

Opening Statement

Chairman Dan Burton

Government Reform Committee

U.S. House of Representatives

**“Autism: Present Challenges, Future Needs -
Why the Increased Rates?”**

Thursday , April 6, 2000

2154 Rayburn House Office Building

Washington, D.C. 20515

This morning we're here to talk about autism. As we learned in our August hearing, the rates of autism have escalated dramatically. What used to be considered a rare disorder has become a near-epidemic. We've received hundreds of letters from parents across the country. They've shared with us their pain and their challenges. My staff tells me they cried from the heart-break of many of these letters.

I don't have to read a letter to experience the heartbreak. I see it in my own family. {Slide 1} My grandson Christian was born healthy. He was beautiful and tall. We were already planning his NBA career. He was outgoing and talkative. He enjoyed company and going places. Then, his mother took him for his routine immunizations and all of that changed. He was given what so many children were given – DTaP, OPV, Haemophilus, Hepatitis B, and MMR – all at one office visit. That night Christian had a slight fever and he slept for long periods of time. When he was awake he would scream a horrible high-pitched scream. He would scream for hours. He began dragging his head on the furniture and banging it repeatedly. Over the week-and-a-half after the vaccinations, Christian would stare into space and act like he was deaf. He would hit himself and others, which was something he had never done. He would shake his head from side to side as fast as he could. He lost all language.

Unfortunately, what happened to Christian is not a rare isolated event. Shelly Reynolds will testify today. Her organization, Unlocking Autism, will be displaying thousands of pictures of autistic children at the “Hear the Silence” Autism Rally this Saturday. Forty-seven percent of the parents who provided these pictures, felt that their child's autism was linked to immunizations.

We frequently hear about children with chronic ear infections and children who became autistic after spiking a fever with their vaccinations.

Liz Burt was one of the hundreds of parents who contacted us. Her five-year-old son, Matthew, has been classified autistic. He was developing normally. At age 15 months, following his MMR vaccine, he began to regress. Since the time of his vaccination, he's had chronic diarrhea. {Slide 2} This is very prevalent in autistic children. He also didn't sleep on a regular basis for over three years. Liz took her son to numerous gastroenterologists in prominent medical facilities in the United States. with no resolution. Finally, this past November, Liz took her son to London, to the Royal Free Hospital. A team of medical experts there examined Matthew. They felt that he had a bowel obstruction. To the family, this seemed impossible since he had constant diarrhea. An x-ray indicated that Matthew had a fecal mass in his colon the size of a small cantaloupe. After the obstruction was cleared with laxatives, Matthew underwent an endoscopy and colonoscopy. The lesions in Matthew's bowel tested positive for the measles virus.

Dr. Andrew Wakefield and Professor John O'Leary will be testifying today. Their research has uncovered a possible connection between inflammatory bowel disorder in children with autism who received the MMR vaccine and have the measles virus in their small intestines.

Since coming home from England and being treated for chronic Inflammatory Bowel Disorder, Matthew has finally begun to sleep through the night. I know it's a welcome relief for his family. Unfortunately Matthew's story is not that unusual in children with autism.

It's important that I make two things very clear today. I am not against vaccinations, and I don't think that every autistic child acquires autism after receiving childhood immunizations. {Slide 3} However, there is enough evidence emerging of some kind of a connection for some children that we can't close our eyes to it. We have to learn more.

Dr. Mary Megson of Richmond, Virginia will testify about the correlation she has seen in children with Autism and Attention Deficient Disorder. She's seen a correlation between Vitamin A depletion and immune-suppression after receiving the MMR vaccine.

There are certainly children who are born with autism. They have what can be called classical autism. There are however, a growing number of children who develop normally and then acquire autism or atypical autism.

There most probably is a genetic component to autism. But genetics is not the only issue. Many children seem to have severe food sensitivities – particularly to gluten and casien – ingredients in the most common foods – dairy and wheat. Many of these children show signs of autism shortly after receiving their immunizations. Some of these children, as we will hear from Jeana Smith, have metal toxicities - aluminum and mercury. What is the source of these toxic substances?

As Dr. Goldberg will testify, maybe what we are seeing is not autism at all, but a neuro-immunologic dysfunction.

I'm very concerned about the increased number of childhood vaccines. I'm concerned about the ingredients that are put in these vaccines. I'm concerned about the way they're given. We've learned that most of the vaccines our children are given contain mercury, aluminum and formaldehyde. Last year the Food and Drug Administration added up the amount of mercury our babies were being given to learn that in the first six months of life they received more mercury than is considered safe. Why is it that the FDA licenses vaccines that contain neurotoxins like mercury and aluminum?

When asked about the increased rates in autism, many will immediately discount that there even is an increase. Even though the latest statistics from the Department of Education show increased rates in every state. {Slide 4} Others will say the increase is due to better diagnostic skills. Others will say it is because the diagnostic category was expanded.

{Slide 5} California has reported a 273% increase in children with autism since 1988. {Slide 6} As for this increase, twenty-one percent of all autistic children in California live in the 29th district.

Florida has reported a 571% increase in autism {slide 7}. Maryland has reported a 513 % increase between 1993 and 1998. {Slide 8} You can't attribute all of that to better diagnostic skills.

{Slide 9} In 1999, there are 2,462 children ages 3 to 21 in Indiana diagnosed with autism. {Slide 10} That is one-fourth of one percent of all the school children in Indiana or 1 in 400. Twenty-three percent of these children live in the 6th district. {Slide 11} This increase is not just better

counting.

If we want to find a cure, we must first look to the cause. We must do this now before our health and education systems are bankrupted, and before more of our nations' children are locked inside themselves with this disease.

Kenneth Curtis, part of Dave's Morning Show at Oldies 100 FM here in Washington, will set the stage by talking about being the parent of an autistic child. He will be followed by James Smythe of Carmel, Indiana. He will share how, through properly looking at autism as an illness, and addressing that illness, his son is improving.

Scott Bono from North Carolina lives close to one of the finest medical facilities in the world – Duke University. However, he has been unable to find medical experts who properly address his autistic son's needs. He is forced to drive 12 hours every four weeks for his son's medical treatments.

Dr. William Danker, the father of a 13 –year-old daughter with autism, and a scientist, will testify about the challenges of finding therapies and treatments that have adequate research. He will also talk about the battles of getting adequate education through the public school system.

We hear repeatedly that parents are not informed at the time of diagnosis by their school system what educational options an autistic child is entitled to. It is only after hiring lawyers and going through the legal process that many children have access to appropriate educational opportunities.

We're learning that the earlier autism is diagnosed and treatments are begun, the better it is for the child. Indiana is fortunate to have the First Steps Early Intervention System – a nationally recognized system that provides early intervention services for children up to two years of age.

Families are forced to spend huge sums of money out-of-pocket – even when they have good insurance, because autism is often specifically excluded. California passed legislation recently to require insurance companies to cover autism. Parents spend 20 and 30 thousand dollars a year. What medical care is covered is often done so after extensive struggles with insurance providers.

We have a long hearing scheduled today with a broad spectrum of ideas presented. We will have a variety of medical approaches presented. We will hear about Secretin, which gained a great deal of media attention in the past year, and from which many parents have seen tremendous success.

Dr. John Upledger, a former advisor to the Office of Alternative Medicine at the National Institutes of Health, will testify on the use of cranial sacral therapy. He is the Director of the Upledger Institute in Palm Beach Gardens, Florida. For more than 25 years Dr. Upledger has been treating autistic children and helping families through this approach. Cranial Sacral Therapy is a gentle, powerful form of bodywork that directly influences the brain and spinal cord. It is used to treat pain, discomfort or trauma to the head or face, including TMJ dysfunction and headaches. Cranial Sacral Therapy can also relieve physical and emotional trauma. In addition to his work with autism, Dr. Upledger has achieved dramatic results in treating post-traumatic stress disorder in Vietnam Veterans.

In addition to medical treatments for the physical symptoms of autism, there are numerous therapies that are needed to help autistic children. Special educational approaches are needed. They can include intensive behavior modification known as A.B.A. or LOVAAS, music therapy, speech therapy, auditory integration and sensory integration as well as play therapy.

We will hear from both the Centers for Disease Control and Prevention and the National

Institutes of Health about ongoing research and future needs. Of particular interest is the Brink Township study that has been evaluating a cluster of autism in Delaware.

This hearing will raise more questions than answer today. We owe it to our children and grandchildren to insure that we're being diligent in looking for the causes of autism. We have to do everything humanly possible to determine if there's something that can be done to unlock our children from the prison of autism. I think that, as a top priority, we have to do much more research on the potential connection between vaccines and autism. We can't stick our heads in the sand and ignore this possibility. If we don't take action now, ten years from now may be too late, not only for this generation of children, but for our taxpayer-funded health and education systems that will collapse from trying to care for these children.

The hearing record will remain open for two weeks.

Testimony

By James Smythe
Carmel, Indiana

Given To

Government Reform Committee Hearing on Autism – Present Challenges, Future Needs
– Why the Increased Rates?

April 6, 2000

Thank you for the opportunity to speak for my son and the tens of thousands of children, and the hundreds of thousands, if not millions of parents, siblings and grandparents suffering from "autism." (See Exhibit 1, Yazbak study). To be brief, our problems are severe, and they are exacerbated by ignorance and resulting inability to help on the part of doctors, health insurance companies, and schools.

Consider the following circumstances in your home, with your child:

Your child urinates or defecates somewhere on the floor every day. He does the same every night in his room, because he is up at least two to four hours between one and five AM every night. If you go to visit friend or relative overnight, his behavior will be even worse, because he is in a strange environment.

If you don't know where he is, and what he is doing, you know that you may regret it. He likes to play in the toilet, leave the water running in the upstairs tub, and open the door and leave. He doesn't know about traffic.

When your child is up at night, he moves the furniture in the room regularly, sometimes pushing an entire dresser through the drywall. He spends hours jumping from the highest places he can climb to onto the hardwood floor. He laughs or screams uncontrollably, as if drunk. No one in the house can really sleep ... night after night.

Your child only eats a few things: carbohydrates and sugars. He carries the food all over your home, and crumbs are everywhere. When you take him to a restaurant,

he runs to strangers plates and begins eating their french fries without any acknowledgement. Or he puts his hand in their drink to get some ice. He may do this at any time during your restaurant visit, while regularly crawling to the floor to eat someone else's food left there.

He will not sit, but must jump from all of the furniture in your home for hours at a time. He will push any lamp, picture, book, papers or porcelain pieces on the floor without thought, sometimes clearing an entire counter with one sweep of his arm. He is not angry, can't be disciplined, and doesn't seem to feel pain.

He sometimes opens the car door while you are driving.

This happened to us for two years, and we are not unique among these families. In our experience, it is hard to find babysitters for a child like this. Only grandparents have the love to help out, and many families do not have these. Some families have two or three autistic children!

The result is that life, as the family knew it before the child, stops. Time and possibilities for children's activities, friendships, and vacations are transformed into doctor's visits, laboratory tests, behavioral and speech therapist sessions, IEP and school educational struggles. Insurance companies refuse to pay medical bills for treatment. Friendships end for lack of communication. Siblings lack the attention they deserve.

Financially, the costs can be devastating. In 1998, we spent over \$30,000 on treatments, programs, medicine and tests for our son John. We couldn't afford this, and needed financial help. Many families don't have such help available to them. They are stuck in a poor neighborhood with this condition, and no place to go for help.

Treatment programs for our son have included Auditory Integration Therapy, Vision Therapy, Speech Therapy, Occupational Therapy, and Sensory Integration Therapy. We have participated in swimming and horseback riding, the Option Program, and picture exchange programs. Tests have included CAT scans, allergy testing, elemental hair analyses, antioxidant tests, urine profiles, stool analyses, and numerous blood analyses.

The uproar over Secretin should be a teaching lesson to everyone that parents are desperate for results. And many ignorant, uncaring, or outright fraudulent providers of "services" of different kinds are preying on us. Our son lost the few words he had after Auditory Integration Training. We saw doctors charging \$1,000 and more for a dose of Secretin.

Our school system would not tell us what programs were available to us, and denied us options we found out should have been fully available until we hired an attorney in the second year of the process. Now we are struggling with the nibbling away of the fifteen hours per week that our son is supposed to be receiving. The provider is subtracting time to prepare materials, take notes, write down observations, and talk to us. Our son is lucky to get 12.5 hours per week, and usually that is spent sitting on a swing observing, or watching him watch the weather channel rather than interacting with him. He is supposed to get 1 hour of speech therapy per day minimally, and gets twenty minutes twice a week from the system that receives federal funds for his autism. But we have learned that our school system is overwhelmed with the increase in incidence of these kinds of children. According to a recent Indianapolis Star article, the State of Indiana is so desperate for

Special Education teachers that they will allow anyone with a college degree to be one. What kind of special education is this?

The insurance companies will pay nothing for a child with autism. We found no company without this exclusion in their contracts. The waiting list for Indiana's Medicaid waiver, if you get on the list and they don't "lose" your spot in the meantime, is now three years. Because early intervention can be critical, the wait can be devastating to a child's ability to recover.

But we now have great hope. After years of reading books about autism, trying to understand why some children come out of the condition and some do not, we have learned that the term "autism", as used today, is a behavioral diagnosis and not a medical diagnosis because of its expanded definition to include so many children with different degrees of anti-social/behavioral conditions. (see Exhibit 2, Washington Post article). However, for most children, the behavior is caused by an underlying medical condition and these children can be treated. None of the insurance companies, school or program providers, or even physicians in Indiana with whom we met, including the pediatric immunologist at our local children's hospital, made this distinction. Ignorance is rampant.

Perhaps because it is not their lives that are altered each day, they are not compelled to interrupt their lives to learn. For example, the pediatric immunologist said he did not treat autism. We said, "we're not asking you to treat autism; we are asking you to find out if he has an immune system disorder." He refused to assist us because: 1) the tests are not traditionally run in cases like John's, and 2) he could not justify running them to an insurance company. When we offered to pay for the tests ourselves, he still refused to order them. He told us that if we wanted these done, we would have to go to California and see Dr. Goldberg. He had Dr. Goldberg's information from us prior to the appointment, but still refused the logic of the reasoning for running the tests.

My wife Denise and I followed the secretin story carefully, as well as Dr. William Shaw's work at Great Plains Laboratory. We called and interviewed the physician who spoke on the television program Dateline, spent significant time on the phone with Dr. Shaw, and read about the peptide work being done. We followed every thread we could find on the Internet, trying to understand all of the pieces of the puzzle and the conditions necessary for it to work, as Dr. Rimland and DAN (Defeat Autism Now) seemed to be promoting the use of Secretin for some children. During this time, I followed the web site of Dr. Sydney Baker, one of the DAN Protocol authors (see Exhibit 3), and found his conclusion "my present view is that autism and related developmental problems in children will turn out to be of viral origin" and his link to Dr. Goldberg's website, neuroimmunedr.com. (see Exhibit 4).

