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SHOTS IN THE DARK

Attempts at
eradicating infectious
diseases are putting our
children at risk

BY BARBARA LOE FISHER



THE WORLDWIDE ACCEPTANCE of mass vaccination to suppress infectious childhood diseases – once fiercely resisted – is one of the most successful public relations stories in the history of medicine. As a result, epidemics of smallpox, which once swept through 18th- and 19th-century port cities such as Halifax, New York, and Boston without warning and cut down entire families, are now dry facts relegated to medical books. Images of children struggling through whooping cough, walking down the street coughing spasmodically, and stopping at curbs to spit up sticky mucus are only fading memories for grandparents alive to talk about what their parents told them. Baby boomers and their parents still remember lining up in school in 1955 for polio vaccinations, with

shots in the dark

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the hope that this magic bullet would keep them out of the dreaded iron lung.

Mass vaccination has dramatically suppressed childhood diseases. In Canada, recorded diphtheria cases dropped from 9,000 in 1924 to two to five by 1994. When measles vaccination began in the United States between 1963 and 1965, doctors reported more than 400,000 cases annually; by 1995, that number had dwindled to 309.

ILLUSTRATION BY BLAIR DRAVSON

Cases of tetanus are almost unheard of in North America and Europe.

Yet the universal use of vaccines as a worthy goal that prevents needless suffering and that benefits all mankind has begun to be challenged.

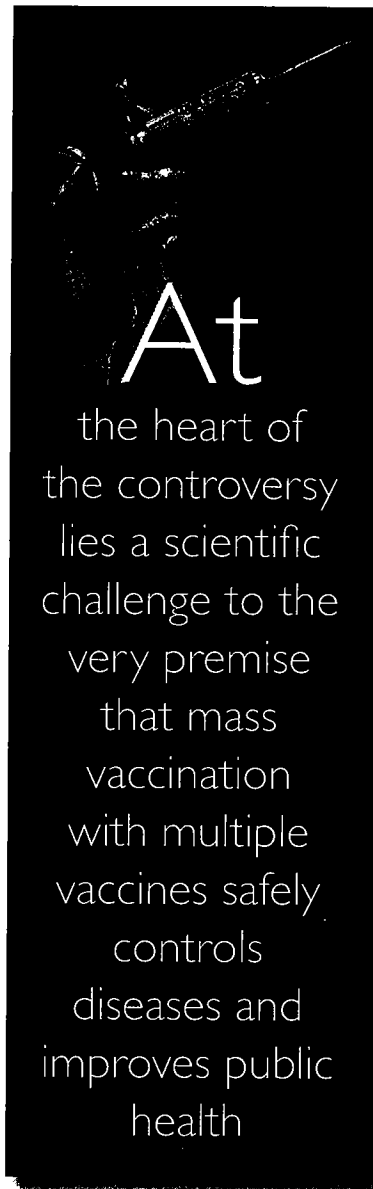
The voices of critics are heard in the living rooms of families whose children have been injured or have died from reactions to routine childhood vaccinations, and in courtrooms, where parents are suing vaccine makers and challenging mandatory vaccination laws. In the U.S. Congress, legislators who have heard them have set up a vaccine injury compensation program. At scientific conferences and in the pages of prestigious medical journals, researchers and physicians are risking their careers by discussing vaccine side effects. On network TV, millions are watching parents, who say vaccines hurt their children, square off with policy makers, who say vaccines rarely hurt anyone at all.

At the heart of the controversy lies a scientific challenge to the very premise that mass vaccination with multiple vaccines safely and effectively controls diseases and improves individual and public health. Simultaneously, ethical and legal arguments challenge the right of government health officials to force vaccination on everyone. Wrapped up in this scientific, legal, and political battle are beleaguered pediatricians losing the trust of parents and a booming pharmaceutical industry with billions of dollars invested in new vaccine development.

How it all began

IN 1796, BRITISH PHYSICIAN EDWARD JENNER, ACTING ON a hunch, scraped cowpox pus onto the arm of an eight-year-old boy. He theorized that a mild bout of cowpox would prevent a more virulent case of smallpox, and he was right. The procedure, which he dubbed *inoculation*, enjoyed limited success at first. But it failed in Jenner's own 11-month-old son, and bad reactions to smallpox inoculation, which eventually used lymph from the cow itself, were legendary.

One mother in England bitterly complained in 1883 about mandatory vaccination laws that allowed public health officials to issue summons, threaten parents with imprisonment, and impose stiff fines for refusing to vaccinate their children. She said, "In no country has the cry of the mothers been allowed a hearing. They who see and realize that their children suffer from this practice have never



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been consulted as to its initiative or its continuance. If the will of the mothers could be made potent and effective, this cruel legislation would be at once and universally repealed."

But 19th-century physicians quickly adopted and promoted Jenner's new procedure despite public protests. Physicians and politicians were desperate for anything that appeared to keep epidemic pestilences from invading the overcrowded, filthy cities of Europe and the New World. They failed to realize that eliminating the root causes of poor health – poverty, malnutrition, water contaminated by human and animal waste, spoiled food, and industrial air pollution, among others – would help prevent the spread of many diseases.

Government-enforced vaccinations led to burgeoning chemical/pharmaceutical industries in France, Germany, and Britain. The Pasteur Institute, founded in 1887 by the famed inventor of the rabies vaccine, eventually created Canada's largest vaccine manufacturer: Pasteur Mérieux Connaught. Today, vaccinations are big business. In 1995, an international high-technology research firm, Frost & Sullivan, projected that the worldwide human vaccine market will increase from \$2.9 billion to more than \$7 billion by the year 2001.

Public health officials in every country assist the industry's growth, often by force of laws that ensure citizens use about a dozen different viral and bacterial vaccines, including ones to suppress even generally mild childhood diseases such as chicken pox. Traditional public health measures – improving sanitation, nutrition, living conditions, health education, and access to affordable medical care, especially in underprivileged populations – often take a backseat to achieving a 100 per cent vaccination rate.

Most medical doctors consider vaccines their single most important tool in protecting public health. "Few would question the profound importance of vaccines to public health," wrote Richard B. Johnston, Jr., MD, medical director of the March of Dimes and chairman of the Institute of Medicine Vaccine Safety Committee, in a 1994 National Academy of Sciences report, *Adverse Events Associated with Vaccines*. "Not only have deaths from the most common childhood infections been almost eliminated, but so have the devastating morbidities of diseases like measles, paralytic polio, and congenital rubella. This revolution has . . . led to major savings in medical costs and gains in work productivity, as well as to reductions in deaths and suffering."

Questioning authority

BUT CRACKS ARE APPEARING IN THE UNITED FRONT THAT the medical establishment has maintained for two centuries. In industrialized countries, dissatisfied patients and alternative health care proponents are questioning orthodox medicine's basic foundations, especially its heavy reliance on surgery and synthetic drugs. The proliferating number of vaccines are just one more target for increasingly well-educated and Internet-savvy health care consumers, who are wary of the many magic bullets drug companies promote.

Remembering when doctors wanted every child's tonsils out, mothers wonder why doctors now insist that they should stay in. Where doctors once prescribed antibiotics for every sore throat, prescription-dependent patients are now being blamed for new strains of antibiotic-resistant bacteria. A new drug promoted as a lifesaver today is sometimes pulled off the market tomorrow for killing those who took it. In the April 15, 1998, issue of the *Journal of the American Medical Association* (JAMA), an analysis of drug side effects found that toxic reactions to correctly prescribed medications make more than two million Americans seriously ill every year and kill 106,000, putting drug side effects among the top 10 causes of death in the United States. Among children, antibiotics and vaccines cause more adverse reactions than any other prescribed medicines,

according to a Canadian study presented at the annual meeting of the American Academy of Allergy and Asthma in 1998. Sandra K. Knowles and her colleagues at the Sunnybrook Health Sciences Centre in Toronto reviewed Canadian data on more than 1,500 cases of drug reactions between 1985 and 1995. The antibiotics amoxicillin and ampicillin accounted for 24 per cent of total adverse reactions, with vaccines coming in second at 19 per cent. Baby boomers wonder what and who to believe.

