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Vaccine Controversies

Are today's vaccines safe enough?

Immunization rates are at all-time highs, and once-dreaded childhood diseases like polio and diphtheria are at or near record lows. But growing numbers of parents and a small group of scientists question the safety of some vaccines, claiming they can cause severe adverse reactions. They also contend that vaccines shouldn't be mandatory for illnesses like chickenpox and hepatitis B — which are mild or rare in children — and that tests on the vaccines have been inadequate. In addition, some scientists say that producing genetically engineered vaccines without knowing the long-term side effects is foolhardy. But drugmakers and health officials say there is no proof of a causal relationship between vaccinations and severe adverse reactions and that maintaining public health demands widespread mandatory immunization.



INSIDE THIS ISSUE

THE ISSUES	643
BACKGROUND	656
CHRONOLOGY	659
AT ISSUE	662
CURRENT SITUATION	664
OUTLOOK.....	666
BIBLIOGRAPHY	668
THE NEXT STEP	669

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THE ISSUES

- 643
- Are vaccines safe?
 - Is the government doing sufficient quality research on vaccine safety?
 - Do vaccine manufacturers have too much influence over policy-makers?
 - Should vaccines be mandatory for all?

BACKGROUND

- 656 **Early Breakthroughs**
In 1796, Edward Jenner noticed that dairymaids exposed to cowpox were immune to smallpox.
- 656 **Mandatory Vaccinations**
State laws requiring immunization date from the early 1800s.
- 657 **DPT Under Attack**
By the early 1980s, some parents said their children had been injured by unsafe vaccines.
- 664 **Immunization Lag**
In the late 1980s, low immunization rates, mainly in inner cities, led to a major measles epidemic.

CURRENT SITUATION

- 664 **Compensation Law**
Critics say the vaccine-injury compensation system is too adversarial.

OUTLOOK

- 666 **New Vaccines**
A flood of new vaccines may protect against diseases ranging from pneumonia to herpes.

SIDEBARS AND GRAPHICS

- 644 **Today's Children Get Many More Shots**
Kids today typically receive 12 different vaccinations.
- 646 **Critics Blame Hepatitis Vaccine for Severe Injuries**
But drugmakers say it's safe.
- 648 **Adverse Effects of Childhood Vaccines**
Scientists say some vaccines can cause diseases.
- 650 **Court Blames Vaccines**
Anna became paralyzed; Richie died.
- 652 **Is Your Child Getting the Right Vaccine?**
Here's what parents should ask.
- 657 **Vaccines for STDs**
Vaccines for sexually transmitted diseases may be given to all children.
- 659 **Chronology**
Key events since 1905.
- 660 **Do Some Vaccines Cause Autism?**
Parents and health officials dispute the evidence.
- 662 **At Issue**
 - Do vaccines cause autism?
 - Should vaccines be mandatory?

FOR MORE INFORMATION

- 668 **Bibliography**
Selected sources used.
- 669 **The Next Step**
Additional articles from current periodicals.

Aug. 25, 2000
Volume 10, No. 28

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Vaccine Controversies

BY KATHY KOCH

THE ISSUES

It's school immunization season, and parents like Suzy Richards, of Friendsville, Tenn., give public health officials nightmares.

Richards* recently decided to discontinue vaccinations for her boys, ages 10 and 6, even though they haven't reacted negatively to earlier vaccines. "There's no way to know for sure whether they will have a negative reaction to the next one," she says.

Her fears were raised by reports about adverse vaccine reactions in *Parents* magazine and on ABC's "Nightline" — sources she trusts. "I've just heard and read too many things about how kids can be harmed or develop autism," she says. "I think they're just cramming these kids full of too many shots too early in life."

Richards worries because the number of vaccines recommended for children has been dramatically increasing. In 1960, children received 19 doses of four different vaccines before they reached school age. Today, an American child receives up to 39 doses of 12 different vaccines, most given during the first two years of life. And, unlike in previous decades, today's youngsters often are given multiple inoculations on the same day.

But immunization experts like Samuel L. Katz, a pediatrics professor emeritus at Duke University, say that parents like Richards threaten the nation's health. "Unless we continue to achieve high levels of immunization," he says, "terrible diseases will return — some in epidemic form."

That's what happened in the former Soviet Union, when vaccination rates dropped in the early 1990s,



National Vaccine Information Center

In the first demonstration of its kind, scores of parents who say their children suffered adverse effects from the DPT vaccine protest outside the Centers for Disease Control and Prevention in Atlanta in May 1986.

public health officials say. A diphtheria epidemic broke out, and diphtheria cases skyrocketed from 839 in 1989 to nearly 50,000 cases in 1994 (including 1,700 deaths), the U.S. Centers for Disease Control and Prevention (CDC) reports.¹

The CDC is quick to point out that most parents do not share Richards' fears. "Vaccination rates are as high as they've ever been," says Benjamin Schwartz, acting director of epidemiology and surveillance for the CDC's National Immunization Program (NIP). "The vast majority of Americans support vaccinations."

But for a growing number of parents, getting their children vaccinated — once a no-brainer — has become an agonizing and confusing decision. It pits parents against their child's pediatrician and school, other parents and local health officials.

A mother in South Carolina recently found out just how hard it is to buck the system. The federal government had compensated her after her first daughter was left with severe brain injuries following a DPT (diphtheria-pertussis-tetanus) vaccine. But when local health authorities found out she was not planning to let her youngest daughter get the same vaccine, they threatened to charge her

with child abuse and take her child away.

"We see cases like this all the time," says Barbara Loe Fisher, president of the National Vaccine Information Center (NVIC), in Vienna, Va. "She finally told them she had a gun and would leave the state to protect her child from vaccine damage if they did not leave her alone."

Fisher helped found the NVIC in 1982 after her own son suffered brain damage after his fourth DPT shot. She

later co-authored a book, *A Shot in the Dark*, about the dangers of the pertussis shot and the politics surrounding its continued use in the United States, 15 years after a safer version was available in Japan (*see p. 661*).

Other parents around the country — including lawyers, scientists and even public officials — who say their children have been injured or killed by vaccines have followed in her footsteps, organizing lobbying groups and Web sites advocating safer vaccines, more informed consent about potential risks and more freedom to choose which vaccines their children receive.

"I'm not anti-vaccine," Richards insists. "I just think the government needs to do a better job of making sure they are as safe as possible."

Vaccine reformers were somewhat vindicated in recent years after the CDC agreed to replace the DPT and oral polio vaccines with safer versions, eliminate mercury from childhood vaccines and recall the new, genetically engineered rotavirus vaccine (for severe diarrhea) after it caused potentially life-threatening illnesses in some children.²

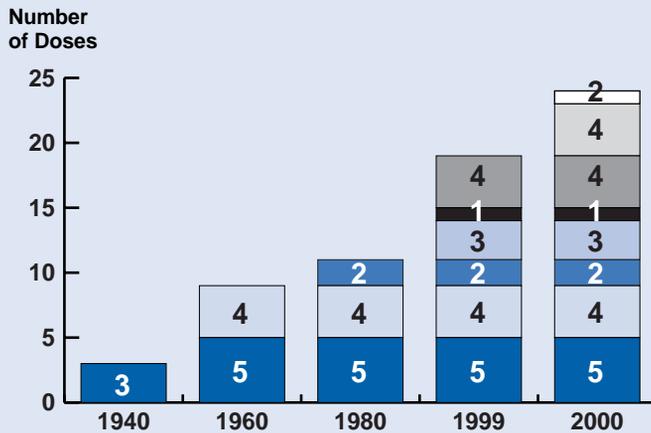
But those actions just fueled the controversy and catapulted the debate from Internet chat rooms to congressional hearing rooms. In the past year,

*Suzy Richards is not her real name.

Today's Children Get Many More Shots

Children today typically receive 39 doses of 12 different vaccines by the age of 6. By comparison, children in 1940 only received 9 doses in three vaccinations to prevent diphtheria, tetanus and pertussis (whooping cough).

Vaccine Doses in the First Six Years of Life



Number of Doses	Type of Vaccine	Disease Prevented
2	Hepatitis A	Mild form of hepatitis
4	Pneumococcal	Pneumonia, meningitis, sinus infection and sepsis
4	Hib	Meningitis and pneumonia
1	Varicella	Chickenpox
3	Hepatitis B	Severe hepatitis, cirrhosis, liver cancer
2	MMR	Measles, mumps, rubella/German measles
4	Polio	Poliomyelitis
5	DPT	Diphtheria, pertussis/whooping cough and tetanus

Source: Advisory Committee on Immunization Practices

House committees have held hearings on the safety of a new hepatitis B vaccine, conflicts of interest among federal vaccine policy-makers, possible links between vaccines and autism, the safety of mercury in vaccines and whether the federal program that compensates people injured by vaccines is working.

And it's not just childhood vaccines that have come under fire.

Hundreds of men and women in the military have chosen early retirement or court-martial rather than be vaccinated with a controversial anthrax vaccine. Other soldiers claim multiple vaccines they received against biological weapons are partly to blame for the mysterious Gulf War Syndrome afflicting many veterans — a claim the Defense Department has denied.

Ironically, the vaccine debate is partly the result of the success of mass immunizations. Childhood immunization rates are at an all-time high, except for pockets in some inner cities. And once-dreaded childhood diseases, such as measles, diphtheria, mumps and whooping cough, are at or near record lows. Smallpox has been wiped off the Earth, and polio has been eradicated from the Western Hemisphere.

"Vaccines have prevented thousands of deaths," says the CDC's Schwartz.

But as vaccination rates climb, chronic diseases and conditions, like asthma, allergies, diabetes, autism and learning disorders, are increasing nationwide among children, often at alarming rates. Some parents and doctors are questioning whether the rise in chronic disease may be a long-term effect of childhood vaccinations.

"Are we living in a different society where people have fewer infections because of immunizations and we have somehow changed our immune systems?" asked Edward Bailey, medical director of the Springfield, Mass., school system.³

Critics say much of their concern stems from the fact that today's new vaccines are not for diseases that occur in epidemic proportions, at least not in the industrialized world. In the 1990s, for instance, the four new vaccines added to state mandatory-immunization schedules were for hepatitis B, rotavirus, *Haemophilus influenzae* (Hib) and pneumococcal disease — infections that don't sweep through populations, wiping out victims by the thousands.

Today's vaccines are different in another way. With the advent of new technologies and years of heavy investment and research in DNA-based vaccines, dozens of biotech companies are now competing with traditional manufacturers to produce genetically engineered vaccines for all kinds of conditions. Parents who think

their kids are already getting too many vaccines might be shocked to learn that more than 200 new vaccines are in the pipeline, to treat everything from cocaine addiction to herpes.

Just because a new childhood vaccine is available, critics say, it shouldn't automatically be included on the mandatory-immunization schedule. That question was raised after the CDC recommended a vaccine for the relatively innocuous chickenpox and one for hepatitis B — a disease primarily found among prostitutes, gay men and drug abusers. (See sidebar, p. 646.)

"We are not discriminating as to which are the appropriate vaccines for the appropriate populations, taking into account what the reasonable risk for that population is," says Ronald Kennedy, professor of microbiology and immunology at the University of Oklahoma.

Vaccine-policy critics also note that once a new vaccine is added to the federal childhood immunization schedule, manufacturers have a guaranteed market because every child in America is generally required to receive it before entering school. The recommendations are also taken into consideration when the World Health Organization (WHO) recommends vaccines for use in Third World countries.

Yet those same manufacturers, as well as pediatricians who administer the shots, are largely exempt from lawsuits by parents of injured children, thanks to a 1986 law that made the government, not the vaccine producers, liable for damages caused by mandatory vaccinations. The fund is financed with taxes on vaccines. As

a result, activists argue, both the government and the billion-dollar vaccine industry have powerful stakes in downplaying vaccine problems.

As the debate over vaccines continues, here are some of the key questions being asked:

Are vaccines safe?

Vaccines are among the "safest pharmacological interventions for disease prevention available," says epidemiologist Roger Bernier, associate director for science at the CDC's National Immunization Program.



Barbara Loe Fisher helped found the National Vaccine Information Center, an advocacy group for children damaged by vaccines, after her eldest son, Chris (center), suffered brain damage following his fourth DPT shot.

National Vaccine Information Center

Health officials are quick to point out that the odds a child will die or become disabled from the diseases targeted by vaccines are far greater than being harmed by the vaccine. Without the diphtheria vaccine, Bernier says, 6 million people would have died during the 20th century.

"The real question," says Paul Offit, chief of infectious diseases at Children's Hospital of Philadelphia, "is, Do the benefits of vaccines definitively outweigh the risks? For all children's vaccines, that is clearly the case."

That was even true for the rotavirus

vaccine, he contends. "A million children got the vaccine, and 100 got sick and one died. Yet now that it's off the market, if a million children don't get the vaccine, 16,000 will be hospitalized and 10 will die. It's still safer to get the vaccine."

Still, Offit adds, vaccines are not completely harmless. Of the 3 million children who receive vaccines each year, "a small percentage will have a severe allergic reaction, such as hives, difficulty breathing and low blood pressure," he says.

Such statements enrage parents like Michelle Helms, whose son Zachary died 33 hours after receiving his childhood vaccinations.

"Why aren't parents told about the real dangers these vaccines pose?" she asks on the Web site for the Global Vaccine Awareness League, the advocacy group she co-founded after Zachary's death. "Knowing that, I could have seen the tell-tale signs of a vaccine reaction and done something to save his life." ⁴

Public trust in official reassurances about vaccine safety began eroding in 1976, when many

people reportedly contracted Guillain-Barré Syndrome after being vaccinated against the swine flu, an epidemic that never materialized. In the 1980s, a television documentary about the dangers of the DPT shot spurred a flurry of lawsuits against DPT manufacturers. Then in the early 1990s, Persian Gulf War veterans began questioning the safety of the many vaccinations they received before shipping out.

Other incidents and revelations have spurred skepticism about vaccine safety, including:

Continued on p. 648

Critics Blame Hepatitis Vaccine for Injuries ...

Bonnie S. Dunbar is not your typical anti-vaccine activist. A professor of molecular and cell biology at Baylor College of Medicine in Houston, she has been honored by the National Institutes of Health for her pioneering vaccine work.

But she began challenging federal vaccine policy six years ago, after her brother and a medical student who worked for her developed severe complications following a series of hepatitis B shots.

Her brother developed severe joint and muscle pain, fatigue, vision impairment and multiple sclerosis-like symptoms. "He hasn't been out of bed since," she says.

