Compounding Regulation & Advocacy

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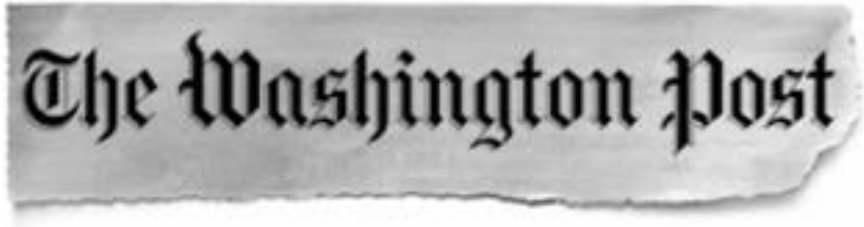
Background: Why Increased Regulation?

- In 2013, contaminated steroid injections compounded by the New England Compounding Center resulted in ~ 60 deaths and ~ 700 illnesses
- Subsequent FDA inspections of traditional compounding pharmacies found widespread safety issues


THE WALL STREET JOURNAL.

Compound Pharmacy Owners and Employees Arrested for Meningitis Outbreak


The Washington Post

FDA finds widespread safety issues at compounding pharmacies.

Drug Quality and Security Act (DQSA)

- Enacted in 2013 in response to New England Compounding Pharmacy meningitis outbreak.
- Allowed for increased oversight by FDA of drugs compounded by licensed pharmacists and physicians.
- Created an “outsourcing facility” status under § 503B.

  Must:
  - Comply with current good manufacturing practices (cGMPs);
  - Be inspected by FDA; and
  - Meet other conditions, such as reporting adverse events

Advocacy Focus

- Office-Use Compounding
  - *Obtain from traditional compounding pharmacy without patient-specific prescription for office use*
- Physician In-Office Compounding
  - *Compound in clinical setting (sterile or non-sterile)*
- Section 503A List of Bulk Drug Substances
  - *Maintaining access to cantharidin, quinacrine, kojic acid*
- Access to Affordable Compounded Drugs

Office-Use Compounding

- In December 2016, FDA finalized guidance prohibiting office-use compounding.
  - *Where compounded drugs are obtained from a Section 503A traditional compounding pharmacy without a patient-specific prescription.*
  - *FDA allows Section 503B outsourcing facilities to distribute compounded drugs without patient-specific prescriptions but issues with low volume and rare and unique conditions.*
- Strategy shift from federal regulatory to legislative focused.
- State law and pharmacy board regulations may also restrict.

Physician In-Office Compounding

- The same December 2016 FDA guidance allows physician in-office compounding (up to a 30-day supply based on prior use).
- However, concerned about state law and regulation, particularly USP and FSMB.
  - U.S. Pharmacopeia Chapter 797 on Sterile Compounding
  - Federation of State Medical Boards Draft Position Statement on Sterile Compounding in Physicians' Offices

Section 503A List of Bulk Drug Substances

- Sections 503A contains various requirements for FDA to develop lists of drugs that may or may not be compounded and lists of bulk drug substances that may be used to compound.
- The FDA makes recommendations for whether a drug should be included, the FDA Pharmacy Compounding Advisory Committee (PCAC) votes on whether it should be included, and then the FDA uses notice-and-comment rulemaking to solicit comments and make the final determination.
- Notable drugs under consideration: Cantharidin, quinacrine, glycolic acid, tricholoracetic acid, kojic acid.

Access to Affordable Compounded Drugs

- Dermatologists work with traditional compounding pharmacists to facilitate access to drugs that would otherwise not be attainable due to cost.
- FDA draft guidance on *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A*

Survey

- After Annual Meeting concludes, you will receive an e-mail survey from staff that asks you about your compounding-related practices and issues accessing compounded drugs.
- High advocacy priority that continues to be an issue on the federal legislative, federal regulatory, and state levels.

Audience Questions

Staff Contact Information

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