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# AAP News

## FDA Update, Pharmacology

### FDA report highlights successes, challenges in pediatric drug research

by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health

In a new report to Congress, the Food and Drug Administration (FDA) outlines achievements as well as continued challenges in pediatric drug development since enactment of pediatric legislation in 1997.



Many products that were used "off-label" now have been studied in the pediatric population, and over 600 products have labels containing new pediatric information. Making the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act (PREA) permanent in 2012 was crucial for industry, regulators, clinicians and most importantly patients by providing a foundation of certainty for treatment and research in children.

However, section 409I, which establishes a pediatric drug clinical research program at the National Institutes of Health, expires in fiscal year 2017. Other areas that still require attention are the need for a global pediatric trials network and advancement of the science required to address the development of products for neonates and pediatric cancer patients.

The FDA recommended changes to PREA to remove exemptions for orphan products and to expand requirements for pediatric cancer studies based on a pediatric tumor's expression of a molecular target, the known molecular mechanism of a new drug or both.

The full report, including details on the FDA's recommendations, can be found at [www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm509707.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm509707.htm).