



# Alliance for a Stronger FDA

**August 9, 2013**

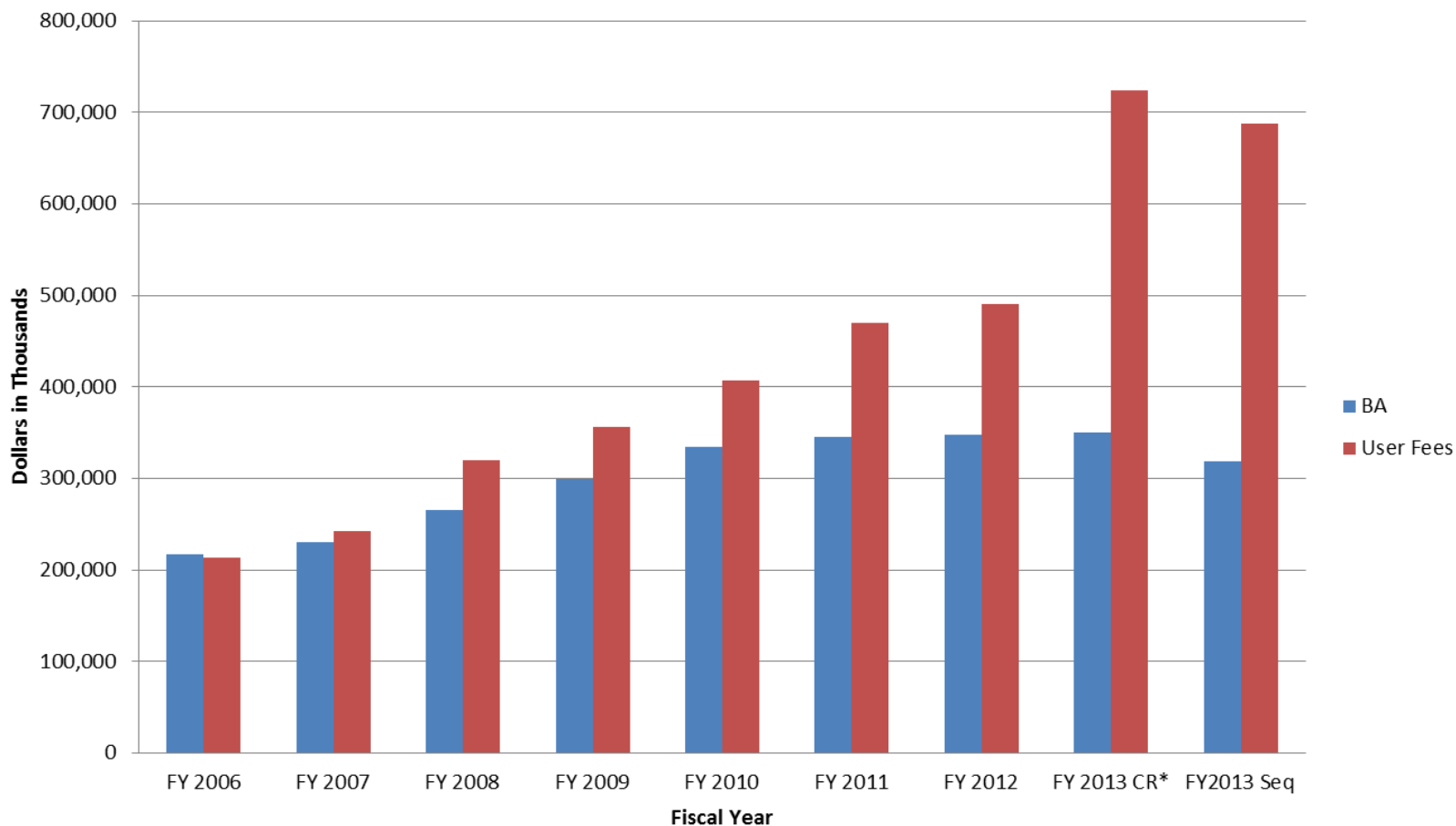


# Overview

- CDER Budget Overview
- CDER's Priorities
- CDER Funding Needs

