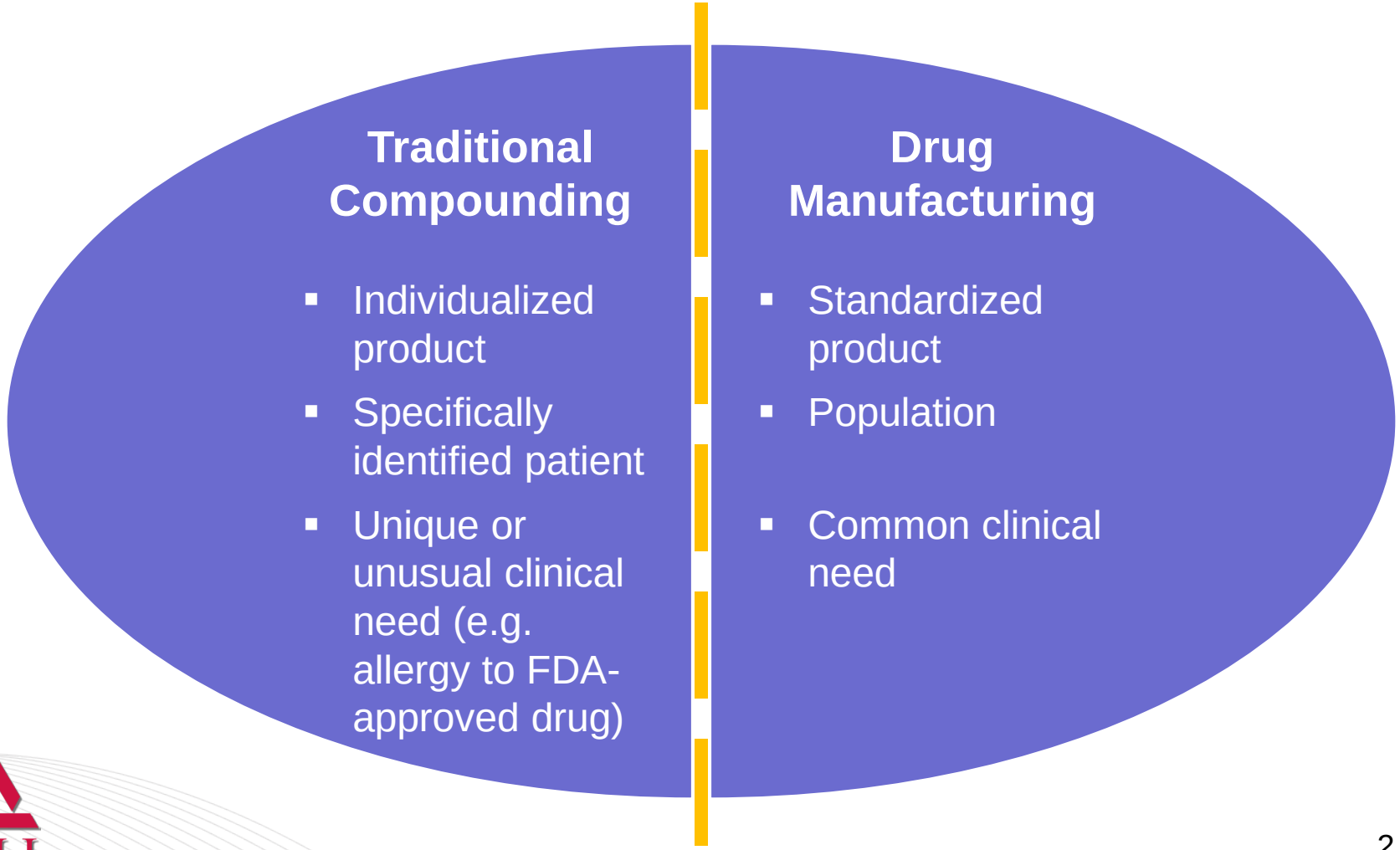
Pharmacy Compounding

A Failure of Enforcement

Sarah Sorscher, JD/MPH
Public Citizen's Health Research Group

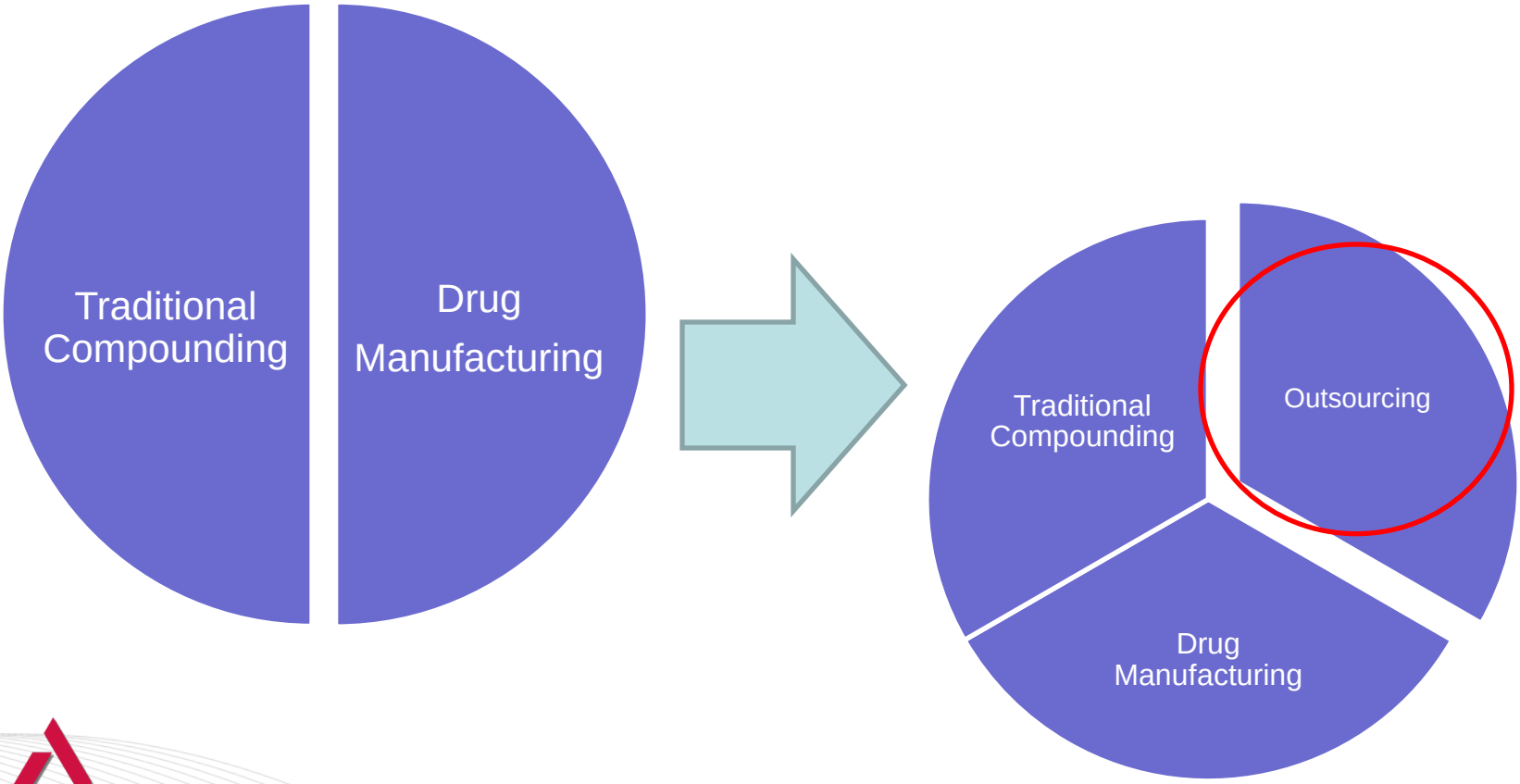
FDLI

Traditional Compounding v Drug Manufacturing



FDLI

New Legislation



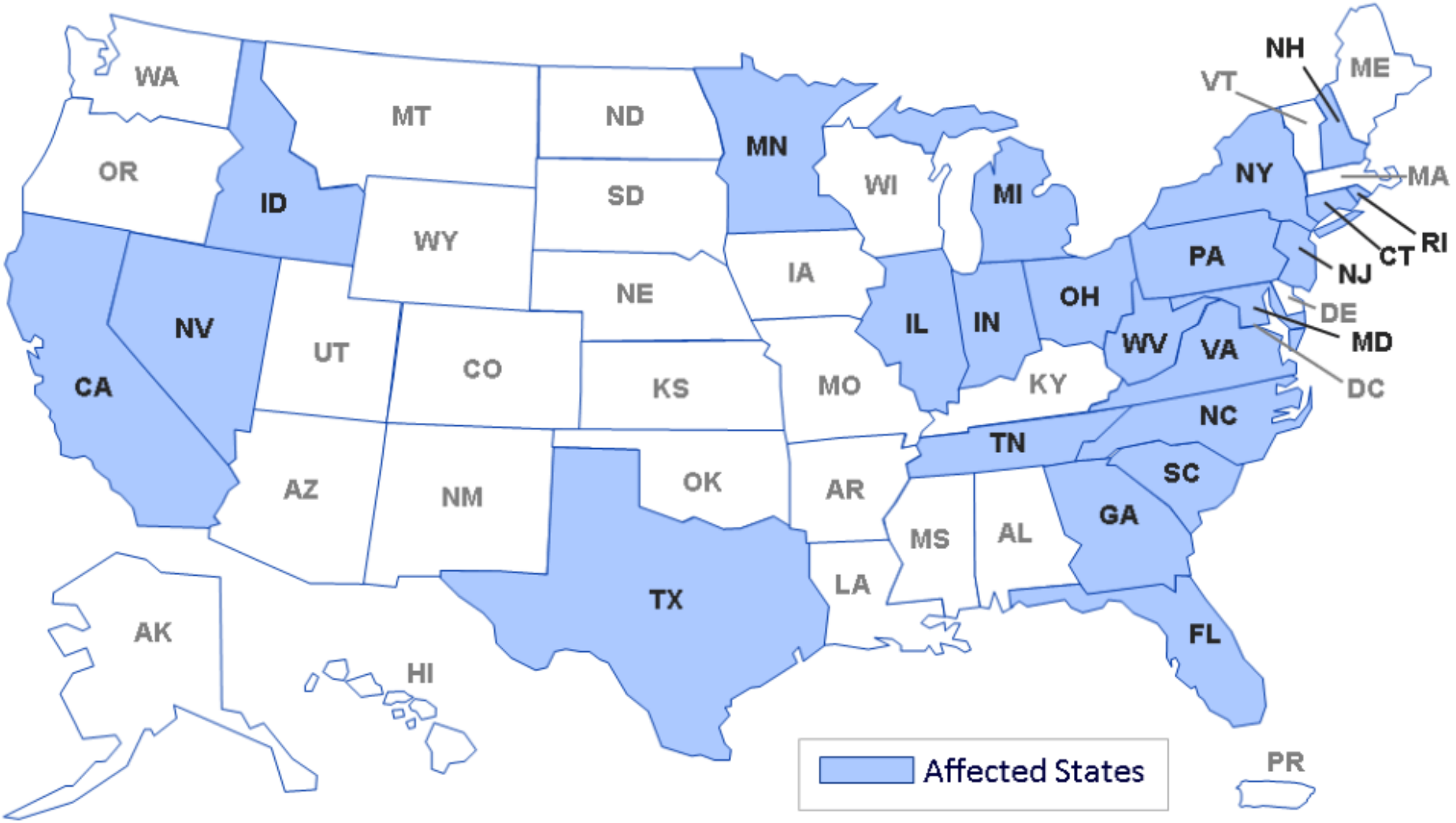
FDLI

Prior Legal Framework

Current Framework:
Similarities and Differences

	Section 503A	**CPG § 460.200**
Similarities:	• limited quantities of anticipatory compounding • No drugs that are "essentially copies" of approved drugs • No withdrawn drugs • Ingredients must meet USP and come from registered facility	• limited quantities of anticipatory compounding • No drugs that are "essentially copies" of approved drugs • No withdrawn drugs • Ingredients must meet USP and come from a registered facility
Differences:	• Only FDA-approved active ingredients • No commercial scale equipment • Cannot sell wholesale • Must comply with state law	• Larger list of potential ingredients • No drugs from "difficulties for compounding" list • Limitations on interstate sale • ~~Limitations on advertising~~

