

## OFFICE OF SPECIAL MASTERS

(Filed: April 20, 2005)

ZEYDA BERNABE,	)	
mother and natural guardian of her son,	)	
ANTHONY BERNABE,	)	
	)	
Petitioner,	)	
	)	
v.	)	No. 03-1494V
	)	DO NOT PUBLISH
SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	
	)	

### DECISION<sup>1</sup> (MEDICAL EXPERT CREDIBILITY RULING)

Petitioner, Zeyda Bernabe (Ms. Bernabe), as natural guardian of her son, Anthony Bernabe (Anthony), seeks compensation under the National Vaccine Injury Compensation Program (Program).<sup>2</sup> On June 21, 2000, Anthony entered Florida Hospital Medical Center/Orlando. *See generally* Petitioner's exhibit (Pet. ex.) 11 at 1. Clifford Selsky, M.D. (Dr. Selsky), a pediatric hematologist/oncologist, diagnosed Evan's Syndrome. *See* Pet. ex. 11 at 11; *see also* Pet. ex. 8 at 1. Evan's Syndrome "is a combination of idiopathic thrombocytopenic purpura and autoimmune hemolytic anemia." Notice of Filing Documents, filed October 23, 2003, Petitioner's Expert Report of Fouad M. Hajjar, M.D. (Dr. Hajjar's Opinion), at 1. Idiopathic thrombocytopenic purpura (ITP) is "thrombocytopenic purpura unassociated with any definable systemic disease." DORLAND'S

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<sup>1</sup> As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

<sup>2</sup> The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

ILLUSTRATED MEDICAL DICTIONARY 1392 (27th ed. 1988). Thrombocytopenic purpura is “any form of purpura in which the platelet count is decreased.” *Id.* Purpura is “a small hemorrhage (up to about 1 cm in diameter) in the skin, mucous membrane, or serosal surface.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1391 (27th ed. 1988). The term “comprises a group of hemorrhagic diseases characterized by the presence of purpuric lesions, ecchymoses, and a tendency to bruise easily.” *Id.* Autoimmune hemolytic anemia is “a general term covering a large group of anemias involving autoantibodies against red cell antigens” leading to the “premature destruction of red blood cells.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 76-77 (27th ed. 1988). The medical community does not know the cause for Evan’s Syndrome. *See, e.g.* Transcript (Tr.), filed April 13, 2005, at 226-27. However, the medical community suspects that in Evan’s Syndrome, the body produces “two separate antibodies” that are “directed toward two different antigens:” blood platelets and red blood cells. Tr. at 227; *see also* Tr. at 37.

After Anthony’s discharge from Florida Hospital Medical Center/Orlando on June 30, 2000, *see generally* Pet. ex. 11, Dr. Selsky and his associate, Fouad Hajjar, M.D. (Dr. Hajjar), a pediatric hematologist/oncologist, monitored Anthony’s Evan’s Syndrome. *See generally* Pet. ex. 8; *see also* Tr. at 30-44. By August 2001, Anthony’s hemolytic anemia had resolved apparently. *See* Pet. ex. 8 at 111; *see also* Pet. ex. 8 at 30; Tr. at 40. However, Anthony’s ITP persisted. *See generally* Pet. ex. 8; *see also* Tr. at 40-44.

