In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. [Redacted] V
Originally Filed: June 28, 2010
Issued Redacted: July 13, 2010
To be Published

JANE DOE/74,	*	
	*	
Petitioner,	*	
	*	
v.	*	Tetanus/diphtheria and MMR;
	*	three weeks later, transverse
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	myelitis/multiple sclerosis
	*	
Respondent.	*	

Ronald C. Homer, Sylvia Chin-Caplan, Boston, MA, for petitioner.
Glenn A. MacLeod, Michael P. Milmoe, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition on April 26, 2007, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she had transverse myelitis (TM) three weeks after receiving tetanus/diphtheria and measles, mumps, rubella (MMR) vaccines, and six

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. This decision is being redacted because of petitioner's July 9, 2010, motion to redact which was granted.

weeks after she received hepatitis B and meningococcal vaccines. Her TM was eventually diagnosed as the onset of multiple sclerosis (MS).

On April 26, 2007, the case was assigned to former Special Master John F. Edwards.

Petitioner finished filing medical records on August 28, 2007. Respondent submitted her Rule 4(c) Report on January 25, 2008 together with an expert report of Dr. Subramaniam Sriram.

On February 29, 2008, respondent filed the medical articles upon which Dr. Sriram relied in his expert report.

The parties' attempt to settle the case proved unsuccessful.

On July 11, 2008, respondent filed the supplemental report of Dr. Sriram.

On July 20, 2008, Special Master Edwards left the Office of Special Masters.

On August 1, 2008, the case was reassigned to the undersigned.

On December 2, 2008, petitioner filed an expert report from Dr. Derek Smith.

On May 6, 2009, petitioner filed additional medical records.

On May 26, 2009, respondent filed a second supplemental report from Dr. Sriram in response to Dr. Smith's report.

On June 3, 2009, petitioner filed medical literature.

On June 10, 2009, a hearing on entitlement was held. Dr. Smith and Dr. Sriram were the only witnesses.

On August 10, 2009, petitioner filed a posthearing brief.

On September 9, 2009, respondent filed a posthearing brief.

On September 23, 2009, petitioner filed a responsive brief to respondent's brief.

FACTS

Petitioner was born on March 5, 1987.

On July 7, 2005, she received meningitis and hepatitis B vaccines.

On August 2, 2005, she received tetanus/diphtheria and MMR vaccines.

On August 22, 2005, she was diagnosed with TM.

On September 12, 2005, petitioner saw Dr. Yevgeniy Isayev, a neurologist. Med. recs. at Ex. 2, p. 76. His impression was that petitioner had a cervical myelopathy most likely transverse myelitis secondary to vaccination. Med. recs. at Ex. 2, p. 78.

In March 2006, she was diagnosed with MS.

Other Submitted Materials

Respondent filed as Exhibit C-4 an article entitled "Multiple Sclerosis" by E.M. Frohman, 87 Med Clin N Am 867-97 (2003). Dr. Frohman states that one hypothesis for the cause of MS is "the role of immune dysregulation in the development of an autoimmune response against central nervous system (CNS) myelin antigens" which "may involve an infectious trigger (virus, bacteria, and so forth)...." Id. at 869. The MS patient may have "inappropriate priming of cellular and humoral immune responses targeted against self proteins. This hypothesis is referred to as *molecular mimicry* [emphasis in original]." Id.

Respondent filed as Exhibit C-5 an article entitled "Tetanus vaccination and risk of multiple sclerosis. A systematic review" by M. Hernán et al., 67 Neurology 212-15 (2006). The authors state that they looked at nine case-control studies of MS among those vaccinated and those not vaccinated against tetanus, and found a one-third reduction in MS risk among the vaccinees. Id. at 214. To try to understand this protective effect, the authors theorize that

tetanus vaccine may be a marker for an unknown protective factor for which they encouraged scientists to conduct a search. Id.