# CDER Budget Overview

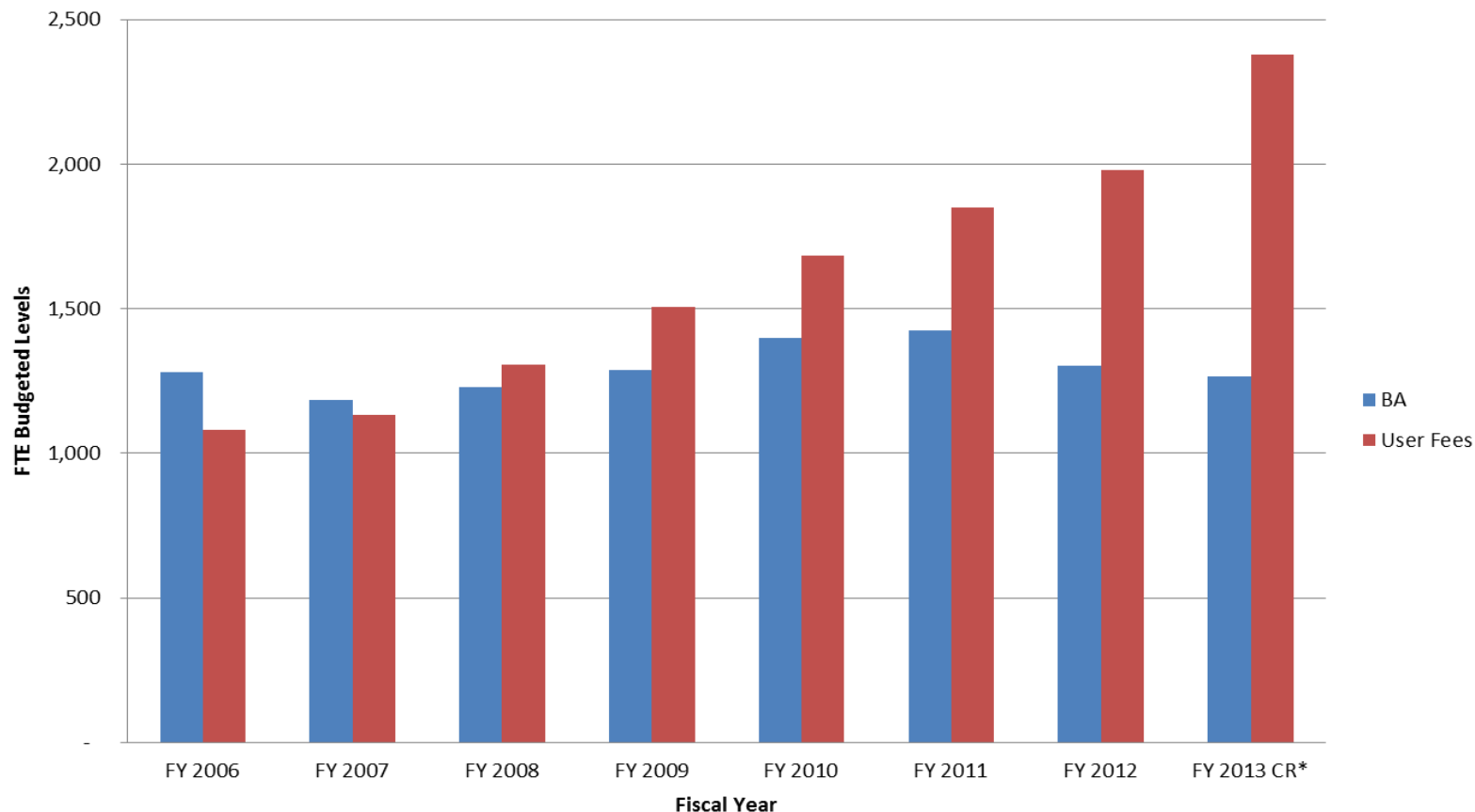
## Food and Drug Administration CDER Enacted Budget FY 2006 - FY 2013



\* The FY 2013 CR funding levels do not account for sequestration and rescission.

