Statement to the
Secretary’s Advisory Committee on Genetics, Health and Society
(SACGHS)

February 12, 2008
Good morning. My name is Dr. Jeffrey Kant, I am a Professor of Pathology and Human Genetics and Director of the Division of Molecular Diagnostics at the University of Pittsburgh Medical Center. I am here today on behalf of the College of American Pathologists, where I Chair a Resource Committee that oversees proficiency programs in genetic testing, to follow-up on written testimony the College provided to SACGHS on its report *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS*. The College appreciates the opportunity to appear before you today and provide our perspectives on the oversight of laboratory-developed tests, and in particular genetic tests.

The College of American Pathologists is a national medical specialty society representing more than 17,000 pathologists who practice anatomic pathology and laboratory medicine in laboratories worldwide. The College's Commission on Laboratory Accreditation is responsible for accrediting more than 6,000 laboratories here and abroad. Our members have extensive expertise providing and directing laboratory services and participate as peer inspectors in the laboratory accreditation program. The College has been a leader in developing quality improvement programs for laboratories, including programs in genetic testing.

We already have better measures of the quality of laboratory tests than the medical profession has for most other aspect of practice. The College’s experience from its proficiency testing and laboratory accreditation programs is that the overwhelming...
majority of genetic tests performed in the U.S. are safe and effective. As noted in the report, performance on multiple CAP molecular genetics surveys has been excellent over a wide range of methodologies used for genetic tests. Of note, the performance of laboratory-developed tests on proficiency surveys is equivalent to assays that are FDA cleared or approved. This is due in part to the robust nature of the analytes along with rigorous attention to CLIA quality standards and practices as well as medical oversight of every clinical laboratory by a physician. The College’s Laboratory Accreditation Program stresses both analytic and clinical validation prior to introducing any new test into routine practice, recognizing that tests will continue to be periodically improved after introduction with each improvement revalidated by the laboratory before use on patient samples.

As medical specialists in the diagnosis of disease, pathologists have a long track record of delivering high quality services to patients through the practice of laboratory medicine. College members feel that genetic tests are not unlike numerous other laboratory tests that they have successfully introduced into medical practice. Indeed, the development and oversight of genetic tests constitutes an important and expanding aspect of the medical practice of pathologists and other laboratory physicians for decades to come. Pathologists therefore have a keen interest in ensuring that our ability to provide high quality diagnostic services to patients and other physicians we serve is not overly restricted. Patient care is compromised when diagnostic testing services are less readily and affordably available because of burdensome regulation.
We recommend that any changes to federal oversight of laboratory-developed tests be made within the context of CLIA to assure diagnostic tests are widely available and affordable for the greatest public benefit. The CAP supports further enhancement of laboratory testing through educational efforts, improvement in the quality of CLIA inspections, and additional federal resources for access to controls and standards. The College agrees that appropriate resources be directed to CMS for required oversight of CLIA and supports SACGHS recommendations for expansion of proficiency testing. Please consider that CLIA already requires assessment of analytical validity for all assays offered by a laboratory regardless of whether these test a regulated analyte, and we are aware of no evidence that alternative assessment leads to poor quality testing. Moreover, CLIA requires knowledge of the clinical utility for tests used in routine clinical practice and stipulates qualifications and responsibilities of the laboratory to patients. We feel that the CAP accreditation program already provides the necessary standards to assure quality laboratory testing as required by CLIA.

The CAP believes that requiring FDA approval for every laboratory-developed test (LDT) would result in numerous unintended consequences that would ultimately harm patients to include delayed implementation of new tests, reduced innovation, increased costs, and greater limitations of access to beneficial assays. Given that high quality genetic testing is already in place, different regulatory requirements for this group of assays do not seem necessary, and since not all laboratory-developed tests are genetic tests, difficult to implement.
The College supports the emphasis in the draft report on public-private partnerships for assessment of laboratory-developed genetic tests. We feel that registration of genetic tests through a public-private partnership could have positive impacts, but that such a system of registration should be voluntary and be devised with broad stakeholder input. CLIA already requires submission of test lists by laboratories as a condition of inspection; thus, additional information submitted should remain within the context of CLIA and CMS. Any new mechanisms for collection of information should be tested before implementation to assure that the most useful information is included and that submissions are not overly burdensome to laboratories. This information could then be made publicly available assuring clinicians and patients of the analytic and clinical validity of tests they are ordering, while not impeding the medical practice of pathologists.

In summary, the CAP believes that CLIA provides the necessary framework and standards to assure quality laboratory testing through its accreditation requirements. We recommend that any changes to federal oversight of laboratory-developed tests be made within the context of CLIA to assure diagnostic tests are widely available and affordable for the greatest public benefit. The CAP supports improving laboratory tests through educational efforts, improved CLIA inspections of laboratories performing genetic tests, and provision of additional federal resources for access to controls and standards. Pathologists and other laboratory professionals are key sources of knowledge and experience on the delivery of high quality, cost-effective laboratory services, and the CAP is willing and eager to contribute to discussions with clinicians, regulators, payers,
and others sharing our common interests. As you consider your final recommendations to the Secretary, we ask the SACGHS to carefully review the impact of those recommendations on the ability of pathologists to practice medicine in the best interest of their patients.