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9 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
10 **FOR THE COUNTY OF SACRAMENTO**

11 **KENNETH P. STOLLER MD**

12 Petitioner,

13 vs.

14 **MEDICAL BOARD OF CALIFORNIA,**
15 **DEPARTMENT OF CONSUMER AFFAIRS,**
16 **STATE OF CALIFORNIA**

17 Respondent.

CASE NO. 2021-80003606

**PETITIONER'S SUPPLEMENTAL
MEMORANDUM IN SUPPORT OF WRIT
OF ADMINISTRATIVE MANDATE**

(Code Civ. Pro., Section 1094.5)

Judge: Hon. James P. Arguelles

Dept: 17

Hearing Date: July 23, 2021

Action Filed March 4, 2021

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Fukida v. City of Angels (1999), 20 Cal. 4th 805.....29

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Rich v. State Board of Optometry (1964),235 Cal.App.2d 591, 45 Cal.Rptr. 512.....15, 16

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1 **PRELIMINARY STATEMENT**

2
3 This writ of administrative mandate seeks to overturn a license revocation order which was
4 based on Petitioner’s writing 10 medical exemptions from school vaccinations mandates which were
5 not based on the CDC’s ACIP (Advisory Committee on Immunization Practices) guidelines. Upon
6 the initial papers and a spirited hearing, the Court denied Petitioner’s Request for a Stay, by Final
7 Ruling dated March 18, 2021, (“Final Ruling”) based on Petitioner’s failure to prove a likelihood of
8 success on the merits.

9
10 The primary bases for the Court’s decision were that it accepted the Board’s conclusion that
11 Petitioner did not consult or consider the ACIP guidelines which the Court held he was required to
12 do under the then applicable law (former Health and Safety Code Section 120370 et. seq., hereinafter
13 “SB 277”), (Final Ruling page 4), that he issued the exemptions in part based on a “genetics-based
14 approach without accepted scientific foundation”) (*Id.*), and Petitioner’s failure to obtain the
15 children’s prior medical records, which failure meant that he did not satisfy the “good faith prior
16 examination” requirement in the Complementary and Alternative Health safe harbor provision in
17 Bus. & Prof. Code Section 2234.1 (1). (*Id.* page 4-5)

18
19 The Court also declined to weigh in on the revocation sanction because it understood the law
20 as giving little review power to courts to overturn sanctions, citing *Landau v Superior Court, (1988)*
21 *81 Cal. App. 4th 191,*) (Final Ruling, page 6). However, as will be shown, the Court’s reliance on
22 *Landau* is misplaced because the general *Landau* language referred to by the Court and argued by
23 Respondent (that courts should basically leave the agencies alone in their sanctions decisions where
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27

1 reasonable minds can differ) is not good law as of the year after *Landau* was decided. (Assuming it
2 was ever a correct interpretation of the law).¹

3 The current law is that courts exercise independent judgement over a sanction decision in
4 determining whether the agency has abused its discretion or was arbitrary and capricious, especially
5 in a case like this one, where the Board terminated Petitioner's fundamental right to practice his
6 chosen profession. The Court's misplaced reliance on *Landau* requires a fresh look at the case under
7 the modern legal standard. Furthermore, now that we have an opportunity to address the Court's
8 conclusions in writing, it will be demonstrated that the proposed possible justifications for the
9 difference in the Board's sanctions in other cases is unsupportable. And even if *Landau* did
10 accurately state some still applicable general rule, there is direct on point case law concerning the
11 mitigation factors which Petitioner raised in the administrative hearing which courts have considered
12 and have used to overturn administrative sanctions despite the supposed hands-off deferential
13 approach in *Landau*.

14
15 The four basic arguments in this Supplemental Memo are:

16
17 1. That SB 277 did in fact grant Petitioner the right to do exactly what he did in this case. The
18 ALJ's and Court's conclusion or critique about not "consulting" the ACIP is incorrect. A close
19 examination of the guidelines and the testimony of Board's witness demonstrates that there is no
20 such thing as "consulting" the guidelines; they are either followed or not followed.

21
22 2. That there was no legal or statutory requirement to obtain prior medical records as part of a
23 "good faith prior examination" under Bus. & Prof. Code 2234.1. The Board proffered no evidence in

24
25 ¹ Part of the *Landau* decision was approved for publication, but it is unclear (at least to Petitioner's
26 counsel) which parts were and were not approved for publication and citable. The case is mostly
27 known for the important procedural point that a writ is the appropriate form of judicial review of a
28 medical board order, (rather than an appeal), and on that point *Landau* is good law and precedential.
However as will be demonstrated *infra*, the extreme deference shown by the *Landau* court to the
sanction findings of the medical board is at odds with more recent cases, and even some past cases.

1 the case that obtaining prior medical records was part of the part of the safe harbor requirement. The
2 ALJ's engraftment of the prior records requirement into 2234.1 (1) is contradicted by the Board's
3 own position in this case and is inconsistent with a physician's standard to record a H&P (history
4 and physical).

5 3. A related evidentiary point is that the ALJ barred Petitioner from adducing evidence which
6 showed that Petitioner relied upon that which stated that the good faith prior examination was a just
7 a requirement that the physician conduct a physical examination. The ALJ issued these ruling both
8 pre-hearing and at the hearing, the effect of which was that Petitioner was unable to adduce proof of
9 the meaning and his understanding of this requirement. Given the Court's finding that Petitioner did
10 not meet the good faith prior examination requirement as a basis of holding that he did not prove a
11 likelihood of success on the merits, the prejudice resulting from the ALJ's rulings is manifest and
12 requires a reversal of the Board's order and a rehearing.

13
14 4. The sanction was arbitrary, an abuse of discretion and excessive; The Board's protect
15 public health rationale makes no sense in terms of the actual public health consequences of writing
16 ten medical exemptions, and failed to consider the case law-based mitigating factors which itself
17 requires reversal of the sanction. Petitioner requests that the Court establish a principle that when the
18 Board revokes a medical license where the physician has asserted legally cognizable mitigating
19 factors, the Board is required to explain why the mitigation factors did not lead to a lesser sanction
20 for there to be a proper record for review. Finally, other doctors who engaged in the same conduct
21 received lesser sanctions, and there is no rational distinction between the conduct or the context of
22 the sanction of Respondent compared to the other physicians who received lesser sanctions. ²
23
24

25 ² The Board has prepared a record consisting of the all the hearing exhibits which will be submitted
26 via a Notice of Lodgment. Each of four days of the hearing transcript (which the Board did not order)
27 was attached to the Verified Petition as Exhibits D1-D4. The only other documents relevant to this
28 writ is the ALJ's Order on Evidentiary Objections, attached to Exhibit C2, and the Board's order of

1 **ARGUMENT**

2 **I. THE BOARD’S FAILURE TO PROPERLY ANALYZE AND APPLY THE**
3 **STATUTORILY CREATED MEDICAL EXEMPTION STANDARD OF CARE**
4 **REQUIRES A REVERSAL OF THE ITS ORDER**

5 **A. THE DIFFERENT TYPES OF STANDARDS OF CARE RECOGNIZED BY THE**
6 **MEDICAL BOARD**

7 The Medical Board itself acknowledges that there are two different sources of the standard
8 of care in its disciplinary actions: community standards, i.e., what practicing physicians view as their
9 standards, and statutory standards, meaning a standard created by a statute. The Board instructs its
10 expert witnesses that “in medicine, standards of care (also referred to as “standards of practice”),
11 whether established by law or the community, are designed to protect patients from the risk of
12 harm.” (RE 30, page 24). This case involves three different standards of care. The community
13 standard of care which is to follow the ACIP/AAP Red Book Guidelines, the SB 277 (statutory)
14 standard of care for writing medical exemptions, and a general statutory standard of care which
15 establishes a safe harbor defense against the type of Section 2234 disciplinary charges set forth in the
16 first three charges in the Accusation against Petitioner. As will be demonstrated, the Board’s expert’s
17 entire testimony was about the community standard of care, which is ultimately the fatal flaw in the
18 Board’s case against the Petitioner because it chose to deny that there was a statutory standard for
19 physicians to write the legal exemption to school mandated vaccination under the statute.

20 **B. THE ACIP GUIDELINES**

21 It would be impossible for this Court to fully understand the issues in this case without a
22 basic understanding of the ACIP guidelines and what they look like. Although the ACIP guidelines
23 is a hundred plus page document, the actual contraindications set out vaccine-by-vaccine for all
24

25
26 _____
27 adoption of the proposed decision which attaches the ALJ’s proposed decision (Exhibit “E” attached
28 to the Verified Petition.

1 vaccines is just a 6-page table, (almost half of each page is empty white space). (See RE 8 pages 52-
2 57, a copy of the entire Section 4 which contains the contraindication/precaution section has been
3 extracted from RE 8 is attached as Exhibit “A” hereto for the Court’s convenience).

4 As the Court can see, each vaccine has anywhere from one to four contraindications (and
5 one or a few precautions). Most of them have only one contraindication, that being a severe allergic
6 reaction to the vaccine, (called anaphylaxis). This six, half empty pieces of paper represent the
7 entirety of the ACIP guidelines with which, according to the Court, Dr. Stoller and every other
8 physician was required to consult with in evaluating the medical circumstances justifying exemption
9 under the California statute. The 4.1 table lists the only conditions that “contraindicate
10 immunization” under the pre-SB 277 law. The listed contraindications and precautions are easily
11 comprehended and well known to pediatricians and family practitioners (and now to the Court after
12 a quick perusal).

