OFFICE OF SPECIAL MASTERS

Filed: November 10, 2005

ADAM GILBERT, a minor, by his mother and natural guardian, DEBRA GILBERT,	*	
Petitioner,	*	No. 04-455V
v.	*	TO BE PUBLISHED
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, Virginia, for Petitioner.

James A. Reistrup, United States Department of Justice, Washington, D.C., for Respondent.

RULING ON PETITIONER'S MOTION FOR PRODUCTION OF DOCUMENTS[1]

SWEENEY, Special Master

During the five years that the majority of cases constituting the Hepatitis B–Neurological Demyelinating Omnibus Proceedings ("Omnibus Proceedings") were pending, petitioner in the above-captioned case failed to seek either formal or informal discovery. However, three and one-half months after the conclusion of the three-day hearing in the Omnibus Proceedings, petitioner filed a motion seeking extensive discovery. According to the motion, petitioner requires certain Vaccine Adverse Event Reporting System ("VAERS")[2] data that, in turn, would

[1] The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secret or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy."

[2] VAERS is "a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA)." Frequently Asked Questions About VAERS, at http://vaers.hhs.gov/vaers.htm (last visited August 5, 2005). "VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks." Id. Any person can file a report with VAERS. Id. In some cases of

then be given to experts to be used to conduct a potentially time-consuming study. If the study yields results and conclusions favorable to petitioner, many petitioners in the Omnibus Proceedings intend to present that information in support of their respective petitions for vaccine-injury compensation.

Although petitioner never sets out precise arguments in support of the motion, the special master interprets petitioner's pleadings as advancing four arguments. First, petitioner claims that the controlling statute permits the extensive discovery requested. Second, petitioner argues that even if not expressly provided for by statute, special masters have inherent authority to order the respondent to produce material otherwise protected by statute. Third, because respondent has permitted the sharing of confidential material with experts regarding the anthrax vaccine, petitioner contends that this constitutes a waiver of that privilege with respect to the requested VAERS data. Fourth, petitioner claims that various perceived deficiencies of the underlying statute should, somehow, grant the special master the equitable authority to permit the release of privileged information. The motion raises several questions, including the authority and scope of a special master's ability to direct discovery and the identity of information subject to discovery.

At bottom, petitioner requests that the special master reset the litigation clock to permit posthearing discovery and posthearing research because petitioner failed to marshal the necessary evidence prior to hearing. It cannot be ignored that the majority of petitioners in the Omnibus Proceedings instituted suit five years prior to hearing, but failed to pursue discovery avenues that counsel claims are available and necessary. It is too late in the day for petitioner to seek extensive discovery for the express purpose of conducting research. As explained more fully below, petitioner has failed to articulate a rational, proper basis for the discovery request and it is therefore denied.

On October 13-15, 2004, the special master conducted the Omnibus Proceedings, in which the above-captioned case was one of four representative cases. During the hearing,

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serious adverse reactions, the CDC and FDA request additional information from the reporter and the reporter is able to submit additional information to VAERS. CDC, National Immunization Program, Overview of Vaccine Safety, at http://www.cdc.gov/nip/vacsafe/default.htm (last updated March 30, 2005). For a detailed overview of VAERS and the usefulness of VAERS data, see Frederick Varricchio et al., Understanding Vaccine Safety Information from the Vaccine Adverse Event Reporting System, 23 Pediatric Infectious Disease J. 287-94 (2004) (attached as Exhibit G to the Response). The CDC and the FDA are both agencies within the Department of Health and Human Services. About HHS, at http://www.hhs.gov/about/index.html (last revised June 24, 2005).

petitioner's counsel in this case[3] stated his intention to file a posthearing motion for the production of certain VAERS data.

On January 24, 2005, petitioner's counsel filed Petitioner's Motion for Production of Documents ("Motion"). The Motion "moves this Court for the production of complete redacted files for the Vaccine Adverse Event Reports filed with the VAERS for the files with the VAERS ID#s attached hereto as Exhibit 1." Exhibit 1 lists approximately 1,462 VAERS identification numbers. On February 25, 2005, respondent's counsel filed Respondent's Response to Petitioner's Motion for Production of Documents ("Response"). Then, on March 14, 2005, petitioner's counsel filed Petitioner's Motion for Production of Documents [sic] ("Reply").

Because petitioner failed to provide a factual or legal basis to support the Motion, the special master issued an order on May 3, 2005, directing counsel for both parties to respond to certain enumerated questions regarding the Motion, Response, and Reply. Accordingly, on May 20, 2005, petitioner's counsel filed Petitioner's Response to Order of May 3, 2005 ("Petitioner's May 20 Response") and respondent's counsel filed Respondent's Response to Order for Additional Authority ("Respondent's May 20 Response"). Then, on May 24, 2005, petitioner's counsel filed Petitioner's Reply to Respondent's Response to Order for Additional Authority ("Petitioner's May 24 Reply"). Because the special master found Petitioner's May 20 Response and Petitioner's May 24 Reply to be wholly inadequate, on June 6, 2005, she issued another order directing petitioner to respond to her questions. On July 6, 2005, petitioner's counsel filed Petitioner's Response to Court's Orders of June 6 and June 29, 2005 ("Petitioner's July 6 Response").

On September 6, 2005, with the special master's permission, petitioner's counsel in a case then recently added to the Omnibus Proceedings, Pecorella v. Secretary of HHS, No. 99-638, filed a Status Report ("Pecorella Brief") that presented arguments in favor of petitioner's Motion.[4] On September 19, 2005, respondent's counsel in Pecorella filed Respondent's Response to Petitioner's September 2, 2005 Filing [sic] ("Pecorella Response").

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[3] Of the four representative cases, Mr. Clifford J. Shoemaker is the counsel of record in the above-captioned case as well as Werderitsh v. Secretary of HHS, No. 99-319. Mr. Ronald Homer is the counsel of record in the two other lead cases: Stevens v. Secretary of HHS, No. 99-594, and Peugh v. Secretary of HHS, No. 99-638. Mr. Homer has not joined in petitioner's Motion.

[4] On September 1, 2005, petitioner's counsel in Pecorella orally requested permission to file a brief supporting petitioner's Motion, stating that his arguments had not been addressed by counsel in the Omnibus Proceedings. The special master received a courtesy copy of the brief via overnight mail on September 2, 2005.

I. BACKGROUND

A. Petitioner's Request

Petitioner's Motion requests that the special master compel "the production of complete redacted files for the Vaccine Adverse Event Reports filed with the VAERS for the files with the VAERS ID#s attached hereto as Exhibit 1. . . . [These ID#s] represent all of the cases in the VAERS system through September 2004 where there is evidence of a positive rechallenge."[5] Motion at 1. The Motion further indicates that petitioner is "prepared to present expert testimony at a hearing for the purpose of further explaining the relevance and importance of this information which is under the control of the Respondent herein." Id.

B. Petitioner's Intended Use of the Requested VAERS Data

Petitioner has requested access to 1,462 redacted VAERS files,[6] all of which are characterized as cases "where there is evidence of a positive rechallenge." While the special master is not convinced that all 1,462 of the requested VAERS files contain evidence of positive rechallenge, see supra note 5, for purposes of ruling on the instant discovery motion, the special master will treat that allegation as true.

In support of the Motion, petitioner claims:

> By having access to this data, it will be possible to see how many of these cases involved neurodemyelinating conditions, how many were diagnosed by a doctor or neurologist, and so forth. Also, many of these files will contain enough medical records to allow experts for the Petitioners to engage in a Delphic

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[5] Exhibit 1 contains, by the special master's count, 1,462 VAERS identification numbers. Of the VAERS identification numbers listed, 472 are categorized as "Positive Re-Challenge Adverse Event Reports," 442 are categorized as "Reaction Aggravation Adverse Event Reports," 116 are categorized as "Multiple Sclerosis," 79 are categorized as "Optic Neuritis," 91 are categorized as "Guillain Barré Syndrome," 58 are categorized as "Myelitis," 70 are categorized as "Encephalitis/ Encephalopathy," 92 are categorized as "Ataxia," and 42 are categorized as "Neuritis." Thus, only 914 of the VAERS identification numbers, those categorized as "Positive Re-Challenge Adverse Event Reports" and "Reaction Aggravation Adverse Event Reports," appear to represent cases of positive rechallenge.

[6] The special master uses the phrase "VAERS files" to denote the combination of the actual VAERS report and any supporting or follow-up medical records associated with the VAERS report.

> approach such as was engaged in by the authors of the article attached hereto as Exhibit 2.[7]
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> . . .
>
> Production of the additional redacted records from the files referenced in this motion will be helpful to Plaintiffs [sic] by allowing them to analyze further evidence of positive rechallenge cases following hepatitis vaccines.

Motion at 1 (footnote added). Because petitioner's Motion was not entirely clear concerning petitioner's specific, intended use of the 1,462 requested VAERS files, the special master turned to the statements made by petitioner's counsel at the October 2004 hearing during his cross-examination of Thomas P. Leist, M.D., Ph.D.:

> Wouldn't it be important to you as a doctor to go in and to actually be able to do something like Dr. Moulton and these other doctors did, where they took a Delphic approach and went in and looked at the actual [medical] records in those positive rechallenge[] cases to try to determine whether or not they fit the criteria that the IOM accepted from Pollard and Selby?[8]

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[7] Petitioner fails to define a "Delphic approach." The term is susceptible to more than one definition. For the purpose of ruling on the instant Motion, the special master assumes that petitioner's counsel is utilizing the term in the same manner as described in Exhibit 2, the article by Sever et al. entitled Safety of Anthrax Vaccine: A Review by the Anthrax Vaccine Expert Committee (AVEC) of Adverse Events Reported to the Vaccine Adverse Event Reporting System, 11 Pharmacoepidemiology 189 (2002). The AVEC is a civilian expert committee charged with performing an ongoing medical assessment of the VAERS reports concerning the anthrax vaccine. One of the AVEC's objectives is to "medically evaluate each reported [adverse event] and, subject to limitations imposed by the incomplete information provided in many VAERS reports, to assess the causal relationship between an [adverse event] and prior receipt of [the anthrax vaccine]." Sever et al., supra, at 191. More particularly, a VAERS report is initially reviewed by a civilian AVEC medical reviewer. Id. at 192. Then, the reviewer's initial assessment, along with the VAERS report and any additional medical records supporting the VAERS report, is reviewed by a panel of the AVEC experts–a "Delphic approach" was used to "achieve expert consensus concerning the causal relationship between each reported [adverse event] and [the anthrax vaccine]." Id.