On Dr. Goldberg's site, I found, for the first time in two years, a cogent medical explanation backed with systems for diagnosis, treatment, and scientific measurements of progress toward healing for children tested to be immune deficient. (see Exhibit 5). The site is an oasis of understanding and treatment possibilities for children with autism, attention deficit disorder (ADD), and progressive developmental disorder (PDD) caused by neuroimmune disorders. It made sense to me that if there is viral or autoimmune cause to the illness, the treatment for such cause would be fundamental to a cure.

We learned, by having blood tests and immune panels prepared from our son John's blood tests (something no physician before had thought to do), that he had high HHV6 titers and low Natural Killer (NK) cells, a condition which is not caused genetically, but which is a disease probably brought on by genetic susceptibility. However, John is now curable! Treatment began a year ago, and despite two setbacks due to illness in the process, John is improving very steadily. The life described in the beginning of this short presentation has dramatically changed, in too short a period to be attributed to maturity. We have a relationship with him. We all laugh and play together now. He always listens and sometimes follows simple directions. He doesn't mess the floor anymore. He has been sleeping through the night since December. His HHV6 titers are down. Dr. Goldberg expects John to mainstream in the next two years. With your help, it could be sooner.

John seemed to developed normally until about age twenty months. We thought he was the brightest of all of our children, and his brother, in eighth grade, just scored 1390 on the college SAT. The immunization schedules of John and his siblings show that John received the Hepatitis B vaccine the day he was born, May 11, 1995, and the third injection before he was age one. This was before his older siblings, who received theirs in 1996. (see Exhibit 6). In addition to this, Denise had gestational diabetes during her pregnancy with John, and he had a history of chronic ear infections beginning at two months of age. (see Exhibit 7). Perhaps, with Denise's diabetes, his pediatrician, a Carmel physician now specializing in the area of autism and ADD who, I am told, now treats over 400 children, should have been more prudent about the use of vaccines on the day he was born, and thereafter as his ear infections signaled a weak immune system. At some point, with all of the stress put on his immune system, perhaps because of the MMR/DPT vaccine or one of his many ear infections by age two, we believe that he suffered the equivalent of an immunological "stroke". We are now trying to recovery from this.

Families with autism need the following kinds of help to deal with this life-changing condition:

- Doctors educated to know that this behavioral condition may be caused by a treatable medical illness, and willing to learn new methods of diagnosis and treatment;
- Schools in which teachers and staff understand that many, if not all of these children are sick, not defective, and can be helped and rehabilitated to have a bright, normal future;
- Education for parents and the medical profession about the difference between the old, classic definition of autism and the new form of acquired autism;
- Insurance companies to recognize that these children are sick, but can and need to be made well;
- Money for research and education, to assist those qualified medical professionals who understand the problem to fill in the answers in the next two years and speed recovery of these children so that they resume normal development and become productive citizens.

In May, 1999, 45 days into treatment for John, I attended a conference on Neuroimmune Dysfunction Syndrome at the National Institute of Mental Health. The curriculum vitae of most of the speakers, and a short summary of the presentations, is attached. (See Exhibit 8).

While I have great respect for the many physicians and professionals toiling to help these children, to my knowledge only the NIDS Medical Research Board combines the application of real science to make many autistic children well today with 1) predictable results, 2) scientifically measurable markers, and 3) commitment to the safety and well-being of the patients. They have a business plan and are confident in their ability to quickly speed their already predictable solutions for autism caused by neuroimmune dysfunction in a short time. (See Exhibit 9). We are only one of the many families seeing significant, predicted improvement. (See Exhibit 10). Independent medical research supports their scientific approach. (see Exhibit 11). Political affiliation among different autism camps will not affect the knowledge gaps needed to be filled for quicker neuroimmune solutions, but can delay the process necessary to attain it. Even if a genetic solution is attainable in ten years, we parents are willing to drive an earlier version of solutions today with our children. For the sake of our children and our families, please support the NIDS research team and the science that produces results now.

**Testimony of
Shelley Hendrix Reynolds**

Before the Government Reform Committee

April 6, 2000

Autism – Present Challenges, Future Needs – Why the Increased Rates?

Mr. Chairman and members, my name is Shelley Reynolds. I reside in Baton Rouge, LA with my husband of eight years, Aidan, and my children, Liam, who is 4 and Mairin, who is 2. I would like to thank you for both holding this hearing and allowing me to testify before you today.

I met Aidan in the tenth grade. We were in love with each other from day one. We dated all through college and got married as soon as we graduated.

We had our own house, two cars, two careers. We were living the American Dream. Right after we were married, Hurricane Andrew, one of the most destructive hurricanes to ever hit the United States, slammed through Baton Rouge. Sustained winds of 100 mph ripped up our roof. Eight days without electricity left us with very little food and water. We promised each other we would never again be unprepared for such a disaster.

But six years, later hurricane force winds blew into our home again, this time the disaster was the diagnosis of autism for our first born son, Liam. It completely tore our home apart. The effects have lasted much longer than eight days. And no amount of preparedness can ready you for a storm such as this.

Liam was a normally developing baby until June 27, 1997, when he received his MMR and Hib vaccines. Developmentally, everything was progressing completely normally. He cooed, rolled over, crept, crawled, pulled up and walked on time. He said all the things that parents crave to hear like “Momma”, “Daddy” and “Love you.” His expressive language increased to around 75 words. He was very social and had a completely infectious laugh. He liked music and learned the hand motions to little songs like "Itsy Bitsy Spider." He loved to interact and show off in front of his grandparents and our friends.

Well baby check-ups were kept on time. I breast-fed him until he was 8 months old. I didn't start solid foods until 4 months old. We did everything completely by the book and more.

When he was 17 months old, Liam started exhibiting some different behaviors. He was constantly taking off his shoes and screaming when we dressed and un-dressed him. He wouldn't let us brush his teeth anymore. He started staring into space when he watched a video on television and wouldn't move if you stood in front of the television. He couldn't tolerate playing in the sandbox anymore. He didn't want to sing favorite songs anymore and would just scream "No! No! No!"

We assumed he was just asserting his independence since he was almost 2.

Somewhere along the way he developed chronic, non-specific diarrhea ...sometimes 8 to 10 times a day.

A month before Liam turned two, visited my parents who live in Tennessee who had not seen Liam since the first week of July, 1997. They were shocked by the changes in him. My mother was alarmed at his lack of response when we tried to speak to him. She urged me to have his hearing tested. I had his hearing tested. It was normal.

By April of 1998 I realized Liam was no longer saying "Momma" or "Daddy" so I took him in for a speech and language evaluation. They told me that my 27 month old child had the language capacity of an 8 month old. This was a child that only months before would chime in "EIEIO" at the appropriate moment when singing "Old MacDonald."

We saw a pediatric neurologist, because that was on the list of things that you do with a suspected case of autism, and found that he had no seizure activity. His 12 hour EEG and MRI were normal. We continued doing blood work, stool and urine samples to determine his body chemistry, which was a complete disaster. His immune system was hardly operating. He had a host of bacterial, parasitic and fungal infections. The blood work also confirmed that he had suffered heavy metal exposure which had stippled his blood cells. Generally this type of the change in the blood is only seen when someone has been acutely exposed to a toxic metal. Liam had amounts of aluminum, mercury, tin, lead, and antimony that were off the charts. Liam was sick and in pain. We were scared and distraught. What had happened to our beautiful baby boy? How could we help him?

We decided to become advocates and work for increased funding for autism research and for awareness. The answers may not come in time to help our son, but we are hopeful that we can persuade you to see the need for intensive research regarding this disorder which affects more and more children every year. In California, only one of the 50 states, at least one child is diagnosed with autism every four hours, twenty-four hours a day, seven days a week. How many children have to slip through your fingers before you take notice that there is a serious problem here and that something other than genetics is causing it?

There are those who will argue that we are better at diagnosing autism today than in the past and that these children were once considered mentally retarded. However, according to a recent study, the mentally retarded have followed normal population increases and remained a steady constant while the autistic population has exploded. Is autism just the diagnosis du jour? Hardly. I would truly like to know where the parents of these autistic children were that did not recognize that their children were not talking, were spinning constantly in circles, doing odd things, abusing

themselves, not making eye contact, having serious gastrointestinal disturbances, eating and sleeping problems, experiencing a failure to thrive due to malabsorption and suffering from excessive allergies. You cannot miss these children.

In Liam's case, we have no doubt that he developed his autism as the direct result of an adverse vaccine reaction. Personally, if I could strike the belief that my son's autism sprang from a routine childhood vaccination that I held him down on the table for, and had to go back to the Russian roulette of genetics, I would take it in a heartbeat. Because the pain knowing that I inadvertently caused him harm, due to a blind trust in the medical community or a matter of the inconvenience of yet another office visit is nearly unbearable.

Many in the medical community continue to dismiss this as a mere happenstance because autism often coincides with the time of vaccination and state that there is no scientific evidence to back this up. My question to you is, how long does it take for a coincidence to surface time and again, case after case after case before it can become a viable hypothesis, especially, when the solution to solving the problem seems so apparent? How can pharmaceutical companies concoct substances with mercury, formaldehyde, antifreeze, lead, aluminum and live viruses not expect that as they continue to pour these highly toxic and reactive substances into children, increasing dose after dose, all on the same day even, that it WON'T alter their developing minds and bodies? Why would it be so completely impossible for a child to actually contract a chronic form of the disease rather than have a "proper immunological response," especially when their immune systems may not be up to par? And where is THEIR scientific evidence to back up the claim that this cannot happen, when it is published in the very package inserts, in their writing, that they have not studied the effects of vaccines for more than a few weeks? Or longer than the incubation period of the disease itself? Or what happens when you give multiple doses in one day or combine different diseases into one hypodermic needle?

Could someone please explain to me why it is acceptable to have products on the market that exposed my child to 37.5 micrograms of mercury in one day when at that time he should not have been exposed to more than .59 micrograms of mercury given his body weight? Even a body as big as mine shouldn't be exposed to more than 5 micrograms of mercury in one day. That is completely unacceptable. One size does not fit all when it comes to vaccines.

Through our organization, Unlocking Autism, we have talked to thousands and thousands of parents from across the country and their story is the same. Child is normal, child gets a vaccine, child disappears within days or weeks into the abyss of autism. If you doubt me, I invite you to attend the Hear Their Silence Rally on April 8th on the mall where our Open Your Eyes project will be displayed. View the thousands of pictures we have collected and realize that 47% of those who participated believe that vaccines contributed to the development of their child's autism.

Parents like me are relying on you to demand that the pharmaceutical companies retrace their steps once again and that the public health community look at the possibility that these things might indeed not be just a coincidence. They obviously have no incentive to do so themselves. They are immune from liability and they have a forced market. They manufacture products that are required for every child in this country. We fear that it is possible that while seeking greater monetary profits there may be some who have lost sight of the medical community's original goal regarding vaccinations---to protect children from harm.

I know my children. I know what happened to my son. As far as I am concerned, the needle that silently slipped into my baby's leg that day became the shot heard round the world.

**Testimony
of
Jeana Smith**

**Before the
Government Reform Committee**

April 6, 2000

Autism - Present Challenges, Future Needs - Why the Increased Rates?

Mr. Chairman and Members. I am Jeana Smith. I live in Denham Springs, LA with my husband Darrell and our four children... 5 year old genetically identical twins, Jesse and Jacob, Garrett who is 3 and our grand finale' Julianna, who is 16 months.

Darrell and I have always loved children. For six years we tried, unsuccessfully, to have a child and decided that it simply wasn't meant to be. To our complete surprise I found out that I was pregnant with twins - a double blessing!

Perhaps, because we had tried so hard to have a child, I took especially good care of my body while I was pregnant with the twins. Our identical twins were born right on time and completely healthy. We were absolutely thrilled. Our family was perfect.

One month later we found dark blood mixed in Jacob's diarrhea. Jacob had never had diarrhea before. We immediately took him to the doctor who assured us the blood was from a rectal tear. He mentioned that in the chaos that generally follows the birth of a baby, much less twins, we had been released from the hospital without vaccinating the twins with Hepatitis B. He wanted to vaccinate Jacob right then. We questioned him because it did not seem right to give a potentially ill child a vaccine, but he convinced us that it was routine and safe. Not to worry.

Two months later, Jacob received his second Hepatitis B vaccine and Jesse his first. On this same day Jacob and Jesse both received their first DTP, Polio and Hib vaccination. From that day, Jacob was constantly coming down with one ear, respiratory or sinus infection after another. Jacob was constantly on antibiotics. As his mother, I was heartbroken to see him sick or in pain practically all the time. As a new mom, it was embarrassing and frustrating to have a child that was always ill. I knew I was doing everything I could for him, and couldn't understand why he continually ill.

Concerned, we asked our pediatrician and he explained that Jesse was the dominate twin, and this was perfectly normal for Jacob, slightly smaller, to have a weaker immune system and to be prone to common infections.

Jacob met every developmental milestone that first year right along with Jesse. They were two peas in a pod and did everything together.

At only 16 months of age Jacob and Jesse received their first MMR vaccine, along with their fourth DPT, fourth Hib, and their third Hepatitis B. The following 24 hours both twins slept most of the time with 100 degree temperatures, in spite of receiving the recommended dosage of

Tylenol every six hours. Just days later, Jacob began exhibiting strange behaviors. He was no longer excited or responsive when Daddy came home from work. He became preoccupied with certain toys. He would spend long periods of time studying the way their wheels would spin or whether or not they were lined up just right. Any attempt to interrupt or distract him was met with great resistance and an eventual fit. During this time, Jesse went along with business as usual.

Back to the doctor we went again, this time with very serious concerns about the growing developmental difference between Jesse and Jacob. And once again, we were met with the dominate twin theory. Jacob would probably be more quiet. Jacob would probably want to play by himself more often. "Jacob is fine, stop worrying."

Finally we could not stand the undeniable difference in their language and communication skills. Something was most definitely wrong with Jacob. He could not express even his most simple needs or wants. He couldn't ask for juice or something to eat. Jesse was chattering constantly. And at times, Jacob was so withdrawn that we absolutely could not reach him.

In a waiting room, in front of several other parents, we received Jacob's first official diagnosis. The Director of LSU's Speech and Hearing clinic callously and simply stated, "Mrs. Smith, Jacob is autistic. There is nothing that we can do for him today. You will need to call back and make an appointment to see one of our speech therapists." I will never forget the day I heard those devastating words, the ones I knew were coming, but words I would not allow my heart to tell my head. I walked out of the office with Jacob in my arms, sobbing and bewildered. THIS IS COMPLETELY IMPOSSIBLE my mind screamed. Autism is genetic and Jesse is fine. What is going on with my baby?

Because we were facing the overwhelming news that our perfect-looking son had a serious life-long disability, the word of one "expert" was simply not good enough. We continued seeking answers. Three more diagnosis' quickly followed.

Jacob is a beautiful child who has abnormal sleep patterns and has lived with continuous physical pain. His lack of sleep keeps me up all hours of the night, and by the time I finally fall asleep, it is time to wake the kids up for school and start the day. We are constantly working with Jacob to help him understand the outside world so that we can maybe go to the grocery store, the mall, the gas station or McDonald's without him getting hysterical from sensory overload from all the fluorescent lights and sounds.