Many believe health requires better nutrition, exercise, managing stress, a positive attitude, and a less intrusive approach.

A 1997 study in the *Canadian Journal of Public Health* estimated that 15 per cent of Canadians had seen an alternative therapy practitioner in the preceding 12 months. A 1998 survey in JAMA found 39 million Americans made more than 600 million visits to alternative health care practitioners in 1997, more than to primary care physicians. The patients paid most of the \$21.2 billion cost themselves because health insurance plans generally don't reimburse patients for alternative health care. The patients wanted alternative therapies primarily to "prevent future illness from occurring or to maintain health and vitality."

Embracing the more spiritual concept of achieving better health through better living rather than through better chemistry, members of the Me generation – who challenged

An ancient philosophical dispute goes modern

The whole idea of man versus nature can be traced back to the origins of western medicine more than 2,000 years ago. In a four-volume book series *Divided Legacy: A History of Schism in Medical Thought* by medical historian Harris L. Coulter, PhD, the centuries-old war between empiricism and rationalism in medicine is revealed as a contest between two competing health philosophies. Is each individual governed by a "vital force" that, through unique reactions to external stimuli, is capable of participating in the healing process, as empiricists, including Hippocrates, have maintained? Or are all human organisms simply a series of complex chemical reactions governed by the laws of physics, chemistry, and mechanics, as rationalists, including Louis Pasteur, have maintained?

Empiricists accept the existence of viruses and bacteria as part of nature and illness as part of the life process. They consider fevers, diarrhea, and runny noses good, not bad, and do not suppress them with chemically based drugs that might interfere with the body's natural ability to harness the immune system to participate in the healing process. They stress that each individual is unique and that individualized therapeutic techniques can stimulate the body to restore health. Empiricists dislike the one-size-fits-all mass vaccination approach.

Rationalists believe that all living organisms are more similar to one another than they are different, and that a common, uni-

versal approach to public health will attain individual health. Viewing symptoms of illness as a sign that a foreign virus or bacteria has invaded the body, they create therapies such as drugs and vaccines to destroy the foreign invader. Rationalists see vaccines – which are designed to prevent micro-organisms from invading their human hosts – as an important weapon in eradicating disease from the face of the earth.

The lines that are being drawn today in the debate about the pros and cons of vaccination are an extension of this ages-old debate about the laws of nature and the best way to maintain health. Philip Incao, MD, a Colorado physician who utilizes a multidisciplinary approach in his alternative health care practice, maintains that health is about the individual successfully overcoming illness. "Physically, health is about balancing acute inflammatory responses to infection, which stimulate one arm of the immune system, and chronic inflammatory responses to infection, which stimulate the other arm of the immune system. Just like a seesaw, the two arms of the immune system must remain in balance to maintain health. Vaccines tend to stimulate only one side of the immune system. Overuse of vaccines to suppress all acute, externalizing inflammations early in life can set up the immune system to respond to future stresses and infections by developing chronic internalizing disease later in life."

B.L.F.

postvaccination symptoms like those described by Hyde, ranging from rashes and fevers that come and go, debilitating fatigue, muscle weakness, joint pain, and memory loss to paralysis and death. Many were diagnosed with rheumatoid arthritis, multiple sclerosis, lupus, and other autoimmune disorders, although most often they did not suffer from classic forms of these diseases. As the U.S. passed laws and Canada recommended children get three vaccine doses or be barred from school, children began to report the same reactions.

Recombinant hepatitis B vaccine is also being challenged by Bonnie Dunbar, PhD, professor of Cell Biology, Baylor College of Medicine in Houston, who has spent most of her 25-year career in academic and laboratory science in new vaccine development. After reactions to hepatitis B vaccinations disabled both her brother and a research assistant, she intensively investigated the vaccine.

With several other U.S. scientists, Dunbar is investigating whether the genetically engineered hepatitis B vaccine “tricks” the immune systems of genetically susceptible individuals into attacking their own bodies, causing debilitating autoimmune and brain dysfunction. Recombinant hepatitis B vaccines contain polypeptide sequences similar to those present in human brain tissues such as myelin while viral polypeptides can induce autoimmune diseases resembling multiple sclerosis and rheumatoid arthritis.

“The drug companies report safety studies that monitored children and adults for only four or five days after vaccination,” said Dunbar. “It takes weeks and sometimes months for autoimmune disorders such as rheumatoid arthritis to develop following vaccination. In fact, a study group on hepatitis B vaccine with members from the CDC, WHO, NIH, Merck & Co., SmithKline Beecham, Pasteur Mérieux Connaught, and Pasteur-Merieux, MSD Joint Venture reported that ‘a reasonable time limit to use for the onset of MS postvaccination is about 60 days.’”

Dunbar is most critical of the science: “No basic science research to determine the biological mechanism of vaccine injury or long-term studies into the side effects of this vaccine have ever been conducted in babies or children. In adults, only limited follow-up has been carried out in genetically restricted populations.”

Dunbar and her colleagues have applied twice for government funding to investigate the role that genetic factors may play in hepatitis B vaccine reactions or in vaccine failures. Their goal of identifying high-risk markers to screen susceptible children and adults out of the mass vaccination program will have to wait. The NIH has twice turned them down.

To continuing reports that the hepatitis B vaccine negatively affects children and adults, U.S. government officials respond, “there is no confirmed scientific evidence that hepatitis B vaccine causes chronic illness, including multiple sclerosis, chronic fatigue syndrome, rheumatoid arthritis, or autoimmune disorders. . . . Surveillance of adverse events

in the United States after hepatitis B vaccination have shown no association between hepatitis B vaccine and the occurrence of serious adverse events including Guillain-Barre syndrome, transverse myelitis, optic neuritis and seizures.”

The CDC insists on vaccinating all newborns and young children on the grounds that they may act irresponsibly later in life. “While most hepatitis B vaccine infections occur among older adolescents and young adults, vaccination of persons in high-risk groups has generally not been a successful public health strategy.”

Yet the vaccine manufacturers themselves don’t know how long vaccine-induced immunity will last. Merck & Co. stated in its 1996 product insert, “The duration of the protective effect of [the vaccine] in healthy vaccinees is unknown at present, and the need for booster doses is not yet defined.”

Government officials have also been on the defensive since last October, when France became the first country to end hepatitis B vaccine requirements for schoolchildren. France’s health minister acted after numerous reports of arthritis- and multiple sclerosis-like symptoms. Pending citizen lawsuits against SmithKline Beecham and Pasteur-Merieux, which make and sell the hepatitis B vaccine, may also have influenced the French decision. In addition, attorneys representing 15,000 French citizens are suing government health officials for understating the vaccine’s risks and exaggerating its benefits.

The day after France withdrew the vaccine mandate, a dismayed World Health Organization stated that “the decision taken yesterday may lead to loss of public confidence in this vaccine and decisions by other countries to suspend or delay introduction of hepatitis B vaccine. . . . WHO strongly recommends that all countries already using hepatitis B vaccine as a routine vaccine in their national immunization programmes continue to do so, and that countries not yet using the vaccine begin as soon as possible.”

Canadian parents take on the establishment

IN CANADA, THE HEPATITIS B VACCINE CONTROVERSY IS also heating up. Although only three provinces (Manitoba, Ontario, and New Brunswick) actually mandate vaccines for school entry, parents can refuse on medical, philosophical, or religious grounds. Even with these informed consent protections, Mary James, co-founder of the Association for Vaccine Damaged Children (AVDC) in Winnipeg, points out that “vaccination is never presented as a choice to parents. Most parents are told that their child must be vaccinated. Since most parents are not aware of vaccine risks or their rights, they comply without questioning.”

