Thursday, November 5, 2020

1:00 – 1:30 PM

Welcome Remarks

Introduction of 2021 Board of Directors

1:35 - 2:35 PM

Lessons Learned from COVID-19 from a Federal Perspective - How will this Change Pharmacy?

Ilisa Bernstein, PharmD, JD, FAPhA, **American Pharmacists Association**

As front-line health care providers, pharmacists and pharmacies have experienced new challenges and opportunities for providing patient care during the COVID-19 pandemic. This session will review the non-stop activity at the national level to clarify and seek new authorities and policies to help pharmacists practice at the top of their license and obtain provider status, provide COVID-19 testing and immunizations, and telehealth services, address pharmacist safety, workforce issues, compounding, drug shortages, supply chain integrity, and more. Efforts are already underway to maintain these authorities and policies. This session also will explore the impact of the challenges and opportunities during COVID-19 on the profession moving forward.

2:40 - 3:40 PM

Addressing Challenges Posed by A Pandemic (COVID-19) to the Practice of Pharmacy

Ronald Friedman, JD, **Karr Tuttle Campbell;** ***Jeffrey Sinko, JD, BS Pharmacy,*** **CVS Health; Van Anderson, JD, MBA, McKesson Corporation;** ***Michael R. Hess, JD*****, Bass Berry & Sims; and** ***Morgan Harber, JD*****, BioMatrix Specialty Pharmacy**

Over the past several months, our healthcare delivery system has been severely challenged, strained, and perhaps forever changed, by the onset of the Covid-19 virus and our efforts to address the pandemic. The object of this presentation will be to discuss, from an industry perspective, such questions as: (a) what challenges were faced in the delivery of services; (b) what changes were made to process to address the pandemic; (c) how to ascertain effectiveness of such measures; (d) what lessons might we learn; and (e) will there be a “new normal” in the delivery of healthcare services, and what will be its likely attributes?

Topics will include: changes made to the pharmacist/patient interface; measures undertaken to protect employees; addressing drug supply (non-virus and virus-related); pharmacy participation in virus treatment; relaxation of federal and state regulation to facilitate medical treatment and delivery of service; onset of telemedicine and telepharmacy; payor challenges; contractual challenges posed by a "force majeure/vis major" to the business of pharmacy.

4:00 - 5:00 PM

Ethics: A Problem in Pharmacy?

Keith Yoshizuka, PharmD, MBA, JD, **Touro University California College of Pharmacy**

This program discusses the basis of ethics founded in the Georgetown Mantra of beneficence, non-malfeasance, respect for autonomy, and justice, as it applies to the practice of pharmacy. Examples of disciplinary actions taken by Boards of Pharmacy for violations of pharmacy law and the relationship to ethics indicate that there is, indeed, a problem of lack of ethics in pharmacy. Evidence reveals that a capacity for higher moral reasoning for a community pharmacist is correlated to clinical performance. Unfortunately, research also shows that the longer a pharmacist is employed in a retail setting, the moral reasoning appears to erode. Ethical dilemmas face practicing pharmacists on a daily basis, giving rise to apply the basic principles, but pharmacists face challenges when the duties and ethical principles conflict with each other.

5:05 - 6:05 PM

Virtual Happy Hour

Friday, November 6, 2020

10:00 - 10:05 AM

Welcome Message

10:05 - 11:05 AM

Wholesale Drug Distribution Legal Update

Todd Nova, JD, **Hall Render; Sylvia Fong, JD, McKesson**

This presentation will assist attendees in identifying current legal issues and best practices related to prescription drug distribution from both a provider and a distributor point of view. Legal issues to be addressed include both federal issues (e.g., DSCSA compliance, Anti-Kickback Statute considerations, DEA reporting requirements, Robinson-Patman Act own-use) and state issues (e.g., in-state and out-of-state licensure/registration, controlled substance act compliance). The presenters will further discuss best practices such as major contracting considerations in the vertically integrated setting (e.g., fill rates, account setups). Finally, the presenters will address other less traditional issues such as the role of traditional distributors in novel delivery models such as patient-specific immuno-therapy drugs (e.g., CAR-T), consignment models and 503B compounders.

