COMPOUNDING: PAST, PRESENT AND FUTURE

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COMPOUNDING COMPETENCY

WHERE DO I START?

- Be well informed with increased awareness
- Have thorough understanding of patient risks
- Cultivate practical abilities

HISTORY OF COMPOUNDING

Early 1900's

- *Traditional* extemporaneous *compounding dominated pharmacy practice*

1945 – 1970s

- *Increase* in industrial *pharmaceutical manufacturing*
- *Academic instruction* slowly *decreased* in pharmacy schools
- *FDA* became *concerned* about *injury and death* of patients

1980s – 2000s

- A *resurgence* of extemporaneous *compounding*
- *Several incidents* of injury and deaths occurred from *contaminated CSPs*
- *Inadequate* quality control *standards*
- *Food and Drug Administration Modernization Act of 1997*

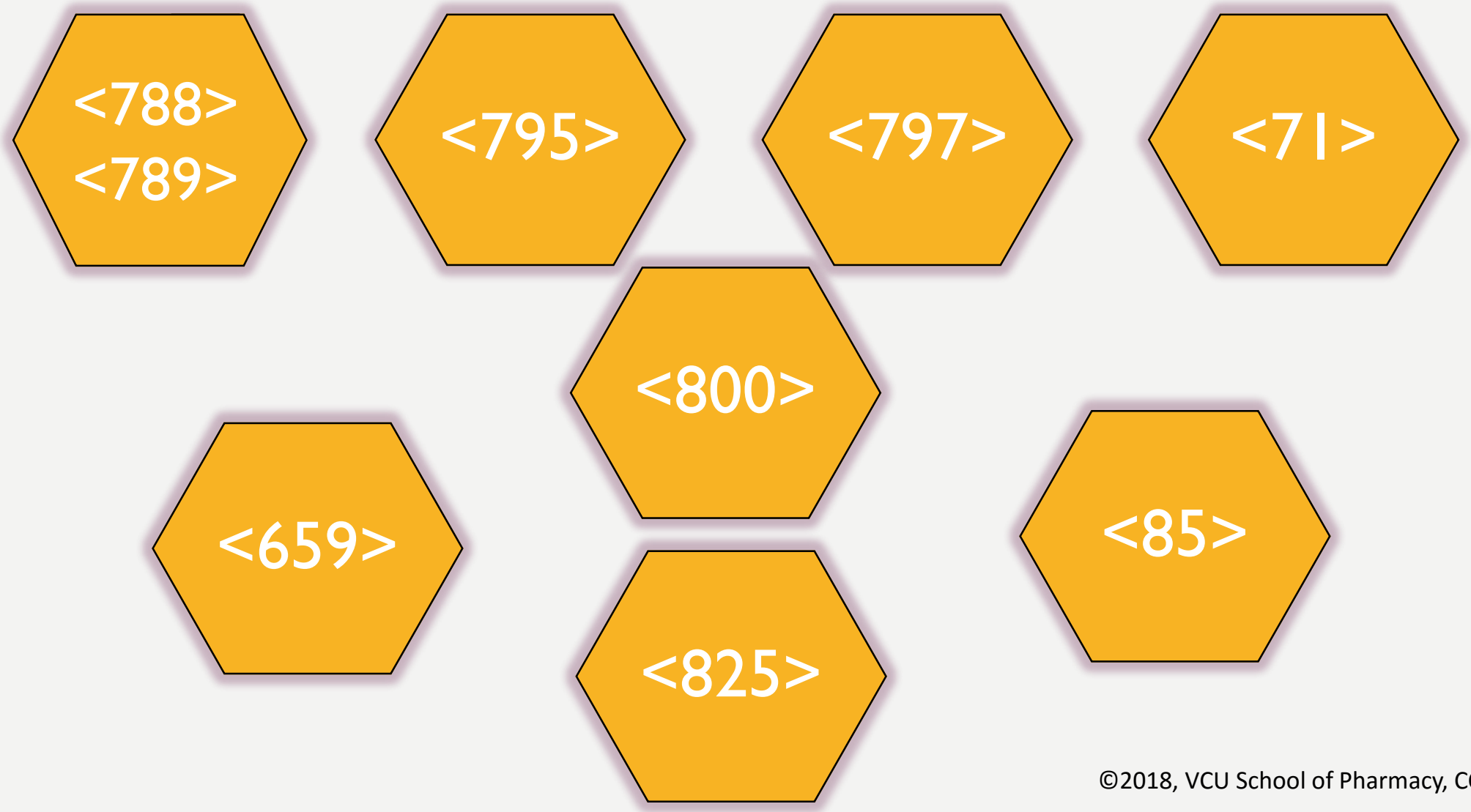
2001 - Present

- Many schools still *do not offer any didactic or practical education* in sterile and non-sterile compounding
- Primarily *knowledge* introduced during *on the job training*
- Sterile and nonsterile compounding *standards enforced*

FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

- Pharmacists compound nonsterile and/or sterile medications for patient if medications meet USP standards
- State boards of pharmacy oversee compounding pharmacies
- Other professional organizations work with state boards to ensure compounding quality, safety: USP, IACP, APhA, ASHP, NCPA
- Compounding commercially available product is prohibited
- Compounding pharmacies not required to follow current good manufacturing practices, adhere to product labeling, or submit drug approval applications
- If community pharmacy sells to healthcare professionals or out-of-state pharmacy, must apply for manufacturing license

ENFORCEABLE COMPOUNDING STANDARDS



WHAT IS COMPOUNDING?

- An ESSENTIAL element of pharmacy
- Preparing customized medications that are not otherwise commercially available.
- Performed by or under the supervision of a pharmacist
- Pursuant to an order from a licensed prescriber for an individual

TYPES OF COMPOUNDING

Sterile

- Medications prepared in cleanroom environment
- Uses aseptic technique to prepare solutions free of microorganisms
- Mainly parenteral and ophthalmic preparations

Nonsterile

- Medications <u>not</u> prepared in a cleanroom but a clean environment
