

Honor Codes and Legal Implications for Colleges/Schools of Pharmacy

- I. What are the Legal Issues?
- II. Case Examples
- III. Practical Tips

Some of the Legal Issues

- School of Pharmacy's Policies and Procedures (Student Handbook)
- Codes of Conduct and Vagueness
- Due Process Concerns
- Equal Protection

Student Handbooks

- Do your institutions have them?
- Are they disseminated to students?
- Acknowledgement of receipt
- Information in Handbook
- IMPORTANT – Policies, Procedures, Codes stated in Handbook must be _____ !

Codes of Student Conduct

Three Major Issues:

- The type of conduct the code will encompass
- The procedures to be used when infractions of the code are alleged
- The sanctions for code violations

Examples.....lying, cheating, stealing, plagiarism, failing to report a violation

- Off-campus activity?

Void for Vagueness

Vague Regulation Requirement:

- The Code must be clear enough for students to understand the standards with which their conduct must comply, and
- The Code must not be susceptible to arbitrary enforcement

Academic vs. Non-Academic Dismissal

- Does it matter from a legal standpoint?
- Can you dismiss a student for “non-academic” reasons?
- Will you be sued?
- What are the courts’ attitude regarding these matters?

Academic Dismissal

“When judges are asked to review the substance of a genuinely academic decision...they should show great respect for the faculty’s professional judgment.”

Academic Dismissal

“Plainly, they may not override it unless it is such a substantial departure from accepted academic norms as to demonstrate that the person or committee responsible did not actually exercise professional judgment.”

Regents of the University of Michigan v. Ewing, 106 S. Ct. 507, 513 (1985).

Due Process

Procedural Due Process

- Standard met “by way of adequate notice, definite charge, and a hearing with opportunity to present one’s own side of the case and with all necessary protective measures” (*Estaban v. Central Missouri State College*, 415 F.2d 1077)

Due Process

Substantive Due Process

- Student must demonstrate “arbitrary and capricious conduct on part of College by showing there was no rational basis for the College’s decision or that dismissal was motivated by bad faith or ill will unrelated to academic performance”

Richmond v. Fowlkes, 228 F.3d 854; 2000 U.S. App. LEXIS 24822.

Equal Protection

- Citizens are protected from “arbitrary or irrational state action” by the Equal Protection Clause
- It is essential that all students be treated equally (Note: This does not mean all students’ results will be the same)

Lack of Professionalism and Student Termination

“Personal hygiene and erratic attendance may be appropriately considered by a medical school as factors bearing on a student’s academic standing in a professional program.”

Board of Curators of the Univ of Missouri v. Horowitz, 435 U.S. 91 (1978)

Violating Student Code and Student Termination

Former student expelled for violating college code (next slide) after pleading nolo contendere to a misdemeanor charge of attempting to obtain a controlled substance with a fraudulent Rx

Student alleged school's standards were unconstitutionally vague

Violating Student Code and Student Termination

Westark College assumes that, by the act of registering, the student agrees to obey all rules and regulations formulated by the College as listed below and to obey all federal, state, and local laws.

Students are expected to conduct themselves in an appropriate manner and conform to standards considered to be in good taste at all times. This implies a consideration for the welfare and reputation of the College and other students enrolled at the College. Students exhibiting behavior problems not compatible with good citizenship can expect to be reprimanded, have certain restrictions imposed, or be denied the privilege to continue as students.

Violating Student Code and Student Termination

Do you feel this Code of Conduct was "vague?"

The court held that the standards' reference to "good citizenship" was sufficiently precise to notify the student that her criminal act constituted unacceptable conduct that could lead to expulsion

Agree or disagree?

Violating Student Code and Student Termination

In cases like this (and subsequent case), it is important for the institution to “articulate a reasonable relationship between the off-campus misconduct and the well-being of the college community.”

If institutions meet this criteria, courts “will not overturn a disciplinary action unless they find that the action was arbitrary, an abuse of discretion, or a violation of a student’s constitutional rights” (Kaplan and Lee 2007).

It is important, though, for the institution to state this in its student code.