11:10 AM - 12:10 PM

Concurrent Session: Pharmacy Workplace Conditions and Medication Errors

Spencer Morris,Pharm.D., BCPS, **Southeastern Continuing Medical Education Consultants, LLC**

Pharmacy workplace conditions and associated medication errors have recently gained national attention. A recent investigative report of community and retail pharmacies revealed pharmacists fail to detect and manage critical drug interactions more than 50 percent of the time when presented with simulated prescriptions of various interacting medications. Peer reviewed observational and cross-sectional studies of community pharmacies indicate medication errors may occur more frequently than previously thought due to increasing prescription volume, inadequate pharmacy staffing ratios and a variety of other practice issues. The purpose of this presentation is to identify specific risk factors associated with medication errors and review current regulatory and statutory efforts to improve pharmacy workplace conditions and patient safety.

11:10 AM - 12:10 PM

Concurrent Session: Topics in Drug Compounding - Here and Abroad

Melissa Madigan, PharmD, JD, **NABP and *Ulrigh Grau, JD*, D+BLawyers**

The regulation of prescription drug compounding is ever-changing, not only here in the US but also in Europe. This session will describe one of the most recent undertakings related to drug compounding: the launch by the National Association of Boards of Pharmacy (NABP) of its compounding pharmacy data sharing system. Established in support of the newly released US Food and Drug Administration) FDA-State Board of Pharmacy Memorandum of Understanding, the aim of this system is to assist the boards of pharmacy and FDA in their efforts to protect the public. In addition, this session will cover a variety of issues related to the regulation of compounding pharmacy in Germany, as well as in Europe as a whole.

12:15 - 12:30 PM

ASPL Business Meeting and Awards

12:35 - 1:35 PM

Concurrent Session: Everything You Always Wanted to Know (But Were Afraid to Ask): An Open Discussion on Recent Developments in Controlled Substance Compliance

Larry Cote, JD, **Cote Law PLLC**

This session is an open forum allowing the audience to direct the focus of the conversation. After briefly discussing recent developments in controlled substance litigation and compliance involving both pharmacies and wholesalers, the presenter will turn over the session to the audience for any question related to controlled substances. No topics or questions are off the table.

12:35 - 1:35 PM

Concurrent Session: Overview of USP Chapters on Compounding and Current Status of FDA's Guidance and Enforcement Efforts Regarding Compounding

Jonathan Keller, PharmD and Esq., **Faegre Drinker Biddle & Reath LLP and *Steve Lokensgard, Esq.,* Faegre Drinker Biddle & Reath PPL**

Our presentation will provide an overview of the current compounding standards established under USP chapters 795, 797, 800 and 825. We will provide a thorough overview of the significant and most relevant sections of these four chapters as it relates to pharmacy compounding requirements. We will also discuss the prior appeals of these chapters, the outcome and the current status of USP chapters 795, 797, 800 and 825. Further, we will provide

our thoughts as to what action USP may take in the future regarding these chapters.

We will also review the current status of FDA guidance and enforcement efforts relating to hospitals and health systems, the 5% rule, the guidance addressing “essentially copies,” office stock, the MOU with states, and the impact on FDA guidance by the COVID-19 public health emergency. We will also review state initiatives on the limits of traditional pharmacy compounding and their position on compounding within hospitals and health systems.

1:40 - 2:40 PM

Concurrent Session: An Update on the Drug Supply Chain Security Act:

Implementation Issues & Impact on Pharmacy Practice as We Approach 2023

***Chris Smith, JD, LLM, and John Linehan, JD,* Epstein, Becker & Green**

With the November 2013 passage of the Drug Supply Chain Security Act (DSCSA), a federal legal scheme was introduced to comprehensively regulate serialization and track and trace for the nation's pharmaceutical distribution supply chain and establish national licensing standards for wholesale distributors and third-party logistics providers. The law broadly implicates a range of pharmaceutical supply chain stakeholders, including manufacturers, wholesale distributors, repackagers, third-party logistics providers, pharmacies, and other dispensers all of whom have worked to satisfy compliance with trading partner-specific legal mandates and implementation deadlines while making necessary operational adjustments.
This presentation will briefly summarize the DSCSA's structure, purpose, scope, and implementation history. Against this backdrop, additional detail will be provided on recent developments significant to pharmacies, including notable FDA DSCSA warning letters to industry stakeholders, the interplay between recent drug importation efforts and the DSCSA, feedback on the FDA pilot projects, the 2019 statutory provisions requiring authentication and verification of serialized product for wholesalers, and 2019 FDA guidance delaying the saleable verification requirements for wholesalers, potential DSCSA scope expansion, and the impact of COVID on the DSCSA. In addition, the presentation will survey important developments, including the upcoming 2020 authentication and verification requirements for dispensers, the evolving path to 2023 interoperable electronic data exchange, the status of national wholesaler licensure standards, and recent legal practice trends involving the DSCSA.

