PNC PHARMA & LIFE SCIENCES

Monthly News Brief

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FDA Approves Lilly Obesity Pill, Triggering Battle with Novo Nordisk *(BioPharma Dive)*

The FDA approved Eli Lilly's once daily oral GLP 1 obesity drug Foundayo (orforglipron), kicking off a high-profile commercial battle with Novo Nordisk's oral Wegovy in the fast-growing obesity market. Foundayo launches about four months after Novo's pill and is positioned around ease of use, while Novo highlights stronger average weight loss results from its clinical data. In clinical trials, Foundayo produced roughly 10–11% weight loss, compared with ~14% for Novo's oral Wegovy, though the drugs have not been directly compared head-to-head. Pricing and access are expected to be critical differentiators: both companies will offer $149/month cash pay starter doses, with Lilly also providing a $25/month option for insured patients under a White House agreement aimed at expanding affordability.

Trump Revives Pharma Tariffs with 100% Charges, but Leaves Loopholes *(BioPharma Dive)*

The Trump administration plans to revive pharmaceutical import tariffs, imposing up to 100% levies on certain branded drugs, but with broad exemptions that limit overall impact. Generics, biosimilars, drugs from key trade partners, and companies investing in U.S. manufacturing or agreeing to "most favored nation" pricing deals are largely exempt. As a result, analysts view the policy as less disruptive than expected, with most large pharma companies already positioned to avoid meaningful impact.

White House Seeks 12% Cut in HHS in 2027 *(Medtech Dive)*

The White House proposed a 12.5% cut to the Department of Health and Human Services (HHS) in its FY 2027 budget request, seeking $111.1B in discretionary funding, about $15.8B less than FY 2026. The proposal includes significant reductions at the National Institutes of Health, cutting its budget by $5B, and would eliminate or shutter several research centers, The budget reflects the administration's effort to constrain non-defense spending while boosting defense funding, but Congress ultimately controls appropriations, and similar proposed cuts in prior years were largely rejected by lawmakers.

US FDA to Monitor Clinical Trial Data in Real Time in Pilot Program Aimed at Speeding Approvals *(Reuters)*

The FDA launched a pilot to monitor clinical trial data in real time, allowing regulators to receive ongoing safety and efficacy signals instead of waiting for post-trial submissions. The approach aims to eliminate administrative delays, accelerate approval timelines by years, and improve global competitiveness, while sharing only aggregated data to preserve patient privacy.

Stakeholders Urge Labor Department to Finalize PBM Transparency Rule *(Healthcare Dive)*

A coalition of employers, lawmakers and patient advocates urged the Labor Department to finalize a rule requiring PBMs to disclose detailed pricing and compensation practices to employer health plans. Supporters say the rule would improve transparency around rebates, spread pricing and fees and strengthen fiduciary oversight, while PBMs argue it is unnecessary and duplicative of voluntary efforts. The debate highlights intensifying federal scrutiny of PBMs, with pressure on the industry expected to continue.

The Top 15 Specialty Pharmacies of 2025: PBM-Affiliated Pharmacies Dominate While Health Systems and Independents Gain Ground *(Drug Channels)*

The U.S. specialty pharmacy market remains highly concentrated in 2025, with PBM-owned specialty pharmacies controlling roughly two-thirds of dispensing revenue. Despite more than 1,900 accredited locations, revenue power remains concentrated as specialty drug spending rose 9.6% to $293.4B, driven by high-cost therapies and accounting for ~40% of all drug spend. Independent and health-system pharmacies are growing, but vertical integration continues to dominate the market.

Mapping the Vertical Integration of Insurers, PBMs, GPOs, Specialty Pharmacies *(Drug Channels)*

U.S. healthcare remains highly vertically integrated in 2026, with major insurers and PBMs controlling multiple parts of the drug supply chain, including specialty pharmacies and pricing. While some firms have adjusted strategies, market power remains concentrated. At the same time, hospitals are expanding in-house specialty pharmacies, nearing one-third of locations, driven by changes to 340B policies. U.S. healthcare remains highly vertically integrated, with major players controlling/owning two or more key services including insurer, PBM, GPO, distribution, specialty pharmacy, retail pharmacy and provider

CMS, FDA Unveil Speedier Medicare Coverage Pathway for Breakthrough Devices *(Medtech Dive)*

CMS and the FDA introduced the RAPID pathway to speed Medicare coverage for breakthrough devices, reducing the timeline to ~2 months post-FDA approval by aligning review processes. CMS will engage with developers to streamline evidence requirements and is pausing TCET candidates while implementing RAPID. Industry groups welcomed the move but noted execution will be key to its impact.

Providers push back on 340B Rebate Model *(Healthcare Dive)*

Hospitals and clinics urged regulators to abandon plans to shift the 340B drug discount program to an after-the-fact rebate model, arguing it would impose significant administrative and cash-flow burdens that could outweigh any benefits for patients. Providers said building and operating rebate-processing systems would be costly and could jeopardize care for low-income and uninsured patients. Drugmakers countered that a rebate model would curb abuse of upfront discounts and improve oversight of the rapidly growing program. The debate highlights the long-running conflict between providers and pharmaceutical manufacturers over how the 340B program should operate.