

Historic milestone: 1,000 drugs, biologics have new pediatric use information in labeling

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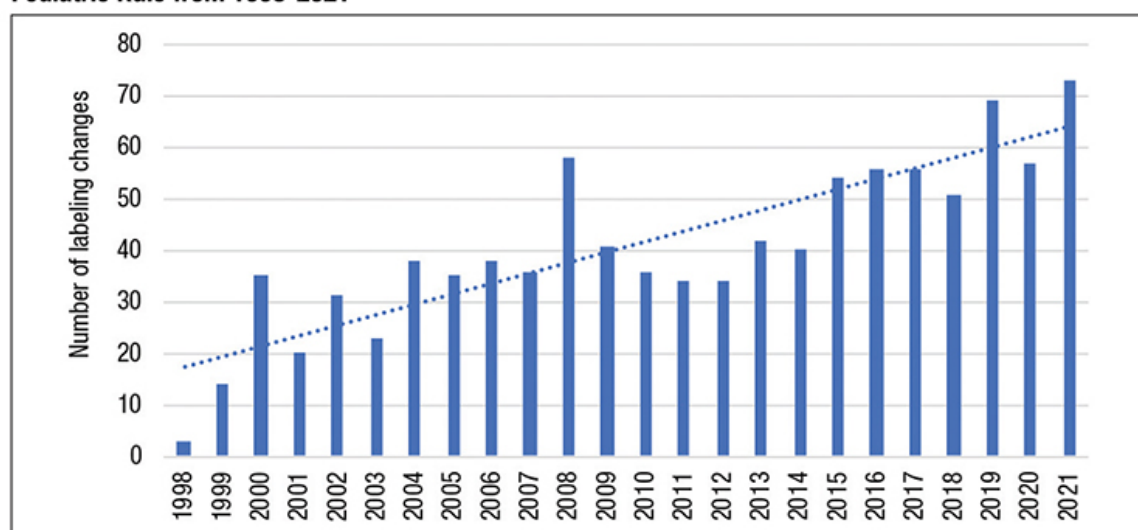


The Food and Drug Administration (FDA) has announced a historic milestone as more than 1,000 drugs and biologics have undergone labeling changes to include pediatric use information.

The changes stem from laws and regulations that have encouraged or required pharmaceutical companies to evaluate their products for use in children.

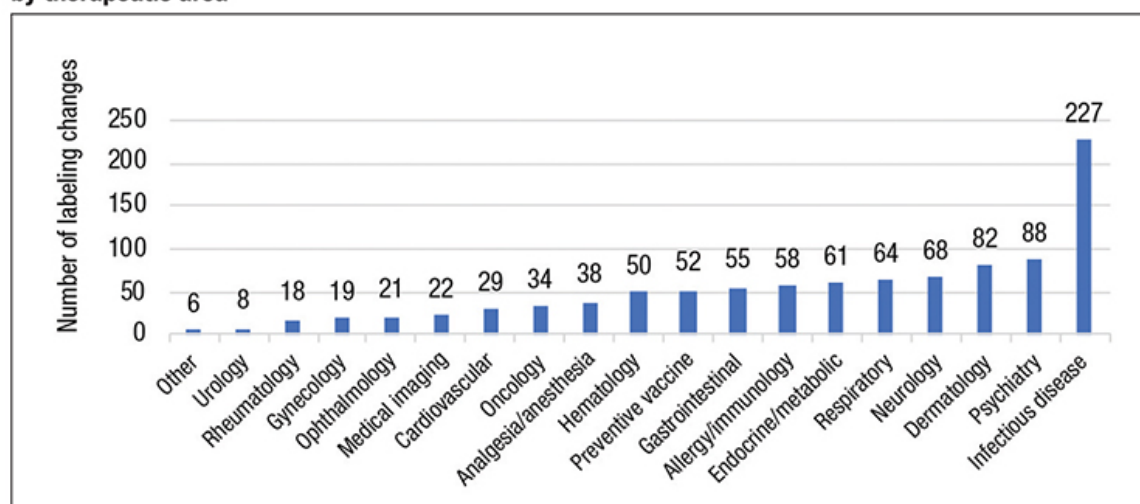
Prior to passage of the first law incentivizing pediatric studies in 1997, more than 80% of approved drugs had no pediatric-specific labeling information. After decades of advocacy by the AAP, FDA and other stakeholders to address inadequate pediatric labeling, Congress passed the Best Pharmaceuticals for Children Act (BPCA) of 2002 and the Pediatric Research Equity Act (PREA) of 2003. These laws and others have increased pediatric drug and biologics research and development and have led to a substantial increase in the number of products with pediatric information in labeling (see figure 1).

