In the United States Court of Federal Claims

No. 99-591V
(Filed under seal March 22, 2005)
(Reissued, April 8, 2005)[1]

ANN MARIE RYMAN,	*	National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1–300aa-34; hepatitis B vaccination; rheumatoid arthritis; indirect causation; *Stevens* factors; preponderance of evidence.
Petitioner,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald C. Homer, Conway, Homer & Chin-Caplan, Boston, MA, for the petitioner.

Catherine E. Reeves, Senior Trial Counsel, Torts Branch, Civil Division, Department of Justice, with whom were *Peter D. Keisler*, Assistant Attorney General, *Timothy P. Garren*, Director, *John Lodge*, Deputy Director, and *Mark W. Rogers*, Assistant Director, all of Washington, D.C., for the respondent.

OPINION AND ORDER

WOLSKI, Judge.

The Petitioner Ann Marie Ryman ("petitioner" or "Petitioner Ryman") has moved to review the entitlement decision of Chief Special Master ("CSM") Golkiewicz denying her compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 – 300aa-34 (2000) ("Vaccine Act"), and directing that judgment be entered for the Respondent the Secretary of Health and Human Services ("respondent"). The petitioner makes three objections. First, the petitioner objects to the CSM's use of the so-called *Stevens* factors for

[1] This opinion was originally issued under seal on March 22, 2005. Pursuant to Vaccine Rule 18(b), the parties were given fourteen days in which to object to the public disclosure of information contained in the opinion prior to public release, but no party has proposed redactions. Accordingly, the opinion is reissued for publication, unsealed.

establishing causation in "off-table" vaccine injury cases, concluding that the *Stevens* test is contrary to law. Second, the petitioner objects to the CSM's failure to consider the opinions of the petitioner's treating physicians, concluding that such failure was arbitrary and an abuse of discretion. Third, the petitioner objects to the CSM's failure to consider the Vaccine Adverse Events Reporting System reports, concluding that such failure was arbitrary and an abuse of discretion. For the reasons set out below, the Court sustains the CSM's entitlement decision denying compensation.

Background

The petitioner suffers from rheumatoid arthritis ("RA"). She received her first hepatitis B vaccination on August 1, 1995, at a pre-summer camp physical. Pet'r's Ex. 1 (Affidavit of Ann Marie Ryman ("Ryman Decl.") ¶ 1). On December 26, 1995, the petitioner was administered her second hepatitis B vaccine. *Id*. ¶ 5; Pet'r's Ex. 2, at 30. Following the second vaccination, the petitioner went to a rheumatologist, who diagnosed her with "auto immune rheumatoid arthritis" at sixteen years of age. Ryman Decl. ¶ 6.

This case is one of five closely-related vaccine compensation petitions, heard before CSM Golkiewicz, all dealing with the issue of whether hepatitis B vaccine causes RA. Of the other four, judgment was entered against the petitioner without appeal in *Ashley v. HHS*, No. 01-221V (Fed. Cl. Oct. 20, 2003); the CSM's decision denying compensation was affirmed by *Capizzano v. HHS*, 63 Fed. Cl. 227 (2004), and by *Manville v. HHS*, 63 Fed. Cl. 482, 2004 U.S. Claims LEXIS 333 (2004); and in *Analla v. HHS*, No. 99-609V (Fed. Cl. Sept. 13, 2004), the petition was remanded for the sole purpose of documenting the facts. The CSM complied with that order on October 22, 2004.

Discussion

When reviewing a decision of a special master, the Court inquires into whether any of the findings of fact or conclusions of law are arbitrary or capricious,[2] constitute an abuse of discretion, or otherwise are not in accordance with law. 42 U.S.C. § 300aa-12(e)(2). *See Turner v. Sec'y of HHS*, 268 F.3d 1334, 1337 (Fed. Cir. 2001); *Capizzano v. Sec'y of HHS*, 63 Fed. Cl. 227, 230 (2004). If the CSM's findings of fact and conclusions of law are not arbitrary and are in accordance with law, the Court must sustain the entitlement decision. Findings of fact are reviewed on the arbitrary and capricious standard; legal conclusions are reviewed *de novo*; and discretionary rulings are reviewed on the abuse of discretion standard. *See Munn v. Sec'y of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

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[2] The Federal Circuit has noted that, in Vaccine Act litigation, "no uniform definition of [the arbitrary and capricious] standard has emerged." *Hines v. Sec'y of HHS*, 940 F.2d 1518, 1527 (Fed. Cir. 1994). Nevertheless, if "the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Id*. at 1528.

