IN THE UNITED STATES COURT OF FEDERAL CLAIMS

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OFFICE OF SPECIAL MASTERS

ROSE CAPIZZANO, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	No. 00-759V Chief Special Master GARY GOLKIEWICZ

PETITIONER'S MEMORANDUM IN SUPPORT OF MOTION FOR REVIEW

I. INTRODUCTION

On June 8, 2004, the Chief Special Master dismissed the petition of the petitioner in *Capizzano v. Sec'y of HHS*, No. 00-759V (Dec. Spec. Mstr. June 8, 2004)(hereafter "Dec. __.") In so doing, the petitioner respectfully submits, the Chief Special Master made findings that are arbitrary, constitute an abuse of discretion, and are "not in accordance with law." 42 U.S.C. §300aa-12(e)(2)(B). For this reason, the petitioner respectfully requests the Court to so find and to remand the petition to the Chief Special Master to assess appropriate compensation.

II. FACTS

The facts are not in dispute. Dec. 2. Rose Capizzano ("Rose") was born on June 18, 1966. She was in good health until 31 years of age. On May 3, 1998, Rose received her 2nd hepatitis B vaccine at her place of employment, Westerly Hospital in Westerly, RI. Within hours of receiving the vaccine, Rose developed a rash on her abdomen. A nurse told her

to take Benadryl. By the next morning, the rash had spread to Rose's arms and her eyelid was swollen. The record notes, "Diagnostic Impression: Possible allergic reaction to Hep B vaccine. . . . advised not to have 3rd dose." Pet. Ex. 1, p. 7. On May 5, 1998, the record states: "This am awoke w/fever, headache post, stiff neck. . .joints and muscles achy tender. Has confluent hives across abd, arms, neck. . . . Neck stiff as are most joints. . . . Severe reaction to Hepatitis Vaccination. Serum Sickness." Pet. Ex. 1, p. 9. Her symptoms continued. On May 6, 1998, she had arm and neck pain, was unable to lift her left arm, her "shoulder c/o elbow-joints swollen. "Serum Sickness/Allergic Reaction 2° to Hepatitis Vaccination." Pet Ex. 1, p. 11.

When Rose's symptoms did not improve after several months, she sought an evaluation by a rheumatologist, Dr. Scott Toder. Pet. Ex. 4, p. 1. On October 1, 1998, Dr. Toder noted: "5/98 Hep B vaccine. . .24 hr later- rash-itchy- Benedryl. . .neck stiff. . . . felt 2° to injection. 48 hr. jt stiff & pain, rash." Pet. Ex. 4, p. 5. Dr. Toder noted his impression on 10/06/98, "Mild periarticular osteoporosis which may be an early finding of erosive type arthritis." Pet. Ex. 4, p. 3. On December 10, 1998, Rose's rheumatoid factor screen was "Present At A Level Generally Associated With Rheumatoid Arthritis." Pet. Ex. 6, p. 14. On February 12, 1999, she was seen by

another rheumatologist, Dr. Peter Himmel, who noted Rose's serum sickness and arthritis were caused by her hepatitis B vaccine. He prescribed gold treatments. Pet. Ex. 6, p. 9. On April 5, 1999, Rose complained of swelling in her wrist. *Id.* at 10. On April 27, 1999, Dr. Himmel noted swelling in Rose's hands/wrists, knees, and ankles. It was "painful to walk and use hands. . . increased swelling in hands. *Id.* at 11.

On June 14, 1999, at an "Independent Medical Examination," Rose was seen by a rheumatologist, Dr. Virginia Parker. In Dr. Parker's opinion, Rose has " a mild inflammatory arthritis. . . compatible with early rheumatoid arthritis." In this regard, Dr. Parker noted, Rose "had no arthritis symptoms or disabilities prior to her hepatitis vaccination. This problem does seem related to the vaccination." In this regard, she observed, "Vaccination has been associated with the onset of an acute arthritis." Pet. Ex. 7, p. 3. On July 26, 1999, Rose was seen by Dr. Toma, another rheumatologist, who noted Rose's "history of joint pain and swelling which started after she had hepatitis vaccine in May [1998]. . .her joint pain and swelling continues with her and she started having stiffness in the morning." Pet Ex. 5, p. 1. On August 11, 1999, Dr. Toma saw Rose for a "flare up" of her rheumatoid arthritis. *Id.* at 3. On June 22, 2000, Rose was seen by Dr. Edmund West. At that time, Rose continued "to have pain involving specifically most

severely her fingers, also her ankles, wrists, and most recently her hips." Pet. Ex. 12, p. 6. In Dr. West's opinion, Rose had "Inflammatory arthritis post vaccination." *Id.* at 8. Since that time, Rose has been treated for joint pain. On March 18, 2003, Dr. Parker wrote, "Diagnosis: Rheumatoid Arthritis . . .Medications: Methotrexate 12.5 mg a wk, Vioxx 25 mg a day, Arava 10 mg a day and folic acid." Pet. Ex. 25, pp. 2-3.

III. THE HEARING

A. Can hepatitis B vaccine cause RA?

(i) Dr. Bell

At the hearing, Dr. David Bell testified on behalf of Rose. Transcript of Proceedings of Hearing in Washington, DC on June 11 and June 12, 2003.[1] A rheumatologist, Dr. Bell has treated patients with arthritis since 1972 and his work in immunology has recently focused on RA.[2] Tr1. 11. Dr. Bell testified it is known that wild hepatitis B virus can cause RA. Tr1. 94. In Dr. Bell's opinion, it is medically plausible that hepatitis B vaccine can also cause RA, (Tr1. 12, 94) and it is more likely than not that hepatitis B vaccine can cause RA. *Id.* at 14. The basis of Dr. Bell's opinion, he stated, is "our own

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[1] All references to the Transcript from June 11, 2003 will be referred to as "Tr1. __" and references to the Transcript from June 12, 2003 will be referred to as "Tr2. __". Please note that Transcript 1 and Transcript 2 contain repetitive page numbering beginning on page 252 through 276.

