In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-662V
Filed: September 2, 2025

ETHEL LYNN MUNN,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Ramon Rodriguez, III, Siri & Glimstad LLP, Richmond, VA, for petitioner.
Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On May 19, 2017, petitioner, Ethel Lynn Munn, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012) ("Vaccine Act"),[2] alleging that a pneumococcal vaccine received on May 22, 2015, caused her to suffer an adverse reaction with bilateral hand pain. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is *not* entitled to an award of compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] Within this ruling, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

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received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

Alternatively, if no injury falling within the Table can be shown, a petitioner could still demonstrate entitlement to an award by instead showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). To successfully demonstrate causation-in-fact, petitioner bears a burden to show: (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 proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In this case, petitioner has alleged that the pneumococcal vaccine caused her to suffer hand pain. Neither "hand pain" nor arthritis in any form is listed on the Vaccine Injury Table relative to the pneumococcal vaccine. Accordingly, petitioner must satisfy the above-described *Althen* test for establishing causation-in-fact.

Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 300aa-13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2 (alternation in original); *see also Snowbank Enters., Inc. v. United States*, 6 Cl. Ct. 476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In finding causation, a program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1279-80. However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be

supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3(b)(1). Special masters must ensure each party has had a "full and fair opportunity" to develop the record. Vaccine Rule 3(b)(2). However, special masters are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

II. Procedural History

This case was originally assigned to a different special master. (ECF Nos. 4, 11-12.) It was reassigned to the undersigned in February of 2024. (ECF Nos. 59-60.) Additionally, petitioner changed counsel in April of 2020. (ECF No. 30.)

The petition was accompanied by affidavits (one by petitioner and one by her primary care physician, Dr. Ryal), a VAERS report,[3] and medical records, marked as Exhibits 1-6. (ECF No. 1.) Petitioner filed additional medical records in January of 2018, marked as Exhibits 7-8. (ECF Nos. 15, 24.) Respondent filed his Rule 4 Report, recommending against compensation, in February of 2018. (ECF No. 16.) Respondent contended that petitioner had not adequately identified the specific diagnosis at issue and had not supplied a medical opinion sufficient to meet her burden of proof. (*Id*. at 7-8.)

After respondent filed his report, petitioner filed a report by Dr. Ryal accompanied by her curriculum vitae and telephone logs from petitioner's patient file, marked as

[3] Vaccine Adverse Event Reposting System ("VAERS") is "a national early warning system to detect possible safety problems in U.S.-licensed vaccines." *About VAERS*, VAERS, https://vaers.hhs.gov/about.html (last visited Aug. 25, 2025). VAERS is a passive reporting system where "[a]nyone can report an adverse event" following vaccination. *Id.* Although "not designed to determine if a vaccine caused a health problems," VAERS "is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine." *Id.*

Exhibit 9-11, respectively. (ECF Nos. 17, 25.) Dr. Ryal distinguished petitioner's alleged vaccine reaction from osteoarthritis and instead characterized it as reactive arthritis. (Ex. 9.) Respondent then filed an expert report by rheumatologist Lianne Gensler, M.D. (ECF No. 19; Exs. A-B.) Dr. Gensler opined that petitioner suffered pre-existing osteoarthritis with insufficient evidence to support either a reactive arthritis or any flare of her osteoarthritis occurring post-vaccination. (Ex. A, pp. 10-11.) Petitioner then filed a supplemental report by Dr. Ryal with supporting literature (ECF No. 26; Exs. 12-19), and respondent filed a further report by Dr. Gensler (ECF No. 29; Ex. C).

After changing counsel, petitioner filed additional medical records in November of 2020 (marked as Exhibits 20-37), and then again in January and May of 2023 (marked as Exhibits 38-55) and March of 2024 (marked as Exhibits 56-61). (ECF Nos. 37-38, 53-56, 62.) A hearing was initially set before the previously presiding special master to be held in October of 2022, but was then reset to be held in May of 2024, at petitioner's request due to an unrelated medical condition.

After the case was reassigned to the undersigned, I issued a Pre-Hearing Order maintaining the previously scheduled entitlement hearing. (ECF No. 61.) Petitioner at first indicated that both she and Dr. Ryal would testify (ECF No. 65), but she later advised that Dr. Ryal would be unable to testify and opted to proceed with the hearing with petitioner being the sole witness (ECF No. 75). Petitioner testified on May 7, 2024. (Transcript of Proceedings ("Tr."), at ECF No. 78.) Thereafter, she filed a motion for a ruling on the written record on July 22, 2024. (ECF No. 79.) Respondent filed his response on September 5, 2024 (ECF No. 80), and petitioner filed her reply on October 17, 2024 (ECF No. 82).

In light of the above, I have concluded that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case on the existing record. S*ee Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs*., 671 F.3d 1368, 1385 (Fed. Cir. 2012)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

III. Factual History

a. Medical Records

Petitioner received the subject pneumococcal vaccine on May 22, 2015. (Ex. 1, p. 7; Ex. 2, p. 3.) At the time of vaccination, petitioner was 66 years old. (Ex. 1, p. 4.) Petitioner's relevant pre-vaccination medical history is significant for osteoarthritis. (Ex. 6, p. 1.) She was being followed by rheumatologist, Gary Siegel, M.D., for diffuse osteoarthritis. (*Id.*) In April of 2011, Dr. Seigel noted that petitioner was initially diagnosed with diffuse osteoarthritis "more than 5 years ago" and recorded petitioner's longstanding neck pain, followed by significant numbness in her bilateral hands. (*Id.*) Petitioner was also being followed by orthopedist Kevin Bonner, M.D., for right knee pain. (Ex. 25, pp. 1-2.) At a follow up appointment in May of 2011, Dr. Bonner recorded progression of petitioner's numbness to include her upper extremities, more so on the

left side than on the right side. (*Id.* at 1.) Dr. Bonner advised petitioner that there could be a number of causes for her symptoms and, due to the involvement of multiple extremities, he recommended that she follow up with a neurologist. (*Id.*) In June, Dr. Bonner noted grade 4 chondrosis of the patella, as well as some other areas of chondrosis medially; however, he advised against surgery as he believed that "the arthritis is more likely causing more of her symptoms." (*Id.* at 3.) In July of 2011, petitioner presented to neurologist Mary Allison Bowles, M.D. (Ex. 26, p. 2.) Dr. Bowles recorded "a 3 month history of numbness and tingling in the right hand, and in the left posterior arm and hand, and left lateral leg and dorsal foot," as well as longstanding neck pain. (*Id.* at 5.) Dr. Bowles order an MRI of the cervical spine to exclude myelopathy and to look for possible nerve root impingement. (*Id.*) The record suggests that she attended physical therapy for her numbness and tingling in 2011. (Ex. 24, p. 26.)

Petitioner had several encounters with Dr. Siegel in 2012. In February, she presented with generalized osteoarthritis in multiple sites. (Ex. 6, p. 7.) She reported a "rapid and aggressively worsening" pattern of joint symptoms primarily affecting the cervical spin and left foot. (*Id.*) Her paresthesia was aggravated by looking down. (*Id.*) In April, petitioner reported the cervical spine and right knee as the primarily affected joints. (*Id.* at 11.) During this encounter, arthrocentesis of the right knee joint was performed, and petitioner received a steroid injection. (*Id.* at 13-14.) Petitioner continued to complain of right knee issues at her follow up appointment in July. (*Id.* at 15.) A further arthrocentesis of the right knee joint was performed, and petitioner received another steroid injection. (*Id.* at 17-18.) In October, petitioner reported that her cervical spine and right knee symptoms were associated with joint stiffness in the morning and "gelling" of the joints after period of inactivity. (*Id.* at 22.) Dr. Seigel noted that petitioner's mother also suffered from osteoarthritis. (*Id.*) Petitioner once again underwent arthrocentesis of the right knee joint and received a further steroid injection. (*Id.* at 24.) During this time, petitioner also continued to see Dr. Bonner. (Ex. 25, p. 4.) In June, Dr. Bonner assessed "[r]ight moderate knee arthritis with a meniscus tear, although I am not sure if her pain is coming from the meniscus versus arthritis." (*Id.*) In November, Dr. Bonner noted that an MRI showed "advanced severe arthritis changes of the second and third tarsometatarsal joint with some moderate inflammation." (*Id.* at 6.) Petitioner also continued to see her primary care provider, Dr. Ryal, for various issues. (Ex. 24, pp. 18-22.)

