TESTIMONY BEFORE THE OHIO HOUSE HEALTH COMMITTEE IN OPPOSITION TO H.B. 559

Kristine M. Severyn, Ph.D., R.Ph. May 23, 2018, Ohio Statehouse, Room 121

Chairman Huffman and members of the Committee: Thank you for the opportunity to address you today in opposition to Ohio House Bill 559. I live near Dayton, Ohio in Representative Jim Butler's district, and am a registered pharmacist with a Ph.D. in biopharmaceutics, specializing in pharmacology, toxicology, and drug kinetics.

During my formal education I was taught that vaccines were public health miracles, all benefit and no risk. Only through 27 years of research do I now realize how naïve I was, and how little medical professionals actually learn about vaccines during their schooling. Mainly, we're taught the vaccine schedule, and not much else.

My first concern with H.B. 559 is that it violates Article 1, Section 21 of the Ohio Constitution, which forbids "federal, state, or local law or rule [which] compel[s]... any person...to participate in a health care system." The section defines "compel" as the "levying of penalties or fines...used to punish or discourage the exercise of rights..." Forcing a family to visit and pay for a health-care provider of the government's choosing under the threat of keeping the child out of school clearly violates the Ohio Constitution.

My second concern with H.B. 559 is that it ignores evidence of vaccine failures. Recently publicized mumps outbreaks at Ohio colleges occurred largely in vaccinated students, as did recent measles and pertussis outbreaks across the country. While H.B. 559 proponents advocate for transparency in reporting vaccination rates for individual schools, the legislation is silent on requiring the Ohio Department of Health (ODH) to publish the vaccination status of each reported case of so-called "vaccine preventable disease" (VPD). Press coverage of VPD outbreaks often mention that some or all VPD cases occurred in vaccinated individuals. And, in virtually all recent U.S. outbreaks, few are hospitalized and no one died.

For medical and scientific accuracy and transparency, H.B. 559 should be amended to mandate that ODH report on its website and in its annual report all VPD cases by age and vaccination status. ODH already collects the age and vaccination status of reported VPD cases when the agency investigates outbreaks. How can the public make informed decisions on vaccines if we don't know how well they work? To help parents identify which schools are actually healthier, not only how many children had vaccine exemptions, ODH should also collect and publish on the ODH website the following data:

- The percentage of fully vaccinated and unvaccinated students who contracted infectious diseases;
- The total number of sick days taken by students due to illness;
- The percentage of students infected with HIV, hepatitis, tuberculosis, syphilis and other transmittable diseases;
- The percentage of chronically ill students on medication for asthma, diabetes, ADHD, epilepsy, anxiety, bipolar disorder and depression;

- The percentage of students with life threatening peanut and other severe allergies;
- The percentage of students with learning disabilities, autism and other conditions requiring special education services.

My third concern about H.B. 559 is that all proponents who testified before this committee a week ago have financial conflicts of interest with drug companies which make vaccines. The American Academy of Pediatrics (AAP) seems to be the worst offender. Please permit me to share a small fraction of such evidence:

- When vaccine makers could be sued for death and injuries caused by vaccines, AAP members served as highly paid expert witnesses to help defend the drug companies. Dr. Edward Mortimer, then at Case Western Reserve University, testified in a Stark County, Ohio court deposition of his and other AAP members assisting drug companies this way. Dr. Mortimer failed to disclose his drug company ties to *JAMA* (Journal of the American Medical Association), as did Dr. James Cherry from UCLA, who received nearly one million dollars from a vaccine manufacturer for his research (LA Times, 3/24/90, p. B3).
- In its 1990 report, "Are Scientific Misconduct and Conflicts of Interest Hazardous to Our Health?", the U.S. House Committee on Government Operations cited Drs. Mortimer and Cherry's lack of JAMA disclosures and conflicts of interest as a "danger to the public."
- Dr. Stanley Plotkin, inventor of the rubella vaccine (the "R" in MMR), testified in deposition that half of his income was derived from vaccine royalties.
- In the early 1980s AAP solicited its "friends in the business community" to build its new headquarters near Chicago. Over the next several years, hundreds of thousands of dollars were donated to AAP from drug companies, baby formula makers, and other companies.
- AAP worked with Congress to pass the National Childhood Vaccine Injury Act of 1986, which established a no-fault (and hence, no discovery) system to compensate those killed or injured by vaccines. U.S. taxpayers now shoulder vaccine makers' liability costs. As of May 1, 2018 the Vaccine Injury Compensation Program has spent nearly \$3.9 billion.
- Vaccines represent an economic boon for pediatricians. Profitable well-baby visits are
 timed to coincide with vaccination schedules established by the AAP and the Centers for
 Disease Control and Prevention (CDC). Indeed, one pediatrician recently testified to the
 Minnesota state legislature that he personally loses hundreds of thousands of dollars in
 income every year for giving his patients the right to opt out of vaccines.
- Drug company lobbyists can wear different hats. In the late 1990s, while collecting between \$50,000-\$100,000 from vaccine maker Wyeth for Texas lobbying activities, the same lobbyist collected \$25,000-\$50,000 from the Texas chapter of the American Academy of Pediatrics to encourage new vaccine mandates in Texas. Unlike Texas, lobbying fees are not public information in Ohio.

- As a front for Merck's campaign to enact a chickenpox vaccine mandate in Illinois, the
 company established and bankrolled the Illinois Children's Health Coalition (ICHC).
 Upon investigation, the ICHC was exposed as a public relations gimmick. Merck's
 similar campaign moved to Ohio with the introduction of SB 254 in 2000, this time using
 the name Ohio Varicella Vaccine Coalition.
- Similar productions were staged during 1999 hepatitis B vaccine safety hearings in Ohio, New Jersey and Washington, D.C. The Washington state-based, drug company-funded PKIDS (Parents of Kids with Infectious Diseases) favored mandatory hepatitis B vaccine legislation in Ohio, testifying in 1999 at the Ohio Statehouse. Carrying identical scripts, these out-of-state PKIDS moms also testified at the New Jersey statehouse and congressional hearings in our nation's capital.
- In January 2017 the journal *JAMA Internal Medicine* expressed concerns that such links between patient advocacy groups and drug companies threaten the public trust.

The State of Ohio recently sued multiple drug companies for their role in the opioid epidemic, including misleading the public about drug safety and charging "artificially high monopoly prices" for drugs used to treat opioid addiction. Vaccine manufacturer Merck is currently being sued in federal court for fraud under the False Claims Act for hiding information about the poor effectiveness of its mumps vaccine. And just last year drug companies spent nearly \$60 million to defeat Ohio Issue 2, the drug price initiative. With such a questionable track record of drug company honesty, why should the Ohio Legislature believe that the same companies tell us the truth about vaccine safety and efficacy?

Attached to this testimony are news articles about shady Ohio Statehouse politics during attempts to mandate hepatitis B and chickenpox vaccines in the late 1990s. You'll also find stories of Ohio families impacted by vaccine injury and death, the sacrificial "soldiers." Some families testified here at the Ohio Statehouse, some received compensation through the federal Vaccine Injury Compensation Program, while others received public assistance, and/or their children enrolled in public school special education classes. All families suffered. Is it any wonder these families were hesitant to vaccinate their remaining children?

I also brought copies of the book, *A Stolen Life*, about one family's experience when their son was profoundly brain damaged from vaccines. I wrote the Forward to this book.

Thank you for your attention to studying all aspects of H.B. 559. I am available for questions.

