Alan G. Phillips
UNC Law School
Scientific Evidence Class
May 2001

CIVIL MANAGEMENT AND CRIMINAL CONSEQUENCES OF VACCINE INJURY

Vaccine injuries can have both civil and criminal ramifications. This paper explores civil management of vaccine injury for victims seeking compensation through the National Vaccine Injury Compensation Program (Part I), and discusses the potentially devastating consequences that can befall a family when injuries caused by vaccines are mistakenly attributed to physical abuse inflicted by a caretaker (Part II).

Part I, Civil Management of Vaccine Injury: The National Vaccine Injury Compensation Program

A. Introduction and Program Purposes

In 1986 Congress passed the National Childhood Vaccine Injury Compensation Act[1] establishing a National Vaccine Program, the purpose of which was "…to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."[2] Program components included the National Vaccine Injury Compensation Program (NVICP or VICP), to compensate victims of vaccine injury and death, and the Vaccine Adverse Events Reporting System (VAERS), a passive reporting system[3] for the statistical monitoring of vaccine reactions. The utility of the VAERS remains questionable, as private and public sources estimate serious adverse events reporting at between 1 and 10% of the actual occurrence of such events. VAERS reports are not automatically submitted to the VICP; injured parties or their representatives must file a petition in a separate process. Therefore, VICP adjudication is even less a measure of the quantity of serious events actually occurring.

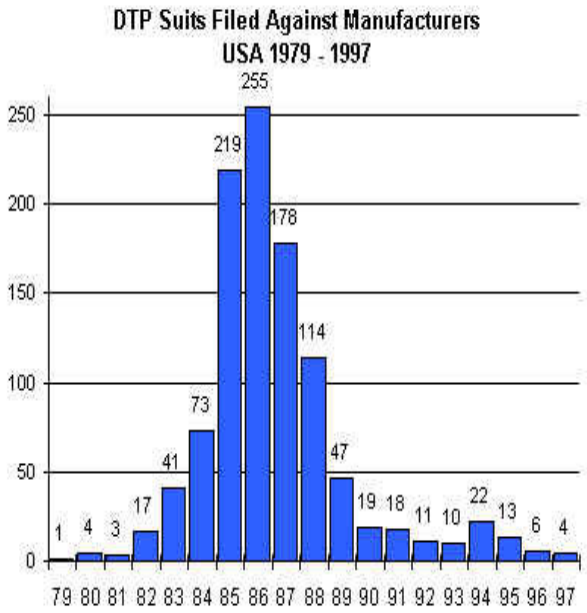

FIGURE 1

The NVICP's primary two purposes were "to keep manufacturers from leaving the vaccine market [many in fact did], while at the same time compensating those individuals

[1] 42 U.S.C.S. §§ 300aa-1 –35.
[2] § 300aa-1.
[3] However, the Act does direct doctors and vaccine manufacturers to report adverse events; s*ee* §§ 300aa-25(b)(1)(A) and (B).

injured by vaccines."[4] Liability insurance costs for vaccine manufacturers grew rapidly in the years preceding the Act, causing prices for some vaccines to rise by over 300% between 1980 and 1986.[5] The objective was to have the federal government, under the auspices of the Department of Health and Human Services (DHHS), assume liability for vaccine-related injuries, to simplify causation issues for those seeking recovery. Figure 1 shows both rising DTP suits in the first half of the 1980's and post-Act declines; the program apparently succeeded in diminishing lawsuits against manufacturers. But has protecting manufacturers from liability provided a disincentive for manufacturers to improve product safety? Some vaccine victims and informed-choice advocates have expressed this concern. If one balances vaccine harm and benefits using VAERS figures and health authorities' assertions about vaccine effectiveness respectively, it seems prudent to take steps to keep manufacturers in the market first, and to worry about product safety second (the risk of return of deadly diseases from a lack of vaccines being presumably greater than the risk of injury occurring to a tiny percentage of vaccine recipients). But factor in under-reporting of adverse vaccine events[6] and the growing body of evidence suggesting that vaccines are not nearly as effective as health authorities would have us believe,[7] and a compelling argument can be made that risking manufacturers' withdrawal from the market may actually have been the safer course of action. In any event, Congress' actions were, predictably, consistent with the former of these two views.

In addition to keeping manufacturers in the market, the VICP was designed to provide an efficient and cost-effective adjudication process for vaccine injuries not available through the traditional tort system. At present the VICP appears to be running smoothly, though a substantial backlog of pre-1986 cases severely curtailed timeliness of proceedings during the program's first several years. Since the program's implementation in October of 1988, the top award has been $8.4 million, and the per-award average is $833,000. Death awards are capped at $250,000 (greater awards address the life-long needs of the permanently disabled), which I must admit I find somewhat unsettling. While caring for a permanently disabled child is far more costly than burying a dead one, and with all due respect for the fact that no amount of money can bring back a deceased child, a dead one is arguably a far greater loss, and thus worthy of greater compensation.

The VICP has also served as a model system potentially applicable to other mass tort litigation. However, such applicability may be limited due to the unique nature of vaccination programs. Vaccines are government mandated and supposed to benefit soci-

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[4] Molly Treadway Johnson, et al., USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM, Federal Judicial Center (1998) at 4.

[5] *Id.* at 8.

[6] Less than 1% of serious adverse vaccine events may be reported, according to Barbara Loe Fisher, President of the National Vaccine Information Center (NVIC) in the Statement of the National Vaccine Information Center, September 28, 1999 (citing former FDA Commissioner David Kessler, 1993, JAMA); less than 10%, according to KM Severyn, R.Ph., Ph.D. of the Vaccine Policy Institute, 251 Ridgeway Dr., Dayton, OH 45459, quoted in the Dayton Daily News, May 28, 1993; about 10% according to the CDC as reported by the American Association of Physicians and Surgeons, Fact Sheet on Mandatory Vaccines, at http://www.aapsonline.org/.

[7] Alan Phillips, *"Dispelling Vaccination Myths"* at http://www.unc.edu/~aphillip/www/chf (1997), *reprinted in* EPIDEMICS, OPPOSING VIEWPOINTS, Greenhaven Press 99-108 (1999).

ety as a whole; these qualities are not present with other products potentially subject to mass tort suits.[8]

Finally, while not a goal of the program per se, the VICP has helped to validate thousands of previously unacknowledged cries of anguished parents who endured not only vaccine deaths and disabilities in their children, but also vehement denials from authorities about the possibility of a vaccine connection. While healthcare authorities continue to downplay and deny the existence of serious vaccine reactions, the federal government, at least, has begun to formally acknowledge the hard reality.

