UNITED STATES OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

No. 93-264V

(Filed: December 1, 2000)

SETH R. PLATT,	*	
	*	
Petitioner,	*	**TO BE PUBLISHED**
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Clifford J. Shoemaker, Vienna, Virginia, for petitioner.

Gabrielle Manganiello, Department of Justice, Washington, D.C., for respondent.

DECISION ON REMAND

HASTINGS, Special Master.

In this case filed under the National Vaccine Injury Compensation Program,[1] petitioner contends that a measles-mumps-rubella ("MMR") vaccination administered to him on June 4, 1990, caused him to suffer acute pancreatitis shortly thereafter, and also either caused his subsequent chronic pancreatitis or significantly aggravated an already-existing pancreatitis condition. For the reasons set forth below, I conclude that petitioner has failed to demonstrate that he is entitled to a Program award.

[1]The applicable statutory provisions defining the Program are found at 42 U.S.C. 300aa-10 *et seq*. (1994). Hereinafter, for ease of citation, all "§" references will be 42 U.S.C. (1994).

I

STATUTORY AND PROCEDURAL BACKGROUND

Under the National Vaccine Injury Compensation Program (hereinafter "the Program"), compensation awards are made to individuals who have suffered injuries that may have been caused by certain vaccines. There are two separate means of establishing entitlement to compensation. First, if an injury listed on the "Vaccine Injury Table" found at § 300aa-14(a) occurred within the time period prescribed in that Table, then the injury may be *presumed* to qualify for compensation. Second, compensation may also be awarded for injuries not listed on the Table, but entitlement in such cases is dependent upon proof by a preponderance of evidence that the vaccine *actually caused* the injury. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(ii).

In this case, petitioner's claim involves his condition of chronic pancreatitis and the MMR vaccination that he received on June 4, 1990. That vaccination is one of the vaccinations covered by the statute, but petitioner does not allege that he suffered any of the injuries listed in the Vaccine Injury Table for that vaccination, so this case does not involve an allegation of a "Table Injury." Instead, the issue here is purely one of the "actual causation" variety. That is, the issue is whether petitioner has demonstrated that it is "more probable than not" that his chronic pancreatitis was in fact either caused by or substantially aggravated by his MMR vaccination of June 4, 1990.

Petitioner filed the instant petition on April 30, 1993, and the case was assigned at that time to Special Master Elizabeth Wright. On June 25, 1993, respondent filed a report in this matter recommending that compensation be denied. Evidentiary hearings were held on June 5, 1995, and December 16, 1996, and extensive post-hearing briefing took place. On December 17, 1998, Special Master Wright filed a Decision concluding that petitioner does not qualify for a Program award.

On April 19, 1999, however, Judge Francis M. Allegra remanded the case to the Office of Special Masters for further consideration. Because Special Master Wright had by then left her position as a special master, the case was assigned to me. After some delay by petitioner in obtaining supplementary expert reports, another evidentiary hearing was held on January 24, 2000. Petitioner requested that post-hearing briefing be permitted, and post-hearing briefs were filed on June 5, 2000, July 24, 2000, and October 30, 2000.

II

FACTUAL BACKGROUND

A. Undisputed facts

The following facts appear to be undisputed.

Seth Platt was born on June 5, 1974. Seth was seen frequently by his pediatrician, Dr. Sidney Berezin, during his childhood, and his examinations were generally unremarkable. (P. Ex. 4.[2]) Seth received the usual childhood immunizations, apparently without any notable reactions.

On June 4, 1990, the day before his 16th birthday, Seth received an "MMR" (measles, mumps, rubella) booster immunization at the office of Dr. Berezin. (P. Ex. 4 at 10; P. Ex. 14.) The immunization was administered in the late afternoon. (P. Ex. 1 at 1.) That evening, Seth felt ill and went to bed early. The next morning, he awoke with intense abdominal pain and stayed home from school because of the pain. *Id*. The following morning, Seth continued to feel intense pain in his abdomen, and his father took him to the pediatrician Dr. Sidney Berezin, who referred Seth to Dr. Stewart Berezin, a pediatric gastroenterologist. (P. Ex. 1 at 1-2.) Dr. Stewart Berezin diagnosed acute pancreatitis, and admitted Seth to the hospital at Westchester County Medical Center, where he remained for fifteen days. (P. Ex. 1 at 2.) No cause for this episode of acute pancreatitis was determined.

The medical records of that June 1990 hospitalization at Westchester County Medical Center contain several references to *earlier* episodes of similar abdominal pain. Specifically, an emergency room history reports "similar episodes in the past which resolved spontaneously." (P. Ex. 18 at 41.) Other emergency room notes state that Seth "experienced similar abdominal pain in past few occasions--lasted 4-5 days in duration with spontaneous recovery." (P. Ex. 18 at 44.) Hospital progress notes indicate that "There is a past [history of] 3-4 such episodes over the past year, each lasting 3-4 days, consisting of dull [abdominal] pain, no vomiting or other associated symptoms." (P. Ex. 18 at 46.) Another hospital note indicates a prior medical history of "2 episodes of epigastric crampy pain in past 1 year, resolved spontaneously, lasting for 4 days." (P. Ex. 18 at 48.) The hospital notes also include an "Assessment" of a "16 [year old male] 3rd episode of epigastric pain presently worse than usual with radiation to the back." (P. Ex. 18 at 49.)

Since recovering from that June 1990 episode of pancreatitis, Seth has suffered many recurrent attacks of pancreatitis, and has been hospitalized numerous times. Because of Seth's recurring bouts of pancreatitis, he underwent a endoscopic retrograde cholangiopancreatography study ("ERCP") in June of 1991, in an attempt to find any anatomic abnormality that might be the cause of his pancreatitis. The study revealed that the main pancreatic duct and biliary tree were normal, but the secondary pancreatic ducts showed changes consistent with chronic pancreatitis. (P. Ex. 5 at 18.) No specific anatomic etiology was found for Seth's chronic pancreatitis. (*Id*.) Two further ERCP studies, in February 1993 and December 1993, also revealed no specific etiology for Seth's chronic pancreatitis. (P. Ex. 17 at 37-38; P. Ex. 25 at 27.) Seth still suffers from chronic pancreatitis. (I-Tr. at 23, 34.)

