"Hepatitis B Vaccine: Helping or Hurting Public Health"

The Subcommittee on Criminal Justice, Drug Policy, and Human Resources
May 18, 1999
10:00 A.M.
2247 Rayburn HOB

OPENING STATEMENT OF CHAIRMAN MICA

Witness List

Panel I - Victims

The Honorable John Joseph Moakley
Congressman, 9th District, Massachusetts

Michael Belkin
Judy Converse
Marilyn & Lindsay Kirschner
Barbara Haun
Karen w/ PKIDS
Betty Fluck

Panel II – Government Officials

Harold Margolis
Chief of the Hepatitis Branch
Center for Disease Control

Susan Ellenberg
Director of Bio-statistics
and Epidemiology Division
Food & Drug Administration

Panel III – Experts

Dr. Samuel Katz
The Infectious Diseases Society of America

Dr. Burton Waisbren, Sr.
http://goodlight.net/nyvic/health/hep-b/default.htm
F.A.C.P.

Testimony of Dr Dunbar
Molecular Biologist
Baylor College of Medicine

Testimony of J. Barthelow Classen, M.D., M.B.A.
President & CEO
Classen Immunotherapies, Inc.

Panel IV – Advocacy

Thelma Thiel

Chairman & CEO
Hepatitis Foundation International

Testimony of Barbara Loe Fisher
Co-Founder & President National Vaccine Information Center

Testimony of Philip Incao, M.D.

Testimony of Dr Scheibner Ph.D.

Testimony of Patti White RN

STATEMENT of the ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS
Submitted by Jane Orient, M.D.

Chairman John L. Mica
May 18, 1999

Hepatitis B Vaccine Safety Hearing

Public health, including vaccine safety, is critically important to this Subcommittee.

Our Subcommittee, which is today exercising its oversight responsibility for the Department of Human Health & Services, is committed to ensuring that our national immunization policies and programs are functioning properly. The Centers for Disease Control & Prevention (CDC) and the Food & Drug Administration are the federal agencies primarily responsible for immunization policy and safety and will be sharing their expertise with us later this morning.

There is no doubt that immunizations have greatly improved the public health in our country. Smallpox has been eradicated and cases of polio, tetanus, and diphtheria are rare. Theses are great victories for our public health system.

Unfortunately, however, and, tragically, the history of immunization shows that sometimes vaccinations injure a child instead of inoculating them. That is why Congress created the Vaccine Injury Compensation Program in 1986, to compensate those who have been harmed by a vaccine.

My colleague the Ranking Member of our full Committee, the gentlemen from California, Mr. Waxman and my brother, a former Member of Congress worked to successfully enact that law. Oversight of that law and program are important Congressional responsibilities. This will be the first oversight hearing held in 13 years on these issues.

The purpose of this law was to protect vaccine manufacturers and also to compensate children injured from a vaccine. I do have some concerns about whether the Compensation fund is working the way Congress intended. The Department of Health &Human Services has issued new rules making it harder to be compensated, so that while there is over $1 billion in the fund, only a fraction of that was awarded last year.

The vaccine experience in the early 1980s also demonstrates that when a pattern of injuries from a vaccine emerges, that vaccine can be made safer. The crisis in public confidence in the Diphtheria, tetanus, pertussis (DPT) vaccine that led to creating the compensation law also resulted in manufacturers creating a safer vaccine. Today, the "whole-cell" vaccine that caused the controversy is coming off the market and has been replaced by a safer, "acellular" vaccine.

Today we have convened individuals from a variety of government, academic, professional and citizen groups in an effort to provide a structured opportunity for the Members of this Subcommittee to ask questions about the federal government's Hepatitis B vaccination policy and its impact on public health.

I want to make clear at the outset that the purpose of this hearing is not to scare parents away from immunizing their children.

The purpose of this hearing IS to examine the effectiveness of the 1986 law, to learn more about how the federal agencies administer their immunization policy and then how they monitor and analyze the safety of the Hepatitis B vaccine, and to review the evidence of adverse reactions to the vaccine.

Hepatitis B virus is certainly a serious disease. We will here from witnesses today who have experienced the terrible effects of this disease. In 1996, the CDC reported 10,637 new cases of Hepatitis B, 279 of who were below age 14. The CDC ***estimates*** that four to five thousand people die a year from Hepatitis B related liver disease.

To combat this disease, the CDC issued guidelines in 1991 recommending that every infant receive the Hepatitis B vaccine. In 1995, the CDC recommended the routine vaccination of teenagers

The FDA first licensed a plasma-derived hepatitis B vaccine in 1981. In 1986, the FDA licensed the first "recombinant" Hepatitis B vaccine, meaning the vaccine is the first genetically engineered vaccine.

Based on the CDC recommendations, 42 states mandate that children be vaccinated before entering kindergarten.

20 million children a year now receive some type of required vaccine. Almost 90% of all children in this country are now immunized.

When a parent takes their child in for a vaccine, they are supposed to be given an information sheet outlining the risks and benefits of the vaccine. While almost all of the states mandating childhood vaccinations allow exemptions, the information sheet does not tell parents that these exemptions exist.

Recent news reports have questioned the safety of hepatitis B vaccines and have suggested an association between the vaccine and multiple sclerosis and other autoimmune disorders. Our job here today is not to "prove" whether or not this vaccine "causes" illnesses or deaths. Instead, we have created a forum for asking questions about what scientific evidence does exist and whether further studies should be completed.

Specifically, I would like this hearing to examine the following issues:

First, what is being done to study the adverse reactions reported in the Vaccine Adverse Event Reporting System (VAERS)?

Second, do the benefits of administering the vaccine to infants outweigh the risks?

Third, what process does the CDC employ to make a recommendation for a vaccine? What role do pharmaceutical companies play in that process? Do conflicts of interest exist?

Fourth, what disclosure is required before the vaccine is given? Is it adequate?

With this outline in mind, I want to recognize the ranking minority member of the Subcommittee.

Michael Belkin Testimony to Congress

Tuesday, May 18,1999

1. **M**y daughter Lyla Rose Belkin died on September 16, 1998 at the age of five weeks, about 15 hours after receiving her second Hepatitis B vaccine booster shot. Lyla was a lively, alert five-week-old baby when I last held her in my arms. Little did I imagine as she gazed intently into my eyes with all the innocence and wonder of a newborn child that she would die that night. She was never ill before receiving the Hepatitis B shot that afternoon. At her final feeding that night, she was extremely agitated, noisy and feisty -- and then she fell asleep suddenly and stopped breathing. The autopsy ruled out choking, The NY Medical Examiner ruled her death Sudden Infant Death Syndrome (SIDS).

But the NY Medical Examiner (Dr. Persechino) neglected to mention Lyta's swollen brain or the hepatitis B vaccine in the autopsy report. The coroner spoke to my wife and I and our pediatrician (Dr. Zullo) the day of the autopsy and clearly stated that her brain was swollen. The pediatrician Dr. Zullo's notes of that conversation are ***"brain swollen ... not sure cause yet ... could not see how recombinant vaccine could cause problem."***

SIDS is a diagnosis of exclusion .. "it wasn't this, it wasn't that, everything has been ruled out and we don't know what it was." ***A swollen brain is not SIDS.*** Through conversations with other experienced pathologists, I subsequently discovered that brain inflammation is a classic adverse reaction to vaccination (with any vaccine) in the medical literature.

I set out to do an investigation of the hepatitis B vaccine and attended a workshop at the National Academy of Sciences, Institute of Medicine on "Neo-Natal Death and the Hepatitis B Vaccine," the Advisory Committee on Immunization Practices (ACIP) February' meeting and a debate in New Hampshire between the Chairman of the ACIP Dr. Modlin and Dr. Waisbren about the safety of the hepatitis B vaccine. I also obtained the entire Vaccine Adverse Events Reporting System (VAERS) database on hepatitis B vaccine adverse reactions and have investigated it thoroughly.

These are my conclusions, supported by the following pages of text and analysis that are too lengthy to present in entirety in the time allotted for this appearance. Please read the results of my investigation, as it will help you understand the magnitude of the hepatitis B vaccine issue.

Newborn babies are not at risk of contracting the hepatitis B disease unless their mother is infected Hepatitis B is primarily a disease of junkies, gays, and promiscuous heterosexuals

The vaccine is given to babies because health authorities couldn't get those risk groups to take the vaccine

Adverse reactions out-number cases of the disease in government statistics

Nothing is being done to investigate those adverse reactions

Those adverse reactions include numerous deaths, convsions and arthritic conditions that occur within days after hepatitis B vaccination

The CDC is misrepresenting hypothetical, estimated disease statistics as real cases of the disease

The ACIP is recommending new vaccines for premature infants without having scientific studies proving it is safe

The US vaccine recommendation process is hopelessly compromised by conflicts of interest with vaccine manufacturers, the American Academy of Pediatrics and the CDC

Conclusion: If (as with the recently-recommended rotavirus vaccine) hepatitis B vaccine was recommended in 1991 without scientific proof that it was safe in a broad sample of racially and genetically diverse babies less than 48 hours old before they established that recommendation, then the CDC has been experimenting on babies like guinea pigs and this Committee should suspend that universal immunization policy.

The hepatitis B vaccine was effectively mandated in 1991 for universal immunization of newborn babies by the Advisory Committee on Immunization Practices (ACIP) -- an adjunct of the Centers for Disease Control and Prevention (CDC). Paradoxically, the CDC's own **Fact Sheet** on the hepatitis B disease does not include newborn babies as a risk group for that disease. That Fact Sheet lists the risk groups as *injection drug users, homosexual men, sexually active heterosexuals, infant/children of immigrants from disease-endemic areas, low socio-economic level, sexual/household contacts of infected persons, infants born to infected mothers, health care workers and hemodialysis patients* ***NOT NEWBORN BABIES***.

Question: *Why then, did the ACIP establish a policy mandating that newborn babies not at risk of the disease be automatically administered the 3-shot hepatitis B vaccine as their first involuntary indoctrination into the pediatric care of America?*

Answer: Here is that rationale from the original ACIP 1991 statement establishing the official

vaccination policy **"Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination** ..." *"In the United States, most infections occur among adults and adolescents ... The recommended strategy for prevent/rig these infections has been the selective vaccination of persons with identified risk factors ... However, this strategy has not lowered the incidence of hepatitis B, primarily because vaccinating persons engaged in high-risk behaviors, life-styles, or occupations before they become infected generally has not been feasible ... Efforts to vaccinate persons in the major risk groups have had limited success. For example, programs directed at injecting drug users failed to motivate them to receive three doses of vaccine ... In the United States it has become evident that HBV transmission cannot be prevented through vaccinating only the groups at high risk of infection ... In the long term, universal infant vaccination would eliminate the need for vaccinating adolescents and high-risk adults ... Hepatitis B vaccination is recommended for all infants, regardless of the HBsAg status of the mother ... The first dose can be administered during the newborn period, preferably before the infant is discharged from the hospital, but no later than when the infant is 2 months of aqe ..."* (emphasis added).

So in the CDC and ACIP's own words, almost every newborn US baby is now greeted on its entry into the world by a vaccine injection against a sexually transmitted disease for which the baby is not at risk '-because they couldn't get the junkies, prostitutes, homosexuals and promiscuous heterosexuals to take the vaccine. ***That is the essence of the hepatitis B universal vaccination program***.

Question: *What are the risks and benefits for administering this vaccine to infants?*

Answer: Hepatitis B is a rare, mainly blood-transmitted disease. In 1996 only 54 cases of the disease were reported to the CDC in the 0-1 age group. There were 3.9 million births that year, so the observed incidence of hepatitis B in the 0-1 age group was just 0.001%. In the Vaccine Adverse Event Reporting System (VAERS), there were 1,080 total reports of adverse reactions from hepatitis B vaccine in 1996 in the 0-1 age group, with 47 deaths reported. Total VAERS hepatitis B reports for the 0-1 age group outnumber reported cases of the disease 20 to 1.

Question: *Why don't they just screen the mother to see if she is infected with hepatitis B (since that is about the only way a baby is likely to get the disease), instead of vaccinating infants?*

Answer: Selling vaccines is extremely profitable and the process of mandating vaccines is fraught with conflicts of interest between vaccine manufacturers, the ACIP and the American Academy of Pediatrics. The business model of having the government mandate everyone must buy your product is a monopolist's delight.

Question: *What studies are being done on the data from the FDA's Vaccine Adverse Event Reporting System (VAERS)?*

Answer: Absolutely nothing. The 25,000 reports are going into a drawer and being forgotten. How *many* reports are enough to show a drug or vaccine is dangerous -- 2,500? 25,000? 250,000? Chen of the CDC and Ellenberg of the FDA monitor this data, write reports and deliver speeches about how VAERS hepatitis B adverse reaction reports show nothing out of the ordinary and show "the

relative safety of HB vaccine when given to neonates and infants." VAERS shows nothing of the kind. **TAKE A LOOK AT THE VAERS DATA YOURSELF**. The health authorities continue to negligently downplay the steady stream of serious adverse reactions to this vaccine and more infants and adults continue to die and suffer central nervous system and liver damage after HB vaccination.

