

The Creating Hope Act of 2011

Providing Incentives to Pharmaceutical Companies to Develop Drugs for Pediatric Rare Diseases.

The Creating Hope Act generates market incentives for drug development through the establishment of a priority review voucher for pediatric rare diseases, including pediatric cancers. Under this program, a company or institution that develops a drug for a pediatric rare disease and receives FDA approval for that drug also receives a voucher. That voucher comes with rights to expedited FDA approval for any other drug - most likely a blockbuster drug, which results in the blockbuster drug getting to market many months earlier. The voucher would be fully transferable and is estimated to be worth tens to hundreds of millions of dollars.

The Creating Hope Act was introduced in August, 2010 in the 111th Congress. It is expected to be reintroduced into the Senate of the 112th Congress in March, 2011.

The Creating Hope Act does not require an appropriation and has bipartisan support. The Creating Hope Act fills an important gap in policy initiatives to encourage drug development for pediatric rare diseases. The Orphan Drug Act's 7-year exclusivity provision has been insufficient for drugs designed expressly for very small markets, including pediatric rare diseases. The Pediatric Exclusivity provision of the Best Pharmaceuticals for Children Act does not benefit drugs that are only for pediatric indications.

The Creating Hope Act builds on the "FDA Amendments Act of 2007," which established a voucher for drug development for neglected tropical diseases. The Creating Hope Act of 2011 will improve upon the original law by allowing the vouchers to be transferable and by shortening to 90 days the current 365 day notice voucher holders must give the FDA before exercising a voucher. The Act also adds Chagas disease to the list of neglected tropical diseases and closes a loophole in the 2007 FDA legislation that allowed pharmaceutical companies to receive vouchers for tropical disease drugs already approved abroad.

For more information on the Creating Hope Act, please visit www.kidsvcancer.org or contact Nancy Goodman at nancygoodman@kidsvcancer.org.