

THE LETHAL DANGERS OF THE BILLION-DOLLAR VACCINE BUSINESS WITH GOVERNMENT APPROVAL, DRUG COMPANIES SELL VACCINES THAT CAN LEAVE YOUR CHILD BRAIN DAMAGED, CAN SPREAD POLIO FROM YOUR BABY TO YOU--AND CAN EVEN KILL. SAFER STUFF IS AVAILABLE. HERE'S WHY YOU HAVEN'T BEEN GETTING IT.

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When Miriam Silvermintz of Fair Lawn, N.J. took her seven-month-old son Nathan to the pediatrician for his third series of vaccinations on Feb. 18, 1991, she was thrilled to hear the doctor say her baby was growing beautifully. Just five hours later, as Nathan lay in his crib, he shrieked in pain. Terrified, Miriam ran in and cradled her baby in her arms. Nathan collapsed, his eyes rolling back in his head, as he suffered a severe seizure. "We called 911, and they worked on him for 45 minutes," says Miriam, "but I knew when I held him in my arms that he was dying."

What killed Nathan? "When I first called the pediatrician after the ambulance arrived, he said Nathan probably was just having a reaction to his DPT shot," Miriam recalls. "But when Nathan died, the doctor did an about-face and said it had nothing to do with the vaccine." Nathan's death was officially attributed to a congenital heart defect. But Miriam, now 36, and her husband Steven, 37 (pictured on page 151), couldn't shake the feeling that Nathan's death was somehow linked to the shot.

They began to search for details on DPT, which prevents diphtheria, pertussis (familarly known as whooping cough) and tetanus. The search led them to the National Vaccine Information Center of Vienna, Va., a 14-year-old nonprofit educational and support group for parents whose children have been harmed by vaccines. There, the Silvermintzes learned that a DPT shot can indeed cause death--as well as adverse reactions ranging from fever and irritability to the permanent brain damage suffered by Joshua Reed, now 13 (pictured opposite), of Great Bend, Pa. They also discovered that some batches of the vaccine cause more problems than others. In fact, because of lax federal recall regulations, Nathan appears to be the first of nine children who died shortly after getting a shot from the same DPT lot.

Finally, the Silvermintzes were confronted by the most painful discovery of all. "We learned," says Miriam, "that there were safer ways to manufacture DPT that weren't being used in this country."

In 1994, the U.S. Court of Federal Claims awarded damages to the Silvermintzes under the National Childhood Vaccine Injury Act of 1986. "It was bad enough suspecting that Nathan's death was caused by a vaccine," says Miriam, "but still I had believed it was one of those one-in-a-million things. When I learned that his death was followed within three weeks by another in New Jersey and then another in Illinois and another in Pennsylvania and five more after that while this batch of vaccine stayed on the market for an entire year, it broke my heart. I feel betrayed by the drug companies who make vaccines and by the doctors and government agencies I'd always trusted to protect us."

Vaccines are indispensable. They save lives, cutting the number of U.S. pertussis deaths to about five last year, for example, from 1,118 in 1950 before state governments made the vaccination mandatory for school admission. No one is suggesting that your kids skip their shots. However, shouldn't your children receive the safest vaccines that can be made? And shouldn't your doctors always alert you to the danger signs--before and after immunization--that you should watch for to prevent tragedy? Neither is the case now. A MONEY investigation of the booming vaccine industry (estimated revenues of more than \$1 billion a year in the U.S. alone, up from \$500 million in 1990) and of its federal regulatory agencies reveals severe violations of public trust. In probing the politics and economics of the two vaccines that have been used longer than any others in this country, DPT and polio, MONEY found that health officials publicly downplay the lethal risks. In addition, medical experts with financial ties to vaccine manufacturers heavily influence government decisions that have endangered the health of immunized kids while enhancing the bottom line of drug companies.

Among MONEY's disturbing findings, we learned that DPT shots cause brain damage at the rate of one case for every 62,000 fully immunized kids. The shots also kill at least two to four people a year, according to a federally funded Institute of Medicine study, and perhaps as many as 900 a year--including a great number misclassified as victims of sudden infant death syndrome--according to the independent National Vaccine Information Center. What's worse, these tragedies can be virtually eliminated by a vaccine that would cost \$19.43 a dose, just \$9 more than the current product. Who wouldn't pay \$9 to protect their child even from a one-in-62,000 risk of severe illness, let alone death?