What may sound like water dripping to us may sound like a massive water fall to an autistic child. What may sound like squealing tires to us may sound like the Indy 500 up close to a child like my son. On days that he is "overloaded" from sound, colors or lights, we can't go anywhere. Autism does not only isolate the child that it affects. We can't take the family out to dinner or out to have fun. When the other children may be waiting in anticipation to go have a day out with mom and dad, one of us will have to stay home with Jacob because he is so agitated. If one child has a school program and Jacob is frustrated, then we have to see that crestfallen look on the child's face because both mommy and daddy cannot go, since one has to stay with their brother. We know if we take him in public, there will be a scene. Little things such as this "rob" life's enjoyment from our other children.

Unlike most parents of autistic children, I don't have to wonder what my child would have been like. I see what he would have been through Jesse every day of my life. I see Jesse excelling in

school, and his social activities. He will be starting a tee ball team this summer. I will have to find a babysitter to watch Jacob so that our family can attend Jesse's games.

This may not seem like a lot to some people, but not being able to do things together is not fair to the other children in the family. We have had to explain to Jesse and Garrett what Autism is. That is not an easy concept for two small children to understand. And it is not easy knowing that someday when my husband and I are gone that one of our children may have to take care of Jacob for the rest of his life. We should not have to prepare our children for that possibility. But we have to think ahead. What happens if Darrell and I go somewhere together and something happens to us? Who will take care of Jacob and see to his needs? Who will understand what he is going through? Who will defend Jacob when we are not there to do it and he cannot do it for himself? Who will understand his frustration if we someday aren't around? These are things that keep us, as parents, awake at night worrying.

For us, there is no denying that in Jacob's case of autism, the answer does not lie in genetics but in a catalyst. The thousands of hours of research that we have spent searching and retracing his regression continue to point to the fact that the road to Jacob's autism began when his immune system was damaged by the Hepatitis B vaccine he received when he was ill. The final blow was the adverse reaction to the host of vaccines he received by 16 months. We are certain that for Jacob, the catalyst was his vaccines.

With Jacob's initial diagnosis, many doctors and professionals suggested that we put him on medications designed to mask autistic behaviors. WHAT AN OUTRAGE! To give our small child drugs to cover up what was actually happening inside his body did not make sense. We wanted to find out what his body was doing and treat that first.

We were blessed with a wonderful Doctor in Louisiana, Dr. Stephanie Cave. She ran blood and urine tests to find out what amino acid, vitamin and mineral deficiencies and immune system dysfunctions Jacob had, along with his exposure to heavy metals, invasive fungal infections and extensive food allergies. The results were shocking. It was amazing this little guy was able to do as well as he did.

After placing Jacob on a structured, nutritious diet, supplementing his deficiencies and working to restore his immune system, Jacob is giving perfect eye contact and beginning to initiate and interact in conversation. He has made incredible strides. Jacob is still autistic. There is no doubt about that. But he is only five. The progress we have seen inspires us to shout from a mountaintop the hope available to so many children! For him, it is evident that autism is not always a traditional congenital genetic disorder. It can be an acquired syndrome. And that is why I am here today.

There is a huge epidemic of autism in this country with countless parents that believe, as I do, that their child's autism is the result of a vaccine reaction. I have talked to thousands of parents and they know their children! They are not looking for a scapegoat. They are looking for answers and truth. They tirelessly look at every possible reason their perfectly normal child could slip away so quickly. If parents were looking for an excuse for why their child could be snatched away so quickly, they certainly would not choose to put the blame on something they did to protect their child and keep them from harm.

I can't bear the thought that, after waiting so long and being so careful carrying my twins I was so easily persuaded to immunize Jacob without knowing all I should have. I should have taken the

time to find out his risk of contracting HepB, I didn't. I should have found out about all the toxic metals that are used to manufacture the vaccines. I didn't. I should have known back then what I do now. I didn't. I trusted his pediatrician, I trusted the CDC. I was persuaded to believe I was doing the best thing I could do to protect my child.

I can assure you that this epidemic will not go away until we address it. Every scientist, doctor, researcher, parent looking for answers and resources should never have to question where their funding will come from. It has to be here now! If you don't deal with this today, how will you deal with it in 15 years?

Three years ago when Jacob was diagnosed, autism affected at least 1 in 500 children. Now it affects one in 300 children nationwide. In some places it affects as many as 1/127. Today, Coast to Coast the school and service systems are over run. In California alone the tax dollars will cost 2 million dollars per child diagnosed with autism. Last year alone almost 2,000 children were diagnosed with autism and added to the already system. We cannot run from this. The numbers are rising. The numbers are real. Autism and the children, and adults and families affected by it are living in the towns and cities of every person in this room.

I implore you to act now. You do NOT have time to wait another year for another hearing and another panel of parents and experts to advise you that an epidemic is waiting in the wings. We are swiftly and silently losing a generation of children to a disease that could possibly be avoided. While we are taking our children every afternoon to the therapies that they need to make it through the day, or charting the 15 supplements that we have to give them in order to keep their body chemistry afloat, or monitoring every crumb or drop that enters their mouth in the hopes that it does not contain a trace of gluten or casein, or educating the teachers that work with our children everyday, or fighting the school system to make sure that our children get the education that they are entitled to, or arguing with the insurance company about the fact that yes that very expensive test was absolutely necessary in determining the best course of medical intervention for my child, or working two jobs to pay for the multitude of services that our children need because the government can't keep up with the demand, we need YOU on the front lines demanding answers from the medical community. We need YOU on the front line requiring the pharmaceutical companies to come up with the research that they should have done decades ago. We need YOU to fund the independent scientists so that they can maintain their objectivity in investigating the possibility of a connection between vaccines and autism. We need YOU to help fund the research that will ultimately lead us to a cure for these kids.

Please, let this country be the leader in seeing the percentage decrease not increase.

Just like Jacob, these children are not without hope. They can get better. Jacob is doing better than we ever imagined. But we have fought, and scratched, and struggled to get him the things that he needs. A child with Autism is a puzzle for us all. And each piece of the puzzle is incredibly important. But closing your eyes and relying on 40 years of medical rhetoric that has dismissed autism as a mere genetic, psychiatric disorder will keep parents like me from having the answers that we certainly deserve. Good science research into the autism/vaccine connection must begin NOW in a serious and accelerated way, with independent research institutes like the M.I.N.D. Institute at U.C. Davis leading the way.

Every night Darrell and I tuck two beautiful little boys into bed. On the outside they look just the same. Their bed covers and pajamas match, their cheeks and hair match, There is nothing on their body that does not match, even their toes are the same. As Darrell and I sit in between their beds

we talk with Jesse about his day. He gives us all the details of his day at school and tells everything he did with his friends. He talks about how excited he is for the birthday party at his cousins house this weekend. He talks with Darrell about working on his batting swing to prepare for T ball this summer. As he drifts off to sleep, we turn to tuck in Jacob. We know, even at only 5, Jacob will never be able to enjoy the simple pleasures of childhood the way Jesse does. He will never be on a sports team. He cannot enjoy the fulfillment of birthday parties or friends. The difference is real! We know Jacob's autism will not go away! When they fall asleep, we once again can see two beautiful matching faces and know what should have been. It is the only time their faces match. Even though they are identical, Jacob's countenance left when he was 16 months old. The light behind his eyes was replaced with a blank, lost, bewildered stare.

I cannot count the times Darrell and I have cried quietly in between their beds while they sleep. We cannot imagine that anyone else could understand such grief. Tomorrow morning, or perhaps, in the middle of the night we will be awakened by the reality of their difference, by the reality that Jacob is autistic.

Testimony

Of

Dr. Wayne M. Danker,
San Diego, California

Before the Committee on Government Reform

April 6, 2000

Honored committee members, fellow panel participants and members of the audience, I feel privileged today to appear before this committee to share my perspectives on autism, foremost as a parent but also from the additional perspectives as a pediatric infectious diseases specialist and a scientist engaged in clinical research and evidence-based medicine. My daughter Natalie, who is now nearly 13 years old, has autism and has taught my family and I a lot about ourselves and how the world around us deals with individuals who appear different from the “norm”. She has been both a joy and a real challenge to live with and we continue to live through these experiences everyday. We have weathered this storm by rejoicing in her triumphs and finding the humor in past events even when those events may have seemed unbearable at that time. We have found that our daughter’s greatest needs have been in the area of education and for a highly structured environment to allow her some control over the events of her life. It is in the area of education that we have experienced our greatest challenge and have been labeled by our local school district administrators as the most difficult parents they have had to deal with. In the context of the meeting that this statement was made, both my wife and I took it as an insult but have been convinced by our friends and family that we should wear it as a badge of honor. If anything, it highlights the advocacy we have championed for our daughter’s rights to an appropriate education that addresses her individual needs and the manner in which she learns best. My greatest hope today is that members of this committee and the audience will gain a better understanding of the unique nature of autism; the challenges and demands placed upon

families caring for autistic children and adults; the significant emotional, financial and community resources required to prepare and involve these individuals in everyday life; and to accept and respect these individuals for who they are.

However, as previously mentioned, I also come to this committee as a trained infectious diseases specialist and clinical scientist and therefore feel compelled to comment on two other areas of importance to me. In the area of medical and other treatments, intended to help autistic children function to the best of their ability, I would hope to see more funding to allow for appropriately controlled and conducted studies to rapidly determine the true effectiveness of these interventions so that families can make informed decisions regarding the best use of their limited resources. Without these studies, I and the other parents of autistic children are forced to make decisions, which may at times prove disadvantageous to all involved, without the benefits of real data.

I would also wish to comment on the current concerns regarding the potential causes for the perceived increase in autism. I implore the committee to be cautious in its statements and conclusions with regard to possible links to environmental factors and medical factors, especially immunizations. Recognizing that there are other parents on this panel who may feel otherwise, as a pediatric infectious diseases specialist I have seen no sound scientific evidence linking autism to the MMR or any other vaccine, yet, there is considerable evidence proving that the MMR vaccine is safe and highly effective in protecting children from serious diseases.

In closure, no matter what conclusions are formed today or where the activities of these hearings may lead, I would like to share an axiom of medicine I have both learned, practice daily, and continue to teach to future doctors, above all do no harm. Thank you.

Testimony before Congressional Oversight Committee on Autism and Immunisation

Dr Andrew J Wakefield MB..BS FRCS

Mr Chairman and members of the Committee,

The purpose of this testimony is to report the results of the clinical and scientific investigation in a series of children with developmental disorders, principally autism. Nothing in this testimony should be construed as anti-vaccine; rather the author advocates the safest vaccination strategies for the protection of children and the control of communicable disease. The opinions expressed in both this text and the attendant presentation, represent those of the author. I am testifying on behalf of the children who have been referred to me for investigation, and am not here on behalf of, or representing, any institution.

These studies were undertaken against a collective background experience of the principal authors, of over 500 peer-reviewed clinical and scientific papers, published in reputable medical journals, and over 1000 peer reviewed abstracts presented to learned societies. The ongoing studies form part of an international, multidisciplinary research program including California's MIND Institute at UC Davis into inflammatory diseases of the intestine and childhood developmental disorders, involving the disciplines of pathology, immunology, virology (particularly, molecular detection of viral genes) and epidemiology. All studies were approved by the appropriate institutional Ethical Practices Committee.

We have now investigated over 150 affected children with autistic spectrum disorders. A preliminary report of the first 12 children has been published (Lancet 1998:351:637-641). A detailed analysis of the first 60 children is due to be published (American Journal of Gastroenterology). The clinical findings; described in these reports have been reproduced in the extended study of more than 150 children. The latter group includes 4 children from the US. Independently, other centres investigating children with autism and gastrointestinal symptoms in the UK, Europe and the US, have confirmed the clinical findings that comprise the syndrome of *autistic enterocolitis*.

Our study was initiated at the request of parents, and was stimulated by the conviction that their children had; 1) developed normally during the first 1-2 years of life; 2) undergone developmental regression to autism, in the majority of cases following measles mumps rubella (MMR) vaccination, and; 3) developed gastrointestinal symptoms that, in the parents' opinion, were closely associated with the behavioral/developmental pathology. Almost without exception, the anxieties of the parents, as described above, had been dismissed by the medical and allied professions. Bowel symptoms had been disregarded without investigation. Raising the issue of the possible role of MMR vaccine in their child's autistic regression had led to an acrimonious breakdown of the doctor-parent relationship in many cases.

One of the fundamental rules of conventional clinical medicine is to listen; to listen to the patient or the patient's parents, and then to investigate the presenting symptoms, without prejudice, in order to determine whether or not they have an organic origin. In this context, the Committee should be aware that the parents' story is remarkably consistent whether, for example, they come from the US, Canada, the UK, mainland Europe, Asia or Australia. The pervasive features include developmental regression and gastrointestinal symptoms following MMR vaccination (Figure 1).

Figure 1. New Straits Times, Kuala Lumpur "After receiving his MMR inoculation at 18 months, Nicholas came down with a very bad case of gastroenteritis. From then on I noticed very distinct changes in his behavior," Ang recounts.

Accordingly, we have conducted a series of detailed studies on behalf of these children, the findings of which, in summary form, include:

- 1 A pattern of symptoms that comprise abdominal pain, abnormal bowel habit (constipation with overflow diarrhoea), bloating, reflux. The pattern and severity of behavioural and gastrointestinal symptoms appear to parallel each other.
2. A frequent history of atopy (asthma, eczema, hay fever)
3. Recurrent, refractory upper respiratory tract/ear infections.
4. A strong family history of autoimmune disease.
5. On direct visualisation of the lower intestine, ileo-colonic lymphoid nodular hyperplasia (swelling of the tonsil-like tissues in the small and large intestine; figure 2), plus inflammation of the colon and, to a lesser extent, the ileum.

Figure 2. Marked lymphoid nodular hyperplasia of the terminal ileum in a child with autistic enterocolitis

6. Low numbers of circulating immune cells (lymphocytes; figure 3) and an inability to respond appropriately to common antigens to which the children have been exposed previously (tetanus, diphtheria, pertussis, house dust mite, Candida). These differences are statistically significant compared with age-matched healthy controls.

Figure 3. CD3+ lymphocyte counts in peripheral blood of autistic children (each blue square represents one child) compared with age-standardised reference ranges, showing the upper (green) and lower (red) limits of normal (5th - 95th centiles)

7 Microscopically, in intestinal biopsy tissue, a specific and subtle inflammatory pathology in the colon (figures 4 & 5) that, overall, appears distinct from that seen in patients with Crohn's disease, ulcerative colitis, idiopathic constipation, and histologically normal controls of a similar age.

Figure 4. Autistic enterocolitis: acute inflammation in a colonic crypt.

Figure 5. Autistic enterocolitis: colonic crypt abscess within the black circle

8. A pattern of colonic inflammation that distinguishes autistic enterocolitis from other common forms of inflammatory bowel disease, as demonstrated by the detection and quantification of specific immune and inflammatory molecules in the intestinal lining.

