



Babies could suffocate on sleep positioners: U.S. groups

September 30, 2010

Patricia Callahan and Ellen Gabler

Chicago Tribune

CHICAGO—U.S. regulators and the nation's leading pediatrician group on Wednesday warned parents that popular baby sleep positioners—marketed as safety products—can be deadly and urged families to stop using them, retailers to stop selling them and manufacturers to stop making them.

The products have been linked to at least a dozen suffocation deaths in the last 13 years, regulators said. The products often have foam bolsters on the sides that help keep a baby in one position, but infants can wiggle or roll into unsafe spots. Babies have suffocated on the foam or have become trapped between the product and the side of the crib or bassinet.

For years, the American Academy of Pediatrics and others have promoted scientifically backed advice calling for babies to sleep on their backs to reduce the risk of sudden infant death syndrome, or SIDS. The sleep positioners appeal to the safety-minded parent who worries a child will stray from that position. Sales of the products, which often cost less than \$20, took off in the last five years.

Although the warning does not constitute a ban, Dr. Joshua Sharfstein, a pediatrician who is the No. 2 official at the Food and Drug Administration, said many of these products are "illegal devices" because they tout their ability to reduce the risk of SIDS. The positioners, he said, have not been cleared for that use.

There is no evidence that they prevent SIDS, said Dr. Rachel Moon, chair of the American Academy of Pediatrics SIDS Task Force.

Even if companies withdraw their medical claims, they still could run into regulatory trouble selling sleep positioners, Sharfstein said.

"I would think good sense would stop a company from marketing a product like this knowing that the Academy of Pediatrics, the FDA and the (Consumer Product Safety Commission) think that they could be dangerous and potentially lead to the death of children," he said.

The joint warning from the FDA and the product safety commission marks a more aggressive style in tackling hazards in the nursery after an avalanche of recalls of cribs, toys and other baby products. Typically, the CPSC recalls products piecemeal, and parents are left to wonder whether other similar

products share the hazard. Although none of these products are subject to a recall, the message was clear that the FDA and the CPSC may pursue recalls or other enforcement actions if manufacturers and retailers fail to remove them from the market.

Babies R Us, Toys R Us and Target said they planned to stop selling the products online and in stores, according to spokeswomen for the retailers. At least five manufacturers told the FDA they planned to withdraw their products.

Judy Sage, a New York mother, lost her 8-week-old son Andy when he suffocated on a sleep positioner in 2002. Andy's pediatrician recommended she position the child, a twin, on his side to help with gastroesophageal reflux, a common problem in infants. She said she thought the Graco sleep positioner would keep Andy safe.

Now she can't shake the image of finding him that January night. "Andy would be here today had I not used a sleep positioner," she said.

Sage has spent the last eight years trying to spread word of the dangers of these products and was elated by the announcement.

Many sleep positioners include a warning that parents should stop using them when a baby begins to move around.

Such a warning is difficult to follow, Moon said, because "you have to assume that your baby may be able to move around during sleep at any time."

The FDA first approved some sleep positioners in the 1980s for babies with reflux or for babies whose heads flattened. In all, 18 products were cleared by the FDA for sale for those purposes.

Manufacturers that want to continue selling those products will have to show evidence that the benefits of the products outweigh the risks of suffocation, said Sharfstein, the FDA official.