In an amended petition that she filed on November 19, 2003, Ms. Bernabe alleges that Anthony suffers “chronic” ITP that is related to a hepatitis B vaccination that he received on June 5, 2000. *See* Amended Petition (Am. Pet.) at 1. Ms. Bernabe understands that she pursues necessarily an actual causation claim. *See* Tr. at 8. According to the United States Court of Appeals for the Federal Circuit, Ms. Bernabe’s burden under the actual causation standard is “heavy.” *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1102 (Fed. Cir. 1996). The mere temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *See Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992). To prevail under an actual causation theory, Ms. Bernabe must demonstrate by the preponderance of the evidence that (1) “but for” the administration of the June 5, 2000 hepatitis B vaccination, Anthony would not have been injured, and (2) Anthony’s June 5, 2000 hepatitis B vaccination was a “substantial factor in bringing about” Anthony’s injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). The actual causation standard requires Ms. Bernabe to present “a medical theory,” supported by “[a] reliable medical or scientific explanation,” establishing “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Grant*, 956 F.2d at 1148; *see also Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994)(citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)). “The analysis undergirding” the medical or scientific explanation must “fall within the range of accepted standards governing” medical or scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Ms. Bernabe’s medical or scientific explanation need not be “medically or scientifically certain.” *Knudsen*, 35 F.3d at 549. But, Ms. Bernabe’s medical or

scientific explanation must be “logical” and “probable,” given “the circumstances of the particular case.” *Knudsen*, 35 F.3d at 548-49.

On October 23, 2003, Ms. Bernabe proffered a medical opinion from Dr. Hajjar. Dr. Hajjar recounted Anthony’s clinical history. *See generally* Dr. Hajjar’s Opinion. Dr. Hajjar noted that “the literature” contains “several reports. . . incriminating the administration of hepatitis B and other vaccines to [sic] the development of” ITP. Dr. Hajjar’s Opinion at 2. In addition, Dr. Hajjar noted that the literature contains “even one report of Evan’s Syndrome occurring after hepatitis B vaccine.” *Id.* According to Dr. Hajjar, the “reports” established that “thrombocytopenia occurred in a certain time frame after the administration of hepatitis B vaccine at much higher incidence than the occurrence of ITP in the general population.” *Id.* Dr. Hajjar said that the “time frame” between vaccination and onset of ITP “ranged between two weeks and three months.” *Id.* Based apparently upon the temporal relationship between Anthony’s June 5, 2000 hepatitis B vaccination and Anthony’s Evan’s Syndrome, and based apparently upon the absence of “other underlying processes,” Dr. Hajjar asserted that Anthony’s June 5, 2000 hepatitis B vaccination “caused” Anthony’s Evan’s Syndrome. *Id.*

The special master convened the informal, yet substantive, Rule 5 conference on February 12, 2004. He discussed comprehensively Dr. Hajjar’s Opinion. He expressed his firm view that Dr. Hajjar’s Opinion was not “legally-sufficient.” *Bernabe v. Secretary of HHS*, No. 03-1494V, Order of the Special Master at 1 (Fed. Cl. Spec. Mstr. Feb. 17, 2004). Therefore, the special master directed Ms. Bernabe to continue the medical investigation of the case. *Id.*

On April 21, 2004, Ms. Bernabe proffered a supplemental medical opinion from Dr. Hajjar. *See* Notice of Filing Documents, filed April 21, 2004, Petitioner’s Supplemental Expert Report (Dr. Hajjar’s Supplemental Opinion). Dr. Hajjar iterated that “ITP following Hepatitis B vaccine occurred at much higher incidence then [sic] ITP in the general population.” Dr. Hajjar’s Supplemental Opinion at 1. Dr. Hajjar maintained that the “temporal relation” between Anthony’s June 5, 2000 hepatitis B vaccination and Anthony’s condition “is within what is described in the medical literature.” Dr. Hajjar’s Supplemental Opinion at 1-2. In addition, Dr. Hajjar maintained that “[a]ll other possible etiologies” for Anthony’s condition “were ruled out.” Dr. Hajjar’s Supplemental Opinion at 1. Thus, Dr. Hajjar insisted that Anthony’s June 5, 2000 hepatitis B vaccination caused Anthony’s condition. *See id.*

