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Client Alert

FDA Regulatory
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Congress Reauthorizes Pediatric Priority Review Voucher Program in FY2026 Budget — Renewed Incentives for Rare Pediatric Drug Development

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Overview

As part of the recently enacted Consolidated Appropriations Act of 2026, Congress has reauthorized the Rare Pediatric Disease Priority Review Voucher (RPD PRV) program, long sought by the biopharmaceutical and life sciences sectors. This critical legislative development renews a key regulatory and commercial incentive for sponsors developing therapies for rare pediatric diseases ("RPDs"), providing renewed clarity and strategic opportunity for companies in these spaces.

What Is Included in the FY2026 Budget

Reauthorization of the RPD PRV Program

The Consolidated Appropriations Act of 2026, signed into law on February 3, incorporates provisions from the Mikaela Naylon Give Kids a Chance Act, restoring authority for the FDA to award RPD PRVs. This legislative vehicle was incorporated into the broader budget package that ended a partial government shutdown earlier this month.

Extended Program Duration

Under the newly enacted statute, the RPD PRV program is now authorized through September 30, 2029, halting a period of legal and commercial uncertainty by reinstating an incentive structure that began in 2012, entered a sunset period and finally lapsed at the end of 2024.

What the RPD PRV Program Does

The RPD PRV program remains structured as a regulatory and commercial incentive for sponsors of therapies that treat RPDs:

- Designation as a Drug for a Rare Pediatric Disease: Sponsors can request the FDA to designate a drug as a RPD drug; such drug must treat a serious or life-threatening condition that primarily affects patients from birth to 18 years of age and has a prevalence of fewer than 20,000 people in the United States;
- Award of voucher: Upon FDA approval of a designated RPD drug (defined under the statutory criteria), a sponsor receives a RPD PRV.
- Voucher utility: A voucher allows the holder of the RPD PRV to secure priority review (an approximately six-month FDA review) for a different new drug application — accelerating traditional approval timelines by several months.
- Transferability: Crucially, these RPD PRVs are fully transferable and marketable, allowing sponsors to sell them to third parties, often generating substantial nondilutive funding.

Historically, the secondary market for these RPD PRVs has seen transactions in the hundreds of millions of dollars, underscoring their strategic importance in corporate development and financing strategies. Recent sales of RPD PRVs include:

- Jazz Pharmaceuticals — $200 million in January 2026
- Abeona Therapeutics — $155 million in June 2025
- Zevra Therapeutics — $150 million in April 2025
- Acadia Pharmaceuticals — $150 million in December 2024
- PTC Therapeutics — $150 million in November 2024
- Ipsen — $158 million in August 2024

Strategic Implications for Life Sciences Companies

Renewed Incentives for RPD Drug Development

The reinstatement of the RPD PRV program effectively restores a long-standing regulatory incentive for advancing RPD therapeutics — an area often challenged by small patient populations and extended development timelines.

Commercial Valuation Considerations

Sponsors with eligible approvals or expected approvals may now contemplate the timing of filings to secure a RPD PRV or consider monetizing an award. RPD PRVs remain a noteworthy component of corporate value and financing discussions in M&A, venture, and licensing transactions.

Program Eligibility and Deadlines

Although the program is now extended through 2029, sponsors should continue to monitor FDA guidance and statutory deadlines — particularly around designation timing and application approval windows — to preserve eligibility.

Ongoing Policy and Operational Considerations

Sponsors should also be mindful of the evolving dynamics around voucher demand and pricing in the context of other FDA expedited pathways (e.g., emerging national priority review initiatives) that may interact with strategic planning.

Next Steps for Industry

1. Assess portfolio eligibility: Evaluate current and planned development of RPD assets for RPD designation eligibility and optimal application timing.
2. Engage FDA early: Engage with the FDA on designation requests and program requirements to align development timelines with RPD PRV opportunities.
3. Develop capital and licensing strategies: Consider potential RPD PRV monetization in broader financing and partnership negotiations, particularly for earlier-stage and specialty biotech companies.

Contacts

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