Vaccine Act litigation can be divided into two types of cases: table and off-table. Table cases are those where the complained-of injury is listed in 42 U.S.C. § 300aa-14. In these cases, the petitioner enjoys the presumption of causation, and the respondent must show that the vaccine did not cause the injury. In contrast, off-table cases are those where the complained-of injury is not listed in 42 U.S.C. § 300aa-14. In these cases, the petitioner enjoys no presumption; he or she must establish by a preponderance of the evidence that the vaccine was both a "but-for" cause of the injury and a substantial factor in bringing about the injury. *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). This showing must include a "logical sequence of cause and effect." *Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Objection One: the Stevens *factors*

The petitioner contends that the use of the *Stevens*[3] factors is not in accordance with law because they have the effect of placing a more burdensome standard of causation on petitioners than otherwise is mandated by the statute.[4] The respondent answers that, whatever the merit of the *Stevens* factors, the CSM did not use them in his decision.

The CSM incorporated into his entitlement decision the legal reasoning and conclusions of his decision in the related case of *Capizzano v. HHS*, 2004 U.S. Claims LEXIS 149 (Fed. Cl. Ch. Spec. Mstr. June 8, 2004), *sust'd Capizzano v. HHS*, 63 Fed. Cl. 227 (2004). *See Ryman v. HHS*, No. 99-591V, at *7 (Fed. Cl. Ch. Spec. Mstr. Sept. 24, 2004) (unpublished decision). Therefore, the Court shall first review the relevant portions of the CSM's entitlement decision in *Capizzano* before proceeding to the application of that case's analysis to Petitioner Ryman's case.

Eschewing the somewhat controversial *Stevens* factors, the CSM in *Capizzano* recited the well-known standards for off-table causation in vaccine cases. The CSM explained that the essential standard is that the petitioner must show that it is more likely than not that the vaccine caused the injury. This is usually established by reference to a legitimate medical theory that causally connects the vaccination to the injury. The medical theory must be substantiated by proof of a logical sequence of cause and effect. In sum, the petitioner must show both but-for and substantial factor causation. *Capizzano* at *11-*13. The Court finds nothing exceptionable about the CSM's recitation of the applicable legal standard.

The CSM went on to discuss the *Stevens* factors. At the outset, he stated the clear preference for epidemiological studies to prove causation-in-fact. In the absence of such

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[3] The *Stevens* factors were first published in the CSM's entitlement decision in *Stevens v. Sec'y of HHS*, 2001 U.S. Claims LEXIS 67, *91-*113 (Fed. Cl. Ch. Spec. Mstr. March 30, 2001).

[4] Such was the opinion of the Court in *Althen v. United States*, 58 Fed. Cl. 270, 281-82 (2003).

"golden" and rare evidence, the CSM concluded that causation can be proved circumstantially, with reference to the following five factors: medical plausibility; consensus of the medical community as to biologic plausibility; type-injury; a medically acceptable time-frame for onset; and an absence of other likely factors. *Id*. at *17- *19.

Without leaving a stone unturned, the CSM addressed the Court's strong critique of the *Stevens* factors in *Althen v. HHS*, 58 Fed. Cl. 270 (2003). In *Althen*, the Court held that three of the five *Stevens* factors had the effect of making the petitioner's burden of proof higher than required under the Vaccine Act, and that, accordingly, their use was contrary to law. *Id.* at 283. The Court concluded that petitioners are required to show only: reliable medical records; reputable medical opinion; a logical sequence of cause and effect; and a medical theory linking the vaccine to the onset of the disease. *Id*. at 286. The CSM interpreted the *Althen* standard to require a theoretical possibility of causation, an appropriate temporal relationship and an absence of other causes. *Capizzano* at *26.