13
14 In case there was any doubt in the ACIP guidelines about the absolutely exclusive nature of
15 the list of contraindications, Section 4.2 is a table tellingly entitled “Conditions incorrectly perceived
16 as contraindications are precautions to vaccination (i.e., Vaccines may be given under these
17 conditions).” This table starts with a list of conditions general applicable to all vaccines which are
18 misperceived as contraindications and precautions, followed by table entries for each specific
19 vaccine. (See table 4.2 at Exhibit “A” attached hereto at page B411). Taking these two tables
20 together, it is completely clear that the guidelines are meant to be an exclusive list of
21 contraindications and precautions.
22

23
24 Nowhere in the guidelines is there a reference to a “medical exemption” from school
25 mandated vaccination, because the ACIP guidelines do not directly deal with that issue (nor does the
26 Red Book guidelines which are substantially identical to the ACIP guidelines.) That is because
27

1 medical exemptions from school vaccination is a *legal construct* usually created by a state statute.
2 Different states have differing requirements for the issuance of a statutory based medical exemption.

3 As referenced by Petitioner’s counsel numerous times during the hearing, New Jersey for
4 example created a simple statutory standard of care for physicians issuing medical exemptions to
5 wit, “medical contraindications and precautions for immunization are based on the most recent
6 general recommendations of the advisory committee on immunization practices (ACIP) . . .” (RE
7 19, page 842, not offered into evidence but judicially noticeable under Evidence Code 452 (a) and
8 (c)). The New Jersey statutory standard tells New Jersey physicians to follow ACIP guidelines. As
9 will be demonstrated, California law has a different approach and a different statutory standard than
10 New Jersey’s, and that different and less definitive approach reflected in SB 277 is why we are
11 before the Court.
12

13 **C. AN ANALYSIS OF SB 277**

14 The most critical issue in this writ proceeding is the legal analysis of SB 277. It is
15 Petitioner’s fundamental contention that the words of the statute, supported by the clearest and *only*
16 specific legislative history on the *exact issue* in this case proves that Petitioner did not have to follow
17 or “consult” with the ACIP guidelines.³
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23 ³ If the ALJ (or the Board) had engaged in a legal analysis of the statute, that analysis would
24 have been subject to independent review by this Court since “[A] person aggrieved by agency
25 determination has a right to independent judicial review of questions of law such as those dealing
26 with the interpretation or application of statutes or judicial precedents.” *Donaldson v. Department*
27 *of Real Estate*, (2005) 134 Cal. App. 4th 948, 954. *citing* *Witkin Cal. Procedure* (4th ed. 1997)
28 Section 111, p. 1156; *see also* *Medical Board v. Superior Court* (Lee Roy Liskey, Real Party in
Interest), (2003) 111 Cal. App. 4th 163, 171.

1 Respectfully, the Court’s prior analysis of SB 277 is flawed, at least because it read into the
2 statute something not in the words of the statute and which was expressly rejected by the bill’s
3 sponsors in clear on-point, persuasive and admissible legislative history.

4 To begin, we need to present a basic and uncontestable legislative fact. SB 277 changed the
5 then existing law in two critical respects. First, the personal belief exemption which parents could
6 use to exempt their school aged children from being vaccinated was removed. Second, SB 277 was
7 intended to strengthen, make more “robust” meaning make the medical exemption more available
8 that it was or was perceived to be under the prior law. The clear legislative intent of making these
9 exemptions broader and more available to conditions theretofore not cognizable as a medical
10 exemption under the prior law will be demonstrated shortly, but it is absolutely indisputable that SB
11 277 used different words and listed different criteria for physician medical exemption decision
12 making. Here is SB 277 showing the changes from the pre-SB 277 law:

13 § 120370. (A) If the parent or guardian files with the governing authority a written
14 statement by a licensed physician to the effect that the physical condition of the child is such,
15 or medical circumstances relating to the child are such, that immunization is not considered
16 safe, indicating the specific nature and probable duration of the medical condition or
17 circumstances ~~that contraindicate~~, INCLUDING, BUT NOT LIMITED TO, FAMILY
18 MEDICAL HISTORY, FOR WHICH THE PHYSICIAN DOES NOT RECOMMEND
19 immunization, that ~~person~~ CHILD shall be exempt from the requirements of Chapter 1. . . .”

20 1. The Prior law

21 The first deep dive we need to take is to examine the difference between the prior law’s
22 designation/limitations of medical condition or circumstance that “**CONTRAINDICATE**
23 **immunization**” from SB 277’s medical considerations or circumstances for which the physician
24 does not recommend immunization which **CONSIDERATIONS include but are “not limited to,**
25 **family medical history.”** (Emphasis added).

1 The word “contraindicate” in the pre-SB 277 law is an infectious disease term of art (or at
2 least the noun form of the word, “contraindications which is defined as “conditions in a recipient that
3 increases the risk for serious adverse reaction to vaccination **are conditions under which vaccines**
4 **should not be administered.”** (ACIP guidelines RE 8, page 49, B401, emphasis added). In other
5 words, a contradiction is a medical condition of the potential vaccinee which because it increases the
6 risk of serious adverse reaction, the vaccine should not be administered, according to the ACIP
7 guidelines.

8
9 It is clear from the pre-SB 277 law that medical exemptions under that law had to be based
10 on anaphylaxis or another medical condition listed in the section 4.1 table. As demonstrated, that
11 table contains the *exclusive* list of the medical conditions for which that vaccine is should not be
12 administered. Nowhere in that prior statute was the physician granted the ability or discretion to
13 write a medical exemption from mandatory vaccination other than the medical indications listed on
14 that 4.1 chart.

15
16 To put it more specifically, there is no statutory reference in the pre-SB 277 law which would
17 allow a physician to base or even consider issuing a medical exemption for a general family history
18 medical circumstance. Family history considerations were simply not a stated or valid **statutory**
19 medical circumstance justifying a medical exemption, nor could it even be considered under the pre-
20 SB 277 law.⁴

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24 ⁴ Section 4.1 contains one reference to family history in the MMR entry (Exhibit “A” page 54 does
25 list “Family history of altered immunocompetence in a first degree relative, but that is the only
26 reference to family history in the chart, meaning only that one vaccine and that one family history
27 condition. There was some testimony about some medical committee which could grant waivers or
extend a contraindication, but that is not mentioned in SB 277 which focuses on the physician’s
judgment in and the criteria or medical circumstance in which the physician could write a statutory
based medical exemption.

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2. Petitioner is Well Aware of the ACIP Guidelines and Did Not Need to Consult Them

During the hearing, Petitioner testified that he was familiar with the guidelines (“Yes, I can’t recite them by heart [the ACIP guidelines for contraindications and precautions], but I know what they generally say, yes. (Tr. Hearing day 2, Exhibit D2 page 69 ln. 22 to page 70). Even the Board’s attorney acknowledged that Petitioner knew the ACIP guidelines (“Q: and the standard of care that I am referring to **is the standard of care that follows the guidelines issued by the CDC and the ACIP, which you are well familiar with.**” (Tr. D3 page 67 lns. 14-16, Emphasis added).

Petitioner’s response further indicated his awareness by saying “A: I am going to answer your question this way; physicians generally understood that based on the statute prior to SB 277, you did not write medical exemptions unless the child had a contraindication that was listed on the CDC list.” (*Id.* at lns. 17-20).

Let us stop and focus on the Board attorney’s question for a moment, as this may be the clearest and most direct rebuttal to the Court’s and the ALJ’s stated view that Petitioner’s violation was that he failed to “consult” with the guidelines: “and the standard of care that I am referring to **is the standard of care that follows the guidelines issued by the CDC and the ACIP which you are well familiar with.**”. (*Id.*) Board counsel understood that it was not Petitioner’s “failure to consult” but rather his failure to follow the guidelines; i.e., the 4.1 table which is the problem with his conduct. Respectfully, Board Counsel’s simple question which both acknowledged that Petitioner knew the guidelines but did not follow them was the problem, not failing to consult them. The Board’s view is that every physician is required to follow the ACIP guidelines (unless perhaps some other body grants some exception), but the notion that an individual physician can decide on his own not to follow the guidelines is, as testified to by the Board’s expert, an extreme departure from the community standard of care.

1 The problem with the Board’s position is that, as will now be demonstrated, its view is not
2 consistent with the words of the statute or the clear legislative history.

3 **3. SB 277 and medical conditions or circumstances including family medical**
4 **history**

5 Let us dig deeper into the SB 277, in which the infectious disease term of art
6 “contraindicate”, was removed and replaced with the new language allowing a medical exemption to
7 be based on a medical condition or circumstance “INCLUDING, BUT NOT LIMITED TO,
8 FAMILY MEDICAL HISTORY, FOR WHICH THE PHYSICIAN DOES NOT RECOMMEND
9 immunization” (Emphasis added).

10 The first thing to say is clearly this is a significant difference from the prior law. And given
11 what we now know about the prior law and the ACIP guidelines which contain a specific and
12 exclusive list of contraindications, it seems a fair interpretation that under SB 277, physicians were
13 no longer required to limit their medical exemption writing to the section 4.1 listed medical
14 conditions. Of course, all of those 4.1 listed medical conditions would certainly be medical
15 conditions which justify writing a medical exemption, but those indications are just some of the
16 bases for writing medical exemption, or so the language of SB 277 facially states.

