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SHALALA APPOINTS CHAIR AND MEMBERS OF GENETIC TESTING ADVISORY COMMITTEE

Health and Human Services Secretary Donna E. Shalala today named the chair and members of the Secretary's Advisory Committee on Genetic Testing (SACGT). The 13-member committee was chartered last year to help the department formulate policies on the development, validation and regulation of genetic tests, particularly DNA-based diagnostics. The decision to establish the Secretary's Advisory Committee on Genetic Testing comes in response to the recommendation of two advisory groups commissioned for the Human Genome Project by the National Institutes of Health (NIH) and the Department of Energy (DOE): the Task Force on Genetic Testing and the JointNIH/DOE Committee to Evaluate the Ethical, Legal, and Social Implications Program of the Human Genome Project.

Members of the SACGT were selected from nearly 200 nominees who have distinguished themselves in the areas of genetic testing, medical genetics, genetic counseling, primary health care, public health, clinical laboratory management, diagnostic technology, ethics, law, psychology, social sciences, and patient/consumer advocacy. One of the appointees is a member of the CDC's Clinical Laboratory Improvement Advisory Committee (CLIAC) and another is a member of the FDA's Medical Devices Advisory Committee (MDAC). Both CLIAC and MDAC have significant roles in ensuring the quality and safety of genetic testing laboratories and genetic test kits.

The SACGT, which will hold its first meeting June 30, 1999 in Bethesda, Md., will advise HHS on all aspects of the development and use of genetic tests, including the complex medical, ethical, legal, and social issues raised by genetic testing. Recommendations made by the Committee will be submitted to the Secretary through the Assistant Secretary for Health.

The chairman is Edward R. B. McCabe, M.D., Ph.D., Professor and Executive Chair, Department of Pediatrics, University of California, Los Angeles (UCLA), and Physician-in-Chief of the Mattel Children's Hospital at UCLA. Dr. McCabe is an internationally recognized authority in medical genetics and biochemical genetics and has broad experience directing basic science and clinical departments and leading national professional organizations and activities, such as the American Board of Medical Genetics, American Board of Medical Specialties, and American Academy of Pediatrics. Dr. McCabe has established and directed clinical service programs in medical and biochemical genetics, conducted

research on a wide variety of disorders, and developed molecular genetic strategies for confirmatory diagnosis in newborn screening for sickle cell disease and cystic fibrosis, among others.

The members of the committee are:

Patricia A. Barr, Partner, Barr, Sternberg, Moss, Lawrence & Silver, P.C., in Bennington, Vt. Ms. Barr is an experienced advocate who has helped form and lead national and state advocacy organizations such as the National Breast Cancer Coalition and the Vermont Coalition for Cancer Control and Prevention. She has extensive policy development experience at the state and national level and served on the NIH/DOE Task Force on Genetic Testing. Ms. Barr is a breast cancer survivor who understands on a personal level the implications of predispositional genetic testing.

Kate C. Beardsley, J.D., Partner, Buc & Beardsley, Washington, D.C. Ms. Beardsley is an authority on matters relating to the regulation of medical devices, including in vitro diagnostic devices. She is knowledgeable about issues of informed consent in genetic testing and the importance of ensuring appropriate privacy and confidentiality protections for genetic information.

Ann Happ Boldt, M.S., Certified Genetic Counselor, Maternal Fetal Medicine and Genetics Center, St. Vincent Hospital, Indianapolis, Ind. Ms. Boldt is trained in genetic counseling and certified by the American Board of Medical Genetics. Her current focus is on the provision of prenatal, cancer, and pediatric genetic counseling services and the training of genetic counseling students, medical residents, and other health care professionals. Ms. Boldt is a past president of the National Society of Genetic Counselors and a charter member of the American Board of Genetic Counseling.

Joann Boughman, Ph.D., Vice President for Academic Affairs and Dean of the Graduate School, University of Maryland, Baltimore, Md. Dr. Boughman is a medical geneticist with professorships in the Department of Obstetrics and Gynecology and Reproductive Sciences and the Department of Epidemiology and Preventive Medicine. She also is Research Professor of Periodontics. Her research interests are in genetic epidemiology and pedigree analysis, and she has focused on such problems as retinitis pigmentosa, deafness, congenital heart defects, and periodontal diseases. Dr. Boughman is a member of the FDA's MDAC.