Question: *Why do the CDC, ACIP and Merck say that there are 140,000-320,000 new infections/yr (70,000-160,000 symptomatic infections/yr) when their own CDC data shows only 1O,000 reported cases year?*

Answer: They are passing off estimated, hypothetical numbers as actual cases. This is statistical fraud. In the financial world such misrepresentation would lead to criminal charges. If a company inflated its earnings or revenues by 300% (as the CDC does hepatitis B disease statistics) and foisted those figures off as official data (and not some back-of-the-envelope guess-timate) - that company would be investigated by the SEC and sued by shareholders. Why doesn't that happen in the medical world? There's no regulator to keep the CDC honest. They do not say those figures are hypothetical estimates, they misrepresent the data. Go try to audit those 320,000 supposed new infections/yr. You will not find them. The whole exercise is designed to increase public hysteria about the risk of a low-risk disease so the CDC can extend it's pervasive influence and Merck can increase its $900 million/year vaccine revenues.

Question: *What process does the Center for Disease Control employ to make a vaccine recommendation?*

I attended the February Advisory Committee on Immunization Practices (ACIP) meeting in Atlanta and was absolutely appalled. Every vote by the Committee on new vaccine mandates was unanimous (except for one dissenting vote on Rotavirus vaccine for premature infants). There was hardly any discussion of adverse reactions, the ACIP simply rubber-stamped every proposal on the agenda. I call it Vaccination Without Representation. In one instance, the ACIP passed a recommendation for Rotavirus vaccine for premature infants ***even though no scientific studies had been done showing it was medically safe***. Dr. Modlin, (Chairman of the ACIP), said in a pro-hepatitis B vaccine debate in New Hampshire *"How do we determine whether something is scientifically valid or not?... 1) Is the theory biologically plausible? 2) Has it been tested by appropriate methods? 3)Is the study well concluded? 4) Are the results statistically sound?* But at the February ACIP meeting, when it came time for the ACIP to rubber-stamp approval of Rotavirus vaccine for premature infants, here are Modlin's quotes from the official transcript: ".. *available data are insufficient to fully establish the safety and efficacy of rotavirus vaccine in premature infants ... there is a section under Adverse Events that details what little information there actually are with respect to premature infants ... To my knowledge we don't have data from a clinical trial specifically ... Some bit of information from Seattle, as I recall, that had suggested that was a slight increase in relative risk for hospitalization for premature infants ...* ***Obviously a situation where we have to make a judgment in the absence of data, and with a vaccine that has not yet been tested in the group ..."*** (ACIP transcript, pages 102-112) Modlin then held a vote and the recommendation for premature infants passed nine to one -- Modlin voted yes, Dr. Glode against. This is a clear example of how the medical bureaucracy (led by the CDC and ACIP), is recommending vaccines without scientific evidence that those vaccines are safe in a broad sample of racially and genetically diverse infants.

What Should Be Done? This Committee should investigate the 1991 ACIP recommendation establishing universal hepatitis B vaccination of newborn babies in the hospital -- and if (as with the Rotavirus vaccine example above) no studies were done to prove this was safe in a broad sample of racially and genetically diverse babies less than 48 hours old before they established that recommendation, then the CDC has been experimenting on babies like guinea pigs and this Committee should suspend that universal immunization policy.

VAERS ANALYSIS (Vaccine Adverse Event Reporting System)

I studied statistics at the University Of California at Berkeley and went on to develop sophisticated proprietary risk/reward statistical models at Salomon Brothers from 1986-91 -- and in my subsequent, ongoing business provide statistical economic and financial forecasts to mutual funds, investment banks, pension funds and hedge funds.

I studied VAERS hepatitis B vaccine data obtained by the National Vaccine Information Center (NVIC) under the Freedom of Information Act. The data has some flaws (incomplete fields, some multiple reports) but ***any qualified, impartial quantitative analyst or statistician not affiliated with Merck, Smithkline, the CDC, the FDA or the AAP who examines these reports will find a clear and undeniable pattern of central nervous system (CNS) and liver disease striking thousands of people within 0-4 days after vaccination with hepatitis B vaccine****any qualified, impadial quantitative analyst or statistician not affiliated with Merck, Smithkline, the CDC, the FDA or the AAP who examines these reports will find a clear and undeniable pattern of central nervous system (CNS) and liver disease striking thousands of people within 0-4 days after vaccination with hepatitis B vaccine.* These reports have been ignored, explained away, or considered "acceptable" by the FDA, CDC and drug companies. This Committee should launch an investigation of the VAERS hepatitis B data by a team of independent scientists not beholden to vaccine manufacturers or the FDA/CDC bureaucracy. The following is intended to be a starting point for such an investigation. This does not profess to be a complete, exhaustive analysis -- simply an overview, highlighting aspects of the data that may not previously have been brought to your attention.

The total 24,775 VAERS hepatitis B reports from July 1990 to October 31, 1998 show 439 deaths and 9673 serious reactions involving emergency room visits, hospitalization, disablement or death. Therefore, more than one third of total reports were serious events. 17,497 of those total reports were for hepatitis B vaccine only, the remainder were vaccine cocktails where hepatitis B was administered along with DPT, HIB, IPV, OPV, etc.

The hepatitis-B-vaccine-only reports show a shocking cluster of reactions in females starting in their teenage years (the male/female reporting ratio is balanced before age 16). ***For ages 16-55, 77% of VAERS reports are women -- more than three times as many women as men are reporting adverse reactions to hepatitis B vaccine****.* The median onset of adverse event after vaccination is one day, 70% of reactions happen within four days of vaccination. independent scientists should investigate why females are more disposed to have adverse reactions to hepatitis B vaccine and/or report them to VAERS. One possible explanation is that nurses have to take this vaccine for their jobs and are thus more exposed than most adults to hepatitis B vaccine adverse reactions. Rather than dismiss that factor as an "over-reporting bias" as Dr. Chen of the CDC did at the February ACIP meeting, perhaps investigators might consider that nurses are alert health care workers and ought to be listened to with

regard to the dangers of adverse events with any vaccine (rather than ignored). Personal case studies reported to the author have showed many teenage girls getting severe, debilitating adverse reactions to hepatitis B vaccine, having nothing to do with nursing. Do women have a greater vulnerability to auto-immune reactions to hepatitis B vaccine? ***Is the government discriminating against women by administering this vaccine without regard for genetic risk of CNS and liver disease?*** Those are questions that independent scientists should investigate.

A second area of concern is the VAERS reports involving hepatitis B vaccine administered with other vaccines (vaccine cocktails). Health officials are fond of dismissing those repeals as being attributable to hepatitis B vaccine, because of the multiple other antigens present (almost as if they wanted to cloak hepatitis B vaccine reactions from scrutiny). Let's avoid that controversy and focus on the extremely disturbing VAERS data of hepatitis B vaccine with other vaccines. These reports amount to only one third of total reports (7,275), but account for two thirds of total deaths (291). The median onset of those deaths was 2 days after vaccination -- displaying a clear temporal association. The median age of death was 0.5 years in this group. 50% of all hepatitis-B-vaccine-cocktail reports were serious (died, emergency room, hospitalized, disabled). I grouped ***convulsive reactions*** together from the hep-B-vaccine-cocktail data and found a deeply disturbing pattern. These were anything labeled convulsions, seizures or tremors in the VAERS hep-B-cocktail data. Of the 1189 such reports, fully 80% (950) were serious (died, ER, hospitalized, disabled) median age 0.5 years, median onset after vaccination 0 days (less than one day). Someone should do follow-up and find out what happened to those poor infants who suffered severe convulsions after a hepatitis B-multi-vaccine cocktail. In the personal reports I've taken of similar adverse reactions, the children were left brain damaged and developmentally disabled. Looking beyond the debate over whether VAERS reports of vaccine cocktails can be attributed to hepatitis B, the data strongly suggests ***combining multiple vaccines may be convenient and profitable for pediatricians -- but fatal or debilitating for infants***. Where are the scientific studies showing hepatitis B vaccine is safe to administer with DPT, HIB, IPV, OPV, etc.? Did anyone doing cost/benefit analysis for those studies include data showing the higher mortality and serious reactions present in the VAERS data? Why not? Is there an identifiable genetic marker in those who suffered convulsive reactions to screen out those vulnerable in the future? These are all matters for independent scientists to audit.

Another area that leaps out of the VAERS database is something I dubbed ***arthritic reactions***. These are joint pains, tingling, numbness, aching, fatigue, etc. I found 2,400 of those reports in just a quick survey of the first reporting column of VAERS (hepatitis B vaccine only). Almost one half of those are serious, involving an ER visit, hospitalization, death or disablement. These are the type of adverse reactions reported by many adults who are forced to take the hepatitis B vaccine for their jobs. In the reports of such adverse reactions I've taken, the symptoms do not go away, most patients complain it gets worse over time. Scientists not corrupted by drug company or CDC/FDA institutional bias should examine the thousands of VAERS hepatitis B arthritic reaction reports and develop a diagnosis of their hepatitis B vaccine-related illness.

Anyone who doubts if hepatitis B vaccine adverse reactions exist should sit down and read the symptoms and text comments of a random selection of VAERS reports. When one does so, they will find a similar but wide-ranging list of CNS and liver reactions that occur within days of vaccination. The Merck package insert claims ***"Injection site reactions and systemic complaints were reported following 17% and 15% on the injections, respectively."*** The standard rule of thumb is only about

10% of reactions are reported to VAERS. So the actual number and full horror of the hepatitis B vaccine reaction story is potentially much larger than even VAERS suggests.

Testimony of Judy Lafler Converse

Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources
Government Reform Committee U.S. House of Representatives

Hepatitis B Vaccine: Is the Vaccine Helping or Hurting Public Health?
May 18, 1999

My name is Judy Lafler Converse. I live on Cape Cod in Massachusetts. I regret having a reason to speak here today. I have no other reason to do so except for the sake of truth, and to spare other families the trauma and loss we have endured.

I also wish to preface my comments by stating that I hold a master's degree in public health and am a registered dietitian. I was trained to accept and encourage immunization and was in no way inclined against immunizing my son, whose name is Benjamin. He is now two and a half years old. There is no history of autism or seizure disorder in either my family or my husband's family. If Ben were here in front of you today, he would seem completely normal, but his appearance belies the struggle he faces every day.

Ben was born full term and normal in every way. His birth was vaginal and without interventions or drugs. His Apgar scores were 9 and 10. All his reflexes were recorded as normal. He was very peaceful. Before discharge, Ben was immunized with Recombivax HB against hepatitis B virus. Neither I nor my husband recall receiving informed consent for this vaccine, nor do we recall seeing Ben get the shot, but it is recorded in his immunization record. No signed informed consent specific to the hepatitis B vaccine was present in the copy of Ben's medical record which we recently requested. Ben's fourth night in this world was his first at home, and we arrived there at about 5 PM. Five hours later, he had his first seizure. Frantic calls to the maternity staff and pediatrician on call fell on deaf ears. The extent of the medical advice we received was to put him on our clothes dryer and turn it on. No one mentioned the vaccine. No one expressed concern that Ben was turning blue, that he couldn't stop screaming, or that he appeared to be having tremors and full body spasms.

Ben had three more seizures, losing consciousness, in the next 8 days, as well as several episodes of arching screaming without losing consciousness. He was vomiting forcefully every day, had a recurring mild fever and eczema, was unable to remain asleep, soaked several diapers a day with glossy mucous and diarrhea, and cried constantly. No one thought any of this was out of the ordinary. I was told these things were normal for a breast fed infant. He was only 12 days old. The third time he passed out, he did not resume consciousness. His breathing was slow and shallow and he was cyanotic. At the emergency room, Ben was tested for several diagnoses and all were negative or inconclusive. He was observed overnight. After nearly losing him, we were sent home the next day with a shrug. No one knew what was wrong, no one mentioned the vaccine, no one expressed interest or concern for the events of the previous week, and no one advised us in any way about what appeared to be seizures and a struggle for Ben's life. Ben's medical record even states, in a gross understatement, that his first days of life prior to this admission via the emergency room were

"uneventful". The same doctor who wrote this note privately admonished me for agreeing with the attending pediatricians to spare Ben the trauma of another spinal tap. Convinced Ben had meningitis, he said, "it's people like you who cause lifelong mental retardation." Ben's discharge note states only that he had "apnea", despite having tested negative for it. We entered the hospital hoping for answers, but we left with absolutely none.

Ben worsened with the second hepatitis B immunization at 4 weeks. It was at this moment that I realized he'd been given the shot at birth and that this may be causing his problems. At two months I asked Ben's pediatrician to postpone his immunizations. I asked only for a delay so that Ben could continue recuperating. I knew that accepted pediatric practice dictates that a sick child should not be immunized. The doctor refused my request. When I persisted, he told me we could either immunize Ben on schedule, which we had to do because it was the law, or we could call DSS. With this threat, Ben was immunized. All of his symptoms worsened. At four months, Ben was immunized again. At six months, I refused further shots and switched doctors.

Ben was seen by neurologists and developmental specialists, but no one could explain why he was too floppy to attempt normal developmental tasks, was unable to sleep day or night, suckled poorly, kept vomiting, why eczema persisted despite being breast fed, or why he passed out in shock when he heard Velcro, plastic bags, or aluminum foil. By age 10 months, Ben could not pull himself to sitting, could not crawl, and had difficulty rolling over. We sought help from the Early Intervention Program and Ben qualified for services based on his gross motor delays. For the first time a formal acknowledgment of his delays was drafted. Reflexes which were normal at birth had disintegrated and his protective responses were inexplicably delayed. A developmental therapist taught him to crawl.