B. Program Overview

The NVICP is located in the U.S. Court of Federal Claims. Vaccine injury cases are adjudicated by special masters who hear only vaccine cases. Petitioners (claimants) are virtually always represented by attorneys, who must be members of the bar of the U.S. Court of Federal Claims,[9] though pro se representation is technically allowed.[10] The respondent is the Secretary of Health and Human Services, represented by 18 attorneys in the Vaccine Litigation Group of the Office of Constitutional and Specialized Torts at the Department of Justice (DoJ). Claims are decided within statutory time limits and are subject to limitations on compensation amounts and attorney's fees (an attorney may be compensated whether or not his client receives compensation[11]). The program incorporates innovative case-management procedures, including "(1) a requirement that virtually all documentation supporting claims and defenses accompany the initial pleadings; (2) use of expert reports; (3) information status conferences; (4) bifurcation of causation and damage issues; (5) telephonic hearings; (6) hearings limited to expert testimony; and (7) direct examination of expert witnesses by the special master."[12]

The VICP provides a statutory scheme for handling causation. If the petitioner can show by a preponderance of the evidence that her injury or death occurred within parameters specified by the program's Vaccine Injury Table (see Appendix A, p. 21), the petitioner is entitled to a presumption of causation. Respondent then carries the burden of proving an alternative cause for the petitioner's injury to defeat the award of compensation. A petitioner may also allege causation-in-fact for a non-table injury, but in so doing carries the burden of proving causation by a preponderance of the evidence utilizing traditional tort standards. Petitioners frequently allege both a table and a non-table injury in the alternative to preserve both causes of action. Congress mandated that the table be updated as new scientific information becomes available, presuming that some petitioners would be compensated erroneously through the use of the table in its initial form.

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[8] *See* Molly Treadway Johnson, et al., *supra* note 4 at 53.
[9] FED. CL. R. app. J 14(a).
[10] FED. CL. R. app. J 14(d).
[11] 42 U.S.C.S. § 300aa-15(e)(1)(B).
[12] *See* Molly Treadway Johnson, et al., *supra* note 4.

Cases under the Act as originally passed required a final judgment within a year of filing; subsequent amendments reduced the time period to 240 days.[13] The substantial backlog of pre-Act cases resulted in the exercise of optional suspension times that extended pre-Act cases up to three and a half years.

There are seven special masters appointed by the Court of Federal Claims to adjudicate VICP cases. They serve four-year terms and may be reappointed by a majority of Claims Court judges. They determine both entitlement to and amount of compensation. Following a special master's decision, parties have 30 days in which they may appeal the decision by filing a motion for review by the U.S. Court of Federal Claims.[14] An appeal is assigned to and heard before an individual judge of the Court of Federal Claims.[15] This judge has 120 days[16] to "(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision, (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction."[17] The next level of appeal is the U.S. Court of Appeals for the Federal Circuit where a three-judge panel hears the case and reviews the legal issues de novo. Parties may appeal to the U.S. Supreme Court from the Federal Circuit. The Supreme Court has heard at least one VICP case, Shalala v. Whitecotten, 514 U.S. 268 (1995). The issue was whether or not the petitioner had made out a prima facie case. She met the table requirement for post-vaccine encephalopathy, but her microcephalic condition (abnormally small head) prior to receiving the vaccine was evidence of encephalopathy that existed before the vaccination. The Special Master denied compensation, and the Court of Federal Claims affirmed, but the Court of Appeals for the Federal Circuit reversed. The Supreme Court unanimously reversed and remanded, holding that a claimant who relies on the Vaccine Injury Table in order to establish a prima facie case for compensation under the National Childhood Vaccine Injury Act does not make out such a case where the claimant's evidence, although indicating that the claimant experienced symptoms of an injury after receiving a vaccination, failed to indicate that the claimant had no symptoms of that injury before the vaccination.[18]

Victims of vaccine damage cannot file a civil suit without first seeking compensation through the VICP. However, the petitioner need not go through the appeals process before filing a civil suit. If within 90 days of a special master's judgment the petitioner elects to reject the special master's judgment, the petitioner may file a civil action for damages against the vaccine manufacturer in state or federal court. Failure to file an election results in a default acceptance of the special master's judgment.

C. Case-Management Procedures

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[13] FED. CL. R. app. J 10(a).
[14] FED. CL. R. app. J 23.
[15] FED. CL. R. app. J 26.
[16] FED. CL. R. app. J 28.
[17] 42 U.S.C.S. § 300aa-12(e)(2); see also FED. CL. R. app. J 27.
[18] Shalala v. Whtecotten, 514 U.S. 268 (1995).

The VICP is unique by virtue of its special rules and procedures for case management. VICP case proceedings are conducted in accordance with Vaccine Rules of the Office of Special Masters, Appendix J of the Rules of the U.S. Court of Federal Claims.[19] Federal Rules of Civil Procedure and Evidence do not apply; formal discovery as a matter of right is prohibited. Due to these and other unique characteristics of this system, the Office of Special Masters has issued practice guidelines for attorneys.

Petitions are filed with the Clerk of the United States Court of Federal Claims in Washington, D.C.,[20] after which the case is assigned by the chief special master to a special master.[21] Most of the information necessary to a ruling must be provided when a petition is filed. This "front-end loading," as it is known among participants, includes documentation supporting the allegations and all relevant medical records including maternal prenatal and delivery records; newborn hospital records with physicians' and nurses' notes and test results; vaccination records; pre- and post-injury physician or clinic records with growth charts and test results; all post-injury inpatient and outpatient records with provider notes, test results, and medication records; and if applicable, a death certificate and autopsy results.[22] Similarly, the respondent's first response must be a report with a medical analysis of the petitioner's claims.[23] These requirements are intended to speed up the processing of claims; they allow getting to the heart of the problem much more quickly than traditional tort litigation, enabling the special masters to identify all of the issues in the case before meeting with the parties.[24]

Cases that survive early dismissal require expert witnesses on both sides. The parties must present the substance of their experts' proposed testimony in affidavits which set forth the experts' opinions and reasoning. Special masters report that they place widely varying levels of weight on these initial reports. In some cases special masters require opinions from medical experts with a particular specialty, such as pediatric neurology.[25]

