

CONGRESSIONAL REQUESTS



June 4-5, 2012

Washington, DC

Congressional Pediatric Cancer Caucus

Congressional Request: Children with cancer, survivors, their families, and advocates urge members of the House of Representatives to join the bipartisan Congressional Pediatric Cancer Caucus and advance legislation and public policy to eliminate cancer as a threat to all children.

Facts about childhood and adolescent cancer

- More than 13,500 children are diagnosed with cancer every year in the United States; the average age of a child diagnosed with cancer is six.
- More than 40,000 children undergo cancer treatment each year in the United States.
- Cancer is the #1 disease killer of children in the United States.
- More than 350,000 childhood cancer survivors live in the United States; two-thirds of them will suffer a late-effect from the cancer treatment they received.

Caucus Founded

June 2009

Co-Chairs

The Honorable Michael McCaul (R-TX)

The Honorable Chris Van Hollen (D-MD)

Mission

The mission of the bipartisan Childhood Cancer Caucus is to serve as a clearinghouse for information on pediatric cancer and a forum to aid Members of Congress in working together to address pediatric cancer. The Caucus will strive to raise awareness about pediatric cancer, advocate in support of measures to prevent the pain, suffering and long-term effects of childhood cancers, and work toward the goal of eliminating cancer as a threat to all children.

Goals

- Improve pediatric comprehensive cancer care and the quality of life for children and adolescents with cancer;
- Support increased funding for childhood cancer research through the NIH, the CDC, and other federal research agencies;
- Encourage collaboration between the public sector and private research organizations to further research on pediatric cancer;
- Promote public policies that address the health needs of pediatric cancer survivors;
- Support the training of skilled pediatric cancer specialists.

To Join

To join the Caucus, please contact Andy Taylor with Congressman Michael McCaul at (202) 225-2401 or Andy.Taylor@mail.house.gov or Erika Appel with Congressman Chris Van Hollen at (202) 225-1402 or Erika.Appel@mail.house.gov.

Congress of the United States
Washington, DC 20515

Join the Pediatric Cancer Caucus

Dear Colleague,

We are writing to invite you to join the Pediatric Cancer Caucus. Pediatric cancer strikes one of our most vulnerable populations, children, with life-altering effects. With nearly 15,000 new cases diagnosed each year, cancer is the number one cause of death by disease in children, cutting short the lives of more children under the age of 20 than any other disease. While long term survival rates for pediatric cancer are fairly high -- 1 child out of 5 who is diagnosed with cancer dies from it -- 3 out of 5 children suffer from long-term side effects.

