Statement of Diana Zuckerman, Ph.D., President
National Research Center for Women & Families
at the
FDA's Public Meeting on
Prescription Drug User Fee Act
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Thank you for the opportunity to speak on behalf of the National Research Center for Women & Families, an independent, non-profit think tank dedicated to improving the health and safety of women, children, and families.

Funding for the FDA

All Americans rely on the FDA to keep us safe and we believe that, like other essential services, the FDA should be fully funded with government appropriations. Since the user fee system is currently a fact of life, it is essential that the FDA make it clear in what they say and do that industry funding does not influence approval decisions or other regulatory decisions. Unfortunately, the current system, focused on meeting industry goals, is undermining the effectiveness and morale of the FDA for all its other responsibilities, including the public health and safety. That is why we continue to endorse legislation proposed by Rep. Maurice Hinchey that the funding from user fees be provided to the FDA with no strings attached.

Protecting the Public Health

We are pleased that the President's FY 2008 budget request would increase funding for the FDA. Unfortunately, it is only enough to allow the FDA to continue to tread water. It is not enough to make up for inadequate funding for so many years, nor to bring the FDA to the 21st century in terms of a fully functioning infrastructure.

As a result of PDUFA, drugs are being approved more quickly, but the safeguards to protect the public health are weakened. PDUFA has put all its emphasis on meeting industry goals, and not to meeting public health goals.

The tentative PDUFA IV agreement calls for an increase of about $29 million for safety efforts and removes the time limit on the use of PDUFA funds for post-market safeguards. Those are good changes, but not enough to protect the public – which is, after all, its mandate. We support the Institute of Medicine's recommendation of more than $100 million for new safety and scientific resources. That means that the PDUFA IV agreement is unacceptable – because it continues to focus on detailed goals for speeding approval, with only very vague provisions such as those to "enhance and improve communication and coordination" for safety.

Meanwhile, adults and children are dying because of the lack of emphasis on safeguards. The post-market surveillance system is a train wreck.

Consumers deserve the same clearly stated deliverables that PhRMA gets. For example:

- The FDA should immediately modernize the IT system for electronic data gathering and data analyzing for adverse reactions.
- The FDA should eliminate advisory committee members with conflicts of interest or we should eliminate advisory committees, and instead just make public on the FDA web site all the same scientific memorandum and other information that is normally prepared for these meetings.
- The FDA should require Phase IV trials of the most common off label use of prescription medications and medical devices.
- The FDA should be doubling the audits of clinical trial data and investigational review board applications.
- The FDA should double the inspection of manufacturing facilities.
- The FDA should set a specific date to use information from the CMS databases to conduct epidemiological studies, and require a specific number of studies per year.
- The FDA should collect civil monetary penalties against at least 50 percent of the applicants who have failed to complete follow-up safety studies or clinical trials.
- The FDA should require safety data on 'unapproved' drugs, most of which were grandfathered onto the market without proving safety and/or efficacy.

Direct to Consumer (DTC) Advertising User Fees

All advertisements for prescription drugs should be required to be cleared by the FDA before they are allowed to be used. The current system does not protect the public from false and misleading information, and neither will voluntary pre-clearance. Pharmaceutical companies have made it clear that the purpose of most ads is to sell products, not to inform the public. That is why risk information in ads is included in formats that ensure that it will be ignored.

Requiring pre-approval would slow down the process for advertising. As one of the few countries that even allow DTC advertising, that is clearly no loss to the public.

In addition, all types of advertising of prescription drugs should be audited, and violators should be given substantial fines. PDUFA resources should be used for those efforts.

The Role of Patients and Consumers

It is outrageous that patients and consumers are not at the table for PDUFA negotiations. Meetings like this are only useful if our recommendations are incorporated into the legislation. Time will tell if this is merely a charade. Consumer groups are lobbying for more funding for the FDA, doing all we can to improve your resources. If the FDA wants that to continue they need to include consumer groups during *negotiations*, not just public forums, for this very important legislation.