PNC PHARMA & LIFE SCIENCES

Monthly News Brief

July 2026

FDA Authorizes More Devices So Far in 2026, But It's Taking Longer *(Medtech Dive)*

The FDA has authorized more medical devices in the first half of 2026 than during the same period in 2025, including 23 PMA approvals versus 13 last year. However, review timelines have lengthened across nearly all pathways, with average Premarket Approvals "PMA" review times rising to about 599 days from 402 days. While the uptick in approvals is encouraging, slower reviews could create challenges for medtech companies, particularly smaller firms that rely on predictable regulatory timelines for funding and commercialization.

CMS's Decision to End Subsidiaries to Medicare's Stand-Alone Drug Plans Could Mean Larger Premium Increases for Some Beneficiaries Next Year *(KFF)*

CMS will end its Medicare Part D Premium Stabilization Demonstration after 2026, eliminating subsidies that helped limit premium increases during the IRA Part D redesign. As a result, some stand-alone Part D plan "PDP" beneficiaries could face higher premiums in 2027. The program cost about $9.8B over 2025-2026, reduced average monthly premiums by $26 in 2025 and $16 in 2026, and helped boost PDP enrollment from 22.8MM in 2024 to 24.9MM in 2026.

Medicare Slashes 340B Payments, Broadens Site-Neutral Policies in Proposed 2027 Payment Rule *(Healthcare Dive)*

CMS proposed a 2027 Medicare rule that would cut 340B drug reimbursement rates and expand site-neutral payments for certain imaging services, aiming to lower Medicare spending and reduce cost differences between hospital outpatient departments and physician offices. The proposal would reduce payments for 340B-acquired drugs from ASP plus 6% to ASP minus 33.4%, a move CMS says better reflects hospitals' acquisition costs. Hospital groups strongly opposed the change, arguing it would hurt safety-net providers that rely on 340B savings to fund patient care.

Court Dismisses PBMs' Lawsuit Against FTC Following Insulin Settlements *(Healthcare Dive)*

A federal appeals court dismissed the PBMs' lawsuit against the FTC after Express Scripts, CVS Caremark, and Optum Rx agreed to settle allegations that they contributed to higher insulin prices through rebate-driven formulary practices. The FTC's case can now proceed under the settlement terms, which include greater transparency and changes intended to reduce incentives to favor higher-cost drugs. The ruling marks a regulatory victory for the FTC and increases pressure on PBMs to reform pricing practices.

Trump Threatens Tariffs on Imported Generic Drugs *(BioPharma Dive)*

President Trump's latest proposed tariffs on imported generic drugs could be significantly more disruptive than prior pharmaceutical tariff threats because generic manufacturers operate on thin margins. The plan would impose tariffs of up to 200% on imported generics unless companies move production to the U.S., raising concerns about drug shortages, supply chain disruptions, and higher costs. Generic drugmakers argue that domestic manufacturing faces structural challenges beyond trade policy, and investors reacted negatively due to the potential impact on profitability.

Judge Stays Trump Administration Policies Set to Shrink ACA Marketplaces *(Healthcare Dive)*

A federal judge temporarily blocked several Trump administration ACA marketplace changes, ruling they could reduce coverage access and increase patient costs. The decision is a near-term positive for ACA-focused insurers as it avoids additional marketplace disruption and potential membership losses. However, the ruling is temporary, and similar ACA restrictions included in recent federal legislation are still expected to take effect in future years.

ACA Enrollment Declines by Nearly 3M *(Healthcare Dive)*

Enrollment in Affordable Care Act health plans declined by nearly 3MM people this year. About 19.2MM people were enrolled in ACA marketplace plans in February, down about 13% from the same time in 2025 after enhanced premium subsidies lapsed last year. The enhanced tax credits, which went into effect in 2021. The tax credits spurred ACA enrollment growth, breaking sign-up records for four years in a row. After the subsidies expired, premium payments rose by an average of 58%.

Compounders Maintain a Firm Grip on the GLP-1 Market *(BioPharma Dive)*

Despite FDA crackdowns, lawsuits from Novo Nordisk and Eli Lilly, and growing safety concerns, compounded GLP-1 weight-loss drugs remain popular. A Gallup survey found nearly 1 in 5 GLP-1 users take non-FDA-approved compounded versions, which gained traction during shortages of Wegovy and Zepbound. While regulators and drugmakers are increasing efforts to limit the market, strong consumer demand suggests compounded GLP-1s will remain a competitive challenge even as branded drug supply improves.

Biotech Startup Funding Gap Widens Despite Rebound in VC Investment *(BioPharma Dive)*

Biotech venture funding rebounded in 1H26, with 68 companies raising over $9.1B, the strongest first-half funding environment since 2022. The recovery has been driven by improved IPO activity and a surge in biotech M&A. However, most of the capital is flowing to later-stage companies with clinical assets, while seed-stage startups and first-time founders continue to face a challenging fundraising environment. Investors remain focused on lower-risk areas such as oncology and immunology, which accounted for more than 40% of the funding, while cell and gene therapy companies continue to struggle to attract capital.

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