Comments of the National Center for Health Research at the FDA Public Meeting on OTC User Fees

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Thank you for the opportunity to speak today. My name is Dr. Diana Zuckerman, president of the National Center for Health Research. Our Center is a think tank that conducts research, analyzes the results of research studies, and synthesizes evidence from credible sources to determine the programs and policies that will improve the quality of medical care and enhance public health. We do not accept funding from the drug or medical device industry and have no conflicts of interest, although I personally have stock in Johnson & Johnson.

While we would prefer that the FDA was fully funded by Appropriations, it is clear that FDA user fees will continue to be an essential source of funding to supplement appropriations. Unfortunately, having generous user fees for prescription drugs, inadequate user fees for medical devices, and no user fees for OTC products has resulted in an imbalance at the FDA. For that reason, we support OTC user fees, so the agency has the resources it needs to ensure the safety and effectiveness of OTC products. User fee funding is urgently needed so that FDA can finalize the remaining OTC monographs. Until that happens, patients and consumers can't be confident in all the OTC products that are widely advertised and used by millions of Americans every day.

More than 4 decades after the OTC drug review process was established, the monograph process still has not been completed for all ingredients and conditions of use. Many products containing Category III ingredients without a GRASE determination continue to be marketed, which is not acceptable. A staff of only 18 people cannot effectively regulate 800 active ingredients for more than 1,400 different therapeutic uses. As a result, warnings are delayed, as are other important labeling changes.

Unfortunately, prescription drug and medical device user fees have been used to speed the approval process, not to make sure that drugs and devices are safe and effective. Post-market review of safety and effectiveness information is utterly inadequate. **OTC user fees should be used to address emerging safety and effectiveness issues.** FDA needs resources to provide ongoing surveillance of marketed products and move quickly when safety signals arise.

When the monographs were first developed in the 1970s, FDA lacked specific data on use in infants and children. FDA did what was customary at the time – it extrapolated the data for adults to children. We now know that is not always appropriate, but we still lack data on appropriate doses for infants and children, as well as whether the products are safe and effective for children at any dose. **OTC user fees are needed to re-examine OTC products that are currently used by children.** The lack of efficacy and substantial risks that were associated with children's cold and cough medications are an excellent example of the importance of evaluating new data as they become available.

OTC user fees should also help pay for the development of product formulation standards. The monographs set forth the conditions under which a specific active ingredient used in a drug product is

not misbranded but do not usually specify the non-active ingredients that can be added. In addition, many product formulation variables affect the dose that is delivered. **Therefore, we recommend development of standards for drug products, not just their ingredients. We strongly urge FDA to include funding for this in user fees.**

Since the monograph system is based on ingredients and since sponsors of monograph drugs are not required to obtain FDA approval prior to marketing, the fee structure must be different than it is for prescription drugs. User fees should, therefore, be structured as a product listing fee based on a sliding scale proportionate to the complexity and FDA resources required for the review. This would provide the agency with a stable and predictable source of funding for the OTC division. We would avoid structuring the fee as a facility fee since it could easily inspire sponsors to consolidate operations into as few facilities as possible. In addition to reducing the user fees, this could cause OTC drug shortages if a facility is removed from operation.

In summary, OTC user fees are needed to finalize OTC monographs, but they are also urgently needed to review emerging safety and effectiveness issues, and to ensure the proper use of OTC products for infants and children.