RDLA Policy Primer:
Prescription Drug User Fee Act (PDUFA)

Background: The Prescription Drug User Fee Act (PDUFA) was a law passed by Congress in 1992. In an effort to support much-needed regulatory review infrastructure within the Food and Drug Administration (FDA), the law facilitated the creation of these resources by allowing the FDA to collect fees from drug manufacturers for the drug approval process at two timepoints throughout a product review: once at the time a New Drug Application (NDA) or Biologics License Application (BLA) is submitted, and once post-approval. These funds are designated for use by the Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) product approval process. In turn, the FDA is required to meet certain performance benchmarks related to the timeline of the review process.

The purpose of PDUFA was to improve the length of time of product approvals at the FDA. The FDA needed additional staff to address the backlog of products waiting for approval for market and had not received enough funding from Congress to do so. Since PDUFA was enacted into law, user fees have played an important part in expediting the drug and medical product approval process.

PDUFA is reauthorized every five years and has been reauthorized five times since 1992 in 1997, 2002, 2007, 2012, and 2017. The next reauthorization, also known as PDUFA VII, will be in 2022.

The last reauthorization, PDUFA VI, was passed in 2017 and included the following improvements:

- Formalized inclusion of Patient Experience Data (PED) into the drug development and review process, including use of patient reported outcomes;
- Use of real-world evidence for regulatory decision-making;
- Dedicated process to improve use of biomarkers as surrogate endpoints in drug development.

Future PDUFA Policy Considerations: PDUFA VII will need to be reauthorized by September 2022. PDUFA VII is an opportunity for the rare disease community to further improve the drug approval pipeline for rare diseases at FDA.

Resources:
RDLA Monthly Webinar (July 2020)
EveryLife Foundation Website on PDUFA VII