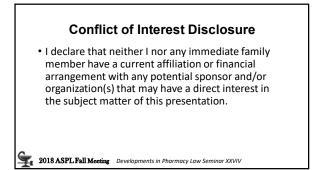
#### **Pharmacy Student Preparation for Compliance** with Pharmacy Laws and Regulations

John D. Jones, RPh, JD

Adjunct Faculty, University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences

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

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

#### Assessment Questions

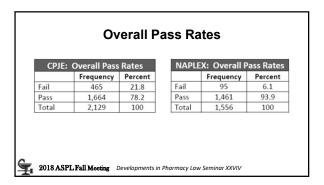
- 1. The CPJE includes True/False questions as part of the exam. • True or False?
- 2. This CPJE questions often involve complex clinical situations where which one of the following is true:
  - a. The correct answers clearly state a conclusion of pharmacy
  - b. The correct answers are the solutions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

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

#### **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%

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV



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.	

te sc of out	hools	of pharma te or foreig	cy pass r	ates	DN higher thar
			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

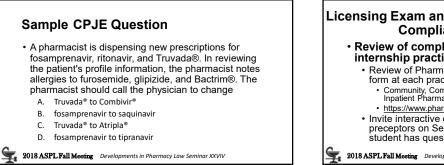
#### Drug Recognition

- Top 200 drugs by both brand and generic names
- Specialty drugs (biologics) by both brand and
- generic names
- Vaccines
- 2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

#### 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"

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

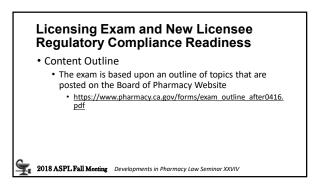




# Review of Pharmacist in Charge Self Assessment form at each practice site

- - Community, Compounding, Hospital Outpatient and Inpatient Pharmacies and Wholesaler self assessments
    <a href="https://www.pharmacy.ca.gov/forms/17m\_13.pdf">https://www.pharmacy.ca.gov/forms/17m\_13.pdf</a>
- Invite interactive discussion with internship preceptors on Self Assessment issues where the student has questions
- 2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

	xam and New Licensee Compliance Readiness
	Collevel, State Roard of Rearings: Science State Stat
	COMMUNITY PHARMACY BELF-ASSESSMENT
	HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT
	The total of collection that of features was total 10 in terms the determinant on unique of and a dimension of the beam at order services of 10 and 10 min terms can be attentions of the constraints and the attention of the services of 10 and or end or end or the transmission of the attention of the services of the determinant of the attention of the attention of the attention of the services of the attention of the attention of the attention of the attention of the services of the attention of the attention of the attention of the attention of the attention of the attention of the attention of the attention of the attention of the attention of the attention of the attention of the attention of the attention on the attention of the attention. The attention of the attention of the attention on the attention of the attention of the attention of the attention of the attention on the attention of the attention.
	The self-assessment must be sempleized in this article), and may be completed unline, printed and networks? In the pharmary, (In red may a secondary, a
	presents a los de la construcción de presentes conservantes de la conservante de la
	(ad) all associate track in last at them the plantacy for three years after 1.5 performed.
	Ruman Rane
	Adres Pass
	Description Interfaces D Partnerskip, D Corporation D LLC D too Interfaces of Miner Splace quark( D)
	hend # Be fee One feets Its bes
	Liken and Monte Compounding Period #
	Annalisative (anticed) from the
	(då fegdraster # (bg. (det (bet af BCA travenaria
	Nazy Western Int Int Int Int
•	
2018 ASPL Fall Meeting	Developments in Pharmacy Law Seminar XXVIV



#### 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

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

#### 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

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

## 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

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

#### **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

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

#### 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

2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV

### Discussion

2017 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIII

#### **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:
  - a. The correct answers clearly state a conclusion of pharmacy law
  - 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
- 2018 ASPL Fall Meeting Developments in Pharmacy Law Seminar XXVIV