When parents were told last year that their children had to get three doses of the new hepatitis B vaccine, James and her AVDC co-founder Leona Rew fought for a court injunction to stop the program, arguing that Winnipeg public health officials were inadequately informing parents of potential risks. Although they lost their bid to stop the

program, members of AVDC joined members of Parents for Informed Consent and the Eagle Foundation in Winnipeg to raise their objections through television and radio appearances.

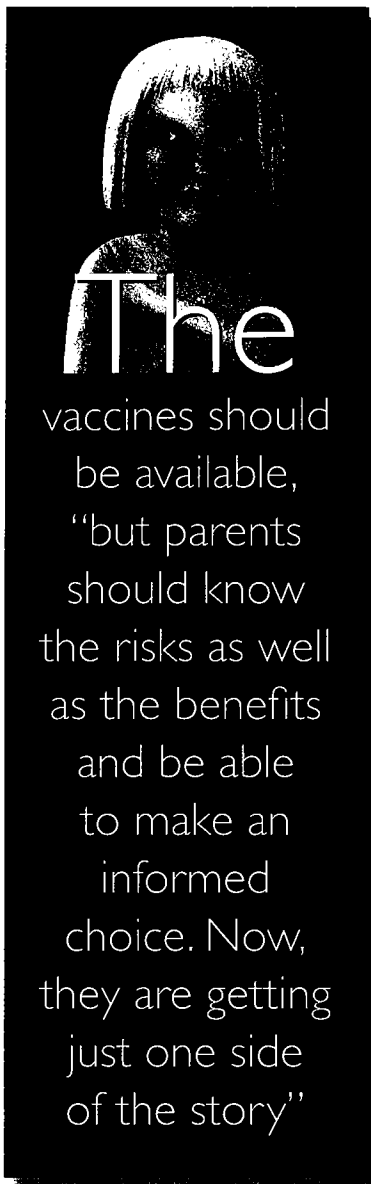
To better monitor vaccine risks, the federal government's Laboratory Centre for Disease Control operates a vaccine reaction reporting system called Vaccine Associated Adverse Events (VAAE). Although most doctors are not required to report health problems following vaccination (except in Ontario, where AVDC activists got a law passed), the system does receive about 4,000 to 5,000 voluntary reports every year. Laboratory Centre for Disease Control officials stress that these reports only reflect "any event that is felt to be temporally related to the administration of an immunization but not necessarily absolutely causally related." They state, "Over 12 million doses of vaccine are distributed every year and very few concerns arise despite intense searching. Until diseases are eradicated, immunization remains our best defence."

Rew disagrees: "Doctors and nurses still do not report adverse reactions. We need a reporting system that has some teeth in it so that doctors are compelled to do their job and report serious health problems that occur after someone gets vaccinated."

James, whose five-month-old daughter was partially paralyzed and died in 1984 following two polio vaccinations, and Rew, whose infant son had bouts of high-pitched screaming and a seizure within hours of a DPT shot, emphasize that AVDC does not advocate banning vaccines. Says James, "The vaccines should be available like any other health care product, but parents should know the risks as well as the benefits and be able to make an informed choice. Right now, they are just getting one side of the story – the one that the government and drug companies want everyone to believe."

American protest forces acknowledgment

CANADA'S GRASSROOTS MOVEMENT RESEMBLES ITS U.S. predecessor. In 1982, a television documentary, *DPT: Vaccine Roulette*, prompted a handful of parents, whose children had been injured by or died from the DPT vaccine, to found an organization known today as the National Vaccine Information Center (NVIC). Soon after, manufacturers threatened to stop producing vaccines unless they were immune to lawsuits. Although most vaccine injury lawsuits were then either won by drug companies or settled on the courthouse steps by weary, cash-poor parents (with all evi-



The vaccines should be available, "but parents should know the risks as well as the benefits and be able to make an informed choice. Now, they are getting just one side of the story"

dence sealed from public view), plaintiffs had won large enough punitive damages in the late 1970s and early 1980s to worry vaccine producers about their liability.

The U.S. Congress immediately began writing legislation for a vaccine injury compensation system and asked physician organizations, vaccine manufacturers, and the co-founders of NVIC to present their concerns. The physicians and manufacturers wanted Congress to remove all liability and to guarantee protection from lawsuits for vaccine injury and death. Congress's final decision required parents to first file for federal compensation by suing the secretary of the Department of Health and Human Services. But parents won the right to sue vaccine manufacturers or negligent physicians if vaccine-injured children were offered too little financial support for their catastrophic vaccine injuries or were turned down entirely – although bringing a lawsuit would then be more difficult. Parents also retained the right to sue for unlimited punitive damages where manufacturers engaged in "fraud or intentional wrongful withholding of information relating to the safety or efficacy of the vaccine," or engaged in "other criminal or illegal activity relating to the safety and effectiveness of vaccines."

Government health agencies opposed the proposed federal compensation legislation, maintaining that vaccinated children who developed serious health problems had an "underlying genetic disorder" or a health problem that would have spontaneously occurred even without a vaccination. It was only after the book *DPT: A Shot in the Dark* (Coulter and Fisher, Harcourt Brace Jovanovich, 1985) was published and parents held public demonstrations at the CDC in Atlanta and in front of the White House the following year, that President Ronald Reagan signed the National Childhood Vaccine Injury Act into law in 1986. (Pressure by parents eventually led to the FDA licensing of a purified pertussis vaccine in 1996, which has been associated with fewer reactions.)

Today, parents of vaccine-injured children and their lawyers criticize the law's implementation because three out of four applicants are turned away. With government lawyers and health officials fighting every claim, more than \$1 billion lies idle in a vaccine injury trust fund. Still, under the act, more than \$1 billion has been paid to 1,000 families whose members, the U.S. Court of Claims in Washington, D.C., has judged, were harmed by routine vaccinations. The majority of the awards have been for DPT-vaccine

every institution and social convention as teenagers – continue to exercise their counterculture instincts as adults by asserting their right to make independent health care choices. Their demand to make vaccination choices puzzles and worries MDs, including some outspoken alternative health care advocates.

Andrew Weil, MD, a respected leader in the alternative health care movement, defends mass vaccination. Sparring with Richard Moskowitz, MD, in *Natural Health* magazine in 1997, Weil asserted, “The debate about immunization could only be going on in a country where the people are mostly immunized. If people in this country lived with these diseases, you wouldn’t hear them questioning immunization.” Moskowitz, a clinician who specializes in homeopathy, countered, “For us to bombard a newborn baby with a whole battery of vaccines as, in effect, their very first immunological experience I think is reckless beyond measure. I would say it borders on the criminal.”

VACCINES ARE SUPPOSED TO FOOL THE BODY’S IMMUNE system into producing antibodies to resist viral and bacterial infection in the same way that actually having the disease usually produces immunity to future infection. Whereas natural recovery from many infectious diseases stimulates lifetime immunity, vaccines only provide temporary protection. That’s why booster doses are often required.

Vaccination raises two equally contentious questions. First, is it better to protect children against infectious diseases early in life through temporary immunity from a vaccine or are they better off contracting certain contagious infections in childhood and attaining permanent immunity? Second, do vaccine complications cause more injury and death than diseases do? Both questions essentially pit trust in human intervention against trust in nature.

The rise of asthma and other autoimmune diseases

PHYSICIANS AND PUBLIC HEALTH OFFICIALS PROMOTING childhood vaccination insist that vaccines do not harm the immune system in any way. They defend the use of vaccines – made in the laboratory from altered viruses and bacteria as well as chemicals, such as formaldehyde, mercury, aluminum, monosodium glutamate, sulfites, and antibiotics – as necessary weapons for shielding vulnerable newborns from the suffering caused by viral and bacterial infections.

Visitors to the U.S. Centers for Disease Control and Prevention (CDC) site on the Internet (www.cdc.gov) learn that “vaccines give your baby’s immune system the chance to practise and make protective antibodies before real germs invade. If left totally to chance, your baby’s first exposure to a disease may be from a germ too strong for your baby to fight. That’s why before parents had vaccines for their children, many children died from whooping cough, measles, diphtheria and other diseases. Those same germs

exist today, but today’s babies are protected by vaccines.”

