

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-799V
Filed: July 19, 2012

Unpublished

REBECCA CROSBY, parent of
ETHAN CROSBY, a minor,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Respondent.

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CORRECTED COPY

Motion for Reconsideration

*Ronald Craig Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioner.
Debra A. Filteau Begly, U.S. Department of Justice, Washington, D.C., for Respondent.*

RULING ON MOTION FOR RECONSIDERATION¹

GOLKIEWICZ, Special Master.

This Ruling concerns petitioner's Motion for Reconsideration of the Decision denying her entitlement to compensation under the Vaccine Act. This Ruling is being filed with swiftness considering the time frame in which a petitioner must file a Motion for Review of a special master's decision. Vaccine Rule 23 (requiring a Motion for Review to be filed within 30 days of the issuance of the decision with no allowance for an extension of time). As such, this abbreviated but considered Ruling denies petitioner's Motion for Reconsideration.

¹ The undersigned intends to post this decision on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.

History

Petitioner filed her Petition on behalf of her son on November 10, 2008, claiming entitlement to compensation under the Vaccine Act.² Petitioner claims her son suffered from a spinal cord injury, transverse myelitis (“TM”), as a result of the vaccinations he received on December 13, 2005. See Petitioner’s Pre-Hearing Submission, filed Apr. 19, 2011. In support of her case, petitioner submitted expert opinions from Dr. James Renfroe and Dr. Vera Byers. Respondent filed her Rule 4(c) Report on April 13, 2009, recommending against compensation. Respondent relied upon the expert opinions of Dr. John Sladky and Dr. Noel Rose in support of this position.

On June 20, 2012, the undersigned issued the Decision on Entitlement, denying petitioner compensation. Decision on Entitlement (“Decision”), filed Jun. 20, 2012. Critical to the Decision was petitioner’s inability to provide preponderant evidence on the third prong of Althen, the medically appropriate timing of the alleged injury.

On July 11, 2012, petitioner filed her Motion for Reconsideration of the Special Master’s June 20, 2012 Decision. P Motion for Reconsideration of the Special Master’s June 20, 2012 Decision (“Motion” or “P Motion”), filed Jul. 11, 2012. Along with her Motion, petitioner filed a portion of the Institute of Medicine’s 2011 publication, Adverse Effects of Vaccines, Evidence and Causality. P Ex 44, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES (“IOM”), ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY (2011). Petitioner’s Motion relies upon her Exhibit 44, stating that this publication was not available at the time of the Hearing in this case. Although, petitioner admits this publication was available prior to the undersigned’s Decision, she argues that the “‘interest of justice’ should persuade the special master to consider the evidence.” P Motion at 9, 9 n. 15. “This is so, [petitioner] says, because [petitioner] did not know the special master’s ruling would hinge on a factual determination that the onset of his TM began within one day after his vaccines.” Id. Further, “[u]ntil the special master issued his decision, [petitioner] was unaware how critical this factual finding would be as the basis of the special master’s denial of compensation.” Id.

Petitioner excerpts one portion of the IOM’s publication that discusses the latency phase that occurs after an immune challenge, such as a vaccination, and the primary immune response. Id. at 10 (quoting P Ex 44 at 51-52). This latency period is “characterized by a lag phase, logarithmic phase, and plateau phase.” The quoted section continues by describing what occurs in these three phases that lead to the primary immune response. Petitioner highlights a portion of this excerpt that describes the timing of the lag phase when a person has encountered the challenge previously. This is referenced as being “primed” in the Decision since petitioner’s son had previously received the same vaccination; thus, his immune system was primed to these antigens and had some immunologic memory. This concept of being primed, as discussed in petitioner’s Exhibit 44, causes an immune response to happen more quickly than when a person first encounters this challenge. The highlighted portion states that the “lag phase [during a

² This Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (2006) (hereinafter “Program,” “Vaccine Act,” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

subsequent exposure to the antigen] is generally one to three days . . .” P Motion at 10 (quoting P Ex 44 at 51-52). Petitioner continues, “[t]he 2011 IOM concluded that following subsequent exposure to the same antigen, i.e. a vaccine, the onset of the anamnestic, or adaptive immune response “is generally one to three days.” P Motion at 11. In petitioner’s view, “the 2011 IOM finding compels the special master to determine that the onset of Ethan’s TM within one day following his vaccines, is a medically acceptable time frame.