By 2013, petitioner's osteoarthritis had progressed to include her cervical spine, right knee, right elbow, and bilateral feet. (Ex. 6, p. 26.) She continued to report joint stiffness in the morning and "gelling" of the joints after periods of inactivity. (*Id.*) Arthrocentesis of the right knee joint was performed, and petitioner received another steroid injection. (*Id.* at 28.) Dr. Siegel suggested gabapentin for petitioner's neck and joint pain, as well as physical therapy if her elbow pain persisted. (*Id.* at 29.) At her next encounter with Dr. Siegel in April, petitioner listed her cervical spine, right elbow, right knee, and left hip as affected joints. (*Id.* at 31.) During this encounter, arthrocentesis of the right elbow joint was performed, a steroid injection was administered, a right elbow x-ray was ordered, and petitioner was referred to physical

therapy. (*Id.* at 33-34.) In August, arthrocentesis of the right knee joint was performed, and a steroid injection was administered. (*Id.* at 38.) Petitioner's elbow x-ray showed no evidence degenerative changes at the tibio-talar joint or of fracture, dislocation, or osteochondral injury. (*Id.*) An MRI of petitioner's left forefoot showed "[a]dvanced osteoarthrosis involving left 2nd and 3rd tarsometatarsal joints with moderate active inflammation," but no fracture of bony destruction, and "[l]esser degenerative changes involving the 1st metatarsal sesamoid and 1st [tarsometatarsal] joint." (Ex. 25, p. 23-24.) By September, petitioner's symptoms had progressed to include her cervical spine, right elbow, left hip, bilateral knees, and left foot. (Ex. 6, p. 41.) Petitioner reported improvement with knee injection and Voltaren gel to the midfoot, though she discontinued use of Voltaren gel due to hypertension. (*Id.*; Ex. 24, pp. 28-29.) During this encounter, arthrocentesis of the left knee joint was performed, and a steroid injection was administered. (Ex. 6, p. 43.) By December, petitioner was reporting "episodic flare-ups with symptoms-free periods in between" and, although she continued to experience joint stiffness in the morning, she reported that her stiffness was resolving more quickly. (*Id.* at 46.) However, petitioner listed her cervical spine, right shoulder, right elbow, left hip, bilateral knees, and left foot as affected joints. (*Id.*) Arthrocentesis of the right shoulder joint was performed, and a steroid injection was administered. (*Id.* at 48.) Petitioner also continued to see her primary care provider, Dr. Ryal, for various issues. (Ex. 24, pp. 23-35.)

In 2014, petitioner reported that her joint symptoms were "stable and nonprogressive." (Ex. 6, p. 51.) During her March 2014 encounter with Dr. Seigel, arthrocentesis of the right subacromial bursa was performed, and a steroid injection was administered. (*Id.* at 53.) However, by June, petitioner was reporting "episodic flare-ups with symptoms-free periods in between" and her morning joint stiffness was persisting for a longer period. (*Id.* at 56.) Arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 58-59.) However, by October, petitioner was reporting "progressive worsening" of her generalized osteoarthritis. (*Id.* at 61.) Arthrocentesis of the bilateral knee joints was again performed, and further steroid injections were administered. (*Id.* at 63-64.) Petitioner also presented for orthopedic evaluations in 2014.[4] (Ex. 25, pp. 9-10.) In evaluating petitioner's left foot pain, orthopedist Nicholas Midis, M.D., diagnosed plantar fasciitis and, relevant here, noted that petitioner had "a history of arthritic changes." (*Id.* at 9.) During an initial physical therapy evaluation for petitioner's foot pain, it was noted that petitioner "has more than her share of arthritis." (Ex. 29, p. 3.)

In March of 2015, just a few months prior to vaccination, petitioner returned to Dr. Seigel for evaluation of her generalized osteoarthritis. (Ex. 6, p. 66.) She reported that she was now only experiencing episodic flare-ups with intermittent symptom-free periods. (*Id.*) She continued to report joint stiffness in the morning and "gelling" of the joints with inactivity. (*Id.*) Arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 68-69.)

[4] In additional to foot pain, petitioner presented for an orthopedic evaluation of her left hip pain. (Ex. 25, p. 10.) Imaging showed only minimal degenerative changes, and she was diagnosed with trochanteric bursitis of the left hip. (*Id.*)

Petitioner received the subject pneumococcal vaccination on May 22, 2015, during a regular encounter with her primary care physician, Dr. Ryal. (Ex. 1, pp. 4-7; Ex. 24, pp. 54-56.) She returned to Dr. Siegel on May 26, 2015, for evaluation of her longstanding generalized osteoarthritis. (Ex. 6, p. 71.) She now included her bilateral hands as among the list of affected joints. (*Id.*) Following a physical examination, Dr. Seigel recorded "erythematous tender left third [distal interphalangeal (DIP) joint] with diffuse Heberd[e]n nodes bilaterally."[5] (*Id.* at 73.) Petitioner was diagnosed with osteoarthritis of the bilateral hands and prescribed Voltaren gel. (*Id.* at 74.) There is no mention of petitioner's vaccination during this encounter.[6]

However, on June 8, 2015, petitioner returned for a rheumatology follow up and was seen by Nurse Practitioner (N.P.) Fredilynn Lansangan. (Ex. 6, p. 75.) During this encounter, petitioner reported that

> she was doing well until she received a pneumonia vaccine last week and developed a small cyst to the left 3rd finger DIP joint. Voices overall improvement to diffuse joint pain with use of Tylenol, but still has some residual swelling to the left 3rd DIP. Denies any joint pain in fingers except if she touches it. She was using Voltaren gel to finger with improvement in swelling.

(*Id.*) On physical examination, N.P. Lansangan recorded decreased range of motion in the left 3rd finger DIP, joint swelling, mild erythema and tenderness to left third DIP, and diffuse Heberden and Bouchard nodes, bilaterally.[7] (*Id.* at 77.) N.P. Lansangan's assessment included osteoarthritis of the hands and cutaneous nodule with a specific notation that petitioner "most likely developed a reaction to the pneumonia vaccine that contributed to her arthralgias." (*Id.*) However, N.P. Lansangan further noted that petitioner's overall symptoms had resolved with the exception of "some mild residual swelling and small, cystic nodule to her finger." (*Id.*) Petitioner was advised to treat her symptoms with warm soaks, compression, and Voltaren gel. (*Id.*) Rheumatologist

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[5] A DIP joint is the interphalangeal joint located distally on any digit. *DIP joint*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=8351 (last visited Aug. 26, 2025). Heberden nodes are "small hard nodules, formed usually at the distal interphalangeal joints of the fingers produced by calcific spurs of the articular cartilage and associated with interphalangeal osteoarthritis." *Heberden nodes*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=92979 (last visited Aug. 26, 2025).

[6] A phone log indicates that petitioner reached out to her primary care provider on May 27, 2025, to report that, since the vaccination, "she has been experiencing muscle and joint pain in her joints close to her finger nails and her finger hurts to touch." (Ex. 11, p. 1.) She was advised that joint pain is common in adults and should subside within 14 days of vaccination. (*Id.*) This record further confirms that petitioner reviewed the subsequently filed VAERS report prior to filing. (*Id.*)

[7] Bouchard nodes are "cartilaginous and bony enlargements of the proximal interphalangeal joints of the fingers in degenerative joint disease." *Bouchard nodes*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=92944 (last visited Aug. 26, 2025).

Michael Cannon, M.D., reviewed and agreed with N.P. Lansangan's assessment. (*Id.* at 78.)

Tanya Jones, a Licensed Practical Nurse (L.P.N.) at Dr. Ryal's office, also submitted a VAERS report on petitioner's behalf in June of 2015. (Ex. 2, p. 3.) In the report, L.P.N. Jones indicated that she administered the pneumococcal vaccine in petitioner's left arm in Dr. Ryal's office on May 22, 2015, at 1:26 p.m. (*Id.*) The alleged adverse event was described as including "joint pain in her knuckle closer to the fingernail" in both hands and joint pain in her left hand. (*Id.*) It was noted that petitioner had osteoarthritis prior to vaccination and that "the injection made it worse." (*Id.*) In response to the question of whether the patient had recovered, L.P.N. Jones wrote "getting better not gone not totally recovered." (*Id.*)

On July 27, 2015, petitioner presented for evaluation by Dr. Ryal. (Ex. 5, p. 53.) Dr. Ryal recorded "a long standing history of arthritis that is in her feet, knees and neck," for which she was being followed by Dr. Seigel and treated with cortisone shots in the knees. (*Id.*) Dr. Ryal further recorded that

> [s]he has Heberden's nodes of her DIP[s] on her bilateral fingers but has never had joint pain in her hands until 2 days after the [pneumococcal] shot. She noted DIP pain and swelling of the left middle finger. She called the office [complaining of] significant bilateral joint hand pain, and an adverse vaccine reaction was reported. She developed a b[l]ister over the left middle DIP joint, and a horizontal line on her nail where her nail bed was damaged with the inflammation.

(*Id.*) Petitioner continued to report ongoing bilateral hand pain, resulting in difficulty opening bottles and using a calculator at work. (*Id.*) The pain was localized to the right carpometacarpal, metacarpophalangeal joint, and interphalangeal joint of the thumb, as well as the left middle DIP joint. (*Id.*) On physical examination of the left hand, Dr. Ryal observed nodules over DIP of all four fingers; erythematous across all four fingers, but worse over the middle finger; and a horizontal line on the nail of the middle finger that did not appear on the other nails. (*Id.* at 54.) A physical examination of the right hand showed nodules over all DIPs with erythema over the second and fourth digit; pain with range of motion of the carpometacarpal joint of the thumb; and decreased active range of motion of the metacarpophalangeal joint of the right thumb. (*Id.*) Petitioner's lab results showed a normal erythrocyte sedimentation rate (ESR) of 3.0 mm/hr (reference range of 0.0-30.0 mm/hr), a normal C-Reactive Protein (CRP) level of <0.3 mg/dl (reference range of 0.0-0.5 mg/dl), a normal TSH level of 2.55 mcU/ML (reference range of 0.27-4.20 mcU/ML), and a negative rheumatoid factor. (*Id.* at 96, 112-14.) Imaging of petitioner's bilateral hands showed no evidence of acute fracture and mild to moderate osteoarthritis. (*Id.* at 135-36.) Dr. Ryal assessed adverse reaction to pneumococcal vaccine and hand arthritis pain, and noted that "[m]ost reactive arthritis last[s] 3-5 months, but then resolves in 6-12 months." (*Id.* at 54.)

