MEDIA TALKING POINTS:

For Use During an FDA Inspection

1. As part of its ongoing evaluation of the country's compounding pharmacies, the federal government's Food and Drug Administration is performing a proactive (i.e., not for cause) inspection of Apothecary By Design.

    - FDA plans to inspect all sterile compounding facilities over the next year or so, according to reports. The administration can take several types of action after completing an inspection.

    - Many inspections result in FDA issuing a "form 483," which is a list of observations. The form can indicate no action, meaning that there are no objectionable findings; voluntary action, meaning that there are objectionable conditions, but no regulatory action is recommended; or official action, recommending regulatory measures. A 483 does not represent a determination about compliance with federal law.

    - Inspections are highly detailed and typically take several weeks. Depending on the findings, pharmacies sometimes respond by providing additional information or clarifying specific results.

2. Apothecary By Design is happy to cooperate with FDA and its inspectors. We're proud of our compounding capability and the steps we take to ensure the high quality of our compounded medications. We're also continuously looking to improve our quality – so if an outside perspective can help, we welcome it.

3. Our commitment to high quality extends so far that Apothecary By Design has voluntarily earned, and holds, accreditation from the Pharmacy Compounding Accreditation Board in both sterile and non-sterile compounding. Only about 400 pharmacies nationwide attain PCAB accreditation, which demonstrates compliance with the industry's highest standards, facilitating safe and effective compounded medications.

4. Apothecary By Design patients can feel reassured knowing that our compounding lab and the medications it prepares are subject to such painstaking scrutiny from our staff and the FDA inspectors.

5. [WHEN INSPECTION IS COMPLETE] As part of its ongoing evaluation of the country's compounding pharmacies, the federal government's Food and Drug Administration has completed a proactive (i.e., not for cause) inspection of Apothecary By Design. Driven by our continuous effort to improve quality, we cooperated fully with the inspection.

    - The findings include [TBD].

    - Apothecary By Design plans to [TBD].

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MEDIA Q&A:

For Internal Use During an FDA Inspection

Why is Apothecary By Design being inspected?

Like Apothecary By Design, the federal Food and Drug Administration takes the quality of compounded medication very seriously. Over the past several years, FDA has been inspecting all pharmacies that compound sterile medications. Inspections typically focus on sanitary conditions and procedures to ensure a medication's quality, purity, and potency.

What is pharmaceutical compounding?

Compounding – a centuries-old, core component of pharmacy practice – is the use of pure, active ingredients or manufactured, FDA-approved products to create individual medications based on individual prescriptions. Through compounding, medication strengths, dosage levels, ingredients, and delivery methods can all be customized to best suit the needs of a specific patient. Almost any type of medication can be compounded into tablets, liquids, topical creams, suspensions, injectables, or even medicated lollipops.

What does Apothecary By Design do to safeguard the quality of its compounded medications?

The Apothecary By Design team follows rigorous protocols to ensure our compounded medications are safe, effective, and of the highest quality.

For medications that require a sterile environment, we carefully maintain and monitor a "clean room," and practice aseptic techniques in everything from hand washing and sterile garb, to general movements about the work area. And no surface in our laboratory is too small to be scrutinized. In fact, each month we use more than 10 gallons of a sterile alcohol solution to meticulously clean our Portland compounding lab.

Our procedures are directly based on guidelines 795 and 797 of the U.S. Pharmacopeial Convention, the scientific organization whose pharmacy standards are used by FDA and more than 140 countries.

In addition, ABD has voluntarily earned, and holds, accreditation from the Pharmacy Compounding Accreditation Board in both sterile and non-sterile compounding. Only about 400 pharmacies nationwide attain PCAB accreditation, which demonstrates compliance with the industry's highest standards, facilitating safe and effective compounded medications.

Why is the federal government involved?

Ensuring high quality in compounded medications has always been a joint responsibility of federal and state government. States are responsible for regulating pharmacies; FDA's duties include overseeing the production of medicines. The state pharmacy boards and FDA already work closely together to achieve their common goal, and recently FDA's role has become more active.

What does it mean if a compounding pharmacy receives a "483"?

After an inspection is complete, FDA may issue a "form 483" that lists observations and whether any action is indicated as a result. In some cases, a 483 may result in a warning letter or a request to recall medications. It's important to understand that a 483 is not a determination about compliance with federal law.

FDA inspectors are very scrupulous, and even the most skilled compounding pharmacies often receive one of these forms. In fact, they were issued to 90% of the more than 150 pharmacies inspected from October 2012 to September 2014. More recently, in the first four months of 2016, FDA issued form 483's to 31 pharmacies, including one as near as Nashua, New Hampshire.

Why are medications compounded?

Compounding allows patients to benefit from lifesaving and life-improving medicines they might not otherwise be able to use. There are many types of patients who rely on compounded medications – for example, patients who have difficulty swallowing pills, are allergic to certain dyes, fillers or preservatives, or require a dosage not commonly available.

According to the International Academy of Compounding Pharmacists, 1-3% of prescriptions filled in the U.S. by community pharmacies are for compounded medications. Virtually all hospitals compound medications. Physicians, dentists, and other healthcare professionals also perform compounding.

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Just five years ago, the practices of New England Compounding Center led to hundreds of illnesses and 64 deaths. Shouldn't the public be concerned that ABD also performs compounding?

Patients can feel assured that all medications they receive from ABD, including compounded ones, are safe and effective. We follow the industry's most rigorous protocols to ensure our compounded medications are of the highest quality. As for the tragedy that occurred in 2012:

- There are more than 3,000 U.S. pharmacies that perform sterile compounding, according to the IACP, and the past actions of one do not characterize the high quality standards upheld each day by Apothecary By Design and other pharmacies.

- NECC was shown to be shipping medications without patient-specific prescriptions, and even using fake prescriptions. The center was preparing large quantities of medication in advance without appropriate due-diligence or quality assurance protocols. In the words of the federal prosecutor, NECC escaped FDA oversight because it "masqueraded as a pharmacy when it was in fact manufacturing drugs."

- Much has been learned since the tragedy of 2012. The next year, Congress passed the Drug Quality and Security Act, clarifying FDA's role in the regulation of compounding pharmacies. FDA has also stepped up the frequency and depth of its inspections. Compounding pharmacies, already known for safety, are getting even safer.

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