Position Paper on National Childhood Vaccine Compensation Program

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The National Childhood Vaccine Compensation Act of 1986 (Act) was passed to avert a potential vaccine shortage and to rescue the nation's vaccine manufacturers from impending doom in a rapidly escalating wave of lawsuits. It was the first time Congress came to the aid of drug makers to allow them to escape liability in most circumstances. It is, indeed, unfortunate how this well-intended win-win program has been doomed to failure by a short institutional memory, activist jurists, overzealous government attorneys who need to win to be promoted, and a blind eye to medical history. More than thirty years after its enactment, it is time for Congress to revisit the Vaccine Injury Compensation Program and make some corrections, as outlined below. The system is broken and is in need of immediate repair.

Historical Background

Prior to the enactment of the National Childhood Vaccine Injury Compensation Act of 1986, a spate of lawsuits emerged across the country. At first, the subject vaccines were oral polio vaccine (OPV), which was the definitive double edged sword, and Diphtheria, Tetanus and Pertussis vaccine (DTP, or DPT), an especially bad idea to be shooting into children as it was designed. The double edge sword aspect of the OPV was that while it was credited with eradicating a polio epidemic in this nation, its continued use was eventually found to be the sole causative agent in sporadic cases of polio. In other words, exposure to the very vaccine that worked a miracle, eventually became the only way for Americans to contract the disease! It was, wisely, removed from the market in the U.S. in 2000, but continues to be sold and administered in other countries.

The other target of by far the overwhelming number of filed cases was DTP vaccine. This was a vaccine that contained toxoids of diphtheria and tetanus, along with killed whole cells of Bordetella Pertussis, which was essentially lab-cultured whooping cough cells that were killed, mixed in to the vaccine, sold and injected. Wide-spread injections of pertussis vaccine were begun following a tragic epidemic of whooping cough, which affected nearly a million children and killed 36,013 the U.S. in the mid-1920's to 1930.

Almost immediately following the introduction of pertussis vaccine, physicians noticed an uptick in abnormal health presentations of freshly immunized children. The children were presenting with high fevers, high pitched cat-like persistent screaming and crying bouts, excessive somnolence, and in some instances seizures and even some deaths. As reports of these reactions began to surface, scientists at Lederle Laboratories, one of the major manufacturers of the pertussis vaccine, began examining their product to determine if there was a potential link between its pertussis vaccine and these strange reactions.

Their working hypothesis was that the reactions were unlikely to be related to any other vaccinations being given, but far more likely to be some sort of irritation as a result of the

introduction of the attenuated pertussis organisms being injected. While marketing the whole cell pertussis antigen, their research lab work focused on deriving the effective immune response of their whole-cell pertussis antigen, yet with less reactive agents than their commercially available product. The research teams determined that the cell wall of the pertussis organism was some sort of endotoxin, and that the resulting reactions were most likely related to the presence of endotoxin in the infants' systems. Scientists at the time, were researching the health effects of endotoxins, and shortly before this time, science identified an influenza bacterium which contained endotoxin, and reactions to various other vaccines, such as cholera, and typhoid were tied to this part of the organism. In the 1930's Lederle scientists developed an alternative preparation to the injected whole pertussis organism, which consisted of the pertussis cell minus the toxic cell wall. Lederle patented this product, and then shelved it. Testimony from litigation in the 1980's revealed that the key reason for not bringing this alternative pertussis vaccine to market, was the fact that manufacturing costs would increase by approximately one-half cent per dose, and the manufacturers made a conscious decision to stay with the less-expensive but more reactive whole cell pertussis component.

