PNC PHARMA & LIFE SCIENCES

Monthly News Brief

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M&A

FTC Allows Amgen's \$28B Deal for Horizon to go Through, with Conditions (BioPharma Dive)

The Federal Trade Commission (FTC) is dropping its challenge to Amgen's \$28B acquisition of Horizon after the drugmaker committed it will not use bundling practices to win favorable insurer contracts for Horizon's gout and thyroid disease medicines. The settlement will likely reassure many in the pharmaceutical sector, as executives and investors had feared an activist FTC might seek to block more acquisitions

Cooper Scraps \$875MM Takeover of Cook Medical Business After FTC Investigation (MedTech Dive)

Cooper terminated its acquisition of Cook Medical's reproductive health business citing struggles to find a way to satisfy the competition concerns of the Federal Trade Commission (FTC). In August 2022, Cooper previously indicated that the deal faced regulatory opposition, telling analysts that it was exploring different options to close the transaction. Ultimately Cooper ended the planned takeover which the FTC said ensures that critical reproductive health markets remain competitive

FDA & Regulation

Medicare Names First 10 Drugs for Price Negotiations (BioPharma Dive)

Medicare announced the initial 10 drugs that will be subject to price negotiations, flexing newly granted authority that for the first time allows CMS to use its market power to lower the cost of certain medicines that are used by more than 8-million people that are covered by Medicare. The list's announcement moves forward an effort to expand the federal government's role in determining what drugmakers can charge for their products beginning in 2026

Boehringer Sues to Block US Drug Price Program (BioPharma Dive)

Boehringer is the latest large drugmaker to challenge Medicare's new power to negotiate prices of top-selling medicines. Merck, Bristol Myers Squibb, Astellas and Johnson & Johnson have each filed separate lawsuits in various district courts, along with the powerful industry lobbying groups PhRMA and the Chamber of Commerce. The companies allege the Inflation Reduction Act "IRA" violates the Fifth Amendment's guarantee of due process and protection against confiscation of property without just compensation, as well as First Amendment's free speech protection

US Signs Consent Decree Requiring EPA to Finalize Ethylene Oxide Rule by March (MedTech Dive)

The U.S. Government has signed a consent decree that requires the EPA to adopt a final rule on commercial sterilization standards by March 2024. The MedTech industry has concerns about the timeline and the emissions targets that the EPA wants to set, citing the deadline is inadequate with substantial analysis and regulatory drafting to complete

Other News

<u>Spine Volumes to Grow 6.5% Next Year as Post-Pandemic Boost Continues</u> (MedTech Dive)

U.S. spine surgeons expect procedure volumes to increase by 6.5% over the next year, suggesting medical device companies are anticipating growth above historical rates. Analysts have polled neurosurgeons and spine-focused surgeons annually since 2019, creating a dataset that shows how the sector was affected by the COVID-19 pandemic and the changes it caused

Blue Shield of California Drops CVS Caremark in Pharmacy Benefit Overhaul (BioPharma Dive)

Blue Shield of California is dropping CVS Caremark as its pharmacy benefit manager "PBM" in favor of a new arrangement that the nonprofit insurer payer expects will save \$500MM annually. The insurer which covers 4.8MM members plans to contract with multiple partners to deliver its pharmacy benefit, with the goal of eliminating any hidden fees or rebates

The Role Manufacturing Will Play in Advancing CGTs (Contract Pharma)

The research and development of Cell and Gene Therapies (CGTs) is growing at an unprecedented rate. Although there are only 7 CGT drugs approved by the FDA on the market right now, nearly 1,200 experimental therapies are currently in development. As these therapies advance from clinical research to commercialization, the manufacture of CGTs will play an essential role in providing these therapies at scale and ensuring these life-changing therapies reach patients. Given the nature of CGTs – which are derived from living cells and employ cutting-edge technologies in their production – they stand out as one of the most fragile and complex therapeutics, and require customized manufacturing processes.

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