The "Ask"

The Benefit Act S373:

The legislation will amend the Food, Drug and Cosmetic Act (FDCA) to ensure that patient experience, PFDD and related data – including information developed by a product sponsor or a third party such as a patient advocacy organization or academic institution – be considered as part of the risk-benefit assessment.

The BENEFIT Act would require that the FDA disclose whether and how patient experience and/or preference data was used in the benefit risk assessment of a new drug. It will ensure that patient voices are being heard and allow for patient stakeholders to continue to work with FDA to refine the data that they need to make decisions.

The Speeding Therapy Access Today, or STAT Act, H.R. 1730/S. 670:

A bipartisan bill that was created with the input of the rare disease community aimed at improving the development of and access to therapies for the rare disease community. The centerpiece of the STAT Act is the creation of a Rare Disease Center of Excellence at the US Food and Drug Administration. The STAT Act will:

- Accelerate rare disease therapy development,
- Optimize interagency coordination,
- Advance science-based regulatory policies, and
- Facilitate access to therapies.

Learn more at StatAct.org.