Hot Potato: A Chronicle of Non-Sterile Compounding

Jim Ruble, PharmD, JD
10 August 2013

Introduction
- Profound events are occurring in pharmacy compounding
- Some suggest there is currently an epic battle over control of compounding
- This presentation is intended to trace historical foundations of compounding, how it has embedded in the profession, and discuss existing oversight frameworks
- Any opinions expressed are those of the individual presenter and do not reflect any other governmental or professional organization

Disclaimer statement
- This presentation and handout materials are not intended to establish an attorney-client relationship between the speaker and any member of the audience.
- Rather, this presentation and handout materials are intended to provide professional education about the topics covered and should not be relied on as legal advice.
- If anyone needs legal advice about the topics covered, separate legal advice should be sought.

Objectives
- By the end of discussion, a participant should be able to:
  - List three (3) compendiums established prior to 1900
  - Identify three (3) professional organizations that advocate on behalf of pharmacy compounding
  - Explain how a federal law and a Supreme Court case affected the FDA Compliance Policy Guide
  - List three (3) key elements to USP 795
  - Prepare an outline for incorporating USP 795 requirements into a Utah licensed pharmacy

Outline
- Discuss origins of compounding
- Identify stakeholders
- Review Federal laws and regulations affecting compounding
- Review recent court cases
- USP 795
- Policy directions

Origins of Compounding
- Hygeia
  - Goddess of good health and cleanliness
  - Implements
    - Mystical healing snake
    - Patera/bowl with healing potion
  - Bowl and Serpent are international symbols of pharmacy

Origins of Compounding

- **Ebers Papyrus**
  - Dates from 1600 BC
  - **Asthma** — A mixture of herbs heated on a brick so that the sufferer could inhale their fumes.
  - **Belly** — "For the evacuation of the belly: Cow’s milk 1; grains 1; honey 1; meaty, oily, costly, take in four portions."
  - **Bowel** — "To remedy the bowels: Melilot (sweet clover), 1; dates, 1; cook in oil; anoint sick part."
  - **Cancer** — Recounting a "tumor against the god Xenus", it recommends "do thou nothing there against."
  - **Remedy to prevent Death** — Half an onion and the froth of beer.


- **De Materia Medica**
  - Dioscorides (40–90 AD)
  - Compendium of pharmacognosy
  - Used for approximately 1700 years
  - Five Books
    - I – aromatics, oils, ointments, trees
    - II – living creatures, dairy products
    - III – roots, juices, herbs
    - IV – herbs and roots
    - V – vines, vines, metallic ores


United States Pharmacopeia (USP)

- Established in 1820, private, non-governmental
- 11 representatives, mostly physicians, and chemists
- Established standards for purity and quality control
  - Purity standards and compendium of drugs
  - Originally, only 217 drugs met qualifications to be included in USP
- Purchased National Formulary (NF) in 1975
- Today has monographs on individual drugs, as well as guidance chapters

National Formulary (NF)

- Established in 1888, by the American Pharmacists Association
- Compendium of commonly prescribed combination pharmaceutical products
  - Intended for the average "retail" druggist to have a list of items that could be made and sold at the drug store
  - Also intended to counter the tendency of physicians to prescribe "mass-produced", but secret formulae
  - Helped transition the profession into the industrial age
- Purchased by USP in 1975

USP/NF organization & “authority”

- Multiple levels of organization
  - Individual monographs
  - Public-private update process
    - Involves expert committees and public comment
  - General reference chapters
    - Numbered 1000 and lower are considered “enforceable”
    - State boards may incorporate chapters by “reference” and enforce as regulations
  - USP 795 and 797
    - USP 1075 – Good Compounding Practices folded into 795
- Will discuss USP 795 in greater detail in a few minutes

Transitions in Pharmaceutical Compounding and Manufacturing

- From approximately 1950s through 1970s, a major shift occurred in responsibility for drug manufacture.
- Emergence of PhRMA companies.
- Corresponding transitions in Pharmacy Practice with increased emphasis on clinical skills
- Compounding remains core component of pharmaceutical education
  - At some point in career, nearly all pharmacists will have to perform some compounding task.
Contemporary Compounding

- Extemporaneous Prescription Compounding
  - “the very nature of providing millions of doses of a product requires that the dosage forms and doses be limited and results in a one-sided approach to therapy... the very nature of the process cannot meet all patient needs.”
  - “newly evolving dosage forms and therapeutic approaches suggest that compounding of pharmaceuticals and related products specifically for individual patients will become more common in pharmacy practice.”