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[2]The evidence in the record consists primarily of exhibits filed by petitioner ("P. Ex. __"), respondent's exhibits ("R. Ex. __"), and evidence taken at the evidentiary hearings. I will refer to the transcript of the hearing of June 5, 1995, as "I-Tr.;" to the transcript of the hearing of December 16, 1996, as "II-Tr.;" and to the transcript of the hearing of January 24, 2000, as "III-Tr."

B. Petitioner's testimony

Petitioner testified during the evidentiary proceedings before Special Master Wright that prior to the administration of the MMR vaccine on June 4, 1990, he had experienced abdominal pain, but "didn't have anything even remotely similar to this. It was in a completely different area of my abdomen. It was lower in * * * my stomach, like a stomach ache. But nothing up in the upper part of my abdomen like pancreatitis."[3] (I-Tr. at 8.) Petitioner added that while in the past he had experienced stomach pains not associated with nausea or diarrhea, those pains weren't "even remotely" like the pain he experienced on June 4, 1990. (I-Tr. at 9-10.)

Mr. Frank Platt, Seth's father, gave testimony generally corroborating his son's testimony. He stated that he never gave a history to medical personnel indicating that Seth had experienced pains similar to those he suffered after his MMR vaccination. (I-Tr. at 44.)

III

EXPERT TESTIMONY

A. Proceedings before Special Master Wright

1. Petitioner's experts

During the proceedings before Special Master Wright, petitioner presented the written reports and oral testimony of four experts: Drs. Joseph Bellanti, Mark Geier, Sidney Berezin, and Myron Shoham. During those proceedings, petitioners' experts expressed the opinion that Seth's pain symptoms on the morning following his MMR vaccination on June 4, 1990, constituted the *first* symptoms of his chronic pancreatitis, and that the vaccination was the likely cause of that pancreatitis.

In forming their opinions, these experts noted the fact that it is medically well-accepted that the mumps virus, in its natural "wild" form, does occasionally cause episodes of acute pancreatitis. They also pointed to a number of reports of individual cases in which persons who have received the mumps *vaccine*, which contains a weakened ("attenuated") form of live mumps virus, have experienced pancreatitis after mumps vaccination. The experts opined that since the pancreas seems to be an organ that is particularly susceptible to damage by the mumps virus, it is reasonable to believe that the mumps virus in its weakened vaccine form caused the acute pancreatitis which developed in Seth so soon after his MMR vaccination on June 4, 1990. They further opined that Seth's acute episode of pancreatitis in June of 1990 likely damaged his pancreas, thereby resulting in the *chronic* pancreatitis from which he has suffered since.

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[3]Later, Seth testified that, at the time he told physicians during his first hospitalization about prior abdominal pain, he was actually referring to episodes of stomach flu or virus. (I-Tr. at 278.)

Petitioner's experts stated that they found this explanation to be particularly plausible in light of the fact that no other cause for Seth's chronic pancreatitis has ever been identified.

In reaching their conclusion, petitioner's experts acknowledged the fact that the mumps vaccine could not have caused Seth's pancreatitis in precisely the same fashion that the "wild" mumps virus is known to cause acute pancreatitis episodes. That is, the wild mumps virus is known to directly attack pancreatic tissue, approximately 12 to 25 days after it invades the body. In such episodes, the 12-to-25-day incubation period is necessary for the virus to replicate (reproduce) itself within the body sufficiently to cause noticeable symptoms. In Seth's case, of course, his symptoms began less than 24 hours after vaccination, far less than the normal incubation period described above. Therefore, petitioner's experts testified, the mumps vaccine portion of the MMR inoculation (or, less likely, the rubella or measles portions) likely caused Seth's pancreatitis in a somewhat different fashion. They opined that the most likely means was that the vaccination provoked on *autoimmune response* from Seth's immune system. In an autoimmune response, the body's immune system, designed to attack foreign invaders such as viruses, mistakenly attacks the body's own tissue. The experts testified that Seth's immune system probably reacted either because it was sensitized directly to the mumps virus by Seth's earlier mumps vaccination when he was a child, or through a process of "molecular mimicry," in which it had been sensitized to some other invasive agent, and incorrectly recognized the mumps virus present in the vaccine as the other invasive agent.

Alternatively, the experts testified, some toxic substance in the vaccine might have *directly* injured Seth's pancreas.

The paragraphs immediately above constitute a general summary of the common threads of the theories set forth by petitioner's experts before Special Master Wright. In addition, I will add below a summary of the specific testimony of each expert.

a. Dr. Mark Geier

Petitioner presented the testimony of Dr. Mark Geier, an obstetrical geneticist.[4] Dr. Geier explained that in formulating his opinion, he consulted Nelson's Textbook of Pediatrics, which lists measles, mumps, and rubella viruses as "known etiological agents that can cause acute pancreatitis." (P. Ex. 12 at 5.) Dr. Geier based his opinion on (1) the fact that MMR vaccine contains live mumps virus which is

[4]Dr. Geier is board-certified in obstetrical genetics and holds a Ph.D. in genetics. (P. Ex. 12.) He is licensed to practice in Maryland and Virginia. (*Id.*) While working at the National Institutes of Health, Dr. Geier performed research involving the injection of viruses into mice and the rates at which such viruses reached the organs of the mice. (I-Tr. at 51, 54.)

known to cause acute pancreatitis; (2) the temporal relationship between the vaccination and the onset of Seth's pancreatitis; and (3) the absence of a known alternative etiology.[5] (*Id.*; I-Tr. at 53.)