On August 6, 2015, petitioner returned for a follow up with Dr. Seigel. (Ex. 6, p. 79.) The history of present illness was substantively unchanged except for the addition of the following statement: "Hand pain with diffuse arthralgias noted two days after receiving updated Pneumococcal vaccine." (*Id.*) Physical examination showed joint swelling; mild tenderness to the left third DIP; diffuse Heberden and Bouchard nodes, bilaterally; and fullness about the base of the right thumb. (*Id.* at 81.) Dr. Seigel reviewed petitioner's lab work and imaging, noting that her recent imaging showed "diffuse degenerative changes over PIP and DIP joints, first [carpometacarpal] area intact." (*Id.*) Arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 81-82.) Dr. Seigel's assessment included osteoarthritis of the hands and knees, and a referral to hand therapy was made for paraffin soaks, splinting, and puddy exercises. (*Id.* at 82-83.)

Petitioner had a follow up appointment with Dr. Ryal on December 3, 2015, during which the arthritis in her hands was noted to be unchanged. (Ex. 5, p. 55.) Petitioner described inability to use her right hand for certain activities due to pain. (*Id.*) Petitioner further reported pain in her knee, neck, and ankle. (*Id.*) A physical examination revealed some DIP nodules of all fingers, pain along the radial aspect of the right thumb with movement, and pain with adduction of thumb, but negative Finkelstein test of the bilateral hands and no evidence of thenar atrophy. (*Id.* at 56.) In pertinent part, Dr. Ryal's assessed arthritis in petitioner's hands that was "likely reactive follow[ing] Prevnar shot in May" and opined that the condition should resolve within a year. (*Id.*) During a follow up with Dr. Seigel on December 7, 2015, petitioner's complaints and exam findings remained unchanged. (Ex. 30, pp. 22-26.) Arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 25.) Dr. Seigel's assessment included generalized osteoarthritis of the knee and bilateral primary osteoarthritis of the first carpometacarpal joints. (*Id.* at 26.) Regarding the arthritis in petitioner's hands, Dr. Siegel suggested that petitioner consider seeing an orthopedist. (*Id.* at 25.)

In the following months, petitioner continued to present for treatment of various issues. In March of 2016, petitioner presented to an otolaryngologist for evaluation of right ear pain. (Ex. 31, pp. 1-5.) A subsequent CT scan of petitioner's neck failed to identify a cause for petitioner's ear pain but revealed advanced degenerative joint disease in the cervical spine. (Ex. 32, pp. 9-11.) Petitioner also had three primary care appointments (April 28, 2016; May 20, 2016; and June 16, 2016), during which she did not complain of hand pain and the arthritis in her hands was not mentioned. (Ex. 5, pp. 58-66.)

By the time petitioner returned to Dr. Siegel on April 5, 2016, her joint symptoms were noted to be "stable and nonprogressive." (Ex. 6, p. 93.) Physical examination showed continued joint swelling; diffuse Heberden and Bouchard nodes, bilaterally; and fullness about the base of the right thumb. (*Id.* at 95.) Arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 95-96.) Dr. Seigel's assessment again included generalized osteoarthritis of the knee and bilateral primary osteoarthritis of the first carpometacarpal joints with a suggestion that petitioner

consider seeing an orthopedist for her hand. (*Id.* at 96-97.) Her condition remained largely unchanged during her August 11, 2016 follow up appointment with Dr. Seigel. (*Id.* at 98-102.) Dr. Seigel observed new evidence of bony enlargement in the bilateral knees, arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 100-01.) Petitioner's CRP level was still normal at 0.3 mg/dl (reference range of 0.0-0.5 mg/dl), as was her ESR of 5.0 mm/hr (reference range of 0.0-30.0 mm/hr). (Ex. 5, p. 99, 110.) Dr. Seigel's diagnoses remained unchanged with a notation suggesting that petitioner see an orthopedist if considering hand surgery. (Ex. 6, pp. 101-02.)

On October 13, 2016, petitioner presented to hand surgeon Lance Davlin, M.D. (Ex. 7a, pp. 2-3.) She presented with complaints of pain about the left 3rd DIP joint and the base of the right thumb. (*Id.* at 6.) Petitioner reported that she received the pneumococcal vaccine in May of 2015 and, within several days thereafter, developed pain, swelling, and stiffness in both hands. (*Id.*) She also experienced a blister on her left 3rd finger and ridging of the nail plate, but both conditions subsequently resolved. (*Id.*) A physical examination showed "typical stigmata of osteoarthritis of both hands evidenced by Heberden and Bouchard nodes." (*Id.* at 7.) There was reduced range of motion in the left long finger and both thumbs with discrete pain at the basilar joint of the right thumb. (*Id.*) An x-ray of the right wrist and thumb revealed "severe narrowing of the 1st CMC joint with lateral translation of the metacarpal in relationship to the trapezium and osteophyte formation" and "moderate narrowing of all IP joints." (*Id.*) An x-ray of the central three digits of the left hand revealed "moderate to severe arthritis of the DIP joints particularly of the left 3rd finger with decreased joint space, osteophyte formation, and subchondral cyst formation." (*Id.*) Dr. Davlin's assessment was osteoarthritis in the basilar joint, right thumb, and left 3rd finger with "far-advanced degenerative changes at the basilar joint of the right thumb." (*Id.* at 3.) After discussing treatment options with petitioner, Dr. Davlin opined that, "[f]rom her history, it sounds as if she had a mucous cyst which resolved and is probably related to her osteoarthritis" and, although she reported being "told by a physician that it may be reactive arthritis in response to the vaccine," Dr. Davlin opined that "it is unclear as to the relationship of the pneumovax vaccine to the development of her osteoarthritis." (*Id.* at 3, 6.) Petitioner elected to forgo treatment with steroid injection. (*Id.* at 6.)

On December 1, 2016, petitioner had a primary care appointment for follow-up on her "hand joint pain that started May of last year after a pneumonia vaccine." (Ex. 5, p. 67.) She was advised to follow-up with Dr. Siegel for steroid injections as needed. (*Id.* at 69.) Two weeks later, petitioner saw Dr. Siegel with complaints of increased pain (7 out of 10) after tripping and falling onto both of her knees. (Ex. 30, p. 38.) She reported symptoms in the cervical spine, right shoulder, left hip, and bilateral knees, hands, and feet. (*Id.*) She was again diagnosed with osteoarthritis in her hands and knees, arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 41-43.) Regarding her hands, Dr. Siegel noted that petitioner was being followed by an orthopedist and that she was treating conservatively. (*Id.* at 42.)

The arthritis in petitioner's hands was not mentioned during her next primary care appointment on February 8, 2017 (Ex. 24, pp. 75-77); however, petitioner returned to Dr. Ryal on March 27, 2017, with complaints of joint pain in her left middle finger and right thumb (*Id.* at 78). She described some relief with the steroid injections in her bilateral knees. (*Id.*) A physical examination revealed some pain with movement of her fingers and thumb but no erythema or warmth. (*Id.* at 79.) Dr. Ryal's assessment was arthritis in her hands, which was likely reactive following the pneumococcal vaccination in May of 2015. (*Id.*) Although more than a year had passed since petitioner received the subject vaccination, Dr. Ryal again noted that reactive arthritis generally resolves within a year. (*Id.*) She advised that petitioner continue to treat with Voltaren gel. (*Id.*)

Petitioner presented to Dr. Siegel on April 10, 2017, with continued pain that was slightly less severe at a 5 out of 10 and affecting the cervical spine and bilateral knees, hands, and feet. (Ex. 30, p. 44.) It was noted that petitioner experienced "[p]ersistent pain in the base of her right thumb and changes in left third distal digits" following pneumococcal vaccination in May of 2015, and "exams in this office on May 26, 2015 and June 8, 2015 confirm[ed] flare in Heberden node." (*Id.*) A physical examination revealed bony enlargement in the first carpometacarpal joint of the right hand; diffuse Heberden nodes, bilaterally; and residual tenderness in the left third DIP joint. (*Id.* at 46.) She was again diagnosed with osteoarthritis in her hands and knees, arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 47-48.) Petitioner returned to Dr. Siegel on August 10, 2017, with increased pain (8 out of 10) in her cervical spine and bilateral hands, knees, and feet. (*Id.* at 49.) A physical examination revealed new knee symptoms, but petitioner's hand symptoms remained stable. (*Id.* at 51.) Arthrocentesis of the bilateral knee joints was performed, and steroid injections were administered. (*Id.* at 51-52.) Although Dr. Siegel diagnosed petitioner with osteoarthritis in her knees, there is no mention of the arthritis in her hands. (Ex. 30, pp. 52-53.)

In the following years, petitioner continued to seek treatment for her persistent arthritis. (Exs. 24, 30, 42, 51, 59.) As recent as January 30, 2024, petitioner was diagnosed with idiopathic osteoarthritis affecting the DIPs, first carpometacarpal joints, and bilateral knees. (Ex. 59, pp. 14-20.) It was recorded that petitioner was to receive injections in the first carpometacarpal joint of the right hand by her hand surgeon. (*Id.* at 14.)

b. Testimony

Petitioner filed a sworn affidavit and provided testimony during the fact hearing that commenced on May 7, 2024. (Ex. 3; Tr. 5-6.) She testified to a history of arthritis in her knees, feet, and neck, for which she had been regularly seeing a rheumatologist for several years prior to vaccination. (Tr. 9-10, 14, 26.) However, although she acknowledged the presence of Heberden nodes on her fingers, she denied experiencing hand pain or any other issues with her hands prior to vaccination. (*Id.* at 10, 14, 17-18.) Petitioner received the subject pneumococcal vaccine on May 22, 2015.