[2] Dr. Bell described RA as "a chronic, inflammatory form of joint disease." Tr1. 14.

observations. . .published in the literature and the reports of others as well which support this relationship." Tr1. 14. RA, Dr. Bell explained, affects adults, but is "more common in females before the age of 50." Tr1. 15. While he does not know the precise cause of RA, Dr. Bell testified that "a prevalent theory is it's triggered by some agent, perhaps, an environment agent. . .in a genetically susceptible host."[3] Id. The disease, he stated, persists and can lead to permanent injury. Id. Describing a likely biological mechanism by which hepatitis B vaccine can cause RA,[4] Dr. Bell testified that the disease process may be started by an "arthritogenic trigger," such as a hepatitis B vaccine, which may bind to "MHC Class II molecules" present on antigen presenting cells. Tr1. 17. This occurs because the MHC Class II molecules and the hepatitis B vaccine have a "shared epitope." Tr1. 106. Subsequently, the activated T-cell engages the "resulting peptide MHC complex." The resulting T-cells can be either CD4 TH1 cells or CD4 TH2 cells. The CD4 TH1 cell, Dr. Bell testified, "is the one which is currently felt to mediate inflammation of the types seen in rheumatoid arthritis." Tr1. 17. "[T]he purpose of T-cells" Dr.

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[3] To illustrate genetic susceptibility, Dr. Bell stated that RA occurs "in families" and is more likely in "identical twins than non-identical twins." Tr1. 16.

[4] *See*, slides used by Dr. Bell to illustrate his opinions at Petitioner's Exhibit 24. ("Pet. Ex. __").

Bell stated, "is to participate in the immune response." Tr1. 20. However, once activated, a T-cell "then has the potential [of]. . .producing an inflammatory response." Tr1. 20. In sum, he said, "the hepatitis B vaccine contains protein constituents or peptides that should bind to the MHC Class II molecules on antigen-presenting cells in. . .RA patients and through binding to the T-cell receptor activate these T-cells and this could then trigger a cascade of events. . .leading to inflammation and arthritis in the joint." Tr1. 33.

This theory of a mechanism by which hepatitis B vaccine can cause RA, Dr. Bell testified, is based upon fundamental principles of immunology and science (Tr1. 25) and is accepted by the medical community. Tr1. 26-27.

If a hepatitis B vaccine were to cause RA, Br. Bell stated, symptoms would likely occur "within a week" of the last dose of the vaccine (Tr1. 25-26) and, at the outset, "four to five weeks afterwards." Tr1. 26. Dr. Bell believes the medical community accepts this time frame. Id.[5]

Dr. Bell is aware of peer-reviewed literature reporting that hepatitis B vaccine is associated with RA. Tr1. 29. He

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[5] In support of his opinion concerning the temporal relationship between the hepatitis B vaccine and RA, Dr. Bell cited the *Pope* article, Pet. Ex. 16, Tab C in *Analla v. Secretary of HHS;* No. 99-609V. To avoid confusion, all references to literature in this memorandum will include exhibit numbers in both *Capizzano* and *Analla v. Secretary of HHS*, No. 99-609V. Thus, the *Pope* article in *Analla* is Pet. Ex. 16, Tab C, in *Capizzano*, Pet. Ex. 17, Tab C. Respondent's exhibits are the same in both *Analla* and *Capizzano*.

knows that the medical and scientific community has seen an association between this vaccine and RA. *Id.* To his knowledge, the scientific community is aware of such an association (Tr1. 29-30) and has been reporting such an association. Tr1. 30. In this regard, he testified, the VAERS[6] database demonstrates "statistically significant" increased incidents of chronic arthritis following receipt of a hepatitis B vaccine.[7] Tr1. 32. Animal studies also support a causal relationship between hepatitis B vaccine and RA. Id; Pet. Ex. 22, pp. 5-7). To test the hypothesis, Dr. Bell used mice "genetically engineered" to "express the human MCH Class II molecules . . .commonly present in rheumatoid arthritis patients." Tr1. 33. Once immunized with hepatitis B vaccine, the research revealed, the "binding score" of these genetically engineered mice was "higher than the binding score of some peptides known to induce arthritis in mice. . . . For example, collagen II." Tr1. 34-35. In other words, he testified, "the hepatitis B vaccine contains structural regions that are able to induce an immune response

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[6] "VAERS" is the Vaccine Adverse Event Reporting System, a database maintained by the Centers for Disease Control (CDC). Since, 1990, physicians have been urged to forego submitting individual case reports to medical journals and instead to report suspected vaccine reactions directly to VAERS. *See*, VAERS web site at http://www.fda.gov/cber/vaers/what.htm and Fenichel, GM., *Assessment: Neurologic risk of immunization.* NEUROLOGY 1999; 52:1546-1552.

[7] Dr. Bell gleaned his VAERS data from an article by Geier and Geier entitled "*A One Year Follow Up of Chronic Arthritis Following Rubella and Hepatitis B Vaccination Based Upon Analysis of VAERS Database.*" CLINICAL AND EXPERIMENTAL RHEUMATOLOGY 20:767-771, 2002. *See*, Pet. Ex. 24, p. 4. The report did not distinguish between arthritis and RA. Tr2. 31-32.

that could potentially trigger rheumatoid arthritis inflammation." Tr1. 36.[8]

In Dr. Bell's view, 18 anecdotal reports of RA[9] also support an association between hepatitis B vaccine and RA. Tr1. 39; Pet. Ex. 24, p. 1. *See*, Pet. Ex. 16, Tabs B and D; Respondent's Exhibit L ("Resp. Ex. __, p. __")(6 patients with RA after hepatitis B vaccine, 3 of whom had worsening after a further vaccine injection (Tr1. 44-45); These are called re-challenge cases (Tr1. 45); *See also*, Resp. Exs. N and O; Tr1. 45).

