United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

November 8, 2005

Via Electronic Transmission

The Honorable Daniel R. Levinson
Inspector General
Department of Health and Human Services
Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Levinson:

The Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, among other matters. Accordingly, the Committee is responsible to the more than 80 million Americans who receive health care coverage under those programs, including payment for drugs and medical devices. As Chairman of the Committee, I am greatly concerned by a special report published in the December 2005 issue of *Bloomberg Markets*, entitled, "Big Pharma's Shameful Secret" (Report). The Report states that "[e]very year, drug companies spend $14 billion to test experimental substances on humans. Across the U.S., the centers that do the testing—and the regulators who watch them—allow scores of people to be injured or killed."

According to the Report, people who participate as patients in clinical drug trials are not always warned adequately of the risks of those trials, are sometimes blatantly endangered and harmed, and, although otherwise healthy, some are dying as a result of the trials. The Report suggests that these problems are arising from a lack of direct Federal oversight and the reliance on largely unregulated private institutional review boards (IRBs) to monitor trials conducted by profit-driven testing centers staffed by poorly trained, unlicensed clinicians. Not only is this treatment of participating patients and their families alarming, but it also undermines the credibility of the pharmaceutical research and development process and places the value of new pharmaceutical products in question. The problems with how some clinical trials are being monitored and conducted may harm important efforts to encourage participation in properly conducted drug trials, which could expand the availability of life-saving new drugs for this country and the world. The more fundamental and important concern, however, is the lack of protections and respect for research participants who place their health and their lives in the hands of clinical investigators and the entities that are expected to monitor and oversee the studies.

Therefore, as Chairman of the Committee, I request that the Office of Inspector General (OIG) review the issues identified in this Report. Specifically, I ask that you assess the previous work undertaken by your office in this area and determine appropriate issues related to institutional review boards that your office can address, including but not limited to FDA oversight of clinical trials. In particular, please advise whether or not administrative, regulatory, and/or legislative corrective actions in this area are needed.

In addition, I note that over the last 10 years previous OIG reports have addressed many of these issues and contained recommendations related to protecting human research subjects, including but not limited to strengthening institutional review boards, improving recruiting practices for human research subjects, and strengthening FDA oversight of clinical investigators. Therefore, I request that the OIG forward a comprehensive list of its recommendations to the appropriate agencies of jurisdiction and to this Committee, along with the date of each recommendation and the OIG's knowledge of the status of each recommendation as of the date of this letter. Please be aware that under separate cover I am requesting that HHS, FDA and NIH provide an accounting to this Committee of their actions taken in response to the OIG reports released in 1995, 1998, 2000, and 2001.

Finally, as Chairman of the Committee, I request that your office keep the Committee apprised of your review of the aforementioned matters. At the earliest opportunity, I would appreciate receiving a briefing from your office. We must take every possible step to ensure that our clinical trial system is in fact the "Gold Standard" that we expect it to be.

Thank you in advance for having your staff coordinate with my staff about this letter by November 10, 2005. I would appreciate your response by November 29, 2005, unless it is available sooner.

Sincerely,

Charles E. Grassley
Chairman