

Do Breast Implants

by Amanda Spake

It was bad enough when we heard that silicone implants could make women sick. Now, new research hints, their children may be suffering serious illnesses too.

A baby nursing at its mother's breast. It is an image of tenderness, love, security. But for many mothers—those who've had their breasts enlarged with silicone implants—it may become an image of fear. Now they may be forced to consider a terrible question: When they so lovingly breast-fed their infants, did they also pass along a legacy of illness? Could their children be facing lifelong health problems?

So far no one can say for sure. Studies are few, and those that have been done, small. The results, experts agree, have been more suggestive than definitive. But a number of doctors are very concerned. Perhaps more alarming, some researchers fear that the risks—if they turn out to be real—may apply to all babies born to women with silicone implants, not just to those who were breast-fed. Thousands of children could potentially be endangered.

Enter the newest victims in a medical controversy that has swirled for at least three decades. Headlines have flared as studies have pointed to unusual and severe health problems in women with implants, yet other studies have found few abnormalities in these women. Claims and counterclaims, lawsuits against manufacturers, settlements, and new challenges about the safety of silicone implants have proliferated. Women are confused, their doctors uncertain. The Food and Drug Administration—the nation's watchdog agency for medical devices—became so frustrated by the

lack of reliable information that in 1992 it called for a moratorium on silicone breast implants until their safety could be established.

Whatever the outcome, one thing is clear: Answers about women's health are long overdue. And with the new worries about their babies' well-being, the questions take on greater urgency. "These children need to be looked at very carefully," says Shanna Swan, Ph.D., an epidemiologist at the University of California at Berkeley.

Early Warnings

It is 1989. Jama Russano, a Northport, New York, mother of two boys, is worried. From the time her sons were born—Richie in 1983, Michael in 1985—they have suffered from one health problem after another. Richie breast-fed successfully, but had unusual rashes and almost constant diarrhea as an infant. Tests for food allergies and infections revealed nothing. "He will outgrow it," Russano's pediatrician assured her.

Michael had practically stopped eating. "He said he couldn't swallow, he felt sick to his stomach, and he had severe burning in the middle of his chest," recalls Russano. Both boys often felt tired and achy, and their throats hurt, although cultures always came back negative.

Russano was also sick. It turned out she was suffering from esophageal dysmotility—a gastrointestinal disorder in which one loses the wavelike motion of the esophagus, which moves food into the stomach. The disorder is part of a connective-tissue disease—systemic sclerosis—that damages skin, blood vessels, nerves, and internal organs (including the

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Babies?

