The
SNP Consortium Ltd.
8770 West Bryn Mawr Avenue, Chicago, IL 60631, USA Fax: +1-773-867-2991 Telephone: +1-773-867-2990

Comments FDA Stakeholder Collaboration Meeting
4/12/00

Bee 4
APR 14 2000
jb

Thank you the opportunity to provide commentary today.

Background Information

- My name is Arthur Holden and I am Chairman and CEO of the SNP Consortium.
- The SNP Consortium, is a 'not-for-profit' consortium of 14 major pharmaceutical companies, information-processing companies, and the Wellcome Trust, that are partnering with five major academic institutions in a unique two-year collaboration, to complete a high-density, genome wide map of SNPs. Our mission is to advance the field of human medicine and the development of genetic based diagnostics and therapeutics through the creation of a high-density SNP map of the human genome. Our goal is simple: By early 2001 we will develop a standardized SNP map, of between with 200,000-300,000 SNPs, that will be placed in the public domain. All parties will be able to access these data free of charge.
- The consortium believes this map will play a major role in supporting the development of pharmacogenomics and pharmacogenetics. In short, pharmacogenomics focuses on defining the relationship between genes/genetic markers and diseases/clinical conditions. Pharmaogenetics focuses on understanding an individual's genetics and their specific response to a specific drug.
- The TSC is a working model of the type of collaboration you wish to define in this forum. We blend a diverse mixture of complementary parties, focused on a clear and elevating objective. Our funding comes solely from our membership. This support is an expression of the desire of our members to see this base genetic information in the public domain, freely available to all researchers, and unencumbered by patents.

[More information is available on the TSC on the attachment.]

OON-0001

TS17

Collaborative Opportunities

My comments will focus on **three** collaborative opportunities.

1. Joint education forums, on pharmacogenomics and pharmacogenetics, for the FDA and the Life Sciences/Pharmaceutical industry. The genomics and genetics fields are progressing very rapidly. It is clear from our members' interactions to date with the FDA, there are significant opportunities for key stakeholders to be educated on the current state of the genomics/genetics and together to understand the prospects and promise of applying genetics to the development and prescription of drugs. Common definitions and a mutual understanding of the science is required if government and the private sectors are to effectively collaborate. A regular series of jointly organized and sponsored educational forums could be developed.

2. Using Pharmacogenetics to improve Safety Assurance in Clinical Trials.

   Pharmacogenetics should enable the doctor to use an individual's patient's medical response profile to predict a patient's likely response to a particular drug prior to prescription. Pharmacogenetics also holds significant promise to stream line the drug development process, facilitate the development and targeting of medicines to those patients most likely to benefit and unlikely to experience adverse events, and enabling more effective post approval surveillance. The FDA could collaborate with the life science/pharmaceutical industry in two areas of pharmacogenetics:

   a. The definition and development of effective protocols for clinical studies utilizing genetic markers / alleles for the development of new effective, safer medicines.
   b. The definition and development of effective protocols for 'extensive regulated post approval surveillance systems' using genetic markers to better profile patient response and adverse events after a drug is launched.

Collaboration would focus on jointly and proactively defining with the FDA, protocols that will best serve both of these important activities.

3. Genotyping of Genetic Markers for Pharmacogenetics.

Robust, cost effective genotyping capability able to effectively characterize an array of genetic markers is essential for the development of pharmacogenomics and pharmacogenetics. Over the next six months, the TSC will be working collaboratively to define the 'user requirements' [both for industrial and large-scale university researchers] for these systems. The FDA could participate in this critical study.