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Senator Mike Braun reintroduces Promising Pathway Act (PPA) & The Accelerated Drug Approval for Prescription Therapies (ADAPT) Act

WASHINGTON — Today, U.S. Senator Mike Braun reintroduced two bills that will help get treatments to American patients more efficiently: The Accelerated Drug Approval for Prescription Therapies (ADAPT) Act and the Promising Pathway Act (PPA).

"Americans are clamoring for real solutions on healthcare. These two solutions were inspired by the lessons I learned in the real world by taking on the healthcare industry in my company and the stories I've heard from Hoosiers struggling with rising costs and dwindling options. The ADAPT Act will create a much needed expedited drug approval process at the FDA, and is a better solution that will help solve this problem and increase market competition between drugs on the marketplace without compromising safety. The Promising Pathway Act will help patients with rare and life-threatening diseases get

meaningful treatments that they simply don't have time to wait for." **– Senator Mike Braun**

BACKGROUND

The Accelerated Drug Approval for Prescription Therapies (ADAPT) Act: this bill would amend the Food, Drug, and Cosmetic Act to create an accelerated approval pathway to act as a "passing lane" for prescription drugs that have already been approved for sale in other developed countries like the U.K. and Canada, with a history of safe and effective clinical trial data. ADAPT Act adds a layer of FDA review that would focus on quality control, supply chain safety, and manufacturing processes in order to drive down prices through increased competition. This approval pathway would also cut down on a long list of drug shortages, allowing American patients more rapid access to meaningful treatments already sold in other developed countries that are proven to work.

Promising Pathway Act (PPA): this bill would expedite beneficial outcomes for patients by requiring the FDA to establish a rolling, real-time, priority review pathway for drugs intended to treat, prevent, or diagnose serious or life-threatening diseases or conditions. Under this pathway, FDA would grant time-limited, provisional approval to drugs that demonstrate substantial evidence of safety, and relevant, early evidence of efficacy. Drug sponsors would be allowed to incorporate scientifically-substantiated surrogate endpoints and real-world data to demonstrate the efficacy of the drugs under review. The period of provisional approval is time-limited and effective for a two-year period. Drug sponsors may request provisional approval status renewal for subsequent two-year periods (up to a total of six years) and can apply for full approval at any time. PPA would require patient registries for all provisionally approved drugs to track patient usage until the drug is fully approved. The FDA would review the drug and renew provisional approval status based on real world data collected in the patient registries—which track patient usage of provisionally approved drugs—until the drug receives full approval or provisional approval expires. Under this provisional approval pathway, those with rapidly-progressing terminal illnesses would have access to drugs that provide their only hope for treatment,

and real world data collected from these patients would be incorporated into the drug approval process.

Click here to watch Senator Braun's floor speech on Promising Pathway Act.

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