The CDC warns that “Immunizations must begin at birth and most vaccinations [be] completed by age 2. . . . Children under 5 are especially susceptible to disease because their immune systems have not built up the necessary defenses to fight infection.”

YET A GROWING BODY OF SCIENTIFIC EVIDENCE SUGGESTS that vaccines may have inadvertently done more than just suppress infectious childhood diseases. Vaccine critics point out that the increase in autoimmune and neurological disorders in the past three decades in industrialized countries coincides with the addition of new vaccines to the childhood vaccination schedule as well as rapidly increasing vaccination rates.

Between 1964 and 1992, the U.S. added six new vaccines to the mandatory vaccination schedule, including five doses of live virus polio; two doses of MMR (measles, mumps, and rubella); four doses of Hib (*haemophilus influenzae* type b, which is a type of meningitis); and three doses of hepatitis B vaccine, while more strictly enforcing existing laws mandating five doses of DPT (diphtheria, pertussis – also known as whooping cough – and tetanus). Vaccination coverage rates rose in American children under age three from between 60 and 80 per cent in 1967 for MMR, polio, and DPT vaccines to between 80 and 95 per cent coverage in 1996 for MMR, polio, DPT, hepatitis B, and Hib vaccines.

Asthma is an autoimmune disorder, an allergic condition that tops the list of chronic respiratory diseases found in children in Western societies today. A 1997 study published in *Science* reported that “the prevalence of asthma in westernized societies has risen steadily this century, doubling in the last 20 years. Asthma now affects one child in seven in Great Britain, and in the United States it causes one-third of pediatric emergency room visits.” Another study found that between 1964 and 1980, asthma in children aged six to 11 years increased 50 per cent. In 1995, the CDC reported that, between 1982 and 1992, asthma increased 52 per cent for persons between the ages of five and 34 years old, and deaths from asthma increased 42 per cent.

The 1978 Canada Health Survey found that only 2.3 per cent of Canadians 15 years and over reported having asthma. By 1991, its prevalence was at 6 per cent. More than 1.5 million Canadians of all ages suffer from asthma.

Even more worrisome, however, are the findings of a large survey of Canadian schoolchildren in 1995-96 that found a 13 per cent prevalence of asthma. From the early 1970s to the late 1980s, the number of Canadian patients under 35 years discharged from hospital with a diagnosis of asthma tripled. The greatest increase has been in children under four years of age. As in the U.S., asthma deaths in Canada have climbed along with its increased prevalence.

Asthma’s economic burden is formidable. According to Canada’s 1994 National Population Health Survey, the long-term disability costs associated with asthma, emphysema,

and chronic bronchitis in 1993 totalled \$1.8 billion, without counting costs associated with treating asthma in children under 11 years old. In the U.S., the total cost of illness related to asthma in 1990 was estimated at \$6.2 billion.

Although public health officials attribute the recorded increases in asthma to better case diagnoses, more air pollution indoors and outdoors, and smoking, some scientists find evidence that vaccination and lack of contagious infectious diseases in early childhood may later encourage the development of asthma and other allergic conditions.

In 1996, the British medical journal, *The Lancet*, published Danish and British findings concerning child health, lung function, and allergy. Noting that the incidence of early childhood diseases in Britain has fallen this century while those of allergic diseases such as asthma, hay fever, and eczema rose sharply, the researchers hypothesized that certain childhood infections, specifically measles, may protect against allergy.

They compared evidence of atopy (allergy) in two groups of young adults, aged 14 to 21, in Guinea-Bissau in West Africa. One group had recovered from measles during a 1979 epidemic (before the measles vaccine was introduced); the other did not get measles as children and were later vaccinated.

The researchers confirmed their hypothesis: About 26 per cent of the vaccinated young adults had allergic conditions, twice the rate of those who had recovered from measles. After adjusting for breast-feeding and other variables, they concluded that their findings may indicate that "measles infection prevents allergic sensitization." Because this was the first population-based study to relate reduced allergies to a specific childhood viral infection, they urged further studies in developing countries, where childhood diseases are still widespread due to low vaccination rates.

Vaccine promoters point out that measles complications kill one million children annually, mostly in underdeveloped countries. In Guinea-Bissau's 1979 measles epidemic, the case-fatality rate in children under 3 was 25 per cent: it is better to have asthma for the rest of your life than die from measles.

Mass vaccination critics counter that West Africa's health and living conditions, which could account for the high death rate, don't apply to Europe and North America, where toddlers who get measles usually recover without complications. Why not eliminate poverty, malnutrition, poor sanitation, and substandard medical care in developing countries so that measles-related death rates come down, as in industrialized countries even before vaccination?

Another study, this time comparing the prevalence of asthma and other allergic disorders in child populations throughout the world, appeared in *The Lancet* in 1998. The authors found that the wealthier, more developed countries in Western Europe and North America and Australia and New Zealand had higher incidences of asthma than did the poorer countries in Eastern Europe, Asia, and Africa.

The authors of the 1997 *Science* article "Asthma: An Epidemic in the Absence of Infection?" tentatively answered yes to their own question, concluding that "childhood infections may, therefore, paradoxically protect against asthma." In a 1997 issue of *Epidemiology*, New Zealand researchers hypothesized that "it is theoretically possible that immunization may contribute to the development of allergic disease." Of 1,265 New Zealanders born in 1977, 23 received no childhood vaccinations, and none suffered childhood asthma. Among the 1,242 who got polio and DPT shots, 23 per cent later had episodes of asthma, 23 per cent had asthma consultations, and 30 per cent had consultations for other allergic illness. Their conclusion was, "The findings presented here are consistent with the hypothesis that some component of infant immunization may increase the risk of developing asthma in childhood."

A tripling of diabetes

DIABETES, A CHRONIC AUTOIMMUNE DISORDER THAT DISRUPTS the blood's glucose levels, afflicts some 125 million people worldwide. That number is expected to double by 2025.

In the U.S., where 600,000 new cases are diagnosed every year, the number of diabetics has increased a record three-fold since 1958, to nearly 16 million, and millions more may unknowingly have it. Now the fourth leading cause of death in the U.S., diabetes can cause blindness, kidney failure, stroke, and heart disease and can lead to amputations. In 1992, the U.S. National Institute of Diabetes and Digestive and Kidney Diseases estimated that diabetes cost the U.S. \$45 billion for medical treatment plus \$47 billion for lost work time, disability payments, and premature death. In Canada, the Laboratory Centre for Disease Control found that the 1993 cost burden of diabetes exceeded \$1 billion, including \$565 million in drug, physician, and hospital costs and \$559 million in mortality-related costs.

As early as 1949, the medical literature reported that some children injected with the pertussis vaccine had reduced blood glucose levels. The pertussis vaccine can cause diabetes in mice. In recent decades, scientists have suggested that viral infections may be a co-factor in causing diabetes. Because both rubella and mumps infections have been associated with juvenile diabetes, the introduction of the live virus vaccines for measles, mumps, and rubella in the 1960s and 1970s also raised questions about whether live vaccine virus could be a contributing co-factor to the onset of diabetes.

In the May 24, 1996, *New Zealand Medical Journal*, J. Barthelme Classen, MD, a former researcher at the U.S. National Institutes of Health (NIH) and the founder and CEO of Classen Immunotherapies in Baltimore, reported that juvenile diabetes increased 60 per cent following a massive hepatitis B vaccination campaign for babies six weeks or older in New Zealand from 1988 to 1991. In the October 22, 1997, *Infectious Diseases in Clinical Practice*, Classen showed

that Finland's incidence of diabetes increased 147 per cent in children under five after three new vaccines were introduced in the 1970s, and that diabetes increased 40 per cent in children aged 5 to 9 after the addition of the MMR and Hib vaccines in the 1980s. He concluded that "the rise in IDDM [juvenile onset diabetes] in the different age groups correlated with the number of vaccines given."