Respondent filed as Exhibit C-9 the article "Immunization and MS. A summary of published evidence and recommendations" by O.T. Rutschmann et al., 59 Neurology 1837-43 (2002). Th authors begin by stating that infectious episodes can exacerbate MS and therefore vaccines could potentially prevent these episodes. Id. at 1837. Because of fears that vaccines were unsafe for MS patients, the MS Council for Clinical Practice Guidelines commissioned a systematic review to determine if this was so. Id. They included 130 articles, 53 experimental or observational studies, and 77 case reports. Id. at 1838. Three MS patients were immunized with live attenuated measles vaccine but did not experience any clinical change in their MS for a month after vaccination. The authors found "there is insufficient published evidence to support or to reject an increased incidence of MS exacerbation after measles vaccination...." Id. at 1839. In the case of tetanus vaccine, there was "suggestive evidence that tetanus vaccine does not increase the risk of relapses in patients with MS...." Id. at 1840. They state that the evidence for whether other vaccines increase the risk of MS exacerbation after immunization is "completely absent" for mumps and rubella vaccine. Id. at 1842. They encourage researchers to conduct prospective trials or at least well designed, retrospective studies. Id. They do, however, recommend delaying vaccination during clinically significant relapses, typically four to six weeks after the start of the relapse. Id. at 1843.

TESTIMONY

Dr. Derek Smith testified first for petitioner. Tr. at 4. He is a board-certified neurologist with a specialty in MS. Tr. at 5. He follows 1,000 patients. Tr. at 6. He is Director of MS Care

of Connecticut which is associated with the National Multiple Sclerosis Society. Tr. at 6-7. Petitioner had a family history of autoimmunity in that her father has HLA-B27 which predisposes someone to autoimmune disease. Tr. at 10.

Petitioner received two different rounds of vaccines in the summer of 2005, followed 20 days later after the second round by a new onset of neurologic symptoms. Id. She had evidence of inflammation in various locations in her central nervous system. Id. She also had serologic studies that showed evidence of autoimmunity in her bloodstream, specifically a positive ANA (antinuclear antibodies) and anti-phospholipid antibodies. Tr. at 10-11. Initially, petitioner was diagnosed with transverse myelitis, but this was eventually recognized as multiple sclerosis. Tr. at 11. About 20 percent of people with transverse myelitis will go on to have a second inflammatory event somewhere else in the nervous system and be diagnosed with multiple sclerosis. Tr. at 11-12. When the brain MRI shows other lesions characteristic of MS, a large majority (85-90 percent) have further inflammatory events and develop MS within five years. Tr. at 12.

Petitioner's first brain MRI was read as normal, but then a neurologist and radiologist went back and looked at it again and found two to three lesions that appeared to be demyelinating. Id. She is within the 85-90 percent of people who move from transverse myelitis to multiple sclerosis. Id.

Dr. Smith stated that MS is a chronic relapsing illness during which, on occasion, cells from the immune system enter the central nervous system and behave as if they are responding to a threat or a foreign antigen. The response of the central nervous system to inflammation is mainly demyelination, i.e., the removal of the myelin coating on nerve axons, but there can also

be damage to the neurons themselves. Tr. at 16. The nervous system does not heal normally. It tends to form glial scars composed of astrocytes, creating a residual neurologic deficit. The accumulation of these lesions over time leads to more permanent neurologic disability. Id.

Dr. Smith testified that the most widely accepted theory explaining MS is that a person forms a group of autoreactive T-cells that become activated outside the central nervous system and travel to the central nervous system. If they encounter a myelin antigen, they generate a more robust immune response that becomes an MS lesion. Tr. at 17. MS is an autoimmune disorder. Id. It is generally thought that, in MS, during the activation of the immune system during an infection, an error occurs wherein a T-cell responding to the infection may also respond against central nervous system protein. Tr. at 18. That is the concept of molecular mimicry. Id.

Because every person has a unique set of T-cells and antibodies, and there are billions of possible genetic rearrangements than can degenerate them, the process of MS may well be very large and entirely different in everyone who develops MS. Tr. at 19. Besides molecular mimicry and T-cell degeneracy, there is the theory of bystander activation wherein nonspecific components of the immune system are important in achieving a robust immune response. Tr. at 20.

Dr. Smith's opinion is that it is difficult to know which of the vaccines petitioner received may have contributed to her central nervous system inflammation because they were given together. Tr. at 23. He was unaware of medical literature connecting meningococcal vaccine to MS. Tr. at 23-24. An autoimmune response is most likely to occur two to three weeks after a vaccination and, therefore, petitioner's August vaccinations are the most likely to

be associated with an autoimmune response afterward. Tr. at 24. He would not however entirely rule out her July vaccinations. Id.