Figure 6. Activation of the immune system in the bowel lining in autistic enterocolitis. A= normal child; B= autistic enterocolitis. Staining represents Class II antigen expression (LN3)

1 In blood, a raised circulating IgG measles antibody titre that is statistically significant when compared with age-matched healthy controls. The same is not seen for antibodies to mumps, rubella or cytomegalovirus.

2. In preliminary studies, the presence in intestinal tissues, of measles-specific antigens (protein), specifically in the follicular dendritic cells of the reactive ileal lymphoid tissue.

Figure 5. Measles virus nucleocapsid protein in the centre of a reactive lymphoid follicle in a child with autistic enterocolitis

3. The absence, in the same lymphoid tissues, of antigens specific for other common viruses including mumps, rubella, adenovirus, herpes simplex virus I and II and HIV.

4. The absence of measles antigen, in intestinal lymphoid tissue from developmental normal children without inflammatory pathology.

5. Investigations including chromosome analysis, metabolic analysis, imaging studies of the central nervous system, electro-encephalography and analysis of cerebrospinal fluid did not reveal any alternative causes for developmental regression in these children.

6. The presence in 3 of the initial 9 children with autistic enterocolitis who were studied by gene amplification technology, of measles virus; hemagglutinin (H)

gene in peripheral blood immune cells (Kawashima H et al. *Digestive Diseases and Sciences*.

March 2000)

7. Subsequent molecular studies of the detection of measles virus genetic material will be described by Professor JJ. O'Leary.

The Issue of coincidence

Many pediatricians have expressed the opinion that, for autism, any association between MMR vaccination and the parents' recognition of the child's behavioral problems is coincidental. Such an assumption is inappropriate in the absence of a thorough history and investigation. For example, symptoms of classical, early onset autism are often noticed initially, in the first and second years of life the child does not develop in the way of normal siblings and peers. Parental concerns about the child's development are often expressed in the second year, when these differences become evident. MMR vaccine is given routinely at this age, and coincidence is therefore inevitable. However, in children with autistic regression, the pattern is of loss of speech, language and social skills, accompanied by bizarre behaviors, in a previously developmentally normal child. This is consistent with an early onset disintegrative psychosis. Furthermore, loss of speech and language are accompanied by symptoms of excessive thirst, bowel disturbances, self-injury, and a self-limited diet associated with cravings for particular foods. Atopy and recurrent, refractory upper respiratory tract infections are prominent features. These symptoms do not feature in the exclusively behavioral descriptors of the diagnostic manual for autism - DSM-IV.

The issue of coincidence may be addressed, in part, by considering those children who have received more than one, measles containing vaccine. If the intestinal pathology and the associated behavioral problems are causally linked to a persistent viral infection of the intestine, then re-exposure to the same virus vaccine might be expected to exacerbate the condition by, for example, eliciting an immune response against virally infected cells. In the cohort of children with autistic enterocolitis under our care, we have 10 children who have received more than one dose of a measles containing vaccine. Developmental/behavioral changes had to be identified contemporaneously, rather than retrospectively. The data for first and second vaccine doses, and initial and subsequent behavioral changes are shown graphically, below (Figure 7).

Figure 7. The graph, where each time line represents one child, shows that for 7 children (2-4 & 6-9) developmental regression accompanied both exposures. In 2 children (1 & 10) it followed the second dose, long after the second year of life. These data are not consistent with coincidence.

Temporal trends in autism

If MMR vaccine is causally related to autism and autistic enterocolitis, then there should have been an increase in the numbers of cases of autism following the introduction of MMR vaccine in different countries. Moreover, since MMR was introduced into different countries at different times, the effect should be one of similar temporal trends in different countries, with any increase corresponding with the introduction of MMR.

Temporal trends for autism cases in California

A dramatic rise in the numbers of new cases of autism seen in the first birth cohorts eligible for MMR vaccination (bar)

There was a rather protracted period over which MMR was introduced in the US, because of the continued availability of monovalent vaccines. (F.Yazback. personal communication)

Source: Office of Developmental Services, Sacramento Ca.

Temporal trends for autism U.K. North London

Data published in the Lancet, compiled by the Public Health Laboratory Services and the Department of Community Paediatrics, Royal Free Hospital. Data show a doubling of autism cases in the first birth cohorts eligible for MMR, with a dramatic and sustained rise thereafter. Bar shows first birth cohorts eligible for MMR

Source: Taylor et al. Lancet,

Temporal trend for autism: US and UK

Superimposing the data for the US and the UK analyses described above, identical time trends are seen, with a delay in the rise in the UK that corresponds to the later in introduction of the MMR vaccine in 1988

It is important to note that the UK and the US use exactly the same diagnostic criteria for autism and yet there is a 10-year delay in rise in the number of cases. These changes are very unlikely to reflect artefacts due to changing diagnostic criteria. This is confirmed by reviewing the temporal trends for autism and learning disabled children in the state of Illinois from 1991-1997.

Figure 12. Temporal trends for autism and learning disabled ($\times 10^3$) in Illinois. In 1994 the broader autism criteria of DSM.III Revised (DSM.III-R) were amended to the more exclusive DSM-IV. Had the increase been an artefact of diagnosis, then the numbers should have levelled off beyond 1994.

The Finnish paper

No evidence for MMR-associated inflammatory bowel disease or autism in a 14-year prospective study. Peltola et al, Lancet 1998; 351: 1327-1328.

The study:

- Identified adverse events following 3 million doses of MMR in Finland during the 3 weeks post-vaccination.
- Traced those individuals with severe gastrointestinal symptoms (diarrhea /vomiting) after MMR, lasting 24hrs or more. There were 31 recorded episodes.
- Followed up those 31 individuals from 1 to 14 years (mean=9 years) after MMR
- None of the 31 children had a diagnosis of autism or inflammatory bowel disease.

The problems

- No one has ever suggested that acute gastrointestinal symptoms within 3 weeks of MMR is a risk for autism or inflammatory bowel disease.
- Parents reported **behavioural changes** as the initial presenting feature in their children
- 31 children is far too small a number, and the children are still too young to assess risk of inflammatory bowel disease.

Conclusion

- Peltola et al tested the wrong hypothesis

The Taylor paper

Taylor B et al (Royal Free & University College Medical School & the Public Health Laboratory Service) published a paper (Lancet 1999;353:2026-2029) that sought to dispel any relationship between MMR vaccine and autism. They performed a Case-Series analysis of children with autism in North West Thames. Reasoning: If there is a causal association between MMR and autism, there should have been a step-up in the numbers of children with autism in the first birth cohorts eligible for MMR. The authors stated that such a step-up should have occurred in those born in 1987 since these were the first children eligible to receive MMR in the second year of life. There was a crucial omission from the paper by Taylor et al. In 1988 - with the introduction of the MMR in the UK - a "Catch-Up" campaign was instituted which targeted pre-school children of one to four years of age who had not previously received monovalent measles, mumps or rubella vaccines irrespective of their immunity to the three infections.

Corroboration of this comes in the form of a contemporaneous paper from Dr Christine Miller, previously of the PHLS, who stated: "Although the program will be aimed mainly at the one to four year age groups, where it will have the maximum effect, MMR vaccine can be given at any age." (Miller C. Introduction of measles/mumps/rubella vaccine. Health Visitor 1988;61:116-117)

Taylor et al noted that the rise in autism occurred in children born in the few years before 1987 and concluded, therefore, that since this rise had started before the introduction of MMR it could not have been caused by MMR. This paper has been cited by various vaccine officials as definitive proof of the safety of MMR in this context.

Taylor et al's omission of the crucial information on the catch-up campaign, led the reader to believe that those, and only those, born in 1987 were the first children eligible for MMR. They were challenged on this omission in a subsequent letter to the Lancet (1999;354). In their reply they acknowledged that they were aware of the catch-up campaign and admitted that no fewer than 36 autistic children in their data-set were born before 1987 and had, therefore, received their MMR over the age of 2 years. They claimed that this was not relevant since symptoms had apparently started in these children before MMR. This is not relevant; testing of a "step up" hypothesis is not based upon analysis of individual case notes, other than to confirm diagnosis. Since they were aware that their cohort contained children who received the MMR after the age of 2 years **it was not scientifically legitimate to test the hypothesis that a step up should be seen in those born in 1987**. The fact that the step up occurs in those born in 1986 is alarming, and would be consistent with an association with MMR.

Such were the anxieties about the quality of this study that it was recently the subject of a special, and highly critical debate at the Royal Statistical Society in London. The conclusion reached was that Taylor et al's study design was wrong.

Further evidence for a temporal association between the introduction of MMR and an increase in the numbers of cases of autism comes from a current study of autism in island populations. The data for Shetland are shown below.

Shetland Islands, Scotland.

A birth cohort effect for autism is seen in those born after the mid 1980's, corresponding with the introduction of MMR vaccine. Source Thrower D.

Figure . A similar birth cohort effect is seen for those born in the Western Isles of Scotland, a geographically distinct group from the Shetlands.

MM R and Compound effects

Parental reports have implicated the polyvalent MMR vaccine, but rarely the monovalent measles vaccine, in autistic regression. Is such a causal association consistent with what is known of the risks for acquired forms of this syndrome? Atypical patterns of exposure to common childhood infections - measles, mumps, rubella and chickenpox - have been associated with autism and autistic regression. In utero and infant exposures have been identified as periods of apparent susceptibility, when both the brain and the immune system are undergoing rapid development (Deykin EY and MacMahon B. American Journal of Epidemiology 1979; 109:628-638). It is notable that a close temporal relationship in the exposure to two of these infections during the periods of susceptibility may compound both the risk and severity of autism. Although historically, these rare patterns of exposure may have accounted for only a small proportion of autism, the widespread use of a combination of the candidate agents in a single vaccine may have changed this. Recently, measles containing vaccines were linked to developmental regression (Weibel RE et al. Paediatrics 1998:101:383-387).

In order to understand why autistic enterocolitis might result from a compound effect - where the interaction of multiple concurrent viral exposures is important - it is helpful to examine the patterns of childhood infection that have been identified as risk factors for persistent measles virus infection and delayed disease. One important pattern of infection that may increase the risk of delayed disease is where different viruses interact, either with each other or both interact with the host immune system simultaneously. A close temporal exposure to measles virus and another infection, including chickenpox or an encephalitogenic enterovirus, is associated with an excess risk for a rare fatal encephalitis (subacute sclerosing pariencephalitis), the onset of which may be delayed for many years. Similarly, atypical patterns of measles infection, including a close temporal exposure to mumps infection, but not other common childhood infections, have been identified as a significant risk factor for chronic intestinal inflammation - Crohn's disease and ulcerative colitis.

Clues that the component viruses of MMR could interfere, one with another, were provided in the very first pilot studies of this vaccine in 1959 (Buynak et al. JAMA 1969:207:2259-2262). However, despite providing compelling evidence of the potential for dose- and strain-dependent

interactions between the component viruses in the MMR vaccine, both in the context of adverse reactions and antiviral immune responses, the matter was left in abeyance.

Six years later, in 1974, the potential for viral interference in MMR was the subject of a more detailed follow-up to the Buynak study, by Minekawa et al (Biken Journal 1974:17:161-167). The most striking observation was of a dose-dependent influence of the mumps vaccine upon not only clinical reactions to the measles component, but also seroconversion to rubella vaccine.

The ability of mumps virus to interfere with the cellular immune response to certain strains of measles virus and, thereby, in particular combinations potentially to reduce viral clearance and increase the risk of persistent infection, is an intriguing hypothesis to some of those involved in the current debate. Whatever the ultimate merits of this hypothesis, the contemporaneous interpretation of Minekawa et al was that further studies were necessary. However, it does not appear, from the published literature, that these further studies were undertaken.

Summary

Autistic enterocolitis is a real syndrome

The swollen intestinal lymphoid tissue provides a focus for searching for the cause(s) of this syndrome.

The virological data indicate that this may be measles virus in some children.

It would be imprudent to interpret the temporal relationship with MMR as coincidence, in the absence of thorough investigation.

Epidemiologic and virologic data support the possibility of a compound effect of multiple concurrent viral exposures influencing: the clinical and immunologic response to MMR; the risk of autism; and, the risk of delayed sequelae, including chronic intestinal inflammation.

Autistic enterocolitis appears to be important part of the current epidemic of autism and autistic spectrum disorders.

Conclusions

If, following thorough independent scientific investigation, it emerges that autistic enterocolitis and other related disorders are causally related to a compound influence of the component viruses of MMR, whether these viruses have been encountered naturally or in the vaccine, then through judicious use of the vaccines, one may have a means for preventing the disease. Spacing the single vaccines, thereby dissociating the exposures that, together, may constitute the risk, provides a way of not only preventing the acute measles, mumps and rubella infections, but also, potentially, the risk of one of the most devastating diseases that it has been our misfortune to encounter.

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Today, I will be speaking about the autoimmunity aspect of vaccines in autism, a medical condition that has been largely ignored by the medical community and federal government for a very long time and yet the incidence of autism is increasing at an alarming rate. An estimated one-half of a million Americans, mainly children, and millions more worldwide are known to suffer from autism, a heart-rending disorder that severely impairs higher brain functions: social interaction, communication, language, imagination and cognition. The disorder is a life-long mental disability with devastating consequences for both the patient and his/her family. Thus the financial burden is huge for the families who care for children with autism.

Autism is an idiopathic brain disorder, which simply means that the etiology of the disorder is not known. And there is no single, clear-cut cause for autism. Causally speaking, I tend to think that autism is a complex disorder, in which autoimmunity to brain plays a key role. Today, in spite of virtually no funding available, autoimmunity is the most extensively investigated topic of research in autism. This is by and large due to the fact that autoimmunity is the prime target of therapy that has proven to be quite effective in ameliorating autistic characteristics. Thus the autoimmunity research, unlike the genetic research, has already significantly improved the health and welfare of individuals with autistic disorder. I have recently coined a term “Autoimmune Autism (AA)” to refer to a subset of autism that has autoimmune etiology. Moreover, there are scientific reasons to think that this subset may indeed be a result of vaccine injuries to children who display autistic regression.

Autoimmunity is an abnormal reaction immune reaction, in which the immune system becomes primed to react against body organs. It’s a mosaic of highly complicated interactions and networking between cells and molecules of the immune system. The body makes autoantibodies against itself, resulting in damage to tissues and organs. The “autoimmune” response is what happens in autoimmune diseases such as lupus, and my research showed that a similar response may account for the brain abnormalities found in people with autism.

Autoimmune diseases are identified and characterized by many factors. The hallmark is the “organ-specific autoantibodies” that have also been identified in people with autistic disorder. To that end, I have recently summarized laboratory data of approximately 400 cases (autistic and controls) and found that up to 80% of autistic children have autoantibodies to specific brain structures, in particular a brain protein known as myelin basic protein (MBP) of the myelin sheath, a fatty coating that insulates nerve fibers and absolutely essential for higher brain functions. These autoantibodies are present quite frequently (65-85%) in autistic children, but only rarely (0-5%) in normal children and other disease controls. Accordingly, I postulated that autism involves a specific autoimmune response to MBP -- an immune assault that impairs myelin development in the developing brain, thereby modifying the nerve cell functions of the brain. Ultimately, by way of impaired wiring diagram in the brain, this results into autism.

