OFFICE OF SPECIAL MASTERS

(No. 94-0353V)

(Filed July 1, 1998)

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STUART COHEN and ROBIN COHEN, on behalf of DREW COHEN, a minor, and in their own right,	*	
Petitioners,	*	
	*	PUBLISHED
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
**********	*	

Ronald C. Homer, Boston, Massachusetts, for petitioners.

David L. Terzian, U.S. Department of Justice, Washington, D.C., for respondent.

DECISION

GOLKIEWICZ, Chief Special Master.

Petitioners, Stuart and Robin Cohen, filed a petition for compensation under the National Vaccine Injury Compensation Program on May 27, 1994.(1) Petitioners allege that their son, Drew Cohen ("Drew") developed an autoimmune disease as the result of diphtheria-pertussis-tetanus ("DPT") vaccinations he received on June 3, August 8, and September 23, 1991, and a rubella vaccine administered on November 25, 1992. Petitioners ("P.") Closing Argument, filed December 2, 1997.(2) Petitioners claim that the autoimmune disease manifested in hepatosplenomegaly, Coombs positive hemolytic anemia, a positive anti-nuclear test, and immune-mediated thrombocytopenia. P. Closing Argument at 1-2. On September 8, 1994, respondent filed a report recommending that the court dismiss this case based on the lack of evidence to support a finding that Drew's condition is vaccine-related.

The parties stipulated to certain facts in this case. Stipulation of Fact, filed February 5, 1997. Thereafter, the court heard medical expert testimony at an evidentiary hearing held on February 19, 1997, and continued on February 24, and September 29, 1997. The first part of the hearing was held in San Francisco, California, during which Dr. Alan Levin testified in person on behalf of petitioners. Dr. Gregory Reaman testified in person for respondent at the second part of the hearing, conducted at the U.S. Court of Federal Claims in Washington, D.C. Subsequently, both Dr. Levin and Dr. Reaman testified by telephone on September 29.(3)

FACTS

Drew was born on March 31, 1991, at St. Mary Hospital in Langhorne, Pennsylvania, following a term, uncomplicated pregnancy. P. exhibit ("ex.") A; P. ex. C at court-numbered p. 2, 3-30. At birth, he weighed seven pounds, 11 oz., measured 19½ inches, and had APGAR scores of nine and nine.(4) P. ex. V. at 1; C at 2. Drew received well baby care from Dr. Aaron Newberg of Allentown Pediatrics. P. ex. V. Drew received his first DPT and hemophilus influenza Type B ("Hib") vaccinations on June 3, 1991. P. ex. V at 2. On August 12, 1991, he received his second DPT and Hib immunizations and his first Oral Polio Vaccine ("OPV"). *Id*. At nearly six months of age, on September 23, 1991, Drew was again

vaccinated with DPT and OPV. P. ex. V at 3. He

received his third Hib vaccination on April 2, 1992, and his fourth DPT vaccine on September 21, 1992. P. ex. V at 4, P. ex. D at 1.

Drew was reported to have several instances of congestion, cough, fever, and upper respiratory infection through his infancy but was consistently reported to be a well child by his pediatrician. P. ex. V at 2-4; P. ex. P at 9, 5. On November 27, 1991, Drew was documented to have been having "head shakes" for one month and a "seizure disorder" was noted in the record. Drew received a measles vaccination that day. P. ex. V at 1, 3. An EEG was performed on December 19, 1991, and the results were considered to be normal. P. ex. F at court-numbered p. 6. Drew was examined by an allergist on November 25, 1992, because the temper tantrums he had been having since three to four months of age had increased in the past few months. P. ex. G at 1-2. The allergist discounted food allergies as the cause of his temper tantrums and advised Drew's mother to contact a developmental-behavioral pediatrician. *Id*.

Drew received his first rubella vaccination on November 25, 1992. P. ex. D at 1. On December 1, 1992, Drew was seen by his doctor for a one-day history of fever, not eating, and vomiting. P. ex. D at 1-2. On December 4, 1992, Drew presented to his doctor with fever, earache, jaw pain, sore throat, loss of appetite, and loss of sleep. P. ex. D at court-numbered p. 2.

On April 21, 1993, Drew was seen by his pediatrician who reported the following: "Monday night vomited twice - felt v. hot - feels warm but he does not let [us] take his temp. has rash on his stomach for 2 wks--falling down a lot and gets [(?)] bruises all over him." P. ex. D at court-numbered p. 3.; *see also* P. ex. Y at 2 (transcription of office notes). Following a fall in which he sustained a large bruise on his right leg, Drew was admitted to St. Lukes Hospital in Bethlehem, Pennsylvania on April 22, 1993, and discharged on April 25, 1993, with the following diagnosis: "Thrombocytopenia, neutropenia, rule out viral suppression or autoimmune disease." The etiology of Drew's thrombocytopenia and neutropenia was noted to be unclear. He was started on gamma globulin and instructed to return for weekly blood tests for eight weeks. P. ex. H at court-numbered pp. 1-2; P. ex. J at court-numbered p. 6.

Drew was examined by hematologist, Dr. Catherine Manno, at The Children's Hospital of Philadelphia ("CHOP") on May 26, 1993, for a second opinion of his diagnosis, prognosis, and treatment options. P. ex. J at 6. Dr. Manno's impression was "Evans syndrome." P. ex. J at 7. Drew continued to receive care from Dr. Manno and still continues under her care for his Evans syndrome. *See* P. ex. DD. He "remains on varying doses of steroids to control his fluctuating platelet count. . . . Although he continues to have some behavior problems, he appears to be developing normally." Stipulation of Facts at 6.

EVIDENCE PRESENTED

Dr. Levin

Dr. Alan S. Levin, board-certified in allergy, immunology, and pathology, testified on behalf of petitioners.[(5)] Dr. Levin believes that vaccines, including DPT, rubella, and OPV can cause hemolytic anemia[(6)] and thrombocytopenia,[(7)] Tr. at 10, 17, 26 59, and that, to a reasonable degree of medical certainty, the aggregate of Drew's vaccinations, and most likely the rubella vaccine (the most proximate vaccination to the event), was the cause or substantial cause of Drew's blood disorders.[(8)] Tr. at 27, 29, 59, 76-77.