Dr. Smith believes that one of petitioner's August vaccinations caused her inflammation in her nervous system. Tr. at 25. Because of the diversity of the T-cell response and the antigenic responses, Dr. Smith cannot pick among the tetanus toxoid, and diphtheria, measles, mumps, and rubella vaccines as the cause of petitioner's MS. Tr. at 27. He thinks one vaccine is more likely than a combination of vaccines to be the cause of the inflammation in petitioner's nervous system since immune responses are very specific. Id. He thinks one of the antigen components of one of these vaccines activated a subset of T-cells that also responded to a central nervous system antigen in petitioner and, in doing so, caused an area of inflammation in her cervical spinal cord 20 days later, causing her neurologic symptoms. Tr. at 28. He believes this medical theory is biologically plausible in the proper individual. Tr. at 29. He also believes there is a logical sequence of cause and effect in his medical theory showing how one of the five vaccines petitioner received August 2, 2005 caused petitioner's MS. Id. He also believes that the time frame between the August 2, 2005 vaccinations and the onset of petitioner's central nervous system demyelination is medically appropriate for causation. Tr. at 29-30. Finally, Dr. Smith believes that if petitioner had not received these five vaccinations on August 2, 2005, she would not have had the onset of her neurologic injury on August 22, 2005, but he does not know if she may or may not have developed MS later in life. Tr. at 30.

Dr. Smith said that petitioner's blood work indicated she might have a preexisting tendency toward autoimmunity, but he did not see any potential alternative cause for her MS. Id. If petitioner had a biologic vulnerability to develop MS, Dr. Smith's opinion is that one of the

five vaccines she received on August 2, 2005 was a substantial factor in causing her MS. Tr. at 31.

There are a number of animal models for central nervous system autoimmune disease in which vaccine provokes the disease. Tr. at 35. Dr. Jonas Salk tried to create a vaccine for MS using myelin protein, but caused an illness in animals resembling acute disseminated encephalomyelitis, a robust central nervous system inflammation. It is known that vaccines can do this in both animals and humans. Id. Dr. Smith believes that it is probable that any vaccine could cause MS in someone. Tr. at 37. Petitioner's July 2005 vaccinations are at the temporal limit of what Dr. Smith thinks would be causally associated with petitioner's MS. Tr. at 38.

Petitioner's positive ANA response and anti-phospholipid antibodies are more frequently found in people who develop MS. Tr. at 39. Dr. Smith agreed that petitioner's development of symptoms after vaccination could just be coincidental. Tr. at 40. Because the onset of MS can predate the occurrence of clinical symptoms, Dr. Smith said that if it could be determined that petitioner's brain lesions were old, Dr. Smith would say that one of the August 2, 2005 vaccinations significantly aggravated her MS by making clinical the previously subclinical MS that she had. Tr. at 41.

Dr. Subramaniam Sriram testified next for respondent. Tr. at 45. He is the Director and Professor of Neurology and Immunology at Vanderbilt Medical Center. Id. He is a neurologist with expertise in demyelinating diseases, and the Director of the MS clinic at Vanderbilt. Tr. at 46. Dr. Sriram sees as many MS patients as Dr. Smith sees. Tr. at 54.

MS is an autoimmune disease. Tr. at 48. Petitioner's MS began in the third week of August 2005. Id. His opinion is that neither tetanus toxoid nor MMR vaccine was associated

with petitioner's development of symptoms in August 2005 because of the lack of sufficient clinical data, even anecdotal data, connecting the two. Tr. at 49. He does believe there is a temporal association. Tr. at 51. There are better studies done on tetanus toxoid and the risk of MS than on MMR and the risk of MS. Those studies fail to show any connection between tetanus toxoid and MS. Tr. at 49. In fact, one study found a lower incidence of MS among tetanus toxoid recipients so one could say that tetanus vaccine has a protective effect. Id.

Dr. Sriram said there is no anecdotal association of MMR vaccine and MS. Tr. at 50. There are no animal models of tetanus vaccine causing MS or MMR causing an MS-like disease. Id. There is no evidence that if someone immunizes people with tetanus vaccine, there is amplification of a pool of autoreactive cells, predisposing the vaccinee to autoimmune disease. Tr. at 52. Dr. Sriram doubts whether MMR vaccine has that propensity either. Id.

Petitioner does have an elevation of her ANA but not significantly so. She does have anti-phospholipid antibodies but people with those might or might not develop MS. Dr. Sriram said she may have a propensity to have some autoantibodies, but not the kind of autoimmune disease that she has. Tr. at 53.

