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Company	Rating	Price	Target
Biotechnology			
ARCT-NASDAQ	Buy	US\$17.85	US\$66.00
RARE-NASDAQ	Buy	US\$31.82	US\$128.00
RCKT-NASDAQ	Buy	US\$3.28	US\$10.00
TNYA-NASDAQ	Buy	US\$1.35	US\$6.00
TSHA-NASDAQ	Buy	US\$3.36	US\$14.00
VRTX-NASDAQ	Hold	US\$396.12	US\$411.00
WVE-NASDAQ	Buy	US\$8.29	US\$19.00

Priced as of close of business 5 September 2025

Genetic medicine for generalists: Primer on the Priority Review Voucher Program

If you pay attention to the therapeutics space, you might have heard about PRVs, a way to accelerate FDA review timeline of a drug for any company that has one, and a lucrative source of non-dilutive capital for those who have one but don't need it. You may have also heard that recent legislative efforts to extend the PRV program were not successful and congress began phasing out the program at the end of 2024, putting a deadline on eligibility. In the current environment, this is particularly problematic for some companies who were/are planning on PRV-sale related cash to extend runway. As a result, many companies (including several in our coverage) are racing against the clock to secure FDA approval of their drugs by 2026.

So what is a PRV exactly? How does a company get one, and what exactly are the benefits of using one? If a company has one to sell, how much would it cost? If you're wondering about these same

questions, or if you kinda know but need a refresher, this is the primer for you. In the following slides we delve into PRVs: what are they, how do they work, how are they monetized, and what are the deadlines ahead.

Genetic Medicine for Generalists: A Primer on the Priority Review Voucher Program

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Background on the PRV program

Key terms defined

Sponsor

An individual or entity that is responsible for a clinical trial investigation.

Orphan drug

A drug for a rare disease or condition.

Rare Disease

The FDA defines rare disease as a condition that affects fewer than 200,000 people in the United States.

BLA

Biologics License Application; a request for permission from the FDA to introduce a biologic product into the market.

NDA

New Drug Application; submission to the FDA to introduce a small-molecule drug into the market.

Section 505(b)(1) of Federal Food, Drug, and Cosmetic Act (FD&C Act)

A specific pathway for a drug applicant to obtain FDA approval for a new drug application (NDA).

Section 351 of the Public Health Service (PHS) Act

Law that outlines the process for submitting a BLA.

PDUFA

Prescription Drug User Fee Act; law that authorizes the FDA to collect user fees from sponsors that submit human drug applications (NDAs or BLAs).

Sources: FDA.gov, Canaccord Genuity Research

A brief history lesson

Precedent for FDA Incentive Programs

- Since passing the Orphan Drug Act (ODA) in 1984, the U.S. has recognized that incentives can promote the development of new drugs for rare diseases.
- The [number](#) of designations and initial approvals has grown substantially since the ODA was enacted. Comparing the first decade (1983–1992) to the most recent (2013–2022), designations increased by nearly seven times and initial approvals by six times.

Priority Review Voucher Program

- The U.S. Congress created the priority review voucher (PRV) program in 2007 to encourage the development of drugs for neglected diseases that may lack market opportunities due to small patient populations and/or high development costs.
- The program was created first for neglected [tropical diseases](#) in 2007, then for [rare pediatric diseases](#) under the *Food and Drug Administration Safety and Innovation Act (FDASIA)* in 2014, and then finally in 2016 for material threat [medical countermeasures](#) under the 21st Century Cures Act.

Type	Definition	Examples
Tropical Disease	Infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations	Tuberculosis , malaria , blinding trachoma, Buruli ulcer, cholera
Rare pediatric Disease (RPD)	Serious or life-threatening rare diseases affecting children 18 years and younger	Cystic fibrosis, Duchenne muscular dystrophy, spinal muscular atrophy
Medical countermeasures	FDA-regulated products that may be used in a public health emergency stemming from a terrorist attack with or accidental release of a biological, chemical, or radiological/nuclear agent, or a naturally occurring emerging infectious disease	Covid, smallpox