Sound like a simple solution? Don't count on it. Although they are now making some small moves, the government and the drug industry have an appalling record of facing up to vaccine problems. For example, MONEY has learned that:

--For decades, American pharmaceutical companies have known how to produce the safer DPT vaccine but decided not to bring it to market because it would increase production costs and lower the drug's 50% or higher profit margins.

--The only cause of polio in the U.S. for the past 17 years has been the oral version of the vaccine itself, and though the Food and Drug Administration has finally recommended a reduction of the oral product's use, there are no plans to take it off the market. The twice-as-costly vaccine administered by injection does not cause polio.

--The oral polio vaccine and the injected variety are commonly made using monkey tissues, which contain viruses that can be harmful to humans. A safer injected vaccine, using human tissue, is available in Canada but not in the U.S., even though it is made by the same company that produces all U.S. injected polio vaccine.

--Federal regulators have stymied many efforts to investigate the impact of those monkey viruses but are now paying attention to particularly disturbing research by a Chicago molecular pathologist linking one to human cancer. This is the same monkey virus that a new Italian study suggests is being passed on sexually by people throughout the world, and from mothers to babies in the womb.

HOW A SAFER DPT SHOT HAS BEEN DELAYED

Manufacturers put profits ahead of vaccine safety--with impunity. A 1986 law promoted by the drug industry dramatically limits vaccine manufacturers' legal liability in cases where their products cause injury or death. The law was enacted to help prevent vaccine manufacturers from being driven out of business by rising liability costs. That was a worthy goal. But in practice the reform effectively removed one of the drug industry's most compelling incentives to ensure that its products are as safe as possible. Rather than filing lawsuits against drug companies or against physicians, victims or their families now must first file claims under a federal vaccine injury compensation program. Also, the damages awarded are not paid by drug companies; they are paid by you--in the form of a user tax tacked onto the price of each vaccination. The tax totals \$33 for a child fully immunized--five vaccinations for DPT, four for polio and two for measles, mumps and rubella--in accordance with federal requirements.

To date, the users taxes have been spent to compensate more than 1,000 people, including the Silvermintzes, at a cost to taxpayers of half a billion dollars. Meanwhile,

manufacturers' profits have risen as the average cost to fully immunize a child at a private physician's office has climbed 243% since 1986, from \$107 to \$367. The most prominent beneficiaries have been the two producers who dominate the U.S. market for DPT and polio vaccines, Connaught Laboratories (\$300 million in U.S. sales last year) and Wyeth-Lederle Vaccines & Pediatrics (\$350 million). U.S. revenues for both companies have increased 300% since 1986, estimates David Molowa, international pharmaceutical analyst at the Wall Street investment firm Bear Stearns.

While the drug companies' revenues have soared, people have needlessly suffered. For example, though most kids develop only minor reactions such as fever and irritability following a DPT vaccination, about one in 310,000 injections results in permanent brain damage, according to a 1993 British study that followed children over a 10-year period. Since damage can occur with any one of the full series of five DPT shots, the odds of suffering brain damage for a child receiving all five doses of vaccine works out to one in 62,000. Additionally, based on a 1979 study conducted jointly by the FDA and UCLA researchers, the National Vaccine Information Center calculates that DPT deaths could exceed 900 per year. And while a 1979 study may seem outdated, consider that in the U.S. the pertussis portion of the vaccine, the component that causes the damage, is little changed from the original crude formula introduced in the 1920s.

At the same time, the safer vaccine costing \$9 more a dose has been used in Japan since 1981. Patented there by scientist Yuji Sato, it has wiped out 83% of minor reactions such as fever and swelling and virtually eliminated seizures, brain damage and death. The reason: The Japanese use an acellular vaccine, extracting only the portion of the pertussis bug that will trigger the body's immune response to protect against the disease. They remove or neutralize poisons that are byproducts of the bacteria, including endotoxin, a substance scientists say can cause serious afflictions, such as Joshua Reed's brain damage. By contrast, until recently, the two licensed U.S. DPT manufacturers, Wyeth-Lederle and Connaught Laboratories, used only the whole bacteria, toxins and all, yielding a whole-cell vaccine that former FDA researcher Charles Manclark has described as being "crude and impure." What's more, tests completed in Italy and Sweden in 1995 indicated that the purified acellular vaccine was not only safer than the whole-cell vaccine but was up to twice as effective in preventing pertussis.

