosa is a 10-year, two-time breast cancer survivor and Executive Vice President for Programs and Planning of the National Breast Cancer Coalition (NBCC). She decided not to undergo genetic testing for fear of employment and health insurance discrimination against her 13-year old daughter in the future. She also fears that this information may not be protected and might even be misused if she tests positive. Ms. Hinestrosa stated that women are afraid to enroll in research and clinical trials that involve genetic testing, and this threatens the viability of the scientific community. She said that NBCC strongly supports H.R. 1910, the Genetic Nondiscrimination Health Insurance and Employment Act. NBCC does not support S. 1053 because they believe it does not contain sufficient enforcement provisions.

Mr. Phil Hardt has two genetic diseases, hemophilia B, a bleeding disorder, and Huntington's disease (HD), a degenerative brain disorder. He and his children and grandchildren have experienced continuing

genetic discrimination. He said that because of advances resulting from the Human Genome Project, Americans now stand on the brink of having information that has the potential to help millions of individuals prepare early for various diseases. However, the knowledge of any particular genetic disorder can be just as devastating as the disease. He said that tens of thousands of individuals with HD have already been included in insurance company's profitability calculations. HD was often not noted on an individual's death certificate because of fears that relatives would face genetic discrimination. Since genetic testing has become available for HD, fewer than 10 percent of those at risk have been tested. In 2001, Mr. Hardt, working with a geneticist, established an anonymous genetic testing program in Arizona.

Mr. Hardt stated that genetic discrimination adversely affects those with HD over and above the negative effects of the disease because of: the unwillingness of those at risk to participate in research; a hesitation on the part of sufferers to seek medical and mental health care on a timely basis; the lack of encouragement for at-risk children to seek education and good careers; the misdiagnosis and incorrect prescription of medications; and the inability to plan a healthy lifestyle.

Discussion

Dr. Collins asked Ms. Fisher about the responses she receives from lawmakers on the Hill, particularly on the House side, given the compelling arguments for genetic nondiscrimination legislation. He asked why the problem has not yet been solved. Ms. Fisher believes that because the U.S. Chamber of Commerce is speaking out against this legislation and has the resources to fight it, they have been able to prevent it from moving forward.

Dr. McCabe noted that the genetics community and members of the general public have been told that genetic discrimination does not exist. In fact, he said, scholarly articles have been referenced in the genetics literature in which the authors made inquiries to insurance companies, all of which claimed there is no genetic discrimination. Yet all of those present at the meeting heard evidence that discrimination exists. He asked Dr. Tuckson if the Chamber of Commerce could be invited to a future meeting to explain its position on genetic discrimination. Dr. McCabe stated that the Committee has been told by various groups that no new legislation is needed because there are many laws, including the Americans with Disabilities Act (ADA), that adequately protect individuals against genetic discrimination. He asked Dr. Majidi if the Department of Justice has ever conducted a systematic review of the current legislation to document whether individuals are protected by current laws. Dr. Majidi responded that they have not been asked to conduct such a review but that a request from the Secretary for this information would have considerable influence. Ms. Masny agreed with Dr. McCabe's statement that the Committee should consider writing a letter to the Secretary to request a review of current legislation. She also mentioned that the Chamber of Commerce declined an invitation to meet with the Committee and referred them to the Society for Human Resource Management (SHRM), which would be participating in the stakeholder panel later in the day. Dr. McCabe asked the SHRM representative to be prepared to state whether SHRM can be considered a spokesperson for the Chamber of Commerce.

In response to an inquiry from Dr. Frohboese about the HIPAA gap, Ms. Hinestrosa commented that the protections ensured by HIPAA are intended for members of group plans and that these protections do not extend to individuals. Ms. Fisher added that the biggest problem is that HIPAA deals only with insurance

and does not address any workplace concerns.

The panelists were thanked for speaking publicly about their experiences with genetic discrimination, even though they were incurring great risk to themselves and their families by doing so.

Panel Two: Health Care Providers
Jeff Shaw, M.S., Penrose Cancer Center
Donald W. Hadley, M.S., NIH
Mark Brantly, M.D., University of Florida

Mr. Jeff Shaw is a genetic counselor and Director of the Hereditary Cancer Service of Penrose Cancer Center. As such, he provides genetic counseling to individuals and families in every area of medical genetics, from prenatal to adult-onset conditions, and especially to patients concerned about hereditary cancer predisposition. The twofold purpose of the Penrose Center is to provide the best estimate of cancer risk so that screening can be modified appropriately to occur when the likelihood of survival is the highest, and to provide appropriate implementation of medical and lifestyle interventions to drastically reduce the risk of cancer, especially in those with inherited predispositions. At the outset, the program created a large database to collect information that might help with the provision of services. The data Mr. Shaw presented covered 7 years of clinical service to more than 900 individuals with hereditary cancer predispositions.

Mr. Shaw stated that the fear of genetic discrimination is a major concern for his patients. If the center offers an individual genetic testing, the staff conducts a lengthy informed consent process, during which 20 percent of those who are eligible decline the test. Of these individuals, 22 percent decline because of a fear of discrimination. Mr. Shaw said that those who would experience the greatest possible benefit from testing are least likely to pursue it. He described the experiences of several of his patients who declined testing because of fears of losing their jobs or their health insurance and concerns about their children.

The center conducts 1-year followup surveys of all patients seen by the program, for which there is a 72 percent response rate. Of those patients testing positive for an inherited cancer predisposition, 70 percent reported significant anxiety about experiencing genetic discrimination at some point in the future. Of those patients not offered genetic testing, many fear discrimination simply from participating in a genetic counseling session. Mr. Shaw cited an article by Geer et al. (2001) that described factors that influence an individual's decision to decline genetic counseling. Geer and colleagues concluded that 40 percent of those who decline do so because of a fear of genetic discrimination.

The Penrose Cancer Center has had a significant number of physician-referred individuals who do not show up for their scheduled appointments. After reviewing the Geer study, the Center decided to conduct an informal 6-month phone survey of patients who did not pursue the referral for genetic counseling. Of the 60 patients who did not show up, 15 percent would not return calls. Of those who could be contacted, 49 percent stated that they had changed their minds because they had heard from their physicians and family that they should not have documentation of genetic testing services in their medical charts.

Mr. Shaw concluded by stating that there are currently more than 1,000 genetic tests available on a clinical or research basis, and the number of tests that will become available for single-gene and complex

genetic disorders is expected to increase exponentially over the next decade. He said that without strong Federal protections, these tests will continue to be underused and patients will not gain the benefits of the genetics revolution.

Mr. Donald Hadley, a genetic counselor at the National Human Genome Research Institute (NHGRI) at NIH, noted that his work has focused primarily on providing education and counseling to families that are threatened with genetic and inherited diseases. Recently, his research focused on identifying factors that influence interest and participation in genetic counseling and testing, including associated psychological, social, and behavioral outcomes. Mr. Hadley has been working with families who are newly diagnosed with hereditary nonpolyposis colorectal cancer (HNPCC) and families who have mutations that have been identified.

Once a family is identified as carrying an HNPCC mutation, Mr. Hadley's research team offers participation to adult relatives who are at 50 percent risk of inheriting the mutation. Prior to the education and counseling sessions, participants are asked to complete a questionnaire that collects demographic data, information about their knowledge of genetics and genetic testing, knowledge of their perceived cancer risk, and their ratings on standardized scales assessing mood, coping style, spirituality, their perception of their own control over their health issues, and family relationships. They also are asked to identify the factors that motivate them to consider genetic testing and any concerns they may have, including those that relate to discrimination. All the questions are validated measures developed and used by the Cancer Genetics Studies Consortium of the NHGRI Ethical, Legal, and Social Implications (ELSI) Program. Each participant is interviewed individually.

