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

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

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
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

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

Issues: Ethical and Legal

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

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
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

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!

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

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
**Current USP Agendas**

- USP <797> Sterile Compounding
  - Much enhanced requirements
  - Personnel issues
  - Facilities
  - Storage
  - Record keeping
  - Quality assurance

**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.

**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

**Compounding Challenges**

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