Next, Dr. Bell cited his journal article as support for the proposition that hepatitis B vaccine caused RA. *Analla* Pet. Ex. 16, Tab C (*Capizzano*, Pet. Ex. 17, Tab C), Janet Pope, *et al.*, The Development of Rheumatoid Arthritis After Recombinant Hepatitis B Vaccination, J. RHEUMATOL. 1998, at 1687-1693. This publication observed 11 patients with RA after a hepatitis B vaccine. Tr1. 50. The symptoms "occurred within 10 to 21 days after the last vaccine dosage." Tr1. 50. None of the 11 cases had "other known risk factors," such as trauma, infection, family history, or other exposures. Tr1. 50. Nine of the

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[8] The Institute of Medicine uses animal studies, case reports, and symptoms from the wild virus to determine biologic plausibility; Stratton, KR, Johnson Howe, C, Johnston, RB, *Adverse Events Associated with Childhood Vaccines Other Than Pertussis and Rubella - Summary of a Report from the Institute of Medicine.* JAMA 1994 May: 25; 271(20): 1602-5.

[9] While insufficient data is provided to determine if the remaining (*i.e.*, beyond 18) cases of arthritis reported after hepatitis B vaccine are RA, "there is polyarthritis reported." Tr1. 46.

eleven cases had a "genetic marker" (*i.e.*, the MHC Class II shared epitope) for RA. Id. In these circumstances, Dr. Bell believes his study demonstrates a causal relationship between hepatitis B vaccine and RA. Tr1. 52.

Finally, Dr. Bell testified that, in his scientific community, there exist "ways to determine" whether there is a causal relationship between an environmental exposure, such as a vaccine, and an illness, such as RA. Tr1. 53. These "ways" consist of "primary and secondary elements." Id. The five (5) "primary" elements are: (1) Temporal association between the exposure and the symptoms; (2) Lack of a likely alternate explanation; (3) Dechallenge;[10] (4) Rechallenge;[11] 5) and Biologic plausibility[12]. The "secondary" elements consist of (6) Analogy or case reports;[13] (7)Dose responsiveness;[14] (8) and

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[10] Did the disorder disappear when the exposure was removed? *Analla*, Pet. Ex. 24, p. 17; *Capizzano*, Pet. Ex. 26, p. 17.

[11] Did the disorder reappear when the exposure was reintroduced? *Analla*, Pet. Ex. 24, p. 17; *Capizzano*, Pet. Ex. 26, p. 17.

[12] Is the disorder plausible based upon *in vivo* and/or *in vitro* effects of the exposure? *Analla*, Pet. Ex. 24, p. 17; *Capizzano*, Pet. Ex. 26, p. 17.

[13] Are there published or unpublished reports of a similar disorder after a similar exposure? *Analla*, Pet. Ex. 24, p. 17; *Capizzano* Pet. Ex. 26, p. 17.

[14] Is the extent or dose of the exposure related to the severity of the disorder? *Analla*, Pet. Ex. 24, p. 17; *Capizzano*, Pet. Ex. 26, p. 17.

Specificity.[15] *Analla*, Pet. Ex. 24, p. 17; *Capizzano*, Pet. Ex. 26, p. 17. To publish findings of a causal relationship, "at least 4 of the 8 elements should be present and at least 3 of the 5 primary elements should exist. The three primary elements must include temporal relationship and lack of a likely alternative cause." *Analla*, Pet. Ex. 24, p. 17; *Capizzano*, Pet. Ex. 26, p. 17.[16]

In support of the proposition that it is medically plausible that hepatitis B vaccine can cause RA, the petitioner has submitted: Duffy, J., *et al.*, *Polyarthritis, Polyarteritis, and Hepatitis B*, Vol. 55 MED. J. No. 1 JAN. 1976, at 19-37. *Analla*, Pet. Ex. 16, Tab A; *Capizzano*, Pet. Ex. 17, Tab A (offered as evidence that RA can be provoked by the wild hepatitis B virus); Gross, K., Combe, C., Kruger, K. and Schattenkirchner, M., *Arthritis after Hepatitis B Vaccination*, Vol. 24 SCAND. J. RHEUMATOL., 1995, at 50-52. *Analla*, Pet. Ex. 16, Tab B; *Capizzano*, Pet, Ex. 17, Tab B (offered for the proposition that cases of hepatitis B vaccine-induced arthritis

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[15] Are the defining symptoms of the disorder the same as those seen in previous cases after exposure to the same environmental agent? *Analla*, Pet. Ex. 24, p. 17; *Capizzano*, Pet. Ex. 26, p. 17.

[16] *Analla*, Pet. Ex. 20; *Capizzano*, Pet. Ex. 23. Miller, *et al.*, *Approaches for Identifying and Defining Environmentally Associated Rheumatic Disorders*, ARTHRITIS & RHEUMATISM, Vol. 43, No. 2; February 2000, pp. 243-249, was submitted to demonstrate how the scientific community assesses individual patients whose rheumatic disorders are suspected to be due to environmental exposures. As the Court undoubtedly appreciates, the authors' reasoned approach to identify likely causes of rheumatic disorders is strikingly similar to the *Stevens* analysis, *infra*.

have been reported in medical journals); Pope, J. *et al.*, *The Development of Rheumatoid Arthritis After Recombinant Hepatitis B Vaccination*, J. RHEUMATOL., 1998, at 1687-1693. *Analla*, Pet. Ex. 16, Tab C; *Capizzano*, Pet. Ex. 17, Tab C (offered as evidence that cases of hepatitis B vaccine-induced arthritis have been reported in medical journals and recombinant hepatitis B vaccine may trigger the development of RA in MHC class II genetically susceptible individuals); Vautier, G. and Carty, J.E., *Letters to the Editor: Acute Sero-positive Rheumatoid Arthritis Occurring after Hepatitis Vaccination*, BRIT. J. RHEUMATOL., 1994, at 991. *Analla*, Pet. Ex. 16, Tab D; *Capizzano*, Pet. Ex. 17, Tab D (offered as evidence of individual case report of RA after recombinant hepatitis B vaccination); Carmeli, Y., Oren, R., *Letters to the Editor, Hepatitis B Vaccine Side-Effect*, Vol. 341 LANCET, Jan. 1993, at 250-1. *Analla*, Pet. Ex. 16, Tab E; *Capizzano*, Pet. Ex. 17, Tab E (offered to show Individual case reports of polyarthritis after recombinant hepatitis B vaccination).

