Compounding versus Manufacturing and Other Light-Hearted Legal Issues in Illinois: Where We Are and Where We Are Headed!

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Disclosures

- Mr. Meyers has no financial conflicts that would create bias in this presentation.
- Except perhaps that his continued employment relies on the accurate tracking of these bills and lobbying on behalf of ICHP.

Disclosures

- Mr. Rickert represents several compounding pharmacies, but has no financial conflicts that would create bias in this presentation.
- The views expressed by Mr. Rickert during this presentation are his own, and not those of any past, current or future clients.

Learning Objectives

- Explain the difference between traditional pharmacy compounding, "non-traditional" pharmacy compounding, and manufacturing under Illinois law.
- Describe current Illinois law regarding outsourcing compounding services on both a patient specific and non-patient specific basis.
- Discuss potential changes to Illinois and federal law regarding sterile and non-sterile compounding, office-use compounding and the outsourcing of compounding services.
- Discuss steps all compounding pharmacies, including hospital pharmacies, should take to ensure compliance with Illinois and federal law.
- Review other legislative and regulatory issues currently in debate in Illinois.

Recent High Profile Compounding Events

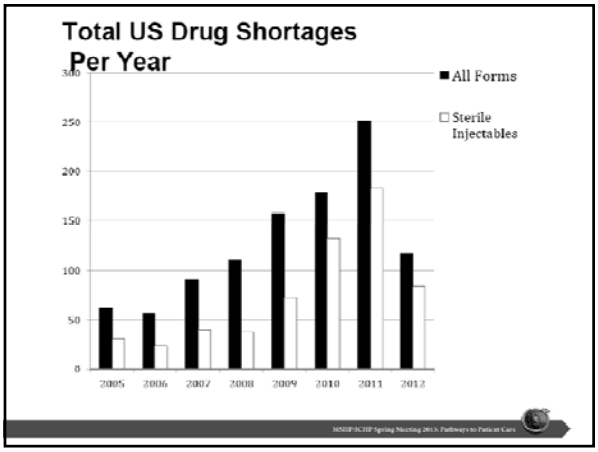
- 2009 Dead Polo Ponies
- 2011 Alabama
  - Contaminated TPN distributed to several hospitals
- 2013 Makena
- New England Compounding Center
- Numerous Additional Safety Related Recalls in late 2012 and 2013

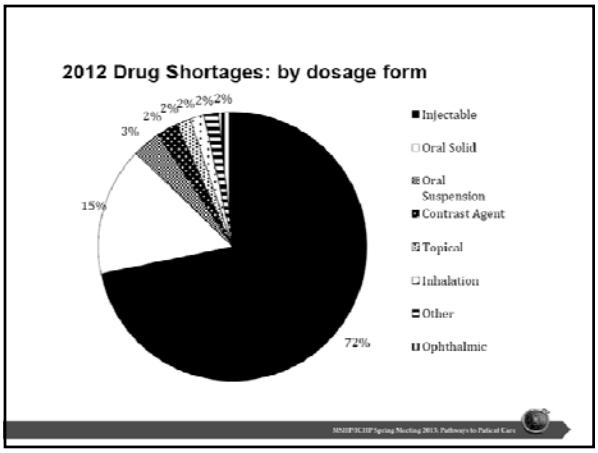
Compounding Under Fire

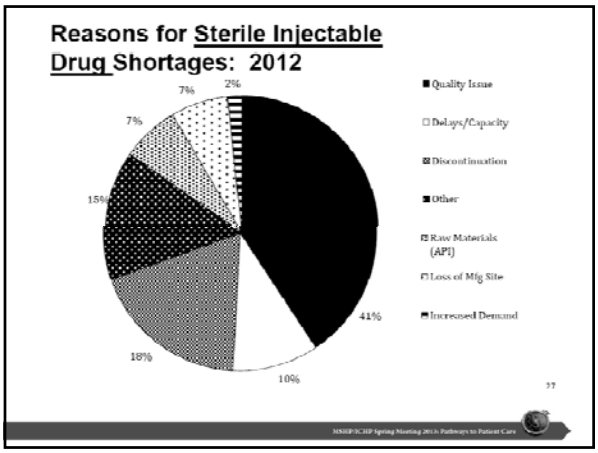
- In recent years, new compounding laws were enacted in 16 states: Alabama, Colorado, Indiana, Kansas, Kentucky, Michigan, Minnesota, Nebraska, New Jersey, Ohio, Oklahoma, Rhode Island, Utah, Virginia, Washington and West Virginia.
- There are currently bills regarding compounding being debated in 7 other states [HI, MA, MS, NH, OK, SC, UT, VA].
- In addition, new regulations and policies regarding compounding have been promulgated by individual state pharmacy boards and agencies, including Illinois.
- Federal legislation seems to be a certainty.