# CDER Budget Overview

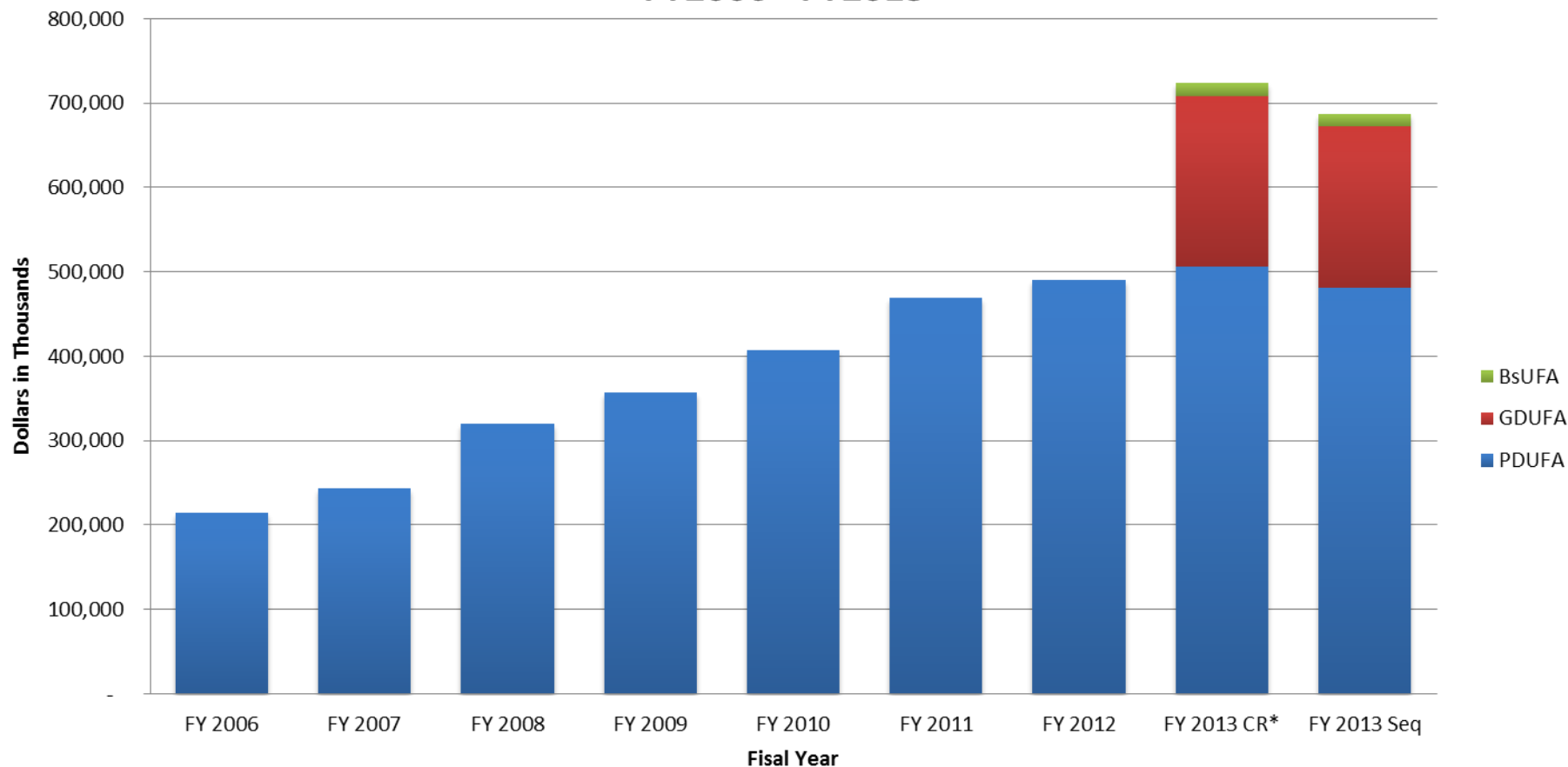
## Food and Drug Administration CDER Budgeted FTE Levels FY 2006 - FY 2013



\* The FY 2013 funding levels do not account for sequestration and rescission.

