

Science Translational Medicine: 'Creating Hope Act' incentivizes pediatric drug R&D

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Recent legislative and regulatory actions make great strides toward establishing much needed incentives for pharmaceutical companies and others to develop and test more medications for pediatric rare diseases, including pediatric cancers, according to commentary by experts from Children's National Medical Center. The commentary appears in the January 19 issue of *Science Translational Medicine*.

"Pediatricians who treat children with serious and life-threatening diseases often find themselves face to face with the inadequacies of pediatric drug development," write Edward Connor, MD, director of the Office of Innovation Development and Investigational Therapeutics at Children's National Medical Center, and Pablo Cure, MD, MPH, Laboratory for Entrepreneurial Achievement in Pediatrics (LEAP) Scholar in the Office of Innovation Development and Investigational Therapeutics.

In a previous commentary for this journal, Dr. Connor noted that despite the fact that children make up nearly 40 percent of the world's population, little research is done to test the effects of "adult therapies" on children, who have unique needs requiring tailored care more sophisticated than merely smaller doses of adult therapeutics. The demand for pediatric drugs, especially those for [rare diseases](#) like childhood cancer, is relatively low compared to the demand for adult drugs, as fewer children develop rare and serious illnesses. To maximize efficacy and return on investment, pharmaceutical developers sometimes focus their efforts on therapeutics that address illnesses common to

larger populations.

Pediatric specialists frequently have to prescribe therapeutics for children "off-label" because many common drugs and devices for treating diseases are only tested in adults but are necessary for the treatment of children. Research, however, has shown repeatedly that drugs and devices for adults can impact children differently.

According to the authors, the Creating Hope Act of 2010 that is pending before Congress recognizes the importance of stimulating pediatric drug development. It updates the existing Priority Voucher for Neglected Diseases Program to include rare and serious diseases of childhood. That program offers a financial incentive to companies developing drugs for neglected diseases.

"Although government support is critical," the authors continued, "it is not sufficient to produce products...for use in children. Incentive programs like the Creating Hope Act and other approaches designed to motivate [drug development](#) for children are also needed. Our investment in biomedical research is providing returns, and we need to assure that children, the most vulnerable among us, benefit from this investment as well."

Provided by Children's National Medical Center

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