Federal / State Balance

- Need to preserve ability to outsource:
  - Pharmacies may not have necessary equipment or facilities to prepare some high-risk preparations,
  - may face medication shortages for commercial products that can only be replicated by a compounding pharmacy
  - "repackaging" of dosage forms must be included







Where Are We Now? Federal Law

- Federal and state law often conflict.
- FDA has relied on selective enforcement to weed out "bad" compounders.
- FDA still considers all compounded products considered to be "new drugs" requiring FDA approval.
- Will FDA take over the regulation of compounding?

History of Drug and Pharmacy Regulation

- Federal Government
  - Regulates manufacturing of drugs
  - Food Drug and Cosmetic Act
- State Governments
  - Regulate practice of medicine and practice of pharmacy
- However, no "bright line" between where federal oversight ends and state oversight begins

FDA Perspective

- "Traditional" pharmacy compounding
  - Combining, mixing, or altering ingredients to create a custom medicine for an individual patient in response to a doctor's Rx.
  - Serves an important public health function
- FDA historically hasn't taken action against traditional compounding

FDA Perspective - Historical

- FDA concerns
  - Manufacturing disguised as compounding
  - Often copies of FDA-approved drugs
  - Lack of procedures to prevent contamination or to ensure proper drug strength, quality, and purity
  - Safety and efficacy not demonstrated (which is why they are considered to be adulterated and misbranded "new drugs"
  - Particular concerns re: sterility
    - E.g., inhaled drugs, injectables, ophthalmic

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT of 1938

- Require "**new drugs"** to be shown **safe before marketing**
- If a "new drug", it is subject to regulation by FDA, including:
  - Approval
  - Compliance with cGMPs

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT of 1938

- Registration Requirement
  - Requires registration of drug "manufacturers" and listing of all Rx products with FDA
- Pharmacy Exemption
  - pharmacies . . . in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs . . . and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail:

Food and Drug Administration Modernization Act (FDAMA) of 1997

- FDCA 503A - Compounding Provisions - Compounded Drugs-exempt from "New Drug" provisions of the FDCA if certain conditions applied
- However, lawyers got in the way . . .
  - Lawsuits in 9th Circuit and 5th Circuit
  - Law declared to by unenforceable in 9th, but may still be partially enforceable in 5th
- FDA does not enforce 503A

FDA Compliance Policy Guideline

- **Generally, FDA will continue to defer to state authorities** regarding less significant violations of the Act related to pharmacy compounding . . .
- **However,** when the scope and nature of **a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer** and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act**, FDA has determined that it should seriously consider enforcement action**.
- In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

FDA Compliance Policy Guideline

- **Compounding of drugs in anticipation** of receiving prescriptions, **except in very limited quantities** in relation to the amounts of drugs compounded after receiving valid prescriptions.
- **Compounding drugs that were withdrawn** or removed from the market for safety reasons. Appendix..
- **Compounding using non FDA approved drugs**
- Receiving, storing, or using drug substances without first obtaining written assurance . . . **made in an FDA-registered facility.**

FDA Compliance Policy Guideline

- Receiving, storing, or using drug components not guaranteed or otherwise determined to **meet official compendia requirements.**
- **Using commercial scale manufacturing or testing equipment** for compounding drug products.
- Compounding drugs for third parties who **resell** to individual patients or offering compounded drug products at **wholesale** to other state licensed persons or commercial entities for resale.