The lab worker lost vision in one eye three weeks after her second injection and ended up in the hospital for two months after her third booster.

Alarmed, Dunbar scoured the medical literature on adverse reactions to the shot, the nation's first genetically engineered vaccine made with recombinant DNA. She found 121 articles in medical journals from around the world listing a variety of adverse reactions, including multiple sclerosis, rheumatoid arthritis, optic neuritis, Bell's Palsy, Guillain-Barré Syndrome and diabetes. In addition, Dunbar insists, a dozen specialists confirmed that her brother had suffered a classic adverse reaction to the vaccine.

Eventually, Dunbar filed a Freedom of Information (FOI) request for all reports from the Food and Drug Administration's (FDA) Vaccine Adverse Event Reporting System (VAERS). "I was overwhelmed by the thousands of reports I received, hundreds of which were identical to the reports I had filed," she told the House Government Reform Subcommittee on May 18, 1999.

Dunbar is now in the vanguard of an increasingly vocal group of parents, health workers and scientists who claim that, for a small segment of the Caucasian population, the hepatitis B vaccine may be worse than the disease. They want the government to study whether some people may be genetically predisposed to react negatively to the shot. And they want it to be voluntary, especially for newborns, which are at minimal risk of contracting the disease.

Public health officials and representatives of health-provider organizations insist that any connection between the vaccine and chronic or autoimmune diseases is purely coincidental.

"Hepatitis B vaccines are among the safest vaccines we have," Harold S. Margolis, chief of the Hepatitis Branch at the Centers for Disease Control and Prevention's (CDC) National Center for Infectious Diseases, told the congressional panel. "Several reviews have not shown a scientific association between hepatitis B vaccination and severe neurological adverse events such as optic neuritis and Guillain-Barré Syndrome. In addition, preliminary data from French and British studies have shown no significant association between hepatitis B vaccination and multiple sclerosis."

Dunbar and other critics say they have repeatedly asked the CDC for copies of those studies, but so far have not received them. "We are still waiting for the data they keep quoting," says Dunbar.

Susan S. Ellenberg, director of biostatistics and epidemiology at the FDA's Center for Biologics Evaluation and Research, echoed Margolis' comments. "At present, we have . . . little in the way of verified serious risks" from the hepatitis B vaccine, she said.

Benjamin Schwartz, acting director of epidemiology and surveillance for the CDC's National Immunization Program, points out that while more than 24,000 adverse reactions have been reported to VAERS, more than 30 million people have been vaccinated safely since the early 1990s.

Necessity of Hepatitis B Questioned

Observers say the fate of the hepatitis B vaccine is being closely watched because it is the first genetically engineered vaccine. Hundreds more are in the pipeline. The so-called Hep B vaccine has been controversial ever since 1991, when the CDC recommended that all newborns receive it before leaving the hospital. States officials then added the vaccine to their mandatory-immunization schedules for public school entrance eligibility, and immunizing newborns became standard pediatric practice.

Hepatitis B is rampant in some Asian and African countries, but in the United States it is primarily spread through infected blood or sex, and those at greatest risk of the disease are intravenous drug addicts, gay men and prostitutes, or babies of infected mothers. Why not just immunize babies whose mothers were carriers of the disease, critics ask.

"The idea of giving this vaccine to a 1-day-old baby, a newborn, is preposterous," Mayer Eisenstein, chairman of the Department of Medicine at St. Mary of Nazareth Hospital in Chicago, told a 1997 Illinois Board of Health hearing.¹

"There is no raging hepatitis B epidemic among babies in this country," says Michael Belkin, whose 5-week-old daughter Lyla Rose died in 1998 with a swollen brain 15 hours after receiving her second hepatitis B booster shot.

Critics say a baby is more likely to have an adverse reaction than it is to contract the disease. Subcommittee Chairman John L. Mica, R-Fla., cited a recent New Hampshire study he "found shocking," showing that serious reactions to the vaccine — including 11 deaths — "were 16 times greater" than incidents of the disease.²

In the early 1990s, federal immunization officials decided to immunize newborns because they felt that not enough adults in the high-risk groups were being immunized. Even though incidence of the disease had been declining for five years, "it wasn't declining fast enough for some of us," says Louis Cooper, vice president-elect of the American

... But Health Officials Say It's Safe

Academy of Pediatrics (AAP). "It appeared we had the potential to wipe this disease out, because we had a vaccine that was safe and effective."

But some critics see a more sinister motive for vaccinating hours-old newborns. "It's a perfect way to disguise any adverse reaction," says Clifford Shoemaker, a Vienna, Va.-based attorney who has represented vaccine-injured children for 30 years. "Then the parent can't say, 'Before the vaccination, my child was like this.'"

Vaccinating infants is the most effective way to combat the disease, which is a serious public health threat, health officials say. "Hepatitis B kills 4,000 to 5,000 Americans each year," Margolis told the House panel. He said national studies carried out by the CDC have shown that 5 percent of Americans — 12.5 million people — have been infected with hepatitis B, and that about 300,000 were infected with the disease every year between 1970 and 1990, including 25,000 children.

Critics say such estimates are way overblown in an effort to frighten parents. They cite the CDC's own annual report on communicable diseases, which says only about 1,000 Americans die each year from hepatitis B, and only 10,416 new cases were reported in 1997. Only 26,611 cases were reported in 1985, when the disease reached its peak, and cases have been declining ever since, according to the report.³

Health officials say the estimates seem high because only about one-tenth of actual cases get reported to the CDC, and three times as many people are asymptomatic carriers of the disease as those who actually get it.

In 1998 a group representing 15,000 French parents and others sued SmithKline Beecham, alleging, among other things, that vaccine companies and health officials had exaggerated the risks associated with hepatitis B. The manufacturer was fined about \$20,000 for causing at least one case of multiple sclerosis, and French health authorities later discontinued their mandatory hepatitis B vaccination program for adolescents.

Safety Studies Described as Inadequate

Critics contend that safety studies conducted for the vaccine were too small, too short and too limited to detect long-term adverse reactions. For instance, when he asked a manufacturer's representative to show him the evidence that the vaccine is safe for 1-day-old infants, Eisenstein said the representative told him, "We have none. Our studies were done on 5- and 10-year-olds."⁴

The drug companies' own product inserts state that the vaccines were tested on fewer than 2,000 persons, who were monitored for only five days after receiving them. And critics told the House panel that several often-cited long-term safety studies for the vaccine were conducted

on Alaskan natives or Asians — not Caucasians, who have been reporting the most adverse reactions.

In fact, the long-term studies in Asia and Alaska were done for an earlier plasma-derived conventional hepatitis B vaccine, not for the genetically engineered version. The FDA allowed the manufacturers to do "abbreviated studies" on the genetically engineered version of the vaccine "to assure they were comparably effective," says William Shaffner, chairman of the Department of Preventive Medicine at Vanderbilt University and an expert on the hepatitis B vaccine. Most mainstream scientists believe genetically engineered vaccines are safer than older versions, but others say more study is needed on their long-term impact.

"The manufacturers and public health officials keep saying there's no study proving that the vaccine is causing these adverse reactions," Belkin says. "I say back to them: 'Show us the proof that these vaccines are safe for all genetic populations.' They don't have any."

A 1994 Institute of Medicine (IOM) study also complained that no large, controlled, observational studies or clinical trials investigated the kinds of long-term adverse reactions described in the medical journals. "The lack of adequate data regarding many of the adverse events was of major concern to the committee [which] . . . encountered many gaps and limitations in knowledge bearing directly or indirectly on the safety of vaccines," the report said.⁵

Marcel Kinsbourne, a pediatric neurologist who often testifies in vaccine-injury cases, suggests that there are no long-term studies because "the best defense in a product-liability case is no research. Then the plaintiffs cannot prevail."

Margolis said several ongoing studies are investigating whether adverse events are associated with the vaccine. But he warned that case reports rarely provide a convincing link between the adverse event and vaccination.

Dunbar says she and other critics will withhold judgment on the studies until they are allowed to see actual data and all of the scientific controls used, with long-term follow-up information. But, she says, "If the studies only concentrate on ethnic, inner-city populations, they still will not prove that the vaccine is safe for all populations, especially Caucasians."

¹ Quoted in "Hepatitis B Vaccine: The Untold Story, The Vaccine Reaction," National Vaccine Information Center, September 1998.

² Quoted in John Hanchette, Gannett News Service, May 19, 1999.

³ "Summary of Notifiable Diseases, United States, 1997," *Morbidity and Mortality Weekly Report*, Centers for Disease Control and Prevention, Nov. 20, 1998.

⁴ "Hepatitis B Vaccine," *op. cit.*

⁵ "Adverse Events Associated with Childhood Vaccines," Institute of Medicine, National Academy of Sciences, 1994.

Adverse Effects of Childhood Vaccines

Scientists believe that some vaccines can cause certain diseases and adverse reactions in rare instances. In other cases, they have noted varying indications of causal links but no conclusive evidence.

VACCINES	STRONGER EVIDENCE		WEAKER EVIDENCE	
	EVIDENCE ESTABLISHES A CAUSAL RELATION	EVIDENCE INDICATES A CAUSAL RELATION	EVIDENCE IS CONSISTANT WITH A CAUSAL RELATION	EVIDENCE FAVORS A CAUSAL RELATION
Diphtheria and Tetanus Toxoids	Anaphylaxis (shock)			Guillain-Barré Syndrome Brachial neuritis
DPT Vaccine		Anaphylaxis; protracted, high-pitched screaming	Acute encephalopathy shock; unusual "shock-like state"	
H. Influenzae Type B				Early-onset H. Influenzae B disease
Measles Vaccine	Death from measles-strain viral infection			Anaphylaxis
MMR Vaccine	Thrombocytopenia; Anaphylaxis			
Oral Polio Vaccine	Polio in recipient or contact; death from polio vaccine-strain viral infection			
OPU/IPUb Vaccine				Guillain-Barré Syndrome
Rubella Vaccine		Acute arthritis	Chronic arthritis	
Hepatitis B Vaccine	Anaphylaxis			

Sources: Institute of Medicine, "Adverse Effects of Pertussis and Rubella Vaccines: A Report of the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines," (1991); "Adverse Events Associated With Childhood Vaccines: Evidence Bearing on Causality" (1994)

Continued from p. 645

- Studies linking the DPT vaccine to seizures and brain damage in rare cases. The U.S. government finally licensed a safer, but less profitable, version of the vaccine (DTaP) in 1996 — 15 years after the Japanese had begun using it.⁵

- In another series of studies, the Institute of Medicine (IOM) concluded that the diphtheria-tetanus vaccine could cause Guillain-Barré

Syndrome and death, the rubella vaccine could cause acute and chronic arthritis and the live measles and oral polio vaccines could cause viral infection and death.⁶

- A French court ruled in 1998 that SmithKline Beecham's hepatitis B vaccine had caused a child to get multiple sclerosis, prompting France to suspend compulsory hepatitis B vaccinations for schoolchildren. U.S. public health officials say there is no proof that the vac-

cine, the first genetically engineered vaccine to be mandated, causes multiple sclerosis or any other chronic or autoimmune disease.

- Mandatory inoculations with the new rotavirus vaccine, genetically engineered from a monkey-human hybrid virus and widely hailed as a breakthrough in the prevention of dehydrating diarrhea, were suspended in 1999 after a significant number of inoculated infants suffered from life-threatening

How Parents Can Prevent Vaccine Reactions

Parents can help to prevent vaccine deaths and injuries by asking themselves these eight questions before having their children vaccinated, according to the National Vaccine Information Center. The NVIC is a nonprofit educational organization founded in 1982 to prevent vaccine reactions by improving information about vaccines available to the public.

- Is my child sick right now?
- Has my child had a bad reaction to a vaccination before?
- Does my child have a personal or family history of vaccine reactions; convulsions or neurological disorders; severe allergies; immune system disorders.
- Do I know if my child is at high risk of reacting?
- Do I have full information on the vaccine's side effects?
- Do I know how to identify a vaccine reaction?
- Do I know how to report a vaccine reaction?
- Do I know the manufacturer's name and lot number?



Centers for Disease Control and Prevention

bowel blockages.

- The Food and Drug Administration (FDA) acknowledged in 1999 that vaccines expose infants in the first six months of life to levels of the neurotoxin mercury considered unsafe by the Environmental Protection Agency (EPA). The CDC recommended a voluntary transition to mercury-free vaccines by next spring, despite urgings from some scientists and parent groups that it should be phased out faster.

- The CDC recommended in January that live, oral polio vaccines be replaced by the inactivated, injectable version because the live vaccine caused up to 10 cases of polio a year among children and their caretakers.

- Scientists are studying whether vaccines produced from animal tissue, like monkey and bovine cells, can transfer previously undetected viruses that can cause cancer or other diseases in humans.

In addition, vaccine-safety advocates cite the warning flags sent up by the government's own Vaccine Adverse Event Reporting System (VAERS). It receives more than 10,000

reports annually, but the FDA says that only about one-tenth of actual cases are reported for all health conditions. (*See table, p. 648.*) The NVIC's own survey found that only 2.5 percent of New York doctors report death or disabilities that occur after a vaccination.

But the CDC's Schwartz says VAERS is not a reliable indicator. "Just because someone reports something doesn't mean that the condition was caused by the vaccine," he says. "It only means that it could possibly be caused by the vaccine."

Moreover, vaccine supporters point out, only 15 percent of VAERS reports describe events considered serious. Even for the more serious reactions, there is often only a "temporal, or time-based" association between the illness and a recent vaccination, said Surgeon General David Satcher.

Critics of vaccine policy also cite the government's National Vaccine Injury Compensation Program, which has paid more than \$1 billion to patients who claimed injury from a vaccine. But health officials say the program's stan-

dard of proof is very low, and that just because someone is compensated does not necessarily mean a vaccine caused their condition.

Vaccine-reform advocates worry that the government's accelerated childhood-immunization schedule may put some children at risk for serious adverse reactions. They say that in a dramatic departure from previously established protocols, children now get more vaccines at earlier ages, receive multiple vaccines on the same day and are vaccinated even when they are sick.

"This whole thing about hitting the newborns with all these shots before they get out of the hospital is really kind of frightening," said Arizona physician Jane Orient, executive director of the Association of American Physicians and Surgeons (AAPS).⁷

The University of Oklahoma's Kennedy says giving babies inoculations for up to nine diseases at once is "just asking for trouble," because the infant immune system is different than an adult's. "I don't even give the monkeys in my lab nine vaccines in one day."