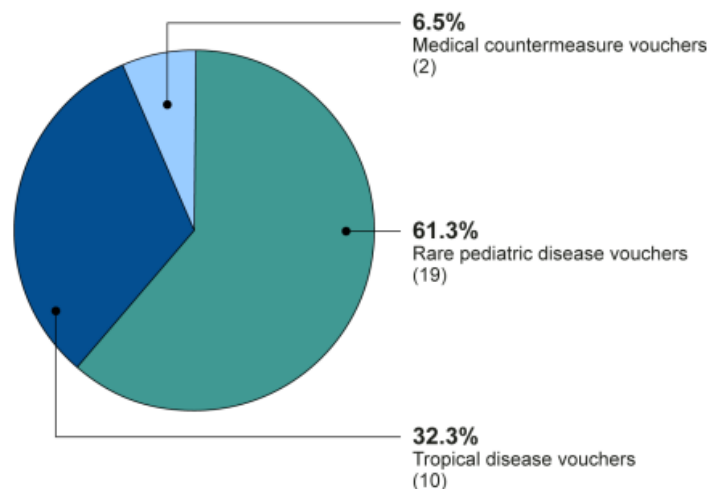
Sources: FDA.gov, Canaccord Genuity Research, Fermaglich LJ, Miller KL. A comprehensive study of the rare diseases and conditions targeted by orphan drug designations and approvals over the forty years of the Orphan Drug Act. Orphanet J Rare Dis. 2023 Jun 23;18(1):163. doi: 10.1186/s13023-023-02790-7. PMID: 37353796; PMCID: PMC10290406.; Berman J, Radhakrishna T. The Tropical Disease Priority Review Voucher: A Game-Changer for Tropical Disease Products. Am J Trop Med Hyg. 2017 Jan 11;96(1):11-13. doi: 10.4269/ajtmh.16-0099. Epub 2016 Aug 29. PMID: 27573627; PMCID: PMC5239674.

Historically rare pediatric disease PRVs have accounted for for most PRVs

RPD PRVs vs. Other PRVs

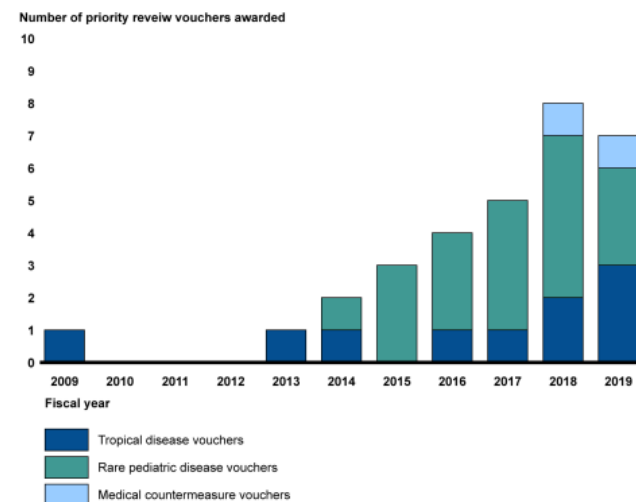
- A [study](#) conducted by the United States Government Accountability Office (GAO) showed that as of September 30, 2019 the FDA awarded 31 PRVs across the 3 PRV programs.
- According to the FDA, all PRVs were awarded for drugs that met unmet medical needs.
- Of the 31 PRVs, the majority were awarded through the rare pediatric disease PRV program.

Figure 2: Priority Review Vouchers (PRV) Awarded by FDA by Program Type, as of September 30, 2019



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-20-251

Figure 3: Number of Priority Review Vouchers (PRV) Awarded by FDA, by Program Type, Fiscal Years 2009-2019



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-20-251

Sources: GAO.gov, Canaccord Genuity Research

For the rest of this primer, we will focus on RPD PRVs

Priority Review Designation

A refresher on FDA's priority review process

- FDA's method of focusing resources towards a particular therapeutic that has fulfilled the criteria of showing significant improvements upon efficacy, prevention, diagnosis, or safety profiles compared to standard of care medications.
- Significant improvement may be demonstrated by the following:
 - Evidence of increased effectiveness in treatment, prevention, or diagnosis of condition.
 - Elimination or substantial reduction of a treatment-limiting drug reaction.
 - Documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes.
 - Evidence of safety and effectiveness in a new subpopulation.
- The standard review time of a drug from initial NDA/BLA application to drug approval is ~10 months.
- Sponsors can apply for Priority Review Designation to shorten the review time from 10 months of review to within 6 months.
- The status of an application for a Priority Review is communicated to a sponsor within 60 days of receipt of the original NDA/BLA submission.
- Refer to our previous [primer](#) for an overview of the FDA development process.