Autoimmunity is commonly triggered by environmental exposures such as viral infections. Virus serology (or virus antibodies) is an excellent tool for studying virus infections in disease states. However, until recently, such studies had not been performed for autism. Because of my ongoing research, I became interested in examining a virus link with autoimmunity in autism. I recently raised two specific questions: (1) Does

autistic children have a hyperimmune response (or increase of antibodies) for a specific virus? (2) Is there a relationship between virus antibodies and brain autoantibodies in autism? I conducted a carefully designed study to address these two questions. Succinctly, I made two very important observations: first, there was indeed a hyperimmune response to a virus and it was specifically for the measles virus (MV), but not for the other viruses tested [human herpesvirus-6 (HHV-6), rubella virus (RV), and cytomegalovirus (CMV)]; and secondly, there was an association between measles virus antibodies and MBP autoantibodies (i.e., the higher the measles virus antibody level the greater the chance of brain autoantibody). Few months earlier in the same year (February, 1998), I had already found that many autistic children had antibodies to a specific protein of the measles-mumps-rubella (MMR) vaccine (MMR vaccine preparation). These viral antibodies were also related to positive titers of brain MBP autoantibodies. This was most probably the first laboratory-based evidence to link measles virus and/or MMR vaccine to autoimmunity in children with autism. Collectively, these observations led me to speculate that autism may be caused by a measles- or MMR vaccine-induced autoimmune response. Unfortunately, due to lack of funding, I have not been able to extend this research and the progress has been hampered.

As I made scientific presentation of my initial findings, a vaccine-autism connection became even more apparent. I compiled a nonscientific, anecdotal survey of vaccine-injured children with “autistic regression” or autistic disorder, as reported by families. Surprisingly, up to 93% of the reported cases had autistic symptoms shortly after vaccinations (52% post-MMR, 33% post-DPT, and 8% post-MMR and/or post-DPT). The remaining 7% of the reported cases were not linked to any vaccination at all. Indeed, if these numbers are reproducible, the data will lead to inescapable conclusion that these vaccines can potentially cause autoimmunity in autism. Quite candidly, this will not be first time that a vaccine has been linked to a disease or disorder. There is quite a bit of literature linking vaccines to autoimmune diseases. Furthermore, an epidemiological study just published in JAMA (March 8th issue) described “extraimmunization” amongst American children and considered it to be a contributing factor for the adverse effects of the vaccines. And I think the vaccines and autism connection is no exception to these adverse effects.

In summary, the rapidly accumulating evidence strongly implicates autoimmunity in autism, which in many may result from a vaccine injury. There is a possibility of an atypical measles infection in autism, but the evidence also suggests a MMR vaccine infection. Without any reservation, I would strongly recommend that this Congressional Committee reviews all the information in bipartisanship, and explore the possibility that drug companies never properly evaluated the safety of vaccines in the first place. If this indeed were true then it becomes imperative that we as a society must pay an immediate attention to this problem; otherwise, an epidemic of autism is a real good possibility. There should be no mistaking about it because autism is on a sharp rise and vaccinations, especially the extraimmunization, could potentially explain this rise. The onset of autism (or autistic regression) post-immunization should no longer be regarded as merely a coincidence with the timing of the vaccinations, as our federal health officials continue to do. We must find new ways to curbe adverse effects of vaccines, including autism. Considering a population of 500,000 cases of autism in the United States, the autoimmunity research, but not the genetic research, has already had a great impact on the health and welfare of autistic people. Since brain autoimmunity is found in up to 85% of

cases, it can potentially help an estimated 425,000 Americans. Indeed, many of them are already reaping the benefits of the experimental autoimmune therapy. Thus there is an urgent need to promote autoimmunity research in autism. This recommendation is in contrast to the opinions held by the directors of the federal agencies and major private foundations (Cure Autism Now and National Alliance for Autism Research) who are erroneously committed themselves to fund genetic research only. Finally, I urge the Government Reform Committee to provide leadership for new solutions to the existing problems surrounding autism research, and request the Committee Members to be visionary and offer new hope to the people with autism -- The essence of life is to care.

Dr. Paul A. Offit

Testimony to Government Reform Committee

Autism – Present Challenges,
Future Needs – Why the Increased Rates?

April 6, 2000

My name is Paul Offit. I am a practicing pediatrician. I am also the Chief of Infectious Diseases and the Henle Professor of Immunologic and Infectious Diseases at The Children's Hospital of Philadelphia and the University of Pennsylvania School of Medicine, and a member of the Advisory Committee on Immunization Practices to the CDC. I am also the co-author of a book entitled "Vaccines: What Every Parent Should Know". My expertise is in the areas of virology and immunology.

In addition, I have been in collaboration with Merck and Co. on the development of a rotavirus vaccine since 1992. My interest in this project is to prevent rotavirus disease. In developing countries rotavirus infections kill about 14 children every day. In fact, more children die every day from rotavirus infections than from any other single infectious disease. In the United States, about 1 out of every 75 children born will be hospitalized with severe water loss (or dehydration) as a result of rotavirus infections. We hope that by developing this vaccine we can prevent the severe disease and death caused by this virus.

My role in these proceedings is to explore the theories that have arisen due to concerns by the public that autism might be caused by the combination of measles, mumps, and rubella vaccines (known as MMR). No evidence exists that proves this association. However, three theories have been used to explain it. In the time that I have been given, I would like to explain why I think that these theories are not valid.

The first theory is that children who get the measles vaccine make an immune response not only to the vaccine, but also to their own nervous system. This kind of reaction is called autoimmunity. To understand why this theory is incorrect, we must first understand differences between natural measles infection and measles vaccination.

During natural measles infection, the measles virus reproduces itself many times in the body and causes disease. In contrast, following measles vaccination, the vaccine virus reproduces itself much less and doesn't cause disease. Because more measles proteins are made during natural infection than after immunization, the immune response to natural

infection is greater than the immune response to immunization.

If the immune response is greater after natural infection, then the autoimmune response would also be greater. If this were the case, then autoimmunity should occur more frequently after natural infection than after vaccination. Or, said another way, if measles virus caused autism, measles vaccination would lower, not raise, the incidence of autism.

The second theory is that the child's immune system is simply overwhelmed by seeing three viruses in a vaccine at the same time. Some have gone so far as to suggest that it may be of benefit to divide the MMR vaccine into three separate vaccines. The rationale behind this theory is that children do not normally encounter such an assault on the immune system. However, this notion is incorrect.

From the birth canal and beyond, infants are confronted by a host of different challenges to their immune system. Their intestines encounter foreign proteins in milk and formula. Their lungs encounter bacteria inhaled on the surface of dust in the air. And literally thousands of different bacteria immediately start to live on the skin, as well as on the lining of the nose, throat, and intestines. So how does the infant deal with this immediate confrontation to their immune system?

Babies have a tremendous capacity to respond to their environment from the minute they are born. The newborn has billions of immunologic cells that are capable of responding to millions of different microorganisms. By quickly making an immune response to bacteria that live on the surface of their intestines, babies keep those bacteria from invading their bloodstream and causing serious disease. Therefore, the combination of the three vaccines contained in MMR, or even the 10 vaccines given in the first 2 years of life, is literally a raindrop in the ocean of what infants successfully encounter in their environment every day.

Because the peak of some diseases (such as pertussis and Haemophilus influenzae type b) occurs in early infancy, it is important to make sure that children are fully immunized against these diseases by 6 months of age. This is easily accomplished. About 95% of infants will develop protective antibodies following immunization because their immune systems are quite capable of responding to vaccines.

The third theory is that the MMR vaccine is given by an unnatural route. The rationale behind this theory is that children normally inhale measles, mumps, or rubella viruses carried on droplets from another person, and do not normally have virus injected under the skin. However, encountering viruses or bacteria under the skin or within the muscles does occur naturally. To meet this challenge, children have collections of immune cells in lymph glands located strategically throughout the body. For example, lymph glands are located behind the elbow and under the arm. Because our skin can be cut, our bodies are ready to encounter challenges at any site. Indeed, although wondrous, the birth process is quite traumatic. Newborns commonly have small cuts on the face and body after passing through the birth canal. Because the birth canal is covered with bacteria, the child will encounter bacteria under the skin immediately. Our species survives because, from the minute we are born, we are quite capable of meeting challenges at all sites.

To review, I have made three points that counter the plausibility that autism would be a consequence of the MMR vaccine, or, more importantly, any vaccines: First, if autism is a

consequence of autoimmunity, then the incidence of autism would have decreased, not increased, after vaccination.

- Second, children from birth are confronted with an enormous array of different challenges to their immune system at the same time.

- Third, challenges to their immune system occur by a variety of routes.

These are medical facts.

Parents testifying here today are asking a scientific question, “Does the MMR vaccine cause autism?” Questions of science are best answered by scientific studies. And the answer to this question is already available. **Brent Taylor and his coworkers** in London have conducted a large, meticulously designed, well-controlled study that disproved an association between MMR vaccine and autism. I believe other studies will confirm Dr. Taylor’s results.

We also have to ask ourselves this question, “What is really at stake here?” In the early 1990s our immunization rates against measles dropped only about 10%. When that happened, measles outbreaks swept across the country. About 11,000 people were hospitalized and 123 died from measles – died from a disease that is easily and safely prevented by a vaccine.

My concern, and it should be the concern of this committee, Mr. Chairman, is that some parents listening to or reading about this hearing might incorrectly conclude that vaccines cause autism. This is clearly not the case – vaccines are extremely safe and highly effective at preventing serious disease and death. I encourage this committee to make that fact clear to every parent in America.

If, as a result of reading about this hearing, some parents choose to withhold or delay vaccines for their children, their tragedy could be profound. If many parents choose to withhold vaccines, the tragedy all across America could be devastating.

Let’s proceed cautiously, carefully, and scientifically.

Mr. Chairman, I am ready to respond to any questions the committee might have.

Testimony of Bernard Rimland, Ph.D.

1. Before House Committee on Government Reform

April 6, 2000

The Autism Increase: Research Needed on the Vaccine Connection

My name is Bernard Rimland. I am a research psychologist (Ph.D.) and am Director Of the Autism Research Institute, which I founded in 1967. I am also the founder of the Autism Society of America (1965), and the editor of the Autism Research Review International. My book, Infantile Autism: The Syndrome and Its Implication for a Neural

Theory of Behavior (1964) is widely credited with changing the field of psychiatry from its claim that autism is an emotional illness, caused by destructive mothers, to its current recognition that autism is a biological disorder. I have lectured on autism and related problems throughout the world, and am author of numerous publications. I served as primary technical advisor on autism for the film **Rain Man**.

My son Mark was born in 1956. It was obvious from birth that this perfectly normal-looking infant had something drastically wrong with him. I had earned my Ph.D in experimental psychology 3 years earlier and had never encountered the word autism. Our pediatrician, with 35 years of experience, had never heard of autism either. Autism was extremely rare then – it is extremely common now.

Some supposed experts will tell you that the increase reflects only greater awareness. That is nonsense. Any pediatrician, teacher or school official with 20 or more years experience will confirm what the studies tell us: there is a real increase in autism and the numbers are huge and growing. The epidemic is serious and world-wide.

Soon after my textbook on autism was published in 1964, I began to hear from other parents. Many parents told me that their children were normal until getting a triple vaccine – the DPT shot. In 1965 I began systematically collecting data on the symptoms and possible causes of autism: In 1967—33 years ago—I began querying the parents, specifically about the child's response to the DPT shot. Many had reported marked deterioration.

During the past few years the Autism Research Institute has been flooded with an upsurge in pleas for help from parents throughout the world – from wherever the World Health Organization vaccine guidelines are followed. The majority of these parents say their children were normal until getting the MMR – another triple vaccine.

Let me dispel several myths promoted by those who deny the autism-vaccine connection:

1. They claim the vaccines are safe, but physicians are indoctrinated to disbelieve claims of harm and are not trained to recognize nor required to report any adverse reactions. From 90% to 99% of the adverse reactions reported to doctors are never reported by those doctors to the government's extremely lax Vaccine Adverse Event Reporting System, known as the VAERS.

2. They say that the suspected linkage between the MMR vaccination and autism has been disproved by a study conducted by Brent Taylor and his colleagues in London, and published last year in The Lancet. The Taylor study is seriously flawed in many ways, as had been noted in a number of letters to the editor of The Lancet and in a number of additional letters on the subject which have been posted on the internet. It was subject to strong attack at a recent meeting of the British Statistical Society. I have been a full-time researcher my entire professional life, for almost 50 years, and I respectfully asked Dr. Taylor for a copy of the data so that I could reanalyze them. He refused this ordinary professional courtesy, and I have subsequently written to the editor of The Lancet requesting that an impartial committee be asked to reexamine Dr. Taylor's statistical methods. If he refuses again, I urged The Lancet to retract his paper.

3. They say that autism has a large genetic component, and therefore vaccines must play a minimal, if any, role in the causation of autism. My book Infantile Autism, published in

1964, was the first systematic attempt to marshal the evidence for genetics as a contributing cause of autism, so I am certainly not hostile to that idea. However, genes do not begin to account for the huge increase in the incidence of autism, ranging from 250% to 500% in various places. I might add that we have just reviewed all of the recent genetic studies for the next issue of the Autism Research Review International, which I edit. The results are spectacularly inconsistent. The best guess is that there are at least 20 different genes involved in the causation of autism. Gene therapy is decades off, and may be infeasible.

4. They claim that autism naturally occurs at about 18 months, when the MMR is routinely given, so the association is merely coincidental and not causal. But the onset of autism at 18 months is a recent development. Autism starting at 18 months rose very sharply in the mid-1980s, when the MMR vaccine came into wide use. A coincidence? Hardly! See the graph below.

Autism is not the only severe chronic illness which has reached epidemic proportions as the number of (profitable) vaccines has rapidly increased. Children now receive 33 vaccines before they enter school – a huge increase. The vaccines contain not only live viruses but also very significant amounts of highly toxic substances such as mercury, aluminum and formaldehyde. Could this be the reason for the upsurge in autism, ADHD, asthma, arthritis, Crohn's disease, lupus and other chronic disorders?

