# Pharmacy Briefing | May 2024

The latest on pharmacy news, trends, and insights

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### Highlights

- Follow-up analysis of SELECT trial confirms long-term weight loss effects of semaglutide
- Phase III SURMOUNT-OSA trial finds that tirzepatide treatment reduces sleep apnea compared to placebo
- Manufacturers Teva and Alvotech announce launch of biosimilar Simlandi (adalimumab-ryvk), FDA approval of Selarsdi (ustekinumab-aekn)

### U.S. Food and Drug Administration (FDA) Approvals and Launches

- Beqvez (fidanacogene elaparvovec-dzkt), a one-time gene treatment for hemophilia B, is approved and launches with a \$3.5 million list price.
- Yesafili (aflibercept-jbvf) and Opuviz (aflibercept-yszy) are approved as interchangeable biosimilars to Eylea.
- Benlysta (belimumab) is approved as a subcutaneous treatment for systemic lupus erythematosus.

### News

#### Follow-up analysis of SELECT trial confirms long-term weight loss effects of semaglutide

- The SELECT trial, originally published in November 2023, found that semaglutide was superior to placebo in reducing incidence of cardiovascular-related death over a mean time-period of 40 months.
- In the follow-up analysis, patients experienced a mean reduction in weight of 10.2% compared to 1.5% in the placebo group after four years of treatment.

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#### Phase III SURMOUNT-OSA trial finds that tirzepatide treatment reduces sleep apnea compared to placebo

- The trial studied patients with moderate-to-severe obstructive sleep apnea over the course of 52 weeks.
- As a secondary outcome, investigators found a mean body weight reduction of 18.1% from baseline compared to only 1.3% with placebo.

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# Manufacturers Teva and Alvotech announce launch of *Simlandi* (adalimumab-ryvk), FDA approval of *Selarsdi* (usetekinumab-aekn)

- Simlandi represents the first biosimilar to Humira that is interchangeable, high-concentration, and citrate-free.
- Selarsdi is a biosimilar to Stelara and has an expected launch sometime in early 2025.

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#### Madrigal Pharmaceuticals provides Rezdiffra (resmetirom) launch update, emphasizes its promising potential

- The drug, approved in March 2024, is the first of its kind to be approved to treat nonalcoholic steatohepatitis (NASH).
- The manufacturer is targeting a nationwide patient population of 315,000 patients diagnosed with NASH and moderate to advanced liver fibrosis.

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# U.S. Department of Health and Human Services (HHS) releases Fiscal Year 2025 Budget proposal, includes biologic interchangeability reform

Several prescription drug reforms are proposed, such as the removal of the distinction between interchangeable and noninterchangeable biosimilars.

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#### U.S. Department of Justice submits proposed regulation to classify marijuana as a schedule III drug

A schedule III designation would allow for easier access to marijuana for research or treatment purposes.

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## The Centers for Medicare and Medicaid Services (CMS) estimates significant increases in spend for Alzheimer's drug *Legembi* (lecanemab)

In a user group call, CMS estimated that costs for the newly launched drug would almost triple, increasing from a per member per month (PMPM) cost of \$1.67 in calendar year (CY) 2024 to \$4.67 in CY 2025.

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## Milken Institute publishes "Modernizing Care for Obesity as Chronic Disease: A How-To Guide for Employers"

- The guide is "intended as a call to action and a resource for employers to accelerate the shift toward comprehensive, person-centered approaches to obesity care."
- The authors created the guide based on interviews with thought leaders in research, technology, care delivery, public health, employers, policymakers, and advocacy.

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#### Quantile Health introduces subscription-based access to gene therapies

The company projects that the market's annual spend on gene therapies will exceed \$25 billion by 2030 and aims to be an improvement over the current fee-for-service model of payment.

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# Drug Channels publishes "The Top Pharmacy Benefit Managers of 2023: Market Share and Trends for the Biggest Companies—And What's Ahead"

- The "Big 3" pharmacy benefit managers (PBMs), CVS, Express Scripts, and Optum Rx, are estimated to possess roughly 80% market share.
- Major market changes occurring in 2024 include Centene's transition from CVS to Express Scripts and MedImpact's acquisition of Elixir.

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### American Society of Health-System Pharmacists (ASHP) publishes drug shortage statistics

- The amount of ongoing and active drug shortages is at its highest since 2001.
- "New Drug Enforcement Administration (DEA) quota changes, along with allocation practices established after opioid legal settlements" are cited as contributors to controlled substance shortages.

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3 Pharmacy Briefing | May 2024