FDA Compliance Policy Guideline

- **Compounding drug products that are commercially available** . . . are essentially copies of commercially available . . . drug products . . . it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different . . . (if) documentation of the medical need . . . for the particular patient.
- **Failing** to operate in conformance with applicable **state law regulating** the practice of pharmacy.
- The foregoing list of factors is **not** intended to be **exhaustive**.

Where Are We Now? Illinois Law

- "Compounding" is part of the practice of pharmacy
  - Must be licensed as an in-state or non-resident pharmacy
  - Could include both “traditional” and “non-traditional” compounding
- “Manufacturing” is not pharmacy
  - Requires “manufacturer” or “wholesale distributor” license

Where Are We Now? Illinois Law

- "Compounding" means the preparation and mixing of components, excluding flavorings
  - as the result of a prescriber's prescription drug order ***or initiative*** based on the prescriber-patient-pharmacist relationship in the course of professional practice
  - for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing.

Illinois Law

- Includes the preparation of drugs in anticipation of receiving prescription drug orders based on routine, regularly observed dispensing patterns.
- Commercially available products may be compounded for dispensing to individual patients only if all of the following conditions are met:

Illinois Law

- The commercial product is not reasonably available from normal distribution channels in a timely manner to meet the patient's needs and
- The prescribing practitioner has requested that the drug be compounded.

Illinois Law

- Defines “manufacturer” as:
  - a person licensed or approved by the FDA to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" set forth in the FDA's regulations and guidances implementing the Prescription Drug Marketing Act
- When a hospital outsources to a sterile compounder, is the sterile compounder a “pharmacy” or a “manufacturer”?

68 IL ADC Section 1330.640 Pharmaceutical Compounding Standards

- Sets minimum standards and technical equipment for compounding drugs.
- Addresses “office use”:
  - Pharmacies may compound drug products to be used by practitioners in their office for administration to patients.

68 IL ADC Section 1330.640 Pharmaceutical Compounding Standards

- Addresses Outsourcing:
  - Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription, including compounding in anticipation of receiving a prescription or order based on routine, readily observed dispensing patterns.

Need to Strike A Balance

- "Traditional" Compounding
  - Not the issue
- "Non-Traditional" Compounding
  - Large scale; Non-patient Specific; Reliance on "Office-Use" provisions
- Legislation should recognize the need for "non-traditional" compounding
  - Gray area
  - FDA authority to regulate exists, but is not ideal
    - NDA
    - cGMPs

Where Are We Going? Federal Law

- Verifying Authority and Legality in Drug Compounding (VALID) Act of 2012 (H.R. 6584) by Rep. Markey (D-MA)
- Support Access to Formulated and Effective (SAFE) Compounded Drugs Act of 2012 (H.R. 6638) by Rep. DeLauro (D-CT)
- One proposal is a tiered approach.
  - Traditional compounding will be regulated by states
  - Non-traditional compounding will be regulated by the FDA

Where Are We Going? Illinois

- There are currently new rules under development in Illinois; adopt USP 797
- Rules will redefine Compounded Sterile Preparations (CSP) and group them into 3 categories
  - Low-Risk Level CSPs
  - Medium-Risk Level CSPs
  - High-Risk Level CSPs
- Revises CSP standards and compounding preparation environments

Compliance Strategies

- Become USP 797 compliant, or partner with a compounding pharmacy that is compliant
- If outsourcing, remember to enter into a "shared service" or "central fill" agreement that complies with IL requirements
  - Include specific P&Ps setting forth obligations of parties

Compliance Strategies

- Verify licensure/registration of pharmacy partner
  - In-state and non-resident
  - FDA registered (required?)
  - Pharmacy versus wholesale distribution/manufacturing registration
- Have they been inspected by FDA?
  - Any 483 observations issued?
  - Warning Letters?

Compliance Strategies

- Have they been disciplined by any state regulatory body?
  - Pharmacy Board
  - Department of Health
- Have they been audited by other agencies or entities?
  - Independent USP 797 or cGMP audits?
- Will they make their SOPs (general and product specific) available for review?

