

# Imbedding History while Teaching Pharmacy Law

William E. Fassett, Ph.D., R.Ph.  
Professor of Pharmacy Law & Ethics  
Washington State University – Spokane

History SIG– AACP Annual Meeting  
Seattle – July 11, 2010

## Some Thoughts on Pedagogy

- I am not a professional historian – but may qualify as an amateur in its best sense:
  - Undergraduate electives in history of science and medicine taught by the late Charles W. Bodemer
  - Graduate courses in historiography, history of western educational thought, sociology of the professions – dissertation anchored in a significant historical review
  - Self-directed reading in history of law, medicine, pharmacy, bioethics, and, in particular, food and drug law
  - Experience in teaching from historical sources: pharmacy law, higher education law, professional ethics, history of pharmacy, and sociology of the professions
  - Some published scholarship in history of pharmacy law and ethics<sup>1</sup>
- History seems to me to provide good stories that enrich the course narrative
- Historical concepts are not principal outcomes in the course but are included throughout and in the text
- I anchor events in periods related to wars or other events (e.g., Woodstock, when their grandparents were young, etc.) the students have heard of – I don't test on dates

<sup>1</sup>See, e.g., Fassett WE. Ethics, law and emergence of pharmacists' responsibility for patient care. *Ann Pharmacother* 2007; 41: 1264-7.

## Pedagogy - 2

- The **major goal** is to have students relate developments in laws affecting pharmacy to the attitudes and beliefs of the periods involved, and to understand the “gradualism” in US legislation and jurisprudence
- A **secondary goal** is to demonstrate how critical events (often popularized as “scandals” or “tragedies”) serve to trigger major changes in underlying law
  - A frankly “political” agenda is to buttress the progressive trend initiated by Theodore Roosevelt that recognizes a need to control the external diseconomies of major US industries
- A **final goal** is to help students understand how pharmacy has evolved partly in response to the legal landscape in which it finds itself
  - I want students to understand pharmacy’s “professional market project”<sup>2</sup> and how professions try to shape the legal landscape in furtherance of that project

-Freidson E. Professional Powers. Chicago: Univ. of Chicago Press; 1988: 59

## Example Historical Questions that might be asked in a Law Course

- When and how did the notion of separation of church and state arise? (As early as the 4<sup>th</sup> Century CE – Gregorian Revolution) How did this affect development of western legal traditions?
- What limitations on sovereignty prevail in the US today that were first imposed by the Magna Carta in the 13<sup>th</sup> Century? (Eminent domain, sovereign immunity) How did that come about?
- When John Adams defended British soldiers after the Boston Massacre (“Facts are stubborn things ...”), where did the law involved come from? After the US declared its independence, but before we had a Constitution, how did we govern ourselves?
- Why do we have jury trials? Why do we have different standards of evidence for criminal, civil, and administrative trials and hearings?
- How and why were our national pharmacopoeias (USP and NF) developed – and by whom? How is their development related to federal and state drug law?
- What events can help explain why it was against the law in the 1960s for pharmacists to put the name of the drug on the label without the prescriber's permission but now pharmacists are violating the law if they don't put the name of the drug on the label? How did we go from an ethic of not discussing medicines with patients to an ethic mandating patient counseling?


## Example Questions - 2

- How did homeopathy, osteopathy, chiropractic, naturopathy, acupuncture, hydrotherapy, and similar “nontraditional” therapies come to have a place in American culture?
- How did professional accreditation and credentialing emerge as important regulatory structures in the US instead of government certification which is more common in other western countries?
- How did the activities of social movements such as the women's health movement set the stage for legal expansion of the scopes of practice for nursing, pharmacy, and other health professions?
- How did corporate ownership of pharmacies become the norm in the US, instead of private ownership such as in Germany, the Netherlands, and France?
- Why don't we have national licensure of pharmacists, physicians, and other health providers, as in many other western nations?
- How did the legal requirement of informed consent come about?
- How did the courts come arrive at the current notions of privacy rights, and rights to refuse treatment including nutrition and hydration? How did the notion of living wills come about? Why do only three states allow physician aid-in-dying (why isn't there a national standard on this)?

## A Medley of Example Uses of Historical References

# Historical Example to Illustrate Application of Legal Principles

## Example: Robert Courtney



- 20 Criminal Charges
  - ◆ Tampering with consumer products (8)
  - ◆ Adulteration (6)
  - ◆ Misbranding (6)
  - ◆ Pled guilty and agreed to minimum sentence of 17 ½ years.
- Jury trial awarded \$2.2 billion in damages.
- KS Board of Pharmacy to receive surrendered license

# Events and Artifacts in the History of US Food and Drug Law

“And pursue with eagerness the fortunes of hope”



## Ruth de Forest Lamb: An American Chamber of Horrors



## 1937

107 deaths. Could only be seized because it was labeled as an “elixir” but contained no alcohol.




Photo courtesy of FDA

Carl Durham, R.Ph.  
Hubert Humphrey, R.Ph.