Violating Student Code and Student Termination

Pharmacy Student Case Example:

- Phrase in question was “detrimental to the interests of the University community”
- Pharmacy student pled guilty to possession of cocaine but claimed that code was vague
- Court stated that a pharmacy student in his last year of pharmacy school was aware that the illegal use and possession of narcotic drugs would violate the law and the Code of Ethics of his profession

Violating Student Code and Student Termination

Lessons from this Case:

- As members of a profession, we may hold our students to higher standards
- Courts may be more willing to “accept much more intrusion into a student’s ‘real world’ experimentation when that student is pursuing a professional degree” (Kiplinger 2006)

Final Thoughts

1. Follow Policies and Procedures, as specified in the Student Handbook (signed Honor Codes)
2. Avoid Vague Language
3. Clearly State Expectations
4. Provide Mechanisms for Students to Report Violators
5. Determine if act makes a detrimental impact on the institution and its mission (this includes off-campus activities)
 - > This may or may not be the same for each College/School of Pharmacy

Final Thoughts

6. Make Decisions that are Timely and Communicated to Student
7. Have Evidence to Support Your Decisions (Documentation)
8. Dismiss Students if Warranted (Our Responsibility to Profession)
9. Respect Confidentiality (FERPA)

Helpful References

Board of Curators of the Univ of Missouri v. Horowitz, 435 U.S. 91 (1978).

Estaban v. Central Missouri State College, 415 F.2d 1077 (8th Cir. 1969).

Kaplan WA, Lee BA. *The Law of Higher Education, Student Version*, 4th ed. Jossey-Bass: San Francisco (2007).

Kiplinger JW. *Defining Off-Campus Misconduct that "Impacts the Mission": A New Approach*. 4 U. St. Thomas L.J. 87 (2006).

Regents of the University of Michigan v. Ewing, 106 S. Ct. 507, 513 (1985).

Richmond v. Fowlkes, 228 F.3d 854; 2000 U.S. App. LEXIS 24822.

Van Dusen, V, Spies, AR. Student Privacy: Implications for Pharmacy Education, *Am J Pharm Educ* 2003; 67(1):Article 8.

Legal Issues in Academic Pharmacy: Student Admissions

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Legal Issues Related To:



- Admissions Process
- Background Checks
- Random Drug Testing

Admissions: ACPE Requirements

- ACPE prohibits discrimination in the admissions process
- **Guideline 16.6:** admission policy “must ...ensure nondiscrimination as defined by state and federal laws and regulations, such as on the basis of race, religion, gender, lifestyle, sexual orientation, national origin, or disability”

Admissions: Legal Issues

- For schools receiving federal funds:(financial aid!)
 - Cannot discriminate based on:
 - Race, color, origin, religion (Title IV Civil Rights Act 1964)
 - Gender (Title IX Education Amendments 1972)
 - Disability (includes learning difficulties; Rehabilitation Act 1973, Section 504)
 - Age (Age Discrimination Act 1975 & some state-specific laws)
 - Same basic laws as when hiring employees

Admissions & FERPA

(Family Educational Rights & Privacy Act 1974)

- | | |
|---|--|
| <ul style="list-style-type: none">➤ Mandates that schools:- Inform students of privacy rights- Allow students access to own educational records- Inform students of right to challenge information in record- Require student consent before information in record is released to others | <ul style="list-style-type: none">➤ Allows schools to:- Release details of campus crime reports WITHOUT student consent (since 1992)- REFUSE access to records:<ul style="list-style-type: none">• Prospective students• Rejected applicants |
|---|--|

Admissions: Our Process

- | | |
|---|---|
| <ul style="list-style-type: none">➤ Admissions Committee- Review all applicant files- Offer interviews based on academic qualifications<ul style="list-style-type: none">• Preference for our pre-pharms- Review interview results- Select candidates for admission<ul style="list-style-type: none">• Candidates notified within ~2 weeks of their status | <ul style="list-style-type: none">➤ All Faculty- Interview candidates in pairs using standardized list of questions (Jan-April)- Assess written (essay) and verbal (interview) skills- Individually score candidates; recommend: admit, deny, or further committee review |
|---|---|

Admissions: Challenges

- Applicant interview process
 - Must base decisions on appropriate information
 - Ask consistent questions
 - Avoid discriminatory questions
 - Age/Spouse/Children
 - Health status/Gender/Sexual orientation
 - Careful of inappropriate comments/jokes during admissions committee meetings

Your Turn:

Write Your Thoughts Here to Discuss Later

- What is your school's greatest challenge regarding legal compliance in the admissions process?