Dr. Levin's theory is somewhat complicated but can be simplified and summarized as follows. Dr. Levin testified that vaccinations can cause acute thrombocytopenia and acute hemolytic anemia. The acute forms of the diseases can, in rare instances, progress to the chronic forms by the same mechanisms by which the acute forms occurred. Therefore, in Dr. Levin's view, it follows that vaccinations can cause chronic thrombocytopenia and chronic hemolytic anemia. Dr. Levin believes that Drew's vaccinations caused him to develop chronic thrombocytopenia and hemolytic anemia from which Drew currently suffers. Dr. Levin's reasoning follows in greater detail.

Whether an individual suffers an autoimmune reaction, Dr. Levin testified, depends on a person's genetic makeup. If an individual is genetically predisposed or has the appropriate genetic make-up, he may develop an autoimmune reaction to vaccinations. Dr. Levin testified that there are "many" possible mechanisms whereby individuals can develop autoimmune reactions, like thrombocytopenia and hemolytic anemia, to the components of DPT vaccine. Tr. at 11, 12, 13, 15-16; Tr. third hearing ("Tr.III") at 7. He testified that there are several plausible mechanisms for the vaccine causing thrombocytopenia and hemolytic anemia in Drew's case, although, he testified "if somebody identifies a different mechanism, it could be another one." Tr.III at 24. According to Dr. Levin, one mechanism, the "innocent bystander method" occurs when:

the individuals begin to respond against . . . most likely the protein code. And this particular protein code gets stuck onto cells, depending upon the individual, and the cells can be red cells, they can be platelets, they can be neutrophils. If these proteins get stuck on any of these cells and the individual begins to mount an antibody response against this particular protein, then the cells are going to be destroyed along with the protein in the process of the body trying to clean up the reaction.

Tr. at 11-12; *see also* Tr. at 8. Thus, the cells are the "innocent bystander" and are attacked along with the targeted protein. Another mechanism involves an individual becoming sensitized to his or her own red blood cells which can happen when "the character of the red cell envelope is changed, or when the ability of the individual's capacity to respond against himself is enhanced." Tr. at 9. Dr. Levin suggests the "antigen antibody complex" phenomenon results when "the antigen, which is the viral protein, is circulating, the antibody binds to that, sometimes these complexes also absorb or stick to the cell and the body then begins to react against those complexes." Tr. at 12-13. The "molecular mimicry" mechanism, according to Dr. Levin, occurs when "there's something on the vaccine itself that looks to the body like something on the body's own cells. And therefore, when the body makes an immune response against the vaccine, that response then goes against the body's own cells." Tr. III at 7. Finally, the "sequestered antigen" mechanism, Dr. Levin explained, occurs when, "during the process of destroying the body's own cells, certain sequestered antigens . . . can be exposed to the body. And then the body makes an immune

response against those sequestered antigens . . . ." Tr. III at 8.

According to Dr. Levin, in the overwhelming majority of cases, when the components of the DPT leave a person's system, the hemolytic anemia and thrombocytopenia resolves. Tr. at 14, 19. However, he explained, in some cases the chronic form of the disease process can be "triggered from an innocent bystander" or the acute form. Tr. at 16; 19-22, Tr. III at 11-14. He testified that four or five percent of people who develop vaccine-induced thrombocytopenia and or/hemolytic anemia "will go on to chronic" illness. Tr. at 19. Dr. Levin acknowledged, however, that the pathogenetic mechanism for chronic thrombocytopenia, chronic hemolytic anemia, and Evans syndrome (which he believes is the same mechanism for each), is different from the mechanism for the acute forms of thrombocytopenia and hemolytic anemia precipitated by the innocent bystander mechanism. Tr. at 34; Tr.III at 15-16.

Dr. Levin believes that in Drew's case, "the antigens[(9)] from the vaccine bound to [his] red cells and to [his] platelets and that then [he] began to mount an antibody response against the antigens and possibly augmented by other confounding factors, like maybe viral illnesses and such, that phenomena went into an innocent bystander type autoimmune disease process which then, by virtue of [his] genetic make-up shifted into a chronic process from which [he] suffers now."[(10)] Tr. at 23, 27 (Dr. Levin's testimony regarding mechanism of Katie Addington's illness (*see supra* n. 3), Tr. at 23, "basically the same" for Drew).

Regarding the role of the viral illnesses Drew suffered between the vaccination and onset of his disease, Dr. Levin acknowledged that the viruses "could have been confounding factors. . . . [I]t's my opinion that but for the vaccination those viral illnesses would not have been responsible for Drew's disease." Tr. at 27-28. Dr. Levin does not believe that one viral illness caused both diseases, especially in light of additional factors in Drew's case, including splenomegaly, lymphadenopathy, and increased lymphoid tissue. Tr. at 28. Dr. Levin acknowledged that viral illnesses are known to cause both the acute and chronic forms of hemolytic anemia and thrombocytopenia. Tr. at 49. However, Dr. Levin insisted "it's more likely that the vaccine would cause both processes than one virus causing both processes, and splenomegaly."[(11)] Tr. at 51; *see also* Tr. at 52, 104. Dr. Levin believes that generally only a debilitating virus could cause thrombocytopenia, hemolytic anemia, and splenomegaly simultaneously in one patient. Tr. at 53. "I don't know of any single virus infection that's associated with all of these things . . . ." Tr. at 54, 58.

Finally, Dr. Levin testified that he disagrees with the conclusion of the 1994 Institute of Medicine ("IOM") 1991 published report that there is insufficient evidence to indicate a causal relationship between DPT vaccine, or the pertussis component of DPT vaccine, or rubella vaccine and thrombocytopenia. Tr. at 69, 70; R. ex. J at 179, 201. Dr. Levin also disagreed with the IOM's conclusion that there is insufficient evidence to indicate a causal relationship between DPT vaccine or the pertussis component of DPT vaccine and hemolytic anemia. Tr. at 71; Respondent's Report, ex. B at 159. He explained that the IOM is "not talking about specific individuals, they're talking about epidemiologic studies. And if you look at specific individuals, then there are links." Tr. at 69. He acknowledged that the IOM reviewed case reports, but countered "they themselves didn't review specific individuals, they reviewed case reports." *Id*.