Court Links MMR, DPT Vaccines ...

Anna had been a bright, healthy baby and had started walking at 13 months. When she had her first MMR shot (for measles, mumps and rubella) at 15 months, the pediatrician told her mother to expect a mild reaction 10 days to two weeks after the shot that might include cold symptoms or a rash.

Nine days later, Anna had a runny nose and a low-grade fever. Although her cold symptoms eventually disappeared, Anna did not return to the happy, playful toddler she had been; instead, she constantly cried and wanted to be held.

Then Anna started tripping and falling down. When her mother called the pediatrician, he told her to put ice on the leg he had injected and give her Tylenol.

Over the next six weeks, Anna lost the ability to sit or walk. One doctor suggested that Anna be seen by a psychologist to determine why she was refusing to walk. A neurologist her mother consulted immediately hospitalized Anna with a suspected tumor on her spinal cord. The MRI scan of her brain showed there were lesions in the white matter of her brain; the other tests came back negative.

Anna continued to deteriorate. When she tried to sit up, she would flop over like a rag doll. Nearly every week

she would run a fever for several days. Lab tests turned up nothing. In a four-week period, she endured seven spinal taps.

Eventually Anna was put on steroid therapy, which helped her to regain her personality and stopped her brain from further deteriorating. However, her lower body remained paralyzed.

Today, 8-year-old Anna attends third grade in a wheelchair. As she becomes taller and heavier, it is hard for her to sit upright. Anna loves to swim underwater because she says it makes her feel free.

In 1993, the U.S. Court of Claims in Washington, D.C., ruled that Anna had suffered post-vaccination encephalopathy following her MMR vaccination and paid a claim to her parents under the Vaccine Injury Compensation Program.

Richie's Death Followed His First DPT Shot

Richie was a thriving 2-month-old, the second son of a family in upstate New York, when he got his first DPT shot. Richie's brother had had severe reactions to his DPT shots, including high fever, uncontrollable screaming, diarrhea and vomiting, but the pediatrician

had reassured Richie's mother, a nurse, that these were "normal" reactions.



National Vaccine Information Center

Anna was a healthy baby until she received an MMR (measles, mumps and rubella) vaccination at 13 months that eventually left her paralyzed from the waist down.

But the CDC's Schwartz disputes the notion that multiple vaccinations overload an infant's immune system. "When a baby is born, it has a repertoire of white blood cells that can respond to more than 100,000 foreign substances," he says.

"It's unfortunate that people believe that [multiple vaccines harm children]," he adds, "because when a new vaccine comes along it provides a wonderful opportunity for us to prevent additional diseases. It would be horrible if some unfounded fears led to underutilization of these important products."

According to a CDC fact sheet on vaccine safety, a multiple vaccination gives the child maximum protection with the least trauma while saving parents both time and money. In fact, researchers want to combine even more antigens into single injections — such as adding chickenpox to the MMR vaccine.

Critics bristle at such plans, arguing that safety considerations often take a back seat to economic concerns and the federal push for higher immunization rates. Rick Rollens, a parent in Granite Bay, Calif., whose son became autistic, says that at fed-

eral advisory committee discussions on accelerating the immunization schedule, "the discussions have nothing to do with safety and everything to do with maximizing as many medical services as possible when you have the child at the hospital or in the doctor's office."

Schwartz says that if a child has had an allergic reaction to a vaccine, it should not get a booster injection of that vaccine.

Public health authorities are constantly concerned about vaccine safety, Duke University's Katz says.

... in Children's Paralysis, Death

By the evening of the day Richie got his shot, the area around the injection began to swell, but Richie's mother remembered how his brother's leg had swelled. Then Richie's hip turned red and purple. Still, Richie didn't have a fever and continued to drink from his bottle so Richie's mother didn't worry.

In the morning Richie woke up screaming "like a cat in pain." After a nap, Richie woke up crying again, but his cry was weaker. He had a bottle and fell back to sleep. An hour later, he had severe diarrhea with mucous in his diapers. Then he fell asleep again until he again woke up crying.

When his mother picked him up, he had soaked through two receiving blankets and gave off a musty, pungent odor. While she washed him, she noticed he was limp and staring at her with "dark eyes."

Richie slowly drank eight ounces of water from his bottle and later that day had three more diapers with diarrhea in them. His leg still seemed to be sore. When he slept, his fingers twitched slightly. Later he gagged on his bottle and vomited a little. Richie's Mom remembered how Richie's brother had had diarrhea and vomiting after his shots, so she didn't worry.

That evening, while Richie was having a bottle, he suddenly stopped sucking and his breathing became shallow and irregular. Alarmed, his mother described the

symptoms to the doctor and asked him to meet them at the emergency room. The doctor said it wasn't necessary, but within minutes Richie had died in his mother's arms as his father and 6-year-old brother watched. It had been 33 hours since a doctor had injected him with his first DPT shot.

Fourteen weeks after his death, Richie's parents received the autopsy report describing an enlarged thymus gland (the gland that helps regulate the immune response in the body) as well as congestion and edema in the lungs and brain.

Not satisfied with the autopsy findings, Richie's parents talked with the coroner, who suggested the death had been caused by sudden infant death syndrome (SIDS). But they knew it wasn't SIDS. Armed with the *Physician's Desk Reference* and studies on DPT vaccine, his mother described in detail exactly what had happened. The coroner listened to her and noted on the death certificate that death had been caused by "Irreversible shock due to a probable reaction to DPT."

Richie's family filed a claim with the Vaccine Injury Compensation Program and, as Anna's case, the U.S. Court of Claims awarded them compensation, ruling that the vaccine had caused his death.¹

¹ See Harris Coulter and Barbara Loe Fisher, *A Shot in the Dark* (1991).



National Vaccine Information Center

Two-month-old Richie died 33 hours after receiving his first DPT vaccination. The coroner attributed death to "irreversible shock" from the vaccine.

The move to eliminate mercury from vaccines "didn't come from the anti-vaccine people," he says. "It came from the vaccine establishment. They made that decision even though there was no evidence at all that the trace amounts in vaccines are harmful. It was just a theoretical risk."

But James Turner, a Washington consumer lawyer, says the vaccine establishment has known about mercury in vaccines for nearly three decades. "I remember attending hearings in 1973 at which the danger from mercury in vaccines was discussed."

Is the government doing sufficient research on vaccine safety?

Parents of vaccine-injured children say that because neither the government nor the manufacturers study the potential long-term or chronic adverse effects of vaccines, they are not recognizing the true scope of the damage done by vaccines.

"Rates of asthma and attention-deficit disorder have doubled; diabetes and learning disabilities have tripled; and most states have experienced a 300 percent or more increase in autism," says Fisher, who has

served on the National Academy of Science and Food and Drug Administration vaccine advisory panels.

"The whole problem with vaccine-adverse effects is that there are too many hypotheses without scientific support," Oklahoma's Kennedy says. "We need to support careful scientific investigations in this area, but unfortunately the federal government and the pharmaceutical companies don't agree and don't support such efforts."

"They are not doing the studies they need to do to put some of these fears to rest," says AAPS's Orient.

Is Your Child Getting the Right Vaccine?

Last year the Centers for Disease Control and Prevention (CDC) recommended an unprecedented number of new vaccine formulas. But this doesn't guarantee that your doctor is using the safest medicine available. According to the National Vaccine Information Center, here's what parents should ask before their children get shots:

Which polio vaccine do you use? Between 1996 and 1999, children usually received two kinds of polio vaccines: two doses of inactive injected vaccine and then two doses of an oral version containing the live virus. Live polio cells can pass through the baby's stool, and in rare cases they cause polio in the child or his caretaker. In January, the CDC recommended that children get all four doses of the inactive vaccine. Most doctors made the switch, but it's still prudent to double-check.

Are you using the new DTaP vaccine? Although sales of the older, cheaper DPT vaccine are dropping, it has not been taken off the U.S. market. Your doctor may still be ordering the older version. So far, the new vaccine really does seem to have fewer side effects. In one study, only 3 to 5 percent of DTaP recipients developed a fever, compared with 16 percent of the patients who received the old formula. Be sure to ask for DTaP when you schedule your appointment. Then, when you're in the office, ask to see the actual vial the vaccine comes in.

Can I get mercury-free vaccines? At least one brand of every vaccine is now made without thimerosal, a mercury-based preservative. Make sure your doctor is using those brands. If he or she isn't, ask the doctor to order them for you. (For a complete list, call the CDC at (800) 232-2522.)

What are the symptoms of a vaccine reaction? After vaccination, you should know how to monitor your child for signs and symptoms that a vaccine reaction is taking place so that you can call your doctor. Depending on the vaccine or combination of vaccines given, signs and symptoms of a vaccine reaction can vary from minutes to several weeks or months. Most adverse reactions to DPT or DTaP vaccine occur within the first 72 hours to seven days and include high-pitched screaming or uncontrollable crying; excessive sleepiness; high fever; unusual twitching, shaking or stiffening of the body; limpness and inability to react normally to stimulation that may signal seizures or brain inflammation. With other vaccines, such as MMR, it can take several weeks for those signs to develop.

What about revaccinating? If your child's health has deteriorated severely following vaccination and you believe a vaccine reaction has taken place, you should consult several health professionals before revaccinating. A previous vaccine reaction can increase a person's risk of having a more severe reaction when more vaccine is given. You have the right to defer vaccination if you believe your child is at increased risk of having a vaccine reaction until you are confident about the medical advice you are being given.

How do I report a vaccine reaction? You should keep your own records of vaccinations your child has received and whether any adverse symptoms occurred. No detail is too small to record. If your child had a severe health problem after vaccination, you have the right to report it to the Vaccine Adverse Event Reporting System (VAERS) — even if your doctor denies it is because of the vaccination and refuses to file such a report. Contact VAERS at (800) 822-7967. The National Vaccine Information Center (NVIC) also accepts vaccine reaction reports and serves as a consumer watchdog on the VAERS system. You can report adverse vaccine events to NVIC at www.909shot.com.

What about compensation for vaccine-related injuries? If your child has been injured by vaccination, you can seek compensation under the National Childhood Vaccine Injury Act of 1986. Call (202) 219-9657 for information.

"There are so many unknowns that the children receiving these immunizations really are experimental subjects." ⁸

"A genuine and vigorous effort to identify risk factors would help dissipate the impression that some citizens have formed that vaccine safety is not a high priority," Marcel Kinsbourne, an expert on vaccine injury, told the House Government Reform Committee last year.

Microbiologist Howard Urnovitz, founder of the Chronic Illness Research Foundation, in Berkeley, Calif., says the government's compensation figures are understated and its cost-benefit analyses skewed because they don't take into account the cost of treating chronic diseases that may be triggered by vaccines. The government "must study whether chronic illnesses, such as learning and behavior disorders, autism, arthritis,

cancer, diabetes, chronic-fatigue syndrome and multiple sclerosis, are triggered by vaccines," he says, "and then calculate the cost of treating those diseases when it makes its cost-benefit analyses."

"They say there's no scientific evidence to prove that vaccines cause chronic diseases, but they won't fund any research in that area either," Urnovitz says. "If you don't look for something, you won't find it."

The government is also not looking for evidence that some children may be genetically predisposed to react negatively to a particular vaccine, Fisher says. "We've seen cases in which three or four children in one family will have already been injured by a particular vaccine, but the health officials still insist that other children in the family be vaccinated or that the already-injured children receive boosters," she says.

"The government has no business forcing vaccinations on these people, or adding more vaccines to the schedule while refusing to do research to discover the genetic markers that would identify who is susceptible to adverse reactions," she says. "It's unconscionable."

The University of Oklahoma's Kennedy says certain vaccines should not be given to individuals with a family history or predisposition to autoimmune diseases, such as lupus, rheumatoid arthritis or multiple sclerosis.

But the CDC's Schwartz says, "There is no good data to support the concept of a familial risk of adverse events. In contrast, we know that vaccines protect against real and significant diseases. In the absence of scientific data, we believe vaccination is the best policy in such a case."

However, the CDC is in the process of setting up a better way to check on adverse events reported to the VAERS, Schwartz says. "We will be following up on people who report certain conditions to VAERS," he says, including neurological conditions or multiple sclerosis. "We know that there are concerns that this is one of the conditions where a genetic predisposition might be involved."

Meanwhile, Schwartz insists, the CDC is looking at possible connections between vaccines and chronic diseases. "The implication that we are ignoring things is not true," he says.

Schwartz warns, however, that just because an allegation is made about a vaccine does not mean that a full-

blown study will be done to determine a connection. The first step is to look at whether a certain condition is more prevalent in a vaccinated population, compared to an unvaccinated population, he says. To do that, the agency established the "Vaccine Safety Datalink," which allows officials to check the health records from four large West Coast managed-care companies.

The CDC is also entering into a contract with the IOM and the National Institutes of Health (NIH) to work with an independent panel being set up to look at emerging issues in vaccine safety, including possible links between vaccines and autism. (*See sidebar, p. 660.*)

Rollens, the California father of an autistic child, will be watching to see if that panel investigates the possible connection between vaccine ingredients and autism.

"Vaccines contain numerous active agents, such as live viruses, bacterial agents, preservatives, and toxic chemicals, including formaldehyde and mercury, as well as human, animal and plant [genetic material]," Rollens told the House Government Reform Committee in July. "[Yet] not a single safety study has ever been done on the short-term or long-term effects of the interaction of this potent cocktail on the developing brain and immune systems of our children."⁹

He called manufacturers' safety studies, which range from a few days of surveillance to a couple of weeks, "woefully inadequate," and said, "I must ask the public health community: Where is the science?"

Oklahoma's Kennedy also complains that manufacturers sometimes do not do sufficient research before vaccines are licensed. Vaccines have gone "directly from rodent studies into human clinical trials," bypassing the monkey phase of testing, he told the committee. Or when problems cropped up during the monkey phase, "these were ignored and the prod-

uct went into human clinical trials anyway," he said.

Unfortunately, says Neal A. Halsey, director of the Institute for Vaccine Safety at Johns Hopkins University School of Hygiene and Public Health, just when the FDA needs highly qualified scientists and resources to address increasingly complex vaccine-safety issues, the research budget for the agency's Center for Biologics and Evaluation Research has been drastically reduced.¹⁰

"Safe, effective vaccines save lives," Rep. Dan Burton, R-Ind., chairman of the committee, responded. "Vaccines that have not been thoroughly tested and reviewed can be dangerous." He cited the rotavirus vaccine as a good example: "The government and manufacturers ignored the warning signs. A lot of babies were injured and required surgery. One baby died before the vaccine was pulled from the market."

