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## EMBARGOED UNTIL 3 P.M. CDT TUESDAY, SEPT. 27, 2011

## Popular supplement has no effect on prostate health, clinical study that includes UT Southwestern urology expert shows

DALLAS – Sept. 27, 2011 – The most widely used over-the-counter supplement for prostate health is no more effective than a placebo in treating men's lower urinary tract symptoms. The findings, in the *Journal of the American Medical Association*, are from a study that included a UT Southwestern Medical Center prostate expert.

In the largest and longest trial investigating saw palmetto extract, North American scientists – including Dr. Claus Roehrborn, chairman of urology at UT Southwestern – at 11 clinical sites tested up to three times the standard manufacturer's dose and found that the supplement did not improve lower urinary tract symptoms in men with prostate enlargement.

"Astonishingly enough, there was not any measurable effect – either in benefits or in toxicity – with increasing doses of the supplement in comparison to placebo," said Dr. Roehrborn, a co-author of the multicenter study. "These supplements are apparently not doing anything measurably above and beyond what we call the placebo effect."

Men with enlargement of the prostate, a common age-related condition, often experience obstruction of the urethra, leading to frequent or painful urination, increased risk of urinary tract infections and urinary retention. About half of males in the U.S. experience prostate enlargement by age 50, and 75 percent by age 80.

Lower urinary tract symptoms may be treated with medications, minimally invasive therapies or surgery. But plant extracts, believed to have anti-inflammatory, anti-hormonal and anti-growth agents, have been widely used for decades in the U.S. and Europe. The most commonly used are extracts of the fruit of the saw palmetto dwarf plant tree. Americans spend billions annually on such food supplements; the global market for saw palmetto extract is about \$700 million a year.

In the current randomized study, conducted between June 2008 and October 2010, researchers tested 379 men ages 45 and older, and discovered that increasing daily doses of a saw palmetto fruit (MORE)

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extract over 72 weeks did not reduce symptoms in the men's lower urinary tract. The scientists also tested the supplement's impact on quality of life issues such as nighttime urination, sexual function, incontinence problems and sleep dysfunction.

"None of them showed any effect whatsoever in contrast to placebo," Dr. Roehrborn said. "These supplements cost about \$30 or more a month, and they obviously don't help."

The study was supported by the National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases, and the NIH's National Center for Complementary and Alternative Medicine and Office of Dietary Supplements.

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