[8] Petitioner's counsel is referring to two distinct studies in this statement. The "Delphic approach" refers to the approach taken by the authors of Sever et al., supra note 7. Dr. Lawrence H. Moulton was one of the authors of this article. However, the article by Sever et al. did not deal with cases of positive rechallenge. Instead, counsel's statement regarding positive rechallenge refers to the Institute of Medicine's ("IOM") 1994 report entitled Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. In this report, the IOM

. . .

> I will probably file a . . . post[hearing] motion to request . . . certain VAERS records . . . . [I]f you go through and find the ones that show positive rechallenge, . . . I would like to file a request to actually obtain [the] redacted records . . . . [W]e can actually look at whatever medical record, whatever evidence has been provided over and above what's in that computer table to be able to look at those positive rechallenge cases and present that evidence as well.

Transcript of October 13-15, 2004 Hearing at 687-89 (footnote added).

Thus, it appears from the posthearing Motion and from counsel's statements at hearing that petitioner wants to accomplish at least three things with the 1,462 requested VAERS files: (1) seek out any cases of positive rechallenge that meet the criteria accepted by the IOM as described in the Pollard and Selby article, (2) analyze the requested VAERS files using a "Delphic" approach to form tentative conclusions about causation such as was done by Sever et al., and (3) ascertain how many of the files contain an adverse event diagnosed by a physician (ideally, those diagnoses made by a neurologist) in order to help prove the reliability of VAERS data.[9]

II. DISCUSSION

A. A Special Master Has the Authority to Permit the Discovery of All Reasonable and Necessary Evidence that Would Aid the Special Master in Reaching a Decision

Petitioner requests that the special master permit the discovery of 1,462 redacted VAERS files. The threshold question is whether the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2000 & Supp. II 2003), and/or the Vaccine Rules provide a special master with the authority to grant such a request. The special master's ability to direct discovery is outlined in 42 U.S.C. § 300aa-12(d)(3)(B) and Vaccine Rules 7 and 8(c).

The Vaccine Act is, necessarily, the starting place for inquiry. In this regard, section 12(d)(3)(B) specifically provides:

> (B) In conducting a proceeding on a petition a special master–

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accepted evidence of positive rechallenge, as demonstrated in a 1978 case report by Pollard and Selby, as favoring a causal relationship between tetanus toxoid and Guillain-Barré syndrome.

[9] Petitioner's Reply reiterates the desire to use the 1,462 requested VAERS files in order to prove the reliability of VAERS data. Reply at 2-3.

> (i) may require such evidence as may be reasonable and necessary,
> (ii) may require the submission of such information as may be reasonable and necessary,
> (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,
> (iv) shall afford all interested persons an opportunity to submit relevant written information–
>
> . . . and
>
> (v) may conduct such hearings as may be reasonable and necessary.
>
> There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

42 U.S.C. § 300aa-12(d)(3)(B). Thus, the plain language of the statute indicates that the special master, and only the special master, may require discovery of evidence or information that is reasonable and necessary to the proceedings in a case.

Another special master provided the following analysis of this section:

> In the Vaccine Act context, . . . the special master is not only the referee of procedural disputes, but also the ultimate factfinder on all disputed factual issues; thus, when a master decides whether to use his or her discovery authority, the test is whether the master concludes that the production of the material in question is "reasonable and necessary" to the master's own resolution of the factual issues to be resolved. In other words, when a special master contemplates whether to utilize his or her authority to require testimony or document production, the master's task is apparently to evaluate the importance and relevance of the material in question in light of the overall context of the factual issues to be decided by the master, determining whether the master reasonably needs that material in order to reach a well-informed decision concerning those factual issues.
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> . . .
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> [I]t seems to me that the "reasonable and necessary" standard means that the special master should require production if the master concludes that, given the overall context of the factual issues to be decided by the master, he or she could not make a fair and well-informed ruling on those factual issues without the requested material. Requiring the requested testimony or document production must also be "reasonable" under all the circumstances, which means that the special master must consider the burden on the party who would be required to

testify or produce documents. That is, the importance of the requested material for purposes of the special master's ruling must be balanced against the burden on the producing party.

In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Various Petitioners v. Sec'y of HHS, Autism Master File, 2004 WL 1660351, at *7, 9 (Fed. Cl. Spec. Mstr. July 16, 2004) (Ruling Concerning Motion for Discovery from Merck Re MMR Vaccine) (footnotes omitted) (hereinafter "Autism Order"). The undersigned concurs with this approach and notes that in the Autism proceedings, discovery is being conducted prior to, not after, hearing.

Petitioner's counsel in Pecorella takes a different view and argues that the Vaccine Act neither limits a special master's power to require discovery nor limits a petitioner's right to obtain "needed information." Pecorella Brief at 2-3. The plain language of the Vaccine Act refutes this contention. First, a special master may require only such evidence and information that is reasonable and necessary.[10] No matter what method of discovery petitioner seeks to utilize,[11] if the evidence or information sought is not reasonable and necessary, the special master may not permit its discovery. Second, only discovery required by the special master is permitted. Thus, petitioner is limited to obtaining evidence or information that is found by the special master to be reasonable and necessary to case disposition. Of course, this should not be construed to mean that the special master will not permit or intends to discourage counsel from seeking pertinent discovery. To the contrary, counsel has an ethical obligation to the petitioner to ensure a full and fair hearing. However, counsel should make all appropriate requests when the need for the information becomes known. Here, it is clear that the need, or at least the desire, for the information now sought was well known prior to hearing. The orderly administration of justice requires that motions for discovery must be made prior to, not after, hearing. Therefore, contrary to counsel's contentions, the Vaccine Act does, in fact, impose limits on discovery.

Next, the special master turns to the Vaccine Rules. Mirroring the statute, Vaccine Rule 7 notes that "[t]here shall be no discovery as a matter of right." Rather, informal discovery is

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[10] The special master notes that petitioner's counsel in Pecorella omitted the "reasonable and necessary" requirement when quoting 42 U.S.C. § 300aa-12(d)(3)(B)(iii). Pecorella Brief at 4.

[11] Petitioner's counsel in Pecorella notes that the Vaccine Act and Vaccine Rule 7 permit the special master to utilize any method of discovery found in Rules 26-37 of the Rules of the United States Court of Federal Claims ("RCFC") and argues that a special master may "fashion discovery methods not contained in Rules 26-[37] if needed to reach needed evidence." Pecorella Brief at 3-4. The method of discovery, however, is not at issue. Instead, the special master must determine whether the 1,462 requested VAERS files are discoverable in the first place, and if so, whether the 1,462 requested VAERS files are reasonable and necessary to the special master's decision in this case.

preferred. However, formal discovery, using the procedures found in RCFC 26-37, is permitted. Requests for formal discovery must specify the reason(s) why formal discovery is being sought and include an explanation why informal discovery was not sufficient.[12] Vaccine Rule 7 also

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[12] Petitioner's Motion provides the following reason for the formal discovery request: "Production of the additional redacted records from the files referenced in this motion will be helpful to Plaintiffs [sic] by allowing them to analyze further evidence of positive rechallenge cases following hepatitis vaccines." Motion at 1. The special master agrees that evidence of other cases involving positive rechallenge can be important evidence in vaccine-injury cases. See, e.g., Capizzano, Ashby, Analla, Ryman, & Manville v. Sec'y of HHS, Nos. 00-759, 01-221, 99-609, 99-591, 99-628, 2003 WL 22425000 (Fed. Cl. Spec. Mstr. Aug. 5, 2003) (attached as Exhibit 3 to the Motion). But, in disregard of the Vaccine Rules, the Motion fails to explain what informal or formal discovery was attempted prior to hearing and why those techniques were insufficient or unproductive. The special master twice asked petitioner to identify which discovery techniques were pursued prior to hearing. It became clear that no attempts were made to obtain the information now sought after hearing. When asked for specific details, petitioner's counsel first responded:

> Counsel was not aware that the people running the VAERS database were categorizing cases as "Asthenia" prior to the hearing. This has been a relatively recent discovery, and it is feared that many cases that would fit the neurodemyelinating category of cases may have been classified in ways that would make it impossible for them to be counted in epidemiological studies . . . .

Petitioner's May 20 Response at 1. Because this response was unclear, the special master again asked petitioner's counsel to explain what steps he initiated to obtain discovery. He responded: "With regard to the requested data from the VAERS database, counsel was not aware of the 'asthenia' cases until after the hearing, so no informal steps were taken prior to the hearing." Petitioner's July 6 Response at 1.

The special master finds neither response compelling. Counsel's position that he was unaware that "asthenia" (asthenia is "the lack or loss of strength and energy; weakness") was one of the many categories of adverse reactions within the VAERS database is irrelevant in explaining why he failed to seek any discovery prior to hearing. Indeed, regardless of the timing of counsel's learning that there was an "asthenia" category in the VAERS database, it is nevertheless true that petitioner failed to request any VAERS information prior to hearing. Nothing prevented petitioner from filing a discovery request after the petition was filed, but prior to hearing. It was only after hearing that petitioner moved for the production of 1,462 VAERS files.

Furthermore, petitioner's counsel claims that Dr. Mark Geier, "an expert in VAERS databases, assisted counsels' preparation for the Omnibus Proceeding by educating them about demyelinating disorders reported in the VAERS database. In this regard, Dr. Geier previously

provides a special master the power to approve the issuance of a subpoena. Further, Vaccine Rule 8(c) provides guidance; it requires the special master to "consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties." However, section 12(d)(3)(B)'s "reasonable and necessary" requirements must first be satisfied.