- Evaluating the need for compounding:
  - Is the product commercially available in the exact dosage form, strength, and packaging?
  - Is the prescription rational concerning ingredients, intended use, dosage, and method of admin?
  - Am I qualified to prepare this prescription?
  - Do I have the proper equipment and supplies?
  - Is there documentation/guidelines for BUD?
  - Will this product satisfy physician intent and patient need?
  - Is there a bona fide patient-pharmacist relationship?
  - Is documentation available on stability and therapeutic properties of the individual ingredients?
  - Are necessary quality control measures available?

- Compounding Types
  - Ambulatory Care/Community Pharmacy compounding
  - Hospital Pharmacy compounding
  - Veterinary therapy compounding
  - Nuclear Pharmacy compounding
  - Emergence of new professional practice guidelines for pharmaceutical compounding


Stakeholders

- Patients/society
  - We must never forget to act in best interests of patient

- Pharmacy Profession
  - IACP, APhA, ASHP, NCPA
  - Independent, community, and hospital pharmacists

- FDA/Govt Agencies
  - Enforcement Actions

- PhRMA

- Legislatures
  - Federal (US Congress)
  - State Legislatures

IACP statement to FDA

- Reasons against FDA involvement in Pharmacy Compounding:
  - Any use of drug outside labeling makes it unapproved new drug, whether compounded or commercial
  - Impractical to require data submission to FDA for the thousands of drugs compounded each day
  - Including hospital IV admixtures
  - Financially impracticable to support S/E studies on all these compounded drugs
  - Unfairly limits the practice of physicians to provide individualized therapy to patient
  - Each vehicle change would required new application
  - FDA does not truly have supply chain at best interests, will NOT occur.

Allen LV. Reasons the FDA Should Not Be Involved in Pharmacy Compounding. Int J Pharm Compound. April 2005

FDA: The Special Risk of Compounding

- FDA Consumer Health Information Publication
  - - "Agency knows of more than 200 adverse events involving 71 compounded products since 1990...some with devastating repercussions"
  - Cordisoplegia solutions – 3 deaths
  - Cataract surgery eyedrops – 2 blinded
  - Mag sulfate soln – 5 bacterial infections
  - New England Compounding Center – contamination of sterile products
  - "Troubling Trend"

- Opposing statement points out:
  - FDA received 324,077 adverse reports from all drugs in 2006.
  - 324,077 x 17 years = 5,509,309 reports.

http://www.lashington.org/ims/dictionaries/ideclopedia/L207_Speech_2008_-_Compatibility_Mode.pdf#page=61
Federal Oversight of Compounding

- Federal agencies (FDA) generally defer their oversight to state licensing authorities (Boards).
- FDA have generally not inspected pharmacies, unless there is a complaint filed with FDA or if the pharmacy is known to conduct "high-risk" compounding activities.
- In the wake of NECC, FDA has substantially increased surveillance of pharmacies, but still much gray area between "manufacturing compounder" and "traditional compounder".
- In a very general sense, traditional compounders are interpreted as having a "safe harbor" from federal oversight, but this is the fundamental policy question under debate.

Food Drug and Cosmetic Act

- **New Drug**
  - (1) Any drug - the composition of which is such that this drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions presented, recommended, or suggested in the labeling thereof;... FDCA § 201 [21 USC § 321(p)].
- **New Drugs**
  - (a) Necessity of effective approval of application
    - No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application (NDA) filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug... FDCA § 505 [21 USC § 355(a)].

Food Drug and Cosmetic Act

- A drug shall be deemed **adulterated**: 
  - (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice... FDCA § 501(a)(2)(B) [21 USC § 351(a)(2)(B)].
- A drug shall be deemed **misbranded**: 
  - (f) Unless its labeling bears (1) adequate directions for use ... FDCA § 502(f)(1) [21 USC § 352(f)(1)].

FDA Registration and Inspections

- [E]very person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with [HHS] the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address.
- Every establishment that is required to be registered with [HHS] under this section shall be subject to inspection 21 USC § 360 (h).

FDA Registration and Inspection

- EXEMPTED: pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, 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. 21 USC § 360 (g)(1).

