



Letter to the Editor

Sent via e-mail March 27, 2008

Re: *Clinical Cancer Research*, "Herbal/Hormonal Dietary Supplement Possibly Associated with Prostate Cancer Progression"

Dear Ms. Hurley,

I am writing to follow up on the response that you provided to an earlier correspondence from the American Herbal Products Association (AHPA), copied below, to request that the UT Southwestern Medical Center issue a correction to address the errors in your press release of January 15, 2008. I am also restating here AHPA's request that the Center correct the erroneous statements made in that press notice.

The January 15 press release, relevant to the publication on that date by Shariat et al. (Herbal/Hormonal Dietary Supplement Possibly Associated with Prostate Cancer Progression; *Clin Cancer Res* 14(2):607-611) falsely identified an illegal drug product as a dietary supplement. The press release included numerous additional errors, each of which were articulated in our initial email and so included below.

Your response, attached here, states that the Center "reaffirms the information included in the press release." This inflexibility, however, is based on the stated, but again erroneous belief that "FDA changed its regulation governing this substance in April 2004," and that "at the time that the research was conducted, the product was correctly labeled as an herbal/hormonal dietary supplement and was sold legally, over the counter to the subjects."

AHPA assumes that the "substance" addressed in your response was androstenedione or a related compound. But FDA did not "change its regulation" with regard to this ingredient in April 2004. It did, in March 2004, issue warning letters to enforce the existing regulations, and I have attached one of these letters here. As you can see, FDA did not inform the recipient that any new regulation had gone into effect, but instead stated that "a product containing androstenedione is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) ... Introduction of such a product into interstate commerce is prohibited under 21 U.S.C 331(a) and (v)."

Thus, it is absolutely clear that FDA did not consider any product that contained androstenedione to have been "sold legally" at the time that the subjects of Dr. Shariat's article purchased this product.

But the "substance" at issue that was intended to be addressed in our initial correspondence was, if the authors' analysis of the subject product was accurate, actually two substances: testosterone and estradiol. Shariat et al. state that hormone analysis of the subject product "revealed that [it] contained testosterone and estradiol." Both of these ingredients are drugs that are not – and never have been – allowed to be included in dietary supplements. In addition, the regulations for labeling of dietary supplements require – and have since they were first established – that all ingredients in a supplement be declared.

Thus it is again absolutely clear that a product that contains or contained undeclared testosterone and estradiol, whether or not declared, at any time since the passage of the Dietary Supplement Health and Education Act in 1994, is not and was not at any time a legally-labeled or legally-sold dietary supplement.

I find it unfortunate that AHPA finds itself in the position of needing to again argue this point. As stated in our initial communication, AHPA decries the presence of illegal and undeclared drugs that masquerade as dietary supplements, and we appreciate any effort made by regulators to remove such products from the marketplace, and by researchers to call attention to them.

But the public is not served when researchers who are uninformed on the specifics of dietary supplement laws misidentify products, or by media outlets that refuse to acknowledge when they have made a mistake.

I therefore again request that UT Southwestern Medical Center do the right thing, and correct the record.

Sincerely,

Michael McGuffin
President, American Herbal Products Association

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