# CDER Budget Overview

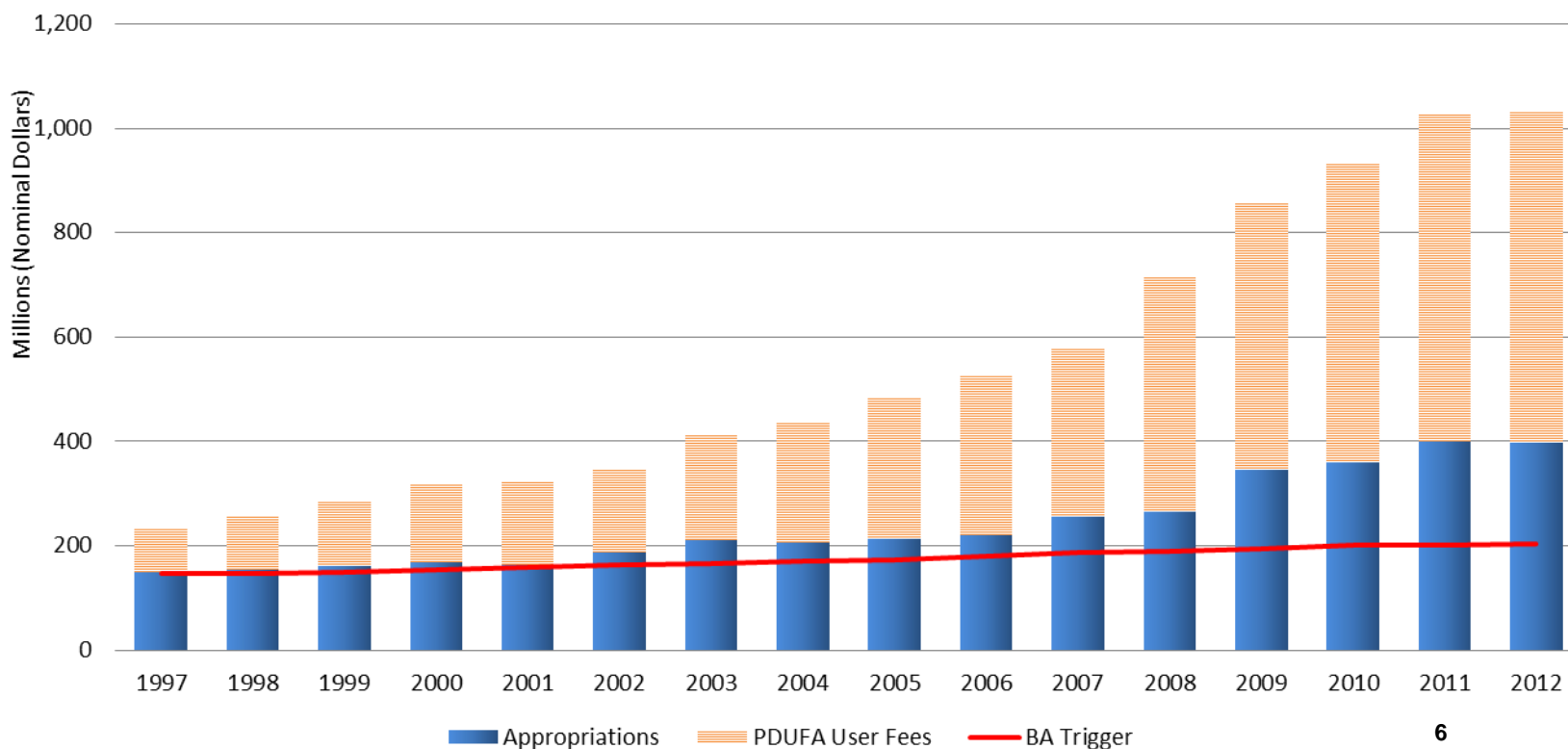
## Food and Drug Administration CDER - User Fee Funding FY2006 - FY2013



\* The FY 2013 CR funding levels do not account for sequestration and rescission.