Examples of Enforcement Failure



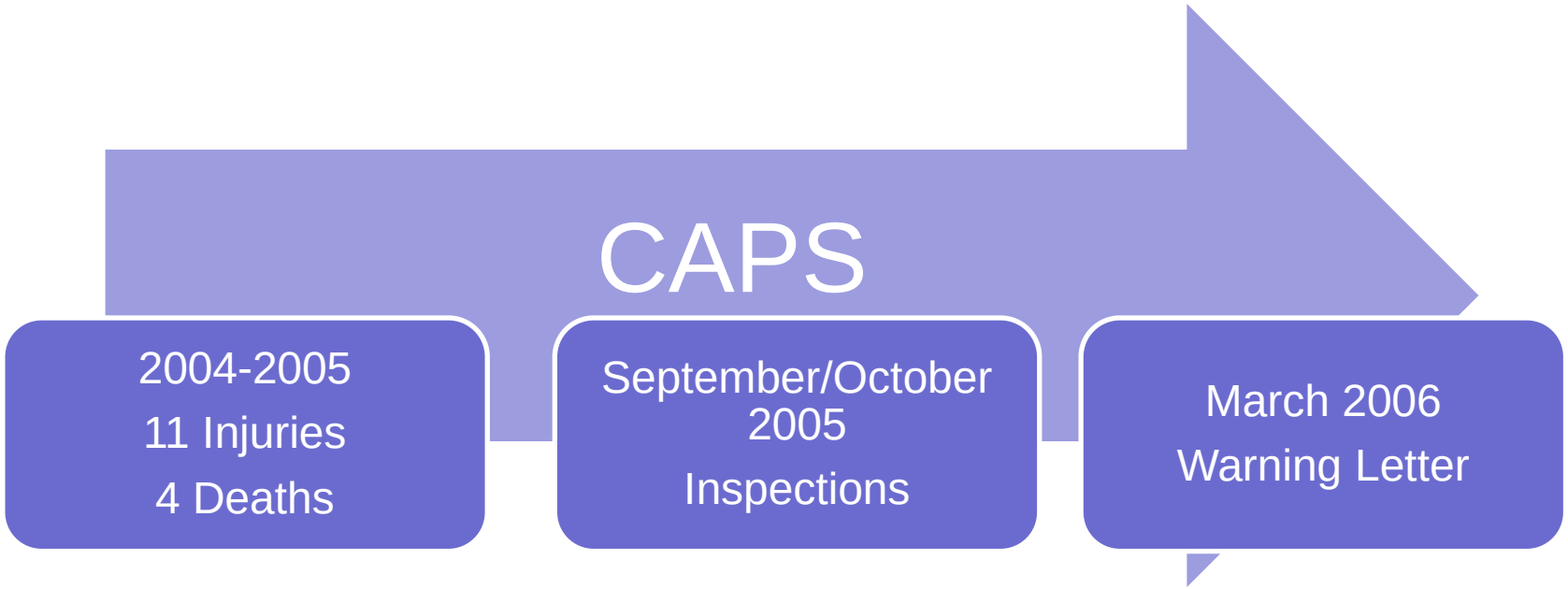
Three lots
13,534 patients exposed
Shipments to clinics in 23 states