Special masters are required to schedule an initial status conference, an off-the-record equivalent to the pre-trial conference of traditional civil litigation, within 30 days of receiving a respondent's initial report. Special masters use this conference to evaluate the case and devise a plan to resolve outstanding issues; they also orally present tentative findings and conclusions.[26] At this point one of three things will happen: a case may be dismissed, a second status conference may be scheduled with requests for more information if the record is incomplete, or a date may be set for the first hearing if the record is substantially complete.[27] Petitioners have found this conference useful in their subsequent

[19] FED. CL. R. app. J 3(a).
[20] FED. CL. R. app. J 17(a).
[21] FED. CL. R. app. J 3(a).
[22] FED. CL. R. app. J 2(e).
[23] FED. CL. R. app. J 4(b).
[24] *See* Molly Treadway Johnson, et al., *supra* note 4 at 26.
[25] *Id.* at 28.
[26] FED. CL. R. app. J 5.
[27] *See* Molly Treadway Johnson, et al., *supra* note 4 at 29.

preparation of witnesses, as it enables them to get a feel for the special master's view of the case. Special masters may conduct additional informal status conferences by telephone conference call from time to time to expedite processing of the case.[28] In addition, either party may request a status conference at any time.

Entitlement and damages are addressed in separate hearings. The most common issues concern the strength of the medical evidence supporting the petitioner's claims and the respondent's theories for alternative causes for the petitioner's injuries; thus, management of expert testimony is critical. For this reason, some special masters further bifurcate entitlement hearings, hearing fact witnesses before hearing expert medical testimony on causation.

To obtain expert witnesses, petitioners' attorneys frequently use the petitioner's treating physician, retain experts who have testified for them previously in vaccine cases, or rely on referrals from other attorneys who have litigated in the vaccine program. Respondents rely on referrals from the Division of Vaccine Injury Compensation (DVIC), use the doctor from that agency who helped them prepare their initial expert report, or occasionally use outside experts obtained by traditional methods—e.g., talking to other witnesses or calling hospitals for referrals. Some respondents have expressed concern about the credibility of DVIC experts, and rely exclusively on outside experts. The most common experts at entitlement hearings are pediatric neurologists, though to a lesser extent experts have included general pediatric doctors, pediatric pathologists, pediatric immunologists, and treating physicians. The most common experts testifying at hearings on damage issues are life-care planners and rehabilitation consultants.[29]

Special masters are permitted to appoint their own experts,[30] though none had done so by the publication of the Federal Judicial Center's review of the NVICP in 1998. This is most likely due to a Special Masters' Office policy against exercising this option as well as general resistance to it by most parties. Special masters do consult information sources other than the evidence presented by the parties, including medical texts and literature.[31]

Hearings may be held in the U.S. Court of Federal Claims building or the Special Master's Office in Washington, D.C. In some instances, such as when the petitioner and their witnesses can't afford to travel to D.C. or a special master needs to assess the credibility of a witness directly, a special master may travel outside of D.C. Some parties or witnesses (especially expert witnesses) participate in hearings by telephone. Video conferencing has been used as a compromise between the need to view witnesses and the logistical complications of coordinating and funding travel by the parties and witnesses.

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[28] FED. CL. R. app. J 6.
[29] *See* Molly Treadway Johnson, et al., *supra* note 4 at 31.
[30] 42 U.S.C.S. § 300aa-12(d)(3)(B)(iii).
[31] *See* Molly Treadway Johnson, et al., *supra* note 4 at 33.

D. Program Problems and the Need for Reform[32]

In the fall of 1999, the House Subcommittee on Criminal Justice held a hearing to determine if the VICP was in need of reform. Barbara Loe Fisher, co-founder and President of the National Vaccine Information Center (NVIC), presented a statement on behalf of the NVIC.[33] Ms. Fisher's statement conveys a clear sense of betrayal felt by parents and NVIC members at the VICP's failure to live up to the Congress' expressed intentions. In particular, the VICP was enacted to provide parents an expeditious and fair, non-adversarial alternative to lawsuits, "which, in the words of Dr. Martin Smith of the AAP [American Association of Pediatrics], would give 'simple justice to children.'" More than ten years after the act was passed, Ms. Fisher states that parents' "faith in the justice, equity, efficacy and basic integrity of this legislative remedy was seriously misplaced."

The NVIC statement makes it clear that Congress' intentions have not been honored. Referring to a 1989 House and Senate Conferee Report expressing Congress' dissatisfaction, the NVIC statement noted "the fact that proceedings had become complicated, time-consuming and emotionally draining for petitioners," and implied that VICP proceedings had fallen victim to "re-invention of the adversarial process [that serves] neither to compensate injured children nor [to] maintain the stability of the immunization program in the U.S."

Ms. Fisher explained that both the Department of Health and Human Services (DHHS) and the Department of Justice (DoJ) were on record as opposing the Act; yet, DHHS was given authority to change rules after the law was passed, and did so to the detriment of petitioners seeking compensation. "The net result has been the creation of an uneven playing field that has often turned what was supposed to be a fairer, expedited, less traumatic, less expensive, no-fault alternative to a lawsuit against vaccine manufacturers and administering physicians into a highly adversarial, lengthy, traumatic and unfair imitation of a lawsuit conducted in front of a Special Master instead of a judge and jury."

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[32] Unless otherwise noted, information from this point forward to the end of this section comes from the Statement of the National Vaccine Information Center (NVIC), Hearing of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, September 28, 1999. Copies may be obtained from the NVIC, 512 W. Maple Ave., Suite 206, Vienna, VA 22180.

[33] The NVIC statement provided relevant background information on the NVIC and its role in the development of the 1986 Act:

> The National Vaccine Information Center (NVIC) is a national, nonprofit educational organization founded in 1982 and dedicated to the prevention of vaccine injuries and deaths through public education. Our organization provides assistance to parents whose children have suffered vaccine reactions; conducts and promotes research to evaluate vaccine safety and effectiveness, including research to identify factors which place individuals at increased risk for suffering vaccine reactions; and monitors federal and state vaccine research, development, regulation, policymaking and legislation. NVIC supports the right of citizens to exercise informed consent when making educated vaccination decisions for themselves and their children.
>
> In 1982, NVIC, then known as Dissatisfied Parents Together, was approached by Congress and the American Academy of Pediatrics (AAP) to participate in the development of legislation which would provide just and comprehensive financial assistance to vaccine injured children and their families.

