

FDA Advisory Committee Reviews Opioids in Kids

Pauline Anderson | September 19, 2016

Children may be the unintended victims in the war against abuse and misuse of prescription opioids.

Pediatricians and other clinicians may be more reluctant than ever to use these drugs in kids, and that may be resulting in undertreatment of pain in this population.

At the same time, clinicians may not have the best information to determine dosages of opioids in children and adolescents they do treat with these drugs.

These were some of the issues that members of a joint US Food and Drug Administration (FDA) advisory committee recently grappled with. The 2-day meeting came in the wake of passage earlier this year by the US Congress of the Comprehensive Addiction and Recovery Act (CARA), which promotes measures to reduce prescription opioid and heroin misuse, including evidence-based interventions for the treatment of addiction and prevention of overdose deaths.

During the FDA meeting, members of its Anesthetic and Analgesic Drug Products Advisory Committee, Drug Safety and Risk Management Advisory Committee, and Pediatric Advisory Committee listened to experts in pediatric pain management, addiction, child and adolescent medicine, and pharmacology.

Known Risks

Some experts presented information on the clinical management of pain in children, including the use of immediate-release and extended-release opioids in clinical practice. Others talked about what is known about the risk for misuse, abuse, and addiction in children who have been prescribed opioids.

Presentations from the FDA touched on regulations under which clinical trials are conducted in kids, ethical considerations with pediatric clinical trials, and the current extent of opioid use in children and adolescents.

The FDA also reviewed the labeling available to help clinicians manage pediatric patients, as well pending studies required under the Pediatric Research Equity Act (PREA).

Meeting chair Raeford E. Brown Jr, MD, professor of anesthesiology and pediatrics, University of Kentucky Medical Center, Lexington, said a main point of debate during the meeting was whether doctors are less likely to use opioids in children in the setting of the current fight being waged across the United States against the abuse and diversion of opioid drugs.

"I think that opioid abuse disorder has changed the way some physicians feel about managing pain in children," Dr Brown told *Medscape Medical News*. "And I think that's an unfortunate by-product of the current public health situation here in the US."

Not appropriately treating pain in children "is an important issue," stressed Dr Brown.

"There can be long-term, even genetic, consequences of that. I'm not talking about the pain of having a little scratch, or the short-term pain of having a tooth pulled, but children have, for example, cancer pain and sickle cell disease, and other medical disease processes. Their whole nervous system can be affected by nontreatment of pain."

Undertreatment of pain in youngsters is all the more important as these drugs will have to be used in this population "for the foreseeable future," said Dr Brown. "There simply is no other drug that is as effective as opioids to treat acute pain in children."

The message that committee members heard loud and clear was that while there is a serious public health issue related to opioids, "that doesn't mean that pain has gone away," said Dr Brown.

Gateway Drug

That's not to say that there aren't potentially serious abuse issues in young people. "It's pretty clear that the opioid prescriptions that get into the hands of adolescents can be gateway drugs for things that are very much more dangerous, like heroin," said

Dr Brown.

"Youngsters aged 12, 13, and 14 years are at a unique place in their central nervous system development, where a part of their brain — the nucleus accumbens — is telling them to do things like drink, smoke cigarettes, use drugs, and have sex, and the frontal lobes, the part of their brain that prevents them from doing things that aren't reasonable, is not yet matured."

Those "controlling mechanisms" don't fully develop until about age 22 to 25 years, said Dr Brown.

He stressed the need to screen for mental health issues, previous drug and alcohol use, and other problems, before prescribing an opioid to a child. Screening should not just include the child but also parents and siblings.

"Every decision made about opioids needs to be made in the context not only of treating pain, but of assuring safety at the same time," said Dr Brown. "Those two things in the past have not always gone hand in hand; we just went directly from kids getting pain to treating the pain."

Education is an important element of this. Dr Brown said he will be working with the American Academy of Pediatrics to create an educational program for parents, young children, and adolescents.

"They need to know that this can be a problem, and that it can happen to any adolescent, and parents need to be on the lookout for it," said Dr Brown.

Extrapolation Alternatives

During the FDA meeting, committee members also addressed many questions put to them by the FDA.

One of these related to extrapolation of data from adults to children. Typically, clinical trials on the safety and efficacy of both and nonopioid analgesic products are carried out only in adults because of the ethical and other difficulties related to including young patients, with metabolic and pharmacokinetic information being translated to children down to age 2 years.

However, the committee heard of situations where the pharmacokinetics in pediatric patients were not similar to adults, as would have been expected.

"The purpose of this meeting was to try to figure out if extrapolation is the right way of doing things or if there needs to be some reconfiguration of the way that the Agency looks at data for children," said Dr Brown.

The 35 committee members agreed that treatment provided to children "could be based on scientific principle rather than just guesses about safety and efficacy data," said Dr Brown.

A possible alternative to extrapolation, he said, could be studies that "use scientific principles and create randomized groups, but not placebo-controlled groups," that would evaluate such things as appropriate doses in children.

The FDA will now take information from these deliberations and consider it in determining whether a change in the way opioids are evaluated in children is needed.

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