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OTC Steroids: Time for the Government to Act Responsibly

An article in the November 22/29, 2000, issue of *JAMA* has finally shaken me into action. Hopefully, the federal government will finally face responsibility for a major potential health problem. Catlin et al,¹ from the UCLA Olympic Analytical Laboratory, report that trace contamination of androstenedione with 19-norandrostenedione is sufficient to cause urine test results for 19-norandrosterone, the standard marker for nandrolone. In the context of International Olympic Committee standards, this means that 20 of 24 men in the study would have tested positive for 19-norandrosterone. In clinical terms, this means that people purchasing and consuming over-the-counter (OTC) "sports supplements" might be inadvertently exposed to contaminants.

To further confirm this potential hazard, the same authors undertook mass spectrometry of nine brands of androstenedione for androstenedione and traces of steroids. Some of the products contained less drug than was listed on the label or even misrepresented ingredients; one had no androstenedione at all, another contained testosterone and, in fact, six of the nine tested were misbranded.

I believe the fault does not lie entirely with the manufacturers, who are simply taking advantage of an enigma in federal drug regulation. After all, "sports supplements" make up only about \$1 billion of the estimated \$12 billion annual revenue of this country's dietary supplement industry. Nor does the blame rest entirely on the gullible public seeking "natural nutritional supplements" for a variety of purported performance-enhancing or aging-prevention effects.

No, the bulk of the blame lies squarely on the shoulders of a federal government that passed the Dietary Supplement Health and Education Act of 1994,² the result of which was the opening of a floodgate of OTC steroids marketed as nutritional supplements; the only stipulation was that their manufacturers do not claim that these supplements diagnose, prevent or cure disease. This enables manufacturers to escape U.S. Food and Drug Administration regulation of their advertising and marketing materials.

The public is currently being exposed to products upon which they cannot rely for content, purity or amount of product stated on the label and for which, in most instances, we have inadequate data on safety and efficacy. These are steroidal drugs we are discussing, not food supplements. Numerous other examples exist, such as unsubstantiated claims of bone sparing with progesterone skin creams.³ I have not even begun to address the problems related to inappropriate use and dangers of the herbal products; the adverse cardiovascular and central nervous system events associated with dietary supplements containing ephedra alkaloids is just one such example.⁴

The federal government must now get off its duff and recognize the potential hazards to which it is exposing the citizens it claims to represent. We, as healthcare providers, have a similar responsibility to create awareness of the problem among legislators and the public. The time for the government to amend the 1994 law is NOW!

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References

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