Mr. Hadley stated that one issue was consistently identified: many participants asked unsolicited questions about how participation in the study might affect insurance coverage. There was overwhelming concern and significant anxiety about this issue—even after confidentiality procedures were explained in detail. The article summarizing the study findings stated that the public perceives the potential for genetic discrimination by insurance companies as an overwhelming risk, and this creates a barrier to scientific, social and behavioral research. Mr. Hadley said Federal legislation to prohibit genetic discrimination would reassure the public, provide an increased opportunity for research to address other, more significant issues, and reduce the mortality and morbidity associated with cancers diagnosed at later stages.

Dr. Mark Brantly, a pulmonary physician and scientist at the University of Florida, told the Committee that he has been involved in AAT deficiency testing since approximately 1983 and has tested approximately 20,000 individuals. He follows approximately 150 AAT-deficient individuals in the clinic at the University of Florida and has firsthand experience with the impact of this diagnosis on patients and their families. Although prevention of certain behaviors and interactions is critical in managing this disease, and an easy testing system has been developed in which patients can provide a blood sample through a finger prick, the fear of genetic discrimination remains a barrier to testing. If patients were identified early on, they could possibly be protected from developing a disability.

Dr. Brantly and colleagues are conducting a longitudinal study that looks at reasons why individuals prefer to be tested in a coded trial rather than through their physicians. Most fear losing their health insurance. Many of these patients said they would not provide test results to their health insurance

companies or their life insurance companies. Only 80 percent of individuals who were profoundly deficient would tell their personal physicians.

During the question and answer period, Mr. Hadley expressed confidence that Federal protections would remove most of the barriers to genetic testing that are based on fear of discrimination. Dr. Brantley emphasized that although legislation will help, societal attitudes also must change. He said that a disability shouldn't be a "scarlet letter." Dr. McCabe agreed, adding that these experiences of discrimination are arbitrary and capricious because we all have genetic predispositions to disorders. He then stated that the day's testimony made it clear that barriers to genetic testing also are barriers to research.

Panel Three: Additional Stakeholder Panel
Kathy Hudson, Ph.D., Director, Center for Genetics and Public Policy (GPPC)
Jane Massey Licata, J.D., Ph.D., Partner, Licata & Tyrrell, P.C.; Adjunct Professor, Rutgers School of Law
Joanne Armstrong, M.D., M.P.H., Senior Medical Director, Women's Health, Aetna, representing America's Health Insurance Plans (AHIP)
Michael Aitken, Director, Governmental Affairs, Society for Human Resource Management (SHRM)

Dr. Kathy Hudson explained that the mission of the Center for Genetics and Public Policy is to provide information about genetic technologies and policies to the public, the press, and policymakers. Over the past 2 years, the GPPC has conducted extensive research in an effort to determine what the general public thinks of advances in genetic technologies. More than 6,000 citizens have been included in two surveys in December 2002 and April 2004. In addition, 21 focus groups have been conducted in 5 cities across the country, and in Summer 2004, the center sponsored a series of public engagements in six cities in 6 weeks called *The Genetic Town Halls: Making Every Voice Count.*

Dr. Hudson stated that virtually everyone surveyed in 2004 agreed that employers should not have access to the genetic information of their employees and 80 percent said this information should not be made available to insurance companies. The issue of genetic discrimination was spontaneously raised in each focus group as an area of major concern. Dr. Hudson then explained that, because surveys and focus groups tend to provide off-the-cuff reactions to sometimes unfamiliar issues, the town hall meetings were structured to provide participants with information about genetic technologies before discussing them. In addition to the six live town hall meetings, online town halls were conducted over a 3-week period. Participants in all town hall meetings were asked such questions as, "What do you think are the factors that should be considered in setting limits for the use of reproductive genetic testing?" and "What are some of the possible benefits and harms for individuals, families, and societies?" In Sacramento and New York, genetic discrimination ranked as the number one issue of concern when considering potential harm from reproductive genetic testing for individuals and families. In Seattle, Fort Worth, and Nashville, it ranked second. As with the focus group participants, town hall participants feared that insurance coverage would become a factor in guiding reproductive choices. In summary, the Center's research shows that an overwhelming majority of Americans do not want insurers or employers to have access to genetic test results.

Dr. Jane Massey Licata, a biotechnology patent and FDA lawyer who teaches at Rutgers, addressed three specific arguments that are made by those who oppose genetic discrimination legislation. The first is a misperception that there is currently significant Federal protection against genetic discrimination. However, she said this is not the case, and she reviewed several current regulations to make her point. HIPAA, for example, does not prevent insurers from collecting genetic information and it does not limit the disclosure of genetic information about individuals to insurers. It doesn't prevent insurers from requiring applicants to undergo genetic testing and it doesn't cover many Americans, because it doesn't apply to the individual market or to many group plans that are exempt.

She went on to say that although the ADA protects individuals with symptomatic genetic disabilities, it is feasible for an employer to obtain extensive medical information about a person, including obtaining and storing genetic samples and requiring genetic screening as a condition of employment. The ADA does not explicitly address genetic information or deal with unaffected carriers of a disease who may never get the disease themselves, individuals with late-onset genetic disorders who may be identified through genetic testing as being at risk of developing a disease, or others identified through family history as being at high risk for developing a disease. It also does not protect workers from requirements or requests to provide genetic information to their employers.

Although Title VII of the Civil Rights Act provides grounds for an argument that genetic discrimination based on racially or ethnically linked genetic diseases constitutes unlawful racial or ethnic discrimination, there are few cases in which that link can be established. Therefore, the American people cannot rely on Title VII to protect them.

The second issue of concern to Dr. Licata was related to the business community. There is a misconception that passing nondiscrimination legislation would create extensive new litigation. Based on her work in the field, she disagrees with this point of view.

The third issue Dr. Licata has heard as an objection to nondiscriminination legislation is that it's not needed because many States already have such laws and it should be left to the States to develop regulations in this area. Dr. Licata noted, however, that not all States have such laws, and those that do exist are not consistent or comprehensive. She concluded by arguing that a threshold level for genetic discrimination protections should be guaranteed through the legislation currently pending in the House.

Dr. Joanne Armstrong, a senior medical director for Aetna, testified on behalf of America's Health Insurance Plans (AHIP). She began by noting that DNA and non-DNA-based genetic testing have been used clinically for many decades. Although genetic testing is not new, the rate of new genetic discoveries entering clinical practice is increasing at a dizzying rate, and the speed of these new discoveries is challenging the health care system's ability to integrate them into clinical practice and to optimize their benefits to prevent and cure disease. Dr. Armstrong argued that because of the complexity of genetic information, the optimal use of genetic technologies requires informed providers, informed patients, and the coordination of services across all delivery systems. She said much work is needed to get it right and that health plans have been and will be instrumental in this coordination of care. In addition, as the science of genetics advances and awareness increases about the health benefits that can be derived from genetic information, concerns about inappropriate uses of genetic information have escalated. She urged responsible policymaking that does not unduly restrict the use of genetic information.

Dr. Armstrong described the current use of genetic information by health insurance plans. She said genetic information is just one of many types of medical information used by plans for risk assessment, preventive screening, disease management, quality assurance, and coordination of care across delivery systems. She claimed health care plans are facilitating the exchange of information in genetics to ensure appropriate counseling, testing, and decisionmaking.

Often, from a health plan perspective, new testing paradigms are needed to assess risk and deliver the most appropriate services to patients in the best possible way. Dr. Armstrong said the most efficient cancer screening scenario for at-risk individuals might involve the testing of an affected family member who is herself not a covered member. She said that Aetna has led the industry in extending, on a voluntary basis, coverage benefits to non-plan members if those test results helped the member.

She noted that as scientists acquire a greater understanding of the role genes play in all disease states, especially chronic diseases, genetic information will be incorporated into disease management programs and pharmacy management programs. Collecting genetic information will become part of standard medical practice, as we learn about its contributions to many diseases and the continued improvements in health outcomes that will occur will be related in many ways to the success of data sharing. Dr. Armstrong stated that AHIP believes in the importance of protecting genetic information from misuse and said it is a myth that health plans use this information to deny coverage or disclose data inappropriately.