B. A Special Master May Not Permit Discovery of Information Contained in VAERS Files that, Pursuant to 42 U.S.C. § 300aa-25(c), Cannot Be Released to the Public

As explained above, the Vaccine Act permits a special master to direct the discovery of evidence that is reasonable and necessary to case disposition. 42 U.S.C. § 300aa-12(d)(3)(B). In

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had conducted extensive research in the area of hepatitis B vaccine and demyelinating disorders." This statement was made on pages 5-6 in "Petitioner's Reply to Respondent's Opposition to Petitioner's Application for Attorneys' Fees and Costs," filed in Cramer v. Secretary of HHS, No. 99-428, on July 13, 2005, by the same petitioner's counsel as in this case. Cramer, filed on July 2, 1999, was a lead case in the Omnibus Proceedings until its voluntary dismissal on July 20, 2004. The special master finds counsel's representations in Cramer concerning Dr. Geier's expertise convincing evidence that petitioner should have known about the "asthenia" category. Certainly, Dr. Geier's "extensive research in the area of hepatitis B vaccine and demyelinating disorders" would have informed him that weakness can be a symptom of all four of the demyelinating disorders represented in the Omnibus Proceedings–multiple sclerosis, Guillain-Barré syndrome, transverse myelitis, and chronic inflammatory demyelinating polyneuropathy. And, Dr. Geier's claimed expertise in "VAERS databases" would have informed him of the multitude of categories used to describe the symptoms associated with the hepatitis B vaccine. Therefore, Dr. Geier would have and should have known to search for incidences of "asthenia" within the VAERS database and thus should have alerted petitioner's counsel.

Second, the special master is concerned that petitioner's counsel, with his many years of experience in trying cases in the Vaccine Program and his proclaimed familiarity with VAERS, see Petitioner's May 24 Reply at 4-7 (section titled "Understanding VAERS"), did not search for all possible, relevant categories when determining which VAERS files he wanted to access. Given the fact that petitioner's counsel identified VAERS files pertaining to ataxia, myelitis, and neuritis, it is hard to conceive that he would not have explored categories related to weakness as well.

Third, and most importantly, petitioner's counsel fails to describe any informal steps taken to request the 1,462 VAERS files actually identified in the Motion. As the special master indicated in her June 6, 2005 order: "If petitioner's counsel again fails to describe any affirmative action taken to obtain any of the sought-after information, the special master will assume that counsel did not take any action." To date, petitioner's counsel has been silent concerning steps undertaken to obtain discovery prior to hearing. Thus, the special master has no alternative but to conclude that petitioner took no steps to obtain informally the 1,462 VAERS files now sought after hearing.

this case, however, prior to determining whether petitioner demonstrated that the 1,462 requested VAERS files were both reasonable and necessary, the special master must first examine whether the information can be disclosed. If it cannot, petitioner's Motion must be denied. In reaching her determination concerning disclosure, the special master relies on 42 U.S.C. § 300aa-25, which governs the collection and dissemination of VAERS data.

Section 25(b) requires health care providers and vaccine manufacturers to report to the Secretary of the Department of Health and Human Services ("HHS") any adverse event listed on the Vaccine Injury Table, any contraindicated reactions described on the vaccine's package insert, and other matters required by HHS regulation. These reports are to include (1) how long after vaccination the adverse reaction occurred and (2) the manufacturer and lot number of the vaccine.

Section 25(c) is unambiguous in identifying to whom information collected by the government pursuant to section 25(b) can be released:

> (c) Release of information
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> > (1) Information which is in the possession of the Federal Government . . . under this section and which may identify an individual shall not be made available under section 552 of Title 5,[13] or otherwise, to any person except—
> >
> > > (A) the person who received the vaccine, or
> > > (B) the legal representative of such person.
> >
> > (2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.
> >
> > (3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

[13] The Freedom of Information Act.

42 U.S.C. § 300aa-25(c) (emphasis and footnote added). Thus, the plain language of the statute precludes, whether under the Freedom of Information Act ("FOIA") or any other discovery tool, the release to the public of the names, street addresses, and telephone numbers of the vaccinated person and the person's legal representative. Nor may the "medical records of such person relating to the administration of the vaccine" be released.[14] While it is true that such protected information may be highly relevant and useful to petitioner, the statute provides no such exception and the special master cannot engraft such a provision onto the statute. However, all other information in the VAERS reports, including the location of vaccination, the vaccine administrator, the date of vaccination(s), and any information regarding a possible adverse vaccine reaction, is public information. VAERS reports also include information such as the identity of the administered vaccine(s), the manufacturer and lot number of the vaccine(s), any illness at the time of vaccination, and any pre-existing physician-diagnosed allergies, birth defects, or medical conditions.

1. Certain VAERS Information Sought by Petitioner Is Protected from Disclosure by Statute

The parties offer differing views concerning whether the Secretary can be directed to produce the VAERS material sought by petitioner. Petitioner's position is that the special master is authorized by the Vaccine Act and the alleged prior practice of other special masters to direct the discovery of VAERS files.

Respondent does not embrace petitioner's view. Respondent argues that section 25(c) prohibits the release to the public by the government of any individually-identifying information, including medical records, not already in the VAERS database published on the Internet.[15] Response at 6-7. Respondent contends that the information in the Internet VAERS database, which reflects most of the information requested on the VAERS report, complies with the public disclosure requirements of section 25(c). Id. at 7. Further, respondent states that any follow-up

[14] In his brief, petitioner's counsel in Pecorella failed to include significant items protected from discovery by 42 U.S.C. § 300aa-25(c), namely, "medical records of such person relating to the administration of the vaccine." See Pecorella Brief at 8. Thus, counsel's assertion that "there appears to be no validity at all for the government's position," is flawed. Indeed, personal medical records, which are specifically protected from discovery, are critical to petitioner's proposed "Delphic" analysis. Nevertheless, as explained infra, neither relevance nor compelling need can create an exception to the statutorily-protected material.

[15] Petitioner's counsel in Pecorella states that respondent's argument is that respondent cannot "be compelled to redact confidential information from otherwise discoverable documents." Pecorella Brief at 6, 8. Counsel mischaracterizes respondent's position.

medical records obtained by the government can be released to the public only if the vaccinated person (or the person's legal representative) signs a release.[16] Id.

In the Reply, petitioner counters that section 25(c) "is difficult to read and understand" but suggests, without citation to authority, that this provision appears to permit the government to release VAERS files to the public so long as certain information is redacted.[17] Reply at 3; see also Pecorella Brief at 9. The explicit statutory prohibition against disclosure of the personal information sought by petitioner notwithstanding, petitioner offers to enter into a protective order to limit the review of redacted VAERS files to petitioner's counsel and to petitioner's designated experts. Reply at 3. To support the view that VAERS information is subject to discovery, petitioner averred that the Chief Special Master granted a similar discovery request for VAERS data in Watson v. Secretary of HHS, No. 96-639. Id.

Because the special master had additional questions regarding what information could be released to the public pursuant to the Vaccine Act and the discrepancy between petitioner's representations and the Chief Special Master's published decision in Watson, the special master solicited additional arguments and information from the parties.[18] However, petitioner's May 20 Response failed to address the special master's questions regarding the discovery permitted by the Chief Special Master in Watson[19] or the scope of section 25 and its impact on petitioner's

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[16] In Respondent's May 20 Response, respondent reiterated prior arguments, and added that "[o]ther information also resides in VAERS, but is not subject to the Vaccine Act, so is not necessarily 'available to the public.'" Respondent's May 20 Response at 3. As respondent notes, however, petitioner is not seeking access to this "other information." Id. Therefore, the special master will focus on what portions of the 1,462 requested files can be made available to the public.

[17] The term "redacted" does not appear in section 25(c).

[18] The decision in Watson, No. 96-639, 2001 WL 1682537, at *3 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), clearly states that petitioner's discovery request was denied. Because the instant petitioner's counsel was also counsel in Watson, the undersigned believed counsel could clarify the factual discrepancy.

[19] In response to the question regarding the Watson case, petitioner explained:

> Unless counsel's memory is failing (which is a distinct possibility), the VAERS files that were produced in Watson were produced well before the hearing with Dr. Verhalen. The problem is that the case predated the time when everything in our office started being scanned, so counsel will have to go through the boxes of old records in this case that are maintained in storage. Counsel is happy to do that, but would ask for a little extra time to pull out the boxes and locate the materials that are believed to be there.

discovery Motion. For that reason, the special master again requested that petitioner respond to her inquiries.

In Petitioner's July 6 Response, petitioner merely reiterated the contents of section 25(c) and stated that "[c]ounsel could find nothing in the legislative history that sheds any further light on the statutory language." Petitioner's July 6 Response at 4. In regard to whether the Chief Special Master permitted discovery in the Watson case as claimed, petitioner's counsel reported that the materials in question had not been produced pursuant to discovery approved by the Chief Special Master; rather, those materials had been obtained through a FOIA request.[20] Id. at 2.

Finally, petitioner's counsel in Pecorella contends that the 1,462 requested VAERS files are discoverable. Pecorella Brief at 5. Arguing that the Secretary of HHS serves as a "substitute respondent" for vaccine manufacturers,[21] counsel asserts that entries in the Physicians' Desk

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Petitioner's May 20 Response at 1-2. Further, in response to the special master's question concerning the source of her authority to promulgate redaction rules, petitioner's counsel prefaced his answer with: "Without conducting a great deal of research . . . " but then failed to provide any legal support for his argument. Id. at 2.

[20] Counsel argued that because redacted materials were produced under FOIA, the special master has similar authority. Petitioner's July 6 Response at 2. The special master does not share counsel's view. The FOIA and the Vaccine Act are separate and distinct statutes. As Watson makes plain, counsel is familiar with and has utilized FOIA in the past to obtain the information now sought. No permission from or notice to the special master is required to pursue a FOIA request. Therefore, counsel failed to pursue an independent avenue for discovery in this case and fault lies squarely upon his shoulders and not with the Vaccine Act, the special master, the Department of Justice, or HHS.