As the years went on, and the pertussis vaccine was used routinely, several astute physicians began to note and report disturbing trends and tied those to being reactions to the DTP. In 1933, Dr. Thorvold Madsen reported two deaths that were attributable to reactions to DTP vaccines in the *Journal of the American Medical Association (JAMA)*.[1] Doctors at Mass General Hospital began to ponder the reason for these strange post-vaccine reactions. Drs. Byers and Moll authored an article which appeared in the very first volume of the medical journal "Pediatrics," which became the official journal of the American Academy of Pediatrics. Their article, titled, *Encephalopathies Following Prophylactic Pertussis Vaccination,* chronicled 15 children, age 5 – 18 months who had been administered DTP vaccine and who suffered acute cerebral symptoms within hours of receiving pertussis vaccine.[2] The study concluded that consistent with the literature, this process might have resulted from either the activity of a specific toxin or from an antigen-antibody response. Byers and Moll concluded, "Further studies should be made to prove this point definitely, for the encephalopathy following pertussis vaccine seems more devastating than the vast majority of the nervous lesions following the use of smallpox vaccine." A year later, Dr. John A. Toomey reported on 12 of his patients who had severe reactions to the pertussis vaccine, also in *JAMA*.[3] Eight had irreversible brain damage, and two others died. That same year, the Bureau of Biologics (FDA) approved a single shot of vaccine containing diphtheria and tetanus toxoids with the whole cell pertussis antigen (DTP).

In 1974, Kulenkampf and Schwartzman postulated that the clinical picture of all of these kids was so much like the complications of the most severe clinical cases of pertussis, that it *had to be* the pertussis component of the vaccine that was the causative factor. Their report, published in yet another prestigious journal, reported on 36 children with severe neurological

[1] Madsen, T. (1933). Vaccination against whooping-cough. Journal of the American Medical Association, 101, 187.
[2] Encephalopathies following prophylactic pertussis vaccine. Pediatrics, 1, 437.
[3] *JAMA.* 1949;139(7):448-450. doi:10.1001/jama.1949.02900240026006

illnesses first noted within a very short time following a DTP vaccination,[4] 23 of them within 24 hours.

Over the ensuing decade the scientific data mounted. More and more reports of severe encephalopathic reactions to the DTP vaccine appeared in medical literature, and that body of knowledge began to slip into the public. In the face of increasing concerns over the safety of the whole-cell DTP, Lederle took not a single step to acknowledge its patented invention from the 1930's. Although it knew that its whole cell component was causing death and devastating brain injury to hundreds, thousands, probably tens of thousands and potentially hundreds of thousands of children, Lederle continued to hide the fact that it could do better. The looming potential for a ½ cent per dose loss of profit was enough to keep the safer product on the shelf, hidden from science.

Lederle was not alone in knowing the avoidable danger of its product. Eli Lilly developed a product called TriSolgen, which it introduced to the market in 1967. This product used a "fractionated" cell, rather than the whole cell. For lack of a better description, the pertussis cells were put into a centrifuge with beads. As it spun, the centrifuge caused the beads to mash the cells against the inner lining of the instrument. At the conclusion of this process, the cell wall material, which was endotoxin – the part of the cell that scientists believed caused the deleterious reactions – was plastered against the inner lining, and the liquid which was extruded from the cell walls and which collected in the bottom of the instrument was poured into the vaccine. Lilly captured a huge portion of the market with its less reactive vaccine. In 1975, citing aging manufacturing facilities and its unwillingness to continue manufacturing biologicals, such as TriSolgen, Lilly dropped its product.

In the meanwhile, Lederle still kept its deep dark secret, yet it did ask one physician in Buffalo, NY, to conduct an informal test of its product vs. Lilly's. Lilly's was exactly one-half as reactive in that study, as Lederle's DTP. Lederle's financial team decided that it was not worth pursuing the Lilly product, since they had their own on the shelf, and they did not want to spend the money on acquiring Lilly's technology, as that would be more costly than coming on the market with their own product.

Wyeth Laboratories, another manufacturer which had been in the DTP market for roughly as long as Lederle, did look into the Lilly technology. In 1981, Wyeth commissioned a comparative study of its whole cell DTP against a preparation manufactured with Lilly's technology. The results were predictably favorable. At a 1982 FDA Symposium on vaccine safety, Dr. Philip Brunell, of the University of Texas Health Sciences Ctr. reported, "a much higher incidence of systemic reactions to the whole cell pertussis antigen." When Wyeth was asked in a deposition in 1984 why it didn't pursue this safer vaccine, Dr. Mahlon Z. Bierly, one of the Wyeth executives testified, "The Office of Biologics (FDA) was not interested in this vaccine, because it would take a lot of highfalutin' statistical workup to demonstrate that it was

[4] Kulenkampf, M., Schwartzman, J. S., and Wilson, J. (1974). Archives of Disease in Childhood, 49, 46. Neurological complications of pertussis inoculation

any better than the existing one." So, Wyeth never tried to convince the FDA that it knew it had reaction issues and it could have done better and prevented neurological injuries.