The American Academy of Neurology has stated that MS patients may safely receive influenza, hepatitis, varicella, tetanus, and other vaccines. Tr. at 54. Dr. Sriram stated that the theories Dr. Smith described in his testimony are in the academic realm of possibility, but clear evidence for them is lacking. Tr. at 57. Dr. Sriram disagrees with Dr. Smith that any vaccine can cause demyelinating disease in someone with the right genetic make-up. Tr. at 57-58. He thinks it is extremely unlikely because if a vaccine were a cause of demyelinating disease, why would it not cause some other autoimmune disease. Tr. at 58. Just because a vaccine is a

protein–an antigen–and an antigen can cause an immune response, both specific and nonspecific, does not mean it has the propensity to cause any type of immune response, autoimmune response, and autoimmune disease. Id.

In Dr. Sriram's opinion, none of the five vaccines caused petitioner's MS. Id. He believes petitioner had MS from the beginning. The MS presented itself as transverse myelitis. Tr. at 59. Petitioner had asymmetric transverse myelitis. She had positive oligoclonal bands. She did not have what is called a sensory level, which is more common in acute monophasic illnesses following vaccine injury. Tr. at 60. She had MS from the beginning of her symptoms. Id. There was dissemination in space, but not in time, at the beginning, but, when it occurred on MRI in February 2006 with a new enhancing lesion, this occasioned the diagnosis of MS. Id.

Dr. Sriram stated that the theory of molecular mimicry for autoimmune diseases is in the realm of the possible. Tr. at 64. It is reasonable that bystander activation can occur purely by the fact of the potency of the immune response requirements. Tr. at 65. One needs to enhance the immune response several fold to get the antibody response to the titer level or T-cell response one wants. Id. He stated that bystander activation probably exists. Id. Dr. Sriram considers four to eight weeks a reasonable temporal relationship, based on the Institute of Medicine (although the IOM goes out to 42 days). Tr. at 70. He amended his reasonable temporal relationship to two to six weeks. Id. Petitioner's hepatitis B and meningitis vaccines were administered about six weeks before her first symptom. Id.

When petitioner was diagnosed with transverse myelitis, her MRI was more suggestive of MS. Tr. at 72. Usually, the transverse myelitis that is part of MS is incomplete, which is what petitioner has. Id. Secondly, the transverse myelitis that is part of MS usually does not have a

sensory level, which is again petitioner's case. Id. Thirdly, petitioner had oligoclonal bands which is usual for a transverse myelitis that is part of MS. Tr. at 73.

DISCUSSION

This case involves the issue of TM/MS occurring three weeks after tetanus/diphtheria and MMR vaccinations, and six weeks after hepatitis B and meningococcal vaccinations. Petitioner alleges that tetanus/diphtheria and MMR vaccines caused her TM/MS. This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (tetanus toxoid caused optic neuritis and acute disseminated encephalomyelitis (ADEM)). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Sec'y of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for tetanus/diphtheria and MMR vaccines, she would not have had TM/MS, but also that the vaccines were substantial factors in bringing about her TM/MS. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999) (a baby developed a high fever after receiving DPT vaccine; he was also harboring E. coli infection which can cause fever; testimony showed that both the vaccine and the infection were substantial factors in causing his high fever that led to his death; petitioners prevailed because the vaccine was a substantial factor).

Close calls are to be resolved in favor of petitioners. Capizzano, 1440 F.3d at 1327; Althen, 418 F.3d at 1280. See generally, Knudsen v. Sec'y of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, 418 F.3d at 1278; Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than an exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, supra, at 3, 1986 U.S.C.C.A.N. at 6344.

> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

The Federal Circuit in Capizzano emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." 440 F.3d at 1326. See also Andreu v. Secretary of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009).

As for epidemiological support for causation, the Federal Circuit in Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994), ruled for petitioners even when epidemiological evidence directly opposed causation from DPT vaccine. The case concerned the cause of a baby's encephalopathy after a vaccination. Respondent provided evidence that more encephalopathies are caused by viruses than by vaccines, convincing the special master to rule against petitioners. But the Federal Circuit held that the epidemiologic evidence should not bar petitioners from prevailing. Even though epidemiological evidence supported respondent's view that viruses were more likely to cause encephalopathy than vaccinations, the Federal Circuit held that that fact alone was not an impediment to recovery of damages. In Knudsen, the Federal Circuit stated:

> The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

35 F.3d at 550.

In the instant action, Dr. Smith's opinion devolves exclusively around the vaccinations against diphtheria, tetanus, measles, mumps, and rubella which petitioner received three weeks before she had TM which turned out to be the first sign of her MS diagnosed later. He pointedly does not include the vaccinations against hepatitis B vaccine and meningitis administered six weeks before the onset of petitioner's demyelinating disease. This distinguishes this case from the cases in which the undersigned has ruled in favor of petitioners involving hepatitis B vaccine and demyelinating diseases with a time interval of up to eight weeks between vaccination and onset. In four cases, respondent asked for a ruling on the record because she indicated she would no longer expend time or money to defend the case: (1) John Doe/64 v. Sec'y of HHS, No. [redacted], 2010 WL 1783539 (Fed. Cl. Spec. Mstr. 2010) (two months between hepatitis B vaccination and MS); (2) Lilley v. Sec'y of HHS, No. 09-31V, 2009 WL 3320518 (Fed. Cl. Spec. Mstr. 2009) (six weeks between hepatitis B vaccine and TM); (3) Jane Doe/29 v. Sec'y of HHS, No. [redacted], 2009 WL 180078 (Fed. Cl. Spec. Mstr. 2009) (two months between hepatitis B vaccine and Devic's disease, a variant of MS); and (4) Pecorella v. Sec'y of HHS, No. 04-1781V, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. 2008) (two months between hepatitis B vaccine and TM).

In addition, in two cases, relying on the holding in Pecorella, the undersigned held after trial that petitioners prevailed even though there was two months between hepatitis B vaccination and demyelinating disease: (1) Fisher v. Sec'y of HHS, No. 99-432V, 2009 WL 2365459 (Fed. Cl. Spec. Mstr. July 13, 2009) (hepatitis B vaccine; two months until onset of optic neuritis, another demyelinating disease); and (2) Hawkins v. Sec'y of HHS, No. 99-450V,

2009 WL 711931 (Fed. Cl. Spec. Mstr. 2009) (two months until onset of ADEM, another demyelinating disease).

These precedents were unavailing here because petitioner's expert Dr. Smith did not identify hepatitis B vaccine, administered six weeks before petitioner's onset of TM, as the probable cause, focusing his attention solely on the vaccinations against tetanus/diphtheria and MMR administered three weeks before onset of TM.

The Federal Circuit affirmed in Althen that tetanus toxoid caused demyelinating disease in the form of optic neuritis and ADEM. The undersigned has previously held that tetanus/diphtheria and MMR vaccines caused demyelinating disease: Johnson v. Sec'y of HHS, No. 99-219V, 2000 WL 1141582 (Fed. Cl. Spec. Mstr. 2000) (tetanus toxoid caused ADEM two weeks later); Tufo v. Sec'y of HHS, No. 98-108V, 2001 WL 286911 (Fed. Cl. Spec. Mstr. 2001) (MMR caused Guillain-Barré syndrome or TM or ADEM two and one-half weeks later).

Special Master Richard Abell recently held that the tetanus portion of DTaP and/or other vaccinations a child received resulted in TM in Hargrove v. Sec'y of HHS, No. 05-694V, 2009 WL 1220986, at *366 (Fed. Cl. Spec. Mstr. 2009). Former Special Master E. LaVon French held that tetanus toxoid caused myelitis, or autoimmune disease, or MS in Rogers v. Sec'y of HHS, No. 94-089V, 2000 WL 1337185 (Fed. Cl. Spec. Mstr. 2000).

The theories underlying all these cases in which petitioners prevailed are the same: the antigenic insult of the vaccine can cause the recipient to develop antibodies to his or her own myelin sheath, causing lesions either in the brain or the spinal cord or both, resulting in demyelinating disease, within a proper temporal period, and did so in that particular case. In this

case, the disease was initially diagnosed as TM, but it was actually the first sign of MS, a common occurrence according to both Drs. Smith and Sriram.

Dr. Smith testified that the medical theory connecting tetanus/diphtheria and MMR vaccines to TM/MS can be explained through molecular mimicry, T-cell degeneracy, or bystander activation. The fact that epidemiologic studies have not shown an increased incidence in demyelinating disease after injections of a Table vaccine does not prevent petitioner from prevailing according to the Federal Circuit in Knudsen, Althen, and Capizzano. As long as petitioner fulfills the three Althen prongs, petitioner prevails.

Of interest in this case, right near the beginning of petitioner's symptoms (September 12, 2005), her treating neurologist, Dr. Yevgeniy Isayev, wrote his impression that petitioner had a cervical myelopathy most likely transverse myelitis secondary to vaccination. The Federal Circuit emphasized in Capizzano and Andreu the importance of special masters taking the opinions of treating physicians seriously in evaluating the merits of a case.