Ms. Fisher argues that the presumption of causation is an integral part of the VICP system, given the lack of scientific data and understanding of the biological mechanism for most vaccine-induced injuries. In brief, where absolute proof is not possible, justice requires that the petitioner (meeting the requirements of the scientifically-supported Vaccine Injury Table) be given the benefit of a presumption that the vaccine is the cause of injury, especially when there is no convincing alternative explanation for a child's injury. However, the DHHS and DoJ have modified the Vaccine Injury Table to eliminate many injuries, requiring a substantial number of petitioners to file for compensation with a presumption against them, despite decades of published medical studies supporting a presumption in their favor. Parents participating in the program's development agreed to give DHHS discretionary authority to modify the table for precisely the opposite reason—to *expand* the list of compensable events to make it more inclusive (to date, three out of four petitioners have received no compensation). Yet DHHS has removed compensable events sanctioned by Congress, and "redefine[d] permanent injuries in the Aids to Interpretation long recognized by the medical community as being associated with vaccine reactions. In the words of one attorney for vaccine injured children, the Secretary's arbitrary redefinition of the medically recognized definition of 'encephalopathy' "is so restrictive that it is believed by petitioners' counsels across this country that they will never again see an injury to a child that falls within the definition's narrow confines." In fact, when the Institutes of Medicine provided new scientific evidence for DTP vaccine-induced brain inflammation in 1994, DHHS removed signs and symptoms of brain inflammation and ecephalopathy from the Table. DHHS has demonstrated that it has little intention of fulfilling the intended spirit of the law.

The NVIC statement also criticizes DHHS' draft legislation, Vaccine Injury Compensation Program Amendments of 1999, finding the DHHS' proposals "lacking in the kinds of substantive improvements required to restore the guiding spirit and intent of the law: to provide a 'fair, quick and generous' federal compensation system alternative to a lawsuit for children who suffer catastrophic vaccine injury or death." Declaring that resolving the problems "will require strong and decisive measures from Congress," the NVIC made proposals for VICP revisions, important components of which are summarized below.

E. <u>NVIC Recommended Revisions for the VICP</u>

1) Return "residual seizure disorder" to the Vaccine Injury Table, and amend the "Qualifications and Aids to Interpretation" section of the Table to replace the current definition of "encephalopathy" with the medically recognized definition, "any acute or chronic significant acquired abnormality of, or injury to, or impairment of function of, the brain." 1995 Amendments to the Table and Aids to Interpretation have made it all but impossible to establish a case for injury following DPT, yet 68% of cases filed with the VICP claim injury following DPT, and 60 years of medical studies acknowledge DPT vaccine injuries.

2) Add "death" to the Vaccine Injury Table. Currently, unreasonable burdens are placed on petitioners. A death within 72 hours following vaccination should be presumed to

be causally related unless an obvious alternative cause of death exists.

3) "Add to the language of the statute a requirement that plaintiff's lawyers receive interim payments for fees and costs during the entire compensation process." Salaried government physicians, administrators, lawyers, and Court officials have a substantial advantage over petitioners' lawyers who do not get any reimbursement until as much as three to seven years following the initial filing of a petition.

4) "Toll the statute of limitations on all claims resulting from the administration of childhood vaccines to the age of majority." Significant vaccine injury may take years to fully manifest; current statutes of limitation are two or three years. Most state laws toll statutes of limitation until a child reaches the age of majority.

5) Require the Secretary "to confer with the Advisory Committee on Childhood Vaccines (ACCV) prior to amending the Vaccine Injury Table."

6) Allow claimants turned down for compensation due to prior table changes to reapply to the system without prejudice.

7) The NVIC supports independent research into adverse vaccine events, but does not feel that funds for such research should come from the Vaccine Injury Compensation Fund (which presently has a billion dollar surplus). This would be the "ultimate betrayal of public trust" in the federal compensation program. Ms. Fisher anticipates that new research will connect many conditions not currently on the table with vaccines, and the current funds will be insufficient to compensate for these new additions. (Indeed, if recent and current independent research on diabetes and autism alone is acknowledged, thousands of new claimants could be added to the system each year.) VICP funds should be reserved exclusively for the children suffering chronic immune and brain dysfunction following vaccination.

   With regard to DHHS using portions of these funds to conduct studies, Ms. Fisher argues that "[i]t is illogical to expect the same federal agency responsible for developing, licensing, regulating, making policy for and promoting the mandatory use of vaccines, which is also a hostile defendant in the vaccine injury compensation process, to be an impartial investigator of vaccine risks." She suggests that DHHS would design studies to disprove vaccine damage where in fact damage does occur. This cynical viewpoint is substantiated by many decades of deceit and deception by health authorities as it pertains to vaccine failure and damage.[34]

8) NVIC opposes lowering the excise tax on vaccines, due to the projected increase in claimants explained above. Also, many of the three-fourths of claimants who have been denied compensation due to the above-mentioned table changes should be allowed to re-file their claims once the table is readjusted to allow for injuries substantiated by the medical literature. Upon doing so, the current surplus in the fund will

[34] *See* Alan Phillips, *supra* note 7.

diminish, so the current excise tax is not excessive.

9) Add a reporting requirement for adverse vaccine events. According to a statement by former FDA Commissioner David Kessler in a 1993 issue of JAMA, if vaccine adverse event reporting mirrors that of events following the administration of prescription drugs, it is less than 1%.

F. HR 1287

On March 28, 2001, Congressman Dave Weldon (R-FL) and Congressman Jerrold Nadler (D-NY) introduced The Vaccine Injured Children's Compensation Act of 2001, HR 1287, in the House of Representatives. This bill provides for changes in four areas:

1) The statute of limitations:
(See E. 4 above);

2) The burden of proof:
To reduce the preponderance standard to that of Veterans' Claims and Workers' Compensation Claims, where the benefit of the doubt goes to the claimant. This would make the program more consistent with Congress' original intention of erring on the side of over-compensating rather than under-compensating as arguably occurs under the present system;

3) Interim fees and costs:
To provide for claimants to petition not more than once every 90 days for payment of interim fees and costs. This would allow experts to be paid in a timely manner, and enable petitioners to conduct the testing and studies necessary to prove their claims. Attorneys for the government are paid every thirty days; attorneys for the children have to wait for years in many cases, which places the burden of financing the case on the shoulders of the family and the attorney. This provision will help level the playing field for the attorneys who are trying to help victims and their families; and