Once he walked, he fell on his head constantly, and toppled backwards when sitting down. He had no skill or strength to go from standing to sitting, but would fall like a tree, without throwing out his arms to protect himself. He became extremely fearful of bumps to his head and soon the slightest touch there, or just the anticipation of being bumped, would produce a seizure. He would have two or three seizures a week during his infancy and early toddlerhood. The events of these seizures never vary, and Ben had one as recently as two months ago. Ben cries hard with one breath, which seems to empty his lungs. He then is silent, mouth open, not breathing, and struggling for air. As he suffocates, he turns red, then blue, then purple; his extremities become blue; his limbs flail about as if he is drowning. Often, on his left side, Ben will have a flapping tremor of his hand while his arm, neck and shoulder are rigidly flexed. As his asphyxiation is complete, he is gray, his eyes lose their luster and open, seeing nothing; his pupils dilate; his eyes roll back into his head and he then is unconscious. He usually regains consciousness quickly once his muscles are relaxed and he can breathe again, but these episodes are traumatic, exhausting, and frightening for Ben. He is sad and scared in the aftermath. They invariably occur in response to a stimulus he can not manage, whether it is auditory, anxiety-related, or from a fall or bump. Even though Ben had seizures like this when he was just a few days old, we were told they were breath holding spells which he consciously contrived in response to our over protectiveness. The doctors withdrew and not only became unsupportive, but blaming: They essentially told us we were causing Ben's seizures, odd behaviors, and developmental delays by bad parenting. I was told I "overnursed" him by one neurologist and asked "why I needed something to be wrong with my son" by a pediatric developmental specialist. I believe this is a grossly ignorant assessment of what may be grand-mal seizure episodes. Ben also

appeared to have petit mal seizures in which he would roll back his eyes and grimace, or suddenly pierce the air above his head with his left hand, elbow locked and hand quivering. These occurred randomly; he would endure the brief spasm then go back to whatever he was doing.

What are our lives like now? Ben was diagnosed with sensory integrative disorder last fall. Last week we learned he is on the autism spectrum as well with a diagnosis of pervasive developmental disorder. This means he can't reliably sense, organize, or prioritize the information his brain receives about anything - gravity, balance, sound, light, emotion, anything. He learned to walk without sensing when he was falling down. He can't tolerate change, being touched without notice first, the feel of food in his mouth, or even the presence of his own peers, whose random squeals and movements terrify him. He can't be placed in group day care and has extreme separation anxiety. These few examples don't begin to describe how profoundly limited Ben is physically, developmentally and socially. Though Ben is extremely bright and verbal, we don't know if Ben will be able to attend school since he can't function in the bright, noisy environment of a schoolroom.

In many ways we are lucky. It is my belief that my nutrition training served me well. I took steps immediately upon suspecting vaccine damage that I believe saved Ben from dying or lapsing into profound autism. Because of this very early and diligent dietary intervention, plus intensive efforts in occupational therapy, Ben has had the opportunity to recover some functioning. With more relentless effort, we fervently hope he will be able to function like other kids. But my husband and I have lost friends, work, income, and nearly lost our marriage as we struggled against the medical providers who were supposed to be helping. Our pediatric providers were so blind, so biased against the possibility that a vaccine could be damaging that, I believe, my son would have died if not for our persistent refusal to follow their advice.

We have had little pediatric guidance or support throughout this journey. Though Ben's current physician agrees not to immunize him and has supported all referrals we have requested for treatment and evaluation, she has not reported his reaction and discouraged me from doing so. She told me we would be harassed by the state department of health and forced to prove damage from each vaccine with invasive blood tests. When we asked for a medical waiver she gave us only a vague philosophical one. She acknowledged to me that the hepatitis vaccine is an unnecessary affront to an infant's well being and that she refuses to give the younger two of her three children this vaccine, because it is of no benefit.

I have absolutely no doubt in my mind that the hepatitis B vaccine damaged my son and caused his developmental disorders. Not just because he was normal at birth, full term, with a family history void of such problems, and with no other events to precipitate such an array of symptoms, but because the progression of events after the shot is in keeping with criteria for a hepatitis B vaccine adverse event as listed by the Vaccine Injury Compensation Program. This is true with one exception: It took longer than four hours for my son to have his first seizure. All symptoms of anaphylaxis were present but had a slower onset and persisted for months. In my mind this fact in no way exonerates the vaccine industry or those that make vaccine policy. It simply means that thousands of healthy newborns can slip through the cracks with severe reactions unacknowledged and untreated; thousands will die, have delays, or become autistic and their pediatric providers will be just as uninformed as ours were.

One final comment as an individual trained in public health sciences: After regarding data on

hepatitis B in the US, it is plain to me that a program to vaccinate newborns is of no worth to anyone except those who sell vaccines. The immunity it imparts wears off before a child is old enough to have sex with an infected partner or use contaminated needles, which are the foremost modes of transmission. There is no benefit, and only risk, for newborns receiving this vaccine.

Testimony of Marilyn & Lindsay Kirschner
On the Hepatitis B Vaccine
May 18, 1999

1. I am here today with my daughter, Lindsay, maintaining a commitment to pave the way so that other parents can make an informed choice in regards to the Hepatitis B vaccine. Lindsay is representative of all the children who fall under the mandate. Six months before the vaccine we had an idyllic life, reveling in the joy of Lindsay's Bat Mitzvah, perfect in every way.

Lindsay received the Hepatitis B vaccine two days before entering High School. The next day she seemed flu-like, the day after that so dizzy she couldn't stand-up without holding the walls. The following day she passed out. So our life goes, since August 1997. Lindsay has had syncopal & pre-syncopal episodes, her ability to stand was compromised for almost six months due to unremitting dizziness. Following our Drs. advice, unknown the vaccine was the culprit, Lindsay had the series of three. It was on the third shot Lindsay became so violently ill within two hours, that I knew the vaccine was the catalyst of her illness.

At 16, Lindsay should be having fun with friends, dating, & driving. Instead her days are filled with Dr. visits (15 specialists), MRI?S, CAT SCANS, SPINAL TAPS, ER VISITS, & Hospital admissions. Lindsay is plagued on a daily basis with HEADACHES (of a severe kind), JOINT PAIN, SEIZURES, NAUSEA, HAIR LOSS, DIZZINESS, GASTROESOPHOGAL REFLUX, & Extreme Fatigue. She has been diagnosed with an acquired Dysautonomia & is unable to hold food down with frequent retching, & vomiting. She takes a minimum of 10 doses of medication daily.

We have traveled to specialists in four States, and will be travelling to two more States before July.

Unfortunately, Lindsay is not isolated in her journey. After WPLG(MIAMI) HEALTH REPORTER, Kristi Krueger, broke Lindsay's story (the 1st one to air in the country), I heard from droves of people who have been or have family members affected by this vaccine. (video)

Family life as we knew it has been destroyed. This illness is an emotional & extreme financial drain, as I am hardly able to work, depending on my family to support us, and often feeling like a beggar for our survival.

As a single parent this vaccine has ripped a part of our lives that can't be replaced. Lindsay, my former National Junior Honor Society President in 8th grade, is now on a

504 Disability Plan. missing 70 days of 9th grade, and pushing beyond that in this her 10th grade year. What about her future? College? A Career? Will my son David ever forgive me for being so unavailable last year when he was a senior, now that he's 3,000 miles away in LA. The joy of his scholarship offers, & prom departure all took a backseat to Lindsay's illness. Or the fact that he's spending his birthday on a plane so we could be at this hearing just after returning Sunday from his 1st year at USC. What about Lindsay's puppy Frisbee, who is boarded almost as much as he's at home?

What about our shattered lives, barely a fragment left of what use to be? Tragedy is not supposed to be the American way. Lindsay, nor anyone should ever have to live like this because of the greed of the manufacturer.

Testimony of Betty D. Fluck for U.S.

1. House of Representatives Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy, & Human Resources. John L. Mica. Chairman

Effectiveness of Hepatitis B Vaccine

May 18, 1999

I would like to thank you for allowing me to come before you today to share my experience with you. Never did I dream that I would have this opportunity. I am a diagnosed victim of the Hepatitis B vaccine. My husband and I are not anti-vaccine. Each of our three boys has been vaccinated per Health Department Guidelines. However, they will not have the hepatitis B vaccine. On December 2, 1997, I took my second Hepatitis B vaccine in the series of three. I was required to have the immunization for my job. I am a Registered Nurse and have been for twenty years. I had just started a new job as a Public Health Nurse for the local Health Department in Kokomo, Indiana. Part of my job description was to give immunizations in the department's weekly clinic.

Roughly twelve hours after receiving my vaccine, I woke up in severe pain - I developed a 104 F fever, nausea and vomiting, respiratory problems, a rash, severe head, neck and back pain, swollen joints and I was unable to move my legs. When the fever broke several hours later, I regained a small percentage of my leg strength. but the severe damage had already been done. I had to use a cane to move around. I had absolutely no energy and I had constant joint and leg pain. I was sleeping approximately 22 hours per day. I continued to rim intermittent low grade fever.

The first doctor that I went to said that I had a reaction to the Hepatitis B vaccine but was unable to help. I went from doctor to doctor looking for help. I ended up at Indiana University Medical Center in Indianapolis. I first saw a doctor who was very kind and told me that he had read about some of the problems with the vaccine. He promised to do some research into the vaccine adverse reactions. He asked me to see one of his colleagues at I. U. Med Center, a rheumatologist. This rheumatologist from I U. was simply hostile to the idea that the Hepatitis B vaccine could have caused my problems. He suggested that some of my problems could be attributed to a kidney

stone. Please be aware that at that point, my fingers were so painful that I could not open a soda can.

I returned to the first doctor at I. U. Med Center one month later for a scheduled follow up. This doctor who had been encouraging and sympathetic one month ago now refused to use the word vaccine and attributed some of my problems to the "aging process". Unhappy with both of these doctors, I requested a meeting with a patient advocate and the I. U. doctors. At this meeting, the first doctor finally told me that I had a "political problem. not a medical one."

My condition continued to deteriorate from cane, to walker, to kneebraces. Finally in September, 1998, 1 was put in full leg braces that run from my toes to my hips. With the use of the braces and forearm crutches, I have some mobility. Eight months after the initial injury, I was able to find an out of state doctor who was treating people for vaccine damage. I must now see him every three months.

The vaccine has caused nerve damage to my legs and hands. The medical name for my problem is Chronic inflammatory Demylenating Polyneuropathy (CIDP). I also have multiple types of auto immune disorders, and I now have an elevated rheumatiod arthritis factor. I undergo weekly IV treatment s that cost several thousand dollars per week. Although I have more energy now there is no real prognosis for my condition.

Immediately after I was injured, I contacted the pharmaceutical company asking them for help. They told me that they had never heard of this problem before. I realized at that point that I was not that unique and decided to write to the FDA through the Freedom of Information Act. I requested any reports on file about adverse reactions to the Hepatitis B vaccine for one particular company from 1991 to present. Four months later I received a box containing a 1045 page report. On each page, there were summaries of approximately eight reactions . These 8000 + reactions ranged from mild to death.

I made an appearance on ABC's 20/20 in January, 1999 on their story about the Hepatitis B vaccine. Since that show was aired. I have received numerous calls from adult victims and parents of children who have been injured after taking the Hepatitis B vaccine. One common theme among victims is that their doctors told them that it couldn't be the vaccine because it was perfectly safe.

I recently testified for the State Senate Committee in Indiana with the intent of removing the mandate for the Hepatitis B vaccine for school entry. The proposed ammendment was designed to give the parents the choice to wave the vaccine for any reason.

On March 2, 1999, it passed the State Senate by a vote of 45 to 4. However, the House sponsor of the original bill killed it rather than bring the bill up for debate.

In Indiana, a doctor from the Department of Health told the Senate Committee that one of the arguments for the vaccine was that it was the "first anti-cancer vaccine." Fortunately, we were able to show that the "anti-cancer vaccine" theme was taken from the PATH website. PATH is an organization within the World Health Organization. PATH suggested that the "first anti-cancer vaccine" theme was a good marketing tool to bring about interest in a "boutique" vaccine.

I have minutes from a CDC Study Group Meeting on the Hepatitis B vaccine held in March, 1997. The minutes of the meeting show that it would take at least a 60 day study to show the onset of MS. Clinical studies done by the two manufacturers were four and five days in length, respectively. It should be noted that the afternoon session of this meeting was chaired by Dr. Robert Sharrar of Merck. This group was to decide how to identify various types of adverse reactions such as MS and demylenating disease and to plan meaningful studies. When Dr. Sharrar appeared on ABC's 20/20 in January he said that he honestly believed that the Hepatitis B vaccine had not caused any problems. Can an employee of a pharmaceutical company that manufactures the vaccine be objective in designing experiments to show fault in a product that generates close to a billion dollars in sales for his company?

The form that people are given about the vaccine was written by the CDC. It does not address serious adverse reactions. When you look at the vaccine insert provided by the manufacturer, several adverse reactions are noted. I have since talked to many Healthcare professionals who are also unaware of the potential adverse reactions listed on the vaccine insert. It makes me wonder why the pharmaceutical company representative that I talked with earlier, the one who was unaware of any adverse reactions, was unaware of what their own company's insert said. A vaccine that still has so many unanswered questions should not be mandated for children. It just does not make sense. The right to decide if it is in the best interest of the child should be made by the parents. After all, it appears that for the most part when a child is severely handicapped by this vaccine. the parents are on their own. No one pushing the mandate is there for help or comfort.

In an article on the Hepatitis B vaccine that was printed in the Washington Post. a spokesperson for the CDC, said that nothing unexpected had been observed in the way of adverse reactions. At first. I thought they meant that their position was that no adverse reactions had occurred. Now, I really don't think it was denial. Despite over 20,000 reports to VAERS for the two manufacturers nothing unexpected had occurred. I really believe that the number and type of injuries is no surprise to the CDC. May be the only surprise for the CDC is just how hard the victims are fighting back.