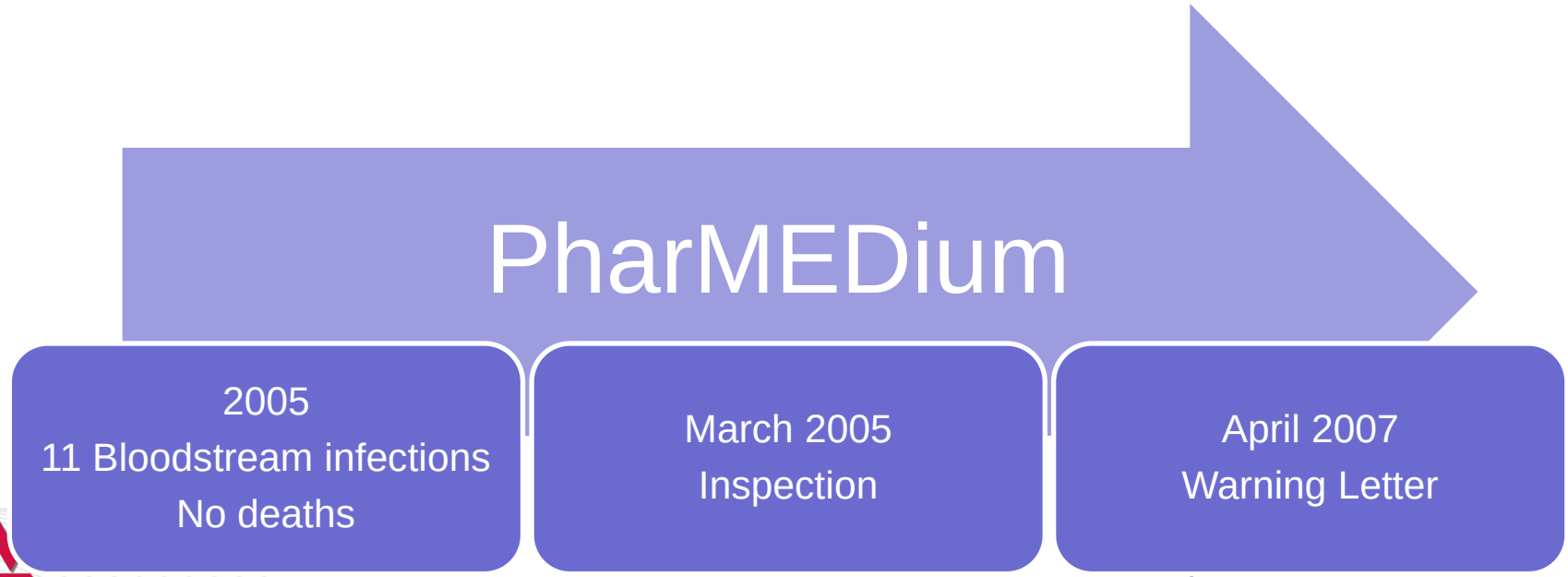
FDLI

Warning Letters

PharMEDium and CAPS

(2005-2007)


CAPS
2004-2005
11 Injuries
4 Deaths
September/October 2005
Inspections
March 2006
Warning Letter


PharMEDium
2005
11 Bloodstream infections
No deaths
March 2005
Inspection
April 2007
Warning Letter

FDLI

Unpublished Actions

CAPS Inspections

- Norcross, GA (2006)
- Homewood, AL (2009)
- Horsham, PA (2009)
- Kansas City, MO (2009)
- Chicago, IL (2009)

PharMEDium Inspections

- Cleveland, MS (2007-08)
- Memphis, TN (2009)
- Sugar Land, TX (2007, 2010)

PharMEDium Outbreak Investigation

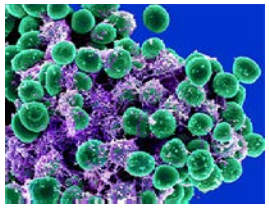
- 8 bloodstream infections (2007)

FDLI

2013 FDA Inspection Reports

CAPS (CT and MA)

- One facility tests only 20% of batches for sterility
- Repeat *Staphylococcus* contaminations



- Live crawling “1-inch insect”
- 75 “winged insects”
- 221 “pest” reports

PharMEDium (TX)

- “White and yellow residue” on HEPA air filters in the clean room
- White particles in clean room
- Most products not tested for sterility or potency

FDLI

Moving Forward

Moving Forward

- Circuit Split Resolved
- 503A ambiguities remain
- Questions about voluntary registration
- Doubts about compliance with cGMP

cGMP Challenges

Nephron Pharmaceuticals and
Leiter's Compounding Pharmacy

Nephron Pharmaceuticals

- Six years to being production
- 6 generic FDA-approvals
- Quality and Compliance:
  - 4 compliance officers
  - 41 quality assurance staff
  - 9 degreed chemists
  - 19 degreed microbiologists

FDLI

Leiter's Compounding Pharmacy

- Six months to begin production
- 11,000 unapproved products
- Quality and Compliance:
  - 1 pharmacist
  - 1 pharmacy technician

FDLI

Strange Bedfellows

"The same safety standards that govern biopharmaceutical manufacturing should also protect patients who are treated with medicines manufactured by large-scale compounders. . . . [W]e believe that an entirely new regulatory scheme is unnecessary to correct the enforcement issues surrounding the tragic NECC incident."

-Jeffrey K Francer

Assistant General Counsel

Pharmaceutical Research and Manufacturers of America

We agree.

FDLI

Thank You