Sources: FDA.gov, Canaccord Genuity Research

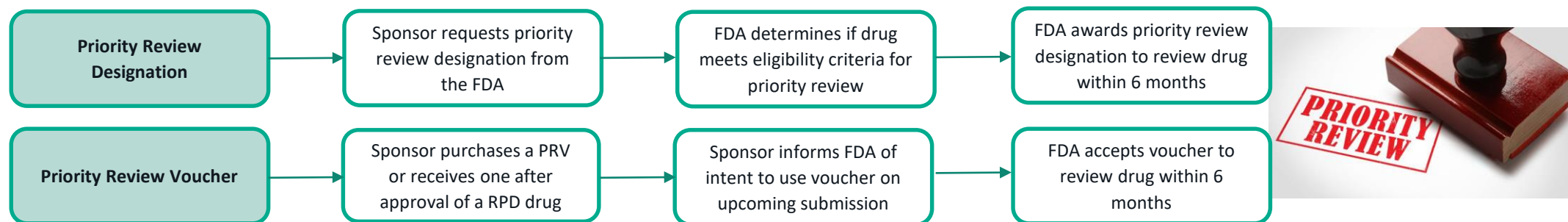
Priority Review Voucher Program

General Priority Review Voucher Program

- Under the priority review voucher program, a sponsor that receives FDA approval for a drug treating a rare or neglected disease can earn a voucher to speed up review of another drug.
- A company can choose to redeem the voucher to receive priority review for a different drug candidate in their pipeline OR they can sell the voucher to another company.

Rare Pediatric Designation Priority Review Voucher (RPD PRV)

- RPD is granted by the FDA to drugs and biologics targeting serious or life-threatening rare diseases affecting children 18 years and younger.
- Upon FDA approval of a RPD drug, the FDA can grant a sponsor a priority review voucher (PRV) allowing for a reduction in review time from 10 months to 6 months for a subsequent application for a different drug.
- Importantly, the PRV does not accelerate approval of the RPD drug itself and serves to incentivize the development of additional treatments for rare pediatric diseases, which might otherwise be under-researched.



Sources: FDA.gov, Canaccord Genuity Research

PRV Program Details

Obtaining a PRV

Purchasing or requesting a PRV

- There are two ways a company can receive a priority review voucher:
 1. they can submit a voucher request to the FDA;
 2. they can purchase a voucher from another company.
- According to FDA's [Draft Guidance on RPD PRVs](#), prior to September 30, 2020, a "rare pediatric disease designation" was not required to get a priority review voucher.
- For any voucher awarded after September 30, 2020, the drug must have been designated as a rare pediatric disease drug by that date.
- Sponsors seeking a RPD PRV submit voucher requests in the original submission of the potential rare pediatric disease product application – either in the initial package sent or up until the point of NDA/BLA filing.
- Sponsors who have already received rare pediatric disease designation can include their designation letter with the voucher request.

Sources: FDA.gov, Canaccord Genuity Research

Cashing in a PRV

Redeeming a PRV for a different drug

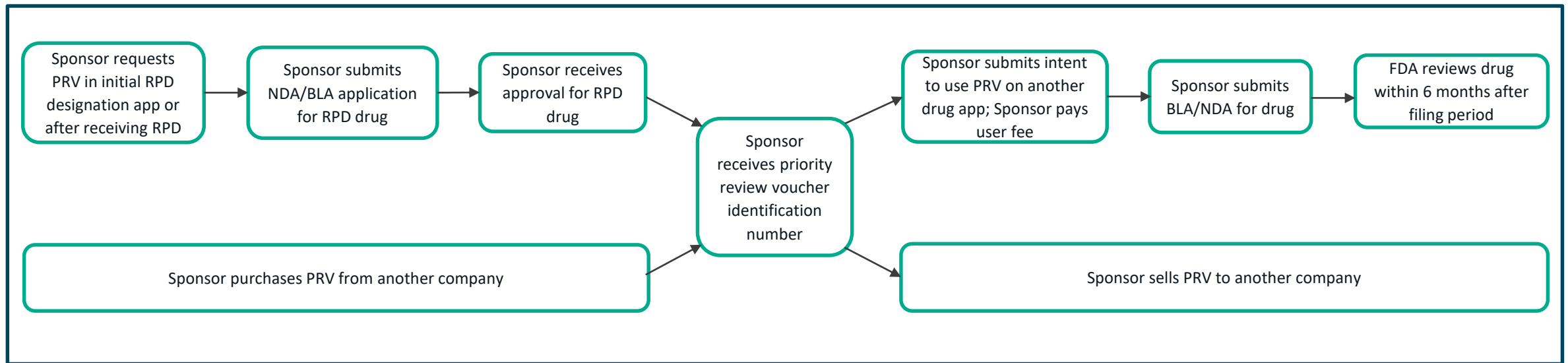
- A sponsor can use a priority review voucher for any eligible drug application submitted to the FDA under either section 505(b)(1) of the FD&C Act (small molecule) or section 351 of the PHS Act (biologics).
- The voucher is not restricted to rare pediatric diseases and can even be used for a new indication of the same drug that earned the voucher.
- Before submitting the application, the sponsor must inform the FDA of their intent to use the voucher at least 90 days beforehand, including the planned submission date.
- Upon submitting this notification to FDA, the sponsor is obligated to pay a priority review user fee (in addition to the standard Prescription Drug User Fee Act (PDUFA) application fee).
- The user fee for priority reviews is set annually to cover the extra cost the FDA incurs to perform a faster-than-standard review of a new drug or biologic; the [FY 2025](#) user fee rate is about \$2.5 million.
- It is important to note that the FDA is not obligated to approve a product using a voucher and their guidance states that while the goal is to act within 6 months after the 60-day filing period, the timeframe is not guaranteed.
- Priority review can get a “good” drug to the finish line sooner, but it can't revive a drug that is already failing.