(*Id.* at 7.) She testified that, although she had received other vaccines in the past, this was the first pneumococcal vaccine that she had received. (*Id.* at 10-11.)

Within a few days following pneumococcal vaccination, she noticed painful "skin pyramid on the side of my finger,"[8] which her rheumatologist could not identify. (Tr. 7, 29.) Petitioner stated that, within a couple days, the "skin pyramid" turned into a "blister" on the first knuckle (closest to the nail) of the left middle finger.[9] (*Id.* at 7-9, 11, 29-30.) She explained that the blister was near the nail and affected the nail, resulting in a "line in my fingernail." (Tr. 31-32.) When she returned to her rheumatologist, it was still unclear what the "blister" was. (*Id.* at 7.) Petitioner described pain when she "popped" the "blister." (*Id.* at 7-8, 11, 30.) Petitioner also described joint pain starting in her left middle finger and progressing to her right thumb after about a week. (*Id.* at 8, 13-14, 27-28; Ex. 5, ¶ 4.) She described the pain as a "sharp, throbbing pain" at the base of her right thumb "that lasted for approximately 5 or 6 months." (Tr. 8; Ex. 5, ¶ 3.) She also described acute soreness in all of her joints that dissipated within "either a week or a few days" following vaccination. (Tr. 26-27; Ex. 5, ¶ 2.)

When petitioner presented for a primary care visit, Dr. Ryal informed her that joint pain can last for up to a year and to "wait a year, [and] see how it goes." (Tr. 12.) She averred that the symptoms resolved over the course of a couple of weeks. (Ex. 5, ¶ 3.) However,

> [t]he thumb pain has never gone away. That's the big issue. The other, where the blister was is a lot better. It got a lot better over a couple of years, and it only hurts if I hit it. But the thumb is what I have a lot of trouble with.

(Tr. 12, 24.) Petitioner presented to a hand specialist, Dr. Davlin, and was told that "there was no cartilage left where the blister was on that knuckle, and none at the base of the thumb." (Tr. 12.) Dr. Davlin suggested surgery, but petitioner declined. (*Id.*) She confirmed some relief with steroid injections. (*Id.* at 17, 19.)

Petitioner averred that she continues to suffer pain in her right thumb with activity. (Ex. 5, ¶ 3.) She described how her joint pain has affected her ability to perform activities of daily living, including blow drying her hair, applying eyeliner, and opening a bottle of water, as well as her ability to perform her work duties, such as taking a file out of the filing cabinet. (Tr. 14-15; Ex. 5, ¶ 5.) She attributed these difficulties to her right hand but averred that she does not have similar problems with her left hand. (Tr. 15.) However, she testified that her left middle finger hurts if she "knock[s] it on something." (*Id.* at 15-16.)

At the time of the hearing, petitioner testified that she is no longer followed by Dr. Ryal. (Tr. 20.) However, she explained that she saw Dr. Ryal every couple of months

[8] In her affidavit, petitioner described that "skin pyramid" as a "cystic nodule at the DIP joint." (Ex. 5, ¶ 3.)

[9] In her affidavit, petitioner described "a blister of cystic nodule at the DIP joint . . . on my left 3rd finger." (Ex. 5, ¶ 3; *see also id.* ¶ 2 (describing "a small cyst on the left 3rd finger DIP joint").)

and that they constantly discussed her joint pain. (*Id.* at 22.) She averred that Dr. Ryal "knew it was from the vaccine." (*Id.* at 22-23.) Petitioner testified that N.P. Lansangan opined that petitioner's blister was "most likely a result of the vaccine. It was the pneumonia vaccine." (*Id.* at 13, 23, 32.)

IV. Expert Opinions

a. Internist Jennifer Ryal, M.D., for petitioner[10]

When petitioner first filed her petition, it was accompanied by an affidavit by Dr. Ryal. (Ex. 4.) In her sworn affidavit, Dr. Ryal indicated that she performed examinations of petitioner on July 27, 2015, December 3, 2015, April 28, 2016, May 20, 2016, June 16, 2015, and December 1, 2016. Based on the petitioner's history and these physical exams, Dr. Ryal opined that petitioner "has suffered and continues to suffer from significant bilateral hand pain, which was most likely caused in fact by the pneumococcal vaccine injection she received on May 22, 2015." (Ex. 4, ¶¶ 2-3.)

Petitioner subsequently filed a "report" by Dr. Ryal dated April 16, 2018. (ECF No. 17; ECF No. 25-1; Ex. 9.) In this report, Dr. Ryal provided more detail regarding her observations. She indicated that petitioner, a patient of hers since 2010, had no complaints relating to her hands prior to the vaccination at issue, except for a complaint of numbness and paresthesia in April of 2011, which resolved. (Ex. 9, pp. 1-2.) Petitioner called her office and complained of joint pain on May 27, 2015, and "[b]ecause joint pain is a very common reaction to such a vaccination, I directed my staff to prepare and file a Vaccine Adverse Event Reporting System report." (*Id*. at 2.) Dr. Ryal stated that:

> When I next saw the patient on July 27, 2015, she complained of debilitating bilateral hand pain since two days after the Prevnar shot. Although she had a longstanding history of osteoarthritis, she never had joint pain in her hands until this incident. The inflammation I observed in both hands on July 27, 2015, in my opinion then and now was not consistent with osteoarthritis. The hand symptoms following the Prevnar vaccination presented a new condition and, based upon the redness and acute joint inflammation I observed, represented reactive arthritis caused by the vaccine.

(*Id*.) In addition to her own personal observations, Dr. Ryal also confirmed that she reviewed the medical records of Dr. Siegel, petitioner's rheumatologist. (*Id*.)

[10] Dr. Ryal received her medical degree from the University of Oklahoma in 2003, before going on to complete a combined family medicine and internal medicine residency at Eastern Virginia Medical School in 2007. (Ex. 10, p. 1.) From there, Dr. Ryal accepted a position as an assistant professor of internal medicine at the Eastern Virginia Medical School. (*Id.*) She was eventually promoted to Medical Director of Primary Care Internal Medicine at Eastern Virginia Medical School in 2017. (*Id.*) She is board certified in internal and family medicine, and she maintains an active medical license in Virgina. (*Id.*; Ex. 9, p. 1.)

Thereafter, petitioner filed a supplemental report by Dr. Ryal responding to specific questions posed by the previously presiding special master. (Ex. 12.)

Asked to explain her theory of causation and to indicate what literature supports the theory, Dr. Ryal indicated that "I am unsure how the pneumococcal vaccine causes arthritis." (Ex. 12, p. 2.) However, "[m]y theory is that the pneumococcal vaccine caused a cytokine response and that this response caused an inflammatory cascade that triggered [petitioner's] pre-existing arthritis in her hands, causing significant pain and loss of function." (*Id*.) Dr. Ryal noted that the rubella, influenza, and Hepatitis B vaccines are all known to cause or exacerbate arthritis and that, while no other vaccine has been associated with arthritis, the package insert for the pneumococcal vaccine reported that generalized joint pain was a solicited adverse reaction in 7.4% of study participants. (*Id*. (citing Prevnar-13 (Pneumococcal 13-Valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]) Prescribing Information [hereinafter Prevnar-13 Package Insert]; Ex. C, Tab 3); *see also* Ex. 12, n.2.)

Dr. Ryal sought to clarify that while she referred to petitioner's arthritis as "reactive arthritis," "I mean that the arthritis she developed was an inflammatory reaction to the vaccine, rather than that she had Reiter's syndrome which is an aseptic inflammatory polyarthritis that usually follows nongonococcal urethritis or infectious dysentery." (Ex. 12, p. 2.) She indicated that the vaccine "triggered the pain in the osteoarthritis of her hands." (*Id*. at 3.) Confusingly, however, in her conclusion Dr. Ryal reiterated that petitioner's post-vaccination hand pain "was a new condition, not part of her long-standing osteoarthritis but rather a reaction caused by the vaccination." (*Id*. at 7.)

Dr. Ryal cited approvingly to literature introduced by respondent for the proposition that "inflammation plays a central role in osteoarthritis and that inflammatory mediators such as cytokines produce and activate cells from joint tissues that lead to joint damage in osteoarthritis." (Ex. 12, p. 2 (footnote omitted) (citing Francis Berenbaum et al., *Osteoarthritis, Inflammation and Obesity*, 25 CURRENT OP. RHEUMATOLOGY 114 (2013) (Ex. A, Tab 2)).) She cited Interleukin 1 beta (IL-1β), tumor necrosis factor (TNF), and Interleukin 6 (IL-6) as the "main proinflammatory cytokines" involved in osteoarthritis. (*Id.* (citing Mohit Kapoor et al., *Roles of Proinflammatory Cytokines in the Pathophysiology of Osteoarthritis*, 7 NATURE REVS. RHEUMATOLOGY 33 (2011) (Ex. 13)).) She cited a study by Kashiwagi et al. for the proposition that the components of the pneumococcal vaccine have been shown to increase IL-1β. (*Id.* at 2-3 (citing Yasuyo Kashiwagi et al., *Production of Inflammatory Cytokines in Response to Diphtheria-Pertussis-Tetanus (DPT),* Haemophilus Influenzae *Type B (Hib), and 7-Valent Pneumococcal (PCV7) Vaccines*, 10 HUM. VACCINES & IMMUNOTHERAPEUTICS 677 (2014) (Ex. 17)).) She further suggested that aluminum adjuvant within the vaccine can stimulate inflammasomes, which can cause tissue damage and induce production of IL-1β. (*Id*. at 3 (citing Kate Schroder & Jurg Tschopp, *The Inflammasomes*, 140 CELL 821 (2010) (Ex. 14); Najwane Saïd-Sadier & David M. Ojcius, *Alarmins, Inflammasomes and Immunity*, 35 BIOMED. J. 437 (2012) (Ex. 15); Mirjam Kool et al., *Alum Adjuvant Boosts*

Adaptive Immunity by Inducing Uric Acid and Activating Inflammatory Dendritic Cells, 205 J. EXPERIMENTAL MED. 869 (2008) (Ex. 16); Kashiwagi et al., *supra*, at Ex. 17).)

