Most newly approved biologics studied in peds population

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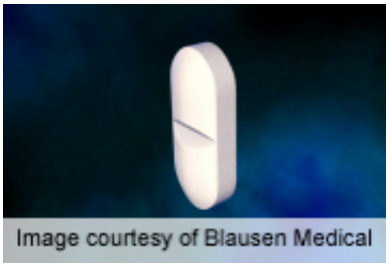

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(HealthDay)—The majority of biologics approved since 1997 include pediatric information in their labeling and have been studied in pediatric trials, according to a review published online Jan. 14 in *Pediatrics*.

Marilyn J. Field, Ph.D., from the Institute of Medicine in Washington D.C., and colleagues reviewed product labels from 96 biologics and 55 vaccines licensed by the U.S. Food and Drug Administration between 1997 and 2010, which were still marketed as of 2010, for information on approved pediatric uses, pediatric studies, or pediatric safety warnings based on analyses of adverse events. Registered pediatric studies of these biologics were identified through ClinicalTrials.gov.

The researchers found that about 60 percent of the biologics had labeling

demonstrating approved pediatric study information or pediatric use or both. At least one registered pediatric trial was completed, underway, or planned for about 85 percent of the biologics. In total, about 90 percent of biologics had one or a combination of the following characteristics: were labeled for pediatric use, had pediatric information in the label, or had a registered pediatric study; as did 95 percent of analyzed vaccines.

"Overall, this analysis indicates substantial investigation of pediatric uses of biologics by government, industry, and non-industry sponsors of research," the authors write. "Most of the products with neither pediatric labeling nor registered pediatric studies are approved for indications that are rare or not diagnosed in children."

More information: Abstract
Full Text (subscription or payment may be required)