Transferring/Selling a PRV

- The sponsor of a drug for a RPD can sell or transfer their PRV to another sponsor.
- The voucher can be transferred an unlimited number of times before it is used, as long as the current holder has not applied to redeem the voucher.

Sources: FDA.gov, Canaccord Genuity Research

Schematic of the RPD PRV process



Sources: FDA.gov, Canaccord Genuity Research

Monetizing PRVs

Understanding the Value of PRVs

The market price of PRVs are influenced by several factors

- To date, the value of PRVs has ranged from as low as \$21.2M (paid by Novartis in 2023 to Pharming Technologies) to \$350M (paid by Abbvie for United Therapeutics' voucher in 2015).
- Variation in price suggest considerable uncertainty about the market price.
- When the PRV system was first introduced in a March 2006 *Health Affairs* [paper](#), the authors estimated that a PRV could be worth approximately \$300 million if used for a “blockbuster” product generating at least \$1 billion in annual global revenue.
- [Company Surveys](#) have been conducted to investigate how much companies are willing to spend to obtain a PRV and how much companies would expect to receive for the sale of a PRV to another organization; estimates ranged from less than \$50 million to more than \$400 million.
- [A model](#) by David Ridley (Co-Author of the Original PRV Proposal) and Stephane A. Régnier (global director of health economics outcomes research for Novartis) estimates the value of a PRV based on three key effects:
 1. Capturing market share from competitors (a third of commercial value);
 2. Earlier sales of a new drug due to expedited review (half of commercial value);
 3. Extended time on the market before generic entry (less than a quarter of commercial value).
- Notably, the value of a PRV is sensitive to supply; if only one priority review voucher is available in a year, they are estimated to be worth more than \$200 million, but if four vouchers are available, the value could fall below \$100 million.

Sources: Canaccord Genuity Research, Ridley DB, Grabowski HG, Moe JL. Developing drugs for developing countries. *Health Aff (Millwood)*. 2006 Mar-Apr;25(2):313-24. doi: 10.1377/hlthaff.25.2.313. PMID: 16522573.; Robertson AS, Stefanakis R, Joseph D, Moree M. The impact of the US priority review voucher on private-sector investment in global health research and development. *PLoS Negl Trop Dis*. 2012;6(8):e1750. doi: 10.1371/journal.pntd.0001750. Epub 2012 Aug 28. PMID: 22953004; PMCID: PMC3429395.; Ridley DB, Régnier SA. The Commercial Market For Priority Review Vouchers. *Health Aff (Millwood)*. 2016 May 1;35(5):776-83. doi: 10.1377/hlthaff.2015.1314. PMID: 27140982.

