

AGENCY PORTFOLIO OVERVIEW

Federal Agency: Food and Drug Administration

Interagency Pain Research Coordinating Committee

March 27, 2012

Highlights of Pain Research Portfolio

- Office of Surveillance and Epidemiology (OSE)
 - Purpose: descriptive studies to better characterize drug safety
 - Acetaminophen Overdose AHRQ/FDA CERTs
 - Outpatient Acetaminophen Dose AHRQ/FDA CERTs
 - Trends in Opioid Prescribing (X3) CMS/FDA
 - Acetaminophen Hospitalization Nationwide Inpatient Sample/FDA
 - ED Acetaminophen Admissions National Poison Control Data/FDA
 - ED Acetaminophen Admissions (X4) National Electronic Injury Surveillance System – Cooperative Adverse Drug Events Surveillance System/FDA
 - Opioid Use/Abuse rates SAMHSA/CDC/FDA
- Office of New Drugs (OND) ACTION

Mechanisms Used to Support Pain Research

- Appropriated funds
 - Excellent mechanism for start up of special projects such as PPPs
- Contracts
 - Restrictive
 - But, get exactly what you ask for
 - Lots of detail work for us
- Grants
 - Less control
 - More flexibility
 - Can still maintain oversight with appropriate operating framework
- Cooperative Agreements
 - Similar to grant
 - Money flow less complex
 - Allows for multi-year agreement with funding as available each year

Partnerships Leveraged to Support Pain Research

- OSE Studies
- SAFE USE Initiative (Education and Outreach)
 - NSAIDs in Older Adults – collaborative of public and private partners
 - Acetaminophen Outreach – collaborative with Consumer Healthcare Products Association and National Council for Prescription Drug Programs
 - Opioid PPA Development – FDA and stakeholder working group with pain medicine community, patients, advocacy groups, etc.
- OND
 - ACTION – Critical Path Initiative public-private partnership, with objective of developing novel analgesic drug products