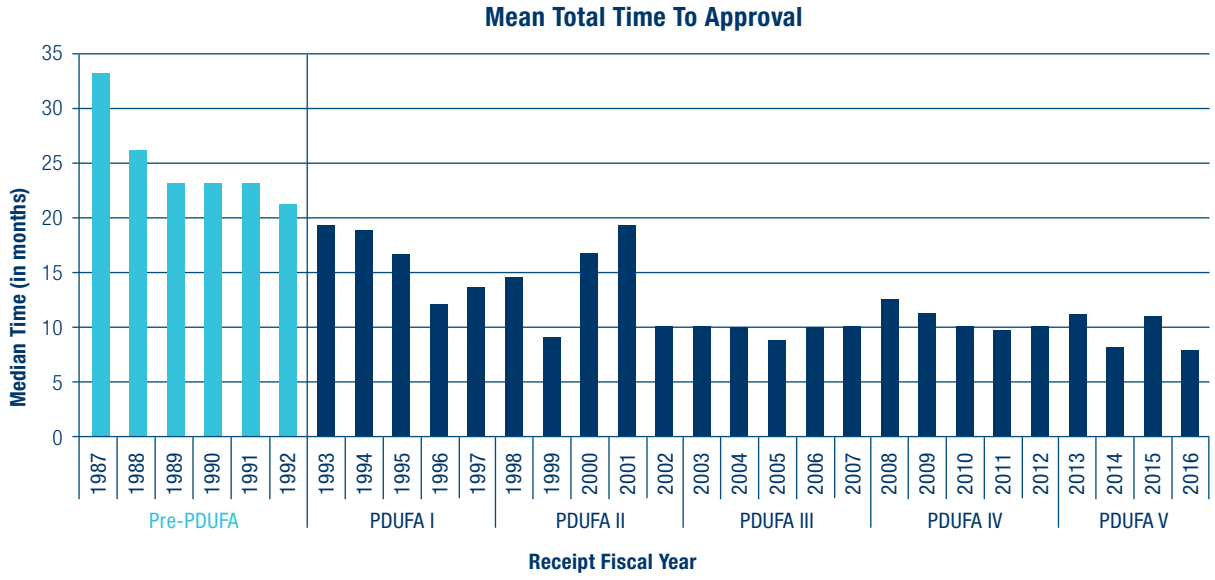
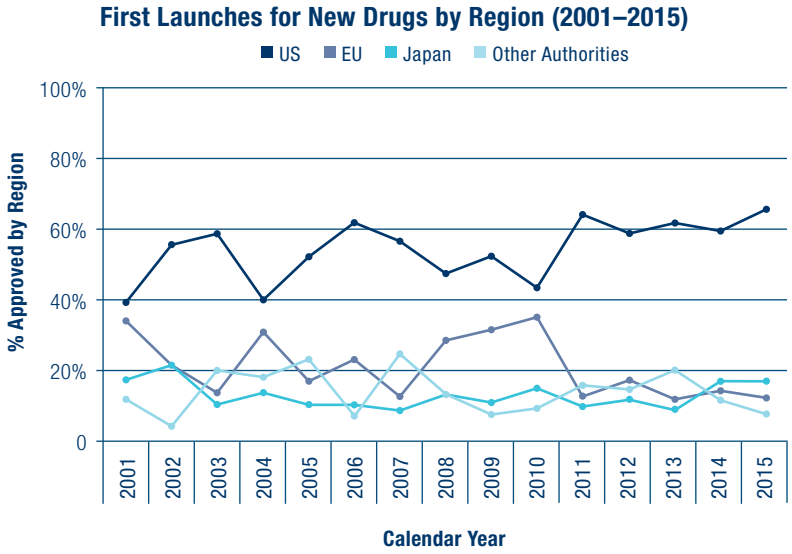
Biotechnology Innovation Organization

PRESCRIPTION DRUG USER FEE ACT (PDUFA)

PDUFA At-A-Glance

- Program began in 1992
- Provides greater consistency, certainty and predictability in the FDA's human drug review programs
- Review times dropped by as much as three-fold in the first five years and have not increased
- FDA considered to be among the most efficient regulators worldwide
- Today, American patients are among the first in the world to have access to new drugs





Source: FDA: CDER New Drug Review: 2016 Update

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PDUFA VI Overview

BENEFITS PATIENTS

- **Incorporates patient perspectives** — Advances the use of a structured approach to benefit/risk assessments that systematically incorporate patient perspectives into regulatory decisions.
- **Monitors post-market drug safety** — Enhances and modernizes the drug safety system through expansion of the Sentinel system to monitor millions of anonymized health records to detect potential post-market drug safety signals.

ADVANCES MEDICAL INNOVATION

- Establishes approaches to help streamline clinical trials, the most time-consuming, complex, and expensive portion of the drug development process.
  - Provides for pilot projects, public meetings, and guidance development to advance the use of cutting-edge drug development techniques, including innovative and adaptive clinical trials designs, model-informed drug development and real-world evidence.
  - Improves the biomarker qualification process and provides for special consultation with drug sponsors on using biomarkers as surrogate endpoints — which can reduce time and cost of clinical trials.

STRENGTHENS FDA

- Invests resources and staff capacity to better foster the development of medicines for patients with serious and life-threatening conditions.
- Builds on the success of the Breakthrough Therapy Program.
- Improves review of combination products (products with both a drug or biologic and a device component), which are essential for personalized medicine, and improves coordination among FDA review centers.
- Ensures PDUFA program sustainability and transparency.
  - Simplifies the collection of fees and reduces volatility in fee revenue due to unpredictability of the numbers of applications submitted.
  - Modernizes time-reporting and enhances financial transparency measures to provide the most precise information to the public about how PDUFA fees are allocated to meet the costs associated with human drug review related activities.