IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

THIRD APPELLATE DISTRICT

KENNETH P. STOLLER, MD, Petitioner, v. SACRAMENTO COUNTY SUPERIOR COURT, Respondent; MEDICAL BOARD OF CALIFORNIA, DEPARTMENT OF CONSUMER AFFAIRS, STATE OF CALIFORNIA, Real Party in Interest.	No. _____ Sacramento County Superior Court No. 34-2021-80003606

Sacramento County Superior Court
The Hon. James P. Arguelles, Dept. 17
Telephone No. 916-874-5511

PETITION FOR WRIT OF MANDATE

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CERTIFICATE OF INTERESTED PARTIES

Pursuant to CRC 8.208(3), there are no interested parties to this Writ Petition other than the parties listed in the caption.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on December 29, 2021 in Westport, Ct.

_____

Richard Jaffe
Attorney for Petitioner,
Kenneth P. Stoller, MD

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TO THE HONORABLE PRESIDING JUSTICE AND HONORABLE ASSOCIATE JUSTICES OF THE COURT OF APPEAL OF THE STATE OF CALIFORNIA FOR THE THIRD APPELLATE DISTRICT:

WHY A WRIT SHOULD ISSUE

Petitioner's medical license was revoked based on his writing 10 medical exemptions to the school immunization mandate under a revision to Health and Safety Code section 120370 et seq. (hereinafter "SB 277"). SB 277 which eliminated the parental personal belief exemption ("PBE") to mandatory school vaccination. However, the legislative history makes clear that the *quid pro quo* for the removal of the PBE was a more "robust" medical exemption than what existed pre-SB 277.

A central issue in the administrative and writ proceedings was or should have been the meaning and interpretation of SB 277. Our position throughout these proceedings is that SB 277 created a different standard of care than the community standard of care which is to follow the guidelines established by the CDC's Advisory Committee on Immunization Practices ("ACIP") and the Red Book vaccine guidelines published by the American Academy of Pediatricians ("AAP"). Petitioner maintains that his actions were consistent with the standard of care created by SB 277.

The administrative law judge did not even address the issue, which we think is problematic because the wrong standard of care was used in evaluating the evidence in the case. We maintain that the lower court failed to recognize that the law allowed physicians to use considerations and methodologies which were not endorsed by conventional medical practitioners who rely on the ACIP or Red Book guidelines (hereinafter jointly referred to as the "Guidelines" or the "ACIP Guidelines").

We assert that the lower court was wrong in concluding that that Petitioner based these exemptions on his "personal beliefs" as opposed to his professional judgement based on medical science. Petitioner (and like-minded physicians) have a different view of the medical circumstances justifying exemptions. That view is based on the scientific literature on vaccine adverse effects and vaccine safety in general, which is at odds with the consensus/conventional/majority view.

Petitioner asserts that the writ should issue for several reasons. First, the legal conclusions in the ALJ's and lower court

decisions are based on an incorrect standard of care, The evidence adduced shows that Petitioner complied with the SB 277.

Concomitantly, both judges conflated minority medical views with the assertion that Petitioner showed a contempt for science or that the exemptions were based on his "personal beliefs." However, the exemptions were based on a minority medical view seemingly permitted by the language of the statute and the only directly on point legislative history and supported by medical literature.

The lower court said it weighed the evidence and found that the weight of the evidence supported the ALJ's proposed decision. In reality, it merely cited some of the incorrect and contradictory evidence adduced by the Board. It completely ignored – as did the ALJ – Petitioner's medical literature evidence supporting the exemptions and his minority risk assessment.

This conflation led both judges to misinterpret and fail to find that the minority view safe harbor defense to standard of care charges (Bus. & Prof. Code[1], § 2234.1) applied to this case.

Finally, the writ should issue because the revocation sanction was arbitrary, capricious and excessive given the circumstances of this case. These circumstances include the fact that SB 277 appeared to allow him to write these medical exemptions based on family history and other factors not recognized by the Guidelines, and allowed him the discretion to

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[1] All undesignated statutory citations are to the California Business and Professions Code.

use his medical judgment based on his knowledge and expertise about the risk of continued vaccination for these children.

Also, he contacted the Board about what the law required, but was rebuffed. He sought advice of counsel and interacted with like-minded physicians to work through the SB 277 based standard of care. Finally, he voluntarily stopped writing medial exemption once the Board informed him that he must follow the Guidelines, and he only wrote medical exemptions because he thought he had the right to do so.

ISSUES PRESENTED

1. Did SB 277 create a different standard of care that physicians could base medical exemptions separate and apart from the community/convention standard of care adhered to by most California physicians?

2. By specifically referencing "family history" in Health and Safety Code section 120372 (hereinafter referred to by its bill designation, "SB 277), did the California Legislature allow and/or intend to allow physicians to write medical exemptions based on "family history" considerations, even though family history is not a "contraindication" or "precaution" to vaccination under the ACIP guidelines?

3. If SB 277 created a new statutory standard of care (in whole or in part), was it reversible error for the ALJ not to use that standard in rendering her decision?

4. Was the exclusion of proposed expert witness James Neuenschwander MD prejudicial error?

5. Was there substantial evidence supporting the ALJ's finding that Petitioner's use of genetic testing was "nonsense," despite the evidence introduced that genetic testing was an appropriate tool in helping making decisions about possible adverse events from vaccination?

6. Did the ALJ mischaracterize the evidence in her finding fault with Petitioner for not obtaining prior medical records?

7. Did the ALJ and the lower court misapply the definitional part of Section 2234.1 in finding that this section did not apply because of an unfavorable risk benefit analysis?

8. Was there substantial evidence supporting the ALJ's finding that Petitioner showed a contempt for science, as opposed to having minority views about when medical exemptions from mandatory vaccination is appropriate under the SB 277 created standard of care?

9. Was the lower's court's determination that the vaccination medical exemptions in this case were just his personal opinions and not his professional judgement based on science i.e., the medical literature?

10. Did the lower court give due consideration to Petitioner's evidence adduced at the hearing which should be required when the ALJ used the incorrect standard of care in throughout the case?

11. In light of the unique factors presented in this case, was the revocation sanction arbitrary, capricious, or excessive?

PETITION FOR WRIT OF MANDATE

By this verified petition, the following facts and causes are set forth for the issuance of the writ:

A. The Parties

1. The Petitioner is Kenneth P Stoller, MD. Until his California medical license was revoked by the Board by adoption order dated February 16, 2021, he practiced medicine in California and other states for almost 40 years. There is no evidence in the record of any disciplinary actions or malpractice judgements or settlements against him.

2. The Respondent is the Superior Court of the state of California, Sacramento County which denied a writ of administrative mandate (§ 1094.5) against the Medical Board of California by notice of judgment dated September 14, 2021. (App., Vol. 1, Exhs. 1 and 2.)[2]

3. The real party in interest is the Medical Board of California (the "Board").

B. Procedural History.

4. The Board filed a disciplinary action against Petitioner on July 23, 2019, for writing eight permanent and two temporary medical exemptions from school immunizations because, *inter alia,* the medical exemptions did not comply with the standard of care based on the CDC's Advisory Committee on

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[2] "App." refers to the Appendix of Exhibits submitted with this petition. "Exh." refers to the Appendix exhibit number. "Exhibit" followed by a letter refers to the exhibit designation in the motion papers to which the exhibit is attached.

Immunization Practices guidelines listing contraindications and precautions for vaccination. (App., Vol. 2, Exh. 14 Exhibit A.)

5. In late September 2020, there was a four-day hearing before the Office of Administrative Hearings. (Hearing transcript, Appendix at Vol. 2, Exh. 14 Exhibit D1, through Vol. 4 Exhibit D4.)

6. On December 13, 2020, a proposed decision was issued by ALJ Judge Juliet Cox revoking Petitioner's medical license. (App., Vol. 5, Exh. 14 Exhibit E.)

7. The ALJ found that Petitioner violated the standard of care based on her acceptance of the Board expert's view that the standard of care is to follow the ACIP guidelines in writing medical exemptions in all cases to which the Guidelines clearly apply and in the cases they do not, medical exemptions must be based on "medial science." (App., Vol. 5 Exh. 14 Exhibit E p. 1039, ¶¶ 83-84.)

8. The ALJ also held that the safe harbor provisions in section 2234.1 did not apply. (App., Vol. 5 Exh. 14 Exhibit E, pp. 1048-1049.) She recommended license revocation because she felt that Petitioner's "contempt for science" made him unrehabilitatable, in part because he used genetic testing which was not in the guidelines and had no proven causal connection or association with the risk of vaccination (App., Vol. 5 Exh. 14. Exhibit E p. 1050, ¶ 12.)

9. The Board adopted the ALJ's proposed decision by order dated February 13, 2021. (App., Vol. 5 Exh. 14 Exhibit E, p. 1017.)

10. Petitioner filed a Petition from a Writ of Administrative Mandate and an *Ex Parte* Application for Stay of the Board's decision on March 4, 2021. (App., Vol. 2, Exhs. 12-14 to Vol. 5, Exh. 14 Exhibit E.)