[21] The special master does not accept this premise. Congress designated the Secretary of HHS as the respondent in Vaccine Act cases because of the federal government's responsibility to protect the nation's public health:

> [T]he Federal government has had the responsibility to prevent the spread of infectious diseases from other countries into the United States and between States within its own borders. In meeting this responsibility, the Federal government has assumed . . . a leadership role in providing immunizations against childhood diseases. . . . This role, repeatedly reaffirmed by the Congress, assures that the country maintains a consistent national policy in protecting our children against preventable diseases.

H.R. Rep. No. 99-908, pt. 1, at 15 (1986). Additionally, petitioners are free to reject the judgment in Vaccine Act cases and pursue a civil action against the vaccine manufacturers in

Reference ("PDR")[22] constitute admissions by the government and thus prove that vaccines are "associated with" the listed adverse events. Id. Counsel contends that the VAERS files provide the basis for the entries in the PDR and should be produced as evidence supporting what he construes as "admissions" by the government. Id. Apparently, counsel believes that respondent should have produced the relevant VAERS files without any request by petitioner.[23] Id. The special master rejects this argument.

As respondent notes, the FDA requires that drug[24] product labels, as reproduced in the PDR, list adverse reactions, defined as undesirable effects that are "reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." 21 C.F.R. § 201.57(g). Vaccine manufacturers must report adverse events to the FDA, whether or not the adverse event is considered to be product-related. Id. § 600.80(a), (c). Further, "[a] report or information submitted by a licensed manufacturer . . . does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an

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state or federal court. 42 U.S.C. § 300aa-21(a). However, even if the Secretary of HHS serves as a "substitute respondent" for vaccine manufacturers, entries in the PDR do not constitute admissions regarding causation.

[22] As explained in the PDR:

> The PDR contains Food and Drug Administration (FDA)-approved labeling for drugs . . . . Each full-length entry provides you with an exact copy of the product's FDA-approved or other manufacturer-supplied labeling. . . . The Code of Federal Regulations Title 21 Section 201.100(d)(1) pertaining to labeling for prescription products requires that for PDR content "indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant warnings, hazards, contraindications, side effects, and precautions" must be "same in language and emphasis" as the approved labeling for the products.

Foreword to the Fifty-Eighth Edition, Physicians' Desk Reference (58th ed. 2004).

[23] Counsel concludes by accusing respondent of pursuing a scorched-earth policy for "resist[ing] all efforts to access data, here and in all other cases." Pecorella Brief at 5. Counsel provides absolutely no support for this accusation. Further, the special master again notes that there is no evidence in the record that petitioner's counsel in Pecorella, like counsel in the above-captioned case, ever informally requested of respondent the discovery of the 1,462 requested VAERS files.

[24] The definition of "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . ." 21 U.S.C. § 321(g)(1); 21 C.F.R. § 3.2(g).

adverse effect." Id. § 600.80(*l*). Thus, federal regulations specifically preclude the contents of drug product labels, as reproduced in the PDR, from serving as admissions regarding causation.[25]

Petitioner's counsel in Pecorella also cites several cases concerning the FOIA to support his argument that the 1,462 requested VAERS files are discoverable. Pecorella Brief at 8. See generally DOJ v. Tax Analysts, 492 U.S. 136 (1989); Forsham v. Harris, 445 U.S. 169 (1980); Burka v. HHS, 87 F.3d 508 (D.C. Cir. 1996). These decisions are inapt for several reasons. First, FOIA has no application in Vaccine Act cases. Counsel in Vaccine Act cases may file FOIA requests, but such requests are not within the purview of the special master. Litigation to enforce a FOIA request would be decided by a federal district court judge, not a Vaccine Act special master. Second, FOIA decisions by federal district court judges are not binding precedent on the special master. Only decisions of the United States Supreme Court, the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), the Federal Circuit's predecessor court (the United States Court of Claims), and the United States Court of Federal Claims in the same case on remand, are binding on the special master. See Hanlon v. Sec'y of HHS, 40 Fed. Cl. 625, 630 (1998). Finally, petitioner in this case is not making a FOIA request. Thus, special master declines to follow FOIA precedent in ruling on the instant Motion as it is irrelevant to the issues in this case. See also John Doe Agency v. John Doe Corp., 493 U.S. 146, 153 (1989) ("[A] court must be mindful of this Court's observations that the FOIA was not intended to supplement or displace rules of discovery.").

In addition to the FOIA cases, petitioner's counsel in Pecorella refers to several cases that discuss discovery of research data from private, civil litigants. Pecorella Brief at 8. See generally Burka, 87 F.3d at 520 n.13. However, counsel does not explain with any specificity the relevance of these cases. As respondent correctly states, "discovery in the context of a federal civil case is far different from discovery in a Vaccine Act claim." Pecorella Response at 7. The special master, and not the parties, determines what materials can be discovered, and is guided by the requirement that the materials be reasonable and necessary for her decision.

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[25] The special master also notes that the specific adverse reactions identified by petitioner's counsel in Pecorella are listed under precautionary headings in the PDR. In the PDR entry for the Engerix-B brand of recombinant hepatitis B vaccine, the adverse events of Bell's palsy, Guillain-Barré syndrome, transverse myelitis, optic neuritis, multiple sclerosis, and seizures are listed under the following heading: "Additional adverse experiences have been reported with the commercial use of Engerix-B. Those listed below are to serve as alerting information to physicians." Physicians' Desk Reference 1487-88 (58th ed. 2004). In the PDR entry for the Recombivax HB brand of recombinant hepatitis B vaccine, the adverse events of Bell's palsy, Guillain-Barré syndrome, transverse myelitis, optic neuritis, multiple sclerosis, seizures, and encephalitis are listed under the following heading: "The following additional adverse reactions have been reported with use of the marketed vaccine. In many instances, the relationship to the vaccine was unclear." Id. at 2075.

2. 42 U.S.C. § 300aa-25(c) Contains a Discovery Privilege that Must Be Strictly Construed

While briefly flirting with the issue, neither party squarely addressed the critical issue of whether 42 U.S.C. § 300aa-25(c) constitutes or contains a discovery privilege pursuant to the RCFC.[26] As discussed above, Vaccine Rule 7 incorporates the discovery rules found in RCFC 26-37. RCFC 26(b)(1) permits the discovery of all relevant information that is not privileged, subject to certain limitations. Privileges "may be created by statute." Baldrige v. Shapiro, 455 U.S. 345, 360 (1982). The statute granting such a privilege must be strictly construed. Id.

In Baldrige, the Supreme Court was confronted with the question of whether 18 U.S.C. §§ 8(b) and 9(a) created a discovery privilege protecting certain census data from disclosure. 455 U.S. at 360. Section 8(b) limited disclosure of census data by the Secretary of the Department of Commerce ("DOC") to "materials which do not disclose the information reported by, or on behalf of, any particular respondent . . . ." Id. at 354. Section 9(a) prohibited any employee of the DOC from (1) using the collected data for "any purpose other than the statistical purposes for which it [was] supplied," (2) publishing any data from which any individual could be identified, and (3) permitting anyone other than a DOC employee to examine individual reports. Id. at 354-55.

The Supreme Court found that sections 8(b) and 9(a) "embody explicit congressional intent to preclude all disclosure of raw census data reported by or on behalf of individuals." Id. at 361. The Court continued:

> This strong policy of nondisclosure indicates that Congress intended the confidentiality provisions to constitute a "privilege" within the meaning of the Federal Rules. Disclosure by way of civil discovery would undermine the very purpose of confidentiality contemplated by Congress. One such purpose was to encourage public participation and maintain public confidence that information given to the Census Bureau would not be disclosed. The general public, whose cooperation is essential for an accurate census, would not be concerned with the underlying rationale for disclosure of data that had been accumulated under assurances of confidentiality. Congress concluded in §§ 8(b) and 9(a) that only a bar on disclosure of all raw data reported by or on behalf of individuals would serve the function of assuring public confidence.

Id.

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[26] The RCFC conform to the Federal Rules of Civil Procedure ("FRCP"), "to the extent practicable given differences in jurisdiction between the United States district courts and the United States Court of Federal Claims." R. Ct. Fed. Cl., 2002 Rules Committee Note at 1. Accordingly, interpretation of the RCFC are guided by the case law and Advisory Committee Notes accompanying the FRCP. Id.

The Supreme Court's reasoning in Baldrige is highly instructive in this case. Section 25(c) prohibits the disclosure, pursuant to the FOIA, "or otherwise," of information that identifies an individual. The language of section 25(c) seeks to provide the same protection as found in Baldrige's "strong policy of nondisclosure." Furthermore, persons who report information pursuant to section 25(b) are informed, in the directions for completing the VAERS report, that individually-identifying information "will not be available to the public." See http://vaers.hhs.gov/pdf/vaers_form.pdf (last visited Sep. 23, 2005). In other words, the FDA encourages the completion and submission of VAERS reports using a promise of confidentiality, another factor seen in Baldrige. Using the strict construction demanded in Baldrige, the special master finds that she cannot direct respondent to produce the following information contained within the VAERS files: the names, street addresses, and telephone numbers of the vaccinated person and the person's legal representative, and the medical records of the vaccinated person relating to the administration of the vaccine. To do so would be to thwart the express will of Congress. It would both defeat the privacy protection afforded to individuals who allegedly sustain an adverse event as the result of vaccination and potentially discourage reporting due to privacy violations.

3. The Discovery Privilege in 42 U.S.C. § 300aa-25(c) Limits the Discoverability of Certain Information Contained in VAERS Files

As explained above, the statutory language of the Vaccine Act makes plain that a special master has the authority to permit the discovery of all information in VAERS obtained pursuant to section 25(b) except for names, street addresses, and telephone numbers of the vaccinated person and the person's legal representative, and "medical records of such person relating to the administration of the vaccine," so long as the special master finds the information to be reasonable and necessary. The holding of the Supreme Court in Baldrige provides additional authority reinforcing congressional intent to protect and keep private personal information.

