Congress of the United States
Washington, DC 20515

Joint Statement on Legislation to Establish a Clinical Trials Registry
To Be Introduced by
Rep. Edward J. Markey and Rep. Henry A. Waxman

September 9, 2004

In the next several days, we intend to introduce legislation that will establish a mandatory registry for clinical trials of drugs and biologics.

This registry will expand www.clinicaltrials.gov to ensure that physicians, patients, and the public have access to information on ongoing clinical trials and to the results of these studies once they are completed. The legislation will also prevent pharmaceutical companies from withholding clinically important information about their products.

The legislation will:

- Meet all of the minimum criteria for a trial registry set out by the International Committee of Medical Journal Editors on September 8, 2004. These include a requirement that researchers promptly disclose the objectives, eligibility criteria, sources of funding, and anticipated timeline of clinical trials;

- Satisfy the objective of the American Medical Association by requiring the results of all clinical trials to be publicly available to doctors and patients. The bill will require the posting of important results that are not published in the peer-reviewed medical literature in a timely fashion;

- Respond to failures to provide information voluntarily by including strong enforcement mechanisms. Among other mechanisms, the bill will make participation in the registry a requirement for Institutional Review Board approval and will provide for civil monetary penalties for noncompliance;

- Provide authority to audit the completeness and accuracy of the information in the registry; and

- Preserve patient access at www.clinicaltrials.gov to enrollment information about clinical trials for serious and life-threatening diseases as established in the Food and Drug Administration Modernization Act of 1997.

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