ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,

Various Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

AUTISM MASTER ~~FILE~~
Special Master George Hasting

PETITIONERS' PROPOSED CONDUCT OF GENERAL CAUSATION HEARING AND SUBSEQUENT EFFECT OF RULING

I. INTRODUCTION

The Petitioners' Steering Committee (PSC) of the Omnibus Autism Proceeding (OAP) respectfully submits this memorandum outlining its positions with respect to various outstanding issues pertaining to the OAP. The Special Master has set a hearing date of June 11, 2007 to begin the presentation of evidence and testimony regarding issues of general causation; that is, whether thimerosal, or the MMR vaccine, or a combination of the two, can cause neurological injuries in certain children. The PSC proposes that the general causation inquiry begin with a "test case" on June 11, an individual claimant currently filed in the OAP that will serve as a representative case for a significant number of children in the program who claim that a *combination of thimerosal exposure and the MMR vaccine caused injury.*

It is expected that additional hearings will follow this hearing, hearings addressing questions of causation involving thimerosal exposure only (without MMR involvement), and MMR exposure only (without thimerosal involvement).

Several significant events will occur before the "test case" hearing in June 2007. The PSC has a pending Motion to Compel that the Special Master will decide. Based on that decision, additional discovery may occur. As part of the hearing both parties will file expert reports. This memorandum will discuss each of these issues. It will address the nature and scope of the evidence to be presented at the hearing. It will address the PSC's view of the proper evidentiary standard to be used by the Special Master, taking into account the Vaccine Act's legislative history, the statute (42 U.S.C. §300aa 1 et seq.) and binding Federal Circuit decisions interpreting the statute.

In addition, the PSC will set out a proposed orderly agenda for the hearing that will address expert testimony with respect to individual "test" cases. Lastly, the memorandum will address the PSC's view of the effect or the Special Master's rulings with respect to the 4,700 cases in the OAP.

II. PROCEEDINGS TO DATE

On July 3, 2002, the Chief Special Master issued an Order "to address an unusual situation facing" the Vaccine Program. Autism General Order #1, page 1.[1] The "situation," the Chief Special Master said, "arises out of a concern in recent years that certain childhood vaccinations might be causing or contributing to an apparent increase in ... a type of serious neurodevelopmental disorder known as 'autism spectrum disorder' ...." Id. At the time the Order was issued, approximately 400 autism claims had been filed in the Vaccine Program. Order, p. 2. It was anticipated that "approximately 3000 to 5000" autism claims would be filed

1 As the Special Master is well aware, the correct cite is In Re Claims For Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopomental Disorder, Various Petitioners v. Sec'y of HHS. For convenience, citations will be to "Order, p. __").

in the Vaccine Program. *Id.* at 2.[2] In this event, it was clear, processing "such a large number of cases [would] stretch thinly the resources" of the Program. *Id.* at 2. Deeming it to be "in the interests of all" that the "the court aggressively but fairly manage this docket to ensure a timely presentation and resolution of the difficult medical and legal issues raised in these cases," the Chief Special Master established the Omnibus Autism Proceeding (OAP). Order at 2. At the suggestion of "an informal advisory group" of petitioners' counsel, a "general plan" was adopted whereby a special master would "conduct a general inquiry into the causation question, then apply the conclusions reached in that inquiry to the individual cases." Order at 3.

At the outset of the OAP, however, petitioners' counsel advised the Special Master that they needed "more time for the science to crystallize, to obtain experts, and in general to prepare their proof concerning the difficult medical and legal causation issues." Autism General Order #1, at 3. In addition, counsel requested "extensive discovery - documents, studies and raw data from government agencies and ... vaccine manufacturers - information relevant to the general causation issue, through this court's discovery process." *Id.* As a result of this request, it was decided that:

> The inquiry will proceed as generally proposed by petitioners' attorneys—i.e. a period for any court approved discovery concerning the general causation issues, followed by a designation of experts for each side, an evidentiary hearing, and finally a special master's ruling on the general causation issue. Subsequently, the general causation conclusions will be applied to the individual cases.

Order at 4.

To represent the interests of petitioners in the OAP, a Petitioner's Steering Committee (PSC) was established and the respondent designated to attorneys to act as "lead counsel." *Id.* at 4. An Autism Master File was established to "constitute an evidentiary record with respect to the

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[2] As of today, "about 4,750" autism claims have been filed in the Program. *See*, "Autism Update - September 7, 2006."

general causation issue" and the file would be "open to inspection by any interested party." *Id.* at 4. Finally, an initial "master schedule" was prepared.

