

Healthcare Policy: Pharmacy, Opioids & Marijuana



Market Benefits Supply Chain – Not Consumer

The pharmaceutical industry in the United States is not functioning as a competitive market because it lacks choice, competition, and information sharing, said health policy expert James Gelfand. He was joined by attorney Loren Speziale of Gross McGinley, LLP, Gelfand in updating LVBCH members during their September 15th webinar presentation, Health Care Policy: Pharmacy, Opioids & Marijuana.

Employers are paying the vast majority of costs, especially prescription drugs, which increases faster than the economy and their ability to pay for them, said Gelfand, Senior Vice President, Health Policy, the Erisa Industry Committee (ERIC), a national association that advocates for large employer plan sponsors. The gaps between list prices and what employers pay is incredible and means that the market isn't functioning in a reasonable manner – preventing employers from being able to evaluate data in order to make informed decisions.

"That does work to the advantage of certain parties, and it's not you and it's not patients, and it's not your beneficiaries," he said. "It works to the benefit of the supply chain system and it's taking place behind the scenes from the time they (the medications) are produced until they get into the hands of the patient. There's all these different parties and middlemen and service providers who are taking a piece of the pie." Consequently, sometimes the supply chain costs are as much as the cost of the drug itself.

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Industry efforts have thwarted market forces, which has resulted in rising costs:

- Drug "coupon" arrangements steer patients to expensive drugs and hinder generic and biosimilar competition.
- Rebates and discounts cause drug formularies to be based on metrics other than value for patients.
- Patent "evergreening" and other methods of extending exclusivity negate statutory limitations on market monopolies.
- Patient groups that are potentially funded by interested parties are lobbying state legislatures to eliminate medical management techniques designed to help patients control costs.
- Pharmacy Benefit Managers develop and maintain formularies of covered medications on behalf of health insurers, which influence what drugs individuals use and determine out-of-pocket costs.
- "Pay-for-delay" agreements between generic and brand manufacturers keep generic competition off the market for a period of time.
- "Product hopping" enables drugs to maintain exclusivity by making small changes so that the patient stays on the drug's newly patented formulation.
- "International freeriding" leads to much lower prices in other industrialized markets, and requires US purchasers to pay many times more.

Meanwhile, the opioid crisis rages on with an estimated 1.7 million people in the United States suffering from substance use disorders. In 2017 alone, the number of deaths due to opioid addiction was a staggering 47,000 deaths. The opioid epidemic began in the 1990s when prescribing guidelines encouraged the use of opioids for pain relief. It evolved into the heroin epidemic as patients turned to a cheaper alternative that was often easier to obtain. Around 2013, the emergence of synthetic drugs, such as fentanyl, proved to be a "death sentence" for many people. This year methamphetamine, an even cheaper drug, has increased. Congressional investigators have studied the matter and found that a huge number of opioids were being funneled through a tiny number of doctors and pharmacies. For example, a pharmacy in a town with only 3,000 residents filled millions of opioid prescriptions. While such abuses were investigated, little blame was ever assigned.

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Certain groups allege the structure of the insurance industry, including high-deductible plans, discourages patients from getting treatment. At the same time, costs related to the epidemic are huge. In fact, 40% of the funding of Medicaid – with 60 million people enrolled – goes toward addiction treatment. In response to the crisis, employers have taken an active role in fighting opioid addiction because the cost of opioids is so significant for employers, but unfortunately, they can expect little help from the government.

"The push on the federal level to address outrageous drug costs is essentially dead," Gelfand said. Senator Chuck Grassley, the main champion of legislation to address costs, has said the democrats won't negotiate and the republicans won't act. If former Vice President Joe Biden is elected, the democrats have said they will expand health care coverage and pay for it though a medication price reduction bill.

President Donald Trump has signed many executive orders on drug pricing, but they won't be implemented before the election and never if he loses. He has issued a "most favored nation" executive order stipulating that for Medicare Part B drugs, the United States would pay the lowest price available in economically comparable countries. Due to an unacceptable response from the pharmaceutical industry, he has threatened to extend this to Part D drugs. Gelfand said we will have to wait to see how it will be resolved.

Also, the federal government has determined that the generic drug companies, the supposed "good guys" have engaged in price fixing. "As if matters weren't bad enough with all of the loopholes in the legal system you have parts of the supply chain that are breaking the law and stealing from employers and patients – which is incredibly worrying," Gelfand said. "But it's good that the Department of Justice has started to police them much more strictly."

Another issue to be concerned about is coverage for mental health services and Gelfand encourages employers to work with benefit providers to ensure they are providing adequate coverage, adding, "Congress is coming for you next year in regard to mental health and mental health parity requirements."

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Medical and Recreational Marijuana

Speziale highlighted changes in medical and recreational marijuana, remarking that a conflict remains between the federal law that prohibits the use of marijuana and state laws that allow it. Pennsylvania, which enacted the Medical Marijuana Act in 2016, now has more than 153,000 people registered for medical marijuana, almost twice as many as a year ago, according to the most recent data. Out of 23 qualifying conditions to obtain a medical marijuana prescription, chronic pain and PTSD/anxiety topped the list of diagnoses.

This year, the Medical Marijuana Coronavirus (COVID-19) Notice temporarily suspended certain provisions of the Medical Marijuana Act due to the pandemic:

- Allowing for the curbside pick-up of medical marijuana.
- Permitting remote certifications for new medical marijuana patients.
- Suspending the background check requirement for caregivers on renewal certifications.
- Increasing the statutory 30-day supply dispensation limit to a 90-day supply.

Speziale said that while recreational marijuana continues to be illegal, Gov. Tom Wolf has called for legislation to legalize to help fill budget gaps resulting from the pandemic but time will tell whether it will gain traction. She also reviewed recent law cases including Palmiter v. Commonwealth Health Systems Inc. et al, in which the judge ruled that employers are subject to a private cause of action under the medical marijuana Act if they violate its anti-discrimination provisions.

Speziale recommended that employers update their drug-free workplace policies, job descriptions for safety-sensitive positions, and drug testing policies. She also encouraged them to ensure processes are in place to prevent a claim of discrimination related to hiring, current employment, and termination.

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ABOUT JAMES GELFAND



Dr. Jaewon Ryu is Geisinger's president and chief executive officer. Throughout his Geisinger career, he's been a driving force for innovative programs, such as Geisinger at Home and 65 Forward. His background is in emergency medicine, with leadership roles at Humana, University of Illinois Hospital & Health Sciences System and Kaiser Permanente. He's passionate about improving health outcomes and making care easier to access and easier to afford. His drive to improve patient experience earned him a spot among Modern Healthcare's 20 Most Influential Clinical Executives.

ABOUT LOREN SPEZIALE



Attorney Loren L. Speziale, Deputy Managing Partner with Gross McGinley, LLP, regularly counsels businesses on corporate and employment matters including business formation, contracts, handbooks and policies, and matters involving personnel policies and claims. She represents private and public corporations as well as privately held businesses. Loren is a member of the City of Bethlehem Human Relations Commission and is well versed in EEOC and PHRC actions. Loren also has experience in general corporate matters, financing, and commercial real estate. She is the President of the Board of Directors for Women's Resources of Monroe County and serves on the Board of Directors for the Rodale Institute. Loren has received multiple recognitions as a legal professional and active community leader including being nominated as one of Lehigh Valley Business's 2018 Women of Influence.

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