Student Background Checks: Why Do Them?

- Minimize liability (school and clinical sites)
- Determine if admitted applicants/students:
 - Safe for school & patient care settings
 - Eligible for eventual pharmacist licensure
- As of 2006:
 - 63% SOPs had a BGC policy
 - 33% did BGC at admission; 33% did > 1 time

Student Background Checks: ACPE Requirements

- Schools must have statement/policy on criminal BGC (as of 2007; see AACP policy guidelines)
 - **Guideline 17.4:** “Criminal and other activities that may restrict the student’s ability to access experiential sites or potentially affect the student’s eligibility for future licensure...should be identified....”

Student Background Checks: Legal Basis

- Applicable laws:
 - Federal
 - Fair Credit Reporting Act 1970
 - Fair & Accurate Credit Transitions Act 2003
 - State FCRA Equivalents
 - Often more restrictive than federal law
 - Some limit use of this information for educational purposes

Student Background Checks: Process

- Inform applicants of your policy
- Student must be accepted for admission in your program before you can conduct BGC
- BGC may show juvenile offenses, arrested but not charged cases, etc
 - If applicants leave this information off the application it looks as if they are trying to hide something

Student Background Checks: AACP/PharmCAS^{5,6}

- Pilot study with CERTIPHI began 6/09 (10 SOP)
 - Admission offers reported weekly in PharmCAS
 - Certiphi notified if school requires BGC
 - Applicant notified by Certiphi of need for BGC
 - Applicant completes forms within PharmCAS
 - Report sent to applicant to review - may clarify or challenge information
 - Final report sent to school within ~ 1 week

Student Background Checks: AACP/PharmCAS^{5,6}

- Potential benefits:
 - Standardize process of BGC
 - Allows BGC to be initiated before matriculation
 - Future BGCs processed more quickly
- Estimated costs:
 - Extra \$15 per PharmCAS user (not just those who receive an offer of admission)

Background Checks: Our Process

- Were doing online just prior to APPEs
- Now - sign BGC release upon acceptance and conduct via PharmCAS/Certiphi
- Final admission contingent on passing BGC
 - If they refuse BGC, we withdraw the offer
 - If they consent and problems show up on the report, we may withdraw the offer

Background Checks: Challenges

- Must have intern license before first IPPE
 - Register with BOP after first day of class (in AL)
 - If license delayed/withheld, interferes with IPPEs
 - Up to 3 months to get license if any BGC problems
 - Example: Drug possession charge at age 15
 - Our BOP will now review BGC problems early

- BOP could still refuse pharmacist licensure even if they grant intern license

Your Turn:

Write Your Thoughts to Discuss Later

- **What is your school's greatest challenge regarding legal compliance in the admissions process?**



Random Drug Tests: Why Do Them?

- Minimize liability (school and clinical sites)
 - Typical contract language: “Must be actively enrolled in a drug monitoring program”
 - Usually do not specify testing schedule/drugs to check

- Determine if admitted applicants/students:
 - Eligible for eventual pharmacist licensure
 - Safe for school & patient care settings

Random Drug Tests: Legal Basis

- Organizations receiving federal funds must (Drug-Free Workplace Act 1988):
 - Have written policies on drug and substance use/abuse
 - Provide a drug awareness program
 - Make a good-faith effort to maintain a drug-free workplace

Random Drug Testing: Our Process

(using PharmCAS/Certiphi)

- Student signs release on admission
 - Test all students randomly twice each year for pot, crack, cocaine, benzos, narcotics
 - Can remove students from testing as needed
- Student has 48 hr to leave sample (~\$35)
 - If positive, student must verify having prescription
 - If cannot verify, retested to confirm
 - If confirmed, SOP notified - we must notify BOP (AL)

Random Drug Testing: Challenges

- Student privacy issues (states, schools view differently)
- No standard screening list, schedule or response to positive tests (once q4 yr vs. every year)
- Potential conflict of interest for testing companies (more frequent testing = more \$ for tester)
- If BOP suspends intern license, students cannot complete IPPEs/APPEs

Your Turn:

Write Your Thoughts Here to Discuss Later

- **What is your school's greatest challenge regarding background testing?**



Resources: Admissions Issues

ACPE. Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree. Chicago, IL: ACPE, 2006.