11. By Order dated March 17, 2021, Superior Court James P. Arguelles denied a stay, holding that Petitioner was unlikely to succeed on the merits, largely because under SB 277, Petitioner was required to "consult" the ACIP guidelines but failed to do so. (App., Vol. 2 Exh. 10, p. 265)

12. The day before the hearing on the writ petition, instead of a tentative decision, the court issued a series of questions to be addressed at the hearing. (App., Vol. 1, Exh. 4.) The hearing was held on July 23, 2021. (App., Vol. 1, Exh. 3.)

13. By decision dated September 13, and Notice of Entry dated September 14, 2021, Judge Arguelles denied the writ of administrative mandate. (App., Vol. 1, Exhs. 1-2.)

14. Although the judge accepted that SB 277 created a new partial standard of care, he concluded that the Petitioner's medical exemptions were based on his personal opinions and not "medical science." (App., Vol. 1, Exh. 2, pp. 16-19.) He also agreed that Petitioner's use of genetic testing was not based on science. (App., Vol. 1, Exh. 2, p. 10.) He found that the Section 2234.1 safe harbor did not apply because Petitioner did not obtain prior medical records and did not satisfy the definitional terms of the statute. (App., Vol. 1, Exh. 2, pp. 11-13.). Although the lower court talked about weighing the evidence, his decision shows that

he accepted the Board's evidence without evaluating Petitioner's evidence, which is *de facto* a substantial evidence standard.

THE BASIS OF THIS WRIT

This writ presents three basic issues: the applicable standard of care. Second, the finding by the ALJ and the Superior Court judge regarding that Petitioner did not satisfy the safe harbor of provisions of Bus. & Prof. Code section 2234.1. And finally, Petitioner's claim that the revocation sanction was arbitrary, capricious, and excessive.

I. Standard of Care Issues.

In this petition, we argue that the ALJ used the wrong standard of care in adjudging the case. SB 277 created a statutory standard of care different from the community standard of care which is based on the ACIP guidelines.[3] This presents primarily a legal issue of interpreting SB 277. The evidence supporting Petitioner's position comes from the text of the statute, as well as the statements by the cosponsors contained in the transcript of the June 9, 2015 committee hearing included in the Appendix at Volumes 5 and 6, Exhibit 18.

A. The Standard of Care Under SB 277.

We know for a fact that under SB 277, physicians could write medical exemptions that would not be permissible under

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[3] The section of the ACIP guidelines which contains the contraindication and precaution schedules is attached to Petitioner's Supplemental Memo. (App., Vol. 1, Exh. 7, starting on p. 181.)

the Guidelines or even based on what the Board's expert viewed as "medical science." We know this because the SB 277's co-sponsors said so.

This critical evidence comes from the Assembly Health Committee's hearing on June 9, 2015, in which SB 277's co-sponsors, Ben Allen and Richard Pan testified, (as did the Board's expert in this case). Senator Pan is a practicing pediatrician.

The lower court quoted extensively from the hearing, but did not cite or discuss an important statement by Senator Allen which is worthy of the Court's consideration.

During the hearing, an opponent to the bill made the following statement "99.99% of children under federal guidelines do not qualify for a medical exemption." Senator Allen then jumped in and made the following statement:

> and I believe you deserve a short answer to your question. No, we would not be in CDC – in compliance with the CDC. The CDC – the committee on immunization practices, the American Academy of pediatrics would be apoplectic about the loosening of all these guidelines and yet I do like the amendment because if the bill passes at least [there would] still be some discretion. But no, we are way out of compliance with the CDC.

(App., Vol. 5, Exh. 18, p. 1190, ln. 15 to p. 1191 ln. 8.)

Senator Allen statement clearly indicates that SB 277 does not require that medical exemptions be based on the Guidelines.

The lower court's final writ decision quotes Senator Pan's statement that under SB 277 a physician could base a medical condition on a cousin. (App., Vol. 1, Exh. 2, p. 18.)

And therein lies the problem: The Board's expert, Dr. Dean Blumberg stated that there was no medical condition of a cousin which would justify a medical exemption under SB 277 (App., Vol. 2, Exh. 14 Exh. D1, p. 507, lns. 4-9) and that writing a medical exemption on that basis would not be within the standard of care. (App., Vol. 2, Exh. 14 Exh. D1, pp. 506-509.)

Dr. Blumberg tried to explain this away by saying that Senator Pan only meant that a physician had the power to write a medical exemption on the basis of a medical circumstance of a cousin, but to do so would be a violation of the standard of care. *Id.* The lower court correctly rejected Dr. Blumberg's attempt to explain away Senator (and pediatrician) statement that under SB 277 medical exemptions for non-first-degree relative like a cousin were permissible. (App., Vol. 1, Exh. 2, pp. 15-16.)

The bigger problem unrecognized by the lower court is that Senator Pan's statement, together with Dr. Blumberg's analysis undercuts the ALJ's and the lower court's standard of care determination, which is to follow the Guidelines or be based on Dr. Blumberg's view of "medical science." That is because according to Dr. Blumberg, a medical exemption based on the condition of a cousin would not be within the standard of care which he defines as requiring adherence to the ACIP Guidelines or some exception supported by medical science.

More generally, the problem is that family history is not a valid basis for a medical exemption under SB 277 according to

Dr. Blumberg view of the standard of care.[4] And yet, it is the one specific medical circumstance listed in the statute which can be used in an SB 277 based medical exemption.

Accordingly, Dr. Blumberg's testimony was not based on the standard of care created by SB 277, at least according to the words of the statute and the statements of Senators Pan and Allen. We pointed this out to the ALJ. However, she did not address it in her proposed decision. Given the fact that the Board has the burden of proof to both establish the applicable standard of care and prove that the Petitioner violated it, the Board's failure to provide the correct standard of care might itself be sufficient legal error to order the lower court to issue a writ of administrative mandate dismissing the case or ordering a rehearing.

B. What is the SB 277 Standard of Care for Writing Medical Exemptions?

Ironically, albeit perhaps unknowingly, the lower court actually set out the standard of care for writing medical exemptions under SB 277. The lower court quoted pediatrician co-sponsor Senator Pan's statement to the Assembly members (and to the people of California).

"If a physician feels that there is a genetic association in a sibling, a cousin, some other relative, it's not safe for a vaccine, they can provide a medical exemption for that vaccine. There is

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[4] Other than the one instance where a first-degree family history condition is a contraindication to one brand of the measles vaccine, but that is a contraindication.

no limitation on a physician from doing that other than their own professional judgment, their knowledge, and expertise about what they believe is safe for the patient." (Final writ decision, App., Vol. 1, Exh. 2, p. 18, third paragraph.)

So, contrary to Dr. Blumberg's asserted ACIP protocol-based community standard of care, SB 277 medical exemptions can be based on a physician's medical judgement informed the knowledge and expertise of the physician, and if the physician believes that the vaccine is not safe for the specific patient. And that kind of determination by a physician is called a risk assessment, which is exactly what Petitioner did.

C. Petitioner's Risk Assessment of the Patients and Documentation.

The evidence in the case showed that after SB 277 was passed, Petitioners and other like-minded physicians met and organized to come up with an approach to writing medical exemptions under the new law. (App., Vol. 3, Exh. 14 Exhibit D2, p. 611, lns. 11-22.) This included consulting with an attorney expert in the vaccine field. (App., Vol. 4, Exh. 14 Exhibit D3, pp 896-897.) With this input, Petitioner developed a comprehensive risk assessment methodology which set out how he would evaluate a child's need for a medical exemption. He conveyed this risk assessment approach in two ways. He produced a lengthy document which he called his "Policies and Procedures (the "P&P")," which he published on his web site. He directed the families who sought a medical exemption to review it.

The P&P was revised over the duration of his writing SB 277 medical exemptions from 2016 until mid-2019. The earliest and latest versions were admitted into evidence at the administrative hearing. Petitioner testified extensively about it and the medical literature contained therein during the hearing. (App., Vol. 3, Exh. 14 Exh. D2, p. 625, ln 24, to p. 631, ln. 6; p. 641, ln. 13, to p. 661, ln. 9.) A copy of the last version is included in the Appendix at Vol. 6, Exh. 20.

The P&P initially quotes the law, lists the contraindications to vaccines, and distinguishes them from a medical exemption. There is also a detailed explanation of the types of evidence used by him to make a medical exemption determination, including the patient's history, family history and genetic information, followed by a list of conditions from vaccine package inserts which are precautions to a vaccine. He also explains when a temporary exemption may be warranted (App., Vol. 6, Exh. 20, p. 1406). (Two of the ten children in this case received only temporary exemptions.) He explains why he feels that Senator Pan supports his use of genetic information in making a risk assessment. (App., Vol. 6, Exh. 20, p. 1409.)

Importantly, he discusses the strength of the medical literature support on the association between polymorphisms for specific genes to vaccine adverse reactions. The Court will note that the P&P also cites the literature supporting his analysis. *Id*.