All of this dishonesty was not being driven by mere corporate greed. There was another far more ominous factor that was making it impossible to admit that they could have done better. Lawsuits.

The effect of the rash of products liability suits against Lederle and Wyeth caused several twists. There was absolutely nothing in the medical literature in the 1940's, 50's 60's and 70's to suggest that pertussis vaccines did *not* cause the neurological devastation reported by Byers & Moll, Madsen, Kulenkmpf, or any of literally hundreds of physicians who reported these reactions to the manufacturers and the FDA/CDC. Every single article written over those four decades freely discussed the rates of reactions, the *fact* that the pertussis element caused intractable seizures, severe mental retardation, spastic quadriplegia, cortical blindness, encephalopathy, and a host of other conditions. Not one article was written refuting a causal connection. Until the lawsuits.

The first suit was filed alleging DTP reaction in Chicago in 1978. By the end of 1984 there were 219 suits filed. That number more than doubled in the following year. For the first ten years of the litigation, a small band of only about 10 law firms represented numbers of brain damaged children reaching into the thousands in all 50 states. The largest law firms in the nation were hired by the five DTP manufacturers. These firms built entire departments of lawyers, paralegals, secretaries and researchers, as they geared up for this flash of litigation. Because of the content of the documents, some of which came right out and proclaimed, their lawyers tell them that if they gave a better warning their liability would go down, and they wouldn't lose all these suits. Other documents discussed how they had three options. They could survive the litigation if 1) they dropped the product – but could not do that because that would anger their expert witnesses, and they wouldn't be able to survive the litigation; 2) make a safer vaccine that they had the technology to do – but they couldn't because the plaintiff lawyers would show the jury just how easily this particular tragic outcome for the child-plaintiff in the wheelchair before them could have been avoided, and wouldn't be able to survive the litigation; or 3) they could seek some sort of immunity from the lawsuits by deploying their lobbyists in Washington, DC, and getting bailed out.

The first step of self-preservation was to increase the selling price to absorb some of the insurance and litigation costs. In 1984, the DTP cost $1.10 for a ten-dose vial. That same product was hiked to $114.00 by 1986. Today a vial of DTaP (acellular) costs over $630.00. Prior to the litigation wave, there were five DTP manufacturers in the 1970's to just two (Lederle and Wyeth) by 1984.

The second step of self-preservation was to coopt the science and change the narrative. The research grant dollars flowed like wine at a bacchanalian orgy. A doctor with a sleepy infectious disease practice stood to make millions upon millions of dollars for conducting – or should we say concocting – studies demonstrating that all the pre-litigation scientific studies,

anecdotal reports and brain damaged and dead kids were a mere miscalculation. Wyeth actually began a study at UCLA in which they were attempting to find a reliable incidence of reaction number, and while that study was ongoing, and the results were incredibly damaging to that company, one of its executives visited the study center, had a conversation with the principal investigator and all the numbers which were headed for a disastrous result suddenly took a turn for the better over the remaining part of the study. The final numbers of reactions – while still disturbingly high – reflected far better for the whole-cell manufacturers. Lederle commissioned a study with the same team that Wyeth had reached, and as part of the original proposal protocol included language instructing the researchers that their reaction rates should be very low and should dispel the myth that DTP vaccine was dangerous.

While all the manipulated science was effective at baffling the regulators and political types who were being educated by lobbyists and industry-sponsored millionaire expert witnesses with big names in pediatrics, infectious diseases, and neurology; the one place that the concocted manipulated science was not playing well was in the courtrooms. All the congressmen with their law degrees and graduate educations from the finest universities, all the FDA regulators with their doctorates, all the financial analysts with their Wharton and Harvard MBA's were buying the manufacturers lies, deceptions and cover-ups. However, with the prospect of groups of 12 jurors made up of plumbers and electricians with GED'S, salesmen with associates degrees, executives with 4 year business degrees, high school drop-outs, single moms working 3 jobs to put food on the table and unemployed men who wanted to get on that jury to get lunch and $7.00 for a day of listening, Lederle, Wyeth, Parke-Davis and Merck just didn't have the power to overcome their documents that showed how the product needed to be priced to absorb the cost of a dead baby found blue in the crib the day after the shot, or the 6 year old child sitting in a wheelchair with his arms flexed backwards staring up at the ceiling with drool running down his chin for days on end in the courtroom.

