**EveryLife Foundation PDUFA VIII Legislative Priority Areas**
***Spring 2026***

## Foundations for Progress

### The Role of the Rare Disease Innovation Hub

- Convene
- Create Content
- Share Learnings
- Identify Common Threads
- Track Progress

### The resources and incentives necessary to drive progress

- Establish dedicated funding for the Rare Disease Innovation Hub
- Fully fund the Orphan Products Grant Program
- Permanently authorize the Rare Pediatric Disease PRV Program
- Restore the Orphan Drug Tax Credit to its original amount

**01**

### Advancing Knowledge Sharing and Decision Transparency

- Develop robust knowledge management systems to memorialize reviewer decisions for shared learning across the agency and support the application of consistent approaches in similar cases
- Increase transparency around patient experience data, including how it informs development decisions early and how it is used in regulatory review
- Share and apply learnings from FDA pilot programs within the agency and with stakeholders
- Expand transparency and available case studies that illustrate how FDA has approached key regulatory decisions

**02**

### Evolving Patient Focused Drug Development

- Build on PFDD to shift from one-time meetings to ongoing engagement pathways
- Create mechanisms for patient organizations leading pre-competitive drug development activities to meet and discuss strategy and learnings with the FDA
- Create a pathway to include patient experience data in labeling to strengthen regulatory, payer, and clinical decision-making

**03**

### Enhance Opportunities for Science-Focused Engagements with Stakeholders Throughout the Development Lifecycle

- Establish a Science-Focused Drug Development meeting mechanism as proposed in the EXPERT Act
- Create a Rare Disease Drug Development Action Plan Task Force to convert insights from SFDD meetings into action that can unlock the ability to move pipelines forward
- Protect and enhance the use of advisory committees to leverage expert and patient insights to solve challenging regulatory science issues
- Establish a Rare Disease and Condition Advisory Committee to harness expertise outside of the Agency to inform challenging rare disease regulatory science issues and align on consistent approaches

**04**

### Strengthen Information Systems, Data Sharing, and Real-Time Learning

- Identify enhancements to data sharing policies and platforms that can enable real-time dissemination and translation of real-world evidence to inform clinical decision making
- Strengthen post-market real-world evidence collection, including the use of digital health tools and technologies.
- Establish and support interoperable data standards and scalable platforms that enable aggregation and reuse of rare disease data across sponsors, institutions, and patient groups.

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