

Compounding Pharmacists are Challenged Daily

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Compounding History in the United States

- Compounding was Pharmacy in the “old days.
- Commercially availability in the 1900’s
- More varieties of strengths and dosage forms
- Economics of investment in drug companies and competition changed availability
- Now less strengths, dosage forms and products
- \$750 million to place a new drug on the market
- ? \$\$\$ to keep them on the market

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Why Compounding as Grown in the United States

- Less dosage forms and strength available
- Hospice symptom relief
- Discontinued drugs and drug shortages
- New drug therapeutic approaches
- Orphan drugs
- Veterinary compounding
- Special patient needs-- various

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Special Patient Needs

- Pediatrics
- Geriatrics
- Bio-identical Hormone Replacement Therapy
- Hospice-Pain Management
- Dental Practice and Patients
- Cosmetically Sensitivity to dyes, scents, preservatives
- Athletic Injuries
- Diabetes—Neuropathies
- Misc. – Blind Studies for ADHD; Desensitization

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Pharmacopeia

- Pharmakon = drug
- Poiein = to make
- Together as Pharmacopeia means any formula or recipe or other standards required to prepare a drug.
- Many local, regional and national pharmacopeias in Europe.
- British Pharmacopeia most prevalent

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U.S. Pharmacopeia

- First Convention – January, 1906, 1820 published in December 1820
- Reissued every 5 years, later annually
- 2002 is the 27th USP
- PSD is the Expert Advisory Panel on Pharmacy formed in 1993
 - General Chapter on Compounding Information
 - Monograph for specific preparations
 - Widely compounded preparations that were not commercially available

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Issues: Ethical and Legal

- IACP* Code of Ethics
 - International Assn. Of Compounding Pharmacists
- FDA Changes
 - Veterinary Compounding
 - Sterile Compounding
 - PCAB

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The FDA

- Grew from a single chemist in 1862 working under the US Dept. of Agriculture
- Advanced under the Division of Chemistry
- The Federal Food & Drug Act passed-1862
- Now under the Dept. of Health & Human Services
- 1938 – Food, Drug and Cosmetic Act
 - **See the FDA Website for Good History**

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The FDA and Compounding Today

- Food Drug Administration Modernization Act of 1997 (FDAMA97) and CPG's (Compliance Policy Guidelines)
(Explained what Pharmacists Can & Can't Do)
 - Pharmacists and Physicians may compound
 - Anticipatory guidelines
 - The Triad: Physician-Patient-Pharmacist
 - USP/NF monographs
 - Commercial Products guidelines
 - Lists: Negative, Positive, Difficult Preparations

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FDAMA97 AND CPG'S CONT.

- Advertising Banned
- Sterile Compounding
 - < 1000 enforceable rules
 - > 1000 informational topics
- Lawsuit – 9th District and Supreme Court
 - Struck down the law!

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NABP and State Pharmacy Boards

- State have the power to regulate pharmacy practice
- Depending on the state, some are very active while others are not
- Standards can vary greatly from state to state

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Current USP Agendas

- Expert Committee on Non-Sterile Preparations
- Expert Committee on Sterile Preparations
- 150 monographs completed 1000 to go
- Chapters complete on Calculations, Good Compounding Practices and Quality Control

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Current USP Agendas

USP <797> Sterile Compounding

- Much enhanced requirements
- Personnel issues
- Facilities
- Storage
- Record keeping
- Quality assurance

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Current FDA Agendas

- Current CPG Problems
- Bulk drugs used in veterinary compounding
 - 11 National Pharmacy Organizations issued joint letters to all the State Boards of Pharmacy requesting assistance with this ban
 - Sept 1 FDA's Center for Veterinary Medicine (CVM) announced a revision promised this fall to allow pharmacists and veterinarians to prepare custom medications from pure pharmaceutical ingredients for companion animals.

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Other FDA/CPG Issues

- Ongoing Controls left over from FDAMA97
- Emergence of the Pharmacy Compounding Accreditation Board (PCAB)
 - 8 Board Organizations and 4 Liaison Groups
 - Voluntary Pharmacy Compounding Accreditation
 - First Emphasis on Sterile Compounding
 - Goal for First Sites Accredited by Year End 2004
 - Cost estimated at \$2,000 to \$4,000/3 years

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Compounding Challenges

- Space
- Staff
- Equipment
- Training
- Supplies
- Marketing
- Networks
- Insurance
- Pricing—Third Party?
- Policies/Procedures
- Quality Assurance
- Testing Program
- Continuing Education
- Commitment

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To Compound or Not to Compound!

- Professional Rewards
- Financial Rewards
- Competition
- Investment
- Limited vs. Compounding Only Pharmacy
- Other Options in your Practice
- Assistance:
 - PCCA Professional Compounding Centers of America
 - ACA American College of Apothecaries
 - IACP International Assoc. of Compounding Pharmacists

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Kelley-Ross Pharmacy -- est. 1925

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