Petitioner also states his overarching consideration which he describes as the "precautionary principal" which justifies a medical exemption to all vaccines and that would be "… a

reaction to one vaccine should factor into the decision regarding exemption to other and all vaccines" (App., Vol. 6, Exh. 20, pp. 11-12.). This is different from an ACIP protocol-based approach.

The second document which contains a much more detailed risk assessment is the Adverse Event Risk Assessment Report that Petitioner provided to each of his medical exemption families. (App., Vol. 6, Exh. 19.)

This report has an extensive discussion of Petitioner's approach. It discusses in detail the science behind the precautionary principle, with reference to and discussion of the medical literature.

It answers in advance, the criticism leveled by the Board's expert adopted by both judges about why a global exemption is given because supposedly "there is no common ingredient in all vaccines". The answer is that it is the common adjuvants and excipients not the antigen, most notably aluminum and polysorbate 80, which cause the problem. (App., Vol. 6, Exh. 19, pp. 1366-1369.). It details other considerations why a global medical exemption from all vaccines is warranted under his risk assessment analysis. *See also* Petitioner's testimony on this issue. (App., Vol. 3, Exh. 14 Exh. D2, p. 631, ln. 7, to p. 641, ln. 12.)

His reports also discuss most of the vaccines on the mandatory vaccine schedule. (App., Vol. 6, Exh. 19, pp. 1374-1382.) Petitioner's review of the medical literature leads him to question the conventional view that vaccines are proven to be safe and effective.

The report then outlines the new personalized vaccine approach, culminating in the results of the patient's genetic testing indicating what polymorphisms/alleles in each gene were found, followed by a recitation of what the gene does and why a variation might increase the risk of an adverse event from vaccination. (App., Vol. 6, Exh. 19, pp. 1388-1393.)

D. What do these Two Documents Mean for this Writ?

The information contained in the patient's adverse event risk assessment report and the P&P are obviously not in accordance with the conventional medicine's view of vaccine safety, nor does it follow the protocol-based ACIP Guidelines for writing medical exemptions which most physicians follow.

Furthermore, we are mindful that in this petition we cannot retry the case or ask this Court to come to a different conclusion. The point is to show that Petitioner's perspective and his precautionary principle which he employed in making these medical exemption judgments is based on medical science, that is to say peer reviewed literature. Relying on a body of medical literature does not show a contempt for science, as found by the ALJ. It does not mean that Petitioner's medical exemption are decoupled from medical science. What it means is that Petitioner (and like-minded physicians) look at the sum total of the medical literature differently, and come to different conclusions about vaccine safety and risk, as it applies to these children than how more conventional practitioners who use the protocol-based ACIP guidelines.

In this petition, we assert that Petitioner's approach is consistent with Senator Pan's representation that a physician can use his knowledge and expertise in making a risk assessment for each individual patient.

It is worthy of note that none of the above information or discussion about the science behind the testimony made its way into the lower court's recitation of the weighing of the evidence, perhaps because it was also all but completely ignored by the ALJ in the proposed decision.

E. Petitioner's use of Genetic Testing as part of his Risk Analysis.

Petitioner's use of genetic testing in making his vaccine medical exemption decisions was criticized by the Administrative Law Judge, and was part of the reason she found him to have a contempt for science justifying license revocation. (App., Vol. 5, Exh. 14 Exhibit E, p. 1050, citing finding 29 set out on p. 1027 that his use of genetic testing was nonsense.) The Superior Court adopted the ALJ's analysis. (App., Vol. 1, Exh. 2 p. 19)

We submit that both judges conflated a minority view position with the absence of scientific evidence. The record contains ample support for Petitioner's use of genetic testing. On a general level, Petitioner discussed a 2015 article in the highly prestigious publication *Nature,* which concluded that identifying the genetic variants predictive for vaccine adverse events for clinical use is feasible. (App., Vol. 5, Exh. 17, and see conclusions on p. 1117.) The ALJ omitted this article from the proposed decision, despite the fact that it showed that practitioners who

have actually looked at the medical literature have publicly advocated for the use of genetic testing in predicting increased risk of adverse events.

The most baffling part of her discussion of the genetic testing issue is that she criticized one article from the patient's adverse event report which related an association between an allele of a gene to a neurological symptom (narcolepsy) with a vaccine. Petitioner used this article to demonstrate that an allele on this important gene has been shown to be associated with an increased risk of an adverse event. (App., Vol. 5, Exh. 14 Exhibit E, p. 1027, ¶ 29, fn. 3.).

And yet, later on she found credible Dr. Blumberg's expert testimony categorial testimony that:

> … no research has identified any specific alleles of any human genes that ever correlate with, let alone cause, differences among patients in their immune responses to vaccination. He testified further that because research has identified no vaccine-relevant alleles of any human genes, genetic testing provides no information that will assist a physician in predicting a patient's response to vaccination. Any recommendation about vaccination based on genetic testing are speculative and irrational!

(App., Vol. 5, Exh. 14 Exh. E, p. 1042, ¶ 91.)

The ALJ obviously knew of one study which showed an association/correlation between an allele and a vaccine adverse reaction. She also knew of the following other studies showing associations between alleles or polymorphisms and adverse reactions from vaccination contained in the same report:

> Autoimmunity. 2005 Mar;38(2):181-94. Concurrent HLA-related response factors mediate recombinant

hepatitis B vaccine major adverse events. Miller JD1 , Whitehair LH.

Common variants associated with general and MMR vaccine–related febrile seizures • Nature Genetics 46, 1274–1282 (2014)
https://www.nature.com/articles/ng.3129

Reif DM, McKinney BA, Motsinger AA, Chanock SJ, Edwards KM, Rock MT, Moore JH, Crowe JE. Genetic basis for adverse events after smallpox vaccination. J Infect Dis. 2008; 198(1): 16-22. PMID: 18454680

Martin YN, Salavaggione OE, Eckloff BW, Wieben ED, Schaid DJ, Weinshilboum RM. Human methylenetetrahydrofolate reductase pharmacogenomics: gene resequencing and functional genomics. Pharmacogenet Genomics. 2006; 16(4): 265-77. PMID: 16538173

Dedoussis GV, Panagiotakos DB, Pitsavos C, et al. An association between the methylenetetrahydrofolate reductase (MTHFR) C677T mutation and inflammation markers related to cardiovascular disease. Int J Cardiol. 2005; 100: 409–414. PMID: 15837084

Lim U, Peng K, Shane B, et al. Polymorphisms in cytoplasmic serine hydroxymethyltransferase and methylenetetrahydrofolate reductase affect the risk of cardiovascular disease in men. J Nutr. 2005; 135: 1989–1994. PMID: 16046727

Partinen, M; et al.: Increased Incidence and Clinical Picture of Childhood Narcolepsy following the 2009 H1N1 Pandemic Vaccination Campaign in Finland. Published: March 28, 2012DOI: 10.1371/journal.pone.0033723

(This is the study mentioned by the ALJ in footnote 3)

COJOCARU, M; et al: ASIA or Shoenfeld's Syndrome – An Autoimmune Syndrome Induced by Adjuvants. ROM. J. INTERN. MED., 2013, 51, 3–4, 131–134 http://www.intmed.ro/attach/rjim/2013/rjim313/art02.pdf

Pope JE, Stevens A, Howson W, et al. The development of rheumatoid arthritis after recombinant hepatitis B vaccination. J Rheumatol 1998;25:1687-93. [PubMed]

Berkovic, S et al.: De-novo mutations of the sodium channel gene SCN1A in alleged vaccine encephalopathy: a retrospective study The LANCET Neurology. Volume 5, No. 6, pp. 488–492, June 2006. http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2806%2970446- X/abstract

McKinney, BA ET AL.: Cytokine Expression Patterns Associated with Systemic Adverse Events following Smallpox Immunization. J Infect Dis. 2006 Aug 15; 194(4): 444–453.

(App., Vol. 6, Exh. 20, p. 1410.)

Therefore, the ALJ's discussion of the narcolepsy article, in conjunction with Petitioner's report demonstrate that Dr. Blumberg is unaware of the medical scientific literature establishing associations between alleles and vaccine adverse reactions. Hence, there was not substantial evidence supporting the finding that Petitioner's use of genetic testing was nonsense, irrational or showed a contempt for science.

The ALJ's finding that Petitioner's citation to the narcolepsy study was nonsense is even more baffling since Petitioner actually explained in detail why he used it, namely that the study confirms that these genes are, in fact, implicated or associated with increased adverse event risk. (App., Vol. 3,

Exh. 3, Exhibit D2, p. 712, lns. 9-11, but discussion starts at p. 711, ln. 23.)

Further, Petitioner explained to the ALJ the alleles the patient did have which showed that she was likely a non-responder to vaccines:

> Q. Okay. So what is your thinking in terms of this patient? Go ahead.
>
> A. Well, I did a literature search on the HLA genes, so I already knew that if you didn't have HLA-DRB113 and you did have HLA-DRB17, the likelihood of you being hyporesponsive, unable -- being a nonresponder to a vaccine was higher than the general population. It's an association.
>
> Q. And are you saying that -- so that's not you making this up? You're saying that that's in the literature?
>
> A. That's right. And in the report to the parent, I cited two of those articles, but there's many more articles than that on the HLA genes and vaccine responsiveness. …
>
> A. Right. So the logic based on the medical literature -- because that's how I figured this out. I went to the medical literature -- I didn't pull this out of a hat like a to certain HLA genes. And lo and behold, this particular child had both genes -- same one, having another, making them double hypo -- at risk for being double hyporesponsive.

