February 1, 2012

The Honorable Fred Upton
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Re: Support for H.R. 3847, the SOUND Act of 2012

Dear Chairman Upton and Ranking Member Waxman,

As members of the Patient, Consumer, and Public Health Coalition, which includes nonprofit organizations and individuals that represent patients, consumers, physicians, scientists, and researchers, we want to express our strong support for H.R. 3847, the Safety of Untested and New Devices (SOUND Devices) Act of 2012. This legislation will protect the public from avoidable harms caused by unsafe devices that should never have been cleared for sale in the first place. It will also help to ensure that decisions on device safety are based on more reliable information.

We have been raising concerns for many years about how the Food and Drug Administration's (FDA) 510(k) clearance process exposes patients and consumers to unnecessary risk by putting unsafe and unproven devices on the market in the United States. The practice of clearing products based on a series of predicate devices has resulted in serious harm, and even deaths, caused by products that have reached the market without any reasonable foundation for the assumption of safety and effectiveness. The logical flaw of assuming that a device which is similar, though not identical, to a previously cleared product will be as safe and effective as its predicate is obvious. But that fundamental flaw in the 510(k) clearance process is also compounded by additional problems which this bill would address.

Relying on unsafe predicates. Current FDA law allows the agency to clear a medical device for sale based on its similarity to a predicate device, or line of predicates, even if one of the products in that line has been removed from the market due to serious safety problems. For example, in 2003 the FDA cleared Obtape, a type of surgically implanted vaginal mesh, because it was similar to another type of mesh on the market. But that predicate product had also been cleared based on its similarity to a previously cleared predicate mesh, called Protegen. The Obtape clearance proceeded based on the intermediary predicate, despite the fact that Protegen had been recalled by the FDA four years earlier because it caused severe permanent harm to women. Allowing device clearance based on a predicate, without requiring examination of the full line of predicates, opens the door to tragic, preventable consequences, as developed in this case. Obtape

was cleared and caused thousands of women to suffer from crippling pain, infections and additional surgeries before it, too, was withdrawn from the market.

Patients suffered needlessly because the FDA does not have the authority to require manufacturers to provide information on the lineage of predicate devices and does not consistently consider that history in making its decisions about 510(k) clearances. Many thousands of women could have been spared lifelong injuries and suffering, if the FDA had the authority to require submission of this additional information.

The SOUND Devices Act would give the FDA the authority to require that manufacturers provide the agency with information not just about the predicate device on which its request for clearance is based, but about the full lineage of predicates. This reform will significantly reduce the chance that a device is approved based directly or indirectly on a product that has already caused terrible harm to patients and consumers. Furthermore, this legislation would ensure that when a medical device is recalled, the FDA can order the manufacturer of a product that was cleared using the recalled device as a predicate to provide information demonstrating that its product does not share the same flaw as its predicate.

Tracking predicate lineage. There is currently no reliable and up-to-date source of information about the predicate lineage of the medical devices marketed in the United States. This makes it cumbersome for the FDA and medical device manufacturers to obtain the necessary information to determine the status of predicates. The barriers are even higher for clinicians, patients or advocates who may want to investigate the safety of a product cleared based on a predicate. To facilitate efficient and effective tracking of the status of medical devices that a manufacturer might use as a predicate for a proposed device, the SOUND Devices Act directs the FDA to maintain an up-to-date database of eligible predicates. This will ensure that the FDA and manufacturers have readily accessible information on the status of devices on the market and their lineage of predicates.

These two reforms will greatly improve medical device safety, offering important protections to patients and consumers. They hold the potential to prevent future tragedies, like the terrible damage done by vaginal mesh products that should never have been cleared for use.

We strongly commend Representatives Markey, Waxman, Schakowsky and DeLauro for taking action to protect patients and consumers from unsafe and unproven medical devices. We rely on the FDA to determine whether products are safe and effective based on evidence, not assumptions, and the SOUND Devices Act of 2012 is a big step in the right direction.

Sincerely,

Annie Appleseed Project
Breast Cancer Action
Center for Medical Consumers
Community Access National Network
Consumers Union
Institute for Ethics and Emerging Technologies
Jacobs Institute of Women's Health
National Consumers League
National Physicians Alliance
National Research Center for Women & Families/Cancer Prevention & Treatment Fund
National Women’s Health Network
Our Bodies Ourselves
Public Citizen
Reproductive Health Technologies Project
The TMJ Association, Ltd.
Truth in Medicine Incorporated
Union of Concerned Scientists, Scientific Integrity Program
U.S. PIRG
Woody Matters