The special master reviewed Dr. Hajjar’s Opinion and Dr. Hajjar’s Supplemental Opinion. On May 13, 2004, the special master directed Ms. Bernabe to file a second supplemental medical opinion from Dr. Hajjar. *See Bernabe v. Secretary of HHS*, No. 03-1494V, Order of the Special Master (Fed. Cl. Spec. Mstr. May 13, 2004). The special master instructed Dr. Hajjar “to explain particularly his assertion that ‘ITP following *Hepatitis B* vaccine occurred at much higher incidence then [sic] ITP in the general population.’” *Bernabe v. Secretary of HHS*, No. 03-1494V, Order of the Special Master at 2 (Fed. Cl. Spec. Mstr. May 13, 2004)(emphasis in original)(citations omitted). The special master reasoned that Ms. Bernabe had proffered only one article discussing a population-based study regarding ITP and immunization. *Id.* citing Pet. ex., Volume II (Vol. II), 3. The special

master noted that the population-based study involved the measles-mumps-rubella (MMR) vaccine rather than the hepatitis B vaccine. *Id.*

On August 26, 2004, Ms. Bernabe filed a status report regarding Dr. Hajjar's second supplemental opinion. *See* Notice of Filing Documents, filed August 26, 2004. Dr. Hajjar did not provide a second supplemental opinion. Rather, Ms. Bernabe declared that an article, Nascimento-Carvalho, C., *et al.*, Thrombocytopenic Purpura After Hepatitis B Vaccine: Case Report and Review of the Literature, *Ped. Infect. Dis.* 2004; 23, 2, 183, addressed "appropriately" the special master's concerns about Dr. Hajjar's Opinion and Dr. Hajjar's Supplemental Opinion. Status Report, filed August 26, 2004, at 1. Ms. Bernabe added that the article supported "further" Dr. Hajjar's "causation opinions." *Id.*

After reading the article, the special master determined that Dr. Hajjar had "failed completely" to comply with the special master's May 13, 2004 order. *Bernabe v. Secretary of HHS*, No. 03-1494V, Order of the Special Master at 1 (Fed. Cl. Spec. Mstr. September 15, 2004). The special master concluded specifically that the article appeared "to refute absolutely Dr. Hajjar's assertion in his two reports on file in this case." *Id.* The special master elaborated that the article's "authors state clearly that 'risk information' regarding the incidence of ITP following Hepatitis B vaccination 'is still lacking.'" *Id.* citing Nascimento-Carvalho, C., *et al.*, Thrombocytopenic Purpura After Hepatitis B Vaccine: Case Report and Review of the Literature, *Ped. Infect. Dis.* 2004; 23, 2, 184. The special master indicated that "Dr. Hajjar's apparent, significant misstatement of available medical evidence, and Dr. Hajjar's seeming reluctance to confront the apparent, significant misstatement of available medical evidence," affected potentially the special master's ultimate "assessment of Dr. Hajjar's inherent persuasiveness and inherent reliability as an expert witness in this proceeding." *Bernabe v. Secretary of HHS*, No. 03-1494V, Order of the Special Master at 1-2 (Fed. Cl. Spec. Mstr. September 15, 2004). Therefore, the special master commanded Ms. Bernabe to "file a supplemental medical expert's report that conforms with the requirements of the special master's May 13, 2004 order." *Bernabe v. Secretary of HHS*, No. 03-1494V, Order of the Special Master at 2 (Fed. Cl. Spec. Mstr. September 15, 2004).

On October 29, 2004, Ms. Bernabe proffered a second supplemental medical opinion from Dr. Hajjar. *See* Notice of Filing Documents (Dr. Hajjar's Second Supplemental Opinion), filed October 29, 2004. Dr. Hajjar stated that in his previous opinions, he "mistakenly quoted" a medical article that "relied on MMR vaccine and not Hepatitis B vaccine." Dr. Hajjar's Second Supplemental Opinion at 1. Indeed, Dr. Hajjar conceded that he found "no formal authority to confirm" his assertion in his previous opinions. *Id.* Nevertheless, Dr. Hajjar maintained his opinion that Anthony's June 5, 2000 hepatitis B vaccination caused Anthony's "thrombocytopenia." *Id.*

The special master convened a hearing on March 10, 2005. Dr. Hajjar testified. The special master listened carefully to Dr. Hajjar during direct examination, cross-examination, rebuttal and surrebuttal. In addition, the special master questioned intently Dr. Hajjar.