Discovery proceedings in the OAP, as the Special Master is aware, have been conducted over the past four years and are continuing. During these years, the PSC has performed extensive legal services on behalf of their autistic clients. Among other things, the PSC has prepared and filed detailed interrogatories and requests for production of documents; reviewed hundreds of thousands of produced documents;[3] responded to the respondent's motion for a protective order; prepared memoranda concerning third-party discovery, judgments, and attorneys fees; prepared notices of depositions and motions for subpoenas; reviewed and responded to Merck's, Baxter's, Wyeth's and SmithKline's motions to intervene; prepared motions and supplemental motions to compel production; prepared and presented oral arguments concerning motions to compel; prepared for and conducted depositions of representatives of the Center for Disease Control and Prevention ("CDC"), the Agency for Toxic Substances and Disease Registry and the Food and Drug Administration ("FDA"); conducted evidentiary hearings with expert witness concerning the need for additional discovery; identified, prepared, and disclosed expert witnesses; prepared a proposal concerning the time, place, and substance of the OAP; and prepared a substantive Motion to Compel Production of VSD documents.

III. PRE-HEARING ISSUES TO BE RESOLVED

a) Discovery

At the present time, the PSC has two remaining discovery requests:

1) The remaining vaccine license materials; and

2) Access to the Vaccine Safety Datalink (VSD), which is now the subject of a Motion to Compel.

[3] Indeed, the PSC's discovery requests have resulted in the production of approximately 216,000 pages of materials from government files. Autism Update - September 9, 2006, page 2.

b) Scheduling Deadlines

The actual dates for the parties' expert reports on the "general causation" issue have been set. At the time the dates for expert filings were set, the PSC did not anticipate presenting a test case for adjudication and did not anticipate that such a test case (involving an actual claimant rather than a "hypothetical" claimant) would be presented as representative of a large number of cases in the OAP. In now proposing an individual test case in June 2007, the PSC also proposes to change the expert report schedule. The PSC proposes that four experts who are preparing reports and planning to testify on issues of causation in the thimerosal/MMR test case file their reports as per the current schedule. Any other expert reports would be deferred because they would not necessarily be directly relevant to the instant test case, they depend in large part on information subject to the pending motion to compel VSD discovery, and they would likely need to be significantly revised in light of any VSD or other population study published during the pendencey of the OAP, limiting their immediate usefulness.

The PSC now proposes the following dates for expert reports in the test case to be adjudicated in June 2007:

PSC expert reports	2/16/07
Respondent's expert reports	4/17/07
First General Causation Hearing (Test Case)	6/11/07

Additional dates for expert reports and hearings on other theories of causation would be set upon resolution of the pending PSC Motion to Compel.

c) Location of Proceedings

The Special Master has decided that OAP hearings will be conducted in Washington, DC at a location yet to be determined. The PSC expects that the facility chosen to house the proceedings will be large enough to accommodate the significant number of persons who may choose to attend.

d) Transparency of Proceedings

The PSC is deferring for the time being taking a position on privacy, confidentiality and public access issues pending resolution of those important issues with the claimant(s) who would participate as test cases in these proceedings.

IV. THE STATUTORY SCHEME - THE VACCINE ACT

a) Legislative History

The Vaccine Program was established (1) to compensate persons injured by vaccines; and (2) to protect the nation's existing vaccine supply and encourage the development of new and safer vaccines. The second goal would be accomplished, Congress believed, by reducing the liability risks of the manufacturers of vaccines. In this regard, it is worth repeating Congress's "principal findings" that required the establishment of the Vaccine Program. They were:

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

H.R. Rep. No. 99-908, 99th Cong., 2d Sess. at 5 (1986).

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

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

b) the instability and unpredictability of the childhood vaccine market ..... Id. at 7.

To remedy these concerns, the Vaccine Program was established. Congress hoped the Vaccine Program would lessen the number of lawsuits against manufacturers. In so doing, it hoped the Vaccine Program would promote the "development of both new and improved vaccines ...." *Id.* at 4. It also hoped it would help to create, "a new system for compensating individuals who have been injured by immunizations routinely administered." *Id.* at 3. Such awards, Congress intended, would "be made to vaccine injured persons quickly, easily, and with certainty and generosity." *Id.*

Prior to enacting the Vaccine Act, congress recognized the uncertainty of the existing science about whether vaccines were even capable of causing serious injuries. However, congress realized, this "uncertainty" of the science did not stop civil lawsuits against vaccine-manufacturers, and congress was loath to pre-empt all rights to file civil litigation against vaccine manufacturers. For this reason, congress resolved to establish a standard of proof in the Vaccine Program that would allow meritorious cases to be resolved in the Vaccine Program. Thus, an excerpt from legislative history of 42 U.S.C. § 300aa-13:[4]

> The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.[5]

H.R. Rep. No. 99-908 at 18; U.S. Code Cong. & Admin. News 1986, at 6359. *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999).