Figure 1. Number of pediatric labeling changes that occurred pursuant to PREA, BPCA and the Pediatric Rule from 1998-2021



The 1,000 pediatric labeling changes resulting from these laws include products spanning 18 therapeutic areas. The therapeutic areas with the greatest number of pediatric labeling changes are infectious disease (227), psychiatry (88) and dermatology (82) (see figure 2).

Figure 2. First 1,000 pediatric labeling changes pursuant to PREA, BPCA and the Pediatric Rule by therapeutic area



Labeling changes for infectious diseases include both antiviral (135) and anti-infective (92) products.

Antiviral product labeling changes include, but are not limited to, products for treatment of HIV (82), hepatitis C (16), influenza (13), hepatitis B (6), COVID-19 (2) and neonatal herpes simplex virus (1).

Anti-infective product labeling changes include, but are not limited to, products for treatment of pneumonia (8), impetigo (4), otitis media (4), sinusitis (4), complicated urinary tract infection and pyelonephritis (3), malaria (2) and inhalational anthrax (1).

Psychiatry labeling changes include, but are not limited to, products for treatment attention-deficit/hyperactivity disorder (42), major depressive disorder (16), bipolar disorder (13), schizophrenia (9), irritability associated with autistic disorder (6) and generalized anxiety disorder (2).

Dermatology labeling changes include, but are not limited to, products for treatment of acne vulgaris (23), atopic dermatitis (17), plaque psoriasis (12) and seborrheic dermatitis (2).

To help pediatric providers remain current on product labeling updates, the FDA shares summaries of pediatric labeling changes and highlights noteworthy pediatric approvals in this FDA Update column. Below are examples of the pediatric approvals stemming from these laws that have been highlighted along the way:

- Epclusa (sofosbuvir and velpatasvir) and Mavyret (glecaprevir and pibrentasvir) were the first all-oral, pan-genotypic (genotypes 1-6) hepatitis C virus treatment regimens for pediatric patients 3 years and older (<https://bit.ly/3SmEZPi>).
- Pradaxa (dabigatran etexilate) was the first oral anticoagulant approved for use in pediatric patients 3 months and older (<https://bit.ly/3bpwBxS>).
- Veklury (remdesivir) was the first treatment for COVID-19 approved for use in pediatric patients 12 years and older (<https://bit.ly/3QbWW19>).
- Benlysta (belimumab) was the first drug approved to treat systemic lupus erythematosus in pediatric patients 5 years and older (<https://bit.ly/3JpmLc2>).
- Victoza (liraglutide) was the first approval for type 2 diabetes mellitus in pediatric patients 10 years and older since metformin and human insulin were approved in 2000 and 1982, respectively (<https://bit.ly/3PVEOsT>).
- Corlanor (ivabradine) was the first drug approved for treatment of heart failure in pediatric patients 6 months and older (<https://bit.ly/3cYle0m>).
- Gilenya (fingolimod) was the first drug approved for treatment of multiple sclerosis in pediatric patients 10 years and older (<https://bit.ly/3ztwJV6>).

- Enbrel (etanercept) was the first systemic treatment for plaque psoriasis approved in pediatric patients 4 years and older (<https://bit.ly/3boXPVv>).
- Entocort EC (budesonide) was the first drug approved for use in pediatric patients 8 years and older with active Crohn's disease (<https://bit.ly/3JIT9MN>).

The FDA's work on behalf of children continues. In 2017, PREA was amended by what is commonly referred to as the Research to Accelerate Cures and Equity (RACE) for Children Act to help ensure the law meets the needs of children with cancer. The FDA also continues to advocate for product development for neonates and children with rare diseases.

The FDA's Office of Pediatric Therapeutics (OPT), Division of Pediatrics and Maternal Health (DPMH) and the Pediatric Working Group in the Center for Biologics Evaluation and Research contributed to this article. OPT resides in the Office of Clinical Policy and Programs in the Office of the Commissioner. DPMH resides in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine within the Office of New Drugs in the Center for Drug Evaluation and Research.

Resources

- [Pediatric labeling changes and study characteristics data](#)
- [FDA's reports to Congress on the implementation of BPCA and PREA](#)