



CONSUMERS UNITED FOR
EVIDENCE-BASED HEALTHCARE

US Cochrane Center
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July 12, 2012

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

Steering Committee:

Co-Chair
Rebecca Burkholder
National Consumers
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Childbirth Connection

John Santa
Consumers Union

Barbara Warren
National Coalition for
LGBT Health

Kate Ryan
National Women's
Health Network

Terrie Cowley
TMJ Association

Dear Representative Markey,

CUE - Consumers United for Evidence-based Healthcare is a national coalition of 37 health and consumer advocacy organizations committed to empowering consumers to make the best use of evidence-based healthcare. CUE works with the United States Cochrane Center in a consumer advocate-scientist partnership to pioneer efforts to improve consumers' ability to engage in and demand high quality healthcare. To this end, we believe patients, consumers and health care providers deserve access to complete, accurate and timely evidence-based information about medical products.

We strongly support H.R. xx, the Trial and Experimental Studies Transparency (TEST) Act of 2012. The TEST Act expands the information that must be registered with and publically accessible on clinicaltrials.gov – a registry and results database of federally and privately funded clinical trials involving human subjects. This legislation will ensure greater transparency of safety and effectiveness information about the prescription drugs and medical devices that are or may become available to patients and consumers. Increased access to data from clinical trials improves patient and consumer safety because it allows for critical analysis of the safety and efficacy of drugs and devices by independent health organizations.

Currently, there is a significant amount of information from clinical trials that is never reported to the clinicaltrials.gov and thus is never available to the public.

- **Many clinical trials do not have to register with clinicaltrials.gov** – for example, trials conducted early in the development process, such as Phase I trials and feasibility trials, and some trials conducted in foreign countries are not required to register with clinicaltrials.gov.
- **Many clinical trials never have to report results on clinicaltrials.gov** – for example, if a company never seeks approval of its medical product from the Food and Drug Administration (FDA) or the approval is denied because the product is unsafe or ineffective, the results do not have to be reported. This is particularly harmful to people who participate in clinical trials because another company could unknowingly put them at risk by attempting a trial with the same product never knowing that it had already been studied and has failed to demonstrate safety and efficacy.

- **Many clinical trial documents never have to be submitted to clinicaltrials.gov** – for example, clinical trial protocols and informed consent documents, which provide crucial information on the trial design and the protections for human subjects, are not included on the list of documents that must be submitted to clinicaltrials.gov despite the fact that they are vital to understanding and interpreting the results of the trial.

The TEST Act addresses all three of these problems. First, it will expand the definition of “applicable clinical trial” so that all interventional biomedical clinical trials involving human subjects must be registered. Second, it will ensure that the results of all clinical trials must be reported to clinicaltrials.gov within one to two years of completion of the study, which would greatly increase the amount of results that have to be publically reported. Third, it will require that all trial protocols and informed consent documents be submitted to clinicaltrials.gov in advance of the company enrolling people in the trial.

This legislation also addresses the current lack of compliance with the requirements of clinicaltrials.gov. Many companies never report the results of their clinical trials, even when it is required, and many never register their clinical trials in the first place. The TEST Act would require the National Institutes of Health (NIH) and the FDA to report to Congress on the status of compliance with the clinicaltrials.gov requirements and any enforcement actions they have taken against non-compliers. This is essential to ensuring that companies are held accountable. Clinicaltrials.gov must have complete and accurate information to provide patients, consumers, and health care providers with the information they need to make evidence-based health care decisions.

We strongly commend Representative Markey for taking action to protect patients, consumers and clinical trial participants from potentially unsafe and ineffective medical products. The increased transparency provided by his bill will also ensure that health care providers and researchers have access to information that will enable them to conduct more thorough research, which will allow them to better contribute to public health knowledge.

Sincerely,



Rebecca Burkholder
CUE Co-Chair



Lorraine Johnson
CUE Co-Chair

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