Dr. Geier opined that the relatively short time-frame between the vaccination and the onset Seth's illness (as opposed to the usual 12 to 25-day period for symptoms following natural exposure to mumps virus) may be attributable to the fact that the MMR vaccine was injected and "may have gotten directly into the bloodstream."[6] (I-Tr. at 54, 78-79.) With respect to the chronicity of Seth's condition, Dr. Geier posited that whatever caused the initial acute onset of Seth's pancreatitis likely also caused the chronic relapses. (I-Tr. at 62-63, 76.)

b. Dr. Joseph Bellanti

Petitioner's second expert, Dr. Bellanti, is a professor of pediatrics and microbiology at Georgetown University School of Medicine.[7] Dr. Bellanti testified that the relatively short time period between vaccination and the onset of Seth's acute pancreatitis (as opposed to the usual interval between contact with a wild virus and the onset of the disease) could be explained by the fact that the vaccine is delivered intramuscularly and the amount of virus being delivered is greater than that delivered by natural exposure.[8] (I-Tr. at 93-94.) Dr. Bellanti based his opinion on the temporal relationship between the administration of Seth's MMR vaccination and the onset of his acute illness, the lack of any other known cause, the literature, and known principles of immunology.

Dr. Bellanti also explained how Seth's condition, the first manifestation of which was an acute attack, could become chronic:

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[5]Dr. Geier cautioned, however, that "it is not possible to absolutely rule-out some of the other etiologies of Seth's acute pancreatitis." (P. Ex. 12 at 5.)

[6]While the MMR vaccine is administered intramuscularly, Dr. Geier testified, there is a chance it got directly into the bloodstream if the needle inadvertently hit a small blood vessel. (I-Tr. at 55, 69.)

[7]Dr. Bellanti also directs the International Center for Interdisciplinary Studies of Immunology, the Division of Virus Disease and Immunology in the Department of Laboratory Medicine, and the Division of Allergy and Immunology in the Department of Pediatrics. (P. Ex. 33; I-Tr. at 82-83). He has published numerous articles related to immunology, some dealing specifically with the immunologic response to either natural infection or viral vaccines. (I-Tr. at 83.) He is board-certified in the fields of pediatrics and allergy and immunology. (P. Ex. 33.)

[8]While he found Dr. Geier's theory about the vaccine inadvertently hitting a blood vessel upon being administered "attractive," Dr. Bellanti did not necessarily subscribe to it. Rather, he indicated that prior sensitization to the virus could lead to a rapid immune response. (I-Tr. at 113-14.)

> The pancreas, unlike other glands, with its high content of enzymes has a propensity to becoming chronic. That is, while some acute pancreatitis can heal, if the insult is large enough you get autobreakdown of the gland itself * * *. And when it breaks down the body's inflammatory response comes into play * * * and fibrosis begins. And if that fibrosis is severe enough it leads to abnormal healing * * * which can lead to chronicity.

(I-Tr. at 97.[9])

Dr. Bellanti could not pinpoint the exact mechanism by which Seth's acute pancreatitis might have been caused by the MMR vaccination. (I-Tr. at 138-39.) He testified that an autoimmune phenomenon was the most likely possibility, and that such phenomenon could have been a result either of the immune's system previous sensitization to one of the MMR viruses, or due to a "molecular mimicry" phenomenon as described above. When asked which mechanism caused Seth's pancreatitis, Dr. Bellanti responded: "Well, one of these mechanisms I'm sure was involved in terms of either molecular mimicry or the genetic response of Seth to his own viral infection."[10] (I-Tr. at 103.) Dr. Bellanti also indicated that mumps virus can go directly to the pancreas itself within hours, bypassing some of the stages involved in a typical immune system response. (I-Tr. at 349-50.) He is not aware of any evidence in the medical literature of such an occurrence, however. (I-Tr. at 362-63.)

Dr. Bellanti testified that his general theory is supported by two case reports involving acute pancreatitis after MMR vaccination. The first involved a 19-year-old woman who was inoculated with MMR and suffered the onset of acute pancreatitis 11 days later. (I-Tr. at 118-19; P. Ex. 26 (J. Adler *et al., Pancreatitis Caused by Measles, Mumps, and Rubella Vaccine*, 6 Pancreas 489 (1991) (hereafter, "the Adler report").) Dr. Bellanti conceded that, in that article, the authors specifically pointed to the fact that the 11-day time period between vaccination and the onset of the disease corresponded to the usual incubation period of the natural mumps virus.[11] However, he believes that a shorter incubation period might occur if the vaccinee was previously sensitized. (I-Tr. at 119.) In the other case report, a letter to a medical journal described a 17-year-old male who developed acute pancreatitis 17 days after receipt of an MMR vaccine. (R. Ex. P (L. Cebria *et al., Acute Pancreatitis Caused by Parotiditis Vaccine. (Letter to the Editor)*, 9 Pancreas 390 (1994) (hereinafter the "Cebria report").)

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[9]Later, Dr. Bellanti testified that "the pancreas is a setup for chronicity due to the breakdown * * * of enzymes which continually autodigest." (I-Tr. at 106.) He opined that a damaged pancreas could be vulnerable to a variety of insults. (I-Tr. at 107.)

[10]Later, Dr. Bellanti testified that "[w]e could invoke many theories. We can invoke molecular mimicry. We could invoke the genetics. We can invoke the anamnestic response. And all of that is really theoretical. The fact of the matter * * * is that it does happen in two days." (I-Tr. at 129.)

