



## **MEDIA TALKING POINTS:**

### **For Use ONLY IF NEEDED During Progesterone Recall**

1. Apothecary By Design has learned that a small batch of compounded progesterone – a common fertility medication – was recently dispensed in defective containers to nine patients, and has requested that the patients return the medication. We don't believe the faulty containers had any effect on the progesterone, or more importantly, on any patient's health.

- The batch had successfully passed tests to ensure its sterility, potency, and compliance with other standards.
- A total of 25 units were dispensed in containers whose metal closure had adhered to a rubber stopper.
- The units were dispensed to nine patients in Connecticut, Illinois, Massachusetts, New York, and Tennessee; [NUMBER, WHEN AVAILABLE] patients have returned their medication so far.
- Six patients used the medication before returning it; none have reported an adverse effect, and we do not expect any will.
- ABD has made arrangements to replace all the patients' medication, and we deeply regret any inconvenience this incident may have caused them.

2. ABD has chosen to take this step out of an abundance of caution – as we would if a medication were dispensed in any manner that doesn't meet our exacting specifications.

- ABD has voluntarily requested the return of the medication; there has been no instruction from any regulatory agency to do so.
- ABD has notified the Maine Board of Pharmacy of our action, as well as the FDA and the pharmacy boards in the five states where the patients reside.

3. Because ABD takes the quality of its medication very seriously, we are working to prevent this type of incident from occurring again.

- Our emphasis on quality is underscored by the fact that we've rarely had to ask a patient to return medication, and that the number of patients affected in this case was relatively small.
- Still, any incident like this is one too many – so we are investigating to determine what went wrong.
- As a result of the incident, ABD already has implemented several process improvements, and will make additional changes to our policies and procedures if needed. We will update the pharmacy boards and our patients about these preventive steps.