Weeks KA. Complying with Federal Law: A Reference Manual for College Decision Makers. Nashville, TN: College Legal Information, Inc. 2003.

Weeks KA. Managing Departments: Chairpersons and the Law. Nashville, TN: College Legal Information, Inc. 1997.

Van Dusen V. and Spies A. Student Privacy: Implications for Pharmaceutical Education. AJPE 2003; 67(1):20-30.

Certiphi & AACP. Criminal Background Checks on Student Pharmacists (presentation). Available at aacp.org [accessed 6/22/09].

AACP. Report of the AACP Criminal Background Check Advisory Panel, November 2006. Available at aacp.org [accessed 6/22/09].

Legal Issues in Academic Pharmacy: Using Forensic Cases

Pamela J. Sims, Pharm.D., Ph.D.

Problems with traditional approach

- Lecture presentation of topic followed by example problem(s)
- Students “memorized” how to work a particular problem
- Problems presented in group work still viewed as “correct” way and memorized
 - problems never engaged students or seemed real to them
- Course content viewed as discrete and disconnected

Topic: Intermittent IV Bolus Dosing

- Peak 1 = D/V
- Trough 1 = $(D/V) (e^{-kt})$
- Peak 2 = $D/V + (D/V) (e^{-kt})$
- Trough 2 = $[D/V + (D/V) (e^{-kt})] e^{-kt}$
= $(D/V) e^{-kt} + (D/V) (e^{-2kt})$
- Peak 3 = $D/V + [(D/V) e^{-kt} + (D/V) (e^{-2kt})]$
- Trough 3 = $\{D/V + (D/V) e^{-kt} + (D/V) (e^{-2kt})\} e^{-kt}$
= $(D/V) e^{-kt} + (D/V) e^{-2kt} + (D/V) (e^{-3kt})$
- Peak ss = $(D/V)[1/(1 - e^{-kt})]$
- Trough ss = Peak ss (e^{-kt})

Traditional “practice” or example problem (case study)

- Quinidine is a drug used to treat cardiac arrhythmias. It is available for IV administration in a solution containing 80 mg/ml
- The pharmacokinetic parameters for quinidine are listed below:
 - Clearance 4.7 ml/min/kg
 - Distribution volume 2.7 L/kg
 - Therapeutic range 2-6 mg/L
- Determine an appropriate IV bolus dosage regimen including maintenance dose, dosing interval, and loading dose for quinidine in a 60 kg patient. (Be sure and check your expected steady-state peak and trough for the dose and interval you recommend.)

Traditional approach

- Student given all of the pertinent information needed to work the problem
 - condition being treated
 - dosage form and strengths available
 - pharmacokinetic parameters
 - therapeutic range
- Student instructed to determine specific information
 - calculate loading dose,
 - maintenance dose,
 - dosing interval
 - check for expected peaks and troughs

PBL problem from clinical setting

- MH has been admitted to the CCU with atrial arrhythmias. You are the clinical pharmacist for that unit. The cardiologist wants to place MH on quinidine and asks you for your recommendations.
- MH is a 80 kg, 50 yo male. His SCr is 1.5 mg/dL.

PBL problem from clinical setting

- Student given some information needed to evaluate the situation and some information not needed for this problem
 - Needed
 - condition, drug, age, wt
 - Not needed
 - SCr
- Student must identify information to retrieve, appropriate sources of that information
 - dosage form and strengths available
 - pharmacokinetic parameter estimates
 - appropriate therapeutic range

PBL problem from clinical setting

- Student must determine
 - appropriate therapeutic range
 - need for loading dose
- Student must determine necessary calculations to make recommendations
 - loading dose
 - maintenance dose
 - dosing interval
 - check for expected peaks and troughs
- Students must determine if/what follow-up is necessary

Forensic problem

- JJ is a 19yo white female who presented to the emergency room of Shelby Medical Center with severe flank pain and nausea. Following radiologic evaluation, the ER physician diagnosed JJ with renal calculus. She was admitted to the hospital and placed on Phenergan® and Demerol®. On the day following admission JJ's boyfriend ran hysterically into the hallway reporting that JJ was having a seizure.
- You are currently on clerkship as a fourth year pharmacy student and are rounding with the medical team caring for JJ.

