

EMBARGOED UNTIL THURSDAY, April 10, 2014, 800 AM ET

**Twenty-Five Medical Societies Join Androgen Study Group To Petition
JAMA to Retract Misleading Testosterone Study**

*Unprecedented action taken to combat “false information” that has “harmed public health, distorted medical science, and violated the trust between medical journals and the consumer.”
Failure to retract amounts to “medical literature malpractice.”*

Boston, MA, April 8, 2014 – In an unprecedented action, twenty-five international medical societies have petitioned the Journal of the American Medical Association to retract the article that precipitated recent concerns regarding cardiovascular risks with testosterone therapy, citing “gross data mismanagement” rendering the study “no longer credible.” Twenty-two societies have added their names since the original petition was submitted to JAMA two weeks ago. The article by Rebecca Vigen and colleagues from the University of Colorado, published in the November 13, 2013 issue of JAMA, is entitled “Association of Testosterone Therapy With Mortality, Myocardial Infarction, and Stroke in Men With Low Testosterone Levels.” The results were widely reported as new evidence that testosterone therapy is associated with cardiovascular risks, resulting in a Food and Drug Administration safety bulletin issued January 31, 2014.

The 25 medical societies represent US and international groups dedicated to education and research in endocrinology, men’s health, andrology, and sexual medicine. These medical societies join more than 160 of the world’s leading figures in urology, endocrinology, and andrology from 32 countries, from every continent except Antarctica. Individual signers include 8 emeritus professors, 9 journal editors, and 67 full professors. Societies recommending retraction are:

American Society for Men’s Health
Brazilian Society of Endocrinology and Metabolism
Canadian Men's Sexual Health Council
Canadian Society for the Study of Men’s Health
European Society for the Study of the Aging Male
European Society for Sexual Medicine
Indonesian Andrologist Association
International Society for Men’s Health
International Society for Sexual Medicine
International Society for the Study of the Aging Male
Italian Society of Andrology
Italian Society of Andrology and Sexual Medicine
Japan ASEAN Council for Men’s Health and Aging
Korean Society for Sexual Medicine and Andrology

Latin American Society for Sexual Medicine
Malaysian Men's Health Initiative
Malaysian Society of Andrology and the Study of the Aging Male
Mens Health Initiative of British Columbia (Canada)
Middle East Society for Sexual Medicine
Russian Society for Men's Health
South Asian Society for Sexual Medicine
Sexual Medicine Society of North America
The Society for Men's Health, Singapore
Society for the Study of Androgen Deficiency
Society for the Study of Andrology and Sexology, Singapore

[Click here to see the full list.](#)

“This is the first time in history a worldwide community of distinguished researchers, scholars, and clinicians has united to demand removal of a study from the literature,” stated Abraham Morgentaler, Chairman of the Androgen Study Group, which submitted the petition to JAMA. “This unprecedented action is a complete repudiation of the false information published by JAMA that has harmed public health, distorted medical science, and violated the trust between medical journals and the consumer. Although science must always be open to new information and ideas, the wholly unreliable data in this study by Vigen et al categorizes these results as *misinformation*. JAMA has been complicit in creating a media frenzy regarding false risks, and is directly responsible for the new wave of medical malpractice cases against physicians. For the good of consumers, physicians, and science, JAMA should retract the article before it causes even greater harm, accompanied by a letter explaining how its editorial process failed and steps taken to correct it.”

This article has already undergone two published corrections, and new revelations raise additional concerns. A first revision was published online November 12, 2013, six days following initial publication, due to the misleading presentation of results as raw data instead of complex, statistically derived estimates. JAMA’s decision to wait two months, until January 15, 2014, before disclosing this was a revised version was an ethical breach. A second correction published March 5, 2014, revealed major errors presented in the article’s text and figure. Specifically, in response to a letter questioning a group of 1132 men, the authors re-examined the data for this group and discovered the correct number of individuals should only have been 128, an 89% error rate, involving more than 1,000 individuals. The value for a second group was increased by more than 900 individuals. Astonishingly, this group included 100 women, meaning nearly 10% were the wrong gender for the study. New information raises additional questions and uncertainties regarding Figure 2 in the text, the key to their results.

“People find it hard to believe that JAMA would publish a study in which the percentages of men who suffered an adverse event was lower by half in men who received testosterone than

untreated men, yet results were reported as if the opposite were true, thanks to absurdly complicated statistical manipulations of the data,” stated Andre Guay, MD, Clinical Professor of Endocrinology at Tufts Medical School. “Now we find out this is the gang that can’t shoot straight. In my 40 years in medicine I’ve never before seen a paper that says, ‘Here are our data, give or take a thousand individuals.’ There is nothing believable in this study.”

The percentage of men who suffered an adverse event (heart attack, stroke, or death) based on reported numbers was 10.1% (123 events in 1223 men) in the testosterone group and 21.2% (1587 events in 7486 men) in the untreated group. Those percentages do not appear in the text of the study.

“This article has caused enormous damage,” stated Mohit Khera, MD, Associate Professor of Urology at Baylor Medical College. “This article created an unfounded negative perception of testosterone therapy. Physicians discontinued treatment for men who were benefitting from treatment. It harmed physician-patient relations, as patients ask why their physicians placed their health at risk. And a new field of medical malpractice has sprung up overnight, with plaintiff attorneys in the US advertising nationwide for patients who suffered a stroke or heart attack after receiving testosterone. And it’s all based on pure nonsense.”

“JAMA has violated the public trust,” concluded Dr. Morgentaler. “Its peer-review process failed. It recklessly promulgated false information that created the perception of medical risks. It withheld news that the study had been corrected, for two months, until interest had waned. It undermined the academic process by allowing the authors to avoid answering questions posed in letters. The lead author didn’t even sign the response to letters. It now stands by a highly statistical study after which it has been revealed that the statistics cannot be trusted. JAMA has left itself vulnerable to criticism that it promotes sensationalism to boost revenues, or is biased against the use of testosterone therapy in men. JAMA’s continued support of this discredited study, defying the worldwide community of experts, represents **medical literature malpractice.**”

To read the full letter, [click here](#).

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About The Androgen Study Group (ASG)

The Androgen Study Group is a newly formed multidisciplinary group of clinicians and researchers dedicated to education and accurate reporting regarding testosterone deficiency in men and its treatment.

For more information, go to www.androgenstudygroup.org.

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