Testimony before the U.S. House of Representatives Subcommittee on Criminal Justice, Drug Policy and Human Resources

1. By

Burton A. Waisbren, Sr., M.D.,
F.A.C.P., F.I.D.S.A.

May 18, 1999

I would like to thank this committee for the opportunity to share with them my concerns regarding the vaccination policies of the Centers for Disease Control and Prevention (CDC) and the Food and

Drug Administration (FDA).

I am a physician and clinical investigator who has practiced internal medicine, infectious disease and immunology in Milwaukee, Wisconsin for 48 years. No ulterior motives or special interests are responsible for my being here. I am here because I feel an injustice is being done to the children of this country. Included among these children are my sixteen grandchildren.

I want to make it clear from the onset that I fully support hepatitis B vaccination for individuals who have known risk factors for hepatitis B infection. The risk factors include: sexually active heterosexual adults with more than one sex partner in the prior six months or a history of sexually transmitted disease; homosexual and bisexual men; illicit injection drug users; persons at occupational risk of infection; hemodialysis patients; household and sex contacts of persons with chronic hepatitis B infection; and infants born to hepatitis B infected women.

My involvement in the field of vaccine toxicity began in 1979 when I discovered that central nervous system demyelination (Multiple Sclerosis) had been caused, in some individuals, by the swine flu vaccine. My involvement was heightened when I found the same thing occurred after hepatitis B vaccination. These findings have been confirmed by many others and have been extended to include other untoward reaction to hepatitis B vaccine. Reactions include other autoimmune diseases such as rheumatoid arthritis, optic neuritis, postvaccinal encephalomyelitis and possibly juvenile diabetes.

An autoimmune disease is defined by the fact that it is caused by the body's immune system turning against it own tissue, be it the central nervous system, the heart, or cartilage. Since the discovery of the autoimmune aspects of the vaccine complications and confirmation of this by numerous investigators, I have been searching the medical literature and studying a number of patients to try to figure out the mechanism or mechanisms by which these autoimmune complications occur. While many explanations have been suggested, the exact mechanism is still unknown. However, this study of the medical literature, of the patients, and of a great number of the reports sent to the *Vaccine Adverse Event Reporting System (VAERS)* has convinced me that a serious, perhaps unique problem, exists in regard to the toxicity of the hepatitis B vaccine. There are at least sixteen articles in the peer reviewed medical literature about the occurrence of diseases of autoimmunity such as multiple sclerosis after hepatitis B vaccination. The editors of the renowned medical journals, in which these articles appear, felt these cases should be brought to the attention of the medical profession. There are thousands, yes thousands, of reports by health professionals to the *VAERS* that adverse events have occurred after hepatitis B vaccination. I am aware of dozens of cases brought against pharmaceutical companies because of damage due to the hepatitis B vaccine. Many of these cases have been settled with the proviso that the settlements remain a secret.

The fact that these well-established adverse reactions to hepatitis B vaccine have not been acknowledged or are being denied by both the CDC and the FDA, is the root cause of the concerns I am about to share with you now.

The first concern is that caused by the experiment sponsored by the CDC which is designed to determine if vaccination at birth of all babies in the U.S. will eventually decrease the frequency of cancer of the liver caused by hepatitis B infection. To arrive at the end point of this experiment will take many years.

This experiment is based on the following assumptions:

1. **The vaccine is safe and effective.** While the vaccine is effective we all know that no vaccine is entirely safe as evidenced by the above-mentioned information.

2. **Five to twenty percent of the people in the U.S. will eventually contract hepatitis B infection.** I doubt these statistics.

3. **Up to 25 percent of patients with hepatitis B infection cannot remember where they got the disease.** Isn't it understandable that the people with the risk factors such as multiple sex partners and injected drug use will not be able to pin point where and when they were exposed to the disease.

4. **There is no other way to control hepatitis B infection in the U.S.** Does anyone in this room agree that there is ever only one way to accomplish a purpose?

I hope that this committee will ask for an independent analysis of these rationales.

This brings up my second concern. That is: how can an experiment such as universal hepatitis B vaccination be adopted nationwide without congressional involvement or approval. Apparently this was accomplished by the joint efforts of an official of an agency that stood to gain much influence and power by the program and by an executive of a drug company which stood to make billions of dollars by the project. What techniques were used and were conflicts of interest involved? Were the rights of parents and children infringed upon?

My third concern lies in the fact that the FDA has apparently not been reacting to the many theories in the medical literature regarding the causes of neurologic complications of vaccination. The FDA does not ask if proposed vaccines exhibit molecular mimicry with human tissue. They do not ask if a vaccine exhibits complimentarity with common viruses that may be in the patients. They have not demanded that the HLA patterns of patients who have untoward results be determined. They have not encouraged the development of synthetic vaccines that contain only immunogenic antigens and nothing else. I am concerned that we may see the same or similar adverse reactions to new vaccines. The new Lyme vaccine is a case in point since that vaccine has more theoretic dangers then does the hepatitis B vaccine because of the autoimmune nature of the disease itself.

When the material I have presented here is considered en toto, I believe it indicates that the present universal hepatitis B vaccination experiment being conducted in the U.S. should be abruptly halted for the following reasons:

1. It appears likely that serious untoward events particularly of the nervous system have followed the vaccination.

2. In view of this, it is reasonable to suppose that some babies who have little or no chance of getting hepatitis B will suffer unnecessary damage to their nervous system.

3. Information regarding the risk/benefit ratio of this vaccine is not known and therefore cannot be given to parents in an informed consent.

4. There is some doubt as to whether the rights of babies are being violated when they are subjected to an experiment even with their parent's consent.

France has already stopped their program of universal hepatitis B vaccination of babies because of reports that surfaced about multiple sclerosis following the vaccination. I hope our country will follow their lead. If we do not, I am afraid public confidence in our vaccination programs will decrease. This would be detrimental to the excellent vaccination programs already in place in the U.S.

I would like to thank the committee again for allowing me to share my concerns with them.

Documentation of all that I have said here is available in the supplemental material I have given this committee.

Dr. Bonnie S. Dunbar
Molecular Biologist
Baylor College of Medicine

1. May 18, 1999

Good morning and thank you for this opportunity to discuss these critical health care issues. My name is Bonnie Dunbar, and I am a research scientist and medical and graduate student professor who has worked in the areas of autoimmunity and vaccine development for over twenty five years (the past 17 years at Baylor College of Medicine in Houston).

I have been honored by the National Institutes of Health as the first Margaret Pittman lecturer for my pioneering work in vaccine development. This honor was special for me because Dr. Pittman's contributions were instrumental in early aspects of vaccine development and because I understand the impact that some vaccines have had, and will continue to have, on our society. My ongoing research in the area of vaccine development continues to be a major commitment. I have worked extensively with the US Agency for International Development and the World Health Organization programs and have a life long commitment to carrying out research to understand, and hopefully, to help solving problems associated with world population as well as disease problems.

As I have been invited to speak to this distinguished subcommittee, it is important to discuss my experience with the clearly apparent severe adverse effects of the Hepatitis B vaccine. About five years ago, I had two individuals working in my laboratory who were required to take the Hepatitis B vaccine. Both of those individuals developed severe and apparently permanent adverse reactions as a result of the vaccine. Both of them were completely healthy and very athletic before this vaccine and have now suffered severe, debilitating autoimmune side effects from the vaccine. I have studied the complete medical history of my brother, Dr. Bohn Dunbar, who developed seriously chronic joint and muscle pain, fatigue, and multiple sclerosis-like symptoms. And now he has further been diagnosed with POTS (an autoimmune, cardiovascular, and neurological problem) and subsequently with chronic inflammatory, demyelinating polyneuropathy. His problems have been attributed to the Hepatitis B vaccine by over a dozen different specialists around the United States of unquestionable medical expertise. He has now been rated permanently and totally impaired at greater than 90%. His health care has already cost the state of Texas about a half million dollars in the Texas Worker's

Compensation Program to date, and that figure will continue to rise given the severity of his health condition.

My other student went partially blind following her first booster injection, a medical condition that was markedly exacerbated by her second booster that resulted in hospitalization. Personal communications are that her eyesight is continuing to deteriorate. Because she is in medical school she has been, understandably in my opinion, afraid to pursue investigation into her medical problems because of her concern that they might affect her medical career.

I am extremely sensitive to the need to evaluate the risk vs. benefits of any vaccine. Because of my experience in this area, it became intuitively clear to me that these two active, healthy individuals working in my laboratory developed autoimmune syndromes within a predictable immunological time frame following their booster injections of the Hepatitis B vaccine. After carrying out extensive literature research on the nature of this virus and this vaccine, it became intuitively obvious to me that there is a significant scientific probability that the vaccine is the cause of those adverse reactions. Both the published studies of reactions to viral infection and the temporal relationship of vaccine administration to adverse events suggest strongly that these adverse reactions are related to the nature of the viral protein, the recombinant surface antigen of which is the principal component of the vaccine.

I have been in contact with numerous physicians and research scientists from several countries who have independently described identical severe reactions to the vaccine in thousands of Caucasians. Their observations have been, for the most part, denied or ignored by the public health systems, as is evidenced by the serious charges against healthcare officials and pharmaceutical companies brought recently in France. The reversal of the vaccine mandate for children in France was not based on lack of documentation. I have now been contacted personally by hundreds or more individuals (including parents of infants and children) who have reported deaths, severe health problems and life long disabilities, resulting in major medical costs following the administration of this vaccine. It appears that the adverse events related to this vaccine are within a gene pool that is capable of genetic definition. I respectfully submit that rigorous scientific studies into the possibility that the vaccine can cause severe autoimmune disorders is necessary.

The following points specifically address the issues listed in my invitation to speak to this committee.

1. The Food & Drug Administration has set up a system for reporting adverse reactions to the vaccine. How does this system work? What is being done to study these adverse reactions.

My first experience with this reporting system followed my observation of the two individuals in my laboratory who developed serious medical problems within a time frame predictable for immunological reactions. After seeing that these reactions were listed in the Physician's Desk Reference text as reported reactions to this vaccine, I learned about the VAER's reporting system. When I first called the FDA about this, I was told by an individual that "this vaccine is a problem and it is a big one." I was initially sent some information on reports of reactions that were similar, if not identical, to those of these two individuals. I attempted to initiate a dialogue with individuals at the FDA but was simply told that I could obtain the information under the Freedom of Information Act. I subsequently paid to obtain copies of these documents; and I was overwhelmed by the thousand of pages of documents I received listing thousands of reports, hundreds of which were identical to the

reports I had filed for the two individuals working in my laboratory. Unfortunately, the details on these lists were insufficient for studies to critically evaluate the mechanisms by which these reactions occur.

There was no response to my subsequent correspondence with members of this branch of the FDA. (I am aware that the cutbacks in FDA funding may have played a role in this issue.) It became apparent that the essential medical details (e.g. patient identity, genetic background, family history of autoimmune diseases, etc.) are not provided by this reporting system and that there is no way to contact physicians reporting these reactions. *This information is, therefore, inadequate and not accessible to those of us who are studying the serious adverse reaction events apparently related to this vaccine. It was also apparent that there is no follow-up on these reactions since the two patients I reported were never contacted to evaluate their deteriorating health conditions.*

What was obvious from the information I obtained from the VAERS reports were that there are thousands of reports listing such conditions as neurological damage, arthritis symptoms, and other serious immunological disorders. These are the same types of medical conditions that, in my extensively detailed investigation of the literature, have been published in dozens of medical journals that cite the correlation of this vaccine and severe immunological reactions. (Table of references to be provided at time of hearing). The fact that this reporting system is "passive", i.e. not mandatory, also suggests that only some fraction of adverse events (estimated by FDA officials as 1-10%). In summary it is my opinion that the VAERS system, as currently structured, is highly inadequate to collect scientifically useful information.

I have now been in direct contact with hundreds of severely ill patients (as well as with physicians who have hundreds more patients) having developed adverse reactions to this Hepatitis B vaccine. I feel that it is critical to investigate the early onset effects as well as subsequent development of autoimmune adverse reactions in the hope that we might find more directed treatments to avert the long term effects in those already afflicted with these problems. I believe this is possible in view of new technologies for treatment of autoimmune diseases that are targeted to the identification of specific autoantibodies to defined epitopes.

2. Do the benefits of administering the vaccine to infants outweigh the risks?

To date my studies have concentrated on the adult population. Sadly, even less is known about immunological reactions in infants, especially since they cannot communicate, as can older children or adults, their severe pain, fatigue, or other neurological or physical disturbances. In the event of deaths following vaccination, there is generally inadequate information collected by pathologists to adequately evaluate these reactions.

I would challenge any colleague, clinician or research scientist to claim that we have a basic understanding of the human newborn immune system. It is well established in studies in animal models that the newborn immune system is very distinct from the adolescent or adult. In fact, the immune system of newborns in animal models can easily be perturbed to ensure that it cannot respond properly later in life.

In contrast, it is highly improbable in the US that a newborn has any significant risk of contracting Hepatitis B as a child because the disease is caused by a blood-borne virus. Newborns are not likely

to engage in intravenous drug use or promiscuous sex. Nor are they likely to suffer an accidental needle stick, as might a medical worker. About the only way they are likely to be exposed to the disease is by being born to an already infected mother.