Do vaccine manufacturers have too much influence over government immunization policy-makers?

Federal immunization policy emanates from two advisory committees. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), recommends whether new vaccines are safe and effective. The CDC's Advisory Committee on Immunization Practices (ACIP) recommends which vaccines should be included on the national Childhood Immunization Schedule, which is usually automatically adopted by most states. They then require all children to have the specified vaccinations before entering school.

Critics have long claimed that certain members of those committees have incestuous ties with agencies that stand to gain power or manufacturers that stand to reap enormous profits from federal vaccine policy. And even when members recuse

themselves from specific votes, they are permitted to participate in discussions, and thus influence the decisions, critics say.

“Vaccines are the only substances that a government agency mandates a United States citizen receive,” said Burton during a hearing of his committee on June 15. “Families need to have confidence that the vaccines that their children take are safe, effective and truly necessary. Doctors need to feel confident that when the FDA licenses a drug, that it is really safe and that the pharmaceutical industry has not influenced the decision-making process. Has that trust been violated?”

Burton’s committee staff investigated how the two advisory panels had approved the ill-fated rotavirus vaccine.

The investigation found that in clinical trials five children out of 10,000 developed bowel obstructions after taking the vaccine, Burton said. “There were also concerns about children failing to thrive and developing high fevers, which, as we know, can lead to brain injury,” he added. Despite these concerns, and others, both advisory committees unanimously approved the vaccine, he said.

Burton’s staff also examined the finances of advisory committee members and found that:

- The chairmen and members of both advisory committees own stock in vaccine-manufacturing companies, and some members of both advisory committees own patents for vaccines affected by decisions of the committee.

- Three out of five of the members of the FDA’s advisory committee who voted for the rotavirus vaccine had conflicts of interest that were waived.

Burton also noted several specific examples of potential conflicts of interest, including:

- John Modlin, chairman of the rotavirus working group of the CDC ad-

visory group, owned \$26,000 worth of stock in Merck, one of the largest manufacturers of vaccines, and serves on Merck’s Immunization Advisory Board.

- Children’s Hospital’s Offit, a member of the CDC advisory committee who voted to recommend adding the rotavirus vaccine to the Vaccines for Children program, holds a patent on a rotavirus vaccine and receives grant money from Merck to develop it.

- Harry Greenberg, chairman of the FDA committee, owns \$120,000 worth of stock in Aviron, a vaccine manufacturer. He is also a paid member of the board of advisers of another vaccine manufacturer and owns \$40,000 worth of its stock. This stock ownership was deemed not to be a conflict and a waiver was granted. To the FDA’s credit, Burton noted, Greenberg was excluded from the rotavirus discussion because he holds the patent on the rotashield vaccine.

If panel decisions on all vaccines on the national immunization schedule had as many conflicts as those discovered for the rotavirus vaccine, Burton said, “then the entire process has been polluted and the public trust has been violated.”

Linda A. Suydam, senior associate commissioner for the FDA, responded that the agency has given high priority to selecting the most qualified clinical and scientific experts for its advisory committees and to “rigorously complying with the statutes and regulations governing these advisory committees.” They are often pre-eminent scientists in their field, she said, and since academic biomedical research in the United States today is increasingly financed by industry, “most active researchers in the private sector have some ongoing or past relationship with regulated industry.”

If the FDA were to exclude any scientist with a relationship with industry from its advisory committees, “We would not get the top scientists

in the field, and the recommendations of the advisory committees would not be of the highest scientific nature, with a likely impact on public health,” she said.

Dixie Snider, the CDC’s associate director for science, said each committee member is required to report stock ownership, honoraria, employment, general partnership interests, contracts and receipt of grant funds that they — or their spouse or minor children — have had within the past 12 months. If members do have a potential or actual financial conflict, she says, they may be granted a limited waiver to participate in committee discussions but must publicly disclose relevant interests at the beginning of each meeting and abstain from votes involving those interests.

Offit says his relationships with pharmaceutical companies don’t cloud his judgment. “When pharmaceutical companies pay me to speak about vaccines, they do it via unrestricted educational grants,” he says. “They have no input in what I say, nor would I ever allow that to happen. If I think a vaccine has certain weaknesses, I say it. Never have they said, ‘Wait a minute, this is not what we want people to hear.’”

Duke University pediatrics Professor Katz, who has served on immunization committees of the CDC, WHO, IOM and FDA, says, “Government doesn’t fund clinical studies of vaccines. Industry does. And nearly everyone who has ever been involved in developing a vaccine has been involved in a clinical study funded by industry.”

Nevertheless, he says, “People are much more sensitive to this issue now than they were 10 years ago. In the past, a lot of us did take consultation fees.”

But Katz says now he does not take any honoraria, “and I make sure neither I nor any members of my family have financial interests in vaccine companies.”

Should vaccines be mandatory for all?

As questions about vaccine safety persist, the debate over whether some parents should be allowed to exempt their children from mandatory vaccines has intensified. It's a debate that pits personal freedom of choice on one side and public health and safety on the other.

All states require children to get all mandated shots — based on the federal immunization schedule — before they can attend school, or day care, in some states. Each state also allows medical exemptions for those with immune system problems, who have allergic reactions to vaccine constituents or who are moderately or severely ill. Fifteen states allow philosophical exemptions, and all states except two allow religious exemptions.

A small but increasing number of parents are seeking exemptions from some or all vaccines. They argue that until there is more convincing scientific evidence that vaccines are safe, they prefer to decide for themselves which, if any, vaccines their children will receive.

Hundreds of military men and women are also caught up in the debate. They have chosen retirement or court-martial rather than be vaccinated with a controversial anthrax vaccine.

But with a new push for higher vaccination rates, some say local health departments and managed-care firms have increased the pressure on non-complying parents.¹¹ Uninoculated children are being kicked out of school. Doctors are balking at treating patients who refuse to have their kids vaccinated; others

report non-compliant parents to social service agencies, which then try to charge the parent with neglect.

Politicians have gotten into the picture as well. States have begun withholding portions of welfare checks from mothers who do not inoculate their children. Members of Congress have suggested disallowing federal income tax exemptions for unvaccinated children.



Centers for Disease Control and Prevention



Centers for Disease Control and Prevention

Parents' fear of polio in the 1940s and '50s was fed by news stories and pictures of children encased in iron lungs, which helped them breathe (top). After a massive nationwide immunization effort, polio cases fell by 90 percent.

The debate has grown even testier as the CDC has mandated vaccines for chickenpox and hepatitis B, which many parents consider non-essential. After all, they say, chickenpox is only a mild discomfort for most children,

and hepatitis B is transmitted through contaminated blood, dirty needles or risky sexual activity. Yet hundreds of recipients say they have suffered serious, sometimes permanent, adverse reactions from the hepatitis vaccine, a claim public health officials say is unproven.

“With hepatitis B vaccine, the case for mandatory immunization with few exemptions is far less persuasive than with smallpox or polio vaccines, which protected against highly lethal or disabling, easily transmissible diseases,” the AAPS’s Orient says. (See sidebar, p. 646.)

Absent a public health emergency, “People should have the right to choose whether to get all these new vaccines,” says consumer lawyer Turner, who is helping to organize a new group, Parents and Professionals for Vaccine Choice.

Orient complains that mandating vaccines profoundly changes the relationship between the patient and doctor. “The [vaccine] manufacturer and the physician administering [it] are substantially relieved of liability for adverse effects,” she says, and the physician “becomes an agent of the state.”

“I have heard reports of physicians threatening to call Child Protective Services to remove the child from parental custody if a parent refused a vaccine,” even after the child had reacted negatively to an earlier dose of the vaccine, Orient says.

She contends that mandating vaccines marks a fundamental change in the concept of public health. Traditionally,

individuals were quarantined only when they had contagious diseases that posed “a clear and present danger to public health,” she says. “Today, a child may be deprived of his liberty to associate with others or his

right to a public education simply because of being unimmunized.”

And that’s just as it should be, says Offit of Children’s Hospital. “It is no more your right to catch and transmit a potentially fatal illness than it is your right to run a red light,” he says.

“Parents should not be able to get their kids exempted from vaccines,” he says. “The notion that one creates a risk-free situation by not vaccinating is incorrect. It is not a medically neutral thing. You are just creating a different risk.” He cites a 1991 outbreak of measles in Philadelphia, which centered on a fundamentalist church where most children weren’t immunized. Some of the children from the church died, he says, but so did two other children who lived nearby, who were too young to be immunized.

“As long as the great majority of children receive their vaccines, we will be able to maintain our current level of disease control,” Duke University’s Katz says. But if the level of community protection drops significantly, “we instantly return to a past era when epidemics were an accepted part of life.”

The nation experienced that during 1989-91, when immunization rates dropped and there was a measles outbreak, he said. There were 55,622 cases of measles, mainly in children younger than 5, more than 11,000 hospitalizations and 125 deaths. ■

BACKGROUND

Early Breakthroughs

The first vaccine breakthrough in modern times came in 1796, when Edward Jenner, an English country physician, noticed that dairymaids exposed to the milder disease cow-

pox were immune to smallpox. He took some fluid from a patient’s cowpox sore and later introduced it into a scratch in the arm of an 8-year-old boy. Forty-eight days later, when Jenner exposed him to smallpox, he resisted the infection. Jenner named his substance “vaccine” after the Latin word for cow.

Another breakthrough came in the late 19th century, when Louis Pasteur, a French chemist, developed chemical techniques to isolate viruses and weaken their effects so they could be used as vaccines.

Yet vaccination continued to provoke controversy. Pasteur’s first administration of rabies vaccines to humans was strongly protested by physicians and the public, and efforts to immunize British troops against typhoid at the turn of the century were bitterly opposed despite the serious risk of typhoid faced by troops serving in the Boer War in South Africa.¹²

By the turn of the century, other scientists had developed “killed” vaccines against typhoid, plague, rabies and cholera. By the mid-1920s, vaccines had been developed against diphtheria — an often-deadly childhood disease characterized by a severe inflammation of the throat — and pertussis, or whooping cough, another often-fatal childhood disease characterized by a loud “whooping” sound as the victim struggles to get air into the lungs after violent fits of coughing.

Children and parents of the 1940s and ’50s especially dreaded paralytic polio, which could paralyze arms, legs or respiratory muscles. News stories showed children with metal braces on their legs or encased in the so-called iron lungs that helped them to breathe.

Two teams of scientists led by Jonas Salk and Albert Sabin each developed a polio vaccine. The Salk vaccine, using killed viruses, was licensed in 1954 and used in mass-immunization campaigns. Within six years, polio cases dropped 90 percent.

But the Salk vaccine did not provide complete immunity against all three polio viruses. By 1961, Sabin had developed an oral vaccine that did, using a live, attenuated virus. It all but replaced the injectible Salk version in the United States. But because it used a live virus, about a dozen persons a year contracted polio from the vaccine or from being exposed to a recently vaccinated child. Consequently, public health officials decided last January to phase out the live, oral vaccine.

By the 1960s, routine vaccination was no longer controversial among the public and the medical community, and live-virus vaccines had been developed for measles (1963), rubella/German measles (1966) and mumps (1968).

Mandatory Vaccinations

To be effective, vaccination depends on universal immunization. Otherwise, anyone who is not immunized can contract a disease and spread it to others. State laws requiring immunization date from the early 1800s, when Massachusetts required smallpox vaccinations. Britain established the principle of universal free vaccination for smallpox three years later. In recent times in the United States, local immunization laws aimed at schools and licensed day-care began with efforts to eliminate measles in the 1960s and ’70s.

Opposition to mandatory vaccinations — largely based on religious, legal, medical or safety grounds — emerged almost as soon as they were implemented. In 1905, the U.S. Supreme Court upheld compulsory-vaccination laws, but anti-vaccination sentiment prevailed in some states.¹³

Nonetheless, the incidence of smallpox continued to decline. The United States reported its last natu-

STD Vaccines for Children May Be Next

The Institute of Medicine and the National Academy of Sciences last year released a report on new vaccines being developed for sexually transmitted diseases and other infectious diseases that may be recommended for adults or children of various ages within the next 20 years. The following vaccines are among those in the works:

- **Cytomegalovirus vaccine.** Cytomegalovirus, a member of the herpes virus group, is spread through blood transmission or sexual activity. May be recommended for all 12-year-olds.
- **Influenza vaccine.** Guards against certain strains of the flu virus. May be recommended for all children and adults.
- **Streptococcus pneumoniae vaccine.** This type of pneumonia is caused by bacteria. May be recommended for all infants.
- **Chlamydia vaccine.** Chlamydia, a sexually transmitted disease, is a type of bacteria that causes genital infections. May be recommended for all 12-year-olds.
- **Hepatitis C virus vaccine.** Hepatitis C is transmitted primarily through infected blood. The U.S. blood supply was contaminated with hepatitis C virus before routine screening was performed. May be recommended for all infants.
- **Herpes simplex virus vaccine.** This virus, transmitted sexually, causes genital, oral and other lesions on the body. May be recommended for all 12-year-olds.
- **Human papillomavirus vaccine.** This virus, transmitted sexually, causes genital warts. May be recommended for all 12-year-olds.
- **Neisseria gonorrhoeae vaccine.** Gonorrhea, another sexually transmitted disease, is a genital-tract infection caused by a bacteria. May be recommended for all 12-year-olds.
- **Respiratory syncytial virus vaccine.** This virus causes the common cold as well as more serious respiratory infections. May be recommended for all infants and 12-year-olds.

Source: National Vaccine Information Center

rally occurring case in 1949. In 1971, routine vaccination for smallpox was discontinued.

By contrast, the polio vaccine resulted in an immediate push for federal action to make the vaccine widely available. After Salk reported positive results from his vaccine in 1955, members of Congress from both parties urged the government to distribute the vaccine itself or help the states.

The Republican administration of Dwight D. Eisenhower branded a Democratic-sponsored bill for universal free vaccines as a form of socialized medicine. By August, Congress had drafted a compromise measure, the Poliomyelitis Vaccination Act, which provided \$28 million to the states for free universal polio vaccines.

Over the next 45 years, the nation would experience a cyclical pattern: Disease risk would appear to dimin-

ish thanks to immunization; then politicians would cut back on immunization funds; vaccination rates would drop, followed by disease outbreaks; then there would be an outcry for more funding for immunizations.¹⁴ For example, polio aid was curtailed in 1957, only to be revived in 1960 after outbreaks of the disease in several cities. To provide broader assistance, President John F. Kennedy asked Congress in 1962 to authorize aid to states to buy vaccines against diphtheria, whooping cough and tetanus, as well as polio.

