



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, at least, to prolong life with quality time.

What if the only things keeping you from that cure or that time with family were bureaucratic red tape? [It doesn't have to be this way.](#)

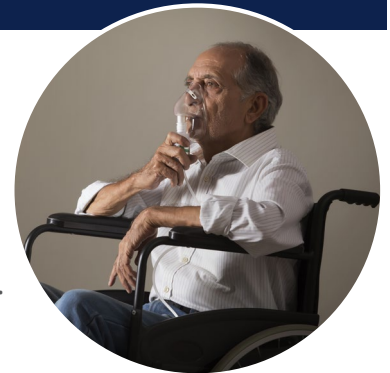
Q: What is the PPA?

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 allow patients with incurable diseases to get access to new treatments quickly.

Patients with rapidly progressing terminal illnesses



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

Real-world data collected from these patients



would be incorporated into the drug approval process.

Reduced bureaucracy



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 FDA to establish a rolling, real-time, priority review pathway for promising new drugs and biologics.

REGULAR APPROVAL PATHWAY

From 10-12 years on average



**2-5
YEARS**

Discovery and
development

**1-2
YEARS**

Preclinical
Testing

**5-7
YEARS**

Clinical
Trials

**1/2-2
YEARS**

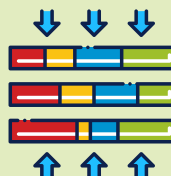
Government
Approval



Approved
Drug

PPA PATHWAY

In most cases, months not years.



Discovery and
development

FDA grants a two-year
approval to drugs and
biologics that demonstrate
early evidence of safety
and efficacy. (Patients
have access.[†])

Real-world
data demonstrates
the efficiency
of the new
pharmaceuticals.

Approved
drug or
biologic

[†]If needed, drug sponsors may request provisional approval status renewal for subsequent two-year periods (up to a total of six years).

BOTTOM LINE:

With the PPA, patients with limited options and time can get the help they deserve and need. Isn't that what you would want for yourself and your loved ones?

The PPA approval pathway excludes vaccines.