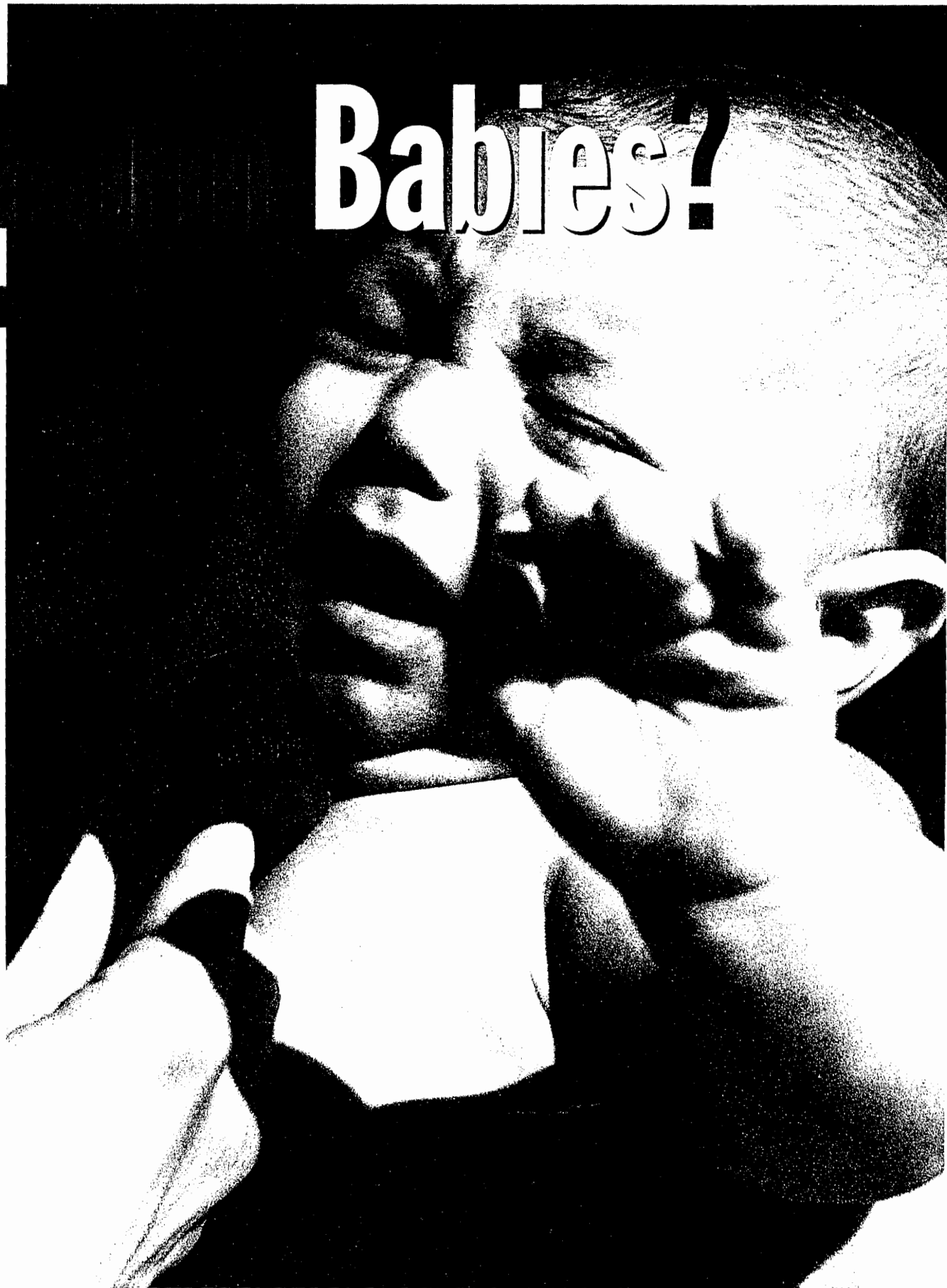
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esophagus), caused, doctors believe, by an immune system gone awry. Instead of mobilizing against foreign invaders such as viruses or bacteria, it attacks the body's own tissue.

And all of Russano's problems might have been caused by the silicone implant she received at age 14 to correct a deformity in her right breast. She hadn't thought about her implant until her internist found silicone in a cyst on her neck in 1989, the result of a disintegrated implant. Not yet connecting her illness to an implant that was nearly 20 years old, and assured by a plastic surgeon that the newer models were safe, Russano elected to replace it.

But her symptoms persisted, and as she continued to have her sons examined and tested for a variety of illnesses, a frightening thought occurred to her: Could her implant be the cause of their illnesses?

IN ATLANTA, PATRICIA BRENT WAS dealing with similar medical uncertainties in her family. Her first four children were perfectly healthy, but her daughter Catherine, born in 1985, after Brent had her breasts enlarged with implants, suffered from constant gastrointestinal problems ("We dubbed her the spit-up queen," recalls Brent). Catherine and Christine, born 15 months later, both complained that their legs ached (Catherine walked only on her toes), and Christine had a measleslike rash that never went away. "We'll watch this," the pediatrician told Brent again and again, as each new symptom appeared.

Brent, like Russano, was also suffering a connective-tissue disease, in her case a mixed disorder that included symptoms of scleroderma, lupus, and polymyositis. Consulting Frank Vasey, M.D., chief of rheumatology at the University of South Florida College of Medicine at Tampa and one of the first doctors to investigate illness in implant patients, Brent was advised to have her implants removed immediately.

Brent was terrified. "Dr. Vasey," she asked, looking straight at him, "I breast-fed two children. Has this done anything to my kids?" His answer: "We don't know. We just don't know."

Brent was determined to find out. She joined a support group and was put in touch with Jama Russano, who in 1992 had started Children Afflicted by Toxic Substances, an organization dedicated to providing and gathering information about children whose mothers

Breast-Feeding: What should mothers with implants do?

It may be years before researchers have definitive answers, but here's what you should know:

Jeremiah Levine, M.D., who has studied digestive disorders in the children of women with implants, says his findings are too preliminary "to advocate eliminating breast-feeding among all women with implants."