[11]Dr. Bellanti also conceded that in the Adler report, the woman was inoculated because there was an outbreak of wild measles on campus. Measles is known to cause pancreatitis. (I-Tr. at 122.)

c. Dr. Sidney Berezin

Petitioner also presented the testimony of Dr. Sidney Berezin, Seth's treating pediatrician, who also opined that Seth's MMR immunization caused his pancreatitis. He based this opinion on the temporal relationship between the vaccination and the onset of Seth's pancreatitis; the plausibility of the notion that the MMR vaccination is capable of producing pancreatitis, and what he termed "ample support in the literature." (P. Ex. 28.) However, when asked what literature he relied on, Dr. Berezin mentioned the Adler report but could not specifically cite any other articles. (Tr. at 154-56.)

d. Dr. Myron Shoham

Dr. Myron Shoham, a gastroenterologist,[12] also testified for petitioner. Dr. Shoham opined that Seth's initial episode of acute pancreatitis was causally related to his MMR vaccination. (P. Ex. 29.) He also opined that Seth's subsequent episodes were "probably related to the initial episode." (*Id.*) Dr. Shoham relied on the temporal relationship between Seth's MMR vaccination and the onset of his pancreatitis; the fact that Seth had never before experienced such an episode; the absence of another known cause; and the assumption that "it has been well substantiated that MMR vaccination has been causally related to acute pancreatitis." (*Id.*) Dr. Shoham, however, indicated that this latter assumption as to substantiation in the medical literature was based upon only two case reports, one of which was the Adler report, and the other of which he had not read. (I-Tr. at 187-88, 200.)

Dr. Shoham also posited that after Seth's initial bout of acute pancreatitis, "in the healing process there was scarring in such a way that the pancreatic ducts and especially the secondary ducts were distorted. And the healing process was not in a normal fashion but in an abnormal fashion which then predisposes to future episodes of acute pancreatitis." (I-Tr. at 190.)

2. Respondent's experts

Respondent presented three expert witnesses before Special Master Wright: Drs. John Bacon, Martin Maksimak, and John Sever. These experts opined that neither Seth's acute episode of pancreatitis in June of 1990, nor his chronic course of pancreatitis since then, was likely caused by his MMR vaccination. They believe it was purely coincidental that the onset of Seth's June 1990 pancreatitis episode so closely followed his MMR vaccination. A synopsis of the testimony of each follows.

a. Dr. John Bacon

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[12]Dr. Shoham is in private practice in gastroenterology and is director of the gastroenterology lab at Fair Oaks Hospital in Fairfax, Virginia. He is board-certified in internal medicine and gastroenterology. (P. Ex. 32.)

Testifying first for respondent was Dr. John Bacon.[13] Dr. Bacon testified that the temporal relationship between Seth's MMR vaccination and the onset of his symptoms--less than 24 hours elapsed between the two events--argues strongly *against*, rather than for, a causal relationship between the two events. (R. Ex. N at 1.) He stated that "[t]he normal incubation period for pancreatitis is 16 to 18 days but cases may occur from 12 to 25 days after exposure." (*Id.* at 1-2.) Dr. Bacon acknowledged that the Adler report suggested a *possible* causal relationship between an MMR vaccination and the onset of symptoms in that individual 11 days later. (*Id.* at 2.) However, he stated that there is no evidence in any medical or scientific literature supporting such a causal relationship with onset of symptoms within *24 hours* of immunization. (*Id.*) He added that "[t]here is no literature that is consistent with Seth Platt's claim that MMR will lead to the development of *chronic* pancreatitis." (*Id.*, emphasis added.)

As to the autoimmune theory upon which petitioner's experts chiefly relied, Dr. Bacon testified that the onset of symptoms within 24 hours of administration of MMR vaccine would not fit any of the known autoimmune reactions. (I-Tr. at 163-66.) He discussed the four types of known autoimmune reactions, and opined that Seth's symptoms did not fit any of the known patterns. He explained that Seth's symptoms were not compatible with a "Type I" autoimmune reaction, which would include episodes of hives, wheezing, shock, or anaphylaxis. (I-Tr. at 163-64.) He stated that Type II reactions require the production of antibodies, which would take two to three days at the least. (I-Tr. at 164.) He ruled out a Type III reaction, which would have involved swollen joints, fever and hives. (I-Tr. at 174-75.) Finally, he noted that a cell-mediated Type IV reaction (similar to that which the body produces in response to a tuberculosis skin test) takes a least two days to occur. (I-Tr. at 175.) Based on the above, Dr. Bacon rejected the notion that Seth's initial bout of acute pancreatitis, which had its onset less than 24 hours after immunization, could have been related to his MMR inoculation.

b. Dr. Martin Maksimak

Also testifying for respondent was Dr. Martin Maksimak, a pediatric gastroenterologist.[14] Dr. Maksimak based his opinion, that Seth's acute pancreatitis was not caused by the MMR immunization he received on June 4, 1990, on several factors. First, Dr. Maksimak opined that Seth displayed the onset of symptoms of pancreatitis *prior* to his June 1990 MMR vaccination. (R. Ex. A at 4; I-Tr. at 228.) He based this view chiefly upon the several histories of Seth's prior abdominal symptoms that were recorded

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[13]Dr. Bacon is board-certified in pediatrics and in allergy and immunology. He is an associate professor of pediatrics at the University of Maryland Hospital and has a private practice in allergy. (R. Ex. O.)

[14]Dr. Maksimak is currently a clinical assistant professor in the Department of Pediatrics at Jefferson Medical College, and the Director of the Department of Pediatric Gastroenterology and Nutrition at the Geisinger Clinic. He is board-certified in pediatrics and pediatric gastroenterology. (R. Ex. B.) Dr. Maksimak has had much experience caring for pediatric patients with chronic pancreatitis. (R. Ex. A at 1.) He is credited with a number of publications in his field. (R. Ex. B.)

during Seth's hospital admission in June of 1990. (See p. 3 above.) Dr. Maksimak explained that about 75% of pediatric patients with chronic pancreatitis suffer recurrent episodes of abdominal pain prior to their first hospital admission,[15] and he believes that Seth's symptoms fit this pattern. (I-Tr. at 231.) He found it especially important that in some instances Seth's prior symptoms had lasted for three or four days at a time, typical of pancreatitis, and in contrast to the typical "common bellyache" one would see in a child or teenager, which would usually last no more than a day or so. (I-Tr. at 232.)