On July 18, 2012, respondent filed her response. R Response to Petitioner’s Motion for Reconsideration (“Response” or “R Response”), filed Jul. 18, 2012. Respondent notes the standard for granting a motion for reconsideration set forth by the Federal Circuit: “(1) an intervening change in the controlling law; (2) the availability of new evidence; and (3) the need to correct clear error or prevent manifest injustice.” R Response at 2 (citing Delaware Valley Floral Group v. Shaw Rose Nets, LLC, 597 F.3d 1374, 1383 (Fed. Cir. 2010)). Respondent argues that petitioner has not established grounds for reconsideration because the 2011 IOM report: “1) was available to petitioner over one year prior to her entitlement hearing and over two years prior to the issuance of the Entitlement Decision, and 2) contains well-known and established immunological principles squarely addressed by the parties’ experts and in the Decision.” R Response at 3.

Respondent notes that the 2011 IOM report was released on August 25, 2011, at least nine months before the Decision. R Response at 5. Also, “the IOM report is not based on original scientific research by the IOM, but rather is a summary of data that was already publically available.” Id. (citing R Ex C at 10)(referencing R Ex D and noting that petitioner’s excerpted section was available over a year prior to the Entitlement Hearing).

Respondent notes that petitioner still fails to recognize the difference between onset of the adaptive immune response and onset of symptoms. Id. at 4. Respondent argues that the submitted portion of the 2011 IOM report is not contrary to the evidence offered in the case. She notes that petitioner relies on the description of the “lag time” phase taking one to three days and points out that this phase is just the initial activation of the B and T cells when the person encounters an antigen – “not the time it would take the immune system to manifest physical symptoms.” Id. (citing Hr’g Tr. at 182-84; 189). Respondent points out that petitioner ignores the next sentence of the IOM report “which states that an increase in serum antibody levels (referred to as the logarithmic phase) does not begin until at least three to five days after introduction of a protagonist.” Id. (citing R Ex C at 58). As her expert pointed out, it would still take days for antibodies to result in the physical manifestation of symptoms after they are first detected. Id. at 4-5. Respondent argues the IOM report does not enable petitioner to establish Althen prong three, even considering this to be “new” evidence. R Response at 6. “Petitioner’s motion also makes clear that she refused to accept the opinion from her own expert, Dr. Byers, that even in a primed individual, it would take at least ‘four to seven days for the vaccination to result in activation of the adaptive immune system resulting in autoimmune disease.’” Id. (citing Hr’g Tr. at 101).

Discussion

The undersigned agrees completely with respondent's cogent arguments. Petitioner's evidence and arguments for reconsideration do not rise to the level to warrant granting reconsideration. More importantly, petitioner's "new" evidence was not new at the time of the June Decision and, when considered, does not change the finding that onset of the alleged injury occurred too soon to be medically appropriate.

Appropriateness of Granting Petitioner's Motion for Reconsideration

There is no change in controlling law alleged by petitioner. Petitioner's Motion appears to be an amalgam of the second and third considerations spelled out by the Federal Circuit in Delaware Valley Floral Group, the availability of allegedly new evidence in the 2011 IOM report and the prevention of injustice.

As respondent points out, the 2011 IOM report was available to the public on August 25, 2011, well before the undersigned's June 20, 2012 Decision.³ Furthermore, the IOM report is not "original scientific research by the IOM, but rather is a summary of data that was already publically available." R Response at 5 (citing R Ex C, 10 ("two streams of evidence support the committee's causality conclusions: epidemiologic evidence derived from studies of populations . . . and mechanistic evidence derived primarily from biological and clinical studies in animals and individual humans")). Respondent also pointed out that petitioner's Exhibit 44 relies upon an article published in February 2010, over one year prior to the May 10-11 2011 Hearing in this case. R Response at 5; R Ex C at 58; R Ex D.