Dr. Hajjar admitted that in his initial opinion in the case, he “misquoted somehow” medical literature that he reviewed. Tr. at 118; *see also* Tr. at 120. In addition, Dr. Hajjar admitted that in his second opinion in the case, he repeated the “error.” Tr. at 119; *see also* Tr. at 120. According to Dr. Hajjar, he must have “copied” incorrectly “pointers on” a “scrap piece of paper” that he used to record his “impression” while reading medical articles before preparing his initial opinion in the case. Tr. at 119-20. And, according to Dr. Hajjar, he must have “relied” on his initial opinion when he drafted his second opinion. Tr. at 120. Dr. Hajjar testified that he did not intend “to mislead the Court.” Tr. at 119; *see also* Tr. at 120. Indeed, Dr. Hajjar described his “mistake” as “very obvious.” Tr. at 119. Dr. Hajjar agreed that his misstatement of available medical evidence was significant. Tr. at 123-24.

Dr. Hajjar indicated that he understood that the special master’s May 13, 2004 order required him to address in writing the basis for his assertion regarding the incidence of ITP following Hepatitis B vaccination in his initial opinion and in his second opinion. Tr. at 122. Dr. Hajjar could not offer “an explanation for” his original failure to respond to the special master’s May 13, 2004 order. Tr. at 123. Dr. Hajjar suggested only that he “was out for about a month overseas.” *Id.*

The special master engages usually in the critical, intellectual analysis of the facts, the medical evidence and the medical testimony under the actual causation standard. *See, e.g., Malloy v. Secretary of HHS*, No. 99-0193V, 2003 WL 22424968 (Fed. Cl. Spec. Mstr. Aug. 6, 2003). However, because the special master considers Dr. Hajjar to be one of the least credible expert witnesses who has appeared before him in his thirteen-year tenure, the special master rejects wholly Dr. Hajjar’s opinion. Thus, the special master does not need to progress to the merits of Ms. Bernabe’s case.

In his initial opinion and in his second opinion, Dr. Hajjar advanced a medical proposition that, given current, available medical evidence, is blatantly wrong. Moreover, it appears that Dr. Hajjar refused to acknowledge readily and candidly his significant misstatement of available medical literature until forced to do so by the special master. *See, e.g., Bernabe v. Secretary of HHS*, No. 03-1494V, Order of the Special Master (Fed. Cl. Spec. Mstr. September 15, 2004). In the best light, Dr. Hajjar is a well-meaning physician who was extremely careless in crafting his medical opinions.<sup>3</sup> In the worst light, Dr. Hajjar is a well-meaning physician who lacks mastery of his subject. Neither scenario instills in the special master any confidence in Dr. Hajjar’s role as an expert witness in this proceeding.

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<sup>3</sup> The record reflects another likely example of Dr. Hajjar’s carelessness. Dr. Hajjar testified that Anthony’s “Coombs test” was “negative” on July 5, 2000. Tr. at 38. Thus, prompted perhaps in part by counsel’s incorrect recitation of Anthony’s clinical course, *see, e.g.,* Tr. at 39-40, Dr. Hajjar testified that Anthony’s hemolytic anemia had resolved by July 5, 2000. *See* Tr. at 40; *see also* Tr. at 38. However, Anthony’s medical records document clearly that Anthony’s “[d]irect Coombs test” was “positive” still on July 5, 2000. Pet. ex. 8 at 1-2.

The special master cannot excuse simply Dr. Hajjar's serious error. Thus, the special master rules that Dr. Hajjar is not a reliable expert. Therefore, the special master concludes that Ms. Bernabe is not entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The clerk of court shall send Ms. Bernabe's copy of this decision to Ms. Bernabe by overnight express delivery.

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John F. Edwards  
Special Master