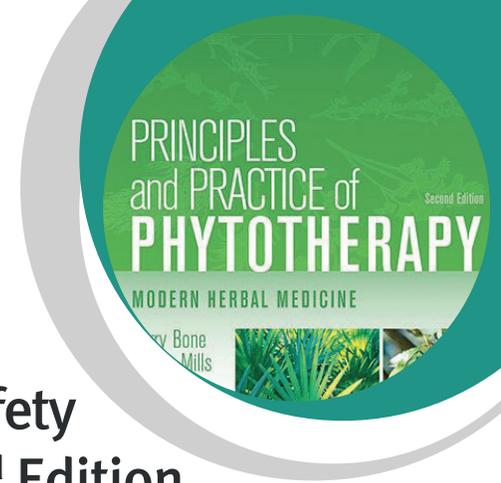


The Sad but True Tale of PC-SPES

An excerpt from Chapter Five: Optimising Safety Principles and Practice of Phytotherapy, 2nd Edition

Kerry Bone and Simon Mills



General side effects

A particularly cautionary tale is that of PC-SPES. PC-SPES was a herbal formulation specifically targeted at the treatment of prostate cancer (hence PC) developed and patented in the early 1990s by a research chemist.⁸¹ It ostensibly contained seven Chinese herbs and one American herb (saw palmetto: *Serenoa repens*). The product was very successful in the US marketplace and there were consistent anecdotal accounts of its efficacy, especially for controlling PSA (prostate specific antigen) levels. In particular, naturopathic physicians and holistic medical doctors recommended the product to many patients. Being a US-sponsored product, they had no reason to believe it was anything other than a herbal product, despite the fact that it was manufactured in China.

PC-SPES soon began to attract the interest of well-respected research scientists including those at Johns Hopkins School of Medicine, Harvard Medical School and the National Center for Complementary and Alternative Medicine.⁸¹ In 2002, three reviews of the use of PC-SPES were published which surveyed the major publications on its pharmacology and clinical activity.⁸²⁻⁸⁴ By early 2002 there were ¹¹⁶ published clinical and laboratory-based studies of PC-SPES.⁸⁵

The reviews highlighted the significant *in vitro* and *in vivo* activities of PC-SPES in prostate cancer models and noted the small number of positive but preliminary clinical trials.⁸²⁻⁸⁴ Oestrogenic activity was confirmed for the product, which was consistent with some of the side effects exhibited by patients taking the formulation such as gynaecomastia, loss of libido, decrease in body hair and superficial thrombosis. However, there was also another worrying and paradoxical side effect of PC-SPES: it was linked to severe bleeding in one case⁸⁶ and suspected of potentiating the effects of warfarin in another.⁸⁷

Another perspective on PC-SPES began to emerge in 2002 at around the same time the above reviews were published. In early April a group of scientists presented their findings to the 93rd Meeting of the American Association for Cancer Research that PC-SPES samples from 1996 to 2001 contained the oestrogenic drug diethylstilbestrol (DES) as well as warfarin and indomethacin.⁸⁸ Their comprehensive results were published later that year.⁸⁹ Earlier in February, 2002 the FDA alerted consumers to stop taking PC-SPES because the California Department of Health Services

had detected the presence of warfarin. Another product called SPES from the same corporation had been found to contain the anti-anxiety drug alprazolam.⁹⁰ The manufacturer undertook a voluntary recall and PC-SPES was subsequently withdrawn from the market.⁸¹

References

81. Ochs R. Going to bat for prostate cancer herbs. Newsday.com October 8, 2002. <http://www.newsday.com/going-to-bat-for-prostate-cancer-herbs-1.344309>. Accessed 14 June, 2011.
82. Oh WK, Small EJ. PC-SPES and prostate cancer. *Urol Clin N Am* 29(1): 59-66, 2002.
83. Thomson JO, Dzubak P, Hajduch M. Prostate cancer and the food supplement, PC-SPES. *Neoplasma* 49(2): 69-74, 2002.
84. Marks LS, DiPaola RS, Nelson P et al. PC-SPES: Herbal formulation for prostate cancer. *Urology* 60(3): 369-377, 2002.
85. Pandha HS, Kirby RS. PC-SPES: phytotherapy for prostate cancer. *Lancet* 359(9325): 2213-2215, 2002.
86. Weinrobe MC, Montgomery B. Acquired bleeding diathesis in a patient taking PC-SPES. *N Engl J Med* 345(16): 1213-1214, 2001.
87. Davis NB, Nahlik L, Vogelzang NJ. Does PC-SPES interact with warfarin? *J Urol* 167(4): 1793, 2002.
88. Arnold K. Tests of three herbal therapies yield disappointing results. *J Natl Cancer Inst* 94(9): 649, 2002.
89. Sovak M, Seligson AL, Konas M et al. Herbal composition PC-SPES for management of prostate cancer: identification of active principles. *J Natl Cancer Inst* 94(17): 1275-1281, 2002.
90. Reuters Health. Prostate herbals contain prescription drugs: FDA. February 8, 2002. Available online: http://abcnews.go.com/wire/Living/reuters20020208_458.html. Accessed February 14, 2002.