

VACCINES

An issue of trust

Misinformation and government foot-dragging are fanning fears.

This is the season of the shots, when parents scramble for appointments to bring their kids' immunizations up to date in time for school openings. The annual ritual is becoming anything but routine for growing numbers of parents who feel they're confronting a terrible dilemma: Do I expose my child and community to the risk of a serious disease? Or do I expose my child to the risk of one of those rare catastrophic reactions to the vaccine itself—reactions that I keep reading about on the Internet?

Even for those who don't have small children or grandchildren, distrust of the vaccine program—one of America's most successful public-health initiatives—is cause for concern. It's contributing to a severe underuse of the adult vaccines for flu and

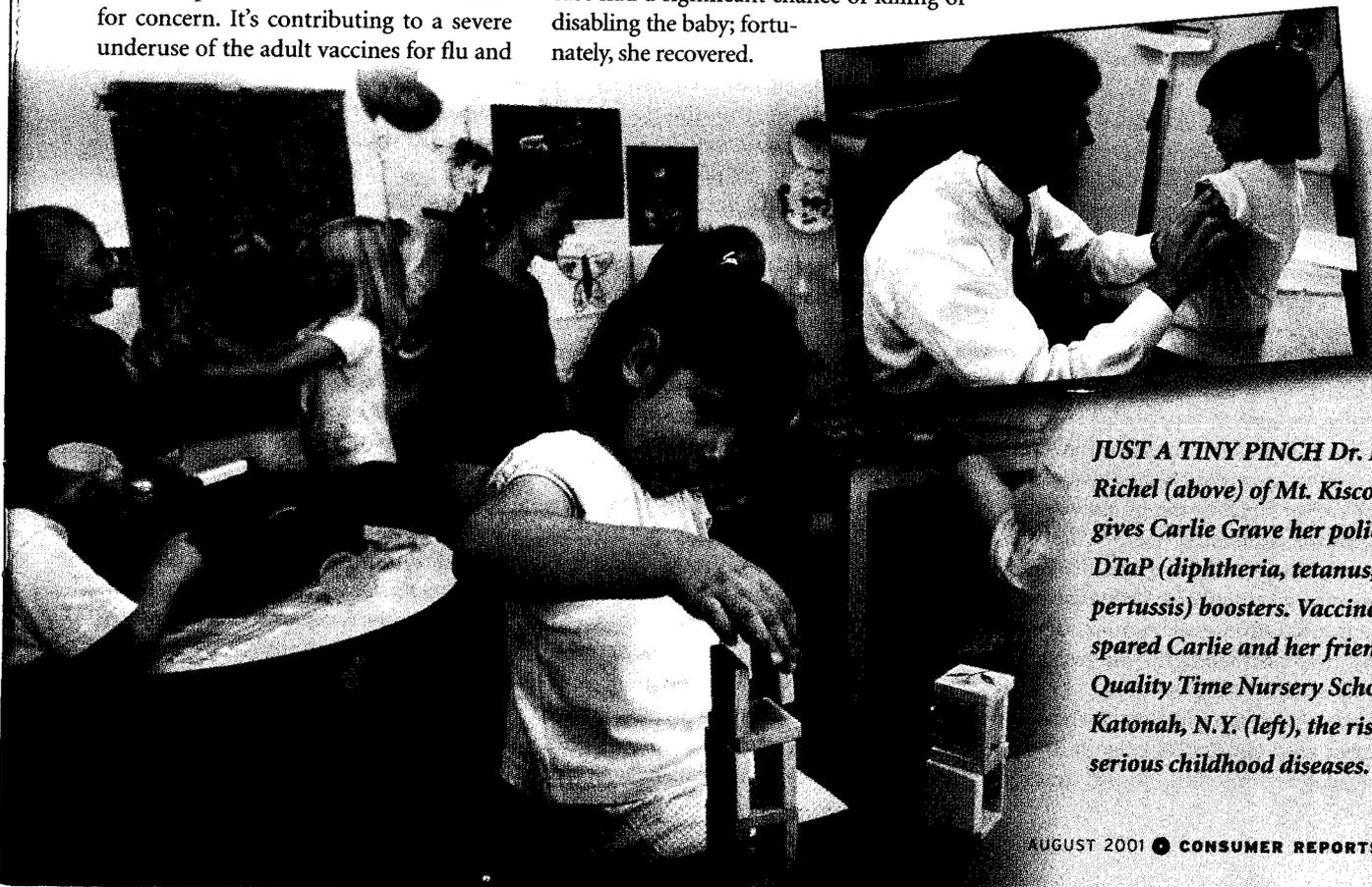
pneumonia and also to local outbreaks of vaccine-preventable diseases.