17 Beyond this straightforward textual analysis of the differences between the two versions of
18 the law, there is further strong evidence that Petitioner’s reading of SB 277 is correct, and that comes
19 from the only SB 277 legislative history which deals specifically with the scope or allowable
20 bases/medical conditions and medical considerations which a physician can use to issue a medical
21 exemption under the then new law. However, before we get into the actual legislative history, we
22 first need to set out the relevant legal standard for the admissibility and persuasiveness of legislative
23 history.
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1 **D. THE STANDARD FOR ADMISSIBILITY OF LEGISLATIVE HISTORY WHICH**
2 **SHOWS THAT SENATOR ALLEN’S AND PAN’S STATEMENTS TO THE**
3 **ASSEMBLY HEALTH COMMITTEE ARE ADMISSIBLE, HIGHLY RELEVANT**
4 **AND PERSUASIVE**

5 We acknowledge that the Court expressed some hesitation about using the statements of a co-
6 sponsor of legislation as an interpretative aide. However, perhaps because this was a stay motion and
7 the complete record was not before the Court, it was not appreciated that it was just not any
8 statement by a cosponsor of the bill. It was the testimony of the cosponsors of the bill at a hearing of
9 the state assembly committee before which the bill was pending. It is black letter law that a
10 sponsor’s statement made in a committee hearing which is considering the bill is admissible
11 legislative history, as is the back-and-forth debate/questions and answers with the committee
12 members. The leading case is *in re Marriage of Bouquet*, (1976) 128 Cal.Rptr. 427, 16 Cal.3d 583,
13 546 P. 2d 1371, which dealt with a letter written by a bill’s co-sponsor. While the court did start with
14 the general proposition that the legislators, and even sponsors expressing their personal opinions are
15 not valid expressions of legislative history, it distinguished that general rule from what is on-point
16 authority in our case:

17
18 “**In the present case, however, the resolution incorporating the Hayes letter**
19 **commands respect because it gives evidence of more than the personal understanding**
20 **of the letter's author. First, the letter casts some light on the shrouded legislative**
21 **history [546 P.2d 1375] of the amendment. Assemblyman Hayes observed not only**
22 **that he intended the bill to apply retroactively, but that he Argued to that effect in**
23 **obtaining the bill's passage. In Rich v. State Board of Optometry (1964),235**
24 **Cal.App.2d 591, 45 Cal.Rptr. 512, the court accepted the testimony of an**
25 **assemblyman as an indicator of legislative intent because the court was satisfied that**
26 **the 'testimony was not an expression of his own opinion . . . but a reiteration of the**
27 **discussion and events which transpired in the Assembly committee hearing when**
28 **the amendments . . . were under consideration.'** (235 Cal.App.2d 591, at p. 603,
29 **45 Cal.Rptr. 512, at p. 520.) Although Assemblyman Hayes did articulate his**
30 **personal view that the statute operated retroactively, he also alluded to the**
31 **argument that he had presented in securing the passage of the amendment.**
32 ***Debates surrounding the enactment of a bill may illuminate its interpretation.*** (Sato
33 **v. Hall (1923),191 Cal. 510, 217 P. 520.) Consequently, the letter lends some support**

1 to the retroactive application of the amendment through the light it sheds upon
2 legislative debates.”

3 *In re Marriage of Bouquet*, (1976) 128 Cal.Rptr. 427, 16 Cal.3d 583, 589-590, 546 P. 2d
4 1371, 1375. (Emphasis added).

5 It would seem that the *Rich* and *Sato* cases cited are dispositive that the statements made by
6 Senator Pan, Senator Allen, and Assemblymen Bonta and Nazarian are admissible and relevant
7 legislative history, and they are exceptionally persuasive since this is the only legislative history in
8 the legislative record which dealt specifically and directly with the intended scope of SB 277
9 medical exemptions as compared to the prior law.

10
11 Other on-point cases by the California courts have specifically looked to individual
12 legislators’ (including co-authors’) comments to the Assembly and Senate committees and found
13 such statements and found such statements to be among others judicially noticed, as “expressions of
14 legislative intent to construe it [the term “managing agent”] in the statute’s relative context. *White v.*
15 *Ultramar, Inc.* 21 Cal.4th 563, 572 fn. 2 (1999). In *Quarterman v. Kefauver* (1997) 55 CA 4th 136,
16 the First District Court of Appeal extracted the sponsor statements from legislative committee
17 analyses. Similarly, the Second District Court of Appeal in *Soil v. Superior Court*, (1997) 55 CA4th
18 872, 878-880 made several references to the statements of the sponsor of the legislation, and those of
19 the opponents, as found in legislative committee analyses.
20
21

22 In short, case law is abundantly clear that the statements made by a bill’s author to a
23 committee which is considering the bill is admissible and persuasive legislative history evidence as
24 is the hearing colloquy between members and the committee and the sponsor. Accordingly, the
25 relevant portions of the transcript of the California Assembly’s Health Committee’s June 9, 2015
26

1 hearing wherein the scope and boundaries of issuing medical exemptions, as well as the Board's
2 expected response to writing broader than ACIP based medical exemptions was discussed and
3 information was provided by the bill's co-author is directly relevant to the live issues in this case.

4 **E. THE HIGHLY RELEVANT LEGISLATIVE HISTORY**

5
6 The legislative history that the Petitioner relies upon is an Assembly Health Committee
7 hearing held on June 9, 2015 chaired by then representative and now Atty. Gen. Rob Bonta. The
8 purpose of this hearing was for the Health Committee to consider SB 277 and the primary witnesses
9 where the two co-sponsors Senators Richard Pan and Ben Allen. Here is how then Assembly Health
10 Committee Chairman Rob Bonta framed the critical question on medical exemptions under proposed
11 SB 277:
12

13
14 “now, as you know, the committee has offered several amendments that we are very
15 happy to accept. They mainly relate to expanding the medical exemption and that is
16 something that I'm very interested in and one of the things we have talked about over
17 and over again is how important it is that there be a strong and robust medical
18 exemption so that anybody who had a legitimate medical concern – genetic
19 predisposition, some sort of immunological problem – they can go to a doctor
20 anywhere in the state and get an exemption from that Dr. That is very important to me
21 and I am glad that the committee, I think, pointed out some weaknesses in the earlier
22 bill and took some steps necessary to expand exemption”

23 Exhibit R 10 page B 578 Ins. 11-24.

24 * * *

25 “Rob Bonta: Thank you, Dr. Pan. And then finally, we have an amendment regarding
26 the medical exemption in a physician's judgement. And I've heard from a number of
27 constituents and Californians regarding concerns that a medical exemption is difficult to
28 obtain or was difficult to obtain. I believe that current law states that a physician has
complete professional discretion over the writing of a medical exemption.

However, I have asked the author to take an amendment to clarify that a medical
exemption is entirely within the professional judgment of a physician. And we have
agreement on that amendment?

Senator Pan: Yes.”

(June 9, 2015 Assembly Health Committee transcript, RE 10, page B 594 ln. 23 to page B 595 ln. 10.)⁵

Now that this Court has reviewed the ACIP guidelines and their application under the prior law, it is in a better position to understand the concerns expressed to then Assembly Health Committee Chairman Bonta that under the then current law people thought it was hard to get a medical exemption. We now know that was because a medical exemption was only available for anaphylaxis or the one or few other medical conditions listed in the 4.1 table.

1. Co-sponsor Ben Allen’s statement that SB 277 is beyond the ACIP (and Red Book) guidelines and that under the bill physicians did not have to follow them

As indicated above, the members of the Assembly committee were concerned about how hard it was to get a medical exemption under the CDC’s guidelines and 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. 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.” (R 10-page B 647 to page 649 ln. 2).

But after hearing Senator Pan’s answer, member Waldron apparently was still unclear or unconvinced and asked the opposition witness, Barbara Loe Fisher to respond and she said that “99.99% of children under federal guidelines do not qualify for a medical

⁵

The entire June 9, 2015 Assembly Health Committee Hearing transcript is reproduced at R 10. The ALJ only admitted a few pages into evidence, but the rest is judicially noticeable under Evidence Code Section 451 as explained in the prior section.

1 exemption.” Senator Allen then jumped in and made the following statement: “and I
2 believe you deserve a short answer to your question. No, we would not be in CDC – in
3 compliance with the CDC. The CDC – **the committee on immunization practices, the**
4 **American Academy of pediatrics would be apoplectic about the loosening of all these**
5 **guidelines and yet I do like the amendment because if the bill passes at least [there**
6 **would] still be some discretion. But no, we are way out of compliance with the CDC.”**

7 *Id.* at page B 653 ln. 15 to page B 654 ln. (Emphasis added).
8

9 **2. Senator Pan’s Statements to the Assembly Health Committee**

10 It is widely known and recognized that Senator Pan is a practicing family medicine physician
11 and he told the Health Committee that in this hearing). (RE 10, B 589 lns. 19-21). So, he is just not
12 any random Senator co-sponsoring a bill. He actually works in the field which is the subject of the
13 bill, and as a family practitioner/pediatrician, he is of course is very familiar with the ACIP
14 guidelines. In his introduction, Sen. Pan himself acknowledged that SB 277 was changing the law on
15 medical exemptions in part based on the demands of the Assembly. Here is what he has to say about
16 that:
17

18
19 “Now, as you know, the committee has offered several amendments that we are very happy to
20 accept.