(App., Vol. 3, Exh. 14 Exhibit D2, pp. 701-702.)

In fact, the discussion of the genetic test results of this patient's starts on page 700 line 13 and continues to page 703 line 8, and starts with a discussion of the HLA gene, continuing with the results of his literature search, and why he felt that as a

likely non-responder, the risk of vaccination for a patient with a congenital heart condition was not worth the potential benefit.

Despite all the testimony about the genetic literature concerning the alleles the genetic test revealed, the only thing that made it into the ALJ's decision was criticism about a reference to an article about a genetic association between narcolepsy and an HLA allele. This article was supposed to be representative of Petitioner's thinking and supposedly proved that his methodology was nonsense. This finding is unsupported by a fair and impartial view of the evidence.

Circling back and summarizing Dr. Blumberg's criticism of Petitioner's use of genetic testing, there were two points. First, that the Guidelines do not recognize the use of genetic testing as a basis or factor in writing a medical exemption. (App., Vol. 2, Exh. 14 Exh. D1, pp. 446-448.) However, since SB 277 requires no such compliance, this criticism is unpersuasive.

And second, he categorially stated that there is no literature support for any association between any gene and a vaccine adverse reaction. His lack of knowledge of the literature led him to the unsound conclusion that information about variations of certain genes (polymorphisms or alleles) contains no important information. Hence it would be illogical to use these genetic differences in making a risk analysis for a vaccine medical exemption. (App., Vol 2, Exh. 14 Exhibit D1, p. 486, ln. 18, to p. 487, ln. 1.)

Of course, as evidenced by the ALJ's footnote 3, the other literature mentioned in the adverse event risk report, and the

medical note listed above, Dr. Blumberg's testimony is inconsistent with the evidence. Accordingly, the ALJ's factual finding that Petitioner's use of genetic testing as one component in making a medical exemption determination was nonsense is unsupported by the evidence in the case and should be rejected by this Court

This finding seems to be an important part of the ALJ's conclusion that Petitioner has a contempt for medical science, and as such, the lack of substantial evidence on the genetic testing finding significantly undercuts the contempt for medical science finding which undercuts the rational for the revocation sanction.

Finally, the lower court cites an admission made by Petitioner that there is no way to quantify the increase in risk from the genetic testing he employs in his risk assessment. (App., Vol. 1, Exh. 2.) This is true, but there is no evidence in the record which states or suggests that risk assessment requires a quantifiable probability as opposed to a qualitative increase under a risk analysis.

As a matter of fact, the evidence in the record suggests otherwise. The Nature article introduced into evidence and discussed by Petitioner (App., Vol. 5, Exh. 17) recommends use of genetic testing despite the fact that there are no quantifiable probabilities of increased risk. But in any event, the lower court's finding lacks any factual basis in the record and should be rejected by this Court.

F. Prior Medical Records.

Both judges faulted the Petitioner for failing to obtain the prior medical records of the patients based on Dr. Blumberg's There are several responses. First, the record in this case demonstrates that Petitioner in fact asked patients to bring prior medical records if they were available. (App., Vol. 6, Exh. 19 [Practices and Procedure].)

Second, as Petitioner testified the family history conditions were at least indirectly verified by the genetic testing which Petitioner required of every patient. (App., Vol. 2, Exh. 14 Exh. D2; as is also set out in his P&P at App., Vol. 6, Exh. 20, p. 1409.) While it is true that there may not be a scientifically proven causal connection between any specific allele and vaccine reactions, there are associations, as set forth above. This lessens the need for prior medical records since the genetics confirm the genetic based increased risk.

Finally, judges can use their common sense and life experience. How often is medical advice withheld until the patient can provide prior medical records to verify something contained in the medical history/patient intake form?

The ALJ did discuss one example of Petitioner's failure to obtain medical records of one of the children where the Board's expert accused Petitioner of exaggerating the medical problem (bleeding after a prior vaccination) as why prior medical records are important. However, the ALJ forgot to mention that Petitioner only wrote a temporary medical exemption and referred the patient back to his primary care physician for a test

to see if the bleeding incident might increase the risk of vaccination. (App., Vol. 3, Exh. 14 Exh. D2, pp. 719-720.) The prior medical records would not have been helpful. What was needed was a work up of the symptom via testing, and that is exactly what the Petitioner said he did as he stated in the above hearing transcript citation.

In short, the core factual issue in this writ is whether Petitioner's medical exemptions showed a contempt for science or were based only on his personal beliefs, (according to the lower court). Or alternatively, whether they were based on his professional judgment based on his knowledge and expertise supported by medical literature, notwithstanding that his approach to writing medical exemptions did not follow the Guidelines, and was a result of a different view of the vaccine safety medical literature.

We maintain that Petitioner properly exercised his profession judgment in these medical exemptions because his decisions were based on the published medical literature, as explained to his patients in the medical exemption reports he prepared for the families, and as generally described in his Policies and Procedures which he published on his website.

In concluding that Petitioner showed a contempt for science, the ALJ conflated the fact that his decisions were based on the medical literature which embodies a minority view with being anti-science.

The lower court's error was different but similar. He dismissed Petitioner's point of view as merely his personal

beliefs. It seems like he has confused the fact that SB 277 removed the parental personal belief exemption with a physician exercising his medical judgment based on his knowledge and expertise to make a determination that he does not believe that a vaccine is safe for the patient. It is also suggested that he also confused a physician's personal belief with a belief that follows the majority or the commonly accepted view of physicians. However, as indicated, the law allowed minority view medical exemptions or at least it did when SB 277 was in effect.

II. The Exclusion of Petition's Proposed Expert Was Prejudicial.

Petitioner listed as an expert witness Dr. James Neuenschwander, who specializes in treating vaccine injured patients. A copy of his expert report is included as Exhibit 21 in the Appendix. Unlike the Board's expert, Dr. Neuenschwander has extensive experience in the harm vaccines can cause. He could have given the ALJ important information about the role of autoimmunity in family members as a predictor of vaccine injury. However, the ALJ excluded him as a witness on the grounds that his testimony was cumulative. We maintain that in light of the ALJ's rejection of the opinions of his only remaining witness, the ALJ's *in limine* order against Dr. Neuenschwander was prejudicial. (The *in limine* order is in the Appendix in Vol. 2, Exh. 14 Exhibit C1.)

III. Business and Professions Code Section 2234.1 Issues

We argue that in issuing the medical exemptions, Petitioner's conduct met all four elements of section 2234.1

dealing with alternative and complementary heath care; i.e., minority view medical practices. The ALJ ruled against Petitioners by reinterpreting two of the requisite elements to fit the hearing testimony of the Board's expert. (This point was exhaustively and repeatedly addressed in the prior writ and will not be repeated herein for the sake of brevity, *but see* the Verified Writ Petition [App., Vol. 2, Exh. 13, pp. 353-358], the Notice and Ex Parte Application [App., Vol. 2, Exh. 12, pp. 331-335], the Supplemental Memorandum [App., Vol. 1, Exh. 7, pp. 167-172] and the Reply Memorandum [App., Vol. 1, Exh. 5, pp. 108-112].)

The lower court agreed with the ALJ because he thought that Petitioner did not do a good faith medical examination because he did not obtain prior medical records. However, prior to the administrative hearing, the ALJ excluded our attorney witness who would have testified that he advised Petitioner and others that the good faith examination requirement in Section 2234.1 refers to a physical exam. At the hearing, we offered into evidence the document containing this attorney's advice, but the ALJ sustained the Board's objection to exclude it. (App., Vol. 4, Exh. 14 Exhibit D3, p. 871, ln. 3 to page 872, ln. 8.)

A copy of the written advice is included in the Appendix as Exhibit 22. The relevant part of which is: "California law protects physicians who offer complementary health care methods, provided the physician ensures the following: *** (**4 Conduct a Physician Exam**. The physician conducts a good-faith examination of the patient." (Bold is in the original).

The exclusion of this document and the proffered but rejected testimony from the attorney was prejudicial based on the position of the lower court (and the ALJ) that Petitioner did not do a good faith exam which is the first element in a section 2234.1 defense. This prejudicial error by the ALJ is grounds for issuing the writ, as it undercuts the rejection of the section 2234.1 safe harbor to the section 2234 charges in the accusation.

The ALJ and the Superior Court also concluded that this section did not apply because of definitional language limiting it to "diagnoses treatment, or healing, that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the healthcare method." (§ 2234.1, subd. (b).)

The problem is that the basis for the finding is Petitioner's failure to follow the Guidelines, and in particular the mainstream view that based on the Guidelines, writing an exemption for mandatory vaccination for these children created more risk than benefit. We believe that such reliance on the Guidelines defeats the very purpose of having the section 2234.1 safe harbor and that the court should reject this conclusion, per subsection section 2234.1 subd. (c).