FDA Scrutiny

- In late 1980s/early 1990s, several instances of compounding "misadventures" 
  - Indomethacin eye drops contaminated
  - Cardioplegia solutions contaminated
- FDA issued Alert Letter advising balance in compounding activities 
  - FDA asserted it had no intention to regulate pharmacies historic exemption to the "new drug" provision in the FDCA, when pharmacists are compounding in reasonable quantities pursuant to a prescription. However, unreasonable batch processing would be monitored and regulated.
FDA Scrutiny

- Intended to re-affirm FDA non-intervention with reasonable and appropriate compounding.
- FDA “shot across the bow”
  - “FDA believes that increasing number of [retail pharmacies] … are engaged in manufacturing, distributing, and promoting unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice…”

FDA Modernization Act (FDAMA)

- FDCA § 503A Pharmacy Compounding
  - Waived adulteration, misbranding and NDA requirements for compounded drugs if:
    - Compounded for individual patient
    - Unsolicited prescription order
    - Compounded by state licensed RPh or prescriber
    - Limited quantities
    - Historical compounding pattern relationship between:
      - Pharmacist, Prescriber, Patient (“triad”)
      - Must use bulk substances, USP compliant
      - Not identified by Secretary (HHS) as having demonstrable difficulties for compounding that (pose risk) for adverse effect on safety or effectiveness of that (compounded) drug
      - May only be compounded if not specifically advertised or promoted (compounding service may be advertised)

Legislative Responses

- Food and Drug Administration Modernization Act (FDAMA) (1997)
  - Congressional received much lobbying pressure and included language to separate and further define pharmacy compounding activities
- Safe Drug Compounding Act of 2007 (bill never filed)

Western States v. Shalala/Thompson

- Compounding pharmacists sued against solicitation and advertising prohibitions, as being unconstitutional restrictions on free speech
- Main legal issue: Govt can regulate commercial speech, however must meet stringent test (“Central Hudson” four-part test)
  - 1) the regulated speech is misleading or concerns unlawful activity;
  - 2) the government has asserted a “substantial” interest in restricting the speech;
  - 3) the government has demonstrated that the regulation “directly advances” the asserted interest; and
  - 4) the restriction is not more extensive than necessary to achieve the asserted governmental interest.
- Pharmacists prevailed at all three levels. However, could not sever free speech issues from the § 503A amendment.
  - Therefore, entire section invalidated. Back to 1992 CPG level

Revised CPG (460.200) (2002)

- In response to the Western States court cases, the FDA revised the Compliance Policy Guide:
  - Reiterated that FDA not interested in regulating pharmacies compounding for individual patients in reasonable quantities
    - “discretionary enforcement”
  - Provided list of factors where FDCA enforcement would occur
    - Essentially same list as FDAMA, sans solicitation and advertising restrictions.

Revised CPG (460.200) (2002)

- In response to the Western States court cases, the FDA revised the Compliance Policy Guide:
  - Reiterated that FDA not interested in pharmacies compounding for individual patients in reasonable quantities
  - Provided list of factors where FDCA enforcement would occur
    - Essentially same list as FDAMA, sans solicitation and advertising restrictions
1. 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.

2. Compounding drugs that were withdrawn or removed from the market for safety reasons.

3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.

4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.

5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.

6. Using commercial scale manufacturing or testing equipment for compounding drug products.

7. 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.

8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

Medical Center Pharmacy v. Mukasey
451 F.Supp. 2d 854 (W.D. Tex 2006); 536 F.3d 383 (5th Cir. 2008)

- Sometimes referred to as the “Midland” case
- 10 pharmacies filed suit against US,
  - challenging FDA authority to regulate compounded drugs
  - inspect state-licensed pharmacies
- District Court sided with pharmacies
  - Compounded drugs implicitly exempt from FDCA
  - Advertising restrictions are severable from FDAMA
- 5th Circuit affirmed

“Split Decision”

- 9th Circuit (Western)
  - CA, AZ, NV, OR, WA, ID, MT, AK, HI, Guam, Mariana Islands
- 5th Circuit (Med. Ctr)
  - TX, LA, MS
- Ambiguity in remaining states

FDA Enforcement Action

- January 2008
  - FDA sent warning letters to 7 pharmacies informing them of violations of FDCA (misbranding and unapproved new drug), for compounding “bio-identical hormone replacement therapy.”
  - Pharmacies given 15 days to report compliance plan back to FDA.
- FDA Actions considered by Judge in Med Ctr. Case and found to be against the CPG 2002.
- Also determined to be presumptive because FDA based warning letters solely off of information provided through pharmacy websites.
Franck's Pharmacy

- April 2009 – 21 polo horses suddenly die in FL
  - cause traced to unapproved equine supplement, Biodyl, that was compounded by Veterinary Pharmacy in Florida
  - Error in compounding
  - Agonizing deaths, occurring over a few hours
- State and Federal investigations of pharmacy
  - FDA orders injunction against the pharmacy
  - Pharmacy files counter-suit

State Regulation of Compounding

(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:

(i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;

(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing;

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(b) "Compounding" does not include:

(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;

(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner;

(iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.

