

### New bill removes barriers to clinical trial participation

It's challenging enough to find volunteers for clinical trials that test treatments for widespread diseases like cancer and arthritis. It's even harder to find volunteers for trials testing treatments for rare diseases, such as Cystic Fibrosis, Amyotrophic Lateral Sclerosis (ALS), Hodgkin's Disease, and numerous others.

A new bill introduced in the US House of Representatives on June 15, 2009, would make it more appealing for volunteers to enroll in clinical trials for rare diseases. The bi-partisan bill H.R. 2866 would exempt up to \$2,000 of compensation earned from taking part in clinical trials for rare diseases.

The resolution, called the *Improving Access to Clinical Trials Act of 2009*, would apply to people who receive SSI (Supplemental Security Income). Those who receive SSI benefits include people with limited income who are over age 65, blind, or disabled.

While not all clinical trials offer compensation, many do. This exemption is important because compensation from trials could potentially put these volunteers' income over the SSI eligibility threshold. The prospect of losing those benefits could deter many volunteers from enrolling in clinical trials for rare diseases.

The term 'rare disease' or conditions refers to any disease that a) affects fewer than 200,000 people in the US, or b) affects more than 200,000 people in the US, and for which there is no reasonable expectation that the cost of developing and selling the drug will be recovered from sales of the drug in the US. The rare and uncommon diseases are named in the Orphan Drug Act of 1983.

House Resolution 2866 was introduced by Representatives Edward Markey (D-Mass) and Cliff Stearns (R- FL), who co-chair the Congressional Cystic Fibrosis Caucus.

### Latest round in the global clinical trials discussion *US FDA Site Inspection Findings, 1997 - 2008, Fail to Justify Global Concerns*

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A newly-published study is the newest volley in an international debate over the safety, validity, and usefulness of some



overseas clinical trials sites. A number of scientists consider sites in certain non-US regions well-run and valuable; others disagree.

These study results also fly in the face of a new strategy announced by the European Medicines Agency (EMA). In December 2008, the EMA expressed concern about whether clinical trials conducted by regions outside Europe and North America are ethical and scientifically valid.

Each year, the FDA conducts inspections of trial investigators, sponsors, and IRBs to check their compliance with regulations and to make sure the data submitted is valid and accurate. Karlberg examined 3,818 US Food and Drug Administration inspections of clinical trial sites around the world from 1997 through 2008.

Karlberg's study found that clinical trial sites in Eastern Europe had the lowest number of infractions, followed by the Rest of the World (regions outside of Europe and North America, including Africa, Asia, Latin America, Russia, and others), followed by North America and last, Western Europe.

Among all the investigations, the most common problems reported were "Failure to follow investigational plan" (34.2%); Inadequate and inaccurate records (25.1%), Inadequate drug accountability (9.6%), Inadequate informed consent form (8.9%) and Failure to report adverse drug reactions (8.5%).

#### PERCENTAGE OF SITES HAVING THREE OR MORE FDA INFRACTIONS

Europe	20.2%
North America	13.4%
Rest of the World	6.5%
Eastern Europe	3.3%* (more than 2 infractions)