Pharmacy Practice and the Law
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New to the Sixth Edition

Chapter 2: Federal Regulation of Medications: Development, Production, and Marketing

- Addition of recent example of how health claims by a food manufacturer can result in the FDA considering that the product is an unapproved new drug.
- Discussion of the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 and what it added to prior laws regulating dietary supplements and OTC drug products.
- Discussion of proposed FDA regulation to amend pregnancy labeling requirements.
- Updated information about the NDC number.
- Discussion of the Food and Drug Administration Amendment Act's (FDAAA) requirement of the public registry of clinical trials by NDA sponsors.
- Discussion of the FDA's authority to require phase IV testing under the FDAAA.
- Discussion of the FDA's authority under the FDAAA to require Risk Evaluation and Mitigation Strategy (REMS) for drug products.
- Discussion of the FDA's authority to require post market labeling changes under the FDAAA.
- Discussion of the FDA's requirement under FDAAA to develop and maintain a website for patients and providers documenting drug safety information.
- Updated discussion of recent regulations and litigation regarding the use of investigational drugs for treatment.
- Discussion of recent congressional debate over whether to allow generic biologics.
- Discussion of the requirement that pharmacies must provide patients with a statement to report side effects and the toll free number to do so.
- Discussion of the Pharmaceutical Research and Manufacturers of America (PhRMA) publication describing ethical conduct between manufacturers and healthcare professionals.
- Discussion of recent issues related to direct to consumer advertising.
- Discussion of the FDA's 2009 guidance regarding the dissemination of off-label use by drug manufacturers.

Chapter 3: Federal Regulation of Medications: Dispensing

- Discussion of the FDA's possible change in position regarding behind the counter (BTC) drugs.
- Discussion of recent developments regarding the sale of Plan B.
- Discussion of recent litigation about conscientious objection.
- Discussion of recent results and FDA comments about the usefulness of consumer medication information.
- Discussion of recent developments about MedGuides.

- Discussion of recent FDA action, as well as recent litigation over pharmacy compounding and whether pharmacy compounded drugs are new drugs.
- Updated discussion of the pedigree and the FDA's mandate under the FDAAA.
- Discussion of recent FTC actions against pharmacies for deceptive and false marketing of dietary supplements.

Chapter 4: The Closed System of Controlled Substance Distribution

- Discussion of DEA action against wholesalers and the responsibility of wholesalers to detect suspicious orders of controlled substances
- Discussion of a DEA advisory resulting in the restriction of 40 mg methadone tablets to opioid treatment programs.
- Discussion of the Methamphetamine Production Prevention Act of 2008.

Chapter 5: Dispensing Controlled Substances

- Discussion of DEA's new position regarding a pharmacist changing or correcting a C-II prescription.
- Enhanced discussion of how a pharmacist can ascertain the legitimacy of opioid prescriptions written by a licensed prescriber.
- Discussion of DEA's final rule allowing the issuance of multiple C-II prescriptions for the same drug to the same patient on the same day.
- Discussion of DEA's proposed regulation to allow the e-prescribing of C-III, C-IV and C-V prescriptions.
- Discussion of Internet pharmacies and the Ryan Haight Online Pharmacy Consumer Protection Act of 2008.
- Discussion of DEA's position and current action regarding the return of controlled substances to pharmacies by ultimate users and skilled nursing facilities.
- Discussion of DEA proposed regulation to convert the triplicate Form 222 into a single-sheet tamper resistant form.

Chapter 6: Federal Regulation of Pharmacy Practice

- Discussion of the effect of the 2009 Health Information Technology for Economic and Clinical Health Act (HITECH) and CMS regulations on pharmacies as applied to HIPAA and protected health information.
- Updates to Medicare Part D discussions.
- Discussions of the effect of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 on pharmacy practice and Part D plans.
- Updated discussion of e-prescribing under Medicare Part D.
- Discussion of pharmacy accreditation for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

- Discussion of recent regulatory, legislative and litigation developments concerning average manufacturer's price (AMP) and the federal upper limit (FUL) list.
- Discussion of recent litigation over average wholesale price (AWP) and its likely effect on pharmacy reimbursement.
- Discussion of the tamper resistant prescription pad requirement for written Medicaid prescriptions.

Chapter 7: State Regulation of Pharmacy Practice

- Expanded discussions of state pharmacy practice act provisions including:
  - The responsibility of the pharmacist-in-charge
  - Issues over state regulation of Internet Pharmacy
  - The importance and ramifications of defining the practice of pharmacy
- Description of ancillary pharmacy personnel including issues of qualifications, degree of supervision, ratio requirements and technicians checking technicians.
- Discussion of automation and issues of whether pharmacists must check prescriptions dispensed by automation.
- Discussion of pharmacies remaining open in the absence of a pharmacist due to taking breaks.
- Discussion of continuing education requirements for relicensure.
- Discussion of state efforts to regulate PBMs.
- Discussion of trend to enact pharmacy quality assurance laws.

Chapter 8: Pharmacist Malpractice Liability and Risk Management Strategies

- Update of recent negligence litigation.
- Update of U.S. Supreme Court decisions regarding the product liability of drug manufacturers for devices and prescription drugs.

