PNC PHARMA & LIFE SCIENCES

Monthly News Brief

October 2025

FDA, Aiming to Lower Drug Costs, Moves to Speed Approval of Biosimilars *(BioPharma Dive)*

The FDA wants to speed the development of biosimilars, announcing new guidance that would no longer require the makers of copycat biologics to run human trials showing their products are as effective and safe as their branded counterparts. Biosimilars have yet to achieve their main purpose: to reduce the costs of complex biological drugs, as generics do for small molecules. The FDA agency said the policy shift should make biosimilar development faster and cheaper, estimating that manufacturers of biosimilars could now save $100MM in development costs per product.

Medtech Industry Closely Watching Section 232 Investigation Impact *(Medtech Dive)*

Medtech companies are closely watching a new development that could affect tariff rates across the industry. After a summer of back-and-forth tariff actions, the Trump administration opened a Section 232 national security investigation into medical equipment in September. The administration has recently used Section 232 as a mechanism to impose tariffs in other industries, such as pharmaceuticals and semiconductors. Medical device trade groups and the American Hospital Association urged the Trump administration to exempt essential medical goods from tariffs and to pursue reciprocal agreements with trade partners.

Mark Cuban says Cost Plus Drugs will Partner with TrumpRX *(BioPharma Dive)*

Online pharmacy Cost Plus Drugs will be participating in President Trump's drug price transparency tool, TrumpRx, according to Cost Plus' founder Mark Cuban. Cost Plus Drugs, which sells certain prescription medications directly to consumers at cost plus a 15% markup, is sharing access to its application programming interface so that TrumpRx can pull price data. President Trump announced TrumpRx last month, saying the website will allow Americans to shop directly for prescription drugs at discounted rates without insurance. Launching early next year, the website will serve as a search platform for direct-to-consumer drug providers rather than selling or distributing medications itself.

AstraZeneca Cuts US Drug Pricing Deal; FDA declares Novo Plant out of Compliance *(BioPharma Dive)*

AstraZeneca inked the pharmaceutical industry's second recent U.S. drug pricing pact with the Trump Administration to sell its drugs to Medicaid at a discount and participate in a new government website allowing patients to buy medications at a lower cash price. The deal also gives a three-year delay on any tariffs for AstraZeneca drugs imposed by the administration's ongoing "Section 232" probe. The agreement follows a similar White House deal with Pfizer and, like that agreement, doesn't affect those on commercial insurance or who won't pay out of pocket.

Cigna's Rebate-Free Pharmacy Model: Three Realities Behind Its Latest Push to Pop the Gross-to-Net-Bubble *(Drug Channels)*

Cigna announced that it would be abandoning traditional manufacturer rebates and moving to a new, "rebate-free" approach—essentially a point-of-sale (POS) rebate model paired with a cost-plus pharmacy reimbursement framework. Moving manufacturers' rebates and discounts to the point of dispensing is a big win for patients, who can share in the savings that pharmacy benefit managers (PBMs) negotiate with drugmakers. It's a practical, patient-friendly step toward shrinking the gross-to-net bubble that has inflated out-of-pocket costs for years.

Lilly, Battling Skepticism, Reinforces GLP-1 Pill's Case with New Study Data *(BioPharma Dive)*

Eli Lilly released the results of two new Phase 3 trials of an experimental GLP-1 pill that the Company says could become a "foundational treatment" for type 2 diabetes. Lilly's medicine, Orforglipron, succeeded on all primary and key secondary endpoints in clinical trials helping patients achieve an average body weight reduction of 12%. However, Wall Street was expecting more with hopes for weight loss of around 15%; Lilly's injectable drug Zepbound produced weight loss of as much as 21%, and Novo Nordisk has achieved 15% weight loss percentages for both oral and injectable versions. The Company plans to submit global regulatory applications for Orforglipron in the treatment of type 2 diabetes next year.

FDA Drug Approval Rates Drop to 73% as Review Delays and Rejections Rise in Q3 *(Medpath)*

The FDA's drug approval rate fell to 73% in Q3, marking a notable decrease from the 87% average recorded over the previous six quarters. This decline represents a significant shift in the agency's approval patterns and suggests potential challenges within the regulatory review process. Simultaneously, the rate of rejected marketing applications climbed to 15%, compared to the "historical average" of 10%.

HRSA Approves 340B Rebate Models to Hospitals' Chagrin *(BioPharma Dive)*

Federal regulators have greenlit 8 drugmakers to pilot a new 340B rebate program next year, upending how savings in the massive drug discount program are normally divvied out to providers. They include frequently prescribed drugs manufactured by companies like Bristol Myers Squibb and Johnson & Johnson, two drugmakers that sued the government after it blocked them from implementing their own 340B rebate plans. Hospital groups slammed the model approvals as benefiting drugmakers at their expense.