OpEd page

Dayton Daily News

HEALTH

Has Ohio's vaccine policy gone too fa

Drug lobby, not science, pushed through hepatitis B immunization requirement

By Kristine M. Severyn

ecause a few in society choose to sleep around or shoot up drugs, all Ohio children will be forced to receive a vaccine for a disease that more than 95 percent of them will never acquire in their lifetimes.

Recent public-health chicanery in Columbus, played out by drug-company lobbyists, unwitting state legislators and the Ohio Department of Health, will force each kindergartner in Ohio to receive three hepatitis B vaccinations by this fall. The mandate will eventually cover all

Meanwhile, France has stopped giving the shots due to evidence that they can cause neurological disorders.

In the United States, hepatitis B is basically an adult lifestyle liver disease of promiscuous homosexuals, heterosexuals and intravenous drug abusers. Blood transfusion recipients and infants born to infected mothers comprise a small percentage of total cases.

The disease is essentially unknown before the age of 10 years. The Ohio Department of Health has never reported transmission in an Ohio school because hepatitis B is not spread by casual contact.

One-fourth of the nation's cases are concentrated in New York and California (source: Centers for Disease Control and Prevention).

Based on the assumption that all babies may grow up to be drug addicts and/or engage in promiscuous sex, federal vaccine bureaucrats recommended in 1991 that all newborns receive hepatitis B vaccine before leaving the hospital, with two more doses before their first birthday.

Vaccine not cost-effective

To vaccinate 170,000 children, the approximate number of Ohio kindergarteners, with three doses of hepatitis B vaccine would cost an estimated \$7 million.

This figure represents only vaccine purchases and does not include administration fees and office visits paid by

private-sector patients. These latter fees can exceed \$2 million.

Thus, according to government statistics, this \$9 million yearly price tag might possibly prevent only one or two hepatitis B-associated deaths 40 or more years in the future. This assumes the vaccine is 100 percent effective, which it is not. No evidence exists that the vaccine's protection would last into the teen and adult years.

Ohio already has a very low incidence of hepatitis B, without mandatory hepatitis B vaccination. Nearly two-thirds of Ohio's counties reported no new hepatitis B cases in 1996 or 1997. *Of 120 new Ohio hepatitis B cases reported in 1996, zero cases occurred in children under age 10. Similarly, in 1997, only two of Ohio's 94 reported cases occurred in children under age 10 (and one case was an infant who presumably acquired the disease from an infected mother). More than 99.7 percent of Ohioans do not carry the virus (source: Ohio Department of Health).

Law by deception and lobbyists

The history of Ohio's hepatitis B vaccine legislation reflects a direct effort to shield the bill from the public eye. In response to drug-company lobbying, Senate Health Committee Chairwoman Grace Drake, R-Solon, sponsored Senate Bill 251, intending to mandate hepatitis B vaccine for all kindergarteners in fall 1999. Upon its introduction on May 19, 1998, S.B. 251 was assigned to the Senate Education Committee.

That same day, again in response to drug-company lobbying, House Health Committee Chairman Dale Van Vyven, R-Sharonville, amended Substitute S.B. 153 (a hazardouswaste bill passed three months earlier) on the House floor to include the S.B. 251 language.

With no discussion or study, the House immediately passed Substitute S.B. 153. The next day, the Senate passed Amended Sub. S.B. 153. On July 1, Gov. George Voinovich signed the bill.

Why were Ohio children denied even minimal legislative review before the mandatory hepatitis B vaccine was enacted? This past spring New Jersey Gov. Christine Todd Whitman pocket-vetoed mandatory hepatitis B vaccine legislation because of insufficient studies.

Citizens become discouraged when corporate lobbying by vaccine manufacturers results in the

deceptive passage of laws that financially benefit these companies.

Nowhere in the 1998 Ohio legislative status sheets was it noted that S.B. 251 had been buried in a hazardous-waste bill. As of late November, even Senate Education Committee Chairman Robert Gardner was unaware that his committee had been circumvented. Such actions also appear to violate Article II, Section 15 (D) of Ohio's constitution, which bars legislators from combining bills with different subject matter.

Mandate is part of a pattern

This is not the first case of deception relating to vaccine mandates. Ohio's 1992 second-dose MMR (measles, mumps, rubella) vaccine mandate for seventh-graders was never passed by the legislature (it failed in committee hearings). To bypass the legislature, the Ohio Department of-Health mandated the vaccine through a director's journal entry, ignoring state rule-making procedures.,

While the legislators involved in enacting the hepatitis B mandate had noble intentions, legislative committee hearings, open to the public, could have revealed valuable information purposely avoided by this stealthy enactment. As more sexually transmitted disease vaccines' become licensed, can we expect further subterfuge in health-care legislation?

For parents whose religious convictions tell them a healthy, wholesome lifestyle, including refraining from illicit drugs and premarital sexual intercourse, is the best prevention against hepatitis B, the legislature provided a limited exemption in the law (Ohio Revised Code 3313.671 · available at your public library).

Vaccine policy has gone too far. Public health: concerns do not warrant hepatitis B vaccine for all Ohio's children. The only proper action is to rescind the hepatitis B vaccine mandate and hold public legislative hearings on the issue. Let'your state lawmakers in Columbus know that you ?~? disapprove of highly paid pharmaceutical. lobbyists controlling your family's private medical decisions.

► KRISTINE M. SEVERYN, a registered pharmacist with a Ph.D. in biopharmaceutics, is director of Ohio Parents for 18 Vaccine Safety, a national nonprofit organization based in ...

Dayton. To receive the organization's general CHC information packet, write to Ohio Parents for Vaccine Safety at 251 W. Ridgeway S Drive, Dayton, Ohio 45459; or call (937) 435-4750.

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THE MALTON

Established October 8, 1877

Publisher Dan Shaw **Editor** Brian Guth Published Daily and Sunday

Profits, not science, drive vaccine mandates

Who should make decisions about the medical treatment of Ohio's children - state legislators at the beck and call of pharmaceutical companies, or parents across the state?

factured in human fetal tissue, will be That's the issue before state lawmakers in Columbus as special interests push for another mandatory vaccine for our schoolchildren, this time for chicken pox (varicella). If the bill passes, chicken pox vaccine, manuthe ninth in the cocktail mix of vaccines required for school attendance.

At the urging of vaccine manufac-turer, Merck, Senator Bruce Johnson (R-Westerville) introduced Senate Bill 254, which mandates the vaccine Ohio marks the latest effort by for schoolchildren in grades K-12.

strongly against the licensure of vari-Lavin asserted: "[Chicken pox] is not major in the sense of disease mortalior morbidity. Therefore, if healthy

cella vaccine for healthy children." Dr

would guarantee Merck annual sales nearly \$7 million for each new cine in every state — a plan that Merck to require chicken pox vacclass of kindergartners in Ohio alone ö

Fetal tissue origins

Chicken pox vaccine is produced in cally aborted human fetuses (Exp. Cell Res. 37: 614-636, 1965; Nature 227: 168-170, 1970). Merck's own literature states the vaccine contains "residual parents find this abhorrent and in components" of fetal lung cells. Many direct opposition to their religious beliefs. Informed consent, a basic lung tissue obtained from two surgi tenet of ethical medical practice, dictates that Ohio citizens should have a choice whether or not they are inject ed with another person's body cells.

tions from Merck. At the request of a Merck lobbyist, Sen. Drake spon-

sored a bill in 1998 to mandatehepati-

preside over SB 254 hearings, accept-

Committee chairwoman, who will

ed significant campaign contribu-

tis B vaccine for Ohio kindergart-ners. To hide the legislation from the public, the mandate (more) language

