

Do Baby Products Prevent SIDS? FDA Says No



The best thing you can do to lower the chance of Sudden Infant Death Syndrome (SIDS) is to place your baby on his or her back to sleep, with nothing else in the crib or bassinet.

That's the recommendation of the Food and Drug Administration (FDA), which is working to prevent manufacturers of over-the-counter sleep products for babies from claiming that their use will prevent or lower the chance of SIDS. These products include infant positioners, mattresses, crib bedding, pillows, crib tents and baby monitors. Baby products that claim to cure, treat or prevent any condition are considered

medical devices, and are subject to FDA regulations designed to protect consumers and patients.

The agency has never approved a product to prevent SIDS—the unexplained death of a baby younger than age 1—and is asking manufacturers to stop marketing their products with these claims until they have received FDA clearance or approval, or to change their labeling to remove all medical claims.

“These products are absolutely not necessary and they can be very dangerous,” says Susan Cummins, M.D., M.P.H., chief pediatric medical officer in FDA’s Center for Devices and Radiological Health.

Dangerous comforts

FDA is aware of 13 infant deaths in the past 13 years associated with sleep positioners, which are used to keep the baby in a desired position. The Consumer Product Safety Commission has received reports of babies found in hazardous positions after being placed in a positioner.

Other products can also be hazardous. Babies can slide down and be trapped by wedges designed to keep them on their back, says Cummins. Blankets, quilts, soft toys and pillow-like crib bedding can smother, she adds.

It’s a matter of A-B-C, says Cummins:

- **A**lone in their own bed. Don’t keep the infant in your bed next to you and risk that the baby will be accidentally suffocated if you roll over.
- **B**ack to sleep—every sleep. “The safest way to put the baby to sleep is on his or her back every time,” says Cummins. “Do not put the baby on his side or on his stomach.”
- Since the national Back to Sleep campaign in 1994 urged parents to place babies on their backs, there has been a 60 percent reduction in SIDS, Cummins says.
- **C**rib. The baby should always be placed in a crib or bassinet to sleep.

Cummins describes the ideal sleep environment for an infant as being free of anything that could block the infant’s movement or breathing. All that’s needed is a firm crib mattress and a tight-fitting sheet.

To parents who have visions of a crib filled with comforts, she says, “Though a crib full of plush toys and soft bedding may look appealing to you, it is hazardous for your baby dur-

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ing his or her first year of life.”

“Your baby will develop faster in that first year than any time after. Newborns can’t even hold up their head, yet by their first birthday they are walking or nearly so,” says Cummins. “In between, your baby will learn to roll, sit, turn, crawl and even may start to climb!”

“So in that first year, your baby constantly and rapidly develops new skills, even in the crib during sleep time,” she says. “Make your baby’s crib a safe place to sleep and move, with nothing to get in the way.”

Safe Sleep Resources


FDA is starting a new website on

SIDS prevention claims (www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SIDSPreventionClaims/default.htm) for parents, caregivers and manufacturers of sleep products for babies. Its purpose is to:


- inform parents and caregivers about the risks associated with over-the-counter products that claim to prevent SIDS.
- help manufacturers understand and comply with FDA laws and regulations governing medical devices, which are designed to protect consumers and patients.

The site also offers advice to parents on reducing the risk of SIDS and a list

of “baby safe sleep” resources.

“The sleep environment is the one place where the baby is alone, so we want to make sure it’s safe,” says Cummins. And in this case, she says, less is more. 

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