Dr. Michael Aitken, the Director of Governmental Affairs for SHRM, explained to the Committee that SHRM believes that employment decisions should not be based on individual characteristics, including genetic information, that have no bearing on job performance. SHRM also argues, however, that any legislative remedies proposed must be carefully drafted so they do not lead to unintended consequences with existing Federal and State employment and benefits laws or existing nondiscriminatory employer practices.

For example, under the ADA, medical records must be used to determine reasonable accommodation of disabled employees. Human resources professionals and employers would face insurmountable challenges in making proper decisions without appropriate medical information. He said the Family and Medical Leave Act (FMLA) creates similar challenges. FMLA allows an employee to take up to 12 weeks of unpaid leave for a serious health condition or the condition of a family member. However, to determine whether an employee qualifies for FMLA leave, the employer must collect relevant medical information on the condition. In addition, State workers' compensation laws require that medical information be disclosed when claims are filed so it can be determined whether injuries are work-related. Employer-sponsored wellness programs often involve confidential, individualized health risk assessments for the employee, which may include family history, blood test results, and other potential genetic information.

Dr. Aitken said SHRM offers the following recommendations for the Committee to consider:

- Legislative proposals should differentiate between the mere possession of genetic information and the use of the information for discriminatory purposes. Any proposed statute should be

directed at controlling discriminatory conduct, rather than attempting to regulate the flow of information.

- If a company intentionally discriminates, remedies should be available. However, legislation should not allow unlimited punitive and compensatory damages.
- Legislative proposals should not impede employer efforts to protect the safety and well being of their employees through workplace wellness programs and other services currently available under State and Federal laws.
- Any legislative proposal regarding genetic discrimination should take into account the protections already available under Federal and State laws to avoid duplication and confusion.

Roundtable Discussion
Facilitators: Agnes Masny, R.N., M.P.H., M.S.N.; Reed Tuckson, M.D.

Dr. Collins asked Mr. Aitken what additional changes to S. 1053 would be required for SHRM to be comfortable with it. Mr. Aitken responded that one of the concerns with S. 1053 is that there is no sunset provision that would help avoid conflicts with employer State laws and provide the opportunity to review the implications of the law as genetic advances are made. In addition, Mr. Aitken noted, there is no Federal preemption in S.1053, meaning that the Federal law does not trump the various State laws, which would create conflicts. There also is some controversy regarding the definition of "family member." Dr. Collins followed up by asking if it is the goal of SHRM to support Federal legislation to prevent genetic discrimination in the workplace. Mr. Aitken indicated that SHRM would not oppose such legislation, although employer groups will not support legislation that creates the potential for lawsuits against them. He said SHRM did not oppose S.1053.

Ms. Berry asked Dr. Licata to address whether ERISA plans are subject to HIPAA. Dr. Licata replied that the HIPAA exemption applies to smaller self-insured plans and that ERISA does have some Federal preemption. However, all plans must establish at least one consistent national level or standard, and a clear understanding of who is covered and who is not covered. Dr. Licata said it's important to be concerned about protecting the individual's rights, while at the same time, giving more certainty to businesses by applying a generalized Federal standard.

Dr. McCabe said that Mr. Aitken had indicated that there was no evidence of widespread use of genetic information in employment discrimination, yet in his presentation he raised a number of examples regarding the potential for discrimination, which seemed contradictory. He also encouraged Mr. Aitken to review the testimony from the initial panel. Mr. Aitken responded that there is concern about possible unintended consequences if legislation isn't carefully developed. He said the current employment laws are well intended, but can result in frivolous lawsuits.

The Committee continued roundtable discussion and agreed that the fear of genetic discrimination is prevalent. They therefore discussed possible actions that could be taken by the Committee to increase the visibility of this issue within the administration.

Dr. Tuckson indicated that the Committee is not permitted to write to Congress directly. The Secretary can forward information from the Committee to Congress, however. Dr. McCabe noted that the President is on record as being supportive of the legislation, as is Secretary Thompson. He stated that part of the

reason to have the Chamber of Commerce come before the Committee is to see whether it is active in holding the legislation back.

Dr. Tuckson asked Mr. Aitken if he could provide a sense of how many organizations have the same opinion or philosophy as SHRM and to explain whether the opinions he presented represent those of the Chamber of Commerce and other interests. Mr. Aitken said the Chamber and SHRM are both members of the GINE Coalition, along with approximately 40 other associations. The principles he laid out have been adopted by the GINE Coalition. Mr. Aitken did not recall whether the Chamber has ever said it was opposed to a bill prohibiting genetic discrimination, but, without speaking for the Chamber, he said that the Chamber has raised concerns about S. 1053 and has shared those concerns with public policy decisionmakers on both sides of the legislature. He said that the Coalition has been very consistent on those principles as they apply to any proposed legislation.

Dr. Tuckson suggested that the Committee obtain a list of the 40 organizations belonging to the GINE Coalition to gain an understanding of the range and depth of the Coalition's interests. Dr. Winn-Deen asked Mr. Aitken what employers are concerned about, because it seems that Federal legislation that standardizes requirements would be helpful to a company that has employees in more than one State. She said the only places that the Federal law would not apply would be in States that have even higher levels of protection. Dr. Leonard then asked Mr. Aitken to describe the GINE Coalition in depth, including its mission and actions taken to date. Mr. Aitken responded that the GINE Coalition is a group of principally employer organizations and health care organizations that have worked with the House and the Senate on legislative proposals dealing with genetic discrimination.

Ms. Berry noted that she has not seen any specific proposals put forward by the GINE Coalition with regard to changes to the Senate bill. She asked Mr. Aitken if the Coalition has actual legislative language, and if so, she wondered whether the Committee would be better off considering recommendations that represented a compromise in language in the interest of moving the bill forward. Dr. Tuckson agreed to return to that point.

Dr. Collins suggested encouraging the Secretary to follow up by contacting the Speaker of the House, the Majority Leader, and the Chair of the Energy and Commerce Committee. Dr. Tuckson then asked if a representative from AHIP could address the Committee to discuss the perspective of the insurance industry.

In response, Mr. Tom Wilder, Vice President for Private Market Regulation, AHIP, told the Committee that AHIP did not oppose the Senate bill but has urged Congress carefully draft legislation in this area. AHIP, he said, has tried to educate members of Congress concerning how health plans use health information as part of disease management and for communication with providers and patients, and wants to be certain that if legislation passes Congress, it doesn't jeopardize those functions.

Dr. Tuckson responded that he would like to see a middle ground achieved so that the Senate bill will accomplish what is needed in a way that is acceptable to all parties. He asked whether a "grammar of coexistence" could be developed. Ms. Fisher noted that some organizations, such as NBCC, are highly politicized and not amenable to compromise. She also said it is difficult for the Committee to approach Congress because of enjoinders against lobbying activities. However, she noted that because Secretary

Thompson's wife, his mother-in-law, and his daughter all have had breast cancer, many in the breast cancer community have been waiting for him to speak out.

Ms. Joanne Howes, with the firm DDB Bass & Howes, noted that she has been working with the Coalition for Genetic Fairness and said that the Senate bill was a fair compromise. They were previously assured that the bill had the support of the Chamber of Commerce and the health insurance industry. Her organization feels stymied at this point. Dr. Tuckson summarized the discussion by stating that there does not seem to be an active effort underway to reach an acceptable compromise.

Dr. McCabe said that the morning's testimony heard by the Committee about discrimination was incredibly powerful, as was the anecdotal documentation provided to Committee members in the spiral-bound notebook. He said this information couldn't easily continue to be ignored. He proposed that the Committee summarize the material in the notebook and forward it to the Secretary.

Dr. Tuckson proposed the following next steps:

- The Committee could request a meeting with the Secretary to inform him about the seriousness with which the Committee viewed this issue and to present him with a summary of the testimony. We could also ask if he would broker a meeting with the Secretaries of Labor, Justice, and Commerce to extend the conversation with other appropriate Departments of the Federal Government.
- As part of that request, the Committee would ask that the document prepared by the Committee on genetic discrimination be transmitted to key individuals and committees in Congress.
- The Committee could send a letter to the GINE Coalition asking it to be specific about its objections to S. 1053.
- The Committee could ask AHIP to articulate its specific concerns about this legislation.
- The Committee could contact the Chamber of Commerce to ask that the organization clarify its position.
- The Committee should include publications with hard data in the materials being compiled.
- The Committee should consider if it cold play a useful role in bringing together those who disagree about this issue, with the goal of resolving differences and reaching a satisfactory compromise.