Beginning his own causation analysis, the CSM noted that the case law did not contain an accepted definition of "logical sequence of cause and effect." *Id*. at *30. He reviewed the numerous ways in which off-table causation — *i.e.*, causation-in-fact — can be established: epidemiological studies; pathological markers[5]; rechallenge[6]; and case reports. *Id*. at *38-*41. Referencing the case law, the CSM drafted the following test for causation-in-fact: (1) acceptance by the medical community; (2) the petitioner meets the profile of the study or mechanism in (1); and (3) an absence of other causes. *Id*. at *44.

Where the epidemiological evidence does not support causation-in-fact, the CSM reasoned that recovery can still be had by proving causation circumstantially. Such a showing consists of: (1) the existence of a biologic mechanism[7] occurring in the petitioner; (2) appropriate timing; and (3) the absence of other causes. *Id*. at *45-*46.

Turning to the evidence presented at the joint hearing, the CSM determined that it was biologically plausible that hepatitis B vaccine causes RA. He made this finding relying upon the

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[5] These include the identification of any genetic predisposition to a disease, which may then be linked to the hypothesized cause of injury.

[6] "A rechallenge case is one where adverse symptoms are noted after a dose of the vaccine, an additional dose of the vaccine is given, and the symptoms worsen." *Ryman v. HHS*, No. 99-591V, at *4 n.6 (Fed. Cl. Ch. Spec. Mstr. Sept. 24, 2004) (unpublished decision).

[7] A biologic mechanism is a medically plausible process by which a component of a vaccine can cause a particular injury.

Maillefert study,[8] which contained three examples of rechallenge; the conclusion of the Institute of Medicine ("IOM") that rechallenge is strongly probative of causation; and the testimony of the petitioner's expert, Dr. Bell. *Id*. at *56-*59.

Although Petitioner Capizzano established biologic plausibility, the CSM concluded that she failed to prove rechallenge because of inadequacies in the petitioner's expert evidence. The CSM noted a number of difficulties with Dr. Bell's testimony. First, Dr. Bell could not explain why a well-respected RA textbook asserted that the incidence of RA may be decreasing with time. *See Transcript* ("Tr.") (June 11, 2003) at 51. Second, Dr. Bell relied mainly upon case reports in crafting his theory, and case reports are the least reliable type of evidence for establishing vaccine injury causation. *Id*. at 51-52. Third, Dr. Bell could not cite any discussion in the medical literature within the last twelve months mentioning a connection between the vaccine and RA. *Capizzano* at *73-*74. *See* Tr. at 246 (testimony of Dr. Phillips). The respondent's experts, Drs. Phillips and Zweiman, offered testimony discrediting Dr. Bell's theory. *Capizzano* at *74-*76. *See* Tr. at 153-54 (testimony of Dr. Moulton). And the CSM cited other evidence showing that the medical community has yet to recognize a relationship between the hepatitis B vaccine and RA. *See Capizzano* at *79-*80. *See* Tr. at 44.

Addressing the data upon which Dr. Bell relied, the CSM noted that Vaccine Adverse Event Reporting System ("VAERS") evidence is not reliable. Tr. at 51-52, 118-19. These reports can be filed by anyone. Resp.'s Ex. KK, at 191. The information provided is often insufficient to make an assessment. *Id*. at 192. And the reports show a bias toward prevailing concepts of adverse events. *See id.* at 200. *See also Capizzano* at *84-*85. The CSM concluded that the medical community has not generally accepted Dr. Bell's theory. *Capizzano* at *87.

The CSM applied this analysis to Petitioner Ryman's case. *Ryman* at *11-*12. The petitioner offered no epidemiological study. She did not identify any genetic markers. She failed to prove that her expert's proposed biologic mechanism occurred in her. She did not establish that the medical community generally accepts the existence of a causal connection between RA and hepatitis B vaccine. And she failed to prove a logical sequence of cause and effect linking the vaccine to her injury. *Id*. at *12. The CSM also noted that the record supported other causes for her injury. The petitioner's May 1996 medical records indicate that she had chronic low back, knee and ankle pain, and had suffered gymnastics injuries. *Id*. *See* Pet'r's Ex. 2, at 25, 40. In light of this evidence, the CSM determined that the petitioner had failed to prove by a preponderance that the hepatitis B vaccine caused her RA. *See Ryman* at *12.