Asked how an immune-mediated process could occur in fewer than 48 hours after vaccination, Dr. Ryal opined that the immune reaction at issue is the innate immune response, which can happen "quite quickly after the injection" and results in muscle aches and joint pains. (Ex. 12, p. 6.) She disclaimed any reliance on an antibody response. (*Id.*) Asked whether osteoarthritis is a condition mediated by the immune system, Dr. Ryal explained that "[w]e've long know that osteoarthritis is a degenerative process that does not involve auto-antibodies, or the acquired immune system." (*Id.*) However, she indicated that cytokines "play a central role in the inflammation seen in the joint in osteoarthritis." (*Id.*) Thus, she opined that "[s]ome of [the] pro-inflammatory cytokines stimulated by the innate immune response in the setting of a vaccine or infection, are also involved in the pathogenesis of osteoarthritis." (*Id.*) Dr. Ryal cited the Institute for Vaccine Safety as concluding that environmental factors, such as infection, may trigger or contribute to the pathogenesis of arthritis, even as the exact mechanism remains unclear. (*Id*. at 7 (citing *Do Vaccines Cause Arthralgia or Arthritis?*, INST. FOR VACCINE SAFETY (last updated Oct. 10, 2023) (Ex. D; *see also* Ex. 12, n.16)).)

Asked why gout or psoriatic arthritis would be less likely than reactive arthritis, Dr. Ryal opined that "it would be very unusual for the initial presentation of gout to be polyarthritis of the hands" and noted that petitioner "has not gone on to develop gout." (Ex. 12, p. 3.) Regarding psoriatic arthritis, she indicated that "I did not think [petitioner's] arthritis was psoriatic or rheumatoid as it lacked the joint swelling, the morning stiffness only lasted 30 minutes and the distribution was consistent with that of osteoarthritis." (*Id*.) Further asked specifically whether petitioner's pain was in an osteoarthritis distribution, Dr. Ryal opined that petitioner's pain "absolutely" was in such a distribution. (*Id*. at 4.) Asked to comment on petitioner's x-rays and whether the findings indicate a progression of osteoarthritis, Dr. Ryal agreed that the x-rays of petitioner's hands showed mild to moderate changes at the PIPs and DIPs without erosions or soft tissue swelling, which she indicated is consistent with osteoarthritis, but not gout, psoriatic arthritis, or rheumatoid arthritis. (*Id*.) However, she declined to comment on whether there was progression of osteoarthritis because she did not have prior x-rays for comparison, though she noted that petitioner had pre-existing Heberden nodes, which were unchanged after vaccination. (*Id*.) Asked to comment on whether the x-ray findings are consistent with the presence of joint inflammation and/or reactive arthritis, Dr. Ryal indicated that she does not believe petitioner had a reactive arthritis reaction. (*Id.*) Inflammatory arthritides, such as reactive arthritis, would typically have white blood cells in the joint. (*Id.*) Although there are no specific findings on radiographs that can establish a diagnosis of reactive arthritis, signs of inflammatory arthritis can include bone erosions, osteopenia, soft tissue swelling, and uniform joint space loss. (*Id.*) Nonetheless, the absence of these findings does not rule out reactive arthritis, and petitioner's distal distribution and joint space narrowing was consistent with both reactive arthritis and osteoarthritis. (*Id.* at 4-5.)

Asked about petitioner's normal erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and negative rheumatoid factor, Dr. Ryal indicated that the negative rheumatoid factor would be consistent with reactive arthritis. (Ex. 12, pp. 5-6.) She indicated that "[w]e know that CRP levels have been correlated to the severity of pain in patients with osteoarthritis, and it seems that the more generalized the arthritis, the slightly more elevated CRP. Given that [petitioner] has generalized osteoarthritis, and the amount of ongoing pain and loss of function she had in her hands, I was surprised that her CRP was not elevated." (*Id.* at 5 (footnote omitted) (citing T Stürmer et al., *Severity and Extent of Osteoarthritis and Low Grade Systemic Inflammation as Assessed by High Sensitivity C Reactive Protein*, 63 ANNALS RHEUMATIC DISEASES 200 (2004) (Ex. 18)).) Dr. Ryal indicated she was "surprised" by petitioner's ESR of 3, noting a study that found that the mean ESR for those with osteoarthritis was 17. (*Id*. (citing Gabriel Horta-Baas & María del Socorro Romero-Figueroa, *Clinical Utility of Red Blood Cell Distribution Width in Inflammatory and Non-Inflammatory Joint Disease*, 22 INT'L J. RHEUMATIC DISEASES 47 (2019) (Ex. 19)).) Nonetheless, she noted that elevated ESR is more likely in an inflammatory arthropathy, such as rheumatoid arthritis, than in osteoarthritis. (*Id*.)

Asked whether nail changes and cysts are associated with osteoarthritis, Dr. Ryal agreed that they are. (Ex. 12, p. 6.) She indicated that petitioner did not have any documented nail changes or cysts when she saw Dr. Siegel on May 26, 2015. (*Id.*) She was first evaluated by Dr. Seigel's office for a small cystic nodule on June 8 and nail changes, which can take about 7 weeks to develop based on the rate of nail growth, were first observed on July 27th. (*Id.*)

Dr. Ryal confirmed that she had reviewed Dr. Gensler's report at Exhibit A and the authorities cited therein, but that she maintained her opinion as stated in her prior affidavit and report. (Ex. 12, p. 7.)

b. Rheumatologist Lianne Gensler, M.D., for respondent[11]

Dr. Gensler opined that petitioner had chronic, pre-existing osteoarthritis and did not develop either reactive arthritis or a reactive-like arthritis post-vaccination. (Ex. A, pp. 10-11.) Dr. Gensler noted that petitioner had both a family history of osteoarthritis and a metabolic syndrome associated with osteoarthritis. (*Id.* at 10 (citing Berenbaum et al., *supra*, at Ex. A, Tab 2).) Petitioner's third finger DIP cyst and observed nail

[11] Dr. Gensler received her medical degree from the Medical School at University of California, Irvine in 2001, before going on to complete an internship and residency at University of California, San Francisco in 2002 and 2004, respectively, followed by a fellowship in rheumatology at University of California, San Francisco in 2008. (Ex. B, p. 1.) From there, Dr. Gensler accepted a position as an assistant clinical professor at University of California, San Francisco. (*Id.* at 2.) She was eventually promoted to associate professor of clinical medicine in the rheumatology division in 2015. (*Id.*; Ex. A, p. 1.) She is the director of the Spondyloarthritis Clinic and the Rheumatology Residency Elective. (Ex. B, p. 1; Ex. A, p. 1.) Dr. Gensler is board certified in internal medicine and rheumatology, and she maintains a medical license in California. (Ex. B, p. 1.) In addition to her rheumatology training, Dr. Gensler completed epidemiology research training and received a certificate in Advanced Training in Clinical Research from University of California, San Francisco. (Ex. A, p. 1.) Dr. Gensler's primary area of interest is Spondyloarthritis, but she has clinical expertise in all areas of rheumatic disease. (*Id.* at 2.)

changes are further consistent with osteoarthritis. (*Id*. (citing Yang-Chih Lin et al., *Nail Changes and Association of Osteoarthritis in Digital Myxoid Cyst*, 34 DERMATOLOGIC SURGERY 364 (2008) (Ex. A, Tab 4)).) She noted that petitioner's osteoarthritis was confirmed radiographically, indicating that such findings "do not occur overnight." (*Id*.) Dr. Gensler noted that soft tissue swelling should be considered a physical exam finding, rather than relying on x-ray imaging; however, she interpreted the available x-rays as showing changes "consistent with long standing osteoarthritis." (Ex. C, p. 3.) Moreover, the nail changes that were observed "take months to develop," rendering a temporal relationship to petitioner's vaccination impossible. (Ex. A, pp. 10-11.)

Dr. Gensler indicated that "osteoarthritis is a degenerative condition that is not inflammatory or set off by the immune system. Vaccines can cause joint pain, typically in a viral joint pain distribution (MCP/PIPs, not DIPs), but this is well beyond the joint pain of vaccine injury." (Ex. A, pp. 10-11.) Moreover, Dr. Gensler disagreed with Dr. Ryal's suggestion that pro-inflammatory cytokines are implicated in the pathogenesis of osteoarthritis, indicating that the assertion is not supported by any evidence. (Ex. C, p. 4.) She stressed that "[t]he innate immune response does not cause arthritis or arthralgias in the context of vaccines, or osteoarthritis or an osteoarthritis flare in general." (*Id*.) In petitioner's case, the normal sedimentation rate is not specific, but it is "reassuring that the patient did not have an inflammatory response to the vaccine in an immune mediated manner." (*Id*. at 3.) However, Dr. Gensler does not agree that CRP can be correlated to pain severity in osteoarthritis, given that it is not an inflammatory condition. (*Id*.)