4) The right to refile:
Where the original claim did not meet the minimum $1,000 unreimbursed expense requirement (which is no longer a program requirement), or where petitioners missed the statute of limitations deadline that HR 1287 would extend.[35]

According to NVIC Director and co-founder Kathi Williams, HR 1287 "does not go far enough, but all the doors have been closed in our faces in attempting to improve this legislation. Lawyers are leaving the field because they cannot compete with the Department of Justice. Our lawyers get paid when the whole deal is over and the DoJ

[35] Kathi Williams, NVIC Director and co-founder, Topica Digest email broadcast to NVIC Leader's Group, received April 19, 2001 (on file with author).

lawyers get paid every 30 days no matter how many years the case might take…It is only a step but if passed would help a lot."[36]

F. Conclusion, Part I

There are serious shortcomings in the NVICP, underscored by the NVIC Statement and HR 1287. The spirit and intent of the program have clearly been violated. Yet, if injuries supported by present and future medical research are added to the Vaccine Injury Table, and if adverse event reporting approaches that of events actually occurring, compensation awards could well exceed the system's capacity to pay. But perhaps this could lead to a greater justice in the long term. If awards exceeded the government's ability to pay, the government could be forced to prohibit vaccine mandates in an effort to relieve itself of responsibility for vaccine injuries. This would mean shifting the responsibility to manufacturers and vaccine recipients, which would put pressure on manufacturers to develop safer products (or get out of the market, taking dangerous products with them), and on individuals to take personal responsibility for their families' health through examination of more complete information on vaccine risks and benefits. This in turn could lead to a more responsible, open, honest and accurate assessment of the true costs and benefits of mass mandatory immunization programs and alternative healthcare systems and strategies. Ultimately, if we are to be free from conflicted authorities imposing health risks upon us without our consent (and which, in the case of vaccines, are questioned by disinterested experts), individuals must be willing to take responsibility for their own health; and we as a society must be willing to grant individuals the freedom to make their own informed healthcare choices.

The point is not so much that absolute power necessarily leads to corruption (though one could so argue), but rather that only the absence of such power can preclude such corruption.

[36] *Id.*

Part II: A Criminal Consequence of Vaccine Injury: Misdiagnosed Shaken Baby Syndrome

A. The Causal Link, Generally

According to Australian researcher Viera Schiebner, Ph.D., there has been a recent epidemic of the so-called "Shaken Baby Syndrome," (SBS) and "[m]any infants who suffer [from it] may be victims of undiagnosed vaccine damage."[1] Dr. Schiebner finds the vaccine damage explanation more probable than the proposition that the unprecedented increase in the syndrome is due simply to an increase in the number of people who are capable or desirous of hurting or killing babies. She has provided expert reports for a number of attorneys representing defendants accused of SBS. Upon reviewing the medical records in these cases, she found that in every one, the symptoms appeared shortly after the child had received a routine immunization.

Until recently, most vaccine deaths have been labeled "Sudden Infant Death Syndrome," especially if obvious symptoms were minimal. But with alarming frequency, one parent—usually the father—is accused of shaking the baby to death. Ironically, the parent may even "confess" to shaking the baby, having done so upon finding the baby not breathing or unconscious, and hoping to revive it. According to Scheibner, some defendants in SBS cases have won in court based on experts' reports showing vaccines to be the cause of the injuries or death. But where the accused caregiver is uneducated, has a criminal record, or where a vaccine injury is accompanied by other physical injuries from another cause, the defendant's chances are remote. Regarding the SBS/vaccine connection, one U.S. social worker told Dr. Schiebner, "many foster parents are rotting in U.S. prisons. First, they are forced to vaccinate their charges, and then, when side effects or death occur, they are accused of causing them."[2]

Medical research acknowledges the ambiguity that may exist when attempting to distinguish SIDS from child abuse. According to Dr. Scheibner, a 1993 study revealed that making the determination challenges pediatricians, family physicians, pathologists and child protection agencies.[3] Other research suggests that there must be findings of blunt impact to the head to eliminate the possibility of spontaneous intracranial hemorrhaging from a rare vascular malformation or bleeding disorder. While there is no dispute that some parents and caregivers cause injuries through mistreatment, Schiebner makes a compelling case that vaccines should be given careful consideration in many instances. "Ever since mass vaccination of infants began, reports of serious brain, cardiovascular, metabolic and other injuries started filling pages of medical journals."[4] In fact, pertussis vaccine has been used to induce encephalomyelitis, which is characterized by brain swelling and hemorrhaging similar to that caused by mechanical injuries, in laboratory

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[1] Information in Part II A. of the paper discussing the vaccine connection to Shaken Baby Syndrome, unless otherwise noted, comes from Viera Schiebner, Ph.D., "*Shaken Baby Syndrome, The Vaccination Link*," NEXUS New Times, Vol. 5, No. 5, 31-34, 75, August-September 1998.
[2] *Id.* at 32.
[3] *Id.* (citing Reece, R. M. (1993) "*Fatal child abuse and sudden infant death syndrome*", *Pediatrics* 91:423-429.)
[4] *Id.* at 32.

animals. Of course, when laboratory animals develop symptoms and die, it is not considered coincidental; but when children develop the same symptoms and die following immunization, one of three things happens: it is considered coincidental, the parents or caregiver are accused of causing the injury, or the cause of death is considered unknown and classified as SIDS. Contributing to this difficulty is the fact that as a result of "immunological intravascular complexing of particulate antigen," delayed reactions from vaccines are the norm rather than the exception; that is, most vaccine injuries and deaths fall outside of the arbitrary medical-legal guidelines set for accepting the causal link between the vaccines and the injury or death. This, combined with the above-mentioned ambiguities, makes for a rather difficult case for defendants, and to be fair, could make for a difficult determination of the truth of the matter one way or the other even for informed physicians and juries in many cases.

Many of the classic benchmarks of abuse can also result from vaccination. Retinal hemorrhages can be caused not only by shaking, but also by vaccines and by attempts at cardiopulmonary resuscitation in children, which may be applied to non-responsive children who suffer breathing distress caused by vaccines. A bulging fontanelle has been documented as being directly caused by the DPT vaccine. Thrombocytopenia, a blood clotting disorder characterized by easy bruising and bleeding and which may result in brain and other hemorrhages, is also a recognized side-effect of vaccines. Add to this the well-documented common occurrence of seizures following vaccines[5]—which can cause injurious falls in young mobile children (and which may go unobserved by parents), and the possibility that vaccine damage may be mistaken for physical abuse becomes quite tenable.