Dr. Reaman

Dr. Gregory Reaman, board-certified in pediatrics and pediatric hematology oncology, testified on behalf of respondent.(12) Dr. Reaman believes, to a reasonable degree of medical certainty, that Drew suffers from Evans syndrome and that his condition was not caused by any of his DPT or rubella vaccinations. (13) Tr. at 118, 144, 183.

Dr. Reaman's opinion can be summarized as follows. He does not believe that DPT vaccine or rubella vaccine can cause acute or chronic thrombocytopenia, chronic hemolytic anemia, or Evans syndrome. Tr. at 131, 132, 184. He believes there may be an association between DPT and acute hemolytic anemia. Tr. at 130. However, Dr. Reaman is unaware of medical literature that suggests that vaccines can cause acute thrombocytopenia and acute hemolytic anemia simultaneously. Tr. at 133. In addition, Dr. Reaman believes there is no support in the medical community for the theory that the diseases, acute thrombocytopenia and acute hemolytic anemia, can ever become, respectively, the diseases chronic thrombocytopenia and chronic hemolytic anemia. Tr. at 121.

Dr. Reaman distinguished acute thrombocytopenia and acute hemolytic anemia, from chronic thrombocytopenia and chronic hemolytic anemia. According to Dr. Reaman, thrombocytopenia that persists for more than six months is chronic and hemolytic anemia that requires therapy for more than six to 12 months is generally referred to as chronic hemolytic anemia. Tr. at 119-20. However, Dr. Reaman was careful to distinguish the term "acute" as it applies to the duration of a disease and as it describes a disease process. He explained "there is a very distinct difference between acute immune-mediated thrombocytopenia or ITP, and chronic immune-mediated thrombocytopenia, or chronic ITP. They're very different disorders, they have very different natural histories and very different responses to treatment." Tr.III at 31. By definition, Dr. Reaman explained, all chronic diseases are acute at one point "[b]ecause when you make the diagnosis at time zero you don't know if it's going to become chronic. So most of these situations are diagnosed as acute and the diagnosis changes when the disease persists . . . ." Tr. at 122; *see also* Tr. at 148, 164. "There are no tests available to predict at the time of diagnosis who has acute thrombocytopenia and who will have chronic thrombocytopenia. The only way you make a decision that a patient has chronic ITP is if their what was thought to be acute ITP lasts more than six months. At that point in time they no longer have acute ITP. They have a totally different disease called chronic immune-mediated thrombocytopenia purpura." Tr. at 148-49.

Dr. Reaman testified that there is support in the medical literature for a causal association between the measles vaccine and acute thrombocytopenia, however, Dr. Reaman does not believe DPT vaccine can cause either acute or chronic thrombocytopenia or Evans syndrome. Tr. at 130-31. According to Dr. Reaman, DPT vaccine is not a viral vaccine as is the measles vaccine. Tr at 128-29. Therefore, the medical articles that refer to the onset of acute thrombocytopenia following live MMR vaccine are describing a completely different situation because "live virus vaccines are manufactured from attenuated virus. The virus is attenuated by serial passages through cell cultures to try and reduce the virulence of the virus. But in some situations those viral vaccines, live virus vaccines, do cause mild and sometimes even subclinical illnesses very similar to the illness itself." Tr. at 129-30. "[L]ive viruses cause disease by replicating in the patient or the host. So they don't just pass through the system as something like pertussis or a component of the pertussis protein would." Tr. at 199. "So in the case of measles vaccine, measles is known to cause acute thrombocytopenia in patients who have clinical measles. And measles vaccine has also been associated with short-lived acute thrombocytopenia, presumably virally-related." Tr. at 129-30.

Dr. Reaman testified he is aware of "a few case reports of associated autoimmune hemolysis or hemolytic anemia following DPT. Whether or not they were truly causal[ly] related is unclear . . . ." Tr. at 130. He testified that, in those case reports that suggest a causal relationship, the hypothesis is "antigen antibody complexes with the pertussis component of the DPT vaccine. Once they're gone then the hemolysis should stop, therefore, it's acute hemolysis. The described reports are acute hemolytic episodes and not chronic autoimmune hemolytic anemia." Tr. at 198-99. In those cases, the literature reports that the onset has occurred within days of the immunization. Tr. at 132.

Dr. Reaman testified that the *seven-month period* between Drew's last DPT and the onset of his illness, and the five-month period between the rubella vaccine and the onset of his illness, are "longer than what's been described [in the literature] as any other immune-mediated conditions that might be associated with some vaccines. Specifically measles vaccine which [Drew] didn't receive." Tr. at 184. According to Dr. Reaman, the literature suggests that the onset of thrombocytopenia generally occurs days to weeks following immunization, not up to a year. Tr. at 132, 133.

Regarding Dr. Levin's theory of the acute form of the disease becoming chronic, Dr. Reaman testified, "The acute going on to develop into chronic because of breaking of tolerance, I have no understanding of that mechanism at all. I'm not sure what that means and I've never seen anything describing that mechanism in the medical literature." Tr. at 121. Rather, Dr. Reaman believes there are two different pathogenic mechanisms, that is, two different means of destruction, of either platelets or red blood cells, that operate in acute versus chronic thrombocytopenia and hemolytic anemia, distinct and different disease processes.[(14)] Tr. at 120, 122; *see also* Tr. at 162.

Dr. Reaman testified that a viral infection can be the cause of either acute or chronic thrombocytopenia and hemolytic anemia. Tr. at 124. According to Dr. Reaman, any number of viruses could cause those conditions and the viruses need not be debilitating, as Dr. Levin testified. Tr. at 124-25. In addition, Dr. Reaman testified that one virus can definitely cause both thrombocytopenia and hemolytic anemia, and subclinical infections (viral infections that do not cause the host to become symptomatic) may also be the cause of both diseases.[(15)] Tr. at 125, 127.

STATUTORY REQUIREMENTS

Petitioners may establish causation in one of two ways. First, petitioners may demonstrate what is commonly referred to as a Table case. The Vaccine Injury Table lists vaccines covered by the Act and certain injuries and conditions that may stem from the vaccines. §14. If the special master finds that a person received a vaccine listed on the Table, and suffered the onset or significant aggravation of an

injury listed on the Table, within the time period prescribed by the Table, then the petitioners are entitled to a presumption that the vaccine caused the injury. §13(a)(1)(A). The petitioners must then show that the injury for which they seek compensation is a sequela of a Table injury. §14(a)(I)(E). The respondent may rebut the presumption of causation with a preponderance of the evidence that the injury or condition was due to factors unrelated to the administration of the vaccine. §13(a)(1)(B).