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[4] §13 of the Vaccine Act governs the standard of proof for not-Table injuries, including the injuries alleged by all claimants in the OAP.

[5] Due to this stated congressional intent, courts have held that "close questions of causation must be resolved in favor of petitioners." *McClendon v. Sec'y of HHS,* 24 Cl. Ct. 329, 334 (1991). See also Althen v. Sec'y of HHS, 418 F. 3d. 1274 (USCAFC 2005).

b) The statute

As enacted, then, the Vaccine Act has a unique evidentiary standard, a relaxed standard, one that facilitates resolution of cases in the Vaccine Program and discourages the diversion of cases to the civil arena. It does not require a petitioner to prove his or her case with scientific certainty. It does not require "truth." It does not require a petitioner to show "cause **in fact**." The statute simply requires a petitioner to show that the vaccine was the "legal" cause of the injury.

Thus, the Vaccine Act speaks of compensating "any illness, disability, injury or condition not set forth in the Vaccine Injury Table *but which was caused by a vaccine* ...." §11 (c)(1)(C)(ii)(I)(emphasis added), which the petitioner "has demonstrated *by a preponderance of the evidence*" (§13 (a)(1)(A)) was due to the vaccine (emphasis added), and that there "is not a *preponderance of the evidence* that the ... injury ... is *due to* factors unrelated to the ... vaccine ...." §13 (a)(1)(B)(emphasis added).

Given this standard, it would be legal error for the Special master to interpret these sections as somehow requiring "cause-in-fact," "truth," or scientific certainty. The PSC is confident that the Special master will not do so.

c) Federal Circuit Interpretations of the Statute

i. Introduction

How has the Federal Circuit interpreted the Vaccine Program's evidentiary standard? The Federal Circuit's interpretations have embraced the congressional spirit of the law. In this regard, it is imperative that the Special Master in overseeing the OAP, give full force and effect to recent Federal Circuit decisions describing a petitioner's burden in the Vaccine Program. Indeed, the PSC submits, unless the proper evidentiary standard is used with respect to the 4,700 autistic children in the OAP, chaos will result. Hundreds of autistic children, perhaps thousands, may find the civil arena more attractive and may opt out of the program to file civil actions against vaccine manufacturers. If this happens, the Vaccine Program will have failed. It will not happen, however, if the proper evidentiary standard, one less restrictive than that in the civil

arena, is used by the Special Master to ensure that the children get their "day in court" in the Program.

ii. Federal Circuit decisions

Since the inception of the Vaccine Program, the Federal Circuit has recognized the Program's relaxed evidentiary standard for a petitioner to demonstrate entitlement to compensation. In *Bunting v. Sec'y of HHS*, 931 F.2d. 867 (Fed. Cir. 1991) this Court stated, "[t]he standard of proof required by the Act is simple preponderance of evidence, not scientific certainty. As stated in *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 432, 440 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969), "it is not plaintiff's burden to disprove every possible ground of causation suggested by defendant nor must the findings of the Court meet the standards of the laboratorian." *Bunting, supra* at 873.

In another case, the Court described a petitioner's burden as to simply demonstrate a "logical sequence of cause and effect" showing that the vaccine was the reason for the injury. *Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In another, *Shyface v. Sec'y of HHS*, 165 F.3d 1344 (Fed. Cir. 1999), the Federal Circuit said a petitioner must only show the vaccine was a "substantial factor" in causing the injury and that "but for" the vaccine the injury would not have occurred. *Id.* at 1352.

The Federal Circuit also has consistently recognized the uncertainty of the science relating to vaccine injuries. Thus, the Court has stated, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the Vaccine Compensation Program." *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). Indeed, the Court said, "[t]he Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." *Id.*

What, then, is sufficient proof in the Vaccine Program? In *Golub v. Secretary of HHS,* 243 F.3d 561, 2000 WL 1471643 (Fed. Cir. 2000)(unpublished opinion),[6] the Court stated that

[6] The PSC is mindful of Federal Circuit Rule 47.6 (b) and does not cite *Golub* as precedent. However, the PSC submits, *Golub* was cited by the Chief Special Master in *Althen v. Sec'y of HHS*, No. 00-170V, (Fed. Cl. Spec. Mstr. June 3, 2003. (See appellate decisions in *Althen v.*

the requirements are modest. It is sufficient, the Court stated, for a petitioner to offer a medical opinion and "reasonably reliable medical theories to substantiate" the claim. *Id.* at 6. In fact, the Court stated, allowing a recovery for an injury that occurs "slightly outside the time periods provided in the statute is also consistent with the ***spirit*** of the Vaccine Act." *Id.* (emphasis added).