Ironically, Sato was merely applying technology developed--but then abandoned--by American manufacturers. By 1972, six U.S. pharmaceutical companies had worked up some purified form of the pertussis vaccine that was safer than whole cell. One of the companies, Eli Lilly, marketed its vaccine, Trisolgen, for 15 years before getting out of the vaccine business in 1976 and selling the rights to Wyeth. Internal Lilly documents reveal that reported adverse reactions to Trisolgen were only a fifth of

those to their whole-cell product and that "severe reactions virtually do not occur." Nevertheless, Wyeth and other manufacturers initially rejected this process. According to a 1977 Wyeth document, its scientists analyzed the Lilly formula and found that the purification process would yield 80% less of the component that fights pertussis than the whole-cell formula, which would result in "a very large increase in the cost of manufacture."

Wyeth-Lederle told MONEY that clinical studies did not show that Wyeth's version of Trisolgen was safer than the whole-cell vaccine. Accordingly, Wyeth-Lederle says, Wyeth began looking into developing an acellular vaccine.

THEY STILL DON'T GET IT

"Sure, you can produce a much less toxic product in very low yields, and anyone who has worked on pertussis knows this," Dennis Stainer, an assistant director of production and development at Connaught Medical Research Laboratories in Canada, told a 1982 symposium sponsored by U.S. Government health officials. "What we are really faced with, I think now, is going from a vaccine that costs literally cents to produce to one that I believe is going to cost dollars to produce."

Connaught began research into an acellular vaccine in 1979 and in 1996 obtained an FDA license to sell it. "To criticize as slow, scientists who achieved the first U.S. license for infant use of Tripedia, an acellular pertussis vaccine, is like criticizing a gold-medal hurdler for not having started the race or cleared the hurdles as early as you think she should have," Christine Grant, Connaught's vice president for public policy, told MONEY.

Since July, Connaught's infant DPT vaccine with a Japanese acellular pertussis component has been on the market. Nevertheless, whole cell continues to be used in about 90% of all U.S. vaccinations. "The FDA needs to pull the license on whole-cell vaccine, as Japan did, and get it off the market," says Mark Geier, a physician and geneticist who worked for nine years at the National Institutes of Health researching toxins and other vaccine contaminants. But the medical community continues to defend the old vaccine. For example, Neal Halsey, chairman of the committee that makes vaccine recommendations at the American Academy of Pediatrics, says, "While acellular does cause lower rates of minor (problems), it doesn't mean whole cell is all bad or shouldn't be used."

Halsey's view is shared by many doctors. Says Geier: "The fact that a lot of pediatricians think whole-cell pertussis vaccine doesn't cause brain damage shows what a lot of money can do. Drug companies have paid a lot of money to people like James Cherry to put forth that image."

Cherry, a physician and professor of pediatrics at the University of California at Los Angeles, is a widely recognized pertussis expert who has been a leader on advisory committees that help frame immunization policy for the American Academy of Pediatrics and the Centers for Disease Control. Back in 1979, at a symposium, he said, "All physicians are aware that pertussis vaccine occasionally produces severe reactions and that these may be associated with permanent sequellae (complications caused by the vaccine) or even death." But by 1990, Cherry had changed his mind, proclaiming in the Journal of the American Medical Association that severe brain damage caused by pertussis vaccine was nothing but "a myth." From 1980 through 1988, Cherry got about \$400,000 in unrestricted grants that he termed "gifts" from Lederle. From 1988 through 1993, he was given \$146,000 by Lederle for pertussis research, and from 1986 through 1992, UCLA received \$654,418 from Lederle for pertussis research. Additionally, drug manufacturers paid Cherry and UCLA \$34,058 for his testimony as an expert witness in 15 DPT lawsuits brought against the companies.

The National Vaccine Information Center, among other consumer groups, protested that because of possible conflicts of interest Cherry should not be allowed on vaccine policy committees at the Centers for Disease Control. When asked whether his acceptance of funding and payments from Lederle created a conflict of interest, Cherry told MONEY, "I got nothing out of it. If having a feeling for children is the charge, then I'm guilty. None of this was done for the companies."

