United States House Committee on
Ways & Means
CHAIRMAN JASON SMITH

H.R. 1691, the *Ensuring Patient Access to Critical Breakthrough Products Act*

Reps. Wenstrup (R-OH), DelBene (D-WA)

Background:

- In 2016, the **21st Century Cures Act** created a new pathway for "***breakthrough***" medical devices to receive expedited Food and Drug Administration (FDA) approval.
- ***Breakthrough*** devices are those that utilize **novel technology** to treat a condition that has no other approved alternatives or a significant benefit above existing therapies.
- The **Medicare coverage process** for these ***breakthrough*** devices after FDA approval remains a **barrier**.
    - The lag time between FDA approval and Medicare coverage is often called the "*valley of death*" for innovators.
    - Devices can wait up to **5 years** for Medicare coverage determinations post FDA approval.
- In 2021, the Trump Administration finalized the **Medicare Coverage of Innovative Technology (MCIT) rule** which created a distinct pathway for breakthrough devices to receive **immediate Medicare coverage** through a transitional coverage period while awaiting a lengthier review process for permanent coverage.
    - Days before MCIT was set to take effect, the Biden Administration **repealed the rule** citing "operational challenges" and promising a speedy replacement.
    - More than two years later, the Biden Admin has still not finalized a replacement rule.
- *Examples of breakthrough medical devices:*
    - CytoSorbents' DrugSorb-ATR system, which reduces bleeding complications during open heart surgeries.
    - ReCor Medical's Paradise System, which delivers high-intensity focused ultrasound energy via a catheter to destroy nerves along the renal artery to treat hypertension.
    - Bluestar Genomics' novel liquid-biopsy cancer diagnostic device, a medical device that screens newly diagnosed diabetes patients to diagnose possible pancreatic cancer.

The Ensuring Patient Access to Critical Breakthrough Products Act:

- Provides a distinct pathway for immediate **four years of transitional Medicare coverage** of breakthrough medical devices – mirroring the Trump Administration final rule and requires the Centers for Medicare and Medicaid Services (CMS) to make a **permanent coverage determination** by the end of the coverage period.
- This expedited coverage pathway will encourage **more innovative medical devices** to come to market and provide Medicare patients with needed treatments and cures quicker.