21 They mainly relate to expanding the medical exemption and that is something that I am very
22 interested in and one of the things we talked about over and over again is how important it is
23 that they are being strong and robust medical exemption so that anybody who had a legitimate
24 medical concern – genetic predisposition, some sort of immunological problem – they can go to
25 a doctor anywhere in the state and get an exemption from that doctor. 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 and I am certainly happy to talk further about
that if you like as well. These are the reasons that I am here as part of this discussion.”

26 (RE 10, page B 578 ln. 11, to page 579 ln. 2).
27

1 The statements by Senators Allen and Pan, and the questions and comments by the health
2 committee members conclusively shows the relevance, admissibility and the highly persuasive nature of
3 this piece of legislative history on the very issue which is the heart of the case, namely the scope of
4 medical exemptions under SB 277 and whether physicians have to comply with ACIP's
5 contraindications the way they had to under the prior law. Let us now delve deeper into the questions
6 which Senator Pan said about how broad the physician's discretion was under SB 277, so broad in fact
7 that was asked and his answer which shed much light on what he as the co-author of SB 277 and with
8 20 years practicing family medicine thought physicians would be allowed to do under the bill that his
9 bill.

11 Here is what he said:

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

18 RE 10, B 692, Ins. 9-16.

19 Chairman Bonta later confirmed Senator's Pan's statement commenting that:

21 "this is an issue that we worked very closely with the office on. This – the
22 amendments that we took – one of the four amendments that we took and we went
23 over together earlier today was specifically designed to address this issue, to make
24 it clear that the physician can act with in his or her professional judgment and
25 discretion based on all sorts of medical factors without limitation including family
26 history. And when we were discussing this amendment, we specifically discuss the
27 scenarios of a parent or an older sibling who had an adverse reaction to a vaccine if
28 that could be an appropriate factor to lead to the decision by Dr. to provide a
29 medical exemption."⁶

30 *Id.* Page B 695 Ins. 13-25.

31 ⁶ As the Court now knows, there is no adverse reaction in a sibling which constitutes a contraindication
32 or precaution under Table 4.1 and hence it would be an extreme departure from the community
33 standard of care to issue one based on that condition of a sibling. See discussion at page *infra*.

1 Of course, as this Court now knows, there is no such thing as a medical
2 contraindication or condition of a cousin, and there is only one time in the entire guidelines
3 table that family history is mentioned as a contraindication. (See page 12, footnote 4
4 *supra*).

5
6 Thus, the statute states, and the only specific legislative history on the issue of the
7 scope of medical exemptions confirms that many factors can be considered to support a
8 medical exemption, and not just limited to the anaphylaxis and the few other medical
9 conditions set forth in section 4.1 table of the ACIP Guidelines. Or in the words of SB 277
10 co-author Ben Allen, the bill is “way out of compliance with the CDC” and the ACIP and
11 the AAP would be “apoplectic about the loosening of all these guidelines.”
12

13 **F. WHY THIS JUSTIFIES A REVERSAL OF THE REVOCATION ORDER**

14 The above analysis of the SB 277’s specific statutory guidance allowing medical
15 exemptions is dispositive of this case. The Board only had one witness, Dr. Dean
16 Blumberg. His testimony was that it is the community standard of care for physicians to
17 write medical exemptions in California based only on ACIP guidelines, (i.e., the 4.1
18 table).⁷ Dr. Blumberg then testified that none of Petitioner’s medical exemptions in this
19

20
21 ⁷ “Q. Is there a generally accepted standard of care in the medical community for immunizations and
22 immunization practices? A. That would be – the standard of care would be the guidance provided by
23 the advisory committee on immunization practices from the CDC as well as the American Academy
24 of pediatrics, the Redbook.: Tr Exhibit D1 page 49 lns. 5- 11.

25 “Q. In these guidelines, are they followed by primary care physicians – well, across the nation? A.
26 Yes they are. In fact that is one of the first questions when a question comes to me is, I asked the
27 question to the clinician, well I say "well what does the Redbook say about that?" Or "what does ACIP
28 say about that?" *Id.* at page 49 ln 24 to page 50 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

1 case conformed to the community standard of practice which is to follow the guidelines,
2 *Id.* at page 52 ln. 22 to page 53 ln. 1.

3 Dr. Blumberg also pointed out that the ACIP and the AAP “do not recommend
4 genetic testing in order to determine eligibility for immunization (*Id.* at page 55 lns. 21-22)
5 and because of that, Petitioner’s use of this testing was below the standard of care (*Id.* at
6 page 56 ln. 22 to page 57 ln. 12), and in fact an extreme departure from the standard of
7 care because “there is no recommendation [from the ACIP or Red Book guidelines] for the
8 genetic testing and, yet, it was done routinely and then it was utilized to prove the
9 exemption.” *Id.* at page 57, ln. 23 to page 58 ln. 3.

11 Dr. Blumberg offered no testimony about any other standard of care, either under the
12 statute or under the CAM safe harbor under 2234.1.

13 It is indisputable that the letters written in this case, as all medical exemption letters are
14 authorized by statute, and that the statute sets out the basic outlines of the conditions under which the
15 letters can be written. It is also indisputable that SB 277 allowed for different medical conditions and
16 circumstances to be considered and upon which to base a medical exemption than the limited ACIP
17 based table. In other words, the statute itself, as clarified by Senators Allen and Pan’s statements
18 and the colloquy with the Health Assembly members, set out a statutory based standard for
19 exemption writing that is very different from the community-based standard upon which Dr.
20 Blumberg opined.
21
22
23

24 _____
25 “contraindications”? A. There is a "contraindications" and "precautions" are the exceptions, yes. *Id.* at
page 50, ln. 23 to page 51, ln. 5.

26 “A. ... if a patient has a contraindication, they should not receive the vaccine. Q. Conversely if a
27 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.” *Id.* at page 51. lns. 19-25.

1 And in the end, it does not really matter what this Court thinks the statute means or does
2 not mean. The job of this Court is to review the evidence in the case and see whether the evidence
3 supports the result. In this case, it does not for the simple reason that the Board offered no evidence
4 whatsoever on the SB 277 statutory standard of care for writing medical exemptions. Both Petitioner
5 and Petitioner’s expert Dr. Sutton opined as to what they thought they were allowed to do under the
6 statute and why. There was no rebuttal to their testimony on their interpretation of the statutory
7 standard of care. Accordingly, since the Board has the burden of proof and since it offered no
8 evidence on the statutory standard of care or that Petitioner’s conduct did not meet that standard of
9 care, this Court must reverse the Board’s order.
10

11 **II. PETITIONER SATISFIED THE 2234.1 SAFE HARBOR REQUIREMENTS**

12 California recognizes the right of physicians to provide treatment and medical
13 consultations/advice that is inconsistent with what a majority of practitioner’s believe about the
14 treatment or advice, which majority view is referred to as the community standard of care. The
15 application of the Bus. & Prof. Code Section 2234.1 safe harbor defense applies to all three of the
16 section 2234 causes for discipline pled against Petitioner in the Accusation, and constitute a defense
17 to the charges if Petitioner can establish that his conduct satisfies the four required elements set out
18 in 2234.1
19

20 **1. The “good-faith prior examination of the patient” requirement**

21 In its Final Ruling, this Court agreed with the administrative law judge’s finding that
22 Petitioner did not satisfy the first requirement because his failure to obtain prior medical records
23 meant that he did not perform the “good faith prior examination” requirement in 2234.1(1).
24 However, a closer examination of the record in this case demonstrates 1. There is no evidentiary
25 basis for the ALJ’s conclusion. Specifically, the Board’s sole witness did not state or imply that
26
27

1 medical records are part of an examination, 2. The Board itself does not think requesting medical
2 records is part of an examination as shown by the questioning on this issue. 3. The ALJ denied
3 Petitioner the opportunity to adduce evidence that the prior examination requirement in this
4 subsection does not include obtaining prior medical records. She did this both prehearing and during
5 the hearing. Since this Court's Final Ruling was in large part predicated on its agreement with the
6 ALJ that Petitioner's failure to request prior records established non-compliance with the first 2234.1
7 requirement, the prejudicial effect of the ALJ's evidentiary rulings is manifest and requires a
8 reversal of the Board's order.
9

10 **1. Lack of evidentiary basis in the record**

11 The first thing to note is that the Board's sole witness, Dr. Dean Blumberg did not purport to
12 be testifying about a standard of care derived from SB 277, or one derived from or allowed under the
13 Section 2234.1 safe harbor. In Dr. Blumberg's view, there is only one standard of care, and that
14 would be the community standard of care (which applies nationally) which is to follow the
15 guidelines. (See page 21, footnote 5 *supra*). If fact, he criticized Petitioner for his apparent attempt to
16 create a new standard of care based on in part on his use of genetic testing which is not authorized by
17 the guidelines. (Exhibit D1 page 94 ln. 18, to page 95 ln. 6). Accordingly, it seems fair and logical to
18 conclude that whatever it was Dr. Blumberg was talking about, it had nothing to do with the safe
19 harbor requirements for complementary and alternative medicine set forth in Bus. & Prof. Code
20 2234.1.
21

22 From the record, it appears that the only thing the witness had to say about obtaining prior
23 medical records was when asked "Q. Do physicians standardly request medical records from other
24 providers in evaluating pediatric patients?" He answered: "A. it's routine to request records when
25
26
27

1 they may be useful in evaluating the condition that you are looking at, yes.” (Tr. Exhibit D1 page 62,
2 Ins. 18-21.)

