Pharmacy Briefing | November 2024

The latest on pharmacy news, trends, and insights

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Highlights

- Federal Trade Commission (FTC) sues PBMs over alleged anticompetitive practices, Express Scripts sues
 FTC over alleged false claims
- State of Texas sues drug manufacturers and PBMs over alleged insulin pricing conspiracy
- CVS Health CEO Karen Lynch steps down, replaced by former executive vice president David Joyner
- Oral semaglutide achieves primary cardiovascular endpoints in phase 3 SOUL trial

U.S. Food and Drug Administration (FDA) approvals and launches

- Vyalev (foscarbidopa and foslevodopa) is approved to treat symptoms of Parkinson's disease
- Hympavzi (marstacimab-hncq) is approved as a treatment for hemophilia A or B
- Ebgllyss (lebrikizumab-lbkz) is approved to treat moderate to severe atopic dermatitis

News

Federal Trade Commission (FTC) sues PBMs over alleged anticompetitive practices, Express Scripts sues FTC over alleged false claims

- In the FTC's lawsuit against the three largest PBMs, they claim the companies engaged in anticompetitive practices, artificial inflation of prices, and impairing access to low priced products.
- The Express Scripts lawsuit against the FTC alleges that an FTC PBM report released in July 2024 contained false and misleading information against the PBM.

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State of Texas sues drug manufacturers and PBMs over alleged insulin pricing conspiracy

- The state alleges that manufacturers made unreasonable increases in insulin prices and colluded with PBMs to promote the utilization of higher-priced insulin products while excluding lower-priced options.
- The attorney general of the state cites this practice as a violation of the Texas Deceptive Trade Practices Act.

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CVS Health CEO Karen Lynch steps down, replaced by former executive vice president David Joyner

Newly appointed CEO David Joyner was also formerly the president of CVS Caremark, the PBM arm of the company, and has 37 years of healthcare and PBM experience.

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Oral semaglutide achieves primary cardiovascular endpoints in phase 3 SOUL trial

- Oral semaglutide, marketed under the brand name Rybelsus, has the same active ingredient as Wegovy and Ozempic.
- The phase 3 study helps to confirm that the drug, in addition to promoting weight loss, has non-cosmetic health benefits.

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Federal government proposes new rules mandating health plan coverage of over-the-counter (OTC) contraceptives with zero cost-sharing

- The proposed rule would apply to "most group health plans and health insurance issuers" and would also expand coverage of contraceptive choices.
- The first OTC oral contraceptive, Opill (norgestrel), was launched in Q1 2024...

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U.S. Centers for Disease Control and Prevention (CDC) advisory committee votes to expand indication for pneumococcal vaccines

- The updated guideline expands the general suggested age range from adults over the age of 65 to adults over the age of 50.
- While the update requires a final approval from the CDC and Department of Health and Human Services (HHS), the departments are anticipated to accept the committee's recommendation.

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U.S. Food and Drug Administration (FDA) removes tirzepatide from drug shortage list

- Tirzepatide, sold under the brand name *Zepbound* and *Mounjaro*, has been a high-demand drug in the treatment of diabetes and weight loss.
- Compound pharmacies had been increasing production of the drug, citing commercial drug shortages as a reason to bypass limitations on compounding limits.

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CMS issues guidance on second round of drug pricing negotiations

- CMS will select up to 15 drugs, in addition to the 10 already selected under the first round of negotiations, for the second round, with any changes to pricing taking effect in January 2027.
- The guidance document cites a projected savings of \$1.5 billion in 2026 for those enrolled in the Medicare program.

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Drug Channels publishes analysis of 340B program, criticizes lack of transparency and accountability

- The analysis cites a 23.4% increase in discounted purchases in 2023 compared to 2022 and a total of \$66.3 billion in spend.
- The program was originally intended to assist healthcare providers in the treatment of low-income and uninsured patients, but critics claim that the market is not achieving this goal.

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Blue Shield of California announces plan to purchase *Humira* biosimilar directly from manufacturer Fresenius Kabi

- The health plan intends to "eliminate the excessive markups often found in a traditional pharmacy benefit manager model."
- The negotiated cost of the biosimilar will be \$525 per monthly dose.

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