Dr. Bell cited the respondent's literature as additional evidence of the medical plausibility of hepatitis B vaccine induced RA. *See*, for example: Gross, K. *et al.*, *Arthritis After Hepatitis B Vaccination*, SCAND. J RHEUMATOL., 1995:24:50-2. Resp. Ex. K (offered to show case report of RA triggered by hepatitis B vaccine); Maillefert, J.F., *et al.*, *Rheumatic*

Disorders Developed After Hepatitis B Vaccination, RHEUMATOLOGY, 1999: 38:978-983. Resp. Ex. L (study determines hepatitis B vaccine might trigger RA); Sibilia, J. *et al. Vaccination and Rheumatoid Arthritis*, RHEUM DIS. 2002:61:575-576. Resp. Ex. M (vaccinations may exacerbate RA).

(ii) Dr. Lawrence Moulton

Dr. Moulton, a biostatistician, testified for the respondent. The *Sturkenboom* study (Resp. Ex. R), in his view, demonstrates that there is not "greater than a 1.4 relative risk associated with developing RA" after a hepatitis B vaccine. Tr1. 125-126. In his experience, "the court system has generally looked for a relative risk of two or greater. . ." Tr1. 125-126. In the *Sturkenboom* study, while the relative risk is "somewhat elevated" (Tr1. 137), it is still "quite a bit from the 2.0." Tr1. 137.

In Dr. Moulton's view, the VAERS reporting system is "a very passive reporting system" which "has so many vagaries in the data system that it's pretty hard to believe. . . . " Tr1., 130-131. However, Dr. Moulton conceded that the CDC has used VAERS data to draw conclusions between the safety of acellular pertussis vaccine versus whole-cell pertussis vaccine. Tr1. 148-149. Dr. Moulton stated that he is "not sure" whether he has used VAERS data "in published articles" to demonstrate that a vaccine caused an injury (Tr1. 146, 148), but conceded that

the VAERS data has been used to demonstrate positive re-challenge. Tr1. 150. [17]

Finally, Dr. Moulton testified that the medical community has agreed that "causative mechanisms" can be established without the use of epidemiology. Tr1. 172. In this regard, Sir Bradford's criteria, described in *Analla*, Pet. Ex. 20; *Capizzano*, Pet. Ex. 23; Tr1. 167, "have been used in epidemiology for decades" to establish relationships. Tr1. 167.

(iii) Dr. Burton Zweiman

Dr. Zweiman, an immunologist, testified that hepatitis B vaccine does not cause RA. Tr1. 176. He believes Dr. Bell's theory that T-cells, stimulated by hepatitis B vaccine, damages the synovium[18] is not supported by the evidence at the present time. Tr1. 188. However, he did concede that T-cells could damage the synovium in several ways, either directly or indirectly. Tr1. 199.

Dr. Zweiman also discounted the evidentiary value of the ability of the wild hepatitis b virus to cause RA. In this regard, he stated, "one cannot extrapolate any findings from the hepatitis virus infection" to the hepatitis B vaccine. Tr1.

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[17] Dr. Moulton also conceded that the causal relationship between rotavirus vaccine and intussusception was "first identified through a routine examination of VAERS reports. . . ." Tr1. 130-131.

[18] The synovial membrane is the connective tissue membrane that lines the cavity of a synovial joint and produces the synovial fluid; it lines all internal surfaces of the cavity except for the articular cartilage of the bones. *Stedman's Electronic Medical Dictionary*, v.5.0, 2000.

206. However, he agrees with the conclusions of the IOM that "it's possible." Tr1. 208.

In the absence of epidemiology, a re-challenge, such as with "tetanus toxoid [and] GBS" might be "convincing" to Dr. Zweiman. Tr1. 222. However, in general, epidemiology would be essential to prove causation to his "level of reasonable certainty." Tr1. 225.

(iv) Dr. Paul Phillips

Dr. Phillips, a rheumatologist, also testified that hepatitis B vaccine does not cause RA. In this regard, he stated, there are "very few cases" and no cases "since 1999." Tr1. 234-235. He agreed with the statement in Resp. Ex. X, p. 2, "when case reports link two uncommon occurrences which would occur together rarely by chance, then the case series or report is likely to identify a true association." Tr1. 253-254. In this case, he believes the case reports in the literature "are suggestive that [hepatitis B vaccine] might cause" RA, "but that's strictly might, not does." Tr1. 254. He also stated that "at present" the community is not seeing and reporting an association between hepatitis B vaccine and RA. Tr1. 255. In this regard, he stated, "there aren't any new reports." Id. Finally, as a clinician to establish that a hepatitis B vaccine caused RA, Dr. Phillips would need to see a "direct temporal

relationship,"[19] a lack of prior joint pain, no antecedent events, the number and which joints were affected, no family history of RA, no active arthritis, and no Reiter's Syndrome. Tr1. 258.

B. Did the hepatitis B vaccine cause Rose's RA?

At the hearing, Dr. Bell testified that Rose has RA (Tr2. 319; Pet. Ex. 7, pp. 1-3; Pet. Ex. 5, pp. 1-2, 8. In his opinion, her RA was caused by her hepatitis B vaccine. Tr2. 319. In this regard, Dr, Bell noted that Rose had no pre-existing joint problems (Tr2. 328) and no symptoms of RA prior to her vaccine. Tr2. 334. He also noted that Rose had no apparent "trigger" other than the vaccine to explain the onset of her symptoms. Tr2. 338.

Testifying for the respondent, Dr. Phillips conceded that Rose has RA (Tr2. 345), but does not believe it was caused by the hepatitis B vaccine. Id. He does not believe hepatitis B vaccine causes RA. Tr1. 254. In Dr. Phillip's view, prior to her vaccine, Rose was not healthy (Tr2. 365) and had a "continuum of musculoskeletal symptoms. . . . " between the years 1992 and 1996. Tr2. 346. While he does not believe these symptoms are related to her RA (Tr2. 375), he does believe

[19] For Dr. Philips, "what would convince me is a relatively brief time interval up to like four weeks." Tr2. 258.