The CDC no longer permits members of its vaccine advisory committee to vote on issues involving any company with whom they have a financial relationship. But they can participate in discussions--which allows them to continue influencing policy. Minutes of a June 1995 CDC advisory committee meeting, at which members voted to delay recommending use of a safer polio vaccine, show that five of the nine members present had financial ties to vaccine manufacturers.

THE HIDDEN RISKS OF POLIO VACCINE

In October 1988, Lenita Schafer (pictured on page 153) brought her three-month-old daughter Melissa for her first oral polio vaccination. A month later, while fixing Thanksgiving dinner at her New England home, Lenita began feeling severe back pain. Within 48 hours she was unable to move her legs; 13 weeks after that, she was told she would be in a wheelchair the rest of her life. Lenita had contracted polio by changing her daughter's diaper.

Lenita had not been given the federally required warning that the oral vaccine contains live polio virus that can cause polio in some babies or in the people who come in contact with live virus shed in the babies' stool and body fluids. But even if

Lenita had been given the current two-page CDC information sheet on the risks and benefits of polio vaccine, she would not have had a true picture of the danger she faced.

The CDC sheet that doctors are required by law to give to parents still states that so-called contact polio is a risk only for people who never have been vaccinated against the disease. Yet Lenita, now 44, was immunized as a child. The CDC knows better. Minutes from a June 1995 meeting of the CDC's advisory committee on immunizations show the organization realizes that people who were vaccinated are susceptible to contact polio: "The previous belief...has not been borne out by experience." Says Walter Kyle, a Hingham, Mass. attorney who has represented Lenita and other contact polio victims: "The CDC's job is to give people the truth."

Furthermore, going beyond the fact that the CDC info sheet is outdated and inaccurate, Lenita would not have contracted polio if her baby had simply received an injection of inactivated polio vaccine (IPV) rather than an oral dose of live-virus vaccine (OPV). The injection protects against the disease but can't cause it because the polio virus has been "killed"--inactivated with chemicals so that it is not infectious.

In addition, federal health policy contributed to Lenita's paralysis. Although the injection was an available option, the doctor was following government policy when he automatically gave Lenita's daughter the oral vaccine. For 30 years until this September, one of the reasons that CDC officials recommended oral vaccine was precisely because the live virus shed in a recently vaccinated baby's body fluids could immunize more people through contact than it threatened, albeit without their knowledge or consent.

Federal health officials were aware that, each year, about 10 children or their caregivers might actually get polio from the oral vaccine. But the feds considered these human sacrifices acceptable for the greater public health goal of preventing polio outbreaks. The policy may well have made sense at the height of the polio epidemic in the 1950s, but since 1979 the only cases of polio in the U.S. have been caused by the oral vaccine itself--a total of 119 casualties from 1980 to 1994 alone in the name of federal public health policy. What's more, in 1994 the World Health Organization declared in a public statement that so-called wild polio (transmitted by any means not related to the vaccine) had been eradicated in the entire Western Hemisphere. "In a polio-free nation, in a polio-free hemisphere, we cannot have eight to 10 individuals paralyzed every year when there are alternatives," says Samuel Katz, a pediatric infectious disease specialist at Duke University.

So why is the oral vaccine still in use in 98% of the 20 million annual polio vaccinations in the U.S.? John Salamone of Oakton, Va., whose son David, now 6, has polio as the result of an oral immunization, says, "The answer is that it all comes down to money. A physician put it in perspective for me when he said I had to understand I was fighting a \$200 million industry."

A \$230 million industry, to be exact, embodied in one company, Wyeth-Lederle, the sole supplier of oral polio vaccine in the U.S. A year ago, the CDC's Advisory Committee on Immunization Practices recommended that the government advise pediatricians to use injected vaccine for the first two polio vaccinations and oral for the final two. The new program, according to CDC reasoning, would reduce vaccine-associated polio to one to five cases a year while still passively immunizing a portion of the U.S. population until wild polio is eradicated in the Third World--a goal health officials expect to reach in the next five years.

The committee's recommendation signaled a victory for Connaught, the sole marketer of injected polio vaccine in the U.S. But the CDC did not formally act on the committee's recommendation until two months ago, in part because Wyeth-Lederle launched an intensive lobbying effort to hold on to its own \$230 million oral polio vaccine business.