The worst thing that could happen to a vaccine manufacture was happening across the country in the federal courts. The truth was being told, juries were angered and most tragically, the stock of the manufacturer slid 3 points on the Dow, as the verdict was returned.

The manufacturers, their investors, Boards of Directors, and their job security were suddenly at risk. The airing of their negligent conduct and callous indifference to the health and safety was putting their very existence in jeopardy.

Knowing that the JD's, MS's, MD's and Ph.D.'s found in Congress, HHS, CDC, and the White House were all such easy marks, compared to the GED wielding plumber, or the Chevy mechanic, Lederle, Wyeth and Big Pharma turned to Congress.

Concessions had to be made. This was back in the 80's, before being of a different political party meant that you were evil … the enemy of the people. Back when Kennedy and McCain used to have lunch. When a Democratic Congressman could find a Republican Senator to sponsor bipartisan, bicameral legislation, and not even the President could stop it if Congress wanted to make it work.

As they say, “politics makes strange bedfellows.” The most disturbing fact for the plaintiff lawyers was that regardless how strong of a case he or she had, the defense attorney had to support a large vaccine trial unit, so even the most meritorious cases which should have been settled before even being filed were being litigated for 3, 4, 5 and even 6 years. After the first couple of cases were tried in federal and state courts, and after the damaging documents showing callous indifference were available to sink the manufacturers at trial, defense teams were still forcing the families of the dead or brain damaged children to endure years of litigation, usually settling within days of trial, and sometimes in a hotel bar where the trial lawyers met the night before a jury was to be picked. But, always, years later! So, getting the lawyers on the same page would be a major part of this.

Plaintiff lawyers had retainer agreements with their clients and stood to earn six and even seven figure fees. The defense attorneys wanted to keep their vaccine departments together and get paid handsome bonuses. This new idea, a government bailout would have some sort of claims process. Defense lawyers would not be involved, resulting in massive layoffs. Plaintiff lawyers would have fees capped at $30,000 per case. A loss of over $300,000 per file on the average. How could this work?

The manufacturers put together a winning strategy. They threatened to stop making vaccines altogether. They pretended to have production problems, causing fake shortages, just to show the medical community how tenuous healthcare was if there were no vaccines. They held Congress and the medical profession hostage as they threatened to just stop making vaccines. This part worked. Congress, CDC, FDA were all brought to their knees. Something had to be done or all the kids in America were going to start coughing and facing certain death.

The defense bar was out of the picture, and was cranking up the intensity of the remaining bits of litigation to generate the billable hours.

The plaintiff bar met in Chicago, still a relatively small number of firms nationally, perhaps 15 or less. They had an ethical dilemma. They could fight the process and continue with the hardball litigation, or could give up large – but hard-earned – fees and get their clients compensation without years of protracted, expensive and harmful litigation. They could get money for their clients faster and begin proper medical treatment sooner, or they could continue. For them, it was a no-brainer. The plaintiff bar joined the politically strong parent’s advocacy groups and began to lobby hard.

There were certain deal-breakers for the plaintiff/claimant bar. First and foremost, if the vaccine court did not make a finding in the plaintiff’s favor, there had to be an option to opt out and pursue civil litigation. The case must be able to be brought in a state or federal court using state law for inadequate warning, defective design or defective manufacture.

Equally importantly, the compensation must be fair and adequate to pay for all the needs attendant to the child sustaining a suitable lifestyle. This means education, therapy, medical treatment, durable goods, etc. For life.

Third, the proceeding must be speedy, and the petitioner must be able to opt out after a period of less than a year and proceed in state or federal court on a products liability theory.

