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Monthly News Brief

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Key Exemptions could Limit Impact of Trump's Pharmaceutical Tariffs *(BioPharma Dive)*

The new 100% (down from 200%) pharmaceutical tariffs recently announced by President Trump could have a limited impact due to multiple exemptions for generics, exports from Europe (tariffs capped at 15%) and companies already onshoring manufacturing. Key details are unclear, however the 100% levies, which are much smaller than the figure previously floated by the Trump administration, alleviate some uncertainty around U.S. drug pricing policy. The tariffs will go into effect October 1st. The flurry of drugmaker investments in U.S. drug production this year…should exempt a wide swathe of the industry's drugs from the new levies. The tariffs won't apply, Trump posted, to companies that are "building their pharmaceutical plant in America," with "building" defined as "breaking ground" or "under construction."

Trump, Pfizer Drug Pricing Deal Short on Details, Possible Impact *(BioPharma Dive)*

Pfizer signed a deal with the Trump administration on September 23rd to offer "most favored nation" drug prices to every state Medicaid program and discounted prices directly to other consumers through a new website. The agreement also delays any tariffs on Pfizer drugs that might arise from the ongoing "Section 232" probe into the effects of pharmaceutical imports on national security. Pfizer additionally vowed to spend $70 billion on "research, development and capital projects" in the next few years. The actual impact of Tuesday's agreement on the prices paid by U.S. consumers may be limited. Since 1990, Medicaid, which provides coverage for millions of Americans, has gotten reduced prices through a mandatory drug rebate program that gives it a 23% discount off the average price paid by wholesalers and other large purchasers.

Section 232 Probe Reignites Tariff Uncertainty for MedTech Firms *(MedTech Dive)*

Medtech companies face more tariff uncertainty as the Trump administration opens a Section 232 investigation into medical equipment started on Sept. 2nd. The investigation applies to a wide variety of medical products, from syringes, needles and scalpels to IV bags, catheters and gauze. A federal register notice also listed more complex devices, such as wheelchairs, insulin pumps, pacemakers, heart valves, blood glucose monitors and imaging machines. Medical device firms are still looking into the potential implications. The earliest any 232 tariff actions would go into effect in summer 2026.

PhRMA Launches ad Campaign Urging Congress to Address '340B Medicine Mark-Ups' *(Fierce Healthcare)*

Pharmaceutical Research and Manufacturers of America (PhRMA), a lobbying group representing drugmakers, is ramping up its opposition to nonprofit health systems' expanding use of the 340B Drug Discount program ($66 billion of discounted purchases in 2023) with the launch of an advertising campaign describing the subsidies as "a hidden tax on patients, employers and taxpayers." PhRMA's campaign is the latest salvo in a fight between the sectors over a decades-old program requiring discounted drug purchases for safety-net providers. Drugmakers and providers have differing opinions on the program. The American Hospital Association, which represents the hospital industry, has broadly contested the pharmaceutical industry's claims and advocates against restrictions on providers' use of the program.

Multi-Cancer Blood Tests aren't Ready for Routine use, Review says *(MedTech Dive)*

Multi-cancer blood tests, with the promise of detecting many cancer types from a single sample, have the potential to transform cancer screening. However, evidence is lacking to support broad use of the tests in people who do not have symptoms, according to recent research. No MCD tests have FDA approval for multi-cancer screening, but some are available in the U.S. as laboratory developed tests, a regulatory pathway that does not require FDA approval. In addition, no insurance providers cover MCD tests for screening. MCD tests are intended to identify cancer before clinical signs or symptoms. The tests use biomarkers, including cell-free DNA, proteins or small molecule metabolites, to detect positive signals for different types of cancer. "These are pretty new technologies, and there's a lot of excitement, but it does take a long time to do all the right studies to figure out if these are actually beneficial."

CVS's Omnicare Files Bankruptcy After $949 Million Judgment *(Yahoo Finance)*

CVS Health. subsidiary Omnicare has filed bankruptcy after the pharmacy-services provider was ordered to pay $949 million over claims it improperly dispensed prescription drugs to individuals in long-term care. Omnicare said Chapter 11 will give it time to evaluate options to resolve the judgment and "address other financial challenges facing the broader long-term care pharmacy industry."