Rose's carpel tunnel syndrome, which preceded her hepatitis B vaccine, was an early manifestation of her RA. Tr2. 350-351.

IV. THE CHIEF SPECIAL MASTER'S DECISION OF JUNE 8, 2004

The Chief Special Master decided Rose had "established that the hepatitis B vaccine *can* cause RA." Dec. 20-21 (emphasis in original). However, he also found that Rose "failed to establish by a preponderance of the evidence that hepatitis B vaccination caused *her* RA." Dec. 1-2. (Emphasis added). In this regard, he determined Rose presented "no evidence of rechallenge, pathological markers, or epidemiologic study in this case." Dec. 21. In addition, the Chief Special Master held, "there is insufficient proof of a general acceptance in the medical community that hepatitis B vaccine causes RA. . . ." *Id.* In sum, the Chief Special Master found:

> *[Rose] has not presented an epidemiological study, nor has she presented evidence of general acceptance* -i.e. *that the medical community is currently "seeing" or "Talking about" a potential relationship between the vaccine and the injury. Furthermore, factually she has not established that she experienced a rechallenge event or that she possesses the genetic markers that her expert testified were necessary to link the development of the disease to the vaccine she received. . . .*

Dec. 37-38.

OBJECTION NO. 1

THE USE OF THE *STEVENS'* PRONGS IS AN ABUSE OF DISCRETION AND NOT IN ACCORDANCE WITH LAW.

(A) INTRODUCTION

In effect, the Chief Special Master applied the "*Stevens* Prongs" to weigh the evidence in this case. In denying compensation, the Chief Special Master held Rose failed to satisfy one, and only one, of the five evidentiary "prongs" set forth in *Stevens v. Secretary of HHS*, No. 99-594V, 2001 WL387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001).[20] Specifically, Rose failed to satisfy Prong II, which requires a petitioner to demonstrate "the medical community is seeing and reporting a suspected association" between the vaccine and the injury. *Stevens*, at 38. Although the Chief Special Master initially believed satisfaction of *Stevens* Prong 2 would not be "a demanding burden," for a petitioner, (*Id.*) it has proved to be an insurmountable one for both Jane Stevens and Rose Capizanno. Indeed, it would be an insurmountable burden for any cause-in-fact case in the Vaccine Program.

In his decision, the Chief Special Master continues his efforts to attempt to fashion uniform criteria to promote consistent results in "cause-in-fact" cases in the Vaccine Program.[21] This is not an easy task. In this case, seeking guidance, the Chief Special Master

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[20] Prong One: proof of medical plausibility; Prong Two: proof of confirmation of medical plausibility from the medical community and literature; Prong Three: proof of an injury recognized by the medical plausibility evidence and the literature; Prong Four: proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury; and Prong Five: proof of the elimination of other causes. *Stevens*, *supra*, pp. 34-41.

[21] *See, Stevens, supra, Watson v. Sec'y of HHS*, No. 96-639V, 2001 WL 1682537 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), and *White v. Sec'y of HHS*, No. 98-426V, 2002 WL 1488764 (Fed. Cl. Dec. Spec. Mstr. May 10, 1992).

asks two important questions. He asks, "[H]ow much proof and what quality are sufficient to tip the scales in petitioner's favor[?]" Dec. 16. He also asks, "from who's viewpoint" should such evidence be weighed. Dec. 13. The answer to the first question is elusive, but the answer to the second question is easy. The viewpoint must be that of Congress.

As this Court is aware, in establishing the Vaccine Program, Congress sought to divert civil lawsuits against vaccine manufacturers into a less rigorous, less adversarial, more fair and more generous arena than the existing federal and state tort systems. Such a Program, Congress hoped, would not only compensate persons injured by vaccines, but also protect vaccine manufacturers and allow them to continue producing existing vaccines and develop new ones.

These goals are threatened by a history of strict, narrow, and inconsistent decisions by special masters in the Program.[22] Without the establishment of a consistent, but workable, evidentiary standard, Program petitioners will be driven back into the civil arena, thereby eviscerating Congressional intent.

While the "evidentiary standard" contemplated by 42 U.S.C. §300aa-11(c)(ii)(II) has been addressed and re-addressed by this Court and the Federal Circuit in a myriad of cases since the inception of the Program, current events demand yet another analysis.

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[22] *See*, detailed analysis of inconsistent findings in *Stevens, supra*, p. *16 et seq.*

The United States' national health policy continues to favor the wide use of available immunizations to combat disease. In addition, this national policy continues to encourage the medical community to develop new vaccines to combat new illnesses, such as SARS and Monkeypox. In the past three years, however, two events have elevated to "critical" the importance of the success of the Vaccine Program. First, the events of September 11, 2001 have spawned a new national policy. "Homeland Security" now demands the development of new vaccines, such as anthrax and smallpox vaccines,[23] to assist the public in combating terrorist threats. Second, in the past 3 years, the Court has been flooded with (4200) claims that MMR vaccine and "thimerosal-containing" vaccines have caused injuries on the autism spectrum.[24] In this regard, most autism claims have been filed by attorneys who intend to withdraw from the Program and file civil actions.[25] If the goals of the Program are to protect vaccine

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[23] On June 29, 2004, the Pentagon announced the "military will begin giving anthrax and smallpox vaccines to tens of thousands of troops. . .to help protect them against biological warfare. . . . " Lumpkin, John J, *Military expands anthrax vaccinations*, Associated Press, The Boston Globe, page A9, June 30, 2004.

[24] *See*, In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Various Petitioners v. Sec'y of HHS, Master Autism File, Autism Update, June 23, 2004.

