



Clinical Trials Amendment

The following press release from the office of US Senator Sherrod Brown announces the introduction of a bipartisan amendment to expand and protect access to clinical trials (Amendment 2871). This proposal would protect patients' health care coverage while an individual is enrolled in clinical trials. This amendment has since been included in the Senate's version of the Health Care Bill. Prior to the filing of Amendment 2871, CISCRP's President and CEO, Diane Simmons, and CISCRP's Board Chair, Ken Getz, conferred with Senator Brown's legislative aide David S. Mitchell.

December 16, 2009

D Washington DC- U.S. Sens. Sherrod Brown (D-OH) and Kay Bailey Hutchison (R-TX) announced a bipartisan amendment to the health reform bill which would protect access to clinical trials for patients with life-threatening diseases. The amendment would prohibit insurers from dropping a policyholder's coverage if the patient chooses to participate in a clinical trial and from denying coverage for routine care that the plan would otherwise provide. The amendment is cosponsored by Sens. Al Franken (D-MN), Sheldon Whitehouse (D-RI), Arlen Specter (D-PA), Benjamin Cardin (D-MD), and Bernie Sanders (I-VT).

"Americans with life-threatening diseases should be able to spend time fighting their illnesses, rather than battling insurance companies," Sen. Brown said. "This amendment prevents insurance companies from denying patients' access to routine medical care just because they are enrolled in a clinical trial. If we're going to make medical breakthroughs, we need to encourage participation in clinical trials, not put up barriers. Patients with chronic conditions should not have their health coverage jeopardized if they choose to enroll in a potentially life-saving trial."

Video footage of Brown speaking on the Senate floor in support of the amendment can be found [HERE](#) (footage takes a few moments to load).

"Maryland's facilities, including Johns Hopkins, the University of Maryland, and the National Institutes of Health, are home to the world's leading medical researchers. For many patients with serious illnesses, clinical trials are their only hope. They should not be denied the benefits of cutting-edge therapies and treatments

because an insurance company refuses to pay for routine costs, such as laboratory services," Sen. Cardin said. In 2000, as a member of the House Ways and Means Committee, Cardin led the bipartisan effort to secure Medicare coverage for routine patient costs associated with federally-funded or reviewed trials.

"I am pleased to join Senator Brown in cosponsoring this amendment," Sen. Specter said. "Clinical trials are vital to advancing research on treatments and cures to serious illnesses that affect so many Americans, and patients should be able to access these trials without having their insurance company reduce or limit their coverage."

Clinical trials often offer cutting-edge therapies that are not available through traditional methods. These experimental treatments save lives and advance research. However, many health insurance policies discourage enrollment in these trials by refusing to cover trial participants' routine health care, those basic services unrelated to the trial and justly owed to the premium-paying policyholder. According to The Ohio State University's Comprehensive Cancer Center, an estimated 20 percent of patients who attempt to enroll in clinical trials are denied coverage by their insurance. These patients are often prevented from exploring clinical trial options because they risk losing health care coverage for routine services like X-rays, blood tests, and doctor visits.

Low participation rates in clinical trials undermine research and medical advancements. Only about two percent of Americans participate in clinical trials annually and only six percent of people who suffer from severe, chronic illnesses enroll in trials. These low participation rates make it harder to conduct timely trials. In fact, delays in patient recruitment for clinical trials account for an average of 4.6 months lost per trial. Nearly 80 percent of trials run over schedule by more than a month, and only six percent are completed on time.

Brown and Hutchison's amendment (#2871) is modeled on existing Medicare policy and on more than 30 state laws and regulations that already guarantee patient access to clinical trials. Amendment 2871 would apply to all insurance products, including those offered in the Federal Employees Health Benefits Program, and to all clinical trials that treat cancer or other life-threatening diseases. Brown introduced similar legislation, the Cancer Clinical Trials Act, in February 2009.