Several recent Federal Circuit opinions are also instructive. In *Althen v. Sec'y of HHS*, 418 F.3d 1274 (Fed. Cir. 2005), the Court described a petitioner's burden as 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. *Althen* at 1278. Commenting on the quantity and quality of proof necessary, the Court stated: "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof [as to] how vaccines affect the human body." *Althen,* at 1280. Indeed, due to the very absence of direct scientific evidence in this field, Congress encouraged "the use of circumstantial evidence" and envisioned that "close calls regarding causation [would be] resolved in favor of injured claimants." *Id.*

In *Capizzano v. Sec'y of HHS*, 440 F. 3d 1317 (Fed. Cir. 2006) ("Capizzano III"), the Federal Circuit once again commented upon the nature, quality, and quantity of proof necessary for a petitioners to be compensated under 42 U.S.C. §300aa-13. Reversing a special master's dismissal of a claim, the Federal Circuit ruled that he had "impermissibly" raised the petitioner's "burden under the Vaccine Act" by denying her the ability to prove her case with "the use of circumstantial evidence [as] envisioned by the preponderance standard." (citing Althen III at 1280). Capizzano III at 1325. Next, the Court rejected the respondent's argument that proof of

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Sec'y of HHS, 58 Fed. Cl. 270(USCFC 2003) and *Althen v. Sec'y*, 418 F. 3d. 1274 (USCAFC 2005). In his decision, the Chief Special Master stated, "[to] be sure, the quality or quantity of evidence sufficient ... in causation-in-fact cases ... is an unresolved legal issue [in the Vaccine Program]." *Althen*, at 16. In addition, the PSC submits, the *Golub* panel captured the "spirit" of congressional intent.

"a logical sequence" between the vaccine and the injury required solid scientific evidence. In this regard, the Court said, "'a logical sequence of cause and effect' means what it sounds like- the claimant's theory of cause and effect must be logical." *Id.*

Capizzano also commented on the evidentiary value of the recorded statements of a petitioner's treating physicians. In this regard, the Court determined:

> ... *Althen* III explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether "a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." *Althen* III at 1280; *see also* 42 USC§300aa-13(a)(1)
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> . . . .

Capizzano III at 1326.

Finally, in P*afford v. Sec'y of HHS,* 451 F. 3d 1352 (USCAFC 2006), the Federal Circuit reaffirmed the principles set forth in *Althen* and *Capizzano* and provided strong support for Vaccine Program petitioners. First, the *Pafford* Court once again recognized that in a non-Table case, a petitioner "must prove by preponderant evidence both that her vaccinations were a substantial factor in causing the illness ... and that the harm would not have occurred in the absence of the vaccination. *Pafford* at 1355. *Pafford* also cited with approval the Federal Circuit's "recently articulated ... alternative three-part test .... (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) ... a proximate temporal relationship between the vaccination and the injury." *Pafford* at 1355. In this regard, the Court stated:

> Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the "but-for" prong of the causation analysis. *See Capizzano* III at 1326 (finding medical opinions that explain how a vaccine can cause the injury alleged coupled with evidence demonstrating a close temporal relationship "are quite probative" in proving actual causation).

Pafford at 1358.

In this regard, while the PSC agrees that proof of an appropriate temporal relationship between the vaccine and the injury is probative, the PSC also agrees with Judge Dyk, who stated in his dissent that such proof is not *required*. *Pafford* dissent at 1361-1362. See also *Grant v. Sec'y of HHS*, 956 F. 2d 1144, 1149 (Fed. Cir. 1992), where the Federal Circuit granted compensation and rejected the respondent's argument that an appropriate temporal relationship is a requirement. Once again, the PSC submits, the requirement is simply "preponderant evidence" based "on the record as a whole." § 13(a)(1).

V. THE CONGRESSIONAL GOALS UNDERPINNING THE 1986 VACCINE ACT MUST CONTINUE TO BE PROMOTED IN 2007.

Once again, in establishing the Vaccine Program in 1986, Congress sought to divert civil lawsuits against vaccine manufacturers into a less rigorous, less adversarial, fairer, and more generous arena than the existing federal and state tort systems. Such a Program, Congress hoped, would not only compensate persons injured by vaccines, but also protect vaccine manufacturers and allow them to continue producing existing vaccines and develop new ones.[7] Promoting these goals, the PSC submits, is even more important today than when the Vaccine Program was established in 1988.

