Physician Compounding

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Overview

- Current oversight paradigms
- Challenges in oversight
- Opportunities to improve oversight

Issues with Physician Compounding

- Several examples of outbreaks attributed to drug products compounded by healthcare providers
  - Adverse events may be underreported
- Concerns about ability to ensure quality of drugs compounded in office setting and physician awareness of applicable regulations
- Challenges in coordination of oversight
  - FDA and other Federal Agencies
  - State Boards of Pharmacy
  - State Boards of Medicine
  - State and Local Departments of Health

FDA Oversight – Applicable Laws

- Section 503A of the Federal Food, Drug and Cosmetic Act (FD&C Act) describes conditions that must be satisfied for drug products compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician, to be exempt from the following sections of the FD&C Act:
  - 501(a)(2)(B) (concerning current good manufacturing practice requirements)
  - 502(f)(1) (concerning the labeling of drug with adequate directions for use)
  - 505 (concerning the approval of drugs under NDAs or ANDAs)
- Even if the conditions of 503A are met, compounded drugs remain subject to other FD&C Act provisions (e.g., insanitary conditions)

FDA Oversight – Challenges & Opportunities

- Challenges with respect to FDA's oversight of physician compounding
  - FDA generally does not inspect ambulatory care settings, such as physician offices, where physician compounding might take place
  - FDA often is not aware of potential problems with drug products compounded by physicians unless and until it receives a complaint, such as a report of a serious adverse event or visible contamination
- FDA is interested in providing support to facilitate greater regulatory oversight of physician compounding by State, territorial, and local health departments