

Statement before the Food and
Drug Administration

Public Hearing on
Prescription Drug User Fee Act
(PDUFA) Renewal

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Academy of Managed Care Pharmacy (AMCP)

- ✦ Professional society
- ✦ Individual pharmacists and other health care practitioners
- ✦ Apply managed care principles
- ✦ 4,800 members nationwide
- ✦ Servicing 200 million Americans

PDUFA 2002

- ✦ Perpetuated the user fee program
- ✦ Made a significant contribution in securing financial resources
- ✦ Helped to expedite FDA drug and biologic review and approval
- ✦ Did little to address postmarket surveillance

Postmarket Surveillance

✦ Ongoing collection and review of data related to problems associated with a drug's use to determine if drug should continue to be marketed:

- ◆ Under original approval
- ◆ Under modified marketing requirements
- ◆ Withdrawn

Epidemiologic Studies of Postmarketing Safety

- ✦ Demonstrate the safety and effectiveness of medications when prescribed in “real world” environments
- ✦ Offer a broader array of data than pre-approval RCTs
 - Comorbidities
 - Polypharmacy
 - Off label uses

Shared Responsibility for Postmarket Surveillance



- ✦ Manufacturers
- ✦ Practitioners
- ✦ FDA

Shared Responsibilities



Manufacturers

- ✦ Responsible for the life cycle of the product

Practitioners

- ✦ Obligation to report adverse events

FDA

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- ✦ Fundamental goal of FDA – promote and protect public health by determining a drug or biologic’s safety and effectiveness based on clinical research
 - ✦ FDA approval does not mean that medications are risk-free
 - ✦ Problems associated with drugs are sometimes identified only after a drug has been on the market and available to a broad population

FDA Continued

- ✦ FDA in unique position to aggregate data on drugs in the marketplace
- ✦ Postmarket surveillance provides expanded data on drug's performance in general population
- ✦ Patient safety data acquired allows health care professionals to minimize risk to patients
- ✦ Information enhances ability of health care professionals to ensure appropriate use of medications

Changes Needed

- ✦ FDA's authority to monitor a drug after approval is limited
- ✦ FDA often asks manufacturers to conduct follow-up studies as a condition of approval
- ✦ Manufacturers agree but frequently fail to comply
- ✦ FDA needs authority to enforce the request

Managed Care Organization Databases

- ✦ CDER has awarded four contracts that give the FDA access to databases that significantly strengthen the FDA Drug Safety Program
- ✦ Databases contain medical claims of health care encounters and outpatient prescription drug use
- ✦ Can be used to study the association of various medicines with serious adverse effects

Legislation Needed To

- ✦ Give the FDA authority to require postmarket studies
- ✦ Provide adequate funding for postmarket surveillance