In view of this lack of scientific and medical information of neonatal immunology, it is remarkable to me that newborn infants, especially those not at risk for the Hepatitis B disease itself are being administrated multiple injections of this vaccine and that there have been few, if any, clinical trials to adequately evaluate the potential long term effects of neonatal immunization especially as it relates to genetic diversity.

3. What process does the CDC employ to make a recommendation for a vaccine: What role do pharmaceutical companies play in that process? Do conflicts of interest exist?

As I am not an expert on public health policy, I am not familiar with all of the nuances of policies for recommending vaccine mandates. It is well documented, however, that committee members advising the CDC and members of organizations (such as the American Academy of Pediatrics, and the World Health Organization) obtain substantial funding from pharmaceutical companies. Furthermore, it is well documented that investigators who have carried out clinical trials on this vaccine also benefit personally and obtain laboratory funding as consultants promoting the vaccine and as expert witness in legal conflicts. It is also documented that lobbyists who consult for pharmaceutical companies are the same lobbyists for medical health care providers. I leave it up to this distinguished committee to investigate and evaluate the seriousness of these apparent conflicts of interest.

However, it is also apparent to me that the lack of government funding specified for independent scientists to evaluate adverse vaccine reactions is a major reason for scientists to seek funding for experiments dictated by pharmaceutical companies.

4. What disclosure is required before the vaccine is given? Is it adequate?

It is apparent to me, as it is to many others who have been investigating this issue, that adequate long-term follow-up information was not collected in clinical trials for this vaccine. This is particularly true with respect to the Caucasian population. One might therefore ask: "Is there is sufficient information concerning risks of this vaccine to be disclosed"? The ominous lists of potential reactions listed in the vaccine inserts appear not to be given to patients by their physicians. The physician-patient relationship is fiduciary. That is why the lawyer representing my brother, who had an adverse reaction to this vaccine, made a claim of fraud, a claim which this lawyer says has a strong basis in the Restatement of Torts.

Many physicians and medical students have told me that, if this vaccine is recommended and mandated by government officials, "why should they look at it or discuss it with their patients?" Others have said that their colleagues do not report these incidences because they "don’t want to get involved." They further tell me that they have been informed that this vaccine is the safest ever developed because it is a recombinant DNA vaccine and "therefore you can’t get the disease". Unfortunately, they have clearly missed a major point of basic immunology. Any peptide (a limited sequence of amino acids of a protein) or a full length or truncated protein (produced by purification from a biological source or using recombinant cDNA technology) when introduced into the body will be "processed by the immune system" and, depending on the nature of that protein, could result in

long term autoimmune reactions.

Sadly, in basic science courses in medical schools, many of these details of immunology (a medical research field that has exploded over the last decade) are not taught. I have taught in the basic science curriculum for over 15 years so I am well aware of this limitation. In fact, I recently was invited to speak at the Institute of Medicine at the National Academy of Sciences on this subject. I was quite shocked when a senior member of a national health committee (involved in recommending mandates for childhood vaccines) came up to me and said: "Very interesting talk. I know you teach beginning medical students. Could you recommend me a basic immunology textbook? I think I need to catch up on some of this immunology stuff."

In summary, it is essential in my opinion that physicians be better educated on the potential risks of this vaccine, as well as the interactions with other vaccines and the increased risks of vaccinations of sick children. It is also critically important to conduct the research necessary so that they will have better information to identify people at risk for adverse reaction. In any event early diagnoses of these reactions will result in more effective therapies.

My colleagues and I have submitted proposals to investigate the scientific bases for these vaccine adverse reactions. Many of these reactions are similar to those reactions from individuals having the virus itself. It is also apparent that there are major histocompatability, genetic linkages among patients who are having the severe reactions. It has already been shown that as many as 10 to 30% have been reported as not developing antibodies when they are vaccinated and, therefore, they may not to be protected from the disease. This non-responsiveness may be attributed to the individual histocompatability genes.

We have proposed to carry out research to determine the long-term prognosis for patients having such adverse reactions for two purposes: (1) Developing a prophylactic strategy of identifying those likely to react adversely so they can avoid the vaccine if at risk; and (2) developing a therapeutic strategy by early and more effective identification of those who have had adverse reactions with the hope of developing more specific therapies. I and my collaborators have well equipped laboratories for state of the art immunological and biochemical analyses and we have already collected blood samples throughout the period of these adverse reactions. We therefore, have unique samples to begin to scientifically pinpoint the reasons for the adverse reactions. We have significant preliminary evidence that may explain these responses and we will continue to seek funding to continue these studies. We have obtained some limited funding from private sources but as yet there are no government funds allocated for studying adverse reactions to this vaccine, so the progress of these studies is slow.

It is apparent that the Hepatitis B virus (and vaccine developed from the Hepatitis B surface antigen) is very unique from many other viruses and vaccines. New theories and experiments (i.e. molecular mimicry and anti-idiotypic antibodies) have been developed which could explain reasons for autoimmune reactions caused by this virus or the viral protein used in the vaccine. (The December 26, 1996, New York Time's article which summarizes studies on "molecular mimicry" theories for viruses causing autoimmune diseases may be right on point.) The fact that there are dozens of publications on the correlation of this virus as well as the vaccine with autoimmune and other connective tissue disorders provides strong evidence for the correlation of this viral antigen causing autoimmune diseases.

In summary, no one, especially myself, would ever assert that the Hepatitis B virus is not causing serious health problems in the world. However, if this, or any other vaccine, by nature of the protein or parts of the protein (native or produced from a cDNA as a recombinant protein), has the ability to adversely effect the immune system of large numbers of individuals resulting in severe adverse reactions (even if restricted to some genetic populations), then the public reaction to ALL vaccines, including those that clearly DON'T have related adverse reactions will be doomed in the public's eye. That includes the development of vaccines to evolving airborne viruses that might become a serious threat to the world population. Thanks to the success of the Government funded Human Genome Project and advances in computer programs, it may soon be possible to evaluate potential molecular structure to predict these problems with vaccine in advance or early in vaccine development.

I will conclude by relating an observation. In my research on vaccines that have been used for the humane control of animal populations, I have had the opportunity to observe first hand African elephant family behavior. Whenever a baby cries, the entire herd of up to a hundred will immediately trumpet, and charge with great flurry to surround the infant elephant. When it is apparent that there is no danger, they will one by one touch trunks with that infant, ensuring that he is okay before going about their business. They would certainly never allow a single baby or family member to be exposed to unknown danger.

I ask you in your task of investigating our public health system that as do our friends the elephants, listen to the cries of babies (and family members) that might have been adversely affected by this vaccine or who may be at risk. Please demand adequate scientific documentation and medical information to make responsible decisions concerning mandating vaccines for children. In addition to your investigation on the adverse reactions of this vaccine I would urge you to help to provide research funds which are currently not available to study the serious adverse reactions of this vaccine as well as other vaccines.

Thank you for the opportunity to appear before this distinguished subcommittee. I will be glad to answer any of your questions or provide you with additional information you may request.

Sincerely,

Bonnie S. Dunbar, PhD, Professor
Department of Cell Biology
Baylor College of Medicine, One Baylor Plaza
Houston, Texas 77030

May 17, 1999

1. The Honorable John L. Mica, Chairman

U.S. House of Representatives

Committee on Government Reform

Subcommittee on Criminal Justice, Drug Policy, & Human Resources

Washington, DC 20515

Dear Congressman Mica,

Thank you for the opportunity to discuss my findings on the association between hepatitis B vaccine and insulin dependent diabetes. I want to state that as a physician I have received the hepatitis B vaccine and believe it is a potentially useful tool for reducing the risk of hepatitis in certain high risks groups such as health care workers exposed to blood products. I am however opposed to universal hepatitis B immunization of the general public because the risks are greater than the benefit when the vaccine is given starting after 8 weeks of life.

The US government approves vaccines for marketing and makes universal immunization recommendations based on safety studies which typically follow patients for 30 days or less post immunization. Our research involves studying the risk of autoimmune induced diabetes in people immunized with certain vaccines and in control populations which do not receive the vaccines. Our results show that the risk of immunization with several recommended vaccines including the hepatitis B vaccine are likely to exceed the benefits of immunization in low risk groups and the adverse events may cost US citizens over $10 billion a year as I will discuss later.

Our research has focused on the effect of vaccines on insulin dependent diabetes (diabetes) , an autoimmune disease. An autoimmune disease is a condition where a person's immune system destroys their own tissue. The effect of vaccines on the development of diabetes are expected to reflect the effect of vaccines on other autoimmune diseases. Vaccines are immune stimulants and would thus be expected to increase the risk of autoimmune disease. We found that the incidence of diabetes rose 60% in New Zealand following a massive hepatitis B immunization program (1). The CDC initiated a study to verify our findings. Their preliminary data has been published and shows hepatitis B immunization when given starting after 8 weeks of age is associated with a 90% increase in the risk of diabetes (2), supporting our findings. The study also indicated immunization starting within 21 days of life was associated with a decreased risk of diabetes compared to immunization starting after 8 weeks of life, which also supports our findings (3).

Currently we are attempting to collect additional data on the hepatitis B vaccine as well as data on other vaccines. Our data shows the hemophilus vaccine is likely to cause diabetes (4) and we have confirmed a rise in diabetes in the US (5) and UK (6) following the introduction of the hemophilus vaccine.

The FDA can tract vaccine adverse events through both the VAERS system and the Large Link Database. The VAERS system relies on voluntary reporting of adverse events shortly after immunization. Our data on diabetes shows that vaccine induced diabetes may not occur for 3 or more years following immunization. The Large Link Database is thus an essential tool for monitoring adverse events.

Our data shows the risks of several vaccines are likely to exceed the benefits in low risk groups and cost US citizens over $10 billion a year. Our recently published data (4) shows that for every child that may have a prolonged benefit from the hemophilus vaccine, 2 to 3 children may develop vaccine induced diabetes. There is less accurate data to compare the risks and benefits of the hepatitis B vaccine. However, there are reportedly about 4,000 to 5,00 deaths each year attributed

to hepatitis B. If we immunized every child after 8 weeks of life with the hepatitis B vaccine there may be an extra 4,000-5,000 cases of diabetes per year. All told we estimate that there are over 10,000 cases of vaccine induced diabetes in the US each year. On average each case may cost $1 million in lost productivity and medical expenses. The estimated liability cost of the vaccine induced diabetes is over $10 billion per year. The current cumulative liabilities to the US government and to manufacturers could exceed $250 billion.

US law prohibits the marketing of vaccines until they have demonstrated safety. We have proven the hepatitis B and other vaccines do not meet this standard yet they are on the market and children are being forced to receive them. I attribute this to the numerous conflicts of interests in those who are regulating vaccines and setting policy. Let me give you just one example.

I attended a meeting where a senior vaccine executive, and former federal employee, was repeatedly stating to the audience that his company's vaccine was proven to be safe. I discussed with a senior FDA employee who attended the meeting that I was disturbed by how the vaccine executive over stated the safety of his product and how I believed that US law prohibited manufacturers from making false claims about their products. The FDA employee agreed but stated it was so hard to enforce the laws. Later this former FDA employee began working for an vaccine manufacturer. Both his employer and the vaccine executive's employer have a financial interest in the hepatitis B vaccine.

Several changes need to be made to the current policy. Independent researchers representing parents need to have equal access to the large link database as those representing the interests of the established medical community. Manufacturers need to perform long term testing of their vaccines on the development of diabetes and other autoimmune diseases. Parents need to be informed of animal toxicity data (7) and epidemiology data linking vaccines to diabetes and that the age when the first dose is given may affect the risk of diabetes. In addition parents need to be informed that there are insufficient funds to cover expenses of many vaccine adverse events. Development of safer immunization technology should be given priority over the development of new vaccines.

Thank you for the opportunity to present our views and data on this important issue.

Sincerely,

J. Barthelow Classen, M.D., M.B.A.

President and Chief Executive Officer

http://www.vaccines.net/toppage1.htm

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March 1, 1999

1. Representative Dale Van Vyven
Chairman, Health Committee
Ohio House of Representatives
77 South High Street
Columbus, Ohio 43266

Dear Representative Van Vyven:

I have been asked by Kristine M. Severyn for testimony regarding hepatitis B vaccination. Dr. Severyn is doing excellent work on behalf of the children of Ohio and of our nation and I am honored to add my voice to hers in a plea for reason and objectivity regarding vaccination policy in the U.S.

I am a physician in private general practice, having received my M.D. degree in 1966 from Albert Einstein College of Medicine in New York City.

For 29 years I have privately and independently pursued a study of vaccinations and vaccine policy. I have served as an expert witness in court trials concerning vaccinations and have submitted medical opinions in cases of vaccine-damaged children adjudicated under the National Vaccine Injury Compensation Program. I was an invited speaker at the First International Public Conference on Vaccinations sponsored by the National Vaccine Information Center in Alexandria, Virginia in September 1997.

I am one of the two physician-signers of the cover letter to the 16-page special report "Hepatitis B Vaccine: The Untold Story" which the **National Vaccine Information Center** sent out recently to 55,000 U.S. pediatricians. The report was also sent to 8,000 state and federal legislators and to 1500 media outlets in the United States.

In October 1998 I was invited to speak at a special workshop on vaccinations in

Manchester, New Hampshire where a citizens' initiative to roll back the hepatitis B vaccine mandate is under way.

As a private physician with no ties to any academic or government institution, I am free to give voice to my conscience without the usual constraints that group affiliation confers. In what follows I am motivated simply to express the truth as I see it, by a deep concern for the *long term* health of our nation's children.

