Learning Objectives

At the completion of this activity, the participant will be able to:
1. Discuss timeline of NECC tragedy
2. List BoP regulations passed in November 2012
3. Outline Chapter 159 of Acts of 2014
4. Summarize Drug Quality and Security Act of 2013
5. Review indictment of NECC personnel

Timeline

- July 1998 Licensed by MA BoP
- April 2002 FDA Form 483 issued (Betamethasone sterility)
- Jan 2006 MA BoP Consent Agreement for Probation. Promised corrective acts overseen by consultant. The consultant had recently been convicted of fraud in IL. Sold unapproved “sterilizer” that resulted in blindness of patients.
- Apr 2011 CO BoP cease and desist order banning bulk medication shipments into CO
Timeline

- May 2012 Lot 05212012@68 compounded from raw material. Uncertain about sterility testing.
- June 2012 Lot 06292012@26 compounded from raw material. Two shipments made prior to final completion of sterility testing.
- Aug 2012 Lot 08102012@51 compounded from raw material. Eleven shipments made prior to final sterility testing.
- A total of 17,500 vials from above lots shipped.
- Sterility testing subsequently found substandard.

Timeline

- Oct 10, 2012 Local, state and federal investigators identify approx 14,000 patients who had received one or more doses from the contaminated lots.
- Oct 18, 2012 FDA & CDC identify contaminate as Exserohilium rostratum, aka Black Mold.
- Oct 22, 2012 NECC principals permanently surrender pharmacist licenses to MA BoP.
- Oct 31, 2012 MA BoP cease and desist to RPh's and techs from compounding any medications.

Timeline

- Dec 21, 2012 NECC files for bankruptcy.
- Oct 2013. CDC estimates that there have been 751 cases of fungal infections with 64 deaths attributed to the tragedy. Patients continue to be treated.
- Sep 4, 2014. Former NECC RPh supervisor arrested at Logan attempting to leave country. He was charged with mail fraud for his alleged role in shipping a batch of MPA that was supposedly safe for human use to one of the specialty pharmacy’s customers in August 2012. First NECC employee charged.

Timeline

- December 17, 2014. 14 NECC employees and principals are charged with 131 counts of racketeering, conspiracy to defraud the Government, mail and wire fraud, criminal contempt, and violations of the Food, Drug and Cosmetics Act, such as introduction of adulterated and misbranded drugs into interstate commerce.
- Cadden and Chin are charged with 25 counts each of second degree murder under RICO laws.
- Carla and Douglas Conigliaro charged with transferring $33M after filing of bankruptcy.

History Repeats Itself

- Urgent Care Pharmacy, Spartanburg SC 2002
- Batch prepared methylpred
- Sent to several states
- Five patients contracted fungal meningitis with one death
- PMIC V Urgent Care
- 2M/6M professional liability policy
- PMIC sought to escape coverage by several arguments. All reviewed and denied by federal court.
FDA Investigations

- The FDA stepped up inspections of compounding pharmacies nationwide. FDA issued 483 Warning Letters by year:
  - 2009: 1
  - 2010: 2
  - 2011: 0
  - 2012: 7
  - 2013: 65
  - 2014: 82
  - 2015: 11 to date

  [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm)

Board of Pharmacy Regulations

- BoP Emergency Regulations (Nov 2012) Licensed Pharmacy requirements:
  - All notices of discipline of any kind must be reported to the BoP within 7 days of receipt.
  - Attestation and volume of dispensed CSP's to BoP every 6 months.
  - Adverse medication events and failed CSP sterility testing to BoP within 7 days.

- Licensed Pharmacist requirements:
  - All notices of discipline of any kind to BoP within 30 days

Governor’s Commission

- Governor’s Special Commission on Compounding (Jan 2013)
  - MSHP only professional group represented
  - 25 different recommendations to improve pharmacy oversight and practice in general and sterile compounding practice in particular.
  - BoP composition, Advisory expertise, BoP staff training, Statutory & Regulatory changes, adoption of USP 795 & 797 definitions, Special Licensure for in-state and out-of-state Sterile Compounders and FDA communication.

