



Pharmacy Compounding

A Failure of Enforcement

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Traditional Compounding v Drug Manufacturing

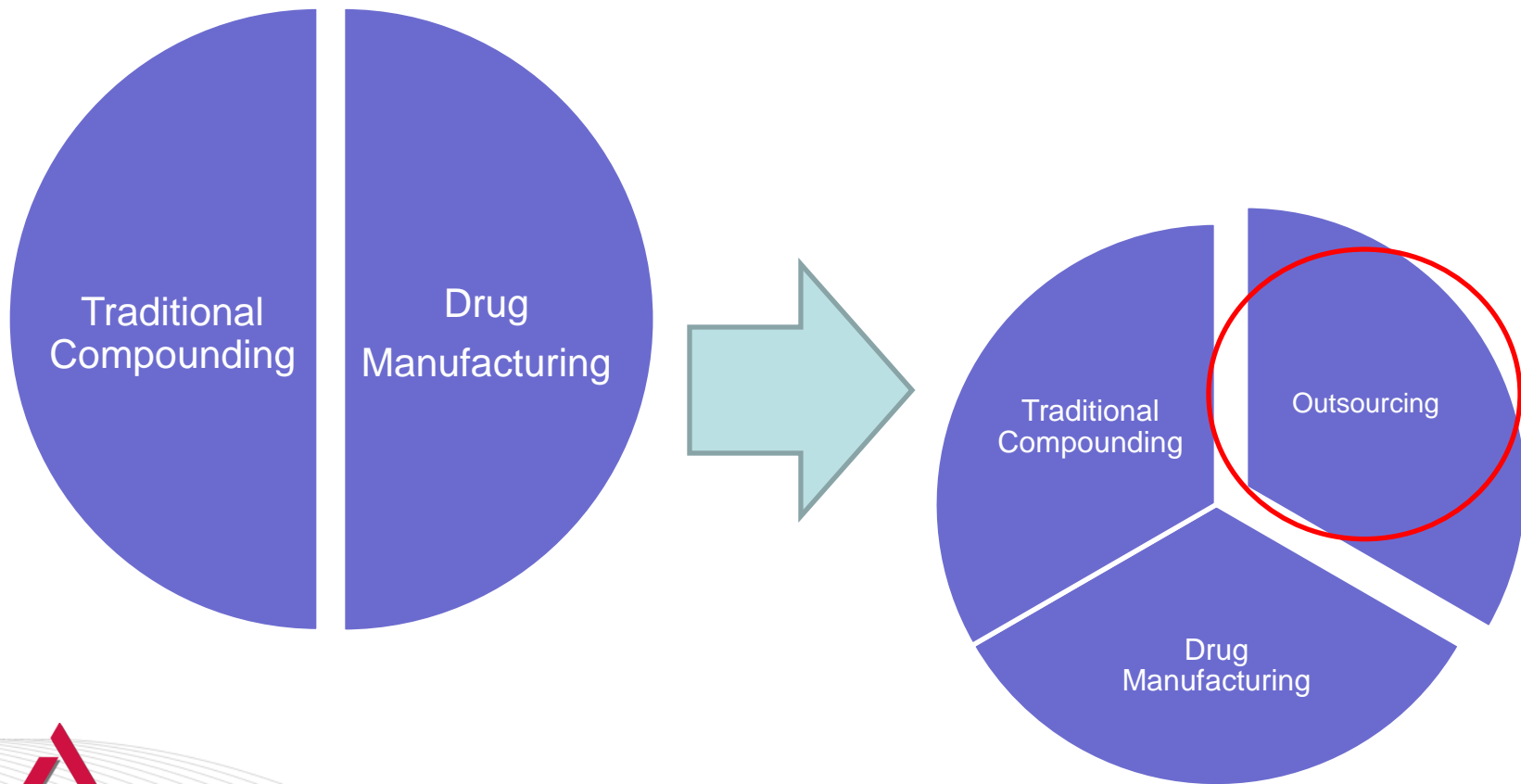
Traditional Compounding

- Individualized product
- Specifically identified patient
- Unique or unusual clinical need (e.g. allergy to FDA-approved drug)

Drug Manufacturing

- Standardized product
- Population
- Common clinical need

New Legislation



Prior Legal Framework

Current and Past Frameworks: Similarities and Differences

	CPG § 460.200	Section 503A
Similarities:	<ul style="list-style-type: none"> • <u>limited quantities of anticipatory compounding</u> • <u>No drugs that are “essentially copies” of approved drugs</u> • No withdrawn drugs • Ingredients must meet USP and come from registered facility 	<ul style="list-style-type: none"> • <u>limited quantities of anticipatory compounding</u> • <u>No drugs that are “essentially copies” of approved drugs</u> • No withdrawn drugs • Ingredients must meet USP and come from a registered facility
Differences:	<ul style="list-style-type: none"> • Only FDA-approved active ingredients • No commercial scale equipment • Cannot sell wholesale • Must comply with state law 	<ul style="list-style-type: none"> • Larger list of potential ingredients • No drugs from “difficulties for compounding” list • Limitations on interstate sale • Limitations on advertising

Examples of Enforcement Failure

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

Unpublished Actions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)

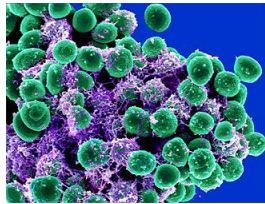
PharMEDium Outbreak Investigation

- 8 bloodstream infections (2007)

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

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

Leiter's Compounding Pharmacy

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

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.

Thank You