# CDER increasingly depends on fee funding and BA spending trigger has not kept pace with increasing costs of the HDR—e.g. case of PDUFA

Human Drug Review Expenditures and BA Trigger Amount



## CDER's Priorities

- CDER's top priorities include the following:
  - Quality-related Drug Safety (e.g. – pharmacy compounding, track and trace, IT related efforts, etc.)
  - Drug Shortages
  - Implement FDASIA
  - Improve and Streamline Drug Development
  - Globalization Efforts

## Globalization Efforts

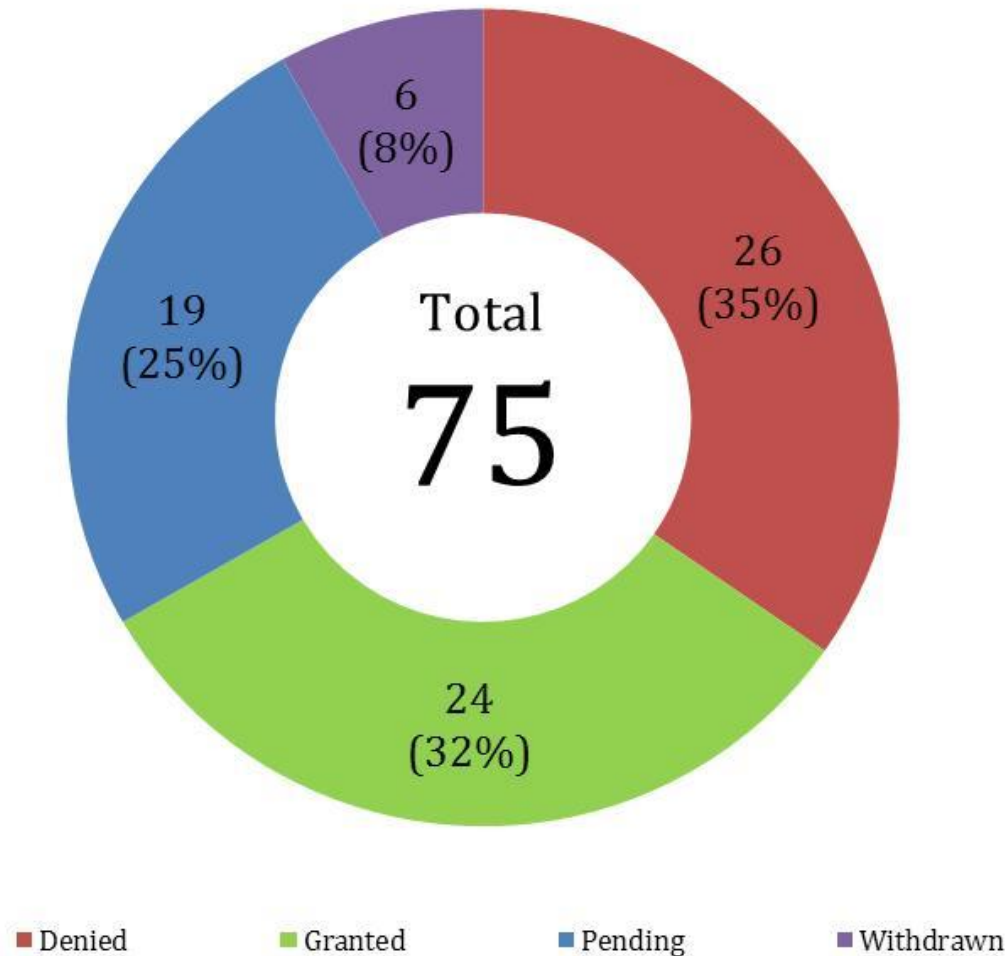
- FDA-regulated pharmaceutical industry is now globally based including drug development, manufacturing, and marketing activities
- CDER strategy
  - International harmonization of regulatory standards—e.g., work via the International Conference on Harmonization (ICH)
  - Global clinical trials
  - Pharmaceutical Quality Platform



# Implementing FDASIA

- Major portions relate to new drug responsibilities and authorities.
  - UFAs provided funding reduced by sequestration but others are unfunded
  
- To-Do's for CDER include:
  - Title I PDUFA V
  - Title III GDUFA
  - Title IV BSUFA
  - Title V Pediatric Drugs
  - Title VII Drug Supply Chain
  - Title VIII Generating Antibiotic Incentives Now
  - Title IX Drug Approval and Patient Access (e.g., Breakthrough Therapies)
  - Title X Drug Shortages

