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Washington, DC 20024

June 1, 2007

BY ELECTRONIC DELIVERY

Reed V. Tuckson, MD
Chair
Secretary's Advisory Committee on Genetics, Health, and Society
National Institutes of Health, Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Re: Draft Report to the Secretary of Health and Human Services (HHS), *Realizing the Promise of Pharmacogenomics: Opportunities and Challenges*

Dear Dr. Tuckson:

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 health-care, agricultural, industrial and environmental biotechnology products. BIO appreciates the opportunity to comment on the draft report of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), *Realizing the Promise of Pharmacogenomics: Opportunities and Challenges*.

General Comments

BIO commends SACGHS for recognizing the significant potential of the emerging science of pharmacogenomics (PGx) and the need to study and address the full spectrum of issues associated with its development and application. We regard the draft report as helpful in

facilitating the efforts of the Department of Health and Human Services (HHS) and stakeholders to construct an informed, coordinated framework for advancing PGx. We would welcome additional focus throughout the draft report on specific areas where policymakers can engage industry on these issues.

BIO believes the draft report presents an accurate and generally balanced discussion of the major opportunities and challenges for PGx. We agree that the prospects for widespread health benefits and economic efficiencies from PGx depend upon a clear, well-integrated policy environment that promotes innovation and the adoption of new technologies.

Our comments below suggest two topics that the draft report should address more completely.

Specific Comments

Section IV.C. Economic Implications of PGx

BIO recommends a more comprehensive discussion of the economic factors surrounding PGx. Specifically, this section should give greater consideration to the role of appropriate reimbursement policies in creating incentives for investment and innovation in the development of PGx technologies, and in ensuring patient access to these innovations.

Resources to Carry Out Initiatives

The draft report should indicate where enhanced congressional appropriations would be required to implement the recommended initiatives. For example, BIO believes the draft report correctly recognizes the importance of investing in basic and translational PGx research programs at the National Institutes of Health (NIH). However, over the past four years, funding for NIH has failed to keep pace with biomedical research inflation. As a result, NIH has lost significant purchasing power needed to harness emerging scientific opportunities like PGx. To restore these resources, BIO and other stakeholders are supporting an increase in NIH funding to $30.8 billion in FY 2008. BIO also suggests that the draft report consider the need for enhanced public funding opportunities for companies to develop innovative diagnostic and research tool technologies to advance PGx.

Additionally, the Food and Drug Administration (FDA) will need resources to facilitate the development/co-development and market entry of PGx products. BIO supports continued implementation of the Critical Path Initiative, and we are requesting that the program be fully funded in FY 2008.

Conclusion

BIO would like to reiterate our appreciation for the opportunity to comment on the draft report, *Realizing the Promise of Pharmacogenomics*. We look forward to working with SACGHS and HHS to ensure that appropriate initiatives are implemented and aligned in order to foster the

development and acceptance of PGx technologies. We would be pleased to provide SACGHS with additional information or clarification of our comments as needed.

Sincerely,

/s/

Sara Radcliffe
Vice President
Science and Regulatory Affairs