

# FDA warns doctors about Glaxo rotavirus vaccine

March 22 2010, By LAURAN NEERGAARD , AP Medical Writer

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(AP) -- U.S. health officials urged pediatricians Monday to temporarily stop using one of two vaccines against a leading cause of diarrhea in babies, after discovering that doses of GlaxoSmithKline's Rotarix were contaminated with bits of an apparently benign pig virus.

Glaxo's vaccine has been used in millions of children worldwide, including 1 million in the U.S., with no signs of safety problems - and the pig virus isn't known to cause any kind of illness in people or animals, said Dr. Margaret Hamburg, commissioner of the Food and Drug Administration.

But vaccines are supposed to be sterile, and because there is a competing vaccine against diarrhea-causing rotavirus that has tested clean - Merck's RotaTeq - the FDA decided to err on the side of caution.

"We don't want to scare parents," Hamburg told reporters. "This was a difficult decision for us to make because there is no evidence at this time that there is a risk to patients who have received this vaccine, and we know there are real benefits for children to be vaccinated against rotavirus."

Rotavirus causes severe diarrhea and is a leading child killer in developing countries. In the U.S., with better health care, about 55,000 children a year were hospitalized for rotavirus infections and several dozen died each year before vaccination began - with Merck's vaccine in 2006 and Glaxo's in 2008.

Glaxo said Monday that regulators abroad have decided not to change how Rotarix is used while scientists probe the relevance of the discovery.

A group of scientists testing a new way to detect viruses in a variety of products stumbled onto fragments of genetic material - broken pieces of DNA - from what's called porcine circovirus-1 in Rotarix and alerted Glaxo, which confirmed the findings and in turn alerted FDA, Hamburg said.

Rotarix, an oral vaccine, is made from a weakened strain of human rotavirus that has to be grown inside living cells before being purified into a vaccine dose. Glaxo uses a line of monkey kidney cells, or vero cells. Hamburg said the pig virus DNA fragments have been found in Glaxo's cell bank, meaning they were present from the vaccine's earliest development. How the original contamination occurred is under investigation.

Merck's competing rotavirus vaccine RotaTeq is made by a very different process, and FDA's testing showed no sign of the pig virus in it.

It's not the first time unwanted viruses have been discovered in vaccines. Best known is a monkey virus that contaminated some polio vaccine in the 1950s; years later, scientists investigated if the SV40 virus might have increased vaccine recipients' risk of later-in-life cancer but concluded it didn't.

"We live in a world that's teeming with microbes," Hamburg said, but until now this particular pig virus is not one that FDA thought vaccine makers needed to check their products against.

Parents should switch to the Merck vaccine for now - it requires three doses instead of Glaxo's two - because rotavirus is too serious a disease to ignore, said Dr. William Schaffner, a vaccine specialist at Vanderbilt

University who was briefed on FDA's decision.

He's bracing for calls from worried parents and will tell them that "this has been an extraordinarily safe vaccine," and that the discovery is "a consequence of our improved science and ability to detect things that we never could before."

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Citation: FDA warns doctors about Glaxo rotavirus vaccine (2010, March 22) retrieved 8 April 2024 from <https://medicalxpress.com/news/2010-03-fda-doctors-glaxo-rotavirus-vaccine.html>

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