UCA 58-17b-102(18)

State Regulation of Compounding

"Manufacturing" does not include the preparation or compounding of a drug by a pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation, compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical analysis. UCA 58-17b-102(35)(c)

State Regulation of Compounding

(i) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

State Regulation of Compounding

- UAC 8156-17b-614 – Operating Standards Class A and Class B
  - Class B facilities engaged in extensive compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

(a) must follow USP-NF Chapter 795, compounding of non-sterile preparations;

(b) may compound in anticipation of receiving prescriptions in limited amounts;

(c) bulk active ingredients must be component of FDA approved drugs listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA;

(d) compounding using drugs that are not part of a FDA approved drug listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA requires an investigational new drug application (IND). The IND approval shall be kept in the pharmacy for five years;

(e) a master worksheet shall be developed and approved by a pharmacist for each batch of sterile or non-sterile pharmaceutical to be prepared. Once approved, a duplicate of the master worksheet shall be used as the preparation worksheet from which each batch is prepared and on which all documentation for that batch occurs.

must keep a master worksheet, preparation worksheet, copy of label, documentation of IND
Why is knowing 795 important?

- Patient safety
- Patient-centered, patient-customized service
  - commercial products may not be available to meet certain individual patient health care needs
- Liability
  - Administrative
  - Civil

**USP 795 outline**
- Introduction
- Definitions
- Compounding Categories
- Compounding Responsibilities
- Compounding Process
- Compounding Facilities
- Compounding Equipment
- Component Selection
- Handling & Equipment
- Stability Criteria & BUD
- Packaging & Containers
- Documentation
- Quality Control
- Counseling
- Training

**USP <795> Purpose**
- Provide compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals
- Compounding is integral part of pharmacy practice and essential to provision of healthcare

**USP <795> Definitions**

- **Compounding**
  - Preparation, mixing, assembling, altering, packaging, and labeling of a drug or device, in accordance with a licensed practitioner’s prescription order, based on the practitioner/patient/pharmacist/compounder relationship
  - Includes:
    - Preparation of drug dosage forms
    - Preparation in anticipation of prescription orders
    - Reconstitution or manipulation of commercial products
    - Preparation for purposes of research, teaching, or chemical analysis
    - Preparation for prescriber’s office

- **Simple**
  - Making preparation that has USP monograph, or appears in peer-reviewed journal that contains quantities of all components, procedure, equipment, and stability data, with appropriate BUD
  - Reconstituting or manipulating commercial products that may require addition of one or more ingredients as directed by manufacturer

- **Moderate**
  - Making a preparation that requires special calculations or procedures (e.g., calibration of mold cavities), to determine quantities of components per preparation
  - Making a preparation for which stability data for that specific formulation are not available

- **Complex**
  - Preparations requiring special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes
  - Transdermal dosage forms, Modified-release preparations, inserts & suppositories with systemic effects
Compounding Process

- When compounding each preparation:
  - Dose, safety, and intended use of preparation evaluated for suitability
  - Master formulation record created & followed
  - Ingredients meet expected identity, quality, purity
    - Ingredients not withdrawn or removed from market
    - COA and MSDA
  - Prepared in clean and sanitized area, dedicated to compounding

Compounding Environment

- Facilities
  - Potable water for hand/equip washing
  - Only PURIFIED WATER for compounding preparations
  - Only PURIFIED WATER for rinsing equipment and utensils
  - Any time special allergenic products are made additional care must be taken to clean equipment and facilities to prevent cross-contamination
Compounding Environment

- **Equipment**
  - Must be appropriate design and size for compounding uses
  - Constructed of materials which will not react, adsorb, nor be additive to finished products
  - Equipment must be inspected, maintained, cleaned and validated at regular intervals to ensure accuracy and reliability of performance

Stability

- **Stability**
  - Extent to which a preparation retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.
  - Must take precautions to minimize rate of product degradation and prevent the production of a toxic compound

Stability

- **BUD** is the responsibility of compounder
  - Determined from time of compounding, NOT time of dispensing
  - Use scientific literature, manufacturers information and analytical laboratory information to determine approp. BUD
  - Good Compounding Practice requires BUD labeling for ALL compounded preparations

