August 2, 2018

To our patients,

You may be aware that the FDA recently issued a warning letter about the use of energy systems such as laser and radiofrequency for the treatment of vaginal atrophy, vulvar pain and painful intercourse. The letter advises health care providers and patients that these devices, although approved for treatment of certain vaginal conditions, are not approved as a treatment for vaginal rejuvenation, vaginal laxity, vaginal atrophy or painful intercourse due to menopause.

We want to be sure that our patients understand the issues posed in the FDA warning letter. This notice calls into question the use of laser for "vaginal rejuvenation" as well as atrophy and painful intercourse. We have not treated you for vaginal rejuvenation or vaginal laxity. Mona Lisa Touch is the laser that we use in our office. The Mona Lisa Touch laser in its current form is designed to treat genitourinary symptoms of menopause (GSM) such as painful intercourse and vaginal atrophy. As noted above, the FDA approved use of the laser for destroying certain vaginal lesions but the manufacturer of the laser did not request approval for atrophy.

When the FDA sent out the warning, they informed us that there have been complications such as vaginal burning (meaning a serious burn, not a "burning" sensation, which is common after laser therapy) and scar formation, but that is not specific to Mona Lisa Touch. There are several other manufactures that make devices that use either laser or radiofrequency energy. When we spoke to physicians involved in tracking complications specific to Mona Lisa Touch treatments, three (3) vaginal burns were noted in over 100,000 procedures. At least two of the three burns were due to improper use of the laser. As far as we know, all the other adverse events occurred in other technologies such as radiofrequency and lasers not as well studied as Mona Lisa Touch.

We have used CO2 laser for thirty years in our gynecology practice and have had no adverse events. Mona Lisa Touch is a version of CO2 laser that allows for safe and effective treatment in the office setting. We selected this particular system because Mona Lisa Touch has more published peer reviewed studies than any other vaginal laser or radiofrequency device used for the symptoms of GSM. Both the safety and efficacy of Mona Lisa Touch have been demonstrated in many peer review studies that we have posted on our website.

After the FDA sent out the warning letter, they sent a separate letter to each of the five manufacturers of laser and radiofrequency devices. The letter to Cynosure (the manufacturer of Mona Lisa Touch) listed concerns that relate to marketing statements on their website but nothing specific to difficulty associated with the treatment itself.

We agree with the FDA warning that more research is needed but from the wording of their statement, it appears that they were not aware of recent published studies that continue to confirm the efficacy of this treatment. We expect the manufacturer to respond to the FDA within the next few weeks.

We are committed to the best care for our patients who are being treated for GSM and will be happy to answer any questions you might have about this issue.

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