Compliance Strategies

- Are they PCAB accredited?
- Do they have a product recall plan in place, and have they used it in the past?
- How does it define and handle errors?
- Obtain and use ASHP "Outsourcing Sterile Products Preparation – Contractor Assessment Tool".

HB1 Medical Marijuana

- Sponsor: Rep. Lou Lang (D-Skokie)
- Creates the Compassionate Use of Medical Cannabis Pilot Program Act.
- Allows for legal possession of up to 2.5 oz of medical cannabis by a registered qualifying patient.
- Allows registered nonprofit medical cannabis organizations to acquire, possess, cultivate, manufacture, deliver, transfer, transport, sell, supply or dispense cannabis, paraphernalia, or related educational materials to registered qualifying patients.
- 60 medical cannabis organization dispersed geographically around the State.
- **STATUS: Placed on Third Reading – Short Debate**

HB11 Unemployed Protected Status

- Sponsor – Rep. Mary Flowers (D-Chicago)
- Amends Pharmacy Practice Act
- A Pharmacy or Pharmacist who receives any Fed/State funds shall not refuse to dispense Rx to anyone who is unemployed (w/ or w/o unemployment benefits
- **STATUS: Placed on 2nd Reading – Short Debate**

HB72/1343 Safe Pharmaceutical Disposal

- Sponsor(s): Rep. Michelle Mussman (D-Schaumburg) /Rep. Joe Sosnowski (R-Rockford)
- Amends Safe Pharmaceutical Disposal Act and Pharmacy Practice Act
- Voluntary Program; Pharmacy to provide container(s) – Pharmacy to incur all costs for supplies & disposal
- No civil or criminal immunity for Pharmacy or Pharmacist
- **STATUS: Referred back to Rules Committee.**

HB0942 Illinois Universal Health Care Act

- Rep. Mary Flowers (D, Chicago)
- Creates the Pharmaceutical and Durable Medical Goods Committee to negotiate prices.
- Coverage open to all Illinois citizens.
- 20% paid by individual, 20% by employer, 60% paid by government.
- **Status: On second reading in the House.**

HB1033 Medicaid – OTC Medications

- Sponsor: Rep. Michael Tryon (R-Crystal Lake)
- Amends Medical Assistance Article of Public Aid Code
- Prescribed OTC meds would be covered
- Pharmacies would be reimbursed at the same rate as prescription medications
- Does not address if OTC meds would fall under SMART Act restrictions
- **STATUS: Referred back to Rules Committee.**

HB2352 Medicaid – Drug Limit – Exemptions

- Sponsor: Rep. Kelly Cassidy (D-Chicago)
- Amends Medical Assistance Article of Public Aid Code
- "Prescriber" Organizations to develop protocols that expedite review & approval of prescriptions for certain psychiatric & chronic conditions
- Allows the Department to exempt antibiotics and other pharmaceutical categories from the 4-Rx limit.
- **STATUS: Referred back to Rules Committee.**

HB2534/SB1696 Prescription Drug Repository

- Sponsor: Rep. Laura Fine (D-Glenview) / Sen. Pamela Althoff (R-McHenry)
- Creates Prescription Drug Repository Program Act – Voluntary Program
- Healthcare Facilities may donate prescription drugs or supplies
- Sets standards for acceptance & dispensing; Medications/Supplies may not be resold
- Provides civil & criminal immunity to Phcy/Pharmacist
- **STATUS: Referred back to Rules Committee in the House and Assignments in the Senate.**

HB2730 Lot Numbers

- Sponsor: Rep. Jack Franks (D-Woodstock)
- Amends the Pharmacy Practice Act
- Requires Pharmacist to include the manufacturer's lot number of dispensed medication in the patient's record and on the prescription label
- **STATUS: Referred back to Rules Committee.**

HB2823 Controlled Substance Schedule II

- Sponsor: Rep. Bill Mitchell (R-Decatur)
- Amends the Controlled Substance Act
- Removes provision that Schedule II prescription shall not be issued for more than a 30 day supply
- **STATUS: Referred back to Rules Committee.**