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Warmly,



Michael McCaul
Member of Congress
Co-Chair



Chris Van Hollen
Member of Congress
Co-Chair

Members of the Congressional Childhood Cancer Caucus

Rep. Rodney Alexander (LA)
Rep. Spencer Baucus (AL)
Rep. Tammy Baldwin (WI)
Rep. Roscoe Bartlett (MD)
Rep. Lou Barletta (PA)
Rep. Shelley Berkeley (NV)
Rep. Howard Berman (CA)
Rep. Jaime Herrera Beutler (WA)
Rep. Gus Bilirakis (FL)
Rep. Rob Bishop (UT)
Rep. Diane Black (TN)
Rep. Marsha Blackburn (TN)
Rep. Bruce Braley (IA)
Rep. Paul Broun (GA)
Rep. Ann Marie Buerkle (NY)
Rep. G.K. Butterfield (GA)
Rep. Ken Calvert (CA)
Rep. Shelley Moore Capito (WV)
Rep. Ben Chandler (KY)
Rep. Steve Cohen (TN)
Rep. Tom Cole (OK)
Rep. Gerald Connolly (VA)
Rep. Jim Cooper (TN)
Rep. Mark Critz (PA)
Rep. Henry Cuellar (TX)
Rep. John Culberson (TX)
Rep. Charlie Dent (WA)
Rep. Scott Des Jarlais (TN)
Rep. Lloyd Doggett (TX)
Rep. John Duncan, Jr. (TN)
Rep. Bob Filner (CA)
Rep. Stephen Fincher (TN)
Rep. Bob Goodlatte (VA)
Rep. Raul Grijalva (AZ)
Rep. Jeb Hensarling (TX)
Rep. Jim Himes (CT)
Rep. Maurice Hinchey (NY)
Rep. Darrell Issa (CA)
Rep. Lynn Jenkins (KS)
Rep. Walter Jones (NC)
Rep. Mike Kelly (PA)
Rep. Peter King (NY)
Rep. Larry Kissell (NC)
Rep. John Kline (MN)
Rep. Leonard Lance (NJ)
Rep. Tom Latham (IA)
Rep. Robert Latta (OH)
Rep. Barbara Lee (CA)
Rep. Blaine Luetkemeyer (MO)
Rep. Tom McClintock (CA)
Rep. Thaddeus McCotter (MI)
Rep. Jim McGovern (MA)
Rep. Carolyn Maloney (NY)
Rep. Kenny Marchant (TX)
Rep. James Moran (VA)
Rep. Sue Myrick (NC)
Rep. Randy Neugebauer (TX)
Rep. Bill Pascrell (NJ)
Rep. Joseph Pitts (PA)
Rep. Todd Platts (PA)
Rep. Jared Polis (CO)
Rep. Bill Posey (FL)
Rep. David Price (NC)
Rep. Phil Roe (NC)
Rep. Mike Rogers (AL)
Rep. Mike Ross (AR)
Rep. Gregorio Sablan (GU)
Rep. Linda Sanchez (CA)
Rep. Loretta Sanchez (CA)
Rep. Janice Schkawosky (IL)
Rep. Allyson Schwartz (PA)
Rep. Bobby Scott (VA)
Rep. Pete Sessions (TX)
Rep. Adam Smith (WA)
Rep. Jackie Speier (CA)
Rep. Patrick Tiberi (OH)
Rep. Bob Turner (NY)
Rep. Fred Upton (MI)
Rep. Timothy Walz (MN)
Rep. Rob Wittman (VA)
Rep. John Yarmuth (KY)
Rep. C.W. "Bill" Young (FL)

Childhood Cancer Survivorship Act

Congressional Request: Cosponsor the Pediatric, Adolescent and Young Adult Cancer Survivorship Research and Quality of Life Act

Background

- Each year, 13,500 children are diagnosed with cancer.
- There are approximately 350,000 survivors of childhood cancer in the United States today.
- Two-thirds of childhood cancer survivors are likely to experience at least one late effect of treatment, and almost one-fourth will face a late effect that is serious or life-threatening.
- Secondary cancers, heart and lung damage, osteoporosis, financial pressures, psychosocial issues, employment and fertility problems are among the many challenges faced by childhood cancer survivors.

The Pediatric, Adolescent and Young Adult Cancer Survivorship Research and Quality of Life Act of 2011 (S. 1613 and H.R. 3015) will provide resources to fund research and survivorship programs to improve the quality of life for all childhood cancer survivors.

On September 22, 2011, the Childhood Cancer Survivorship Act was introduced by Senators Jack Reed (D-RI) and Kay Bailey Hutchison (R-TX) and Representatives Jackie Speier (D-CA) and Michael McCaul (R-TX).

Why This Legislation is Needed

The population of survivors of childhood cancer has grown significantly as a result of research and improved treatment. In 1960, only four percent of children with cancer survived more than five years. Today, almost eighty percent of children with cancer pass the five-year survival mark.

Research now tells us that as many as two-thirds of childhood cancer survivors can experience at least one late effect because of their cancer or treatment. Late effects can include disabilities or health problems, such as heart disease, infertility, and increased incidence of a secondary cancer. It is critical that resources are available to address the long-term effects faced by survivors of childhood cancer.