Dr. Gensler noted that the arthralgia known to be caused by Rubella-containing vaccines, as cited by Dr. Ryal, is only mild and transient. (Ex. C, p. 1 (citing *Do Vaccines Cause Arthralgia or Arthritis?*, INST. FOR VACCINE SAFETY (last updated June 1, 2017) (Ex. C, Tab 2)).) However, joint pain is a nonspecific symptom that cannot be equated with osteoarthritis, a degenerative condition that has not been described as an adverse event following vaccination. (*Id*.) Dr. Gensler challenged the notion that vaccination "could result in the continued self-perpetuated activation of the innate immune system necessary for a chronic rheumatologic disease." (*Id.* at 2.) Dr. Gensler stressed that the Institute for Vaccine Safety publication cited by Dr. Ryal explicitly indicates that "[o]ther vaccines currently routinely recommended to the general population in the U.S. have not been shown to cause chronic arthralgia or arthritis." (*Id*. (quoting INST. FOR VACCINE SAFETY, *supra*, at Ex. C, Tab 2, p. 1).) And, whereas Dr. Ryal cited reported instances of joint pain as a solicited event as discussed in the vaccine package insert, Dr. Gensler pointed out that the placebo group had the same proportion of new and aggravated joint pain, meaning that this data does not support the hypothesis that the Prevnar vaccine can cause or exacerbate joint pain. (*Id* (discussing Prevnar-13 Package Insert, *supra*, at Ex. C, Tab 3).) Dr. Gensler also disagreed that the alum adjuvant within the vaccine can be causal of arthritis, suggesting that this has been extensively studied. (*Id*.)

Dr. Gensler explained that reactive arthritis is an immune mediated inflammatory arthritis that can occur 1-3 weeks following an antecedent infection; however, it typically

occurs in the lower extremities, whereas petitioner's symptoms were primarily in her fingers. (Ex. A, p. 10.) Moreover, the vaccine at issue is not known to cause reactive arthritis. (*Id*.) "Even if we called this a reactive-like arthritis, the timing, joint distribution, lack of inflammatory symptoms (morning stiffness < 60 minutes) and signs (no swelling of typical inflammatory joints) are not consistent." (*Id.*) Although the petitioner associated her symptoms to her vaccine, she has a prior history of such attribution at a rate that is higher than generally expected and includes some associations that are "highly improbable." (*Id*. at 9.) For example, petitioner has asserted elevated blood pressure from Voltaren gel and intra-articular steroid injections, as well as esophageal constriction related to hydrocholorthiazide and hair loss, receding gums, and rash related to amlodipine. (*Id*. (citing Ex. 5, p. 68).) Dr. Gensler strongly implies that petitioner's perception of an adverse reaction to her vaccination is more consistent with a pattern of misperceiving adverse reactions to medical treatments. (*Id*. at 9-10.)

Dr. Gensler opined:

> There is no valid mechanistic or epidemiologic data that supports an association of the Prevnar-13 vaccine and the development of a non-immune mediated degenerative condition like osteoarthritis (or osteoarthritis flare) or reactive arthritis (which is essentially moot as this is not a reactive arthritis presentation). There is no epidemiologic data or case report that supports a relationship of any kind. Association and causation are very different entities. Still, neither association or causality is supported in the literature or in this case.

(Ex. A, p. 11 (citing MT Sanchez-Santos et al., *Association of Metabolic Syndrome with Knee and Hand Osteoarthritis: A Community-Based Study of Women*, 48 SEMINARS ARTHRITIS & RHEUMATISM 791 (2019) (Ex. A, Tab 1); Berenbaum et al., *supra*, at Ex. A, Tab 2; Paolo Durando et al., *Safety and Tolerability of 13-Valent Pneumococcal Conjugate Vaccine in Elderly: An Observational Study in Liguria Region, Italy*, 11 HUM. VACCINES & IMMUNOTHERAPEUTICS 172 (2015) (Ex. A, Tab 5)).)

V. Analysis

Petitioner argues that the vaccination at issue "caused her to suffer an inflammatory reaction to the vaccine manifesting as joint pain and subsequent decreased range of motion in the thumb and DIP joints of both hands which, despite her past medical history of osteoarthritis and other conditions, she had never previously experienced." (ECF No. 79, p. 16.) Thus, petitioner frames her argument under the *Althen* test for causation in fact. (*Id*. at 17-20; ECF No. 82, pp. 6-9.) Respondent contends, however, that petitioner has not come forward with a defined and recognized injury that could support compensation. (ECF No. 80, p. 16.) Moreover, he argues that petitioner's proffered medical opinion by Dr. Ryal does not articulate a theory of causation. (*Id*. at 17.) Thus, he urges that petitioner cannot meet the *Althen* test for causation in fact. (*Id*. at 16-18.) Respondent stresses that petitioner did not pursue any

argument that her pre-existing osteoarthritis was significantly aggravated by her vaccination. (*Id*. at n. 2.)

a. Medical theory of causation (*Althen* prong one)

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (quoting *Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006)). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *See Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [their] theory." *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). "While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Id.* (quoting *Knudsen*, 35 F.3d at 548-49).

A threshold question with respect to petitioner's *Althen* prong one showing is what condition petitioner is theorizing to have been vaccine-caused. In her motion, petitioner does not specify. She argues only that Dr. Ryal has demonstrated a theory showing that petitioner developed "an immune system mediated reaction that manifested initially as generalized arthralgias that later subsided leaving Petitioner with persistent joint pain and de[c]reased range of motion in the base of her right thumb and DIP of the left third finger." (ECF No. 79, p. 17.) However, Dr. Gensler explained that joint pain is only a nonspecific symptom. (Ex. C, p. 1.) Thus, respondent challenges the notion that this is adequate to meet petitioner's burden of proof under *Althen* prong one. (ECF No. 80, pp. 16-17.)

As respondent suggested in his motion response, petitioner "must specify [her] vaccine-related injury and shoulder the burden of proof on causation." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'"[12] *Stillwell v. Sec'y of Health & Human Servs.*, 118 Fed. Cl. 47, 56 (2014) (emphasis omitted) (quoting 42 U.S.C. § 300aa-11(c)). In order to present an

[12] Of course, it is also the case that "the function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu*, 569 F.3d at 1382 (quoting *Knudsen*, 35 F.3d at 549).

"injury" cognizable under the Vaccine Act, "[m]edical recognition of the injury claimed is critical" and petitioner must assert "more than just a symptom or manifestation of an unknown injury." *Broekelschen*, 618 F.3d at 1349. To the extent Dr. Ryal does purport to opine that vaccination can activate the innate immune system to result in joint pain, this would be unpersuasive as applied to chronic arthritis broadly. Although Dr. Ryal purported to show that several different vaccines can cause arthritis (Ex. 12, p. 2 (citing INST. FOR VACCINE SAFETY, *supra*, at Ex. D)), Dr. Gensler persuasively noted that the literature Dr. Ryal relied upon established only that Rubella-containing vaccination can cause some transient joint pain (Ex. C, p. 1 (citing INST. FOR VACCINE SAFETY, *supra*, at Ex. C, Tab 2)). Otherwise, Dr. Ryal conceded that "I am unsure how the pneumococcal vaccine causes arthritis." (Ex. 12, p. 2.)

Dr. Ryal's repeated references to an inflammatory reaction leading to arthritis does call to mind reactive arthritis. And, indeed, Dr. Ryal did initially invoke reactive arthritis in attempting to describe why she viewed petitioner's post-vaccination symptoms as a new and distinct vaccine-related condition. (Ex. 9, p. 2.) On a different record, reactive arthritis could conceivably represent a compensable claim. *E.g.*, *Hock v. Sec'y of Health & Human Servs*., No. 17-168V, 2020 WL 6392770, at *25 (Fed. Cl. Spec. Mstr. Sept. 30, 2020) (discussing prior program history with respect to allegations of vaccine-caused reactive arthritis). Importantly, however, the potential relationship between vaccination and reactive arthritis is informed by a close temporal relationship and a transient presentation. *Id.* Thus, it is distinguishable from the chronic presentation at issue in this case, and Dr. Ryal has not actually presented enough information to establish that reactive arthritis can be caused by vaccines in addition to infections. In particular, Dr. Gensler is persuasive in pointing out that Dr. Ryal has not adequately addressed how the post-vaccination cytokine-mediated mechanism she has proposed could be self-perpetuating. (Ex. C, p. 2.) But in any event, while Dr. Ryal's opinion is somewhat confusingly stated, it does appear to be clear in explicitly disclaiming that this petitioner suffered reactive arthritis. Specifically, she stated: "'Reactive arthritis' or Reiter's Syndrome is an inflammatory arthritis. This and other inflammatory arthritides would typically have white blood cells in the joint. This is not the reaction I think [petitioner] had." (Ex. 12, p. 4.)

Instead, while Dr. Ryal opined that petitioner's post-vaccination presentation was a "new condition" (Ex. 12, p. 7), she "absolutely agree[d] that [petitioner's] pain is in an osteoarthritis distribution" (*Id*. at 4) and opined that the vaccine "triggered the pain in the osteoarthritis of her hands" (*Id*. at 3). And, although Dr. Ryal repeatedly referenced a new inflammatory and vaccine-caused condition, she also opined that "[s]ome of [the] pro-inflammatory cytokines stimulated by the innate immune response in the setting of a vaccine or infection, are also involved in the pathogenesis of osteoarthritis." (*Id*. at 6.) Moreover, she proposed that environmental factors, such as infection, can trigger osteoarthritis. (*Id*. at 7.) Thus, considering Dr. Ryal's opinion as a whole, it is best understood as proposing that osteoarthritis is itself inflammatory and that a post-vaccination cytokine response can therefore trigger its symptoms. Indeed, the VAERS report prepared by Dr. Ryal's office characterized petitioner's symptoms as a worsening of her osteoarthritis. (Ex. 2, p. 3.)