- Sterile techniques are not required
- Mainly capsules, solutions, suspensions, ointments, creams, and suppositories

REGULATORY COMPLIANCE

New England Compounding Center

- Tainted steroid injections
- 750 fungal infections
- 64 deaths
- Causes

USP 797

USP 800

FDA

Board of Pharmacy

Drug Quality and Security Act

USP <795> Non Sterile Preparations

ROLE OF UNITED STATES PHARMACOPEIAL (USP)

- Scientific non profit organization that ***sets standards for identity, strength, quality and purity of medications, food ingredients and dietary supplements manufactured, distributed and consumed*** worldwide

- ***No enforcement or regulatory authority***

- Guidelines are ***enforceable*** under the law
  - State Boards of Pharmacy
  - The FDA
  - The Joint Commission (TJC)

ROLE OF THE FOOD AND DRUG ADMINISTRATION (FDA)

- Has regulatory authority over ***manufacture, distribution and labeling*** of drugs, medical devices and foods
- ***Enforces*** USP's drug standards in the US
- Regulates compounding under the adulteration and misbranding provisions of the 1***938 Food, Drug & Cosmetic Act***, but usually defers to State Boards of Pharmacy
- Inspect sterile and nonsterile compounding pharmacies

STATE BOARDS OF PHARMACY REGULATORY OVERSIGHT

- USP <797> (2004), first enforceable national compounding standard of practice, revised 2008
- USP <795> (2011), revised 2014
- All states license pharmacists to compound
- All states have adopted USP 795 as the baseline for safe and legal nonsterile compounding. In short, adhering to USP 795 standards puts pharmacists and technicians on the right sides of health care practice and the law.
- Varying degrees of regulations, oversight and enforcement of compounding practices exists among the states for sterile compounding
  - 32 states require full compliance with USP 797
  - 11 states have strong standards with 10 classified as "equivalent to or stricter than"
  - 6 states and District of Columbia require other compounding quality standards
    - Includes Pennsylvania, for example, traditional pharmacies must adhere to compounding quality standards, though the standards do not specify minimum equipment or facility requirements for compounding, a key component of Chapter
  - 1 state, Kansas, does not impose any particular compounding quality standards.