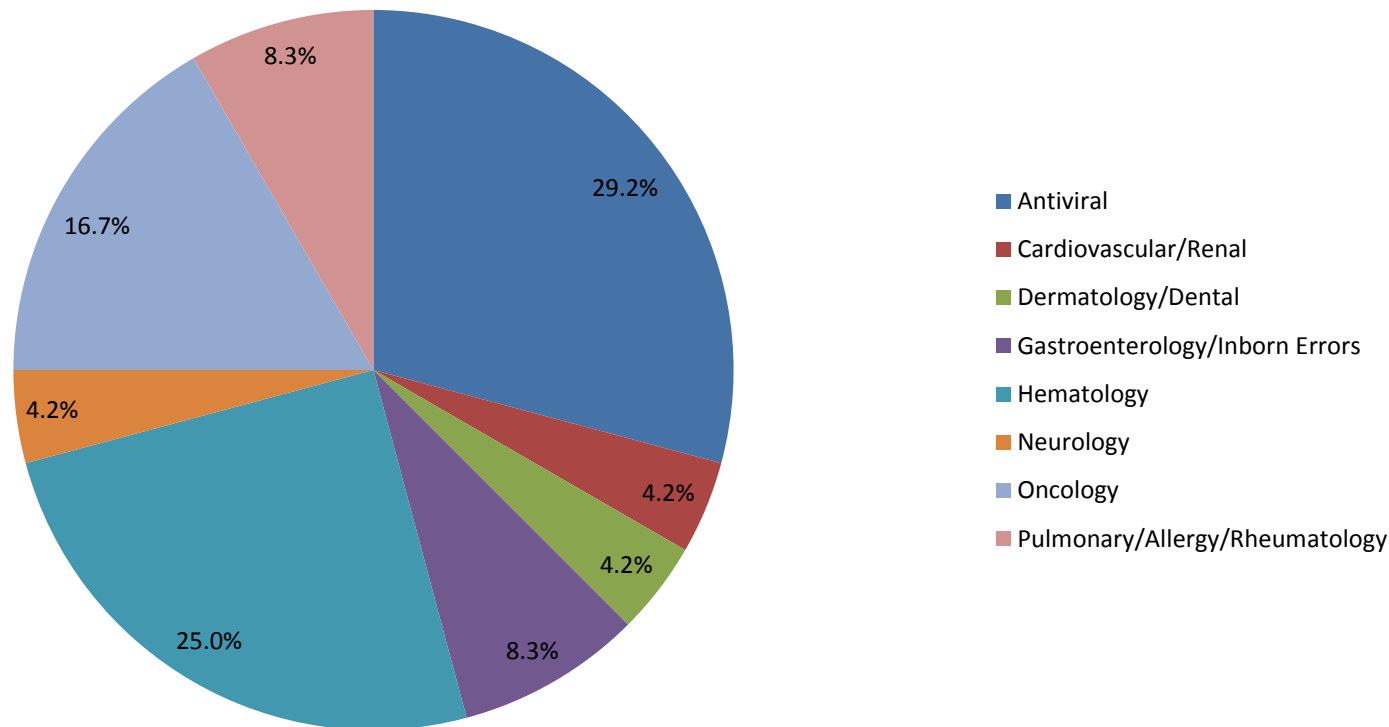
## Breakthrough Therapy Designation Requests\* (as of July 31, 2013)



\* A single IND application may have multiple breakthrough designation requests for different indications

# CDER Breakthrough Designation Requests Granted

Distribution of breakthrough requests granted by the FDA since the program inception on July 9, 2012 through August 7, 2013.



\* Data was obtained from the PADSS Breakthrough Request Report, produced by OPSA.

# Improve and Streamline Drug Development

- The goal is to reduce regulatory burden and scientific uncertainty in drug development and review
- Examples
  - Data Standards
  - Pharmacometrics
  - Patient Focused Drug Development
  - Patient-Reported Outcome (PRO) qualification

# CDER Funding Needs

- What programs have been supported by the additional appropriations?
  - Prior to FY 2013, CDER's BA increases have concentrated on Sentinel, eDRLS, generic drug review, human subject protection in clinical trials, medical countermeasures (MCM), and biosimilars.
- In FY 2013, due to the Continuing Resolution and sequestration, CDER did not receive additional BA funding, however, CDER received \$10M in one-time, no-year funds for drug safety activities including pharmacy compounding efforts.

