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(Submitted via email to cfomous@od.nih.gov)

December 21, 2007

Secretary's Advisory Committee on Genetics, Health, and Society
Attn: Cathy Fomous, Ph.D.
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 700
Bethesda, MD 20892

Dear Ladies and Gentlemen:

The following comments are provided by the Biotechnology Industry Organization (BIO). BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the annual BIO International Convention, the global event for biotechnology. BIO appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health and Society's (SACGHS') Draft Report on the *"US System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS."*

BIO supports a regulatory system that ensures that patients and healthcare providers have access to products that are proven safe and effective in a timely manner. At the same time, we also believe that the regulatory system must keep pace with scientific advances that offer patients better care. These principles are consistent with BIO's support for the Food and Drug Administration's (FDA's) *Critical Path Initiative*.

We believe that the level of regulatory review for any particular test should be based upon the risk that the test could pose to the health and safety of the patient. We believe that FDA has a key role in the oversight of laboratory developed tests (LDTs), based on a risk-based and flexible approach. The system should not be based upon the technology used to reach a result nor should it be based upon the entity that develops, commercializes or distributes the test. BIO believes that all high-risk tests should be subject to FDA regulation. Risk to the patient should be the overriding principle determining the level of regulatory review.

Advancements in our understanding of the genomic and molecular sciences have created the opportunity to develop healthcare products that more precisely target disease at the genetic, molecular and cellular level. BIO is pleased that the Secretary's Advisory Committee on Genomics, Health and Society is evaluating the need for enhanced oversight of genetic testing. To take full advantage of the scientific advances in the life sciences, we believe it is critical that we update our current system of evaluating genetic tests, while at the same time review the regulatory paradigm for all advanced diagnostics regardless of whether they are based on genomic, molecular or other technologies. We must ensure public safety and enhance public confidence to realize the potential of advanced diagnostics to enable the promise of personalized medicine.

To assist SACGHS and HHS in their efforts to achieve this goal, BIO is providing the following comments, which follow the order of the draft report and focus on Chapter 4, "Analytical Validity, Proficiency Testing and Clinical Validity".

SACGHS Recommendation 2:

BIO agrees with SACGHS' recommendations for supporting public resources to fill in "gaps in the extent to which analytical and clinical validity data can be generated and evaluated for genetic tests". We support the establishment of a laboratory-oriented consortium for sharing information regarding method validation, quality control, and performance issues (Chapter 4, Recommendation 2.B), and public-private efforts to support, develop, and enhance public reference databases to inform clinical validity assessments (Chapter 4, Recommendation 2.C). BIO suggests that SACGHS add language recommending that such initiatives be structured to encourage robust participation, e.g., that such a consortium provide mechanisms for anonymous reporting and/or protections from liability to encourage information sharing among members.

SACGHS Recommendation 3:

BIO supports SACGHS' view that a system of genetic test registration is necessary to provide stakeholders with information about the spectrum of tests being offered. Making test performance characteristics and reference information (analytical validity and clinical validity) publicly available should increase confidence in these types of tests among healthcare providers and patients, and could help improve the proper utilization of genetic tests. In addition, a genetic test registry would assist regulatory agencies (and Congress, where necessary) in evaluating these tests and developing appropriate pathways for oversight.

While we support the recommendation for a genetic test registry through a public-private partnership (Chapter 4, Recommendation 3.A), BIO believes that registration should be mandatory for certain moderate- to high-risk categories of tests. We also believe that the registry should be housed at and managed by a federal regulatory body, such as the FDA, to maintain its credibility and independence. The responsible agency should develop clear criteria that include specific examples or a list to delineate which tests, clinical situations, and intended uses are subject to mandatory registration, and which are not. The structure of the registry and the format for submissions should be developed with stakeholder input and pilot-tested to ensure that they are not overly burdensome and generate useful, accessible information for the intended purposes.

SACGHS Recommendation 4:

BIO believes that patient safety must always come first. We believe that the level of regulatory review for any particular test should be based upon the claims and associated risks that the test could pose to the health and safety of the patient.

BIO supports SACGHS' recommendation that HHS "convene relevant HHS agencies, including FDA, CMS, CDC, AHRQ, and NIH, as well as stakeholders to provide further input into the development of a risk-based framework for the regulation of LDTs" (Chapter 4, Recommendation 4.A). However, such a forum should not be limited to consideration of the oversight of genetic LDTs specifically, but should seek to develop an appropriate regulatory model for diagnostics more broadly. BIO supports, and would actively participate in, a formal, deliberative and interactive process to enhance understanding and transparency of the broad regulatory environment for advanced diagnostic tests. We recommend that a formalized structure and rationale be developed for the classification and regulation of specific subsets of in vitro diagnostics, including all genetic tests and molecular diagnostics. This recommendation is consistent with BIO's comments on the FDA's draft guidance on In Vitro Diagnostic Multivariate Index Assays (Docket No. 2006D-0347).

On a related point, we suggest that the SACGHS report more fully recognize inconsistencies and opportunities for enhancement in the current regulatory system. The regulatory system for diagnostic tests should be harmonized to ensure consistency in the standard of review for tests within the same categories of risk.

We believe that the regulatory oversight of diagnostic tests should be evaluated comprehensively so that the appropriate government bodies are enabled to focus their limited resources on tests that pose a higher risk to patient safety, regardless of whether testing is provided by a laboratory or provided by a diagnostic test manufacturer. Regulatory requirements should not be solely based upon the technology used to reach a result nor should they be based upon the entity that develops, commercializes or distributes the test. Again, this recommendation is consistent with BIO's belief that patient safety and mitigating risks should be the overriding principle of our regulatory system.

We greatly appreciate the opportunity to comment on the SACGHS draft report and look forward to further discussions leading to a clear, predictable, and transparent risk-based regulatory system that helps to ensure the safety and accuracy of advanced diagnostics, including genetic testing, and enhance the public's confidence in the benefits of these innovative technologies.

Respectfully submitted,

Chris Colwell
Director, Healthcare Regulatory Affairs