DPT Under Attack

By the early 1980s, infectious epidemics that killed hundreds of

children a year had drifted into distant memory, and some parents were beginning to start questioning the need for massive inoculations.¹⁵ A small number of those parents felt that their children had been damaged by vaccines that were not as safe as they could be — particularly the DPT shot.

Among them was the NVIC's Fisher. In 1980 her toddler Chris suffered a severe reaction after his fourth dose of DPT and an oral polio vaccine. After studying the medical literature on vaccine reactions, she learned that he had suffered convulsions and collapsed shock, a rare, adverse reaction to a DPT shot.

After that, Chris was different — physically, mentally and emotionally. "He no longer knew his numbers or the alphabet, he had poor concentration levels, constant ear infections and diarrhea that would not stop,"



English physician Edward Jenner (left) coined the term “vaccine” after discovering how to protect against smallpox. Jonas Salk (center) led the team that developed the first polio vaccine in 1954 in Pittsburgh. Albert Sabin (right) developed an improved oral polio vaccine in 1961 at his University of Cincinnati lab.

Sources: Centers for Disease Control and Prevention, Archive Photos and Corbis-Bettmann Photos.

Fisher says. “He became emaciated and stopped growing.”

Fisher learned that similar adverse events related to the DPT shot in Japan, Sweden and the United Kingdom had led to drops in immunization rates in those countries, and subsequent epidemics of pertussis.

In 1982, Fisher and other mothers founded the advocacy group that evolved into the NVIC. Their goal: get Congress to demand safer DPT vaccines.

By then Japan was already using a safer version of the vaccine, produced, ironically, with technology developed by the NIH. In fact, a U.S. company, Eli Lilly, had marketed the safer version in the 1960s and '70s, but when Wyeth bought Lilly in 1976, it discontinued the product. A 1977 Wyeth internal document said producing the safer DPT shot would result in “a very large increase in the cost of manufacture.”¹⁶

“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. health officials. “What we are faced with is going

from a vaccine that costs literally cents to produce to one that I believe is going to cost dollars to produce.”¹⁷

By the mid-1980s, at least 300 lawsuits had been filed against U.S. DPT manufacturers. “They knew that the older pertussis vaccine was making kids sick,” recalls Ted Warchafsky, a Milwaukee attorney who represented parents seeking damages.

In 1991, Fisher documented the development of the DPT vaccine in *A Shot in the Dark*, explaining how the more toxic whole-cell pertussis portion of the shot was causing so many problems, and why a safer, acellular version had not been widely marketed in the United States.

“When word went out that I was writing that book, people started leaving packages of documents, with transcripts from government meetings, on my doorstep in the middle of the night,” Fisher says. “One physician told me, ‘You are on the right track, but I will never stand up beside you publicly and say that.’”

Fisher says “it was all about money,” but, in fact, health officials and drug firms also wanted to keep the price of vaccines low enough for impoverished Third World governments.

“It’s the same for every . . . vaccine,” said Stanley Plotkin, medical and scien-

tific director for Pasteur-Merieux-Connaught, a Paris-based pharmaceutical company. “Research costs are recouped in North America and Europe, and the vaccines are sold in the developing world at much, much lower margins.”¹⁸

Stainer went on to ask at the 1982 meeting whether it was right to switch to the safe DPT vaccine: “Are we . . . going to have two vaccines, one for the wealthy and one for the rest? I don’t think any of us want that.”

But that is exactly what has happened. The U.S.

government stopped purchasing the whole-cell DPT vaccine in 1996 and recommended that doctors switch to the acellular DTaP version. Only about 6-7 percent of the pertussis vaccines in the U.S. still contain the whole-cell DPT. But it is widely used in the Third World.

But back in the mid-1980s, faced with increasing lawsuits, one of the three DPT producers stopped producing it, and the remaining manufacturers found it was increasingly difficult to obtain liability insurance. “Shortages of the vaccine occurred in some areas of the country, and prices escalated dramatically,” Duke University’s Katz recalled.¹⁹

But instead of selling the safer Japanese vaccine, Warchafsky says, U.S. manufacturers asked Congress to limit their liability for adverse reactions to any vaccine mandated by the government, hinting they might stop producing children’s vaccines without it.

“And then the industry started buying up the experts,” he contends, citing the example of James Cherry, a widely recognized pertussis expert who has served on both the ACIP and the AAP’s vaccine advisory committee.

Cherry was a principal author in a 1978-79 study sponsored by the FDA

Continued on p. 664

Chronology

1900-1940s

Large-scale immunization programs launched in U.S.

1905

U.S. Supreme Court upholds state law mandating smallpox vaccinations.

1906

Vaccine against pertussis (whooping cough) is developed.

1921-1928

Effective vaccine against diphtheria is developed.

1950s-1960s

Vaccines against polio and other diseases are developed. Congress approves aid to ensure free polio vaccinations.

1954

Jonas Salk develops first polio vaccine in United States. An oral vaccine later developed by Albert Sabin is approved in 1961.

1955

Poliomyelitis Vaccination Assistance Act funds free distribution of polio vaccine.

1962

Vaccination Assistance Act authorizes government purchase of vaccines at negotiated prices and provides grants to states for mass vaccinations.

1963

Measles vaccine is licensed; incidence of the disease drops by 95 percent in U.S. within five years.

1970s-1980s

Decrease in government support for immunizations leads to new outbreaks of some diseases. U.N. begins world-wide immunization program.

1981

Japan licenses safer DPT shot, the acellular DTaP shot, partially developed at the National Institutes of Health.

1982

Vaccine against hepatitis B becomes available. Parents of vaccine-injured children establish Dissatisfied Parents Together to push for safer DPT vaccines. It eventually becomes the National Vaccine Information Center.

1986

Vaccine Injury Compensation Act establishes a no-fault compensation system for persons who suffer serious side effects from legally required vaccination.

1987

Vaccine against *Haemophilus influenzae* type B (Hib), the leading cause of bacterial meningitis, is licensed.

1989-1991

U.S. measles epidemic causes 132 deaths.

1990s-2000s

President George Bush increases funding for immunizations but is faulted for not doing more. President Clinton proposes plan to assure universal access to vaccines for poor and underinsured children.

February 1991

Federal Centers for Disease Control and Prevention (CDC) recommends universal infant immunization with the first genetically engineered vaccine — for hepatitis B.

June 1991

President Bush refuses request for extra funds to boost lagging immunizations.

April 1, 1993

Clinton administration introduces plan to increase immunization rates but later modifies provisions for universal government purchase of vaccines.

1996

CDC's Advisory Committee on Immunization Policy recommends that doctors use the safer DTaP shot instead of the whole-cell pertussis shot.

1998

French court rules that SmithKline Beecham's hepatitis B vaccine had caused a child's multiple sclerosis. France suspends compulsory hepatitis B vaccinations for teens.

1999

New genetically engineered rotavirus vaccine is pulled off market after significant numbers of inoculated infants become seriously ill. FDA acknowledges that vaccines expose infants to unsafe levels of mercury. Congress begins hearings on vaccine safety.

2000

CDC recommends replacing "live" oral polio vaccine with inactivated injectable version because live vaccine caused up to 10 cases of polio a year.

Parents of Autistic Children . . .

An audible gasp erupted from the audience at a congressional hearing in July after a presentation by a group of parents of autistic children from New Jersey.

Their 85-page report on their exhaustive search of medical literature included a chart listing 75 symptoms characteristic of autism — such as social withdrawal, obsessive-compulsive traits, arm flapping, head banging and toe walking. Alongside those traits, they had listed 75 symptoms attributable to mercury poisoning. As they read the chart, members of the audience gasped. The two lists of symptoms were nearly identical — for all 75 symptoms.

“As a trained scientist, my reading of the mercury literature indicates that every trait that defines autism can be induced by organic mercury [poisoning],” said Albert Enayati, a chemist and president of the New Jersey chapter of the Cure Autism Now Foundation (CAN), which did the study. His son Payam developed normally until he received his DPT and MMR shots, after which he stopped talking and interacting with people and began toe walking, head banging and arm flapping.

Enayati and other parents at the hearing claimed that excessive amounts of mercury from multiple vaccines may have triggered their children’s late-onset autism, a new type of autism in which a normally developing child suddenly loses speech and social and cognitive skills. Classic autism is considered a genetic condition that exists from birth.

Theories about autism have been tested and discarded for decades. Medical associations and public health officials insist there is no scientific evidence that vaccines cause autism. However, in recent years — with rates of the disorder skyrocketing across the country — frantic parents are increasingly questioning the vaccine-autism connection.

And mercury in vaccines is not the only concern. Doctors and researchers are examining whether — for a small, mercury-sensitive segment of the population — the measles vaccine, perhaps in conjunction with mercury or other environmental

toxins, may trigger “autism-spectrum disorders” ranging from learning disabilities and attention-deficit disorders on the mild end to autism on the severe end.

The American Medical Association (AMA) recently said that up to 20 percent of children have one of a spectrum of neurodevelopmental conditions that includes autism, learning disorders and attention-deficit/hyperactivity disorder. In California, autism diagnoses soared 273 percent and diagnoses of related disorders skyrocketed 1,966 percent between 1987 and 1998. Maryland reported a 513 percent rise in autism between 1993 and 1998, and several dozen other states have reported increases of 300 percent or more.

Mercury, a potent neurotoxin linked to mental retardation, cerebral palsy and central nervous system disorders, has been used in vaccines since the 1930s, in a preservative called

thimerosal. Thimerosal is present in more than 50 vaccines and other medicines, even though it has been banned in many over-the-counter medications since the 1980s.

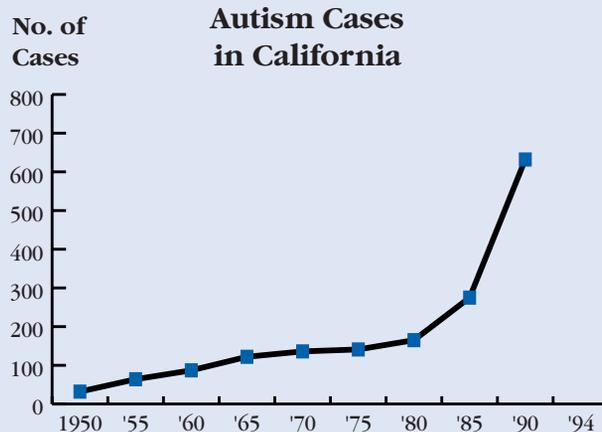
Because children in the past decade have begun receiving more vaccines at earlier ages — often multiple vaccines in a single day — concerns have arisen about how much mercury infant brains are being exposed to from vaccines.

“My grandson received vaccines for nine different diseases in one day,” said House Government Reform Committee Chairman Dan Burton, R-Ind., who said the child is now autistic. “He may have been exposed to 62.5 micrograms of mercury in one day through his vaccines. According to his weight, [that] is 41 times the amount at which harm can be caused.” And Burton added, “These vaccines are still in use.”

Lyndale Redwood, a nurse from Atlanta, told the hearing that her autistic 2-month-old son had received 125 times his allowable daily exposure of mercury after getting two infant vaccines in one day. “These large exposures

Cases of Autism Rose Sharply

*The number of autistic children seeking state services in California more than doubled in the 1980s and nearly doubled again in the first half of the 1990s.**



**More recent figures are not available because it generally takes several years after birth to determine if a child is autistic.*

Source: California Department of Developmental Services

... Blame Mercury Poisoning

continued at 4, 6, 12 and 18 months,” she said. She also discovered that the injections she received during the first and third trimesters of her pregnancy and an hour after delivery to prevent RH blood incompatibility also contained mercury. An analysis of her son’s hair revealed that he had five times more mercury than was considered safe.

Mercury is extremely toxic to developing fetal brains. In many parts of the country, pregnant mothers are advised not to eat canned tuna fish, which contains high levels of mercury. Emissions from coal-fired power plants are another major source of mercury contamination.

Parents at the hearing were particularly concerned about the impact of mercury on the brains of hours-old newborns, who, since 1991, have been immunized with a thimerosal-containing hepatitis B vaccine before they leave the hospital. They angrily demanded to know why federal agencies had not banned the use of mercury.

William Egan, acting director of the Food and Drug Administration’s (FDA) Office of Vaccine Research and Review, said, “There is no convincing data or evidence of any harm caused by the low levels of thimerosal that some children may have encountered in following the existing immunization schedule.” Furthermore, the federal guidelines for mercury exposure include margins of safety, and most vaccine exposure is within that margin of safety, he said.

Benjamin Schwartz, acting director of epidemiology and surveillance for the Centers for Disease Control and Prevention’s (CDC) National Immunization Program (NIP), says “There’s a difference between chronic, daily exposure and what a child can be exposed to on any given day.” The agency interprets the mercury guidelines as how much a person can be exposed to over six months.

Nevertheless, Egan said, even though the threat from mercury is only “theoretical,” the government last year asked manufacturers to voluntarily remove or significantly reduce by next spring the thimerosal from all vaccines routinely administered to infants. It was not banned outright in order not to disrupt the nation’s vaccine supply, he said.

As a result, said Roger H. Bernier, associate director for science at the NIP, the amount of mercury an infant may be exposed to from routine immunizations has been reduced by 60 percent in the past year. Plus, responding to concerns about newborns, the CDC recommended that physicians temporarily discontinue giving them the hepatitis B vaccine at birth until a mercury-free vaccine was available. Mercury has since been removed from the vaccine, and it is again given routinely to newborns.

Redwood also cited a West Coast study of the mercury exposure of 120,000 children, which showed a “statistically significant (albeit weak) association” between thimerosal exposure and attention deficit disorders, tics, speech and language delay and neurodevelopment delays in general.”

But Bernier said the CDC duplicated the study but did not get the same results. “These results require further scrutiny,” he said, “but the direction of the findings is reassuring.”

However, Neal Halsey, director of the Institute for Vaccine Safety at Johns Hopkins University, said, “Uncertainties rising from the new data do not resolve any of the controversies or differences of opinion regarding the potential risks from thimerosal in vaccines,” he said. “Additional studies need to be conducted.”¹

Bernier said the CDC is studying whether autism is related to the measles vaccine. The agency is also collaborating with the National Institutes of Health (NIH) on a study of autistic regression and vaccination. Finally, the CDC, NIH and Institute of Medicine (IOM) have recently established a standing committee on vaccine safety, which will assess new evidence about possible adverse health effects — including autism — from vaccines.

