



# 2016 ASPL Fall Meeting Hilton Austin - Austin, TX November 10-13, 2016



## *Developments in Pharmacy Law Seminar XXVII*

ASPL is a nonprofit professional association for individuals with an interest in legal issues as they pertain to pharmacy, pharmaceuticals and related products and services. The ASPL annual seminar brings together over 250 industry professionals to share the most up-to-date, relevant and practical information.

### ***Seminar goals include:***

- Educate attendees on current and relevant information on wide-ranging pharmacy law issues.
- Provide pharmacy law educators with learning opportunities on the latest teaching methodologies and course curriculums relevant to pharmacy law education.
- Assist attendees with continuing education requirements through a program comprised of speakers and topics that offer 15-17 hours of continuing legal and pharmacy education credits to pharmacists, attorneys, pharmacist-attorneys and pharmacy-law educators.

**Register Today at [www.aspl.org](http://www.aspl.org)**



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## Developments in Pharmacy Law Seminar XXVII

### Accommodations:

A block of rooms at a discounted rate has been reserved for the ASPL Seminar at the Hilton Austin. The hotel is located at 500 East 4th Street. The discounted room rate is \$189 per night plus tax as long as you make your reservation by October 16, 2016.

Make your reservation by calling the hotel at 1-800-236-1592 or [online](#). If calling, be sure to identify that you are with the ASPL meeting so that you get the group rate.

### Travel:

#### Air Transportation:

The Hilton Austin is conveniently located 7 miles from the Austin-Bergstrom International Airport (AUS).

#### Ground Transportation:

**Rental car:** 10+ national chains service the Austin-Bergstrom International Airport. For a listing and contact information, [click here](#).

**Taxi:** Taxis are available curbside, outside baggage claim. Approximate cost is \$30 (plus gratuity) each way.


**Shuttle:** SuperShuttle "Shared Ride" or ExecuCar "Private Sedan/SUV." Make reservations at [www.SuperShuttle.com](http://www.SuperShuttle.com) or [www.ExecuCar.com](http://www.ExecuCar.com) use code HILTN for a 5% discount off published online fare.



### ACPE Continuing Education Credits

Participants may earn up to 15 contact hours (1.5 continuing education units) of Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) credit. Sessions approved for CPE credit are listed with an ACPE universal activity number and number of continuing education units. To receive credit for successful completion for any activity, the participant must complete an attendance form and an activity evaluation form at the conclusion of the program. Verification of participation will be reported to the CPE tracking service, CPE Monitor, within 4 weeks after the program, and will then be accessible to participants at [MyCPEMonitor.net](http://MyCPEMonitor.net).

You will need your NABP e-profile ID to note on your CE form so that it may be reported to CPE Monitor. If you have not yet obtained your NABP e-Profile ID, you may do so by visiting [MyCPEMonitor.net](http://MyCPEMonitor.net), creating an e-Profile, and registering for CPE Monitor. Be sure to register for CPE Monitor to ensure that your e-Profile ID is fully activated.

The Washington State University  College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

**CPE now requires that all pharmacy continuing education (CE) credits must be processed and claimed no later than 60 days from the date of the live activity.**



### Continuing Legal Education Credits

If you intend to apply for continuing legal education credits, please be sure to indicate the state (or states) in which you are licensed and the corresponding license number(s) on the conference registration form. Quarles & Brady, LLP will process the CLE credits for the Developments in Pharmacy Law Seminar.



**Continuing Legal Education credit will be applied for based on attendee return of the "Continuing Legal Education Credit Certificate of Attendance Form" at the conclusion of the seminar.**

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# 2016 ASPL Fall Meeting

## Hilton Austin - Austin, TX

### November 10-13, 2016

## Developments in Pharmacy Law Seminar XXVII

### Thursday, November 10, 2016

- 9:00 a.m. to 5:00 p.m. **ASPL Board Meeting**
- 3:00 p.m. to 5:00 p.m. **Registration Open**
- 5:30 p.m. to 7:00 p.m. **ASPL Opening Reception**

### Friday, November 11, 2016

- 7:00 a.m. to 5:00 p.m. **Registration Open**
- 7:00 a.m. to 8:00 a.m. **Breakfast**
- 8:00 a.m. to 8:30 a.m. **Opening Welcome, Installation of 2017 Officers and Board of Directors**

8:30 a.m. to 9:30 a.m.