Chapter 159 Acts of 2014

- Three bills filed at start of 2013-2014 legislative session including Governor Patrick’s bill. All bills combined into one which passed. The highlights are:
  - Change BoP composition
  - Train and expand BoP staff (cont.)

- Additional CE requirements, 20 per year and extra for CE for sterile (5) and complex non-sterile (3) compounded medication
- New Pharmacy licensure categories including retail and hospital based sterile, and retail complex non-sterile compounding pharmacies
- Limited definition of compounding
  - Individual order
  - Anticipatory compounding
  - No copies of FDA approved meds
Chapter 159 Acts of 2014

- Grant BoP authority to license out-of-state sterile product pharmacies
- Criteria for need for FDA licensure (cGMP)
- Criteria for compliance review
- New track and trace requirements
- Reporting CSP prescription volume to BoP
- Create defective drug log

Chapter 159 Acts of 2014

- Medication labeling requirements for sterile and complex non-sterile medications
- Board managed web site of sterile compounding pharmacies
- SADE reporting requirements (state & feds)
  - Own errors
  - Other pharmacy errors

Chapter 159 Acts of 2014

- Employee training in “Lean” concepts
- Manager of Record reporting requirements
  - Name and title of all employees involved in compounding
  - MOR and staff have all education and CE’s
  - Certify to Board pharmacy is in compliance with all Board regulations - attestation

Chapter 159 Acts of 2014

- Codifies summary suspension and summary quarantine authority
- Creates advisory committee to evaluate practice of pharmacy across settings and recommend regulations or policies to the BoP. Committee charged with reviewing central-fill pharmacy, central processing pharmacies, outsourcing facilities and telepharmacy.

Compounding Bill

- H-1972: An Act Adopting Administrative Simplification for Hospital Pharmacists
  - Remove telephone number from label requirement
  - Exempt hospitals from the sterile product volume reporting requirement

Federal Legislation

Several bills were filed in the House and Senate. One bill is passed, HR 3204, The Drug Quality and Security Act. The bill was signed on November 27, 2013. DSQA is combination of the sterile compounding law and pedigree (track and trace) law.
Notable elements of the DQSA:

- Provides an option for a facility engaged in compounding of sterile drugs to register with the FDA as an outsourcing facility.
- Any drugs removed from market may not be compounded.
- FDA approved drug may not be compounded unless there is a documented shortage.
- Require FDA to facilitate meaningful communication between the FDA and the State Boards of Pharmacy about concerns raised, or actions taken, against compounding pharmacies.

Federal Legislation

An outsourcing facility that opts to register with the FDA must:

- Give a licensed pharmacist direct oversight over the drugs compounded;
- May only compound drugs from bulk ingredients that appear on a list developed by the Secretary. This list will be developed through a notice published in the Federal Register following a 60 day comment period, and must take into consideration clinical need;
- Report to the Secretary upon registering, and every 6 months thereafter, the drugs sold in the previous 6 months;
- Be inspected by FDA according to a risk-based inspection schedule, and pay annual fees to support such inspections;
- Report serious adverse event experiences, and conduct follow up investigation and reporting similar to drug manufacturers;
- Label products with a statement identifying them as a compounded drug and other specified information about the drug.

Pedigree or Track and Trace Law

- Medications moving through supply chain must transfer certain information about pharmaceutical transaction when the drug changes ownership. Entities in the supply chain may only accept drug product if this information is provided. Preempts any state pedigree laws.

FDA recently sent letters to state hospital pharmacy leadership and state regulatory leaders notifying them that the DQSA law is in effect. The FDA also requested that any hospital wishing to engage a compounding pharmacy require as a contractual agreement that the pharmacy register with the FDA.

