

UCI School of Pharmacy &
Pharmaceutical Sciences

Pharmacy Law and Ethics

Lecture #9

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Opioid Litigation Follow up



Johnson & Johnson has [finalized a \\$26 billion settlement](#) with three of the largest drug distributors in the country to resolve thousands of lawsuits over their roles in the opioid epidemic. The settlement seeks to resolve around 3,000 cases filed by state and local governments, blaming the companies for flooding communities with opioid pain medications while ignoring warning signs that the drugs were being abused and illegally trafficked. Under the terms of the agreement, McKesson Corp, AmerisourceBergen Corp, and Cardinal Health Inc will [pay up \\$21 billion over the next 18 years](#), while Johnson & Johnson will contribute \$5 billion over nine years. An additional \$2.3 billion will be set aside to cover legal fees. The money will be used to fund treatment programs and other initiatives to address the opioid epidemic. "Billions of dollars are now going to flow to treatment, recovery, education, and abating this public health crisis," [said Paul Geller, a lawyer for local governments at Robbins Geller Rudman & Dowd, according to Reuters](#). Several states have refused to accept the agreement, including Alabama, Oklahoma, Washington, and West Virginia. Officials in New Hampshire have not come to an agreement with Johnson & Johnson to settle their lawsuit. Those states can sign onto the settlement at a later date or continue to pursue their claims in court.

THE OPIOID LITIGATION

MDL "TRACK 1" OFFERS & AG-WON SETTLEMENTS: 2015-2019

Two lines of litigation, both alike in dignity /
In this fair infographic, where we lay our scene
- Shakespeare, *Romeo & Juliet*, Act 1, prologue (adapted)

CITY, COUNTY, TRIBAL GOVERNMENTS

are the plaintiffs in the multi-district litigation (MDL) in federal court

the **BIG PHARMA DEFENDANTS** frequently sued in both federal and state lines of opioid litigation:

AmerisourceBergen Johnson & Johnson
Cardinal Health McKesson
Endo (generics) Teva
Henry Schein Walgreens

A **GLOBAL SETTLEMENT** would allow big pharma defendants to settle out of their federal and state court opioid suits. Because states continue to fail to spend their big tobacco litigation proceeds wisely, city, county, and tribal governments in the opioid litigation fight for inclusion in global settlement discussions to ensure their access to abatement funds.

STATE GOVERNMENTS

are the plaintiffs in those state Attorney General (AG)-led suits in state courts

Jan 2017 **West Virginia** settles w/ *Cardinal Health*: \$20m, *AmerisourceBergen*: \$16m

Dec 2015 **Kentucky** settles w/ *Purdue*: \$24 m



12/12/2017 Judicial Panel on Multidistrict Litigation transfers MDL 2804 — *In Re National Prescription Opioid Litigation* — to Judge Polster's federal court in the Northern District of Ohio



4/11/2018 Judge Polster schedules **bellwether trial** date for "Track 1" plaintiffs

A **bellwether trial** is a "nonbinding trial [of] issues representative of the common claims in a larger mass-tort proceeding, held to determine the merits of the claims and the strength of the parties' positions on the issues" (*Black's Law Dictionary*).

3/6/2018 Judge Polster creates "litigation track" to run in tandem to settlement negotiations, facilitate **global settlement**

10/1 *Johnson & Johnson* offers \$20.4 m
9/11 Judge Polster certifies "**negotiation class**" of 34,500 cities, counties to encourage **global settlement**
9/8 *Mallinckrodt* offers \$30m
8/30 *Allergan* offers \$5m
8/20 *Endo* offers \$10m to settle out of 10/21 bellwether trial



10/21 **Judge Polster postpones bellwether trial** for remaining defendant *Walgreens*

AmerisourceBergen, *Cardinal Health*, *McKesson*, and *Teva* offer \$260 m to settle with bellwether plaintiffs just a few hours before opening statements were to begin. *Henry Schein* makes offer to Summit County only (not named in Cuyahoga suit).

9/15 *Purdue* files for bankruptcy, offers ~\$12 billion if treated as a **global settlement**



10/21 \$48 billion **global settlement framework** proposed by North Carolina, Pennsylvania, Texas, and Tennessee AGs. The deal would apportion 15% of funds to local governments. As of press time, just less than half of state AGs are on board.