Dr. Ryal's theory with respect to osteoarthritis rests primarily on three points. First, she opines that osteoarthritis responds to environmental factors and that pro-inflammatory cytokines, including IL-1β, have been shown to "play a central role" in the pathogenesis of osteoarthritis. (Ex. 12, pp. 2, 6 (citing Berenbaum et al., *supra*, at Ex. A, Tab 2; Kapoor et al., *supra*, at Ex. 13)[13]). Following from that premise, she raises two additional points to support the notion that the pneumococcal vaccine can be among the environmental factors that can trigger osteoarthritis symptoms. She proposes that pneumococcal vaccination has been shown to elevate pro-inflammatory cytokines, including IL-1β[14] (*Id*. at 2-3 (citing Kashiwagi et al., *supra*, at Ex. 17)), and she observes that the pneumococcal vaccine package insert shows that a subset of vaccine recipients report new or aggravated joint pain following vaccination (*Id*. at 2 (citing Prevnar-13 Package Insert, *supra*, at Ex. C, Tab 3)). However, this theory is not persuasive on any of these points. On the whole, Dr. Gensler, who is better qualified than Dr. Ryal on this subject, is persuasive in suggesting that Dr. Ryal has overstated the evidence supporting her view.

First, while the Institute for Vaccine Safety publication cited by Dr. Ryal does suggest that infections may cause arthritis, Dr. Ryal is not persuasive in relying on the Institute for Vaccine Safety to implicate vaccines as being among the causes of chronic arthritis. As Dr. Gensler notes (Ex. C, pp. 1-2), that publication explains:

> Based on both cases reviewed and knowledge about the natural infection, the IOM concluded that there was some mechanistic evidence in support of a causal relationship between rubella vaccine in women and arthralgia; however, there was less evidence for a relationship between rubella vaccine in women and chronic arthralgia or arthritis. There was little evidence for a relationship between rubella vaccine and arthropathy in men, transient arthralgia in children or chronic arthropathy in children, for influenza vaccine and onset or exacerbation of arthropathy, or for hepatitis B vaccine and onset or exacerbation of arthritis. The IOM also concluded that there was no mechanistic evidence for an association between all other vaccines and arthralgia, arthritis, or arthropathy.

(INST. FOR VACCINE SAFETY, *supra*, at Ex. D, p. 3 (footnotes omitted).) When considered in full, it is clear that this passage counsels *against* Dr. Ryal's theory. While, as Dr. Gensler acknowledges, this passage potentially supports the notion that the rubella vaccine, in particular, may result in transient arthralgia, it is clear in limiting that association to that particular vaccine and to disclaiming a relationship to either chronic

[13] Dr. Ryal additionally cited Mary B. Goldberg & Miguel Otero, *Inflammation in Osteoarthritis*, 23 CURRENT OP. RHEUMATOLOGY 471 (2011), as being a supporting reference within Berenbaum et al., *supra*, at EX. A, Tab 2, but did not separately produce a copy of the article.

[14] Although Dr. Ryal does cite other cytokines as important to the development of osteoarthritis, IL-1β is the only cytokine which she has identified as being implicated both in the development of osteoarthritis, as well as in the immune response to pneumococcal vaccination. (Ex. 12, pp. 2-3.)

arthralgia or arthritis. (*Id.*) Moreover, it includes several other instances of proposed relationship that are *not* supported. (*Id*.) Indeed, the publication states flatly that "[o]ther vaccines currently routinely recommended to the general population in the U.S. have not been shown to cause chronic arthralgia or arthritis." (*Id*. at 1 (emphasis omitted).)

Nor, contrary to Dr. Ryal's assertion, does the subject pneumococcal vaccine package insert otherwise demonstrate a propensity of the vaccine at issue in this case to cause chronic arthritis. While one clinical trial of adults from the Netherlands indicated that 7.4% of vaccine recipients reported new generalized joint pain and 5% reported aggravated generalized joint pain (Prevnar-13 Package Insert, *supra*, at Ex. C, Tab 3, pp. 19-20), Dr. Gensler stressed that these findings were not statistically different as compared to the placebo controls (Ex. C, p. 2). Moreover, the finding cited by Dr. Ryal is from only one of several clinical trials of the Prevnar vaccine. Other studies disclosed in the package insert show the Prevnar vaccine to have lower rates of reported joint pain as compared to other formulations of pneumococcal vaccine. (Prevnar-13 Package Insert, *supra*, at Ex. C, Tab 3, pp. 19-21.) In any event, while the package insert does list "joint pain" among the reported adverse reactions, it does so along with other transitory reactions, such as injection site pain or redness, fatigue, headache, muscle pain, fever, chills, rash, and decreased appetite. (*Id*. at 1.) Joint pain, which Dr. Gensler noted to be a nonspecific symptom, is not defined within the package insert and neither arthritis nor arthralgia is included among the reported adverse reactions.

And, although Dr. Ryal relied on a study by Kashiwagi et al. to demonstrate that the pneumococcal vaccine generates relevant pro-inflammatory cytokines, this is not persuasive without more. Nothing in the Kashiwagi study purports to examine the condition at issue in this case. Nor does the Kashiwagi study suggest that the observed cytokines were pathogenic. (Kashiwagi et al., *supra*, at Ex. 17.) The Kashiwagi study has been raised in numerous prior cases and has generally not been viewed as helpful to petitioners. Generally, the study is viewed as confirming that vaccine(s) produced transient cytokines as part of the expected immune response to vaccination, without evidence that these cytokines are injurious. *See, e.g.*, *Bohannon v. Sec'y of Health & Human Servs.*, No. 23-235V, 2025 WL 413454, at *22 (Fed. Cl. Spec. Mstr. Jan. 2, 2025); *Bohn ex rel. G.B. v. Sec'y of Health & Human Servs.*, No. 16-0265V, 2021 WL 4302367, at *18-19 (Fed. Cl. Spec. Mstr. Aug. 23, 2021); *Dean ex rel. I.D. v. Sec'y of Health & Human Servs.*, No. 13-808V, 2017 WL 2926605, at *17 (Fed. Cl. Spec. Mstr. June 9, 2017).

Even acknowledging that the vaccine can induce some inflammatory immune response, mere invocation of a vaccine's intended immune response is not in and of itself sufficient to carry petitioner's burden under *Althen* prong one. *See Elvira ex rel. D.E. v. Sec'y of Health & Human Servs.*, No. 17-531V, 2024 WL 4966035, at *20 (Fed. Cl. Spec. Mstr. Nov. 6, 2024); *Vanore v. Sec'y of Health & Human Servs.*, No. 21-0870V, 2024 WL 3200287, at *18 (Fed. Cl. Spec. Mstr. May 31, 2024); *Kalajdzic ex rel. A.K. v. Sec'y of Health & Human Servs.*, No. 17-792V, 2022 WL 2678877, at *23 (Fed.

Cl. Spec. Mstr. June 17, 2022), *mot. for rev. denied*, No. 17-792V, 2024 WL 4524777 (Fed. Cl. Oct. 18, 2024), *aff'd*, No. 2023-1321, 2024 WL 3064398 (Fed. Cir. June 20, 2024); *Cordova v. Sec'y of Health & Human Servs.*, No. 17-1282V, 2021 WL 3285367, at *17 (Fed. Cl. Spec. Mstr. June 23, 2021). There must be some additional evidence linking the vaccine's immune response to the pathology of petitioner's actual condition. For example, the Chief Special Master has observed:

> I have on many occasions considered theories asserting a vaccine-caused, cytokine-driven process led to injury, but have repeatedly deemed such theories wanting, absent evidence connecting the process (no matter how scientifically plausible it might be) with additional proof sufficient to render it "more likely than not" that the immune processes outlined could be rendered pathogenic by introduction of a vaccine. Otherwise, such a theory only attempts to transmute the expected reaction to a vaccine into pathology.

M.R. v. Sec'y of Health & Human Servs., No. 16-1024V, 2023 WL 4936727, at *27 (Fed. Cl. Spec. Mstr. June 30, 2023) (citing *Dean*, 2017 WL 2926605, at *17); *see also Kaltenmark v. Sec'y of Health & Human Servs*., No.17-1362V, 2023 WL 8870299, at *28 (Fed. Cl. Spec. Mstr. Nov. 27, 2023) (the undersigned observing that, "[e]ven where there is some reason to suspect a condition may be cytokine mediated, this does not automatically lead to the conclusion that vaccines can cause the injury merely because vaccines produces some cytokine elevations").

Although Dr. Ryal is correct that a pathologic role for pro-inflammatory cytokines in osteoarthritis is suspected, her theory moves well beyond what is accepted or known regarding the role of cytokines in the pathogenesis of osteoarthritis. Her primary reference, Kapoor et al., explains that "the exact sequence of pathological events in [osteoarthritis] remains unclear; the temporal relationship between subchondral bone damage, chronic inflammation of synovial tissue and cartilage erosion is still largely unknown." (Kapoor et al., *supra*, at Ex. 13, p. 1.) Regarding the role of IL-1β in particular, the evidence is especially murky. The authors explain:

> Simultaneous injection of IL-1β and TNF into rabbit knee joints, for instance, causes more cartilage destruction than either cytokine alone. Although IL-1β is widely accepted as a proinflammatory cytokine, deletion of *Il1b* accelerates the development of [osteoarthritis] lesions in a mouse model of the disease, suggesting a complex role for this cytokine in maintaining cartilage homeostasis.