[25] The Vaccine Act requires a person with a vaccine-related injury to file a petition in the Vaccine Program before proceeding in either state or federal court. 42 U.S.C. §300aa-11(a)(2)(A). Civil plaintiffs with autism who have filed in state and federal courts have been routinely directed to the Vaccine Program in accordance with 42 U.S.C. §300aa-11(a)(2)(B). *See*, for example, *Lui v. Aventis Pasteur*, 219 F. Supp. 2d 762 (W.D.Tex. 2002); *Owens v. American Home Products Corp.* 203 F. Supp 2d 748 (S.D. Tex 2002); *McDonald v. Abbott Laboratories*, 2002 WL 32074880 (S.D. Miss. Aug. 1, 2002); *Strauss v. American Home Products Corp.*, 208 F. Supp 2d 711 (S.D. Tex. 2002); and

manufacturers from crippling civil lawsuits and to compensate persons injured by a vaccine then, why are the 4200 autism cases now pending in the Program poised to exit the Program[26] and proceed with civil actions? How is it possible for the twin Congressional goals (and the national policies they encourage) be so easily obliterated? The answer is apparent. It is because evidentiary standards in the Program, to date, have been more difficult than the evidentiary standards in civil litigation. Obviously, this is not what Congress intended.

While the twin Congressional goals are distinct, they are also co-dependent. Persons fairly compensated in the Vaccine Program won't sue manufacturers. In this regard, a person with an injury likely caused by a vaccine should never withdraw from the Program or reject an award.[27] How can these persons be kept in the Program? The answer is simple. An evidentiary standard which promotes Congressional intent must be fashioned. While the Chief Special Master attempted to do so in *Stevens*, his decision required too much of a petitioner and, if upheld, surely will divert thousands of

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Bertrand v. Aventis Pasteur Laboratories, Inc. 226 F. Supp. 2d 1206 (D. Ariz. 2002).

[26] 42 U.S.C. §300aa-21 permits a petitioner to withdraw from the Program if a case is not resolved within certain time periods. USCFC Vaccine Rule 12 permits a petitioner to reject a judgment of the Court of Federal Claims and file a traditional civil action.

[27] The Vaccine Program, unlike civil lawsuits, involves relaxed standards of proof, eliminates the fault or negligence requirement, provides generous compensation, and gives 100% of the compensation to the injured person, not a significant percentage of it to the attorney.

petitioners to the civil arena. Any evidentiary standard must anticipate, and deal with, this reality.

(B) LEGISLATIVE HISTORY

As the Court is reminded *ad nauseum*, the Vaccine Program was established for two purposes. One is to compensate persons injured by vaccines. The second is to protect the Nation's existing vaccine supply and to encourage the development of new and safer vaccines. The second goal would be accomplished, Congress believed, by reducing the liability risks of the manufacturers of vaccines.

It is worth repeating Congress's "principal findings" that required the establishment of the Program. They are even more important today. They are:

> 1. the availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities;
>
> 2. the Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by these vaccines have access to sufficient compensation for their injuries; and
>
> 3. private or non-governmental activities have proven inadequate in achieving either of these goals. . . .

H.R. Rep. No. 99-908, 99th Cong., 2d Sess. 12 (1986); reprinted in 1986 U.S.C.C.A.N. 6346.

In sum, Congress stated: "two overriding concerns have led to the development of this legislation:

(a) the inadequacy, from both the perspective of the vaccine-injured persons as well as vaccine manufacturers, of the current approach to compensating those who have been damaged by a vaccine; and

(b) the instability and unpredictability of the childhood vaccine market. *Id.* at 6348.

To remedy these concerns, the Program was established. Congress hoped the Program would lessen the number of lawsuits against manufacturers. In so doing, it hoped the Program would promote the "development of new vaccines and the improvement of existing vaccines." *Id.* at 6344. It hoped it would help to create, "a new system for compensating individuals who have been injured by immunizations routinely administered." *Id.* Such awards, Congress intended, could "be made to vaccine injured persons quickly, easily, and with certainty and generosity." *Id.*

(C) INTERPRETATIONS OF THE VACCINE ACT'S EVIDENTIARY STANDARDS

While Rose concedes it is her burden to prove the hepatitis B vaccine caused her RA, she strongly disagrees with the requirements of proof imposed by the Chief Special Master. In this regard, courts have enunciated, in various ways, a petitioner's burden of proof in actual causation cases in the Vaccine Program. In *Strother v. Sec'y of HHS*, 21 Cl. Ct. 356, 370 (1990), aff'd without opinion , 950 F.2d 731 (Fed. Cir. 1991), this Court held a petitioner must show a

medical or scientific theory causally connecting the vaccination and the injury. *Id.* The petitioner's burden, the Court stated, is to prove a "logical sequence of cause and effect showing that the vaccine was the reason for the injury." *Id.* In *Shyface v, Sec'y of HHS*, 165 F.3d 1344 (Fed. Cir. 1999), the Court of Appeals for the Federal Circuit elaborated. To establish causation in a case in the Vaccine Program, the petitioner must show the vaccine was a "substantial factor" in causing the injury and "but for" the vaccine the injury would not have occurred. *Id.* at 1352.

However, this Court has recognized that the Vaccine Program is a unique creation of Congress to further specific statutory goals. For this reason, the Court observed, vaccine cases do not require "application of traditional tort litigation standards of proof." *Sharpnack v. Sec'y of HHS*, 27 Fed. Cl. 457, 462 (1993). Indeed, the Court noted, "such a concept would be an anomaly in this Program that seeks to provide a substitute system of compensation for vaccine injury in lieu of traditional tort litigation." *Id.* The Federal Circuit has agreed, stating "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the Vaccine Compensation Program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." *Knudsen v. Sec'y of HHS*, 35 F. 3d 543, 549 (Fed. Cir. 1994).

What, then, is sufficient proof in the Vaccine Program? In

Golub v. Sec'y of HHS, 243 F. 3d 561, 2000 WL 1471643 (Fed. Cir. 2000) (unpublished opinion), the Court announced a workable evidentiary standard, one which would promote Congressional intent and address societal realities. It is sufficient, the Court stated, for a petitioner to offer a medical opinion and "reasonably reliable medical theories to substantiate" the claim. *Id.* at 5. In fact, the Court stated, allowing a recovery for an injury that occurs "slightly outside the time period provided in the statute is also consistent with the *spirit* of the Vaccine Act. *Id.* (Emphasis added). The Court concluded:

> *Evidence of a temporal relationship, with nothing more, would not suffice to establish a causal link. Should the petitioner advance claims substantiated by medical records and/or by medical opinion, along with evidence demonstrating a strong temporal relationship between the injury and the vaccination, however, such a showing may suffice to establish a causal link.*

Id. at 5.