It is without question that our national health policy continues to favor the wide use of available immunizations to combat disease. In addition, this national policy continues to encourage the medical community to develop new vaccines to combat new illnesses, such as SARS, Monkeypox, and the Avian flu. In recent years, however, two events have elevated to "critical" the importance of the success of the Vaccine Program. First, the events of September 11, 2001 have spawned a new national policy. "Homeland Security" now demands the development of new vaccines, such as anthrax and smallpox vaccines[8] to assist the public in

[7] Since the Vaccine Program was established in 1988 the following vaccines have been developed and added to the Vaccine Table: hepatitis A and hepatitis B vaccines, *hemophilus influenzae* type b (Hib) vaccine, varicella vaccine, rotavirus vaccine, pneumococcal conjugate vaccines, and the adult flu vaccine. *See*, 42. U.S.C. §300aa-§14.

[8] *See, for example*, the United States Department of Defense web site at www.vaccines.army.mil/ for continuing defense-related vaccine issues.

combating terrorist threats. Second, more on point, in the past 5 years the Vaccine Program has been overwhelmed with over 4,750 claims by autistic children who claim that MMR and "thimerosal-containing" vaccines have caused them to suffer injuries on the autism spectrum. Significantly, attorneys who intend to withdraw from the Program and file civil actions have filed many "autism" claims. [9]

If the goals of the Program are to protect vaccine manufacturers from financially devastating civil lawsuits and to compensate persons injured by a vaccine then, why are many of the 4,750 autism cases now pending in the Program prepared to exit the Program and proceed with civil actions? How is it possible the twin congressional goals (and the national policies they encourage) are so easily obliterated? The answer is apparent. It is because evidentiary standards in the Vaccine Program may be *more* difficult than those standards in civil litigation. The Special Master cannot permit this to happen. Certainly, this is not what Congress intended.

Simply put, the PSC says, it is essential that the Vaccine Program, rather than crippling civil litigation, resolve the cases of the autistic children in the OAP. Persons fairly compensated in the Vaccine Program won't sue manufacturers. In fact, if congressional intent is implemented, a person with a vaccine injury should *never* withdraw from the Vaccine Program or reject an award. How can these persons be kept in the Vaccine Program? The answer is simple. An evidentiary standard, which promotes congressional intent, must be employed.[10] Congress

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[9] The Vaccine Act requires a person with a vaccine-related injury to file a petition in the Vaccine Program before proceeding in either state or federal court. §11 (a)(2)(A). Civil plaintiffs with autism who have filed in state and federal courts have been routinely directed to the Vaccine Program in accordance with §11 (a)(2)(B). *See*, for example, *Lui v. Aventis Pasteur*, 219 F. Supp.2d 762 (W.D.Tex. 2002); *Owens v. American Home Products Corp.* 203 F. Supp.2d 748 (S.D. Tex 2002); *McDonald v. Abbott Laboratories*, 2002 WL 32074880 (S.D. Miss. Aug. 1, 2002); *Strauss v. American Home Products Corp.*, 208 F. Supp.2d 711 (S.D. Tex. 2002); and *Bertrand v. Aventis Pasteur Laboratories, Inc.* 226 F. Supp.2d 1206 (D. Ariz. 2002).

[10] The respondent, as in the past, will attempt to elevate the evidentiary bar to an unattainable level to defeat the claims of the autistic children. In this regard, the PSC concedes, the science linking vaccines and symptoms on the autism spectrum is equivocal. In fact, the PSC's experts will rely, exclusively, on circumstantial scientific evidence. However, as the Supreme Court has

intended to create a "user-friendly program" that would stop outside civil lawsuits. The Special Master and the parties must ensure a "user friendly" OAP.

VI. NATURE, QUANTITY, AND QUALITY OF EVIDENCE NECESSARY TO PROVE A "LOGICAL SEQUENCE OF CAUSE AND EFFECT" UNDER THE STANDARD ESPOUSED BY THE FEDERAL CIRCUIT?

In the PSC's view, in general, the only *required* evidence "to prove logical sequence of cause and effect" is a showing that a petitioner: (1) was healthy (or more healthy); (2) received a covered vaccine; (3) subsequently suffered an injury that, in theory, can be caused by the vaccine; and (4) the absence of a more likely cause of the injury. Unless he or she proves each of these elements, The PSC submits, the claim will be fatally defective. Proof of each element is required.

