RegenMed

ARTICLE

THE $200 BILLION BIOLOGICS FRONTIER

www.rgnmed.com | circles@rgnmed.com

THE MARKET CATALYST: THE 51% SPEND CRISIS

By early 2026, biologics have become the primary economic driver of U.S. healthcare. While these complex, large-molecule treatments represent only **5% of all prescriptions**, they now account for an staggering **51% of total drug spending** as of late 2025. The U.S. biologics market is currently valued at approximately **$203.6 billion**, with projections indicating it will exceed **$483 billion by 2034**.

Commissioner Marty Makary has identified this concentration of spend as a systemic inefficiency, often referring to the high cost of biologics as a barrier to patient access. In response, the FDA has initiated a pivot toward **"Analytical Veracity"**. For new biologics — particularly monoclonal antibodies (mAbs), which account for nearly 70% of the market share — the agency is beginning to replace multi-year human trials with advanced laboratory characterization and real-time monitoring.

THE EVIDENCE GAP: THE HIGH-STAKES LICENSING RISK

As the FDA accelerates the approval of these molecules through the **National Priority Voucher** and other fast-track programs, the primary risk for manufacturers and clinicians moves from "regulatory approval" to "market sustainability". When a biologic with a six-figure annual price tag is approved on an accelerated timeline, payers — both public and private — demand more than a preliminary snapshot; they demand **Verified Clinical Veracity**.

Legacy healthcare data systems fail this test. Most existing data consists of **Administrative Proxies (Data Exhaust)** captured for billing, which lacks the clinical depth to prove long-term efficacy or address the **"Measurement-to-Management Gap"** that stalls value-based transitions. Without **Audit-Ready "Ground Truth"**, high-value biologics face the constant threat of "reimbursement limbo".

THE CIRCLE SOLUTION: BUILDING THE INFRASTRUCTURE OF EVIDENCE

The **Circles** platform provides the **Regulatory-Grade Governance** required to secure these high-valuation assets across any specialty, from oncology to immunology. By defining the data architecture via **Observational Protocols (OPs)** *before* the biologic is administered, Circles ensure that every patient encounter generates a high-fidelity dataset.

Outcome Engineering: Circles capture **Standardized Longitudinal Scores** (e.g., functional assessments and metabolic markers) at the point of care, providing the permanent audit trail necessary to justify premium pricing to payers.

Insurable Integrity: By providing **Verified Clinical Veracity**, Circles create a "shield" for the clinical node, making billing errors or protocol deviations technically impossible and ensuring the data is ready for federal scrutiny.

Strategic Monopoly: High-volume, high-veracity data sets within a Circle enable the use of **Synthetic Control Arms (SCAs)**, which can supplement or even replace traditional clinical trials, creating a strategic advantage for manufacturers and clinical networks alike.

STRATEGIC OUTCOME: VALUATION VIA TECH-ENABLED ASSETS

In the legacy model, biologics were a "pass-through" cost for clinics. In the 2026 regulatory environment, the data generated by these treatments is the asset. By utilizing Circles to provide **Insurable Integrity**, a Management Services Organization (MSO) reclassifies itself as a **Tech-Enabled Asset**.

This shift is the primary driver for **Multiple Expansion**, moving an organization from a standard **6–8x service multiple** to a **12–15x asset multiple**. The value is no longer in the administration of the drug, but in the **"Ground Truth"** evidence that secures its place in the market.

GET INVOLVED OR LEARN MORE — CONTACT US TODAY!

If you are interested in contributing to this important initiative or learning more about how you can be involved, please contact us*:

RegenMed | www.rgnmed.com

circles@rgnmed.com

SCAN ME

*If the links do not work for you, please download the PDF.