#### **Legislative and Regulatory Update**

0071-9999-16-013-L03-P (1.0 credit hours, 0.10 CEU)

The Legislative and Regulatory Update provides conference attendees with a general overview of current laws and regulations impacting pharmacists and national pharmacies. The event will occur immediately following the election so will provide a preview of what to expect in 2017. The speaker for this session has extensive experience in pharmacy legislation and regulations and currently works for organizations that represent community/retail pharmacists and managed care pharmacists. This will give attendees a broad-based perspective.

*Mary Jo Carden, RPh, JD, Academy of Managed Care Pharmacy*

9:30 a.m. to 10:30 a.m.

#### **Medication on Demand - Online Drug Sellers: A Discussion of Legal and Patient Safety Issues**

0071-9999-16-014-L03-P (1.0 credit hours, 0.10 CEU)

One in four Americans buy medicines online according to the US FDA, yet NABP has found 96% of the websites peddling medicine are operating out of compliance with US laws and pharmacy practice standards. These sites often sell counterfeit, unapproved and otherwise illegal medicines to patients, operate without the required pharmacy license, and sell prescription medicines without a prescription. And though WHO reports 50% of the medicines sold online are counterfeit, sadly only 12% of Americans are aware of the threat of counterfeits according to a recent survey sponsored by Sanofi. Speakers will address legal issues related to the operation of pharmacy websites, share new data on Internet pharmacy trends, and offer tips and tools to protect patients online, including the recent launch of the .pharmacy top-level domain.

*Marty Allain, JD, National Association of Boards of Pharmacy; Libby Baney, JD, FaegreBD Consulting; John Hertig, PharmD, MS, CPPS, Purdue University College of Pharmacy*

10:30 a.m. to 10:45 a.m. **Break**

10:45 a.m. to 11:45 a.m.

#### **Preventative Medicine: Conducting a Pharmacy Compliance Checkup**

0071-9999-16-015-L03-P (1.0 credit hours, 0.10 CEU)

Pharmacy operations are subject to increasing scrutiny from federal and state regulators. In response to the growth in prescription drug abuse, enforcement authorities and legislators have strengthened efforts to prevent the abuse and diversion of controlled substances and to enforce compliance with the myriad federal and state laws and regulations that impact the distribution, prescribing, dispensing and disposal of these drugs. This program will outline the proactive steps pharmacies can take to evaluate their operations and identify areas of potential compliance risk so that issues can be addressed before they result in regulatory violations or the diversion of controlled substances. The presentation will also provide guidance on how to handle drug diversion issues and regulatory violations if they occur.

*Shannon Cox, JD, Stephen Cummings, JD, King & Spalding; Cari Kay Robertson, Consultant/Former DEA Diversion Investigator, square-2 solutions*

11:45 a.m. to 12:30 p.m. **Lunch**

12:30 p.m. to 12:45 p.m. **Annual Meeting**

1:00 p.m. to 2:00 p.m. **CONCURRENT SESSIONS**

#### **The Continuum of Pharmacist Prescriptive Authority: A Review of State Strategies**

0071-9999-16-016-L03-P (1.0 credit hours, 0.10 CEU)

A dizzying array of state laws has gone into effect in 2015 and 2016 that enables pharmacist prescriptive authority in some way, shape, or form. Multiple states broadened their Collaborative Practice Agreement laws. Other states launched Statewide Protocols for certain products such as oral contraceptives and naloxone. Other states expanded their limited formularies from which pharmacists can independently prescribe. Given the different approaches states have taken, it is often challenging for stakeholders to make sense of all the changes. What are the pros and cons of different approaches? What truly represents progress? What is the "ideal" law? This session will provide attendees with a framework for understanding the different state approaches to prescriptive authority for pharmacists, and will provide insight into future trends.