A friend's doubts about vaccine safety worried Suzanne Walther of Murfreesboro, Tenn., who decided to search the Internet for information. "I just typed in the word 'vaccines' and everything that popped up was antivaccine material," says Walther, who decided as a result to postpone immunization of her infant, Mary Catherine.

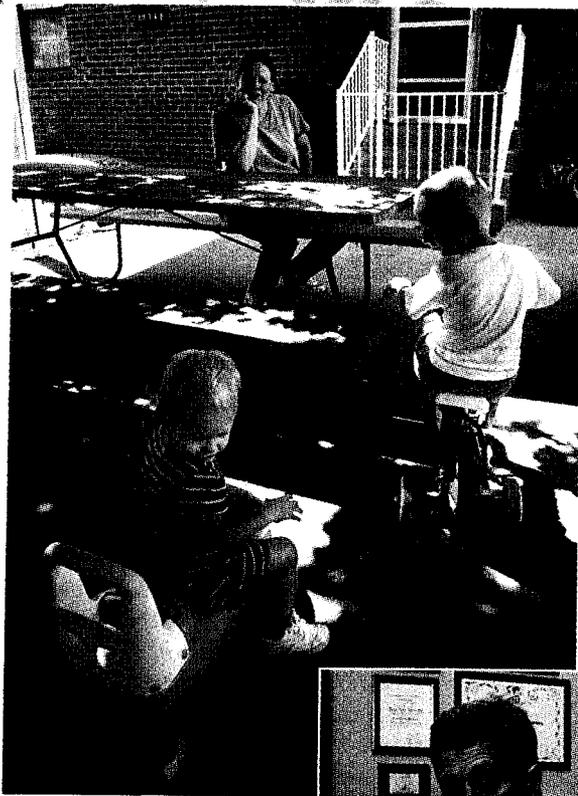
She waited too long. On the eve of her first birthday, Mary Catherine contracted *Haemophilus influenzae B* (Hib) meningitis and landed in intensive care. It was the first case the hospital had seen in eight years; Hib meningitis has become rare since the 1987 introduction of a vaccine against it. The disease had a significant chance of killing or disabling the baby; fortunately, she recovered.

Ninety percent of pediatricians and 60 percent of family doctors recently surveyed by University of Michigan researchers said they cared for at least one child whose parent refused immunization. A study in Colorado found that unimmunized children were 22 times more likely to contract measles and 6 times more likely to contract pertussis (whooping cough) than vaccinated children.

"In the middle are parents who are trying to do the right thing," says Bruce Gellin, M.D., a preventive-medicine specialist at Vanderbilt University and executive director of the National Network for Immunization Information, an independent source of scientifically verified vaccine information.



JUST A TINY PINCH Dr. Peter Richel (above) of Mt. Kisco, N.Y., gives Carlie Grave her polio and DTaP (diphtheria, tetanus, pertussis) boosters. Vaccines have spared Carlie and her friends at Quality Time Nursery School, Katonah, N.Y. (left), the risk of 11 serious childhood diseases.



A CLOSE CALL Anti-vaccine arguments persuaded Suzanne Walther of Murfreesboro, Tenn., to postpone vaccination for baby Mary Catherine (in striped romper). Just before her first birthday, the baby contracted a serious case of vaccine-preventable Hib meningitis. Luckily, she recovered fully.