Classen discounts the conclusions of many vaccine safety trials, especially 48-hour or several-day vaccine reaction follow-ups, which can miss the development of autoimmune dysfunction that can take years to develop. According to Classen, "Previous vaccine trials are flawed because they are not designed to detect associations between vaccination and autoimmune diseases, such as diabetes. Prospective clinical trials are needed."

Government health officials dispute Classen's research, and that of others concerned about mass vaccination policies. In 1997, U.S. federal health officials did admit that one of their own studies showed that "the possibility that hepatitis B vaccination, particularly at older ages, may increase IDDM risk cannot be ruled out and will require larger more detailed studies." Nevertheless, in 1998, they told the public in a report written to rebut Classen's findings, "Dr. Classen's results are not consistent with current scientific thinking and have not been verified by other researchers.

. . . Comparison of diabetes rates between countries with different vaccination policies also provides weak evidence because many factors, including different vaccination schedules, may differ by country. Many factors, including genetic predisposition and a number of possible environmental exposures unrelated to vaccines, may influence the development of diabetes in different countries."

Last year, after Classen discussed the possible link between diabetes, certain vaccines, and the timing of early childhood vaccinations on ABC's *World News Tonight*, he was summoned to a closed meeting at Johns Hopkins University chaired by Neal Halsey, MD, chairman of the American Academy of Pediatrics Committee on Infectious Diseases, AAP liaison member of the CDC's Advisory Committee on Immunization Practices, and Director of the Institute of Vaccine Safety at Johns Hopkins University. Officials from NIH, the Food and Drug Administration (FDA), and the CDC, as well as representatives from vaccine manufacturers also attended the meeting. There, they criticized Classen for speaking publicly about his findings. Later, World Health



Eight
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Organization (WHO) officials joined those in the U.S. in berating Classen.

Undaunted, Classen and a colleague appealed to vaccine policy makers in a letter published in the January 16, 1999, *British Medical Journal*. "We believe that the public should be fully informed that vaccines, though effective in preventing infections, may have long-term adverse effects," they wrote. "An educated public will probably increasingly demand proper safety studies before widespread immunization. We believe that the outcome of this decision will be the development of safer vaccine technology."

Autism soars

OTHER SCIENTISTS RESEARCHING health problems associated with vaccines have also felt the ire of public health officials. In 1998, an unsuspecting young British gastroenterologist suddenly found himself in the eye of a hurricane for discovering a possible connection between the MMR vaccine and autism.

In the February 27, 1998, issue of *The Lancet*, Andrew Wakefield, MD, and 13 colleagues reported on a new syndrome involving inflammatory bowel disease and autism in children. Eight out of 12 normal children who developed severe intestinal disorders soon after an MMR vaccination also became autistic. Previously, five of those eight children had reacted adverse-

ly to vaccinations.

The team of British scientists, who had inadvertently stumbled upon the connection while studying Crohn's disease and other inflammatory bowel dysfunction in children, emphasized that they had not proved a cause-and-effect relationship. They called for more studies to investigate whether persistent viral infection, either from natural disease or live virus vaccines, can lead to central nervous system damage in some children.

Nevertheless, in the same issue of *The Lancet*, CDC officials Robert Chen, MD, and Frank DeStefano, MD, charged in an editorial that "vaccine safety concerns such as that reported by Wakefield and colleagues may snowball" when the public and the media "confuse association with causality and shun immunization." Other CDC officials discounted the study's importance, saying that the children's health problems were "coincidental" and not caused by vaccination.

Soon after, a Reuters newswire story quoted Johns Hopkins's Halsey saying it was "highly inappropriate" for Wakefield and his colleagues to discuss a possible connection

between the children's health problems and measles or MMR vaccines. Wakefield was later called before the Medical Research Council where British, U.S., and WHO health officials criticized his report for unnecessarily scaring the public.

In contrast, autism experts defended Wakefield.

Bernard Rimland, who has a PhD in experimental psychology and is founder and director of the Autism Research Institute in San Diego, said, "It is ludicrous to claim that the link between many causes of autism and vaccination is just coincidental. Dr. Wakefield's group has greatly expanded our understanding of one possible mechanism. The blunt truth is that some children are harmed by vaccinations. Research, not denial, is the proper response to this report."

Portia Iverson, founder and president of CAN, the Cure Autism Now foundation in Los Angeles, also took issue at the government-led criticism: "Approximately one-half of the hundreds of parents who call our office each month report that their child became autistic shortly after receiving a vaccination. Isn't it the responsibility of the government to take a pro-active position on behalf of these children rather than a defensive one?"

Like incidences of asthma and diabetes, the incidence of autism has climbed dramatically in the past 30 years. Although the medical literature identified only a handful of cases in the 1940s, by the mid-1960s, after the DPT vaccine had been widely used and the measles vaccine introduced, autistic children began flooding doctors' offices. (Parents in the U.S. and Canada who report vaccine-associated autism most often mention that their children's autistic behaviors followed DPT or MMR vaccination.) Today, 1 in 1,000 children are diagnosed as autistic, making autism more prevalent among children than cancer, multiple sclerosis, or cystic fibrosis. A recent California study put the figure at 1 in 312 children, a 273 per cent increase between 1987 and 1998.

Hepatitis B vaccine takes a hit

CANADIAN PHYSICIANS HAVE ALSO FACED CRITICISM FROM government health officials who dismiss vaccine side effects. Byron Hyde, MD, chairman of the Ottawa-based Nightingale Research Foundation and an internationally recognized authority on myalgic encephalomyelitis (chronic fatigue syndrome), has accumulated data on several hundred cases of serious immune and neurological dysfunction following hepatitis B vaccination. His first case reports, in the early 1990s, came from Quebec nurses who reported a constellation of autoimmune symptoms, including pain, fatigue, and mental dysfunction, and were unable to work.

Hyde, a vaccination advocate, spoke out publicly about the side effects in September 1997 at the First International Public Conference on Vaccination sponsored by the National Vaccine Information Center in Washington, D.C. He told more than 500 parents and doctors that in the early 1990s, both the vaccine manufacturer and the Canadian health

authorities repeatedly rebuffed his requests for an investigation into signs of demyelinating disease, measurable loss of IQ, loss of stamina, intractable pain, blindness, skin lesions, and other problems affecting health care workers following their hepatitis B vaccinations.

Hundreds of cases later, he has concluded that "almost all of these people who had adverse reactions after the first immunization, after the second immunization were individuals who had immunological side effects and who told their physicians, and the physicians did nothing about it but continued to proceed with immunization. . . . I think part of the problem is the pharmaceutical companies and the governments themselves have attempted to say, 'Here, take this sugar pill, it is danger-free, it is a wonderful thing, it has no risk, no problems,' and doctors have become lazy and actually believed this dangerous philosophy put out by the pharmaceutical companies and the governments."

Researchers like Hyde are at the centre of a growing controversy about the recombinant DNA hepatitis B vaccine licensed in the U.S. in 1986. Although health officials estimate that more than 300 million people worldwide have chronic hepatitis B, both Canada and the U.S. have historically had among the world's lowest rates, even before the vaccine was introduced. Unlike in parts of Asia and Africa, where the disease often affects 5 to 20 per cent (and sometimes more) of the population, in Canada and the U.S., less than 1 per cent have hepatitis B, and about 95 per cent of those infected recover and get permanent immunity. However, health officials emphasize that those who become chronically infected suffer dire consequences: poor health, liver disease, and sometimes liver cancer.

Unlike whooping cough, a respiratory disease that can kill babies and small children, which the pertussis vaccine was designed to prevent, hepatitis B is not a childhood disease. Spread through infected body fluids, primarily blood, it is most prevalent in high-risk adult populations such as intravenous drug users, prisoners, individuals with multiple sexual partners, those undergoing blood transfusions, and health care workers exposed to infected blood. Doctors reported about 10,000 hepatitis B cases in the U.S. in 1997 with only 306 occurring in children under 14.

