



February 27, 2009

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

To Whom It May Concern:

The Endocrine Society welcomes the opportunity to respond to the Request for Comments issued January 13, 2009 titled "Participation of Certain Population Subsets in Clinical Drug Trials; Request for Comment." In response, we submit the Society's white paper *Increasing Minority Participation in Clinical Research* (attached). The paper has been endorsed by the National Medical Association in addition to the 13 medical societies listed on the back cover.

Founded in 1916, The Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. Today, The Endocrine Society's membership consists of more than 14,000 scientists, physicians, educators, nurses and students in more than 100 countries. Together, these members represent all basic, applied, and clinical interests in endocrinology.

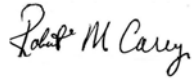
The Society has a major interest in improving human health and the U.S. healthcare system, and a large component of improving care is to alleviate the disparities that exist among underserved and underrepresented populations. The complex problem of health disparities has roots in each step along the path to treatment and best practices, including those in the clinical trial phase.

As part of its efforts to address health disparities, The Endocrine Society assembled a task force of experts to examine the underrepresentation of minority populations in clinical research, both as trial participants and as investigators. The appended white paper presents the task force's findings, summarizing the major impediments to participation and identifying recommendations for solutions. We invite you to pay particular attention to the recommendations section beginning on page 26. Among other actions, we recommend specifically that FDA consider immediately adopting NIH guidelines on inclusion of women and minorities and that adherence to these guidelines should be required rather than recommended.

While the white paper focuses largely on issues facing racial and ethnic minorities, similar approaches could be used to increase participation by other underrepresented populations mentioned in the Request for Comments.

The Endocrine Society supports the FDA's efforts to improve human health by ensuring that all U.S. citizens are represented in the clinical trials that examine the safety and efficacy of treatments and practices. We look forward to working with the Agency to eliminate health disparities in this country. If you would like to discuss the Society's recommendations in more detail, or if we can be of any further assistance, please contact Loretta Doan, Associate Director, Science Policy at [ldoan@endo-society.org](mailto:ldoan@endo-society.org).

Sincerely,

A handwritten signature in cursive script that reads "Robert M. Carey".

Robert M. Carey, MD MACP  
President, The Endocrine Society