Good morning. My name is Dr. Hal Lawrence and I’d like to thank the FDA for giving me the opportunity to speak today on behalf of the American College of Obstetricians and Gynecologists, also known as ACOG.

As the nation’s leading group of physicians providing health care for women, ACOG advocates for quality health care, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness of the changing issues facing women’s health care.

I do not just speak on behalf of ob-gyns, I AM an ob-gyn. I have no financial disclosures to report.
In my comments today, I won’t repeat the details of ACOG’s Special Report on Power Morcellation and Occult Malignancy in Gynecologic Surgery, which we released in May of this year. We have already provided that report to FDA representatives.

And, of course, the committee members today will hear an abundance of data from other presenters.

Instead, my remarks are intended to add some perspective for the committee members to consider.

Let me start off by saying that, without a doubt, it is tragic for any woman to undergo the experience of having a uterine sarcoma worsen because of the use of a power morcellator.
It is essential that we – the gynecologists, the regulators, and the industry – work to minimize the threat of this. I assure you that NO gynecologist wants this outcome for his or her patient. We do not take this lightly.

That is why ACOG released our special report, which addresses the risks and benefits associated with power morcellation. The report discusses the incidence of an undiagnosed uterine sarcoma being spread by a power morcellator, and lays out the steps that a gynecologist should take to evaluate and mitigate the risk for each individual patient.

That report was not the result of new research, but rather of a thorough review of the current literature.
Our work reflects science. I believe that we do ourselves, and our patients, a disservice if we respond to emerging safety concerns in a way that does not reflect science.

That is why I urge the advisory committee to focus its deliberations today and tomorrow on the available data, as ACOG did.

Admittedly, the data are limited regarding power morcellation and occult uterine sarcoma. Additionally, there are factors that complicate our attempts to calculate risk, for example the rarity of uterine sarcomas and the sample size.
Despite these challenges, our assessment of the incidence of an occult sarcoma diagnosed following power morcellation is approximately 1 in 500 women. This is not statistically different from the FDA’s estimate of 1 in 350.

The evidence that is available demonstrates that power morcellation can be a treatment option for certain women, based on each woman’s unique needs, when considered among the full range of treatment options.

When used during a minimally invasive hysterectomy or myomectomy, it can help certain women avoid the inherent risk, and potential significant morbidity and mortality, associated with a total abdominal hysterectomy.
As physicians, we realize that all procedures have risk. Our job is to recognize that risk, and to take steps to mitigate that risk.

After all, we clearly state in our report that in certain cases, power morcellation should not be used.

But as long as gynecologists have patients who might benefit from power morcellation – patients who might be spared the mortality associated with total abdominal hysterectomy, who are at low risk of a uterine sarcoma, who want a less-invasive surgery and a faster recovery – then power morcellation should remain a treatment option for them to consider with their gynecologist.
Let me reiterate. When a patient is diagnosed, post-morcellation, with an occult malignancy – indeed, when a patient experiences any complication – it is devastating.

But it is unacceptable that, in an effort to avoid one risk, we should subject women to another.

Every physician in this room knows that there is no one-size-fits-all treatment option for patients. Each patient is different from the thousands of patients who came before, and we must consider each patient’s needs in making our treatment decisions.
And, we must have a variety of treatment options to consider in order to choose the best one for each patient – the one that best reflects her unique medical and personal situation.

In fact, ACOG has previously recommended vaginal hysterectomy because it is associated with better outcomes and fewer complications than the alternatives of laparoscopic or abdominal hysterectomy.

But still, one surgical procedure is not right for all patients, and that is why we need options.
It is appropriate for us to discuss the potential complications associated with power morcellation, because that will help to increase awareness among patients and physicians about the associated risks and benefits of the procedure.

It will help to emphasize to industry the need for improved diagnostic tools, and for the creation of more data for us to consider. We welcome this discussion.

It is also appropriate for the FDA to take steps, such as calling for the establishment of a registry. This will help us gather the data that we need to better understand the risk associated with power morcellation. And, it will further promote patient safety and help to tailor patient care in the future.
I also urge caution against the adoption of solutions that may, on the surface, appear to be “answers,” but are not tested and may give a false sense of security.

Currently available surgical bags could be torn by a morcellator, or are an insufficient size to capture the tissue being removed.

We still lack a reliable tool to diagnose a uterine sarcoma prior to surgical intervention. Widespread use of fibroid biopsies has been urged, but would potentially lead to dangerous false negative results. Because patients often have multiple, possibly dozens of, fibroids, the biopsy needle could easily miss small spots of malignant tissue.
In some ways, it may seem easier to recommend a ban on morcellation. That would, of course, remove the risk associated with that specific procedure.

But it would also leave physicians and patients with fewer options – patients at the lowest risk of an occult malignancy, who might otherwise have to undergo a total abdominal hysterectomy.

Complications and risks are, unfortunately, part of health care.

We should not hold one procedure, in this case power morcellation, to a higher standard than other procedures.
What we can do is work together to improve use of those procedures in the future, as we make complex, important treatment choices with our patients.

I urge the committee today to recognize the importance of treatment options for all physicians, including ob-gyns.

Again, I thank you for your time today.