Caution:  
Federal law prohibits dispensing without prescription.  
(Rx Only)

Phocomelia

Europe's deformed baby crop seen at 7,000

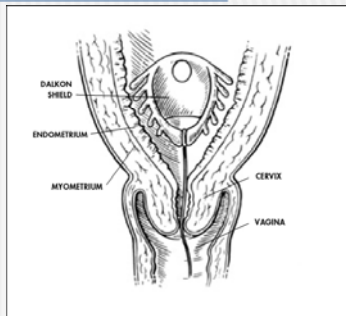
Sleeping pill deforms unborn child

Deformity drug's toll not final



Dalkon Shield

- 25 years of litigation
- \$2.6 billion settlement trust
- Demise of A.H. Robins Co.
- Led to Device Amendments in 1976



Tylenol in Chicago  
Excedrin & Sudafed in WA



Stella Nickell



Chicago, 1982; WA 1988, 1992

Historical Cases Relating to Compounding

Seven Freedoms Pharmacy – Miami, FL, 1979

- Prepares "GH-8" on prescriptions from Club Sene-X, a/k/a Sene-X Eleemosynary Corporation.
- Consists of 2% lidocaine taken orally or in topical formulation
- Promoted by club to reverse effects of aging
- US Court of Appeals rules that Seven Freedoms Pharmacy is not operating as a bona fide pharmacy, and GH-8 is an unapproved new drug

## Doc's Pharmacy – Walnut Creek, CA, 2001

- *Serratia marcescens* in betamethasone injections
- Caused meningitis
- Three deaths
- Owner of pharmacy commits suicide
- Pharmacist-in-charge (right) surrenders license



## Western States Medical Center v. Shalala

- Compounding pharmacies in several states file lawsuits against advertising restrictions in FDAMA
- Cases consolidated in Nevada
- District Court holds that §503A prohibitions on advertising violate First Amendment
  - The Court rules that government fails to show the restrictions meet the Central Hudson tests.
    - Speech must be misleading or related to unlawful activity
    - Government must show substantial interest to be achieved by restriction on commercial speech
    - Restriction must directly advance the government interest
    - Restriction must be no more extensive than necessary to achieve the desired interest
  - The Court rules that the advertising restrictions may be "severed" from the rest of the Act.
- 9<sup>th</sup> Circuit affirms District Court findings that the Act violates the First Amendment, but holds that the restrictions on speech are not severable, and therefore all of §503A is unconstitutional and void.
- Supreme Court affirms on First Amendment issue, is silent on severability.

## Medical Center Pharmacy v. Gonzales (2006)

- Federal district court in Texas granted summary judgment to 10 pharmacy plaintiffs that:
  - Western States decision invalidated only those elements of §503A that impaired free speech; the remainder of the section is valid
  - Pharmacy compounding in accordance with state laws in pharmacies that adhere to those laws does not create new drugs within the meaning of the FDCA
  - CPG is an internal policy guide that cannot be enjoined prior to improper FDA acts.
  - FDA is enjoined from engaging in certain inspection procedures applicable only to firms required to register with FDA
- July 2008: 5<sup>th</sup> Circuit generally affirms district court decision, holding that compounded drugs are exempt from the new drug provisions of FDCA if they are compounded in accordance with §503A.

## Landmark Court Decisions

### Pharmacists must take action when problems are discovered

- "A pharmacist has a duty to take corrective measures when confronted with a prescription containing an obvious or known error, such as obviously lethal dosage, inadequacies in the instructions, known contraindications, or incompatible prescriptions."

□ Washington Supreme Court, McKee v American Home Products, 1989

## Gonzales v Oregon (US Supr Ct No 04-623, January 17, 2006)

- ◆ Case arose when AG Ashcroft ruled in 2001 that use of controlled substances in accordance with Oregon's Death with Dignity Act would not constitute prescribing for a "legitimate medical purpose ... in the usual course of ... professional practice" under 21 CFR § 1306.04.
- ◆ Oregon, a physician, a pharmacist, and several terminally ill patients in Oregon challenged the rule.
- ◆ Supreme Court held that "the CSA does not allow the Attorney General to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide under state law permitting the procedure."
- ◆ Decision indicated that the AG's rule making discretion under the CSA is limited to:
  - Registering individuals and entities under the Act (or removing them from the registry)
  - Establishing which schedule a controlled substance should be placed in – in consultation with FDA
- ◆ Congress has, so far, left regulation of medicine and pharmacy to the States

## Within My Lifetime but Not My Students'

### Maintaining Patient Records - History

- Recording all prescriptions has been a requirement in WA since at least 1939
- The first state to require patient profiles was New Jersey, in 1973
  - WA adopted a rule in about 1974 requiring pharmacists to maintain such records as would enable the pharmacist to "attempt" to detect drug-drug interactions, multiple prescribing of similar drug classes by different physicians, and the like.
- More specific regulations adopted in 1984

### Changes in Practice to Allow Medication Records

- Allowing refill information to be kept in the medication record, rather than on the back of the prescription
- Allowing (prior to computers) pharmacists to refill prescriptions without going back to the original prescription each time, if the patient record contained a correct copy of the original
- Recognizing that a system of records could be used to meet needs for patient information as well as records of distribution of drugs. In some facilities, patient charts could be part of the medication record system

