

## HHS secretary says girls under 17 must consult doctors to get Plan B

Nancy Frazier O'Brien Catholic News Service | Dec. 9, 2011

WASHINGTON (CNS) -- The U.S. bishops' pro-life spokeswoman said she was relieved that the Obama administration has decided not to allow the Plan B One-Step "morning-after pill" to be sold without a prescription to those under 17.

"Luckily, things did not go from bad to even worse," Deirdre McQuade, assistant director for policy and communications at the USCCB Secretariat of Pro-Life Activities, told Catholic News Service Dec. 8. "We're pleased that they did not expand access to this very powerful drug."

McQuade said Plan B One-Step, known generically as levonorgestrel, "is 40 times more potent than comparable progestin-only birth control pills for which a prescription is required" even for adult women.

Announcing the decision Dec. 7, Kathleen Sebelius, secretary of the Department of Health and Human Services, said the drug manufacturer, Teva Women's Health, had not proven that those under 17 were sufficiently mature to use Plan B One-Step properly.

"There are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age," who could be as young as 11, Sebelius said.

Although "science has confirmed the drug to be safe and effective with appropriate use," she said, "the switch from prescription to over-the-counter for this product requires that we have enough evidence to show that those who use this medicine can understand the label and use the product appropriately.

"I do not believe that Teva's application met that standard," Sebelius said. "The label comprehension and actual use studies did not contain data for all ages for which this product would be available for use."

At a Dec. 8 news conference, President Barack Obama said he fully supported the decision but had not been involved in the process that led to it.

"I will say this, as the father of two daughters. I think it is important for us to make sure that we apply some common sense to various rules when it comes to over-the-counter medicine," Obama said. "And as I understand it, the reason Kathleen made this decision was she could not be confident that a 10-year-old or an 11-year-old (going) into a drugstore, should be able -- alongside bubble gum or batteries -- be able to buy a medication that potentially, if not used properly, could end up having an adverse effect. And I think most parents would probably feel the same way."

Sebelius' decision rejected a recommendation by the Food and Drug Administration's Center for Drug Evaluation and Research to approve Teva's application.

Dr. Margaret Hamburg, FDA commissioner, said in her own statement that center experts, "including obstetrician/gynecologists and pediatricians, reviewed the totality of the data and agreed that it met the

regulatory standard for a nonprescription drug and that Plan B One-Step should be approved for all females of child-bearing potential."

"I agree with the center that there is adequate and reasonable, well-supported and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential," Hamburg added.

The U.S. Conference of Catholic Bishops has long opposed over-the-counter sales of Plan B, with McQuade saying in 2009 that it "has no authentic therapeutic purpose, and can actually cause harm to women and their newly conceived children."

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