The only babies at risk are those born to hepatitis B-infected mothers, but because few hospitals screen pregnant women for hepatitis B infection, in 1991, the CDC recommended vaccinating all newborns before discharge from the hospital nursery. The CDC maintains its recommendation despite this 1997 admission: "Hepatitis B continues to decline in most states primarily because of a decrease in the number of cases among injecting drug users and, to a lesser extent, because of a decline in cases associated with both male homosexual practices and heterosexual practices."

Widely touted as almost risk-free, health care workers in the U.S. and Canada were among the first to get this, the first genetically engineered recombinant DNA vaccine. Soon after, nurses and doctors in both countries reported

realizing where we think we would want to use universal application of such a vaccine.”

As the number of reported AIDS cases in the U.S. continues to drop (about 58,000 in 1997 compared with 103,691 in 1993) and the number of AIDS cases in the Third World veers out of control, vaccination supporters have accelerated their push to put an AIDS vaccine on the market. In 1997, President Bill Clinton challenged scientists and industry to make an AIDS vaccine available within 10 years and added more money to the annual \$150 million already committed to this purpose. The U.S. media compared his call to President John F. Kennedy’s challenge to American scientists to put a man on the moon.

At least three dozen different experimental HIV vaccine trials are underway in the U.S., using numerous approaches. Pasteur Mérieux Connaught has created one vaccine from a weakened, genetically engineered canarypox virus. Researchers are testing it as an injection, and it also will be swabbed or dripped onto the genital and urinary tracts and nose and throat. Another experimental vaccine uses a new strategy based on genetically engineered salmonella bacte-

voluntary consent of the human subject is absolutely essential.” The code speaks specifically to the use of human beings in medical research, but since it was adopted internationally and followed in 1964 by the passage of the Declaration of Helsinki, the Nuremberg Code has served as the “gold standard” in the ethical practice of medicine and as the basis for guaranteeing all patients the right to informed consent to any medical procedure that could harm them.

Patients today are guaranteed informed consent protections when undergoing routine surgery or diagnostic tests or taking medications carrying a risk of injury or death, but mandatory vaccinations have been exempted from informed consent standards. If the state cannot determine which individuals are genetically or otherwise at high risk for being injured or dying from vaccines, does state-forced vaccination translate into a de facto medical experiment and an immoral application of utilitarianism?

Philosopher Hans Jonas reminds us that a state may have the right to ask an individual to volunteer to die for what the state has defined as the common good, but rarely, if ever, does a state have the moral authority to command it. He concluded: “Let us not forget that progress is an optional goal, not an unconditional commitment, and that its tempo in particular, compulsive as it may be, has nothing sacred about it. Let us also remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having.”

B.L.F.

ria. In 1998, the Chicago-based International Association of Physicians in AIDS Care called for use of an experimental live HIV vaccine, although physician advocates admitted that a live HIV vaccine could theoretically mutate into an AIDS-causing strain. A report on monkey tests from the 12th World AIDS Conference last July confirmed that many monkeys or their offspring died or developed AIDS symptoms after receiving live HIV vaccines.

Last June, the FDA gave VaxGen, Inc., a San Francisco biotechnology company, permission to start Phase III human clinical trials of a genetically engineered vaccine containing recombinant forms of two HIV strains. VaxGen, which “is committed to making an HIV vaccine for worldwide use,” is testing its vaccine on 5,000 volunteers in Thailand and North America, including cities such as Philadelphia and Los Angeles.

Most HIV-negative volunteers who get an HIV vaccination in experimental AIDS vaccine trials will test HIV-antibody-positive for life. In New York City, technicians now ask those getting blood drawn if they have volunteered in an AIDS vaccine trial – stark acknowledgment of a new generation of vaccine-induced HIV positives who, researchers insist, are not HIV infected.

As public health officials increasingly define disease control in global, rather than national, terms, mass vaccination proponents and vaccine makers must find ways to finance delivery of newer and more expensive vaccines to poor countries. They accomplish this by first making the vaccinations mandatory in rich countries, as HIV vaccine developer Stanley Plotkin, MD, of Pasteur Mérieux Connaught explained in 1996: “The keystone of the [global mass vaccination] system is that the research costs [of drug companies] are recouped in North America and Europe, and the vaccines are sold in the developing world at much, much lower margins. . . . The relatively high rate of childhood vaccination seen lately in most parts of the world is the result of that system.”

Just last year, the CDC illustrated this funding formula by recommending that all American babies under six months receive three doses of the newly licensed live rotavirus vaccine for diarrhea. Although a serious health problem in the Third World, where 870,000 babies lacking adequate nutrition or medical care die from dehydration caused by severe diarrhea every year, most American and Canadian babies fully recover from bouts with rotavirus and are left with permanent immunity. About 20 to 40 babies die of rotavirus infection in the U.S. every year.

Vaccine production problems and new epidemics

THE ROTAVIRUS VACCINE, WHICH WILL COST \$40 A SHOT in the U.S., is the first rhesus-human reassortment vaccine, created by co-cultivating rhesus monkey rotavirus strains with human rotavirus strains to create a genetic human-monkey hybrid strain of rotavirus. This production

process, while more sophisticated, recalls the use of rhesus monkeys to produce the original Salk polio vaccine.

In the rush to put a polio vaccine on the market in 1955, polio vaccine pioneer Jonas Salk unknowingly used rhesus monkey kidney tissues contaminated with monkey viruses. In the late 1950s, after lab technology advances could screen for monkey viral contaminants, scientists identified simian virus 40 (the 40th monkey virus identified in the vaccine). SV40 was found to cause cancer in lab animals in 1959, but by then, some 98 million American children had already received the vaccine. Today, Michele Carbone, MD, a molecular pathologist at Chicago's Loyola University Medical Center, and other researchers around the world are culturing out SV40 from cancerous brain, bone, and lung tumors in adults and children in an effort to understand the inexplicable rise of these rare cancers.

After they discovered the SV40 contamination, polio vaccine makers in the U.S. switched from the rhesus monkey to African Green monkey kidney tissues to produce live polio vaccine. However, African Green monkeys can be infected with simian immunodeficiency virus (SIV) and not appear sick. In 1992, Walter S. Kyle, whose article "Simian retroviruses, polio vaccine and origin of AIDS" was published in *The Lancet*, hypothesized that SIV contaminated both experimental and general use oral polio vaccines using African Green monkey kidney tissues. "There could have been multiple crossovers of the SIV virus from monkeys into the human population at different points in time where, in humans it took the form of HIV," he wrote. "This may explain why different populations have been affected at different times with HIV during the past 30 years" – a time span that correlates perfectly with the dates that those populations were vaccinated in their respective countries during different phases of the worldwide polio vaccination campaigns.

At the 1996 Eighth Annual Houston Conference on AIDS in America, a retrospective scientific analysis by California microbiologist Howard B. Urnovitz, PhD, supported the thesis that SIV, which is highly similar in genetic structure to HIV-2, may have contaminated experimental live oral polio vaccines. In some African children given this contaminated vaccine in the Congo between 1957 and 1959, says Urnovitz, SIV could have recombined with their own normal genes to create the monkey-human hybrid now known as HIV-1.

There is no scientific consensus on HIV's origin. Earlier this year, Beatrice Hahn, MD, and Anthony Fauci, MD, pointing to chimpanzees that Congolese were slaughtering and eating, announced that they had solved the mystery. Hahn reported that three West African chimps were infected with SIV strains that very strongly resembled three HIV subgroups.

Kyle and Urnovitz both challenge these findings. "They have been eating monkeys in Africa for thousands of years," said Urnovitz. "Why did HIV only crop up in the late

1950s? The buffet theory of the origins of HIV just doesn't hold any water. . . . There are many confounding theories being forwarded, but they all come back to contaminated polio vaccines." Adds Kyle, "Hahn's discovery could as easily be explained by the fact that chimps also eat African Green monkeys."

