

# RxIpsa Loquitur

AN OFFICIAL PUBLICATION OF THE AMERICAN SOCIETY FOR PHARMACY LAW



## President's Message

Mary Jo Carden  
ASPL President

### *Time for Giving and Thanks, Reflections on the Annual Seminar and a Look Ahead*

In this season of giving and of thankfulness, I begin by noting how honored I am to serve as the President for the next year. I know that for me, like many of us, as the days begin turning cooler and shorter, we look forward to a weekend in November where we meet friends who have become colleagues and colleagues who become friends. The Annual seminar was one of the most well attended and discussed some of the most important issues facing pharmacists and lawyers today. I particularly enjoyed the new member reception which had a great turnout! I hope the new members enjoyed the seminar and that you found a home with ASPL.

The members of the Education Subcommittee and ASPL staff did a wonderful job of compiling timely topics, sessions and speakers, including:

- Managing opioid treatment and substance use disorder in light of ever-evolving laws, regulations and addressing difficult challenges that pharmacists often face when trying to provide patient care as well as ethical issues faced by pharmacists and lawyers facing substance use disorder.
- Contractual and reimbursement issues in pharmacy benefit management company relationships with pharmacies.
- Updates on the current state of the professional role of pharmacists and standard of care.

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## Featured Case



*Park Irmat Drug Corp. v. Express Scripts Holding Company et al.*, No. 4:17-cv-00979-RLW, E.D. Mo.

### Defunct Mail Order Pharmacy Moves to Revive Express Scripts Suit

*By Roger N. Morris, Leah Tinney, and Richard Davis*

On November 16, 2018, now-defunct mail order pharmacy, Park Irmat Drug Corp. ("Park Irmat"), filed a motion in federal court to overturn a February 21, 2018 dismissal of its antitrust and breach of contract lawsuit against Express Scripts Holding Co. and Express Scripts, Inc. ("Express Scripts"). In its motion, Park Irmat argues that Express Scripts' new policy to cover mail order pharmacies shows that the PBM had no legitimate reason to exclude Park Irmat from its network, and erodes the court's basis for dismissing the original suit.

Park Irmat filed its initial complaint against Express Scripts in March 2017 in the United States District Court for the Eastern District of Missouri. Park Irmat argued that Express Scripts' May 2016 decision to exclude the pharmacy from its network was improper, because the pharmacy had not breached the amended terms of the parties' provider agreement. Specifically, Park Irmat claimed its most-recent recredentialing application notified Express Scripts that it was acting as a mail order pharmacy and that, upon approving the application, the PBM effectively nullified portions of the parties' 2014 provider agreement forbidding pharmacies from engaging in mail order activities.

Park Irmat's original complaint further alleged that Express Scripts was illegally conspiring with other PBMs to exclude certain mail order pharmacy competitors from the market. In support of its common motive theory, Park Irmat noted that several PBMs (including Express Scripts) regularly communicate via a common trade association; that other PBMs terminated the pharmacy from their networks after Express Scripts did so; and that Express Scripts and other PBMs acted against their own economic self-interest by terminating the pharmacy.

Despite these arguments, the court rejected Park Irmat's assertions, and concluded that Express Scripts did not breach its contract or conspire to exclude the pharmacy from the mail order market. Park Irmat's appeal to this determination is pending in the Eighth Circuit Court of Appeals.

However, on October 12, 2018 Express Scripts issued notices to its member pharmacies that it would now allow in-network pharmacies to offer mail order services. In response, Park Irmat filed its newest motion, arguing that such a reversal "indicates that Express Scripts' prior prohibition on mail order was never justified by any legitimate business rationale and was, indeed, against Express Scripts' economic interest – a 'plus factor' evidencing a conspiracy." Park Irmat's motion further states that Express Scripts' reversal also "demonstrates the unconscionable nature of the network provider agreement that it foisted upon Irmat, and affirms that Express Scripts' termination was made in bad faith."

In a November 9, 2018 filing before the Eighth Circuit, Express Scripts stated that its plan to create new separate networks for mail order pharmacies does not "plausibly suggest that

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## Recap of Developments in Pharmacy Law Seminar



*The 29th Developments in Pharmacy Law Seminar began with a Welcome Reception for attendees on November 1st.*



*During the ASPL Annual Meeting, President Mary Jo Carden awarded the Fink Family Scholarship to Marc Wagner of Penn State Dickinson Law.*



*Members of the 2019 ASPL Board of Directors are administered the Oath of Office by Past President Laura Carpenter.*

ASPL hosted its 29<sup>th</sup> Developments in Pharmacy Law Seminar November 1-4 in Hilton Head, South Carolina. Two hundred and eighty-two individuals attended the annual event, marking the 2<sup>nd</sup> highest attendance in the Seminar's history. This year's attendance boasted of 75 first time attendees, and represented 37 states across the country.

In addition to the myriad of networking opportunities, there were 15 hours of continuing education credit available. Session topics included PBM Contract Terminations, Exploring the Drug Supply Chain Security Act, DEA Enforcement, DIR Fees, Ethics in Pharmacy and Law, IT in Pharmacy, and a Board of Pharmacy Mock Hearing. To start the event off, ASPL Past President, Laura Carpenter of Bula Intelligence, administered the Oath of Office to the 2019 ASPL Board of Directors. The newly sworn in Board includes the following:

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Planning for the 30<sup>th</sup> Developments in Pharmacy Law Seminar will begin in February with a Call for Abstracts. Next year's Seminar is scheduled for November 7-10, 2019 at the Westin Gaslamp Quarter in San Diego, CA.