B. A Case Study: The Story of Baby Alan

1) The Facts

Baby Alan Yurko (his father's name is also Alan) was born September 16, 1997. Labor was induced at 35 weeks due to a deficiency of amniotic fluid. The mother had many medical problems prior to and during pregnancy, including a history of colon problems, gestational diabetes, and a group B streptococcal infection during pregnancy which itself poses a high risk of infant death. She was sick and lost weight during the pregnancy, placing the fetus at great risk for nutritional deficiencies and retardation. The combination of medical concerns "placed a guarded prognosis on the baby at time of birth."[6]

Baby Alan spent his first seven days in the hospital, with three in intensive care. During his 10-week life, baby Alan suffered from pneumonia, respiratory distress, and jaundice. In November of 1997, at about 8 weeks of age, despite significant contraindications, baby Alan was given six vaccines simultaneously: DTP, Hib, OBV,

[5] One in 300 DPT vaccines result in seizures, according to a doctor's report for attorneys (cited in "*DPT Report*," The Fresno Bee, Community Relations, 1626 E. Street, Fresno, CA 93786, December 5, 1984).
[6] Harold E. Buttram and F. Edward Yazbak, *"Shaken Baby or Vaccine Induced Encephalitis? The Story of Baby Alan,"* International Review of Chiropractic, November/December 2000 at 72.

and Hepatitis B. Ten or eleven days later, he developed a high pitched scream and fever, but having been forewarned of this possibility (these are common vaccine reactions), the parents did not become overly concerned. This was accompanied by lethargy and a lack of feeding, a pattern that continued for three days. It culminated when at one point the baby stopped breathing, at a time when the father happened to be alone with the baby and his four-year-old daughter. After the father's failed attempts to resuscitate the baby, he got a neighbor to take them to the hospital where the baby was successfully resuscitated. In total, there were some 20-25 minutes of apnea before the hospital resuscitation. The baby was transferred to another hospital and put on life support. A brain scan was interpreted as showing a subdural hematoma (blood clot or swelling in the outer covering of the brain or spinal chord), one or two sites of "entraparenchymal bleeding," and pulmonary infiltrates (inflamed lungs). After 75 hours in the hospital, baby Alan was pronounced dead.[7]

Alan Yurko was charged with aggravated child abuse and first-degree murder of his infant son, Alan; he is now serving a life sentence without possibility of parole at Washington Correctional Institution in Chipley, Florida. Mr. Yurko insists that he did not kill his son; rather, he now claims that his son died from a combination of medical mistreatment and an adverse reaction to immunizations. Doctors and scientists from 15 countries have rallied to support Alan's innocence, as have members of anti-vaccination/pro-choice groups from around the world.

The medical examiner's post-mortem findings included: minor contusions and a small bruise; swollen brain; hemorrhages on both brain hemispheres, at the base of the brain and over some areas of the spinal chord; bleeding in one eye; old healing fractures in four ribs on the back left side; and mildly hemorrhagic, inflamed, congested lungs. Based on these findings, the medical examiner concluded that the baby died of shaken baby syndrome.

A report analyzing Mr. Yurko's case was published in the November/December 2000 issue of International Review of Chiropractic (IRC). The authors (Harold E. Buttram, M.D., a family physician, hospital staff member, and Diplomate in Environmental Medicine; and F. Edward Yazbak, M.D., a retired pediatrician), present a chilling and compelling case for Mr. Yurko's innocence. Following some 2000 hours of review and research,[8] they concluded that the baby Alan died of a vaccine reaction.

2) Summary of the Trial and Medical Evidence

The state provided four witnesses, including the medical examiner and a neuropathologist; the public defender provided only one witness, a neuropathologist. Two of the state witnesses testified twice, making a total of six expert witness presentations for the state to only one for the defense. It appears from the record that the state witnesses did not see or study medical records from the neonatal (first six weeks afterbirth) hospi-

[7] *Id.* at 72.
[8] Letter from Alan R. Yurko, AX13917, Washington Correctional Institute, 4455 Sam Mitchell Drive, Chipley, FL 32428, February 28, 2001, to Alan G. Phillips (on file with author).

talization of the baby. For instance, one state witness denied finding evidence of hypoxia (oxygen deficiency), yet the hospital records explicitly reported this. The hypoxia and chronic jaundice could have caused the neurological damage described by the defense. The state also neglected to mention the prolonged apnea that preceded the hospital admission, which also could have caused complications and pathologic findings described by the state, including acute degeneration of brain cells with reddish discoloration and swelling of the blood vessels. All four state witnesses agreed that the father was guilty of child abuse, and that the baby had died of shaken baby syndrome.[9]

The three primary issues at trial were rib fractures, cerebral hemorrhages, and meningitis. A brief examination of these and other issues follows.

a) Rib Fractures: Baby Alan had four rib fractures on his back left side. Callous formations indicated they were old. One callous formation was larger than the rest, which the state used to argue that the fractures had occurred at different times, thus indicating a pattern of abuse. Several factors suggest otherwise:

   i) No one saw evidence of external bruising: not grandparents, mother, babysitter, nor pediatrician at weekly visits;
   ii) Rib fractures from trauma are accompanied by internal thoracic injuries 85% of the time; there were none in baby Alan;
   iii) The difference in callous formation could indicate a difference in severity of the injury rather than a difference in time;
   iv) Medical research shows a strong correlation between temporary brittle bone disease (TBBD) and decreased fetal movement during pregnancy (the mother reported decreased fetal movement during pregnancy), supporting the defense's contention that the rib fractures took place during labor before birth. The mother suffered from chronic oligohydromnios (deficiency of amniotic fluid), which would have constricted fetal movements. Decreased amniotic fluid would also explain the retarded development of baby Alan's kidneys (found in autopsy), and pulmonary hypoplasia (underdevelopment of the lungs) that was evident both in a birth video and in symptoms that persisted throughout the baby's life;
   v) It was plausible that advanced vitamin C deficiency also predisposed the baby to rib fractures.