But pediatricians like Stephanie Cave of Baton Rouge, La., are not waiting for any more studies. She says she is seeing major improvements using timed-release chelation therapy to remove mercury and other heavy metals from autistic and learning-disabled children’s bodies. “As the treatments progress,” she says, “we’re seeing eye contact, socialization and speech. The children are literally turning around.”

But she and other researchers do not think that mercury is the only culprit. She thinks the mercury may compromise babies’ immune systems, so that when babies get their measles, mumps, rubella (MMR) vaccines at age 15 months, the body may not be able to fight off the viruses as well as it should.

A related theory set off a firestorm two years ago, when a report appeared in the influential British medical journal *Lancet* arguing that the MMR vaccine might trigger a bowel disorder that may allow toxins like mercury to cross from the blood into the brain, causing regressive autism. The report was widely criticized as methodologically flawed, and at least two subsequent epidemiological studies did not find a link. Additional studies are being conducted.

But Rick Rollens, a Granite Bay, Calif., parent whose child developed late-onset autism following vaccines, thinks independent studies must be done on this subject, without influence from either the vaccine industry or the public health agencies. Prodded by Rollens and the parents of other autistic children, the California legislature appropriated \$34 million for a study of neurodevelopmental disorders at the University of California at Davis.

“Asking the public health community to investigate the role of vaccines in the development of autism is like asking the tobacco industry to investigate the link between lung cancer and smoking,” Rollens says.

¹ From the Institute for Vaccine Safety Web site, www.vaccinesafety.edu/ACIP-thim-0621.htm.

At Issue:

Do vaccines cause autism?

DR. BERNARD RIMLAND

*Director, Autism Research Institute, San Diego, Calif;
www.autism.com/ari*

FROM LOS ANGELES TIMES, APRIL 26, 2000

first, do no harm. If the multibillion-dollar vaccine industry had heeded Hippocrates' ancient dictum and concentrated on making vaccines safe, the 300-500 percent nationwide increase in autism probably would not have occurred.

Concern for vaccine safety might have prevented the simultaneous sharp rise in other chronic and debilitating diseases such as asthma, allergies, attention deficit/hyperactivity disorder [ADHD], learning disabilities and arthritis.

The cause of the skyrocketing rates of these disorders, like the rise in autism, has mystified the experts. Many thoughtful and informed people believe that medical overexuberance has resulted in an unintended trade-off: Vaccination against acute diseases such as measles and rubella has increased susceptibility to chronic disorders such as autism, asthma, arthritis and ADHD. . . .

We learned in the latter half of the 20th century that one must be careful in tinkering with Mother Nature. Those marvelous pesticides, herbicides, gasoline additives and other miracles of modern chemistry have a downside. While we now know that toxic pollution of the environment is bad news, we are just beginning to learn that pumping toxins — viruses, bacteria, mercury, aluminum and formaldehyde, for example — into the body in the form of vaccinations for immediate gain may prove to be costly in the long term.

Those who share my view do not oppose vaccines. What we oppose is overvaccination and unsafe vaccines. . . .

In 1965, parents began telling me that their children became autistic upon getting the DPT (diphtheria, pertussis, tetanus) shot — a triple vaccine. When another triple vaccine, MMR (measles, mumps, rubella), was introduced in the 1980s, the alarming reports from parents and the prevalence figures for autism rose sharply. Corroborating evidence is plentiful.

In his testimony before the House Government Reform Committee, Paul Offit, the chief of infectious diseases at Children's Hospital of Philadelphia — who acknowledged at the hearing that he also is paid by the Merck Co. to educate doctors about vaccines — attacked the "notion" that giving three vaccines at once is unsafe. . . .

Don't just tell us vaccines are safe. Where are the scientific data? There are none. It is no secret that . . . doctors report only 1-10 percent of the adverse reactions they learn about. We cannot afford to deny, dismiss or sidestep the issue of vaccine safety. Research on this critical problem must be undertaken as the highest priority.

REP. HENRY A. WAXMAN, D-CALIF.

FROM LOS ANGELES TIMES, APRIL 17, 2000

rep. Dan Burton, R-Ind., chairman of the House Government Reform Committee, held a hearing this month to publicize his conviction that childhood vaccines cause autism. We heard heart-rending testimony from parents of autistic children who sincerely believe that vaccines caused their children's condition. And a few hand-picked researchers lent a scientific veneer by testifying that they believe vaccines may cause autism.

This is the kind of news that can alarm millions of families. That's why it's essential that parents know that the American Medical Association, the American Academy of Pediatrics, the Centers for Disease Control and Prevention and virtually every medical expert around the world have reached a different conclusion: Scientific evidence does not support a causal association between vaccines and autism.

Disregarding this evidence or overstating the dangers of childhood immunization runs the risk of needlessly scaring parents from vaccinating their children. Failing to immunize our children exposes them to risks of serious illness, disability and death. Every year, 2.5 million children die and 750,000 are crippled worldwide from childhood diseases. Once common and now rare in our country, rubella causes deafness, blindness and mental retardation. Measles, mistakenly viewed by some as an innocuous childhood illness, caused 11,000 hospitalizations and 120 deaths in our country during a 1989-91 epidemic. . . .

The dangers of a vaccine-autism scare are real. In 1998, British surgeon Andrew Wakefield published a preliminary report alleging that autism in 12 children was associated with the measles-mumps-rubella vaccine. The resulting hysteria quickly drove measles immunization rates in Britain below the level experts say is necessary to avoid an epidemic. . . .

Large-scale studies in Sweden, Finland and Britain have found no causal connection between vaccines and autism. The British government has reviewed and refuted the allegations, concluding — most recently on April 3 — that "there is no new evidence to suggest a causal link between MMR vaccination and autism."

Everyone agrees that more autism research is essential. . . . Yet as we increase research, we must also make sure that every parent knows that the best available science does not support a link between vaccines and autism. Nothing could be more harmful than to mislead parents about these facts and to encourage an unwarranted mistrust of vaccines, leaving our children defenseless before terrible childhood diseases.

At Issue:

Should vaccinations be mandatory?

SAMUEL L. KATZ, M.D.

American Academy of Pediatrics (AAP), Infectious Disease Society of America (IDSA)

FROM TESTIMONY BEFORE HOUSE COMMITTEE ON GOVERNMENT REFORM, AUG. 3, 1999

it is true that despite all that vaccines have done to improve the health of individuals and communities in the United States and throughout the world, they are not perfect. However, one simple fact cannot reasonably be disputed — the benefits of immunizations far outweigh any possible risks.

I would just like to remind you of a few anecdotal events. Where were the last big measles outbreaks in older youngsters in this country? In a school for Christian Science college students where there were deaths due to measles because they don't follow immunization. . . .

The last epidemics of polio in this country [were] in a boys' school in Greenwich, Conn. for a religious group who do not practice immunization; among an Amish population in Pennsylvania and several other states because they do not practice immunization. Should we allow our community immunity to wane, we will negate all the progress we have made and allow our communities to be at risk from threats that are easily prevented. . . .

Immunization has a clear community benefit in addition to its benefit to the individual patient. An individual's freedom to ignore a stop sign, to pollute the environment . . . or to spread disease do not serve the public good ultimately. We do place certain restraints on individual freedom because of our belief in the greater social well-being. . . .

Ongoing vaccine safety efforts and continuous monitoring of adverse events, be they alleged, potential, or real, are crucial to our nation's childhood immunization program. As science and resources allow, we are obligated to continue to improve the effectiveness of these safety-monitoring measures.

The AAP and the IDSA have seen allegations that a variety of illnesses may be caused by various vaccines. It's easy to understand how a family with a tragedy can believe that a vaccine caused the sudden, unexpected death of a child or the appearance of autism. . . . We give vaccines in the first two years of life, when all of these disorders have their common onset, so that guilt by temporal association is very difficult to separate from guilt by causality.

A robust system of checks and balances exists to monitor the safety and effectiveness of our vaccines, a system that we strive continuously to perfect. These efforts are designed to ensure that our recommendations about immunization and procedures reflect the best available science.

DAWN RICHARDSON

President, Parents Requesting Open Vaccine Education (PROVE), Cedar Park, Texas; prove@vaccineinfo.net; www.vaccineinfo.net

parents love their children and want to protect them. But vaccines, like the diseases they are designed to prevent, carry an unpredictable risk of injury or death. Parents should be free to make their own informed, voluntary vaccination decisions without being subjected to government sanctions.

All diseases and vaccines are not the same, and neither are all children. Yet current mandatory-vaccination laws treat chickenpox like smallpox. Over 200 new vaccines being developed for everything from cocaine addiction to sexually transmitted disease (STD) will be candidates for mandates. Additionally, some children are at greater biological risk than others for reacting to vaccines. "One-size-fits-all" mass vaccination policies don't take these differences into account and fail to minimize the risk of vaccine-induced injury and death for too many children.

Annually, 12,000-14,000 reports of hospitalizations, injuries and deaths following vaccinations are made to the federal Vaccine Adverse Event Reporting System (VAERS), but only 1-10 percent of doctors report. More than \$1 billion has been paid out under the federal vaccine-injury compensation program, but three out of four applicants are turned away and left to cope on their own.

Recent congressional hearings have raised eye-opening questions about inadequate vaccine licensing and safety standards; conflicts of interest between drug companies and vaccine policy-makers; and huge gaps in scientific knowledge about how vaccines impact the body.

Health officials measure public health in terms of high vaccination rates and low infectious-disease rates, and yet the rate of chronic disease and disability in children is at an all-time high. With children now getting as many as 39 doses of 12 different vaccines by school entry — while the brain and immune system are developing at the most rapid rate — nobody knows whether over-vaccination has contributed to the dramatic increases in asthma, allergies, learning disabilities, autism, attention-deficit disorder, diabetes and other chronic neuroimmune illnesses. Yet, the Centers for Disease Control and Prevention (CDC) insists all children, regardless of their personal disease risk, must get every government-mandated vaccine for the theoretical "greater good."

Because vaccination is a medical procedure that carries an inherent risk of injury or death, informed consent to vaccination should be the right of every American. Every parent deserves to be given truthful, unbiased information about diseases and vaccines and be allowed to make informed, voluntary, vaccination decisions for their children.

Continued from p. 661

and the University of California at Los Angeles (UCLA), which found that an alarming number of children receiving the DPT shot, one in 1,750, was at risk of suffering from “collapse shock” and an equal number of having convulsions.

Yet by 1990, after having received a \$400,000 grant from Lederle, he declared in the *Journal of the American Medical Association* (JAMA) that severe brain damage caused by the vaccine was a “myth.” By 1993, Lederle had given Cherry and UCLA an additional \$834,000 for pertussis research and expert testimony in lawsuits brought by parents of injured children.²⁰

Meanwhile, Congress in 1986 limited the liability of manufacturers of mandated vaccines and health practitioners who administer them. The National Childhood Vaccine Injury Compensation Act also:

- Established a “no-fault” system of compensation for injuries or deaths reasonably associated with the administration of childhood vaccines;
- Ordered CDC to set up a centralized system for reporting adverse reactions to vaccines; and
- Required periodic independent reviews of the scientific evidence on adverse events.

Immunizations Lag

By the late 1980s, immunization rates were slipping again. Then,

in the first years of George Bush’s presidency, the nation got a wake-up call on the dangers of incomplete immunization: A major measles epidemic in 1989-91 killed at least 132 persons.

Concentrated in Chicago, Houston, Los Angeles, New York and Philadelphia, the outbreak had infected 18,000 people by 1989. More than three-fourths of the cases in-



KRT Photo/Kim Foster

The U.S. military’s push to inoculate all service members against anthrax spread by germ warfare has been highly controversial. Many service members quit rather than take the vaccine or were court-martialed for refusing to take it.

involved unimmunized preschool children, mostly blacks and Hispanics.

“Everyone knows that when immunization levels drop, it is just a matter of time before you get an epidemic,” said Philip A. Brunell, former chairman of the AAP Committee on Infectious Diseases.²¹

In recent years, concern about vaccines has deepened as officials have begun adding new vaccines for non-epidemic diseases to the mandatory schedule, and as enforcement of mandatory vaccinations has begun to tighten. (See graph, p. 644.)

Some doctors, rewarded by managed-care companies for achieving high inoculation rates, won’t treat patients who refuse vaccination.

States, which receive federal grants for achieving high inoculation rates, are pressuring local health departments to improve inoculation rates. And welfare mothers in some states are having their checks reduced if their kids don’t get vaccinated.

The Clinton administration has won legislation to extend vaccination programs to the poor and has recommended new legislation to improve vaccination levels. Since 1994, the Vaccines for Children program has allowed the government to provide free pediatric vaccines for low-income children.

In addition, the federal government is overseeing establishment of a network of state electronic vaccine-tracking registries. So far, 22 states have set up or are in the process of establishing such registries, whereby all children are enrolled at birth. One state is using the database to contact parents of children who have not received all their

federally mandated vaccines. ■

CURRENT SITUATION

Compensation Law

Debate over implementation of the 1986 vaccine-injury compensation law heated up during congressional hearings last September, when critics claimed the administration had

turned lawmakers' intent on its head.²²

"We were betrayed," says the NVIC's Fisher, whose group helped draft the original legislation. Fisher had been promised the system would be fair and non-confrontational, she says, but instead it has become "highly adversarial," rejecting three out of four claimants.

However, program Director Thomas E. Balbier Jr. told the subcommittee that 42 percent of petitions have been awarded compensation. "This compares to a compensation rate of only 23 percent for those who file medical malpractice lawsuits through the usual tort system."

The law set up a "no-fault" system to compensate parents of vaccine-injured children "quickly, easily and with certainty and generosity." The program was to replace the expensive product-liability and medical-malpractice suits that were becoming so burdensome in the mid-1980s that pharmaceutical companies threatened to stop manufacturing vaccines.

Unique in U.S. law, the compensation system is supported by a 75-cent surcharge on each mandatory vaccine and is administered by special masters at the U.S. Court of Claims. The law listed conditions covered for each vaccine and the time period following vaccination when the condition must occur.

As of Aug. 3, 1999, more than 1,400 families had received awards totaling over \$1 billion, most for injuries suffered following the whole-cell DPT shot.

But in 1995, Health and Human Services (HHS) Secretary Donna Shalala tightened the requirements for several compensable conditions, including encephalopathy, or brain damage, one of the most common conditions claimed by DPT vaccine-injury victims. Under the new terms, a child would have to suffer a "diminished level of consciousness" for

more than 24 hours before being compensated. Plus, residual-seizure disorder, another DPT-related side effect, was removed from the compensable-injuries table.