Committee Review and Discussion of SACGHS Revised Draft Report on Coverage and Reimbursement of Genetic Tests and Services

Report of the Deliberations of the Coverage and Reimbursement Task Force
Cynthia E. Berry, J.D.
Chair, Coverage and Reimbursement Task Force

At the March priority-setting meeting, the Committee identified the coverage and reimbursement of genetic technologies and services as a high-priority issue requiring in-depth study. At the June meeting, the Committee considered a preliminary draft report on coverage and reimbursement. The Coverage and Reimbursement Task Force formed by the Committee in June examined the report and revised it based on recommendations put forward at the last meeting and by members of the public. A Task Force meeting

to obtain additional input from the Committee, ex officio members, and members of the public so that the Task Force can develop thoughtful, concrete, and productive recommendations for addressing barriers to coverage and reimbursement.

Ms. Berry said the report offers a comprehensive analysis of the barriers to coverage and reimbursement and offers recommendations to address them. The overarching goal of the report and its recommendations was to improve access to genetic technologies, genetic services, and genetic tests.

At the last meeting, the Committee requested a presentation on the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) project, recently launched by CDC. EGAPP was identified as a potential model for assessing when the evidence base is sufficient to establish clinical utility and to make coverage decisions, as well as the need for a mechanism to address gaps when there is no real evidence to support coverage for genetic technologies.

Evaluation of Genomic Applications in Practice and Prevention: Implementation and Evaluation of a Model Approach
Linda Bradley, Ph.D.
Geneticist, Office of Genomics and Disease Prevention, CDC

Dr. Linda Bradley noted that EGAPP does not represent a new concept, but an evolution of ideas and methods dating back to the 1997 report of the Task Force on Genetic Testing. This report emphasized the need for evidence-based review of new tests during translation from research to practice and for a coordinated process to collect data in pre-market and post-market periods. It also described assessment criteria in the context of genetic tests. The Secretary's Advisory Committee on Genetic Testing (SACGT), through its subsequent deliberations, affirmed the task force's assessment criteria and added emphasis on ethical and social issues as a component of evaluation. SACGT also encouraged collaboration for data collection and education and made other specific recommendations, among them that CDC should play a coordinating role in data gathering and analysis.

Dr. Bradley said that in 2000, CDC took a step toward addressing the need for pre-market review of data by funding a cooperative agreement, along with the Foundation for Blood Research, to evaluate the ACCE model system. ACCE reflects the components of evaluation laid out by the task force and SACGT. It's based on the premise that the specific disorder or phenotype to be tested for is first identified, followed by the test and the setting in which the test is to be performed. An analytic framework—in this case, sets of targeted questions that can be used to systematically review evidence on each component—then define the test's analytic validity; clinical validity; clinical utility; and related ethical, legal, and social implications. This process was designed to assess the availability, quality, and usefulness of data on DNA-based tests for disorders with a genetic component. ACCE used an ad hoc approach to grading the quality of evidence, versus a more structured approach, to extract maximum information. ACCE reports include the review, analysis, and integration of data and the identification of gaps in knowledge and the data needed to resolve identified gaps. ACCE's objective was not to suggest policy or make recommendations, but to provide complete, accurate, up-to-date summaries in formats useful to a range of audiences.

Dr. Bradley noted that five ACCE reviews were posted for comment and that a great deal had been

learned from this process. Bradley said it is clear that, in moving beyond the published data, the field can discover new and useful information.

From a public health perspective, the question to ask is, "What would a non-regulatory process for the evaluation of genetic tests look like?" Dr. Bradley said that evaluation must occur at two key points: 1) The transition from research and development to clinical practice, ideally before a test enters widespread use. It should include systematic review of evidence on clinical validity; and 2) During the post-market period, an assessment of performance in practice and the impact on public health must take place, beginning with basic information on utilization and access.

Dr. Bradley explained that EGAPP is a 3-year model project with the goal of establishing and evaluating a systematic mechanism for pre-market and post-market assessment of genetic tests and other genomic applications in the United States. EGAPP is a public health initiative with a population focus, and like ACCE, the objective is a first or early look at new tests and technologies to determine what is known and to identify important gaps in knowledge.

EGAPP will utilize information and recommendations developed through this and other advisory processes, as well as the knowledge gained from the ACCE project. Partnerships and collaborations are vital to the success of this project, including international collaborations and relationships with other projects and initiatives. The process aims to provide a clear linkage between the evidence developed and the recommendations made, minimizing conflicts of interest in the review process. The project will develop a plan for effective dissemination of information to target audiences.

Dr. Bradley stated that the central element of the project will be an independent, non-Federal, and multidisciplinary working group consisting of 10 to 12 experts from fields such as health care, genomics, epidemiology, health technology assessment, evidence-based review, public health, and health economics. The working group will develop an organizational plan that defines protocols for evidence-based review and the development of recommendations. They will consider input from stakeholders, develop criteria for selecting topics, and then select and prioritize topics for review. When a topic is selected, the working group will commission or conduct an evidence-based review and consider the strategies for post-implementation monitoring, data collection studies, and evaluation of the project.

The stakeholders identified will serve as a source of content expertise and will provide technical assistance, review reports, and be involved in the development of informational messages for key target audiences. In years 2 and 3 of EGAPP, two pilot data collection studies will be conducted and the success of the project will be evaluated. The group plans to have a methodology meeting with a relatively small group of experts in July 2005. It will also address questions about the use of unpublished datasets and "gray" literature, and will deal with proprietary data. The results will be used to inform EGAPP working group deliberations and hopefully will be published.

Dr. Bradley noted that EGAPP is focused on genetic tests and other genomic applications; in response to the demand from health care professionals, policymakers, and the public for a source of reliable and reasonably objective information about the appropriate use of genetic tests. However, the knowledge gained about successful evaluation approaches, methodologies, and infrastructure should be applicable to the assessment of other tests and emerging health care technologies.

Discussion

Ms. Masny asked if the process for review would be the same as for the methodology meetings. Dr. Bradley responded that the standard methodologies that are being used in many evidence-based review practices are going to be problematic with genetic tests because of a lack of quality evidence in many cases. She said the methodology conference will provide an opportunity to look at different ways to approach these issues.

Dr. Tuckson asked if the invitations to the methodology conference had been sent out and asked who was being invited. Dr. Bradley indicated that a list of invitees was still in the process of being developed. Dr. Leonard expressed concern that laboratories were being included as stakeholders, rather than active participants. Dr. Bradley responded that laboratory representatives will play an important role as experts by providing technical assistance to the working group.

Review and Discussion of the Revised Draft Report

Ms. Berry led the Committee in a section-by-section review of the revised report, *Coverage and Reimbursement of Genetic Tests and Services*. She emphasized that further input will be requested from the public and that the day's discussion would not result in a final report.

Genetic Tests and Services

Dr. Leonard noted that the Priorities Report defined genetics as the study of inheritable traits and variability, and genomics as inheritable and acquired. Yet, in the document, the phrase "or acquired" was used in the definition of a genetic test. The Committee discussed the importance of definitions and the need for consistency. Dr. Tuckson suggested that a small group be formed to work on the internal consistency of the definitions. He noted that one of the Committee's tasks is to educate the public and that they should take every opportunity to remind people about the meaning of fundamental terms.

Health Care Financing in the U.S.

Ms. Berry noted that the report describes coverage decisions in the Medicare program, other public programs, and the private sector. It also describes fee schedules and billing processes. No changes were suggested for these sections.

