

Parents Advised to Stop Using Sleep Positioners

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The Consumer Product Safety Commission and the Food and Drug Administration are warning parents to stop using infant sleep positioners, saying the devices – initially developed as a way to prevent colic, gastrointestinal reflux disease, and flat head syndrome in infants – may have caused up to 12 infant deaths over the past 13 years.

In addition to the deaths, which occurred in infants aged 1- 4 months, the CPSC said it has received dozens of reports of infants who were placed on their backs or sides in sleep positioners but became entangled in the devices and were found by caregivers in potentially hazardous positions. Most of the infants who died suffocated after they rolled from a side position to a stomach position, according to the FDA and the CPSC.

“Our goal is to make sure parents and child care providers are informed about the safety risks for infant sleep positioners and stop using them,” said Dr. Joshua M. Sharfstein, a pediatrician serving as FDA Principal Deputy Commissioner. “Both agencies are working together to stop the use of these and get them off the market.”

The FDA and the CPSC decided it would be more effective to go public with their message to stop using the devices than to issue individual recalls for products, Dr. Sharfstein said in a press briefing. However, he said the agencies might conduct some recalls or take other action to remove products from the market if manufacturers don’t comply quickly with the recommendation to stop selling them.

The FDA first reviewed infant sleep positioners more than 2 decades ago, Dr. Sharfstein said. “These positioners came on the market in the 1980s, and at the time they were approved [by the FDA] with the idea they may be able to relieve symptoms of reflux or prevent flat head syndrome,” he said. “Given the risk, the modest evidence of benefit does not outweigh the risk of death.”

The FDA has formally approved 18 infant sleep positioners, and has contacted those manufacturers, asking them to voluntarily remove their products from the market, Dr. Sharfstein said. However, the agency believes there are multiple infant sleep positioner products on the market that may be making health claims about sudden infant death syndrome (SIDS) or reflux, but that never have been reviewed by the FDA.

The FDA and the CPSC are asking any manufacturers marketing such a device to remove it from the market voluntarily, but will be prepared to take enforcement action if it becomes necessary, he said.

Most babies – up to 80% – have some sort of reflux, but most are “happy spitters,” and the condition represents a clinical problem in only a small percentage, said Dr. Rachel Moon, chair of the American Academy of Pediatrics’ SIDS task force. There’s no evidence that these infant sleep positioners protect infants from SIDS, either, she said at the press briefing.

Dr. Moon reiterated the message that infants should be placed on their backs to sleep, which reduces the risk of SIDS by 50%.

In addition, she said, parents or caregivers never should place pillows, stuffed animals, heavy blankets or comforters, or other soft items in babies’ cribs because of the risk of SIDS. ■