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REP. WAXMAN, SEN. KENNEDY RELEASE NEW GAO REPORT ON INCLUSION OF SENIORS IN DRUG TRIALS

WASHINGTON, DC — Rep. Henry A. Waxman and Sen. Edward M. Kennedy today released a new GAO report on FDA's inclusion of seniors in clinical drug trials for prescription drugs. The report finds that in several key areas, FDA rules for drug approval fail to guarantee the safety and effectiveness of drugs for seniors.

"Seniors use more drugs than any other age group, but they are not getting enough attention in the drug approval process," said Rep. Waxman. "FDA medical officers need to do a better job assessing the safety and effectiveness of drugs in older populations."

"The FDA must do more to ensure that its drug reviewers demand that seniors are included in clinical trials and that those reviewers scrutinize the available data to assess the safety and effectiveness of drugs for seniors," said Sen. Kennedy.

To conduct the study, GAO reviewed 36 New Drug Applications (NDA) filed with FDA from January 1, 2001, through June 30, 2004. Findings of the report include:

- **Inclusion of seniors in clinical trials.** GAO found that drug manufacturers "generally included elderly persons and reported safety and effectiveness data for elderly persons in clinical trials." However, in a number of cases, selected drug trials excluded participants on the basis of age, restricting the participation of seniors.

- **Inadequate FDA guidance.** FDA has failed to clarify important requirements in the drug evaluation process for seniors, resulting in potential information gaps. For example, FDA does not require that medical officers determine whether a sufficient number of seniors participated in drug trials.

- **Failure to document safety and effectiveness.** According to GAO, one-third of new drug reviews failed to include documentation of FDA medical officers' review of drug safety and effectiveness data for seniors.

"The new GAO report identifies some important gaps in assessing the safety and effectiveness of drugs in seniors. Oversight will be needed to make sure FDA responds to the GAO findings." concluded Rep. Waxman.

The complete GAO report is available online at www.oversight.house.gov.