3 Thus, there does not appear to be any evidence in the record that Dr. Blumberg stated or
4 implied that obtaining prior medical records was part of a “good faith prior examination” as required
5 under 2234.1 and which the ALJ concluded with any apparent evidentiary support in this case. The
6 absence of any evidence in the record on this critical factual issue means that the ALJ abused her
7 discretion under Cal. Code of Civ. Proc. Section 1094.5 (c) which requires a reversal of the Board’s
8 decision.
9

10 **2. The Board itself believes that ordering prior records is a separate step from a**
11 **patient examination**

12 All physicians are taught to take and record what they call a “H&P” meaning a history **and**
13 physical. Consistent with this painfully obvious medical distinction/separate steps/components of a
14 medical interaction with a patient, the following exchange took place on Dr. Blumberg’s direct: “Q.
15 Is that standard practice in terms of the **steps that a physician takes in making a medical decision**
16 to take a complete history? A. Yes. Q. Does that also involve completing a full examination? A. Yes
17 in general, that does. There are some exceptions to that, like influenza vaccine, which are widely
18 administered by others.” (Tr. D1 page 48 ln. 20 to page 49 ln. 2, emphasis added).
19

20 Obviously, both the Board’s counsel as well as the Board’s sole witness understood that in a
21 patient encounter, the history component is a **separate and distinct step** from the examination. In
22 her decision, the ALJ just melded the two requirements together in order to find that Petitioner had
23 not satisfied the “good faith prior examination” requirement in first element of the 2234.1 safe
24
25
26
27

1 harbor defense.⁸ But as shown here, neither the Board’s expert nor the Board really think that is the
2 case.

3 **3. Petitioner repeatedly proffered direct evidence that the good faith prior**
4 **examination in 2234.1 meant a physical examination, but the ALJ rejected all**
5 **such attempts**

6 Petitioner submitted an expert and a factual statement from attorney Greg Glaser, who is an
7 expert on the legal aspects of vaccines. He is also the General Counsel for a physician organization
8 Petitioner belongs to concerning vaccine safety. (See Mr. Glaser’s witness statement at R 25.) He
9 also advised the Petitioner and other doctors about the legal requirements for writing medical
10 exemptions under SB 277 and under the 2234.1 safe harbor provisions.

11 Mr. Glaser’s written statement evidencing this advice was attached to his witness statement.
12 The ALJ granted the Board’s motion in limine to strike him as a witness on the grounds that the
13 testimony would either “repeat counsel’s legal arguments in this matter, or will repeat other
14 testimony about community standards among some or all of California physicians.” (Order on
15 Prehearing Evidentiary Objections, Exhibit C 1 page 2)

16 Thereafter, Petitioner listed his written advice on the 2234.1 issue, which was attached to Mr.
17 Glaser’s witness statement as an exhibit in the case. (R 11). The written statement provides in part
18 that: “4) **Conduct a Physical Exam.** The physician conducts a good faith examination of the
19 patient.”
20

21 Petitioner sought to have this document admitted based on advice of counsel and reliance by
22 the Petitioner. Tr. Exhibit D3 page 132 ln. 2-20. However, the Court sustained the Board’s objection
23 on the grounds that it “goes to the nature of the argument.” *Id.* at page 133 lns. 4-8). We also tried
24

25
26 ⁸ In case the Board argues that the words “good faith” magically incorporates medical records, the
27 Court should reject that or be prepared to hold that the physical part of an H&P is somehow not in
28 good faith, and only the separate step of the history makes it so.

1 to have Respondent’s expert witness Dr Kelly Sutton talk about this document, but the Board
2 objected and the Court sustained the objection because she didn’t think that Mr. Glaser’s advice to
3 her and Petitioner’s group is “helping me understand what the community standard actually is.” *Id.*
4 at page 154 ln 19 to page 158 (continued discussion to page 162. Ln 15).

5 The exclusion of Mr. Glaser’s advice that the good faith prior examination meant a physical
6 examination was highly prejudicial in light of the Court’s adverse finding on this critical issue, and
7 should lead the Court to overturn the Board’s order for this reason alone.

8
9 **4. The Genetic Testing Used by Petitioner is Safe Harbored under 2234.1**

10 Petitioner does not dispute that he used genetic testing as one component in making his
11 medical exemption evaluation. He also does not dispute that using such information is not a relevant
12 factor in making a contraindication or precautions evaluation under the ACIP or Redbook guidelines.
13 The ALJ was very critical of Petitioner’s use of this genetic testing which was noted by the Court as
14 a basis of the revocation sanction. At the hearing, Petitioner testified that he got the idea of using
15 genetic testing information from the sponsors’ testimony in the June 9 assembly health committee
16 hearing:
17

18 “Well, it was 2015 when I heard Dr. Pan and Sen. Allen say genetic Association in a
19 sib, a cousin, some other relative, and I think Mr. Allen, Sen. Allen used the word “genetic
20 disposition”. But when I heard that and went, oh well, I am already doing that for my patient,
21 all I need to do is find out what genes are associated with adverse events and identify them
22 and see if people have mutations on them and make a risk assess assessment based on their
23 genomics.” TR. D2. Page 63 lines 12 – 19

24 In addition, Petitioner talked about a 2015 published article which stated that the time for the
25 use of genetic testing in predicting vaccine adverse events has arrived. The article was admitted into
26 evidence as R 31. The fact that Dr. Blumberg testified that genetic testing is not part of the ACIP
27 guidelines is irrelevant to the issue as to whether Petitioner and at least the authors of this article felt

1 there was a reasonable basis to do so and whether the use of information is the type of information
2 usable under SB 277's broader definition of the factors which physicians could use to base a medical
3 exemption determination.

4 Accordingly, the ALJs findings that Petitioner's use of genetic testing was a violation of the
5 statutory SB 277 standard of care was an abuse of discretion. Moreover, since the genetic testing is
6 part of the alternative and complementary medical care given to the patients under Section 2234.1, it
7 would be inappropriate for the Court to justify the revocation sanction on that basis.
8

9 **III. THE BOARD'S REVOCATION ORDER MUST BE REVERSED**

10 **A. THE COURT USED THE WRONG STANDARD IN REVIEWING THE SANCTION** 11 **DECISION**

12 The Court's decision that Petitioner was unlikely to prevail on the merits on the sanction part
13 of the Board's order is grounded on its quote from *Landau v Superior Court, (1988) 81 Cal. App. 4th*
14 *191* that "In reviewing the exercise of this discretion we bear in mind that the principal 'courts
15 should leave administrative boards and officers work out their problems with as little judicial
16 interference as possible'" (Final Ruling, page 6).
17

18 We submit that this part of the *Landau* decision is not now nor was it ever good law on the
19 issue of the standard of review of a revocation sanction in a medical board case involving license
20 revocation. We are mindful that the *Landau* court said what the Court quoted, and also said what the
21 was quoted in Respondent's opening brief and adopted by the Court that "Because we conclude that
22 reasonable minds could differ over the appropriateness of the penalty imposed, we find no manifest
23 abuse of discretion". (Respondent's Memo at page 7, lns. 7-8)
24

25 However, we believe that is plain error in terms of the standard of review and the Court's
26 lack of power to exercise its independent judgement on the Board's revocation decision. Medical
27

1 board sanctions which involve a fundamental right carry a different standard of review as recognized
2 as early as *Bixy v Piero* (1974) 4 Cal 3d. 130, 143. Since *Bixby*, the decisions all courts (other than
3 the *Landau* panel) have recognized that when an administrative agency’s decision affects a
4 petitioner’s fundamental rights, the trial court exercises its *independent judgment* based on the
5 administrative record. *Pirouzian v. Superior Court of L.A. Cnty.*, 1 Cal.App.5th 438, 447, 204
6 Cal.Rptr.3d 538 54 (Cal. App. 2016). The *Pirouzian* court framed the independent review standard
7 as follows: "although the ‘starting point’ for the trial court is a presumption of correctness
8 concerning the board's decision, the trial court is *‘free to substitute its own findings after first giving*
9 *due respect to the agency's findings.’* (*Fukida v. City of Angels* (1999), 20 Cal. 4th 805, 817 – 818,
10 85 Cal Rptr. 2d 696, 970 7 P. 2d 693)”
11
12 *Id.* (Emphasis added).