Ronald Saldarini, president of Wyeth-Lederle Vaccines & Pediatrics, told MONEY that his objection to the policy change had nothing to do with loss of market share but was based on several factors, including "compliance, systemic immunity, and lack of data and experience with the recommended schedule," as well as the public health risks of using a vaccine that does not passively immunize people. "Wild polio is just a plane ride away," he said.

Wyeth-Lederle's lobbying paid off. CDC director David Satcher announced in September that the agency would recommend two doses of injected vaccine followed by two doses of oral. But he also said that the alternatives of giving four doses of oral or four of injected would be acceptable. "Unless patients specifically request injected vaccine," says John Salamone, "doctors are inclined to do the easy thing, which is continuing to give the familiar oral polio vaccine." Cost may also be a factor in what is offered, especially at public health clinics. The federal government currently buys oral vaccine for \$2.32 a dose, compared with \$5.40 for injected.

A DEADLY NEW WORRY

There is another polio vaccine risk--"a ticking time bomb," according to Harvard Medical School professor Ronald Desrosier--that public health officials are reluctant to discuss frankly. What is it? The polio virus that is used in both Wyeth-Lederle's

oral vaccine and Connaught's injected version is grown on monkeys' kidney tissue. "The danger in using monkey tissue to produce human vaccines," says Desrosier, "is that some viruses produced by monkeys may be transferred to humans in the vaccine, with very bad health consequences." Desrosier acknowledges that you can test monkeys before using their tissue and screen out those carrying harmful viruses. But he warns that you can test only for those viruses you know about--and that our knowledge is limited to perhaps "2% of existing monkey viruses."

The danger is not hypothetical. In 1959, Ben Sweet, a 35-year-old scientist at Merck, the pharmaceutical giant, discovered that a previously undetected monkey virus called SV-40 had contaminated oral polio vaccines given to Americans for the prior five years. When testing revealed that SV-40 was a cancer-causing agent, producing tumors in hamsters, the FDA and manufacturers agreed that rhesus monkeys would no longer be used in vaccine production. Instead, the manufacturers would use African green monkeys, in whom the virus was easier to detect and screen out. But federal health officials knew the potential problem was enormous because, by then, as many as 30 million Americans had received both injectable and oral polio vaccines contaminated with SV-40. "Seeing that viruses could jump species really opened our eyes," says Sweet. "Merck stopped all polio vaccine development cold."

Even though SV-40 was being screened out, scientists such as John Martin, a professor of pathology at the University of Southern California, warned that other monkey viruses could be dangerous. But government officials rebuffed Martin's attempt to research those risks back in 1978 and again in 1995 when he was denied federal funding and vaccine samples he needed to investigate the effects of simian cytomegalovirus (SCMV), an organism that his studies indicate causes neurological disorders in the human brain. The virus has been found in monkeys used for polio vaccine production. Similarly, Cecil H. Fox was also rebuffed when, as a senior scientist at the National Institutes of Health in 1988, he asked to examine archived lots of polio vaccine to learn whether they contained simian immunodeficiency virus (SIV), which has been screened out of polio vaccines since 1987 because of potential human impact. "The resistance of those in authority to face the issue of prior vaccine contamination is particularly unfortunate," says Martin, "because research establishing a viral cause for neurological disorders or cancers can lead to effective antiviral treatments."

Beginning in 1992, scientific evidence supporting fears about prior contamination began to mount. Studies suggested that SV-40 was a catalyst for many types of cancer, not only in people who had received polio vaccine containing the virus but in their children as well.

In a series of papers published from 1992 through 1996, Michele Carbone, a molecular pathologist at Chicago's Loyola University Medical Center, examined the same types of tumors in humans that were known to develop in hamsters exposed to SV-40. He discovered SV-40 genes and proteins in 60% of patients with mesothelioma, a particularly deadly form of lung cancer, and in 38% of those with bone cancer. His most recent research, presented at a medical conference in July, connects SV-40 and these cancers even more clearly by describing the mechanism through which SV-40 turns a cell cancerous. Carbone's research shows that SV-40 switches off a protein that protects cells from becoming malignant. Not everyone who is infected with SV-40 gets cancer for the same reason that not every smoker gets lung cancer: A variety of assaults on the immune system usually combine to trigger malignancy. But SV-40 could be a factor that predisposes some people to develop tumors of the brain, bone, and tissue that surrounds the lung.

