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### **Study Finds Additional Evidence for Contamination of Herbal Supplement for Prostate Cancer**

A chemical analysis of PC-SPES, a recently recalled herbal dietary supplement commonly used to treat advanced prostate cancer, has shown that the supplement was contaminated with the synthetic drugs warfarin, diethylstilbestrol and indomethacin. Diethylstilbestrol and indomethacin have known anticancer properties.

Later preparations of PC-SPES, which contained less diethylstilbestrol and indomethacin than earlier preparations, showed a corresponding decrease in anticancer potency by as much as sixfold. The findings appear in the September 4 issue of the *Journal of the National Cancer Institute*.

PC-SPES ("PC" stands for prostate cancer, "SPES" is Latin for hope) is a mixture of seven medicinal herbs plus saw palmetto; it was introduced in the United States as a dietary supplement in 1996. Early studies suggested that the preparation was effective in reducing levels of prostate-specific antigen (PSA, a marker for prostate cancer) in both hormone-responsive and hormone-resistant prostate cancer patients.

However, concern grew because of evidence that the preparations were being contaminated with synthetic drugs, says Jeffrey White, M.D., of the National Cancer Institute, in an accompanying editorial. Subsequent studies found that PC-SPES contained the synthetic estrogen diethylstilbestrol, the anti-inflammatory drug indomethacin, and the blood thinner warfarin. Earlier this year, BotanicLab, the California-based manufacturer of PC-SPES, voluntarily recalled the product and has since gone out of business.

In this analysis of eight lots of PC-SPES manufactured at different times between 1996 and 2001, Milos Sovak, M.D., of the Biophysica Foundation in La Jolla, Calif., Robert Nagourney, M.D., of Rational Therapeutics, Inc., Long Beach, Calif., and their coworkers found that all lots

contained indomethacin and most of the lots contained diethylstilbestrol. Warfarin began appearing in varying amounts in lots manufactured after July 1998.

“The origin of the three potent synthetic drugs in PC-SPES is puzzling,” the researchers write. They note that the amount of diethylstilbestrol present in the lots would have been enough to exert anticancer activity. Lots manufactured after the spring of 1999 contained significantly less diethylstilbestrol and indomethacin than earlier lots and had two to six times less anticancer activity.

In his editorial, White says that “herbal research is complicated enough without having to deal with the added problem of potential product adulteration.”

He says that preclinical and clinical trial research of promising herbal interventions should continue. However, he urges investigators to consider regular quality control evaluations by independent laboratories throughout the course of their research.

The lessons from PC-SPES must be learned well, he says, “because the loss of a product that symbolized hope to some should not occur without leading to an ultimate gain for all cancer patients.”

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Sovak M, Seligson A, Konas M, Hajduch M, Dolezal M, Machala M, et al. Herbal composition PC-SPES for management of prostate cancer: Identification of active principles. *J Natl Cancer Inst* 2002;94:1275–81.

Editorial: White J. PC-SPES—A lesson for future dietary supplement research. *J Natl Cancer Inst* 2002;94:1261–3.

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