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U.S. Pharma Consulting (USPC)
Special Edition: 2025 - 2026 Segment-Specific Industry Update
Brand/Innovator Drugs, Generics, Biotech, Cell & Gene Therapy and PBM's

Brand/innovator drugs

The global branded drug segment continues to represent the largest share of pharmaceutical value, driven by high-value specialty medicines and sustained investment in innovation. In 2025, growth remains concentrated in therapeutic areas where clinical differentiation, durable intellectual property, and integrated patient support models can justify premium pricing. Branded products in oncology, immunology, metabolic disease, and rare disorders continue to anchor revenue for large and mid-cap pharmaceutical companies, even as several legacy blockbusters face loss of exclusivity.[1,2]

Branded pharmaceutical strategy increasingly reflects a shift toward lifecycle optimization rather than pure pipeline expansion. Companies are prioritizing indication extensions, formulation improvements, combination strategies, and global launch sequences to maximize post-approval value. Payers and health systems are exerting greater pressure on pricing and access, reinforcing the importance of early evidence generation and outcomes-based narratives to support reimbursement decisions.[3,5]

In hospital and acute-care settings, branded portfolios are also being reassessed through the lens of antimicrobial resistance. Rising rates of resistant infections, particularly those driven by Gram-negative pathogens, are elevating the clinical and strategic value of differentiated anti-infective agents. Global health authorities continue to identify AMR as a critical threat, reinforcing the importance of novel mechanisms, extended-spectrum coverage, and therapies that can integrate effectively with antimicrobial stewardship programs.[2,3] In this context, branded hospital antibiotics are increasingly evaluated not solely on volume potential, but on reliability, resistance coverage, and their role in protecting broader health-system outcomes.

Generics and biosimilars

Generics remain essential to healthcare systems worldwide, accounting for the vast majority of prescription volume while delivering substantial cost savings. In the United States and other developed markets, generics continue to face intense pricing pressure driven by competitive tendering, buyer consolidation, and regulatory expectations around quality and supply continuity. Despite these pressures, generics play a foundational role in maintaining access to both chronic and acute therapies.[5]

In biologics, biosimilars represent an expanding segment as regulators and policymakers work to lower development barriers and accelerate competition in high-cost therapeutic classes. Regulatory agencies are increasingly focused on streamlining approval pathways and clarifying evidentiary requirements to support broader biosimilar adoption.[6] While uptake varies by market and therapeutic area, biosimilars are expected to remain a central component of long-term drug cost containment strategies.

Key distribution development - Private-label biosimilars represent a meaningful inflection point in wholesaler vertical integration, signaling a shift from passive distribution to active market shaping. McKesson's NorthStarx securing an NDC for a pegfilgrastim biosimilar for NEULASTA® underscores how ownership of product, combined with control over buy-and-bill distribution, contracting, and data, can directly influence provider behavior and market access. This is less about incremental margin on a single molecule and more about wholesalers testing whether they can evolve into true market makers—using private-label biosimilars to steer utilization, strengthen negotiating leverage with manufacturers and providers, and capture value across the channel rather than at a single transactional point.
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process

Within hospital settings, antimicrobial resistance materially affects generic antibiotic portfolios. While pricing power remains limited, the strategic importance of generic injectable and inpatient antibiotics has increased due to their role as first-line and backbone therapies in empiric and targeted treatment protocols. Healthcare systems rely heavily on consistent access to these essential medicines, and supply disruptions or quality failures can directly compromise patient care and AMR stewardship efforts.[3] As a result, manufacturing resilience, redundant sourcing, and transparent quality systems have become critical differentiators for generic manufacturers serving hospital markets.

In ventilated and critically ill patient populations, the importance of antimicrobial resistance is further amplified, as ventilator-associated pneumonia and severe pulmonary infections represent some of the highest-risk, highest-cost complications in hospital care. These settings demand immediate, empiric coverage with reliable agents capable of addressing resistant pathogens, where delays or therapeutic failure can rapidly escalate mortality, ICU length of stay, and downstream resource utilization. As a result, both clinicians and hospital systems place heightened value on antibiotics that demonstrate predictable efficacy in ventilated patients, support stewardship goals, and integrate seamlessly into ICU protocols, reinforcing the strategic and clinical importance of dependable inpatient anti-infective portfolios in AMR-driven care pathways.[4]

In economic terms, ventilator-associated infections exert disproportionate pressure on hospital DRGs by extending ICU stays, increasing ventilator days, and triggering downstream complications that are often unreimbursed, making effective AMR-focused therapies in ventilated patients a direct lever for both clinical outcomes and hospital financial performance. This emphasis underscores why continued innovation in anti-infective resistance drug development is essential for severe, hospital-acquired, and ventilator-associated infections, which are fundamentally different from self-limiting outpatient respiratory illnesses and cannot be addressed by legacy or low-acuity treatment paradigms.