The present growing distrust of vaccinations by concerned parents nationwide is a grassroots movement that will not go away because it springs from a very real source: from a frequency of acute and chronic adverse effects of vaccinations far greater than is being officially acknowledged. This grassroots movement is only bound to increase until its concerns are acknowledged and dealt with in a scientifically objective and forthright manner.

In 1979 the Centers for Disease Control stated: "Vaccinations are recommended and administered to millions of children and other individuals each year *on the presumption* (emphasis mine) that the benefits far outweigh the risks. The benefit side of the equation is straightforward: vaccinations can prevent serious disease. The risk side is not as straightforward since it includes factors that are known and others that may exist but have not yet been discovered. It is necessary, therefore, to maintain surveillance of potential risks of vaccination to continually reevaluate whether individual vaccinations are, on balance, good for people."

The above clear statement of purpose to monitor vaccine safety has unfortunately been totally eclipsed by our nations' enormous intellectual, bureaucratic and economic commitment to vaccination as *the* method to eradicate illness.

This commitment has made it virtually impossible to achieve an open, fair and unbiased risk-benefit evaluation of any vaccination in use today. With a *conflict of interest* of this magnitude, the pressures that exist to maintain the momentum of our national vaccine initiative and to avoid "alarming the public" overshadow by far those voices who might question the wisdom of such a one-sided and politicized health agenda.

In addition, severe constraints are placed on the media in the name of "responsible journalism" with the result that the American public very seldom hears both sides of the vaccination story, and comes to have an unquestioning faith in vaccinations as our greatest hope against future imagined disease plagues. In this fear-based scenario, the questioning voice of reason is drowned out amid the hysteria surrounding the emerging "killer infections" which are such a favorite media topic.

This propagation of fear by the media and by its sources in the public health industry has resulted in a growth of power of this industry far beyond the usual checks and balances of our democracy.

One aspect of this power is the ability of many state health departments to legally mandate a new vaccination for all children completely bypassing any discussion or deliberation in that state's legislature. In a democracy this cannot and must not be.

Practicing physicians and the general public rely on the monitoring capacity and the scientific objectivity of the C.D.C., the F.D.A. and the health departments of our 50 states to alert us to the very real risks of vaccinations in use today, and to provide us with as accurate an assessment of that risk, both acute and chronic, as is scientifically possible.

In fact, the C.D.C. has retreated utterly from its 1979 statement quoted above emphasizing the importance of vaccine safety monitoring.

It is extremely regrettable, but no exaggeration to say that with regard to informing physicians and the public on vaccine safety, the responsible agencies have failed the American people.

In support of this assertion, I cite the following facts:

1. In 1994 a special committee of the Institute of Medicine of the National Academy of Sciences published a comprehensive review of vaccine safety which had been commissioned by federal law. Of five possible and plausible adverse effects of the hepatitis B vaccination which the committee investigated, they were unable to come to any conclusion for four of them because they found to their dismay that the relevant research had not been done!

Why aren't the agencies responsible for vaccine safety commissioning such research? For the fifth adverse effect, anaphylactic shock, the committee concluded that the evidence positively established a causal relation to the hepatitis B vaccination.

2. In contrast to the lack of research on the adverse effects of hepatitis B vaccination found by the Institute of Medicine, the National Vaccine Information Center in its recent special report on hepatitis B vaccination sites *38* reports in the international medical literature, some dating back to 1987, that hepatitis B vaccination is causing chronic autoimmune and neurological disease in children and adults.

3. In July 1998, 15,000 French citizens filed a class action lawsuit against the French government accusing it of understating the risks of hepatitis B vaccine and of exaggerating its benefits for the average person. In October 1998 the French government declared a moratorium on hepatitis B vaccination in public schools while it evaluates more carefully the true risk-benefit profile of the vaccine.

4. Since July 1990, 17,497 cases of hospitalizations, injuries and deaths in America following hepatitis B vaccination have been reported to the Vaccine Adverse Event Reporting System (VAERS) of the U.S. government. This figure includes *146 deaths* in individuals after receiving only hepatitis B vaccine without any other vaccines, including *73 deaths* in children under 14 years old.

In 1996 alone there were 872 serious adverse events in children under 14 years old reported to VAERS. 658 of those injuries were following hepatitis B vaccination in combination with other vaccinations and 214 of these injuries were after hepatitis

B vaccination alone. In these children under 14 years old, there were *35 deaths* after hepatitis B vaccination in combination and *13 deaths* after hepatitis B vaccination alone, for a total of *48 deaths*. Compare these statistics with the total number of hepatitis B cases nationwide reported that same year (1996) in children under 14, *just 279*, and the conclusion is obvious that the risks of hepatitis B vaccination far outweigh its benefits.

In those infants who died under one month of age, most of the deaths are classified as Sudden Infant Death Syndrome (SIDS). However, in the past this syndrome has never struck infants so young, and SIDS is officially defined as beginning only *after* one month of age.

With 6,000 children dying of SIDS every year, we have no idea how many of these deaths are actually caused by hepatitis B vaccination. Though the Vaccine Adverse Event Reporting system was created by federal law to permit a more accurate assessment of the risks of vaccination, and although the raw data it generates is analyzed, the individual reports of injury or death are rarely, if ever, investigated. If one factors in that fewer than 10% of physicians report adverse reactions to vaccines because we are taught to regard them as merely "temporally related", as only a *coincidence*, it would be quite plausible to say that the risks of hepatitis B vaccination clearly outweigh its benefits for 99% of the children who receive it.

5. The best way to determine the risk-benefit profile of any vaccination is well known and in theory is quite simple: Take a group of vaccinated children and compare them with a matched group of unvaccinated children. If the groups are well-matched and large enough and the length of time the children are observed following vaccination long enough, then such a study is deemed the "gold standard" of vaccine research because its data is as accurate a reflection as medical research is capable of achieving of how vaccinations are actually affecting our nation’s children.

Incredible as it sounds, such a common-sense controlled study comparing vaccinated to unvaccinated children has never been done in America for any vaccination.

This means that mass vaccination is essentially a large-scale experiment on our nation’s children.

6. A critical point which is never mentioned by those advocating mandatory vaccination of children is that children’s health has declined significantly since 1960 when vaccines began to be widely used. According to the National Health Interview Survey conducted annually by the National Center for Health Statistics since 1957, a shocking 31% of U.S. children today have a chronic health problem , 18% of children require special health care or related services and 6.7% of children have a significant disability due to a chronic physical or mental condition. Respiratory allergies, asthma and learning disabilities are the most common of these.

Three controlled studies comparing vaccinated to unvaccinated children in England and New Zealand have shown that the vaccinated children have significantly more asthma, ear infections, hospitalizations and inflammatory bowel disease than their unvaccinated cohorts.

Since vaccinations have a lasting effect on the immune system, and since it is known that many vaccines shift the balance of the immune system away from its acutely-reacting "Th1" side and toward its chronically-reacting "Th2" side , it is a *very plausible* scenario that vaccines are contributing greatly to the large-scale and unprecedented increase in chronic conditions such as allergies, asthma, diabetes and a wide range of neurological dysfunctions including learning disabilities, attention deficit disorder, seizures and autism in U.S. children today.

The shocking facts that 31% of U.S. children today suffer from a chronic condition and that the rate of *disability* from such chronic conditions in children has seen nearly a *fourfold increase* since 1960 ought to seriously challenge our medical research establishment.

But, far from taking a proactive approach toward these disturbing facts, our medical establishment remains curiously uninterested in children's *chronic* diseases and instead continues to pursue its narrow focus of using vaccines to eradicate every possible *acute* childhood illness, even those like hepatitis B and chicken pox which pose no threat to 99% of children.

The idea that illnesses exist in an ecological balance like everything else in nature and that eradicating acute diseases could very likely upset the balance and cause chronic disease to *increase* is not seriously considered or pursued in medical science today. Whenever any evidence pointing in this direction is published, usually in the international medical literature, it is usually dismissed out of hand by American physicians or angrily repudiated with the implication that such research is "irresponsible" because it might cause the American public to lose trust in our vaccination program.

With such a total commitment of our medical community to a policy of universal vaccination, is it any wonder that new and potentially upsetting discoveries relating to the role of vaccinations in the alarming prevalence of chronic illness in our children are never seriously considered much less pursued?

When the Institute of Medicine published its Federally mandated reports on vaccine safety in 1991 and 1994, their disturbing conclusion was that there is very little data on vaccine safety because *the necessary research is simply not being done*.

7. Eugene Robin, M.D., Emeritus Professor of Medicine from Stanford Medical School is one of the world's leading experts on risk/benefit analysis in medicine. He authored the definitive book on the subject, Matters of Life and Death: Risks vs. Benefits of Medical Care.

In a statement at the First International Public Conference on Vaccination in September, 1997, Dr. Robin said the following:

> "…The scientists who develop vaccines should be given great credit and respect for their pioneering work. But it must be recognized that once a promising vaccine is available, that should be the beginning and not the end of the process.
>
> Accurate assessment of the risk/benefit ratio of the vaccine by means of a … controlled clinical trial should be obligatory. An educational process involving the public should be mandatory in which the risks and uncertainties are described as well as the potential benefits.
>
> So, what can we 'teach' the public if we ourselves, the medical scientific community, have not done the proper and required studies?
>
> *A true process of informed choice would, for example, raise grave questions about the vaccination of young children for hepatitis B.*
>
> *We must be honest and admit that we do not know the impact of administering multiple, different vaccines on very young children or, indeed, on anyone.*"

8. My final comments are drawn from my 27 years of experience as a general practitioner of medicine. Twenty-three of those years were in a rural farming community in upstate New York where as many as 50% of my pediatric patients were unvaccinated due to their parents' conscientious personal choice.

When I started my practice I believed, as I had been taught in medical school, that the benefits of vaccinations outweighed the risks. I also believed that the right of parental choice in vaccinations ought to be respected.

For 23 years I had the opportunity to observe my young patients grow from infancy to young adulthood and to appraise their overall health and vitality. It was out of this experience that my present views took shape. I observed that my unvaccinated children were healthier, hardier and more robust than their vaccinated peers. Allergies, asthma and pallor and behavioral and attentional disturbances were clearly more common in my young patients who were vaccinated.

My unvaccinated patients, on the other hand, did not suffer from infectious diseases with any greater frequency or severity than their vaccinated peers: their immune systems generally handled these challenges very well.

Conclusion

Like all science, medicine has radically changed many of its views over time. What seems wise and prudent today may be totally repudiated a decade or two later.

Vaccinations are powerful medical tools which impact human immune systems to achieve the desired effect of preventing certain infectious disease manifestations.

In the early 1900's when diphtheria and whooping cough were life-threatening, the uncritical acceptance and implementation of vaccination was understandable and perhaps unavoidable. Today, when far more children suffer from allergies and other chronic immune system disorders than from life-threatening infectious diseases, it is neither reasonable nor prudent to persist in *presuming* that the benefit of any vaccination outweighs its risk.

When the medical scientific community makes a total and one-sided commitment to any public policy, no matter how noble its intentions, then vigorous debate and fact-finding tend to be neglected.

The facts on hepatitis B brought out by Dr. Severyn and by the special 16-page report of the National Vaccine Information Center deserve our very careful consideration. They indicate that the risk of hepatitis B vaccination outweighs its benefit for the vast majority of American children today.

When these facts are ignored, and when vital medical research on the safety and adverse effects of hepatitis B vaccine is left undone, then the truth suffers, our children suffer and we all suffer.

Yours,
Philip Incao, M.D.

Hearings on Hepatitis B vaccine

1. ***Blackheath 16.6. 1999***

Dear Miss Pinkerton,

Your name as a contact appears on the information flyer in relation to Hearing on Safety of Hepatitis B vaccine held on May18, 1999 at 2247 Rayburn House Office Building?

As my letterhead says, I am a Principal Research Scientist (Retired) and since1986, I have been involved in the study of vaccination and SIDS (Cot death) in Australia. The starting point was longitudinal recording of breathing of babies with computerised Cotwatch Breathing Monitor invented by my late husband, Leif Karlsson, who was a Swedish electronics engineer resident in Australia. Fortuitously, while recording breathing of a number of babies, many of them were vaccinated and we could see within one hour the effect of vaccination on the stress level in breathing on our computer printouts. This started me off to initiate a thorough research of vaccination issues as published in refereed medical journals of the likes of the Lancet, British Medical Journal, New England Journal of Medicine etc. and resulted in the documentation of the causal link between administration of a great variety of vaccines and serious reactions including

permanent brain damage and death. Indeed, vaccination is the single biggest cause of SIDS.

There is another aspect to problems with vaccination: contrary to what you may have heard even from some of those who are calling for the discontinuation of mandatory vaccination in the United States, vaccines do not prevent diseases. The presumed and publicised "eradication" of diseases like smallpox and Polio, or Hib meningitis is a myth not supported by even the staunchest pro-vaccinators' research. Smallpox was on the way out, indeed epidemics disappeared decades before the WHO decided to conduct the final "eradication" campaign. It is also well-documented that the largest epidemics occurred in the most highly vaccinated populations, while whose who were unvaccinated, did not have the same epidemics. Smallpox still occurs, although on a much smaller scale, particularly in the countries suffering extreme conditions like wars or economic hardship in Africa, India and other parts of Asia (Nepal). The same factor which did away with bubonic plague, against which mass vaccinations have never been conducted, did away with smallpox, namely a much better nutrition mainly in reference to better Vitamin C status of populations in the Old and the New Worlds.