FDA Registered Outsourcers

- Currently, there are 50 Registered Outsourcers with the FDA
- There have been 40 inspections to date (3/17/15)
- There have been 39 483’s issued as a result of the 40 inspections
- Of the 50, 39 have indicated they will be perform sterile compounding from “Bulk Drug Substances”
- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm
NECC Civil Liability

- Each patient harmed by a tainted steroid injection may be either filing an individual suit or joining a class that is suing on behalf of multiple patients.
- NECC and its corporate partners have filed for Chpt 11 Bankruptcy protection.
- Owners, insurers and providers will contribute $135 million into a settlement account. The account will be distributed by the Bankruptcy Trustee.

NECC Professional Liability

- Board of Pharmacy Proceedings
  - NECC principles have voluntarily surrendered licenses permanently.
  - NECC, Ameridose and Alunus have either surrendered or agreed to restrictive orders preventing continued operation.
  - BoP Cease and Desist letter to all NECC pharmacy personnel. States they may be serious threat to public safety. Orders them to stop any working in any capacity with respect to compounding. Require BoP approval to resume working in that capacity.

NECC Criminal Liability

- Criminal Indictment under Federal RICO Laws
  - Second degree murder (Cadden-P and Chin-P): wanton and willful disregard that their actions would cause great harm or death (state of death’s definition).

NECC Criminal Liability

- 1. Racketeering Conspiracy (Cadden-P, Chin-P, Svirskiy-P, Leary-P, Connolly-T, Carter-T, Stepanets-P and Evanosky-P): Defrauded NECC’s customers and the patients of those customers, by selling for a profit purportedly sterile drugs that were made and tested in a manner that did not meet the standards set forth in USP-797 and USP-71.
- 2. Conspiracy to Defraud the United States (Cadden-P, Carter-T, Stepanets-P, Ronzio-S and G Conigliaro-D): Defraud the United States by interfering with and obstructing the lawful governmental functions of the FDA.
- 3. Misbranded Drugs (Cadden-P, Chin-P, Svirskiy-P, K Chin-P, Stepanets-P, and Thomas-P): Delivered drugs whose labeling was false and misleading, contrary to the provisions of Title 21, USC, Sect 352(a) or without a valid prescription, contrary to the provisions of Title 21, USC Sect 353(b)(1).
- 4. Criminal Contempt (Carla Conigliaro-O and Douglas Conigliaro-O): Transfer of 33.3M dollars after order of Bankruptcy Court to hold all assets.
Burden of Proof in RICO Racketeering Case

To prove a RICO violation, “the Government must prove beyond a reasonable doubt that:
1. The enterprise affected interstate or foreign commerce,
2. That the defendant under consideration associated with the enterprise,
3. That the defendant participated in the conduct of the enterprise’s affairs, and
4. That the defendant’s participation was through a pattern of racketeering activity.”

United States v. Shifman, 124 F.3d 31, 35 (1st Cir. 1997)

Potential Difficulties in NECC Case

Potential difficulties in proving a RICO charge
- The government must prove that the defendants Cadden and Chin had the necessary mental state to support convictions for second degree murder.
- The Government alleges the defendants’ conduct showed “an extreme and appalling indifference to human life.”
- There are contrary facts in the indictment including some level of sterilization of the meds and some sterility testing.

The government must distinguish NECC from prior instances of pharmacies placing contaminated medications into the stream of interstate commerce. Criminal charges have been rare in those instances and despite some these events leading to fatalities, no other event has led to second degree murder charges. In 2011, in the Main Street Family Pharmacy case, a TN compounding pharmacy and its owner pled guilty to a misdemeanor criminal violation for selling contaminated MPA—the same drug produced by NECC. The owner was prosecuted by the US DoJ and sentenced to one year of probation and a $25,000 fine.

Key Takeaways

- Key Takeaway #1
  - The state has passed new law that will increase regulatory oversight of sterile compounding practice
- Key Takeaway #2
  - MSHP and other state-wide organizations are attempting to ameliorate the burden of the new law
- Key Takeaway #3
  - Poor practice can lead to professional, civil and criminal penalties

Questions