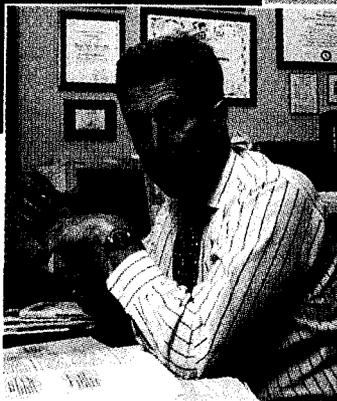
The small but influential antivaccine groups circulating the information that Walther found are doing the nation both a disservice and a service. Their best-known accusations—that too many vaccines “overwhelm” the immune system and that the MMR vaccine against measles, mumps, and rubella causes autism—appear groundless, according to the latest research.

But the noise-making has shaken up the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), the two agencies most concerned with vaccine safety.

Our examination of the vaccine-safety record has found that in some areas this shake-up is long overdue:

- ▶ There are significant gaps in the system for monitoring the safety of newly introduced and older vaccines.
- ▶ The guardians of vaccine safety have been slow to address correctable problems, such as the use of mercury as a preservative in some infant vaccines.
- ▶ The adversarial treatment of the 150 or so Americans who apply each year for compensation for adverse effects from vaccines has angered many and provided recruits to the antivaccine forces.

In this report, we'll discuss where the vaccine-safety system has fallen short and how it can be improved. We will examine



THE ANSWER MAN Walther credits Dr. Bruce Gellin of Vanderbilt University, where Mary Catherine was treated, for taking her concerns seriously and finding answers to her questions. “I never felt like I was being blamed,” Walther says. She is now an ardent supporter of childhood immunizations.

the evidence behind the main arguments of the antivaccination activists. And we will suggest ways in which consumers can benefit from immunization while minimizing risks. In an upcoming report this fall, we'll take a closer look at adult vaccines.

THE PRICE OF SUCCESS

Under the current schedule, children receive 23 shots against 11 diseases before starting kindergarten. Before the vaccines were introduced, the toll of 10 of these vaccine-preventable diseases—diphtheria, measles, mumps, pertussis, polio, rubella (German measles), tetanus, hepatitis B, pneumococcus, and Hib—was nearly 2 million reported cases of disease per year, based on their peak year of incidence. Even the “mildest” vaccine-preventable disease, chicken pox, claimed 100 lives each year.

But the youngest Americans who can remember diphtheria and whooping cough are on Medicare. The youngest who can remember polio and measles are in their 50s and 40s, respectively. Most parents making

immunization decisions today are in their 20s and 30s.

“We're prisoners of our own success,” observes William Schaffner, M.D., chairman of the Department of Preventive Medicine at Vanderbilt University. “When formerly dreaded diseases have been pushed into the shadows—or eliminated—questions about the vaccines themselves spring up.”

The next decade is likely to bring new vaccines against HIV, genital herpes, type 1 diabetes, Epstein-Barr virus, cervical cancer, and streptococcus A and B, to name just a few under development. That will make oversight of the benefits and risks of vaccines more crucial.

Improving the safety record of vaccines is no small task for several reasons:

- ▶ Since vaccines are given to healthy people, serious risks are unacceptable. But what's “serious”? If a vaccine prevents 1,000 deaths, are 10 vaccine-related injuries an acceptable trade-off? If you or your child is one of the 10, the answer is probably no. If you are a public-health official, the answer isn't so obvious.

- ▶ Most childhood vaccines enjoy almost total protection from product-liability lawsuits. While this has kept manufacturers in the vaccine business, it has also removed one important incentive to improve safety beyond current levels.

