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Monthly News Brief

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How Trump's Trade Fight Could Impact the MedTech Industry *(MedTech Dive)*
President Trump's tariff plans, both real and threatened, are roiling the medical device industry due to a complex supply chain dependent on offshore manufacturing. The effect could be costly, and it is not clear whether tariffs directed at China, Mexico and Canada would be short- or long-term. Medical device companies rely on overseas sourcing, and they may be producing devices in the U.S. but sourcing raw materials and assemblies from other countries

Device Industry Scrambles as FDA Job Cuts Cause Delays *(MedTech Dive)*
The cuts at the FDA could delay the time it takes to bring new products to market and add to pressure on remaining staff at the FDA's device center. Advamed, one of the industry's largest lobby groups, has criticized the cuts, saying they would negatively affect medical device companies and could put patients at risk. The expectation is for the staff cuts to dramatically slow the process for preparing and reviewing medical device submissions, especially for devices with complex components such as artificial intelligence

Drug Compounders Sue FDA over Declaration Ending Wegovy Shortage *(BioPharma Dive)*
Drug compounders are suing the FDA again over obesity and diabetes drugs, claiming that the agency's decision to remove Novo Nordisk's semaglutide from its shortage list will deprive patients of a vital treatment. The original shortage declaration had permitted drug compounders to supply alternative versions of semaglutide, which Novo sells as Wegovy for weight loss and Ozempic for diabetes. The compounders argue a shortage still exists because the FDA acknowledged that there may still be "intermittent and limited localized supply disruptions as the products move through the supply chain"

FDA Greenlights First Clinical Trials for Genetically Modified Pig Kidney Transplants in Humans *(American Kidney Fund)*
Two companies have received FDA approval to conduct clinical trials transplanting genetically modified pig kidneys into patients with kidney failure. These trials will allow researchers to study how well the pig kidneys work and how safe they are for human patients. The goal is to increase the availability of transplantable organs to offer a therapeutic alternative to a lifetime on dialysis for a large population of patients who are unlikely to receive kidney transplants

Vertical Integration Redux: How Pharmaceutical Wholesalers are Transforming the Buy-and-Bill Market *(Drug Channels)*
The largest three pharmaceutical wholesalers—Cardinal Health, Cencora, and McKesson—are using vertical integration to build significant market positions in businesses beyond drug distribution

The Big Three PBMs' 2025 Formulary Exclusions *(Drug Channels)*
The three largest pharmacy benefit managers (PBMs)—Caremark (CVS Health), Express Scripts (Cigna), and Optum Rx (United Health Group)—have again each excluded hundreds of drugs from their standard formularies. For 2025, the Big Three PBMs shifted national formularies to favor their private-label biosimilars over Humira and its many biosimilar competitors. In fact, nearly all marketed Humira biosimilars are excluded from the larger PBMs' 2025 formularies. Like it or not, PBMs' financial benefits from their private-label product align with the benefits to plan sponsors and patients. But the PBMs' strategies, combined with the warped incentives baked into the Inflation Reduction Act, raise questions about the viability of the biosimilar marketplace

Pfizer Stops Selling Hemophilia Gene Therapy, Citing Weak Demand *(BioPharma Dive)*
Weak demand for Pfizer's hemophilia B gene therapy Beqvez has led the company to "cease further development and commercialization" of the one-time treatment. Pfizer's decision to drop Beqvez essentially marks the company's exit from the field of virally delivered gene replacement treatments. The company cited "the limited interest patients and their doctors have demonstrated in hemophilia gene therapies to date."

Lilly Expands US Manufacturing build-out with $50B Target *(BioPharma Dive)*
Eli Lilly will invest tens of billions more dollars in U.S. drug manufacturing in a significant enlargement of plans. Lilly, which makes the popular obesity medicine Zepbound, previously pledged to spend $23 billion on constructing and refurbishing factories in the U.S. Recently, the company more than doubled that target, saying that it expects to pour over $50 billion into U.S. capital expenditures. The company's decision to further invest in domestic manufacturing capacity reflected its conviction in its drug pipeline. "Our confidence positions us to help reinvigorate domestic manufacturing, which will benefit hard-working American families and increase exports of medicines made in the U.S.A."