As a parent and as a full-time professional researcher, I am bitterly disappointed with the medical establishment's dismal record with regard to autism over the past 60 years. The medical schools, as well as the governmental agencies, have consistently supported outmoded, unproven and even disproven theories from the very beginning, and have actively opposed the most promising approaches for the treatment of autism. They supported the psychoanalytically-based theories which held the mother responsible for causing autism through her supposedly hostile attitude toward the child. They opposed the use of behavior modification, the most uniformly beneficial treatment for autism, by claiming that it neglected the deep-seated emotional blocks that were supposedly at the root of autism. They have ignored, and continue to ignore, the long series of studies conducted both in the U. S. and Europe showing that the elimination of foods containing gluten and casein from the diet brings about marked improvement in many autistic children. They have consistently ignored the series of 18 consecutive studies, conducted by researchers in 6 countries, which showed that almost half of all autistic children and adults respond favorably to high doses of vitamin B6 and magnesium., with no adverse effects. Eleven of these studies were double-blind placebo-crossover experiments. There is no drug that comes close to B6/magnesium in terms of safety, efficacy and positive research findings.

Tens of millions of dollars have been spent on non-productive lines of research, while virtually no money at all has been given to research on the methods of alternative medicine, which are far more promising in terms of both safety and efficacy.

The most interesting questions are not being asked: Why does the majority of the population survive such epidemics as autism, the bubonic plague, Legionnaires' disease, polio and AIDS, while relatively few succumb?

The answer is that the survivors have a healthy, effective immune system. Would

enhancing the immune system decrease the likelihood of adverse reactions to vaccines (including the anthrax vaccine – DOD please note!)? Very probably.

It is well known that the immune system must be adequately supplied with many nutrients if it is to function properly, including especially vitamins A, C, E, B6 and a number of minerals, including zinc, magnesium, and selenium. Nutritional levels of these substances are not only harmless, they are essential to good health. Since people do not change their diets readily, I believe that foods should be fortified with these nutrients – especially foods that will be consumed by infants and children. Research along these lines – as well as on the safety of the vaccines – is desperately needed.

As a parent and a researcher, I believe there should be a marked redirection of effort and funding, along the lines suggested above.

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ADHD/ADD - LEARNING DISABILITIES

IMMUNE DYSFUNCTION

CFS/CFIDS

AUTISM

April 6, 2000

Gentlemen,

I am Dr. Michael Goldberg, a Fellow of the American Academy of Pediatrics and Director of the non-profit NIDS Medical Board and Research Institute. I wish to thank all of you for giving me the opportunity to speak here today and for taking the time to examine the urgency of this epidemic.

I have put together a packet of articles detailing my scientific hypothesis and current treatment philosophy. I suggest they be included in the record. I have also provided information on the emerging science and technology describing Neuro Immune Dysfunction whose common pathway is involved in many immune or autoimmune diseases including the development of the Autistic Syndrome. We finally have an understanding of how the brain interrelates with the endocrine and immune system. We are confident that we can apply this new understanding rapidly to evolve a treatment plan within the next six to twelve months, through an unprecedented blend of private enterprise and government-supported research.

The purpose of this hearing is to investigate why we have a large increase in this phenomenon that we have called autism. But to understand that, one must step back and look at the increased understanding and incidence of auto-immune disorders across-the-board, from the early/mid

1970's, when I completed my medical training, to the present day. All one has to do is look at the medical literature to realize that nearly every disorder we have associated as immune connected, immune-mediated, defects in the immune system - lymphoma, multiple sclerosis, Alzheimer's, lupus, Ulcerative colitis, rheumatoid disease, and even aging - have all become recognized as in part autoimmune diseases or illnesses where the friendly fire of our own bodies causes the damage as my colleague Dr. Galpin, an infectious disease and immunology authority, often is quoted to say.

If we are going to save this generation of children from a lifetime of suffering the incurable stigma of being diagnosed with autism and other cognitive delays, we must rapidly realize that all of these disorders result from a treatable rather than untreatable disease process. As written in the enclosed articles, and as a pure basic fact of science, it is medically impossible to have an epidemic of a genetic or developmental disorder. Further, while many have spoken of an "epidemic of autism," the truth is: the disease process many of these children have is not autism (as taught to physicians 30 - 40 years ago).

If a child is born developmentally miswired, "damaged", something happened in utero. But, a child cannot learn to speak and use language and then lose these abilities if the cause of their disorder is developmental, structural, etc. Such a child cannot respond to treatment and become a regular child once more, as has been the case in my practice over and over again, if the cause of their disorder is a "fixed" process, congenital or genetic disorder. It has been repeatedly apparent that 4, 5, 6 yr. old children are starting over where they left off at 18 months, 2 years of age. Parents who were told their children would never talk, could never be social, could never have feelings, now have children who are normal functioning or who are still struggling to catch up and get back to that fully normal functioning child, in either case these parents can see or are beginning to see a future for their child. It is my intent and hope in the time I have here, and through the articles I have submitted, to sow the realization that we are not talking about saving the next generation of children, but rather that we must focus our efforts on saving this generation of children before it is too late. The ramifications are enormous.

At the end of a research symposium in October 1997, one which brought together top researchers from around the country to discuss Alzheimer's, adult dementias, social brain, and Autism/Pervasive Developmental Disorder (PDD), this statement was made: if a child developed normally during the first twelve, fifteen, eighteen months of life, developed any language/words, and then somehow went into the autistic spectrum, it was a 100 percent certainty that the process had to be immune/viral. IF a child developed normally the first 12, 15, 18 months of life and had NO words, 99% it was an immune / viral process, and no one there could rationalize any other possible mechanism.

While there is ongoing controversy regarding past brain biopsy findings and their implications, if any, to this generation of children, we do have NeuroSPECT Scans, which show reproducible, quantifiable blood flow in the brain. Blood flow corresponds directly to function. When NeuroSPECT Scans of children diagnosed as autistic/PDD have been correlated with MRI's and CAT Scans, the combination consistently shows no pre-existing damage to the brain, but rather points toward an immune shutdown consistent with that found in adults with Chronic Fatigue Syndromes and other adult dementias and with children diagnosed as quiet ADD and mixed ADD.

I stumbled into the field of autism somewhat by accident. My wife had had Chronic Fatigue Syndrome for over ten years. Jokingly, my son asked me "Why are you sending Mom all over the

country to doctors? Why don't you just fix her?" That began my journey into clinical research. It rapidly became apparent we were dealing with some component of the immune system, an autoimmune like reaction. During that time, as I was investigating all options for my wife, a few "Autistic" children were referred to my practice. Much to my surprise, these children had blood work comparable to that of my wife and other adults with this undiagnosed disorder, and to that of children I had been seeing diagnosed with quiet ADD and mixed ADD. I remember thinking then, "What could the immune system have to do with autism?"

Paralleling this, beginning in the 1980's was the initially slow, now epidemic incidence of disorders in children labeled as Autism/PDD and the increase of reports of autoimmune diseases in the animal literature, of altered ecological balance, immune system abnormalities in various species. We either have to assume that this increase of disorders in the human population is mass-hysteria, mass-psychosis, schizophrenia, and/or behavioral developmental disorders in children or we must step back and realize that maybe we have a large number of adults and children suffering from a disease process that is affecting how their brain and nervous system functions, in ways that physicians had never understood (or had the technology to understand). I have family after family within my "new" practice in which there is a mother or father with Chronic Fatigue Syndrome, an older child with ADD/ADHD, and a younger child or two with Autism/PDD. As noted, unless we assume this is all random, there is unfortunately a logical connection between the above disorders and their rapid emergence as a crisis.

We are looking at what appears, supported by increasing data and reports in the literature, to be auto-immune, Neuro-immune disorders or what my associates and I have termed Neuro Immune Dysfunction Syndromes or NIDS. If you are an adult with an intelligent, developed brain or an older teenager, when this process attacks, you will likely end up being diagnosed with the illnesses known as Chronic Fatigue Syndrome, Adult ADHD, etc. If you are a younger child, five, six, seven, or eight years old when this process is triggered, with some cognitive, social and language capabilities already developed, you will likely develop what is called quiet ADD or mixed ADD. If you are twelve, fifteen, eighteen months old, however, when this process begins, you will have barely begun to develop cognitive, language, and social skills and you will wind up with what has been called Autism/PDD.

The good news is that this concept is supported by common sense medical logic. The bad news is that we must unify and focus efforts or we will continue to see more adults that are supposed to be paying taxes and earning a living, finding themselves on welfare, unable to function, unable to produce. Even graver is that if nothing changes, we are currently raising an entire generation of children to this fate.

There is hope. Research from many prominent institutions support the idea that the brain is pliable at least into adolescence, maybe into early adulthood. It has been my rewarding experience as a pediatrician to see five, eight, ten, and even a twelve year old boy who could not talk, begin to use language. Parents who were told their child would never be independent, never be able to earn a living, and who one day might have to be placed in an institution, have seen their children become top of their class academically. I have children within the practice scoring in the 97th, even the 99th percentile on California and Illinois state testing.

The potential multiple triggers for this illness, we are calling NIDS, will need many, many years of ongoing research to learn how multiple factors such as stress, viral, or environmental may play a role. The key is to focus treatment efforts, rapidly, effectively – NOW – to keep from losing an entire generation of children while the ultimate "answers" are still being investigated. We can use

technology to accurately define “subgroups” of these children and adults now, setting up the possibility of new therapy approaches in as little as the next 6 – 8 months, rather than after years of further investigation and study. Technology exists to help these children and to help many of the adults out there to become productive individuals again. At this time, as noted in the enclosed articles, I have been using a combination of diet elimination, anti-viral therapy, anti-fungal therapy, and application of low-dose SSRI’s (Selective Serotonin Re-uptake Inhibitors), based on our NeuroSPECT findings, immune markers, and viral titers in these children. Thankfully, I have had many children return to normal and above-normal functioning, but this is not yet fast enough, simple enough, or perfect enough. This may be a holding approach thus far wherein balancing the many neurological immune regulating proteins known as cytokines and chemokines may in turn rebalance behavior itself. As many others are noting, I would propose there is a future for logical application of “alternative” medicines and combination treatment protocols with good pharmaceutically pure agents and medications.

In 1996, I was a speaker at the Autism Society of America Conference. Approximately 2000 parents and professionals gathered for this event. My wife, milling around, questioned me "Where are the doctors? The M.D.'s?" Sadly she had figured out the truth in a matter of minutes. The medical community had abandoned these children once they became labeled as "Autistic." These children were regarded as defective, mentally un-trainable, even retarded!

Sadly, with the label of autism, many children were not even given a simple blood test for anemia/iron deficiency (a simply-counteracted, possible cause of brain dysfunction). Reviewing case after case of children labeled as having Autism/PDD, I am horrified at how little has been done medically for these children, as they are not considered to be “normal.” Their pain, their misery, their "illness," goes essentially unrecognized. Many are thought of as insensitive to pain, but how many are actually just “numb” to the pain that their brain/system is constantly in? Simple steps that could be taken, are not taken to help these children or their parents.

I have been fortunate to work with Dr Israel Mena and Dr. Bruce Miller, who helped show through NeuroSPECT Scans, that these children had a physiological dysfunction going on in their brains. For the majority, there was a decrease in blood flow and function of the temporal lobe of the brain consistent with that predicted by neuro anatomists. I have many, many more scans that show the same decrease in blood flow. I would shudder to think of what dysfunctions you might have if your brain had lack of blood flow in those areas. In fact, if one listens to an adult with Chronic Fatigue Syndrome, or the "typing" of a child unable speak, one can only begin to imagine how truly horrible this is.

Many of these children have a low number of Natural Killer (NK) cells, which are a more primitive immune system cell, responsible for clearing “radicals” in our body, clearing foreign cells / cancerous cells, and considered a strong marker for a healthy or stressed immune system. These cells, when low in number, are now linked to viral reactivation in many auto-immune illnesses, and low NK cells has become an extremely strong marker in a subgroup of these children with NIDS.

Another frequent finding is the likely presence of an active HHV-6 virus (a human herpes virus) or other related Herpes viruses in these children. Similar findings are also being reported for various adult auto-immune disorders and recently even the Center for Disease Control published an article focusing on our emerging knowledge of HHV-6 related disorders.

The issue of vaccines is an important one. Again, one must understand the problem in terms of the new altered immune state (part of the bigger picture), rather than necessarily the vaccines themselves. Most doctors would agree that not vaccinating in this country would be a disaster. As I remember the Academy of Pediatrics and the fights in the 70's over the DPT vaccine, in the end the statistics of children supposedly damaged by the vaccine were no more than the "natural" incidence in life or 1 in 300,000. In fact in England and Japan, where for a time the DPT vaccine was stopped, the incidence of pertussis (whooping cough) resulting in serious illness and death, far exceeded any possible "vaccine connection." Likewise, in discussing the current "Autistic" / NIDS epidemic, while there may be a possible "triggering" factor with Rubella, Measles, "multiple" vaccines, one must understand this as only one of a possible combination of stresses causing dysfunction, within the concept of a preexisting "immune reactive" or "stressed" state. Vaccines (by themselves) remain an unlikely cause of Autism.

BUT injecting common sense, general awareness of health and appropriate "past" considerations of separations of vaccines, "stresses", choice of age, etc might save untold children potential reactions/disasters. Consistent with the question of whether there is a peculiar or unusual immune reactivity when a child is younger, waiting till a child is 3 or 4 could not be faulted, but with ongoing measles outbreaks occurring at times, it is not something easy to recommend routinely at this time. Infancy unfortunately represents a child's most vulnerable time to measles (but there is no real risk from rubella or mumps at that age).

Any injury or loss of a child that could have been prevented remains unacceptable. There is no way to adequately console the parent of a lost or damaged child. If "focused" correctly, we do have the ability to accelerate understanding and identification of potentially higher risk children. That would help immensely in considering the risks versus the gains of modifying vaccination schedules, diet advice, treatment choices, etc. We must work together with organized medicine and the pharmaceutical companies as allies to solve these questions, not as" adversaries, fighting to defend principles, which in the end we all believe in.

It has been my personal experience within the practice to literally have "high risk" children with "one foot in, one foot out" of the NIDS disorder, and prevent it from becoming full-blown Neuro immune dysfunction solely through use of "preventative" pediatrics. Via dietary eliminations, selective usage of antihistamines, "bacteriostatic" antibiotics (when indicated), aggressive allergy prevention and "health maintenance" providing a simple, preventative program to a seemingly-increasing number of families with high-risk factors for NIDS. While only an anecdotal observation, to date, NO family with whom I have instituted a preventative program for NIDS has had another "autistic spectrum" disorder child.

The bottom line is that these children have a disease, open to fascinating research on all its potential causes and triggers, but one that currently warrants and deserves immediate medical intervention. In my clinical practice, "miracles" seem to be happening routinely. One must realize, recoveries and significant cognitive improvements could not happen IF these children were truly born "defective" - thankfully, they were not. I have an increasing number of children who have been with me 2 or 3 years now and as they return to their regular pediatricians for their annual checkup, their pediatricians are seeing the children growing better and developing better, motor, body and brain wise. In a nice manner, while still not understanding this process (but smiling at the child they see before them), these pediatricians are advising the parents to continue therapy, as I continue to monitor medications appropriately.

