PNC PHARMA & LIFE SCIENCES

Monthly News Brief

October 2024

That's a Wrap: 5 Takeaways from the MedTech Conference *(MedTech Dive)*
Thousands of medical device professionals gathered at The MedTech Conference to discuss upcoming policies, new technologies and MedTech trends. Discussions about artificial intelligence and machine learning, upcoming deadlines for the FDA's laboratory developed test LDT rule, continued slow M&A activity, increasing diversity and patient representation in clinical trials, and the impact of the upcoming U.S. election led the agenda

CVS Replaces CEO Karen Lynch with Caremark Head *(BioPharma Dive)*
CVS replaced their CEO as the healthcare and pharmacy giant's financial challenges continue. The new CEO most recently headed up CVS' pharmacy benefit manger Caremark. The shakeup comes as CVS has faced a declining stock price since 2021 due to challenges with both its pharmacy operations and Medicare Advantage insurance segment. The pharmacy giant slashed its earnings outlook three times this year and confirmed it would lay off ~3,000 workers

Wealthy Nations Might be Reaching a Life Expectancy Limit, Study Suggests *(STAT News)*
People generally live a lot longer than they used to as global life expectancy has soared from 30 years in 1870 to 71 years in 2021. Reasons for the increase include vaccines, antibiotics, clean water, sanitation, and improvements in health care. This trend has now substantially slowed in wealthier nations, which appears to be nearing a limit in life expectancy improvements from modern medicine. Lower- and middle-income countries may experience rapid rises in life expectancy this century, but these increases will largely come from public health benefits that have already happened in wealthier nations. Sizable additional increases in life expectancy aren't likely unless researchers find a way to slow aging itself, with the authors declaring that "humanity's battle for a long life has largely been accomplished." Increases in life expectancy would slow because treating individual diseases wouldn't stop the aging process — the accumulation of damage to cells and tissues over time

Abbott CEO sees 'Mass Market Potential' for CGMs *(MedTech Dive)*
Abbott CEO touted the continuous glucose monitoring "CGM" space as having "mass market potential" as users continue to be drawn to new diabetes technology. Management outlined a global CGM market with ~10MM current users but ample room for growth with ~100MM people with diabetes in the developed world and ~500MM globally. Abbott looks to expand its diabetes business by reaching new users with one of the first over-the-counter CGMs targeted at patients without diabetes

Legacy Medical Devices Keep Regulators Up at Night *(MedTech Dive)*
Congress passed regulations in 2023 specifying cybersecurity requirements for medical device manufacturers, and the FDA issued a final guidance later that year. The new regulations are designed to ensure new/future devices are secure, but one thing keeps regulators up at night are legacy medical devices that have outdated or unsupported software. Many of those legacy devices are currently in operation in hospitals and while they perform as intended, they present cybersecurity vulnerabilities

The Number of AI Medical Devices has Spiked in the Past Decade *(MedTech Dive)*
The Food and Drug Administration authorized 950 AI or machine learning-enabled devices between 1995 and Aug. 2024, with 76% of those in radiology and 10% in cardiology. The pace of approvals has increased from six in 2015 to 221 in 2023. The trend has been driven by more connected devices, more investment into AI and machine learning and growing familiarity with how software is regulated as a medical device. About 97% of approved AI-enabled devices were cleared via the 510(k) pathway which is less rigorous, faster and cheaper than the agency's other market authorization options. Software intended to help clinicians make decisions has been a gray area. The FDA issued guidance in 2022 clarifying that AI intended to make specific recommendations around a diagnosis or treatment should be considered a medical device

FDA, Facing Pressure, to Review Position on Zepbound, Mounjaro Shortage *(BioPharma Dive)*
The FDA agreed to allow compounding companies to continue producing copycat versions of Eli Lilly's obesity and diabetes drugs Zepbound and Mounjaro while it reevaluates its decision to declare the drugs back in supply after having been on the FDA shortage list. Demand for the medicines has been so strong it's outstripped supply, leading to manufacturing shortages that have made it possible for direct-to-consumer companies to step in and offer compounded alternatives. Lilly and Novo have spent billions recently to boost manufacturing to meet demand for a GLP-1 market that is forecast to exceed $100 billion a year next decade. Lilly's moves have already paid dividends, as on Oct. 2, the FDA stated that "product availability and manufacturing capacity can meet the present and projected national demand." That declaration meant that legal restrictions on mass producing compounded copycats were back in place