EDITORIAL

Industry sponsored research

Two trials, MTOPS (Medical Therapy of Prostatic Symptoms) and PCPT (Prostate Cancer Prevention Trial) have appeared as major landmarks in the urologic literature recently. Although both trials were primarily focused on the role of finasteride, the observations from both studies were far reaching, and will influence many facets of the management of prostatic disease, including LUTS/BPH, prevention of prostatic disease (benign and malignant), screening for prostate cancer, and the management of localized prostate cancer.

Although both studies were positive, polls taken at several meetings suggest that Canadian urologists are reluctant to fully embrace finasteride for the routine management of BPH and prostate cancer prevention. This hesitance is reasonable. One example, the tamoxifen breast cancer prevention trial, reinforces the merit of a cautious approach. This positive trial resulted in tamoxifen being accepted by the FDA as a chemoprevention agent. Five subsequent tamoxifen prevention trials have shown a 48% reduction in ER-positive cancers, but an increase in endometrial cancer and thromboembolic events. Accordingly, the use of tamoxifen for prevention is restricted to very high risk individuals. This risk-benefit scenario is clearly analogous to the PCPT data, where the 25% reduction in incidence was accompanied by an increase in high grade cancers. While many believe that this increase is spurious, it seems prudent to focus cancer prevention efforts using finasteride on high risk patients.

This issue of the journal contains an article entitle "An economic evaluation of doxazosin, finasteride, and combination therapy in the treatment of BPH", by Macdonald, Hux, Brisson, Bernard, and Nickel. The study shows that combination therapy is cost-effective, and this increases with rising PSA.

The CJU had some difficulty deciding how to handle this article. This economic analysis was funded by Merck Frosst, and four of the five authors are either employees of Merck Frosst, or employees of a contract research organization under contractual agreement with Merck Frosst.

Medical journals and the lay press have had much to say recently regarding the relationship between the pharmaceutical industry and the medical profession. The pharmaceutical industry plays a significant role in many facets of medical practice, from medical education to influencing the choice of drug treatment for patients.

There is a view, resoundingly articulated in a recent book "Science and Private Interests: Has the Lure of Profits Corrupted Biomedical Research" by Sheldon Krimsky, PhD, that medical research is no longer a search for a scientific truth, but rather a process designed, engineered, and completed in order to produce money. He calls this 'utilitarian science' as opposed to public interest science, which is carried out 'primarily to advance the public good'. Examples that support this view include two Canadian cases, the Olivieri imbroglio, and the case of Dr. David Healy, a psychiatrist recruited by the University of Toronto whose job offer was revoked after he wrote extensively about the connection between an antidepressant and suicide. The drug's manufacturer was a generous supporter of the Toronto Centre for Addiction and Mental Health.

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EDITORIAL

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There is partial truth to the view that the profit motive drives the medical research agenda. In an ideal world, public funds available to support clinical research would be sufficient to eliminate the need for industry support.

That world, however, does not exist. In the real world of limited public resources, pharmaceutical support for clinical research is essential.

The track record of the pharmaceutical industry in developing new drugs, and rigorously testing them, is high (although not unblemished). The pharmaceutical industry produces many publications in medical journals, including urology journals. Some of these are outstanding. (The MTOPS and PCPT trials are two examples). In contrast to the overly simplistic view that pharmaceutical companies are only interested in data that supports their product, the results in some of these published studies have indeed adversely affected the sponsor.

As a safeguard, it is CJU policy that if a pharmaceutical company has funded a study, this must be stated clearly in the manuscript. Any financial association between an author and a company must be declared.

An author's declared association with a sponsor should not undermine the value of the study. However, it does reinforce the importance of maintaining a critical perspective when reading medical literature.

We concluded that the finasteride pharmaco-economics article is timely, employs an appropriate methodology, has incorporated full disclosure of conflict of interest, and therefore warranted publication.

The pharmaceutical industry-physician relationship is a contentious one. I encourage readers with strong opinions on this subject to write in.

Laurence H. Klotz
Editor-in-Chief