A Brave New World

IN 1997, CDC OFFICIAL WALTER ORENSTEIN, MD, TESTIFYING before the U.S. Congress, painted a picture of the future in his annual appeal for more vaccine funding. "On the horizon are vaccine technologies that would have been considered science fiction just a decade ago but are now reported at scientific meetings," he said. "Snippets of synthetic DNA have worked as experimental vaccines in animals. Edible plants have been bioengineered to become vaccine factories. . . . Vaccines have been enclosed in microscopic capsules, permitting them to be released slowly over time."

Vaccine researchers are seeking \$500 million from all the world's governments to create a genetically engineered "supervaccine" that will be given orally at birth. This supervaccine – the CDC and CVI call it the "Holy Grail" – will contain raw DNA from 20 to 30 viruses, parasites, and bacteria that will insert itself directly into the cells of babies. The vaccine will be time-released over several months. Disease organisms scheduled to be included in the supervaccine, many containing multiple strains or types of each virus, bacteria, or parasite, are pneumonia (three viruses), AIDS (two viruses), dengue haemorrhagic fever (four viruses), diarrheal disease (several viruses and bacteria), diphtheria, hepatitis, malaria (two parasites), measles, meningitis (six viruses and bacteria), polio (three viruses), schistosomiasis (one parasite), tuberculosis, typhoid fever, and pertussis.

In all, vaccine manufacturers and U.S. government researchers are developing more than 150 different viral and bacterial vaccines. A nasal spray flu vaccine targeting children will be ready by the fall of 2000; adhesive skin patch vaccines and high technology jet guns will deliver vaccines designed to prevent ear infections, strep throat, asthma, genital herpes, gonorrhea, stomach ulcers, and even cancer and the common cold. If the microbe fighters have their way, the "Brave New World" of the future will truly be infection-free.

Or will it? In 1993, scientists at the American Society of Microbiology annual meeting reported that diseases such as tuberculosis, meningitis, and gonorrhea have become resistant to antibiotics because of their overuse in the past decades. One study shows that pediatricians are prescribing antibiotics to 44 per cent of children with common colds. In 1998, evidence of penicillin-resistant strep bacteria caused worry that more people will suffer or die from severe pneumonia, bacteremia, and meningitis.

Last year, a U.S. Public Health Report warned that the overuse of antibiotics in animals, which transfers resistant

related brain damage or death, with a lesser number for MMR and polio vaccine reactions. (NVIC's web site, www.909SHOT.com, describes some of the vaccine injury cases.)

The 1986 law, which mandated the Institute of Medicine (IOM) of the prestigious National Academy of Sciences (NAS) to review the medical literature for evidence that vaccines can cause injury and death, was historic societal acknowledgment that vaccines can be harmful. In 1991 and 1994, NAS published the evidence in three landmark reports.

One high-level physician committee examining the medical literature wrote, "the lack of adequate data regarding many of the adverse events under study was of major concern. . . . The committee encountered many gaps and limitations in knowledge bearing directly or indirectly on the safety of vaccines." Nevertheless, the IOM did find enough scientific evidence to confirm that the DPT vaccine can cause acute brain inflammation and permanent brain damage that ranges from learning disorders to severe and profound retardation; the DT (diphtheria and tetanus) vaccine can cause Guillain-Barre syndrome, including death, as well as brachial neuritis; the rubella vaccine can cause acute and chronic arthritis; the live oral polio vaccine can give polio to the person being vaccinated or to someone who comes into contact with that person's body fluids; and the MMR vaccine can cause shock as well as a potentially fatal infection from a vaccine strain of measles virus.

Because scientific studies did not exist, physician committees could not properly evaluate a long list of other vaccine-associated health problems, including some of the chronic autoimmune and neurological disorders – such as diabetes and multiple sclerosis – at the centre of the vaccine safety controversy. The big news, though, was that the medical community had told the public that vaccines can injure and kill. While health officials stressed anew that "the benefits [of vaccines] outweigh the risks," parents of healthy children better understood the cry of parents of vaccine-injured children: "When it happens to your child, the risks are 100 per cent."

Under the 1986 law, the federal government also set up an improved vaccine reaction reporting system, which, like Canada's reporting system, depends on physicians' reports. The U.S. Vaccine Adverse Event Reporting System receives between 12,000 and 14,000 reports of hospitalizations, injuries, and deaths following vaccination every year, but as in Canada, parent groups claim that less than 10 per cent of doctors report vaccine-associated health problems and that the government does not adequately follow up.

A matter of law

UNLIKE CANADA, HOWEVER, EVERY U.S. STATE LEGALLY requires vaccinations, and public health officials vigorously enforce these laws. Refusing to vaccinate one's children can result in denial of an education, including enrol-

ment in day care, elementary school, high school, college, and graduate school; denial of health insurance; denial of employment; and threatened denial of government benefits for poor children, including food and medical care. In addition, parents who don't comply with vaccination laws have been charged with child medical neglect and threatened with having their children taken from them.

All 50 states provide a medical exemption to vaccination laws that doctors licensed to prescribe drugs can write. All but two states allow exemptions for religious beliefs, but some states require that parents belong to a religion that has a written tenet opposing vaccination (several state high courts have found this requirement unconstitutional). Some 16 states provide for philosophical or "personal belief" exemption, but most parents are unaware of these exemptions and fewer than 1 per cent in most states exercise them.

Although American vaccine laws fall under state, rather than federal, jurisdiction, as soon as the CDC licenses a new vaccine and recommends it for "universal use," state health officials automatically make it mandatory. So, while state health officials only required children to show proof of smallpox vaccination to enter school in 1949, in 1999, most states require children to be injected with 33 or 34 doses of nine or 10 different vaccines.

Tracking system to enforce vaccination

TO ENCOURAGE HIGH VACCINATION RATES, FEDERAL officials give grants and other financial incentives to state health and education agencies, or withhold them. In 1993, the Clinton administration launched an "Immunization Initiative," and Congress authorized more than \$400 million for states that enforced mandatory vaccination by using social security numbers to track children from birth. Simultaneously, a grant program rewards state health departments with up to \$100 for each fully vaccinated child.

The government eventually plans to link state vaccine tracking systems together to create a government-operated centralized electronic database monitoring everyone's medical records, including vaccination status, from birth. One federal proposal would link a national ID "smartcard" to obtaining a driver's licence and other societal privileges, such as health care or getting a job. Individual legislators, at both the state and federal levels, have already proposed tax penalties for citizens who don't fully vaccinate their children.

In addition to government grants, the Robert Wood Johnson Foundation (Johnson & Johnson) has awarded nearly \$10 million to states to set up vaccine tracking systems to enforce vaccine laws. In 1989, Johnson & Johnson joined with Merck & Co., the U.S. manufacturer of the MMR, chicken pox, and hepatitis B vaccines, to form Worldwide Consumer Pharmaceuticals Company, with the goal of becoming "one of the premier worldwide consumer products companies." By 1997, Merck's vaccine sales had reached \$1 billion.

Tracking would eventually become global

A NUMBER OF PRIVATE COMPANIES AND ORGANIZATIONS are already working with governments around the world to ensure "the integration and harmonization of immunization registries" through the promotion, standardization, and acceptance of computerized patient records systems that would monitor the health status of every citizen.

The Children's Vaccine Initiative (CVI), launched in 1990 at the World Summit for Children in New York City, wants to develop global strategies for "the development and utilization" of vaccines by all the world's children. Headquartered in Geneva, CVI receives money from the United Nations Children's Fund, the United Nations Development Programme, the World Bank, WHO, and the Rockefeller Foundation. CVI is also financially supported by the world's largest manufacturers and marketers of vaccines. To conform to CVI goals, in 1994, CDC health officials developed a National Vaccine Plan for the U.S., which "provides a framework in which diverse domestic and international, public and private-sector activities in immunization and vaccine development can be effectively coordinated" and

"describes the way in which the United States should promote immunization to protect the health of all people," including "accelerating the development and use of promising new and improved vaccine candidates."

An HIV vaccine for children?