Biotechnology

The biotechnology sector continues to serve as a primary engine of pharmaceutical innovation. Emerging biopharma companies contribute a substantial proportion of active development programs globally, particularly in specialty and first-in-class therapeutic areas. Over the past decade, smaller and mid-size biotech firms have accounted for a growing share of pipeline assets advancing into late-stage development, underscoring their importance to the future drug supply.[7]

In 2025, collaboration remains a defining feature of the biotech landscape. Larger pharmaceutical companies increasingly rely on licensing, co-development, and acquisition strategies to access innovative science while managing internal risk and capital allocation. Dealmaking trends reflect a focus on asset quality, clinical differentiation, and translational readiness, with investors and strategic partners favoring programs that demonstrate clear paths to regulatory approval and commercialization.[8]

The biopharma dealmaking landscape is poised for a decisive acceleration in 2026**,** driven by a convergence of capital returning to the sector, increased urgency around pipeline diversification, and a maturing cohort of AI-enabled drug discovery platforms that are finally producing clinically validated assets.

Cell and Gene therapy (CGT)

Cell and gene therapy continues to evolve as a distinct and strategically important segment of the pharmaceutical industry. These modalities offer the potential for transformative and, in some cases, curative treatments across oncology, rare genetic disorders, and select neurological conditions. In 2025, the clinical development ecosystem supporting cell and gene therapies continues to expand, with increasing numbers of trials, manufacturing investments, and regulatory engagements worldwide.[9]

At the same time, execution complexity remains high. Manufacturing scalability, supply chain coordination, comparability requirements, and site-of-care logistics continue to shape development and commercialization strategies. Large pharmaceutical companies are selectively expanding internal capabilities and acquiring specialized platforms to address these challenges, while also rationalizing portfolios to focus on programs with the highest likelihood of sustainable clinical and commercial impact.[10]

Recent regulatory activity in the United States also highlights the continued use of **single-arm clinical trials** as a pathway to accelerated approval for therapies addressing serious or unmet medical needs, particularly in areas where conventional randomized controls are impractical or infeasible.

For example, the U.S. Food and Drug Administration granted accelerated approval in 2025 to datopotamab deruxtecan for advanced EGFR-mutated non-small cell lung cancer on the basis of compelling single-arm data demonstrating meaningful response rates in a heavily treated population, reflecting the agency's willingness to rely on such evidence when traditional clinical trial designs present challenges. [12] Additionally, novel treatments for rare and serious conditions have been developed under regulatory flexibility that can accept adequate evidence from single-arm studies, reinforcing the strategic importance of innovative development approaches for high-impact indications where historical controls, surrogate endpoints, or early response signals can reasonably predict clinical benefit. [13]

Payers – PBM's (A Paramount Outcome – Economic Shift)

On February 4, 2026, the Federal Trade Commission announced a binding consent order requiring Express Scripts and affiliated Cigna/Evernorth entities to materially restructure core PBM incentive frameworks historically tied to list price (WAC) and rebate magnitude, particularly within insulin categories[14,15]. Below are the order mandates structural changes including:

- ✓ Removal of formulary designs that favor higher-WAC drugs when lower-WAC equivalents exist[16]
- ✓ Patient cost-sharing based on net price rather than list price[14]
- ✓ Mandatory point-of-sale rebate and discount pass-through no later than January 1, 2028[17]
- ✓ Delinking PBM compensation and manufacturer fees from list-price benchmarks[18]
- ✓ Prohibition of spread pricing and rebate guarantees within the standard offering[18]
- ✓ Expanded drug-level and claim-level transparency for plan sponsors[19]
- ✓ Transition to acquisition-cost-plus reimbursement for retail community pharmacies[20]
- ✓ Relocation and disclosure compliance requirements for rebate GPO operations[21]

Implementation is phased, with certification triggers and full operational compliance required no later than January 1, 2028[15,17], subject to independent compliance monitoring and reporting obligations[15].

Strategically, this represents a structural pivot away from rebate-maximization models and toward a net-price-first environment at the point of sale. If similar frameworks extend across the broader PBM landscape, implications move beyond insulin into formulary contracting, manufacturer fee architecture, pharmacy reimbursement structures, and overall channel economics.

Against this backdrop of enforceable PBM restructuring[14,15], and reinforced by CMS Health Tech Ecosystem initiatives emphasizing interoperability, governed data use, and utilization-linked reimbursement expectations, strategic advantage increasingly accrues to organizations capable of aligning contracting strategy, regulatory positioning, real-world evidence generation, and commercialization architecture within a transparent, net-price-driven framework.

U.S. Pharma Consulting (USPC) – From Molecule to Market and, most importantly, Market back to Molecule development – operates at this convergence point, translating structural policy shifts into practical, value-protective execution across regulatory, payer, and commercial domains. A Board-Level Executive Advisory Brief is available for $1,750 per organization.

External Sources

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19. FTC Consent Order, Section XI (Expanded plan sponsor transparency and reporting obligations).
20. FTC Consent Order, Section XII (Retail community pharmacy acquisition-cost-plus reimbursement framework).
21. FTC Consent Order, Section XIV (Rebate GPO relocation and federal safe harbor disclosure compliance requirements).

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