

Statement of the Biotechnology Industry Organization

**Before the
Secretary's Advisory Committee on Genetics, Health and Society
March 13, 2009**

Daryl Pritchard
Director, Research Programs Advocacy
Biotechnology Industry Organization
1201 Maryland Ave, SW
Suite 900
Washington, DC 20024
(202) 962-9200

Statement to the Secretary's Advisory Committee on Genetics, Health, and Society
March 13, 2009

The Biotechnology Industry Organization (BIO) appreciates this opportunity to testify before the Secretary's Advisory Committee on Genetics, Health, and Society. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO understands that appropriate reimbursement based on an accurate payment methodology is essential to providing beneficiary access to care, improving quality of care, and encouraging continued investment in innovation. As we work to reform healthcare, the use of novel molecular diagnostics is essential to providing efficient, quality care that focuses on personalized diagnoses and treatments. These medical advances depend upon the adoption of new reimbursement policies that reflect the value that this technology brings to patient care. Indeed, the current lack of a clear and predictable system of reimbursement for molecular diagnostics has already had an adverse impact--by delaying the adoption of innovative technologies that have the potential to improve outcomes and efficiency in health care delivery. Our current healthcare system reflects a time before many diseases and conditions could be accurately diagnosed and treated with molecular diagnostics. To help achieve the promise of 21st century medical advances, molecular diagnostics must be developed and utilized—both of these factors depend upon proper reimbursement.

In order to realize the promise of personalized medicine, payers must recognize that innovative diagnostics can provide tremendous value by optimizing patient management and reducing the overall cost of an episode of care. Diagnostics must receive timely and adequate reimbursement that reflects their added value to patient care. BIO firmly believes that the current reimbursement system does not provide sufficient incentives for the development of new important molecular diagnostics and may stymie innovation. The current reimbursement landscape also emphasizes treatment of acute conditions, rather than prevention and chronic disease management. It is necessary to develop new policies that expand payer coverage and reimbursement of diagnostics and services focused on disease prevention.

The CMS reimbursement methodology must be modified so that it encourages appropriate use of beneficial diagnostics. Many innovative diagnostics, including those in development, represent an entirely new generation of diagnostics that can predict which patient is likely to develop certain cancers and other diseases, whether and how a patient will respond to particular therapeutics, what dosage of a particular drug is optimum for that patient, how combinations of drugs will be metabolized by individuals with particular genetic traits, the likelihood of recurrence of certain diseases, and the possibility of organ rejection. Furthermore, many other novel molecular diagnostics are being developed for disease sub-typing, disease prognosis, and treatment side-effects. These diagnostics will facilitate treatment that is far more tailored to

individual characteristics and could save lives and health care dollars. Targeted diagnostics must be viewed as the gateway to personalized care and reimbursed at a level reflective of their value to lead to delivery of targeted interventions, earlier in the course of a disease. Right now, the system imposes obstacles on their use. For example, certain diagnostic tests do not fit into a current reimbursement model because of the comprehensive testing requirements that must be done on the patient's blood or tissue specimen. Often the laboratory that is able to perform the tests is at a different location than where the specimen was collected. This changing paradigm requires a new approach and new thinking towards coverage and reimbursement in order to fully stimulate and reward development of sophisticated diagnostic tests.

As the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) considers the future of the healthcare system, BIO encourages the Committee to:

- Move forward in submitting an action plan for implementation of the recommendations made in the SACGHS Report "Coverage and Reimbursement of Genetic Tests and Services" (February 2006), and consider areas that may need to be updated or emphasized that take into consideration demonstrated problems in the CMS rate setting methodology;
- To have an immediate impact, recommend to the Secretary to direct CMS to take long-overdue action to update and reform the antiquated Clinical Lab Fee Schedule;
- Recommend ways to create a transparent and predictable reimbursement system that will stimulate and reward innovation, and reflect the added value of diagnostic tests.

We appreciate the opportunity to discuss each of these points in greater detail, below.

Targeted diagnostics and companion technologies can enhance the safety and efficacy of therapies by: predicting an individual's susceptibility to disease, detecting the onset of disease at the earliest moments, preempting the progression of disease, and targeting therapies and dosages more precisely and safely to each patient on the basis of molecular factors. Thus, it is in the "patient's best interest" for payers to have a long-term system-wide view that includes personalized diagnostics and therapies when making coverage and reimbursement decisions. Furthermore, molecular diagnostics, as a part of personalized medicine, may ultimately reduce long-term healthcare costs by helping payers target their resources more effectively. As healthcare reform proposals are developed, it is imperative that the Department of Health and Human Services include reimbursement system reform, and consider the recommendations made by the SACGHS in this area. Healthcare reform must take into consideration the tremendous value of novel diagnostics to patients in terms of clinical outcomes, quality of care, and potential cost savings, and reimbursement policy must reflect this value.

The CMS rate-setting methodology in the Clinical Lab Fee Schedule is an example of a system that does not adequately reflect the value these innovative diagnostic tests provide. Currently, new diagnostic tests' rates are determined by CMS by either "crosswalking" the test into an existing code and rate or creating a new code for the test and allowing the carriers to "gap fill" or establish their own prices for the new code for a period of time until a national rate is calculated. Neither methodology is market-based, and the pace of innovation is slowed accordingly. BIO looks

forward to working with SACGHS and the Secretary to implement reforms to the CMS rate-setting methodology that will stimulate and reward innovation and reflect the value of these tests.

Developing and bringing to market this new generation of diagnostic tests typically is far more costly and complex than for traditional lab tests. And even under CMS's gapfilling methodology, aimed at new tests for which there is no comparable, existing test, BIO is concerned that pricing variations among contractors may be so great, and so unpredictable, that innovation will be stifled and beneficiary access to these tests impeded. We also are concerned that setting a national payment amount when the market for the tests is not yet well-established and for which little claims experience is available will lead to inappropriate reimbursement with little opportunity for adjustment even if the pricing later is acknowledged to have not been set appropriately. In addition, because many of these new tests are proprietary and may be offered and performed by only one lab in the country, the gapfilled price established by the carrier serving that lab becomes a de facto national price, and if it is insufficient, it may not be economically feasible for the lab to offer the test at all. Additionally, BIO believes that the cross-walking process lacks transparency and predictability. CMS does not clearly state its decision making process when determining reimbursement amounts via the cross-walking process. Lack of a transparent and predictable rate setting methodology can discourage industry from entering the development process for important new diagnostic tests, particularly those requiring expensive prospective clinical trials.

BIO also requests that SACGHS begin a dialogue to explore the research, therapeutic, and economic environments in which these next generation diagnostic tests are developed. SACGHS can then recommend how to revise Medicare's payment policies to reflect the investment of human and capital resources that go into discovery and development of these diagnostics, as well as the tremendous potential benefits, in terms of cost savings, clinical outcomes, and quality of life for Medicare beneficiaries. In the short term, we also ask that CMS seek input from interested parties in this arena regarding the appropriate guidance and criteria to provide to contractors that are setting reimbursement rates under Medicare for these novel lab tests. By ensuring appropriate value recognition of molecular diagnostic tests, the agency will create financial stability and attractiveness for the industry further facilitating continued investment and development of these diagnostics. This will go a long way toward realizing the promise of personalized medicine

* * * * *

Thank you for the opportunity to present this statement on behalf of BIO. I would be pleased to answer any questions.