

OFFICE OF SPECIAL MASTERS
NOT FOR PUBLICATION
April 20, 2005

BARBARA CUNNINGHAM, the Natural *
Parent and Guardian of Minor Child, *
APRIL YOUNG, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES, *

Respondent. *

Basil L. North, Jr., Kansas City, MO, for petitioner.
Althea W. Davis, Washington, DC, for respondent.

No. 01-483V
MMR caused idiopathic
thrombocytopenia

MILLMAN, Special Master

DECISION¹

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). 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.

Petitioner² filed a petition dated August 21, 2001, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that MMR vaccine, administered on July 22, 1998 caused April Young (hereinafter, “April”) to contract idiopathic thrombocytopenic purpura (hereinafter, “ITP”), whose onset was August 22, 1998 or 31 days later.³

The parties agreed on the diagnosis of the disease. The only fact in dispute was the onset of April’s bruising, which would mark the onset of her ITP. A hearing was held on March 8, 2005. Testifying for petitioner were Barbara Cunningham (April’s mother), Kimberly Bettis (April’s day care provider), William Gulley (April’s maternal uncle), and Dr. J. Scott Nystrom. Testifying for respondent was Dr. James Nachman.

FACTS

April was born on March 27, 1992. Med. recs. at 5. She received MMR vaccine on July 22, 1998. On June 23, 1999, she saw a pediatric hematologist/oncologist, Dr. Gerald M. Woods, at Children’s Mercy Hospitals. Ms. Cunningham told him that April had been healthy and active, but she suffered an upper respiratory infection about one month prior to this visit. Ms. Cunningham first noted an increased bruisability of April’s arms and legs about two weeks prior and also April developed a rash on her upper chest. April did not have any other complaints except for “short” nosebleeds in the past two weeks. She probably had ITP. Med. recs. at 227.

Other Submitted Material

² Initially, Phillip Young was also a petitioner in this case. However, due to his untimely demise, Barbara Cunningham became the sole petitioner. See Order dated March 9, 2005.

³ An extraordinary amount of time was taken to determine what date April’s 1998 vaccination was administered. Finally, the parties agreed it was July 22, 1998.

Petitioner filed an article entitled “Idiopathic thrombocytopenic purpura and MMR vaccine” by E. Miller, et al., 84 *Arch Dis Child* 227-29 (2001), which notes that children receiving MMR can develop ITP within six weeks after vaccination. Two of every three cases of ITP in the six-week post-immunization period were caused by MMR, according to the authors. Filing of March 23, 2004.

Petitioner also filed an article entitled “A new method for active surveillance of adverse events from diphtheria/tetanus/pertussis and measles/mumps/rubella vaccines” by P. Farrington, et al., 345 *Lancet* 567-69 (1995), which notes a causal association between MMR vaccine and ITP occurring 15-35 days post-vaccination. Filing of March 23, 2004.

Petitioner filed the affidavit of Christine Tumlin, April’s maternal grandmother, dated October 30, 2004. Ms. Tumlin stated that she first began noticing red bruising and red spots on April in late summer, August 1998. She initially thought they were the result of anemia or a vitamin deficiency. Filing of November 1, 2004.

Respondent filed a Declaration of Dr. Gerald M. Woods (Ex. I) dated September 15, 2004, in which he states that it is his customary practice to ask for a prior medical history. He suspected that April suffered from acute ITP because of her increased bruisability two weeks prior to her visit to his clinic. If he had been informed that she had been bruising for six months to one year prior to her visit to his office, he would have noted that in his records and diagnosed her with chronic ITP.

TESTIMONY

Barbara Cunningham testified first for petitioner. Tr. at 13. She noticed April’s bruises the first time on August 22, 1998. Tr. at 15. She spoke to her husband and her mother about it.

Tr. at 49. April's bruising sometimes got better and sometimes worse. Tr. at 14-15. The bruises were sometimes large and sometimes small. Tr. at 18.

Kimberly Bettis testified next for petitioner. Tr. at 85. She was April's day care provider from the beginning of August 1998 until the end of September 1998. Tr. at 86. She noticed April's bruising a little after she began caring for April. *Id.* The bruises were mostly on April's arms. Tr. at 89. Ms. Bettis was concerned that April had been abused. *Id.* She consulted with her family over whether to report April's parents to the authorities, but decided to approach Ms. Cunningham privately. *Id.* Ms. Bettis recalls that Ms. Cunningham did not think anything was bad enough to take April to see a doctor. Tr. at 91. They decided to change April's diet to include vegetables, fruit, and red meat, but the bruising continued. *Id.* Ms. Cunningham told Ms. Bettis about April's nosebleeds. Tr. at 92. Ms. Bettis did not see anything on April's legs. *Id.* She is not personal friends with Ms. Cunningham. Tr. at 93.

William Ray Gulley testified next for petitioner. Tr. at 102. In late July or August, he goes on vacation and takes his daughter to see April. Tr. at 103. He was in Kansas City in late August 1998 and stayed at his parents' house. *Id.* He noticed April in the wading pool in the backyard with bruises on her arms mostly, and some on her legs. Tr. at 104. His mother thought nothing of it. Tr. at 105. He did not talk to Ms. Cunningham at all. Tr. at 106.

Dr. J. Scott Nystrom, a hematologist/oncologist since 1972, testified next for petitioner. Tr. at 114. He is board-certified in internal medicine and in hematology and oncology. Tr. at 115. His opinion is that MMR caused in fact April's ITP because substantial medical literature supports MMR causing ITP within 6 to 7 weeks post-vaccination. Tr. at 117. April's family saw easy bruising within 6 to 7 weeks of April's MMR vaccination. *Id.* Her 1999 platelet count was

21,000. *Id.* She had chronic bruising for 8 months prior to her diagnosis of ITP in June 1999, which is consistent with chronic ITP, but not consistent with an ITP which would resolve spontaneously, i.e., acute ITP. Tr. at 117-18. Most children with ITP have acute ITP following an upper respiratory infection. Tr. at 118. Those with acute ITP have a platelet count below 10,000, whereas April's platelet count initially was 21,000. Tr. at 118-19. April's ITP was atypical because she had bruising for many months and was chronic from the time she was diagnosed. Tr. at 120.