Now, in what could be a crucial piece of the puzzle, a study by Italian researchers published in October in the U.S. medical journal *Cancer Research* suggests that the reason all three cancers are on the rise is that the SV-40, originally introduced to humans through polio vaccine, is now being spread sexually and from mother to child in the womb. The study found SV-40 present in the blood and semen of 25% of healthy study subjects. According to one of the study's authors, biology and genetics professor Mauro Tognon of Italy's University of Ferrara's School of Medicine, this would explain why SV-40 was detected from 1992 on in the brain tumors of children who were born after 1965 and therefore presumably did not receive vaccine containing SV-40. Tognon also points to SV-40 as one possible reason for the 30% increase in U.S. brain tumors over the past 20 years.

Howard Strickler, senior clinical investigator at the National Institutes of Health's National Cancer Institute, told MONEY that the federal government is taking recent reports about SV-40 very seriously. "They are plausible, but it's not a done deal," Strickler said.

The accumulating body of evidence from research around the world has heightened the fears many scientists have expressed for years about the dangers of using monkey tissue in vaccine production, particularly when there are safer alternatives available. "There's no question that our polio vaccines should be made exclusively with killed viruses grown on human diploid tissue," says Howard Urnovitz, a microbiologist in Berkeley.

Connaught uses human diploid cells to produce Poliovax, the inactivated polio vaccine it manufactures and markets in Canada. The company is licensed to sell Poliovax in the U.S. but now markets Ipol here, a vaccine grown on monkey tissue. "Ipol is the more widely used vaccine, and it was a company decision (to continue

selling it here) based on what best meets the needs of the U.S. market," Connaught's Christine Grant told MONEY.

The FDA is equally dismissive of the potential dangers. Peter Patriarca, deputy director of the division of viral products at the FDA, says he sees no need to stop producing polio vaccines with monkey tissue.

Government thinking is best summed up by Neal Halsey, who is a member of advisory committees on immunization practices at both the CDC and the American Academy of Pediatrics. Halsey cautioned MONEY against "raising a hypothetical concern that could jeopardize vaccine supply. If it were a real concern, the FDA wouldn't allow the production of vaccine on monkey tissue." That viewpoint, of course, overlooks the fact that the FDA allowed the production of polio vaccine that contained SV-40, SIV and SCMV, with human health consequences that are just beginning to be understood.

MOVES THAT MUST BE MADE RIGHT NOW

Evaluating the safety record of vaccines such as DPT and polio is especially important in light of the vaccine industry's explosive growth. According to Frost & Sullivan, a technology market research firm in Mountain View, Calif., current worldwide revenues of nearly \$3 billion are expected to more than double to \$7 billion over the next five years as scores of new vaccines come to market. The industry is no longer focused primarily on life-threatening diseases, or on children but wants to introduce adult vaccines like those in the research pipeline to fight herpes and other sexually transmitted diseases.

What can be done in our interest? Much of the necessary change involves reforms in public health policy. In a joint effort with doctors and scientists, the government should:

--Ban dangerous products. To immediately improve the safety of existing vaccines, we must use only acellular DPT vaccines and inactivated polio vaccines. And we must discontinue use of monkey tissue in the production of all vaccines. Cost should not be a factor. "To avoid even a small risk of brain damage or death, what mother wouldn't pay even \$50 more for a safer vaccine," says Victor Harding, a Milwaukee attorney who has represented parents of children harmed by vaccines.

--Expand research. "We want to see scientific proof that you know precisely what is happening in the human body when you give vaccines to our babies," says Barbara Loe Fisher, co-founder and president of the National Vaccine Information Center. She and other experts recommend that the NIH take half of the \$415 million spent on

promoting immunization and new vaccine research and allocate it to studies investigating the cause-and-effect relationship between existing vaccines and immune and neurological disorders suspected to result from their use. An Institute of Medicine committee appointed to evaluate vaccine safety in 1994 noted that its analysis had been hampered by lack of such studies. Out of 59 health problems suspected to be associated with a variety of vaccines, the committee found that no scientific studies had been conducted on 40 of them (see the table on page 157 for a list of the key risks). To aid such evaluations, experts want the FDA and manufacturers to provide samples of current and archived vaccines to independent researchers.

