



# H.R. 2725: FDA 'S.O.S.' Act

*FDA Safety Over Sequestration Act of 2013*

Jenny Carey

Associate Director – Federal Government Relations

California Healthcare Institute

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# What is the problem?

- *FDA Safety and Innovation Act (FDASIA)* renewed FDA's authority to collect user fees, and made improvements to regulatory review processes
  - *Increased* industry-paid user fees to support regulatory system & process improvements
- FDA relies heavily on user fees to supplement congressional appropriations for its product review activities:
  - Human Drugs & Biologics: ~60-65% user fees
  - Devices & Diagnostics: ~30% (approx. one-third) user fees
- FY13 sequester cuts FDA budget by approx. 5%
- Unanticipated OMB decision: user fees INCLUDED in sequester
  - In FY13 alone, sequestration locks away ~\$85M in industry-paid FDA user fees
- **A well-funded, science-based FDA and consistent, predictable and transparent product review processes are critical to and necessary for biomedical investment, innovation and improvements in patient care.**
- **If left unaddressed, sequestration is likely to:**
  - **Hinder FDA from conducting full range of review activities**
  - **Disrupt the progress of necessary regulatory process improvements under FDASIA**
  - **Slow product review times, increase regulatory unpredictability**
  - **Further aggravate an already significant downturn in life sciences venture capital investment**
  - **Delay patient access to innovative new technologies**

# What does H.R. 2725 do?

- **Exempts industry-paid FDA user fees from across-the-board cuts in FY14 & beyond**
  - Only exempts FDA user fees for drugs, biologics, devices and diagnostics
  - Does not affect other FDA user fees, such as tobacco or mammography facility inspection fees
  - Does not release \$85M sequestered in FY13

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- AdvaMed
- ALS Association
- American Association of Orthopaedic Surgeons (AAOS)
- American Cancer Society Cancer Action Network, Inc.
- American Society of Clinical Oncology (ASCO)
- Bavarian Nordic
- BIO
- BIOCOM
- California Healthcare Institute (CHI)
- Genentech
- Generic Pharmaceutical Association (GPhA)
- Gilead
- HealthCare Institute of New Jersey (HINJ)
- Johnson and Johnson
- Leukemia & Lymphoma Society (LLS)
- Medical Device Manufacturers Association (MDMA)
- National Health Council (NHC)
- NORD
- Patient Services Inc.
- PhRMA
- Research!America
- USAgainst Alzheimer's (USA2)
- Parkinson's Action Network (PAN)

*Endorsements current as of 10/11/13*



# Staff Contacts

## **Erin Katzelnick-Wise**

Legislative Director

Rep. Anna G. Eshoo (D-CA)

(202) 225-8104

[Erin.Katzelnick-Wise@mail.house.gov](mailto:Erin.Katzelnick-Wise@mail.house.gov)

## **Helen Dwight**

Senior Legislative Assistant

Rep. Leonard Lance (R-NJ)

(202) 225-5361

[Helen.Dwight@mail.house.gov](mailto:Helen.Dwight@mail.house.gov)

# Contact CHI in DC

## **Jenny Carey**

Associate Director – Federal Government Relations

(202) 974-6323

[carey@chi.org](mailto:carey@chi.org)

## **Todd Gillenwater**

Senior Vice President – Public Policy

(202) 974-6313

[gillenwater@chi.org](mailto:gillenwater@chi.org)