FOWH responds to the FDA Statement:
September 2018

FDA Update

On July 30, the FDA issued a vaginal laser safety communication.

In their warning, the FDA stated that "We are aware that certain device manufacturers may be marketing their energy-based medical device for vaginal "rejuvenation" and/or cosmetic vaginal procedures. The safety and effectiveness of energy-based medical devices to perform these procedures has not been established."

Comment: We respectfully disagree. There are numerous peer-reviewed published articles in the medical literature that demonstrate safety and efficacy of the Mona Lisa Touch vaginal laser for the treatment of symptoms caused by loss of estrogen. A partial listing is presented at the bottom of this web page.

The warning also states "To date, we have not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function. The treatment of these symptoms or conditions by applying energy-based therapies to the vagina may lead to serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain."

Comment: The Mona Lisa Touch is not FDA approved for the indication for which it is being used but it is approved as safe. The FDA approves drugs for medical indications and approves devices for safety. On September 5, 2014 the Mona Lisa Touch laser received 510K (K133895) marketing clearance for "incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery."

The practice of medicine goes far beyond what the FDA does or does not approve. Medication approved for one condition is widely used for other conditions and the same thing can be said about devices. The FDA does not determine what the standard of care of the practice of medicine is. This is determined by the consensus of a large number of experienced practicing physicians.

The warning states "We are aware that certain device manufacturers may be marketing their energy-based medical device for vaginal "rejuvenation" and/or cosmetic vaginal procedures. The safety and effectiveness of energy-based medical devices to perform these procedures has not been established. We are aware that certain device manufacturers may be marketing their energy-based medical device for vaginal "rejuvenation" and/or cosmetic vaginal procedures. The safety and effectiveness of energy-based medical devices to perform these procedures has not been established.

Comment: We agree completely. We do NOT use the term vaginal rejuvenation because it does not have a clear-cut definition. However, the diagnosis of post-menopausal vaginal atrophy is quite clear, which is symptoms of painful sex, vaginal dryness, vaginal burning, and/or urinary urgency associated with the loss of estrogen due to menopause. Furthermore, this condition has been proven to be safely and effectively treated using the Mona Lisa Touch vaginal laser. We further agree that laser manufacturers are known to make exaggerated claims in order to sell their devices and the FDA should crack down on this.

References

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