September 24, 2012

The Honorable Edward J. Markey
2108 Rayburn House Office Building
Washington, DC 20515

RE: TEST Act Legislation, H.R. 6272

Dear Representative Markey:

I am writing on behalf of Public Responsibility in Medicine and Research (PRIM&R) to express support for the goal of increasing transparency in clinical research that you are seeking to achieve in the Trial and Experimental Studies Transparency (TEST) Act of 2012. PRIM&R is a 38-year-old nonprofit organization, based in Boston, dedicated to advancing the highest ethical standards in the conduct of research. We accomplish this goal by providing educational programming and professional development services to the full array of individuals and organizations involved in biomedical, social science, and behavioral research, particularly the members and staff of Institutional Review Boards (IRBs). Through a variety of conferences and other educational activities, PRIM&R provides balanced, thorough, and accurate information on a range of ethical and regulatory issues affecting research.

PRIM&R believes that legislation that increases transparency of clinical trials would promote the ethical conduct of human subjects research. Broader and more comprehensive requirements for the registration and reporting of clinical trials would ultimately lead to increased public awareness of the research process and results. Access to both positive and negative trial results of all phases of domestic and international research could also support improved research design and greater accountability for researchers and provide valuable information to IRBs and potential research subjects. For example, negative research results would inform potential researchers of areas that would not be worthwhile to pursue. A comprehensive registry of clinical trials is essential for this purpose because negative results are often not published in the literature. Such benefits are fully aligned with PRIM&R’s mission to advance the ethical conduct of research and we fully support your efforts in this area.

PRIM&R is concerned, however, that the current registration and reporting system under ClinicalTrials.gov is flawed, and that consequently the TEST Act as written will do little to enhance transparency. Current reporting requirements for the registry result in tables of raw data and study information written in highly technical language. This format is not interpretable or helpful for the layperson, thus thwarting the registry’s stated aim of providing accurate and timely clinical research data to “individuals with serious or life-threatening diseases or conditions, to other members of the public, and to health care providers and researchers.” [Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (March 2002)] Specifically, existing law states “[t]he Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.” [P.L. 110-85, Sec. 801(j)(2)(B)(iv)] If the current system is not being implemented in accordance with such requirements, it will be fruitless simply to enlarge the scope of the registry.
PRIM&R believes that additional information is required to learn whether, as appears to be the case, the current registry system is not functioning as intended. If it is not, then expanding the registration and reporting requirements will do little to further transparency and knowledge, at least for the general public. Fundamental changes to the current system may be necessary before its requirements are broadened.

PRIM&R recommends, therefore, that the bill mandate that a thorough assessment of the strengths and weaknesses of the current registry system be completed before expanding the scope of its requirements. Data should be collected about how the registry is used, by whom, and whether it provides the information that researchers, physicians, and the public require for making decisions about research design and participation. Such a study should also draw on experts in the communication and dissemination of health-related and research information to recommend ways to improve the utility of the registry for users from industry, biomedical research, physicians, and the public.

PRIM&R is grateful for the opportunity to share its views on this important bill and is happy to provide any additional support or information you and your staff may require to achieve the bill’s laudable goals.

Sincerely yours,

Joan Rachlin, JD, MPH
Executive Director