Compilation of known RPD PRVs illustrates a range of prices

While there is no official FDA public record of all PRVs, the following table contains a representative sample of RPD PRVs

Company Selling PRV	RPD Indication for which PRV was granted	Drug	Price (million USD)	Buyer	Used For
Pharming Technologies	Activated PI3Kδ syndrome	Joenja	\$21.20	Novartis	
BioMarin	Morquio A	Vimizim	\$67.50	Regeneron/Sanofi	Praluent
Ultragenyx Pharma/Kyowa Kirin	X-linked hypophosphatemia	Crysvita	\$80	Gilead	
Ultragenyx Pharma	X-linked hypophosphatemia	Crysvita	\$81	Gilead	
Novimmune	hemophagocytic lymphohistiocytosis	Gamifant	\$95	AstraZeneca	
Eiger BioPharmaceuticals	Progeria	Zokinvy	\$95	AbbVie	Qulipta
Bluebird bio	Cerebral adrenoleukodystrophy	Skysona	\$95	Bristol Myers Squibb	
Rhythm Pharmaceuticals	Genetic obesity	Imcivree	\$100	Alexion	
Mallinckrodt	Deep Partial Thickness Thermal Burns	Stratagraft	\$100	Novartis	
Krystal Biotech	Dystrophic epidermolysis bullosa	Vyjuvek	\$100	Unknown	
Sarepta Therapeutics	Duchenne muscular dystrophy	Amondys 45	\$102	Unknown	
Bluebird bio	Beta-thalassemia	Zynteglo	\$102	Argenx	
Sarepta Therapeutics	Duchenne muscular dystrophy	Eleviodys	\$102	Unknown	
Biogen	Spinal muscular atrophy	Spinraza	\$103	Unknown	
GW Research	Seizures associated with Lennox Gastaut-Syndrome and Dravet syndrome	Epidiolex	\$105	Biohaven Pharma	Nurtec
Y-mAbs Therapeutics	Neuroblastoma	Danyelza	\$105	United Therapeutics	Tyvaso
Prometic Bioproduction	Plasminogen deficiency type 1	Ryplazim	\$105		
Albireo	Progressive familial intrahepatic cholestasis	Bylvay	\$105	Ares Trading	
X4 Pharma	WHIM	Xolremdi	\$105	Unknown	
Sarepta Therapeutics	Duchenne muscular dystrophy	Vyondys 53	\$108	Vifor	Vafseo
Day One Biopharma	Glioma	Ojemda	\$108	Incyte?	
Spark Therapeutics	Biallelic RPE65 mutation-associated retinal dystrophy	Luxturna	\$110	Jazz Pharma	Xywav
BridgeBio Pharma/Origin Biosciences	Molybdenum cofactor deficiency	Nulibry	\$110		
Mirum Pharma	Cholestatic pruritus	Livmarli	\$110	Johnson & Johnson	
BioMarin	Achondroplasia	Voxzogo	\$110	Eli Lilly	
Marinus Pharma	CDKL5 deficiency disorder	Ztalmy	\$110	Novo Nordisk	
Sarepta Therapeutics	Duchenne muscular dystrophy	Exondys 51	\$125	Gilead Science	Descovy
BioMarin	Batten disease	Brineura	\$125	Novartis	Mayzent
Marathon Pharma	Duchenne muscular dystrophy	Emflaza	\$130	GSK/ViiV	Juluca
Ultragenyx Pharma	Mucopolysaccharidosis type VII	Mepsevii	\$130	Novartis	Beovu
Wellstat Therapeutics	Hereditary orotic aciduria	Xuriden	\$150	Teva	Ajovy
Acadia Pharma	Rett Syndrome	Daybue	\$150	Unknown	
Zevra Therapeutics	Niemann-Pick disease type C	Miplyffa	\$150	Unknown	
PTC Therapeutics	Aromatic L-amino acid decarboxylase deficiency	Kebilidi	\$150	Unknown	
Ipsen Biopharmaceuticals	Fibrodysplasia ossificans progressiva	Sohonos	\$158	Unknown	
Asklepion Pharma/Retrophin	Bile acid synthesis disorders and peroxisomal disorders	Cholbam	\$245	Sanofi	Soliqua
United Therapeutics	Neuroblastoma	Unituxin	\$350	AbbVie	Rinvoq

Sources: Federal Register, GAO, Company Reports, Canaccord Genuity Research

The story behind the \$350M PRV purchased by AbbVie

AbbVie's \$350M investment on PRV Used for Rinvoq pays off

- In 2015 AbbVie acquired a PRV for \$350 million from United Therapeutics, who received the PRV for Unituxin, a drug for neuroblastoma, a rare pediatric disease.
- At the time, there was only [one](#) voucher available and the company was heavily dependent on Humira for most of its income.
- Based on [models](#) described earlier, a \$320 million voucher price is associated with fifth-year US drug sales of \$1.25 billion, so it was clear that AbbVie expected to use the voucher for a “blockbuster” drug.
- The company reportedly used the United PRV for Rinvoq, which was approved for moderate to severe rheumatoid arthritis in 2019 (3 years after they bought the PRV).
- Since then, Rinvoq has also been approved for several other indications and as of 2Q25, Global Rinvoq Net Revenues Were \$2.028 billion.