Barriers and Potential Recommendation, Medicare Screening Exclusion

Ms. Berry then led the Committee's discussion as they focused on several barriers and recommendations in depth, attempting to reach consensus on each one. Ms. Berry said members also could suggest alternative recommendations.

The Committee addressed the screening exclusion in Medicare, which is a critical barrier to coverage of genetic tests and services in that program. Dr. Winn-Deen suggested rewording the recommendation to clarify that the barrier applies only to *some* genetic tests. Dr. McCabe suggested moving the discussion

on the preventive nature of genetic services to the front of the section so it serves as a lead-in that describes the importance of screening. The Committee then decided to move the discussion of all public-private barriers so it appears first in the document and is followed by the barriers specific to Medicare.

Four potential recommendations were listed under the Medicare Screening Exclusion section. Ms. Berry noted that the Centers for Medicare and Medicaid Services (CMS) has indicated that it is very unlikely that Recommendation 4 would be acted upon (CMS unilaterally modifying its interpretation of Title XVIII of the Social Security Act to allow the agency to cover screening services without any legislative action). Some staff members at CMS thought that Recommendation 1 (Congress amending the Social Security Act to add a benefit category for preventive services) would be a better approach. They acknowledged, however, that it would be difficult to get Congress to change the Medicare statute in this way.

After considerable discussion about whether to integrate Recommendations 1 and 2 or leave them separate, members agreed that that they would be offered as discrete options. However, Recommendation 1 would be amended to flesh out what the legislation would do and to ensure that evidence-based decisionmaking is part of the recommendation and there is not automatic coverage. Recommendation 2 (national coverage for genetic tests for those with a family history) could be acted upon if further discussion and public input indicate that urgent action is required on the part of CMS. It could then be implemented in the absence of congressional authorization. The Committee agreed that Recommendations 3 (redefining diagnostic laboratory tests) and 4 would be deleted, as they were unlikely to be implemented and could weaken the case for 1 and 2.

National versus Local Coverage Decisions

Ms. Berry said the local coverage decision process allows a certain amount of flexibility, taking into account local practices, while the national coverage decisionmaking policy preempts local policies and has broad applicability across the country. She said the task force recognized that there probably always will be and should be a healthy mix between local and national coverage decisionmaking processes. Section 731 in the new Medicare law requires the development of a plan to evaluate new local coverage decisions to determine which ones should be adopted nationally, with the idea of providing greater consistency in Medicare coverage policies when possible. The Committee also agreed that it should recommend that CMS be encouraged to move forward with its plan, as outlined in the new Medicare law.

Genetic Counseling

Ms. Berry stated that the Medicare statute does not permit genetic counselors to directly bill Medicare, which is a barrier to access. Five potential recommendations were included in the report to address this barrier:

- Encourage States to enact licensure programs for certified genetic counselors.
- Add genetic counselors to the list of non-physician providers eligible to bill Medicare directly.
- Conduct a demonstration project under the auspices of CMS that would examine genetic counseling, its value, and its effectiveness.
- Commission the Institute of Medicine to assess the effectiveness of genetic counselors.

- Conduct an analysis of the health disciplines to determine which should be providing genetic counseling services, decide the appropriate level of supervision for each, and state whether they should be allowed to bill Medicare.

The Committee discussed moving this section to the umbrella of public and private, with a separate discussion of issues that apply to Medicare only. Other editorial suggestions were made that were considered important to the readability of the report. The Committee then discussed issues related to the five recommendations.

The Committee agreed that State licensure of certified genetic counselors is part of the solution, although it was not clear how this could be implemented. Dr. Winn-Deen felt the report did not adequately address what the qualifications for genetic counselors are and recommended further discussion of national standards for this function. Ms. Harrison stated that those who are certified by the American Board of Genetic Counseling or similar bodies are clearly qualified. However, other professions are qualified who are not certified, which is more difficult to address. The Committee agreed that genetic counselors should be directly reimbursed for their services, but it expects resistance by those in the system who will have to pay. More data will be needed to prove that the service has value. Dr. Tuckson made the point that, ultimately, genetic testing will decrease health costs. Mr. Margus stated that it's important to document the damage that's done when people aren't receiving counseling and present this information to Congress.

Ms. Berry suggested merging the last two recommendations. A study to assess the effectiveness of genetic counselors could be undertaken by a body other than the Institute of Medicine, but regardless of who conducts it, an analysis of health disciplines working in genetic counseling could take place at the same time.

Due to the need to move on to public comments, the Committee agreed to rework the recommendations and continue reviewing the draft report the following day.

Public Comments

Kelly Ormond, M.S., C.G.C.
President, National Society of Genetic Counselors

Ms. Kelly Ormond stated that the National Society of Genetic Counselors (NSGC) is the leading voice, authority, and advocate for the genetic counseling profession. It represents more than 2,000 members who provide genetic counseling for prenatal, pediatric, and adult genetic indications, as well as working in academia, research, and biotechnology companies. A high percentage of clinically practicing members offer some form of predispositional genetic testing on a regular basis, whether carrier testing or presymptomatic testing, for adult-onset disorders. She noted that NSGC was disappointed that S. 1053 was not taken up by the House for discussion. Ms. Ormond then addressed two issues related to the provision of genetic services: genetic discrimination by employers and insurers; and coverage and reimbursement of genetic counseling services, which includes the related topic of genetic nondiscrimination legislation.

Ms. Ormond stated that there are very few documented cases of genetic discrimination taking place in either the insurance or employment setting, even though this is clearly an ongoing problem for some families with inherited disorders. A paper currently in press states that 7 percent of survey respondents at risk for colon cancer perceived that they or a healthy family member had experienced genetic discrimination based on either genetic testing or family history. Also, regardless of the rate at which genetic discrimination occurs, data suggest that individuals want to keep their genetic information private and are afraid that they will be discriminated against based on genetic information. As a result, the topic of potential genetic discrimination is discussed frequently in genetic counseling sessions and is usually raised by the client, rather than by the genetic counselor. This fear may result in at-risk individuals declining genetic counseling and genetic testing or hiding their risk from their physicians or insurers. They may undergo testing using an alias or in an anonymous manner, or may not bill health insurance for the testing. Some individuals obtain life insurance or other policies prior to undergoing testing.

Ms. Ormond stated that although education through the media and health professionals will be useful, currently, fear related to genetic discrimination appears to be pervasive. Because State and Federal laws do not offer sufficient protections, NSGC strongly supports the passage of Federal genetic nondiscrimination legislation to alleviate the majority of concerns regarding genetic discrimination and to allow its members to use this information to help clients make informed medical and personal decisions. Ms. Ormond expressed her commitment to work with SACGHS until such legislation is passed.

She concluded by addressing the issues of coverage and reimbursement for genetic counseling services. Although some payers contract directly with the health plans to include genetic counseling as a covered service and some services are covered by Medicaid and Medicare when provided to individuals with disabilities, Ms. Ormond stated that the bulk of genetic counseling services are not currently reimbursed.

Sharon Terry, M.A.
President and CEO, Genetic Alliance

Ms. Sharon Terry stated that the Genetic Alliance is a group of 600 genetic disease advocacy organizations that represents 14 million individuals. Those in the Alliance are appalled that many families and individuals experience genetic discrimination and fear knowledge of their own risk, as well as fearing participation in research. The organization believes that all genetic information, including family history, deserves strong protections against misuse in health insurance and employment. Ms. Terry said genetic nondiscrimination legislation will reduce the likelihood of genetic information being misused in health insurance or employment decisionmaking and will help the public take full advantage of medical advances that could prevent disease.

She went on to say that fear of discrimination discourages those who have disease-causing mutations from participating in genetic research, adding another hurdle to the path from basic science to the development of cures. The Genetic Alliance and the Coalition for Genetic Fairness have worked for years on this issue and have, in the past year, presented a letter to Speaker Hastert signed by hundreds of organizations and individuals. Ms. Terry said the two groups will continue to work together on this issue until legislation is passed. She stated that the Alliance strongly supports S. 1053 and asked the Committee to be bold in its communication with the Secretary on this subject.