What this Legislation Will Do

The Childhood Cancer Survivorship Act will improve access to high-quality health care for the 350,000 childhood cancer survivors in the United States today. Specifically, the legislation will:

- Enhance research on late effects and health care disparities;
- Create pilot programs to evaluate model systems of care and identify the most effective ways to provide follow-up care to survivors;
- Authorize grants to eligible entities to establish clinics to provide comprehensive, long-term follow-up care; and
- Strengthen the emphasis on psychosocial care for childhood cancer survivors.

Developing and Preserving Access to Pediatric Drug Treatments

Congressional Request: Support policies through PDUFA that maintain access and advance development of new therapies for children with cancer.

Background

Several initiatives affecting the development and availability of treatments for childhood cancer patients have been pending before Congress during this past year.

Rather than addressing them individually, portions of them have now been rolled into a much larger bill. Known as the Prescription Drug User Fee Act – PDUFA, it is “must pass” legislation that authorizes user fees that are collected from pharmaceutical manufacturers to support the FDA review process.

Accordingly, some provisions of the bills below are now included in the PDUFA bill. The bill is poised to pass both the House (H.R. 5651) and Senate (S. 3187) and will need support from advocates to insure that those provisions are retained and strengthened.

Among them:

- **Best Pharmaceuticals for Children Act (BPCA) & Pediatric Research Equity Act (PREA)**
These laws provide both incentives (BPCA) and requirements (PREA) for drug testing and development in pediatric diseases. Both are up for renewal this year and need to be renewed by Congress. While BPCA and PREA have made significant advances in how medicines can be used in children, the laws have had very modest impact on the development of new drugs for children with cancer. In fact, PREA itself has had no meaningful impact.

Language has been added that requires a Food & Drug Administration (FDA) public meeting to examine the effectiveness of BPCA and PREA on children with cancer. The meeting is to occur no later than December 31, 2013.

The legislation also mandates an internal FDA report examining the impact of the laws on studying drugs for children with cancer, and calls for recommended modifications to the programs to facilitate the development of new and better therapies for children with cancer.

- **Drug Shortages** - Over the past year pediatric cancer patients have faced growing shortages of critical drugs used in life-saving treatments, including methotrexate and vincristine used to treat childhood leukemia and other cancers. Without access to the preferred and most clinically appropriate drug treatments, physicians are forced to substitute less effective alternatives and/or ration the limited supplies available. Furthermore, shortages have a significant impact on clinical trials of promising new therapies with delays in patient accrual and increased research costs.

The Food & Drug Administration (FDA) needs the authority for an early warning system, requiring manufacturers to provide notification of a discontinuation or prolonged interruption of a medication's production.

The FDA needs the resources to expedite approval of supplemental new drug applications or conduct foreign inspections when there are shortages of critical life-saving drugs.

Long term, comprehensive solutions to this ongoing problem – including economic incentives need to be pursued quickly.

- **Creating Hope Act** – The Creating Hope Act generates market incentives for drug development through the establishment of a priority review voucher for pediatric rare diseases, including pediatric cancer. Under this program, a company or institution that develops a drug for a pediatric rare disease and receives FDA approval also receives a voucher. That voucher comes with rights to priority FDA review of any other drug which results in the second drug getting to market many months earlier. The voucher would be fully transferable.

Language in the House version of the PDUFA bill calls for a demonstration project that provides up to three priority review vouchers. The GAO would then conduct a study for Congress to evaluate the effectiveness of the program. Congress may then determine whether to continue the incentive.

In the past 20 years, the FDA has approved only one new drug for any pediatric cancer, in contrast to numerous new drugs developed for adults.

Children with cancer do not have adequate drugs available to them. 1 of five children diagnosed with cancer dies. Children who survive cancer often have debilitating long-term side effects.

Note: PDUFA legislation is being debated in the Senate and House of Representatives in May and could change. Information provided here is current as of May 21, 2012.