HB2824 Pharmaceutical Assistance Program

- Sponsor: Rep. Bill Mitchell (R-Decatur)
- Amends the Senior Citizens & Disabled Persons Property Tax Relief
- Reinstates Pharmaceutical Assistance Program (Circuit Breaker Program)
- **STATUS: Referred back to Rules Committee**

SB73/HB1052 Nurse Practitioner Collaboration and Prescribing

- Sponsor: Sen. Heather Steans (D-Chicago) / Rep. John Bradley (D-Marion)
- Amends the Nurse Practice Act
- Revises requirements of written collaborative agreement.
- Allows the APN to practice more broadly.
- **STATUS: SB73 Referred back to assignments / HB1052 on 2nd reading in the House.**

SB622 Medical Disciplinary Fund

- Sponsor: Sen. John Cullerton (D-Chicago) / Rep. Michael Madigan (D-Chicago)
- Amends the Med Practice/Public Util/State Finance
- Increase Physicians Fee from $300 to $700 every three years
- Transfers $6.6 million from Local Govt Tax Fund to State Medical Disciplinary Fund
- State Medical Disciplinary Fund must repay $1.1 million each year for the next six years
- **STATUS: Signed by the Governor**

SB1217 Dental Practice Pharmacologics

- Sponsor: Sen. William Haine (D-Alton)
- Amends Illinois Dental Practice Act
- Would have allowed Dentists to administer vaccinations – opposed by ISMS.
- No regulates the number of assistants and hygienists they may supervise.
- **STATUS: On Third Reading in the Senate.**

SB1454 Amends the Controlled Substance Act

- Rep. William Delgado (D, Chicago)
- Amends the CSA to expand the PMP to include all medications.
- Requires all e-HRs to interface with the PMP by Jan. 1, 2015.
- **Status: Held in Human Services Committee.**

SB1610 Influenza Vaccine Required

- Sponsor: Sen. Ira Silverstein (D-Chicago)
- Amends Dept of Public Health Powers & Duties Law of the Civil Admin Code
- Requires facilities licensed by Dept to mandate influenza vaccination of affiliated HCW or HCW must wear surgical mask while performing duties
- Facility must maintain vaccination records
- **STATUS: On Second Reading in the Senate.**

SB1623 Pertussis Vaccine Act – Newborns

- Sponsor: Sen. Andy Manar (D-Staunton)
- Amends Pertussis Vaccine Act
- Provides parents/guardians and immediate family members of a newborn in neonatal ICU be informed about the importance of the Pertussis Vaccine and where they may obtain it.
- **STATUS: On Third Reading in the Senate.**

SB1741 Amends State Finance Act

- Senator Koehler, D-Peoria is the sponsor.
- Would sweep funds from several of the dedicated funds in the Illinois Treasury.
- Would sweep $2.054M from the Pharmacy Disciplinary Fund, leaving it almost empty.
- This would result in licensing and registration fees to be increased to make up the sweep and keep the Department running!
- **Status: In Senate Appropriations II Committee.**

SB1934 Pharmacy Practice - Biosimilars

- Sponsor: Sen. Antonio Muñoz (D-Chicago)
- Amends the Pharmacy Practice Act
- Establish definitions for Biological Product, Biosimilar, & Interchangeable (same as Section 351 Public Health Service Act - 42 U.S.C. 262)
- Substitution allowed as under current Pharmacy Practice Act
- Pharmacist must inform Prescriber w/in 5 business days of substitution
- Retain a written record of interchangeable substitution for at least 5 years
- **STATUS: On Second Reading in the Senate.**

SB2187/HB3074 Prescribing Psychologist Certification

- Sponsor: Sen. Don Harmon (D-Oak Park) / Rep. John Bradley (D-Marion)
- Amends the Clinical Psychologist Licensing Act
- Grants certification as prescribing psychologists – renewal every 2 years
- Authority to dispense medications
- **STATUS: On Second Reading in the Senate/ Referred to Rules Committee in the House**

Questions

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