HOW VACCINES ARE TESTED

Most vaccines come to market with an incomplete safety record. A new vaccine is typically tested on 10,000 to 20,000 people before the FDA approves it. That's enough to study disease protection but not enough to reliably detect rare complications. In 1998, the FDA licensed *RotaShield*, a vaccine to prevent an intestinal infection that was striking an average of 3.5 million babies in the U.S. a year and killing 20. Of the 10,054 babies vaccinated during the tests, 5 developed a condition called intussusception, a life-threatening collapse of the bowel. Since intussusception can also occur spontaneously, it wasn't mathematically clear whether or not the vaccine caused those cases.

But within six months of the vaccine's introduction, after some 1.5 million babies had received it, monitoring studies found

PHOTOS BY RANDY PILAND

Details on vaccinations

The 11 diseases prevented by childhood vaccines were bad ones, as this table demonstrates. The damage they caused far outweighed even the most troublesome known vaccine-related complications. This chart shows the most common complications unique to each vaccine. In addition, any vaccine can cause minor reactions such as a mild fever or pain at the injection site. And very occasionally, any vaccine (or one of its inactive ingredients) can cause an immediate, serious allergic reaction known as anaphylaxis.

VACCINE	YEAR OF INTRODUCTION	PEAK ANNUAL DISEASE TOTAL	1999 TOTAL	CONSEQUENCES OF NATURAL DISEASE	% OF CHILDREN VACCINATED	KNOWN VACCINE SIDE EFFECTS	
Chicken pox (varicella)	1995	4 million*	N/A	Encephalitis (2/10,000 cases), bacterial skin infections, shingles (300,000/year)	59.4	Mild rash (1/20 doses)	
DTaP						83.3	Prolonged crying, fever of 105 °F or higher
Diphtheria	1923	206,939	1	Death (5 to 10/100 cases), muscle paralysis, heart failure			
Tetanus	1927	1,560*	40	Death (30/100 cases), fractured bones, pneumonia		Peripheral neuritis, Guillain-Barré syndrome (temporary paralysis—rare)	
Pertussis	1926 (whole cell) 1991 (acellular)	265,269	7,288	Death (2/1,000 cases), pneumonia (10/100 cases), seizures (1 to 2/100 cases)		Brain disease (0 to 10/1 million doses—whole-cell vaccine only)	
H influenzae B (childhood)	1985	20,000*	71	Death (2 to 3/100 cases), meningitis, pneumonia, blood poisoning, inflammation of epiglottis, skin or bone infections	93.5		
Hepatitis B	1981	300,000*	7,694	Death from cirrhosis or liver cancer (4,000 to 5,500/year)	88.1		
MMR						91.5	Fever of 103 °F or higher (5 to 15/100 doses)
Measles	1963	894,134	100	Encephalitis (1/1,000 cases), pneumonia (6/100 cases), death (1 to 2/1,000 cases), seizure (6 to 7/1,000 cases)			
Mumps	1967	152,209	387	Deafness (1/20,000 cases), inflamed testicles (20 to 50/100 postpubertal males)			
Rubella	1969	56,686	267	Blindness, deafness, heart defects and/or retardation in 85 percent of children born to mothers infected in early pregnancy		Temporary joint pain (25/100 adult doses in women)	
Pneumococcal** (childhood)	2000	93,000*	New vaccine	Meningitis (800 cases/year), pneumonia (77,000 cases), blood poisoning (15,000 cases)	New vaccine	Fever over 100.3 °F (22/100 doses)	
Polio (paralytic)	1955	21,269	0	Death (2 to 5/100 case in children), respiratory failure, paralysis, postpolio syndrome	89.6	Vaccine-induced polio (oral vaccine only—1/2.4 million doses)	

Source: Centers for Disease Control and Prevention *Estimated **Journal of the American Medical Association, March 15, 2000

that vaccinated babies had a 21-times higher chance of intussusception than normal within the first few weeks after their shots. The vaccine is no longer in use.

The obvious way to catch such problems before marketing is to vaccinate more test subjects. But the price of new vaccines is already high—a single dose of the newest, a vaccine against childhood pneumococcal disease, costs \$58—and testing more subjects would drive costs still higher. Moreover, it's hard to recruit enough volunteers even for the modest-sized trials. "Everybody wants more babies studied, but whose babies are these going to be? Your baby or somebody else's baby?" asks Kathryn Edwards, M.D., a Vanderbilt University pediatrics professor who has worked on many vaccine research projects.