Second, petitioners may establish causation by proving by a preponderance of the evidence that the vaccine actually caused the alleged injury. Actual causation requires proof of a "logical sequence of cause and effect showing that the vaccine was the reason for the injury." *Strother v. Secretary of HHS*, 21 Cl. Ct. 356, 370 (1990), *aff'd without opinion*, 950 F.2d 731 (Fed. Cir. 1991). The mere temporal relationship between a vaccination and the injury, and the absence of other apparent etiologies for the injury, are patently insufficient to prove actual causation. *Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668, at *3 (Cl. Ct. Spec. Mstr. June 8, 1992). Rather, petitioners must show a medical or scientific theory causally connecting the vaccination and the injury. *Strother*, 21 Cl. Ct. at 370 (*citing Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983)).

"[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for a petitioner seeking to prove causation in fact. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), *reprinted in* 1986 U.S. Code Cong. and Admin. News 8344, 6356. In this regard, the recent Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), is instructive. While that case dealt with the admissibility of scientific evidence and here we are assessing the scientific validity of evidence already presented, *Daubert* is helpful in providing a framework for evaluating the reliability of scientific evidence.[(16)] The Court in *Daubert* wrote:

[I]n order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation -- *i.e.*, "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.

Id. at 2795. The Court goes on to suggest a key criterion of scientific reliability is whether a theory has been tested and subjected to peer review and publication. *Id*. at 2796-97. While acknowledging that publication is not a *sine qua non* of admissibility, the Court finds the submission of a novel scientific theory to the scrutiny of publication is a component of 'good science' and the fact of publication is a relevant, though not dispositive, consideration. *Id*. at 2797. Finally, the Court noted while not a precondition, the general acceptance of a theory within the scientific community of a scientific theory can have a bearing on the question of assessing reliability while a theory that has attracted only "minimal support" may be viewed with skepticism. *Id*.

Inasmuch as Drew's condition, chronic hemolytic anemia and chronic thrombocytopenia, is not one listed on the Vaccine Injury Table, petitioners' claim that the DPT and rubella vaccinations Drew received on June 3, August 8, and September 23, 1991, and November 25, 1992, caused his condition, is one of causation-in-fact. Therefore, the issues to be decided are: (1) *can* DPT or rubella vaccinations cause chronic hemolytic anemia and chronic thrombocytopenia? and (2) *did* the vaccination(s) cause chronic hemolytic anemia and chronic thrombocytopenia in Drew's case? *See Guy v. Secretary of HHS*, No. 92-

779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995) (two-step causation-in-fact analysis used); *Alberding v. Secretary of HHS*, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. March 18, 1994) (two-step causation-in-fact analysis used).

DISCUSSION

There was a great deal of discussion and disagreement between the medical experts in this case regarding the mechanisms by which DPT or rubella vaccine may or may not cause chronic thrombocytopenia and chronic hemolytic anemia. That evidence was technical and complicated. After a great deal of review and consideration, the court finds the crux of the matter is simply this--there is no showing that medical literature or the scientific community supports a causal relationship between DPT or rubella vaccines and either of the two involved medical conditions. What is left before the court are the highly speculative, unsupported opinions of Dr. Levin. These opinions are not credible.

Dr. Levin relies on literature that does not support his opinion and rejects that which clearly contradicts his opinion. First, Dr. Levin rejects the conclusions of the IOM. The Act which established this Program charged the IOM of the National Academy of Sciences with reviewing the medical and scientific literature on possible adverse consequences of certain childhood vaccines and preparing a report on the results of its review. The 1991 published report, Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines*, (Nat. Academy Press 1991) (hereafter "IOM Report"), presents the following conclusions: "There is insufficient evidence to indicate a causal relation between DPT vaccine or the pertussis component of DPT vaccine and thrombocytopenia." IOM Report at 179; R. ex. J at 179. "There is insufficient evidence to indicate a causal relation between the currently used rubella vaccine (RA 27/3) and thrombocytopenic purpura." IOM Report at 201; R. ex. J at 201. "There is insufficient evidence to indicate a causal relation between DPT vaccine or the pertussis component of DPT vaccine and hemolytic anemia." IOM Report at 159; R. Report, ex. B at 159.

The Act does not require the special masters to accept the IOM Report as dispositive. *Estep v. Secretary of HHS*, 28 Fed. Cl. 664 (1993). However, considering the charge given to the IOM and the scope of its review, the court considers the conclusions of the IOM to be authoritative and subject to great deference in this Program. Dr. Levin believes the IOM "had to be very circumspect about the data because of their governmental position, but I think the data is quite clear and any scientist can evaluate the data and show that there is a probable causal relationship between the vaccine and the thrombocytopenia, and in addition the hemolytic anemias." Tr. at 73. Dr. Levin is wrong. For one, Dr. Reaman, an eminently qualified, well-respected physician, does not conclude there is a probable causal relationship. Nor, it seems, does the medical and scientific community responsible for generating the literature on the topic at issue. As for Dr. Levin insinuating without a shred of evidence that the IOM was less than forthcoming in formulating its conclusions, that serves only to spotlight Dr. Levin's eagerness to advocate petitioners' position, and casts doubt upon his own impartiality.

Dr. Levin attempted to demonstrate that DPT or rubella vaccine can cause acute thrombocytopenia or acute hemolytic anemia. He then attempted to show that those acute diseases, through one of several mechanisms, may become chronic thrombocytopenia or chronic hemolytic anemia. Dr. Levin conceded that he cannot point to anything in the literature to support his theory about *how* the process happens, Tr. at 35, 40, however, he referred to several medical articles to support that the phenomenon does occur.

Dr. Levin proved to be a poor witness. His interpretation and application of the literature to the case at bar was manipulative and unpersuasive. He extrapolates from the conclusions of the articles that report causation by viruses or vaccines other than DPT, and extends those conclusions undeservedly to the DPT vaccine. He interprets the language of the medical articles as though the articles were ambiguous legal documents or statutory provisions that may be interpreted several different ways to lead to several different conclusions. [(17)] There are instances where Dr. Levin stretches his construction beyond the limits of reasonableness.

