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Contacts: Tricia Enright w/ Harkin @ 202-224-3254
Dave Lackey w/ Snowe @ 202-224-8667
Johanna Ramos-Boyer w/ Mikulski @ 202-228-1122
Karen Lightfoot w/ Waxman @ 202-225-5051

HARKIN, SNOWE, MIKULSKI, WAXMAN RELEASE GAO STUDY ON WOMEN'S INCLUSION IN CLINICAL STUDIES

Bipartisan group of lawmakers calls on HHS Secretary Tommy Thompson to ensure proper FDA oversight

WASHINGTON – U.S. Senators Tom Harkin (D-IA), Olympia Snowe (R-ME), and Barbara Mikulski (D-MD) and Congressman Henry Waxman (D-CA) today **released a General Accounting Office (GAO) study showing problems with the analysis and reporting of data when women are included in the Food and Drug Administration's (FDA) clinical drug trials.** The bipartisan group of lawmakers called on Tommy Thompson, Secretary of Health and Human Services to conduct a review of FDA's practices and adopt a plan of action to address these problems.

"While there is now evidence to suggest that women are finally being included in clinical trials, it is still very troubling that there is no procedure in place to properly record and track women's participation in these studies or ensure that appropriate safety regulations are being followed," said **Harkin**. "And when we are talking about the health and safety of more than half of the citizens in this country, half a loaf just doesn't cut it."

"The GAO report we are releasing today demonstrates that the FDA needs to be more vigorous in enforcing reporting standards, because -- while progress has been made since we first identified the exclusion of women from clinical trials in 1991 -- more women still need to be included in drug trials from their earliest stages. Alarmingly, almost 40 percent of the new drug reports included in the GAO's study failed to provide required separate male and female demographic information," said **Snowe**, who authored the legislation creating the Office of Women's Health.

"I'm pleased that FDA has made some progress to correct the decades of inadequate research on drug safety and efficacy for women, but we still have work to do," said **Mikulski**. "This report tells us that the FDA has some plans to reach our goals, but now they need the resources and the guidance to put them into action. That's why I've been working with my Senate colleagues to make the Office of Women's Health at FDA and other agencies permanent. Women's health offices in HHS can't be shortchanged or shut down just to save a few bucks, and I will stand sentry to make sure that doesn't happen."

"While this report shows that much progress has been made, it also reveals seriously deficient oversight and compliance with FDA regulations. It is intolerable that these basic guidelines are not being met. Women's research should not be the poor stepsister. Given that under the current regulatory scheme the job is not getting done, we may need to take legislative action. We need to ensure that analysis of sex differences is conducted for all drugs which women use," said **Waxman**.

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According to the GAO study, neither the industry nor the FDA itself reliably abides by the FDA guidelines for data on women. While the GAO concludes that, overall, a sufficient number of women were included in research, it identifies a number of shortcomings in data analysis and presentation, shortcomings that could result in overlooking serious problems. Specific shortcomings were found in new drug summary documents, presentation and analysis of data related to sex differences, and management of information about women in research.

Earlier this year the GAO published a preliminary report of the study which revealed the alarming fact that eight out of the 10 drugs withdrawn from the market by the Food and Drug Administration (FDA) in the past four years had dangerous health risks for women. The Legislators called on Secretary Thompson to address these problems and the need for policies that can expand public and private efforts to increase our understanding of how diseases affect women specifically, and how diagnosis and treatment efforts could be improved.

Last year at the request of these Congressional leaders on women's health, the GAO conducted a study into the National Institute of Health (NIH). The study showed that while the National Institute of Health did a good job of including women in their clinical trials – they did a poor job of determining how men and women responded differently to the same drug. Then the bipartisan group decided to ask the GAO to determine the extent to which the FDA was including women in their clinical drug trials.

Attached is a copy of the letter to Sec. Thompson (one page). Copies of the GAO report are available upon request.