Sen. Drake did nothing to remedy this

was buried in a hazardous waste bill

deception. The other hepatitis B vac-

Favorable cost: benefit lacking

to stay home with a sick child is there any cost advantage to using chicken pox vaccine (JAMA 271: 375-381, 1994; J. Ped. 124(6): 869-874, 1994). From the medical and health-care cost perspectives, chicken pox vacone funded by Merck, found that only if lost wages are included for a parent cine is a loser. Indeed, two studies

chicken pox disease carries a very low While providing lifelong immunity risk of complications and death. Writ-

ists and Ohio state lawmakers. Lobby-ists and fellow legislators rebuiked state Rep. Jeff Jacobson's, R-Dayton, legisla-tive efforts to reform lobbying regula-

KRISTINE SEVERYN

Not just in Ohio

Guest Columnist

different hats. While collecting between \$50,000-\$100,000 from vaccine maker Wyeth for Texas lobbying activities, the same lobbyist collects Drug company lobbyists can wear ter of the American Academy of Pediatrics to encourage new vaccine manwww.ethics.state.tx.us via the Inter-\$25,000-\$50,000 from the Texas chap net; click on "disclosure filing.") Texas. 5 dates

> ing in the British medical journal, the Lancet (343: 1363, 1994) Dr. Arthur Lavin, Department of Pediatrics, St. Juke's Medical Center in Cleveland Ohio, presented concerns that "argue

Julike Texas, lobbying fees are not public information in Ohio.

Pediatricians beholden to drug companies

children were fully vaccinated it is unclear in what significant way the health of the children or the economic

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health of their families would

improved."

atrics, a major supporter of mandatotuous financial ties with Merck. When The American Academy of Pediry chicken pox and other vaccine mandates across the country, shares incessuburban Chicago, the AAP solicited unds from Merck, and received constructing its new headquarters \$100,000 for its building campaign.

Sen. Grace Drake (R-Solon), Health, Human Services, and Aging

Legislators for sale

boon for pediatricians. Profitable Vaccines represent an economic well-baby visits are timed to coincide with vaccination schedules estabished by the AAP and the Centers for Disease Control and Prevention.

U.S. vaccination policy?

SmithKline

cine manufacturer, SmithKline Beecham, lobbied the House Health, Retirement, and Aging Committee. In 1993 and 1994, Sen. Drake

opposed legislation to restore vaccine informed consent to Ohio parents. Despite a 94-3 vote in the Ohio House favoring informed consent, Sen. Drake refused to hold hearings on the bill

Immunization Practices, a group of individuals hand-picked by the CDC, recommends which vaccines are administered to American children. Working mainly in secret, ACIP members frequently have financial The Advisory Committee inks to vaccine manufacturers.

state al vaccine funds can be denied to "vigorously tors to mandate new vaccines. Federdirectives by influencing state legisla-Dependent on CDC funding, vaccination programs follow states which do not

A recent investigative report in

Columbus cited other examples

after its assignment to her committee

'symbiosis' between corporate lobby-

cial bounties to state departments of child. In a recent year, the Ohio enforce" mandatory vaccination laws. Conversely, the CDC offers finanhealth for each "fully vaccinated" Department of Health received \$1

million in such CDC bonus payments. At CDC national immunization conferences, Merck and other vaccine manattendees who make their livings proufacturers wine and dine thousands of moting and administering vaccines.

Traveling circus

than a public relations gimmick. Merck's similar campaign moved to As a front for Merck's campaign to enact a chicken pox vaccine mandate in Illinois, the company established and bankrolled the Illinois Children's Health Coalition. Upon investigation, the ICHC was found to be no more Ohio with the introduction of SB 254

Offit of Philadelphia, spoke at the rehearsed performance extolling the Merck consultant, vaccine patent holder, and ACIP member Dr. Paul Tenn. State lawmakers from around American Legislative Exchange Coun cil's August 1999 meeting in Nashville benefits of mandatory vaccination country witnessed

Ohio and later in hepatitis B vaccine safety hearings in Washington, D.C.. ing 1999 hepatitis B vaccine hearings in Similar productions were staged dur-

The Washington state-based Parents of Kids With Infectious Diseases favored tion in Ohio, testifying in 1999 at the Ohio Statehouse. Carrying identical scripts, these out-of-state PKIDS moms also testified a few weeks later at congressional mandatory hepatitis B vaccine legisla hearings in our nation's capital.

ers, including state legislators. It's about time state lawmakers say "no" The vaccine industry has corrupt ed government vaccine policy makto drug company lobbyists and "yes'

pharmacist with a Ph.D. in biopharmaceutics, is director of the Dayton-based Vaccine Policy Institute. Kristine M. Severyn, a registered

OpEd Page

Is chickenpox vaccine a good idea?

By Kristine M. Severyn, R.Ph.,Ph.D.

lowing media reports of the recent U.S. licensure of chickenpox (varicella) vaccine do not reveal the entire picture. This essentially experimental product may soon be required for all children who cannot prove they had the disease ("Chickenpox vaccine wins OK of FDA," Dayton Daity News March 18, 1995, pg. 1A; "Families eager to obtain new chickenpox vaccine," Dayton Daily News, April 16, 1995, pg. 2A).

Press coverage seems critical of the Food and Drug Administration's (FDA) delay in approving chickenpox vaccine, citing Japan's experience with the vaccine. The two countries' chickenpox vaccine experiences vary greatly. First, the Japanese vaccine is formulated differently from the U.S. vaccine. Second, the U.S. population is more ethnically and racially diverse than Japan's. Finally, vaccines are voluntary in Japan, unlike in the U.S., where vaccines are mandated for daycare, school, and college admission.

U.S. marketing of chickenpox vaccine was postponed by concerns about injecting this live herpes virus into children, possibly causing shingles or delaying chickenpox into adulthood, where chickenpox is more dangerous. Vaccine maker Merck and Co. (who will sell more than \$150 million of chickenpox vaccine in the U.S. per year) has not resolved these concerns.

Dr. Philip Brunnell, head of pediatric infectious disease at Cedars Sinai Hospital in Los Angeles was cited in *The New York Times* (July 7, 1993) that to justify giving all children a vaccine for a disease that is essentially harmless, the vaccine must be totally risk-free. No one knows if the new chickenpox vaccine satisfies this criterion.

Your "civic duty" to vaccinate

Despite the many unknowns involving chickenpox vaccine's safety and effectiveness, proponents of its use, including Dr. Anne Gershon of Columbia University, assert that instead of vaccinating just a few high-risk children (such as those with leukemia), we should vaccinate millions of healthy children every year to protect leukemic children from chickenpox. Dr. Gershon absurdly noted that another benefit of vaccinating healthy children is that if they later develop leukemia, at least they would be theoretically protected against chickenpox!

Children as "guinea pigs

FDA Commissioner Bavid Kessler stated that "...we expect (chickenpox vaccine) to be 70-90 percent effective..." This means no one really knows how well or how long the vaccine works. Vaccine immunity is not proven to last longer than six to seven years, and Merck asknowledges that anyone over 12 years of age will need at least two shots.

The FDA assures us that Merck will "perform post-marketing studies to determine the (vaccine's)

OTHER VOICES

This column gives readers a format to share ideas, opinions and experiences. Columns should be interesting to the general public, timely and concise. Length should be between 400 and 1,000 words. Send to Other Voices, *Dayton Daily News*, Box 1287 Dayton, Ohio 45401. Include your address and a telephone number where you can be reached during business hours.

long-term effects and whether there is a need for a booster immunization." How will this work?