Fourth, compensation must be certain for cases that are on a table of injuries. Death, seizures or certain other neurological symptoms within a certain time frame must be considered caused by the vaccine. The mere fact that a certain injury is not on a table of injuries cannot preclude a case being filed as long as there is a good faith basis for filing.

Fifth, existing litigation should be allowed to proceed without having to be forced into the system if the plaintiff wishes.

Sixth, the manufacturers must be saddled with product improvement responsibility.

And, seventh, the proceedings must be non-adversarial, with all inferences interpreted in the favor of the injured child. It is better to errantly compensate a claimant than to deny compensation to a deserving child.

The Act

The National Childhood Vaccine Injury Compensation Act of 1986 was sponsored in the House by Rep. Henry Waxman (D CA) and Senator Paula Hawkins (R FL). This bipartisan bill was written by a combination of Congressional Staff, lawyers from both sides of the issue, lobbyists for Big Pharma and the medical profession, and parent organizers. In fact, the only detractors, who fought the enactment of the Vaccine Program were the US Department of Health and Human Services and the US Department of Justice, who fought this measure so vigorously, that their boss, President Ronald Reagan made it known that he was waiting for the bill to cross his desk so he could veto it! It was only signed with the greatest reluctance when it passed.

Of course, it is necessary to emphasize that the only opposition to the Act was by the two government agencies that are charged with its administration. HHS, which administers the entire Vaccine Program, and DOJ, which represents HHS in the proceedings. This has led to hostile proceedings and erosion of the intent of the Act at every juncture.

It is not mere conjecture that HHS and its attorneys in the DOJ Vaccine Division hold the Program in contempt. Perhaps most illustrative of the flat-out disdain for the entire process by DOJ and HHS occurred during a hearing before a Special Master in a death case. The case was hotly contested by the Respondent and went to trial. The parents were forced to relive the

death of their child and the grim discovery of the deceased baby. At the conclusion of the very emotional hearing, the Special Master delivered his finding that the DTP vaccine did not cause the death of the infant. Upon the Special Master announcing the finding for the government, the DOJ lawyer literally jumped up from her seat, fists clenched, arms extended to the ceiling of the courtroom as the attorney shouted ***"YES!!!!"*** at the top of her voice, as the grieving parents broke into tears for the child they found lifeless, cold and blue in his feet pajamas in his crib just a couple of years earlier! This action led to many questions being asked by participants in the program, and was the point where it was discovered that the program itself ran counter-culture to the Department of Justice. While the program was designed to assure swift and adequate compensation to victims of vaccine injury, which would tend to be measured by the number of children compensated – the more the better – the culture of DOJ was that promotions were based on how many cases the trial attorney won!

Opt Out

As originally drafted, there were certain limitations placed on petitioners' rights to sue civilly, but there was a right to opt out if the Claims Court did not complete the process within 240 days, and the petitioner could bring a lawsuit in a state or federal court on a design defect claim, as well as a failure to give adequate warnings. Subsequent to its passage, the physicians were able to get language added by way of an omnibus funding bill, which would remove them from potential litigation.[5] This amendment did nothing to change the potential liability of negligent manufacturers. Remember, the lack of a right to pursue litigation was a deal breaker for the petitioners and their lawyers.

All the legal draftsmanship in the world cannot prevent a determined Supreme Court from rewriting the Act to favor Big Pharma. In 2011, the Supreme Court decided the case of *Bruesewitz v. Wyeth,* which cut off the legal rights of vaccine injured persons to sue drug companies for design defect and failing to improve an FDA licensed vaccine to make it less harmful. At least three of the seven Justices had previously worked in firms that represented pharmaceutical companies, and one worked as an in house counsel for Monsanto, the largest chemical company in the world. Justices Sotomayor and Ginsberg wrote a strong dissent, objecting to the majority's inaccurate interpretation of the law and its legislative history. As the result of the majority ruling in this Supreme Court case, vaccine manufacturers enjoy total immunity from lawsuits, regardless how diabolical their conduct is. A reading of the *Bruesewitz* case leaves the distinct taste of judicial activism in the mouth of those who truly understand the letter, spirit and purpose of the Vaccine Compensation Act. The majority tortured every word possible to reach a decision which is so clearly opposite to the intent of the original legislation!

Worse, however, is that the *Bruesewitz* decision took away any incentive for the vaccine industry to improve upon vaccine safety. The industry that balked at spending ½ cent per dose

[5] U.S. Congress. Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203). Subtitle D – Vaccine Components. Sec. 4306. Vaccine Administrators. Pg. 224. Dec. 22, 1987.

to save hundreds of thousands of children from a lifetime of seizures, learning disabilities and mental and physical suffering, is now free to produce the most profitable products they can, unfettered by any potential liability! Legislators have reasoned that the manufacturers will want to do the right thing!

Legislative Erosion

Starting in 1987, Congress began amending the program. These amendments one-by-one eroded the rights of victims, favored procedural change to benefit the government, limited individual rights and gave unprecedented protection to the checkbooks of Big Pharma. The program, which was based upon a presumption of causation unless there was a more plausible cause proffered, was becoming as adversarial as proceedings against Lederle and Wyeth in the federal district courts.

Congress stepped in and worsened matters by passing amendments and granting broad rule making authority to HHS, the agency that never liked the program in the first place. Naturally, HHS took steps to weaken the Act, and to make life as easy as it could for their friends in Big Pharma to alter and weaken the original Act.[6]

Having suffered through watching their infants slip into neurological and physical distress, or witnessing the death of their children, perhaps the most important element of the Program was the prevention of this horrific suffering for others. While it was the goal of the lawyers to assure their clients that the Act would not compromise their rights to proceed to civil litigation should they not be satisfied with the result in the Vaccine Program, it was the Act's safety, product improvement and research provisions, that most interested the parents. To their great disappointment, those provisions in the original Act designed to help prevent vaccine injuries and deaths, have been seriously eroded.

The Vaccine Injury Compensation Program has been neglected by Congress, which has yet to revisit the program with a single oversight hearing in the 30 years of this program's existence. It has perpetually flown under the radar of any House or Senate Committee, as those chambers both routinely do as HHS asks as if this multi-billion-dollar program were on autopilot! Congress has enabled DHHS and the Department of Justice to turn what was originally intended and touted as "a non-adversarial, expedited, less expensive, fairer and more predictable federal vaccine injury compensation program," as promised at the negotiation table

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[6] 42 USC Chapter 6A, Subchapter XIX: Vaccines. Public Health Service. National Childhood Vaccine Injury Compensation Act of 1986 with amendments; H.R. 2202. Preventive Health Amendments of 1993. Section 708: Simplification of Vaccine Information Materials. Sponsor: Rep. Henry Waxman, (D-CA) (original draftsman of the Act); DHHS. Final Rule: National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table. *Federal Register* Feb. 8, 1995; 60(26): 7678-7695; Department of Health and Human Services. Notice of Proposed Rule Making. 42CFR Part 100; RIN0906-AB14. National Vaccine Injury Compensation Program: Adding the Category of Vaccines for Pregnant Women to the Vaccine Injury Table. *Federal Register* Apr. 4, 2018.

with Mr. Waxman's and Ms. Hawkins' staff, the manufacturers and their lobbyists, the parents and their legal representatives, into a legal nightmare which drags on as long as the civil cases that precipitated the Act used to drag on for.

The Special Masters of the U.S. Court of Federal Claims have become hardened, to the point that post-hearing rulings for the petitioners are becoming a scarcity; the presumptions have turned against the intent of the program as passed in 1986; the process is fraught with hostile adversarial advocacy; and the results, which should be plainly predictable – especially for "table injuries" – are impossible to predict and depend upon the particular Special Master assigned to the case.

What the parents gave up for this program was a case which allowed for full discovery to be presented in a court of law in front of a jury of 12 peers – plumbers, teachers, store clerks, cashiers and others who would listen and evaluate every word of the witnesses and every document that said the manufacturers knew about the death and destruction, but preferred to save ½ of one cent, rather than safeguard the needs of the severely injured quadriplegic child they saw in the court room. What they got in exchange was a jury of one.