A child I began treating at five is now in sixth grade, getting straight A's, was the Vice-President of his 5th grade class – not how most people view an autistic child. I have an increasingly large number of these children where "academics" are the least of anyone's worries for the child. Many are in regular if not honors classes and many are happy, well adjusted, indistinguishable from their peers. In reality these children are likely just the opposite of what this country and the world of medicine had come to think of them: as retarded, unable to develop fully, with some hope of compensation, but not real treatment or recovery (for one can not recover from a developmental disorder). Recovery and improvement in my patients, as previously mentioned and as explained in the attached articles, has been accomplished through a combined program of dietary elimination, anti-virals, anti-fungals, and low dose SSRI's. I have attempted to do this following good pediatric principles, while "combining" steps/therapies based on the emerging science of "Neuro-immune."

This past week a mom came in and told me her 5 yr. old child (who has been with me about 8 months now), said to her, "Mom do you want to pretend I can't talk? REMEMBER when I couldn't talk?" We have so misunderstood and misjudged these children. What harm are we doing to these children as a result?

If we can channel the technology that we have today and employ immune modulating agents, we could begin objective testing of new therapy protocols in as little as 6 – 8 months, with one (or more) related agents. Immune modulators, will give us the tools to regulate the Neuro-immune system as has never before been possible, help to create a "normal," essentially healthy state. A healthy immune system has the potential to "normalize" brain function, enabling the brain to turn back on and begin developing again.

If we can focus a unified effort to identify the specific immune markers (e.g. low natural killer cells, high alpha interferon's, high or low cytokine / chemokine profiles) that will let us understand which patient is the most likely candidate for which immune agent, separate this "mixed" population of children into logical subgroups, allowing more rapid understanding of vaccine or other potential related factors, and if we can proceed with the linking of a country wide, potentially world wide network of NeuroSPECT centers, to our already existing database of NeuroSPECT scans, the immediate pay-off will be to have a chance at saving this generation of children.

There is good, solid science in the NIDS Hypothesis. It has been reviewed and verified by at least four pharmaceutical companies to date. We need to see the urgency of this situation: we are already spending approximately 13 billion dollars annually on Autism and related disorders and this figure is projected to be significantly more in the near future. In reality, if treated young enough, most of these children could still become healthy, productive members of society, with full, rich lives of their own. I would dare say, many of these "Autistic" children are in reality supposed to be this country's "future" leaders, having starting off with that capability and background, and not as "defective" children (as had been previously thought). With the reported 263% increased incidence of autism in California, and a 500% increase in Florida, among other statistics, I cannot emphasize enough that we are truly losing a generation of children.

What may have often been presented to you as impossible or can't happen, in reality, can happen, but to occur, we must approach this as it's never been done before. In the normal course of medicine, with multi-million dollars of research, this is a slow evolution that will take an estimated five, ten years or longer to come together, to even begin to think of how can we treat

this and deal with it. Within the NIDS Institute, our researchers, who are all heavily-credentialed, many are involved in current NIH and other activities and, with the NIDS Hypothesis, there is logic that says we can take this knowledge, these abilities, unify other researchers in institutions across the country, using technology, instead of being limited to colleagues or materials available within a given institution. We can literally pick-and-choose top people around this country, around this world to focus on this as the true crisis it has become. With that ability, we can look at applying these new therapies, new agents, within the next six months to a year at most. Instead of thinking about what are we going to do for the future, we can change this now.

I plead with you, Mr. Chairman and members of this Committee. These children are supposed to be a productive part of our country's future, not a health cost and burden. These children have the potential for full, productive, intelligent lives; contrary to the old idea, their genetics are not the determining factor. A child can NOT develop normally, develop some language and lose it all except in a disease process. We can apply good sound science and logic to help solve this crisis NOW. Unless we act NOW, we will continue to lose this generation of affected children, and will potentially watch the "bankrupting" of our current education and social system. Today's ill children cannot wait for the "normal" path of academic science to catch up (it has begun to move in the right direction, but all too slowly). We must leap forward in a way/model never done in medicine before. I am extremely fortunate to have three healthy children and one grandchild. I selfishly want the rest of my future grandchildren, all of yours and others out there, to have the same chance.

Thank you.

Michael J. Goldberg, M.D., F.A.A.P.

John E. Upledger, D.O., O.M.M.

An Etiologic Model for Autism

The following model was first formulated based upon hands-on experience with autistic children, historical information gained from their parents, observations of the children's behaviors, their responses to treatments, and our laboratory results.

During the normal, physical growth period of the child's brain and cranium, it is necessary that the meningeal membranes that line the cranial vault and cover the surface of the brain grow and expand in synchrony with the growth of these structures in order to accommodate the natural maturation process. For some reason the meningeal membranes, especially the dura mater, lose their accommodative growth abilities, thereby disrupting the normal expansion of brain and cranial vault. This loss of accommodative quality of the dura mater is most likely due to biochemical changes in its make-up. These biochemical changes may be the result of febrile stressor episodes for any reason, such as viral infections, vaccine reactions and so on.

The manual stretching of the restrictive dura mater by the use of CranioSacral Therapy techniques has provided impressive improvement in autism. The therapy must be continued until the child has reached full growth, because once the dura mater has lost its accommodative ability, it must be physically stretched by a therapist. CranioSacral Therapy accomplishes this task non-invasively by using the various related bones to

which the dura mater attaches as handles to stretch the membranes.

Background

In the fall of 1976, as a clinician-researcher at Michigan State University (MSU), I began a study of autism at the Genessee County Center for Autistic Children in Flint, Michigan. My co-investigators included Ernest Retzlaff, Ph.D. in neurophysiology, Jon Vredevoogd, M.F.A. associate professor of design at MSU, and a wide array of graduate students in the MSU colleges of osteopathic and allopathic medicine, as well as a few in the department of psychology. Our research project lasted three school years (September – June). We worked onsite two days per week during these school years. The center for autism was a day school and it was closed during the summer. We consistently averaged 28 to 30 autistic children in our program. About two-thirds of these children were in this study for at least two of the three years.

The grant support for the study was awarded on an annual basis. It is my understanding that the monies originated from NIMH and were funneled to me as principal investigator via the state of Michigan and Genessee County. The funding ended at the end of the third year quite abruptly. My understanding at that time was that the state chose to put the monies into other more pressing projects. I was told by the Genessee County officials that autism was not the highest priority and that the tax base in the state was not very stable.

During these three years and subsequently, I saw private patients diagnosed as autistic coming from a variety of sources. These children were seen at the university clinic.

After leaving MSU in 1983 I moved to Florida where, in 1985, we founded The Upledger Institute. During the interim, 1983 to 1985, I developed a prototype wholistic healthcare center for Unity Church of Palm Beach. During this period with Unity Church I treated only a few autistic children. Shortly after The Upledger Institute was begun we developed a one-week intensive treatment program for autistic children, which is still in operation. It is offered three or four times each year for only autistic children. The program is a five-day week, with approximately six hours per day of hands-on treatment. Parents are included and offered training in the treatment and management of their autistic children.

Since the beginning of my work with autistic children, CranioSacral Therapy has been the main therapeutic focus, coupled with nutritional supplements as they seem indicated.

Observations

Since my first experiences with autistic children I have made several observations that have been consistent and have influenced my concepts of etiology and therapeutic management.

These observations are as follows:

1. Historically, the onset of autistic behaviors is often preceded by some sort of febrile episode. This febrile episode occurs most often about two weeks prior to the parent noticing behavioral changes. However, the time between the fever and the onset of noticed symptoms may vary from a few days up to a few months. Certainly, the length of time reported is dependent upon the powers of observation by the parents, their level of denial and so on. The fever could be resultant to viral infection, a vaccine reaction or any

other cause. Our historical information comes from parents interviewed by me personally in the US, Canada, England and Belgium. In all of these places I took histories from parents. I also evaluated the children from a craniosacral system perspective.

2. Some of the behaviors observed in autistic children are attempts to change/correct physiological and/or anatomical dysfunctions that may be causing pain or discomfort. Many autistic children are known to bang their heads, chew on their wrists and/or the bases of their thumbs until deep tissue (tendon sheath) is visible, and/or they may suck on their thumbs so vigorously that the front upper teeth begin to displace forward. Actually, these thumb-sucking children are pressing on the roof of the mouth as hard as they can.

We have observed that, when specific corrections of the craniosacral system are successfully carried out, these behaviors spontaneously cease. It is my opinion that the head-banging child is trying to release a compressive force in the head that is quite painful. When we release this compression, head banging stops. This compression is from the front to the back of the head.

Regarding the chewing on the wrist and thumb base, there are three theoretical possibilities that may be valid. First, this self-mutilating activity may be a substitution of a controlled pain that overrides and is more acceptable than a head pain that is not controllable. Second, the self-mutilation may also serve to stimulate the synthesis and release of the natural pain relievers (endorphins) that are nature's way of offering relief from pain biochemically. Also, there is a gate theory of pain developed by Melzack and Wall that suggests that, when the quantity of pain impulses coming into the brain exceeds an upper threshold, all impulses are blocked from entry into pain-perception centers in the brain. The autistic child may have found that when he/she inflicts more and more injury/pain upon himself/herself, the pain is no longer present.

I have seen consistently that, when we are able to release reactions of the membranous lining of the floor of the cranial vault in a front to back direction, these "autistic" behaviors (listed above) disappear "spontaneously."

3. It was consistently observed that CranioSacral Therapy directed at alleviation of abnormal transverse (side to side) compression of the cranial vault resulted in the child immediately demonstrating love and affection. The child will often hug and kiss the therapist after the compression has been released. Subsequently, improved socialization is often demonstrated by showing love and affection to parents and caretakers, as well as beginning to interact with other children and adults, whereas previously their interactions were with inanimate objects. Additionally, during the CranioSacral Therapy session the child often releases a lot of emotion.

4. Thermographic monitoring of the autistic child's hand during successful but basic CranioSacral Therapy sessions demonstrates hand warming, often as much as 2 to 3 degrees Fahrenheit. This offers evidence of increased blood flow to the hand resultant to the CranioSacral Therapy that is applied to the head. The increased blood flow is necessarily related to relaxation of the autonomic (sympathetic) nerve control of the blood vessels. This sympathetic nervous system relaxation results in a reduction of internal physiological and emotional stress factors.

5. It has been noted that most autistic children are very shallow breathers. While working

at the Genessee County Center for Autism, I had the children breath 10% carbon dioxide in 90% oxygen for about five minutes in the morning, five days per week. This seemed to enhance the breathing activity for an extended period of time after the five-minute session was completed.

6. Hair analysis for toxic minerals was done on all children in the Genessee County study. We could see no consistent patterns of abnormality in mineral levels in the hair of the children.

7. Extensive blood analysis was done on all children in the Genessee County study. This analysis included standard blood-cell counts, routine blood-chemistry studies, isoenzyme studies, and protein electrophoresis studies. No consistent patterns of abnormality were seen.

8. Ultimately, all of our examinations consistently revealed that the intracranial membranes were very tight. Our findings suggested that for some reason the meningeal intracranial membranes, especially the dura mater that is very tough and waterproof, were not expanding along with the normal growth of the skull bones and the brain. I tested this concept by examining 63 children who had been rated as either autistic or childhood schizophrenic by Dr. Bernard Rimland who directed the Child Behavioral Research Center in San Diego. I had seen none of these children, nor their records, previously. I was able to pick out the autistic children from the sample with over 90% accuracy simply by manually evaluating each child's craniosacral system.

9. Favorable responses to CranioSacral Therapy were often lost when there was no treatment for three or four months. This suggests the lack of growth of the dura mater while the skull and brain grow as a contributing cause for autism.

Suggested Conclusions

The aforementioned observations, coupled with the observed clinical responses to CranioSacral Therapy, suggest that compromise of the accommodative quality of the intracranial meningeal system, especially the dura mater, to growth of the skull and brain is at the very least a large contributor to the problems of the autistic child. The dura mater can be stretched by the use of CranioSacral manual techniques applied to the external surface of the cranium. This work affords some relief from the membranous restriction imposed upon brain and skull bones. The treatment must be continued regularly because the accommodative enlargement of the membrane compartment is quickly used up as the child and his/her brain and skull continue to grow.

The Treatment

The treatment that I suggest is regular CranioSacral Therapy until the child is fully grown. This treatment is best administered on a weekly basis. However, it can be administered at longer intervals if close watch is kept for signs of regression. When these signs do appear, treatment should be resumed. If signs of regression appear, it may take up to five or ten sessions to re-establish the accommodations for brain and skull growth by the dura mater membrane. On a weekly basis, one treatment is usually enough to maintain favorable growth conditions.

It is also suggested that nutritional supplements be given in order to ensure the restoration

of vitality of a brain that has been compressed for a significant amount of time. Among the suggested nutrients are B complex, B12, docosahexaenoic acid (Neuromins), alpha lipoic acid, and a good multivitamin and mineral preparation.

We have had some success in teaching parents to treat their autistic children using CranioSacral Therapy. This offers them some degree of independence from geographical location requirements near CranioSacral Therapists. If the child shows reasonable progress using parental treatment, we suggest re-evaluation by a skilled CranioSacral Therapist about every six months.

**Testimony of
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Before the

House Committee on Government Reform

April 6, 2000

Mr. Chairman, Thank you for the opportunity to present testimony concerning Autism Treatment Options and Research. I am here today as director of the Indiana Resource Center for Autism located at Indiana University's Indiana Institute on Disability and Community and as a member of the Board of Directors of the Autism Society of America.

I would like to begin by commending this Committee for directing its energies toward today's hearings. For too long, individuals with autism spectrum disorders have not had their voices heard. While I have the attention of the Members of the Committee, let me urge you to do two things that will help. First, please send a letter to your colleagues at the Appropriations Subcommittee that funds the Centers for Disease Prevention and Control (CDC). Ask them to provide the proposed funding to expand the CDC's work in gathering national data on the prevalence of autism. Second, join 41 of your Colleagues in co-sponsoring H.R. 3301, an omnibus children's health bill that provides clear direction to the CDC and the National Institutes of Health for speeding up the research and public education in autism.

The increasing incidence of autism has generated a renewed and much needed focus on autism spectrum disorders. As the incidence increases, research into both the causes and effective treatment options becomes paramount. Across the United States, families are struggling with the many challenges presented by a family member with autism and the systems which are needed to support him/her. Below are a few comments which reflect major issues often heard. These major issues include, research into potential causes, early intervention, insurance coverage/funding mechanisms, adult options, and trained professionals,

Research into Potential Causes. Autism is referred to as a spectrum disorder to highlight the differences among a population who share a common diagnostic label. Just as these individuals differ in their characteristics, so may they differ in the causes of their autism. It seems clear that autism is a genetic disorder. Children are born with a genetic predisposition for developing the characteristics of autism. At some point prior to, during or after the birth process, something occurs that triggers autism to occur. Potential triggers include environmental factors, illness, complications during the birth process, or factors related to diminished immune systems. One of the triggers that is being considered and discussed by families is the measles-mumps-rubella (MMR) vaccination. While this is not a statement in support of eliminating vaccinations, it is a plea for examining this potential relationship and for developing ways in which to more safely vaccinate children. The hope in examining potential causes is two-fold. First, the idea is that if the cause can be found, a cure will soon follow. While finding a cure may be in the distant future, research into potential causes can have a more immediate impact. If causes are found, such as the MMR vaccination, that can be dealt with immediately, we may be able to prevent numerous families and children from being affected by autism. However, I encourage the committee to support research which will look broadly at potential causes.