--Stop hiding facts. When federal health officials and pediatricians refrain from warning the public about risks out of fear that parents will stop immunizing their children, they insult parents' intelligence and endanger the public's health. Parents deserve the facts so they can make informed choices. Geneticist and former NIH researcher Mark Geier says that when he speaks out publicly about vaccine risks or testifies on behalf of vaccine-damaged children, he is frequently criticized by other physicians. Says Geier: "They agree privately that what I say is accurate but warn that if I'm not careful, I'll scare people away from taking vaccines. That's certainly not my goal--my own kids are vaccinated. But if you operate on the premise that you can't tell the public about problems with vaccines because you'll scare them away, then unfortunately, the problems don't get fixed."

MORE VACCINE HEALTH RISKS THAT MUST BE CHECKED OUT

In addition to the vaccine-related problems disclosed in the accompanying article, many other risks have been discovered through lab experiments and random cases reported by victims or doctors. The government and the medical community, however, have failed to follow up these findings with the comprehensive studies that could prove a definite causal link between the vaccine and the disease. A "controlled clinical trial" is considered the gold standard of scientific inquiry, and "controlled observational studies" rank as the next best. According to the Institute of Medicine, a private, nonprofit organization for the examination of health policy matters, neither method of inquiry has been used to check out any definitive connection between the medical problems listed in this table and the vaccines that preliminary scientific research suggests can cause them.

Vaccine DPT

(Problem) Encephalopathy (inflammation of the brain resulting in loss of consciousness that can range from stupor to coma); demyelinating diseases of the central nervous system (infections of linings around nerve cells that can cause problems such as muscle weakness and blurred vision); Guillain-Barre syndrome

(nerve condition characterized by numbness and weakness of the limbs); anaphylaxis (severe and sometimes fatal allergic reaction)

(Vaccine) Measles

(Problem) Epilepsy; optic neuritis (inflammation of the optic nerve that causes blurred vision and can be an early sign of multiple sclerosis); transverse myelitis (spinal cord disease); Guillain-Barre syndrome; death from vaccine strain viral infection

(Vaccine) Mumps

(Problem) Encephalopathy; aseptic meningitis (inflammation of membranes covering the brain, causing fever, headaches, stiffness in the neck, drowsiness and sometimes loss of consciousness); sensorineural deafness; sterility; thrombocytopenia (a reduction in the number of platelets in the blood, manifested by a rash, nosebleeds, a tendency to bruise easily and prolonged bleeding from cuts)

(Vaccine) Oral polio

(Problem) Transverse myelitis; death from vaccine strain viral infection

(Vaccine) Hepatitis B

(Problem) Guillain-Barre syndrome; demyelinating diseases of the central nervous system; arthritis

Sidebar: DECEPTIVE NUMBERS AND DANGEROUS DECISIONS DECEPTIVE NUMBERS AND DANGEROUS DECISIONS

Since 1990, doctors have been required by law to report all adverse vaccine reactions through a centralized federal system overseen by the Food and Drug Administration and the Centers for Disease Control. But they frequently fail to do so--either because they don't recognize that a subsequent health problem is related to a vaccination, or they consider it relatively harmless. From 1991 through August 1996, 48,743 adverse reactions were reported. Unfortunately, those figures represent only a small portion of the dangers. For example, a 1995 CDC study found that reporting rates were less than 1% for serious reactions such as loss of consciousness after a DPT shot. A 1994 survey of doctors' offices in seven states, conducted by the National Vaccine Information Center, found that only 28 of 159 offices said they file a report after a patient has an adverse reaction to a vaccine.

Underreporting is an important problem because those figures are what the FDA relies on to identify exceptionally dangerous lots of vaccine. When doctors don't report harmful effects, there is little chance a "hot lot" can be identified early in its market life and recalled before more children are hurt. What's more, unfortunately, even with timely reporting, the FDA is reluctant to act. For example, the lot that killed Nathan Silvermintz produced exactly 70 adverse reactions, including nine deaths--yet was never taken off the market. Why? "This lot did have a relatively large reporting rate for serious and fatal reactions," Marcel Salive, chief of the FDA's epidemiology branch, told MONEY, "but there were other lots of vaccine of smaller size that had higher numbers of reports in those categories, so it was felt no action was needed."

What does it take to get action? No horror is enough, apparently. Salive confirms that no lot has been recalled because of adverse effects since the centralized reporting system was set in place six years ago. --A.R.