Vacating the special master's decision, the Federal Circuit ruled "she ignored petitioner's evidence demonstrating a strong temporal relationship." We find that this constitutes an abuse of discretion." *Id.*

In *Althen v. Sec'y of HHS*, No. 00-170v (Decision of September 30, 2003), the Court of Federal Claims uprooted the *Stevens'* Prongs. In so doing, the Court elaborated upon the "workable" evidentiary standard announced in *Golub*. In this regard, the Court held a petitioner must prove causation in fact

only by a "preponderance of the evidence" in accordance with 42 U.S.C. §300aa- 13 (a)(1). *Althen*, at 16. In this regard, the Court stated, whether a petitioner has satisfied the "preponderance" standard is "based on the totality of evidence in a particular case." *Id.* at 18. Thus, "in Vaccine Act cases," a claimant must present "evidence of a strong temporal relationship and either reliable medical opinion or scientific theory explaining a logical sequence of cause and effect. . . ." *Id.* (Emphasis in original). In this regard, the Court stated, "as a matter of law", a lack of peer-reviewed scientific literature supporting a petitioner's theory "does not preclude a petitioner from meeting a preponderance standard. . . ." *Id.*

(D) ROSE HAS SATISFIED THE REQUIREMENTS OF 42 U.S.C. §300AA-13 (A)(1)(A)&(B)

Rose has demonstrated she is entitled to compensation. She had an immediate reaction to her hepatitis B vaccine of May 3, 1998, confirmed by the medical records, and was advised against receiving another vaccine. Pet. Ex. 1, p. 7. The temporal relationship between the vaccine and her joint pain is strong. Within days, she had stiff and painful joints. Pet. Ex. 1, p. 11. A treating rheumatologist, Dr. Peter Himmel, ascribed her arthritis to her hepatitis B vaccine. Pet. Ex. 6, p. 9. An "independent" rheumatologist, Dr. Virginia Parker, also attributed her arthritis to the vaccine (Pet. Ex. 7, pp. 1-

3), as did a third rheumatologist, Dr. Toma. Pet. Ex. 5, pp. 1-2. Finally, a consulting physician, Dr. Edmund West, diagnosed "inflammatory arthritis post vaccination." Pet. Ex. 12, pp. 6-8. In Dr. Bell's expert opinion, Rose's RA was caused by her hepatitis B vaccine. Tr2. 319. Again, the respondent offered no credible alternate explanation for Rose's symptoms.

In *Althen*, the Court of Federal Claims explained that a petitioner must satisfy the "preponderance" standard "based on the totality of evidence in a particular case." *Id.* at 18. Thus, "in Vaccine Act cases," the Court said, a claimant must present "evidence of a strong temporal relationship and either reliable medical opinion or scientific theory explaining a logical sequence of cause and effect. . . . " *Althen*, at 18 (Emphasis in original). Rose has shown her RA was caused by her hepatitis B vaccine by a preponderance of the evidence presented in this case. She has shown a strong temporal relationship between the vaccine and her RA; she has filed medical records; evidencing this; she has presented expert testimony of a scientific theory "explaining a logical sequence of cause and effect;" all of her treating doctors ascribe her RA to her vaccine. No other explanation for her RA has been offered. She is entitled to compensation.

OBJECTION NUMBER 2

THE CHIEF SPECIAL MASTER'S FAILURE TO CONSIDER THE OPINIONS OF ROSE'S FOUR (4) TREATING PHYSICIANS WAS ARBITRARY AND AN ABUSE OF HIS DISCRETION.

In his decision, the Chief special Master trivialized the significance of the opinions of Rose's treating physicians. While he recognized that "several of [Rose's] treating physicians attributed her injuries to the vaccine," (Dec. 2) in his extensive, 38 page, literature laden decision, he afforded this critical evidence no evidentiary value. In fact, he reduced six years of clinical treatment by several physicians to a mere footnote, almost an afterthought to his decision. He characterized the value of their opinions in the following manner:

> *[Rose] also points out that her various treating physicians attributed her illness to the hepatitis B vaccine she received. . . . The court considered this evidence in its analysis and finds it unpersuasive. It appears that the diagnoses of RA in [Rose] that were made by Drs. Himmel, Parker, Toma and West, were based primarily on the temporal relationship of development of RA in [Rose] after the hepatitis B vaccination. None of these physicians presented affidavits, nor were they present at the hearing for questioning. Thus the court can only speculate as to the basis of their statements concerning the vaccine's role in the development of RA. . .and cannot attribute much evidentiary weight to these medical records.*

Dec. 35, fn.42

As all special masters know, the opinions of treating physicians have always been afforded great weight in the Vaccine Program. It is beyond axiomatic. To discard their observations

defies common sense. As one special master stated, in the Vaccine Program:

> *The court gives considerable weight to the opinions of treating physicians. . . . Treating physicians provide practical wisdom and expertise gained from hands-on experience as they tend to take a practical view in treating and diagnosing their patients' symptoms. The court ascribes validity to the clinician's methods. . . . Treating physicians are clinicians who are daily in the trenches of diagnosis and treatment. They pursue their profession by applying the tools of the clinician's trade . . .informed intuition based on experience and learning. Neither clinicians nor the vaccine program require scientific certainty. Both, however, rely on probability. Doctors have their own levels of determining causation derived through valid principles of clinical medicine. The application of 'differential diagnosis' is a common and respected method for determining diagnosis and treatment.*

Rogers v. Sec'y of HHS, No. 94-89V (Dec. Spec. Mstr. April 24, 2002), *aff'd Rogers v. Sec'y of HHS*, (U.S.C.F.C. Hodges, J. unpublished opinion, May 7, 2002).