Forensic problem

- What issues does the medical team (physician, pharmacist, nurse) need to address to properly treat JJ's seizure?
- What may have caused the seizure?
 - Past medical hx
 - Current medical problems
 - Could the medications be involved?
 - What are the generic names of these meds.
 - Based on the pharmacology and chemistry of these meds, would you expect seizures?
 - If so, how were the meds administered-dose, frequency, route, duration?

Forensic problem

- JJ was in an automobile accident 3 months ago and sustained a closed head trauma. She has no personal hx of seizures. Her distant family hx is positive for seizure. During her hospital stay, she has had a normal body temp.
- Attached are the medication administration records and her laboratory findings.

Handwritten medication administration record (MAR) for a patient named JJ. The record shows various medications including Phenytoin, Gabapentin, and others, with columns for dates and times. There are handwritten notes and checkmarks throughout the document.

FLUORIMETRY ASSAY

DATE PRINTED: 02/21/1994 09:20

REPT DATE: 12/29/93

BIOSOURCE: 12294

REPT: 7

W * * * * * CHEMISTRY * * * * * PATRICK L.

***** PHOSPHORUS *****

COLLECTED 12/21/1993 2:17 NORMALS 2.4- 4.1 mg/dL

***** URIC ACID *****

COLLECTED 12/21/1993 2:15 NORMALS 2.4- 8.1 mg/dL

NO	TEST	RESULT	CL	CC
133	K	3.8	98	23
142	CL	1.2	148	23
143	WBC	14.2	4.8	30
144	HGB	14.2	14.8	30
145	HCT	42.8	42.4	30
146	PLT	142	148	30
147	PT	14.2	14.8	30
148	PTT	14.2	14.8	30
149	INR	1.1	1.1	30
150	APTT	14.2	14.8	30
151	FIB	14.2	14.8	30
152	D-DIMER	14.2	14.8	30
153	CRP	14.2	14.8	30
154	ESR	14.2	14.8	30
155	RF	14.2	14.8	30
156	ANCA	14.2	14.8	30
157	ASO	14.2	14.8	30
158	ASCA	14.2	14.8	30
159	RF	14.2	14.8	30
160	ANCA	14.2	14.8	30
161	ASO	14.2	14.8	30
162	ASCA	14.2	14.8	30
163	RF	14.2	14.8	30
164	ANCA	14.2	14.8	30
165	ASO	14.2	14.8	30
166	ASCA	14.2	14.8	30
167	RF	14.2	14.8	30
168	ANCA	14.2	14.8	30
169	ASO	14.2	14.8	30
170	ASCA	14.2	14.8	30
171	RF	14.2	14.8	30
172	ANCA	14.2	14.8	30
173	ASO	14.2	14.8	30
174	ASCA	14.2	14.8	30
175	RF	14.2	14.8	30
176	ANCA	14.2	14.8	30
177	ASO	14.2	14.8	30
178	ASCA	14.2	14.8	30
179	RF	14.2	14.8	30
180	ANCA	14.2	14.8	30
181	ASO	14.2	14.8	30
182	ASCA	14.2	14.8	30
183	RF	14.2	14.8	30
184	ANCA	14.2	14.8	30
185	ASO	14.2	14.8	30
186	ASCA	14.2	14.8	30
187	RF	14.2	14.8	30
188	ANCA	14.2	14.8	30
189	ASO	14.2	14.8	30
190	ASCA	14.2	14.8	30
191	RF	14.2	14.8	30
192	ANCA	14.2	14.8	30
193	ASO	14.2	14.8	30
194	ASCA	14.2	14.8	30
195	RF	14.2	14.8	30
196	ANCA	14.2	14.8	30
197	ASO	14.2	14.8	30
198	ASCA	14.2	14.8	30
199	RF	14.2	14.8	30
200	ANCA	14.2	14.8	30