The first article to which Dr. Levin referred, he believes, demonstrates that "people can get acute thrombocytopenia purpura from MMR, and that a certain small number of them can go chronic." Tr. at 88. That article describes 23 people who developed post-MMR vaccine acute thrombocytopenia, 22 of whom recovered. U. Nieminen, *et al*., *Acute Thrombocytopenic Purpura Following Measles, Mumps, and Rubella Vaccination. A Report on 23 Patients.*, 82 Acta Paediatr 267 (1993) (hereafter "*Report on 23 Patients*"); P. ex. N, tab 3. Dr. Levin believes that DPT vaccine will cause the same results. However, neither this article, nor any he submitted for that matter, supports that theory.

Dr. Levin would have the court accept that this article demonstrates that patients who developed acute thrombocytopenia as a result of vaccination can go on to develop chronic thrombocytopenia. The literal words of the article do not make, nor attempt to make, that point. However, Dr. Levin, through semantic acrobatics, attempted to press the issue.

THE WITNESS: . . . Okay. Now, if you look at the numbers here, they talk about 23 people who developed acute thrombocytopenia and track 22 of them into recovery, one of them didn't recover, so one out of 23 is roughly four plus percent.

BY MS. COLEMAN:

Q Okay. The conclusion, doctor, states, "Despite an abrupt onset, the overall course of TP was predominantly benign with complete recovery of TP in less than six months."

A Right. But, realize, they didn't say absolutely benign and recovery always at six months, they say predominantly, and that means that there's a small percentage of them that don't recover.

Q And where does . . . it say that?

A Well, it says that in the words they use, "predominantly benign" meaning not absolutely benign. It's real clear. They would say absolutely benign if it was absolutely benign, but it's not. I mean there's a

certain number of people who go on to chronic illness. . . . Well, I mean in looking at this, if you count up the number of patients, 22 recovered and one didn't.

Q So, we don't know what happened to that one, do we?

A We know he didn't recover.

Q But, we don't know what happened?

A Well, unless he got hit by a bus, the most likely is that he became chronic. . . .

Q Okay. Where in this article, does it conclude that the MMR vaccine causes the acute, which then in turn can cause the chronic?

A Just that, it's predominantly benign.

Tr. at 37-38. Aside from the difficulty in understanding Dr. Levin's interpretation of the article, Dr. Levin also makes an unreasonable assumption. He assumes the one patient who did not recover suffered a chronic course, however, there is no indication of that in the article. In fact, he may *have* been hit by a bus. The point is, it is pure speculation by Dr. Levin to say what happened to that one patient.

According to Dr. Reaman, the article in no way suggests that the acute process can go into the chronic process. Tr. at 140. Rather, it distinguishes specifically acute from chronic, stating, *e.g.*, "The pathogenic mechanisms of acute ITP have been suggested to differ from those involved in chronic ITP; the latter is supposed to be of autoimmune origin." *Report on 23 Patients*, at 267. Dr. Reaman stressed that the article deals only with acute thrombocytopenia associated with MMR vaccine. Tr. at 141. In addition, he emphasized there is no suggestion of the disease becoming chronic in any of the patients. "I believe 22 of the 23 [patients] had acute self-limited thrombocytopenia. . . . It quite clearly and specifically states that the natural history of post-vaccination thrombocytopenia is similar to acute childhood immune-mediated thrombocytopenia, not associated with vaccination. It in no way says anything about this going to chronic." Tr. at 140.

Dr. Levin, in attempting to show that DPT can cause hemolysis, referred to an article that describes three infants who developed severe hemolytic anemia following DPT vaccinations. Bjorn Hanfberg, *et al.*, *Acute Hemolytic Anemia Related to Diphtheria-Pertussis-Tetanus Vaccination*, 67 Acta Paediatr Scan, 345 (1978) (hereafter "*Acute Hemolytic Anemia*"); P. Prehearing Submissions, tab 6; Tr. at 96. The article states "[t]he appearance of hemolysis shortly after the second DPT-vaccination in cases 1 and 2 implicates the vaccine as a possible causative agent. . . . The results of our [*in vitro*] experiments showing that the diphtheria and tetanus vaccines had an affinity to human erythrocytes, could therefore help explain the initial steps in the pathogenesis of the hemolysis." *Acute Hemolytic Anemia* at 348-49; Tr. at 96.

Dr. Reaman testified, "I think [the article] suggests that there may be an acute self-limited hemolysis associated with DPT . . . but certainly doesn't prove that DPT causes hemolytic anemia. . . . And it certainly has nothing to do with Evan's Syndrome." Tr. at 167. The IOM Report had the following to say about this particular case report:

[C]ontrols were not well described, and the antibodies detected were not shown to be specific to DPT vaccine. Evidence of a shared antigen in the DPT vaccine and on the human red blood cell would strongly increase the plausibility of a causal relation with the vaccine, but no such evidence has been reported.

IOM Report at 159. Finally, the court notes the article's use of the phrases "*possible* causative agent" and "*could* therefore help explain" (emphasis added). There is nothing in those phrases *concluding* that DPT causes hemolytic anemia. There is merely a suggestion by the authors that DPT *may* have some causal relation to hemolytic anemia.

Next, Dr. Levin testified there is support in the literature for DPT, specifically, causing chronic thrombocytopenia. Maxwell M. Wintrobe, *et al.*, *Chapter 47: Thrombocytopenia*, Clinical Hematology 1093; P. Prehearing Submissions, tab 7 at 1093. He referred to a table within the article that lists the etiological classifications of thrombocytopenia. One entry lists "Infections" as possible causes and includes under the subheading "Viral", *inter alia*, rubella, measles, and pertussis. Dr. Levin explained that the heading or title of the list did not differentiate between acute and chronic thrombocytopenia which to him means the list covers both the chronic and acute diseases. Tr. at 43-45, 102.