However, the PSC also submits, the words "logical sequence of cause and effect" are not words in the Vaccine Act. This phrase is mere *dicta*. The nature, quality, quantity, and sufficiency of the "evidence" required by the statute for a petitioner to prevail will necessarily vary in each individual case. In the end, however, in each individual case, any determination of the sufficiency of evidence "required" to prove "a logical sequence of cause and effect" must be viewed in the precise words of the statute. A petitioner must show he or she sustained "any illness, disability, injury or condition not set forth in the Vaccine Injury Table ...." (§11 (c)(1)(C)(ii)(I)), that he or she "has demonstrated by a preponderance of the evidence" was due to the vaccine (§13 (a)(1)(A)), and that there "is not a preponderance of the evidence that the ... injury ... is due to factors unrelated to the ... vaccine .... " §13 (a)(1)(B). In this regard, in tabulating a petitioner's evidence to see if it meets the "preponderance" standard, special masters must consider "all ... relevant medical and scientific evidence contained in the record." §13(b)(1). This includes all relevant evidence gleaned from "the record as a whole." §13(a)(1).

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stated with respect to the relevance of expert testimony, it is the "methodology underlying the testimony" that must be "scientifically valid ...." *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579, 592-593 (1993). Thus, "[t]he inquiry envisioned ... is, we emphasize, a flexible one. It's overarching subject is the scientific validity - and thus the evidentiary relevance and reliability - of the principles that underlie a proposed submission ... not on the conclusions that they generate." *Id.* at 594-595.

Significantly, the Vaccine Act does not specify the nature, type, amount, quality, or quantity of evidence necessary. It leaves this chore to special masters. Their job is to determine, once again, whether, "on the record as a whole" there is preponderant evidence that a vaccine caused an injury.

Required evidence, however, is different than *relevant* evidence. In this regard, the PSC submits, all relevant evidence in the record is pertinent to the issue of a "logical sequence of cause and effect." In the OAP, for example, the parties may present a variety of circumstantial evidence. This evidence may include expert testimony in the fields of immunology, neurology, virology, gastroenterology, pharmacology, toxicology, epidemiology, biology, biochemistry, and vaccinology. It may include, *inter alia*, scientific literature, animal studies, *in vivo* and in *vitro studies*, case reports, case series, epidemiological studies, IOM reports, government reports, manufacturer's records, medical records, anecdotal reports, journal articles and letters, manufacturers disclosures, Physician Desk Reference (PDR) disclosures, institutional findings, VAERS data,[11] and documents produced during discovery in the OAP.

In addition, as in other cases, concessions by the respondent's experts and materials from the respondent's written submissions will certainly provide additional support for the petitioners' cases.

All of this evidence, albeit circumstantial, forms a part of the "record as a whole." All submitted evidence, by both parties, is relevant to the issue of whether there is a logical sequence of cause and effect between the vaccine and the injury. If a combination of this evidence suggests "a logical sequence of cause and effect" between the vaccine and the injury, then a petitioner has made out a *prima facie* case with preponderant evidence.

Past Federal Circuit decisions, the PSC submits, are consistent with this interpretation of the nature of permissible evidence in Vaccine Program proceedings. In *Grant, supra*, despite

[11] "VAERS" is the Vaccine Adverse Event Reporting System, a database maintained by the Centers for Disease Control **("CDC").**

epidemiology to the contrary, a petitioner proved a "logical sequence" with evidence of: (1) a healthy child; (2) who received a pertussis vaccine (Quadrigen); (3) had seizures 10 days after the vaccine; and (4) the absence of a likely alternative cause. In finding in favor of the petitioner, the Chief Special Master had relied on the opinions of experts and treating physicians, opinion "evidence based solely on apparent temporal connection, animal studies, chemical studies, in vitro studies, and unpublished studies." *Id.* In this regard, the Federal Circuit noted, the Vaccine Act "specifically permits consideration of the types of evidence the Special Master considered in this case."[12] *Id.* at 1149.

In *Jay v. Sec'y of HHS*, 998 F. 2d 979 (Fed. Cir, 1993), the Federal Circuit again found that a petitioner had shown a "logical sequence of cause and effect" in an off-Table case. In *Jay*, the evidence showed:

> [A] healthy child received a DPT shot; the DPT shot caused fever, directly or indirectly limpness, and intermittent inconsolable extended screaming; the child missed his normal nightly feeding, the child died with 18 hours of the shot, the autopsy was inconclusive; and a medical expert testified, uncontradicted, that the DPT shot caused the death, the medical theory being that an encephalopathy occurred.

Jay at 984.

Finding for the petitioner as a matter of law, the Court noted:

> Analogous to tort law, causation in fact requires **only** 'proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury (here, death)....

Jay at 984(emphasis added)(*citing Grant* at 1148).

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[12] The statute (§13 (b)(1))states, "In determining whether to award compensation ... the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record -- (A) any diagnosis, conclusion, medical judgment ... contained in the record regarding the nature, causation and aggravation of the petitioner's illness, disability, injury, condition or death, and (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions."