04921 0218-A GEORGE F HILL, PATRICK L. 3

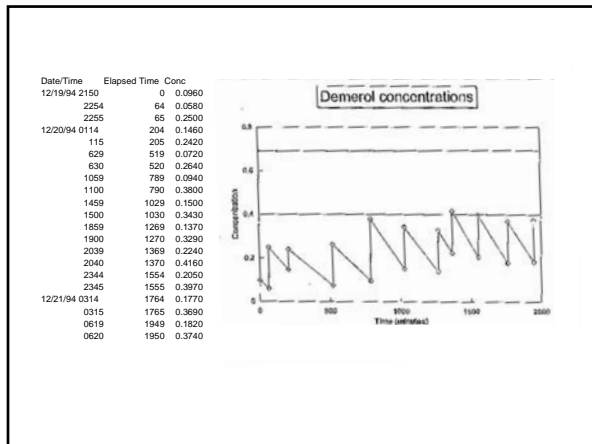
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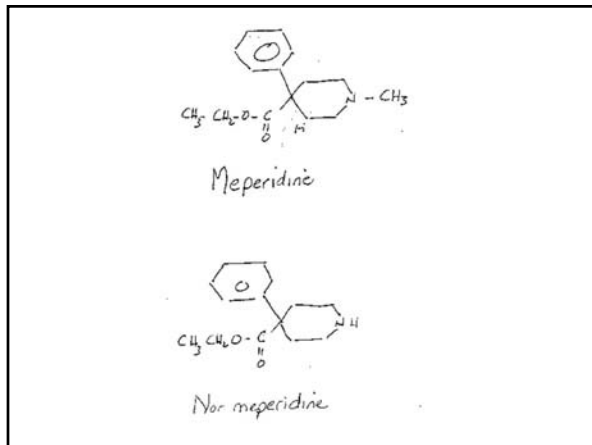
Forensic problem

- What questions should the pharmacist ask and answer for the medical team to determine the cause, future prevention and tx of JJ's seizures?
- Do Phenergan® and Demerol® cause seizures at subtherapeutic, therapeutic or toxic concentrations?
- Could a drug interaction or a metabolite be the problem?
- Based upon the dosing of the drugs would her serum conc be adequate to cause seizures?
- Are any medical consults available to address the contribution of the previous MVA and closed head trauma to the seizure?

December 19, 1994	
2150	Demerol 25 mg + Phen 12.5 mg
2255	Demerol 50 mg
December 20, 1994	
0115	Demerol 25 mg
0240	Phenergan 12.5 mg
0630	Demerol 50 mg
1100	Demerol 50 mg
1500	Demerol 50 mg
1900	Demerol 50 mg
2040	Demerol 50 mg + Phen 12.5 mg
2345	Demerol 50 mg
December 21, 1994	
0315	Demerol 50 mg + Phen 12.5 mg
0620	Demerol 50 mg
0630	Pt had seizure

12/19/94 2150	25mg	Phen	12.5mg	Dem	25mg	Phen	12.5mg	Dem	25mg
12/19/94 2255									
12/20/94 0115									
12/20/94 0240									
12/20/94 0630									
12/20/94 1100									
12/20/94 1500									
12/20/94 1900									
12/20/94 2040									
12/20/94 2345									
12/21/94 0315									
12/21/94 0620									
12/21/94 0630									





Forensic problem

- Patient's actual drug administration
 - complexity of equations
 - accumulation to steady-state
- Ideal drug administration
 - simplification of equations at SS with consistent dose and interval
 - predictability

Leading the REVOLUTION
2009 Annual Meeting and Seminars

Sources of Forensic Cases/Problems

- FDA actions
 - Recalls
 - Changes in labeling
 - Black-boxed Warnings
 - Changes in indications
 - Dear Health-care provider letters
 - Med Watch reports
- News
- Primary Literature
 - Case reports
- Boards of Pharmacy
 - Disciplinary actions
- Court Cases

