

## AARC Supports Balanced Approach to Drug Safety

February 27, 2007

Balancing drug safety with the need to deliver new medications to chronically and severely ill patients in need is receiving AARC support.

As a member of the National Health Council (NHC), the Association recently signed off on a new letter that went out to the Food and Drug Administration (FDA) outlining what the NHC believes must be done to enhance and modernize the FDA's drug safety system without curtailing drug research or unduly slowing the delivery of new medications to the market.

The letter supports the FDA's Prescription Drug User Fee Act (PDUFA) agreement, which would give the agency the authority to collect \$392.8 million in user fees from industry, with \$37.9 million earmarked for drug safety initiatives that would give the FDA better means to:

- Make greater use of its Critical Path Initiative, which holds the potential to revolutionize the practice of medicine and streamline the drug review process.
- Expedite the drug development process and reduce the potential for wasted experimentation.
- Move the FDA and industry towards an all electronic environment to increase the efficiency of the review process.
- Regularly assess drugs that may present risks throughout the life of a drug without impeding access to new medical products that can be used safely and effectively.
- Reestablish medication safety reviews, which have been curtailed by a lack of funding.
- Remove legal language preventing the agency from conducting postmarket surveillance throughout the life of a drug.
- Move from a passive reporting system to an active surveillance system by creating an automated systematic approach to drug surveillance through a network of databases.
- Establish a comprehensive program to inform physicians and patients about the both the risks a marketed drug may present and the benefits that a drug may provide.

The NHC also calls on Congress to provide more appropriate funding to the FDA to reduce the agency's dependence on user fees and offers to work with the agency to develop risk communication strategies that will ensure balance in the information it delivers on the risks and rewards of drugs.

This page is located at: [http://www.aarc.org/headlines/drug\\_safety/index.cfm](http://www.aarc.org/headlines/drug_safety/index.cfm)