13 Immediately thereafter, the *Pirouzian* court noted that in terms of appellate review of a
14 superior court’s determination which raises "pure questions of law and ‘issues regarding the nature
15 or degree of an administrative penalty are given a *de novo* review, the latter being examined to
16 determine whether the administrative agency abused its discretion.”” *Id.* So, both the superior court
17 and the appellate courts analyze sanctions issues *de novo*, after the presumption of correctness.
18

19 According to *Pirouzian*, to determine whether there was an abuse of discretion in the
20 sanction which “may be found if, under all the facts and circumstances, ‘the penalty imposed was ...
21 excessive.”” *Id.*

22 In this case, the sanction was clearly excessive, and the ALJ’s explanation for the revocation
23 is not rational. Finally, the proposed decision fails to address the mitigating factors pled in the case
24 and supported by Petitioner’s hearing testimony. The failure to even consider the mitigating
25 circumstances should be sufficient cause for this Court to reverse the Board’s order. But in any
26

1 event, since there were no findings of fact regarding the proffered mitigating factors, there is
2 certainly no presumption that those non-findings were correct

3 **B. THE REVOCATION SANCTION WAS ARBITRARY, CAPRICIOUS AND**
4 **IRRATIONAL IN LIGHT OF THE FACTS AND CIRCUMSTANCES IN THIS CASE**

5 The ALJ's stated rationale that only license revocation would protect the public is stated in
6 the last paragraph in the proposed decision which states:

7 "Respondent's issuance of medical vaccination exemptions to patients 1
8 through 10 undermine public health and welfare. In addition, the matters stated in
9 findings 10, 18, 29, 39, 85, 87, and 94 and legal conclusions three – four, five, and 10
10 demonstrate both respondent's contempt for medical science and his unsuitability for
11 probation. Public safety requires revocation of respondent's physicians and surgeons
12 certificate."

11 (ALJ Decision Exhibit E, Page 32 para. 12). Let us examine this in detail:

12 **1. The ten medical exemptions do not undermine public health and welfare and all the**
13 **disciplined physicians showed the same "contempt for science" by not following the**
14 **guidelines**

15 The revocation order based on the facts is irrational. The Court can take judicial notice that there are
16 over 6.7 million students in the California public and private K-12 school system.⁹ The Court has
17 already taken judicial notice of the fact that three other physicians who wrote a few medical
18 exemptions were given probation or a letter of censure. Since the stay motion, one other doctor has
19 been sanctioned by the Board based on another Oakland administrative law judge's decision. That
20 physician wrote three medical exemptions and he was given five years' probation. (*See* Petitioner's
21 Supplemental Request for Judicial Notice. Another sanction is pending before the Board panel
22 involving a letter of censure for four medical exemptions).
23

24
25
26 ⁹ <https://www.cde.ca.gov/ds/ad/ceffingertipfacts.asp> which number is judicially noticeable under
27 Evid. Code 452 (g) and (h).

1 Logically and rationally, the difference between three or four medical exemptions written by
2 a physician and ten cannot justify a revocation order for several reasons. First, both three and ten
3 medical exemptions are the same extremely small order of magnitude when compared to the 6.7
4 million California school students, in terms of their effect on public health.

5 Second, and as was discussed at the hearing, the number of patients listed in an accusation is
6 arbitrary in the sense that it is just based on the number of complaints filed with the medical board
7 (usually by a school board or an HMO). There is no necessary or established relationship or
8 correlation between the number of complaints filed and how many exemptions these physicians have
9 written. It might well be the case that the physicians who were placed on probation wrote many more
10 medical exemptions than the Petitioner. There is no way to know, in part because none of these
11 settlements (or the recently litigated case) explicitly consider the total number of exemptions written
12 as either an enhancing or mitigating factor.¹⁰ Accordingly, the Board's decision to revoke was
13 arbitrary and an abuse of discretion considering the sanctions meted out in other cases involving the
14 same conduct. All of these doctors exhibited the same contempt for science by using medical
15 considerations and factors not recognized as constituting contraindications or precautions.
16
17

18 **2. There is no such thing as a failure to “consult the guidelines”**

19 As discussed in Point I above, the statute explicitly states, and Senators Pan and Allen and
20 Chairman Bonta all said that medical exemptions were not limited to the contradictions referenced in
21 the earlier version of the law. Thus, the conundrum faced by Petitioner and the other physicians.

22 It is meaningless and illogical to base a sanction revocation decision of the failure to
23 “consult” with guidelines which purport to list the exclusive criteria or grounds for issuing a medical
24

25 _____
26 ¹⁰ There was one case involving a letter of censure. There is another censure letter involving four
27 medical exemptions pending approval by a Board panel, but which has been signed off by the board
28 staff, which is further evidence the arbitrary nature of the Board's actions in these cases

1 exemption under the “community standard of care” where the very statute authorizing the medical
2 exemptions on its face allows for basing an exemption of factors not listed in the guidelines. A
3 physician has a binary choice. He limits exemptions to the 4.1 table; in which case he complies with
4 the community standard. Or, he does not, and bases his decision to exempt on medical conditions
5 and circumstances like family history or genetic testing, in which case he is not in compliance with
6 the community standard of care but is following the statutory standard of care. And recall that this
7 issue was specifically discussed in multiple exchanges between the bill’s authors and the health
8 committee assembly members.
9

10 Therefore, to the extent that the ALJ’s and the Board’s decision is based on a failure to follow
11 the ACIP guidelines, it is erroneous as a matter of law over which the Court has *de novo* review.
12 (*See the de novo* review of matters of law in page 10 footnote 3 *supra*). Based on a *de novo* review,
13 the Court should overturn the Board’s order.

14 **C. THE BOARD’S FAILURE TO CONSIDER MITIGATING FACTORS REQUIRES**
15 **REVERSAL OF THE ORDER**

16 Aside from its irrationality, the biggest problem with the revocation order is the ALJ’s and the
17 Board’s failure to consider mitigating factors, and in particular, that Petitioner had a reasonable belief
18 that he was allowed to write exemptions beyond the limited ACIP criteria (which was pled in the
19 Amended Notice of Defense, a copy of which is contained in Complainant’s Exhibit C1, page A32-
20 33).
21

22 To remind the Court, *Pirouzian* discusses *Magit v. Board of Medical Examiners* (1961) 57
23 Cal.2d 74, 17 Cal.Rptr. 488, 366 P.2d 816, wherein the appellate court reversed a medical board
24 revocation order in part because the physician’s action dealt an ambiguous technical issue not
25 previously addressed by any case law, and on which physician had sought and followed the advice
26 of his counsel. *Magit* is direct authority for the mitigating factors asserted by Petitioner and as such
27

1 we contend that the failure to address mitigating factors in a revocation decision itself requires
2 reversal as a denial of due process. At the very least, since mitigation was ignored, there is obviously
3 no deference or presumption of correctness accorded to this non-finding.

4 As Dr. Magit did, Petitioner sought and followed the advice of counsel as to the
5 interpretation of the new law (though through both pre-hearing and hearing rulings, the ALJ all but
6 prohibited Petitioner from presenting the advice of counsel defense, and refused to admit the written
7 advice of counsel document which Petitioner relied on (as set forth in detail in the Verified Petitioner
8 (Page 9 para. 30 and page 17 para. 61 to page 18 para 63). The Petitioner also testified that the Board
9 issued no guidance documents interpreting SB 277, and that his attempt to find out from the Board
10 its position was rebuffed. (Tr. Exhibit D 2, page 66 lns. 12-17).

12 Furthermore, as shown in Point I above, SB 277 certainly appeared to grant physicians the
13 right to depart from the conventional community standard of care which is adhering to ACIP
14 guidelines. We remind the Court that Senator Allen said the medical establishment would be
15 apoplectic on how much latitude beyond the guidelines SB 277 gave physicians. Senator Pan said
16 exemptions could even be based on the medical condition of a relative, even a cousin, which of
17 course is not permitted under the guidelines. Petitioner heard, trusted and believed the sponsors
18 representations to the committee members.

20 As fate would have it, testifying alongside Senators Allen and Pan in support of SB 277 was
21 the Board expert in this case, Dr. Dean Blumberg.¹¹ He was asked on cross examination about the
22 inconsistency between his testimony in this case and what he heard his co-advocates say about how
23 much broader medical exemptions were under the new bill versus the ACIP guidelines. His response
24 was that Sen. Pan just meant that physicians had the legal authority to write any exemption they
25

27 ¹¹ He testified immediately after Dr. Pan's introductory testimony, on pages B 579-584)

1 want, or that SB 277 just set out the process for writing medical exemptions, but he interpreted
2 Senator Pan as saying that it would still be a violation of the standard of care and hence prosecutable
3 by the Board if a physician did what Senator Pan had told the health committee members physicians
4 could do! (Tr. Exhibit D1 page 115 ln. 10 to page 119 ln 14.)

5 However, Dr. Blumberg was also there when Senator Pan repeatedly advised the health
6 committee members that the medical board does not investigate or discipline physicians for writing
7 medical exemptions which greatly allayed the concerns of the health committee members. He also
8 heard Senator Pan testify that SB 277 would not put a cloud over the head of physicians, meaning
9 they didn't have to worry about the medical board prosecuting them for writing non ACIP
10 conforming exemptions¹² which, according to Senator Allen would drive some professional medical
11 societies apoplectic.

13 A fair reading of Dr. Blumberg's testimony is that the sponsors of SB 277 intentionally
14 misrepresented the effect the bill would have on the ability of physicians to safely write medical
15 exemptions, which was a key concern expressed by several members of the assembly health
16 committee. Nowhere in the Assembly hearing transcript did either of the testifying sponsors *or Dr.*
17 *Blumberg* tell the committee members that while physicians had the technical power to write these
18 broader than ACIP guideline medical exemptions, if they did, it constituted a violation of the
19 standard of care and prosecutable by the Board. Based on Dr. Blumberg's interpretation, we ask this
20

21 _____
22 ¹² "... the medical board, to my knowledge has never investigated or removed the license of a
23 physician for granting a medical exemption for immunization that I'm aware of" Exhibit R 10 page B
24 234 lns.