39 state AGs oppose the negotiation class as an intrusion on state sovereignty



26 state AGs—most Democrats—oppose *Purdue*'s offer and would rather seek recompense via bankruptcy proceedings

10/10 **Ohio AG's** request to delay federal MDL denied by fed. appeals ct.



5/26 **Oklahoma** settles w/ *Teva*: \$85m

5/2 **West Virginia** settles w/ *McKesson*: \$16m

3/26 **Oklahoma** settles w/ *Purdue*: \$270m

8/26 **Oklahoma** wins trial against *Johnson & Johnson*: \$465m



2015

2016

2017

2018

January

February

March

April

May

June

July

August

September

October

The Pharmacist-in-Charge

The Pharmacist in Charge (PIC) Duties

Responsibilities & Expectations

- B&P § 4036.5: “Pharmacist-in-charge” means a (1) pharmacist (2) proposed by a pharmacy and (3) approved by the board as the supervisor or manager responsible for ensuring the pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy
- CCR § 1715: P.I.C. must complete a self-assessment of Pharmacy’s compliance with Federal and State Pharmacy law.
The primary purpose of the self-assessment is to promote compliance through self-examination & education

The Pharmacist-in-charge (PIC) - Benefits vs. Risks

- Benefits:
 - Every pharmacy must have one
 - A chance to control your professional destiny
 - Job security
 - Self protection
 - Broadens your practice
- Risks:
 - Personal liability
 - Regulatory compliance
 - Oversight capabilities
 - Uncooperative ownership
 - Business goals > Patient Safety Goals

The Pharmacist in Charge (PIC) Duties

- Legal Protections

B&P § 4081: for recordkeeping, the PIC shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the PIC had no knowledge, or in which she did not knowingly participate

B&P § 4330: Any pharmacy owner who subverts or tend to subvert the efforts of the PIC to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor

CCR § 1709.1(b): The pharmacy owner shall vest the PIC with adequate authority to assure compliance with the laws governing the operation of a pharmacy

The Pharmacist in Charge (PIC) Duties (cont)

- Legal Protections (cont)

CCR § 1709.1(c): A pharmacist may be the PIC for two pharmacies, so long as they are not farther than 50 miles driving distance from each other

But, § 1709.1(f): A pharmacist may refuse to be the PIC at a second pharmacy if she/he determines, in the exercise of her/his professional judgment, that assuming responsibility for the second pharmacy would interfere with the effective performance of her/his responsibilities under the Pharmacy Law

Furthermore, § 1709.1(g): The employer may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section

The Pharmacist in Charge (PIC) Duties (cont)

- Legal Protections

B&P § 4306.6: If the board disciplines a PIC for violating state/federal law or regulation that was committed by another, and the PIC reported that violation to the board, the board will then use the report as a mitigating factor if ALL of the following conditions are met:

- a) PIC did not engage, either directly or indirectly, in any conduct that violated any law or regulation pertaining to the practice of pharmacy
- b) PIC did not permit, encourage, approve of, either tacitly or implicitly or through willful ignorance, any conduct committed by another person that violated the law
- c) PIC reported the violation or suspected violation to the board as soon as reasonably possible following the discovery of the violation
- d) PIC took all actions reasonably necessary to stop and remedy the violation or suspected violation, as soon as reasonably possible following the discovery of the violation

Case Study

- You take a new position as the PIC at a busy independent home infusion pharmacy
- The owner is a pharmacy technician who is financed by his family to own and operate the pharmacy
- The owner makes it clear that all of the business aspects of the pharmacy are to be done by him and your responsibility as PIC is to take care of patients and provide excellent clinical care
- The pharmacy is Joint Commission Accredited and the owner has made it clear that he will deal with the accrediting organization and as PIC it is not your job responsibility to be involved
- You are aware that there are a number of lawsuits that the pharmacy is engaged in with insurance companies but since you haven't been called as a witness or named as a party, the owner says you shouldn't be concerned

Case Study

- Patients complain to your home care nurses that they are upset by the billing practices of the pharmacy
- The owner tells you to stay out of the business side of the pharmacy and to stay in your own lane (clinical only)
- What should you do to protect your license?

