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Groups slam testosterone study, call for retraction

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Three professional medical societies and an international group of 130 scientists and physicians have petitioned *JAMA* to retract a recent article that reported an association between the use of testosterone therapy and increased risk of death, heart attack, or ischemic stroke.

In a letter addressed to *JAMA* Editor-in-Chief Howard Bauchner, MD, the newly formed Androgen Study Group cites "gross data mismanagement," rendering the article "no longer credible."

The article (*JAMA* 2013; 310:1829-36) was one of two studies that prompted the FDA to issue a safety bulletin on the use of testosterone products on Jan. 31.

The article has already undergone two published corrections, according to the group. The first was published Jan. 15, due to misreporting of primary results. A second correction, published on March 4, revealed what the group called "major errors" in the article's text and figure.

The letter was signed by the International Society for Sexual Medicine, the Sexual Medicine Society of North America, and the International Society for the Study of the Aging Male, as well as more than 125 scientists and physicians from 24 countries. Several of the co-signers are prominent U.S. urologists.

"This is an extraordinary event. In my 25 years in academic medicine, I have never witnessed anything like this response to a journal article," said Abraham Morgentaler, MD, of Harvard University, Boston, who serves as chairman of the Androgen Study Group. "To call for retraction of an article is exceedingly rare. To have several professional societies and so many of the most accomplished experts in the field unite in this action indicates the seriousness of the article's errors, and the magnitude of damage this article has caused to the public's perception of testosterone therapy."

"Lost in the media frenzy that followed this article's publication is the fact that substantial evidence accumulated over 30 years has shown repeatedly that higher testosterone levels are associated with better cardiovascular outcomes. In the interests of medical science and the public good, *JAMA* should do the right thing and retract the article."

The letter states that the study authors, led by Rebecca Vigen, MD, of the University of Texas Southwestern Medical Center, Dallas, had improperly excluded 1,132 men from analysis who had received a testosterone prescription after experiencing an MI or stroke.

"The authors indicated they had revisited this value presented in the text and Figure 1, and had made 'an incorrect notation' regarding this value," the letter stated. "They now assert the numbers of men excluded for this reason was 128, not 1,132. This is an 89% error rate, involving >1,000 individuals. The number of men now excluded due to missing coronary anatomy increased from 397 to 1,301, a 69% error rate, involving 904 individuals."

"Many of my patients stopped taking testosterone because of the *JAMA* article, even those who had experienced substantial benefits," added Androgen Study Group member Martin Miner, MD, of Brown University, Providence, RI. "And now we find out it was all based on nothing but sloppy science. We are talking about real consequences on individuals' health and quality of life."

The Androgen Study Group says it is dedicated to education and accurate reporting on the science of testosterone deficiency in men and its treatment. It was organized specifically to respond to the "recent unwarranted, unscientific attacks" on testosterone therapy in the medical press and public media.

Dr. Morgentaler has served as a consultant/adviser and investigator to Actient Pharmaceuticals LLC; as a consultant/adviser to Antares and Merck; as an investigator for Auxilium Pharmaceuticals, Endo Pharmaceuticals, and GlaxoSmithKline; and as a meeting participant/lecturer for Merck.