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### *Featured Case*

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any earlier alleged prohibition on mail order services within its retail pharmacy network was against its economic interest," and does not "support the contention that it was unconscionable for [its] agreement to prohibit retail pharmacies from operating predominantly as mail order pharmacies." Ultimately, Express Scripts maintains that this subsequent policy change does not contradict or alter its legitimate reasons for not wanting pharmacies like Park Irmat to engage in mail order services.

The court has yet to decide whether Park Irmat may revive its original suit.

*Roger N. Morris, JD, RPh, is Partner and Member of the Executive Committee at Quarles & Brady; Leah Tinney, JD, MPH, and Richard B. Davis, JD, are Associates in the firm's Health Law Practice Group. Mr. Morris and Ms. Tinney practice at in the firm's Phoenix office; Mr. Davis practices in Milwaukee.*

## Take Aways from the Hilton Head Meeting - An Attendee's Perspective

By Efre M. Grail

Last month I was privileged to attend the 29th Annual Meeting of the American Society of Pharmacy Law, on Hilton Head Island, South Carolina. Here are some few general 'takeaways' for our health-care provider and physician practitioner/practice groups specifically, and business clients generally:

Compliance isn't about getting the right answer on any given occasion or, in the words of the United States Sentencing Guidelines Commission's guidance for business entities, preventing and detecting violations of law in every instance. From "big pharma" all the way to the corner drug store, it's about having reproducible processes and verifiable systems with integrity in place that conduct due diligence 100% of the time. No system is perfect, no judgment call will always be accurate, and everyone gets it wrong occasionally. The key to defending a civil audit, an administrative enforcement investigation or a federal grand jury inquiry is being able to demonstrate that your business has processes to ensure laws and regulations are in place and employs people

dedicated to making sure they are utilized.

Everyone acknowledges the opioid epidemic is killing our citizens, without discriminating by wealth, race, gender or any other category or classification, and that "something must be done" about it. But there remains a deep, cultural divide between those in health care who believe the solution is treatment, and those in law enforcement who believe the solution is enforcement – and this culture war shows no sign of détente in the near future.

There are now over 900 lawsuits against manufacturers, distributors, pharmacies and other defendants seeking money damages arising out of the opioid crisis, giving rise to a cottage industry of opioid case lawyers, on both sides of the cases. We'll all end up paying for them in the long run.

Investigation of suspected violation(s) of statutes and regulations of wholesale pharmaceutical distributors, retail dispensers (i.e., pharmacies) and providers varies widely from judicial district to judicial district. Having local connections with

regulators and enforcement personnel has no substitute for business and business persons when it comes to knowing how regulations are interpreted in specific regions of the country, and between regions that are connected.

"PBMs," or pharmacy benefit managers who, as third-party administrators of prescription drug programs for insurers, government health care provider programs and other payor plans, have an inordinate amount of influence over how we get our medicines in this country, who we get them from, and what we pay for them.

Overall, the ASPL meeting was highly informative and worth attending for industry professionals and counsel. As more pharmacies, distributors and retail stores are sued and investigated, attorneys need to be proactive in providing their clients timely advice to avoid the rising costs of legal proceedings.

*Efre M. Grail, JD, is Principal, The Grail Law Firm, Pittsburgh, PA. This article is reprinted with permission of The Grail Law Firm.*

### President's Message

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- Sessions on trends in health care including drug donation and safety net programs; tele-pharmacy in integrated settings; 340B regulations; anti-discrimination regulations; and, precision medicine.
- Last but not least, no ASPL seminar would be complete without the case law update.

This year, the seminar featured a new addition to the Saturday afternoon lineup: a mock board of pharmacy hearing. This successful session was added based on feedback from members.

The pharmacy law educators' program continues to grow in popularity. This year, a session focused on how educators can provide students with practical information to maximize their experience in pharmacy law courses. The program also featured groundbreaking advice on how to incorporate standard of care regulations into pharmacy law curriculum from Idaho, the first state to implement these regulations.

Thank you again to everyone who attended and developed the 2018 Seminar! ASPL continues its collaboration with the American Pharmacists Association to offer pharmacy law sessions at its meeting in Seattle, Washington, March 22-25, 2019.

In looking ahead for the next year, ASPL will expand educational offerings by introducing webinars! The need for education of pharmacists in law and policy continues to be critical as we cannot escape the intersection of practice and laws and regulations. For health lawyers, pharmacists, pharmacist/lawyers, and other professionals in health law, the body of case law, regulations, and statutes continues to grow. It can be overwhelming even for those who are immersed in the issues regularly. By expanding ASPL's educational reach through webinars, we can help better meet our mission to provide education to pharmacist lawyers. This can also help expand our membership base and attract new members to ASPL's Seminar. Look for information soon.

And finally, in another reflection, ASPL has identified the need to expand its use of technology to the members. Many of you

probably used the app which was a great addition to the seminar. This will be the last paper mailed edition of the newsletter. Beginning in January 2019, the newsletter will only be provided in electronic form. We have identified an interface that resembles a print version and is interactive and modern!

In closing, I wish everyone a happy holiday season and a happy new year! Serving as President is one of the many blessings in my life!

### Get Connected!

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**2019 ASPL Fall Meeting**  
**American Society for Pharmacy Law**

**November 7-9, 2019**  
**The Westin San Diego Gaslamp Quarter**  
**San Diego, CA**