Risk Mitigation for PICs when there is a violation

- Is the violation related to record keeping requirements?
- Is the PIC unable to identify the dispensing pharmacist?
- Is there a lack of security?
- Is there a disregard for pharmacy law?
- What should a PIC do with a noncompliant situation
 - Report to Management
 - Demand remediation
 - Quit if unsatisfied
 - Document the situation upon leaving (departing inventory)
 - Report violations to the Board of Pharmacy identifying yourself as the PIC

Precedential Case

Sternberg and PIC responsibility Discussion

- Facts:
 - During Sternberg's tenure as a PIC at a Woodland Hills Target Pharmacy, a technician stole at least 216,000 Norco tablets (hydrocodone/APAP) by throwing out purchase records and committing theft
 - Sternberg had no prior history of discipline
 - Sternberg discovered a bottle of Norco in the storeroom, and given he knew the pharmacy rarely dispensed Norco, he immediately reported it to his next level manager
 - Surveillance caught the technician in the act of receiving an order of Norco
 - Sternberg was still held responsible and his license was revoked, the revocation stayed and then put on probation, he appealed and he lost

Sternberg and PIC responsibility Discussion

- Legal Basis for Discipline:
 - Failure to maintain complete and accurate inventory records for 3 years
 - Allowing a technician to sign for an order
 - Failure to properly supervise and secure facilities
 - Failure to provide effective controls
- Do you agree with the decision upon appeal?
- What would you do differently if you were the PIC?

Sternberg and PIC responsibility Discussion

- What happens if the violations of pharmacy law occur over a long period of time?
- What happens if the violations of pharmacy law potentially involve many pharmacists over a period of years?
- What happens if both PICs and staff pharmacists come and go in their employment at the pharmacy during the time the violation is occurring?
- What happens if the PIC can't tell which pharmacists were involved with the prescriptions violating pharmacy law?
- What happens if the PIC regularly conducts staff meetings regarding compliance with pharmacy laws? What happens if they happen but aren't documented?
- Does it matter that there is no other history of pharmacy law violations?

Case Study

- You are the PIC for a large university teaching hospital inpatient pharmacy
- The hospital is having severe financial restrictions and your budgeted items for pharmacy regulatory compliance staff was denied by the hospital administrator
- You meet with the hospital leadership team which is chaired by a nurse but includes the medical team, housekeeping, facilities management and other departments
- You have put forth a list of deficiencies for the pharmacy department concerning staffing, pharmacy security, recordkeeping, automation and others
 - The leadership team tells you to hold off on remediation efforts until the next fiscal year
- The hospital won't go through Joint Commission Accreditation for two more years
- Hospital licensure is governed by California Code of Regulations Title 22

Case Study

- The leadership team knows that the new biologic drugs coming to the market and dispensed from the hospital pharmacy cause a very large part of their budget constraints and beseech you to tighten those expenses
- The California Department of Health Care Services gives notice that it will audit the hospital including the pharmacy for compliance with Title 22 regulations which governs hospital licensure in California
- The audit reveals a significant number of deficiencies in the pharmacy department—the same ones noted in your earlier budget requests
- The hospital administration enters into a corrective action plan with the Department of Health Care Services and dismisses its pharmacy leaders including the PIC—New leadership is brought in to bring the facility into compliance with Title 22
- What lessons come from this case study?

Case Study: Self Assessment Retention

- You are the veteran PIC of a busy 24 hour pharmacy in Rancho Cucamonga.
- You are greeted on a busy Monday morning by what seems like a new California Board of Pharmacy Inspector who tells you he is there to visit your pharmacy.
- The inspector asks you for the last ten years of PIC self inspection forms.
- What would you do?
- Do inspectors ever get it wrong?

Pharmacist in Charge Designation and Termination

1709.1 Designation of Pharmacist in Charge

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy

(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.

The Keys to the Pharmacy

- The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy
- Must be maintained in a tamper evident container for the purpose of:
 - 1) delivering the key to a pharmacist
 - 2) providing access in case of emergency.
- An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.



PIC Self Assessment

COMMUNITY PHARMACY SELF-ASSESSMENT/ HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

https://www.pharmacy.ca.gov/forms/17m_13_2021.pdf

PIC Self Assessment

HOSPITAL PHARMACY SELF-ASSESSMENT

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https://www.pharmacy.ca.gov/forms/17m_14_2021.pdf

PIC Self Assessment

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

https://www.pharmacy.ca.gov/forms/17m_39_2021.pdf

How long do self inspections need to be kept on file?