Post-marketing studies of vaccine adverse events are currently monitored through the Vaccine Adverse Events Reporting System (VAERS), supervised by the FDA. Despite about 1,000 vaccine adverse events, including serious injuries and deaths, reported monthly to VAERS, the federal government dismisses VAERS reports as "anecdotal." If past experience with other vaccines is indicative, chickenpox vaccine adverse event reports will likewise be ignored by the FDA. and left to languish in a government computer database. So much for FDA's assurance of "post-marketing

studies."
Compared to individual vaccines, potentially greater problems exist when vaccines are combined.
Chickenpox vaccine will be combined with MMR (measles, mumps, rubella) vaccine. However, federal health officials admit there are no medical studies proving the safety of combination vaccines (Advisory Commission on Childhood Vaccines, March 1, 1995).

D.B. JOHNSON/L.A. TIMES

Other considerations:

From the medical and health care perspectives, there is no cost advantage in vaccinating all children against chickenpox. Two studies — one funded by

Merck — found that only if lost wages were considered for a parent to stay home to care for a sick child, was there any cost benefit to using chicken-pox vaccine? Thus, our government now recommends vaccination for parental convenience.

Many parents find abhorrent that Merck's chickenpox vaccine was cultured in lung tissue obtained from two surgically aborted human fetuses (one female, one male) at approximately three months' gestation.

Could vaccine make matters worse?

Dr. Arthur Lavin, Department of Pediatrics, St. Luke's Medical Center in Cleveland, Ohio, wrote in the respected British medical journal, *The Lancet*, of "three concerns...(he) believe(s) argue strongly against the licensure of varicella vaccine for healthy children."

First, chickenpox "is not major in the sense of disease mortality or morbidity. In childhood, mortality is very low, and morbidity is usually minor..."

Second, routine chickenpox vaccination in healthy children might pose a "grave danger of advancing the age of onset of chickenpox into adulthood," where the death rate can be quite high. (This happened from routine use of measles vaccine in children. In the late 1980's U.S. measles resurgence, about half the cases occurred in adolescents and adults, most with a history of measles vaccination as young children.)

Third, Dr. Lavin has deep concerns about longterm genetic effects of "injecting millions of young children with a mutant strain of (live) heroes

virus...Although the risk of deleterious effect is remote, the application of this risk to hundreds of millions of (individuals) increases the chance that we will see some adverse effect

chance that we will see some adverse effect (emphasis added)."

Dr. Lavin believes that "...not all infections demand (vaccine) intervention...", and says, "The Varicella Immunization Program...may

be too much of a good thing (emphasis added). Until we actually know the duration of immunity and the risks involved in injecting mutated (herpes) DNA into the host genome (genetic structure), I argue strongly against licensing this vaccine for use in all children."

Parents worried about the many unknowns surrounding chickenpox vaccine should not be forced to enroll their child(ren) in a massive medical experiment with potentially devastating consequences for the child and society. State legislators need to hear from concerned parents before the vaccine is mandated. Too many safety and effectiveness issues remain unresolved to shoot this vaccine into our children without voluntary parental consent.

■ DR. KRISTINE SEVERYN is a registered pharmacist with a Ph.D. in biopharmaceutics. She lives in Dayton, Ohio, where she heads Ohio Parents for Vaccine Safety and writes on medical/legal issues.

OHIO PARENTS for VACCINE SAFETY 251 W. Ridgeway Dr. Dayton, Ohio 45459 (Adron, Ohio)

Parents may be right to fear vaccines

The writer is a registered pharmacist with a doctoral degree in biopharmaceuticals and is director of Ohio Parents for Vaccine Safety. She lives in Dayton.

BY KRISTINE SEVERYN

The Children's Defense Fund blames Ohio's allegedly low preschool vaccination rates on the worn-out excuses of cost, limited access to medical care and uninformed or disinterested parents ("Kids missing vaccinations," Beacon Journal, May 19). More important factors are ignored in this analysis.

Some parents delay or do not vaccinate their children because the Food and Drug Administration is not doing its part to assure safe and effective vaccines for America's children.

For example, within a 39-month period ending November 1993, the FDA's Vaccine Adverse Events Reporting System collected nearly 32,000 reports of bad reactions following vaccination, with more than 700 deaths. DPT (diphtheria, pertussis, tetanus) vaccine was associated with more than 12,000 of these reports, including 471 deaths. The FDA acknowledges that this voluntary reporting underestimates the actual number of reactions.

Instead of taking these reports of deaths and injury seriously, the FDA dismisses them as "coincidental," so the reports languish in a government computer data base. This violates the intent of Congress when it established VAERS in the National Childhood Vaccine Injury Act of 1986, as well as FDA's statutory obligation to assure safe and effective vaccines.

When motivated, the FDA and medical communities can act decisively, as in the FDA's embargo of improperty labeled orange juice, or the American Medical Association's recommended ban on baby walkers following the deaths of six children in three years. Why isn't this same attention paid to a product associated with hundreds more deaths that is mandated for children in order to attend school or day care?

Post-marketing surveillance of vaccines by FDA and vaccine manufacturers is inadequate, as recently reported by the NBC news program NOW. One family discovered through the Freedom of Information Act that their child was permanently brain damaged by a specific lot of DPT vaccine that the FDA already knew to be associated with six previous deaths. The lot continued to be used, and at the time of the NBC broadcast, the FDA had received reports of 10 deaths from that same vaccine lot.

But the FDA felt that 10 deaths and many adverse reaction reports were insufficient to withdraw the lot. An FDA official admitted on NOW that the government has no policy about the how many adverse reactions are necessary to initiate recall of any vaccine lot. This lack of action by the FDA, to say nothing of its lack of policy, is not reassuring.

The Ohio Department of Health also appears unconcerned about vaccine safety. In 11 of 12 lots of DPT vaccine recently purchased by ODH, significant numbers of reaction reports have been received by the federal government, including 27 deaths, as of Oct. 31, 1993. ODH was formally notified of this situation in mid-April, but has failed to respond.

Another problem with pertussis, or whooping-cough vaccine, is poor efficacy (55 percent failure rate in one study). The Chicago Department of Health noted that of 186 confirmed pertussis cases last fall, "72 percent were as up to date as possible on their immunizations for their age." Between 1987 and 1991, according to Ohio's health department, one-half of reported whooping-cough cases occurred in vaccinated children, in cases where vaccination status was known. Similar vaccine failures occurred in Cincinnati's highly publicized fall 1993 pertussis epidemic.

But of 315 children who contracted whooping cough in Cincinnati last year, an infectious-disease expert was quoted in the Cincinnati Enquirer: "The disease was very mild; no one died, and no one went to the intensive-care unit." Likewise, no one died in last fall's pertussis outbreak in Chicago.

Germany withdrew routine use of pertussis vaccine, and Sweden discontinued its use years ago, due to poor efficacy and high incidence of adverse reactions. Both countries have had virtually no problems with whooping cough.

Vaccine manufacturers enjoy the enviable position of having their products mandated and their liability costs shouldered by the U.S. taxpayer. Victims of vaccine injury or death are prohibited from suing drug companies until they are denied assistance from the federal Vaccine Injury Compensation Program, created by the NCVIA.

If victims lose in the compensation program, or find this limited compensation inadequate, state and federal courts tell them that vaccines are "unavoidably unsafe," absolving the drug companies of all responsibility. There are many examples in case law that back this up.

Congress' stated purpose in passing the NCVIA in 1986 was to give children safer vaccines. The only real change since 1986 is that children receive even more vaccines today, often in questionably safe combinations.