*Alex Adams, PharmD, MPH, Idaho State Board of Pharmacy; Krystal Weaver, PharmD, National Alliance of State Pharmacy Associations*

**Register Today at [www.aspl.org](http://www.aspl.org)**

1:00 p.m. to 2:00 p.m. **CONCURRENT SESSIONS** (continued)

**340B Drug Discount Program: Evolving Compliance Standards for Covered Entities and Contract Pharmacies in Wake of Proposed 340B Mega Guidance and Orphan Drug Ruling**

0071-9999-16-017-L03-P (1.0 credit hours, 0.10 CEU)

This program will discuss the latest 340B issues and developments impacting Covered Entities and Contract Pharmacies. Topics will include HRSA's Proposed 340B Drug Pricing Program Omnibus Guidelines (the "Proposed Mega Guidance"); Medicaid managed care duplicate discounts; current trends in HRSA contract pharmacy audit findings; best practices for self-assessments and external compliance reviews; business considerations for contract pharmacies; and potential legislative and regulatory developments on the horizon.

*Alan Arville, Epstein Becker Green*

2:05 p.m. to 3:05 p.m. **CONCURRENT SESSIONS**

**Corresponding Responsibility -- Attacks from All Sides**

0071-9999-16-018-L03-P (1.0 credit hours, 0.10 CEU)

This seminar will focus on the emerging disputes surrounding the doctrine of corresponding responsibility in the practice of pharmacy. In addition to a primer on the responsibilities of pharmacists in this area, the seminar will focus on the approaches of Boards of Pharmacies to dispensing controlled substances, but will also feature discussion of the perspectives of the DEA and physicians. Pharmacies in the US have received numerous Boards of Pharmacy citations and complaints in this area, yet pharmacies have also received lawsuits and complaints from patients and physicians about the refusal to fill prescriptions. At the conclusion of the seminar, attendees will better understand not only the corresponding responsibility doctrine, but also the balance that is required in executing its obligations.

*Jonathan Klein, JD, Kelly, Hockel & Klein PC; Michael Simko, RPh, JD, Walgreens*

**Putting the Nutritional Supplement Industry to the Test - Looking for Transparency**

0071-9999-16-019-L03-P (1.0 credit hours, 0.10 CEU)

The nutritional supplements industry is under increasing and ever-changing regulatory scrutiny by federal and state authorities. This presentation will address how the focus of the nutritional supplement industry is affecting current and future conduct of this burgeoning industry from legal, regulatory and compliance viewpoints.

*Frederick Fern, RPh, JD, Marina Plotkin, RPh, JD, Harris Beach PLLC*

3:05 p.m. to 3:20 p.m. **Break**

3:20 p.m. to 4:20 p.m. **CONCURRENT SESSIONS**

**Naloxone: The Science and Legal Issues**

0071-9999-16-020-L03-P (1.0 credit hours, 0.10 CEU)

There is no question that opioid overdose is a rising public health problem. There is much experience with the use of naloxone, a prescription opioid antagonist, by paramedics and emergency medicine physicians to safely reverse opioid toxicity. This session will review opioid toxicity, the public health implications of opioid overdose, the science behind naloxone, naloxone's comparison to other opioid antagonists, data on the various routes of administration of naloxone, safety issues with naloxone, a comparison of the dosage forms of naloxone including the non-FDA approved intranasal

spray, the growing interest in state's allowing community naloxone distribution, the status of legal barriers to increase naloxone access to opioid users and third parties, the role of the Good Samaritan Law in naloxone community use, and a comparison of state laws and regulations surrounding community access to naloxone.

*Allison Muller, PharmD, DABAT, Acri Muller Consulting LLC*

**Emerging Trends in a Pharmacist's Duty to Warn**

0071-9999-16-021-L03-P (1.0 credit hours, 0.10 CEU)

This session is designed to provide an update regarding the "learned intermediary" doctrine in the U.S. and current trends in a pharmacist's duty to warn regarding the known side effects of prescription medications. This presentation will focus on recent federal and significant state law cases addressing the tort liability of pharmacists who have properly filled and dispensed prescribed medications as ordered by the treating physician. The "duty to warn" cases will discuss the traditional doctrinal limits provided by the "learned intermediary doctrine" and the reasonableness test advocated by the plaintiffs' bar.