The Court finds no legal error in the CSM's analysis or its application to the petitioner's case. Contrary to the petitioner's contention, the CSM did not apply the *Stevens* factors, although he did reference them in *Capizzano* and *Ryman*. *See Capizzano*, 63 Fed. Cl. at 230; *Ryman* at *3. The CSM recited the proper standard in *Capizzano*. 2004 U.S. Claims LEXIS 149, *11-*14.

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[8] J.F. Maillerfert, J. Sibilia, *et al*., *Rheumatic disorders developed after hepatitis B vaccination*, 38 RHEUMATOLOGY 978 (1999), Resp.'s Ex. L.

And he applied that standard to this case. Far from limiting his analysis to a pre-defined framework, the CSM searched through the record trying to find any basis for causation. He found nothing that would support a logical sequence of cause and effect. Neither can this Court.[9]

The CSM's analysis also is consistent with the standards for expert testimony enunciated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In *Daubert*, the Supreme Court assigned the trial judge a "gate-keeping" function to ensure the reliability of evidence presented to the trier-of-fact. The CSM, of course, performs this same function when he determines whether a particular petitioner's expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon. *See* Vaccine Rule 8(c) ("The special master will consider all *relevant, reliable* evidence, governed by principles of fundamental fairness to both parties") (emphasis added); *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (special masters guided by *Daubert*).

Daubert sets forth several factors by which the admissibility of expert testimony is to be adjudged: (1) whether a theory or technique can or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential rate of error and whether standards exist for controlling that risk of error; and (4) whether the theory or technique is generally accepted in the relevant scholarly or professional community. *See Daubert*, 509 U.S. at 592-95; *Terran*, 195 F.3d at 1316 n.2. The flexible standards set forth in the *Stevens* test essentially encapsulate the important considerations that the *Daubert* factors impose upon "gate-keepers." The *Stevens* factors concerning biologic plausibility and confirmation by medical literature are at bottom reformulations of all the *Daubert* factors made applicable to vaccine cases. The *Stevens* factors concerning proof of injury and acceptable temporal relationship are means by which the CSM can determine if the legitimate medical mechanism proposed by the petitioner can likely be applied to the petitioner's particular facts. These considerations go beyond *Daubert* in that they pertain to the responsibilities of the trier-of-fact; but in vaccine cases, not only is the CSM a gate-keeper, he is also a trier-of-fact and therefore may properly consider the credibility and applicability of medical theories. The final *Stevens* factor — elimination of other causes — is an element of the petitioner's causation analysis that stands apart from *Daubert* but must perforce be conducted by the CSM. *See Munn*, 970 F.2d at 865; *Pafford v. Sec'y of HHS*, 2005 U.S. Claims LEXIS 31, *34-*35 (2005).

Considering all the medical evidence before him, the CSM diligently applied the "logical sequence" test required by precedent. His analysis was no doubt influenced by the *Stevens* factors, but it was not dictated by them. Moreover, the Court can find no error in the CSM's

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[9] The petitioner suggests that this Court follow the causation standard set forth in *Golub v. HHS*, 243 F.3d 561 (Fed. Cir. 2003) (table). This is an unpublished opinion, which cannot be cited or accorded precedential weight before the Federal Circuit. *See* Rule 47.6(b) of the Rules of the United States Court of Appeals for the Federal Circuit. Accordingly, this Court shall disregard *Golub* and continue to adhere to the existing, binding precedent of the Federal Circuit.

using his considerable experience in vaccine cases to formulate a framework by which he can analyze the evidence presented, and, at the same time, give parties fair notice of how they should structure their cases. By organizing the analytical criteria that have been developed over the course of many years' worth of fact-finding, the CSM has made more articulate — and, hence, transparent — the otherwise tacit process of factual determination. In this endeavor the CSM should be lauded. The record supports the CSM's determination that the petitioner has not established the existence of a plausible biologic mechanism occurring in her. Tr. at 40, 290; Pet'r's Ex. 2, at 27. Similarly justified was the CSM's discounting of Dr. Schned's testimony purportedly supporting rechallenge. *Compare* Pet'r's Ex. 2, at 14 *with* Pet'r's Ex. 2, at 28. The CSM's rejection of Dr. Bell's theory, because insufficiently corroborated by independent peer review, was in accordance with law. The Court agrees with the analysis set forth in *Manville*, affirming the CSM's entitlement decision and discussing the deference the special masters enjoy in fact-finding:

> With this wide berth charted for his analysis, the chief special master did not act arbitrarily and capriciously when reviewing the facts of petitioner's case. The [deferential standard] is illustrative of the medical evidence available to the chief special master, and his acknowledgment of it and discussion of its probative value are sufficient to pass muster under the arbitrary and capricious standard.

