



Women s Health: Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement: Gao-01-754

By -

Bibliogov, United States, 2013. Paperback. Book Condition: New. 246 x 189 mm. Language: English . Brand New Book ***** Print on Demand *****.This report reviews the Food and Drug Administration s (FDA) inclusion of women in clinical drug trials. GAO found that women were a majority of the clinical trial participants in the new drug applications (NDA) it examined and that every NDA included enough women in the pivotal studies to be able to statistically demonstrate that the drug is effective in women. Although these findings are welcome, GAO also found three areas of concern. The first is the relatively small proportion of women in early small-scale safety studies. These early studies provide important information on drugs toxicity and safe dosing levels for later stages of clinical development, and many of the NDAs GAO examined found significant sex differences in a drug s pharmacokinetics, or how it is absorbed, distributed, metabolized, excreted, and concentrated in the bloodstream. Second, GAO is not confident that either NDA sponsors or FDA s reviewers took full advantage of the available data to learn more about the effects of the drug in women and to explore potential sex differences in dosing. This is because NDA...



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