Stability

- If no data available for BUD, use empiric guide
  - **Nonaqueous Formulations**
    - NOT Later than the time remaining until the earliest expiration date of any API, or 6 months, whichever is earlier
  - **Water-Containing Oral Formulations**
    - BUD is NOT later than 14 days when stored at controlled cold temperatures
  - **Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations**
    - BUD is NOT later than 30 days

Ingredient Selection

- **Sources**
  - Preferred: USP/ NF grade
  - Secondary: other high-quality, reliable source
    - ACS, AR, FCC
    - Compounder MUST establish purity and safety of products, by reasonable means
      - Lab analysis (COA), mfg reputation, reliability of source
  - May NOT compound preparations with a product withdrawn from the market
    - "negative" list
    - See CPG 460.200

Checklist

- Five questions
  - Have physical and chemical properties and medicinal, dietary, and pharmaceutical uses been reviewed?
  - Are quantity and quality of each active ingredient identifiable?
  - Will active ingredients be effectively absorbed, locally or systemically according to prescribed purpose, from the preparation and route of administration
Checklist

- Are added substances, confirmed or potentially present from manufactured products, that may be expected to cause undesirable reactions (allergic, irritation, toxicity, etc.)? Are added substances present that may be unfavorable (pH or inadequate stability, etc.)?
- Were all calculations and measurements confirmed to ensure that the preparation will be compounded accurately?

Compounding Process

- Label Rx containers to include:
  - Name of preparation
  - Internal identification number
  - BUD
  - Initials of compounder
  - Storage requirements
  - Other statements, required by law
- Sign, date Rx, confirming procedures used
- Thoroughly and promptly clean all equipment and store properly

Records & Documents

- Formulation Record, Compounding Record, MSDS, COA, other certifications
- There may be state AND federal requirements for record documenting
- There may be additional reasons for records
  - Civil
- Often no exact formats required, but all required information must be available in some format

Master Compounding Record

- Official or assigned name, strength, dosage form
- Needed calculations
- Compatibility/stability info & references
- Equipment needed
- Preparation instructions (step-by-step)
- Labeling information
- Packaging and storing information
- Description of final preparation
- Quality control procedures

Compounding Record

- Official or assigned name, strength, dosage
- Master Formulation Reference
- Names & Quantities of all components
- Sources, lot numbers, expirations of all components
- Total quantity compounded
- Names of preparer, quality evaluation, approver
- Date of preparation
- Assigned control or rx number
- BUD
- Duplicate label
- Description of final preparation
- Quality Control documentation

Additional Records & Documents

- MSDS
- COA
- Equipment validation / calibration
**Quality Control**

- Safety, quality, & performance depends on:
  - Correct ingredients,
  - Calculations,
  - Accurate and precise measurements,
  - Appropriate formulation conditions,
  - Procedures followed, and
  - Prudent judgment by pharmacist

Must establish Standard Operating Procedures (SOPs) for compounding activities

**Patient Counseling & Education**

- At time of dispensing, SHALL be counseled about:
  - Proper use
  - Storage and handling
  - Disposal
  - Evidence of instability
  - Report any adverse effects

**Training**

- All personnel SHALL:
  - Read and become familiar with <795>
  - Read and understand all steps in compounding preparation
  - Have all training documented
  - Demonstrate proper procedure to trainer
  - Trainer shall sign training documentation records when personnel meets training expectations
  - Supervisors shall continuously monitor compounding personnel

**Pharmacy Compounding Compliance**

- All pharmacies who conduct compounding, whether sterile or non-sterile should:
  - Identify all activities and classify according to category
  - Critically review all pharmacy processes
    - Facilities, maintenance, cleaning
    - Personnel training
    - Operations – selection of ingredients, master records, compounding records, stability and quality determinations
    - Documentation of quality assurance/quality control procedures
    - Patient education activities and documentation
  - Inspectors will be looking for Standard Operating Procedures, Record keeping, and quality documentation

**New Era in Compounding**

- The governmental debates regarding authority and oversight will continue over the forthcoming months
- Nevertheless, there is new awareness in the public about accountability and oversight
  - Whether or not fair, pharmacy has received much attention on accountability
  - Largely due to some spectacular failures and real patient harm
  - New focus on transparency, quality, and accountability

**Summary**

- We have reviewed
  - The origins of pharmacy compounding
  - Development of compounding practice guidelines and ethical presumptions
  - Recent changes to Federal laws and subsequent court determinations
  - Public Policy and stakeholder agenda’s
  - State laws regarding compounding
- Pharmacy Compounding remains a fundamental contribution to patient care; however dynamic viewpoints are attempting to substantially alter a 4000 year old professional skill.