Although the FDA is charged by Congress to oversee vaccine safety, the agency has caved in to political pressures by not questioning the safety of already licensed vaccines. Speaking out about vaccine safety and effectiveness need not conflict with the Clinton administration's goal of preventing illness in U.S. children.

The current ambivalence by the FDA toward vaccine adverse reaction reports has caused parents to lose faith in our country's vaccination program. Is it any wonder that some families refuse to expose their children to products that the FDA licenses then proceeds to forget?

The public is repeatedly told that the benefits of vaccines outweigh the risks. Yet, we do not know what the risks are because our government is not interested, or perhaps afraid, to find out. It's time for the FDA to do its job of properly monitoring safety and efficacy of licensed vaccines.

Until then, children will continue to suffer needlessly.



Families meeting with Congressman Tony Hall on 3/22/93, left to right: Orallee Robinson (Bellefontaine, OH--baby died 17 hours after DPT shot); Doris and Jim Hart with daughter, Amanda (Huber Heights, OH--Amanda is mentally retarded from DPT shot as an infant); Joy Niemiera with 11-year-old son, Gregory, in wheel chair (Loveland, OH--Gregory is quadriplegic and severely mentally retarded from DPT shot received as an infant. Joy also has a teenage daughter with rheumatoid arthritis caused by MMR (measles, mumps, rubella) vaccine received at 15 months of age.);

Tiffani Rose (Cardington, OH--baby died three days after vaccines); AnnHeeley (Sidney, OH--baby reacted within 12 hours of DPTvaccine and died three days later; first case compensated in federal Vaccine Injury Compensation Program); Jack and Margaret Beard with son Joshua (Urbana, OH--Joshua is mentally retarded from DPT vaccine received as an infant); Tim and Kathleen Gade, holding their two healthy children (Greenville, OH--Their first child, Robbie, died from DPT vaccine received as an infant.)

VACCINE VICTIMS AND FAMILIES TESTIFYING FOR OHIO HOUSE BILL 200 AGAINST MANDATORY HEPATITIS B VACCINE AT OHIO STATEHOUSE, APRIL 14 AND 28, 1999 (See page 18 for their stories.)



Front Row: (in wheelchairs, left to right) Barbara Tison and John Schneider. Back Row: Dana Busson, Mr. Schneider, Elizabeth Schneider, Cheryl Lombardi, Betty Fluck, Betty's husband and three sons.



Front row: (in wheelchairs, left to right) Joshua Beard, Nicole Redinbo, John Schneider. Back row: Margaret and Jack Beard, Wanda Redinbo, Harold Sword, Mr. Schneider.



Sarah Frances Corzine died at 2 months of age, 14 hours after receiving 6 vaccines. For Sarah's website, see: www.ties.org/Sarah/memorial.

Misinformation abounds in debate over vaccines

Readers would be better served by truly investigative reports on vaccine issues, rather than the Ohio Department of Health's public-relations version in *Dispatch* Medical Reporter Mark D. Somerson's recent column "Ohio children will benefit from hepatitis vaccination."

Describing the recent Ohio legislative debate on mandatory hepatitis B vaccine for kindergartners as inane is insulting and insensitive to families of vaccine-injured children. Parents whose children died or became severely brain-damaged from vaccines traveled to the Statehouse at significant trouble and expense, many with wheelchair-bound children, to show lawmakers the fallout of national vaccine policy. Like Somerson, these parents once believed what they were told by doctors and public-health authorities. Unfortunately, these families learned the hard way.

Somerson echoes the prevailing attitude that a few children can be sacrificed for the good of society. If he or his loved ones are ever injured by a vaccine, maybe he'll realize how much information is withheld and distorted by drug companies and government vaccine bureaucrats to facilitate 100 percent vaccination rates. Two such practices are inflating diséase-incidence data to mislead the public into thinking a disease is more common than it really is and minimizing reports on adverse reactions to vaccines.

Somerson ridicules the "misguided concerns of a few" Ohioans who questioned mandatory hepatitis B vaccination. The Associated Press reported that Ohio legislators were deluged with mail opposing the mandate. The Association of American Physicians and Surgeons also opposed the mandate, as did others. At recent congressional hearings, additional physicians and scientists outside of government questioned the lack of science behind mandatory hepatitis B vaccines.

I invite Somerson along on my next trip to the national Centers for Disease Control and Prevention in Atlanta to see how little research and how much conflict of interest are involved in vaccine policy.

Kristine M. Severyn, director Vaccine Policy Institute Dayton

OHIO HOUSE BILL 200 PROPONENT WITNESSES TO RESCIND MANDATORY HEPATITIS B VACCINE FOR KINDERGARTENERS OHIO HOUSE HEALTH, RETIREMENT, AND AGING COMMITTEE MARCH 24 or APRIL 14, 1999

- 1. Dr. Kristine M. Severyn, R.Ph., Ph.D., Director, Ohio Parents for Vaccine Safety, Dayton, OH
- 2. Jeffrey Starre, M.D.: Board-certified Family Practice physician, Jewett, Ohio.
- 3. Derrick Lonsdale, M.D.: 20-year pediatric experience at Cleveland Clinic; currently practices in West Lake, Ohio.
- 4. Joshua Beard (13 years old; Urbana, Ohio): Had seizure the night of his first DPT (diphtheria, pertussis, tetanus) vaccine as an infant. Continues to have seizures. Mentally and physically handicapped. Awarded compensation from federal Vaccine Injury Compensation Program (VICP). (Parents: Jack and Margaret Beard)
- 5. Ann Heeley (Sidney, Ohio): Infant son Brad (6 1/2 months) experienced Grand Mal seizure and 109-degree fever less than 24 hours after DPT shot. Taken by ambulance to Dayton Children's Medical Center. Died three days later. Cause of death listed as "anaphylactic shock and multiple organ system failure." Awarded compensation through the VICP.
- 6. Harold Sword (Columbus, Ohio): Infant daughter Natalie received DPT shot between about 12:00 noon one day in 1975. Baby found dead 2 1/2 hours later. Currently pursuing claim through the VICP.
- 7. Barbara Tison, J.D. (Lebanon, Ohio): Contracted polio from live oral polio vaccine given to her now adult son when he was an infant. Son is fine, but Barbara lost use of her legs and is wheelchair bound. Awarded compensation through VICP. She graduated from University of Cincinnati College of Law in June, 1998.
- 8. Eric Jeffries (Cincinnati, Ohio): Received hepatitis B vaccine June, 1997. Within 4-5 days experienced extreme illness with headache, joint pain, soaking sweats, and rash. Condition has since worsened. He can not walk normally and has been unable to work for the past 6 months. Pursuing disability claim.
- 9. John Schneider (5 years old; Hudson, Ohio): Good Apgar scores at birth. At 12 hours after birth received hepatitis B vaccine in the hospital. Within 1 hour went into shock. Parents took home baby with poor muscle tone, where before the shot muscle tone was present. John is now physically and