Dr. Levin fails to bridge the gap, however, between the vaccination and chronic thrombocytopenia. Missing is evidence that a DPT or rubella *vaccination* is capable of causing a pertussis or rubella *infection*. Dr. Levin made no attempt to establish that link. When questioned as follows, "So, it doesn't specifically say that the DPT vaccine can cause chronic thrombocytopenia," Dr. Levin replied, "Right." Tr. at 44-45. In fact, the issue of whether a DPT vaccine can cause a pertussis infection (whooping cough) has been addressed in other Program cases. In *Barnes v. Secretary of HHS*, No. 90-1510, 1992 WL 97196 (Fed. Cl. Spec. Mstr. April 21, 1992), the special master expressed the following: "It is axiomatic that whooping cough the disease is not listed on the Vaccine Table. This is most telling. . . . Nor was any evidence presented to support a contention that the DPT vaccination itself is capable of causing pertussis." *Barnes*, at *5.

Dr. Levin relies on an article he filed after the hearings that discusses thrombocytopenia following immunization with DPT. L.S. Arya, *et al.*, *Thrombocytopenic Purpura Following DPT Vaccination, Letter to the Editor*, 10 Pediatric Hematology and Oncology, 381 (1993); P. ex. BB. The article describes two cases of thrombocytopenia following DPT immunization. One case involves an 18-month old child with onset of thrombocytopenia 72 hours after DPT vaccine. The other case report is of a child who, at the age of three months, developed thrombocytopenia eight days after receiving DPT vaccine. Dr. Levin himself, however, minimizes the significance of the article. "It's just simply an article in a peer-reviewed medical journal that relates these phenomena to DPT vaccine, that's all it is. It confirms the -- or it's a confirmatory article. It's not proof one way or the other." Tr.III at 17. Dr. Reaman testified that the article appears in a peer-reviewed journal, but only as a letter-to-the-editor, subject to significantly lower levels of scrutiny than would be an original article. Tr.III at 32-33, 48. Dr. Reaman explained the significance of it not appearing as an original article is "there's no cause and effect in this case. It's purely a case report

and a description of an apparent association, but there's absolutely nothing in this article that says that DPT causes thrombocytopenia." Tr.III at 32-33. In fact, Dr. Reaman believes the author of the article makes a statement that there's an association between DPT and thrombocytopenia based on timing of onset alone. Tr. at 34.

Next, Dr. Levin claims there is support in the literature that all childhood immunizations have been associated with acute ITP and the acute form can become chronic. Alton L. Lightsey, *Thrombocytopenia in Children*, 27 Pediatric Clinics of North America 293 (1980); P. Prehearing Submissions, tab 2; Tr. at 89-91. He relies specifically on the following language:

A history of an antecedent febrile illness has been reported in 50 to 85 percent of these [acute form] cases, most of which are nonspecific upper respiratory tract infections; however, all of the usual childhood illnesses and immunizations have been associated. Hemorrhagic symptoms generally occur 10 days to two weeks following the infection or immunization. The differentiating characteristic of this acute form is the spontaneous and permanent recovery within six months of onset.

Thrombocytopenia in Children, at 320. Dr. Reaman testified that nowhere in the article is the suggestion that the acute form becomes chronic. In fact, Dr. Reaman testified:

[I]f anything, it says the opposite because then it begins the next paragraph [on page 302] with [--] Chronic thrombocytopenia purpura in childhood being different in [its] presentation, occurring in a different age group of patients, and having a pathogenetic mechanism similar to that which is seen in adults [--] which implies that it's different than the pathogenetic mechanism of the usual form of thrombocytopenia which is seen in children, that is the acute form.

Tr. at 156-57.

In response to the court's inquiries, Dr. Levin testified:

THE WITNESS: . . . So, when they talk about chronic thrombocytopenia, they're talking about something that goes from acute to chronic. And when they label it acute, they label it acute because it simply gets better.

THE COURT: Well, I don't see where you're saying, when they're talking about chronic they're talking about something that goes from acute to chronic.

THE WITNESS Well, here it goes -- "The differentiating characteristic of this acute form is the spontaneous recovery within six months of onset." So, the differentiation of this acute form from the chronic form is the recovery within six months.

THE COURT: Well, I understand that part. I guess I don't understand where you make -- what support

for the other statement that you made when they're talking about chronic they're talking about something that progresses from acute to chronic.

THE WITNESS: Well, it progresses from thrombocytopenia of short duration to long duration. I mean that's what I get from this particular paragraph.

Tr. at 90-91. Dr. Levin crosses the boundaries of reason here. The court reread the text referred to and concludes that Dr. Levin ascribes a meaning to those words that was simply unintended. There is no suggestion that acute ITP becomes chronic ITP. Nor is there suggested anything more than an "association" between childhood immunization and acute ITP.

Aside from the problems with Dr. Levin's interpretation of the literature, his testimony was also confusing and inconsistent. Dr. Levin proposes that the acute illnesses, thrombocytopenia and hemolytic anemia, may become chronic through a mechanism called "the breaking of tolerance"--the reduction in a person's ability to suppress a response against his or her own tissue. He explained "the innocent bystander phenomena triggers this particular chronic reaction." Tr. at 35. Dr. Levin testified that Drew's condition developed when "the antigens from the vaccine bound to [his] red cells and to [his] platelets and that then [he] began to mount an antibody response against the antigens and possibly augmented by other confounding factors, like maybe viral illnesses and such, that phenomena went into an innocent bystander type autoimmune disease process which then, by virtue of [his] genetic make-up shifted into a chronic process from which [he] suffers now." Tr. at 23, 27. The court was led to believe, then, that this was the mechanism Dr. Levin believes occurred in Drew. However, Dr. Levin's opinion became much less clear when, at the third hearing, he added "there are any number of mechanisms" by which the acute illness may become chronic and he described several of them, including "breaking of tolerance." Tr.III at 10-13. Further, he contradicted his earlier testimony, stating that he could not say which mechanism was responsible:

Q It's your position that the plausible mechanisms for the vaccine causing the thrombocytopenia and hemolytic anemia in these two cases is one of three? The molecular mimicry, the innocent bystander theory or the sequestered antigen?

A Right.

Q It's one of those three, then?

A Right. Well, it's one of those three, or if somebody identifies a different mechanism, it could be another one. But at least one of those three would explain the phenomena.

Q You don't know which one in this case?

A No.

Tr.III at 23-24.