That "one," is a Special Master of the Court of Federal Claims, who is – through no fault of their own – looking for any excuse to rid his or her docket of as many cases, as quickly as possible. When the Program began 30 years ago, there were six covered vaccines and eight special masters. The first two years of the program, there were 24 and 148 filings, respectively. Over the past two years, there have been 2230 new cases filed. There are still eight Special Masters, and rather than having an average of 21.5 files each as they did the first two years, today, each Special Master must handle well over 278 cases, just based upon the last two years of filing (and they all have residual cases from further back than that). To make matters worse, there are now 16 vaccines covered in the program, nearly triple the amount originally covered. Simply put, the system is overburdened.

Because of this overburden, Special Masters have no time to ponder cases that present any individually unique facts. They can only process cases based upon repeated facts, seen in other cases that they have dealt with previously. Because of the simple mathematics involved, the number of hours in a day divided by the number of cases that must be considered, justice simply cannot be served.

As the number of "table injuries" decreases, the number of cases requiring proof to a preponderance of the evidence increases. As that number increases, so does the workload of the Special Masters. Cases are now being processed in terms of years, rather than months anticipated in 1986. If people were free to sue in civil courts, they would be able to process many of their cases in this time span. Thus, the Program is not the faster alternative it was designed to be.

This overburden problem is fixable. First, there must be more special masters hired. The Program is limited by the original statute to eight of them. This number needs a legislative fix to allow for at least double that amount. Increasing the number of Special Masters alone

will not guarantee success. There must be additional injuries, which are regularly seen in the process in the Program, added to the Injury Table. For instance, it has been known for decades that the flu vaccines can cause *Guillain Barre Syndrome (*GBS*).* Rather than force each petitioner to prove that this was the cause of their illness, this must be added to the table. Similarly, SIRVA, or Shoulder Injury Related to Vaccine Administration has become a common claim in many cases. This is a mechanical injury caused by poor administration practices most often with influenza or pneumococcal vaccines. Making this a table injury would dispose of hundreds of cases in very short order.

Time to Fix the Act

When the Act was passed, what was envisioned by the parents, was a program that would compensate victims of childhood vaccine injury and that the manufacturers would be working steadily to improve their market position by improving their vaccine's safety profile. The lawyers sought a program that worked so well that it would place members of the bar in a potential ethical dilemma if they did not put their clients through the Program in the first instance, all the while knowing that if the clients were not treated fairly, they were free to opt out ant sue the manufacturers and doctors civilly. The manufacturers wanted to escape from under expensive, risky and unwinnable lawsuits, where they would not have to stand in front of juries and explain how they could have made it safer but simply didn't want to take a lot time doing "highfalutin' statistical workup to demonstrate that (the new vaccine on the market) was any better than the existing one."

The Vaccine Injury Compensation Program is broken. It should not be done away with. It should be fixed. Much has been gained by the program, and much more can be done to make it work. Under what remains of the Act after all the revisions, political positioning and self-serving actions is still very positive. The act is responsible for mandating legal requirements for clinicians to give better warnings than the manufacturers urged before its passage; for them to keep better records and reports of adverse reactions; for the government to make reaction statistics available in a public manner; and for federal agencies to study vaccine safety on an ongoing basis. The Act is also the reason that the licensed vaccines on the market today *can and do* cause harm and even death.

It is a "no fault" compensation system. As such, Congress should enact corrective legislation establishing a lessened burden of proof for petitioner. This can be partially accomplished through the corrections of the table discussed already. The standard of proof needs to be reflective of the original intent of the Act, fostering a payment system which is fair, adequate, and far faster than the program has become. This lessening of the standard of proof, the doubling of the number of special masters and the inclusion of additional medical conditions on the Injury Table should all act to relieve the stress on the system by setting realistic demands on the time of the Special Masters, and making the program more predictable.

There must be an incentive for Big Pharma to reintroduce product safety research and accountability to their vaccine ventures. If the federal government is going to give the manufacturers the gift of immunity from liability, there must be a system of milestones interjected into the system. A former legendary FDA Commissioner, Dr. David Kessler, once said that the tort system is an integral part of the development, marketing and distribution of our pharmaceutical industry. If the incentive of fear of liability suits is indeed removed, there must be an incentive for manufacturers to stay on the market and make their profits.