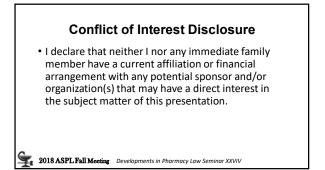
Pharmacy Student Preparation for Compliance with Pharmacy Laws and Regulations

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American Society for Pharmacy Law elopments in Pharmacy Law Seminar XXVIV 2018 ASPL Fall Meeting - November 1-4, 2018 Hilton Head Marriott Resort & Spa - Hilton Head Island, SC



Learning Objectives

- · At the completion of this activity, the participant will be able to:
 - Identify methods of preparing students for the California Pharmacy Jurisprudence Exam (CPJE)
 - Understand the CPJE pass and fail rates of newly graduated pharmacist applicants
 - Recognize areas of weakness in regulatory compliance among new practitioners that are likely to result in exam questions

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Assessment Questions

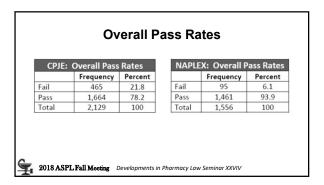
- 1. The CPJE includes True/False questions as part of the exam. • True or False?
- 2. This CPJE questions often involve complex clinical situations where which one of the following is true:
 - a. The correct answers clearly state a conclusion of pharmacy
 - b. The correct answers are the solutions that best address the clinical fact situation
 - c. The correct answers directly address the validity of the prescription

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Observations by California Board of Pharmacy

- Many new pharmacists have difficulty understanding pharmacy regulatory compliance requirements
- Jurisprudence exam changes are in response to lack of preparation in many areas
- Most recent pass rates measured April 2018 through September 2018: CPJE pass rate is 78.2%

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| 5 – Year Comparison of CPJE and NAPLEX Pass Rates (Percentage) | | | | | |
|---|------|------|--------|-----|--|
| | | PJE | NAPLEX | | |
| | Fail | Pass | Fail | Pas | |
| April 2013 – Mar. 2014 | 19.9 | 80.1 | 4.5 | 95. | |
| April 2014 – Mar. 2015 | 21.3 | 78.7 | 4.3 | 95. | |
| April 2015 – Mar. 2016 | 21.6 | 78.4 | 5.8 | 94. | |
| *April 2016 – Mar. 2017 | 34.6 | 65.4 | 10.1 | 89. | |
| April 2017 - Mar. 2018 | 29.7 | 70.3 | 7.9 | 92. | |

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|-----------------|------------|---------------------------|-------------|-------------|-------------------|
| | | | CJPE P/F | | |
| | | | F | Р | Total |
| | California | Count | 111 | 965 | 1076 |
| | | % within school | 10.3% | 89.7% | 100.0% |
| | Other US | Count | 310 | 628 | 938 |
| | | | | | |
| | | % within school | 33.0% | 67.0% | 100.0% |
| | Foreign | % within school Count | 33.0% 44 | 67.0% 71 | 100.0% |
| 5.00 | Foreign | | | | |
| Total | Foreign | Count | 44 | 71 | 115 |

Licensing Exam and New Licensee Regulatory **Compliance Readiness**

 Instruction to pharmacy law prior to or at the beginning of pharmacist internship Best to have a basic understanding of pharmacy law to begin internship

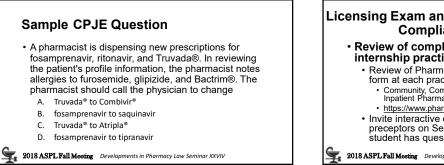
Drug Recognition

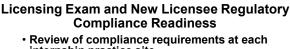
- Top 200 drugs by both brand and generic names
- Specialty drugs (biologics) by both brand and
- generic names
- Vaccines
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Sample CPJE Question

- Which of the following auxiliary labels belongs on a bottle of Vivotif Berna®?
 - A. "Refrigerate"
 - B. "For external use only"
 - C. "Avoid sunlight"
 - D. "Shake well"

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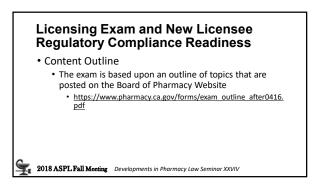




Review of Pharmacist in Charge Self Assessment form at each practice site

- - Community, Compounding, Hospital Outpatient and Inpatient Pharmacies and Wholesaler self assessments
 https://www.pharmacy.ca.gov/forms/17m_13.pdf
- Invite interactive discussion with internship preceptors on Self Assessment issues where the student has questions
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| | xam and New Licensee Compliance Readiness |
|------------------------|--|
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| | COMMUNITY PHARMACY BELF-ASSESSMENT |
| | HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT |
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Licensing Exam and New Licensee Regulatory Compliance Readiness

- CPJE questions involve clinical situations seeking the best answer given complex facts
 - No "True/False" questions
 - No "Is this legal?" questions
 - Answers do not directly address validity of the prescription but instead invite best solution to the question

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Sample CPJE Question A 37-year-old patient with schizophrenia has been treated with clozapine 500 mg daily for the past 4 months. The patient has the following past CBC results: Neutrophils WBC June 30 10.1 7.3 June 22 10.7 7.4 June 16 6.5 3.5 June 9 6.3 3.4 June 2 6.7 3.8 On July 7, the patient's WBC is 7.2 and neutrophils are 4.3. The MOST appropriate recommendation for the pharmacist to make is to:

| Α. | continue current therapy. |
|----|--|
| в. | discontinue therapy. |
| C. | hold therapy for 1 week and resume at 400 mg daily |
| D. | repeat CBC and fill if WBC is greater than 8 |

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The CPJE Tests the Application of Law to General Pharmacy Practice

• Students who focus on a specific area of pharmacy practice in their internship sites may be at a disadvantage since the law questions tend to be varied as to areas of practice

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CPJE Composition

- The exam writers are not Identified but Represent Academia and Advanced Areas of Practice
- The questions tend to change reflecting the types of cases coming before the Board of Pharmacy
- Common question themes are evolving to include:
 Corresponding responsibility and Controlled Substance Dispensing
 - Opioid Therapy in general
 - Compounding of drugs and requisite record keeping

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Next Exam Revisions

 Currently going through changes to assess exam effectiveness and testing of themes important to readiness for the challenges of current practice
 May impact the 2019 or 2020 exams

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Discussion

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Assessment Questions – Answers

- The CPJE includes True/False questions as part of the exam.
 True or False?
- 2. This CPJE questions often involve complex clinical situations where which one of the following is true:
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