

PNC PHARMA & LIFE SCIENCES

Monthly News Brief

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[To Be \(a Device\) or Not To Be. That's The Legal Question](#) *(Citeline)*

In its final rule, the FDA phases out its general enforcement discretion of laboratory developed tests (LDTs) over four years, placing them under the same regulatory purview as other in vitro diagnostics (IVDs). Essentially, the final rule classifies LDTs as medical devices. But are LDTs medical devices? The central argument focuses on whether the tests are defined as medical devices, which the agency regulates without question. The FDA also contends it needs to regulate LDTs to help ensure they are safe and reliable because they have become more complex over time and because patients with often life-threatening diseases rely on their results

[Lab Industry Sues to Stop FDA's New LDT Rule](#) *(MedTech Dive)*

The American Clinical Laboratory Association (ACLA) sued the FDA, arguing that the agency does not have the authority to regulate laboratory developed tests (LDTs) as medical devices. The FDA moved forward with the controversial rule in April, tightening its oversight of the widely used tests to make them safer and more accurate. The ACLA argues that LDTs (a category of in vitro diagnostics designed and used within a single laboratory) are services (and not devices) carried out by laboratory professionals and Congress did not grant authority to the FDA to regulate them

[FDA Panel Backs Guardant's Blood Test for Colon Cancer](#) *(MedTech Dive)*

An FDA advisory committee recommended the agency approve Guardant Health's blood test for colorectal cancer, concluding the potential benefits of the screening outweigh its risks. Guardant's test is intended to detect colorectal cancer ("CRC") by sequencing the cell-free DNA isolated from a patient's blood sample. While colonoscopy remains the gold standard for colon cancer detection, and other screening options including stool-based tests are widely available, Guardant believes the convenience of a blood test will increase patient participation in screening for CRC

[Pfizer and Lilly are Elbowing into the Direct-to-Consumer Market. Will it Work?](#) *(BioPharma Dive)*

Eli Lilly and Pfizer have both recently launched direct-to-consumer platforms allowing patients to bypass an in-person doctor visit or brick-and-mortar pharmacy. Their decisions suggest large pharmaceutical companies are exploring new ways to reach patients and could indicate a growing trend. Lilly also announced it was teaming up with Amazon Pharmacy as a third-party dispensing provider. The program circumvents traditional pharmacies and offers access to Amazon's pharmacists around the clock. Pfizer told The Financial Times in May it plans to launch its own DTC website before the end of the year

[FTC Targets 'Junk Patents' on Ozempic, Other Top Drugs](#) *(BioPharma Dive)*

The FTC is challenging more than 300 patents filed with the FDA to protect market exclusivity for 20 top-selling drugs. The FTC first put the pharmaceutical industry on notice about abuse of the Orange Book in September, saying the agency would fight companies that try to "weaponize" the database. By filing bogus patent listings, pharma companies block competition and inflate the cost of prescription drugs, forcing Americans to pay sky-high prices for medicines they rely on. The FTC is fighting these illegal tactics and making sure that Americans can get timely access to innovative and affordable versions of the medicines they need

[Drug Patents Protect Pharma Profits. Track When They'll Expire Here](#) *(BioPharma Dive)*

Patents reward drugmakers for their inventions and, effectively, the large sums of money they invest in research and development. The legal monopoly that patents provide keeps generic copies at bay for many years, even decades. A major patent cliff faces the pharma industry later this decade, putting more than \$200 billion in annual revenue at risk through 2030. This will force companies into major decisions: Will they pour more money into research? Or will they buy their way out of trouble?

[Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: A May 2024 Update](#) *(Drug Channels)*

Over the last decade, there has been significant vertical consolidation among insurers, pharmacy benefit manager (PBM), pharmacies, specialty pharmacies, and providers. Today, 5 of the 6th largest PBMs are now owned by vertically integrated organizations. Five of the largest pharmacies are owned by vertically integrated organizations, with ~80% of all prescription claims processed by 3 companies. Businesses within these vertically integrated organizations have become significant customers of other jointly owned businesses within the same organization resulting in renewed scrutiny from the FTC, the Office of Inspector General, and Congress regarding their business practices

[US Hikes Tariffs on Medical Products From China](#) *(MedTech Dive)*

The U.S. is raising tariffs on medical products imported from China, amid a broader set of tariff hikes. The rate hikes focus on areas where the US has sought to boost domestic production, such as medical supplies that were essential to the COVID-19 pandemic response. The increases are intended to "encourage China to eliminate its unfair trade practices regarding technology transfer, intellectual property, and innovation"

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