(*Id*. at 2 (footnotes omitted).) On the whole, they indicate that, IL-1β "seems to be associated with cartilage destruction" whereas it is TNF that is "driving the inflammatory cascade." (*Id*. at 1.)

Ultimately, Dr. Gensler forcefully disagrees with Dr. Ryal's assertion that pro-inflammatory cytokines can be invoked to assert that osteoarthritis – which she stresses to be a degenerative condition – can be caused by an innate immune response. (Ex. C,

p. 4.) Neither Dr. Ryal nor Dr. Gensler explain their views in depth; however, Dr. Gensler's opinion carries greater weight as a general matter. Although Dr. Ryal is petitioner's treating physician,[15] she is an internist and her curriculum vitae does not demonstrate any special competency with respect to either arthritis generally or osteoarthritis in particular. (Ex. 10.) Dr. Gensler, by contrast, is a rheumatology specialist with a research interest and publication history relating to arthritis (mostly ankylosing spondylitis). (Ex. B.) Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("Assessments as to the reliability of expert testimony often turn on credibility determinations . . . ."); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act."). In that regard, a special master may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g.*, *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (finding petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications). Here, while I accept that Dr. Ryal is qualified to render a medical opinion in this case generally, *accord Acton v. Sec'y of Health & Human Servs.*, No. 19-647V, 2024 WL 5290861, at *25-29 (Fed. Cl. Spec. Mstr. Dec. 12, 2024), I conclude that Dr. Gensler's opinion is entitled to greater weight with respect to general causation given their respective qualifications, especially but not only, in light of Dr. Ryal's concession that "I am unsure how the pneumococcal vaccine causes arthritis" (Ex. 12, p. 2).[16]

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[15] Treating physician opinions are generally viewed as "quite probative." *Capizzano*, 440 F.3d at 1326. However, this is because they are "likely to be in the best position to determine whether a local sequence of cause and effect show[s] that the vaccination was the reason or the injury." *Andreu*, 569 F.3d at 1375 (alteration in original) (quoting *Capizzano*, 440 F.3d at 1326). That is, treating physician statements are often favored in the context of specific causation relative to *Althen* prong two. Even in that context, the opinions of treating physicians are not binding. *E.g.*, *Synder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 745 n.67 (2009) (observing that treating physician statements are not "sacrosanct" and can be rebutted). However, the status of a treating physician is less relevant in the context of general causation. For example, in *Nuttall v. Secretary of Health & Human Services*, the Court of Federal Claims explained that the advantage a treating physician has over testifying experts is that the treating physician "was familiar with the patient both before and after the alleged vaccine injury." 122 Fed. Cl. 821, 832 (2015), *aff'd*, 640 F. App'x 996 (Fed. Cir. 2016). Absent that particular advantage, a treating physician's opinion is not necessarily entitled to any added consideration. *Id*. In this case, Dr. Ryal's familiarity with petitioner both before and after vaccination is probative with respect to *Althen* prong two, but is irrelevant to the question of whether the pneumococcal vaccine can as a matter of general causation cause (or trigger symptoms of) osteoarthritis.

[16] I stress that I am not treating this statement as the sum total of Dr. Ryal's opinion or suggesting that it is dispositive in itself. Moreover, the statement enhances Dr. Ryal's credibility insofar as it demonstrates her candor. However, especially when considered in the context of the experts' qualifications, it does also have the effect of highlighting her relative lack of experience with the subject matter upon which her theory of general causation is based.

Accordingly, for all the reasons discussed above, petitioner has not met her preponderant burden of proof under *Althen* prong one.

a. *Althen* prong one is dispositive

Because I have concluded that petitioner has not demonstrated that the pneumococcal vaccine likely can cause (or trigger symptoms of) osteoarthritis, it is not necessary to address in detail whether the vaccine did so in this particular case. Given the outcome regarding *Althen* prong one, by definition it likely did not. Thus, I address *Althen* prong two only briefly. *Trollinger v. Sec'y of Health & Human Servs.*, 167 Fed. Cl. 127, 142 (2023) (affirming the Chief Special Master's dismissal based on a dispositive finding that petitioner had not satisfied *Althen* prong one). In particular, I note out of an abundance of caution that the evidence relevant to *Althen* prong two is not so robust as to otherwise influence the analysis under *Althen* prong one. *See Patton v. Sec'y of Heath & Human Servs*., 157 Fed. Cl. 159, 169 (2021) (finding treating physician opinions relevant to assessing the reliability of the expert's theory of general causation). To be clear, the question is not whether petitioner suffered any transitory post-vaccination symptoms of any kind, but rather, whether her symptoms of osteoarthritis, in particular, can be attributed to her vaccination.

While I do give credence to Dr. Ryal's opinion with respect to *Althen* prong two and would generally be inclined to credit her direct clinical observations as far as they reasonably go (*see* note 15, *supra*), Dr. Ryal's opinion has significant limitations:

- First, Dr. Ryal is petitioner's primary care provider. Petitioner does have a treating rheumatologist, Dr. Seigel, who she saw both pre- and post-vaccination for osteoarthritis. However, Dr. Seigel's records do not offer any indication that he agreed that petitioner's chronic osteoarthritis was affected by her pneumococcal vaccination. While a nurse practitioner in Dr. Siegel's office did indicate on June 8, 2015, that petitioner had a likely reaction to her pneumonia vaccine that transiently contributed to her arthralgia (noted by that time to have mostly been resolved) (Ex. 6, p. 77), Dr. Seigel's own encounter records both before and after that evaluation (on May 26, 2015, and August 6, 2015) do not include any similar assessment despite also noting the reported history of post-vaccination hand pain. (*Id*. at 71-74, 79-83.) The history recorded by Dr. Seigel's office otherwise places petitioner's hand pain in the context of a known history of "episodic flares" of her osteoarthritis. (*Id.* at 75.)

- Second, consistent with both the above discussion under *Althen* prong one and Dr. Seigel's nurse practitioner's notation, Dr. Ryal's initial observation that prompted her to report petitioner's condition to VAERS was based at least in part on the assumption that the symptoms would be "short lived." (Ex. 12, p. 4.) Especially given that Dr. Gensler persuasively challenged Dr. Ryal's theoretical premise of a self-perpetuating cytokine reaction, Dr. Ryal's opinion does not adequately grapple with whether the initial suspicion of vaccine causation should have been revisited once the symptoms persisted.

- Third, several of Dr. Ryal's specific observations undermine petitioner's claim:

    - Dr. Ryal observed that "[t]he distribution of joint changes and [petitioner's] age is consistent with osteoarthritis," which she noted to be a degenerative condition. (Ex. 12, pp. 5-6.) Moreover, Dr. Ryal acknowledged petitioner's osteoarthritis to pre-date the vaccination at issue. (*Id.* at 2, 7; Ex. 9, p. 2.)

    - Having acknowledged that petitioner's osteoarthritis was "longstanding" (Ex. 9, p. 2), Dr. Ryal further conceded that she "can't comment [on] the progression of [petitioner's] osteoarthritis as I do not have previous x-rays with which to compare her July 2015 studies." (Ex. 12, p. 4.)

    - Instead, Dr. Ryal concluded that petitioner's x-ray findings were consistent with "mild to moderate degenerative changes." (Ex. 12, p. 4.)

    - Although Dr. Ryal observed some signs of osteoarthritis post-vaccination (namely, a cyst and fingernail changes), she also noted that petitioner had pre-existing bilateral Heberden nodes on her fingers, also an indicator of osteoarthritis, that were unchanged after vaccination (Ex. 12, pp. 4, 6). Thus, while Dr. Ryal stresses petitioner's subjective complaint of hand pain as a new symptom, she does not appear to suggest that petitioner's hands were previously unaffected by her osteoarthritis.

    - Although petitioner complained of new or increased symptoms post-vaccination, Dr. Ryal indicated that she was "surprised" that petitioner's CRP, which she opined should correlate to symptom severity, was not elevated. (Ex. 12, p. 5.)

    - Dr. Ryal purported to explain petitioner's condition as inflammatory, but she indicated broadly that inflammatory arthritides "would typically have white blood cells in the joint" and that "[t]his is not the reaction I think [petitioner] had." (Ex. 12, p. 4.)

Even if petitioner did demonstrate that she experienced a transitory vaccine reaction that might have included erythema and some generalized arthralgia, she has not preponderantly demonstrated a logical sequence of cause and effect whereby her vaccine caused chronic osteoarthritis of the hands. The Federal Circuit has explained that, "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992)); *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting

the vaccine and injury"), *aff'd per curiam*, 475 F. App'x 765 (Fed. Cir. 2012); *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to *Althen* prong two when respondent conceded that petitioner met *Althen* prong three).

VI. Conclusion

Although petitioner has my sympathy for the pain and discomfort she has endured, for all the reasons discussed above, I find that she has not met her burden of proof. Therefore, pursuant to §300aa-12(d)(3)(A) and Vaccine Rule 10, this decision concludes that petitioner is not entitled to an award of compensation. Absent a timely motion for review, the Clerk is directed to enter judgment dismissing this case for insufficient proof in accordance with Vaccine Rule 11(a).

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master