PNC PHARMA & LIFE SCIENCES

Monthly News Brief

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FDA Sets Advisory Panel for Galleri Multicancer Screening Test *(Medtech Dive)*
The FDA will hold an advisory committee meeting in September to review Grail's Galleri multi-cancer blood test, a key milestone in the company's pursuit of FDA approval. Although Galleri missed the primary endpoint in a major U.K. study, Grail maintains the test can help detect certain cancers earlier and still expects approval in early 2027. Investors are closely watching the panel's recommendation, as Galleri could become the first FDA-approved multi-cancer early detection (MCED) blood test if ultimately approved.

Guardant Aims to Expand Cancer Screening With a Blood Test *(Medtech Dive)*
Guardant Health said its Shield blood test is helping expand early colorectal cancer screening by reaching patients who have historically avoided colonoscopies and other traditional screening methods, with adoption aided by recent support from the American Cancer Society and coverage from UnitedHealthcare. The company is also developing a next-generation version of Shield to improve detection of early-stage cancers and precancerous lesions, while expanding into multicancer detection with a test targeting 10 common cancers. Management ultimately intends to seek FDA approval for the multicancer platform as it gathers additional clinical and real-world evidence.

Roche, Eli Lilly Gets FDA Nod for New Alzheimer's Blood Test *(BioPharma Dive)*
The FDA cleared Roche and Eli Lilly's Elecsys pTau217 blood test to help diagnose Alzheimer's disease in patients 55 and older with signs of cognitive decline. The test measures a key biomarker linked to amyloid plaque buildup and could make diagnosis more accessible by reducing reliance on PET scans and spinal fluid testing. Labcorp and Quest plan to offer the test as competition in the Alzheimer's diagnostics market continues to intensify.

CMS Seeks Feedback on Faster Coverage for Breakthrough Devices *(Medtech Dive)*
CMS is seeking feedback on a proposed program called RAPID (Regulatory Alignment for Predictable and Immediate Device Coverage) that could significantly speed Medicare coverage for certain FDA-designated breakthrough medical devices. Under the proposal, CMS could issue a proposed national coverage decision on the same day a device receives FDA authorization, allowing Medicare coverage to begin as soon as 60 days. The initiative aims to accelerate patient access to innovative technologies by aligning CMS and FDA reviews earlier in the development process, though in vitro diagnostics and devices already far along in development would not be eligible.

Moderna and Merck Cancer Vaccine Returns 'Landmark' Result in Melanoma *(BioPharma Dive)*
Moderna and Merck reported that their personalized mRNA cancer vaccine, used in combination with Keytruda, met the primary goals of a Phase 3 melanoma trial by significantly reducing the risk of disease recurrence and spread following surgery compared with Keytruda alone. The result is viewed as a major milestone for the cancer vaccine field, which has struggled for decades to produce successful therapies. While detailed data have not yet been released, analysts called the outcome a potential breakthrough and believe the treatment could generate billions in sales if approved. The companies are also evaluating the vaccine in lung, kidney, and bladder cancers.

How Cost and Perception Could Reshape the GLP-1 Market *(BioPharma Dive)*
As Eli Lilly and Novo Nordisk compete for leadership in the rapidly growing GLP-1 obesity market, success will depend not only on product performance but also on affordability, physician preferences, and patient access. Surveys indicate physicians generally favor Lilly's Zepbound for weight-loss efficacy and tolerability, while Novo's products are viewed more favorably on cost and access. High out-of-pocket expenses remain a key barrier to long-term use, causing many patients to discontinue therapy, while improving public acceptance suggests cost and access may be just as important as clinical performance in shaping future market share.

Lilly Files Six Lawsuits in Bid to Shut Down 'Black Market' for Retatrutide *(BioPharma Dive)*
Eli Lilly filed six new lawsuits targeting the unauthorized sale of retatrutide, its investigational obesity drug, alleging that online sellers and peptide vendors are marketing potentially counterfeit or improperly dosed versions. The company has referred more than 200 entities to regulators and flagged over 14,000 websites, ads, and social media listings as it works to curb a growing black market ahead of an expected FDA submission next year.

Ortho Firms Unfazed by Medicare Joint Replacement Changes *(Medtech Dive)*
Orthopedic device makers do not expect Medicare's new CJR-X joint replacement payment model to materially pressure implant pricing, despite shifting more financial responsibility to hospitals. Management teams noted that implants represent only ~14%-15% of total joint replacement costs, with most savings expected to come from improved care efficiency, fewer readmissions, shorter hospital stays, and greater use of outpatient and ASC settings. While the model may encourage adoption of cost-saving technologies such as remote monitoring and digital physical therapy, the industry largely believes it will have little impact on orthopedic implant pricing.

The K-Shaped Pharmacy Shakeout: Consolidation in Cities, Lost Access in Rural America *(Drug Channels)*
The U.S. pharmacy industry is experiencing a "K-shaped" shakeout, with pharmacy closures having vastly different impacts depending on location. While nearly 8,000 pharmacies have closed since 2018, prescription revenue continues to rise due to specialty drug growth. Closures are often absorbed in urban markets, but in rural areas they can eliminate local access to medications, leaving more Americans in pharmacy deserts as industry consolidation accelerates.