FDA Recalls

FDA Recalls	July 1, 2009
Adipex (pregabalin tablets) Injection	
Four 1.5 mL single-dose vials, 200 units per mL, sterile, white/grey, No. only, NDC 01689-001-01	
Manufacturer:	Evans Pharmaceutical, Inc., Wallingford, CT
Recalled by:	Manufacturer, by letter dated March 27, 2008. Firm initiated recall in progress.
Recall date:	TX, Australia, Colombia and France, 2008 & all parts.
Reason:	Extended impurity specification, 6-month stability testing.
Recall number:	01-022-2008
Depositions (DSD Oral Solution)	
100 mL bottles, 0.25 mg/mL in 1 mL, and also 100 mL (Dose Dependent) and 200 mL bottles (2 bottles/L), No. only, and NDC 00889-024-01, 00889-024-02, 00889-024-03	
Manufacturer:	VitalPharm, Inc., Largo, FL
Recalled by:	Manufacturer, by letter on April 6, 2008. Firm initiated recall in progress.
Recall date:	Manufacturer, 4/7/08 and oral suspension, 2/24/08.
Reason:	The product is not labeled in that the expiration date listed exceeds the current expiration date duration that is approved.
Recall number:	01-022-2008
Aspenex (Dexamethasone HCl) Inhalation Solution	
1.25 mg/5 mL, sterile unit-dose vials	
Manufacturer:	Cardinal Pharma Solutions, LLC, Woodstock, IL
Recalled by:	Supplier, Inc., Marlborough, MA, by e-mail on May 1, 2008. Firm initiated recall in progress.
Recall date:	06/17/2008 units.
Reason:	Incorrect expiration date.
Recall number:	01-022-2008

FDA Recalls

- Impurity testing
 - Pharmaceutics
 - Sterile compounding
- Stability testing
- Expiration date
 - Pharmaceutics
 - Compounding
- How do pharmaceutical manufacturers test for/prevent impurities
- How do compounding pharmacists test for/prevent impurities

FDA Recalls

FDA Recalls June 3, 2009

Furosemide Tablets
USP, 40 mg, 1000 tablets, Rx only, 0781-1966-10.
Manufacturer: Sandoz, Inc., Broomfield, CO.
Recalled by: Sandoz, Inc., Princeton, NJ, by letter on April 10, 2009. Firm-initiated recall is complete.
Distribution: Nationwide; 5773/1000-tablet bottles.
Reason: Furosemide tablets were out of specification for tablet thickness and potency.
Recall number: D-423-2009.

EDITORS' NOTE: Tabulation prepared from information provided by FDA. The agency has three classes of recall. Class I - violative product poses reasonable probability of serious adverse health consequences or death; Class II - violative product may cause temporary or medically reversible adverse health consequences; probability of serious consequences remote; Class III - violative product not likely to cause adverse health consequences. Editors of "The Pink Sheet" appreciate hearing from any company that would like to provide additional information on any recall listed in a weekly tabulation.

FDA Recalls

- Pharmaceuticals
 - Manufacturing of Tablets
 - Thickness
 - Potency
 - Bioequivalence
- How are tablets tested for potency?

FDA: Advertising

Numbers Don't Lie: Update on Claims of False and Misleading Advertising

In preparing for its 14th Drug Advertising Conference, the FDA announced its latest review and analysis from FDA's Division of Drug Marketing, Advertising and Communications, along with OIG's review and past year activities and resources for advertising enforcement ("The Pink Sheet," May 12, 2009, at 16). Speaking at a June 10 meeting of the Drug Information Association annual meeting in San Diego, DRMAC Director Thomas Altman gave an update of the division and enforcement activities from June 2008 through May 2009.

Advertising Claims

- OIGMC issued a total of 40 enforcement letters: 13 Warning Letters and 27 untitled letters
- 14 of those letters addressed sponsored link promotional pieces ("The Pink Sheet," April 13, 2009, p. 32)
- 23 of the letters addressed DTG ads

Drug Information

- Promotion and dissemination of the information
- Promotion of unapproved uses and branding the indication of drugs
- Misleading efficacy claims
- Failure to submit on form FDA 2024

Drug Information Policy Updates

- Increased number of DTG reviewers from six to 12
- Added another DTG review group
- Held 18 reviews in 2008
- Increased the number of social scientists from two to three
- Added two new functions: product management (brand law project manager), and social scientist to the division

Drug Claims by Drug

- Three lawyers, to bring total counsels up to four
- One new social scientist
- A technical compliance assistant secretary

Advertising

- Drug Information
- Ethics
- Law
- Public Health

FDA: Compounding

FDA Takes Action against Compounded BHRT Drugs

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms "bio-identical hormone replacement therapy" and "BHRT" to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of "bio-identical" as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html.

