

**OFFICE OF SPECIAL MASTERS**

(Filed: August 17, 2005)

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MICHAEL DOHERTY,	)	
father and next friend of his son,	)	
DREW DOHERTY,	)	
	)	
Petitioner,	)	
	)	
v.	)	No. 01-0393V
	)	
SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	
_____	)	

**ORDER<sup>1</sup>**

Petitioner, Michael Doherty (Mr. Doherty), as next friend of his son, Drew Doherty (Drew), seeks compensation under the National Vaccine Injury Compensation Program (Program).<sup>2</sup> In an amended petition that he filed on May 28, 2002, Mr. Doherty alleges that Drew suffers juvenile dermatomyositis (JDMS) that is related to the third in a series of three Hepatitis B vaccinations that Drew received on July 10, 1998. Amended Petition (Am. Pet.) at 1. Mr. Doherty identifies the first symptom of Drew’s JDMS as persistent “stomach pain” that began within hours following Drew’s July 10, 1998 Hepatitis B vaccination. Am. Pet. ¶ 4.

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<sup>1</sup> Because this order contains a reasoned explanation for the special master’s action in this case, the special master intends to post this order 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). Therefore, 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” order 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.

The special master convened an informal status conference on August 15, 2005. He discussed petitioner's progress in obtaining an opinion from a new medical expert. *See, e.g., Doherty v. Secretary of HHS*, No. 01-0393V, Order of the Special Master (Fed. Cl. Spec. Mstr. May 11, 2005). In addition, he discussed respondent's continued defense of the case in light of *Althen v. Secretary of HHS*, No. 04-5146, slip op. (Fed. Cir. July 29, 2005).

In *Althen*, the United States Court of Appeals for the Federal Circuit (Federal Circuit) iterated that the actual causation standard requires a petitioner to adduce "preponderant evidence" demonstrating: "(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*, slip op. at 5; *see also id.* at 10 (Under the "court's well-established precedent," a petitioner must "provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes."). According to the Federal Circuit, the "preponderance standard" contemplates specifically "the use of circumstantial evidence" and promotes "the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id.* at 8], citing *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). Indeed, the Federal Circuit declared that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Id.* (emphasis added).

Frederick W. Miller, M.D. (Dr. Miller),<sup>3</sup> posits in his review, INFLAMMATORY MYOPATHIES: POLYMYOSITIS, DERMATOMYOSITIS, AND RELATED CONDITIONS, an "attribution analysis" for cases of "suspected environmentally[-]associated rheumatic disease." Respondent's exhibit (R. ex.) 1 at 16. Dr. Miller advances five factors: biologic plausibility; "an appropriate temporal association with the exposure;" absence of "alternative explanations;" an "improvement in the syndrome if the agent is removed (dechallenge);" and "deterioration if it is clinically appropriate to reexpose the patient to the environmental agent (rechallenge)." *Id.* In the special master's view, aspects of the actual causation standard, as described in the Federal Circuit's decision in *Althen*, are remarkably similar to aspects of Dr. Miller's attribution analysis.

According to Dr. Miller, "most" inflammatory myopathies are likely "autoimmune or immune-mediated diseases." R. ex. 1 at 2. Dr. Miller identifies "[v]accines" as "[p]ossible environmental triggers" for inflammatory myopathies. R. ex. 1 at 16; *see also* Tr. at 64 (There exists

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<sup>3</sup> Dr. Miller is "a rheumatologist and immunologist." Statement of Frederick W. Miller (Miller Affidavit), filed June 25, 2004. As Chief of the Environmental Autoimmunity Group of the Office of Clinical Research, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), Miller Affidavit ¶1, Dr. Miller conducts "laboratory and clinical studies" regarding "the pathogenesis and treatment of autoimmune diseases, generally, and myositis syndromes, specifically." Miller Affidavit ¶2. Dr. Miller is likely "one of the world's experts in myositis." Transcript (Tr.), filed January 27, 2005, at 25-26.

“biologic plausibility for” an “association” between vaccines and JDMS.). In fact, because “[b]iologic plausibility and reports of polymyositis (PM) and dermatomyositis (DM) following immunizations suggest that vaccines may serve as environmental risk factors for the development of myositis in genetically susceptible individuals,” Dr. Miller has designed a government-funded study “[t]o assess possible differences in clinical presentations and autoantibodies between M[yositis]A[fter]V[accinations] and I[diopathic]I[nflammatory]M[yopathies].” R. ex. 7 at 1.

Dr. Miller believes that the “appropriate temporal relationship” between an environmental trigger and the onset of an inflammatory myopathy varies “depending upon the particular exposure.” Tr. at 48. And, Dr. Miller believes that periodic reexposure to an environmental trigger may reduce the time necessary to develop an inflammatory myopathy. *See* Tr. at 50. Dr. Miller cited particularly circumstances involving “an immune-mediated response.” Tr. at 50. Dr. Miller explained that because the body produces “memory cells” following the initial exposure to a “foreign antigen,” the “secondary immune responses” occur “much quicker,” perhaps even “in a matter of hours.” Tr. at 50-51.

Drew “is enrolled” in Dr. Miller’s government-funded study. Miller Affidavit ¶ 6. Dr. Miller included Drew in the government-funded study because Drew met “specific criteria.” Tr. at 64; *see also* Tr. at 65. Dr. Miller elaborated that Drew’s medical history did not reveal “a likely alternative explanation” for Drew’s condition. Tr. at 62; *see also* Tr. at 65.

Thus far, the record appears to contain significant evidence supporting many elements of Mr. Doherty’s actual causation claim. Medical literature--endorsed by Dr. Miller, one of the world’s leading authorities on myositis--confirms the biologic plausibility of a proposition that vaccines can cause JDMS. Dr. Miller, one of the world’s leading authorities on myositis, provides a medically-based, rational explanation for the seemingly short time frame between the administration of Drew’s July 10, 1998 Hepatitis B vaccination and the onset of Drew’s JDMS. Dr. Miller, one of the world’s leading authorities on myositis, indicates that there is not a “likely alternative explanation” for Drew’s JDMS.

The special master recognizes certainly that Congress prohibited special masters from awarding compensation “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a); *but see Sword v. Secretary of HHS*, 44 Fed. Cl. 183 (1999) (affirming special master’s authority to adopt a medical theory that was not advanced by either party). Given his status as a government employee, Dr. Miller cannot offer an opinion regarding the ultimate issue in this case. And, Mr. Doherty is pursuing currently a medical opinion that unites the evidence that has evolved while this case has been pending.<sup>4</sup>

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<sup>4</sup> Mr. Doherty proffered previously an opinion from Daniel H. Cohen, M.D. (Dr. Cohen). However, Dr. Cohen refuses apparently to participate further in any Program cases. Regardless, the special master considers Dr. Cohen’s opinion to be infirm. Although Dr. Cohen is a board-certified rheumatologist, Dr. Cohen has not examined Drew; does not possess apparently *any* substantive (continued...)

Nevertheless, the special master considers this case to be at a critical juncture. The special master determines that respondent's counsel and respondent must review the continued defense of this case in light of *Althen* and the present record. By no later than **September 9, 2005**, respondent shall file a comprehensive memorandum regarding respondent's continued defense of this case in light of *Althen* and the present record.

The special master's secretary shall provide a courtesy copy of this order to the parties by facsimile.

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John F. Edwards  
Special Master

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<sup>4</sup>(...continued)  
experience with JDMS; and did not address the evidence that the special master has discussed in this order.