Although April has been in remission for two years, she had a period of chronicity. *Id.* She had a low platelet count for a number of months before being diagnosed. Tr. at 121.

Acute ITP can go chronic. Tr. at 126. However, April's chronic course starting in August 1998 is consistent with her refractory course after diagnosis. *Id.* The definition of "chronic ITP" is that it lasts longer than four weeks. Tr. at 127. Dr. Nystrom's opinion is that April had acute ITP after MMR but not severe enough to bring her to the doctor. Tr. at 128. Her acute ITP slipped into chronic ITP. *Id.* The distinction between acute and chronic ITP is not the severity of the symptoms, but the duration of the disease. Tr. at 130. A higher platelet count means the symptoms are not that severe. *Id.* April's 21,000 platelet count was high for a child with ITP. Tr. at 131. Her platelet count was high enough to prevent excessive bruising, but it got worse and went into a chronic phase. Tr. at 132.

Dr. James Nachman, board-certified in pediatrics and in pediatric oncology/hematology, testified for respondent. Tr. at 154. He described ITP as having a sudden onset in children. Tr. at 156. In 12 hours, they have extensive petechiae and bruising. *Id.* They may or may not have nosebleeds and a very low platelet count (50% have less than 15,000). *Id.* In pediatrics, whether

someone has chronic ITP depends on the length of time the ITP persists. Tr. at 157. Fifty percent recover after one month, 30% recover after 6 months, and 10% recover after one year. *Id.* Chronic ITP from the beginning of the disease is extremely rare in pediatrics. Tr. at 158. Dr. Nachman testified that ITP associated with vaccination is almost always explosive in onset. Tr. at 160. It is very rare not to have explosive ITP after MMR. *Id.* A diagnosis of chronic ITP depends not on the symptoms, but on the duration of the illness. Tr. at 163. The vast majority are diagnosed within 24 hours. Tr. at 164. His opinion is that April's ITP began in 1999 with petechiae. Tr. at 165. Her low platelet count lasted beyond 6 months or a year, putting her in the category of chronic ITP. *Id.* Dr. Nachman opined that MMR was irrelevant to April's ITP. Tr. at 166.

DISCUSSION

Because petitioner alleges onset 31 days after MMR vaccination, petitioner cannot benefit from the Table injury of ITP which requires onset of 7-30 days post-vaccination. See 42 C.F.R. § 100.3(a)(V)(A). Therefore, petitioner is proceeding on a theory of causation in fact.

To satisfy her burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, *supra*, 956 F.2d at 1149. Mere

temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must not only show that but for the vaccine, April would not have had ITP, but also that the vaccine was a substantial factor in bringing about her ITP. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

The medical literature petitioner filed is ample proof that MMR causes ITP out to six or seven weeks post-vaccination. If April's onset were 31 days post-MMR, she would clearly show a causal relationship between the MMR and her ITP.

Dr. Nystrom testified that her ITP began as a not very severe acute ITP which became chronic. That her course did not resolve quickly showed him that her ITP was chronic both before and after her June 1999 diagnosis. Dr. Nachman testified that April's ITP was acute, occurring within one month of her June 1999 diagnosis. Dr. Nachman testified that it is extremely rare for a child to have chronic ITP from the beginning, particularly after receiving MMR. This, however, does not mean it does not happen. By analogy to the Federal Circuit's holding in Knudsen, an event that is rare does not mean it did not happen.

In Knudsen, the Federal Circuit ruled for petitioners even when epidemiological evidence directly opposed causation from a vaccine and supported the opposite conclusion, i.e., 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, stating:

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.

Both medical experts agreed in this case that the difference between chronic and acute ITP does not depend on the severity of the symptoms, but on how long the symptoms last. We know from the medical records that, after her diagnosis, April's ITP lasted longer than those who have a spontaneous remission. To answer when April's symptoms began, we must examine the lay fact testimony.

The undersigned finds that Ms. Bettis' testimony was persuasive as to onset. She is not a personal friend of Ms. Cunningham and expressed her dismay in August 1998 at April's bruises, wondering if April were being abused and if Ms. Bettis should report April's parents to the authorities.

The undersigned also finds Mr. Gulley's testimony persuasive. Even though he is a relative (the maternal uncle) of April, his testimony that he noted April's bruised arms the last week of August 1998 was consistent with petitioner's allegation as well as Ms. Bettis' testimony (and Ms. Tumlin's affidavit) as to time of onset. To the undersigned, Mr. Gulley sounded like a "straight shooter."

Whether or not April's onset was a less severe acute ITP or a chronic ITP from its beginning, the undersigned holds that it began in late August 1998 and continued in a chronic form until it worsened in the spring of 1999, continuing its chronicity for an extended period of time. Because of compelling evidence from both the medical literature and Dr. Nystrom's testimony that MMR causes ITP within 6 or 7 weeks of vaccination, and April's onset was 31

days post-MMR, the undersigned holds that petitioner has prevailed in proving that MMR caused in fact April's ITP.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will convene a telephonic status conference soon to discuss the filing of life care plans, unless the parties agree on a joint life care plan. The parties should be aware that alternate dispute resolution is available to them as well, and if they choose ADR, they should contact the undersigned. Should the parties not be able to settle this case, the undersigned will hold a damages hearing.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master