b) Cerebral Hemorrhages: The defense asserted that cerebral hemorrhages resulted from insults to the blood vessels caused by the pre-hospitalization apnea and advanced meningitis. The hemorrhages were all fresh, within 24 hours in the opinion of the defense expert, placing their occurrence after the final hospital admission. Supporting this conclusion was the administration of blood thinner at the hospital, in connection with the administration of intravenous fluids and/or in anticipation of organ harvesting. In contrast, two state witnesses attributed the bleeding to trauma, and estimated its origin at two to five days prior to death. This time period, however, overlaps the three-day hospitalization period, so the state at

[9] *See* Harold E. Buttram and F. Edward Yazbak, *supra* note 6 at 74.

least implied that the bleeding could have been post-hospitalization, despite its conclusion to the contrary.

c) Meningitis: The defense witness described extensive evidence of meningitis that was possibly weeks old, clearly originating before the final hospitalization. The medical examiner denied finding evidence of meningitis. However, he admitted to not having examined the spinal fluid, nor did his pathological report describe the meninges (covering around the brain and spinal chord), which would have provided evidence for or against a meningitis diagnosis. A second state witness acknowledged meningeal inflammation, but attributed it to the hemorrhages instead of meningitis. However, this contradicted his own statement that such inflammation appears only 3-4 days after a hemorrhage, and he agreed that most of the hemorrhages found at autopsy were fresh.

d) Disseminated Intravascular Coagulation (DIC)[10]: DIC was allegedly caused by shaking the baby immediately prior to the final hospitalization; this was a cornerstone of the prosecution's case. However, the lab tests were more consistent with chronic DIC than with acute DIC, according to a July 1999 study, again suggesting injury long before the final hospital admission.

The defense's position was that baby Alan died of "natural causes," based on several findings, including:

1. At the time of baby Alan's final hospital admission he had advanced pneumonia and meningitis, either one of which might have been fatal, but together would almost certainly be fatal;
2. The brain hemorrhages were due to the apnea and meningitis;
3. There were brain and spinal injuries at or near birth; and
4. The baby experienced "failure to thrive," evidenced by immature kidneys, lack of weight gain, nerve degeneration, and severe hypoglycemia.

In the IRC review of the medical evidence and testimony, Drs. Buttram and Yazbak state that the defense, accurate in every count in their opinion, put on a "brilliant presentation." They suggest further that the defense testimony must have been beyond the grasp of the jury, or was otherwise overshadowed by the prosecution's six witness presentations to the defense's one. It may also be that juries feel compelled to find someone to blame when an infant dies, and are more likely to blame a parent than to find fault with medical authorities or attribute an infant death to "natural causes." Maintaining his innocence to the end, Mr. Yurko refused to plea bargain—"a courageous act, one which would have been made only by a person conscious of his own innocence,"[11] but he was found guilty nonetheless. Under these conditions, Florida state law required a life sentence without parole.

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[10] DIC is "[a] pathological form of coagulation that is diffuse rather than localized, as would be the case in normal coagulation. The process damages rather than protects the area involved…generalized bleeding may occur." TABOR'S CYLCOPEDIC MEDICAL DICTIONARY, 16th Edition, 1989.

[11] *See* Harold E. Buttram and F. Edward Yazbak, *supra* note 6 at 76.

None of the witnesses for either side mentioned vaccination as a possible cause of any of the injuries. Despite this, an analysis of the evidence shows vaccines as a probable primary cause of baby Alan's decline and death.

3) The Vaccine Analysis:

a) Contraindications: Baby Alan was vaccinated despite contraindications, including acute infection and prematurity. Drs. Buttram and Yazbak state, "[a]lmost certainly a medical consensus would agree that vaccinations would have been contraindicated and should not have been given," and "[a] serious, possibly catastrophic reaction to the vaccines would have been predictable under these circumstances."

b) Mechanisms: The IRC report describes two possible mechanisms which, either alone or in combination, could have initiated a series of events culminating in death:

i) Immune Paralysis from the Vaccines:

There are medical studies supporting immune paralysis from vaccination. One such study found that T-helper lymphocytes of subjects vaccinated with tetanus dropped to levels seen in active AIDS patients; the implication of this for baby Alan's receipt of multiple vaccines are rather alarming. The IRC authors cite a study that cites 20 references and case reports that show immune suppression following various vaccines. Baby Alan had bilateral pneumonia and failure to thrive when he was vaccinated; the resulting immune suppression could well have led to the spread of the infection to other parts of the body, including the brain.

ii) Vaccine-Induced Encephalitis:

Pertussis, Hib, and Hep B vaccines either alone or in combination would be the prime suspects for this. VAERS reports of Hep B deaths of neonates document cerebral hemorrhages, pulmonary bleeding, bloody diarrhea, and blood in upper airway passages; one study catalogued 45 different types of reactions in medical literature from around the world. Other studies associate pertussis endotoxin with bleeding and coagulation disorders. Regarding baby Alan's retinal hemorrhage, studies dispute the belief that shaken baby syndrome is the only possible cause, as reported by Dr. Scheibner and mentioned in Part II, A. above.

Regarding the latency period between the shots and the symptoms of encephalitis (inconsolable screaming, etc.), the 10-11 day period occurring in this case is outside of the VICP's Table Injury Chart time frame of 3-7 days. The IRC authors call this time limitation "outdated and unrealistic," and cite

studies to support the longer time occurring in this case. Editorials and studies dating back to the 1930's have documented the onset of nervous system disorders and encephalitis following vaccination ranging from 10 to 13 days after a shot. More recent studies from the 1970's have shown encephalitis occurring largely within a three-day period, for reasons unclear to the authors of the IRC report. One study (perhaps the only one) that studied the DPT reactions long term was the independent one by Karlsson and Scheibner, which found clear patterns of stress-induced breathing in infants following immunization. Peak stress times post-immunization were days 2, 5, 6, 8, 11, 13-16, and 18-21. These findings support a causal relationship between the vaccines and baby Alan's difficulties.[12]

c) Autoimmune Reaction: The medical legal standard of 3-7 days for a vaccine reaction excludes an entire category of adverse events, that of delayed autoimmune reactions. Little is known about vaccine-induced autoimmunity due to the lack of study of the subject, but one recent review cites a temporal relationship of two to three months between vaccination and autoimmune reactions.