Once a vaccine goes on the market, the

main way of tracking unexpected complications is through a federal program called the Vaccine Adverse Event Reporting System (VAERS). But this system has major drawbacks: It's voluntary (except for manufacturers), and reports don't necessarily mean that the adverse reaction is truly associated with the vaccination.

To compensate for these failings, the government also finances a smaller but more complete program, the Vaccine Safety Datalink, that uses the comprehensive records of several large managed care organizations to track vaccine outcomes. Additional safety research programs are under development as well.

TWO SAFETY LAPSES

In two recent cases, vaccine-safety agencies were slow to act on emerging problems:

Mercury in vaccines. Even minuscule doses of mercury can impair the cognitive development of babies and young children. Just this year, the FDA warned pregnant and nursing women and very young children to avoid certain mercury-containing fish. Yet until last year, the same agency permitted the use of childhood vaccines containing mercury in quantities that many, including Consumers Union, consider unsafe.

Mercury is a major constituent of thimerosal, a preservative that for the past 70 years has been added to multidose vials of vaccines to inhibit bacterial growth. There has never been a scientific study of the safety of using this product in children's vaccines. Nevertheless, its use continued until 1999, when the FDA added up vaccine-related thimerosal exposure for the first time, as part of an agencywide

study of mercury-containing products.

At the time, three vaccines routinely given to newborns and infants, hepatitis B, Hib, and DTP, contained thimerosal. An average-sized baby given vaccines containing the maximum concentration of thimerosal was being exposed to 187 micrograms of mercury, more than twice what the Environmental Protection Agency deems safe for very young children. (Exposure didn't exceed the much looser FDA guideline, which Consumers Union believes is too high.)

Nevertheless, the FDA and CDC allowed immunizations with thimerosal-containing vaccines to continue—while cooperating with manufacturers to create thimerosal-free versions as quickly as possible. Not until early

the injectable, inactivated vaccine that cannot cause polio. During that 20-year period, there were eight to nine cases of vaccine-associated paralytic polio each year.

"Why did it take 20 years to make the change?" says John Salamone, a Virginia parent whose 11-year-old son developed paralytic polio from his second dose of oral vaccine. "It was an egregious act by the government."

Some vaccine experts agree that the vaccine's safety should have been considered sooner. "The decision could have been made 10 years earlier," says Neal Halsey, M.D., director of the Institute for Vaccine Safety at

Vaccine Information Center, the most prominent of the antivaccine groups.

While Fisher's argument—that the pertussis vaccine caused an increase in epileptic and learning-disabled children—appears baseless, her activism led to the creation of a compensation system for vaccine victims and prompted the CDC to plan a major expansion of programs to study vaccine safety.

Other arguments and suppositions of antivaccine activists, Fisher included, are either incorrect or misleading. Here are the main ones:

Vaccines "overwhelm" the immune system and cause it to turn against itself. Vaccines work by stimulating the production of protective antibodies. So the idea that multiple vaccines can "overstress" the immune systems of infants seems reasonable. It's behind the belief that the measles component of the measles-mumps-rubella (MMR) vaccine has caused an epidemic of autism.

In fact, vaccines tax the immune system much less than natural diseases, says Halsey. A natural infection can lead to the stimulation of as many as 25 to 50 separate immune responses. "When we give something like the Hib vaccine, we're giving only two antigens," says Halsey. "The immune system's potential is enormous. It can respond to 10 million to 100 million antigens."