Polio has not been eradicated by vaccination, it is lurking behind a redefinition and new diagnostic names like viral or aseptic meningitis. When the first, injectable, polio vaccine was tested on some 1.8 million children in the United States in 1954, within 9 days there was huge epidemic of paralytic polio in the vaccinated and some of their parents and other contacts. The US Surgeon General discontinued the trial for 2 weeks. The vaccinators then put their heads together and came back with a new definition of poliomyelitis. The old, classical, definition: a disease with residual paralysis which resolves within 60 days has been changed to a disease with residual paralysis which persists for more than 60 days. Knowing the reality of polio disease, this nifty but dishonest administrative move excluded more than 90% of polio cases from the definition of polio. Ever since then, when a polio-vaccinated person gets polio, it will not be diagnosed as polio, it will be diagnosed as viral or aseptic meningitis. According to one of the 1997 issues of the MMWR, there are some 30,000 to 50,000 cases of viral meningitis per year in the United States alone. That's where all those 30,000 - 50,000 cases of polio disappeared after the introduction of mass vaccination. One must also be aware that polio is a man-made disease since those well-publicized outbreaks are misrepresented that those huge outbreaks were causally linked to intensified diphtheria and other vaccinations at the relevant time. They even have a name for it: provocation poliomyelitis.

JAMA (1993) published that the fall in the incidence of Hib meningitis occurred in the age group below the age of one year at the time when none of the Hib vaccines were even licensed for that age group. The recent outbreaks of meningitis in the US College students can be clearly linked to the enforced MMR vaccination as a condition for enrolment to Colleges in the U.S.

The incidence of whooping cough increased three fold after 1978, which was the time when individual U.S. states started mandating vaccination as the enclosed pages from Hutchins et al. (1988) show. One does not have to be a rocket scientist to see this from this article, unfortunately, one merely has to be a medical doctor not to understand their own data. Medicine developed a special kind of absurd reasoning, like that the causal link between vaccination and the observed reactions has never been demonstrated, without defining just what exactly they would consider to constitute the evidence of the causal link and while publishing raw data which clearly show the

causal link between vaccination and the documented increased occurrence of diseases. JAMA in 1992 published that the incidence of whooping cough as based on hospital admission is up to 126,000 per year in the U.S. This is well and truly the pre-vaccine level. When they were testing the ascellular whooping cough vaccine in Sweden, as soon as the test babies were given 3 doses of the trial vaccine (meaning they were fully vaccinated) they had a huge epidemic of whooping cough in the fully vaccinated. They discontinued the trial before the targeted time of 2 years. I also need to add, that practically all Swedish children below the age of 1 year participated in the trial. They expected 20 deaths and observed 45 (pus one accidental death) and yet this very significant increase was glossed over by saying that all deaths were judged unrelated to vaccination, even though there were deaths there within 24 hours or a few days.

Vaccinators failed to eradicate measles, so now they claim success in reducing measles incidence between 1970 and 1987. However, it has been published that the very unvaccinated Amish communities did not report a single case of measles between 1970 and 1987. Then, since 1987, both the unvaccinated Amish and the well vaccinated outside communities started experiencing huge outbreaks of measles. Quite obviously, vaccination was totally irrelevant. Quite likely, the sustained small outbreaks of measles between 1970-87 in the vaccinated was achieved by vaccination, which kept measles occurring.

Indeed, measles and whooping cough epidemics in the U.S. and elsewhere occur mainly in the fully vaccinated populations.

Instead of honestly admitting that vaccination failed, the vaccinators resorted to outrageous lies and misrepresentations. The worst desperado is the Shaken Baby Syndrome. I enclose my own paper on the subject, emphasisng that all those retinal haemorrhages and detachments which are considered as a fool-proof evidence f trauma (like shaking the babies by their parents or nannies) can and are caused by vaccination, as the enclosed Lancet and other papers show.

Indeed, we don't need any more research; everything we ought to know to realise that vaccines do not prevent diseases and that they are indeed causally implicated in causing diseases and very serious reactions, has already been published.

I am sending you my book Vaccination which is based solely on the study of medical literature.

Knowing all this, I reached an inevitable conclusion that we don't need any vaccines at all. There is only one immunity, natural immunity, which is achieved by going through the infectious diseases of childhood. No children at this age should die from any of these diseases: if they do, it is due to medical mismanagement, As I pointed it out at the seminars on dangers of vaccination organised by the Royal Australia College of GP's (the postgraduate training program for GP's), to which I was invited to present the case against vaccination, if doctors administer antibiotics to a child with measles, they are asking for trouble. Antibiotics, another sordid chapter in the medical assault on the immune system, knock out the gut flora, suppress the immune system and cause serious side effects while the affected children are going though infectious diseases.

You may be told by some groups warning about side effects of vaccination that I am radical. Not only do I consider this highly defamatory, but also very unwise and illogical: is it radical knowing what I know (which includes ample published evidence that vaccines to not provide any benefit,

because they do not protect against infectious diseases, and that reactions are very prevalent, affecting practically all vaccinated children to a lesser or greater degree) and therefore be against all vaccinations?

Is it reasonable whilst knowing that one in about 270 children in California suffer autism, that one in 250 U.S. children suffers some form of serious behavioural and learning disability, not withstanding that one in 500 children develop leukaemia and cancer which are also caused by vaccination and knowing that infectious diseases are beneficial for children by priming and maturing the immune system and representing developmental milestones and still be looking for better vaccines?

There is no such thing as a better vaccine: the introduction of the pathogen (and many other contaminating agents and toxic substances) is not going to result in immunity. Officially, the immunological research has been demonstrating since the turn of this century that vaccine injections do not immunize: they sensitise, make the recipients more susceptible to diseases which the vaccine is supposed to prevent, but also to a host of unrelated bacterial and viral infections. Vaccinated children suffer a never ending stream of ear infections, which in the U.S. alone cost some 3 billion dollars per year.

A young Australian lady, living in England, organized one of my many seminars there and told me that her father told her "go to Viera's seminars and do not vaccinate your children. All those ear infections, and problems like glue ear, are caused by vaccination". When I asked her who is her father, she said "he is an ENT specialist in Brisbane, Australia". I also asked her whether he tells other parents to do the same thing. This is not a singular example of the dishonesty of the vaccination system that they are afraid to take their own medicine.

The Medical Observer in Australia published my response to an attack by a fanatical pro-vaccinator in which I challenged him to go on television, allow himself to be injected with the baby vaccines adjusted to his body weight by a doctor of my choice and in my presence (the article is enclosed). We haven't heard from him. I think that this is a reasonable request to be issued to all vaccinators. And let's just watch the horror in their eyes.

I think that I outlined to you some of the essential facts about vaccination. Mandatory vaccination in the USA is indeed an arrogant insult to the American Constitution, freedom of choice and to just plain human decency and represents medical tyranny. It must be discontinued if the U.S. wants to continue claiming to be the guarantor of freedom for all and from all forms of tyranny. Charity starts at home.

To the Subcommittee on Criminal Justice, Drug Policy, and Human Resources
of the Committee on Government Reform
U.S. House of Representatives
RE: HEPATITIS B VACCINE HEARINGS
SCHOOL NURSE PERSPECTIVE

Submitted by Patti White, RN

May 17, 1999
Mr. Chairman and Members of the Subcommittee:

This is a school nursing perspective for the congressional hearings to be held on May 18, 1999 regarding the safety of the hepatitis B vaccine that is being mandated for newborns and now older children in America. We ask you to please consider the following information and submit it into the congressional testimony. As nurses we continually see more and more damaged children entering our schools, and we are very concerned that a major portion of that damage may be due to the hepatitis B vaccine's assault on the newborn neurological and immune system.

My name is Patti White, R.N. I am a registered professional nurse and the district health services coordinator for a multi-school district. I am writing on behalf of the school nurses in our district. We have very grave concerns about the hepatitis B vaccine.

For the past three or four years our school district has noted a significant increase in the number of children entering school with developmental disorders, learning disabilities, attention deficit disorders and/or serious chronic illness such as diabetes, asthma and seizure disorders. Each of the past four years has been worse than the year before. There is only one common thread we have been able to identify in these children: they are the children who received the first trial hepatitis B injections as newborns in the early 1990s.

As the hepatitis B compliance rate in newborns has gone up in our community, so has the percentage of damaged children. This is very alarming. Because of having so many damaged children we have tried to find the long term clinical trials that ruled this vaccine "safe and effective". We discovered through an exhaustive Medline search that the FDA based its decision to approve hepatitis B vaccine for administration in the first hours of a newborn baby's life upon clinical trials and upon post-marketing surveillance studies in which patients and their doctors were asked to report any adverse effects they noticed within 4-5 days after each injection [4 days for SmithKline and 5 days for Merck].

The problems being reported in increasing numbers as occurring after hepatitis B vaccination appear to be autoimmune and neurological in origin. Such problems take weeks to months to produce noticeable symptoms, and cannot be spotted in a 4-5 day observation period. These are the only clinical studies that have been done by Merck or SmithKline. There is not one long-term study that we could find.

The CDC and FDA have no idea what the long term effects will be on the newly

developing neurological and immune systems of the infants who are injected with this vaccine. They seem to only be concerned with denying the connection between these damaged children and the hepatitis B shot they received within a few hours of birth. The CDC even admits the lack of study and states they do not even know how long the vaccine will be effective. We found this amazing since the vaccine was developed for a population at risk for hepatitis B: IV drug users, high risk medical professionals and those who are involved in high risk sexual practices.

In 1950 (before mass immunizations began), the USA had the third lowest infant mortality rate in the world. By 1986, the USA dropped to 17th place. In 1995 the USA dropped to 23rd and now the USA has dropped to the appalling position of 24th in the health of its children. But the USA is now first in vaccine compliance through government mandates.

The elementary grades are overwhelmed with children who have symptoms of neurological and/or immune system damage: epilepsy, seizure disorders, various kinds of palsies, autism, mental retardation, learning disabilities, juvenile-onset diabetes, asthma, vision /hearing loss, and a multitude of new conduct/behavior disorders.

We have come to believe the hepatitis B vaccine is an assault on a newborns developing neurological and immune system. Vaccines are supposed to be making us healthier, however, in twenty-five years of nursing I have never seen so many damaged, sick kids. Something very, very wrong is happening to our children. The census of ill children treated in our health rooms each day has increased by 300% in only four years.

In our last school nurse meeting we discussed whether the combination of so many vaccines/viruses at one time (hepatitis B vaccine at the same time of the DPT, OPV or MMR) is causing the infant's immune system to be overwhelmed and unable to mount a sufficient defense response. We are advocating clinical studies to determine: Is the combination of all these viruses at one time an assault on an infant's immune and neurological system that increases the chances for adverse reaction AND what are the long-term neurological and immune system responses to these vaccines. We are all continuing to research this issue and will be happy to share the many resources we have found with you. I hope you will do the same as you open up this issue.

We have talked many times about the possible cause(s) of the continuing increase in pervasive developmental disorders (PDD), such as autism. From the literature we have found, we should expect a rate for PDD of about 2-5 in 10,000. In our community the rate in 1st and 2nd grade is about 1 in 150 and in kindergarten, 1 in 100.

As school nurses, we have had many parents calling and asking how they can exempt their children from the hepatitis B vaccination (HPB). Many of them have spent long hours in study and research perplexed over this issue. For the past six months we have been studying documents, books and research articles published by internationally respected doctors and scientists that cause us grave concern. You must understand that we began this study to reassure our parents and show them the truth about how safe vaccines are.

Unfortunately, our sincere, honest, dedicated study has caused a complete reversal of our once strongly held beliefs. Instead of being able to reassure the parents, we have found ourselves being drawn deeper and deeper into this unbelievable controversy over vaccines that is raging among physicians, scientists, researchers, parents, and the government. We pray you will have the courage to shine the light on this controversy through these hepatitis B hearings.

My daughter's own experience with the hepatitis B vaccine made me much more open-minded to the information we have been receiving from parents, teachers and other nurses in our community. I personally have had to research this on my own to determine if I have been enforcing a policy that is actually harming more children than it will ever help. I have spent countless hours reading books, vaccine-hearing testimony, research papers, medical journal articles and Internet web-sites from around the world. I did not come to my decision easily or lightly, I assure you. Twenty-five years of total belief in something does not shake that easily.

I have repeated the well-rehearsed refrain "Be Wise; Immunize" thousands of times during those years and reassured countless parents that they were doing the right thing by vaccinating their precious children . . . even the ones who came to me with serious doubts and reservations. I will now have to live with that.

We are all now faced with a moral dilemma: will we protect the "sacred cow of conventional vaccine philosophy" or will we stand up and speak out for the "health and well being of innocent children"? We choose children. We wonder, which will our government choose?

Because the hepatitis B vaccine was developed for those at risk of disease, including IV drug users and sexually promiscuous individuals, efforts to require administration of the vaccine to most, if not all of the U.S. population is very controversial. The increasing number of adverse reaction reports connected with this vaccine exacerbates the controversy. The controversy stems to a great extent from our lack of understanding of the mechanisms of the immune response to the hepatitis B surface antigen and

lack of long term follow-up of individuals who have received the vaccine. In a January 27, 1999 press release, the National Vaccine Information Center (NVIC) released figures which show that the number of hepatitis B vaccine-associated serious adverse event and death reports in American children under the age of 14 outnumber the reported cases of hepatitis B disease.

