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F.D.A. Approval of OxyContin Use for Children Continues to Draw Scrutiny

By Catherine Saint Louis
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Ever since the Food and Drug Administration approved the use of the narcotic painkiller OxyContin for certain children in August, it has faced unabated criticism from lawmakers and public officials who are wrestling with devastating rates of prescription opioid abuse in their communities. Last week, Hillary Rodham Clinton brought the issue to the presidential race, calling the agency's action "absolutely incomprehensible."

The crux of the issue is whether the agency's approval will lead to more prescriptions for OxyContin in young patients. For years, the powerful long-acting drug has been prescribed off-label to very sick children in severe pain from cancer or spinal-fusion surgery. (Doctors can prescribe an approved drug to anyone and for any use they see fit regardless of specifications on the label.) The agency's approval means those doctors will finally have "information about how to do it appropriately," like dosage recommendations, said Dr. Stephen Ostroff, the agency's acting commissioner, in an interview.

"We recognize this is a very nuanced issue," said Dr. Ostroff, when asked about Mrs. Clinton's recent comments. "It needs to be understood in the context of why this was done."

Dr. Kathleen A. Neville, a pediatric oncologist at Arkansas Children's Hospital, routinely treats children with unremitting pain caused by cancer or sickle cell anemia. Her patients are the kind the F.D.A. envisioned would benefit from OxyContin, despite its "risks of addictions, abuse and misuse" as a warning on the new label says.

Dr. Neville, who said she had no financial ties to makers of painkillers, applauded the agency's approval. "Just because OxyContin has been abused or prescribed inappropriately doesn't mean we should deprive the children who need the drug," she said, adding it is "our obligation to have the best level of evidence for its use in children."

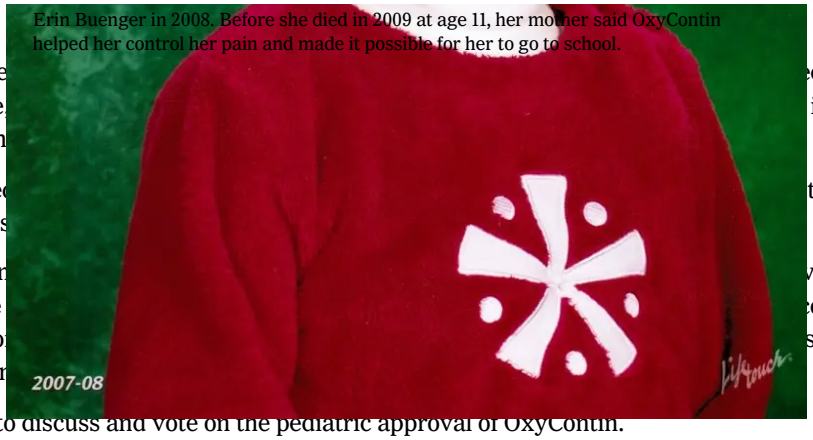
As for people who say no child should ever be prescribed OxyContin, she does not mince words: "Come be one of my kids whose pelvis gets eaten out by cancer."

The new label specifies that OxyContin should be used only for children 11 or older in severe pain who have already been on an opioid for at least five days. That means it is not supposed to be prescribed to children as a first-line opioid painkiller, and it is not meant for short-term pain, like the kind that plagues teenagers after wisdom teeth are pulled.

Some drug industry observers are skeptical that Purdue Pharma, the maker of OxyContin, shares the F.D.A.'s rationale.

"Manufacturers don't pursue regulatory approvals simply to provide prescribers and patients with additional information," said Dr. G. Caleb Alexander, an internist and a director of the Center for Drug Safety and Effectiveness at Johns Hopkins Bloomberg School of Public Health in Baltimore. "This approval allows Purdue Pharma to market and promote this product for use in children, and the obvious concern is this approval will change the pattern of use."

It is too early to tell whether it will. But, Dr. Alexander lamented, "With this ruling, the horse is out of the barn."



Erin Buenger in 2008. Before she died in 2009 at age 11, her mother said OxyContin helped her control her pain and made it possible for her to go to school.

In an emailed statement this we ecretary Clinton's concerns about opioid overuse and abuse information for OxyContin to pediatricians or other physician

In 2007, Purdue Pharma pleade ts and regulators about OxyContin's potential to be abus

Some of the criticism stems fro venes an independent advisory committee to hear from outside controversial. In 2012, a committee discussed another lo s approval. Still, as it can do, the agency went against the par

No such committee was called to discuss and vote on the pediatric approval of OxyContin.

"I'm almost certain an advisory committee would have voted against a pediatric indication for OxyContin," said Dr. Andrew Kolodny, the executive director of Physicians for Responsible Opioid Prescribing.

Dr. Alexander of the drug safety center, who is the chairman of another F.D.A. committee, said that "it's hard to imagine any scientific advisory board would have recommended approval of OxyContin for this purpose in the current environment."

The agency asked Purdue Pharma to conduct studies as part of a broader effort to accrue evidence about how drugs work in children differently from in adults. "We did the right thing here," said Dr. Janet Woodcock, the director of the F.D.A.'s Center for Drug Evaluation and Research. "There are children in need. It would be unethical not to have the right dose information."

She continued, "It has been a real scandal that children in the United States receive drugs without proper evidence of their dosing and safety."

Vickie Buenger said she was "really happy" that the F.D.A. laid out the right dosing for OxyContin, so that other families would not have to rely on a doctor's "best guess," as her family did. Her daughter Erin had cancerous tumors in her abdomen, pressing on her spine. Yet, in 2009, the year she died at 11, Erin wanted to go to school. OxyContin, which controlled her round-the-clock pain for 12-hour stretches, made it possible. "She couldn't lift her head, when she wasn't under pain medication," Ms. Buenger said.

The F.D.A. has also required Purdue Pharma to conduct postapproval studies. One study requires annual reporting for three years of adverse events like respiratory depression, overdoses, accidental exposure in patients, ages 11 to 17. A comprehensive analysis of these side effects and medication errors is required.

The company will also have to report nationally representative data on the volume of OxyContin prescriptions for children younger than 17, which types of clinicians are prescribing OxyContin and for what conditions.

That way, Dr. Ostroff said, "we can have assurances that it's being used in pediatric patients based on the labeling indication. In effect, this will give us much better information regarding how this drug is being used in children than we would ever have gotten through prior practices in off-label fashion."

Dr. Ostroff and Dr. Woodcock promised that some of the data would be made public.

That postmarketing data could prove revelatory and useful. "It's not a given, but it could help us better address the problem of prescription drug abuse in adolescents," said Dr. Neville, who is the chairwoman of the Committee on Drugs for the American Academy of Pediatrics. At the very least, she said, the F.D.A. will know if some doctors are inappropriately "prescribing OxyContin for pulled muscles."

A correction was made on Nov. 11, 2015*: An earlier version of a picture credit of the photograph of Dr. Kathleen A. Neville accompanying this article misspelled the surname of the photographer. She is Karen Segrave, not Seagrave.*

A version of this article appears in print on , Section A, Page 20 of the New York edition with the headline: F.D.A. Approval of OxyContin Use for Children Continues to Draw Scrutiny