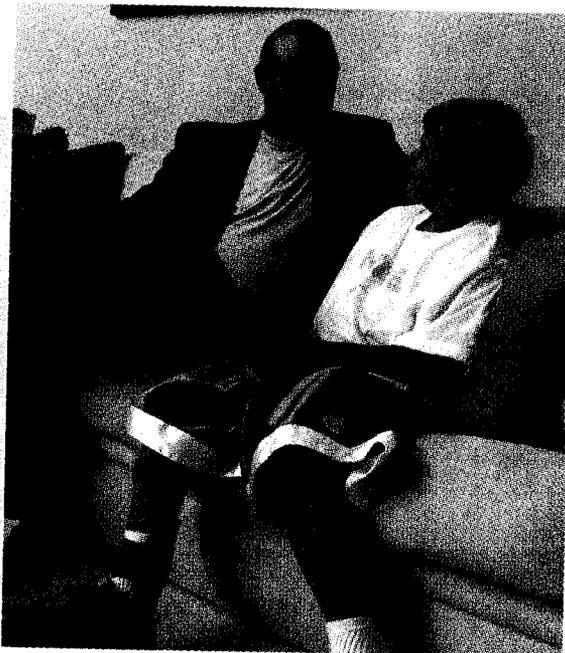
Vaccines are as dangerous as the diseases. The statistics can be misleading. In 1999, nearly 12,000 vaccine "adverse events"—established or presumed, and mostly mild—were reported to government health officials. That same year, the diseases themselves caused only 6,777 cases of illness or injury. But that does not mean that vaccines are a poor risk.

Except for polio, vaccine-preventable diseases are still around. The Colorado study that documented an increased risk of measles and pertussis among unvaccinated children also found that vaccine refusal puts the community at risk, because vaccines don't "take" in everybody who gets them. The researchers found more measles and whooping cough among vaccinated children in schools with many unvaccinated children than in schools where nearly all children had been vaccinated.

If someone gets sick soon after getting a vaccine, the shot is to blame. This idea is at the root of the most contentious vaccine-safety issues: the alleged links between vaccines and autism, brain damage, and multiple sclerosis. Some antivaccine web sites feature accounts of lively toddlers who,

POLIO FROM VACCINE

David Salamone, now age 11, got polio from the oral vaccine he received as a baby more than a decade after the last case of "wild" polio in the U.S. His father, John, spearheaded the successful effort to force a switch back to the safer killed-virus injectable polio vaccine.



in 2001, more than a year and a half after the issue first surfaced, were all childhood vaccines made without significant amounts of thimerosal.

Vaccine-associated polio. The oral polio vaccine in use from 1960 on had an advantage over the original killed-virus Salk vaccine. The live, weakened virus it contained replicated and spread from person to person, immunizing many who were exposed to it even though they weren't vaccinated themselves. This so-called herd immunity is why experts expect that polio will soon be the second disease in history, after smallpox, to be eradicated from the globe.

But the oral vaccine has a little-known downside: In about 1 in every 2.4 million doses, the ingested virus mutates back into a virulent form capable of causing disease. Since 1979, the only cases of polio in the U.S. have been caused by the oral vaccine. Yet not until 1999 did the CDC's vaccine policy-making group vote to switch back to

Johns Hopkins University.

Salamone believes the turning point came when affected families appeared before the CDC committee that sets immunization policy. "Until these doctors saw these kids in wheelchairs, they never put faces on what they were doing," he says.

THE ANTIVACCINE ARGUMENT

This is not the only example of how vocal parents and antivaccine activists have pushed government agencies to improve vaccine safety. In 1985 Barbara Loe Fisher, a Washington, D.C., mother whose son developed neurological and cognitive disorders after his pertussis vaccination, wrote "A Shot in the Dark." The book was a well-researched history and indictment of a vaccine that even its supporters concede caused an unusual incidence of reactions, from fever to seizures, because it was made from whole, killed whooping-cough bacteria. Fisher went on to found the National

after receiving their MMR shot, turned into neurologically impaired preschoolers.

But are vaccines really to blame? To date, two expert panels, one convened by the American Academy of Pediatrics and the other by the National Academy of Sciences, have studied the MMR vaccine and autism. They found that autism cases did not increase along the same trend lines as increases in the percentages of children who received the MMR vaccine. Both expert groups have concluded that although more needs to be learned about autism—and above all about the apparent increase in the numbers of autistic children—the MMR vaccine is almost certainly not to blame.

