

PNC PHARMA & LIFE SCIENCES

Monthly News Brief

July 2023

2023 Earnings

[J&J Earnings a 'Positive Early Indicator' for MedTech in Q2](#) *(MedTech Dive)*

Johnson & Johnson ("J&J") raised its full-year earnings forecast for the second quarter in a row, reflecting improved procedure volumes and a steady stream of new product launches in its MedTech segment. J&J's better than expected performance seems like a positive early indicator for what's ahead for the rest of the MedTech industry

[Thermo Fisher eyes \\$450MM in Cost Cuts Due to Slowing Demand](#) *(MedTech Dive)*

Thermo Fisher will make additional cost cuts in 2023, citing a more challenging macroeconomic environment in 2Q23. The reduction is mainly due to economic activity in China slowing significantly and biopharma customers growing more cautious in 2Q23 due to continuing funding challenges

FDA and Regulation

[FDA Adopts New Sterilization Standard to Support Switch from Ethylene Oxide](#) *(MedTech Dive)*

The FDA added an alternative sterilization method in response to pressure to reduce ethylene oxide (EtO) use and to support medical device supply chain resiliency. Manufacturers can now make declarations of conformity to the International Organization for Standardization's ("ISO") recommendations on low-temperature vaporized hydrogen peroxide. The FDA plans to modify its list of recognized consensus standards to include hydrogen peroxide vapor later this year

[Congress Puts PBMs in the Spotlight During a Busy Week on Capitol Hill](#) *(Bio News)*

Legislation to enforce pricing transparency of PBM activities was front and center on Capitol Hill in July. Bipartisan house committee advanced two bills to the full house - *The Transparency in Coverage Act* would make PBMs disclose rebates from drug makers, and then *The Hidden Fee Disclosure Act* would make PBMs disclose all fees they charge to drug makers. Separately, the Senate announced a draft of the *Medicare PBM Accountability Act* which is intended to increase pricing transparency

[New Antitrust Merger Guidelines Could have Chilling Effect on Healthcare Deals](#) *(BioPharma Dive)*

FTC and DOJ have proposed updates to U.S. merger guidelines that could free up regulators to crack down on consolidation in the healthcare industry. If guidelines are finalized, vertical and cross-market mergers will not be allowed to create anticompetitive market structures, and regulators will be able to examine vertical mergers even if below 50% market share. Also, the guidelines would enable regulators to scrutinize mergers that control products or services its rivals may use to compete and deals involving access to rivals' sensitive competitive information

[More, but Slower, MedTech Approvals](#) *(Evaluate Vantage)*

The medical device regulators have granted approval or clearance to 45 innovative products in 1H23, which is only one less than in the entirety of 2022. The caveat is, the agency took an average of nearly three years to grant the 22 approvals for high-risk devices, a much longer period than in prior years. The agency has launched the *Total Product Lifecycle Advisory Program*, which is an initiative aimed at shortening review times by offering swifter responses from the FDA during the premarket process

[Pharma's Strike-From-All-Sides Attack on the IRA Could End up at the Supreme Court](#) *(BioPharma Dive)*

The pharmaceutical industry is attacking the Inflation Reduction Act (IRA) with lawsuits that take a strike-from-all-sides approach, with companies and associations targeting different constitutional elements of the legislation. Merck and Bristol Myers are challenging using the First and Fifth Amendments, while others also include the Eighth Amendment in their lawsuit. The purpose is to ultimately force the government to overturn or limit the impact the IRA can have

[FDA Grants Eisai's Leqembi Full Approval, Opening Door to Wider Use of Alzheimer's Drug](#) *(BioPharma Dive)*

The FDA awarded full approval to the Alzheimer's disease treatment Leqembi. FDA concluded the drug was reasonably likely to provide some level of benefit to patients, based on results from a ~850-person study. Analysts estimate that Leqembi could reach \$10B in annual sales, meanwhile, the company estimates at least 10,000 patients will be on the drug by the end of 2023

Other News

[For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market](#) *(Drug Channels)*

Analysis reveals that more than 33,000 pharmacy locations, more than 50% of the U.S. pharmacy industry, act as contract pharmacies for the ~9,600 hospitals and other healthcare providers that participate in the 340B program. Five multi-billion-dollar, for-profit, publicly traded pharmacy chains and PBMs account for 75% of all 340B contract relationships. The 340B program mandates that pharmaceutical manufacturers provide outpatient drugs to certain healthcare providers at significant discounts

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