The Promising Pathway Act (PPA)

When you or a loved one gets a scary medical diagnosis, you want two things:

Access to the best specialists

Access to the most promising treatments

to cure or treat the illness to ensure a high quality of life.

What if the only things keeping you from that cure, treatment, or quality of life were bureaucratic red tape? It doesn't have to be this way.

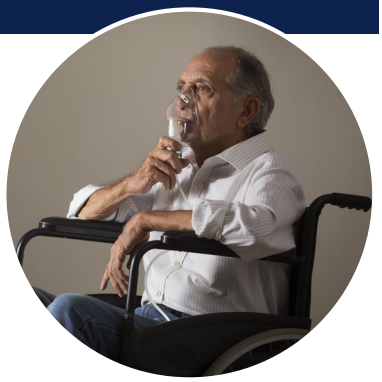
Q: What is the PPA?

A: S. 1644 and H.R. 3761, the Promising Pathway Act (PPA), allows patients—advised by their doctors—to choose early access to promising therapeutic treatments.

THE PPA PROVIDES:

- ✓ **Access to More Treatments**
- ✓ **Innovative Drugs and Biologics**
- ✓ **Hope for the Future**

Primarily, the PPA opens a **safe and effective approval process** for new therapeutic treatments. These could treat, prevent, or diagnose serious or life-threatening diseases or conditions.



WHO IT HELPS:

This bill will help patients, including those with life-threatening diseases, to get access to new treatments quickly.

Patients with rapidly progressing terminal illnesses

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would have access to drugs that provide their only hope for treatment.

Real-world data collected from these patients

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would be incorporated into the drug approval process.

Reduced bureaucracy

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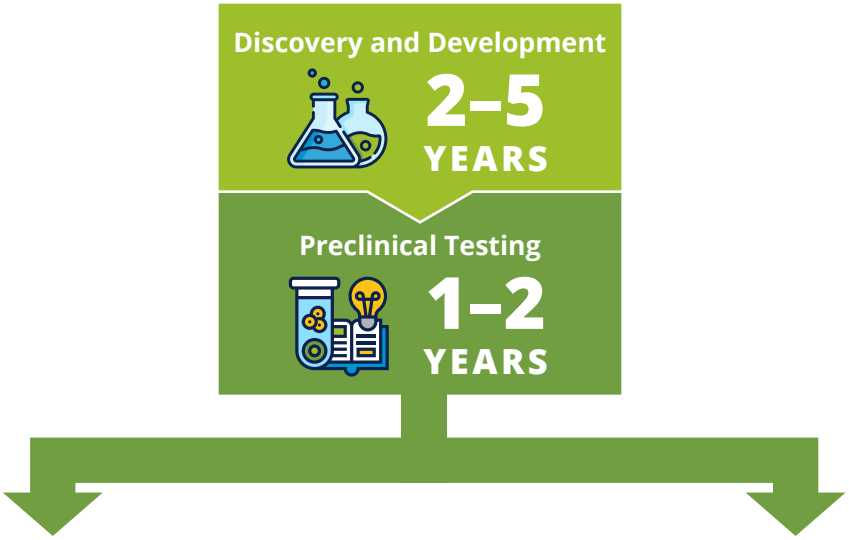
would accelerate the availability of life-improving and life-saving new medical treatments.

Overall, the PPA modernizes our health care system for future generations, making it more patient-focused.

HOW IT WORKS:

The PPA would require the Food and Drug Administration to establish a rolling, real-time, priority review pathway for promising new drugs and biologics.



REGULAR APPROVAL PATHWAY

From 10–12 years on average

PPA PATHWAY

In most cases, months not years

BOTTOM LINE:

PPA provides a structured way to respond to terminal patient needs for innovative treatment while still retaining the ability to balance efficacy with patient safety.

1. If needed, drug sponsors may request provisional approval status renewal for subsequent two-year periods (up to a total of six years).
2. This enables informed decision making using the most up-to-date data.
3. Availability contingent on evidence of patient benefit.