During our research we discovered a copy of the grant proposal submitted recently to the National Institute of Health by Dr. B. S. Dunbar, who has worked in autoimmunity and vaccine development for over twenty years and was honored two years ago by the National Institute of Health. Dr. Dunbar is working with a team of veteran vaccine researchers from all over the world. Their grant is requested for the purpose of studying the hypothesis that: hepatitis B recombinant vaccine does cause adverse autoimmune reactions in genetically susceptible individuals. This study will also provide new insights into the predictability of determining adverse side effects of the hepatitis B vaccine in individuals at risk as related to their histocompatability subtypes. Their study of auto-immune diseases/symptoms caused by the hepatitis B vaccine include: lupus erythematosus, rheumatoid arthritis, vascular disorders, Guillain Barre syndrome, demyelinating disorders such as optic neuritis (blindness), Bell's palsy, demyelinating neuropathy (multiple developmental disorders), multiple sclerosis, diabetes mellitus and chronic fatigue syndrome to mention the most common.

This group of internationally respected vaccine researchers headed up by Dr. Dunbar also point out that, "The studies (for the approval of HPB) were not designed to assess serious, rare adverse events; the total number of recipients were too small; and the follow-up was too short to detect rare or delayed, serious, adverse reactions." Finally they point out that "overall the number of examples of adverse neurologic outcomes following receipt of hepatitis B vaccine are of concern, particularly those resulting in demyelinating neurologic disease."

They continue, "In view of these observations. . . it is medically crucial to evaluate the nature of the autoimmune reactions (i.e. risks) associated with the hepatitis B vaccine and to determine if individuals who will have these adverse reactions can be identified in advance of receiving the vaccine". There are critical questions that must be addressed to establish the risk/benefit of the current hepatitis B vaccines in the United States. These questions are particularly important in view of recent mandates to vaccinate all children including newborn infants."

Many groups have called for a moratorium on hepatitis B vaccination until some of these questions can be answered adequately. The NVIC reported "Newborn babies are dying shortly after their shots and their deaths are

being written off as sudden infant death syndrome. Parents should have the right to give their informed consent to vaccination and Congress should give emergency, priority funding to independent scientists, who can take an unbiased look at this vaccine, instead of leaving the search for truth in the hands of government officials who have already decided to force every child to get the vaccine". We agree completely. The NVIC can be contacted at

1. http://www.909shot.com for further information.

Our own school district's confidential health statistics show at least 20% of our children (K-3) have significant neurological damage and/or chronic illness. The last three years have shown an acceleration in the numbers of children who are entering our schools with these "developmental disorders". (Could these be the same infants who received the first trial doses of hepatitis B as only a few hour-old newborns?) As school nurses, working with these damaged children on a daily basis, we pray this is not true. If it is, the ramification to this generation of children is unthinkable!

Should we not pause, call for a moratorium on these poorly tested, rapidly approved vaccines, and allow independent American physicians and researchers to study them before blindly injecting an experimental vaccine into an entire generation? (We have found the only ones declaring the vaccine's safety are the ones who are making millions of dollars from its sales, whose employment depends on it or the ones being supported by the drug companies vast number of grants and fundings. The independent researchers seem to be coming up with an entirely different report.)

Vaccine producers have nothing to lose since our U.S. Congress has made them immune from responsibility or liability for injuries caused from their vaccines. The push is on for them to create more and more vaccines. There are huge amounts of money being made by these people who no longer worry about the consequences of their inadequate clinical trials. The United States government has had to pay out nearly a billion dollars in damages to families who can prove their children have been damaged or killed by vaccines, and there are thousands more cases pending.

We believe, as medical professionals, that we are doing a great disservice to our country by forcing government mandated vaccines on all children. Please research this and we pray you have the courage to speak out and tell the nation what you find.

(The views expressed are my personal beliefs and observations and do not necessarily reflect those of the school district.)

Patti White, RN

STATEMENT of the ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS
to the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the Committee on Government Reform
U.S. House of Representatives

1. RE: HEPATITIS B VACCINE

Submitted by Jane Orient, M.D.
June 14, 1999

Mr. Chairman and Members of the Subcommittee:

My name is Jane Orient, M.D. I am a practicing internist from Tucson, Arizona, and serve as the Executive Director of the Association of American Physicians & Surgeons ("AAPS").

AAPS is a nationwide organization of physicians devoted to defending the sanctity of the patient-physician relationship. AAPS revenue is derived almost exclusively from membership dues. We receive no government funding, foundation grants, or revenue from vaccine manufacturers. No members of our governing body (the Board of Directors), have a conflict of interest because of a position with an agency making vaccine policy or any entity deriving profits from mandatory vaccines.

AAPS thanks this Committee and Chairman Mica for leaving the record open for a longer period to permit an opportunity to review the hearing transcript, written testimony, and raw data from the Vaccine Adverse Event Reporting System (VAERS).

It is apparent that critical medical decisions for an entire generation of American children are being made by small committees whose members have incestuous ties with agencies that stand to gain power, or manufacturers that stand to gain enormous profits, from the policy that is made. Even if such members recuse themselves from specific votes, they are permitted to participate in discussions and thus influence the decision. Moreover, there is the potential for deal-making. Or there may be a simple disinclination to cause problems for one member's agenda in the expectation that that member will reciprocate.

Once a vaccine is mandated for children, the manufacturer and the physician administering the vaccine are substantially relieved of liability for adverse effects. The relationship of patient and physician is dramatically altered: in administering the vaccine, the physician is serving as the agent of the state. To the extent that the physician simply complies without making an independent evaluation of the appropriateness of the vaccine for each patient, he is abdicating his responsibility under the Oath of Hippocrates to "prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone."

Should a physician advise against a mandated vaccine, he faces increased legal liability should the patient acquire the disease. Moreover, he may risk his very livelihood if he is dependent upon income from "health plans" that use vaccine compliance as a measure of "quality."

It is perhaps not surprising, although still reprehensible, that physicians sometimes behave in a very callous manner toward parents who question the need for certain vaccines.

Federal policy of mandating vaccines marks a profound change in the concept of public health. Traditionally, public health authorities restricted the liberties of individuals only in case of a clear and present danger to public health. For example, individuals infected with a transmissible disease were quarantined. Today, a child may be prevented from attending school or associating with others simply because of being unimmunized. If there is not an outbreak of disease and if the child is uninfected, his or her unimmunized state is not a threat to anyone. An abridgement of civil rights in such cases cannot be justified.

With hepatitis B vaccine, the case for mandatory immunization with few exemptions is far less persuasive than with smallpox or polio vaccines, which protected against highly lethal or disabling, relatively common, and easily transmissible diseases. An intelligent and conscientious physician might well recommend AGAINST hepatitis B vaccine, especially in newborns, unless a baby is at unusual risk because of an infected mother or household contact or membership in a population in which disease is common.

AAPS awaits the release of full information concerning the licensure of hepatitis B vaccine and the mandate for newborn immunizations, as requested under the Freedom of Information Act by the National Vaccine Information Center. It is imperative that independent scientists have the opportunity to review the raw data. In the meantime, all coercive means for increasing the immunization rate should be immediately discontinued. Fully informed consent should be sought before vaccine is administered. This requires full and honest disclosure of the risks and uncertainties of the vaccine, in comparison with the risks of the disease.

Information given to parents about this vaccine often does not meet the requirement for full disclosure. For example, it may state that "getting the disease is far more likely to cause serious illness than getting the vaccine." This may be literally true, but it is seriously misleading if the risk of getting the disease is nearly zero (as is true for most American newborns). It may also be legalistically true that "no serious reactions have been known to occur due to the hepatitis B recombinant vaccine." However, relevant studies have not been done to investigate whether the temporal association of vaccine with serious side effects is purely coincidental or not.

An independent review of the VAERS data; publications by governmental, pro-vaccine, and anti-vaccine groups; and a sample of the medical literature leads to the following conclusions:

- Ø For most children, the risk of a serious vaccine reaction may be 100 times greater than the risk of hepatitis B. Overall, the incidence of hepatitis B in the U.S. is currently about 4 per 100,000. The risk for most young children is far less; hepatitis B is heavily concentrated in groups at high risk due to occupation, sexual promiscuity, or drug abuse. VAERS contains 25,000 reports related to hepatitis B vaccine, about one-third of which were serious enough to lead to an emergency room visit, hospitalization, or death. It is often assumed that only 10% of reactions are reported. (This committee has heard testimony about persons being actively discouraged from reporting, even if they are aware of the reporting system.) Thus, if there have been some 80,000 serious adverse reactions associated with 20 million doses of vaccine, the risk is about 4 in 1000. (This calculation

depends on many assumptions. Moreover, many of the patients experiencing temporally associated adverse reactions had simultaneously received more than one vaccine. Nevertheless, a better estimate has not been put forth.) It should be noted that a less than 1 in 1,000,000 purely hypothetical risk may be used to justify costly federal regulations on highly useful products that are used voluntarily.

Ø In nearly 20% of VAERS reports, the first of eight listed side effects suggests central nervous system involvement. Examining the first listed effects shows about 4,600 involving such symptoms as prolonged screaming, agitation, apnea, ataxia, visual disturbances, convulsions, tremors, twitches, an abnormal cry, hypotonia, hypertonia, abnormal sensations, stupor, somn-olence, neck rigidity, paralysis, confusion, and oculogyric crisis. The last is a striking feature of post-encephalitic Parkinson's disease, or it may occur as a dystonic reaction to certain drugs such as phenothiazines. The CDC admits that the results of ongoing studies on a potential association of hepatitis B vaccine and demyelinating diseases such as multiple sclerosis are not yet available.

Ø There may be large genetic differences in susceptibility to vaccine adverse effects. The committee has been told that serious reported adverse effects seem restricted to Caucasians. Yet the oft-cited long-term safety study was conducted in Alaskan natives, and many studies involved Asians. In adults, 77% of the reactions involve women, who are generally more susceptible to autoimmune diseases. This deserves serious study, not off-hand dismissal ("nurses always over-report"). Universal immunization could lead to disproportionate injury to susceptible populations, who might also be the least affected by the disease one is trying to prevent.

Ø Striking increases in chronic illnesses have occurred in temporal association with an increase in vaccination rates. Asthma and insulin-dependent diabetes mellitus, causes of lifelong morbidity and frequent premature death, have nearly doubled in incidence since the introduction of many new, mandatory vaccines. There is no explanation for this increase. The temporal association, although not probative, is suggestive and demands intense investigation. Instead of following up on earlier, foreign studies suggesting a greater-than-chance association, the CDC, through vaccine mandates, is obliterating the control group (unvaccinated children). Dr. Classen testified concerning his opinion that hepatitis B vaccine could precipitate diabetes mellitus. Of note, VAERS contains more than 4,000 reports of abdominal symptoms that could have been due to pancreatitis, which was probably not specifically sought and thus missed if present. Even more alarming is the huge increase in reports of autism and attention deficit/hyperactivity disorder, with devastating, life-long impacts. Much of this could be due to over diagnosis (now rewarded by numerous government subsidies). The change in behavior that many parents observe related to vaccines could be coincidental, or it might reflect a desperate need to explain a disastrous occurrence. Nonetheless, the implications are so grave that immediate investigation is needed. Measles, mumps, rubella, hepatitis B, and the whole panoply of childhood diseases are a far less serious threat than having a large fraction (say 10%) of a generation afflicted with learning disability and/or uncontrollable aggressive behavior because of an impassioned crusade for universal vaccination. There are plausible mechanisms such as molecular mimicry whereby vaccines could have such effects. Basic

research, as well as epidemiologic studies (starting with a long-term follow-up of reactions reported to VAERS), is urgent.

Ø Hepatitis B vaccine as a cause of sudden infant death has not been ruled out. The mere observation that the incidence of SIDS has decreased while hepatitis B immunization rates have increased proves nothing whatsoever. In other contexts, the Back to Sleep campaign is credited with a dramatic fall in SIDS; the fall might have been much greater without hepatitis B immunizations. The presence of findings such as brain edema in healthy infants who die very soon after receiving hepatitis B vaccine is profoundly disturbing, especially in view of the frequency of neurologic symptoms in the VAERS. Does SIDS occur on the day after hepatitis B vaccine with a greater-than-expected frequency? Does it occur at a younger-than-expected age? Are the autopsy findings different in babies who just received the vaccine? The fact that vaccine just happens to be given during the time period that babies are most likely to die of SIDS complicates the analysis. Also, there are a number of other confounding variables (sleep position, socioeconomic status, and possibly smoking behavior). The data in VAERS are probably too incomplete to answer the questions. A very detailed statistical analysis and an aggressive attempt to obtain more complete information are urgently needed. Glib reassurance, based on the secular trends shown to this Committee, is dangerous.

CONCLUSIONS

Public policy regarding vaccines is fundamentally flawed. It is permeated by conflicts of interest. It is based on poor scientific methodology (including studies that are too small, too short, and too limited in populations represented), which is, moreover, insulated from independent criticism. The evidence is far too poor to warrant overriding the independent judgments of patients, parents, and attending physicians, even if this were ethically or legally acceptable.

AAPS opposes federal mandates for vaccines, on principle, on the grounds that they are:

1. An unconstitutional expansion of the power of the federal government. 2. An unconstitutional delegation of power to a public-private partnership. 3. An unconstitutional and destructive intrusion into the patient-physician and parent-child relationships. 4. A violation of the Nuremberg Code in that they force individuals to have medical treatment against their will, or to participate in the functional equivalent of a vast experiment without fully informed consent. 5. A violation of rights to free speech and to the practice of one's religion (which may require one to keep oaths).

AAPS would specifically oppose the campaign for universal immunization against hepatitis B, even if the above did not apply, because the safety of the vaccine is in question.