*Andrew Kopon, Esquire, Kopon Airdo LLC*

4:30 p.m. to 5:30 p.m.

**Legal and Regulatory Issues in Telehealth and TelePharmacy**

0071-9999-16-022-L03-P (1.0 credit hours, 0.10 CEU)

The delivery of healthcare is evolving rapidly in a heavily regulated landscape. Regulators may not be able to predict the direction of new models for providing patient care. As a result, innovators face challenges when providing patient service using new patient care models, as emerging technologies out pace the development of the laws, regulations and reimbursement models. This session will examine a variety of cutting edge topics, including: Telemedicine, Health and Wellness Applications, Clinics in Pharmacies, Shared Service Arrangements and Automation in Pharmacy.

*Edward Rickert, BS Pharm, JD, Quarles & Brady LLP; Phil Wickizer, JD, DaVita Rx*

6:30 p.m. to 8:30 p.m. **Casual Dinner**

**Saturday, November 12, 2016**

7:00 a.m. to 12:00 p.m. **Registration Open**

7:00 a.m. to 8:00 a.m. **Breakfast**

8:00 a.m. to 9:00 a.m.

**Regulatory Challenges in the Long-Term Care Pharmacy Industry**

0071-9999-16-023-L03-P (1.0 credit hours, 0.10 CEU)

The long-term care pharmacy industry and its nursing facility partners operate in a highly regulated industry in which State Boards of Pharmacy, State Departments of Health, the Center's for Medicare and Medicaid Services, the Drug Enforcement Administration, and other state entities regularly legislate, regulate and enforce. This session will provide a practical overview of the unique regulatory and operational challenges that affect the long-term care pharmacy industry. Some of the highlighted issues will include the state and federal regulation of emergency kits, drug destruction, pharmacy automation, consultant pharmacy services, reimbursement challenges, and recordkeeping requirements.

*Charles Hartig, PharmD, JD, CVS Health; Harold Hilborn, PharmD JD, Much Shelist*

9:00 a.m. to 10:00 a.m.

### **House of Cards: The FDA and State Law Come Tumbling Down on the Practice of Compounding**

0071-9999-16-024-L03-P (1.0 credit hours, 0.10 CEU)

This session will review the current legal and regulatory environment surrounding compounded medications. It will cover legal/regulatory developments, industry trends, and practical tips for compounders. The presentation also will discuss recent legislation, FDA and State Board regulatory efforts, trends in FDA inspections of compounders, and best practices. Highlights of an actual FDA inspections and lessons learned that apply to all pharmacies also will be examined.

*Elizabeth O’Keeffe, JD, MPH, LLM, CHC, CHPS, Koshy Mathew, PharmD, MBA, RPh, DAAPM, Advanced Infusion Solutions*

10:00 a.m. to 10:15 a.m. **Break**

10:15 a.m. to 12:15 p.m.

### **Case Law Update**

0071-9999-16-025-L03-P (2.0 credit hours, 0.20 CEU)

This annual summary provides pharmacists, compliance personnel, and attorneys an overview of some of the most important court decisions, lawsuits, and settlements since October 2015. The summary will address issues ranging from pharmacists’ liability, application of the Learned Intermediary Doctrine, civil liability of compounding pharmacists, False Claims Act claims and retaliation against employees, managed care and antitrust claims, state regulatory boards’ authority, and more.

*Roger Morris, RPh, JD, Quarles & Brady LLP; William Stilling, RPh, MS, JD, Parsons Behle & Latimer*

2:00 p.m. to 4:30 p.m.

### **Pharmacy Law Educators**

#### **Formative and Summative Assessment in Pharmacy Law Courses**

0071-9999-16-026-L03-P (1.0 Credit Hours, 0.10 CEU)

The past decade has seen substantial focus on the types of assessment used in pharmacy education. Accreditation guidelines and descriptions of best practices suggest use of formative and summative assessments are ideal for achieving competency based outcomes in pharmacy education. This session is intended to provide pharmacy law educators with a review of assessment formats, discussion of professional education accreditation standards for assessment, and to generate peer discussion about strengths and weaknesses of assessment practices in pharmacy law courses.

