

## **Policy/Position Statement**

## Policy of The American Society of Gene Therapy Financial Conflict of Interest in Clinical Research Adopted April 5, 2000

Potential conflicts of interest may arise in the course of all clinical research, including gene therapy. In principle, the ethical standards for clinical research in gene therapy should be the same as those demanded in all areas of medicine. Therapeutic agents used in clinical trials are often produced by for-profit companies, which can give rise to circumstances that present a financial conflict of interest to the investigators. An extreme case would be that a clinical reagent, be it a small molecule, a protein or a gene transfer vector, that is manufactured by a company wholly or partly owned by the Principal Investigator conducting the clinical trial. The guiding principle is clear: clinical investigators must be able to design and carry out clinical research studies in an objective and unbiased manner, free from conflicts caused by significant financial involvement with the commercial sponsors of the study.

Clinical trials are often sponsored by industry, where legitimate costs in conducting the research are covered. The Regulations on Objectivity in Research and the Investigator Financial Disclosure Policy adopted by the National Institutes of Health and the National Science Foundation on July 3, 1996 have established that: "Investigators are required to disclose to the institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding by the PHS. The institution will review those disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research and if so, the institution must report the existence of such conflicting interests to the PHS Awarding Component and act to protect PHSfunded research from bias due to the conflict of interest". The same documents also established significant financial interests as equity ownership in companies exceeding 5%, and/or aggregate payments received from companies in excess of \$10,000/year. Academic institutions have also established policies governing investigators' financial conflicts of interest that are consistent with these federal regulations.

The American Society of Gene Therapy is not a regulatory body and it should beware from becoming one. However, in order to pursue its mission to promote gene

therapy research and development, the Ethics Committee recommends to the Board of Directors to adopt the following resolution:

"In Gene Therapy trials, as in all other clinical trials, the best interest of the patients must be always primary. International, national and institutional guidelines on standards of care must be rigorously followed, approved protocols strictly adhered to, serious adverse events promptly reported to all appropriate regulatory and review bodies. Relevant federally and institutionally established regulations and guidelines in financial conflicts must also be abided by. In addition, all investigators and team members directly responsible for patient selection, the informed consent process and/or clinical management in a trial must not have equity, stock options or comparable arrangements in companies sponsoring the trial. The American Society of Gene Therapy requests its members to abstain from or to discontinue any arrangement that is not consonant with this policy."

© 2000-2003 All rights reserved. American Society of Gene Therapy