Compounding

- Pharmaceutics
- Ethics
- Law

FDA: Safety, Labeling Changes

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at www.fda.gov/cder/dsn/default.htm and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at www.fda.gov/medwatch/safety.htm.

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FDA: Drug Safety

Acetaminophen May Get Pulled From Rx Combo Products After Narrow Vote

FDA will have to balance the goal of preventing liver injury with concerns about access to treatment and accurate abuse as it weighs whether to implement a limit on acetaminophen's active ingredient in combination products.

The recommendation would effectively move drugs like Abbot's *Wendol* (acetaminophen, hydrocodone), *Elderly's* *Pain Relief* (acetaminophen, codeine) and their generic equivalents from Schedule 2 to Schedule 3 controlled substance status, triggering the attendant prescribing limits for them.

But the June 30th vote - in which 10 members highly recommended acetaminophen's removal, 10 recommended its removal, and 17 did not recommend its removal - could have many unintended consequences, some of which include increased abuse potential, physician prescribing difficulty and whether such Schedule 3 drugs would join the ranks of products awaiting an opioid Risk Evaluation and Mitigation Strategy.

"It's very easy to see how this would take care of the liver problem, but we're trying to get a sense of what the ripple effect will be associated with regulations," said Sandra Kessler, Deputy Director, Office of New Drugs.

FDA convened three committees - the Drug Safety and Risk Management, the Nonprescription Drugs and the Anesthetic and Life Support Drugs panels - to address liver toxicity associated with acetaminophen in prescription and over-the-counter products.

For Rx products, one universal concern of the members was the drug's potential for increased abuse if restricted from acetaminophen.

"We're talking about the fact that half of all the unintentional overdoses in the country occur due to prescription types of acetaminophen products," said Neil Parhar, University of California, San Diego. "So we're talking about a quarter of all the overdoses happening in a year because of this."

"It would be concerned that if we force everyone into pure narcotics, that there would be an abuse issue," agreed Neal Benowitz, University of California, San Francisco.

Is This a Job For Risk Management?

To be sure, Kessler noted that it's not entirely clear at this point whether FDA will include Schedule 3 opioids in its forthcoming REMS ("The Pink Sheet," June 8, 2009).

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Drug Safety

- Pharmacology
 - ADR, ADE
 - Hepatotoxicity
- Medicinal Chemistry
 - Hepatotoxicity
- Pharmaceutics
 - Drug approval, post-marketing surveillance

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Prescriptions

- Law
- Ethics

FDA and News

FDA Study Suggests Consumers are Seeking More Choice for Avoiding the Pill
FDA recently announced the results of a year-long investigation, which suggests that consumers are buying drugs online to avoid the need for prescriptions. The investigation, involving information collected from September 2006 through August 2007, found that consumers are buying generic drugs from online sources. The study found that 12% of the generic drugs purchased online were not available in the U.S. The study also found that 12% of the generic drugs purchased online were not available in the U.S. The study also found that 12% of the generic drugs purchased online were not available in the U.S.

FDA Finds Consumers Still Buying Potentially Fake Medications via Internet
FDA continues to warn the American public about the danger of buying medications from the Internet. ...

Death in Canada Tied to Counterfeit Drugs
A Canadian man died after taking counterfeit drugs purchased on the Internet. ...

Study Shows Consumers Still Buying Potentially Fake Medications via Internet
FDA continues to warn the American public about the danger of buying medications from the Internet. ...

Discussion: Student Codes of Conduct

- Are Code provisions tied to mission of institution?
- Are there mechanisms in place for Students to report Code violations?

**Discussion:
Admissions Process & Interviews**

- What is involved in your process?
- Who conducts the interviews?
- When are they done?
- Common policies/procedures?
- Most problematic issues

**Discussion Topics:
Student Background Checks**

- How many schools are using them?
- What is involved in the process?
- When are they done?
- Who pays for them? How much are they?
- Common policies?
- Most problematic issues

**Discussion:
Random Drug Tests**

- How many schools are using them?
- What is involved in the process?
- When are they done?
- Who pays for them? How much are they?
- Common policies?
- Most problematic issues

Discussion

– What are sources you can use for real life forensic cases for your topics?

Discussion

– Other Questions?