Dr. Reaman disagreed fervently with Dr. Levin regarding this issue. He testified the acute and chronic forms of thrombocytopenia and hemolytic anemia are very distinct, different disorders. "[F]or the specific vaccine, or a specific vaccine to cause something by numerous mechanisms in different patients is really very, very difficult to accept, and basically impossible." Tr.III at 37. In addition, Dr. Reaman testified that none of the mechanisms about which Dr. Levin testified relate to Evans syndrome. Tr.III at 30. He emphasized that the innocent bystander mechanism may be responsible for some cases of acute thrombocytopenia but it is not involved in hemolytic anemia. Tr.III at 30, 36-37.

While the primary basis for rejecting Dr. Levin's testimony is the lack of support for his opinion that the DPT can cause simultaneously chronic thrombocytopenia and chronic hemolytic anemia, the court addresses briefly several related issues. As with the primary issue, Dr. Levin unpersuasively addresses these matters as well.

Dr. Levin believes that Drew's condition was caused by his vaccines, in part, because "of the nature of the disease process. . . [t]he fact that [he] . . . developed, splenomegaly[,] thrombocytopenia and hemolytic anemia." Tr. at 51-52. Dr. Reaman testified that the nature and character of the disease process of Evans syndrome does not change depending on the causative agent. Tr. at 146, 188. "I think the nature and character of [Drew's] Evans syndrome was absolutely classic for Evans syndrome. And I think there's no basis for saying [his] Evans syndrome was caused by these immunizations based on nature and characteristic and presentation" as Dr. Levin suggests. Tr. at 187. While splenomegaly is not commonly seen with Evans syndrome, Dr. Reaman testified it does occur. Tr. at 145; *see* Ching-Hon Pui, *et al.*, *Evans Syndrome in Childhood*, 97 The Journal of Pediatrics 754, 755 (1980); P. Prehearing submission, tab 1 at 755 (of seven patients with Evans syndrome in study, five had splenomegaly).

Dr. Levin was unconvincing that Drew's condition was DPT-induced because of the particular characteristics of his course. Dr. Levin pointed to nothing in the literature to suggest that the course would be different depending upon the causative agent. In fact, Dr. Levin was unable to state with any certainty which agent he believes to have been the causative agent in Drew's case. At one point, Dr. Levin testified the rubella vaccination was the most likely culprit although he believes it was the aggregate of Drew's vaccinations that caused his condition. Later, he testified he could not say which vaccine, OPV, rubella, or DPT was responsible:

Q And in the Cohen case, you testified today that it was the OPV, the rubella, or the DPT vaccine, is that correct. That caused --

A Well, it was the vaccination that caused it, yes.

Q But you don't know which one?

A I guess I don't, no.

Q So in your opinion, it could be either the OPV, the rubella or the DPT vaccine?

A Yes.

Tr.III at 26.

The fact that Drew did not have an apparent "debilitating" virus is another of the bases for Dr. Levin's opinion. He believes only a debilitating virus could cause simultaneously thrombocytopenia and hemolytic anemia and splenomegaly as Drew had. Tr. at 51-53. When asked where in the literature is support for that claim, Dr. Levin responded, "I don't have it here but it's well known . . . ." Tr. at 53.

Dr. Reaman disagreed with Dr. Levin that only a debilitating virus could have caused Drew's condition. He testified he has never seen anything in the literature to support that theory.

It definitely does not have to be a debilitating viral illness. . . . Cytomegalovirus has been associated with both thrombocytopenia and autoimmune hemolytic anemia, as has Epstein Barr virus. Any one of a number of adenoviruses can also cause this. Most acute ITP or immune-mediated thrombocytopenia is seen following an intercurrent upper respiratory viral infection or gastroenteritis. So there are many, many viral infections that have been associated with both of these disorders.

Tr. at 124-25. In fact, the literature filed in this case is replete with references to viral illnesses or live virus vaccinations causing hemolytic anemia or thrombocytopenia.

Dr. Levin was unable to cite to literature demonstrating that DPT vaccine can cause simultaneously chronic thrombocytopenia and chronic hemolytic anemia. Tr. at 46-47. He also claims Drew's viral illnesses may have had a "confounding" role and "augmented" the development of his autoimmune condition. Tr. at 23, 27. Nevertheless, he offers no support for how a viral illness and DPT immunization may act in conjunction with each other to ignite the autoimmune process.

Finally, Dr. Levin testified that, although Drew did not develop thrombocytopenia and hemolytic anemia until seven months after vaccination, the timing of the onset of the disease still places it "within the range for vaccine induced hemolytic anemia." Tr. at 27. In his expert report, Dr. Levin asserts that "[a]lthough the mean interval between inoculation and his disorder is 19 days, the range extends to one year." P. ex. N at court-numbered p. 2. Dr. Reaman testified that the onset of thrombocytopenia or hemolytic anemia generally occurs days to weeks following immunization, according to the literature. One article relied upon by Dr. Levin reports onset of thrombocytopenia purpura between seven to 59 days after vaccination. *Report on 23 Patients*, at 268. During testimony, Dr. Levin agreed that article did not support his theory of up to one-year onset. Tr. at 56. He testified that there is an article, not part of the record in this matter, that states onset can occur up to one year and that he could find the article. No such article has been filed. *Id*.

The Supreme Court has counseled the lower courts to test the adequacy of an expert's testimony by requiring some showing that the opinions proffered are not mere speculative pronouncements of the expert, but have been "derived by the scientific method." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2795 (1993). This requires that the proponent demonstrate that there is "some objective, independent validation of the expert's methodology." *Daubert*, 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), *on remand from*, 113 S.Ct. 2786 (1993). It is clear from reviewing the medical evidence submitted in this case, and after reviewing the medical testimony, that Dr. Levin's proffered theory is devoid of objective support.