At the same time, I would like to speak to the federal framework of support for those 500,000 individuals currently diagnosed with autism spectrum disorders and their families. These individuals and their families can benefit dramatically from early intervention, special education, and adult services. Yet, there are many barriers to their ability to secure such supports.

Early Intervention. The National Academies of Science and the National Institute on Health are to be applauded for their efforts in examining the status of research related to educating young children with autism spectrum disorders. While there is generally professional agreement regarding essential features of intervention for children with autism spectrum disorders, there is less agreement regarding the "best" specific program. The hope is to be able to identify treatment approaches which will have the greatest long term impact and which are responsive to the core deficits of autism spectrum disorders. Based on testimony provided by leading professionals to the National Academies of Science, it is clear that additional research is needed to determine critical features of programs.

Full Funding for IDEA and Professional Development Efforts. In a recent report, it was noted that 44 out of 50 states are not in compliance with the "free and appropriate education" mandate of the Individuals with Disabilities Education Act (IDEA). While the reasons for this situation may differ in each state, we do know that states need financial support when mandated to provide services.

While IDEA authorizes funding for personnel development, the funding allocated is not sufficient to meet the need. As the incidence of autism grows, we are encountering a stark gap between the demand for trained personnel and the availability of teachers and medical professionals who have had training in how to identify and respond to individuals with autism. In some cases, professionals with little or no training are taking primary responsibility for the education of children who challenge the most trained professional. Across the country, families cry out for training of pediatricians and other medical personnel. Physicians are often the first source of information for families whose children are newly diagnosed. They have a tremendous responsibility for starting parents on the right track. In order to do so, physicians must have more and better information related to diagnosis and treatment.

Insurance Coverage/Funding Sources. When faced with the high cost of interventions, therapies, medications and other necessary support services, families look to state and local agencies for financial resources, and/or to their insurance companies. Often times individuals with autism spectrum disorders are not eligible for insurance coverage. For example, one individual was ineligible for insurance coverage for an appendectomy because autism was considered a pre-existing condition. In other words, even though a physical illness is completely unrelated to autism or its behavioral manifestations, sometimes individuals with autism are denied coverage. This policy is based on a very distorted understanding of what autism spectrum disorders are and how they affect a person's physical health. When faced with the high costs of medical care, therapies, medications, and other treatment approaches and interventions, many find themselves mortgaging their homes to ensure that their child has the best possible care. The financial and emotional toll on the entire family is enormous. Families then turn to other state and local agencies for financial support. These resources are scarce, and in some states non-existent. Families are told that they have a window of opportunity in which to intervene with their child. When resources and services are not available during this critical time period, families are willing to risk financial devastation. The end result is tremendous stress on their marriages, and intense levels of personal stress in coping with their child's autism. And again, this impact is felt by the entire family, including siblings and grandparents.

Employment and Supported Living. Today, a high percentage of individuals across the autism spectrum remain unemployed. When employed, they are often either under employed or in jobs which do not match their talents. Some of our most talented individuals face a life of poverty. For others, living options which allow them to reside in their community and receive needed support is only a dream. While progress has been made in this arena, much is still left to do.

Conclusion

While I commend the Committee for taking this opportunity to listen to families today, I also urge you to support authorizing legislation and appropriations provisions that would further the state of autism research. Support Congressional efforts to fully fund IDEA, providing the supports and services that students with autism need, including adequate training for education personnel. We need better training for medical professionals, more opportunities for employment and supported living, and access to health care coverage. While much progress has been made, there is still much to do.

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April 3, 2000

Honorable Dan Burton
Chairman
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Washington, DC 20515-6143

Dear Representative Burton and Colleagues:

Thank you for the opportunity to testify on the topic of autism. I am speaking as the brother of the late Kenneth Wade Cook who had many of the problems of children and adults with autism, as a physician who cares for many patients with autism, and as a researcher trying to increase our knowledge of the causes of autism and to increase our ability to treat this devastating disorder.

I recall being an 8 year-old boy with a 2 year-old brother that my family had just realized was not developing normally. I remember the pain of my parents vividly. I further recall that we went to a meeting where, to my recollection, we were told that "patterning," a special diet, rebreathing through a mask, and related methods still practiced today would cure his problems. I remember our family being skeptical for part of the meeting. By the end of the meeting, we and the other families in the group were sold on this treatment because it was too painful to accept what we knew was happening. If there is anything I have not forgotten, it is that hope is something essential in working with children with severe challenges. I am thankful to those who were interested enough in children to spend so much time with my brother and my family. They knew that providing us the tools to work to teach my brother the basics of communication and motor skills was helpful and I suspect that many of them were practicing this method for the same reason we were. They had to try.

I could complain about the 5 AM mornings in which it was physically exhausting to perform the patterning, but I'm sure it was at least good training for the schedule of a physician-scientist and provided a shared task for our family. However, I'm not pleased that there wasn't more time spent teaching me to play with my brother instead of trying to teach him to read, when it wasn't close to being an appropriate next step. Our family learned to accept and love my brother deeply. I am thankful that children today more opportunity for education due to Congressional legislation. Excellent community support

was vital to my family during my brother's last years in St. Louis. Mostly I miss him since his death at the age of 29. His death remains as unexplained as his original problem, although the two are likely to be related. It reminds me that there is mortality as well as morbidity associated with autism and related developmental disorders.

We have an extremely long way to go to provide full access to adequate care for children, adolescents, and adults with autism. It is very difficult to confront attitudes as a physician that I only suspected as a child. Insurance companies, state agencies, school administrators, and other physicians continually turn away from caring for people with autism. Much more attention is given to paperwork than provision of care and services. This is not the main purpose of our meeting today, but I can not speak without mentioning this. Although many of the most severe problems are emotional and behavioral, insurance companies discriminate against the best treatments by the most qualified providers, with the result often being time lost from work for parents, depression in parents, and most importantly, suffering would otherwise be treatable.

The needs of the patients and problems in the systems of care and education have seemed overwhelming since I started my practice in the mid 1980s, so the thought of an increase in the prevalence of autism is probably something I wouldn't want to confront. However, comment on changes in systems that are largely responsible for the apparent increase is appropriate. An increase in autism in Illinois schools has been cited as evidence a rise in autism prevalence rates, but autism is still underestimated in Illinois schools. The increase is based on the introduction of autism as a possible educational classification in autism. In addition to many educational systems not recognizing autism, many diagnosticians didn't recognize it in the past. Autism spectrum disorders are only beginning to be accurately estimated. Based upon its widespread ethnic distribution, it has most likely been challenging people with autism and their families for thousands of years, but it has taken us this long to recognize what it is. Thus, the committee's ongoing work is important and a sense of urgency is necessary to catch up for lost time.

This brings to mind the medical saying, "first do no harm." One harm worse than doing nothing was blaming mothers because of their physical and emotional closeness to their children. Not only were individuals hurt by blaming mothers for their child's autism, but we probably lost a couple of decades following an impression of causation rather than focusing on the same science that was leading to improved treatments in cancer and heart disease. Without evidence to support a relationship between vaccinations and autism, we need to be careful about wasting precious resources on another case of guilt by association. Mothers were guilty because they were physically close to children with autism. Now vaccinations are being blamed largely because they are given at the same time as the regressions that occur for a substantial minority of children with autism (between the first and second birthday). Certainly, GI findings that have not been demonstrated to be specific for autism do not provide support for MMR vaccinations as a cause of autism. Data may be provided today which are credible in support of a connection, but the data to date do not support the hypothesis of MMR vaccination caused autism.

It has been a privilege to be involved in the development of new treatments for children with autism. Lost in the media's overfocusing on "miracle" cures over the more than three-and-a-half decades I have been involved, are small changes in our available treatments. Although limited to improving aggressive behavior, anxiety, and depression,

medications that potently inhibit the reuptake of serotonin into nerve terminals (SSRIs)(e.g. Prozac, Luvox, Paxil, Zoloft, Celexa) have provided the first medication class that reduces the core symptoms of repetitive behavior leading to distress for many people with autism. Of course, it isn't enough, but it demonstrates that improvements through development of effective medications are possible. As far as research challenges and needs are concerned, pharmacological treatment research needs to be enhanced so that we have better data about whether each of these drugs works in autism, for which symptoms, at what ages, and for which patients. In addition, it would be extremely helpful to know which patients will worsen on small doses and what treatments to provide such patients.

As many know, not all of our attempts to improve treatment have been successful. A relatively classic story is that of fenfluramine, originally thought to raise I.Q. and reduce symptoms of autism. After considerable work, fenfluramine was found to be a good placebo. Although we were hopeful that secretin would be serendipitous powerful treatment, at least two carefully controlled trials have shown it to be similar in effect to fenfluramine in providing a good placebo effect. Further studies are ongoing to make sure a positive effect is not present under certain circumstances, but it may be about to end up as part of the long history of good, honest attempts to hit a home run in autism treatment that struck out. There is no reason not to try, except that we have to be careful about the risks to the children and the costs to the families if we overly promote treatments without evidence from controlled trials.

There is a problem when thousands of doses of secretin from pigs could be administered to children with claims of benefit while clinical trials to study safety and efficacy were being delayed by federal policies against expediting research review for secretin clinical trials. This ironic situation allowed the supply of secretin to be depleted, thus delaying initiation and completion of our multi-site trial.

Having several hats as brother, physician and scientist can be very painful. I recall my anger as a child when investigators found that patterning wasn't effective. How could they do such a thing and how could I now be in their shoes in contributing to data about the lack of efficacy of secretin? All I have to say is that I shed a tear when the data were analyzed for secretin, much as I shed many tears when I came to the realization that "patterning" was not going to let me know my brother without his severe problems.

I suppose it is obvious why so much of my time is devoted to research reaching down to basic mechanisms. On the one hand, I am desperate to improve the situation for my patients, many of whom are reminders of my brother. On the other hand, for some of my patients I have seen medical treatments provide relief I didn't think possible before our first use of Prozac in autism shortly after its release in 1988. By the way, there is no reason to have lengthy discussions about who tried it first, since I know I had parents discuss it around the same time or before professionals were considering it.

The riskiest thing for a physician-scientist to do is translational research, especially when it is from the bedside to the bench. Basic science has a much more appealing longitudinal logic. Clinical science has relevance. As much as both are pioneering, translational research often requires almost autistic perseverance. However, eventually the bridge has to be crossed.

Our laboratory has worked on neurochemistry, neuroimmunology, neuroendocrinology, neuroimaging, and neurogenetics of autism. The reason for our current focus on genetics is that the data, not impressions, show it to be the most powerful influence in the etiology of autism. It is not the only influence and it is not a simple, single gene disorder. However, it is a rare event in my lifetime to realize that suddenly that molecular genetic study of autism spectrum disorders provides one of the best scientific opportunities in medicine. Of course, this would not be possible without the considerable basic science advances and applied science advances ranging from sequencing of the human genome, to development of rapid methods of genotyping, to the development of powerful statistical approaches. It is new for established researchers in other fields to be drawn into autism and related disorders because of the scientific opportunity.

It is unlikely that gene therapy will be the result of genetic research in autism. It is also unlikely that genetics of autism will explain a relatively recent increase in measured autism prevalence. The point of genetic research is to develop treatments that will correct the missing or abnormal signals for a small set of nerve cells in the amygdala, hippocampus, and cerebellum so that the nerve cells mature. If we knew the signals, what has long been a too complicated puzzle of autism will become simple enough for us to understand. Although the simple idea is to provide gene therapy, oral delivery of more traditional small molecules is likely to be more feasible and preferable.

Even more important has been the emerging voice of families of children with autism. I can not begin to list and thank the parents, brothers, sisters, aunts, uncles, and grandparents who are not only taking on the extraordinary challenge of caring for their family members, but who are speaking for people with autism who because of their communication problems are not as able to speak for themselves as we wish they could.

The need to learn more about autism is self-apparent and the scientific opportunities are abundant. The challenges are in learning about something as complicated as the developing brain and development of some of the most uniquely human qualities of higher level communication and social behavior.

Two recent developments in the broader field of developmental disorders show that complex situations may be better understood through molecular genetics. The first is the finding of the gene for FRAXA mental retardation. This is very relevant to autism since a substantial proportion of children with FRAXA have autism spectrum disorders. Although one wishes knowledge of a gene will lead to new treatment sooner, the results of a decade of research to understand the mechanism of this disorder is leading to an almost exponential growth in understanding of complex interactions of molecules in the process of learning. Another development is the recent cloning of the gene for Rett syndrome. This is actually one of the most severe autism spectrum disorders. It is notable that it is caused by a single gene, MECP2, but that it has a course of regression in social behavior and communication between the first and second birthday. Knowing the gene has led to a breakthrough in the systematic approach to investigation of Rett syndrome in terms of how it affects the development of the brain. Study of both FRAXA and Rett syndrome will lead to basic knowledge about how autism and related conditions develop.

Although we don't know the specific genes involved, several groups have been finding evidence that an extra part of chromosome 15 leads to a high risk for autism, especially if

inherited from the mother. Although responsible for less than 4% of cases of autism, these 15q11-q13 duplications, like Rett syndrome and FRAXA, are likely to help us understand autism more generally. Several laboratories, including our own, are searching for a gene in this region. As an example of our concern about not wanting to waste precious resources, the probability of there not being a gene in this region is about 5 in 100,000, but we're not sure yet. Of course, we'll have to get beyond regions with likely autism genes to actually finding the specific genetic changes and then getting on with the work of using the information to improve treatment. (More information about molecular genetic studies and autism is available at our web site at:

<http://psychiatry.uchicago.edu/ldn>).

It's a good thing there are people doing good clinical research and trying to improve educational and other interventions while we are working out the fundamental causes. It's also good that people are asking questions about prevention and even taking shots to improve medication delivery, either trying to hit for average with medications like Prozac, or swinging for the fences with an occasional secretin trial. However, it's important not to think we have more of an effect than we can back with controlled data. History teaches us that zeal without skepticism may have negative consequences (e.g. false accusation of fathers of children with autism who underwent facilitated communication).

The challenges of autism research are obvious. In terms of needs, I mostly want to thank Congress for the appropriation of increased funds for biomedical research. All of the pertinent NIH institutes are now engaged in active support of autism research. A simple statement of needs is that there are many important and feasible questions about autism not able to be asked with current resources. There are not enough well-trained researchers in the field, partly because the area was almost totally unfunded five short years ago. Most importantly, questions that are being asked well and efficiently, such as in the area of molecular genetics, are not being answered at an optimal rate given current funding in the area. Again, this is not meant as a criticism, but as a statement of scientific opportunity.

Thank you for the opportunity to communicate.

Sincerely,

Edwin H. Cook, Jr., M.D.

Associate Professor of Psychiatry and Pediatrics