Miriam O'Day
Alpha-1 Association

Ms. Miriam O'Day told the Committee that alpha-1, which is both a pediatric and adult onset liver disease, is a good model for discussion on genetics, health, and societal issues. It is treated in the end stage with lung transplantation, and the Association believes that individuals with alpha-1 are at a disadvantage in the allocation process. Ms. O'Day noted that the organizations her group represents have had to take responsibility for finding their way around the patchwork State legislation on genetic discrimination. In the absence of Federal protective legislation, they established an ELSI Working Group to conduct targeted screening and detection. They are seriously impacted in their ability to identify the 95 percent of alpha-1 patients who are not yet diagnosed.

The ACT study, funded by the Alpha-1 Foundation and conducted at the Medical University of South Carolina, offers a free and confidential finger-stick test that the patient can complete at home. Ms. O'Day said the results are mailed directly to the individual participant. Since 2001, the ACT trial has performed 2,400 tests, and the protocol has been shared with NIH at its request. A follow-up questionnaire evaluates the perceived risks and benefits of genetic testing. They show that, of those who responded to the survey, more than 30 percent reported that the reason for seeking confidential testing was a fear of losing insurance. Thirty-four percent reported concern about higher health care costs if the results were made public and 85 percent sought testing for the genetic knowledge. Ms. O'Day closed by stating that the Association strongly endorses the passage of Federal protective legislation.

Gary Martucci
Myriad Genetics Laboratories

Mr. Gary Martucci told the Committee that Myriad Genetics began providing clinical and genetic testing for common hereditary cancer syndromes 8 years ago. He said that in 1996, two of the greatest barriers to genetic testing were the fear of discrimination and the unknown rate of reimbursement from insurance carriers. However, he has been successful in securing coverage and reimbursement from health insurers nationwide. Myriad's experience is that genetic testing for common hereditary cancer syndromes is covered by insurers 90 percent of the time. However, the fear of discrimination is prevalent.

Mr. Martucci has discussed genetic services with hundreds of medical directors, physicians, and patients across the United States. Concerns about discrimination arise in virtually every discussion. To reduce this anxiety, Myriad implemented a policy that patient test results are not released to anyone except the ordering health care provider or designee without the patient's express written consent. Insurance plans representing approximately 200 million covered lives comply with this policy because they recognize the clinical value of cancer genetic testing, which leads to effective medical interventions. Mr. Martucci said that Myriad's policy results in numerous protections for consumers of cancer genetic tests, although gaps remain. He said the fear of genetic discrimination remains the most commonly cited reason for both patients and providers avoiding the use of genetic services to prevent life-threatening cancer.

Although peer-reviewed literature suggests that actual genetic discrimination is not a significant problem, Mr. Martucci said the media continue to portray genetic discrimination as a common risk to individuals who take advantage of the health benefits offered by genetic services. Citing an article by Roth, et al., he

stated that, "Unless these people believe that they and their families will be adequately protected from discrimination and from the possibility of losing or being denied health insurance, many will choose not to be tested for genetic conditions or predisposition to disease."

Mr. Martucci told the Committee that genetic services and testing offer the hope of reducing the burden of hereditary cancers for many families. He said tens of thousands of individuals have benefited from genetic tests as a way to guide their providers in the most appropriate medical management. More than a million U.S. citizens carry mutations predisposing them to cancer, yet fewer than 2 percent are aware of it.

Mr. Martucci closed by saying that to integrate the promise of the Human Genome Project into clinical care; patients, clinicians, and insurers need the best available information to coordinate medical management. Without the information available from genetic risk assessment, patients and health care providers are left only with limited knowledge of how best to manage the risk of disease. He said the fear of genetic discrimination must be eliminated through comprehensive legislation to allow the public to participate in the benefits of genetic medicine.

Christine Broderick
National Partnership for Women and Families

Ms. Christine Broderick testified that the Senate has taken an important step in advancing genetic testing and research by passing the Genetic Information Nondiscrimination Act. She said this legislation, if enacted, would provide Americans with much-needed protection from genetic discrimination in health insurance and in the workplace. She said that women and families stand to benefit tremendously from genetic testing for diseases such as breast and ovarian cancer. However, Ms. Broderick noted, advances in testing will not help women and families if, by participating in genetic research or taking a genetic test, they can or fear they can be denied job opportunities, health care, or both.

She said the National Partnership for Women and Families leads the Coalition for Genetic Fairness, a diverse group of disability, women's advocacy, and civil rights groups that recognizes the need for meaningful protections against genetic discrimination. To illustrate the impact of genetic discrimination and the fear of genetic discrimination, the Coalition prepared a report entitled *Faces of Genetic Discrimination*, which provides telling statistics and first-person accounts about this issue.

Ms. Broderick described the four core principles that the Coalition believes must be part of any legislation. First, all genetic information that predicts future health risks, including family history, must be protected. Second, health insurers and employers must not be allowed to collect predictive genetic information and use it to discriminate in the health care system and the workplace. Third, individuals who experience genetic discrimination must have the right to seek redress through legal action with access to meaningful remedies. Fourth, entities holding genetic information about individuals must be prohibited from disclosing it to third parties without the individual's permission. Ms. Broderick closed by stating that as science progresses, it becomes increasingly more critical that Congress act to ensure that Americans are protected from genetic discrimination.

Donald Horton
Director of Public Policy and Advocacy, Laboratory Corporation of America

Mr. Horton stated that as a national leader in genomic and genetic testing, LabCorp views genetic discrimination and the coverage and reimbursement of genetic tests and services as highly important issues. LabCorp supports Federal legislation to prohibit discrimination based on genetic information in health care and health insurance and employment matters. He said LabCorp believes that it is only through Federal legislation that the fear of genetic discrimination and its practice will be banned from the health care system. He went on to say that existing Federal laws are inadequate and State laws vary significantly in their depth and scope of protection. Further, ERISA can preempt the protections of State law. He closed by urging the Committee not to give up, but to move forward in their work for comprehensive Federal protections.

Tuesday, October 19, 2004

Continued Review and Discussion of the SACGHS Revised Draft Report on Coverage and Reimbursement of Genetic Tests and Services

Cynthia E. Berry, J.D.
Chair, Coverage and Reimbursement Task Force

Ms. Berry began the day with a review of the revised set of potential recommendations, developed the previous evening by staff, on screening exclusions and national versus local coverage decisions as they relate to genetic counseling. The new recommendations for the report stated that:

- A comprehensive review and analysis is needed concerning who is qualified to provide genetic counseling services (and under what conditions), who should be supervised, and how genetic counselors should be reimbursed. The effectiveness and value of providing these services also should be reviewed.
- Any gaps that are uncovered through this analysis could lead to a Medicare demonstration project that would provide additional data to help address some of the questions and barriers outlined in the report on access to genetic counseling.
- If the data analysis and the data from the demonstration project support it, the Committee could advocate a legislative change that would add all appropriate health care providers to the list of non-physicians who can bill Medicare directly.
- Licensure of genetic counselors requires further discussion by the Committee.

The Committee discussed these recommendations as they related to the draft report. They began by addressing the significance of licensing for genetic counselors and the fact that many kinds of health care providers currently provide and will increasingly be engaged in genetic counseling. It was agreed that the language in the report should be broadened to take into account different specialties working in this area. The Committee decided that more clarity was needed around qualifications and scope of practice before making a recommendation on reimbursement for genetic counselors. The idea of a review of the literature on the outcomes of genetic counseling by different practitioners also was discussed, and Drs.

McCabe and Khoury felt that any analysis of this literature should be made more public. The Committee agreed that there was a need to gather more information about several issues, including licensure for genetic counselors. They accepted the first three recommendations and agreed that further changes might be proposed based on the additional work conducted.