If your implant has ruptured or scar tissue has formed around the implants, you should see your plastic surgeon before nursing. You may have difficulty breast-feeding. "The breasts may become abnormal in shape and scar tissue could interfere with lactation ducts, making milk production more difficult," says Ruth Lawrence, M.D., a professor of pediatrics and obstetrics-gynecology at the University of Rochester School of Medicine.

What if you are breast-feeding now? If your implants aren't interfering, Dr. Levine advises that you still have regular ob-gyn checkups. And if your child is weaned but seems to have recurrent symptoms, see the appropriate specialist—a gastroenterologist for digestive problems, or a rheumatologist for joint pain. If the symptoms appear unusual to the doctor, the doctor may consult with Dr. Levine by calling 718-470-3430.

Additional information is available through the support group Children Afflicted by Toxic Substances, 60 Oser Ave., Hauppauge, NY 11788; 516-273-2287.

—BETTY WONG

had silicone breast implants. Today the two women, along with hundreds of other worried mothers and doctors, are undertaking that difficult investigation.

What's Making These Children Sick?

Jeremiah Levine, M.D., a pediatric gastroenterologist at Schneider Children's Hospital on Long Island, is one of those investigators, his concern sparked by the puzzling results

of his examinations of the Russano boys in 1992. Both had esophageal dysmotility. Like their mother, both had decreased peristalsis in the lower two-thirds of the esophagus and decreased sphincter pressure, which was probably causing stomach acid to come up the esophagus.

But although motility problems are common in infants and very young children, this lower type is not, explains Dr. Levine, especially in children as old as Michael and Richie Russano. You might see these disorders in babies, he says, but they're unusual in 6- and 8-year-olds, the boys' ages at the time. In 12 years of practice, the only other children Dr. Levine had seen with this kind of motility disorder were children with scleroderma, Jama Russano's connective-tissue disease. But Michael and Richie did not have scleroderma.

Nor did they seem to have any inherited illness. "I don't know any hereditary disease that shows these symptoms," Dr. Levine says. "There may be a genetic predisposition, but as far as an actual disease, I don't know of one."

What he did suspect was a possible link to Russano's breast-implant problems. And so, with his colleague Norman Ilowitz, M.D., a pediatric rheumatologist, and families referred to him through Russano's support group, Dr. Levine began his investigations. Their first study, published in the prestigious *Journal of the American Medical Association* in 1994, compared the health of 11 "implant" children (8 breast-fed, 3 bottle-fed) to that of 17 children whose mothers didn't have implants but who had similar gastrointestinal complaints.

Their findings? The bottle-fed kids and the control group of "nonimplant" children had some degree of difficulty with esophageal motion and sphincter pressure. But six of the eight breast-fed kids suffered esophageal dysmotility. The doctors admitted they weren't sure how these problems had developed, but hypothesized that "substances released into breast milk from women with silicone implants" may adversely affect the delicate digestive systems of newborns.

This study has been criticized for its small size and inherent bias in selecting children who were known to have gastrointestinal symptoms, shortcomings the doctors readily acknowledge. The FDA issued a statement that called the report "inconclusive and

preliminary." But the agency conceded that the study raised concerns that required further research.

Interestingly, the agency also privately advised the Human Milk Banking Association, a nonprofit organization that administers breast-milk banks in U.S. hospitals, to start screening for women with implants. Since milk from banks is used to feed premature and critically ill babies, "we had to be above suspicion," explains the association's chairperson, Laraine Borman. The HMBA issued a directive in March 1994 that stated "Mothers with silicone breast implants will not be accepted as donors."

Gastrointestinal disorders aren't the only health risks doctors have documented in "implant" babies. In 1994 Suzanne Teuber, M.D., and Eric Gershwin, M.D., immunologists at the University of California at Davis, published a report in the *International Archives of Allergy and Immunology* on two girls, ages 3 and 9, who suffered muscle and joint pain. Each of their mothers had similar symptoms and each may have had trouble with their implants (one mother's had ruptured while she was pregnant; the other's, a sonogram suggested, had possibly ruptured). Neither of the children had juvenile-onset rheumatoid arthritis, a possible explanation for their pain. "These are unusual problems in children," says Dr. Gershwin.