### Landmark Legislation Affecting Pharmacy

### Omnibus Budget Reconciliation Acts (OBRA)s

- "Omnibus" means "having many purposes", "all-encompassing"
- Passed at the last minute by Congress to reconcile Senate and House budget versions ("reconcile": to bring into harmony)
- Omnibus Budget Reconciliation Acts
  - Originally, COBRAs (Consolidated Omnibus Budget Reconciliation Act), e.g., 1986 - health insurance transfers on change of employment
  - OBRA-87, use of psychotropics in LTC facilities
  - OBRA-90, Medicaid drug programs
- Purpose: to save taxpayer dollars or to deal with other budget-related issues

### OBRA-90

- Designed to save Medicaid dollars by reducing waste and misuse of drugs, and by preventing drug-related problems
- Mandatory manufacturer rebates
- Mandated HCFA demonstration projects
  - OPDUR
  - Payment for pharmacists' cognitive services
- Retrospective drug use review
- Prospective drug use review
- Maintain patient drug use histories
- Pharmacists must offer to counsel Medicaid patients

## Historical Interactions Among Legislation, Court Decisions, and Administrative Actions

## Patients with limited English proficiency (LEP)

- Discrimination based on national origin is prohibited by Title VI of the Civil Rights Act of 1964 (42 USC §2000d)
- US Supreme Court has held that conduct that has a disproportionate effect on LEP persons constitutes discrimination based on national origin (*Lau v. Nichols*, 414 U.S. 563, 1974)
- President Clinton signed Executive Order 13166 in August 2000: "Improving Access to Services for Persons with Limited English Proficiency"
  - Every federal agency required to provide guidance to recipients of federal funds on how they can provide meaningful access to LEP persons.
  - Pharmacies filling Medicaid, SCHIP, Medicare or other federally-paid prescriptions are subject to Title VI and EO 13166

32

## A Gallimaufry of my Favorite Resources

## History of Medicine and Pharmacy

- *Devils, Drugs and Doctors* (Haggard HW [1913]. New York: Pocket Books; 1946.)
- *Eleven Blue Men and Other Narratives of Medical Detection* (Rouche B. Boston: Little, Brown; 1953.)
- *The Epic of Medicine* (Marti-Ibañez F. New York: Clarkson N. Potter; 1962.)
- *Four Thousand Years of Pharmacy* (LaWall CH. Philadelphia: Lippincott; 1927.)
- *History of Pharmacy* (Kremers G, Urdang B. Philadelphia: Lippincott; 1940.)
- *A Contribution to Western Pennsylvania Pharmacy* (Reif E, Reif T. Pittsburg: Univ. of Pittsburgh Press; 1959.)
- *Great Moments in Pharmacy* (Bender GA. Detroit: Northwood Institute Press; 1966 – digitized and posted with permission by WSU College of Pharmacy: <http://www.pharmacy.wsu.edu/history/>)
- *A History of Drugs* (Mez-Mangold L. Basle: F. Hoffmann-La Roche & Co. Ltd.; 1971.)
- *An Educational History of the Western World*, 2<sup>nd</sup> Ed. (Meyer AE. New York: McGraw-Hill; 1972: n.b. Ch. 6]

33

## History of Law and Laws

- *Law and Revolution: The Formation of the Western Legal Tradition* (Berman HR. Cambridge: Harvard Univ. Press; 1983.)
- *Harvey W. Wiley: An Autobiography* (Wiley HW. Indianapolis: Bobbs-Merrill; 1930.)
- *Medication, Law & Behavior* (Gibson JT. New York: Wiley; 1976.)
- *FDA's Creative Application of the Law: Not Merely a Collection of Words* (Degnan FH. Washington, DC: Food and Drug Law Institute; 2000.)
- *Searching for Magic Bullets: Orphan Drugs, Consumer Activism and Pharmaceutical Development* (Basara LR, Montagne M. New York: Pharmaceutical Products Press; 1994.)

## Ethics and Sociology of Professions

- *The Social Transformation of American Medicine* (Starr P. New York: Basic Books; 1984.)
- *The Quest for Authority and Honor in the American Professions* (Haber S. Chicago: Univ. of Chicago Press; 1991.)
- *Professional Powers* (Freidson E. Chicago: Chicago Univ. Press; 1988.)
- *The Birth of Bioethics* (Jonsen AR. New York: Oxford Univ. Press; 1998.)
- *Strangers at the Bedside* (Rothman DJ. New York: Basic Books; 1992.)
- *The Abuse of Casuistry: A History of Moral Reasoning* (Jonsen AR, Toulmin S. Berkeley: Univ. of California Press; 1988.)
- *Pharmacists for the Future: the Report of the Study Commission on Pharmacy* (Ann Arbor: Health Administration Press; 1975)
- *Ethical Responsibility in Pharmacy Practice* (Buerki RA, Vottero LD. Madison: AIHP; 1994.)