*James Ruble, PharmD, University of Utah College of Pharmacy*

### **Using a Mock Trial to “Flip the Classroom” as Pedagogical Tool for Pharmacy Law Educators**

0071-9999-16-027-L03-P (1.0 Credit Hours, 0.10 CEU)

Recognizing there are various ways to achieve a “flipped” classroom, pharmacy law educators use a variety of mechanisms to deliver content, among which are: didactic lecture, case readings and Socratic Method instruction. West Coast University School of Pharmacy successfully designed and implemented use of a mock trial in a PY1 second semester evidence-based practice course, and this method and design can very readily be applied in pharmacy law education. This session will discuss the underlying principles of a “flipped classroom” and examine the methodology and use of a mock trial to flip the pharmacy law classroom.

*Ettie Rosenberg, PharmD, JD, West Coast University School of Pharmacy*

## **Sunday, November 13, 2016**

7:00 a.m. to 12:00 p.m. **Registration Open**

7:00 a.m. to 8:00 a.m. **Breakfast**

8:00 a.m. to 10:00 a.m.

### **Ethics for Pharmacists and Lawyers**

0071-9999-16-028-L03-P (2.0 credit hours, 0.20 CEU)

There is no more confusing study for any professional than the application of ethical principles. Often perceived as black & white and right versus wrong, ethics are usually never so clear when applying them to life and everyday practice. Using the pharmacy code of ethics and the Federal or ABA code of professional conduct along with the teaching of Aristotle, this program is designed to apply ethical principles to real or hypothetical cases. The audience will be a part of this program as they will apply the rules and principles to the cases presented Using an ethical decision making algorithm to these cases the lawyers and pharmacist will each come to a decision - right or wrong.

*Ken Baker, BS Pharm, JD, Renaud Cook Drury Mesaros*

10:00 a.m. to 10:15 a.m. **Break**

10:15 a.m. to 11:15 a.m.

### **Off Label Marketing as Protected Free Speech: What Pharmacies Need to Know**

0071-9999-16-029-L03-P (1.0 credit hours, 0.10 CEU)

Current laws and regulations restrict proactive promotion of off-label information, including clinical and economic information. However, recent federal court decisions, such as Amarin Corporation, Pacira Pharmaceuticals and Vascular Solutions, among others, challenge the current legal restrictions by holding that off-label communications are protected under the First Amendment as long as they are truthful and not misleading. As a result, Congress has questioned the Food and Drug Administration’s (FDA) regulatory authority in this area and urged the FDA to publicly clarify its position on off-label communications given that they are constitutionally permissible. This session will address the quickly-shifting status of the law and discuss the implications for biopharmaceutical manufacturers and pharmacists if restrictions on off-label communications are lifted.

*Tami Millner, JD, PharmD, Shire; Matthew Newcomer, JD, Post & Schell, PC; Soumi Saha, PharmD, JD, Academy of Managed Care Pharmacy (AMCP)*

11:15 a.m. to 12:15 p.m.

### **Overview of the PBM Regulations, Legislation, and Litigation: Ways to Improve PBM-Pharmacy Relationship**

0071-9999-16-030-L03-P (1.0 credit hours, 0.10 CEU)

The presentation will focus on the pharmacy/PBM relationship. The speakers will present information on (1) pending and passed PBM legislation and its effect on pharmacies (focus on audit laws); (2) pharmacy v PBM litigation. The session will finish with an interactive session analyzing the direction of PBM-pharmacy relations and brainstorming on how the relations can be improved. The attendees will have the opportunity to talk about their experiences, express their concerns, and ask questions.

*Natalia Mazina, Esq., Sweta Patel, JD, Kelly, Hockel & Klein; Jeffrey Mesaros, PharmD, JD, CVS/Caremark*



# 2016 Developments in Pharmacy Law Seminar XXVII

## November 10 - 13, 2016

Hilton Austin - Austin, Texas



To Register Online Now!

