DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

MAY 6 1996

The Honorable Arlen Specter
Chairman, Subcommittee on Labor, Health
and Human Services, and Education
Committee on Appropriations
United States Senate
Washington, D.C. 20510-6025

Dear Senator Specter:

I am writing in response to your March 25 letter, in which you asked whether alternative therapies are incorporated into NIH clinical trials, specifically inquiring about saw palmetto as a treatment for benign prostatic hypertrophy (BPH). You also posed questions about the exchange of scientific information among biomedical investigators and how to encourage free exchange for the advancement of medical research.

On the subject of clinical trials and alternative therapies, the NIH does support the study of alternative therapies and, to facilitate that work, has established the Office of Alternative Medicine (OAM) in my office. Grant applications to study alternative medicines may be submitted by interested investigators to appropriate institutes for peer review, and the OAM is notified of these applications. Regarding treatments for BPH, the FDA has approved only three drugs—finasteride, terazosin, and doxazosin—and has banned the sale of all over-the-counter products for the condition, including those containing saw palmetto (*serenoa repens*). The announcement of that ban was published in the *Federal Register* on February 27, 1990. It is unlikely that a local institutional review board (IRB) would approve an application to conduct a clinical trial involving use of a substance banned by the FDA. Since IRB review and approval are generally required for research involving human subjects, a clinical trial application involving an FDA-banned substance would not be considered by the NIH.

The clinical trial you mention, which is being conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, is designed to study the basic biology and progression of BPH and other prostate disorders, because little is definitively known about the causes, mechanisms, and natural history of BPH. The trial will study the effects of two of the FDA-approved drugs (finasteride and doxazosin), alone and in combination, to evaluate how either drug delays or prevents progression of BPH.

Your other questions related to exchange of scientific information raise the issue of striking the appropriate balance between supporting proprietary interests and maintaining the benefits of free and open communication of scientific results. Although withholding

information that could save a patient's life is indefensible, as Dr. Rosenberg notes in his *New England Journal of Medicine* article, the laws of this country allow protection of proprietary rights of private companies and individuals. This protection helps provide financial rewards and professional acknowledgment to the men and women who make seminal findings. To some extent, however, the impact of secrecy generated by commercial interests (which slows the exchange of information) is already being countered by other developments such as the increasing speed of electronic communications and the shortening of publishing schedules, both of which make the transmission of many types of results faster than ever.

Firm rules already exist—imposed both by the NIH and by the major scientific journals—to discourage unnecessary and capricious secrecy agreements involving researcher scientists and commercial interests. Scientists who receive government funding or publish in the journals must be willing to share their information and reagents. The NIH strongly encourages government-supported scientists to attend meetings and share their results. In the area of genetic research, for example, NIH grantees are required to deposit gene sequencing data in the public database, GenBank. And the NIH was instrumental in development of a Universal Biological Materials Transfer Agreement that enables much easier and faster exchange of research materials between investigators at signatory institutions.

In addition to these measures to encourage exchange of information, all of the medical journals and most research institutions—including the NIH—have special exceptions or expedited patenting and publishing procedures to allow scientists who make breakthrough medical discoveries to get the information out quickly while still protecting their rights to publish and patent the information. NIH will continue to pursue this course, releasing life-saving medical results to doctors as soon as the data are available.

I hope that this information is helpful to you. I appreciate your interest in the NIH and in the broad range of issues involved in biomedical research. I look forward to our discussions at the upcoming hearings.

Sincerely,

Harold Varmus

Harold Varmus, M.D.
Director