Wylie Burke, M.D., Ph.D., Associate Professor of Medicine, Department of Medicine, Division of General Internal Medicine, University of Washington School of Medicine, Seattle, Wash. Dr. Burke is a primary care physician with expertise in genetics, genetic testing, and public health genetics. Her scientific research has focused on the clinical validity and utility of genetic information in single gene disorders, including neurofibromatosis, cystic fibrosis and hemochromatosis, and in common multifactorial disorders, including breast and colorectal cancer. Dr. Burke's policy work has focused on the integration of genetic diagnostics into clinical medicine, the role of genetic counseling in the delivery of genetic testing services, and the psychosocial implications of genetic testing.

Patricia Charache, M.D., Program Director, Quality Assurance and Outcomes Assessment, Department of Pathology, Johns Hopkins University Hospital, Baltimore, Md. Dr. Charache holds professorships in the Departments of Pathology, Medicine, and Oncology and is an expert in clinical laboratory management, including quality assurance and performance improvement in genetic testing laboratories. Dr. Charache is a member of CLIAC and Chair of the Microbiology Panel of the MDAC.

Mary Davidson, M.S.W., Executive Director, Alliance of Genetic Support Groups, Washington, D.C. Ms. Davidson, a clinical social worker and psychotherapist by training, is an experienced community organizer, social outreach program innovator, and consumer advocate. She leads a national coalition of consumers,

professionals and genetic support groups that serves as a voice for the common concerns of children, adults and families living with, and at risk for, genetic conditions. Through her work and her own personal experience, Ms. Davidson has gained deep insights into the impact of genetic disorders on individuals and families.

Elliott D. Hillback, Jr., Senior Vice President, Corporate Affairs,Genzyme Corp., Cambridge, Mass. Mr. Hillback is an expert in genetic testing, diagnostic technology development, and clinical laboratory management. He is knowledgeable about the impact of genetic testing on consumers as well as the challenges posed by genetic testing for primary care providers. Mr.Hillback has played a leadership role within the biotechnology industry to increase awareness of the ethical and social implications of advances in genetic diagnostics. He was a member of the NIH/DOE Task Force on Genetic Testing.

Barbara A. Koenig, Ph.D., Executive Director, Center for Biomedical Ethics and Co-Director, Program in Genomics, Ethics and Society, Stanford University, Palo Alto, Calif. Dr. Koenig is a medical anthropologist by training; she works in the inter-disciplinary field of biomedical ethics. Her research has explored cultural/ethnic pluralism and ethical decision-making in clinical practice, ethical issues in health promotion and disease prevention, and the social and ethical impact of presymptomatic genetic testing.

Judith A. Lewis, Ph.D., R.N., Associate Professor, Department of Maternal Child Nursing and Director of Information Technology, School of Nursing, Virginia Commonwealth University, Richmond, Va. Dr. Lewis' academic interests are in the area of infertility, ethical aspects of reproductive technology, and genetics and genetics testing. Her family was deeply affected by heritable genetic disease and involved in founding cystic fibrosis patient support and advocacy efforts in New England.

Victor Penchaszadeh, M.D., Sc.M., Professor of Pediatrics, Albert Einstein College of Medicine, Yeshiva University, and Chief, Division of Medical Genetics, Beth Israel Medical Center, New York, N.Y. Dr. Penchaszadeh is an expert in medical genetics, genetic testing, and public health. He has directed clinical programs, conducted research on a variety of genetic disorders, and explored a range of ethical and cross-cultural issues and policy questions in the provision of genetic services.

Reed Tuckson, M.D., Senior Vice President, Professional Standards, American Medical Association, Chicago, Ill. Dr. Tuckson is an expert in public health, primary health care, and medical education. Prior to joining the AMA, he was President of the Charles R. Drew University School of Medicine and Science, Senior Vice-President for Programs at the March of Dimes Birth Defects Foundation, and Commissioner of Public Health for the District of Columbia. He has played an important role in national policy discussions on issues concerning community-based medicine, the moral responsibilities of health professionals, and the development of leadership skills among physicians.

Note: HHS press releases are available on the World Wide Web at: http://www.hhs.gov. Information about the SACGT is available at: http://www4.nih.gov/od/oba/sacgt.htm