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Changing the landscape of pediatric research

Dear friends,

Last week, the US House of Representatives Energy and Commerce Committee passed the Creating Hope Act as part of a larger FDA bill! We now have the Senate to go.

Tuesday, the Senate will consider an FDA bill on the Senate floor that does not yet include the Creating Hope Act. We need your help to ensure the Creating Hope Act is attached to the Senate FDA bill. Senators Harkin (D-IA) and Enzi (R-WY), as the Chairman and Ranking Member of the Senate HELP Committee, have the power to include this important language in the FDA bill.

Please take 5 minutes TODAY to call Chairman Harkin's and Ranking Member Enzi's offices and tell them why this is important to you.

We will only be successful if YOU take ACTION immediately. Senator Harkin and Senator Enzi need to receive hundreds of calls before 5pm EST today to



understand that it is important for pediatric cancer patients. YOU can make the difference.

Make your calls and then please share this action alert via email, Twitter and Facebook.

Below are the numbers for Harkin & Enzi's offices. Please speak with the staff member who answers the phone, using the script below. If no one answers, leave a voicemail. Be respectful to the staff, but express your urgent concern.

Chairman Harkin (D-IA): [202-224-3254](tel:202-224-3254)
(if you live in Iowa please say so on the call)

Ranking Member Enzi (R-WY): [\(202\) 224-3424](tel:202-224-3424)
Toll-Free [\(888\) 250-1879](tel:888-250-1879)
(if you live in Wyoming please say so on the call)

Sample Scripts:

Parent/Family/Caregiver/Friend: I am a parent of a child with cancer. I am calling you because I'm concerned that the Senate FDA bill does not include the Creating Hope Act, legislation to promote drug development for pediatric cancers and other pediatric diseases. Please make sure the Creating Hope Act is included in the final version of the FDA bill. My child is (a pediatric cancer survivor)/(undergoing treatment for a pediatric cancer)/deceased.

Physician/researcher: I am a physician working to treat pediatric cancers / rare diseases calling because I'm concerned that the Senate has not yet included the Creating Hope Act in the FDA bill. The Creating Hope Act provides market incentives for new drug development for pediatric cancers and other rare pediatric diseases. Please include the language from the House FDA bill's Creating Hope Act in the Senate FDA bill.

Please share how your calls went on our Facebook page <https://www.facebook.com/kidsvcancer> or info@kidsvcancer.org.

More information on The Creating Hope Act:

Although the United States is a leader in drug development, almost no drugs

are being developed for American children. Some 27% of those affected by one of the 350 most "common" rare diseases die before their first birthday because there are inadequate or no drugs for these babies. In addition, in the past 20 years, there has been only one initial FDA approval for a drug for any pediatric cancer. Because the market for pediatric rare disease drugs is small relative to other diseases, pharmaceutical companies cannot develop drugs for children with serious and rare diseases.

The Creating Hope Act generates market incentives for drug development through the establishment of a priority review voucher for pediatric rare diseases. 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 approval for any other drug which results in the second drug getting to market many months earlier. The voucher would be fully transferable.

The Creating Hope Act does not require any tax payer spending and has bipartisan support. It has 168 cosponsors in the House. On September 23, 2011 Representatives Michael McCaul, G.K. Butterfield, Sue Myrick, and Chris Van Hollen introduced the Creating Hope Act (H.R. 3059) into the House. It was introduced into the Senate on March 17, 2011 by Senators Robert Casey, Scott Brown, Sherrod Brown, Al Franken, and John Isakson (S. 606).

On May 9, 2012 the House Energy and Commerce Committee passed the Food and Drug Administration (FDA) Reform Act of 2012, which includes the Creating Hope Act as Section 865. Chairman Upton and Ranking Member Waxman agreed to Section 865, which modifies the Creating Hope Act to be a demonstration project of three vouchers with a sunset and GAO evaluation.

The Creating Hope Act fills an important gap in policy initiatives to encourage drug development for pediatric rare diseases. BPCA and PREA only provide for relabeling of adult drugs for use by children, not for new children's drugs.

The Creating Hope Act builds on the "FDA Amendments Act of 2007," which established a priority review voucher for drug development for neglected tropical diseases. The Creating Hope Act of 2011 closes a loophole that allows pharmaceutical companies to receive vouchers for drugs that are already marketed abroad and allows the vouchers to be transferable.

Sincerely,
Nancy