Here, petitioner specifically requests "complete redacted files for the Vaccine Adverse Event Reports." Motion at 1. The court construes this request to mean that petitioner seeks the production of both the VAERS reports as well as any supporting or follow-up medical records associated with those reports. Clearly, section 25(c) categorizes medical records relating to the vaccine administration as "information which may identify an individual" and accordingly prohibits their release to the public.[27] The special master cannot contravene the plain meaning of

[27] Petitioner makes a point of stating that the special master can avoid the literal interpretation of section 25(c) by providing for the redaction of individually-identifying information. Reply at 3. However, petitioner could not point to any provision in the Vaccine Act granting a special master the authority to direct the production of otherwise-private information (i.e., the "medical records of such person relating to the administration of the vaccine") by having the private information redacted. The Vaccine Act is the source of a special master's authority. In the special master's view, to follow the course suggested by petitioner would be to overstep her authority.

the statute and force the production of documents protected by a statutorily-created discovery privilege.[28]

Removing the supporting and/or follow-up medical records from petitioner's request leaves petitioner with a request for the production of VAERS reports. Again, according to the statutory language of the Vaccine Act and the application of Baldrige, the special master can only approve a request for the non-individually-identifying information included in the VAERS reports. The determinion of how best to provide this information to petitioner resides with the FDA.[29]

Now that the special master has determined what can be discovered, she must turn to the issue of whether the discoverable information is reasonable and necessary to her decision in the Omnibus Proceedings.

C. The Non-Individually-Identifying Information Contained in the 1,462 Requested VAERS Reports Is Not Reasonable and Necessary for the Special Master's Decision

The special master first addresses the reasonableness of petitioner's request. One aspect of reasonableness is the timing of petitioner's Motion. Petitioner's Motion, a formal request for discovery, was filed more than three months after the hearing. In typical litigation, discovery is accomplished prior to trial. See generally Fed. R. Civ. P. 26. Of course, the special master is aware that Vaccine Program cases are not typical civil litigation–the adjudication of cases under the Vaccine Act is meant to be more flexible. See 42 U.S.C. § 300aa-12(d)(2)(A)-(B). However, flexible ought not be construed to mean disorganized. More than two-thirds of the cases in the Omnibus Proceedings have been pending since 1999. The hearing was not conducted until October 13-15, 2004.[30] Thus, counsel had ample time–more than five years–in which to make

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[28] The special master's determination on this point does not preclude petitioner from obtaining nonprotected information via other means, such as a FOIA request.

[29] Contrary to respondent's representations, the information supplied on the Internet would not satisfy petitioner's request. The VAERS reports contain more data than the Internet database; namely, the entire narrative reported in Box 7 of the VAERS form ("Describe adverse events(s) (symptoms, signs, time course) and treatment, if any") may not be included. The "Symptom_Text" field in the Internet version of the VAERS database only contains 512 characters worth of information. See http://vaers.hhs.gov/search/README.txt (last updated Oct. 2003). The special master's cursory review of some VAERS data downloaded from the VAERS website indicates that more than a few records contain abbreviated "Symptom_Text" fields.

[30] While this particular case was filed on March 19, 2004, it replaced another lead case, Cramer v. Secretary of HHS, No. 99-428, which was filed on July 2, 1999. There is no evidence in the record that counsel sought formal or informal discovery in Cramer. If the instant case was

his discovery request.[31] Petitioner argues in the Reply that: "[p]etitioner cannot be expected to file a complete analysis of VAERS records that may be relevant to the issues in a particular claim when that claim is filed." Reply at 2. The special master agrees. However, the special master would expect that counsel would evaluate his cases on an ongoing basis to determine what evidence was necessary to prevail and seek to obtain evidence once it was determined to be necessary. In the Omnibus Proceedings, petitioner had over five years before the hearing to identify the necessary evidence and to seek discovery by formal or informal means. Here, petitioner failed to act. Thus, petitioner's failure to make a timely discovery request weighs against a finding of reasonableness.

A second aspect of reasonableness is the effect of petitioner's request on the special master's statutory mission to adjudicate cases as expeditiously as possible. In crafting the Vaccine Act, Congress explicitly stated that the Vaccine Program was to provide "a less-adversarial, expeditious, and informal proceeding for the resolution of petitions." 42 U.S.C. § 300aa-12(d)(2)(A). Congress further made it explicit that it desired special masters to issue decisions "as expeditiously as possible." Id. § 300aa-12(d)(3)(A)(ii). As stated above, many of the cases in Omnibus Proceedings already have been pending for over five years. Petitioner's posthearing discovery request has the potential to impede significantly the statutory requirement of the expeditious resolution of Vaccine Act petitions. This further delay mitigates against a finding of reasonableness.

Another aspect of reasonableness is the burden that petitioner's request places on the responding party. See Autism Order at *9. See generally Pecorella Response at 8-10. Petitioner seeks approximately 1,462 VAERS files. The VAERS files are in the custody of the FDA. Respondent provided the affidavits of two employees of the FDA: Robert Ball, M.D., and Ms. Beth Brockner Ryan. Response at Exhibits M & N. Dr. Ball states that it would require one person working full-time for four-to-six weeks to produce the requested documents. Ms. Ryan reports an even greater burden: that it would require one person working full-time for 313 days to redact the requested documents.[32] Thus, according to the special master's calculations, it could take the FDA 67-69 weeks, or well over a year, to satisfy petitioner's request. Such a

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not sufficiently developed, counsel should not have offered it as the substitute test case replacing Cramer.

[31] Furthermore, in these same five years, petitioner could have made a request for the VAERS files under the FOIA, as petitioner's counsel did in Watson.

[32] The estimates provided by Dr. Ball and Ms. Ryan are based on the production and redaction of approximately 1,462 VAERS files that include both the VAERS reports and the associated medical records. The special master has already found that she cannot direct the discovery of any medical records due to the constraints found in section 25(c). Because it is unclear how many of the VAERS files contain medical records, the court will treat these time estimates as maximums.

request, especially one made posthearing, is unduly burdensome. Even if petitioner's request required only 26 weeks of an FDA employee's time, see supra note 32, the request is unfairly burdensome. Respondent does not provide any cost estimates for satisfying petitioner's request. Instead, respondent states: "The VAERS [] is operated by a government contractor, so the processing of this request would almost certainly require a substantial expenditure of funds." Response at 13.

Petitioner's Reply suggests a way to alleviate any burden undertaken by the FDA in producing the 1,462 requested VAERS files. Petitioner proposes that prior to the production of any VAERS files, petitioner should be provided with access to the entire "Symptom_Text" field[33] for all 1,462 requested VAERS files. Petitioner would then review all of the "Symptom_Text" fields to identify the relevant files. To be certain, petitioner's suggested procedure appears on its face to be more efficient than the production of the complete set of requested VAERS files. In actuality, petitioner's suggested procedure may be just as time consuming as the initial request. While time might be saved by having the FDA produce fewer VAERS files, petitioner's plan adds an extra step: the production and review of the "Symptom_Text" field. Petitioner provides no estimated time period for the review of the "Symptom_Text" fields and there is no guarantee that the number of cases selected by petitioner will not be just as large as the initial request.

Also affecting respondent's burden is the fact that petitioner's discovery request does not end with the receipt of the VAERS data. Instead, in general terms, petitioner's goal is to take that raw data, analyze it, and provide the special master with the results of the analysis. Petitioner provides no estimated period of time for how long such an analysis might take. Given the enormous amount of time and costs expended by counsel for all parties in preparing their respective cases for hearing, it is a waste of counsels' resources to try these cases for a second time. Petitioner's proposed posthearing analysis is inherently unfair and squanders the resources of the court and of the parties.

Considering the posthearing posture of this case, coupled with the affidavits provided by respondent, petitioner's proposal for selecting VAERS files for production, and petitioner's intended use of the sought-after data, the special master finds that the burdens associated with petitioner's discovery request weigh against a finding of reasonableness.

A fourth factor weighing on reasonableness is what respondent refers to as the "vagueness" of petitioner's request. Respondent argues that many of the requested files are irrelevant to the Omnibus Proceedings. Response at 10-11. As examples, respondent provided a short list of cases he saw as irrelevant. See Response at Exhibit L. The court agrees that the cases selected and highlighted by respondent seem to be completely irrelevant. Of course, there is no way to determine how many of the 1,462 requested VAERS files are irrelevant without examining each entry in the VAERS database. This task should have been performed by

[33] See supra note 29.

petitioner prior to submitting the Motion in order to make the Motion as narrowly-tailored as possible. The lack of a narrowly-tailored Motion weighs against reasonableness.

In sum, the special master finds that petitioner's posthearing request for the production of 1,462 VAERS files is unreasonable. Furthermore, even eliminating the production of medical records from its reasonableness analysis,[34] leaving only a request for 1,462 VAERS reports, the special master still finds petitioner's request to be unreasonable–respondent might have a lighter burden, but the other facets of unreasonableness remain.

However, even if petitioner's discovery request were reasonable, the special master finds that the information to be provided as a result of the discovery request is unnecessary to her resolution of this case.

First, the special master again notes that petitioner's discovery request does not end with the receipt of the VAERS data. Petitioner intends to (1) seek out any cases of positive rechallenge that meet the criteria accepted by the IOM in the Pollard and Selby article, (2) analyze the requested VAERS files using a "Delphic" approach to form tentative conclusions about causation, and (3) ascertain how many of the files contain an adverse event diagnosed by a physician (ideally those diagnoses performed by a neurologist) in order to help prove the reliability of VAERS data. Petitioner's proposed uses of the requested VAERS files implicate an important issue related to the necessity question: whether petitioner would be able to accomplish the intended goals with the information the special master is statutorily authorized to permit to be discovered.

As stated above, the Vaccine Act permits only the disclosure of non-individually-identifying information contained in the VAERS reports; the associated medical records are protected by a statutory privilege. This constraint would prevent petitioner from performing a "Delphic" analysis of any medical records associated with the VAERS reports. This constraint also prevents petitioner from being able to determine whether a physician diagnosed the injury reported in the VAERS report.[35] Furthermore, the constraint effectively prevents petitioner from being able to confirm reactions that meet the IOM's criteria in the Pollard and Selby article. Accordingly, it seems unlikely to the special master that petitioner would be able to present any evidence, pursuant to petitioner's proposals, that would be reasonable and necessary to the special master's decision.