Moreover, Dr. Blumberg has no credentials or knowledge of the alternative and complementary heath care standards, and did not even recognize that such a standard exists. (See Dr. Blumberg's testimony (App., Vol. 2. Exh. 14 Exhibit D1 pp.440-445.) Therefore, on a technical and mechanical level, there is an absence of any evidence from the Board on this issue.

Finally, the lower court misconstrued Petitioner's position in the final writ decision, by stating that we conceded that we had the burden of proof and that he agreed with the ALJ that we did not meet it. (App., Vol. 1, Exh. 2, p. 19.)

It is true that section 2234.1 is a safe harbor for which Petitioner has the initial burden of proof. Petitioner argued in the writ below that he met this initial burden of proof on all four elements, and that the Board failed to rebut the Petitioner's *prima facia* case. That got translated in the final writ decision into a finding Petitioner admitted that he admitted that he had the burden of proof and failed to meet it.

IV. The Sanction was Arbitrary and Capricious in light of the Unique Factors in this case

As set out in the memo of law, this Court gives no deference to the Superior Court's decision to uphold the sanction imposed by the Board. We submit that the revocation penalty was arbitrary and capricious because of the combination of factors in this case some of which are quite unique. These factors are:

a. the fact that the terms of SB 277 and the on-point statements by the law's co-authors indicated that physicians could write medical exemptions based on family history and other factors even if they were not consistent with the Guidelines and would not justify an exemption according to the Board's expert.

b. Other states like New Jersey have clearly stated in their law that medical exemptions must be based on ACIP guidelines. Petitioner should not be so severely sanctioned because of the legislative poor draftsmanship. If SB 277 had

indeed required all physicians to limit medical exemptions to the guidelines or based on the opinions of infectious disease specialists like the Board's expert, it could have clearly so stated. (*See* the New Jersey law, App., Vol. 5, Exh. 16 Exh. D.)

c. The Board put out no guidance on how physicians should apply SB 277. (App., Vol. 3, Exh. 14 Exh. D3, 644.)

d. Petitioner and at least one other doctor attempted to obtain the board's view on the appropriateness of writing medical exemptions beyond the guidelines but was rebuffed. (App., Vol. 3, Exh. 14 Exh. D2, p. 613.)

e. The Petitioner and a group of like-minded physicians had meetings and other communications in order to come up with their own guidelines and even sought legal advice about the meaning and interpretation of SB 277. (App., Vol. 3, Exh. 14 Exhibit D2, p. 611.)

f. As indicated in the prior section, the ALJ's finding that there was no science behind using genetic testing in vaccine exemption determinations is simply incorrect as proven by hearing Exhibit 45 (App., Vol. 5, Exh. 17), and the publications on the associations between alleles and vaccine adverse reactions. These articles demonstrate that the Board's expert was ignorant of the relevant literature. It has also been shown that the ALJ's proposed decision is self-contradictory for both criticizing Petitioner's use of an article showing an association, while crediting Dr. Blumberg's categorical testimony that there are no such studies.

g. The fact that the Petitioner has no prior disciplinary or malpractice history whatsoever; that he stopped when the Board finally informed him that he was required to follow the Guidelines, and that he would not have written any medical exemptions if the Board had published its interpretation of SB 277.

There are two other factors to consider. First, other Board sanctions for the same offense. At the prior writ, we produced other disciplinary decisions by the Board for writing medical exemptions beyond the ACIP guidelines. (App., Vol. 5, Exh. 16 Exhs. A-C, and Vol. 1, Exh. 8 Exh. A, starting on p. 200.) At the time, Petitioner had been the only physician whose medical license had been revoked. We argued that difference between his treatment and the treatment of other physicians was the number of medical exemptions in the Accusation. All the other cases involved only a few (up to three) medical exemptions, while this case involves 10. We argued that this was irrational because there is no necessary correlation between the number of cases in an accusation and how many medical exemptions a physician has written, and because it is the same basic conduct.

Earlier this month, the Board revoked another physician's license for writing eight medical exemptions. So, while Petitioner is no longer the only physician whose medical license has been revoked, the stated irrationality of the decision still stands. If a physician only is charged with writing one or a couple of these medical exemptions, the sanction is either probation or a letter reprimand. But write more than a few, the doctor gets revoked.

I would like to apprise the court of the following. Petitioner is the first physician challenging a disciplinary order based on writing SB 277 medical exemptions. However, there have been a number of special proceedings (Board motions to compel compliance with an investigational subpoena) in which arguments similar to those being made here were asserted, albeit with a less extensive record. In fact, undersigned counsel has been involved in two of those proceedings and the Board's counsel has been involved in at least two of them. Those cases, including one recent case in the Sacramento Superior have accepted the Board's view that SB 277 did not change the law with respect to medical circumstances which could be used to write a medical exemption. However, as shown in the accompanying Memorandum, this interpretation violates core principles of statutory interpretation, especially that changing the terms of a statute is presumed to change the meaning.

These other decisions, as well as the lower court also point to the general legislative history's aspirational goal of full vaccination as being a reason why Petitioner's interpretation of expanding medical exemption is inconsistent with the statute. However, why cannot it be the case that the statute aspires towards full vaccination, but also allows for expanded medical exemptions? Then there is the fact that use of a general point to contradict a specific point violates the statutory and general rule of construction of applying the specific over the general (*Generalia specialibus non derogant*).

Should the Court so desire, we are prepared to submit or agree to a request for judicial notice of every court decision in any district which have addressed this issue. Obviously, none of these decisions are binding on this Court, and they all are against Petitioner's position on the issue. However, it might facilitate or help the Court's analysis by showing how far courts are willing to depart from accepted rules of interpretation in order to explain away the clear words of the statute and the even clearer statements by the law's co-sponsors. In some sense, these constrained interpretations of the law support Petitioner's view that the Board's sanction was arbitrary and capricious, since by showing that these statutory interpretations are so at odds with the rules of statutory construction.

We submit that the unique combination of factors makes the revocation sanction unduly harsh, excessively punitive and arbitrary and capricious.

V. The Authenticity of the Exhibits.

All exhibits are copies of exhibits which were filed in the Superior Court either as pleadings in that case, pleadings in the administrative case or exhibits at the administrative hearing. The exhibits to this petition are incorporated herein by reference.

The reporter's transcript of the hearing on the writ of administrative mandate is included in the Appendix as Exhibit 3.

VI. Timeliness of the Petition.

This petition is being filed within 120 days of the entry of Notice of Entry of the denial of the writ of mandate, and could not be brought any sooner due to the complicated nature of this case.

There are other reasons including the need to wait for a decision in a substantially related case referenced in the sanction section above. Petitioner is not seeking a stay of the Board's order. Finally, although not directly applicable, we note that due to the pandemic, the California statute of limitations on civil cases has been tolled by emergency order. The reason for the emergency order is of course the pandemic which presents some additional challenges.

VII. Basis For Relief.

California Code of Civil Procedure section 1085, subdivision (a) empowers this court to issue a writ of mandate to the Superior Court "to compel the performance of an act which the law specifically enjoins." In addition, "the writ must be issued in all cases where there is not a plain, speedy, and adequate remedy, in the ordinary course of law." (*Id*., Code Civ. Proc., § 1086.).

There is no remedy of law insofar as the sole remedy for a denial of a superior court's writ of administrative mandate is via extraordinary writ. (§ 2337.)

PRAYER

WHEREFORE, Petitioner respectfully prays that this Court issue a writ of mandate commanding the Superior Court to issue a writ of administrative mandate dismissing the Board's complaint for failure of proof, or alternatively, remanding the case back to the Office of Administrative Hearings for reconsideration of the case in whole or the sanction, or for such other general, alternative or preemptive writ relief that the court deems appropriate to facilitate the review of this extraordinary

writ including order the Respondent to file a response to this petition.

Dated: December 29, 2021

Richard Jaffe

VERIFICATION

I am the attorney of record for the petitioner in this case and have authority to execute this verification.

I am over the age of 18, and of read this petition for writ of mandate and know its contents. The facts alleged are within my own personal knowledge and I know these facts to be true (except for those stated on information and belief, of which I am informed and believed are true).

I declare under penalty of perjury under the laws of the state of California that the foregoing is true and correct.

Dated: December 29, 2021

Richard Jaffe

MEMORANDUM OF POINTS AND AUTHORITIES

I. The General Standard of Review

This Court's review of a Superior Court's denial of a Code of Civil Procedure section 1094.5 writ of administrative mandate is via an extraordinary writ. (Code Civ. Proc., § 2337.)

On a Code of Civil Procedure section 1094.5 writ, the superior court's scope of review is to determine, *inter alia*, whether there has been a "prejudicial abuse of discretion" which the statute states is established "if the respondent has not proceeded in the manner required by law, the order or decision is not supported by the findings, or the findings are not supported by the evidence." (Code Civ. Proc., § 1094.5, subd. (b).)

If the court is authorized to exercise its independent judgment (as it is in this case and all cases involving professional discipline), "abuse of discretion is established if the court determines that the findings are not supported by the weight of the evidence." (Code Civ. Proc., § 1094.5, subd. (c).)

Case law interpreting the scope of review in a writ of administrative mandate states that this translates into a strong initial presumption of correctness to the agency's findings. (*Fukuda v. City of Angels* (1999) 20 Cal.4th 805, 816-817.)

As to issues of law, "[A] person aggrieved by agency determination has a right to independent judicial review of questions of law such as those dealing with the interpretation or application of statutes or judicial precedents." (*Donaldson v. Department of Real Estate* (2005) 134 Cal.App.4th 948, 954, citing Witkin Cal. Procedure (4th ed. 1997) § 111, p. 1156; see also

Medical Board v. Superior Court (Lee Roy Liskey, Real Party in Interest) (2003) 111 Cal.App.4th 163, 171.)

In reviewing a superior court's decision on a writ of administrative mandate, the standard of review by this Court depends on which parts of the lower court's order (and the agency action) is being challenged. Factual findings are generally reviewed under the substantial evidence rule. (*Pirouzian v. Superior Court of L.A. Cnty.* (2016) 1 Cal.App.5th 438, 447.) Admittedly, this is a heavy burden, as pointed out in *Shenouda v. Veterinary Med. Bd.* (2018) 27 Cal.App.5th 500, 512. Under the standard, a court looks at the Respondent's evidence on a factual issue or conclusion. If there is any plausible evidence support the finding, the court affirms it. However, it will be argued in the next section that in this case, the Court should use a different standard and a different methodology.

As with the standard of review by the lower court, pure questions of law, as well as "'issues regarding the nature or degree of an admininstative penalty are given a *de novo* review, the latter being examined to determine whether the administrative agency abused its discretion." (*Pirouzian v. Superior Court of L.A. Cnty., supra*, 1 Cal.App.5th at p. 447); see also *Deegan v. City of Mountain View* (1999) 72 Cal.App.4th 37, 46 [appellate court gives no deference to trial court's determination of the discipline the agency imposed].) An abuse of discretion may be found if, under all the facts and circumstances, "the penalty imposed was… clearly excessive." (*Szmaciarz v. State Personnel Bd.* (1978) 79 Cal.App.3d 904, 921.)

II. Petitioner's Central Contention in this Writ and Proposed Modification of the Standard of Review.

Petitioner's primary contention in the writ below was that the ALJ applied the wrong standard of care to the evidence in the hearing. The ALJ accepted Dr. Blumberg's view that the ACIP and Red Book vaccination guidelines provide the only legitimate basis and methodology for analyzing circumstances justifying medical exemptions.

The lower court, while indicating that SB 277 created a partial standard of care, filled-in the rest by reference to the ACIP/Red Book methodolgy of protocol based medical exemptions and vague references to exceptions in undefined highly unusual cases which he called "medical science." Petitioner asserts that the lower court's view of the SB 277 standard of care was also incorrect.

The problem with the use of an incorrect standard of care is that it led both the ALJ and the lower court to reject Petitioner's evidence without a meaningful review or analysis. Instead, both just cherry-picked some facts in the record without the full context, or literally made up some conclusion to support the Board's ACIP/Rebook standard of care. Petitioner's extensive discussion of the relevant medical literature and the literature itself was all but completely ignored.

Petitioner contend that the use of an incorrect standard of care might itself justify the issuance of the writ of administrative mandate. However, it certainly should have lead the lower court to take a much harder and deeper look at the Petitioner's

evidence. Instead, the lower court searched the record for support of the ALJ's findings and conclusion under a *de facto* extremely limited substantial evidence standard.

Unfortunately, there is no case law on this precise issue in the adminstrative professional discipline jurisprudence. Except, however in this case, where the lower court did find that the ALJ used the incorrect standard of care. However, as indicated, practically speaking, it applied a substantial evidence analysis (and the standard of care he used was also incorrect). And this is why Petitioner thinks this writ of mandate should issue.

A. Case law Analogues in Suport of a New Standard of Review.

As stated, there does not appear to be any case law concluding that a professional board used an incorrect standard of care, so there is no case articulating the standard of review that a superior court court should use which so finds. However, in the civil litigation context, there are cases or analogues. In *Richardson v. United States* (9th Cir. 1981) 645 F.2d 731, 735, the Ninth Circuit reversed a bench trial judgment due to the lower court's using an incorrect lower standard of due care, because the application of the correct standard of care "may have caused a different result" under the facts adduced at the trial. (*See also Emerick v. Raleigh Hills Hospital* (1982) 133 Cal.App.3d 575 [lower court used an incorrect lower standard of care which was one of the reasons for reversal of bench trial verdict of no liability].)

A somewhat higher standard for reversal was utilized in *Weaver v. Chavez* (2005) 133 Cal.App.4th 1350. The Court of Appeal reversed a jury verdict because the trial court used a lower state standard of care for highway safety jury charge, instead of using the applicable higher federal standard of care jury instruction.

On the precise issue of what showing was necessary to support a reversal, the court used what it called a "miscarriage of justice" standard which is satisfied wherein "after examining all the evidence, we conclude 'it is reasonably probable that a result more favorable to the appealing party would have been reached in the absence of error.' (*Pool. v. City of Oakland* (1986) 42 Cal.3d 1051, 1069 [232 Cal. Rptr. 528, 729 P.2d 1163].)." (*Weaver v. Chavez*, *supra,* 133 Cal.App.4th at p. 1356.)

Differences between the precise nature of the standard aside (i.e., "might have" vs. probably would have), the three cases employ the same methodology; all of them consider and indeed primarily rely on the appellant's evidence at trial, rather than focusing on the appellee's evidence which is how it works in a substantial evidence determination. And that makes sense since the appellate question in an appeal/writ claiming an incorrect standard of care was used, is whether the appellant/petitioner's evidence might or probably would have led to a different result, which is basically a determination of prejudice.

This was specifically articulated by the court in *Emerick v. Raleigh Hills Hospital* in a procedurally analogous review of a sufficiency of the evidence argument on appeal.

The court noted that in a standard lack of substantial evidence claim, the courts have to accept the full force of appellee's evidence with every favorable inference and "excluding all evidence in conflict therewith, the evidence in support of the findings is so barren, so slight, so tenuous, that it does not create real and substantial evidence to support the judgment." (Citation omitted). (*Emerick v. Raleigh Hills Hospital, supra,* 133 Cal.App.3d at p. 580.) The court then noted that under the substantial evidence standard, the judgement would be affirmed, but since the plaintiff/appellant asserted that the trial court used the wrong standard, it looked at the plaintiff's evidence, based on which and other reasons, the court of appeals reversed the jury verdict. *Id.* The Ninth Circuit in *Richardson v. United States*, *supra,* 645 F.2d at p. 735 also looked at the appellant's evidence and as indicated above, reversed because it found that that evidence might have led to a different result if the correct standard of care had been used.

Looking through the lens of these three civil cases, the court can clearly see how the lower court, while saying it weighed the evidence, in actuality simply used the substantial evidence rule. It looked for findings and evidence in support of the ALJ's findings and evidence, and threw in a reference or two to a statement Petitioner made. The lower court's analysis is not consistent with the level of analysis provided to the appellants' evidence in these three civil cases. Further, it might not even be consistent with the Code of Civil Procedure section 1094.5, subdivisions (b) and (c) required review of the evidence, except

insofar as that rule states or *de facto* means a very limited substantial evidence rule.

What the lower court did not do was meaningfully consider Petitioner's evidence, some of which is discussed in detail in the writ petition, especially with respect to the genetic testing issue. We assert that if this Court considers the Petitioner's evidence which logic and these three civil cases suggest should be done, it will conclude that the Board might have or probably would have come to a different result. Petitioner did what any good physician should do when faced with a problem that does not have to be resolved via a written protocol; he did a literature search, he ordered tests, and then made a professional judgment based on his knowledge, experience and results of the literature search. And that is exactly what co-sponsor Richard Pan stated is how a physician should act under his bill.

B. The legal implications of the Standard of Review and the Board's use of an Incorrect Standard of Care

Petitioner contends that in a writ of administrative mandate of a disciplinary order where the court concludes that an administrative disciplinary board used the wrong standard of care, the reviewing court must provide a meaningful and complete review of the petitioner's evidence to determine whether that evidence could have led to a different result in a finding, conclusion or the sanction.

In this writ, we argue that the ALJ's use of the wrong standard of care infected every part of the administrative case, from before the hearing until the proposed decision. Prior to the

hearing, the ALJ excluded a key witness, Dr. Neuenschwander who has extensive experience treating vaccine injured patients. He would have testified about the association between autoimmunity problems as increasing the risks of adverse events from vaccines supported Petitioner's non-ACIP Guideline approach to writing the medical exemptions in this case. Although nominally the basis of the ALJ's *in limine* order was redundancy, it is better explained by the fact that ALJ did not consider such testimony relevant. If the standard of care is to base exemptions on the Guidelines, Dr. Neuenschwander's testimony about the connection between family history of autoimmunity as a predictor of increased risk of adverse events is irrelevant, because the standard of care is to base exemptions on the Guidelines.

III. The Two Standards of Care Put Forth by the Parties

Because this is the fulcrum of Petitioner's argument about why this Court should issue an extraordinary writ, it is worth delving in greater detail and providing some context and commentary about the different standards of care asserted by the parties, at the expense of some repetition with the petition.

A. The Board's Standard of Care

The Board only called one witness, Dr. Dean Blumberg. He was asked by Board counsel what is the standard of care applicable to the 10 cases set out in the Accusation. Here is the exchange:

Q. Is there a generally accepted standard of care in the medical community for immunizations and immunization practices?

A. That would be – the standard of care would be the guidance provided by the advisory committee on immunization practices from the CDC as well as the American Academy of pediatrics, the Redbook.

(App., Vol. 2, Exh. 14 Exhibit D1, p. 440, lns. 3-11.)

Q. In these guidelines, are they followed by primary care physicians – well, across the nation?

A. Yes they are. In fact that is one of the first questions when a question comes to me is, I asked the question to the clinician, well I say "well what does the Redbook say about that?" Or "what does ACIP say about that?"

(App., Vol. 2, Exh. 14 Exhibit D1, p. 440, ln. 24, to p. 441, ln. 4.)

Q. And based upon the CDC, ACIP and AAP guidelines, are there some children who should not receive vaccines or should receive them on some other than the recommended schedule?

A. Yes, since they specified these exceptions from the routine schedule.

Q. Are those exceptions called “contraindications”?

A. There is a "contraindications" and "precautions" are the exceptions, yes.

(App., Vol. 2, Exh. 14 Exhibit D1, p. 441, ln. 23, to p. 442, ln. 5.)

A. … if a patient has a contraindication, they should not receive the vaccine.

Q. Conversely if a patient does not have one of those contraindications, is it standard practice to recommend vaccines?

A. Yes.

***

A. As long as they do not have a precaution.

(App., Vol. 2, Exh. 14 Exhibit D1, p. 442, lns. 19-25.)

To his credit, Dr. Blumberg was clear and definitive that the standard of care is to follow the ACIP and Redbook guidelines.

Dr. Blumberg then testified that none of Petitioner's medical exemptions in this case conformed to the community standard of practice which is to follow the guidelines. (App., Vol. 2, Exh. 14 Exhibit D1, p. 443 ln. 22, to p. 444, ln. 1.)

Dr. Blumberg also pointed out that the ACIP and the AAP "do not recommend genetic testing in order to determine eligibility for immunization (App., Vol. 2, Exh. 14 Exhibit D1, p. 446, lns. 21-22) and because of that, Petitioner's use of this testing was below the standard of care (App., Vol. 2, Exh. 14 Exhibit D1, p. 447, ln. 22, to p. 448, ln. 12), and in fact an extreme departure from the standard of care because "there is no recommendation [from the ACIP or Red Book guidelines] for the genetic testing and, yet, it was done routinely and then it was utilized to prove the exemption." (App., Vol. 2, Exh. 14 Exhibit D1, p. 447, ln. 23, to p. 448, ln. 3.)

Dr. Blumberg went so far as to say that Petitioner's use of genetic testing suggested that he was trying to create a new standard of care. (App., Vol. 2, Exh. 14 Exhibit D1, p. 486, lns. 3-6.)[5]

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[5] "So that's why I would consider this extreme departure because it appears that a whole new guideline is trying to be

Dr. Blumberg offered no testimony about any other standard of care, either under SB 277, or under the minority view safe harbor under Business and Professions Code section 2234.1.

B. Petitioner's Asserted SB 277 standard of care.

As is clear, Petitioner believes that SB 277 created a different standard of care from the community standard presented by Dr. Blumberg which is to follow the Guidelines. Petitioner's standard is supported by the text of SB 277 and confirmed by the relevant legislative history.

1. Textual Analysis of SB 277.

SB 277 provides:

> (A) If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances ~~that contraindicate~~ , INCLUDING, BUT NOT LIMITED TO, FAMILY MEDICAL HISTORY, FOR WHICH THE PHYSICIAN DOES NOT RECOMMEND immunization, that ~~person~~ CHILD shall be exempt from the requirements of Chapter 1. . . ."

(Strike through is deleted material from pre-SB 277 law. All caps reflect additions to the prior statute.)

SB 277 removed the term "contraindicate" from the prior law. Contraindicate is a term of art referencing the ACIP or Red

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created by Dr. Stoller by this routine practice of the genetic testing. So that sounds like a new guideline."

Book guidelines on vaccination. Having removed "contraindicate," the medical conditions and circumstances referenced in the new law which could support a medical exemption "including but not limited to family history for which the physician does not recommend immunization" certainly appears to do so. Family history has virtually no role in a ACIP or Red Book analysis of the safety of vaccines to an individual. Therefore, the reference to family history, among other medical circumstances and conditions must mean that medical exemptions can be written under SB 277 that were not limited to or consistent with the Guidelines.

The Board's view is that SB 277 did not change the law and does not create a new statutory standard of care. However, its view (and the view of other courts which have adopted the Board's position) violates a fundamental rule of statutory interpretation, the reenactment canon; when legislature amends or reenacts a provision other than by way of a consolidating statute or restyling project, a significant change in language is presumed to entail a change in meaning. The lower court seemed to have adopted this criticism of the Board's view in its final writ decision.

Based on the text and the relevant legislative history, the lower court nominally found that SB 277 created a new partial standard of care. However, because of the importance of this issue, it is worth restating the relevant legislative history and its effect on this case.

2. The Legislative History Analysis

a. The SB 277 co-authors statements are admissible

In these proceedings, Petitioner relies heavily on the statements of SB 277 co-authors Senators Ben Allen and Richard Pan MD (a practicing pediatrician).

It is black letter law that statements of sponsors made in a formal legislative session to explain the bill to a legislative body are admissible legislative history. The leading case is *in re Marriage of Bouquet,* (1976) 16 Cal.3d 583, 589-590, wherein the California Supreme Court stated that arguments made to the legislature to assist in a bill's passage are admissible, citing *Rich v. State Board of Optometry* (1964) 235 Cal.App.2d 591, as are debates surrounding passage of a bill citing *Sato v. Hall* (1923) 191 Cal. 510. *See also White v. Ultramar, Inc.* (1999) 21 Cal.4th 563, 572, fn. 2, and *Quarterman v. Kefauver* (1997) 55 Cal.App.4th 1366 (same result).

b. The relevant legislative history.

The Assembly Health Committee hearing held on June 9, 2015 was to consider SB 277. It heard from the two sponsors (and ironically, Dr. Dean Blumberg), and members of the public. Here is the relevant legislative history:

i. Expanding the medical exemption

Senator Allen framed the critical question on medical exemptions under proposed SB 277:

> now, as you know, the committee has offered several amendments that we are very happy to accept. They mainly relate to expanding the medical exemption and that is something that I'm very interested in and one of the things we have talked about over and over again is how important it is that there be a strong and robust medical exemption so that anybody who had a legitimate medical concern – genetic predisposition, some sort of immunological problem – they can go to a doctor anywhere in the state and get an exemption from that Dr. That is very important to me and I am glad that the committee, I think, pointed out some weaknesses in the earlier bill and took some steps necessary to expand exemption ….

(App., Vol. 5, Exh. 18, p. 1134, lns. 11-24.)

Senator Allen's statement supports Petitioner's interpretation in two important respects. First, he specifically stated that the sponsors accepted the committee's amendments to "expand the medical exemption" to make it strong and robust. That surely means that the scope of permissible medical exemptions under SB 277 was different from what had been allowed under the previous law. It is impossible to read his statement in any other way.

This means that Dr. Blumberg's and the Board's view of the standard of care for writing medical exemptions is wrong since neither recognized that SB 277 changed the permissible criterial or grounds for writing medical exemptions under SB 277.

The other significant aspect is that he specifically stated that a legitimate medical concern would include a "genetic predisposition." There are two ways to determine a genetic disposition, the indirect way of looking at family history, and a

direct lab determination looking at the individual's genetics, meaning a genetic test like the ones employed by Petitioner in this case. Senator Allen's statement is consistent with and arguably supports Petitioner's position that genetic testing under SB 277 was permissible.

But of course, there is even more evidence that SB 277 rejected the notion that medical exemptions had to follow what mainstream infectious disease experts thought were justified under conventional science.

ii. Senator Allen's statement that ACIP does not limit medical exemptions.

Despite the introductory testimony of Senator Richard Pan, the members of the Assembly health committee were concerned about how hard it was to get a medical exemption under the CDC's ACIP guidelines. They were concerned that California physicians would be forced to follow them, and not use their discretion to write exemptions that were not consistent with the guidelines.

Assembly Health Committee Member Waldon asked Senator Pan "would you say that SB 277 would still conform to the CDC guidelines regarding a medical exemption? Senator Pan assured the committee that a physician could exercise his professional judgment despite the limitations in the CDC guidelines."

But after hearing Senator Pan's answer, Assemblyman Waldron apparently was still unconvinced and asked the opposition witness, Barbara Loe Fisher to respond. She expressed

her concern that "99.99% of children under federal guidelines do not qualify for a medical exemption."

Senator Allen then jumped in and made the following statement:

> and I believe you deserve a short answer to your question. No, we would not be in CDC – in compliance with the CDC. The CDC – the committee on immunization practices, the American Academy of pediatrics would be apoplectic about the loosening of all these guidelines and yet I do like the amendment because if the bill passes at least [there would] still be some discretion. But no, we are way out of compliance with the CDC.

(App., Vol. 5, Exh. 18, p. 1190, ln. 15, to p. 1191, ln. 8.)

Senator Allen could not have made it any clearer that physicians had the discretion not to follow the ACIP and Red Book guidelines in making vaccine exemptions decisions. Beyond that, his statement manifests that the SB 277 discretion would not be welcomed news to the infectious disease establishment in charge of determining making these guidelines.

The Board's expert, Dr. Blumberg as the head of pediatric infectious disease at a large medical school would be a card-carrying member of those who would be "apoplectic." The reason being that these guidelines are the infectious disease establishment's consensus view on when it is safe and unsafe to administer vaccines to children. Any departure from consensus view would not be a "best practice," would be unscientific and cause "apoplexy" in these high priests of vaccine safety.

We know this to be the case because the guidelines provide not only the "best practices" (the ACIP's term for what it is doing)

for when a person should not receive a vaccine, but they also list some of the common and uncommon medical conditions and vaccine reactions which do not contraindicate administering vaccines. (See Section 4.2 of the ACIP guidelines entitled "Conditions incorrectly perceived as contraindications or precautions to vaccination (i.e., vaccines may be given under these conditions." (App., Vol. 1, Exh. 7, pp. 191-193.).

Ironically, when Senator Allen was telling the committee members how apoplectic the infectious disease establishment would be with loosening up medical exemptions from the clutches of the ACIP and AAP Red Book followers, Dr. Blumberg was likely sitting at the witness table since he was spoke before and after the two Senator co-sponsors as the AAP's Red Book designated defender. Perhaps apoplexy, like vengeance is a dish best served cold.

iii. Senator Pan's Medical exemptions for cousins

Here is what co-sponsor Richard Pan, a pediatrician with 20 years' experience said:

> If the physician feels that there's a genetic association in a sibling, a cousin, some other relative, it's not safe for a vaccine, they can provide a medical exemption for that vaccine. There is no limitation on a physician from doing that other than their own professional judgment, their own knowledge and expertise about what they believe is safe for the patient.

(App., Vol. 5, Exh. 18, p. 1247, lns. 9-16.)

This statement by co-sponsor pediatrician Dr. Richard Pan is arguably the most important on the central issue in this case,

namely the scope of permissible medical exemptions under SB 277, and whether Dr. Blumberg's testimony at the Petitioner's administrative hearing about the standard of care was correct.

Dr. Blumberg admitted on cross examination that there is no medical condition of a cousin which would justify a medical exemption under SB 277. Here are his exact words:

> Q. … can you point to an ACIP or Red Book guideline that permits a medical exemption based on something [that] happened to a cousin? Is there such a thing?
>
> A. I'm not aware of that.
>
> Q. How about some other relative? Let me – other than a first degree relative – are you aware of any medical condition in another than first degree relative that could support a medical exemption written by a California physician under SB-277. Are you aware of any such condition?
>
> A. No. I am not aware.

(App., Vol. 2, Exh. 14 Exhibit D1, p. 506, ln. 24 to p. 507, ln. 9.)

In short, Dr. Blumberg's testimony on what he thinks is the standard of care for physicians writing medical exemptions during the time SB 277 is irreconcilable with what co-sponsor Dr. Richard Pan said his bill permitted physicians to do. In an attempt to explain away his co-speaker's statements at the committee hearing, Dr. Blumberg proffered the absurd interpretation that Senator Pan was just talking about the process of writing exemptions not whether they would conform to the standard of care. (App., Vol. 2, Exh. 14 Exhibit D1 at p. 507,

ln. 15 to p. 508, ln. 2.) This ridiculous interpretation was rejected by the lower court. (App., Vol. 1, Exh. 2, pp. 15-16.)

Senator Pan's statement proves that Dr. Blumberg's view of the standard of care in writing SB 277 statutory medical exemptions is wrong. Dr. Blumberg's interpretation of SB 277 is inconsistent with the co-sponsors' statements, and also inconsistent with plain meaning of the statute. Accordingly, the Board's sole expert's testimony was fatally flawed in that it did not relate the actual standard of care for Business and Professions Code section 2234 charges contained in the Accusation.

iv. Legislative history mistakenly used to support the ACIP based standard of care.

The lower court cited and the Board has argued that legislative history which shows that SB 277's goal was to increase school immunization towards 100%. However, that goal may not necessarily be inconsistent with expanding the medical exemption. Assuming arguendo it is inconsistent, this general aspirational language is inconsistent with the specific legislative history supporting medical exemptions based on non-Guideline and non-conventional medicine's view of medical science. Under basic principles of interpretation, (g*eneralia specialibus non derogant*), the specific legislative history on the precise issue of the scope of medical exemptions wins over the general aspiration goal of working towards full vaccination under SB 277. (See, e.g., *United States & State v. My Left Foot Children's Therapy, LLC* (9th Cir. 2017) 871 F.3d 791, 797 [applying the rule to contract

interpretation]; *Perez-Guzman v. Lynch* (9th Cir. 2016) 835 F.3d 1066, 1075 [applying it to a federal statute].)

c. The SB 277 Standard of Care

The prior section demonstrated that SB 277 allowed physicians to base medical exemption of medical conditions and circumstances beyond the contraindications and precautions set out in the Guidelines. Judge Arguelles was correct that this was just a partial guideline, but he was incorrect that the other part of the SB 277 guideline was detailed in the ACIP or Red Book guidelines, or what those authors and other like-minded infectious disease doctors like Dr. Blumberg thought would be justified by "medical science."

As stated in the writ, Judge Arguelles actually set out the rest of the SB 277 as articulated by co-author Dr Pan, that medical exemptions had to be based on the physicians "professional judgment, their knowledge, and expertise about what they believe is safe for the patient." That is the standard of care. The problem with the Board's case is that it did not adduce testimony on this standard of care.

C. Genetic Testing

The ALJ's and the lower court's analysis of Petitioner's use of genetic testing was infected by their use of the wrong standard of care. As discussed in detail in the writ petition, the ALJ completely ignored the literature based medical evidence in support of Petitioner's use of genetic testing. That evidence would include the article in *Nature* (Vol. 5, Exh. 17) which reviewed studies using genetic testing to help in risk assessment

for vaccination, The article concluded that the use of this testing is clinically viable. The article was published 2015, before Petitioner wrote any of the medical exemptions in this case. Neither the ALJ nor the lower court discussed or cited this article. This article is further evidence that Dr. Blumberg was completely unaware of the medical literature supporting the genetic testing approach employed by Petitioner. Consideration of this evidence by the lower court under the proper standard of review and under the correct standard of care would have or should have let the lower court to conclude that the weight of the evidence did not support the ALJ's finding on the genetic testing issue. And for this reason, the factually incorrect statements of Dr. Blumberg, the factual findings of the ALJ on this issue, her conclusion that Petitioner's use of genetic testing and his citations to the literature was nonsense, is not supported by the record under any standard of review.

IV. The Sanction Issue

This Court's *de novo* review of the sanction is set out in *Pirouzian v. Superior Court of L.A. Cnty., supra,* 1 Cal.App.5th at p. 447. *Pirouzian* assesses factors similar to the what is presented in this case. The writ adduces the factors which Petitioner believes justifies a finding that the revocation of his license was arbitrary, capricious and excessive. But the most important reason is the core of this case, that the ALJ (and the lower court) used the wrong standard of care and that led her to conclude that Petitioner showed a contempt for science because he did not accept and apply the ACIP guidelines. The lower court

accepted all of the ALJ's conclusions which were not supported by the evidence. It did not meaningfully review Petitioner's evidence. We believe it should have done so by logic and how it is done in the civil litigation context, when a reviewing court determines that the fact finder did not apply the correct standard of care.

A meaningful and complete review of the evidence under the correct standard of care might have or probably would have resulted in a different sanction, which means this writ should issue.

CONCLUSION

For the foregoing reasons, the court should order Respondent to submit a response to this writ and allow the case to proceed to the next step and then ultimately issue the writ.

Dated: December 29, 2021

Richard Jaffe

WORD COUNT CERTIFICATE

I, Richard Jaffe, counsel for Petitioner, hereby certify, pursuant to rule 8.204(c)(1) of the California Rules of Court, that I prepared this **PETITION FOR WRIT OF MANDATE**, and that the word count is 13,749 (not including the cover, tables, or case caption.

I certify that I prepared this document in Microsoft Word, and that this is the word count Microsoft Word generated for this document.

Dated: December 29, 2021

Richard Jaffe