

Susan Kellogg-Spadt, MSN, CRNP, PhD

When It Comes to Botanical Prosexual Preparations, Clinicians and Consumers Beware!

Q: I've recently had a barrage of patients asking me about an Internet-based "natural" drug to treat female sexual dysfunction (FSD). Apparently, they are reading ads for this product in the lay literature. How do I help patients make knowledgeable, informed decisions about this product?

A: This is a GREAT question! I can't tell you how many patients I've also heard from, especially when, everywhere they turn, from *Forbes* to *Redbook*, they (or their significant other) read about a supposedly "harmless" natural product that claims to enhance desire, arousal, lubrication, orgasm, and satisfaction. This prompts me to quote a common adage, "If it sounds too good to be true, it probably is."

First of all, let's define terms. FSD refers to psychogenic and organic causes of desire, arousal, orgasm, or sexual pain disorders that cause personal distress.⁽¹⁾ Labels on many of the new oral prosexual botanicals claim that the preparations are approved by the US Food and Drug Administration (FDA) to treat FSD. Alternatively, less-than-savvy consumers who see an expensively packaged and promoted product assume that it, like all prescription medications, is regulated by the FDA.

This is the case with the new mass-marketed oral agent Avlimil. This drug is packaged in a dial pack (similar to oral contraceptive pills) with instructions that women should take one pill per day. Most women with whom I have spoken surmise that this drug has undergone extensive testing in placebo-controlled trials, simply because of the marketing campaign and the packaging. In reality, advertisements for the drug cite data from 40 women who took Avlimil for 3 months: **No published trials exist.** In addition, drugs like Avlimil are assumed to be devoid of side effects because of their claim

to be "100% natural." In reality, one of the primary ingredients in this product is sage leaf, an herb that contains the neurotoxin thujone and has been associated with vomiting and hallucinations in certain doses.⁽²⁾ This fact, however, is not mentioned in the package insert. **Buyer beware.**

Advertisements for another oral offering, known as Cerniplex, appear in mainstream women's magazines throughout the United States. Although, these ads suggest that this agent has been evaluated by "three separate tests," **none of these tests have been published.** The ingredients of this medication can be difficult to research for consumers, because the ads state that it is a blend of "Chinese herbs" that are not well specified, and can be difficult to reference in traditional herbal resources. Instructions suggest that the product "should be taken for at least 3 months" before sexual enhancement is realized. A mere \$150 to \$210 later, consumers can judge its effectiveness.

Sex Rx

Another group of prosexual products are the topical arousal enhancement creams and oils. These products are available through Internet marketing companies or through "distributors near you." Most of these products, including Alura, Femore, and Vigel, contain some combination of the amino-acid L-arginine and a menthol-type base. Although L-arginine, in oral form, is a precursor of nitric oxide, which enhances genital vasodilation and engorgement, the drug in topical form has not been conclusively proven to have the same bioavailability or effectiveness. In addition, L-arginine supplementation has been associated with potentiation of herpes simplex virus (HSV)-1 or -2 outbreaks in women with known histories of HSV infection.

The topical menthol cream bases of these products definitely produce a warm "tingling" effect to the tissue to which they are applied. Unfortunately, this is frequently due to a direct irritative effect on sensitive vulvar and vaginal areas; it should not be mistaken for true arousal.

The preceding warnings notwithstanding, a few well-researched, effective botanicals for female sexual enhancement are available. One such herbal supplement is ArginMax. Available commercially, this oral blend of damiana, L-arginine, ginseng, and ginkgo biloba has undergone well-controlled scientific trials, the published results of which showed that, after 4 weeks, 73.5% of the ArginMax group improved in satisfaction with their overall sex life, as compared with 37.2% of the placebo group ($P < 0.01$).⁽³⁾ Notable improvements were also observed in sexual desire, reduction of vaginal dryness, frequency of sexual intercourse and orgasm, and clitoral sensation. No significant side effects were noted. Of note, the product does contain significant amounts of L-arginine; thus, care should be taken by women with a history of HSV infection. This supplement is widely available through health food and drug stores throughout the United States.