In *Knudsen v. Sec'y of HHS*, 35 F. 3d 543 (Fed. Cir. 1994), the Federal Circuit, ruling in favor of a petitioner, said:

> Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is "logical" and legally probable, not medically or scientifically certain ....

Knudsen at 548-549.

In the end, all relevant evidence, albeit circumstantial, forms a part of the "record as a whole." All such evidence, regardless of the source, is pertinent to the issue of "logical sequence." If a compilation of this evidence indicates "a logical sequence of cause and effect" between the vaccine and the injury, then a petitioner has made out a *prima facie* case. Once again, as the Federal Circuit stated in *Capizzano*, "'[a] logical sequence of cause and effect' means what it sounds like- the claimant's theory of cause and effect must be logical."[13] *Capizzano* III at 1326. It is logical if a healthy person receives a vaccine, sustains an injury that can be caused by the vaccine, and no other likely cause exists.

VII. THE CONDUCT OF THE PROCEEDINGS

a) One Special Master

It is impossible to overstate the importance of the OAP. It is important to 4,750 autistic children and their families. These injuries, the Special Master will learn, have an indescribably devastating impact on the autistic child. Equally devastating is the emotional and financial toll on the autistic child's family. For a special matter to be asked to consider the fate of 4,750 such children and their families is no small matter.

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[13] In other words, it can't be **illogical.** It is illogical, for example, if there is no possible medical theory, if the injury preceded the vaccine, if the temporal relationship was inappropriate, or if there is a more likely cause of the injury. It would be illogical to allege that a vaccine caused a broken arm.

The OAP is equally important to vaccine manufacturers. Vaccines protect all of us. If droves of cases leave the Vaccine Program to enter the civil arena, there will be a new crises, one far surpassing the crisis of 1986. Again, for one special master to be asked to resolve issues impacting our national health and defense policies is no small matter.

However, it is the opinion of the PSC that Special Master Hastings, and he alone, consider the evidence and decide the "general causation" issues in the OAP.

In this regard, the Office of the Special Masters (OSM) has suggested an alternate approach, whereby the evidence would be heard simultaneously by three (3) special masters, who would write three separate decisions. The PSC does not support this approach, and believes it would create such mass confusion about the "general" issues that the individual cases would take years to resolve. The PSC also believes that the autistic petitioners in the OAP are entitled to a judgment that can be reviewed. The suggested "3-special master" approach may well be an appellate court's nightmare. In these circumstances, the PSC strongly favors a **one** special master "general causation" proceeding (i.e. Special Master Hastings).

The PSC also believes one Special Master, Special Master Hastings, should decide the "test" cases heard as part of general causation proceedings. However, beyond the "test cases" it is impractical to expect one special master to resolve the remainder of the cases in the OAP.

While the number of autistic children who have filed claims in the Vaccine Program is unprecedented, the use of one special master in "general causation" omnibus proceedings have been extremely useful in the past in resolving "groups" of cases. In *Ahern v. Sec'y of HHS*, No. 90-1453V (USCFC Spec. Mstr. January 11, 1993), 1993 U.S. Claims LEXIS *51, for example, after a "general causation" hearing as to whether a rubella vaccine can cause arthropathy, this Special Master established criteria, or guidelines, as to whether or not a petitioner was entitled to compensation. Id at page 14. This approach led to the resolution of in excess of 100 cases. This year, a "general causation" omnibus hearing was conducted by Special Master Millman to determine whether hepatitis B vaccine can cause demyelinating injuries. The decision by Special

Master Millman will eventually lead to the resolution of 40 cases. See, for example, *Stevens v. Sec'y of HHS*, No. 99-594V, (USCFC Spec. Mstr. February 24, 2006).

In these circumstances, the PSC is confident that one Special Master is appropriate, despite the large number of claimants. If, after the general causation hearing, the Special Master determines that vaccines can cause any, some or all of the symptoms on the autism spectrum, then hopefully many of the cases in the OAP will resolve as have cases in past omnibus proceedings. For those cases that fail to resolve after a "general causation" decision, the services of additional special masters to decide individual cases may be necessary. In this event, the PSC will have no objection to new special masters using the "general causation" evidence to assist in the resolution of individual cases.