The Committee asked Andrew Faucett of the American Board of Genetic Counseling (ABGC) to participate in and inform the discussion. He said that ABGC is a national accrediting and credentialing body for the profession of genetic counseling. Mr. Faucett noted that three States currently have licensure and 14 or 15 are working toward obtaining licensure. The Committee asked him whether literature exists that demonstrates the efficacy of genetic counseling. He stated that, although there is not an extensive amount of literature, what is there is very powerful and worth compiling. The Committee agreed that a systematic review of the literature should be completed and asked Mr. Faucett and Ms. Ormond if they would be willing to provide the information. The resulting paper would then inform the proposed studies of genetic counseling and any Committee recommendations in this area.

Medicare Clinical Laboratory Fee Schedule

Ms. Berry led the Committee in a discussion of the draft report's section on laboratory fees, noting that the Committee has heard repeatedly that the costs of clinical lab tests exceed what Medicare will pay. Further, the amount of Medicare reimbursement for lab fees is currently frozen. The potential recommendation states that, as a method to temporarily redress the extreme discrepancies between cost and payment for genetic tests, the Secretary could change rates through a well established process called "inherent reasonableness." Ms. Berry asked for opinions on the recommendation or other suggestions to address the fee discrepancy. Several participants pointed out that there are regional variations on the amounts paid, depending on the carrier. Dr. McCabe stated that the inherent reasonableness mechanism might address the lack of uniformity in payments from region to region. Dr. Rollins of CMS verified that local carriers have the discretion to make payment decisions based on what they think is reasonable. He said the recommendation in the report was a valid way to approach CMS and ask for further evaluation. The Committee agreed to accept the wording of the recommendation as written, but to add more detail on the case for it in the text of the report.

Medicaid and SCHIP

Ms. Berry reviewed the two potential recommendations in this section. The first proposed an information dissemination function for CMS, by which they would provide States with a solid evidence base for providing and covering genetic services. The second recommendation would provide States with financial incentives for covering indicated genetic services. Ms. Berry felt the latter proposal was not realistic in light of the current budget environment. The Committee discussed whether States would consider the coverage of genetic services a higher priority than other services they are struggling to cover, such as prenatal care. They also addressed the broadening recognition of the need for newborn screening and the fact that these efforts need to be standardized. Ultimately, the Committee decided to accept the first recommendation as is, but to amend the second to reference the fact that HHS is already providing some grants and assistance to the States and the Committee urges the agency to continue doing so.

Public and Private Insurers

The next recommendation considered by the Committee stated that private insurers should not wait for Medicare to act to make coverage decisions for genetic tests and services. After some discussion, the Committee agreed that this recommendation could be integrated with a later section of the report that addresses evidence-based practices in both the public and private sectors.

Informational Utility and Medical Effectiveness; Preventive Nature of Genetic Services; and Factoring Cost into Coverage Decisions

Ms. Berry described the three barriers in these sections leading to a potential recommendation that the Secretary task an appropriate group to develop a set of principles guiding decisionmaking for coverage of genetic tests, including categorizing tests in terms of those that should be covered and not covered. She said the principles would help employers and health plans address cost-effectiveness, the preventive nature of a test, and the test's clinical versus informational benefits. The Committee discussed at length whether there is a severe lack of guidance for public and private payers concerning genetics and genomics and if it merits a recommendation to the Secretary to set up a task force. Because there was insufficient time to reach consensus on the issue, the group ultimately decided that the deadline for the completion of the report should be pushed back by one Committee meeting.

Public Comment

Andrew Faucett, M.S., CGC
American Board of Genetic Counseling (ABGC)

Mr. Andrew Faucett said the ABGC believes it is critical to resolve the two issues discussed by this Committee during the meeting, i.e., genetic discrimination and coverage and reimbursement. He said comments from the public and from working genetic counselors make it clear that some individuals are fearful of genetic discrimination and are afraid to seek the help of trained genetic professionals. In addition, in requesting answers to important questions about their risks of developing medical conditions with an inherited component, these individuals often receive incomplete or incorrect information that prevents optimal health care interventions from being pursued. Mr. Faucett said legislation designed to reduce genetic discrimination must be developed so that individuals may freely discuss their concerns about genetic conditions with professionals who can provide accurate information.

He further stated that the difficulties with billing and reimbursement for genetic counseling services could impede the development of new counseling programs and interfere with the ability of institutions housing clinical genetics programs to support the activities of genetic counselors. In addition, a lack of reimbursement for genetic services could result in a decrease in these services, affecting not only patients and their families, but also decreasing the availability of clinical training sites for genetic counseling students. Potential students may hesitate to enter the field of genetic counseling because of the uncertainty of reimbursement for services.

Mr. Faucett closed by stating that knowledge about genetics and related social and ethical implications is becoming increasingly essential for many health care providers. Genetics health care professionals have

been and will continue to be the ones who will train and educate other health care professionals about the complexities of genetic medicine, including the potential for discrimination. Clinical genetics services must be recognized by the health care industry and reimbursed appropriately so that genetic professionals can be trained and patients can receive quality genetic services.

Scope, Charge, and Progress to Date of the National Academy of Sciences' Committee on Intellectual Property Rights in Genomics and Proteomic-Related Inventions
David Korn, M.D.
Member, National Academy of Sciences Committee
Senior Vice President for Biomedical and Health Sciences Research
Association of American Medical Colleges

Dr. David Korn explained that NIH asked that a National Academy of Sciences committee examine trends in the number and nature of patents being issued for technologies related to genomics and proteomics. As part of this process, the committee looked at the policies, procedures, and operations of the U.S. Patent and Trademark Office. The focus has been on the ways in which the patenting of genomic and proteomic inventions and licensing practices may be affecting research and innovation. Dr. Korn said that every one of the patent criteria established by U.S. law has been challenged in this area of gene patents. They've been challenged on the basis that the applicant does not convincingly demonstrate what they've claimed.

He said the committee will be looking at international policies and practices in Europe and Japan to find information about the ways that individuals, entities, and companies have managed what Rebecca Eisenberg dubbed the "patent thicket." To move forward with a patent, he explained, it is often necessary to negotiate intellectual property rights with numerous different owners of bits and pieces of information.

Dr. Korn addressed the research or experimental use exemption. He said only one appellate court deals with intellectual property; the Court of Appeals for the Federal Circuit (CAFC). This court makes the laws on patents. He discussed the 1813 case of *Whittemore* v. *Cutter*, which dealt with experimental use exemptions. The court ruled that work on a patent for experimental purposes, but not for profit, was allowed. For almost 200 years, that ruling was the basis of case law in this area and it has protected university research. However, in 2002, in the case of *Duke University* v. *Madey*, the CAFC ruled in favor of an inventor of free electron laser equipment, and significantly narrowed the experimental use doctrine.

Dr. Korn said his committee is working with other organizations in Washington to conduct a blinded survey of post-Madey university experiences to see whether there are challenges and demands for licenses and payments. He noted that almost anyone working in the field of genomics or proteomics must use someone else's research tools in some way. Dr. Korn described material transfer agreements, which are the contractual documents that faculty use when they share materials, reagents, organisms, or cell lines with others in industry or in universities. These agreements have become major impediments to the sharing of these materials.

Dr. Korn discussed problems that occur because owners of a piece of knowledge due to intellectual property laws can prevent other qualified professionals from using that knowledge to deal with patients.

He questioned whether it's in the interest of public health for the field of genomics to proceed in this manner. He noted that France and Canada don't recognize such sweeping, exclusive patents. Dr. Korn then discussed the statutory exemptions passed by Congress through the Patent Act related to these situations. He encouraged the Committee to address the ways in which intellectual property rights are managed to make sure the health of the public is not impaired. In conclusion, he noted that his committee is working at a fast pace and expects to release a report by June 2005. The Committee agreed to review the results of the report at that time.

Discussion of Proposed Plans for Addressing SACGHS Priority Issues

Large Population Studies
Huntington F. Willard, Ph.D.
Member, Large Population Studies Task Force

Dr. Hunt Willard said the task force identified potential topics in the area of large population studies for the Committee to discuss, which was presented to the Committee in a three-page report. He said the primary questions for consideration were: Should the Committee advise the Secretary to find resources to mount a large cohort study in this country? What information is needed to make that assessment?

