

New Momentum for a Time-Limited Conditional Approval Pathway for Rare Disease Drugs



On October 4, 2024, a US House version of the revised Promising Pathway Act (PPA) 2.0 was introduced, sponsored by Rep. Bruce Westerman (R-AR). The bill ([H.R.9938](#)) mirrors a US Senate version that was introduced in May 2024 ([S.4426](#)) that would authorize the US Food and Drug Administration (FDA) to grant time-limited conditional approval to drugs for rapidly progressive, terminal diseases with substantial unmet need for treatments that are eligible for the Orphan Drug Act and result in a substantially shortened lifespan, substantial reduction in quality of life, or other substantial adverse health effects.

Read the full insight [here](#).