1:40 - 2:40 PM

Concurrent Session: The Government Is At Your Door: You Are About To Have A Very Bad, No Good Day

***Efrem Grail, J.D.,* The Grail Law Firm and *Dennis Wchern*, Prescription Drug Consulting, LLC**

This presentation will demonstrate the anatomy of a joint federal criminal/state regulatory enforcement investigation of a pharmaceutical company. Particular attention will focus on the role and rules for investigation subjects, targets, counsel, witnesses, federal and state agents, Assistant U.S. attorneys and regulatory board enforcement prosecutor in a timely, reality- based hypothetical then in the news, to give it context and promote interest among the attendees.
The presenters will narrate, explain and raise questions regarding procedure and substantive law, and the difference between what happens and theory and what happens in real life.

2:45 - 3:45 PM **Virtual Happy Hour**

Saturday, November 7, 2020

10:00 - 10:05 AM **Welcome Message**

10:05 - 11:05 AM

Bottle of Lies

***Katherine EbanM Phil, MA* , Vanity Fair**

This talk will take listeners deep into the hidden world of low-cost generic drugs manufactured overseas, where fraud is endemic and the imperative of speed to market governs manufacturing decisions. The U.S. drug supply is largely dependent on these drugs made with minimal oversight and inadequate accountability.

11:10 AM - 12:10 PM

Ethics: African American History and Where We Go From Here

***John Clark, PharmD,* University of South Florida Taneja College of Pharmacy/University of South Florida; *Gregory Bond, PhD*, American Institute of the History of Pharmacy; and *Sarah Steinhardt, PharmD, JD(Esq),* MS, University of South Florida Taneja College of Pharmacy**

This session discusses the role of pharmacy schools at historically black colleges and universities and their impact on the education of African American pharmacists. This session also investigates the desegregation of pharmacy education in the United States South during the twentieth century. The speakers will highlight the ongoing contemporary relevance of research about the history of African Americans in pharmacy.

12:30 - 2:30 PM

Case Law Update

***Roger Morris, RPh, JD,* Quarles & Brady LLP and *William Stilling, RPh, MS, JD,* Stilling & Harrison Care Law**

ASPL's annual case law update will provide summaries of court decisions, lawsuits, and settlements from the last twelve months. The presentation will explore a variety of civil and criminal cases at the state and federal level involving pharmacy employment issues, fraud claims by employees and the government (e.g., False Claims Act cases), negligence (malpractice), managed care, disciplinary actions by regulatory boards, controlled substances, and more. Whether you are an attorney, pharmacist, compliance officer, or work in any area related to pharmacy law, this fast-paced overview will inform you of the most important legal decisions affecting your practice.

2:35 - 3:35 PM

Pharmacy Law Educators

***Katherine Eban, M Phil, MA,* Vanity Fair**

In this interactive presentation, we will discuss the regulation of overseas drug-manufacturing plants, the activities at those plants that impact quality, recent legislative and executive efforts to "reshore" drug manufacturing to the U.S., and the impact of the coronavirus on our drug supply.

2:35 - 3:35 PM

The History, Development and Future of 503B Outsourcing Facilities

***Francis Palumbo, RPh, PhD, JD,* University of Maryland and *Lee Rosebush, PharmD, JD, MS, MBA,* Outsourcing Facilities Association**

Since the New England Compounding Center catastrophe, many changes in compounding have been implemented. When Congress passed the Drug Quality and Security Act that went into effect in 2013, some changes were made to Section 503A affecting traditional compounding, but the greatest change was the Passage of Section 503B of the Food and Drug and Cosmetic Act establishing outsourcing facilities. In the first year about 70 outsourcing facilities were registered. In the interim some went by the wayside and others emerged as the industry matured. It became clear that some were just not equipped to take on the mantel of a manufacturer with FDA registration and compliance with GMPs. Today the outsourcing facility industry is much more mature with more knowledge and experience with good manufacturing practices and it is geared up and ready take on very critical issues of the day such as drug shortages as well as shortages of other materials. For example, as a result of Covid-19 there is a critical shortage of hand sanitizer and outsourcing facilities have been authorized by FDA to produce this product for immediate use. We will chronicle the inception and development of the outsourcing facility industry and we will focus on the strengths and weaknesses and how these were and are dealt with by the industry and by the FDA. We will include a discussion of the outsourcing facilities' startup experiences as well as the experiences that led to withdrawals from the industry. This will include an in-depth discussion of such topics as FDA inspections, and FDA 483 forms resulting from the inspections. We will also comment on the current strength, in general, of the outsourcing facility industry and how, in the midst of COVID-19, outsourcing facilities are playing a key role in relieving shortages of vital drugs and PPE.