Id. at *41-*42. Accordingly, the Court denies the petitioner's first objection.

Objection Two: failure to consider opinions of treating physicians

The petitioner objects to the CSM's decision not to credit Dr. Schned's subjective medical history. The CSM found several difficulties with Dr. Schned's account. First, Dr. Schned reported that the petitioner received her two vaccinations in the Spring or Summer of 1995, Pet'r's Ex. 2, at 14, when in fact she received them in August and December of 1995. Ryman Decl. ¶¶ 1, 5. Second, Dr. Schned reported that the petitioner completed the vaccination series prior to her canoe trip, Pet'r's Ex. 2, at 14, when in fact she received only the first vaccination prior to summer camp. Ryman Decl. ¶ 1. Third, Dr. Schned implied that the petitioner was diagnosed with "trigger finger" shortly after the canoe trip, Pet'r's Ex. 2, at 14, when in fact she was not diagnosed until December, 1995. *Ryman* at *9; Pet'r's Ex. 2, at 28. The CSM was also concerned that Dr. Schned's account was written one year after the second vaccination. The CSM conceded that Dr. Schned's account of the onset of the petitioner's "trigger finger" could support a finding of rechallenge, but the estimated time-frame — four or five months — could place onset either before or after vaccination. *Id*. at *9-*10. The CSM concluded that Dr. Schned's account was not probative of rechallenge.

The Court finds no error in the CSM's analysis or in his weighing of evidence. As noted in the entitlement decision, the case law expresses a preference for contemporary medical history, not subjective recounting. *See Cucuras v. Sec'y of HHS*, 993 F.2d 1525, 1526-27 (Fed. Cir. 1993). And where the medical evidence of causation is in dispute, a high level of deference is

due the CSM's fact-finding. *See Hodges v. HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993). The CSM was also within his discretion to discount the petitioner's own affidavit. In this affidavit the CSM found a number of difficulties. First, the petitioner asserted that she had visited a hand specialist shortly after her first hepatitis B vaccination. Ryman Decl. ¶ 4. But the contemporary medical records indicate that the petitioner did not see a hand specialist until December, 1995, after her second vaccination. *See Ryman* at *10; Pet'r's Ex. 2, at 14. This conflict is material because a showing of rechallenge requires that there be a worsening of symptoms following the second exposure. If the complained-of symptoms were not documented until after the second vaccination, no rechallenge can be shown. The CSM also found a conflict in the affidavit where the petitioner stated that she had been taking large amounts of ibuprofen following the first vaccination to reduce her joint pain, and her desire to conceal her symptoms from her parents so as not to miss out on certain drama roles at school. Ryman Decl. ¶ 5. But in the same affidavit, the petitioner stated that she had had difficulty performing routine tasks following the first vaccination. *Id*. She also related to Dr. Schned that her father had suspected a problem when she told him it hurt her wrist to turn the ignition in her car. *Ryman* at *10-*11; Pet'r's Ex. 2, at 14. The CSM could not reconcile the petitioner's desire and apparent success to conceal her pain with her allegations that she could not perform with ease basic functions like brushing her hair and teeth. The CSM was also troubled that the petitioner had failed to present any witness testimony attempting to reconcile her affidavit with the contemporary medical records. *Ryman* at *11.

While the Court might have weighed the evidence differently, or perhaps not given as much consideration to the inconsistencies in the petitioner's affidavit as did the CSM, this is entirely beside the point. In fact-finding, the special masters receive deference from the Court unless they have acted arbitrarily or capriciously. The CSM's discounting of both the petitioner's affidavit and Dr. Schned's subjective medical history was neither arbitrary nor capricious.