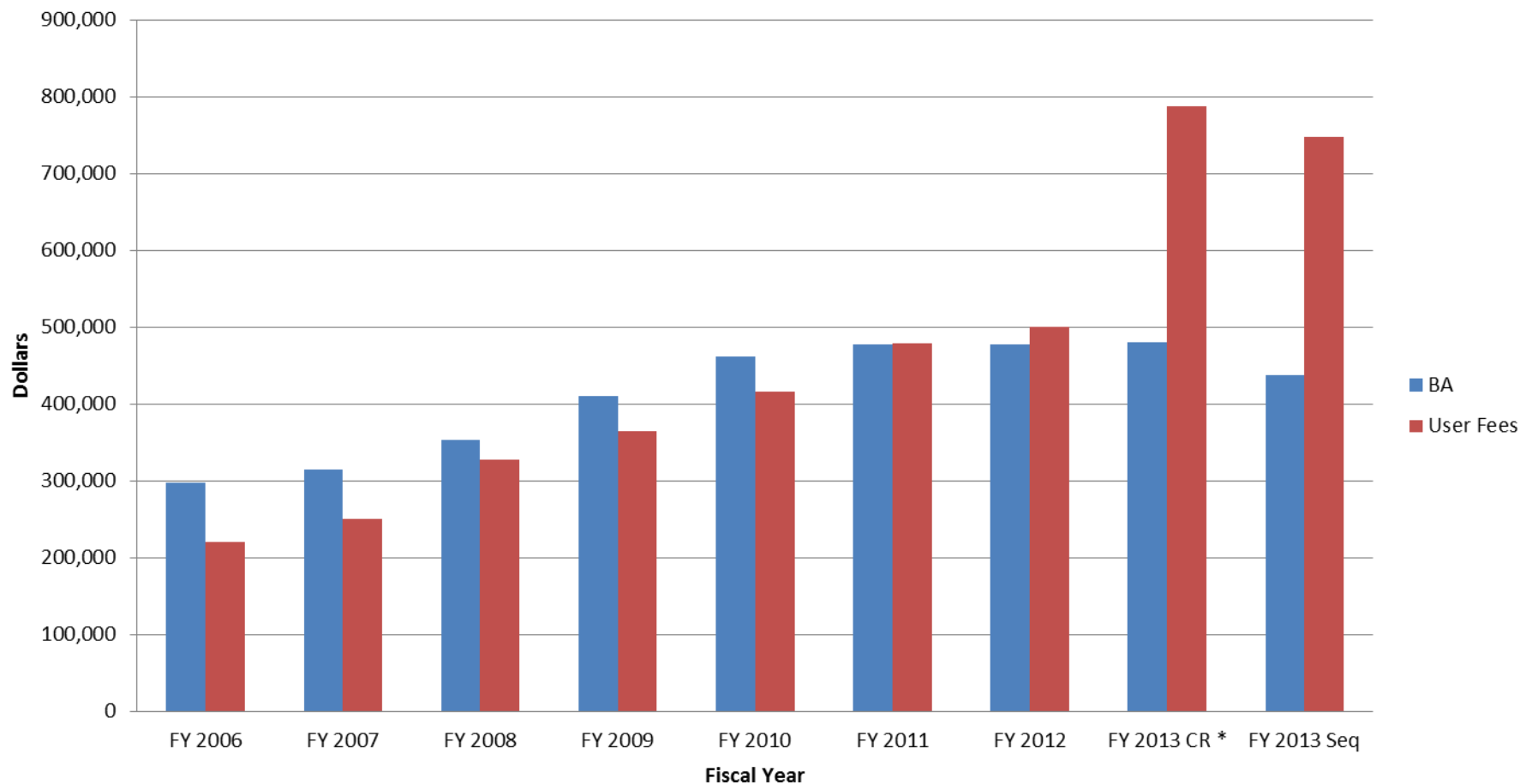
# CDER Funding Needs

- What are some of CDER's biggest challenges?
  - Sequestration and rescission
  - Maintaining BA levels to protect user fee program triggers for PDUFA, GDUFA and BsUFA
  - Unfunded Mandates (e.g. Pediatrics)

## Appendix – Human Drugs Program

- Includes CDER and ORA data for the Human Drugs Program.

