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Statement of the National Center for Policy Research (CPR)  
for Women & Families  
At the FDA Meeting on Risk Management for Prescription Drugs

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In recent years, a great portion of FDA's resources have focused on the acceleration of the drug approval process. Drugs that pose safety concerns are now approved with the promise that risks will be managed. Unfortunately, post-marketing safety programs have been weakened as a result of inadequate resources. The additional resources that will likely be made available for risk assessment as a result of PDUFA III provide an opportunity for improvement. However, major hurdles remain.

As noted by the May 1999 report of the FDA's Task Force on Risk Management, the current pre-marketing risk assessment process is clearly inadequate for evaluating two elements critical to patient safety: 1) rare but potentially dangerous side effects, and 2) long-term outcome. Pre-approval clinical studies are far too small in size to detect rare side effects and much too short in duration to assess long-term outcome. These intrinsic deficiencies in the new-drug approval process must be addressed as the FDA works to improve post-marketing risk management programs.

*Rare but Potentially Dangerous Side Effects*

As demonstrated by a number of cases in the past decade (e.g. Lotronex and ischemic colitis), close monitoring of adverse events is essential for ensuring patient safety. Prescription drugs are frequently prescribed for uses and patient subpopulations for which they were not initially intended. Unfortunately, the FDA currently relies on a *passive* and *voluntary* adverse event reporting system that misses the vast majority of adverse drug events. Possible remedies include:

- Instituting an *active* and *mandatory* adverse event reporting system where the FDA actively solicits adverse event reports for newly-approved drugs -- perhaps for the drug's initial 3 years on the market. Health professionals who have prescribed a new drug would be required to respond to such FDA requests for adverse event reports. The current passive, voluntary system could be used after this initial, intensive monitoring period.

- Substantially increasing the number of FDA staff assigned to monitoring and reporting on adverse drug events.
- Fully engaging patients in the adverse event reporting process by providing easy-to-understand MedGuides for all prescription drugs and prominently displaying information about the FDA's MedWatch program on all product labels.

### *Long-term Outcome*

The current emphasis on rapid drug approval does not permit the gathering of long-term outcome data prior to the marketing of a new prescription drug. It is therefore crucial that drug manufacturers perform comprehensive long-term safety and outcome studies after a new drug is marketed. This is especially essential for drugs that are used for chronic conditions. As a recent FDA report to Congress showed, pharmaceutical companies have failed to complete most of the post-marketing commitments that were required of them.

A recently-negotiated agreement between the FDA and industry would permit the use of a small portion of prescription drug user fees for post-marketing surveillance activities. However, use of those user fees would be restricted to drugs approved starting in FY 2003 and would be restricted to two years for most new drugs. These limitations do not reflect appropriate concern about managing risk. Possible remedies include:

- Requiring comprehensive long-term post-marketing safety and efficacy studies for all newly-approved prescription drugs.
- Committing a greater share of prescription drug user fees and appropriations to funding the FDA's post-marketing surveillance programs.
- Removing any time limits placed on the FDA for using user fees in post-marketing safety activities.
- Requiring pharmaceutical companies to file annual reports on the status of required post-marketing safety activities.
- Granting the FDA greater authority to enforce post-marketing surveillance requirements -- including the authority to impose significant civil monetary penalties and to review direct-to-consumer ads prior to their release.

Clearly, implementation of more effective risk management programs will require greater resources and regulatory authority for the FDA. For too long, the overwhelming emphasis has been on the rapid approval of new drugs. The concerns presented in this statement are only a few of the important issues that must be addressed in FDA's risk management of prescription drugs. However, the most basic need is clear: pre-marketing and post-marketing risk management activities must be given equal priority and resources.