In dramatic testimony, Michelle Clements, a parent from Milwaukee, told the subcommittee how the changes had affected her. Several hours after her 7-month-old son Andrew received his third DPT shot in 1992, he went into convulsions — and continued to have them over the next three years. Then on Sept. 8, 1995, he suffered a convulsion lasting four and a half hours and his temperature climbed to 108.8 degrees. When doctors finally allowed the Clements to see their son, "We saw a child double the size he was when he came into the hospital."

Today he cannot walk, talk, eat or drink. He is fed through a tube in his stomach. "His body is 7 years old but his brain is like a 3-month-old," she told the panel.

Yet the family was turned down for compensation. "The special master told us that if we had applied a year earlier, she would have found in our favor, but because of the changes in the injuries table, she had to find for the government."

"The government forces us to give our children these vaccines," Clements said, "and then when something goes wrong — too bad — you're on your own." She was especially furious when she learned that a safer DPT shot existed in 1992, but the government had waited until 1996 to recommend that doctors use it.

Ironically, parents who helped write the compensation law had understood that Congress granted the HHS secretary broad discretionary authority to alter the injuries table primarily to expand the list of compensable events and make the system more, not less, inclusive. Instead, the secretary has used her discretionary authority to remove or "redefine permanent injuries long rec-

ognized by the medical community as being associated with vaccine reactions," Fisher says.

The General Accounting Office pointed out last December that while Shalala did add some injuries to the table, most parents would find it harder to receive compensation with the new changes, because "far more claims have historically been associated with injuries HHS removed from the table than for injuries HHS added to it."²³

Although a group of injured parents sued HHS in 1995, claiming Shalala had overstepped her authority in changing the table, a judge disagreed with them.

Other witnesses complained that because Justice Department lawyers have made the process so adversarial, cases can take up to nine years, compared with the nine months envisioned by Congress. Moreover, Clifford J. Shoemaker, an attorney who has represented vaccine victims for over 20 years, told the subcommittee that even when the court rules in the parents' favor, it can take years to receive compensation. Shalala's changes "effectively devastated the program," he said.

Compensation program Director Balbier defended Shalala's revisions, saying that the law mandated that the secretary should modify the table to "bring it in line with science." The program was never intended to serve as a compensation source for a wide range of naturally occurring illnesses and conditions," he said.

Fisher told the committee that the latest IOM studies support the connection between encephalopathy and the DPT vaccine.

But Balbier says the changes were approved by the program's advisory committee after several months of public comment and deliberation, and were based on scientific evidence available at the time. The definition of encephalopathy that was finally adopted was actually broader than

some of the scientific advisers thought it should be, Balbier says, but “it was decided that we should give the plaintiffs the benefit of the doubt.”

But pediatric neurologist Kinsbourne, who has testified as an expert witness in many vaccine-injury cases, told the subcommittee that the government now puts the burden of proof on the victims. Instead of presuming the injury was caused by the vaccine, as the original law intended, he said, the secretary now requires the plaintiff to prove the injury was definitely caused by the vaccine.

Because DPT vaccine injuries have become so difficult to prove under the compensation program, some lawyers are threatening to go back to civil court to pursue lawsuits against the manufacturers, exactly what the act was intended to prevent.

“We’re going back to war,” said Boston attorney Michael Hugo. “The vaccine program is an abysmal failure. It is an uncertain, slow, horrible system.”²⁴ ■

OUTLOOK

New Vaccines

A flood of new vaccines, many of them genetically engineered, soon may be in use for diseases from pneumonia and tuberculosis to chlamydia and genital herpes. About 100 new vaccines are already in clinical trials.

All are not aimed at children, but scientists at the Children’s Vaccine Initiative (CVI), a global organization of private and government groups, are working on a genetically engineered “supervaccine.” To be given orally at birth, it would protect against childhood diseases as well as pneumonia, typhoid,

encephalitis, diarrhea, strep and influenza. The project is spurred by estimates from the WHO that up to 8 million children around the world die each year from preventable diseases.

Researchers are also examining novel ways of delivering vaccines, such as nasal sprays and genetically engineered fruits and plants. “An edible vaccine could be easy to produce, safe, affordable and effective,” said Carol O. Tacket, a University of Maryland medical professor. “This novel approach to developing vaccines [could] protect individuals around the world, especially in regions where injected vaccines are less practical.”²⁵

But some critics fear that the lure of profits may be more powerful than safety considerations. “With every child (and possibly adult) on Earth a potential required recipient of multiple doses and every health-care system and government a potential buyer, it is little wonder that countless millions of dollars are spent nurturing the growing multibillion-dollar vaccine industry,” writes Alan Philips, director of Citizens for Healthcare Freedom, in Durham, N.C.²⁶ “Without public outcry, we will see more and more new vaccines required of us and our children. And while profits are readily calculable, the real human costs are being ignored.”

“We must have more scientific information to make sound medical policy on different vaccines — especially if vaccines are to continue to be mandated,” says molecular biologist Bonnie S. Dunbar of the Baylor College of Medicine in Houston.

Surgeon General Satcher told Burton’s subcommittee on Aug. 3, 1999, “As the number of vaccines available for our use increases, an improved safety-assessment program will be critical, and effective risk communication will be essential.”

But critics say pediatricians rarely provide parents with the vaccine risk-benefit information sheets that they are required by law to provide.

“If we had informed-consent protections in place, the public could exert economic pressure on the companies to improve existing vaccines by refusing to use them if they prove to be too dangerous,” Fisher says. “But that system is not in place, and the drug companies continue to profit while taking no financial responsibility for vaccine injuries and deaths.”

Critics also fear that the government’s zeal to immunize every American child may soon begin to seriously infringe on privacy rights and constitutional protections. They are particularly fearful that new computerized vaccine-tracking systems could lead to harassment of parents of unvaccinated children.

Some vaccine “choice” advocates worry that the vaccine registries may be used to force universal vaccination against the AIDS virus, once a vaccine is developed. “Any effort to try to make the HIV vaccine mandatory will run into one heck of a battle,” consumer lawyer Turner says. “There are so many better ways to control HIV without a vaccine. It’s not necessary to vaccinate the entire population.”

Meanwhile, some scientists have begun to question the wisdom of trying to eradicate every childhood disease, since some studies indicate that childhood infections may actually increase the body’s ability to fend off chronic diseases, such as diabetes and asthma.²⁷

Parent advocates say more oversight and accountability is needed over public health policies that could have such long-term impacts on society.

Some health-care professionals fear that if the impending wave of vaccinations is aggressively promoted at the same time that public trust in vaccines is eroding, many of the public health gains made in the last century could be undermined. Non-compliance might be driven underground, creating even greater danger of disease outbreaks.

“When I was a young doctor and was faced with a ward full of polio

victims, or 1,000 children damaged by congenital rubella, the benefits of vaccines were very compelling," recalls Louis Cooper, vice president-elect of the American Academy of Pediatrics.

"But in the 21st century, with those kinds of epidemics fading into memory, and with so many new vaccines in the pipeline, many of us are looking at what kinds of vaccines should be mandated, what should be recommended and what should be optional," Cooper says.

"A lot of thoughtful people are saying it's time to develop some principles for dealing with the new era of vaccination." ■

Notes

¹ See CDC report "Six Common Misconceptions about Vaccination," at www.cdc.gov/nip/publications/6mishome.htm.

² For background, see Craig Donegan, "Gene Therapy's Future," *The CQ Researcher*, Dec. 8, 1995, pp. 1089-1112.

³ Quoted in Susan Fenelon Kerr, "Poor health among children confounds parents, doctors," *Union News, Sunday Republican*, July 30, 2000.

⁴ The Web site is: www.gval.com

⁵ For details on the DPT vaccine controversy, see Andrea Rock, "The Lethal Dangers of the Billion-Dollar Vaccine Business," *Money*, December 1996.

⁶ Kathleen R. Stratton et al, "DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis" (1994).

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⁹ Testimony before House Government Reform Committee, July 18, 2000.

¹⁰ Neal A. Halsey, "Limiting Infant Exposure to Thimerosal in Vaccines and Other Sources of Mercury," *Journal of the American Medical Association*, Nov. 10, 1999.

¹¹ For background, see Adriel Bettelheim, "Managing Managed Care," *The CQ Researcher*, April 16, 1999, pp. 305-328.

¹² From Susan S. Ellenberg and Robert T. Chen, "The Complicated Task of Monitoring Vaccine Safety," *Journal of the U.S.*

FOR MORE INFORMATION

Autism Research Institute, 4182 Adams Ave., San Diego, Calif. 92116; (619) 281-7165; www.autism.com/ari/. This nonprofit, established in 1967, conducts research on autism and disseminates its findings to medical personnel and to parents.

Immunization Action Coalition, 1573 Selby Ave., Suite 234, St. Paul, Minn. 55104; (651) 647-9009; www.immunize.org. The coalition works to boost immunization rates. Receives some funding from vaccine manufacturers.

National Network for Immunization Information, www.infoinc.com/innews2/ Web site operated by the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, the American Academy of Pediatrics and the American Nurses Association. Funded by the Robert Wood Johnson Foundation, it receives no funds from the vaccine industry.

National Vaccine Information Center, 512 W. Maple Ave., Suite 206, Vienna, Va. 22180; (703) 938-3783; www.909shot.com. The center, the oldest and largest national group advocating reform of the vaccination system, provides assistance to parents of children who have experienced vaccine reactions.

National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Rd., Mailstop E-05, Atlanta, Ga. 30333; (800) 232-2522; www.cdc.gov/nip. This government program plans, coordinates and administers immunization activities nationwide.

About the Author

Kathy Koch specializes in education, youth and social-policy issues. She was one of several *CQ Researcher* writers who won the 1999 Society of Professional Journalists Award for Excellence for a 10-part series on health issues. Kathy has worked as a daily newspaper re-

porter in South Florida and as a freelancer in Asia and Africa for the *Christian Science Monitor*, *USA Today* and other publications. She also covered environmental legislation for *CQ Weekly*. She received a journalism degree from the University of North Carolina at Chapel Hill.

Public Health Service, Public Health Reports, January/February, 1997; Vol. 112, No. 1; pp. 10-20.

¹³ *Jacobson v. Massachusetts* 197 U.S. 11 (1905).

¹⁴ For background, see Kenneth Jost, "Childhood Immunizations," *The CQ Researcher*, June 18, 1993, pp. 529-552.

¹⁵ For background, see Mary H. Cooper, "Combating Infectious Diseases," *The CQ Researcher*, June 9, 1995, pp. 489-502.

¹⁶ Rock, *op. cit.*, p. 153.

¹⁷ Harris L. Coulter and Barbara Loe Fisher, *A Shot in the Dark* (1991), p. 209.

¹⁸ "Industry Perspective: An Interview with Dr. Stanley Plotkin," *IAVI Report*, June 1996, p. 7.

¹⁹ Katz's comments were made in testimony Aug. 3, 1999, before the House Government Reform Committee.

²⁰ Rock, *op. cit.*, p. 153.

²¹ Jost, *op. cit.*, p. 540.

²² The hearings were before the House Subcommittee on Criminal Justice, Drug Policy and Human Resource, Sept. 28, 1999.

²³ "Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily," *Letter Report*, GAO, Dec. 22, 1999.

²⁴ John Hanchette and Sunny Kaplan, "National Vaccine Compensation Program For Children Draws Fire," *Vaccination Nation*, Gannett News Service, Aug. 11, 1998.

²⁵ Quoted in Ronald Kotulak and Jon Van, "Discoveries," *Chicago Tribune*, July 30, 2000.

²⁶ Philips' comments appeared on the group's Web site: www.UNC.edu/~aphilip/www/chf/

²⁷ For details, see "Plagued by Cures," *The Economist*, Nov. 22, 1997.

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Coulter, Harris L. and Barbara Loe Fisher, *A Shot in the Dark: Why the P in the DPT Vaccination May Be Hazardous to Your Child's Health*, Avery Publishing Group Inc., 1991.

This book documents the dangers of the DPT vaccine by tracing the history of its development and use. Coulter, a medical historian, and Fisher, president of the National Vaccine Information Center whose son suffered vaccination damage, provide parents with important questions to ask their child's physician about vaccines.

Offit, Paul A., and Louis M. Bell, *Vaccines: What Every Parent Should Know*, IDG Books, 1999.

This pro-vaccine parents' guide, written by two doctors from Children's Hospital of Philadelphia, has a chapter on each childhood vaccine in which the authors discuss the risks and benefits of each shot.

Oldstone, Michael B. A., *Viruses, Plagues and History*, Oxford University Press, 1998.

The author, director of the viral immunobiology laboratory at the Scripps Research Institute and an editor at the medical journal *Virology*, traces the long-term medical campaigns to eradicate diseases that have long tormented humankind: measles, smallpox and polio. He also discusses efforts to tame modern plagues caused by the Ebola virus, Hantavirus and AIDS virus.

Murphy, Jamie, *What Every Parent Should Know about Childhood Immunization*, Earth Healing Products, 1993.

Decidedly anti-vaccine, this medical researcher tells parents "more about the risks [of childhood vaccines] than your pediatrician wants you to know." He describes the toxic chemicals in vaccines and cites numerous medical journal articles describing adverse reactions to childhood vaccines. He advises parents how to legally avoid vaccinating their children.

Articles

Ellenberg, Susan S. and Robert T. Chen, "The Complicated Task of Monitoring Vaccine Safety," *Journal of the U.S. Public Health Service, Public Health Reports*, January/February 1997; Vol. 112, No.1.

This article describes the history of vaccines, as well as the method by which their safety is monitored today.

Goodwin, Jan, "The Trouble With DPT," *Redbook*, August/September, 2000, pp. 158-175.

This article chronicles the case of a New York anesthesiologist convicted of manslaughter after his daughter

died of what prosecutors said was "shaken baby syndrome" but what several doctors testified was actually a vaccine reaction. It says a growing number of parents are being blamed for the side effects of vaccines given to millions of babies each year.

Halsey, Neal A., "Limiting Infant Exposure to Thimerosal in Vaccines and Other Sources of Mercury," *Journal of the American Medical Association*, Nov. 10, 1999.

The director of the Vaccine Safety Institute at Johns Hopkins University argues for limited the exposure of infants to thimerosal until vaccines free of this mercury-laden preservative are available.