Second, Dr. Maksimak opined that the brief period of time between immunization and the onset of Seth's symptoms would preclude the MMR vaccination as a causative factor. (I-Tr. at 228.) Noting that the usual incubation time for a mumps infection is approximately 14 days, he testified that the onset of Seth's symptoms only hours after his immunization renders it extremely unlikely that Seth's pancreatitis was in any way related to his immunization. (R. Ex. A at 4-5.) Finally, he opined that the recurring nature of Seth's pancreatitis creates a medical picture that has never been documented following MMR immunization. (I-Tr. at 228-29; R. Ex. A at 3-4.)

Dr. Maksimak reviewed and discussed the scientific literature relating to pancreatitis following infection with the "wild" measles, mumps, and rubella viruses. Although pancreatitis associated with measles and rubella has been reported, it is extremely uncommon. (R. Ex. A at 2.) He acknowledged the numerous case reports of pancreatitis being associated with the wild mumps virus, but noted that the incubation period in these cases is 14-24 days (usually about 17-18 days), a far cry from Seth's case. (*Id.* at 2-3.) Further, Dr. Maksimak explained that while the wild mumps virus is known to cause *acute* pancreatitis, there is no well-documented evidence that the virus has ever been associated with *chronic* recurrent pancreatitis.[16] (*Id*. at 4.)

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[15]In cases of acute pancreatitis that do *not* become chronic or relapsing, "probably zero" percent of patients have a prior history of similar abdominal pain, according to Dr. Maksimak. (I-Tr. at 252.)

[16]Dr. Maksimak noted two cases in which abdominal pain was reported to have recurred following mumps virus. In one case, a 4 ½-year-old boy developed mumps, with symptoms including abdominal and testicular pain. Within a few months, the child began to experience recurring episodes of abdominal pain. (I-Tr. at 242-244; R. Ex. A at 3; R. Ex. H (C. B. Wood *et al*., *Chronic Pancreatitis in Childhood Associated with Mumps Virus Infection*, 28 British Journal Of Clinical Practice 67 (1974).) At age 15, he was diagnosed as having pancreatitis, but was then found to have an *anatomical anomaly* which, in Dr. Makismak's view, was the probable cause for his recurring pancreatitis. (R. Ex. A at 3.) In the other instance, a letter to a medical journal in 1980 outlined the history of a man who had experienced a mumps infection at age 34, along with symptoms including severe abdominal pain lasting for about one week. At age 58 he began to suffer episodes of severe epigastric pain, and he was diagnosed with pancreatitis at age 60. (Tr. at 245-46; R. Ex. A at 3; R. Ex. I (J. Graham, *Mumps Causing Chronic Calcific Pancreatitis*, 2 Medical Journal Of Australia 454 (1980)).) Dr. Maksimak opined that that letter provides no evidence of a linkage between the initial mumps infection and the patient's pancreatitis occurring some 24 years later. (R. Ex. A at 3-4.)

Dr. Maksimak then argued that in contrast to the *wild* mumps virus, the scientific literature simply does not support the view that the mumps *vaccine* can cause either acute pancreatitis or chronic recurrent pancreatitis. (R. Ex. A at 4.) Dr. Maksimak cited a large study involving the administration of over six thousand doses of mumps vaccine to children and 163 doses to adults. Careful monitoring of side effects showed no detectable illness. (*Id*.; R. Ex. J (J. Hilleman, *et al., Live, Attenuated Mumps-virus Vaccine*, 278 New England Journal of Medicine 227 (1968)).) As to the Adler report, Dr. Maksimak explained that no definite association can be drawn between that patient's MMR vaccination and her onset of pancreatitis 11 days later, because the vaccination came at a time when there was an outbreak of the measles *disease* on the patient's college campus, so that the patient's acute pancreatitis could just as easily have been caused by the wild measles virus. Dr. Maksimak also stressed that neither the patient in the Adler report, nor the 17-year old boy in the Cebria report noted above, who developed abdominal pain 17 days after receiving an MMR vaccination, went on to develop *chronic* pancreatitis. (I-Tr. at 234, 240-41; R. Ex. A at 4; R. Ex. P.)

Dr. Maksimak also took issue with the theory of petitioner's experts that a severe episode of *acute* pancreatitis would predispose a patient to *chronic* pancreatitis. He disagrees that there exists sufficient evidence upon which to base such a proposition. (I-Tr. at 238.) To the contrary, he explained that when a cause for an acute case of pancreatitis in a child is identified, recovery is usually complete with no recurrences. (I-Tr. at 230.) He also pointed out that it is not unusual for someone to have chronic pancreatitis and to have no cause identified, as is the case with Seth; he explained that in about half of all cases of chronic pediatric pancreatitis, no cause is ever identified. (*Id*.)

c. Dr. John Sever

Also testifying for respondent was Dr. John Sever, an expert in pediatrics, virology and immunology.[17] Citing the lack of any clinical, laboratory, or cellular evidence that Seth had any hypersensitivity, allergy, or immune reaction to his MMR inoculation, in addition to the lack of any epidemiologic data in the literature supporting such an association, Dr. Sever rejected the notion the MMR vaccination caused Seth's pancreatitis. (II-Tr. at 290.) Dr. Sever testified that while about eight million doses of MMR vaccine are administered annually (II-Tr. at 341[18]), to his knowledge, there has never been a case report of any individual experiencing autoimmune hypersensitivity response to MMR vaccine. (II-Tr. at 336.)

