

ARTICLE

THE VELOCITY OF VERACITY

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THE REGULATORY CATALYST: THE 60-DAY REVIEW

In 2025, FDA Commissioner Marty Makary introduced the **Commissioner's National Priority Voucher (CNPV)**, a pilot program that reduces the standard 10–12 month review clock to a mere 30–60 days. Designed to fast-track treatments that align with "U.S. National Interests"—such as onshoring manufacturing, increasing affordability, or tackling the chronic disease crisis—the NPV replaces the traditional, sequential review process with a multidisciplinary, "tumor board style" evaluation.

By January 2026, the first wave of approvals has proven that the "red tape" of the past century can be bypassed. However, this acceleration has created a "Scientific Reputational Risk". Career scientists and outside experts have expressed concerns that ultra-compressed windows may sacrifice the rigor required to identify long-term safety signals. For the manufacturer, the prize of early market entry now comes with a significant tail of legal and clinical liability.

THE EVIDENCE GAP: THE "SPEED-TO-PAYER" BARRIER

The true bottleneck is no longer the FDA; it is the payer. Public and private insurers have historically been skeptical of products that bypass traditional evaluation pathways, often delaying coverage until "sufficient" real-world safety and efficacy data emerges.

This creates a "Measurement-to-Management Gap." A drug or device may be legally approved in 60 days, but if the manufacturer cannot provide **Verified Clinical Veracity** of its performance in the real world, it will languish in "reimbursement limbo". Legacy "Data Exhaust"—static snapshots from billing and claims—is too slow and too imprecise to satisfy insurers who are now assessing the adequacy of the FDA's truncated review.

THE CIRCLE SOLUTION: INSURABLE RISK MODELING

The **Circles** platform provides the infrastructure to bridge this gap through **Insurable Risk Modeling**. By establishing Regulatory-Grade Governance at the clinical node, Circles allow manufacturers and providers to monitor performance in real-time, effectively extending the "clinical trial" into the "real-world" without loss of data integrity.

Verified Clinical Veracity: Circles capture **Standardized Longitudinal Scores** directly from the patient and provider, creating an **Audit-Ready "Ground Truth"** that can be shared with payers to accelerate coverage decisions.

Safety-in-Motion: Because Circles operate with pre-structured **Observational Protocols (OPs)**, it can identify safety or efficacy signals months faster than traditional post-market surveillance. This "Safety-in-Motion" is the only viable defense against the liability risks inherent in accelerated approvals.

Surgical-Delay Proof: For clinical organizations, this data architecture ensures that Value-Based Care transitions are not stalled by insurer skepticism. You aren't just performing a procedure; you are generating the **Insurable Integrity** that justifies the payment.

STRATEGIC OUTCOME: CAPTURING THE "INTEGRITY PREMIUM"

In a 60-day review environment, the "Insurable Integrity Premium" becomes the primary driver of enterprise value. Organizations that rely on administrative proxies will be seen as high-risk liabilities. Organizations that utilize Circles to provide transparent, verifiable outcomes will be viewed as **Tech-Enabled Assets**.

For the healthcare executive, this is the path to **Multiple Expansion**. By owning the veracity of the data, the clinical entity moves from a 6–8x service multiple to a **12–15x asset multiple**, fundamentally decoupled from the volatility of the new regulatory speed.

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