Hanchette, John and Sunny Kaplan, "National Vaccine Compensation Program For Children Draws Fire," *Vaccination Nation*, Gannett News Service series, June, 1998.

Silver bullet vaccines have nearly wiped out many childhood diseases. But this five-part series uses government documents to disclose how some vaccines trigger dangerous reactions resulting in lifelong disability or even death.

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This article exposes the politics and economics behind the billion-dollar vaccine industry and explains why safer versions of certain vaccines took so long to replace the standard-issue shots.

Reports and Studies

"Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily," *Letter Report*, GAO, Dec. 22, 1999.

The General Accounting Office last December pointed out that while Health and Human Services Secretary Donna Shalala added some injuries to the list of those the government compensates vaccine-damaged children for, most parents would find it harder to receive compensation because "far more claims have historically been associated with injuries HHS removed . . . than for injuries HHS added."

Stratton, Kathleen R., et al., "Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality," *Institute of Medicine, National Academy Press*, 1994.

In a study mandated by Congress, the IOM examined possible links between pertussis and rubella vaccines and adverse reactions in children.

The Next Step

Anthrax

“Air Force Major Charged in Vaccine Refusal,” *The Washington Post*, Jan. 15, 2000, p. A10.

A decorated pilot believed to be the highest-ranking Air Force officer to refuse the anthrax vaccine was charged with disobeying an order. Maj. Sonnie Bates has said his fears that the vaccine would harm his health grew after he saw other members of his squadron develop unexplained illnesses.

“Pentagon Gives Anthrax Maker Another \$12 Million,” *UPI News*, April 13, 2000.

The Pentagon has awarded the troubled manufacturer of its anthrax vaccine another \$12 million to help its new laboratory pass an inspection by the Food and Drug Administration, Defense Department officials acknowledged. The money comes on top of the \$40 million the Pentagon gave the company to bail it out of financial trouble last fall. BioPort, of Lansing, Mich., is the only potential source for the anthrax vaccine in the country.

Graham, Bradley, “Air Force Censures Vaccine Critic; Nurse Wrote Letter to the Editor Questioning Anthrax Shots,” *The Washington Post*, Aug. 2, 1999, p. A2.

An Air Force nurse has been punished by superiors for writing a letter to the military newspaper *Stars and Stripes* questioning the safety and effectiveness of anthrax inoculations being administered to all U.S. troops. Capt. Debra J. Egan, a pediatric specialist, raised concerns about the vaccine’s possible side effects.

Ricks, Thomas E., “Anthrax Shots’ Effect Challenged; Army Disputes Expert Who Reviewed Vaccine Tests,” *The Washington Post*, July 18, 2000, p. A21.

The controversial anthrax vaccine that the Pentagon is trying to inject into 2.4 million troops does not provide complete immunity to an anthrax attack, according to an outside expert who has examined Defense Department records of laboratory tests. Soldiers exposed to anthrax may become quite sick and be incapacitated for up to two weeks, even if they have received the full set of six inoculations.

Vaccine Development

“A Shot to Stop Smoking? Scientists Working on It,” *Chicago Tribune*, Dec. 19, 1999, p. A17.

One day, folks who want to quit smoking may find help by getting a shot. Researchers sponsored by the National Institute on Drug Abuse are doing laboratory tests on a vaccine that works against nicotine, with a target of beginning human trials by 2002. The vaccine, now being tested on rats, is designed to keep nicotine, the main addictive component of tobacco, from reaching the brain.

“Food for Thought: Biotech Firm Turns Potatoes Into Oral Vaccine,” *Chicago Tribune*, July 14, 1999, p. A7.

A U.S. plant institute and a British biotechnology company have high hopes that people may one day eat their genetically altered potatoes to be vaccinated against hepatitis B, a big cause of liver cancer. Officials with the Boyce Thompson Institute for Plant Research said the potato vaccine, whose development has been funded by groups such as the National Institutes of Health, would be a booster to existing injectable hepatitis B vaccines.

Baltimore, David, “Why Isn’t There an AIDS Vaccine?: The Challenges Are So Great and the Climate So Politicized That We Are Farther From it Than We Need to Be,” *Los Angeles Times*, July 11, 2000, p. B9.

Vaccines against viruses can produce miracles — smallpox was eradicated from the world with a vaccine and polio is almost eradicated. Yet so far no anti-HIV vaccine has been produced. Why not?

Carlsen, William, “Gates Foundation Puts Millions Into Safe Vaccination Drive,” *San Francisco Chronicle*, Dec. 14, 1999, p. A9.

Bill and Melinda Gates spent several years in research and consultations before they decided to create the Children’s Vaccine Program through their \$17 billion foundation. The program was established to shorten the period — as long as 15 years in some cases — between the introduction of new vaccines in industrialized countries and their subsequent low-cost distribution in the developing world.

Christian, Sue Ellen, “Vaccine for Meningitis May Fight Ear Infections,” *Chicago Tribune*, Jan. 29, 1999, p. 1.

At the height of the season for one of the peskiest of childhood maladies — the ear infection — most parents figure they have little choice but to hope that those thick pink antibiotics work and that their children suffer no long-term side effects. But in a medical twist, researchers think they may have stumbled onto a permanent solution for many ear infections: a vaccine.

Cimons, Marlene, “Vaccine Could Quell Long-Lived Scourge in Time to Ease Aging of Baby Boomers,” *Los Angeles Times*, Aug. 19, 1999, p. A20.

Researchers are on the brink of perfecting a vaccine that may prevent shingles — a disease that most often afflicts the elderly and can produce blisters so painful that it has driven some to suicide.

Jacobs, Paul, “FDA Revisits Forbidden Ground; Biotech Gains Lead It to Rethink Ban on Vaccines Grown in Cancer Cells,” *Los Angeles Times*, Feb. 8, 1999, p. C1.

A biotechnology company working on a new AIDS vaccine wants to be able to test it on volunteers. Another company has a new influenza vaccine that can be quickly

manufactured in the face of a fast-moving sudden epidemic. But neither firm can proceed in the U.S. because these new vaccines are grown in “neoplastic” cells — cancer cells or cells that cause tumors when injected into animals — and their use is prohibited. That may be about to change. The Food and Drug Administration is considering ending a 45-year-old ban on using such cells to produce vaccines.

Jacobs, Paul, “Tobacco Plants Could Offer Vaccine to Treat Non-Hodgkin’s Lymphoma,” *Los Angeles Times*, Feb. 1, 1999, p. C4.

Tobacco plants may provide a new way of treating non-Hodgkin’s lymphoma, a cancer that will strike an estimated 56,800 Americans this year.

Manning, Anita, “Federal Panel Approves Vaccine to Protect Children,” *USA Today*, Feb. 18, 2000, p. A4.

The federal government gave the go-ahead to a vaccine that combats a microbe responsible for bacterial meningitis and a million ear infections each year. But not everyone is celebrating. Barbara Loe Fisher, an advocate for vaccine safety and a member of the FDA advisory committee that reviewed clinical data on the vaccine, says she’s not convinced enough testing has been done.

Shook, David, “New Vaccine From American Home Products Aimed at Kids,” *The Record of Hackensack*, N.J., Feb. 17, 2000.

American Home Products expects government approval to market a new vaccine for babies and children designed to prevent meningitis, pneumonia, and ear infections. Prevnar protects against infection from a bacteria called pneumococcus, commonly found in hospitals and which often infects children under the age of 5. Prevnar was 15 years in development and combines seven bacterial vaccines. It has an excellent safety profile, although its effectiveness and safety will be further tested once the vaccine is introduced.

Sternberg, Steve, “Vaccine Takes Aim at AIDS in Africa,” *USA Today*, July 12, 2000, p. D1.

Scientists are set to begin human trials of the first experimental AIDS vaccine designed specifically for Africa. The vaccine is made from snippets of DNA, and it is based on insights from studies of some Nairobi prostitutes who are immune to HIV, the AIDS virus.

Vaccine Safety

“Diarrhea Vaccine for Infants Is Recalled; Risk of Bowel Blockage Prompts Firm to Act,” *Chicago Tribune*, Oct. 16, 1999, p. A8.

Just a year after the government approved it, RotaShield, the world’s only vaccine against the leading cause of childhood diarrhea was pulled off the market because of

fears that it may increase infants’ risk of a dangerous bowel obstruction. The government advised doctors in July to suspend vaccinating babies against rotavirus after counting 20 infants who developed bowel obstruction shortly after swallowing the vaccine.

“Hepatitis B Vaccine: U.S. Scientists Discounting Reports of Bad Side Effects,” *Chicago Tribune*, May 27, 1999.

Federal scientists say hepatitis B vaccine is safe and effective, despite reports that it can cause serious and even life-threatening side effects. Testifying before a House subcommittee investigating vaccine safety, officials said use of the vaccine has been monitored for 15 years and it has not been proven to be the cause of any deaths and is only rarely linked to serious side effects.

“Study Shows New Vaccine for Whooping Cough Is Safer,” *Chicago Tribune*, Jan. 23, 2000, p. A6.

The most disturbing side-effects from whooping cough vaccine have declined sharply since the introduction of a new treatment that includes only the “safe” parts of the germ responsible for the disease, researchers say. The findings were expected to reassure parents about the safety of immunization, at a time when some members of the public claim that vaccinations pose an unnecessary risk for serious health problems, including sudden infant death syndrome.

Atlas, Terry, “Smallpox May Survive Death Sentence; U.S. Rethinking Plan to Incinerate the Last of Its Laboratory Samples,” *Chicago Tribune*, March 16, 1999.

After directing one of the great public health achievements of the 20th century, the international effort to eradicate the deadly disease smallpox, Dr. Donald Henderson fears that the once-dreaded killer may escape its own death sentence. The smallpox virus is known to still exist only as laboratory samples under lock in the U.S. and Russia, and scheduled to be incinerated in three months. That plan is now in doubt.

Condor, Bob, “A Shot in the Dark: Parents Need to Stay Informed Regarding Childhood Vaccinations,” *Chicago Tribune*, Aug. 1, 1999, p. A3.

Immunizations represent one of the first medical decisions parents will make for their child. But some parents aren’t given the opportunity — or don’t have the facts — to make that all-important first decision. Even as the safety of vaccines is coming under closer scrutiny — from government and activist groups alike — more American kids are immunized than ever before.

Christian, Sue Ellen, “Panel Backs Chickenpox Vaccine for All Kids,” *Chicago Tribune*, April 20, 2000, p. A1.

A state immunization advisory committee recommended that every child be vaccinated for chickenpox before entering an Illinois school, drawing criticism from those

who call the mandate overkill and fear the vaccine is potentially dangerous.

Christian, Sue Ellen, “Parents Raise New Concerns on Vaccines,” *Chicago Tribune*, April 23, 2000, p. A1.

For years, parents have dutifully, almost mechanically, vaccinated their children against a host of potentially life-threatening diseases: polio, measles, mumps, rubella, diphtheria, pertussis. They did so without question. But as the number of vaccines that children receive increases — and that will only continue to rise in coming years, experts say — so does the level of concern among parents. How many vaccines can a child’s immune system handle?

Kaufman, Marc, “Hepatitis B Vaccine Effort Draws Fire; Critics Cite Reports of Adverse Effects in Opposing Mandatory Inoculations of Children,” *The Washington Post*, Feb. 2, 1999, p. Z11.

Armed with federal statistics they say show the hepatitis B vaccine has resulted in thousands of “adverse reactions” — including conditions similar to rheumatoid arthritis and multiple sclerosis — critics are demanding that parents be allowed more easily to choose not to give their children the controversial vaccine.

Manning, Anita, “Now Parents Fear Shots,” *USA Today*, Aug. 3, 1999, p. A1.

Fueled by the withdrawal of a vaccine because of safety concerns and frightening Internet discussions about vaccines, a growing number of parents and politicians are asking whether the sheer number of immunizations now required by states for many children really is necessary — or safe.

Manning, Anita, “To Vaccinate or Not to Vaccinate,” *USA Today*, July 17, 2000, p. D5.

Some researchers have published reports that suggest a link between vaccines and autism, diabetes or other chronic or developmental disorders. Other researchers have disputed the findings, but the controversy has become the focus of several congressional hearings and countless Internet chat-room discussions.

Manning, Anita, “Vaccine-Autism Link Feared,” *USA Today*, Aug. 16, 1999, p. D1.

A stunning increase in the number of children diagnosed with autism has schools straining to provide services and health officials urgently seeking answers. And the increases are fueling a grass-roots movement of

parents determined to expose what they believe is a connection between autism and vaccines.

Shaw, Donna, “Madison, N.J.-Based AHP Takes Its Rotavirus Vaccine off the Market,” *Philadelphia Inquirer*, Oct. 16, 1999.

American Home Products Corp. said it was withdrawing its rotavirus vaccine from the market after 100 infants who received it suffered obstructed bowels. It was the first time in nearly 45 years that a vaccine was withdrawn because of safety concerns.

Silverman, Edward R., “U.S. House Panel to Probe Conflicts of Interest in Approval of Lyme Vaccine,” *Newark Star-Ledger*, June 2, 2000.

A House committee, which plans hearings on conflicts of interest among academics, government panels and drug makers that develop vaccines, is now probing events that led to the approval of the controversial vaccine for Lyme disease. The hearings by the House Committee on Government Reform will focus on ties between drug makers and academic researchers who sit on government panels that approve vaccines. The hearings coincide with an increasing amount of attention paid to financial ties between the pharmaceutical industry and academic researchers who conduct clinical trials or consult for drug makers.

Sternberg, Steve, “Researchers Dismiss Vaccine-Asthma Link,” *USA Today*, May 2, 2000, p. D9.

Pertussis vaccine does not increase the risk of childhood asthma, researchers reported in a study, perhaps the largest of its kind, involving nearly 170,000 children who are members of four major West Coast managed-care plans.

Vergano, Dan, “Oral Polio Vaccine Used Despite Risks,” *USA Today*, Nov. 9, 1999, p. D6.

Despite federal warnings, many infants may still receive an oral polio vaccine that places them at risk of paralysis, pediatricians say.

Vollmer, Tim, “Who Should Call the Shots; As More and More Parents Resist Vaccinations Given Young Children, Questions Arise on How to Balance Health and Public Trust,” *San Francisco Chronicle*, Oct. 10, 1999, p. Z1.

Fears about vaccine side effects have given rise to a fledgling social movement, which, borrowing a potent phrase from the abortion debate, calls itself “pro-choice” in regards to vaccines and other medical decisions.

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