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[17] Dr. Sever is a professor of pediatrics, obstetrics and gynecology, and microbiology and immunology at George Washington University School of Medicine. He holds a Ph.D. degree in microbiology in addition to his medical degree. (II-Tr. at 287; R. Ex. R.) Dr. Sever is board certified in pediatrics. He is credited with numerous publications. His primary research has been in the area of infectious diseases. (II-Tr. at 287.) Dr. Sever has studied and published articles on a number of viral vaccines, including measles, rubella, and mumps. (II-Tr. at 287-89.)

[18] Around four million of those are *second* doses of MMR vaccine. (II-Tr. at 335-36.)

As to the Adler report, Dr. Sever noted that the primary association made by the author was a temporal one -- that is, the patient developed pancreatitis 11 days following immunization with MMR, consistent with the incubation period of the natural disease. Likewise, the boy in the Cebria report was noted to develop the onset of symptoms of pancreatitis 17 days after immunization with MMR--a time frame also consistent with the incubation period of the natural mumps virus. (R. Ex. P.) Because of these two published reports, Dr. Sever would be willing to concede the *possibility* of a causal relationship between an MMR vaccination and an episode of acute pancreatitis *if* the interval between inoculation and onset of symptoms coincided with the expected incubation period of the natural mumps virus. (II-Tr. at 309-310.) But that was not the case with respect to Seth, he stressed.

B. Special Master Wright's ruling

In her Decision filed on December 17, 1998, Special Master Wright denied petitioner's claim. She concluded that the testimony of respondent's experts was more persuasive than that of petitioner's experts. Special Master Wright noted that she did find it to be at least plausible that an MMR vaccination might trigger a case of *acute* pancreatitis, in a situation where the onset of symptoms after vaccination *coincided* with the ordinary incubation period for mumps virus (*i.e.*, about 12-25 days after exposure). However, in the very different circumstances of Seth's case, she found it unlikely that either his acute pancreatitis episode or his chronic pancreatitis was vaccine-caused, for at least three reasons.

First, Special Master Wright simply found the basic causation theory of petitioner's experts, involving an autoimmune response, to be "purely theoretical" (Decision at 18), without substantial support in medical literature (*id*. at 16-17). Second, she found a complete lack of evidence that a vaccination could cause a case of *chronic* pancreatitis. (*Id*. at 17.) Finally, she found it likely that Seth's chronic pancreatitis condition actually *predated* his MMR immunization in question, and thus could not have been caused by it. (*Id*. at 17-18.)

C. Expert testimony after remand

On remand, petitioner presented additional testimony from Drs. Bellanti and Geier. In presenting their testimony on remand, the petitioner's experts accepted Special Master Wright's conclusion that Seth had experienced episodes of pancreatitis prior to his MMR immunization on June 4, 1990. They testified that, making that assumption, Seth's preexisting pancreatitis was likely *significantly aggravated* by his MMR vaccination.

As to the purported mechanism of the aggravation, the testimony of petitioner's experts did not significantly differ from their testimony before Special Master Wright. They continued to opine that the vaccination probably triggered some type of *autoimmune* reaction in Seth, although they think that an alternative possibility is that some toxic substance in the vaccine might have *directly* injured Seth's pancreas. (See, *e.g.*, Ex. 44 (filed 12-15-99), p. 2; Ex.45 (filed 12-17-99), p. 1; III-Tr. at 7-8, 55-60, 102-107, 109.) The two experts added that they found their theories to be even more plausible based on

the assumption that Seth had already suffered from some earlier undiagnosed episodes of pancreatitis. In that case, the experts explained, his pancreas would have been weakened and even more susceptible to damage by reaction to the vaccination.

Respondent also provided additional testimony on remand, by Drs. Maksimak and Sever. Again, the testimony did not differ substantially from the testimony before Special Master Wright. Generally, the two experts contended that there exists no substantial evidence for the *general* proposition that any component of the MMR vaccine is likely to prompt any sort of a damaging autoimmune reaction, much less for the *specific* proposition that the MMR vaccine can, through triggering an autoimmune response, *exacerbate* an underlying *pancreatitis* condition. Respondent's experts find it far more likely that whatever factor caused Seth's preexisting pancreatitis simply continued its natural course, causing the pancreatitis episode in June of 1990 and then further episodes over the following years.

IV

DISCUSSION

I have thoroughly studied the entire record in this case, including the proceedings before Special Master Wright. Based upon that study, I find that petitioner has failed to establish[19] his entitlement to a Program award. A full explanation for my conclusion follows.

A. The legal standard

Over the years of the existence of the Program, a number of cases have discussed the burden of proof on the petitioner in a case alleging "actual causation" (also known as "causation-in-fact") under the Program. See, e.g., *Hines v. Secretary of HHS*, 940 F. 2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F. 2d 731 (Fed. Cir. 1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-51 (1989). The petitioner must demonstrate a "medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). However, as indicated in the Order of Judge Allegra in this case dated April 19, 1999, additional controlling case law clarifying that burden was issued in *Shyface v. Secretary of HHS*, 165 Fed. 3d 1344 (Fed. Cir. 1999). The *Shyface* decision clarified that when a petitioner alleges "actual causation"--*i.e.*, that the vaccination in fact caused an injury or in fact aggravated a preexisting condition--the petitioner need not demonstrate that the vaccination was the *sole* cause, or even the *primary* cause, of the injury or

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[19]Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harland, J., concurring).

aggravation. Instead, the petitioner need only show that the vaccination was a *substantial factor* in causing the injury or aggravation, and that *but for* the vaccination the injury or the aggravation would not have occurred, or would have been less severe.

I note that when Special Master Wright issued her Decision in this case on December 17, 1998, the *Shyface* decision had not yet been issued. Thus, it appears to me that it may be appropriate that I evaluate not only petitioner's *aggravation* causation theory presented on remand, but also petitioner's *original* theory of causation (*i.e.*, the theory that Seth's pancreatitis had its *initial onset* in June of 1990 and that onset was caused by the vaccination) under the *Shyface* standard. Accordingly, I have divided my discussion into two parts below. In Part B, I evaluate petitioner's *original theory* under the *Shyface* standard. In Part C, I evaluate petitioner's *aggravation theory*, advanced on remand, under the *Shyface* standard.

