
EDITORIAL

Male Enhancement Products: Kudos to the FDA

All urologists, most other health care providers and a large number of adult consumers are very familiar with the historic introduction of sildenafil (Viagra) over 10 years ago. Since that time, several other FDA approved medications have been released that act in a similar fashion to sildenafil: inhibition of the phosphodiesterase type 5 pathway to enhance penile blood flow and treat many cases of erectile dysfunction. A variety of over the counter (OTC) enhancement products have been available long before sildenafil. The public dialogue about erectile dysfunction, due in large part to the publicity surrounding sildenafil and other approved erectile dysfunction drugs, has led to an explosion in non-prescription alternative, natural, herbal supplements to enhance sexual desire and performance.

While urologists are familiar with sildenafil, vardenafil and tadalafil, most are probably not familiar with sulfoildenafil and hydroxythiohomosildenafil. These are phosphodiesterase type 5 analogues that have been recently identified by the FDA as components of numerous OTC products that have been subjected to government recalls. The fraudulent addition of these analogues to these so called "safe" or "natural" OTC supplements can result in interactions with nitrates and cause life threatening side effects as well as the spectrum of other side effects that are possible with the parent and FDA approved medications. The onset of erectile dysfunction can herald several other significant medical conditions such as cardiovascular disease and cancer. The ability for consumers to self medicate for erectile dysfunction without physician interaction is another potential concern over these OTC male enhancement products.

Over the last 5 years dozens of so called "all natural" male enhancement products that contain other non-declared ingredients have been identified by the FDA through public recalls (see www.fda.gov/safety/MedWatch). While the sale of many products is limited to the Internet, some are sold by leading drug stores that add legitimacy to many of these potentially unsafe products. These recalls and advisories are not limited to the United States. Just this past summer, Health Canada seized "ExtenZe" sexual enhancement supplements and informed the public of the risks associated with unauthorized or regulated ingredients in these products such as DHEA.

While these male enhancement products are one potential aspect of urologic practice, the problem of illicit contamination of dietary supplements is a much wider issue. Several years ago the "miracle" cure for prostate cancer from the Far East (at that time sold as "PC-SPES") was in fact contaminated with estrogens. It was the estrogens and not any other herbal ingredient that reduced PSA levels in many men. As another urologically significant example, aromatase inhibitors have been found in diet supplements that may cause decreased sperm production, infertility and other prostate problems.

Urologists and all health care providers must be vigilant in determining if patients are taking any natural, herbal or OTC supplements as part of the history and physical evaluation regardless of the presenting complaint. The FDA and other agencies are to be commended for protecting consumers from these undeclared and potentially harmful drug ingredients. Many of these are sold under the erectile dysfunction or "male enhancement" umbrella, an area that is traditionally in the scope of urologic practice.

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