The CSM's discounting of Dr. Bell's theories also was perfectly proper given that, by his own admission, Dr. Bell's biologic mechanism theory depended entirely upon the petitioner's affidavit. *See Ryman* at *11; Tr. at 290. Dr. Bell implied that proof of RA rechallenge for hepatitis B vaccinations required that symptoms appear within thirty days of the second exposure. *See Ryman* at *8; Tr. at 40. The petitioner sought medical help for joint pain in April, 1996, three months after the second vaccination. *Ryman* at *8; Pet'r's Ex.2, at 27. Hence, it is clear from the foregoing that the CSM did not impose upon the petitioner some insurmountable burden to establish causation. He abided by the "logical sequence" test, but found that the petitioner's evidence could not substantiate her expert's theories. The petitioner's second objection concerns at heart the deference owed to the CSM's fact-finding. The CSM explained in his entitlement decision that:

> [w]hat may appear to be unreasonable nitpicking of petitioner's affidavit is in reality the critical determination of the substance of petitioner's case. The absence of corroborating notations in the medical records, the several contradictory documents regarding the timing of events, and the absence of any

> explanatory testimony leads the undersigned to the firm and inescapable conclusion that the contemporaneous medical records are to be relied upon for the facts of this case. . . It must follow, therefore, that petitioner's affidavit is found to be inherently unreliable. [¶] With these findings, because the undersigned cannot rely on petitioner's affidavit, [her] case of rechallenge must fail.

Id. at *11. As the *Capizzano* Court stated in affirming the CSM's entitlement decision, "special masters have wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence." 63 Fed. Cl. at 231 (citing *Whitecotton v. HHS*, 81 F.3d 1099, 1108 (Fed. Cir. 1996); *Burns v. HHS*, 3 F.3d 415, 416-17 (Fed. Cir. 1993); *Munn v. HHS,* 970 F.2d at 871)). In the CSM's weighing of Dr. Bell's theories, Dr. Schned's medical history, and the petitioner's affidavit, the Court finds no error. The petitioner's second objection is denied.

Objection Three: failure to consider VAERS reports

The petitioner objects to the CSM's decision not to accord substantial weight to the VAERS reports, which allegedly establish a causal link between hepatitis B vaccine and RA. *See Capizzano* at *84-*86. As was noted above, the CSM found several difficulties with the VAERS reports. First, the reports can be filed by anyone. Resp.'s Ex. KK, at 191. Second, the quantity and quality of information obtained in the reports is often insufficient to make an informed decision as to whether a causal link exists between the vaccination and the injury. *See id*. at 192. Third, the reports may be biased towards pre-existing notions of adverse events. *Id*. at 200. Fourth, the respondent's expert Dr. Moulton, a biostatistician, testified that VAERS reports "offer very little information regarding causality." *Capizzano* at *85; Tr. at 119.

The CSM did not entirely discount the VAERS reports, but he did state that, despite the eleven months given Petitioner Capizzano (and Petitioner Ryman) to supplement the record, no additional evidence was presented to show a causal link. This failure to amplify the record was especially noteworthy to the CSM given that the number of hepatitis B vaccinations is increasing. *Capizzano* at *85. He reasoned, with good cause, that one ought to expect the number of incidents of RA following hepatitis B vaccination to increase if the number of vaccinations is also increasing. The petitioner's VAERs objection was also raised before the *Manville* and *Capizzano* Courts, and both determined that the CSM's discounting of the reports was well within his discretion. *See Manville* at *43-*44; *Capizzano*, 63 Fed. Cl. at 231. This Court is in agreement: the CSM did not act arbitrarily or capriciously in refusing to accord substantial weight to the VAERS reports. The petitioner's third objection is denied.

Conclusion

Having reviewed the record and considered the petition's objections, the Court finds no error in the CSM's entitlement decision. The CSM applied the proper legal standard for determining causation in off-table cases. The CSM acted within his discretion in discounting the evidentiary weight of the petitioner's affidavit, Dr. Schned's medical history, and the VAERS

reports. The CSM also properly declined to follow Dr. Bell's theories, given the latter's express reliance on the petitioner's affidavit.

Accordingly, the entitlement decision of the CSM is **SUSTAINED**. The petition for review is **DISMISSED** with prejudice. The Clerk of Court is directed to enter judgment for the respondent.

IT IS SO ORDERED.

VICTOR J. WOLSKI
Judge