IN A FEBRUARY 12, 1997, MEETING OF THE CDC'S ADVISORY Committee on Immunization Practices, which makes vaccine policy for the U.S., committee member Neal Halsey reminded HIV vaccine researchers and developers that the government plans to target preteens for universal application of an HIV vaccine. Halsey told them, "One of the things that's happened in the past with vaccines is that sometimes the manufacturers have developed them and tested them primarily in an age group or a population which may not be the final target population that this committee has considered. . . . We really see age 11 to 12 as the target age for introduction of vaccines for prevention of sexually transmitted diseases. . . . It would be nice if there were studies that were planned in parallel when you move another step in the direction of actually having a candidate vaccine,

In the name of the greater good

Every child must get vaccinated for the greater good of society, say mass vaccination proponents, and parents who do not vaccinate their children place all children at risk. The state should require vaccine risks to be shared equally by all because the minority of children harmed by vaccines is outweighed by benefits to the majority. In short, when it comes to forced vaccination, the ends justify the means.

Those questioning the wisdom of mass vaccination, both for individual and public health, counter that the risks have not been scientifically quantified, putting some children at higher risk for injury and death. In effect, mass vaccination amounts to a medical experiment on potentially genetically susceptible children. Besides, they say, those who choose to vaccinate should have nothing to fear from those who choose not to vaccinate—if the vaccines are truly protective.

As government health officials translate science and medicine into law, the public debate is stirring up some of the ethical questions addressed after the dark days of the Second World War. While the grotesque medical experiments systematically conducted in concentration camps during the Holocaust are an entirely different issue, the universal ethical principles debated during the Nuremberg Trials are relevant. Does the state have the moral authority to command that citizens give their lives against their will for what the state has determined to be the greater good?

U.S. Supreme Court jurist Oliver Wendell Holmes applied a utilitarian ethic in 1927 to justify the forced sterilization of a mentally retarded woman, saying that "the principle that sustains compulsory vaccination is broad enough to cover cutting the fallopi-

an tubes." A decade later, Hitler would implement the utilitarian ethic in its most extreme and tragic form. In a remarkable series of articles published in the November 1996 issue of the *Journal of the American Medical Association*, bioethicists and lawyers describe how physicians, in service to the German state before and during the Second World War, employed the utilitarian rationale that a lesser number of individuals can be sacrificed for the happiness or theoretical benefit of a greater number of individuals. Scientific experiments on individuals, including injection of experimental vaccines, were justified on the grounds that they advanced medical knowledge and benefited humanity.

The Nuremberg Tribunal, which held the 1946-47 Doctors Trial at Nuremberg and tried Nazi doctors for crimes against humanity, discredited the pseudo-ethic of utilitarianism as inherently immoral. The resulting Nuremberg Code, explains Yale law professor, physician, and ethicist Jay Katz, "if not explicitly then at least implicitly commanded that the protection of the advancement of science bow to a higher principle: protection of individual inviolability. The rights of individuals to thoroughgoing self-determination and autonomy must come first. Scientific advances may be impeded, perhaps even become impossible at times, but this is a price worth paying."

Katz also has said that the judges of the Nuremberg Tribunal, overwhelmed by what they had learned, "envisioned a world in which free women and men, after careful explanation, could make their own good or bad decisions, but not decisions unknowingly imposed on them by the authority of the state, science, or medicine."

The First Principle of the Nuremberg Code states that "the

microbes from livestock to humans through the food chain, is producing resistant bacteria, including antibiotic-resistant salmonella, enterococci, and *E. coli*. Health officials warn food producers that antibiotics should never substitute for "inadequate hygiene."

Now there are signs that viruses and bacteria, eager to survive, may be outsmarting vaccines. A 1998 *British Medical Journal* study found that *B. pertussis* infection (whooping cough) is occurring in vaccinated populations in the Netherlands, Norway, and Denmark despite vaccination rates as high as 96 per cent. Among other causes of the whooping cough outbreaks, scientists have found an increasing incidence of strains of *B. pertussis* with a mutated surface protein.

Last year, a CDC study identified eight distinct genotypes of a wild-type measles virus in populations around the world, possibly because the vaccine put pressure on the virus to mutate. In January of this year, the CDC reported a 1998 measles outbreak in Alaska in which 51 per cent of the children had received one or more doses of measles vaccine. Will health officials add yet another booster dose, as they did during measles outbreaks in the late 1980s when they realized that one dose failed to do the job?

While the global village gets smaller and smaller, our health officials warn parents that terrible diseases killing children in the Third World are "just a plane ride away." The only way to protect yourself and your children, say the doc-

tors, is to do what we say and use all the vaccines we have created to keep everyone safe.

Yet some parents and doctors, concerned about the future, are looking beyond the present. "What we forget is that millions of years of evolution have taken place on this planet, and up until the last 100 years, humans have lived in relative harmony with microbes. Yes, there have been epidemic infectious diseases in history, but they have always resolved themselves," said Richard Moskowitz, MD. "I don't think there is any real appreciation for what we may be doing by using so many vaccines to try to eradicate so many organisms."

If we stay the present course, will mankind be free from infectious disease but crippled by chronic disease? Will eradication of feared diseases, such as AIDS, through mass vaccination be one of man's greatest triumphs or will we live in fear of deadly mutations of microbes that have outsmarted man's attempt to eradicate them? We may look back at the crossroads we are at today and wish we had decided to make peace with nature instead of trying to dominate it.

Whatever government and industry decide to do, public support for mass vaccination programs may continue to erode if public policy precedes science and individual health is dismissed as less important than public health. Perhaps the peace we need to make is not as much with nature, as with ourselves. □

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She served on the National Vaccine Advisory Committee at the Department of Health and Human Services for four years, where she was chair of the subcommittee on vaccine adverse events. She was appointed to the Vaccine Safety Forum at the Institute of Medicine in 1995, where she has helped coordinate five public workshops on vaccine safety. She has recently been appointed as the consumer voting member of the FDA Vaccines and Related Biological Products Advisory Committee. The mother of three children, her oldest son was left with multiple learning disabilities and attention deficit disorder after a severe reaction to his fourth DPT shot in 1980 when he was two and a half years old.

THE NATIONAL VACCINE INFORMATION CENTER (NVIC), founded in 1982, is a non-profit, educational organization dedicated to preventing vaccine injuries and deaths through public education. NVIC promotes scientific research into the biological causes of vaccine injury and death in order to identify factors which place individuals at high risk for suffering vaccine reactions and advocates the institution of oversight mechanisms within the mass vaccination system to more effectively monitor the vaccine research, development, regulation and promotion activities of federal and state public health agencies and drug companies.

After launching a national vaccine safety and informed consent movement in the U.S. in the early 1980's, NVIC's co-founders worked with Congress to create the National Childhood Vaccine Injury Act of 1986. This historic law set up a vaccine injury compensation program and included vaccine safety provisions such as mandatory recording and reporting of hospitalizations, injuries and deaths following vaccination.

In 1989, NVIC conducted an International Scientific Workshop on Pertussis and Pertussis Vaccines and in 1996, one of NVIC's major goals was realized when a purified pertussis vaccine was licensed for American babies after a decade and a half of public advocacy work. In 1997, NVIC held the First International Public Conference on Vaccination at which scientists and physicians from the U.S., Great Britain and Canada discussed scientific evidence for vaccine-associated chronic autoimmune disease and neurological dysfunction.

NVIC maintains that well designed, independent scientific research must be conducted to define the biological mechanism of vaccine injury and death and to evaluate the long term effects of multiple vaccination on individuals and the public health. Simultaneously, with respect for the Nuremberg Code, the Helsinki Declarations and the moral principles embodied in every faith, NVIC defends the human right for all people to make informed, voluntary decisions about medical interventions which can cause injury or death, including vaccination.

THE NATIONAL VACCINE INFORMATION CENTER is supported by voluntary contributions, which are tax deductible. For more information and a list of publications, books, tapes and videos available, contact:

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