Also, petitioner claims she was unaware of the importance of the factual timing element in this case. The undersigned has difficulty believing this unawareness is genuine. A rather substantial amount of testimony was given by four qualified experts – two neurologists and two immunologists – in a two day Hearing on the relevant timing issues: when Ethan's TM started and what the medically appropriate timing would be for vaccine-causation. See Decision at 9-27 (discussing the expert evidence presented). Specifically, the report of Dr. Byers, petitioner's immunologist, notes, "I was asked to discuss the events which occurred between the time the 12/13/05 vaccine was given and the onset of the disease The purpose of this report is to point out that the physical signs and symptoms that Ethan displayed during the first 3-4 days of his illness were non-specific and most likely due to his innate immune systems activation by the vaccines." Decision at 12; P Ex 31. This report, the first opinion from Dr. Byers and well before the May 2011 Hearing, goes to the heart of the timing matter, even specifically addressing a major neurological symptom – "decreased spontaneous movement of his legs" – upon which the undersigned relied for the finding of Ethan's TM onset. Decision at 12.

Petitioner relies upon Shaw v. Sec'y of the Dept. of Health & Human Servs., 91 Fed. Cl. 715 (Fed. Cl. 2010), for her argument for reconsideration with the new evidence based upon the "interest of justice." P Motion at 8. In Shaw, the case was remanded to the special master to reconsider petitioner's newly filed evidence and allow a response by respondent's expert.

³ In fact, the 2011 IOM report was the subject of the Vaccine Breakout Session conducted at the Court of Federal Claims' October 2011 Judicial Conference. Petitioner's counsel's entire firm attended that session.

Respondent correctly notes that Shaw is not controlling authority. R Response at 6. “However, even if Shaw were controlling authority, it would not dictate a different result.” Id. at 6-7. Respondent notes that petitioner in Shaw was afforded the opportunity to present evidence on an injury that was found by the special master but not previously asserted. Id. “Unlike Shaw, petitioner here was fully aware that timing was a key issue to this case, and she had a full opportunity to present evidence on that very issue. As such, unlike the allegations in Shaw, petitioner already had a full and fair opportunity to present her case.” Id. at 7. As discussed above, timing of onset and timing related to medical appropriateness were both issues petitioner was aware of in prosecuting her case.

As noted, there is no new evidence to warrant granting petitioner’s Motion. The 2011 IOM Report was available prior to the Decision and contained no information that was not available before the Hearing.

Considering Petitioner’s Newly Filed 2011 IOM Report

Petitioner attempts to use the 2011 IOM report to show that onset of symptoms within 24 hours after vaccination is medically appropriate. Petitioner relies on the reference to the one to three day lag phase in primed individuals. Petitioner, however, seems to disregard the other phases discussed and the fact that the article does not reference time until onset of symptoms. Petitioner also notes the undersigned’s use of the 1994 IOM report, recommending a special master “should seriously consider the 2011 IOM findings.” P Motion at 12 n. 17 (citing Cedillo v. Sec’y of the Dept. of Health & Human Servs., No. 98-916V, 2009 WL 331968, *93-94 (Fed. Cl. Spec. Mstr. 2009)).

Respondent finds petitioner’s assertion regarding the 2011 IOM report is “based on her refusal to accept that even if she could prove that the initiation of an adaptive immune response could occur within one day, it does not establish how quickly that immune response could manifest in physical symptoms.” R Motion at 6. Respondent, as noted above, further objects to petitioner’s Motion because the “new” evidence still does not satisfy Althen prong three.

The distinction between onset of an adaptive immune response and onset of symptoms is critical in this case. It was set forth early in the Decision to highlight the potential confusion to a reader.

The experts discuss two concepts: a) an adaptive immune response or an autoimmune response that is evident at first only by measurement of antibodies in a patient and b) the development of symptoms of an injury caused by that autoimmune or adaptive immune response, signs that actual damage is occurring in a patient. The former would be measured by antibodies circulating in a person’s system. The latter would be the symptoms, such as the inability to use one’s legs with TM, that a person experiences or observes. It was stressed that these are two phases separated by some amount of time when discussing an injury caused by an autoimmune process. One must first develop the immune response before one sees the symptoms of injury from that response. In order for the symptoms of the autoimmune injury to manifest, the autoimmune or adaptive

immune response must have developed, proliferated, traveled to the site of injury and had sufficient time to cause enough damage that the injury manifests symptoms.

Decision at 8 (internal citations omitted).