In sum, Dr. Levin failed to provide any persuasive scientific evidence to support his theory in this case. He submitted literature indicating causal relationships between certain viruses and vaccines other than DPT or rubella. Glaringly absent in the reports he produced are straightforward conclusions that killed virus vaccines or non-viral vaccines such as DPT can do the same. Dr. Levin was unable to point to support in the literature that *specifically* makes such a conclusion. When questioned about a particular article that distinguishes live viral vaccination, Dr. Levin simply replied, "Yes, they're talking about live virus and live virus obviously causing an infection can cause more serious problems. But, I think both live and -- I know both live and killed virus can cause the same disease." Tr. at 92; *see also* Tr. at 103. The court was unimpressed with Dr. Levin's testimony. He provided speculative opinions premised on unreasonable interpretations of the literature. His testimony was inconsistent, weak, and unsupported. Dr. Reaman, on the other hand, was an impressive witness whose testimony was well-reasoned, reliable, and persuasive. Because Dr. Levin has failed to satisfactorily demonstrate a logical sequence of cause and effect showing that the DPT or rubella vaccines could have caused Drew's condition, petitioners fall short of the required standard of proof.

CONCLUSIONS

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioners are not entitled to compensation in this case under the Vaccine Act. The Clerk of the Court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

Gary J. Golkiewicz

Chief Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C.A. §300aa-1 *et seq*. (1991 and Supp. 1998). For convenience, individual sections of the Act will be sited without reference to 42 U.S.C.A. §300aa.

2. Petitioners originally alleged that Drew suffered a Table injury (*see* §14; discussion of statutory requirements *infra* p. 9) although they did not specify which Table injury. Petition at court-numbered p. 4. It has become clear through the course of the proceedings, however, that petitioners' claim is one of causation-in-fact and not a Table claim.

3. The expert testimony provided by Dr. Levin and Dr. Reaman at the three-part hearing served as evidence in another case with nearly identical medical issues. The petitioners in that case, Addington v. Secretary of HHS, No. 94-137V, are also represented by attorney Ronald Homer.

4. An APGAR test measures heart rate, respiration, muscle tone, responsiveness to stimulation, and skin color. Generally, two tests are performed at exactly one minute and five minutes after birth. The maximum score is ten. The Merck Manual 1858 (15th ed. 1987). The score taken at one minute is an index of asphyxia, while the five minute score is an index of the likelihood of death or neurological residua. Nelson Textbook of Pediatrics 362 (13th ed. 1983). The accuracy of the score for the prediction of long-term outcome, however, is inconsistent. R Summitt, Comprehensive Pediatrics 370 (1990).

5. Dr. Levin completed a post-doctoral fellowship in immunology and joined the faculty of the University of California, San Francisco where he has been since 1971. Tr. at 6. He testified that he has treated a large number of patients with autoimmune hemolytic anemia and autoimmune thrombocytopenia. Tr. at 7. Dr. Levin testified that he has treated and managed two cases of Evans syndrome in the last ten years and is managing currently five cases of chronic thrombocytopenia and no autoimmune hemolytic anemia cases. Tr. at 31.

6. "Anemia" is a "reduction below normal in the number of erythrocytes . . . ." Dorland's Illustrated Medical Dictionary, 76 (27th ed. 1988). "Hemolysis is the "disruption of the integrity of the red cell membrane causing release of hemoglobin." *Id*. at 749.

7. "Thrombocytopenia" is the "decrease in the number of blood platelets." Dorland's Illustrated Medical Dictionary, 1717 (27th ed. 1988).

8. Dr. Levin testified that "it was the vaccination that caused" Drew's condition, but he does not know whether it was the OPV, rubella or DPT vaccine. Tr.III at 26. In his expert report, Dr. Levin claimed, "[s]ince all of these disorders are associated with vaccinations such as DPT and rubella, it is more likely than not that the vaccinations that this patient received were a cause or a substantial contributor to his present immune mediated disease." P. ex. N at 2.

9. Dr. Reaman explained that an antigen is "a protein which may induce an antibody response in the appropriate host." Tr.III at 39. "DPT vaccine can act as an antigen, that's why it's given to people, and it induces the formation of antibodies." Tr.III at 41. "[A]ntigens, of course, can become attached to human cells. That's how they work." *Id*.

10. Dr. Levin testified that the fact that Drew got the disease indicates he had the appropriate genetic make-up to get it because "[a]ll human disease relates to the genetic make-up of the host." "In order to be

able to get the disease, you have to have the appropriate genetic make-up." Tr.III at 23.

11. Dr. Levin explained that when the two diseases occur together and have no known etiology, the condition is called "Evans syndrome" which is chronic in nature. Tr. at 18, 33, 49-50. He does not believe Drew has Evans syndrome because he believes DPT vaccine caused the disorder. Tr. at 32.

12. Dr. Reaman is Chairman of the Department of Hematology Oncology and Director of Medical Specialty Services at Children's Hospital in Washington, D.C. Tr. at 113. He has cared for 10 to 12 children with Evans syndrome. He sees about 100 children per year with either acute or chronic thrombocytopenia and, in the last five years, has treated about 10 children with hemolytic anemia. Tr. at 116-17.

13. Dr. Reaman agrees with the treating hematologist's diagnosis of Evans syndrome and believes that the course and symptoms of Drew's illness fit the classic definition of Evans syndrome with the exception of splenomegaly which resolved within a couple days and is known to occur with Evans syndrome although not commonly. Tr. at 144.

14. Dr. Reaman described the two processes as follows:

The thrombocytopenia that may be acute and in response to a virus is likely related to antigen antibody complexes that are on the viral membrane or on the platelet membrane. And as offending antibody or antigenic material is depleted from the body then the thrombocytopenia should disappear.

In chronic thrombocytopenia, which is autoimmune in nature, the patient manufactures an antibody that reacts with his or her platelets. It's a self-perpetuating thing. It may be that the platelet membrane likely becomes altered and the antibody is in response to an alteration or a defect in the changed membrane of the platelet.

Tr. at 196.

15. Dr. Reaman testified that bacterial and viral infections Drew suffered in December may have a causal link to his Evans syndrome, but he does not know. Tr. at 185, 186. Dr. Reaman testified that no tests were done in this case to determine whether Drew was infected by a specific virus. Tr. at 127-28.

16. In *Daubert*, the Supreme Court held Federal Rule of Evidence 702 is binding on federal courts with respect to establishing the admissibility of scientific evidence. *Daubert*,

113 S. Ct. at 1795. The Federal Rules of Evidence are not binding on this tribunal.

17. In fact, Dr. Levin testified that he has "been reading these articles for 34 years and doing research, and in the law you recognize that you have to follow the words . . . ." Tr. at 43. It is interesting to note that Dr. Levin is also a lawyer licensed to practice. Tr. at 31.