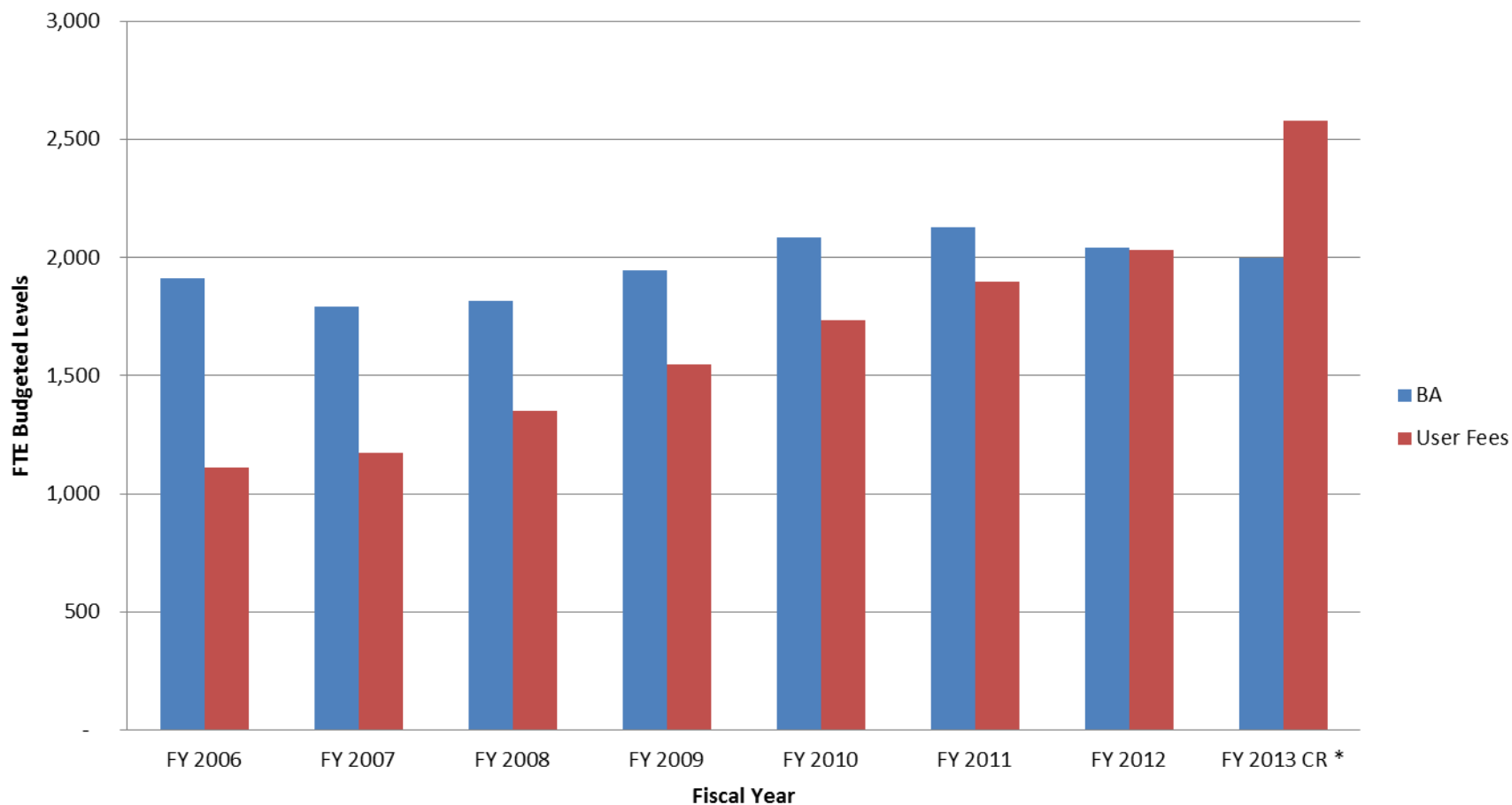
## Food and Drug Administration Human Drugs Program Enacted Budget FY 2006 - FY 2013



\* The FY 2013 funding levels do not account for sequestration and rescission.



## Food and Drug Administration Human Drugs Program Budgeted FTE Levels FY 2006 - FY 2013



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