The Pew Charitable Trusts, "Best Practices for State Oversight of Drug Compounding" (2018), http://www.pewtrusts.org/~/media/assets/2018/02/best_practices_for-state_oversight_of_drug_compounding.pdf

DRUG QUALITY AND SECURITY ACT

- Signed into law November 27, 2013 by President Obama
- The Drug Quality and Security Act is a law that amended the Federal Food, Drug, and Cosmetic Act to grant the Food and Drug Administration more authority to regulate and monitor the manufacturing of compounded drugs.
- 503A
- 503B

NONSTERILE COMPOUNDING

- Typically extemporaneous (prepared for specific prescription for a specific patient)
- Hospice medications
  - Patients have difficulty swallowing tablets
- Veterinary medication
  - Alterations for size and breed
  - AVMA publishes “Guideline for Veterinary Prescription Drugs”

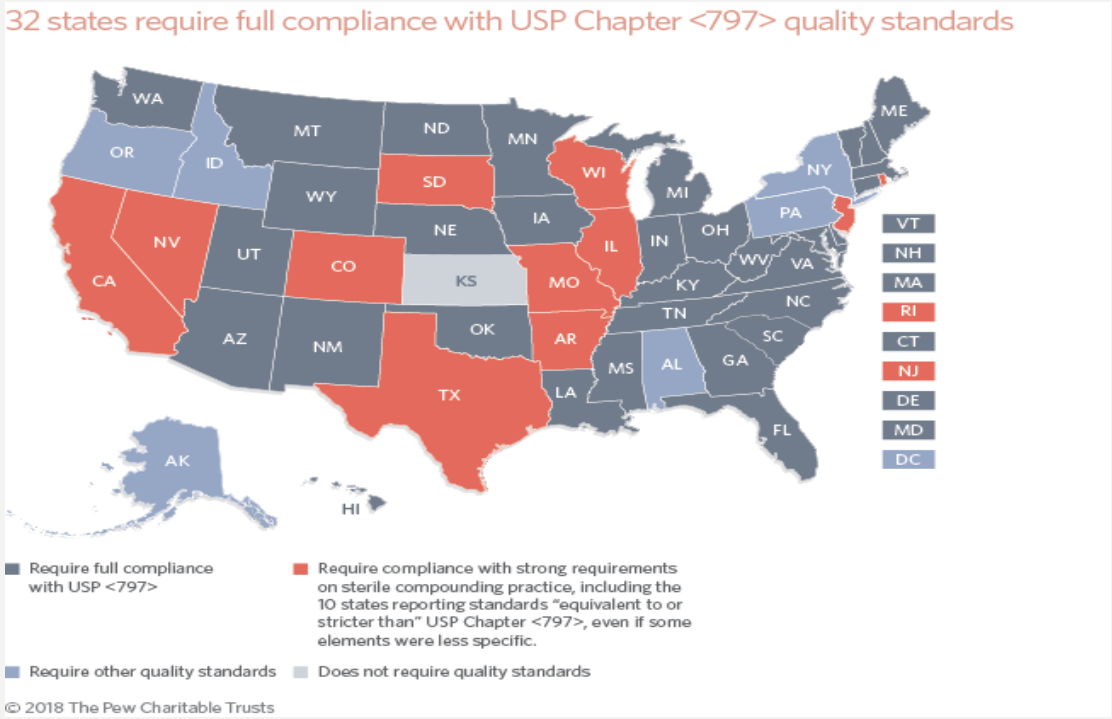
NONSTERILE COMPOUNDING

Three levels of complexity:

