Evaluate Vantage

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A slow (and low) year for FDA approvals

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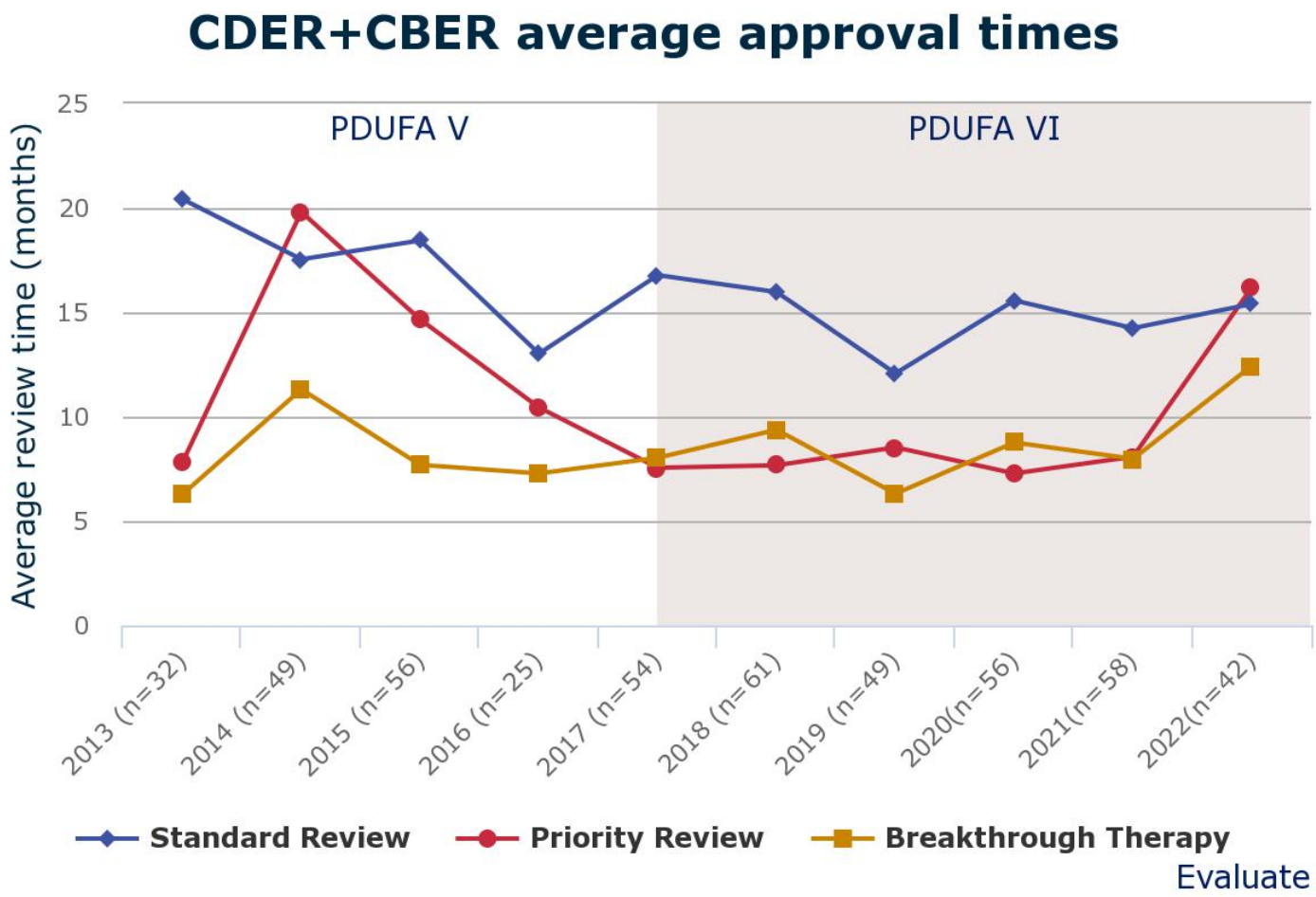
Much hand-wringing ensued when the FDA's novel drug approval tally dipped below the 10-year average last year – a dip in accelerated approvals might have had something to do with it – and a separate *Evaluate Vantage* analysis now finds that the agency also seemed to take longer to make a decision. This was most notable in the priority and breakthrough therapy applications and, being based on averages, a number of outliers explain this finding. Provention Bio's Tzield and another Sanofi-acquired drug, Enjaymo, both took around two years to win approval, despite having both priority review and breakthrough status. These should respectively take nine and six months, according to FDA guidance. The mean for this cohort is even higher if you include Mallinckrodt's Terlivaz, which took a remarkable 13 years to reach the market. The kidney disease drug has been through several owners, and received several complete response letters. Delays to Gilead's long-acting HIV agent Sunlenca and Pfizer's Jak inhibitor Cibinqo also pushed the numbers higher for the priority review category. Perhaps fewer setbacks will see a return to historical means next year, which will come under the seventh iteration of the Pdufa legislation.



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