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[34] As discussed supra, medical records are protected from discovery by a statutory privilege.

[35] Because the special master cannot and will not approve the discovery of medical records associated with VAERS reports, she will forgo any discussion of whether proof of a physician-diagnosed injury truly helps prove the reliability of VAERS data.

Petitioner further argues that due to the uncertainty of how the Federal Circuit's pending decisions in Althen[36] and Capizzano might affect the amount of proof required to prove causation, petitioner must pursue all available avenues of discovery. Reply at 2. The special master interprets this contention as a necessity argument. For purposes of weighing the merits of any discovery motion, the special master is bound by the applicable statute and case law. The special master cannot and should not speculate concerning possible future decisions of the Federal Circuit. Nor should a special master tailor a discovery ruling to aid in the gathering of data potentially useful to a petitioner in contravention of a specific statutory provision. As described above, section 25(c) clearly prohibits the release of much of the information petitioner seeks.

There is another factor that sheds light on the necessity of the evidence petitioner intends to submit for the special master's consideration. The special master must return to the issue of the passage of time. Two-thirds of the cases within the Omnibus Proceedings have been pending at least five years. As counsel in the Omnibus Proceedings were gathering evidence and otherwise preparing their cases for a causation hearing, there was apparently no attempt to obtain the 1,462 requested VAERS files by way of a FOIA request or other means. The VAERS database has been collecting adverse event reports since 1990. See Frequently Asked Questions About VAERS, supra note 2; VAERS Public Data Download Instructions, at http://vaers.hhs.gov/scripts/data.cfm (last visited July 13, 2005). Thus, much of the data now sought by petitioner has been available during the entire pendency of the Omnibus Proceedings. Further, petitioner's counsel has been aware of the existence of VAERS data at least since he made his FOIA request in Watson on December 17, 1997.[37] See Petitioner's July 6 Response at Tab 2. If

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[36] During the pendency of this Motion, the Federal Circuit issued its decision in Althen. Althen v. Sec'y of HHS, 418 F.3d 1274 (Fed. Cir. 2005). The special master notes that in Althen, the Federal Circuit instructed:

> Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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. If [petitioner] satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994) (alteration in original) (citation omitted).

Id. at 1278.

[37] Given petitioner's counsel's handling of Vaccine Act cases since the inception of the Vaccine Program, it is more likely that he has been familiar with VAERS since its inception.

petitioner believed that the requested VAERS data and any conclusions that could be derived from the VAERS data were necessary to the special master's decision, counsel is hard-pressed to explain–indeed, he cannot explain–why he waited over five years, and until three and one-half months after the conclusion of the hearing, to initiate discovery.

Petitioner attempts to justify the untimely discovery request by explaining: "While counsel for this Petitioner may feel that this claim has already been proven and no further evidence is necessary, counsel is not free to play Russian roulette with claimant's future." Reply at 2. Petitioner's argument is not compelling. First, if petitioner does not believe the information is necessary, then the motion is unnecessary. Second, if petitioner's counsel did not wish to "gamble" with petitioner's case, then he should have sought discovery prior to hearing, not after the hearing ended. Discovery is to be conducted prehearing, not posthearing.

D. The Parties Raise Additional Issues that Must Be Addressed by the Special Master

Although the special master has found that the Vaccine Act grants her the authority to permit the discovery of only a portion of what was requested by petitioner but that petitioner's request is neither reasonable nor necessary, the parties have raised additional issues that require comment.

1. The Special Master Has No Authority to Direct the Conduct of a Scientific Study Within the Confines of the Vaccine Program

As a general matter, the special master believes that it is inappropriate for her to direct scientific research within the framework of the Vaccine Program. As the Federal Circuit in Knudsen ex rel. Knudsen v. Secretary of HHS explained:

> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies.

35 F.3d 543, 549 (Fed. Cir. 1994). Further, another special master recently noted:

> Thus, in the special master's view, the Program is not the appropriate forum for–and a special master should not preside over wide-ranging discovery, or should not devise unique procedures, aimed at–developing original scientific or medical theses. Indeed, scientific or medical "research" conceived and conducted in the context of litigation poses an inherent danger: scientific or medical "research" conceived and conducted in the context of litigation is not subjected usually to the time-honored practices in the scientific and medical communities of peer-review and of publication–two of several, significant

> touchstones of evidentiary reliability. See, e.g., Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593 (1993) ("[S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected."); Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995).

Schneider v. Sec'y of HHS, No. 99-160V, 2005 WL 318697, at *5 (Fed. Cl. Spec. Mstr. Feb. 1, 2005) (footnote omitted).

With the Vaccine Act, Congress created the National Vaccine Injury Compensation Program as a means to provide compensation to people injured by vaccines. See H.R. Rep. No. 99-908, pt. 1, at 3 (1986). The Vaccine Act established the position of "special master" to conduct proceedings to determine compensation. 42 U.S.C. § 300aa-12(a), (d). In addition, the Vaccine Act gave special masters the authority to perform specific, enumerated functions. Id. § 300aa-12(d). Of all of the functions enumerated in section 12(d), not one of them grants a special master the authority to direct or require vaccine research.

Petitioner argues that "[s]tudies in the context of litigation are nothing new in our system of jurisprudence" and that "government experts have been reviewing this data and publishing articles about vaccine safety throughout the course of litigation, many of which are directed at issues that are in dispute at the time." Reply at 4-5. While it is true that the government conducts ongoing research regarding issues that may be relevant to pending Vaccine Act cases, this special master is not aware that any special master has specifically directed the government to conduct these studies. A special master does not have the statutory authority to direct a government agency to conduct vaccine research, and a special master certainly cannot direct research pertaining to a specific case.

2. The AVEC Study Is Not Comparable to Petitioner's Proposed Analysis and Study of the VAERS Data

Petitioner's proposed analysis of the requested VAERS files differs from the AVEC study that it promises to model itself after.[38] The AVEC looked at all VAERS reports concerning the

[38] Petitioner explicitly states his desire to perform an analysis "such as was engaged in by the authors" of the AVEC study. Motion at 1. Respondent distinguishes the use of VAERS data by AVEC by stating that AVEC used data in VAERS that cannot be released to the public pursuant to the Vaccine Act (because the data was not collected pursuant to section 25(b)). See Respondent's May 20 Response. Petitioner takes exception to respondent's attempt to distinguish the operations of AVEC from how other parts of HHS operate in analyzing and reporting on VAERS data and submits articles showing that HHS regularly reviews and reports on VAERS data. See Petitioner's May 24 Reply at Tabs A-H. Petitioner's Motion proposes a "Delphic" analysis of the requested VAERS files such as performed by AVEC and described in

anthrax vaccine to make some tentative conclusions about causation. Petitioner proposes to look at a subset of hepatitis B vaccination reports (1,462 VAERS files that petitioner alleges to be cases of positive rechallenge, but see supra note 5) in order to produce cases exhibiting positive rechallenge as accepted by the IOM or to make tentative conclusions about causation.

The first difference is that petitioner does not propose analyzing all hepatitis B-related VAERS files, just the files identified as possible positive rechallenges. AVEC analyzed all anthrax reports. Second, petitioner did not identify a panel of experts to analyze the requested data. In fact, only one physician was ever referred to in petitioner's pleadings. Certainly, an expert consensus cannot be reached by one individual. Third, unlike in the AVEC study, petitioner does not identify any denominator data.[39] Thus, the lack of similarities to the AVEC study is another reason preventing the special master from approving petitioner's Motion.

3. Petitioner's References to the Vaccine Safety DataLink Project Are Irrelevant to Petitioner's Motion

The Vaccine Safety DataLink ("VSD") Project:

> involves partnerships with seven large health maintenance organizations (HMOs) to continually monitor vaccine safety. VSD is an example of a large-linked database (LLDB) and includes information on more than six million people. All vaccines administered within the study population are recorded. Available data include vaccine type, date of vaccination, concurrent vaccinations (those given during the same visit), the manufacturer, lot number and injection site. Medical records are then monitored for potential adverse events resulting from immunization. The VSD project allows for planned vaccine safety studies as well as timely investigations of hypotheses. At present, the VSD project is examining potential associations between vaccines and a number of serious conditions. The database is also being used to test new vaccine safety hypotheses that result from

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the article by Sever et al. Accordingly, HHS's other studies, HHS's access to data, or any of HHS's practices are irrelevant. The only relevant issue here is whether petitioner can duplicate AVEC's methodology.

[39] In the AVEC study, the expert panel had access to denominator data from the Defense Medical Surveillance System ("DMSS"). DMSS contains one record for every dose of administered anthrax vaccine. Sever et al., supra note 7. However, petitioner did not provide evidence that similar denominator data exists for VAERS reports. See also Neal A. Halsey, M.D., Anthrax Vaccine and Causality Assessment from Individual Case Reports, 11 Pharmacoepidemiology & Drug Safety 185, 185 (2002) (attached as Exhibit J to the Response).

the medical literature, VAERS, changes in the immunization schedule or from the introduction of new vaccines.

Overview of Vaccine Safety, supra note 2.

Neither petitioner's Motion nor petitioner's Reply mentioned the VSD project or database. Then, in Petitioner's May 20 Response, in attempting to answer the special master's question about petitioner's prior attempts to obtain the 1,462 requested VAERS files, petitioner states: "The attached IOM report details the difficulties that external researchers have had in accessing the Vaccine Safety Datalink (VSD) database."[40] Petitioner's May 20 Response at 2. Petitioner adds: "Petitioner would like some Court–and hopefully this Court–to oversee and require proper access to the VSD data by Petitioner's experts." Id. at 2.

Then, in Petitioner's May 24 Reply, petitioner twice refers to the VSD database in discussing the access granted to government and private-sector experts to the VAERS and VSD databases. Petitioner's May 24 Reply at 4, 7.