- mentally disabled, requiring daily professional nursing care. He operates on the level of an infant (mother: Elizabeth Schneider).
- 10. Nicole Redinbo (13 years old; Sidney, Ohio): Within 1 hour of first DPT shot at 2 months old, started "horrible, high-pitched cry" which persisted for 7 hours without letup. During this time Nicole could not be consoled. Nicole is now mentally and physically disabled, can not care for herself, is wheelchair bound and attends Shelby County special education public school programs. Unable to care for her in their two-story Sidney farmhouse with no downstairs bathroom, the parents built a one-level, handicap-accessible house across the street. (Parents: Ted and Wanda Redinbo)
- 11. Betty Fluck, R.N. (Kokomó, Indiana): Received hepatitis B vaccine in December 1997 as requirement for employment. Within 12 hours had 104-degree fever and suffered from severe pain and swelling. Condition worsened to paralysis of both legs. Wears full-leg braces and walks with crutches. Unable to work.
- 12. Jeffrey Miller (Loveland, Ohio): Received hepatitis B vaccine in March 1997 as recommended by employer. Missed work for next seven days with body aches, high fever, and congestion. In April 1997 had second hepatitis B injection. The next day had swelling and pain in elbow of arm where vaccine injected. Over the next month, swelling and pain progressed to knees, shoulders, hips, arms, hands, and feet. After seeing six medical specialists (30 doctor visits) to obtain relief, he relies on daily medication just to facilitate simple movement. He pursues a Workman's Compensation claim (wife: Judy).
- 13. Cheryl Lombardi (Columbus, Ohio): Received hepatitis B vaccine as requirement for employment. Previously very athletic, she is now disabled, receives disability benefits from her employer, and with her husband, must sell their two-story house and move to a one-level residence to accommodate Cheryl's disability.
- 14. Dana Busson (Doylestown, Ohio): Infant son received hepatitis B vaccine after birth in the hospital. Within hours, the previously healthy baby (Apgar scores 9 and 9) developed a fever, rash over most of his body, wheezing, congestion, and difficulty in breathing. He continues to have respiratory problems.
- 15. Devin and Natalie Corzine (Cincinnati, Ohio). Two-month old daughter, Sarah, died twelve hours after visiting pediatrician, who gave child clean bill of health and injected her with six vaccines. The Corzines, supported by Sarah's two grandmothers, testified at the Ohio Statehouse just two days after Sarah's April 26, 1999 funeral.



Some parents learn the dark secret of vaccinations for their children

Price to pay



WALLY NELSON/DAYTON DAILY NEWS

Nicole Redinbo's mother Wanda is convinced that vaccine caused paralysis

Sidney-area girl thought to be DTP shot victim

By Julia Heigason DAYTON DAILY NEWS

hen Nicole Redinbo flashes those flirty eyes and that sly smile, she's hard to resist.

As a charmer, Nicole functions just fine. Her facial muscles work

But when her mother picks her up, the fragile 5-year-old flops at the waist, her limp arms and legs dangling like a rag doll's. She can't walk, crawl or sit up without help.

Nicole lives on a farm south of Sidney with her parents, Ted and Wanda Redinbo, and her 8-year-old sister, Sarah. She weighs but 32 pounds and has the

She weighs but 32 pounds and has the same symptoms as someone with cerebral palsy.

Her mother is convinced she was disabled by the pertussis, or whooping cough, component of a routine diphtheria, tetanus and pertussis shot.

Physicians concede that Nicole suffered a severe reaction to the vaccine. The words No-Pertussis are streaked across every page of her medical chart. But doctors stop short of blaming the shot for Nicole's brain damage, suggesting that her premature birth could have caused it.

There are some who say they aren't surprised doctors would be hesitant to blame vaccinations.

"Any time a physician speaks out against vaccines, he or she is taking on the American Medical Association, the American Academy of Pediatrics and the entire United States government," said Kristine

SEE VACCINE/8A

VACCINATIONS: A PRICE TO PAY

Vaccine

CONTINUED FROM 1A

Severyn, director of Ohio Parents for Vacdne Safety. Severyn founded the group two years ago to educate parents, and to assist vaccine-damaged children.

Most parents don't realize that childhood immunizations are a numbers game, Severyn said. Statistically, it's a fact that some children will have reactions, sometimes severe reactions, to the shots. Health officials and drug companies acknowledge this, but say a few thousand vaccine-damaged children are the price that has to be paid for protecting millions from the ravages of childhood diseases.

Or, put another way, the needs of the many outweigh the good of the few.

Vaccines good, but . . .

There is no doubt that vaccines have improved the lot of most children. Since the turn of the century, smallpox has been eradicated in the United States and in most of the world. Diphtheria, measles, mumps, whooping cough, polio, rubella and tetanus have declined dramatically.

Vaccines deserve most of the credit, though improved sanitation and nutrition are also significant factors.

Though health officials are certain that the benefits of vaccines far outweigh the risks, nobody knows - really knows what those risks are.

The parent information brochure dis-tributed by the U.S. Department of Health and Human Services indicates that one DTP shot in 1,750 may cause convulsion or shock-collapse.

If the brochure's numbers are taken a step further, and assuming that each child gets the recommended five shots, the incidence of convulsion or shock-collapse becomes one in 350 children.

A safer pertussis vaccine has been used for a decade in Europe and Japan. The Food and Drug Administration recently approved its use for toddlers and older children, but not for infants.

And for all its dangers, the pertussis yaccine isn't as effective as doctors would like. From 1987 to 1991, there were 737 cases of whooping cough reported to the Ohio Department of Health. Of the 531 cases for which vaccination status was known, 267 were vaccinated, 264 were not.

Nicole Redinbo was vaccinated during that time. She was born on Dec. 20, 1987, several weeks premature. At 2 months she weighed less than eight pounds. Yet she and other premature infants routinely receive the same dose of pertussis vaccine as 50-pounders entering preschool.

Within an hour of that first injection, Ni-cole began to scream, "a horrible, highpitched cry like I'd never heard before," her mother said. For seven hours without letup, Nicole screamed inconsolably.

The next day she lapsed into a deep, coma-like sleep. In the days that followed, she cried all night, every night. The doctor called it colic. Wanda Redinbo sensed something more serious.

She knows now that Nicole's symptoms were consistent with pertussis-induced encephalitis - inflammation of the brain as reported by numerous other parents of pertussis-damaged children.

Nicole's mind is way ahead of her body. She hears and understands. She laughs at jokes. But she can't talk. So she picks at the laces in her hightop shoes until she gets them untied and pulls them out. Then she beams at the accomplishment.



Nicole Redinbo's mind is way ahead of her body; she hears and understands; she laughs at jokes; but she can't talk

Nicole changed after shot

Her mother thinks back to the changes in her daughter. Before the shot, Nicole sucked her thumb. After the shot, she did

Before the shot, her pupils were identical. After the shot, the right was noticeably larger

Before the shot, Nicole gained eight ounces a week. After the shot she gained

Nicole attends Shelby Hills School, operated by the Shelby County Board of Mental Retardation and Developmental Disabilities. For half-days during the school year, she enjoys scheduled activi-ties and social interaction with other handicapped children.

At home she's often bored and easily frustrated.

Nicole's father is a fourth-generation Ohio farmer and a mail carrier for the U.S. Postal Service. His earnings don't stretch to cover the extras Nicole requires, yet he earns too much to qualify for most kinds of financial aid. So the Redinbos worry about meeting Nicole's future needs.

They live in an 80-year-old house built by Ted Redinbo's grandfather. The twostory home has sentimental value and turn-of-the-century charm - but no downstairs bedroom

As Nicole grows older and heavier, she'll need ramps and wider doorways to accommodate her wheelchair. And her parents won't be able to carry her upstairs to bed, as they do now. Cost estimates to adapt the house to Nicole's needs are higher than estimates for building a new one.

successful lawsuit would assure the necessities, Wanda Redinbo said, "but I've talked to 19 lawyers, and I've been turned down 19 times.

Vaccine lawsuits in Ohio don't get far. Ohio courts have held vaccines to be "unavoidably unsafe," and have ruled that drug companies need not warn individuals of adverse reactions — that warnings in the package insert to physicians are sufficient.

This means Ohio parents are responsible for reading inserts that are not available to them, and which, in most cases, they aren't aware of.