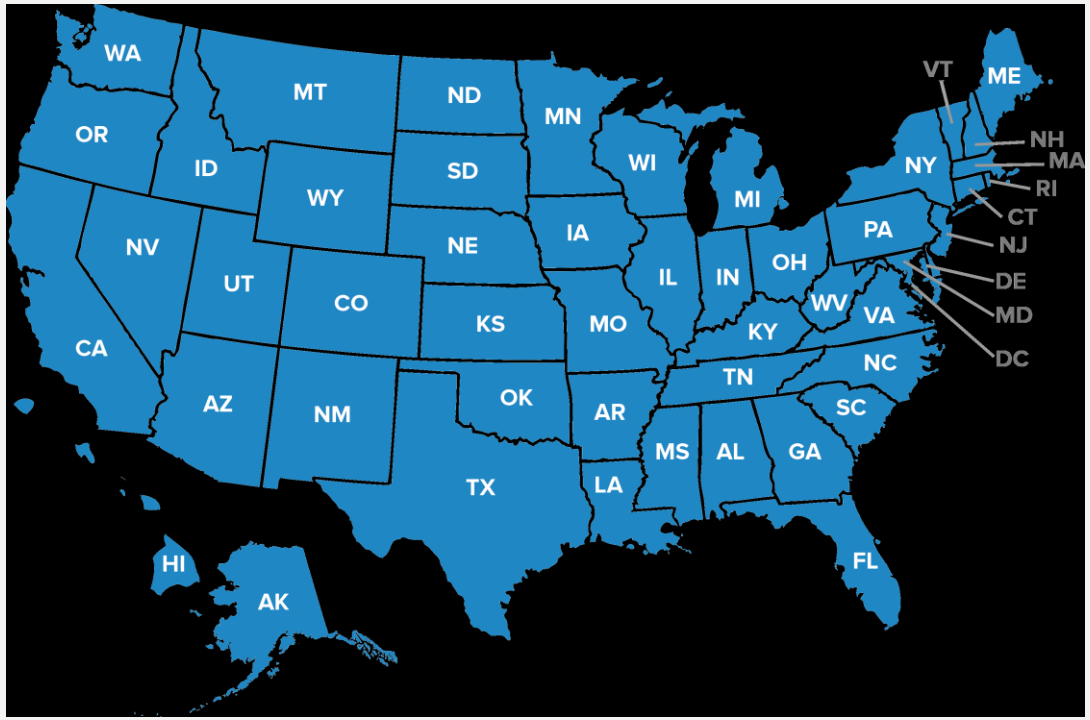
Simple	Moderate	Complex
• Reconstituting and combining commercial products following USP monograph instructions or peer-reviewed article instructions • No unknown calculations	• Requires some special calculations	• Requires special calculations, decision-making, training, procedures, equipment, environment

COMPLIANCE WITH COMPOUNDING STANDARDS STERILE AND NONSTERILE

STERILE



NON-STERILE



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ACCREDITATION

- Accreditation provides competitive edge in the marketplace
- Voluntary accreditation through the Pharmacy Compounding Accreditation Board (PCAB), ACHC
- Pharmacy must agree to meet all standards for sterile and nonsterile compounding
- Includes monthly or quarterly spot check
  - Random product sent to outside lab for analysis
  - Product must be +/-2% of potency
  - Any corrective action must be documented and dated by pharmacist
  - Compounding pharmacies must have continue quality improvement (CQI) process to identify and resolve any problems

ENSURING PROPER COMPOUNDING TECHNIQUES

- Properly identifying all nonsterile compounding being done
- Categorizing nonsterile compounds
  - Simple, Moderate, or Complex
- Personnel requirements
  - Supervisor and compounders
- Facility requirements
  - Nonhazardous or Hazardous
- Component Selection
  - USP-NF Compendium
- Compounding practices
  - Selecting, storing, compounding, dispensing, monitoring the patient
- Packaging and Storage
  - Meet USP requirements
- Documentation
  - Policies and procedures
  - Safety data sheets
  - Master formulation records
  - Compounding records
- Quality Assurance Plan

RISKS ASSOCIATED WITH COMPOUNDING

- Patient Safety
- Accuracy
- Appropriate dosage forms
- Drug efficacy
- Compounder safety

QUESTIONS ANYONE . . .