Finally, and inexplicably, in Petitioner's July 6 Response, petitioner makes numerous references to the VSD database, as if petitioner's Motion requested information from both VAERS and VSD. Petitioner's July 6 Response at 1-3. Further, petitioner appended two exhibits to Petitioner's July 6 Response that deal solely with the VSD database. Exhibit 1 is entitled "So-called 'Access' to VSD" and Exhibit 3 is the "Public Notification of Award of Contract 200-2002-00732, American Association of Health Plans," the ten-year contract awarded to manage the VSD project.

It is beyond dispute that petitioner's Motion did not request discovery from the VSD database. Therefore, the special master finds petitioner's references to the VSD database to be irrelevant to the issue at hand. For the purposes of ruling on the instant Motion, the difficulties encountered by petitioner's counsel and/or any experts retained by petitioner's counsel in obtaining data from the VSD database, although unfortunate, are not pertinent. The special master's sole concern in this case is petitioner's Motion requesting discovery of 1,462 VAERS files. Petitioner's interchanging use of the acronyms VAERS and VSD, which are separate and distinct databases, creates confusion. These databases are not one and the same and petitioner's anecdotal stories describing the difficulties that arose in other cases do not lend support for the granting of the instant Motion.

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[40] Petitioner did not attach the referred-to report from the IOM, and has not subsequently filed it despite the stated intent to do so, but the court believes petitioner is referring to the report titled "Vaccine Safety Research, Data Access, and Public Trust," published by the IOM in early 2005. According to the IOM, the report deals solely with the policies and procedures regarding researcher access to the VSD database. See IOM, Vaccine Safety Research, Data Access, and Public Trust, at http://www.iom.edu/report.asp?id=25184 (last visited July 17, 2005).

4. The Hearings Requested by Petitioner Are Unnecessary

Petitioner makes several requests for a hearing in the Motion and supporting pleadings. Motion at 1; Reply at 4-5; Petitioner's May 20 Response at 3; Petitioner's May 24 Reply at 7; Petitioner's July 6 Response at 1, 5. The hearing requests center around the relevancy and proposed uses of the requested VAERS files, researcher access to the VSD database, and the admissibility of evidence supplied by Dr. Geier.[41] In regard to the relevancy and proposed uses

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[41] Petitioner states: "Quite frankly, this counsel is getting tired of ad homonym [sic] attacks on Dr. Geier, simply because he refuses to be intimidated and continues to publish articles in the peer reviewed medical literature that deal with causation issues in these cases." Reply at 4. Petitioner then adds a footnote citing Exhibit I to the Response as an example of such a "vicious" attack. Exhibit I is a statement by the American Academy of Pediatrics ("AAP") entitled "Study Fails to Show a Connection Between Thimerosal and Autism," that critiques an article by Dr. Geier and David A. Geier: Thimerosal in Childhood Vaccines, Neurodevelopment Disorders and Heart Disease in the United States, 8 J. Am. Physicians & Surgeons 6-11 (2003) (hereinafter "Thimerosal in Childhood Vaccines").

Petitioner makes several comments regarding the AAP statement. The first comment is that the statement is unsigned. This is true and the special master thus assumes that the statement is the position of the AAP. Petitioner's second comment is that the statement concerning Dr. Geier has been removed from the AAP website. By conducting a search from the AAP homepage, however, the special master was easily able to find the statement.

Petitioner's third comment was: "The AAP has in fact published a Letter acknowledging that they were wrong about what was said in an article in their journal criticizing Dr. Geier for not having denominator data that he clearly did have, and which had in fact been provided by the CDC." Petitioner did not provide a copy of the letter. However, special master research revealed a September 2004 article in Pediatrics, the journal of the AAP, by Parker et al. entitled "Thimerosal-Containing Vaccines and Autistic Spectrum Disorder: A Critical Review of Published Original Data." Part of the article discusses Thimerosal in Childhood Vaccines, and, inter alia, questions Dr. and Mr. Geier's access to and use of certain denominator data. In a letter to the editor published in the January 2005 issue of Pediatrics, Parker et al. explained that Dr. Geier had informed them that he did indeed have access to the denominator data they questioned.

First, the special master notes that while Pediatrics is the official journal of the AAP, the articles published in the journal are not necessarily the views or opinions of the AAP. See AAP, About Pediatrics, at http://pediatrics.aappublications.org/misc/about.shtml (last visited August 8, 2005). Further, the AAP statement was issued prior to the publication of the article by Parker et al., and accordingly, does not cite the article. Thus, the Parker et al. article has little bearing on the AAP statement.

of the requested VAERS files, the special master finds that she has sufficient information from the pleadings to forgo a hearing. The Vaccine Act controls the outcome of petitioner's Motion and makes a hearing unnecessary. Further, because the VSD database is not the subject of petitioner's Motion, the special master finds no reason to conduct a hearing regarding difficulties in accessing the VSD database.

Finally, with regards to the admissibility of evidence supplied by Dr. Geier, the special master finds that a Daubert hearing is unnecessary. As discussed above, the Motion indicates that petitioner wants to use the requested VAERS data in the following ways: (1) to seek out any cases of positive rechallenge that meet the criteria accepted by the IOM in the Pollard and Selby article, (2) to analyze the requested VAERS files using a "Delphic" approach to form tentative conclusions about causation, and (3) to ascertain how many of the files contain an adverse event diagnosed by a physician in order to help prove the reliability of VAERS data. The Motion may be interpreted to indicate an intention to use Dr. Geier to look for cases of positive rechallenge. While the analysis of VAERS data requires a medical expert, the mere identification of cases of positive rechallenge, a simple, clerical activity, does not seem to require any medical expertise.[42]

Second, the AAP statement identifies numerous criticisms regarding the methodology behind Thimerosal in Childhood Vaccines; denominator data was merely one aspect of the AAP's criticism. Thus, even if the Parker et al. letter to the editor was directed at the comments in the AAP statement and applied to the AAP's criticism, other methodological criticisms remained. The AAP statement is not discredited by the subsequent publication of the letter to the editor of Parker et al.

The special master cannot see any ad hominem or "vicious" attacks directed against Dr. Geier within the AAP statement or the article by Parker et al. Certainly, both publications discuss and critique the methodology used by Dr. and Mr. Geier. However, this type of critique is aimed at and necessary for the furtherance of science.

[42] Further, petitioner submitted an article by Dr. Geier and Mr. Geier as Exhibit 1 to the Reply. M.R. Geier & D.A. Geier, A Case-Series of Adverse Events, Positive Re-Challenge of Symptoms, and Events in Identical Twins Following Hepatitis B Vaccination: Analysis of the Vaccine Adverse Event Reporting System (VAERS) Database and Literature Review, 22 Clinical and Experimental Rheumatology 749 (2004). Dr. Geier and Mr. Geier undertook "a retrospective examination of the VAERS database," evaluating "reports of autoimmune conditions including arthritis, rheumatoid arthritis, myelitis, optic neuritis, multiple sclerosis (MS), GBS, glomerulonephritis, pancytopenia, and thrombocytopenia" and positive rechallenge reports of "arthralgia, arthrosis, arthritis, neuritis, fatigue, chronic (based upon a one year follow-up) fatigue, myalgia, gait abnormalities, neuropathy, tremor, GBS, flu syndrome, erythema multiforma, and alopecia" following hepatitis B vaccinations. Id. at 750-51 (emphasis added). This article was published in 2004 and the authors indicate that they evaluated VAERS reports from many of the same categories of VAERS files requested by petitioner. Thus, it appears that

Additionally, the "Delphic" analysis contemplated by petitioner requires a panel of experts, not a lone individual, to analyze the data. Finally, there is no reason to believe that Dr. Geier's services are required to determine whether a physician diagnosed an injury (and even if Dr. Geier did perform this task, it requires no actual analysis; rather, it is a question of straight fact). Because the court cannot see where Dr. Geier's services as an expert are necessary to perform the tasks contemplated by petitioner in the Motion, the special master concludes that a Daubert hearing is unnecessary.[43]

5. Petitioner's Motion Is Not the Appropriate Vehicle for Redress of Perceived Ills Associated with the Vaccine Program

Petitioner's pleadings raise a litany of complaints against the Vaccine Act and the Vaccine Program. For example, in petitioner's Reply, counsel states: "While counsel is not suggesting that efforts were being made to hide [the cases categorized as "asthenia"], it does seem rather curious that over 1600 cases of adverse reactions after hepatitis B vaccine were put under such an unlikely descriptive term."[44] Reply at 5. But, then, in Petitioner's May 20 Response, petitioner states: "[C]ounsel has very little faith in the way [the cases categorized as "asthenia"] may have been hidden from external investigators." Petitioner's May 20 Response at 1. It is apparent to the special master that petitioner believes that the FDA is hiding information in its processing of VAERS data. Petitioner's statement is made without support[45] and the special master fails to see how categorizing a symptom as "asthenia" establishes any wrongdoing on the part of the FDA.

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much of the work petitioner implies would be done by Dr. Geier has already been done by Dr. Geier.

[43] As explained supra note 42, petitioner submitted an article written by Dr. Geier and Mr. Geier as Exhibit 1 to the Reply. The article describes the authors' review of case reports from the literature and from VAERS and concludes that there are reports of adverse events and positive rechallenges that have been associated with the hepatitis B vaccine. This article is better suited as evidence pertaining to causation and not evidence pertaining to whether petitioner's Motion should be granted. The court will treat the article submitted as Exhibit 2 to the Reply, Shaw et al., Postmarketing Surveillance for Neurologic Adverse Events Reported after Hepatitis B Vaccination. Experience of the First Three Years, 127 Am. J. of Epidemiology 337 (1988), in the same manner. Respondent may respond to these two articles in his posthearing brief if he chooses to do so.

[44] Petitioner fails to explain why a term that means "lack or loss of strength; weakness" is "such an unlikely descriptive term" for an adverse reaction after a hepatitis B vaccination.

[45] Petitioner attempts to use the IOM report entitled "Vaccine Safety Research, Data Access, and Public Trust," see supra note 40, to support his argument. However, the report concerns the VSD database and not the VAERS database.