Lawsuits on behalf of children allegedly hurt by vaccines have met with more success in some other states. Hundreds of such suits were filed in the mid-1980s, and by 1985 damage claims had reached \$3.1 billion. Several manufacturers withdrew from the vaccine business. Others raised vaccine prices as a hedge against liability.

The U.S. government, fearing continuing price hikes and vaccine shortages, passed the National Childhood Vaccine Injury Act of 1986. The legislation created

the National Vaccine Injury Compensation Program, with a plan to compensate vaccine victims.

It effectively eliminated the liability factor for manufacturers, thus eliminating their incentive to make safer vaccines, critics say. And it placed that liability directly on the shoulders of U.S. taxpayers.

The Vaccine Injury Compensation Program has processed an overwhelming volume of claims. As of Sept. 8, the program had awarded \$369.1 million to 924 families or their attorneys, and was backlogged with more than 2,900 unresolved cases. The program has a potential shortfall of \$177.2 million for fiscal 1993, which ends this month, said spokesman Matthew

Pertussis damage tops claims

Three-fourths of the claims came from families of children damaged by pertussis. Nicole didn't even make the waiting list. Because she was premature, no doctor is willing to say for sure that the pertussis

vaccine caused her brain damage. U.S. law mandates that physicians report vaccination "adverse events," to the FDA, yet the FDA estimates that only 10 percent are reported.

Wanda Redinbo reported Niçole's reaction because physicians refused to, though reporting is of little use. The FDA acknowledges it does not investigate incidents, but looks at trends.

Critics of the vaccine delivery system say the parent information brochure for pertussis misleads parents when it says, Rarely, brain damage that lasts for the child's life has been reported after getting DTP. However, most experts now agree that DTP has not been shown to be a cause of brain damage."

Though there is much anecdotal evidence, there is no scientific test that can prove or disprove that the pertussis vaccine caused brain damage to any particular child.

The pertussis vaccine in common use throughout the United States is a wholecell vaccine. The safer "accellular" vaccine used in Europe and Japan contains

only part of the pertussis organism. But pertussis vaccine is not given to infants in Europe and Japan, so there is no proof that the vaccine is effective for infants. For this reason, infants in this country continue to receive the more potent,

and perhaps more dangerous, whole-cell product.

Parents who believe a child has been injured by a vaccine sometimes will later go to extremes to prevent physicians from vaccinating their other children.

Some doctors insist that the chances of a second vaccine mishap in the same family are practically nil. But parents worry that inherited metabolic chemistry places sibling at a higher, not lower, than average risk.

Kristen Niemiera, 14, of Loveland, has had rheumatoid arthritis since she received her first measles, mumps and rubella vaccine at 15 months, though the disease is more common in post-pubescent girls who receive rubella vaccine up to 20 percent, according to the parent information brochure.

Kristen's brother, Greg, 11, is quadriplegic, blind and epileptic from his first DTP shot, which he received when he was 2 months old. On one occasion, when Greg was very ill, the children's mother, Joy Niemiera, called the family pediatri-cian. "I'll never forget it," she said, "The doctor told me he wouldn't treat Greg unless I also brought my baby in to be vaccinated." Niemiera took Greg to a hospital emergency room, where he was diagnosed with pneumonia.

Not in writing

Though one physician acknowledged Greg's disabilities resulted from the vaccine, he refused the Niemieras request to put it in writing.

Court records in Mercer County, N.J., show that the Niemieras filed suit against the vaccine manufacturer. In dismissing the case, the judge ruled that the drug company was not liable since vaccines are 'unavoidably unsafe."

Linda Dye, formerly of Middletown, was even less fortunate. Dye's daughter, Mandy, developed a severe seizure disor-der after her third DTP shot at six months. Her second daughter, Abby, had a similar reaction to a second shot. Both girls' conditions worsened progressively. Both died in 1983.

Court records show that Mrs. Dye settled with the vaccine's manufacturers for an undisclosed amount.

Dr. Sherman Alter, director of the infectious disease department at Children's Medical Center, acknowledges that whole-cell pertussis vaccine is less than perfect. But he is adamant that it's "better than no vaccine at all," particularly so this year, as whooping cough is on the rise in Montgomery County.

Only two cases were reported in the first seven months of last year, compared to 16 cases in the same period this year.

Doctors are calling the disease epidemic in Hamilton County, where Children's Hospital Medical Center treated 111 cases in August — the most they have seen in one month.

Dylan Long was one of the Montgomery County cases.

The 16-month-old son of Bryan and Kimberlie Long of Dayton was diagnosed

Second shot avoided

He had had an allergic reaction to his first DTP shot - fever, rash and diarrhea, his mother said. So she decided not to risk a second shot.

When Dylan came down with whooping cough, he suffered prolonged coughing bouts that took his breath away and turned his lips blue, though he was never hospitalized.

"If I had it to do over," Long said, "I would give him the shot and take my chances.

But Kimberlie Long hasn't met Nicole

At age 5, Nicole is just beginning to say a few words, though only her family can understand her. And only her family responds to the woeful plea she repeats so

"Help me."

Young lives changed forever



Mandy Hart, 9, of Huber Heights, screamed for six hours after a DTP shot at 4 months. Doctors acknowledge that Mandy was permanently brain damaged by DTP. She has frequent seizures and is mentally retarded. She jabbers, but her speech is unintelligible.



■ Glenn Asher of Hamilton, pictured at age 8 in 1988, was permanently brain damaged by DTP as an infant. The vaccine's manufacturer settled with his family for a minimum of \$2 million payable over Glenn's lifetime, his lawyer



■ Robbie Gade, son of Tim and Kathleen Gade of Greenville, died June 13, 1989. After his third DTP shot at 6 months, Robbie started screaming - a shrill high-pitched scream. He subsequently lost his eyesight and all muscle control. Doctors told the Wades the shot was to blame but declined to put it

Joshua Beard, 8, of Urbana, is retarded and non-verbal. He had a seizure the night of his first DTP shot, and continues to have grand mal seizures. Joshua was the first Ohio child processed by the Vaccine Injury Compensation Program. Though he was approved for a generous award, he hasn't received the first dollar because the coffers are

Donovan Wilson, 18, of Columbus, had a seizure reaction to his secand DTP shot. He has uncontrolled seizure disorder, uses a wheelchair, and is profoundly mentally retarded. His case is still pending before the Vaccine Injury Compensation Program.

Ashton Rose, son of Tiffani Rose of Cardington, died of cardio-pulmonary arrest in September 1992 three days after DTP. HIB and polio immunizations. He was 10 weeks old.

WARNING SIGNS

The Centers for Disease Control recommends that children not be vaccinated against pertussis or whooping cough if they have experienced any of the following after a previous DTP. vaccination:

Brain disease: Within seven days.

Selzure: Within three days.
Collapse or limpness: Within 48

Fever of 105 degrees: Within ■ Crying persistently and incon-

solably: For more than three hours. A family history of adverse reaction to DTP is not considered sufficient reason not to vaccinate, nor is family history of seizures.

VACCINATION SCHEDULE

Recommended for children under 2: ■ Diphtheria, tetanus and pertus-

sis: Four vaccinations. ■ Polio: Three vaccinations

Meningitis (Haemophilus Influenzae B): Three vaccinations. ■ Hepatitis B: Three vaccinations

Measles, mumps and rubella: One vaccination.

SOURCE: The National Immunization

'The government is . . . in some cases, lying to us'

By Julia Helgason DAYTON DAILY NEWS

hen Kristine Severyn of Centerville read in 1991 that the Ohio legislature might mandate measles, mumps and rubella shots for college students, she bristled.