For now, the most likely explanation for the seeming link is pure coincidence. Many childhood neurological and developmental problems first emerge at an age when children are getting vaccines frequently.

COMPENSATING THE INJURED

When the pertussis vaccine controversy surfaced in the U.S. in the mid-1980s, vaccine manufacturers threatened to get out of the business rather than risk ruinous lawsuits. (Today, there are only four major childhood-vaccine manufacturers in the U.S.: Glaxo SmithKline, Aventis Pasteur, Wyeth Lederle, and Merck & Company.)

As a result, the federal Vaccine Injury Compensation Program was created in 1988. Funded by a small tax on every lot of vaccine, it is in essence a no-fault insurance plan against childhood-vaccine injuries.

The program set up a list of conditions such as vaccine-associated polio that, based on scientific evidence, seem to be vaccine-related. Anyone with a condition on the list is entitled to compensation for "pain and suffering" and for ongoing medical expenses. The trade-off: giving up the right to sue manufacturers and doctors.

"With respect to manufacturers and physicians, the system has been an unqualified success," says Peter Meyers, a law professor who heads the vaccine-injury law clinic at George Washington University. "But it's been a much more mixed record with respect to consumers."

"It's very difficult to bring a claim under this program," Meyers says. "The government is very aggressive. If there are any technical loopholes, they raise them. They fight everything to the bitter end."

Even claimants who win compensation can run into trouble. "I have had to fight to get my son two pairs of braces a year, to keep up with his growth," says Salamone, whose son contracted polio from the vac-

cine. "They said one pair should be enough. They asked why he needed physical therapy once a week."

Vaccine-victim advocates say the program's accumulated \$1.6 billion balance is evidence of its lack of generosity. The government says the surplus is the result of the development of ever-safer vaccines.

RECOMMENDATIONS

► Consumers should ask for the safest vaccines. The whole-cell pertussis vaccine, childhood vaccines containing thimerosal as a preservative, and the oral polio vaccine may still be in the distribution system. Tell your doctor not to use these vaccines.

► Be sure to let the doctor know if the child has a fever, diarrhea, or other significant medical symptom at the time of an immunization appointment. The doctor may recommend postponing the immunization. If this occurs, it's critical to promptly make up the missed vaccine doses. For additional information, consult the CDC's Contraindications for Childhood Immunization document, available on the Internet at www.cdc.gov/nip/recs/contraindications.pdf.
► Ask the doctor which post-vaccination symptoms are normal—and which warrant medical attention. Mild fever and fussiness are common consequences of vaccine-induced immune reaction. But a high fever or seizure is out of the ordinary.

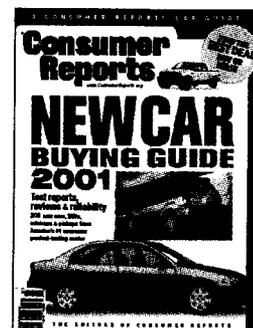
► Seek information from reliable sources such as the CDC (www.cdc.gov/nip), the National Network for Immunization Information (www.immunizationinfo.org), the Immunization Action Coalition (www.immunize.org), and the Vaccine Education Center (www.vaccine.chop.edu). Be aware that some groups with official-sounding names, such as the National Vaccine Information Center and Parents Requesting Open Vaccine Education, are actually anti-vaccine networks.

► Policy-makers should continue—and adequately finance—improvements in tracking and analyzing vaccine injuries. This includes expanding state immunization registries (with proper privacy safeguards), which are invaluable for researching safety concerns. Vaccine-safety guardians need to keep faith with parents by taking prompt action when possible problems or concerns surface.

► The Vaccine Injury Compensation Program should use some of its burgeoning surplus to become more user-friendly. And physicians and health educators must deal fully and respectfully with the vaccine-safety concerns of patients and parents. It's no longer enough to say, "Trust us, we're the experts." ®

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