d) Hot Lots: The vaccine lot for baby Alan's DTaP shot was later discovered to be a "Hot Lot"—one with a disproportionately high death and disability rate compared to other lots. Alan's lot—DTAP81507, ranks as number one in deaths, and number four in total events reported.[13]

e) Vitamin C: The 1970's work of Archie Kalokerinos, M.D., showed a direct connection between infant mortality following immunization and vitamin C. In this case, the mother's weight loss during pregnancy and inability to take her vitamins almost certainly resulted in vitamin deficiencies, which would have left baby Alan more vulnerable to the later vaccines. It would also have contributed to the fractures, as vitamin C is important in the formation of connective tissue in the bones; a deficiency at birth could have left baby Alan susceptible to "green stick" fractures during the stresses of the birth.[14]

f) Lymphocytosis and Brain Edema: The meningitis "with heavy infiltration of lymphocytes" and the brain edema may well have been due to the vaccines. The active component of pertussis has been known as the "lymphocytosis promoting factor," and brain edema has been found to be "a feature of pertussis-induced encephalopathy." Three studies reported infants with bulging fontanelles following DPT vaccination. Here again there is a basis for connecting baby Alan's symptoms with his vaccines.[15]

4) Conclusion, Part II

[12] *See* Harold E. Buttram and F. Edward Yazbak, *supra* note 6 at 78.
[13] *See* Letter from Alan R. Yurko, *supra* note 8.
[14] *See* Harold E. Buttram and F. Edward Yazbak, *supra* note 6 at 77.
[15] *Id.* at 79.

A section of the IRC report summarizing vaccine adverse events as they may relate to SBS cases generally bears quoting directly:

> A NEW SYNDROME EMERGING FROM TRAGEDY?
>
> As yet based largely on observation and a limited but suggestive body of medical literature, in many cases thought to represent SBS it appears that we may be witnessing the adverse effects from interactions of highly potent vaccines given in combination, which potentially include: Hepatitis B (hemorrhagic vasculopathies, autoimmune reactions, neuropathies), Hemophilus influenza (hypersensitization), tetanus (hypersensitization), and pertussis (hypersensitization, brain edema, and hypercoagulability with vascular inflammation from endotoxin). At least two of the vaccines, (Hib and pertussis), when given together, have been shown to increase their sensitizing potencies. Usually within a period of 12 days these interactions bring about a combination of brain edema, hypercoagulability of the blood, and inflammation of blood vessels, these in turn resulting in a shearing effect on subdural blood vessels and subdural hematomas, thus mimicking what is now though to represent the SBS.

Drs. Buttram and Yazbak conclude their report by pointing to baby Alan's pneumonia and viral meningitis and/or vaccine-induced encephalitis: "Shaken Baby Syndrome has never caused pneumonia and meningitis. Baby Alan died of a vaccine reaction." Dr. Scheibner and others have reviewed the medical reports in this case and come to the same conclusion.

The possible occurrence of an epidemic of misdiagnosed Shaken Baby Syndrome cases is a sobering thought. There is no scientific DNA breakthrough that can clear these innocent victims' names with a single test as has occurred with other wrongly convicted murderers. As demonstrated in the IRC Report, research exists that could enable proper analysis to determine whether or not vaccines played a role, but since few doctors and defense attorneys are knowledgeable about vaccine adverse events, this analysis is very likely seldom undertaken in SBS cases.

Concluding Remarks

Vaccine injury can have devastating consequences to victims and their families in both the civil and criminal arenas. On the civil side, it is reasonable for the government to take action to ensure that only genuine vaccine injuries are compensated under the NVICP. However, the system as presently structured makes it difficult if not impossible for many legitimate victims to get compensation. Extensive program revisions are badly needed. Meanwhile, the larger problem—recognition of the widespread failure of, and full extent of the damage from, mass mandatory immunization programs—remains substantially unaddressed and under-acknowledged. Safe and effective alternatives, such as homeopathic prophylaxis, continue to remain beyond most people's awareness and are

not a legal alternative (only traditional vaccines fulfill state immunization requirements). These conditions perpetuate unnecessary death and disability, in support of medical politics and pharmaceutical profits. However, grass roots organizations dedicated to raising awareness of the vaccine controversy are gaining ground, despite a heavily financed medical-industrial-complex propaganda-machine that is being increasingly utilized in attempts to undermine their effectiveness and credibility.

In the criminal arena, genuine child abusers should be given appropriate psychological or psychiatric help as needed, and be dealt swift justice if their acts are committed with the relevant mens rea. Nevertheless, evidence strongly suggests that some so-called shaken-baby-syndrome cases may actually be misdiagnosed vaccine injuries. These cases need to be distinguished and managed outside of the criminal justice system (unless we wish to prosecute those public health officials who have violated laws by approving improperly tested vaccines, as France has done,[16] and punish those healthcare practitioners who administer vaccines despite obvious contraindications, as occurred in the baby Alan case). Defense attorneys and vaccine dispensers need to be educated about vaccine injuries, to protect the freedom of those who have committed no wrong (not to mention giving them the "space" to grieve for their tragic losses), and to bolster the integrity and effectiveness of our otherwise flawed criminal justice system. Sadly, the blanket denial of vaccine death and injury by healthcare authorities has the potential to undermine educational efforts that implicate vaccines as a cause of death or disability. Thus, educational efforts may be hampered. There's probably no way of knowing just how often caretakers are mistakenly accused and convicted, and no systematic way of getting information to them that could prevent the conviction or save them on appeal. Still, baby Alan's story is getting lots of attention in the alternative and complementary health circles, and that segment of society itself is growing.

Ultimately, I believe the death and disability caused by vaccines in the 20th and 21st centuries will be more widely acknowledged, and vaccines as we know them today will eventually fade from widespread, mandatory use. Safer, more effective alternatives that support and strengthen our marvelously complex immune system, rather than intervening and damaging it, already exist. These eventually will—indeed, eventually must—replace today's vaccines.

[16] J. Barthelow Classen, M.D., M.B.A., President and CEO, Classen Immunotherapies, Inc., letter to The Honorable Dan Burton, Chairman U.S. House of Representatives, Committee on Government Reform, Washington, DC 20515, October 12th, 1999, at www.vaccines.net.

APPENDIX A: Excerpt From NVICP Vaccine Injury Table

HRSA HEALTH RESOURCES AND SERVICES ADMINISTRATION • HHS
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National Vaccine Injury Compensation Program
Vaccine Injury Table

(Effective Date: December 18, 1999)

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT; Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Brachial Neuritis	2-28 days
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
II. Vaccines containing whole-cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTaP, DTP, P, DTP-HiB)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	72 hours
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours