The Regulatory Framework of **Compounding**

Presentation to the **NASEM Committee**

Presented by Rachael G. Pontikes

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ReedSmith
Driving progress
through partnership

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Reed Smith's national reputation in health care law stems from a practice – established more than 40 years ago – that is multidisciplinary, involving the skills and experience of a large core practice group devoted entirely to the health care field.

Rachael leads Reed Smith's Chicago team, which, in particular, is nationally recognized for its expertise in the compounding space. Rachael and her team represent a wide variety of industry stakeholders, including outsourcing facilities and traditional compounding pharmacies.

Today's Speakers

- Dr. Angela DeRosa, DO, MBA, CPE, Medical Director, Belmar Pharmacy, Belmar Select Outsourcing
- Doug Cammann, R.Ph., Vice President of Operations, AnazaoHealth Corporation
- Donald Prentiss, President of Operations, Carie Boyd's Prescription Shop
- Dr. Thomas C. Kupiec, Ph.D., President/CEO ARL BioPharma, Inc., DNA Solutions, Inc., The Kupiec Group, LLC

Where Do Compounded Drugs Fit in the Drug Supply Chain?

Section 503A and Section 503B

Missing Link

- **Commercially available drugs and compounded drugs serve different treatment needs in the drug supply chain**
- **Commercially available drugs are a one-size-fits-all drug product that can go through new drug approval**
- **Compounded drugs are tailored made to fit the needs of a patient or patient population**
  - **Only** when the physician determines a commercially available drug is inadequate to treat the patient.
- **So… compounds are regulated differently.**

Compounded Drugs Are Exempt from the New Drug Approval Process

As a matter of Statute (via 503A and 503B), Congress and FDA agreed to exempt compounds from new drug approval… but why?

- **New Drug Approval is an "especially poor fit" for compounds;**
- **Forcing compounds through new drug approval would eliminate them, and entire disease states would go untreated; and**
- **Larger batches to allow for cGMP are not indicative of a large enough sample size for new drug approval.**

Rigorous Regulatory Schema for Compounded Drugs

- **503A Pharmacies**
- **Section 503A of FDCA**
- **State law**
- **FDA and states required to share information**
- **503B Pharmacies (Outsourcing Facilities)**
- **Section 503B of the FDCA**
- **State law**

Outsourcing Facilities

- **Primarily regulated by FDA via Section 503B**
- **Subject to cGMP quality standards;**
- **Federal inspections; and**
- **Allowed to compound non-patient-specific medications for office use.**
- **ALSO regulated by the States**
- **Separate state quality regulations;**
- **State inspections; and**
- **State registration requirements**

Compounding Serves A Critical Medical Need in the Drug Supply Chain

- **Physicians need compounded drugs for proper treatment;**
- **Physicians prescribe compounded drugs when they determine the commercially available option is medically unsuitable to treat the patient; and**
- **Physicians need compounded drugs from both 503A and 503B facilities to properly treat all patient populations.**

The Coalition's Proposed Recommendations To Address the Study's Charge

- **Compounded BHRT is not demonstrably difficult to compound;**
- **There is a clear clinical utility in treating patients with compounded BHRT; and**
- **BHRT medications compounded by both 503A and 503B facilities are integral to the drug supply chain.**