Zestra is a topical blend of botanical oils, including borage seed oil, evening primrose oil, extract of angelica, extract of coleus, and

antioxidants that are rated as GRAS (generally recognized as safe) by the FDA.⁽⁴⁾ The product has undergone a small but impressive placebo-controlled scientific clinical trial for efficacy, which is of particular note because the FDA does not require this type of rigorous validation for botanical preparations. In the trial, Zestra was evaluated in 10 women with female sexual arousal disorder (FSAD) and in 10 women without the disorder, assessing their responses both before and after use. Researchers looked at changes in four indices of female sexual response: desire, arousal, genital sensation, and ability to experience orgasm. Each woman used Zestra 5 times and placebo oil 5 times. Participants and researchers were blinded to the content of the study oils. Results indicated that women with FSAD reported satisfaction with sexual arousal less than 33% of the time when using placebo oil but a significant 85% of the time when using Zestra. In the control group (women without FSAD), satisfaction with arousal was 73% with placebo oil and 95% with Zestra. Results of the trial were published in the peer-reviewed [*Journal of Sex and Marital Therapy*](#).⁽⁵⁾


With the ever-changing, multibillion dollar sexual dysfunction market continually bombarding our patients with "quick fixes," it is incumbent upon clinicians to self-educate and evaluate new botanical offerings for FSD with the same thoroughness that we evaluate new prescription options. A valuable, objective, evidence-based resource for natural product evaluation is found at naturaldatabase.com. The Natural Medicines Comprehensive Database was originally devised in 1999, and is updated daily. It is a comprehensive listing of brand-name products and their ingredients, evaluated by 50 clinical pharmacists and physicians.

It is gratifying to see FSD being given the same attention by botanical and pharmaceutical manufacturers that male sexual dysfunction has been given in the past. For women's healthcare providers, however, this attention comes with added risk and responsibility.

References

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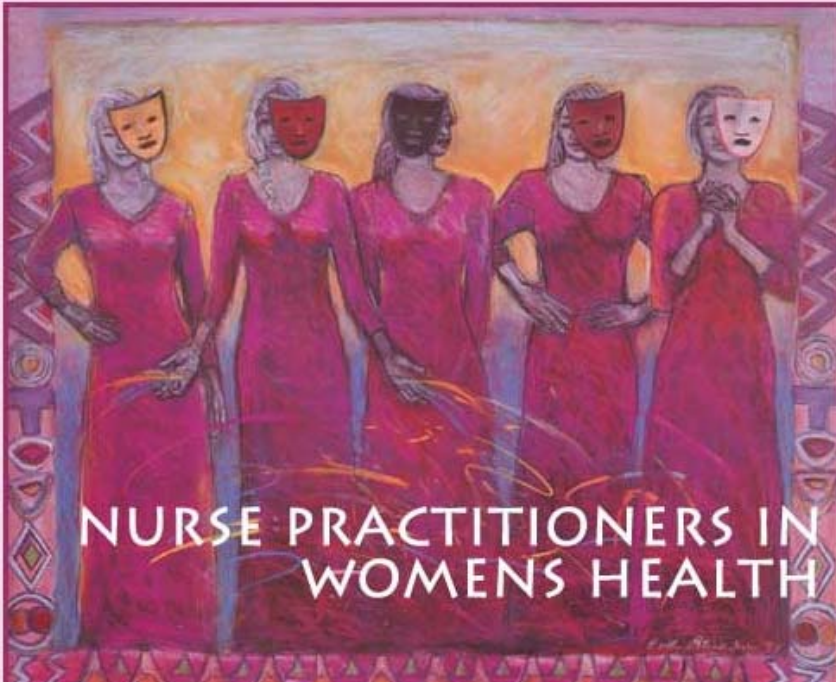
You may contact Dr Kellogg-Spadt with questions for the Sex Rx column at npcskspadt@aol.com.



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