Physician Compounding

Inter-governmental Working Meeting on Drug Compounding
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Emily Gebbia
CDER, Office of Compliance
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