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Pediatric committee advises FDA on medical product research, labeling, adverse events

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The Pediatric Advisory Committee (PAC) is among numerous committees and panels that provide independent expert advice to the Food and Drug Administration (FDA) on scientific, technical and policy matters to support the agency's mission to protect and promote public health.

The PAC's duties include identifying research priorities related to pediatric therapeutics and medical devices and discussing issues and making recommendations pertaining to the ethics, design and analysis of pediatric clinical trials. In addition, the PAC may recommend actions the FDA should take in response to reports of adverse events in children related to FDA-regulated therapeutics.

In recent years, the FDA has convened the PAC for advice on several important labeling, adverse event and drug development topics.

In 2017, the PAC discussed use of prescription opioid products containing hydrocodone or codeine for the treatment of cough in pediatric patients. In general, committee members agreed the benefits of hydrocodone or codeine for treatment of cough associated with allergy or the common cold did not outweigh the risks (https://www.fda.gov/media/108204/download).

In 2019, the FDA sought advice from the PAC and the Drug Safety and Risk Management Advisory Committee regarding the benefits and risks of montelukast (Singulair), which is used to treat asthma and allergic rhinitis. Serious neuropsychiatric events associated with the drug had been reported, including agitation, depression, sleeping problems and suicidal thought and actions.

Based on data regarding neuropsychiatric events and advisory committee discussion, the FDA elevated the existing montelukast prescribing warnings to a boxed warning — the agency's most prominent warning (https://bit.ly/3vNeg47). For allergic rhinitis in particular, the FDA recommended that montelukast be reserved for patients who have not responded adequately or who cannot tolerate other allergy medicines. Additionally, the FDA required that a new Medication Guide be given to patients with each montelukast prescription.

Advisory committee meetings generally are open to the public and include time for an open public hearing. In addition, comments on issues pending before the committee can be submitted in writing before the meeting.

The PAC membership generally includes individuals with pediatric research and subspecialty expertise as well as consumer, pharmaceutical industry, pediatric health organization and patient/family representation.

The FDA accepts nominations of qualified individuals to serve as members of its advisory committees (https://bit.ly/3LgyQAp).

The FDA's Office of Pediatric Therapeutics (OPT) and Division of Pediatric and Maternal Health (DPMH) 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 in the Office of New Drugs in the Center for Drug Evaluation and Research.

Resources

For more information on the FDA's Pediatric Advisory Committee, visit https://bit.ly/3EW3zk2.