Even considering the newly filed 2011 IOM report, petitioner is still unable to prevail. With regard to the use of the 1994 IOM report, this report specifically discusses the hypothetical time from exposure to onset of actual symptoms. It states:

the expected latency between an antecedent event (when infection or administration of antigen occurs) and the **first symptoms** of GBS is mainly between 7 and 21 days. . . . On the basis of these observations and inferences, a conservative estimate of the limits of the latencies for both GBS and ADEM is considered to be from 5 days to 6 weeks throughout this report.

R Ex A-5 at 4 (emphasis added).

The submitted language from the 2011 IOM report does not address the same time frame; the section is specifically titled “Latency Between Antigen Exposure and **Peak Adaptive Immune Response.**” P Ex 44 at 51 (emphasis added). The entire section provides a general background presentation of what occurs upon initiation of an immune response. It discusses the events occurring in terms of what the specific components of the immune system – such as T cells, B cells, macrophages, dendritic cells –are doing after exposure. “While this discussion is not specific to a particular antigen, it can be used as a reference point for the latency between antigen exposure and **the initiation of some of the immune-mediated mechanisms below.**” P Ex 44 at 52 (emphasis added). There is no discussion in the section of the 2011 IOM report provided by petitioner that states how long after initiation of the “immune-mediated mechanisms” symptoms will present. It also does not support petitioner’s proposition that clinical symptoms of TM can present in 24 hours.

Even when considering the 2011 IOM report, petitioner remains unable to satisfy her burden of preponderant evidence that onset of TM within 24 hours of vaccination is medically appropriate.

Petitioner Requests a Finding Regarding the Appropriate Time for Onset of TM

In another footnote, P Motion at 12 n. 16, petitioner requests a finding from the undersigned regarding the time necessary for “a clinical response[s]” in an unprimed and primed individual. As noted in the Decision, the experts’ handling of these two different time frames was not always clear. What was clear, however, was that 96 hours was the minimum amount of time necessary for an adaptive immune response, which is the type of immune response petitioner alleged caused the TM. This evidence was agreed to by petitioner’s own immunologist. Dr. Byers specifically testified that onset within 24 hours would not be an appropriate time frame. Decision at 45 (citing Hr’g Tr. at 108); see also Hr’g Tr. at 101-02 (testifying that 72 hour onset of TM would also not be an appropriate time frame and that it

would take “four to seven days for the vaccination to result in activation of the adaptive immune system resulting in an autoimmune disease.”). Petitioner’s expert was often vague regarding whether 96 hours was the time required for the adaptive response to mount or whether it was the time for the adaptive response to actually cause clinical TM symptoms. Respondent’s expert was clearer, adamant that 96 hours was the minimum time for the adaptive immune response, not manifestation of the TM symptoms. Petitioner’s Exhibit 44 does not appear in conflict with this evidence.

As with the undersigned’s finding in the June 20, 2012 Decision, the undersigned finds 24 hours between vaccination and onset of **symptoms** of TM is not medically appropriate to find the vaccine causation, even when the person had previous exposure to the vaccines. As Ethan’s symptoms were found to have started within 24 hours, the timing is not medically appropriate. Any finding beyond this is unnecessary.⁴ As stated in the Decision, such a finding is better left to a future case where the experts squarely address these important timing issues.

Conclusion

Accordingly, petitioner’s Motion for Reconsideration of the Special Master’s June 20, 2012 Decision is **DENIED**.

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Special Master

⁴ Finally, although it is not part of the “new” evidence, petitioner references the Fenichel text, which was considered in the Decision and states TM “evolves in hours or days.” P Motion at 12 n. 18 (quoting P Ex 20-A). This is a general statement in a description of TM and it appears that petitioner mischaracterizes this quote. This language appears to discuss evolution of the condition after onset; it does not reference time between exposure to the causative agent and the first symptom of TM. The undersigned has heard testimony on TM, including testimony from petitioner’s expert neurologist in this case, that supports this understanding. Notably, petitioner’s expert immunologist has not testified in this or other cases that the time between exposure and onset of actual symptoms can occur within hours. Furthermore, the Fenichel text specifically states there is “[n]o evidence to support this belief” that “a prior infectious illness or immunization causes transverse myelitis” P Ex 20-A at 3.