25 "... there's no limitations in the law [for writing medical exemptions]. We've just heard from the
26 medical board. There – we are not aware of any physician who has been disciplined or investigated
27 because they provided a medical exemption. So there's no cloud hanging over them to be able to do
28 this." *Id.* page B 694 lns. 6-11)

1 Court to hold that the intentional misrepresentations to the state legislature where the false
2 representations were relied upon by the Petitioner in writing these ten medical exemptions is a valid
3 mitigating factor. The Board's failure to specifically address any of these mitigating factors should
4 result on the reversal of the Board's order

5 **CONCLUSION**

6 For the reasons set forth herein, Petitioner respectfully requests that the Board's revocation
7 order dated February 16, 2021 be reversed via this writ of mandate and that the Board be ordered to
8 set the case for a new hearing.

9 DATED: June 7, 2021

10 RESPECTFULLY SUBMITTED

11 

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DECLARATION OF SERVICE BY EMAIL

I am a member of the California bar and I am counsel to the Respondent (and over 18 and not a party to this action).

On June 7, 2021, I served this Supplemental Memorandum by email on:

Deputy Attorney General Lawrence Mercer
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-3488
415-703-5480 (fax)
Larry.Mercer@doj.ca.gov

Mr. Mercer is known by me to be the Medical Board’s attorney on the Medical Board Case and we communicate extensively via email.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration was executed on June 7, 2021, in Westport, Ct.



Richard Jaffe

EXHIBIT “A”

4. Contraindications and Precautions

Updates

Major changes to the best practice guidance in this section include 1) enhancement of the definition of a “precaution” to include any condition that might confuse diagnostic accuracy and 2) recommendation to vaccinate during a hospitalization if a patient is not acutely moderately or severely ill.

General Principles

National standards for pediatric vaccination practices have been established and include descriptions of valid contraindications and precautions to vaccination (2). Persons who administer vaccines should screen patients for contraindications and precautions to the vaccine before each dose of vaccine is administered (Table 4-1). Screening is facilitated by consistent use of screening questionnaires, which are available from certain state vaccination programs and other sources (e.g., the Immunization Action Coalition, <http://www.immunize.org>).

Contraindications

Contraindications (conditions in a recipient that increases the risk for a serious adverse reaction) to vaccination are conditions under which vaccines should not be administered. Because the majority of contraindications are temporary, vaccinations often can be administered later when the condition leading to a contraindication no longer exists. A vaccine should not be administered when a contraindication is present; for example, MMR vaccine should not be administered to severely immunocompromised persons (1). However, certain conditions are commonly misperceived as contraindications (i.e., are not valid reasons to defer vaccination).

Severely immunocompromised persons generally should not receive live vaccines (3). Because of the theoretical risk to the fetus, women known to be pregnant generally should not receive live, attenuated virus vaccines (4).

Persons who experienced encephalopathy within 7 days after administration of a previous dose of pertussis- containing vaccine not attributable to another identifiable cause should not receive additional doses of a vaccine that contains pertussis (4,5). Severe Combined Immunodeficiency (SCID) disease and a history of intussusception are both contraindications to the receipt of rotavirus vaccines (6).

Precautions

A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity (e.g., administering measles vaccine to a person with passive immunity to measles from a blood transfusion administered up to 7 months prior) (7). A person might experience a more severe reaction to the vaccine than would have otherwise been expected; however, the risk for this happening is less than the risk expected with a contraindication. In general, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution if the benefit of protection from the vaccine outweighs the risk for an adverse reaction.

The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines ([Table 4-1](#)). The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition. The safety and efficacy of vaccinating persons who have mild illnesses have been documented (8-11). Vaccination should be deferred for persons with a moderate or severe acute illness. This precaution avoids causing diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination or superimposing adverse effects of the vaccine on the underlying illness. After they are screened for contraindications, persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved. Studies indicate that failure to vaccinate children with minor illnesses can impede vaccination efforts (12-14). Among persons whose compliance with medical care cannot be ensured, use of every opportunity to administer appropriate vaccines is critical.

Hospitalization should be used as an opportunity to provide recommended vaccinations. Health-care facilities are held to standards of offering influenza vaccine for hospitalized patients, so providers are incentivized to vaccinate these patients at some point during hospitalization (15). Likewise, patients admitted for elective procedures will not be acutely ill during all times during their hospitalization.

Most studies that have explored the effect of surgery or anesthesia on the immune system were observational, included only infants and children, and were small and indirect, in that they did not look at the immune effect on the response to vaccination specifically (16-35). They do not provide convincing evidence that recent anesthesia or surgery significantly affect response to vaccines. Current, recent, or upcoming anesthesia/surgery/hospitalization is not a contraindication to vaccination, but certain factors might lead a provider to consider current, recent, or upcoming anesthesia/surgery/hospitalization as a precaution (16-35). Efforts should be made to ensure vaccine administration during the hospitalization or at discharge. For patients who are deemed moderately or severely ill throughout the hospitalization, vaccination should occur at the earliest opportunity (i.e., during immediate post-hospitalization follow-up care, including home or office visits) when patients' clinical symptoms have improved.

A personal or family history of seizures is a precaution for MMRV vaccination; this is because a recent study found an increased risk for febrile seizures in children 12-23 months who receive MMRV compared with MMR and varicella vaccine (36).

Neither Contraindications Nor Precautions

Clinicians or other health-care providers might misperceive certain conditions or circumstances as valid contraindications or precautions to vaccination when they actually do not preclude vaccination (2) (Table 4-2). These misperceptions result in missed opportunities to administer recommended vaccines (37).

Routine physical examinations and procedures (e.g., measuring temperatures) are not prerequisites for vaccinating persons who appear to be healthy. The provider should ask the parent or guardian if the child is ill. If the child has a moderate or severe illness, the vaccination should be postponed.

TABLE 4-1. Contraindications and precautions^(a) to commonly used vaccines

| Vaccine | Citation | Contraindications | Precautions |
|----------------|-----------------|--|---|
| DT, Td | (4) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component | GBS <6 weeks after previous dose of tetanus-toxoid–containing vaccine History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine Moderate or severe acute illness with or without fever |
| DTaP | (38) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP or DTaP | Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized GBS <6 weeks after previous dose of tetanus-toxoid–containing vaccine History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine Moderate or severe acute illness with or without fever |
| Hepatitis A | (39) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component | Moderate or severe acute illness with or without fever |
| Hepatitis B | (40) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Hypersensitivity to yeast | Moderate or severe acute illness with or without fever |
| Hib | (41) | Severe allergic reaction (e.g., anaphylaxis) after | Moderate or severe acute illness with or without fever |

| | | | |
|---------------------|------|--|---|
| | | a previous dose or to a vaccine component Age <6 weeks | |
| HPV | (42) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including yeast | Moderate or severe acute illness with or without fever |
| IIV | (43) | Severe allergic reaction (e.g., anaphylaxis) after previous dose of influenza vaccine or to vaccine component. | GBS <6 weeks after a previous dose of influenza vaccine Moderate or severe acute illness with or without fever Egg allergy other than hives, e.g., angioedema, respiratory distress, lightheadedness, recurrent emesis; or required epinephrine or another emergency medical intervention (IIV may be administered in an inpatient or outpatient medical setting and under the supervision of a health care provider who is able to recognize and manage severe allergic conditions). |
| IPV | (44) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component | Pregnancy Moderate or severe acute illness with or without fever |
| LAIV ^(b) | (43) | Severe allergic reaction (e.g., anaphylaxis) after a vaccine component Concomitant use of aspirin or aspirin-containing medication in children and adolescents LAIV4 should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours. Pregnancy | GBS <6 weeks after a previous dose of influenza vaccine Asthma in persons aged 5 years old or older Medical conditions which might predispose to higher risk of complications attributable to influenza ^(c) Moderate or severe acute illness with or without fever |

| | | | |
|------------------------|---------|---|---|
| MenACWY | (45) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component | Moderate or severe acute illness with or without fever |
| MenB | (46,47) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component | Moderate or severe acute illness with or without fever Pregnancy |
| MMR ^{(d),(e)} | (1) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Pregnancy Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy ^(f) or patients with HIV infection who are severely immunocompromised) Family history of altered immunocompetence ^(g) | Recent (≤ 11 months) receipt of antibody-containing blood product (specific interval depends on product) History of thrombocytopenia or thrombocytopenic purpura Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing ^(h) Moderate or severe acute illness with or without fever |
| MPSV4 | (48) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component | Moderate or severe acute illness with or without fever |
| PCV13 | (49) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose of PCV13 or any diphtheria-toxoid-containing vaccine or to a component of a vaccine (PCV13 or any diphtheria-toxoid-containing vaccine), including yeast | Moderate or severe acute illness with or without fever |

| | | | |
|-----------|------|--|---|
| PPSV23 | (50) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component | Moderate or severe acute illness with or without fever |
| RIV | (43) | Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine | GBS <6 weeks after a previous dose of influenza vaccine Moderate or severe acute illness with or without fever |
| Rotavirus | (6) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component SCID History of intussusception | Altered immunocompetence other than SCID Chronic gastrointestinal disease ⁽¹⁾ Spina bifida or bladder exstrophy ⁽¹⁾ Moderate or severe acute illness with or without fever |