The undersigned well understands the concerns of respondent's expert Dr. Sriram that no animal experiments have been done linking tetanus/diphtheria and MMR vaccines with MS. In addition, there are no epidemiologic studies or anecdotal reports upon which a medical specialist in MS can rely in cautioning his patients not to receive these vaccines. In fact, these vaccines are routinely recommended. But the Federal Circuit does not view these omissions to be significant as long as petitioner has proved the three Althen prongs. Moreover, the fact that the medical advisory groups recommend particular vaccines does not vitiate the concept, expressed most strongly in the Federal Circuit in Knudsen, that rare reactions can occur. But, then, this is the reason Congress created the Vaccine Program--to remedy the rare reaction when individuals

follow the national policy of receiving vaccinations. The undersigned sees no conflict between the recommendations of national vaccine advisory groups and the purpose of this Program.

As for Dr. Smith's not knowing which of the five vaccines (tetanus toxoid, diphtheria, measles, mumps, rubella) is the one that caused petitioner's TM/MS, that really does not matter since all five are Table vaccines. Similarly, in Special Master Abell's case Hargrove, although petitioner's expert Dr. Marcel Kinsbourne focused his analysis on the tetanus toxoid portion of DPaT, he also admitted that the pneumococcal vaccine that the child received at the same time could have caused his TM. 2009 WL 1220986, at *12 ("Dr. Kinsbourne ascribed tetanus as the most potential cause, but acknowledged the potential effects of the pneumococcal vaccine....").

Dr. Sriram in the instant action admitted that MS is an autoimmune disease and, if he agreed that petitioner's vaccinations could have caused her TM/MS, the timing of three weeks was appropriate for causation. He noted that Hernán and his co-authors in respondent's Exhibit C-5 did a meta-analysis of studies showing a decreased risk of MS among those who received tetanus vaccine, but were unable to explain why the reasons for this. If this result is accurate, it does not mean that no one who receives tetanus vaccine can get MS. It just means the risk is less. In any event, since Dr. Smith does not know which of the five vaccines that petitioner received on August 2, 2005 (tetanus, diphtheria, measles, mumps, rubella) provided the antigenic stimulation that resulted in petitioner's autoimmune reaction, the undersigned finds the conclusions of the Hernán article not in conflict with a holding of causation in this case.

In the study to determine whether vaccinations for MS patients would cause exacerbations of their MS in respondent's Exhibit C-9, the authors found insufficient evidence to support or reject whether measles vaccine exacerbates MS, completely absent evidence for

whether mumps and rubella vaccines exacerbate MS, and suggestive evidence that tetanus vaccine does not exacerbate MS. Whether or not tetanus toxoid can cause MS, Dr. Sriram did not discuss the fact that this article says absolutely nothing that disputes that measles, mumps, and rubella vaccines may exacerbate MS. He focused only on the protective effect that Hernán found with the use of tetanus toxoid. Since the use of tetanus toxoid is practically ubiquitous in the western world, one wonders why, if the conclusions are true, the western world does not have a one-third lower incidence of MS compared with the rest of the world. It is hard to take the Hernán conclusions seriously.

Thus, in the literature that respondent filed, the undersigned finds nothing persuasive against the theories which petitioner's expert Dr. Smith explained in describing the basis for his opinion that any of the five vaccines petitioner received August 2, 2005 can cause TM/MS, that they did cause TM/MS in her case, and that the timing of three weeks is medically appropriate for causation.

Petitioner has fulfilled the first Althen prong by proving through Dr. Smith's testimony that an antigen in diphtheria/tetanus or MMR vaccines can cause demyelinating disease, such as TM/MS, through an autoimmune process whether molecular mimicry, T-cell degeneracy, or bystander activation.

Petitioner has fulfilled the second Althen prong by proving through Dr. Smith's testimony that one of the vaccines she received in August 2, 2005 did cause her TM/MS. Her treating neurologist Dr. Isayev supports this "did it?" prong with his notation that her recent vaccines caused her TM.

Petitioner has fulfilled the third Althen prong by proving through both experts' testimony that three weeks is a medically appropriate time interval between vaccination and TM/MS to show causation in fact.

Petitioner has prevailed in proving that her August 2, 2005 vaccinations caused her TM/MS.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes the parties may reach an amicable settlement. A telephonic status conference will be set soon to discuss how the parties will proceed in resolving damages.

IT IS SO ORDERED.

June 28, 2010
DATE

s/ Laura D. Millman
Laura D. Millman
Special Master