

July 2, 2012

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

Dear Representative Markey,

The undersigned members of the Patient, Consumer and Public Health Coalition, which includes nonprofit organizations and individuals that represent patients, consumers, physicians, scientists, and researchers, are writing to express our strong support for the Trial and Experimental Studies Transparency (TEST) Act of 2012. This legislation will ensure that patients, consumers, and health care providers have better information about the drugs and devices available to them.

The Food and Drug Administration Amendments Act (FDAAA) of 2007 greatly expanded and enhanced the reporting requirements for clinicaltrials.gov, helping thousands of health care providers, patients, and consumers learn more about clinical trials. But clinicaltrials.gov remains a work in progress, with many information gaps. Representative Markey's bill would ensure that the transparency goals regarding disclosure of clinical trial information established by FDAAA are fully implemented by closing definitional loopholes and by requiring the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to report enforcement actions they have taken against non-compliers. In addition, the bill makes great strides towards transparency in an ethically contentious area by requiring better reporting of study results, rulemaking on registration of foreign clinical studies, and public disclosure of informed consent documents and protocols.

Closing Loopholes

The bill would expand the definition of "applicable clinical trial," to ensure that all interventional biomedical studies on humans are required to be registered on clinicaltrials.gov. Under the current definition, many clinical trials involving humans are not required to register. They are exempted because they are conducted early in the testing phase, despite the fact that they still use human subjects.

Taking Enforcement Actions

Crucially, the bill requires the Director of the NIH and the Commissioner of the FDA to provide a progress report to Congress assessing industry compliance with the registration requirements and reporting of FDA enforcement actions that have been taken against those evading the law by conducting trials but never registering them. For clinicaltrials.gov to be an accurate source of information for patients and consumers, sponsors of clinical studies must comply with the law.

Increasing Public Transparency

The bill strengthens reporting requirements to include better reporting of study results, which is crucial for patients and consumers because it will provide more information than is currently available about the drugs and devices on the market. Better and more complete data also would

encourage innovation and save industry resources by informing companies about clinical trials that were stopped because they caused harm or demonstrated lack of efficacy. This would prevent another company contemplating the same pharmaceutical approach from wasting precious research and development dollars. It would also save prospective human subjects from harm or, at the very least, false hopes about a potential treatment. The bill would also require informed consent documents and protocols to be submitted, giving the public a better understanding of how trials are being run today.

Including Foreign Clinical Trials

According to the Department of Health and Human Services (HHS) Office of Inspector General, in 2008 “eighty percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials” with the number only expected to rise as outsourcing clinical trials becomes the standard practice.¹ Unfortunately, many of these trials are not required to be registered with the clinicaltrials.gov database. The TEST Act directs HHS to issue regulations requiring foreign clinical trials used in support of an FDA marketing application to meet the registration and reporting requirements mentioned above.

The TEST Act will improve patient, consumer, and provider access to information about the drugs and devices that are being tested and the subsequent results so they can make informed medical decisions. It will also increase the transparency of the globalized clinical trials system in which millions of men, women, and children partake.

Thank you for offering this valuable piece of legislation.

American Medical Women’s Association

Annie Appleseed Project

Breast Cancer Action

Center for Medical Consumers

Consumer Federation of America

Consumers Union

CT Center for Patient Safety

Jacobs Institute

National Research Center for Women & Families Cancer Prevention and Treatment Fund

National Women's Health Network

Our Bodies Ourselves

Public Citizen

Reproductive Health Technologies Project

The TMJ Association

Union of Concerned Scientists

U.S. PIRG

Woody Matters

¹ <http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf>