Appeal No. 2015-5043

United States Court of Appeals

for the

Federal Circuit

FRANCIA HIRMIZ and PETER HIRMIZ, as best friends of their daughter, J.H.,

Petitioners-Appellants,

– v. –

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

APPEAL FROM THE UNITED STATES COURT OF FEDERAL CLAIMS
IN CASE NO. 1:06-VV-00371-CFL, JUDGE CHARLES F. LETTOW

REPLY BRIEF FOR PETITIONERS-APPELLANTS

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SUMMARY OF ARGUMENT

Decisions in this program are to be based upon the reliable evidence contained in the entire record. Where unreliable evidence of symptoms of developmental delay and loss of tone before the flu vaccinations conflicts with well documented evidence of crippling chronic spasticity arising thereafter a decision based upon the former is arbitrary and capricious. The injury in issue here is spasticity, a neurological condition which totally disables this child. Not only is there is no evidence of a neurological injury prior to the flu vaccinations, all reliable evidenced points to a catastrophic adverse reaction to two half doses of flu vaccine. The disregarded reliable evidence includes the opinion of Dr.Aurella Z. Peera, JH's treating physician as to the timing of onset, an opinion fully supported by the objective evidence. It is arbitrary and capricious to ignore objectively supported expert opinion in favor of one contradicted by the same expert's analysis of the significance of the objective evidence.

Here, respondent argues that aggravation of a pre-existing condition was not before the court previously. In doing so, respondent ignores the Special Master's statement that he was rejecting the petitioners' claim that JH's degenerative condition was "…caused or exacerbated by two half doses of influenza vaccination…" a statement respondent quoted. Respondent's Brief, pg. 6. However, on this record, the evidence of a neurological injury caused by the flu

vaccinations, which is distinct from any pre-existing condition, is overwhelming. Ignoring that fact to declare symptoms predated the flu vaccine due to weak and debatable evidence of a prior unknown and significantly different condition is arbitrary and capricious. A child need not be completely well to be eligible for compensation for a clearly catastrophic vaccine injury.

As the Court below ignored the overwhelming evidence in the record, including numerous concessions made by the respondent's expert, the opinion of petitioner's highly qualified expert as well as the opinion of JH's treating physician and the objective evidence. Thus, the decision below is arbitrary and capricious.

RESTATEMENT OF PETITIONERS' POSITIONS

DTaP

Contrary to the respondent's assertions, petitioners did not argue that the DTaP vaccine caused or contributed to their daughter's current condition. Petitioners argue only that if there were any symptoms of any injury before the flu vaccination, they were minor and completely different from the post flu vaccination symptoms. Further, those symptoms closely followed the DTaP vaccination of July 16, 2004. That vaccination is the only other event in this record which could explain any injury evidenced before the flu vaccinations.

It is the respondent who has asserted that JH's condition arose before the flu vaccinations, thus, it is the respondent's obligation to prove with reliable evidence,

that the condition existed, that it is the same condition JH now suffers from and that it was not caused by any vaccine identified in the petition as possibly causative. The holding below that her condition simply emerged with no cause in the summer of 2004, is implausible, is contrary to the record and violates 42 U.S.C. 300aa-13 (i)'s ban on an idiopathic unrelated cause.

CREDITING UNRELIABLE EVIDENCE

The only evidence offered on the issue of this pre-existing condition was an expert's opinion based upon the parents' testimony and a highly debatable loss of skills. That loss was not seen by Dr. Peera, it was reported by the parents, A602, whose' testimony was heard by Special Master Abel and found to be unreliable. A46. Based upon this frail evidence, respondent's expert opined that JH's injury arose in the summer of 2004 and followed its natural course. His position was that the flu vaccination had no effect. Respondent's expert made no effort to isolate the injury from the DTaP vaccination or to explain how JH's pre-flu conditions were the same as, or even related to, the admittedly extremely different post flu condition.

Petitioners argued in their opening brief that as DTaP can cause this kind of injury, as it was identified as suspect in the petition, the respondent had to exclude it to meet its burden on alternate cause. Further, and more importantly, the objective symptoms of the pre and post flu vaccine conditions were the opposite of

one another, a fact developed only by the experts after Special Master Abel's decision. Thus, respondent failed to establish that the injury in question, chronic crippling spasticity, was the same as the possible slight loss of developmental trajectory and muscle tone in the summer of 2004. The court below ignored the fact that no relation between these two distinct conditions has been established by the respondent.

OVERWHELMING EVIDENCE AS TO THE POST FLU VACCINE ONSET

The decision below, that her crippling condition arose before her first flu vaccination is contrary to the evidence. The weight charts and the contrast between Dr. Peera's October 16, 2004 record and the findings of the Physical Therapist at Children's Hospital on December 9, 2004, establish that a catastrophic event followed the administration of the two halves of the flu vaccine. Compare A591 with A566-568. Dr. Peera's notes of July of 2005, A616, and her September, 2005 letter to the insurer, A693, both place onset after the flu vaccinations. Finally when asked by respondent's counsel:

> Q. You would agree that when Jessica does go to get physical therapy and the evaluation that she has spasticity and that the condition has somewhat deteriorated since the October visit?

respondent's expert responded

> A. From hypertonia to spasticity is quite the progression, yeah. One's the opposite of the other."

A294 L 1-6. In addition, the weight charts show JH's weight to have been in the 75% range at her 6 and 9 month examination and to have declined rapidly thereafter. A694. Respondent's expert explained that this showed that, "there was an insult to the child at that time" A306 L 17-21. These two admissions establish that the injury in issue was the opposite of anything seen previously and arose after the October 16, 2004 visit at which JH received the first flu vaccination.

The record also establishes that loss of muscle tone is a muscle disease and spasticity is neurological. TR 61 L 9-20. Respondent's expert agreed that loss of muscle tone is not the same as spasticity. A321 L16-22. Both experts agreed that a neurological degenerative disease, such as that JH suffers from, had to have resulted from some sort of insult. A322 L 23- A323 L 8. No evidence of any insult to JH's nervous system has been submitted other than the flu vaccinations, particularly none occurring in the clearly defined time period between the DTaP vaccination and the flu vaccinations. Any question about this is resolved by the treating physician, Dr. Peera, who noted in her records that JH developed normally until 9 months and that regression continued from the end 2004 through September of the following year, causing Dr. Peera to seek to refer JH to the Mayo Clinic. A591, 693.

Petitioners further assert that the respondent's evidence of earlier onset; 1. fails to meet the requirements of reliability due to lack of support in the record and, 2, does not exclude all vaccines identified in the petition as the engine of the damage.

ARGUMENT

STANDARD OF REVIEW

Respondent asserts that where the Special Master has explained his decision, the Court below and this Court may not re-evaluate his factual conclusions. This Court in *Paluck v. HHS,* 14-5080 – May 21, 2015, disagreed:

> Where, as here, a special master misapprehends a petitioner's theory of causation, misconstrues his medical records, and makes factual inferences wholly unsupported by the record, the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law. See Andreu, 569 F.3d 1367,1375 (concluding that a special master erred in disregarding probative testimony from a petitioner's treating physicians); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir.2006) (concluding that a special master "impermissibly raise[d] a claimant's burden under the Vaccine Act"); Althen, 418 F.3d at 1280–81 (concluding that a special master improperly required medical literature linking a particular vaccine to the claimant's injury). While review of the factual findings made by a special master is highly deferential, see Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011), both this court and the Court of Federal Claims have a duty to ensure that the special master has properly applied Vaccine Act evidentiary standards, "considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for [his] decision." Hines ex rel. Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

In *Paluck v. HHS*, the child's:

> …problems prior to the vaccinations on January 19,2005, were neurological, the impairment was small and not evident to the treating physicians.”). In the wake of his January 2005 vaccinations, K.P .experienced a precipitous and well-documented neurological decline. By February 11, 2005, twenty-three days after the date of the vaccinations, K.P.’s chiropractor determined that he was “spastic.

In contrast to *Paluck*, JH had no evidence of any issue with her central nervous system prior to the October flu vaccination. Dr. Oleske’s testimony that lack of muscle tone is a muscle issue while spasticity is neurological was not contradicted. TR 61 L 9-20. After the flu vaccinations, JH’s current severe neurological malfunction manifested itself rapidly and is well documented, as it was in *Paluck.* Unlike *Paluck,* here there is no evidence of an underlying condition or that the pre and post vaccination conditions are related to one another.

This Court has the authority to review and reverse well explained decisions of a special master which are erroneous based upon the record or which violate Vaccine Act evidentiary standards. Id.

.

RESPONDENT FAILED TO PROVE A CAUSE UNRELATED

Respondent asserts that as she did not put forth an alternate cause, but simply asserted that as JH’s symptoms of an injury arose before the flu vaccination, respondent is not require to establish that cause was predominant, was not vaccine related nor that it was more likely than not the cause of her injury. Here, however, the amended petition attributed the injury to one of more vaccines

JH received before and including the flu vaccinations, A70. Further, the respondent's expert admitted that the type of injury JH had, had to have been caused by an insult. Thus, weak evidence of some arguable lack of developmental progress following the DTaP vaccination is not evidence of an injury "unrelated to the administration of the vaccine described in the petition" as required by 42 U.S.C. 300aa-13 (a)(1)B.

Petitioner's expert determined that the evidence of a loss of trajectory during the summer of 2004 was insufficient to evidence an injury from the DTaP vaccination let alone is it anything remotely similar to her post flu vaccine catastrophic decline. Thus, the flu vaccine was the cause of her permanent injury. Whether JH had any issue or not as of October 16, is immaterial as there can be absolutely no question of the extreme deterioration which occurred after that date thus, immediately following the flu vaccinations. As in *Paluck,* pg 15-16

> …the chiropractor's notation that [K.P.] was 'spastic' on February 11, 2005," was "an identifiable neurodegenerative event" showing that "the neurodegenerative process [had] begun.
>
> . . .
>
> In the face of this compelling evidence of post vaccination neurodevelopmental regression, the special master had no reasonable basis for concluding that K.P. did not experience the progressive neurodegeneration

PETITIONER MET ALL THE ALTHEN PRONGS

Contrary to the conclusion below and as argued here by respondent, petitioner met all the requirements of *Althen v. Sec'y HHS* 418 F.3d 1274, 1281

(Fed. Cir,2005). The decision below to the contrary violates the standards of proof applicable to Vaccine Act cases.

ALTHEN PRONG 1

Dr. Oleske, a highly qualified expert in autoimmunity, did establish, based upon his experience treating children with neurological issues due to autoimmune malfunction, that the flu vaccine can cause the type of injury JH evidences. The process is autoimmune. Precisely how that occurs in any particular case is unknown. "…(A)s an immunologist understanding that there can be focal damage done by adverse immune reactivity in the central nervous system that doesn't produce hydrocephalus or small brains or abnormal EEG, none of which Jessica had, can still, nevertheless, cause severe damage." TR-14 L 3-8. Identifying that injury would require an invasive and dangerous procedure which doctors will not use on this type of case.

An opinion by a highly qualified expert as to causation is prima facie evidence of biologic plausibility, unless their lack of credibility or bias is established or current scientific evidence is proffered to the contrary, none of which happened here. *Dobrydnev v. Secretary of Health and Human Services* 98 Fed.Cl. 190, 206 (Fed.Cl., 2011).

In addition, the fact that the flu vaccine can cause an autoimmune reaction affecting the nervous system is well accepted as sufficient to satisfy prong one of

Althen. *Daily vl Secertary HHS,* 2011 WL 2174535 (Special Masters 2011). In *Daily* it was understood that these events are extremely rare, thus, there would be little or no medical literature on the topic and none is required. Here, unlike in *Daily*, we have a completely undiagnosed catastrophic injury, one unseen by medical science previously. It immediately followed not one but two separate exposures to the flu vaccine, a vaccine capable of causing Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), an autoimmune disease with symptoms similar to those of JH's condition. As Dr. Oleske testified, "(t)he vaccine is the same, the injury is the same and there is no other reasonable explanation."

Where, as here, a plausible theory has been constructed based on existing scientific knowledge, it is no answer, under the Vaccine Act, that the theory is unproven or undocumented in the medical literature. *Daily Supre* *6. The theory is based upon well accepted phenomena; 1. an animistic response and 2, challenge-re-challenge, two well-established autoimmune phenomena recognized by medical science. Dr. Oleske has made reliable inferences therefrom, inferences firmly supported by JH's weight charts which confirm her pediatrician's statements as to the timing of onset of her condition. *Daily, supra* *8. The disbelief of respondent's expert is insufficient, where, as here, the record shows a catastrophic decline in JH following the second flu vaccination and the only abnormality found in her, by two prestigious medical institutions, the Mayo Clinic and Children's Memorial

Hospital, is consistent only with the sequella of over activity of the immune system of her central nervous system. Finally, all other possibilities having been excluded by extensive work of those same prestigious medical institutions. Therefore, the autoimmune phenomena as opined by Dr. Oleske is not only more likely than not, there is no other reasonable explanation. See *Walther v. Sec'y of HHS,* 485 F.3d 1146, 1149–50 (Fed.Cir.2007) (exclusion of all other possibilities is affirmative proof of causation where other evidence is insufficient). Here the Mayo Clinic and Children’s Hospital have eliminated all other possible causes.

ALTHEN PRONG 2

Dr. Oleske explained how an anamnestic reaction to the vaccine and/or challenge re-challenge, via molecular mimicry, well accepted engines of autoimmunity, caused JH’s injury. No better explanation is known to medicine. The legislative history indicates that this program is to provide compensation despite limited knowledge of how vaccines cause injury, and that, until more is known, compensation is to be given despite the possibility of error. H.R.REP.99-908,1986 U.S.C.C.AN 6344, 6359.

ALTHEN PRONG 3

The evidence shows that JH deteriorated markedly between the second flu vaccination, November 16 and December 9, 2004, 23 days. This Court has held

> “the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect

> the human body"). Accordingly, the fact that K.P.'s first clinically evident sign of neurodegeneration—spasticity— was documented twenty-three days, rather than twentyone days, after vaccination does not preclude a finding that it was a symptom of vaccine-induced neurologic injury. *See Andreu*, 569 F.3d at 1380 (emphasizing that relevant medical "evidence must be viewed . . . not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard").

Paluck pg. 19. Of course, here the injury was more than just noticed on December 9, it was well advanced. . A566-568. In addition, JH's mother testified, as in *Paluc*k, JH was fussy and could not take a bottle after the first flu shot, A-89 L 11-15. The reaction to the second flu vaccination is well documented. Such facts are "…such strong proof of causality that it is unnecessary to determine the mechanism of cause—it is understood to be occurring." *Capizzano v. Sec'y HHS, 2004 WL 1399178 *15.* (CL Ct 2004), see. Pg. 23 of petitioners opening brief. Even without re-challenge however, the record fully supports Dr. Oleske's conclusion that JH suffered an anamnestic response.an injury which closely followed the second flu vaccination.

> In other words, if close temporal proximity, combined with the finding that hepatitis B vaccine can cause RA, demonstrates that it is logical to conclude that the vaccine was the cause of the RA…

Capizzano v Sec'y HHS Supra, 440 F.3d 1317 1326 (Fed. Cir 2006).

AMENDMENT TO ASSERT AGGRAVATION OF A PRE-EXISTING CONDITION

The petitioner has asserted that the only possible pre-existing condition found in this record is a possible reaction to a prior vaccination, in particular, the

DTaP vaccination. Any such reaction, if it existed at all, was slight and completely different from the catastrophic reaction to the flu vaccination. The Court below seemed to believe that this was a pre-existing condition which was aggravated by the flu vaccination. However, the petitioner could not amend the petition to conform to the proof as that would be unfair to the respondent.

Here, to the extent there is any argument that the flu vaccination aggravated a prior condition, that evidence was placed in the record by the respondent. Respondent's expert asserted that the condition arose before the flu vaccine, but admitted that the weight charts established that JH was injured after October 16, 2004. He admitted that her condition deteriorated and changed from hypertonia to spasticity rapidly between October 16, 2004 and December 9, 2004. His testimony alone establishes the aggravation claim when combined with just the medical records of October 16 and December 9. As stated above, JH's condition on October 16 is known as is her condition as of December 9. The difference shows a major change for the worse.

The petition in this matter asserted that the catastrophic reaction could be due to the action of one or more identified vaccines. The fact that there may be a prior reaction to DTaP or another is in the pleading. The possibility was discussed by petitioner's expert at the hearing and dismissed as JH's pre-flu vaccine condition, if any, was consistent with variations seen in normal development,

Further, her lack of tone is a symptom completely different from those of her post flu vaccine condition. Indeed, the only evidence in the record of any connection between the pre and post flu condition is the respondent's expert's opinion that her catastrophic deterioration of November-December of 2004 was just the natural progression of her pre flu vaccination disease. But where, as here, JH's condition is unknown, its natural progression cannot be known. But respondent's experts admissions have not been rebutted and are binding on the respondent and this court. They establish that JH's nervous system was injured, causing her spasticity after October 16, 2004, shown by her weight chart. It is spasticity not loss of muscle tone or delay. Thus his speculation about a prior condition is not reliable and would not be admitted in any other court. See ex. *Blake v. Bell's Trucking, Inc*., 168 F.Supp.2d 529, 532 (D.Md.2001), *Collier v. Varco–Pruden Bldgs.*, 911 F.Supp. 189, 192 (D.S.C.1995) (expert's opinion excluded as speculative where it is not supported by the record). Unreliable evidence cannot support a decision. Vaccine Rule 8(b)(1).

The respondent has presented evidence which, if credited, would establish aggravation of a pre-existing condition. Rule 15(b)(2) of the Rules of the United States Court for Federal Claims provides that were

> an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings. A party may move—at any time, even after judgment—to amend the pleadings to conform them to the evidence

If there was aggravation of a pre-existing condition, rather than a distinct injury from the flu vaccination, the petition should be amended.

CONCLUSION

The purpose of the Vaccine Injury Program was to grant injured children awards "quickly, easily, and with certainty and generosity," H.R.Rep. No. 908, 99th Cong., 2d Sess. 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344, thus, close questions are to be resolved in favor of a claimant. On this record all issues were resolved against a gravely injured little girl based upon expert testimony which would not be admissible, let alone credited, in an Article III court. The Special Master and the Court ignored overwhelming evidence that the flu vaccinations caused this child's injury and in particular ignored the opinion of her treating physician and her weigh charts as to the timing of the injury. This Court has the authority to review and reverse factual findings so grossly inconsistent with the record and to remand this case for assessment of damages and should do so in conformity with the weight of the evidence and with Congress's stated intentions.

Dated New York, N.Y.
June 8, 2015

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United States Court of Appeals for the Federal Circuit

CERTIFICATE OF SERVICE

FRANCIA HIRMIZ, ET AL. V. SECRETARY OF HEALTH AND HUMAN SERVICES
APPEAL NO. 2015-5043

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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On June 8, 2015, Counsel for Appellants has authorized me to electronically file the foregoing **Reply Brief for Petitioners-Appellants** with the Clerk of Court using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

/s/ Robyn Cocho
Robyn Cocho

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