Silicone Under Suspicion

If breast implants do play a role in these families' illnesses, doctors believe it will likely involve the complicated immunology of silicone itself. It's well documented that the silicone gel inside an implant "bleeds" through its meshlike outer shell into surrounding tissue. Ruptures and leaks spill larger quantities of gel.

Silicone has been shown in numerous studies to migrate to other organs. What happens to this silicone is a matter of debate, but doctors no longer believe it's inert. The response may be similar to what happens when you get the flu, explains David Smalley, Ph.D., director of diagnostic and cellular immunology at the Baptist Regional Laboratory and associate professor of pathology at the University of Tennessee. "When the flu virus enters the body, the immune system goes through a recognition process," he explains. The immune cells have



Concerned that the illnesses afflicting her and her sons, Richie, top left, and Michael, may be linked to her breast implant, Jama Rusanno has formed a support group. Patricia Brent, above, with daughters Catherine, left, and Christine, is among the 4,000 women who've called Russano.

a "memory" of what they have tried to kill, forming specific immune responses for each invader. This is the reason why most people don't get chicken pox or the same flu twice, and why flu vaccines that are made with a live virus work: The immune system recog-

nizes the virus and mobilizes itself to kill it when it enters the body a second time.

When the invader is silicone, however, the immune system army can't destroy it. It's not alive, like a virus, and it's always there. So, the theory goes, the army continues to attack, taking the battle to wherever it finds this foreign material, and eventually damaging the body's tissue itself.

But is that what's happening with these children? To find out, Dr. Smalley, working with Douglas Shanklin, M.D., a pathologist and obstetrician-gynecologist also at the University of Tennessee, tested children born (continued on page 109)

that overlooks the Mediterranean. She surrounds herself with art, mainly naive paintings by Eastern Europeans, which she buys through a gallery in Paris at an addictive pace. Because her walls are full, she piles new acquisitions on the floor.

The serene sanctuary is a far cry from Copperfield's loft near Las Vegas, an elaborately secretive Bruce Wayne-style hideout in a former nut-and-bolt warehouse. (The door is actually a mirror that slides open at the touch of a mannequin's nipple.) For a while, Schiffer says, the two were looking for a place to buy together in Monaco, but their lack of time together there barred any serious house hunting. Copperfield performs more than 500 times a year. Schiffer, who once said she'd leave the fashion world when she turned 25, now says she'll continue modeling indefinitely—and pursue a career as an actress. She would like to have children, but acknowledges that she's both too young and too busy to plan the large family she'd like anytime soon. "I want to be able to spend time with my children, and there are still so many projects I want to do," she says.

For now, Schiffer is content to do

her glorious model pose for the camera. Two hours into the day's session, she throws her cascade of tousled hair down her bare spine as the words "My name is Prince, and I am funky" blast on the studio sound system. Schiffer spreads her legs, thrusts out her chest, and shifts her hips. She blows through her lips like a horn player. Whistling downward, she lowers her eyelids, then suddenly looks up. Bystanders in the studio melt at this sexy barefoot vision in velvet. She turns on her naughty pout and flirts with the camera. She's good. And she knows it.

After two clothing changes, Schiffer is eager to be on her way. Petulantly, she runs onto the set with jeans extending under her dress, a little miffed that she's being detained for a third fitting. But later, minding her good-girl manners again, Schiffer smiles and apologizes. Hustling into the dressing room, she's on the move. She grabs her black quilted Chanel bag and tortoiseshell headband, tones down her makeup with a tissue, and bounces out to her limo. There are no knots in her hair, no visible flaws of any kind. She's a woman in love, struck by a thunderbolt out of nowhere. Very happy. Very human. □

Silicone

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before their mothers had implants and those born after. None of those born before had any immune-cell "memory" of silicone, a major component of silicone. The researchers found that most of the children born after the implants did. To the doctors' surprise, some of the children who tested positive had not been breast-fed. Could this disturbing news mean they were exposed to the silicone in another way, through the placenta as they grew in their mothers' wombs?

"There's certainly some worrisome suggestions that silicone crosses the placenta," says Dr. Levine. If that's the case—and doctors really aren't ready to say—it could mean bottle-fed kids aren't automatically protected against problems associated with their mothers' implants.

