Information Sharing & Collaboration

Inter-governmental Working Meeting on Drug Compounding
September 26, 2017

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Presentations followed by panel Q&A

- Kathleen Anderson, Deputy Director, Office of Unapproved Drugs and Labeling Compliance, CDER/FDA
- José Martinez Jr., Supervisory Consumer Safety Officer, Office of Pharmaceutical Quality Operations, ORA/FDA
- Susan Alverson, Executive Secretary, Alabama Board of Pharmacy
- Beth Ferguson, Deputy Director, Minnesota Board of Pharmacy
- Lauren DiPaola, Testimony Specialist, Office of Policy and Risk Management, ORA/FDA

FDA perspectives and examples

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Compounding pharmacy in AL

- FDA inspected in March 2016 and observed insanitary conditions, including poor sterile production practices
- FDA had serious concerns, but the firm was uncooperative
  - In March FDA recommended a recall of all non-expired lots of drug products intended to be sterile, but the compounding pharmacy refused.
  - In April FDA issued a statement alerting health care professionals not to use purportedly sterile drugs from the compounding pharmacy.
  - In May, FDA sent a formal letter to the firm requesting they recall all products intended to be sterile within expiry.
- FDA and the state collaborated to identify ways to address issues at the firm, and the state was able to take certain actions. Ultimately the firm ceased sterile operations.

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Compounding pharmacy in NJ

- State-shared information about an outbreak catalyzes FDA inspection
  - State regulators alert FDA of two clusters of infections in patients that had received drugs sourced from the compounding pharmacy.
  - Just a few days after this information was shared FDA was able to deploy investigators to the firm to conduct a for-cause inspection.
  - FDA identifies concerning production quality problems at the firm (unrelated to the outbreak) and issues a 483.
- FDA was able to work with the state to identify ways to address issues at the firm and get them to cease operations

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- Information sharing helps FDA and states take coordinated and effective oversight actions.
- Information sharing mechanisms, such as 20.88 agreements, or permitted information sharing with commissioned officials, are how FDA and states can discuss non-public information about compounding facility inspections, open investigations, and other efforts.
- State officials in both New Jersey and Alabama are covered by information sharing agreements with FDA and/or are commissioned officials

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21 CFR 20.88

- Discretionary sharing
- Of certain non-public information (NPI), according to law and procedures
- With a state or local government agency
- Having counterpart functions to FDA:
  - Regulatory law enforcement
  - Health oversight
  - Public health function
- Case-Specific and Long-Term Options

Commissioned Officials

- Qualified state regulatory official
- Commissioned to “receive and review official FDA documents”
- May receive FDA’s NPI, including confidential commercial information and trade secret information

How FDA can support state actions

- Request that states join FDA on compounding inspections
- Provide factual witness testimony
- Provide copies of un-redacted or partially redacted
  - Establishment Inspection Reports (EIRs)
  - Forms FDA 483
  - Warning Letters and Untitled Letters
- Proactively share information with states
- Discuss with states the significance of the observations in Forms FDA 483 and the violations in warning and untitled letters and the actions, if any, FDA is considering taking to address them

How states can support FDA actions

- Alert FDA to facilities that may be in violation of provisions of federal law, such as the prescription requirement, or the prohibition on copying approved drugs.
- Alert FDA to emergent outbreaks associated with compounded or repackaged drugs.
- Share findings when following up with firms referred by FDA.
- Provide information about nonresident compounders that ship into the state.
- Provide information about resident facilities that ship compounded products out of the state.

Information sharing action items

- Availability of current and historical drug shortage information on FDA's website (Action Item #4)
  - FDA encourages state officials to review FDA's Drug Shortage Database to determine whether a drug is or has been in shortage, and to contact FDA at IGA@fda.hhs.gov with any questions. Information on historical periods of shortage may be accessed through https://archive.org/web/.
  - Once on FDA's archive site, enter FDA's drug shortage page URL (www.fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm) to see archived versions of FDA's shortage list.
- Opportunity for FDA technical assistance regarding federal law during development of state law or regulation (Action Item #5)
  - FDA encourages state officials to contact FDA at IGA@fda.hhs.gov if, as they engage in potential legislative or regulatory changes, they have questions concerning similarities or differences with Federal law. FDA can provide technical assistance as requested.

Complimentary Actions supported by Information Sharing

- FDA's primary civil enforcement tools against compounders and compounded drugs are injunctions and seizures.
- FDA may recommend or request, but not require, recalls of compounded drugs.
- States often have the ability to use different tools and act more rapidly than FDA to stop unsafe activity when identified, such as through immediate state licensure suspension.
- FDA greatly values state enforcement actions and encourages states to seek FDA's support in their enforcement actions where such support would be helpful.