

# PNC PHARMA & LIFE SCIENCES

## Monthly News Brief

June 2023

### FDA & Regulation

#### **EPA's Proposed Ethylene Oxide Regulations May Cost Sterilizers More than Estimated** *(MedTech Dive)*

Commercial medical device sterilizers may need to spend more than the \$220MM estimated by the EPA to meet the Agency's proposed lower Ethylene Oxide (EtO) emissions limits and to ensure enhanced pollution controls are working. Capital spending and operating costs would increase for commercial sterilizers if the EPA's proposal becomes regulation

#### **Merck Sues to Block Medicare Negotiation of Drug Prices** *(BioPharma Dive)*

Merck has sued the U.S. government over Medicare's newly granted authority to negotiate the prices of certain top-selling medicines, intensifying the pharmaceutical industry's attack on a law that drugmakers claim will hurt their ability to develop innovative therapies. In a lawsuit filed, Merck asked a federal court to declare the new pricing powers unconstitutional and block the government from enforcing their provisions, which were set out in last year's Inflation Reduction Act

#### **Medicare Sets Next Tranche of Drugs to Face Price Hike Penalties** *(BioPharma Dive)*

Administration announced it will levy penalties on the manufacturers of 43 prescription drugs for increasing prices within Medicare faster than inflation. The result is Medicare beneficiaries will pay lower coinsurance rates for 43 medicines starting next quarter. With the new coinsurance rates, consumers who take any of the fined drugs could pay between \$1 and \$449 less per average dose

#### **FDA Sets Decision Dates for Vertex, CRISPR Gene Editing Drug** *(BioPharma Dive)*

The FDA has accepted an application for what could be the first marketed medicine based on CRISPR gene editing technology, officially starting a review of a treatment Vertex Pharmaceuticals and partner CRISPR Therapeutics have developed for two rare blood disorders. The companies announced that the FDA will issue separate verdicts on the treatment's use in sickle cell disease and beta thalassemia. The treatment is the first of its kind to be brought to U.S. regulators and will be a best case for how the agency views the gene editing technology

#### **With FDA Approval in Hand, BioMarin Lays Out Plan to Sell \$2.9M Gene Therapy** *(BioPharma Dive)*

BioMarin secured FDA approval for its new hemophilia gene therapy known as Roctavian for certain people with hemophilia A, the more common form of the rare bleeding disorder. While there are other effective treatments already available, the hope surrounding Roctavian has been that, at least for some patients, it could be a one-time cure for their disease

#### **FDA Set to Unveil New Rule on Laboratory Developed Tests this August** *(Agency IQ)*

The FDA plans to release a proposed rule in August 2023 that would make explicit that laboratory developed tests (LDTs) are labeled as medical devices. The FDA's view on their regulatory oversight of LDTs has shifted, as clinical laboratories and diagnostic science have grown more advanced. LDTs are a kind of in vitro diagnostic (IVD) that are designed, manufactured, and used within a single laboratory which are regulated under the Clinical Laboratory Improvement Amendments (CLIA), which splits up regulatory oversight between the FDA, CMS, and CDC. Historically, the Agency did not exert its regulatory authority over these labs/products, while still maintaining that they were technically subject to the regulations that FDA was not enforcing at that time

#### **FDA Seeks Feedback on Technologies that can Enable Healthcare at Home** *(MedTech Dive)*

The FDA is asking for public input on the transition to at-home care and how it can support enabling technologies. As part of a push to advance health equity, the FDA has posed a series of home-care questions to the MedTech industry, about how it can support the development of devices for use in non-clinical care settings. The COVID-19 pandemic accelerated uptake and validation of telehealth and remote monitoring, setting the stage for wider use of the technologies

### Other News

#### **Interest in Elective Surgeries up 115% Over Pre-COVID Levels, Google Searches Show** *(MedTech Dive)*

Google searches for elective surgeries were up 115% in the U.S. over pre-pandemic levels, as analysts tracked searches in June for 20 elective procedures. Needham, which runs the reports on Google search trends weekly, has found that Google Trends are highly correlated with growth of the medical device market. As procedure volumes have increased since the start of 2023, some medical device companies raised their revenue expectations for the full year

#### **More Than 1 Billion People Could Have Diabetes by 2050** *(MedTech Dive)*

More than 1.31B people worldwide could be living with diabetes by 2050, compared with ~529MM people who had diabetes in 2021. The rise in prevalence is expected to be driven by increases in Type 2 diabetes. Overall healthcare spending related to diabetes is expected to rise to over \$1 trillion by 2045, global spending in 2021 was estimated at \$966B by the International Diabetes Federation

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