Doctors are quick to caution that this is all preliminary. Even Dr. Levine's larger study now under way hasn't found the same digestive disorders in bottle-fed children that he had seen in those who nursed,

although many complain of intestinal symptoms. Nor has Dr. Shanklin, who has been studying placental tissue directly, found any identifiable lesions that might be related to a disease process.

Could They Be Wrong?

Many researchers also question whether silicone is a culprit. It's unlikely that small amounts of silicone just passing down an infant's esophagus would, per se, cause digestive disorders. "Children have ingested silicone for decades," says Cheston Berlin, M.D., a pediatrician and professor at the Pennsylvania State University College of Medicine. There are silicone nipples, he points out, and Mylicon drops (used to treat colic), which are made from the same kind of silicone as that used in implants.

But how much silicone leaks out of nipples? asks Dr. Levine. And how many infants take two to three feedings of Mylicon every day for seven months? "The implants are sitting right by the breast ducts, and this stuff passes through tissue relatively simply. It should be able to diffuse (continued on page 110)

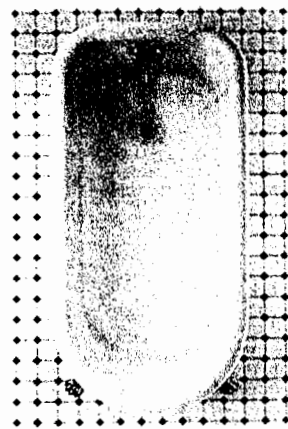


figure 1. BEFORE
Over time, porcelain can become porous, allowing soap scum to become deep-set into its surface.

Pull the plug on old bathtub rings.



figure 2. AFTER

Introducing Comet Heavy Duty Cleanser.

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Flavor from fruit, not fat.



Nature Valley® Low Fat Fruit Granola has raisins, dates, and baked-in bits of real apple and orange—so you can have a bountiful breakfast with great taste that's low in fat.



Silicone

(continued from page 109)
right into the breast ducts," he says.

But Dr. Berlin also points to the small numbers of sick children. "About a million women have breast implants in the U.S. You would think that if this were happening, there would be more reports of problems in these kids."

It might be that further research will show some other source of these children's illnesses, perhaps a genetic predisposition to maternal connective-tissue disease and similar illnesses. Or there may be more sick children out there than anyone knows, and their doctors just haven't connected their health problems to their mothers' implants. Or it could be that these children's health problems, because they're so rare, need extraordinarily large studies to detect whether the implants are responsible.

One criticism has been made of the recent surveys that gave implants a clean bill of health. In last year's much-publicized Mayo Clinic study, for example, researchers found no

association between breast implants and such connective-tissue diseases as lupus, scleroderma, and systemic sclerosis. Similarly, one report from Harvard and Brigham and Women's Hospital, part of the large ongoing Nurses' Health Study, found that women with and without implants had about the same rate of disease, although a second Harvard Nurses' Study did find a small but significant increase in rheumatoid arthritis among those who had implants.

The Mayo study was the largest United States survey of its kind: Researchers reviewed the medical charts of 749 women with breast implants and 1,498 without. Yet the authors agree it would take a much bigger sample—62,000 of the estimated 800,000 to 1 million U.S. women with implants compared with 124,000 without—to detect diseases as rare as scleroderma and systemic sclerosis. "Our results," they wrote, "cannot be considered definitive proof of the absence of an association between breast implants and connective-tissue disease."

None of this troubling speculation will be settled until those larger studies—on women and their children—are undertaken. Until then,

what should mothers with implants who've nursed their infants do? They certainly do not need to panic; the complications, if proved to exist, seem to affect only a small number of children. (See "Breast-Feeding: What should mothers with implants do?" on page 88.) Women who develop symptoms of connective-tissue diseases—extreme fatigue, muscle aches, pain in the joints—should consult a doctor and make sure the doctor knows they have implants. One study showed that in 70 percent of cases, removing the implants relieved the illness as long as the women did not receive new implants.

NO MATTER WHAT THE RESEARCH eventually concludes, everyone agrees that women should not, 30 years later, have so many unanswered questions. "This never should have happened," says Jama Russano. "Women wanted the product, but they wanted a safe product and they thought they were getting it."

Whether they got a safe product or not is still a question. And considering the vast numbers of women and children who've been affected, that is the true scandal. □