B. Petitioner's original theory

Petitioner's original theory, as explained above, was that Seth's symptoms in June of 1990 marked the *onset* of his chronic pancreatitis condition, and that such condition was caused by his MMR inoculation. Under *Shyface*, the correct standard for evaluating that theory is whether, based upon the record, it appears "more probable than not" that the MMR vaccination was a "substantial factor" in initially causing Seth's pancreatitis. After considering the entire record, I must answer that question in the negative.

On this point, I will provide only a brief analysis, because I agree completely with the discussion already set forth by Special Master Wright in her decision dated December 17, 1998. Like Special Master Wright, I found the testimony of the respondent's experts to be far more persuasive than that of petitioner's experts. First of all, I agree completely with Special Master Wright that it appears very likely, with the benefit of hindsight, that the abdominal pain symptoms that Seth experienced on several occasions prior to June of 1990, were, in fact, symptoms of an already-existing pancreatitis condition. (See Special Master Wright's discussion of this point at pp. 17-18 of her Decision, which I endorse.) This means, quite obviously, that the vaccination could not have been even a "substantial factor" in *initially causing* Seth's pancreatitis condition. Further, I agree with Special Master Wright's additional stated reasons for rejecting petitioner's original theory.

Accordingly, even applying the *Shyface* standard, I conclude that petitioner's original theory regarding causation of Seth's pancreatitis must be rejected.[20]

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[20]I note that in addition to the expert opinions discussed at pp. 4-8 above, petitioner also filed an extremely brief written opinion of Dr. Leonard J. Newman. (Pet. Ex. 41.) I have considered that opinion, but find that it is far outweighed by the other evidence of record.

C. Petitioner's aggravation theory

On remand, as noted above, petitioner has advanced a somewhat different theory, arguing that assuming that Seth did have prior episodes of pancreatitis, his MMR vaccination of June 4, 1990, *significantly aggravated* his preexisting pancreatitis condition. But after full consideration, I find that petitioner has failed to demonstrate that it is "more probable than not" that the MMR vaccination was even a "substantial factor" in causing the worsening of Seth's pancreatitis condition.

Initially, I acknowledge that plainly, Seth's pancreatitis condition *did* worsen soon after his MMR vaccination on June 4, 1990, in the sense that he obviously experienced pain that was worse than during his prior attacks, pain so severe that he was hospitalized for the first time. And his condition obviously continued to worsen thereafter. But the record before me does not offer significant support for the proposition that Seth's MMR vaccination had any role, much less a substantial role, in *causing* that worsening.

I note that, as indicated above, the theories of petitioner's two experts as to how the vaccine might have *aggravated* Seth's pancreatitis condition were not significantly different from their theories as to how the vaccine might have been the *initial cause* of Seth's pancreatitis. That is, the two experts theorize that the vaccination probably triggered an *autoimmune* reaction in Seth, although they also think it possible that some toxic substance in the vaccine might have *directly* injured Seth's pancreas. (See, *e.g.*, III-Tr. 7-8, 55-60, 102-107, 107-108, 109.) However, like Special Master Wright, I found these theories to be almost purely theoretical, devoid of any substantial support in medical literature. I found these theories to be no more persuasive as an explanation for an *aggravation* of Seth's pancreatitis condition than they were as a purported explanation for the *initial cause* of his pancreatitis condition.[21]

In this regard, I am persuaded by respondent's experts that the available medical literature simply provides no substantial support for the basic autoimmune response theory upon which petitioner's experts place almost all their reliance. To be sure, this theory has at least some *theoretical* appeal, since we know that on occasion human immune systems do malfunction, resulting in destructive autoimmune responses prompted by a particular antigen's invasion of the body. However, as respondent's experts pointed out, there is a dearth of actual evidence indicating that *MMR vaccinations* have resulted in *any* type of destructive autoimmune responses at all, despite the fact that approximately eight million MMR vaccinations (four million of which are booster vaccinations) are administered every year in this country alone. And, of course, there is no substantial evidence that MMR vaccinations have ever caused, or aggravated, the *specific* type of autoimmune response alleged here--*i.e.*, an attack of *pancreatitis*.[22]

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[21]In fact, I find these theories to be *even more unlikely* in the aggravation context.

[22]See my discussion of certain case reports of pancreatitis after MMR vaccination at pp. 16-17, below.

And as to the apparent *alternative* theory of petitioner's experts, that some type of toxin in the vaccine might have directly attacked Seth's pancreas (see, *e.g.*, III-Tr. at 107-108), such theory was almost totally unexplained, and certainly no significant evidence was offered in support thereof. I find this theory to be of no persuasive value at all.

In contrast to the purely theoretical and almost totally unsubstantiated theories advanced by petitioner, the theory of respondent's experts concerning Seth's case seems logical and straightforward. That is, under respondent's theory, Seth already had experienced several episodes of pancreatitis, although that condition was as yet undiagnosed. Whatever was the cause of that earlier pancreatitis, the pancreatitis condition simply followed its natural course, erupting into serious inflammation and pain on or about the morning of June 5, 1990, purely coincidentally to the MMR vaccination on June 4. This explanation is supported very convincingly by the testimony of Dr. Maksimak, the only pediatric gastroenterologist to testify and the expert with the best credentials to opine concerning pancreatitis in teenagers. Dr. Maksimak explained that the course of chronic pancreatitis experienced by Seth, beginning with several undiagnosed episodes of abdominal pain followed by a series of more severe attacks resulting in hospitalizations, is quite common. In about half of such cases, as with Seth, no cause is ever definitively established.

In my view, it seems far more likely that Seth's case falls into this common pattern suggested by respondent's experts, rather than constituting the theoretically possible but unprecedented and unique phenomenon theorized by petitioner's experts.