Using a single Special Master to resolve the general causation issues in the Omnibus Proceeding is also consistent with federal court practice in multidistrict litigation involving mass torts pursuant to 28 U.S.C. §1407 and the Rules of Procedure of the Judicial Panel on Multidistrict Litigation. Individual District Court judges regularly accept the transfer of thousands of individual injury claims involving common issues of fact that are complex and numerous. The individual transferee judges in MDLs generally then handle all pretrial matters common to the transferred cases, including discovery, the presentation of expert testimony, ruling on the admissibility of evidence and testimony relating to general causation, and deciding motions for summary judgment involving issues common to the consolidated cases. Decisions of the transferee judge are then binding on the individual cases when those cases are remanded to their districts of origin for trial. Significantly, transferee judges in MDLs often conduct individual trials of representative "bellweather" or "test" cases, just as the PSC proposes in this instance.

The circumstances that support individual judges handling thousands of consolidated, transferred personal injury claims through the MDL process are present in the OAP: a large number of individual claims; common issues of law and fact; complex and numerous issues of law and fact; the need to avoid duplicative procedures; the need to avoid inconsistent or

repetitive rulings; and the preservation of judicial resources, including appellate resources, that is obtained by a single judge deciding the common issues.

The PSC proposal to have one Special Master rather than multiple Special Masters conduct the general causation hearings in the OAP (including the June 2007 test case) is therefore consistent with the Vaccine Act, with practice in other NVICP omnibus proceedings, and with the procedures that govern mass tort litigation in the federal judiciary.

b) General Causation

Due to the extraordinary volume of evidence that will be presented during the "general causation" hearing, the PSC has attempted to prepare a design for the proceedings that will assist the Special Master in understanding the complex scientific evidence to be presented and provide "fundamental fairness" to the parties. See USCFC Vaccine Rule 8. The PSC envisions three distinct theories of causation and three distinct hearings in which evidence of those theories is presented to the Special Master. In each hearing, the PSC suggests that the following procedure:

(i) Petitioners' Opening Statement

(ii) Respondent's Opening Statement

(iii) Petitioners expert testimony re:

(iv) Respondent's Expert Testimony

(v) Petitioner's Rebuttal Expert testimony

(vi) Oral Closing by petitioners, then respondent

(vii) Simultaneous written post hearing briefs

(viii) Simultaneous reply briefs

(ix) SM will issue decision in each test case presented, listing criteria, if any, to be applied to individual cases proceeding under that theory of causation.

(x) 90 day period for parties to settle "test" cases

(xi) If not settled, SM will issue ruling on each test case without additional evidence and enter "appealable" judgments.

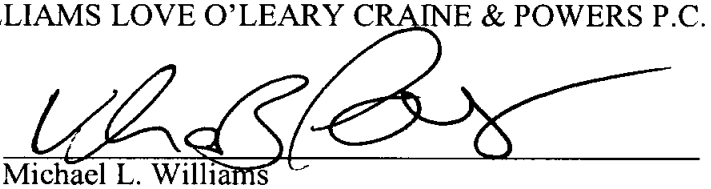
VIII. EFFECT OF RULING

As the Special master is aware, without the express agreement of the parties, a "general causation" decision in the OAP will not be binding on any individual claimant or the respondent. In addition, as the Special Master also knows, decisions by special masters or by judges of the U.S. Court of Federal Claims in individual cases are not binding on other special masters, other judges, or other individuals.

What, then, will be the effect or a "general causation" ruling that relies largely on adjudicating representative test cases? Over the past four years, the efforts of the Special Master, the respondent, and the PSC to move the OAP forward have been extraordinary. These efforts have not been in vain. The causation decisions in representative test cases, the PSC expects, will serve as a guideline for both reasonable petitioners and a reasonable respondent. The decisions, the PSC expects, will have the same effect as previous "general" rulings in omnibus cases. It will induce the parties to assess cases realistically and in light of the available evidence. The decisions, it is expected, will express the considered opinions of a respected special master with 18 years of experience in the Vaccine Program. The Special Master, the PSC expects, will issue decisions that has considered the circumstantial evidence adduced in light of the Vaccine Act's legislative history, the Vaccine Act, and the Federal Circuit's opinions in *Althen*, *Capizzano*, and *Pafford*. In other words, reasoned decisions, the PSC expects, will lead to the resolution of the vast majority of the cases now pending in the OAP, as nearly all of those cases would be encompassed by one of the three general theories of causation the PSC expects to present in 2007.

DATED this 5th day of January, 2007.

WILLIAMS LOVE O'LEARY CRAINE & POWERS P.C.

By: 

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CERTIFICATE OF SERVICE

I hereby certify that on January 5, 2007, I served the foregoing **PETITIONERS' PROPOSED CONDUCT OF GENERAL CAUSATION HEARING AND SUBSEQUENT EFFECT OF RULING** on the following individuals:

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via electronic e-mail with a hard copy to follow via U.S. Mail, regular first class mail.

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