"That word 'mandate' struck a nerve. College students are adults and should be able to decide for themselves whether they need more shots, said Severyn, a registered pharmacist with a doctorate in biopharmacéutics.

After she testified before a legislative committee in Columbus, the bill died.

"I didn't know much about vaccines in those days," she said.
"But the more I researched, the more I realized that the govern-



Severyn

ment is withholding information about vaccines — and in some cases, lying to us."

To educate parents, Severyn founded and funds Ohio Parents for Vaccine Safety. "We're not against vaccines," she said. "We're not against anything. We're for informed consent."

Parents should have access to truth about vaccines, she said, and based on the facts, should then decide which vaccines their children should or should not have.

It's very difficult to get a child in school without the required vaccinations, she said, and there have been cases in which welfare checks were withheld until children were vaccinated. "That's not informed consent."

Severyn points out that vaccinations are the only medical procedures — and vaccines the only prescribed drugs — that U.S. citizens can't refuse.

"There's no opting out, and to me that's scary."

Severyn has researched and published extensively on vaccine policy, and has testified before vaccine policymakers in Columbus and Washington. She suggests that the following vaccine facts warrant public concern:

- Some of the influential members on vaccine policy making boards receive money such as research grants or expert witness fees from vaccine manufacturers.
- A recent upsurge of measles in infants was caused by vaccinations. Infants used to acquire temporary immunity from mothers who had had measles, but they get no immunity from their vaccinated mothers.
- Hepatitis B vaccine, recommended for all infants, immunizes against a sexually transmitted disease that infants don't get unless their mothers are infected. (In October 1992 Merck reported a 17 percent increase in third-quarter earnings and company officials said the hepatitis B vaccine was one of its strongest performers.)
- Sen. Ted Kennedy, D-Mass., has proposed a national vaccine tracking system with a high potential for misuse. The system would cross state lines to track unvaccinated children, and would establish a registry of such children and their parents.
- A chicken pox vaccine is moving closer to general use, though chicken pox is more a nuisance than a threat. The benefit would be reductions of absenteeism of children from school and parents from work.
- The United Nations has committed \$150 million to develop a "super vaccine" providing immunity against 30 childhood diseases with a single shot, though no one knows what effect such a combination of toxins might have on a tiny body.

DPT shot blamed for ailment

Federal fund will cover treatment for kidney failure

BY TIM BONFIELD

The Cincinnati Enquirer

Kimberly Barnard, who has endured four failed transplants during a 19-year battle with kidney failure, finally knows what caused her plight — a severe reaction to a childhood vaccine.

The revelation won't cure the 24-year-



old Springdale resident, but it could help solve her family's financial troubles.

The Barnards have won a four-year legal battle for compensation from the National Vaccine Injury Compensation Program, a special fund established by Congress in 1988. The fund was

established to cover the liability of vaccine makers so they would stay in business.

Illness followed shot

Kimberly's original kidneys failed in 1975, about three weeks after getting a booster shot for diphtheria, pertussis and tetanus (DPT).

Since then, she has had four kidney transplants. The newest kidney, transplanted in 1991, now functions at 30 percent normal and is steadily getting worse despite massive doses of anti-rejection drugs. Those drugs have given Kimberly a puffed appearance known as "moonface."

In addition to the transplant operations, Kimberly has had her gall bladder and thyroid glands removed. She has osteoporosis, which has rendered her bones so fragile she broke an ankle just stepping out of the car. Doctors say her medical problems all stem from the kidney failure.

Family struggles with bills

Over the years, Kimberly has had more than 30 surgeries. She takes 24 medications. Her slowly deteriorating condition has left her deeply depressed.

Medicaid and Medicare have paid for most of Kimberly's medical expenses. But the family's finances have been taxed by many uncovered medicines, treatments and travel expenses.

Many groups and individuals responded with cash, gifts and well wishes for Kimberly after an *Enquirer* profile printed in March 1993. Now, the Barnards may not

(Please see KIDNEY, Page B4)



Six-year-old Sarah Davis (West Chester, Ohio) developed seizures four hours after DPT (diphtheria-pertussis-tetanus) vaccine received at six months of age. She takes anti-seizure medication for her severe seizure disorder. Sarah is enrolled in multihandicapped special education classes in Lakota Public Schools. She talks, but is not conversational, and still wears diapers. Sarah is receiving compensation through the federal Vaccine Injury Compensation Program.

Kidney: Doctor convinced the court

CONTINUED FROM PAGE B1

have to depend on the kindness of

strangers much longer.
The U.S. Court of Federal Claims — the Washington, D.C. court that handles vaccine injury claims — has approved creating a "life care plan" for Kimberly that is supposed to cover her uninsured medical needs for the rest of her

Attorneys for the government and the family are still negotiating the details of the plan. But payments could begin this year, said the Barnards' attorney, Paul De-Marco.

Kimberly's victory is unusual because most medical experts do not recognize kidney failure as a side effect of the DPT vaccine. But the testimony of kidney expert Dr. Earl Ginn was enough to convince the court.

TUESDAY, AUGUST 16, 1994 SECTION

Ginn testified that the DPT shot "more likely than not" caused Kimberly's kidney failure because the illness occurred so soon after the vaccine was given. Ginn testified that the antibodies generated by the DPT vaccine could have caused kidney failure by destroying the organ's blood-filtering capillary networks.

No other medicines Kimberly was taking at about that time could have caused the reaction, Ginn said. He also said Kimberly's case resembled a few other cases of DPT-caused kidney failure he had

seen

Such testimony is not proof beyond a reasonable doubt, but Kimberly needed to provide only a "preponderance of evidence" to win her case.

"Dr. Ginn's testimony . . . demonstrated a logical sequence of cause and effect between the DPT vaccine and petitioner's injuries," wrote Gary Golkiewicz, chief special master of the court. "Therefore, petitioner shall be compensated in this case."

Severe reactions to vaccines are rare, but more common than many might think. As of March 1993, the federal vaccine injury compensation program has awarded \$329.5 million for injuries and deaths, according to Ohio Parents for Vaccine Safety.

cine Safety.

Reactions to the DPT shot can range from persistent soreness at the injection site to rare cases of brain damage and death. Severe reactions to DPT shots are among the most common vaccine-injury claims, the parents group reported.

The amount Kimberly receives "will be substantial," DeMarco said. The exact amount depends on what medical and family expenses are covered by the life care plan. There will be no punitive damages against the vaccine manufacturer, which in this case is not known, DeMarco said.

It may still be a month or more

before the life care plan kicks in. Among the issues still under negotiation: whether to move Kimberly into a group home, a government proposal the family opposes. If the two sides cannot agree in the next few weeks, a hearing to decide the issues will be held Sept. 22, De-Marco said.

In the meantime, friends are sponsoring a carnival to benefit Kimberly. The event is set for 11 a.m. to 7 p.m. Saturday at the St. Rita School for the Deaf in Evendale. The family still needs help making ends meet while waiting for their vaccine case to be settled.

Besides, Kimberly could use a party, said her mother, Jan Barnard

"She's been so depressed," Jan Barnard said. "She gets up in the morning to take her pills and then she goes back to bed. She hardly ever goes outside. Pretty much all she does is watch TV and sleep."

Kimberly's father, Terry Barnard, works as a carpentry subcontractor. Jan Barnard quit a marketing job to care for Kimberly.

Even with court documents in hand, Jan Barnard finds it hard to imagine the day when she no longer has to scrape to pay Kimberly's hills.

"It's hard to believe we've actually won," Jan Barnard said. "I guess I'll believe it when we see it."