A couple of other points merit additional discussion. Petitioner has pointed (see Ex. 43 (filed 9-17-99), pp. 2-3 and attachments) to a series of case reports taken from a database kept by the federal government's Vaccine Adverse Event Reporting System ("VAERS"). The VAERS is a reporting system under which physicians or others may report the occurrence of an adverse event suffered by a vaccine recipient after a vaccination. It is intended as a tool to alert medical researchers if an unusually large number of adverse events of a similar type are happening after a certain type of vaccination. Petitioner notes that a recent VAERS search turned up 17 reports involving situations in which individuals experienced pancreatitis within 544 days after MMR vaccinations. Although they did not discuss this point in much detail, petitioner's two experts on remand seem to suggest that the existence of these reports supports petitioner's causation theory in this case.

After careful examination of the 17 VAERS reports, which appear at R. Ex. Y,[23] I conclude that they offer no significant support to petitioner's claim. First, I note that two of the 17 reports refer to Seth's own case. (III-Tr. at 20, 76.) There are also two other sets of duplicate reports (numbers 94488 and 96436--see III-Tr. at 133-35; and numbers 127880 and 128057--see III-Tr. at 137), meaning that the total number of reported cases other than Seth's own case totaled 13, rather than 17. Further, only three

[23]At Ex. 43, Dr. Greier supplied only small excerpts from the VAERS reports in question. Respondent later filed the entire reports as Ex. Y.

of those 13 involved the onset of pancreatitis very soon after vaccination, in a time frame similar to that of Seth's onset. (See case report numbers 96745, 92500, and 96436, discussed at III-Tr. at 80-82, 91-92, 93; Ex. Y, pp. 3-4, 7-8.) And, as Dr. Sever explained (*e.g.*, III-Tr. at 122-123) isolated case reports of this type are of very little help in resolving medical causation questions, especially when, as in the case of VAERS reports, the full files of the cases have not been closely examined by medical personnel to look for other potential causes of the adverse events or to verify the reported information. Such reports are usually useful only as a means of *identifying possible* correlations, to prompt more systematic studies of a potential causal relationship.

In the case of these particular VAERS reports, and the proposition for which petitioner offers them, the obvious problem is that there is no good way to tell whether the temporal relationship between the MMR vaccination and the onset of symptoms was anything more than pure coincidence. After all, with more than eight million MMR vaccinations administered in this country alone (the VAERS reports submitted included reports from other countries), it would not be surprising that a number of onsets of pancreatitis would occur shortly after MMR inoculations *simply by pure chance*. Petitioner's experts in this case have offered *no* analysis indicating that that is not the case with the VAERS reports cited here.

Moreover, none of the VAERS reports seem to involve persons with *pre-existing* pancreatitis, as Seth had, nor do they seem to involve *chronic* pancreatitis, from which Seth suffers. In short, the VAERS reports, while interesting, simply cannot be viewed as offering significant support to the theories of petitioner's experts here.[24]

Finally, I note one more reason to question the theories of petitioner's experts on remand here--the fact the testimony *now* offered is contradicted to a considerable extent by the very testimony of *petitioner's own experts* during the proceedings before Special Master Wright. During the proceedings before Special Master Wright, Drs. Geier, Bellanti, and Shoham all explained that a major reason for their conclusion that Seth's *chronic* pancreatitis was vaccine-caused was their view that whatever caused the *first* episode of a person's pancreatitis was probably the cause of any ensuing *chronic* pancreatitis. (See, *e.g.*, I-Tr. at 62-73, 76, 106-108, 188-91, 212.) Dr. Geier even indicated that if Seth in fact suffered from preexisting pancreatitis, his opinion *would be different*. (I-Tr. at 69-70.) Yet on remand, Drs. Bellanti and Geier have abandoned, without explanation, their previously-stated view that the cause of a person's first episode of pancreatitis is likely the cause for any ensuing chronic pancreatitis. Instead, they now assert that it was the vaccination, *not* the cause of Seth's first pancreatitis episodes, that resulted in the chronic

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[24]Petitioner argues in his reply brief that the "Respondent seems to feel that the medical literature must contain a case exactly like Seth's in order to be meaningful." (Reply Brief at 8.) I agree with petitioner that medical literature could, in theory, offer substantial support for a causation theory in a particular Program case even if it did not contain "a case exactly like [the petitioner's]." Here, however, I have carefully evaluated *all* of the medical literature discussed by petitioner's experts and simply find that, for the reasons discussed by Special Master Wright and discussed above in this Decision, it simply does not offer substantial support for the theories of petitioner's experts.

pancreatitis. This abrupt change of direction was not only unconvincing, but, to be frank, makes me doubt very much that either expert was actually offering a *candid* opinion of the case in the testimony before me.

In short, for all of the reasons stated above, I conclude that petitioner has failed to demonstrate that it is "more probable than not" that Seth's MMR vaccination played a substantial role in aggravating his pancreatitis condition.

V

CONCLUSION

Obviously, it is very unfortunate that Seth Platt suffers from chronic pancreatitis, and one cannot help but feel sympathy for him. However, for the reasons stated above, I find that petitioner has failed to carry his burden of demonstrating that his MMR vaccination was a substantial factor in either initiating or aggravating his pancreatitis. Therefore, I find that he is not eligible for Program compensation.

It is not clear under either the statute or the currently-applicable Rules of this court whether the filing of this "Decision on Remand" automatically triggers a new 30-day period for seeking review under Appendix J, Rules of the United States Court of Federal Claims, Rule 23. It is *arguable* that in the absence of a motion for review filed within 30 days of the date of this Decision, the Clerk of this court should automatically enter judgment in accordance herewith. But that is not completely clear. The parties and/or the Clerk may wish to seek guidance from the chambers of Judge Allegra as to the appropriate procedure at this time.

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George L. Hastings, Jr.
Special Master