June 1, 2007

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

Dear Dr. Tuckson:

The American Society for Pharmacology and Experimental Therapeutics (ASPET) appreciates the opportunity to offer public comment on the draft report to the Secretary of Health and Human Services, *Realizing the Promise of Pharmacogenomics: Opportunities and Challenges*. ASPET is a 4,500 member professional society whose members conduct biomedical research in academia, industry and the government.

ASPET would like to mention four items that the draft report might address with greater specificity to more adequately address the broad range of policy issues raised by the use of genetic tests, including:

A. Use of human specimens for the development of biomarkers

The three entities that have a stake in the use of human specimens for the developments of biomarkers are the Federal government, including NIH, FDA, CDC and NSF; for-profit pharmaceutical, biotechnology and diagnostic laboratories; and non-profit academic research organizations and medical schools.

Federal agencies clearly want to develop biomarkers, are willing to fund research in this area, and are willing to allow the investigators to keep and exploit any resulting intellectual property (IP). Pharmaceutical and related for-profit companies also want to develop biomarkers, but in so doing, they want to own and exploit all IP. Pharmaceutical companies often develop biomarkers in conjunction with their clinical trials conducted at non-profit academic research organizations and medical schools. However, in contracting with non-profit academic research organizations, pharmaceutical companies are often perceived to use over-reaching IP language whereby the pharmaceutical firm keeps all rights to the resulting IP to newly discovered and/or developed biomarkers, regardless of whether the inventors are from pharmaceutical companies, academic research organizations, or joint ventures from both. Academic research organizations increasingly want to keep the IP rights to their own discoveries. Related to this issue is whether academic research organizations should be “selling” the specimens they have collected to pharmaceutical companies for commercial exploitation. These competing economic interests need to be fully discussed and should be made more transparent in the final HHS report [section II-D].

To encourage co-development of both diagnostic biomarkers and pharmacogenomic testing, ASPET recommends the final report include language encouraging equal sharing of IP between the various parties involved. Also, the benefits of placing data immediately into the public sector in advancing the science have clearly been demonstrated. Thus, this practice should be encouraged as much as possible.
B. Use of electronic patient medical records

Increasingly, pharmaceutical and biotech companies have been coming to academic research organizations to contract with them to use the academic research organization’s electronic medical records in order for the pharmaceutical company to “mine” these data for developing biomarkers, investigating prescribing profiles for their own and their competitors’ compounds, and helping to develop either new drugs, or determining new therapeutic areas for development.

In negotiating contracts between pharmaceutical companies and academic research organizations, the pharmaceutical company is often perceived to use over-reaching language whereby they will own all resulting IP developed from this “mining” effort, regardless of who the inventors are. Related to this issue is whether academic research organizations should be “selling” the rights to “mine” their patients’ medical records for commercial exploitation. [section II-F, recommendation 6B; section IV-B]

C. Enhanced Guidelines for Health Care Professionals

ASPET feels the educational recommendations in the report need to be enhanced. [section IV-A]. This will be a major obstacle for realizing the promise of pharmacogenomic testing. To address this issue, more emphasis needs to be placed on rejuvenating training programs in clinical pharmacology and rewarding those programs that place a strong emphasis on the application and interpretation of pharmacogenomic information in making diagnostic decisions. The inability of physicians to adequately interpret and apply pharmacogenomic information, particularly in the context of drug-drug interactions, is a major challenge. Merely providing decision-making tools in electronic medical records will not solve this problem. Rather, institutions will need to develop pharmacogenomic consulting teams to facilitate the interpretation and application of pharmacogenomic information, which will require a cadre of individuals trained in this specialty.

D. Encourage Integration

With regards to basic and translational research, the report fails to encourage the integration of pharmacogenomics into the Clinical and Translational Science Centers that are being developed to replace the traditional General Clinical Research Centers. This should be done. Second, although work remains, our knowledge of genetic variation in pharmacokinetic parameters has advanced well beyond our knowledge of genetic variation in pharmacodynamics. Basic research efforts should emphasize a pathway and/or whole genome approach and be weighted toward further elucidating variation in pharmacodynamic parameters. Specifically, it is clear the use of SNP tags as developed through the HapMap project represent a major step forward, but significant limitations remain. Ultimately, the actual clinical implementation of pharmacogenomic results will need to focus on causative variants and as such, more emphasis should be placed on the development and improvement of technologies for economically feasible whole genome sequencing.

On behalf of the ASPET Council I would like to thank you again for soliciting comment on this important issue.

Sincerely,

Elaine Sanders-Bush
President