

## **MOST DRUGS WITHDRAWN IN RECENT YEARS HAD GREATER RISK FOR WOMEN**

On February 8, Rep. Waxman, along with Senators Harkin, Mikulski, and Snowe, released a GAO report showing that most of the prescription drugs withdrawn in recent years posed a greater risk for women than for men.

According to the GAO report, eight of the ten prescription drugs withdrawn since January 1, 1997, posed greater health risks for women than for men. Four of the drugs may have led to more adverse events in women because they were prescribed more often to women than to men. The other four drugs had more adverse events in women even though they were widely prescribed to both women and men.

In 1992, Rep. Waxman requested the first GAO study regarding FDA's policies and the pharmaceutical industry's practices regarding research on women in prescription drug testing. The 1992 report found that women were underrepresented in drug trials and recommended that FDA revise its policy to ensure the appropriate participation of women and to ensure that gender analyses be performed. As a result of this study, FDA issued new guidelines regarding the inclusion of women.

Rep. Waxman said, "This new GAO report calls into question whether FDA and the pharmaceutical industry are following a drug review process that adequately protects women. In particular, it raises serious questions as to whether the drug companies are including women in clinical trials in adequate numbers and analyzing the data by sex before putting the drug on the market. It is critical to discover sex-related variations *before* drugs are approved and in widespread use. Women need to be certain that when they take a prescription drug, it has been found to be safe and effective for them."

Rep. Waxman and Senators Harkin, Mikulski, and Snowe have called for a further GAO investigation regarding this matter. A more in-depth GAO report is expected to be released in late April.