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, this Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. 1/21). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Case Study

- You are the PIC of a busy pharmacy that specializes in pain management therapies
- On a cold, sad and rainy morning you arrive to your pharmacy where you find that your technician is slurring her speech and behaving oddly
- Upon questioning her about this, she tells you that she is an alcoholic and had too much gin and juice that morning
- She also admits to have just taken carisoprodol (Soma) from the pharmacy shelf for her sore left shoulder
- What do you need to do?
- What does your pharmacy need to address this scenario?

Pharmacist in Charge Designation and Termination

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B&P § 4101 Termination of Pharmacist in Charge

Any PIC who ceases to act as the PIC shall notify the board in writing within 30 days of the date of that change in status

Licensed Employees: Theft or Impairment

4104. Licensed Employee, Theft or Impairment: Pharmacy Procedures

(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

Licensed Employees: Theft or Impairment

4104. Licensed Employee, Theft or Impairment: Pharmacy Procedures

- c) Every pharmacy shall report and provide to the board, within 14 days of the receipt or development thereof the following information with regard to any licensed individual employed by or with the pharmacy:
 - 1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.
 - 2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.
 - 3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
 - 4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.
 - 5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
 - 6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.
- d) The report required in subdivision (c) shall include sufficient detail to inform the board of the facts upon which the report is based, including an estimate of the type and quantity of all dangerous drugs involved, the timeframe over which the losses are suspected, and the date of the last controlled substances inventory. Upon request of the board, the pharmacy shall prepare and submit an audit involving the dangerous drugs suspected to be missing.
- e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

Receiving an Order from a Wholesaler

4059.5. Who May Order Dangerous Drugs or Devices: Exceptions; Compliance With Laws of All Involved Jurisdictions

- a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist

Limited Exceptions and Caveats:

- Hospital Pharmacy (central receiving area) - Must be received by the hospital pharmacy within one working day
- Secure storage facility in the same building as the pharmacy – Access by PIC or designated pharmacist only
- Remote dispensing site pharmacy – May be signed and received by a pharmacy technician, controlled substance orders need to be separated and countersigned by a pharmacist

Can a PIC leave a pharmacy for a lunch or a break if the PIC is the only pharmacist present in the pharmacy?

1714.1. Pharmacy Operations during the Temporary Absence of a Pharmacist.

(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

(b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

(c) During such times that the pharmacist is temporarily absent from the pharmacy, the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(d) During the temporary absence of a pharmacist as authorized by this section, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist.

(e) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial Welfare Commission, and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.

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Case Study

Fred is a PIC for a community pharmacy and has always managed his resource costs by hiring “intern talent” instead of additional pharmacists

Fred hires you and 3 other interns from UCI to work the 9-5 shift 5 days a week M-F. During these shifts he is the only pharmacist he has on schedule

Fred also allows the interns to check each other’s work as a final prescription check, believing this method is better to train the interns for real life

Fred also allows his interns to take new phone in prescriptions during his daily 30 minute lunch break at Taco Bell

He runs the pharmacy on his own on Saturdays and the pharmacy is closed on Sundays when he golfs

What should you do as his intern?

PIC Preparedness

Pharmacy Compliance Manual/ Box

Contents

- Completed Pharmacist Self-Assessment(s)
- Copies of pharmacist and pharmacy technician licenses
- Master list of pharmacist and pharmacy technician initials/signatures
- Power of Attorney for DEA 222 Form
- Drug Invoices (CII separated)
- Biennial Controlled Substance Inventory
- Inventory reconciliation reports
- Executed DEA 222 Forms or CSOS reconciliation
- DEA 106 Forms for Loss/Theft (report to BOP)
- **Policies and procedures**

Pharmacy Compliance Manual/ Box (cont)

Policies and procedures:

- QA for medication errors and records of past errors
- Impairment and Theft (14 days)
- Immunizations
- Protocols for timely access when licensee refuses to fill (ethical, moral, religious grounds)
- Drug Take Back program
- Automated dispensing machine use
- Assisting patients with low English proficiency – interpretive service provider/access codes

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