In this regard, Rose's treating physicians, specialists, believed her RA was caused by her hepatitis B vaccine. First, her treating rheumatologist, Dr. Peter Himmel, ascribed her arthritis to her hepatitis B vaccine. Pet. Ex. 6, p. 9. Then, "independent" rheumatologist, Dr. Virginia Parker, also attributed her arthritis to the vaccine (Pet. Ex. 7, pp. 1-3), as did a third rheumatologist, Dr. Toma. Pet. Ex. 5, pp. 1-2. Finally, a consulting physician, Dr. Edmund West, diagnosed "inflammatory arthritis post vaccination." Pet. Ex. 12, pp. 6-8. Clinicians medical probabilities versus academic's quest for scientific certainty. While the Chief Special Master found

these opinions without value, they in fact are invaluable. They establish a strong temporal relationship. They establish that arthritis after a hepatitis B vaccine is a known association. They establish, through their use of the tool "differential diagnosis" that there were no likely alternative caused for Rose's RA. In these circumstances, the Chief Special Master's dismissal of this evidence was arbitrary and an abuse of his discretion.

Objection Number 3

The Chief Special Master's failure to consider the relevance of VAERS reports was arbitrary and an abuse of his discretion.

In his decision, the Chief Special Master also disregarded the relevance of VAERS data. In this regard, he found VAERS data "problematic" because "*anyone*" can file such a report. Dec. 33 (Emphasis in original). For this reason, "the quality and quality" of this information is "insufficient for assessment." *Id.* "Most troubling," however, to the Chief Special Master, is that there has been "a *decrease* rather than an *increase* in the number of reported cases." Dec. 33-34. (Emphasis in original).

While Rose agrees VAERS data does not have the statistical significance of an epidemiological study,[28] it is not valueless. For example, Dr. Bell found the VAERS database demonstrated a "statistically significant" increase in the number of cases of chronic arthritis following hepatitis B vaccine. Dr. Moulton, the respondent's expert deemed "without a doubt the most qualified expert in this case on statistical matters" (Dec. 33), conceded that the CDC uses VAERS data to draw conclusions about the safety of vaccines (Tr1. 130-131); that VAERS data has been used to show positive re-challenge injuries caused by vaccines (Tr1. 150); and that the causal relationship between rotavirus vaccine and intussusception was first identified by use of VAERS date (Tr1. 130-131).

Contrary to the assertion of the Chief Special Master, there have been a significant number of recent "case reports" of reactions to Hepatitis B vaccine.[29] In this regard, several hundred cases associating Hepatitis B vaccine with rheumatological reactions have been reported to VAERS over the last several years. Indeed, approximately 153 of these cases are specific to RA and hepatitis B vaccine. This corroborates

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[28] For the Court's information, epidemiological studies are not used to support petitioners' expert opinions in the Vaccine Program. In this regard, not one Table injury (where the injury is presumed to be caused by the vaccine) is supported by an epidemiological study. *See*, 42 U.S.C. §300aa-14.

[29] While VAERS data is not peer-reviewed, doctors no longer submit formal case reports of vaccine injuries to journals. They are instructed to report suspected vaccine-related injuries to VAERS. See footnote 6.

compelling evidence that the medical community is seeing an association. *Id.* In these circumstances, the Chief Special Master's conclusion that arthritis following hepatitis B vaccines is decreasing is not only irrelevant, it is unfounded.

V. CONCLUSION

If the Chief Special Master is correct scientific proof, not scientific probability, is necessary to prevail in the Vaccine Program. If the Chief Special Master is correct, millions of pages of medical records created by tens of thousands of treating doctors, who've treated thousands of petitioners in the Program also have little or no evidentiary value. If the Chief Special Master is correct, VAERS, a governmental program established to monitor vaccine injuries should be dismantled. If he is correct, the civil arena will be far more inviting to vaccine-injured persons, especially those alleging vaccine-related symptoms on the autism spectrum. If the Chief Special Master is correct, 4,200 autism cases filed against vaccine manufacturers will create a far greater crises than the one which inspired the Vaccine Program in 1986, at a time when our national health and defense policies can least afford it. If he is correct, the Program will fail.

Rose, of course, believes the Chief Special Master is wrong. She acknowledges she has not proved her case to a scientific certainty. She has no epidemiology. She has no

"pathological markers." She has no evidence of "rechallenge".[30] However, she believes she has adequate evidence. She believes she need only prove her case by a preponderance of the evidence. She believes her medical records, the opinions of four (4) treating doctors, her expert medical opinion, the scientific literature, and the expert opinions and literature presented by the respondent, tip the scales in her favor. She has RA. The likely cause was her hepatitis B vaccine.

Finally, Rose believes *Golub* and *Althen*, not *Stevens*, correctly interpret the Vaccine Act and give the Vaccine Program a chance to succeed. She urges this court to weigh carefully the evidence she has presented in light of Congressional intent and present societal demands. Much is at stake.

DATED: July 7, 2004

Respectfully submitted,

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[30] Rose was injured by the 2nd vaccine in a three shot series. At the advice of her treating physicians, she declined to have the last vaccine in her series. Had she received the 3rd vaccine she may well have had a "rechallenge" case. Would the respondents' experts have been comfortable in recommending that she receive the 3rd shot? Rose thinks not. To do so, Rose submits, would have been medical malpractice.

CERTIFICATE OF SERVICE

I hereby certify that on July 7, 2004, a copy of **PETITIONER'S POSTHEARING BRIEF**, and Certificate of Service for same, was sent by U.S. mail, postage paid, to:

ANN DONOHUE
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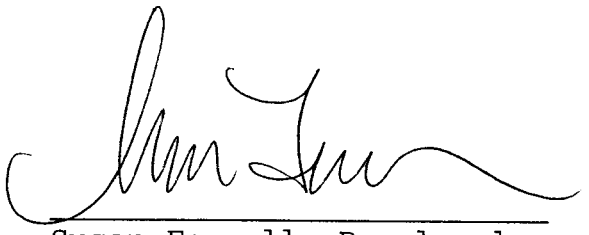

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