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



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Reviews

The publication is simple in go through preferable to fully grasp. I am quite late in start reading this one, but better then never. It is extremely difficult to leave it before concluding, once you begin to read the book. (Mrs. Josiane Collins)

WOMEN S HEALTH: WOMEN SUFFICIENTLY REPRESENTED IN NEW DRUG TESTING, BUT FDA OVERSIGHT NEEDS IMPROVEMENT: GAO-01-754



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 summary documents are not required to include analyses of sex differences, and many of them do not. Third, FDA lacks appropriate management systems to monitor how many women are in clinical trials, to be certain that NDAs and investigational new drug applications (IND) annual reports comply with regulations for presenting outcome data by sex and tabulating the number of women included in ongoing trials, and to confirm that its medical officers have adequately addressed sex-related issues in their reviews. Although FDA has taken some promising initial steps to address these deficiencies, it is important that the agency finalize the pilot...

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