Sources: Canaccord Genuity Research, Morrison C. AbbVie buys last available priority voucher for \$350 million. Nat Biotechnol. 2015 Nov;33(11):1120. doi: 10.1038/nbt1115-1120. PMID: 26544127.; Ridley DB, Régnier SA. The Commercial Market For Priority Review Vouchers. Health Aff (Millwood). 2016 May 1;35(5):776-83. doi: 10.1377/hlthaff.2015.1314. PMID: 27140982.

Where PRVs stand today

Status of the PRV program today

To qualify for a PRV, FDA approval of RPD drugs must be obtained by September 30, 2026

- At the end of 2024, Congress did not reauthorize the rare pediatric disease priority review program.
- The FDA began sunseting the program as of December 20, 2024, which means the agency cannot award any new PRVs to drugs that do not already have a rare pediatric disease designation.
- Companies with existing pediatric designations will have to get their drugs approved by **September 30, 2026** to earn their priority review voucher.

Give Kids a Chance Act may extend that deadline another 5 years

- Bipartisan legislation was introduced in 2024 Congress to accelerate the development and availability of treatments for pediatric cancers and rare pediatric diseases.
- Aims to allow the FDA to authorize trials for drug combinations, reauthorize the RPD PRV program, and improve pediatric study requirements for drugs.
- The 2024 bill passed the House of Representatives but failed to pass the Senate and as a result was not included in a government funding bill in December 2024, causing the PRV program to expire on December 20, 2024.
- In early 2025, the legislation was reintroduced in both the House and the Senate.
- If the 2025 version of the bill passes, the RPD PRV program will be reauthorized for another 5 years, renewing the FDA's authority to award RPD PRVs through September 30, 2029.

Sources: FDA.gov, congress.gov, Canaccord Genuity Research

Companies under our coverage with pipeline candidates eligible for RPD PRVs

The following is a list of pipeline candidates from the companies we cover that have reportedly received RPD designations and are eligible for a PRV, but have not yet received FDA approval

Ticker	Indication with RPD Designations	Drug Candidate	Current Stage of Development	Anticipated future catalysts
ARCT	Ornithine Transcarbamylase Deficiency	ARCT-810	Phase 2	Phase 3 initiation 2026
	Cystic Fibrosis	ARCT-032	Phase 2	Phase 3 design 1H26
TSHA	Rett Syndrome	TSHA-102*	Pivotal	Part B patient enrollment 4Q25
VRTX	APOL1-mediated kidney disease (AMKD)	Inaxaplin (VX-147)*	Phase 3	Enrollment completion in by YE25
WVE	Duchenne Muscular Dystrophy	WVE-N531	Phase 2	NDA/CTA submission 2026
RARE	Sanfilippo syndrome type A	UX111*	Phase 3	Resubmit BLA upon resolving CRL (approval expected in 2026)
	Osteogenesis imperfecta	Setrusamab (UX143)*	Phase 3	Phase 3 final analysis by YE25
	Glycogen Storage Disease type Ia	DTX401*	Phase 3	BLA submission in 4Q25
RCKT	Dannon Disease	RP-A501	Phase 2 Pivotal	Hold recently lifted; completion TBD
	Leukocyte Adhesion Deficiency Type I	RP-L201 (Kresladi)*	Registrational	Submission of complete BLA to resolve CRL YE25
	Fanconi Anemia	RP-L102	On Pause	Paused due to corporate restructuring and pipeline prioritization
TNYA	MYBPC3 associated hypertrophic cardiomyopathy	TN-201	Phase 1	Data update in 4Q25

* Should the 2025 version of the Give Kids a Chance Act fail to pass and the deadline remain September 30, 2026, the starred candidates may still have a chance of obtaining a PRV.

Sources: Company press releases, SEC Filings, Canaccord Genuity Research

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Sell	6	0.66%	0.00%
Speculative Buy	133	14.52%	60.15%
	916*	100.0%	

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