### LAST DAY TO PRE-REGISTER FOR SEMINAR - OCTOBER 31, 2016

Please print or type participant information exactly as you would like it to appear on your badge. **Please use a separate form for each registrant.**

Name: \_\_\_\_\_

Credentials: (i.e. RPh, JD, PharmD, etc.) \_\_\_\_\_

For CLE Credit, please provide:

Licensure State(s): \_\_\_\_\_ License #(s) \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Medically necessary dietary needs: \_\_\_\_\_

In case of emergency contact: \_\_\_\_\_

Phone: \_\_\_\_\_

Registered guest(s): \_\_\_\_\_

- I am a first time ASPL Conference attendee
- I plan to attend the Saturday afternoon Pharmacy Law Educators Session

**Please indicate:**

- Pharmacist
- Attorney
- Pharmacist/Attorney
- Student
- Technician
- Paralegal
- Other \_\_\_\_\_

**Please indicate which meals you/guests plan to attend:**

- Thursday**  Reception
- Friday**  Breakfast
- Lunch
- Reception
- Saturday**  Breakfast
- Sunday**  Breakfast

You have a choice between receiving your conference materials electronically on a thumb drive or in a conference binder. Please select one option.

- I want my materials electronically on a Thumb Drive
- I want my materials in print via a Conference Binder

### REGISTER BY OCTOBER 16 FOR EARLY BIRD DISCOUNT

FULL CONFERENCE:	Early	Late/Onsite
<input type="checkbox"/> ASPL Member	\$625.00	\$725.00
<input type="checkbox"/> Nonmember	\$755.00	\$855.00
<input type="checkbox"/> Spouse/Guest	\$280.00	\$280.00
<input type="checkbox"/> Student	\$355.00	\$455.00
<b>ONE DAY REGISTRATION:</b>		
<input type="checkbox"/> ASPL Member <input type="checkbox"/> Fri	\$355.00	\$455.00
<input type="checkbox"/> Sat or <input type="checkbox"/> Sun	\$230.00	\$330.00
<input type="checkbox"/> Nonmember <input type="checkbox"/> Fri	\$425.00	\$525.00
<input type="checkbox"/> Sat or <input type="checkbox"/> Sun	\$255.00	\$355.00
<input type="checkbox"/> Student <input type="checkbox"/> Fri	\$230.00	\$330.00
<input type="checkbox"/> Sat or <input type="checkbox"/> Sun	\$155.00	\$255.00
Total Fees: _____		

Registration fee for Seminar includes attendance at all seminar sessions, breakfast, refreshment breaks, Thursday and Friday receptions, Friday lunch and all seminar materials.

**Cancellation policy:** Cancellations must be received in writing. You can email to [jbascom@associationcentral.org](mailto:jbascom@associationcentral.org) or fax to 217-529-9120. Your cancellation is null and void unless you receive confirmation of cancellation from the ASPL office. Refund of registration (less a \$50 administrative fee) will be granted for cancellations received in writing on or before October 1, 2016. Refund of registration (less a \$150 administrative fee) will be granted for cancellations received in writing after October 1, 2016 but on or before October 31, 2016. Refunds will not be granted for no-shows or cancellations received after October 31, 2016 regardless of cause. In the event of a no-show or cancellation after October 31, 2016, meeting materials will be forwarded to the address provided on your registration form.

### Payment Method:

Check enclosed for full payment.

Please charge my:  MasterCard  Visa

Card Number: \_\_\_\_\_

Exp. Date: \_\_\_\_\_ CVV# \_\_\_\_\_

Name on Card: \_\_\_\_\_

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### Register on-line at [www.aspl.org](http://www.aspl.org)

ASPL is accepting on-line registrations at [www.aspl.org](http://www.aspl.org) or, you can mail registration form to:

### American Society for Pharmacy Law

3085 Stevenson Drive - Suite 200 - Springfield, IL 62703  
or fax to: 217-529-9120.

Payment must accompany registration.

Direct registration questions to

Janet Bascom at [jbascom@associationcentral.org](mailto:jbascom@associationcentral.org) or 217-529-6948

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