Next, regarding perceived Vaccine Program failings, counsel claims:

Discovery. Petitioners do not have "discovery as a matter of right." Petitioner's May 20 Response at 3. Further, "the DOJ argues that Petitioners should not be allowed any discovery that would assist them in proving causation." Petitioner's May 24 Reply at 3-4.

Access to Data. Petitioners do not have "access to the same databases used by Respondent's experts." Petitioner's May 20 Response at 3.

Interim Fees and Costs. Petitioners are not entitled to "interim fees and costs to allow counsel to spend the money that needs to be spent to seriously attack these cases with numerous experts in multidisciplinary fields." Id. And, "Petitioners receive no interim fees and costs, so they cannot afford to hire experts and conduct the studies that are normal in civil litigation." Petitioner's May 24 Reply at 4.

Access to Experts. "When it comes to seeking out experts, Petitioners are competing with the United States government, an entity that pays for its experts' time and expenses promptly and without question, an entity that grants awards which many of these doctors rely upon for their very survival, and an entity that pays the experts to first conduct studies with full access to the VAERS and VSD databases and then pays them again to come testify about the results of their peer-reviewed articles (articles that are often published with the prodding and encouragement of the government, as evidenced by Tab I[46])." Id. (footnote added). Further, "Respondent's experts have a tremendous advantage over Petitioners' experts because of their unfettered access to data and materials that they collect from the very victims who are claiming injuries and seeking compensation. The Respondent is then using tax dollars, and even worse, funds from the NVICP, to pay their experts to publish articles that can be used against these very victims in this remedial compensation program that some of us pushed for years ago to get these cases out of the civil arena and into a fair system for determining causation." Id. at 6-7.

Burden of Proof. "The DOJ constantly pleads that Petitioners are supposed to file 'complete' petitions in the program, with all medical records, affidavits, expert reports, etc. attached. In other words, Petitioners are supposed to be able to prove their cases completely before they are even filed." Id. at 3; see also Pecorella

[46] Tab I is a letter from José F. Cordero, M.D., M.P.H., Assistant Surgeon General and Director of the National Center on Birth Defects and Developmental Disabilities, to Jerold F. Lucey, M.D., Editor in Chief of Pediatrics, requesting "an expedited review and consideration" of an enclosed manuscript concerning thimerosal and autism.

> Brief at 3. Further, petitioners "face an uncertain burden of proof that to many seems more onerous than the one faced in front of juries every day in this country." Petitioner's May 20 Response at 3. The "burden of proof in the NVICP has proven to be an elusive target that, in the humble opinion of this counsel, is higher than what would be faced before most juries in this country. Additionally, because of the doctrine of the waiver of sovereign immunity, the benefit of the doubt always goes to the government." Petitioner's May 24 Reply at 4.
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> Special Masters. Petitioners appear before "Special Masters who have heard so much from so many experts that they can hardly avoid developing preconceived notions that often must be overcome." Petitioner's May 20 Response at 3.

Petitioner's counsel concludes: "It is a situation that this counsel has lobbied Congress to repair for at least 6 years, to the point where a legal name change to 'Don Quixote' would not be inappropriate." Id. at 3. Counsel further laments: "For some of us who have spent our lives trying to make this example of tort reform work, testifying before Congress and lobbying for changes that seem so reasonable and necessary[,] there is a yearning that is growing to return to the civil arena from which we came. The frustration of knowing that you could do more to help people who deserve help, but knowing you can't do more is oppressive." Petitioner's May 24 Reply at 7 (footnote omitted). Finally, petitioner's counsel states that he "began testifying on the Hill in 1999, and has been arguing ever since for (1) changing the ridiculous 3-year statute of limitations; (2) lowering the burden of proof; (3) providing interim fees and costs; and improving some elements of damages, but Don Quixote had better success." Id. at 7 n.4.

Although the special master regrets counsel's frustration with the Vaccine Program and applauds his goal to achieve compete justice for his clients, the remedies sought by counsel reside with Congress. Certainly, this special master has no control over those areas that require legislative change (i.e., right to discovery, interim fees and costs, reducing the burden of proof, statute of limitations, and the appropriate allocation of tax dollars). Additionally, the special master is guided by the same statute and case law that guide petitioner in determining the correct burden of proof in Vaccine Act cases. Further, the special master has no control over the funding of government research and how much the government compensates experts for their services. Likewise, the special master lacks the statutory authority to remedy any perceived inequalities in the access to vaccine-related data.[47] The only issue properly before the special master is whether

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[47] As discussed above, petitioner has a previously-utilized means for obtaining the requested VAERS files: a FOIA request. The court also notes that government agency employees have access to information that the agency collects for routine use. 5 U.S.C. § 552a(b). Further,

> [d]ata and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other

to grant petitioner's Motion and she rests her decision entirely upon the provisions of the statute in its present form.[48]

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special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

21 C.F.R. § 20.84 (2005).

[48] Three of petitioner's complaints require special comment. First, petitioners are not required to prove their case before filing their petitions. However, the Vaccine Act does require petitions to contain an affidavit containing information regarding certain jurisdictional issues, all of the relevant medical records, and a statement identifying anything that was unavailable at the time of filing and the reasons for the unavailability. 42 U.S.C. § 300aa-11(c).

Second, counsel is incorrect when he states that special masters have certain unfair preconceived notions about evidence presented in Vaccine Program, which prejudice them against petitioners.

Third, the special master rejects petitioner's implication that respondent's experts offer testimony adverse to petitioner's claims solely because they are well-paid. That suggestion, made without specific, concrete evidence, is unfair and inappropriate. The special master strongly believes that the vast majority of expert witnesses who testify in Vaccine Program cases do so because of their sincerely-held beliefs and not due to any financial pressures. As petitioner's counsel is fully aware, vaccines are generally safe. Nevertheless, on rare occasions, individuals can experience an adverse reaction to a particular vaccine. The fact that two honest and competent experts reach diametrically opposed conclusions regarding whether a vaccine can cause and did cause an injury does not render one of those experts dishonest. Moreover, the state of the research concerning vaccine-related injuries and deaths is such that researchers have arrived at numerous, conflicting conclusions. It is therefore not surprising that petitioners and respondent are able to locate experts who support their respective cases.

The special master is not blind or unsympathetic to the frustrations that face petitioners, their counsel, and their expert witnesses. That said, because the special master cannot fashion a remedy for any of petitioner's perceived ills arising from the statute, counsel's energies are better focused elsewhere when seeking to amend the Vaccine Act to ensure full and complete relief for a client.

6. Petitioner's Request to Strike Respondent's Epidemiological Evidence Should Be Made in a Posthearing Brief

In Petitioner's May 20 Response, petitioner makes the following request: "In the alternative, Plaintiff [sic] would ask that every single epidemiological article used by the Respondent to be stricken from the evidentiary record in these cases, and that their experts not be allowed to rely on any arguments or statements concerning 'the lack of epidemiological evidence.'" Petitioner's May 20 Response at 3. This request stems from petitioner's complaint that he has been prevented from accessing VSD data. Because VSD data is not at issue here, the special master denies petitioner's request. If petitioner desires to make an argument regarding the weight the special master should afford respondent's epidemiological evidence, the argument should be made in the posthearing brief.

7. Petitioner Is Not Entitled to a Presumption that the 1,462 Requested VAERS Files Support Petitioner's Claim

Finally, petitioner's counsel in Pecorella[49] contends that if the special master cannot compel the production of the 1,462 requested VAERS files, respondent should be deemed to have destroyed evidence, thus entitling petitioner to the presumption that the "destroyed" evidence supports petitioner's case. Pecorella Brief at 6. Counsel primarily relies upon RCFC 37(b)(2)(A),[50] which permits the court to establish an adverse factual determination if a party fails to comply with a discovery order.[51] Id.; RCFC 37(b)(2)(A). Counsel's reliance on RCFC

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[49] It is noteworthy that this petitioner recently opted into the Omnibus Proceedings. Nothing precludes this petitioner from filing her own FOIA request.

[50] Counsel erroneously asserts that RCFC 37 is not incorporated by Vaccine Rule 7. Pecorella Brief at 6; see also id. at 3-4, 8-9.

[51] Petitioner's counsel in Pecorella also cites case law that supports the proposition that in cases of spoliation through negligence, gross negligence, or actual knowledge, the adversely-affected party is entitled to a rebuttable presumption that the missing evidence would be favorable. Pecorella Brief at 6. See generally Residential Funding Corp. v. DeGeorge Fin. Corp., 306 F.3d 99 (2d Cir. 2002); One Beacon Ins. Co. v. Broad. Dev. Group, Inc., No. 04-5517, 2005 WL 2077499 (6th Cir. Aug. 29, 2005) (per curiam). Counsel has made no showing that the information now sought has been withheld or destroyed for any of those three reasons. In fact, counsel cannot make this showing because respondent has not disregarded a discovery request. There is no evidence in the record that petitioner sought discovery prior to hearing. In addition, respondent is waiting for the instant decision of the special master as to whether he must produce the 1,462 requested VAERS files. Thus, it is wholly unfair to attribute constructive destruction of evidence where petitioner failed to seek discovery, where respondent has not disregarded a discovery order of the special master, and where some of the key information sought by

37(b)(2)(A) is misguided. First, prior to this ruling, the special master has not issued any discovery orders; thus, respondent has not disobeyed a discovery order. Second, because the special master has found that petitioner's request for the production of the discoverable portion of the 1,462 VAERS files is unreasonable and unnecessary, respondent is not obligated to produce any materials. Therefore, respondent cannot be deemed as having "destroyed" evidence or failing to comply with a discovery order.

III. CONCLUSION

For the reasons stated above, Petitioner's Motion for Production of Documents is DENIED.

Because no outstanding posthearing motions remain to be decided, the special master is prepared to schedule deadlines for the posthearing briefs in the Omnibus Proceedings. A briefing schedule will follow.

IT IS SO ORDERED.

Margaret M. Sweeney
Special Master

petitioner is protected from disclosure by statute. It is hard to conceive of a more unjust and inappropriate case to apply constructive destruction than the case at bar.