3:40 - 4:40 PM

Virtual Happy Hour

Sunday, November 8, 2020

10:00 - 10:05 AM

Welcome Message

10:05 - 11:05 AM

Privacy (and Security) Please! Hot Topics in Pharmacy Related to Data Privacy and Security

***Simone Colgan Dunlap, JD, Meghan O'Connor, JD,* Quarles & Brady LLP; Quarles and *Nicholas Gonzales, JD, MBA, CHC, CHPC,* The Kroger Company**

This presentation will discuss current hot issues in pharmacy data use and disclosure, including privacy, security, and contracting issues. As we continue with the trend of generating, collecting, using, and analyzing pharmacy data, big data can be leveraged throughout the pharmacy supply chain to identify efficiencies and improve quality and adherence. However, use of data at this scale, volume, and frequency poses novel challenges and risk. The presenters will break down the current issues, discuss trends, and offer operational and risk mitigation strategies. Topics discussed will include:

- Disaster preparedness issues and lessons learned from COVID-19
- CCPA and other state consumer privacy laws and the practical impact of these law on pharmacy practice and operations
- New state legislation addressing data brokers.

- Privacy issues unique to specialty pharmacy, including disclosures to Hubs, data aggregators, and disclosure to manufacturers and related contracting considerations.
- Operationalizing de-identification and tokenization in data sharing.
- Sale of data, including new marketplaces models.
- Information blocking, including discussion of the new final rule
- Special considerations for data sharing with manufacturers, payers and PBMs, hubs, and vendors.

11:10 AM - 12:10 PM

Ethics in the Practice of Pharmacy Law

Robert Harrison MHA, JD, LLM, CHC, CHPC **, Stilling & Harrison, PLLC**

This session will review ethical obligations of attorneys representing clients in pharmacy law and life sciences practices. Particular attention will be paid to information privacy and security considerations arising from representing clients who are covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the privacy and security provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. The intersection of legal ethics and pharmacy ethics will be highlighted.

12:20 - 1:20 PM

State Statutory and Regulatory Update - Emerging Trends and Hot Topics

Lisa Kimbrough, MA, **Bula Intelligence**

Expanding Prescriptive Authority (10-15 minutes with a 2-5 minute Q&A);
For years, prescriptive authority has been held in the hands of certain, limited medical professions. Now, we see states expanding that authority more and more to include pharmacists, psychologists, and even dental hygienists. Where are we seeing the biggest expansion of this authority? How can pharmacies expand their service to include prescribing and dispensing? How do pharmacists maintain their end of dual responsibility when they may not know who is writing the script?

The Role of the Pharmacy in Vaccination and POCT (10-15 minutes with a 2-5 minute Q&A);
As we've seen this year, viruses are becoming global pandemics with frightening rapidity. Vaccines are a firewall to protect communities from infection. Pharmacists are on the front lines of outbreak prevention. Where are we seeing the biggest changes to pharmacist prescribing and administering vaccinations? What are states doing to include the pharmacist in ordering and administering testing?

Medication Disposal (10-15 minutes with a 2-5 minute Q&A);
New Jersey's "Charlie's Law" now mandates that all retail pharmacies become authorized collectors of controlled substances. Are other states about to follow New Jersey's lead? What extra onus does this place on retail pharmacies and pharmacists? Where are the potential compliance challenges? Are there opportunities in becoming an authorized collector?

Cold Chain (10-15 minutes with a 2-5 minute Q&A);
With the rise of delivery services for prescription medication, how are pharmacies maintaining storage and temperature requirements mandated by states? How different are state requirements pertaining to temperature of prescription drugs? Where does the pharmacy's liability end when they hand prescriptions to a third party for delivery?