In response to a query from Dr. Tuckson, Dr. Guttmacher explained that a working group within NIH explored what the science of such a study might look like. Staff members from several NIH institutes are now developing a document based on the findings. It will address the advantages and disadvantages of different participant sizes; potential costs; and the phenotypic, genotypic, and environmental exposure data the study might gather. He said it might be helpful if the Committee recommended to the Secretary that the Department explore a large cohort study, as it could benefit the health and well being of the American public. Dr. McCabe said, however, that there might be competing projects within HHS, and that the Committee may want to hold back on advocating for the large population study until they have more information. Dr. Willard agreed, stating that they wanted to avoid duplication of effort and should perhaps wait until there is something to review from the HHS working group. Dr. Guttmacher suggested that the Committee be prepared to consider the issue at the next meeting. Ms. Carr noted that the Secretary will be alerted to the importance of the topic when he receives the roadmap report from the Committee, although that is not the same as an endorsement letter. The Committee then agreed that the discussion should be tabled and later revisited if there is room at the February/March meeting for at least a half-day discussion of the subject.

Pharmacogenomics
Emily Winn-Deen, Ph.D.
Chair, SACGHS Pharmacogenomics Task Force

Dr. Emily Winn-Deen summarized the pharmocogenomics task force's discussion by saying they attempted to group potential topics into four areas:

- *Setting the stage* so that everyone on the Committee would have the same level of basic understanding
- *Translational efforts* to assess the pharmocogenomics issues they are facing

- *ELSI issues* to determine those that are unique to pharmacogenomics
- *Government agencies involved* so that the Committee can ensure that there is coordination of effort and shared knowledge of what is happening in different HHS arenas

Dr. McCabe noted that the Committee may also want to consider addressing medicolegal issues in pharmacogenomics. Dr. Winn-Deen said that topic fits under ELSI issues, although the task force may not have looked closely enough at the specifics. Ms. Masny added that the Committee may want to look at pharmacogenomic tests in light of coverage and reimbursement issues.

Dr. Winn-Deen asked Dr. Steve Gutman about the status of revisions to FDA guidance documents. Dr. Gutman replied that there has been a fair amount of activity at FDA and that a document was published 18 months prior on general diagnostic uses related to the platforms that support testing in pharmacogenomics and pharmacogenetics. The agency received some useful comments, including the idea that the document was trying to do too much. As a result, they are moving forward with a narrower, genetics-oriented document that they are hoping to publish by the end of the year.

Dr. Gutman also described a working group headed by Joe Hackett that is aggressively interacting with industry, as well as government and academic groups, to educate core staff on the diagnostic nuances of the new technology of pharmacogenomics. He said that in the FDA Center for Drug Evaluation and Research, Dr. Lesko has taken the lead, and the center has published a document encouraging the submission of voluntary datasets. Dr. Gutman said he was surprised that companies have come forward with their datasets, and a working group is being formed to create the appropriate firewalls and controls so the companies will not be harmed. A guidance document establishing the core of that program is being revised, with a target time for completion at the end of the year. The agency hopes to have it vetted in time for the third pharmacogenomics workshop in April 2005. He then stated that although the agenda will include a wide variety of topics, Dr. Gutman said he considered the vetting of the joint diagnostic therapeutic guidance document the most important planned activity for the workshop.

Dr. Gutman went on to say that the agency has promoted its interest in ensuring that it is a partner, rather than an impediment to translational research. FDA has introduced a program called the Critical Path Program, which will proactively seek ways to bring products to market more quickly. Pharmacogenomics has been targeted as a pilot, and the new program will create an opportunity for marketing within the product lines that FDA regulates.

Dr. McCabe noted the overlap between the topics under discussion: large population studies and pharmacogenomics. He said pinpointing the genetic basis for rare side effects will require the study of large populations. He asked if there should be some discussion of the order in which these areas should move forward, and Dr. Winn-Deen noted that there will be more information available in February or March. The Committee addressed the fact that two major drugs were recently taken off the market. Mr. Margus noted that for CMS and private carriers, there is a real value to pharmacogenomics beyond coverage. Although hundreds of millions of dollars are being spent reimbursing people for some drugs, a large percentage of those taking them are not responding to them. Pharmacogenomics could, in some cases, identify those who are actually at risk of side effects.

Review of the Status of Priority Issues
Sarah Carr
SACGHS Executive Secretary

Prior to turning the floor over to Ms. Carr to discuss topics for the next meeting, Dr. Tuckson noted that the genetic discrimination issue and the topic of coverage and reimbursement will be on the agenda and will require considerable attention. Ms. Carr then reviewed a timeline indicating the 12 priority issues the Committee had identified in March 2004 and the focus of each SACGHS meeting relating to these issues. She then reviewed the current status of these issues for the Committee, and suggested the following presentation topics:

- Health information technology, as it pertains to family history and pharmacogenetics. This technology also relates to the use of electronic health records to enhance privacy.
- A presentation by the HRSA Committee on Newborn Screening concerning the recommendations it is making to the Secretary
- Two presentations by CDC on rare disease testing: enhancing access to and quality of genetic testing for rare diseases; and enhancing quality assurance and quality control through the laboratory services program

In closing, Dr. Tuckson reviewed the Committee's work during the 2-day meeting and listed the decisions made:

- The Committee will receive more information on the Family History Initiative. They will send the Secretary a letter endorsing the importance of family history as a medical tool and asking him to encourage DHHS agencies to participate in the project.
- The Committee will compile the day's testimony on genetic discrimination, including the names of those who commented, including their congressional districts and background materials. The Committee will then ask to meet with the Secretary to discuss this information. The Secretary may be asked to convene at the same time with leaders at the Departments of Justice, Labor, and Commerce to resolve differences among the agencies. The Committee will ask the Secretary to send the compiled materials to Congress, especially the Speaker, the Majority Leader, and Congressman Barton.
- The EEOC will analyze gaps in current State and Federal legislation.
- The Committee will ask the GINE Coalition for its analysis and recommendations concerning genetic discrimination.
- The Committee will ask AHIP to analyze the problems preventing the Senate legislation (S. 1053) from moving forward and to report back on steps to solve these problems.
- The Committee will send a letter to the Coalition for Genetic Fairness requesting clarification on whether it opposes the use of genetic information for care coordination and whether there are other issues that are prevent consensus.
- The Committee will investigate the possibility of having either congressional people or their senior staff at the next meeting to see if they can clarify what is needed to achieve success in the area of legislation for genetic nondiscrimination.
- The Committee will consider holding a roundtable discussion at the next meeting to achieve consensus on genetic discrimination legislation from key parties, such as the Chamber of

Commerce. A conference call will take place to plan next steps.

- The Committee will continue to consider coverage and reimbursement issues related to genetic counseling, beginning with the licensure issue. They will conduct a literature review and analysis before the next meeting.
- Work on the draft coverage and reimbursement report will continue.
- Concerning the intellectual property issue, the Committee will wait for the NAS report and then determine whether any action by the Committee in this area is appropriate.
- The latest report from the HRSA genetic services study will be reviewed to see if it has information that can inform the reimbursement report.
- The Committee will continue discussion of a large population study and of pharmacogenomics at the next meeting.

Dr. Tuckson asked the Committee for permission to suggest in the letter to the Secretary that a "czar" or other authority be appointed in HHS to receive the work of the Committee. This person would serve as an official coordinator across agencies that deal with genetics and genomics issues. The Committee agreed to this step.

Ms. Harrison suggested that efforts should be made to further disseminate the testimony on genetic discrimination. Dr. Tuckson and the Committee agreed to formalize this information in a synopsis and provide it to the major advocacy organizations.

Dr. Tuckson thanked the Committee for their hard work and expressed appreciation to Ms. Carr and her staff. He then adjourned the meeting.

We certify that, to the best of our knowledge, the foregoing meeting minutes of the Secretary's Advisory Committee on Genetics, Health, and Society are accurate and correct.

Reed V. Tuckson, M.D.
SACGHS Chair

Sarah Carr
SACGHS Executive Secretary