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|------------------------------|------|--|---|
| Tdap | (51) | <p>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</p> <p>Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap</p> | <p>GBS <6 weeks after a previous dose of tetanus-toxoid-containing vaccine</p> <p>Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized</p> <p>History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid-containing or tetanus-toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid-containing vaccine</p> <p>Moderate or severe acute illness with or without fever</p> |
| Varicella ^{(d),(e)} | (52) | <p>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</p> <p>Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy^(f) or patients with HIV infection who are severely immunocompromised)^(e)</p> <p>Pregnancy</p> <p>Family history of altered immunocompetence^(g)</p> | <p>Recent (≤ 11 months) receipt of antibody-containing blood product (specific interval depends on product)</p> <p>Moderate or severe acute illness with or without fever</p> <p>Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination)</p> <p>Use of aspirin or aspirin-containing products⁽ⁱ⁾</p> |

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|--------|------|--|---|
| Zoster | (53) | <p>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</p> <p>Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy^(f) or patients with HIV infection who are severely immunocompromised)^(e)</p> <p>Pregnancy</p> | <p>Moderate or severe acute illness with or without fever</p> <p>Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination, for zoster vaccine live only)</p> |
|--------|------|--|---|

Abbreviations: DT = diphtheria and tetanus toxoids; DTaP = diphtheria and tetanus toxoids and acellular pertussis; DTP = diphtheria toxoid, tetanus toxoid, and pertussis; GBS = Guillain-Barré syndrome; Hib = *Haemophilus influenzae* type b; HIV = human immunodeficiency virus; HPV = human papillomavirus; IIV = inactivated influenza vaccine; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MenACWY = quadrivalent meningococcal conjugate vaccine; MMR = measles, mumps, and rubella; MPSV4 = quadrivalent meningococcal polysaccharide vaccine; PCV13 = pneumococcal conjugate vaccine; PPSV23 = pneumococcal polysaccharide vaccine; SCID = severe combined immunodeficiency; RIV = recombinant influenza vaccine; Td = tetanus and diphtheria toxoids; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis.

(a) Events or conditions listed as precautions should be reviewed carefully. Benefits of and risks for administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered. Whether and when to administer DTaP to children with proven or suspected underlying neurologic disorders should be decided on a case-by-case basis.

(b) In addition, ACIP recommends LAIV not be used for pregnant women, immunosuppressed persons, and children aged 2-4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health-care provider stated that they had wheezing or asthma within the last 12 months. LAIV should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV, or should avoid contact with such persons for 7 days after receipt.

(c) **Source:** (52).

(d) HIV-infected children may receive varicella vaccine if CD4+ T-lymphocyte count is $\geq 15\%$ and should receive MMR vaccine if they are aged ≥ 12 months and do not have evidence of current severe immunosuppression (i.e., individuals aged ≤ 5 years must have CD4+T lymphocyte [CD4] percentages $\geq 15\%$ for ≥ 6 months; and individuals aged > 5 years must have CD4+percentages $\geq 15\%$ and CD4+ ≥ 200 lymphocytes/mm³ for ≥ 6 months) or other current evidence of measles, rubella, and mumps immunity. In cases when only CD4+cell counts or only CD4+percentages are available for those older than age 5 years, the assessment of severe immunosuppression can be based on the CD4+values (count or percentage) that are available. In cases when CD4+percentages are not available for those aged ≤ 5 years, the assessment of severe immunosuppression can be based on age-specific CD4+counts at the time CD4+counts were measured; i.e., absence of severe immunosuppression is defined as ≥ 6 months above age-specific CD4+count criteria: CD4+count > 750 lymphocytes/mm³ while aged ≤ 12 months and CD4+count ≥ 500 lymphocytes/mm³ while aged 1 through 5 years.

Sources: (1,50).

(e) MMR and varicella-containing vaccines can be administered on the same day. If not administered on the same day, these vaccines should be separated by at least 28 days.

(f) A substantially immunosuppressive steroid dose is considered to be ≥ 2 weeks of daily receipt of 20 mg or 2 mg/kg body weight of prednisone or equivalent.

(g) family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings), unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory

(h) If active tuberculosis is suspected, MMR should be delayed. Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin or IGRA testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for ≥ 4 weeks after the vaccination. If an urgent need exists to skin test or IGRA, do so with the understanding that reactivity might be reduced by the vaccine.

(i) For details, see (55).

(j) No adverse events associated with the use of aspirin or aspirin-containing products after varicella vaccination have been reported; however, the vaccine manufacturer recommends that vaccine recipients avoid using aspirin or aspirin-containing products for 6 weeks after receiving varicella vaccines because of the association between aspirin use and Reye syndrome after varicella. Vaccination with subsequent close monitoring should be considered for children who have rheumatoid arthritis or other conditions requiring therapeutic aspirin. The risk for serious complications associated with aspirin is likely to be greater in children in whom natural varicella develops than it is in children who receive the vaccine containing attenuated VZV. No association has been documented between Reye syndrome and analgesics or antipyretics that do not contain aspirin."

| TABLE 4-2. Conditions incorrectly perceived as contraindications or precautions to vaccination (i.e., vaccines may be given under these conditions) | |
|--|--|
| Vaccine | Conditions commonly misperceived as contraindications or precautions |
| General for all vaccines, including DTaP, pediatric DT, adult Td, adolescent-adult Tdap, IPV, MMR, Hib, hepatitis A, hepatitis B, varicella, rotavirus, PCV13, IIV, LAIV, PPSV23, MenACWY, MPSV4, HPV, and herpes zoster | <p>Mild acute illness with or without fever</p> <p>Lack of previous physical examination in well-appearing person</p> <p>Current antimicrobial therapy^(a)</p> <p>Convalescent phase of illness</p> <p>Preterm birth (hepatitis B vaccine is an exception in certain circumstances)^(b)</p> <p>Recent exposure to an infectious disease</p> <p>History of penicillin allergy, other nonvaccine allergies, relatives with allergies, or receiving allergen extract immunotherapy</p> <p>History of GBS^(c)</p> |
| DTaP | <p>Fever within 48 hours after vaccination with a previous dose of DTP or DTaP</p> <p>Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP</p> <p>Seizure ≤ 3 days after receiving a previous dose of DTP/DTaP</p> <p>Persistent, inconsolable crying lasting ≥ 3 hours within 48 hours after receiving a previous dose of DTP/DTaP</p> <p>Family history of seizures</p> <p>Family history of sudden infant death syndrome</p> <p>Family history of an adverse event after DTP or DTaP administration</p> <p>Stable neurologic conditions (e.g., cerebral palsy, well-controlled seizures, or developmental delay)</p> |
| Hepatitis B | <p>Pregnancy</p> <p>Autoimmune disease (e.g., systemic lupus erythematosus or rheumatoid arthritis)</p> |
| HPV | <p>Immunosuppression</p> <p>Previous equivocal or abnormal Papanicolaou test</p> <p>Known HPV infection</p> <p>Breastfeeding</p> <p>History of genital warts</p> |
| IIV | <p>Nonsevere (e.g., contact) allergy to latex, thimerosal, or egg</p> <p>Concurrent administration of Coumadin (generic: warfarin) or aminophylline</p> |
| IPV | <p>Previous receipt of ≥ 1 dose of oral polio vaccine</p> |

| | |
|------------------------|--|
| LAIV | <p>Health-care providers that see patients with chronic diseases or altered immunocompetence (an exception is providers for severely immunocompromised patients requiring care in a protected environment)</p> <p>Breastfeeding</p> <p>Contacts of persons with chronic disease or altered immunocompetence (an exception is contacts of severely immunocompromised patients requiring care in a protected environment)</p> |
| MMR ^{(d),(e)} | <p>Positive tuberculin skin test</p> <p>Simultaneous tuberculin skin or interferon-gamma release assay (IGRA) testing^(f)</p> <p>Breastfeeding</p> <p>Pregnancy of recipient's mother or other close or household contact</p> <p>Recipient is female of child-bearing age</p> <p>Immunodeficient family member or household contact</p> <p>Asymptomatic or mildly symptomatic HIV infection</p> <p>Allergy to eggs</p> |
| PPSV23 | History of invasive pneumococcal disease or pneumonia |
| Rotavirus | <p>Prematurity</p> <p>Immunosuppressed household contacts</p> <p>Pregnant household contacts</p> |
| Tdap | <p>History of fever of $\geq 40.5^{\circ}\text{C}$ ($\geq 105^{\circ}\text{F}$) for < 48 hours after vaccination with a previous dose of DTP or DTaP</p> <p>History of collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP</p> <p>History of seizure < 3 days after receiving a previous dose of DTP/DTaP</p> <p>History of persistent, inconsolable crying lasting > 3 hours within 48 hours after receiving a previous dose of DTP/DTaP</p> <p>History of extensive limb swelling after DTP/DTaP/Td that is not an Arthus-type reaction</p> <p>History of stable neurologic disorder</p> <p>History of brachial neuritis</p> <p>Latex allergy that is not anaphylactic</p> <p>Breastfeeding</p> <p>Immunosuppression</p> |
| Varicella | <p>Pregnancy of recipient's mother or other close or household contact</p> <p>Immunodeficient family member or household contact^(g)</p> <p>Asymptomatic or mildly symptomatic HIV infection</p> <p>Humoral immunodeficiency (e.g., agammaglobulinemia)</p> |

| | |
|--|--|
| Zoster | <p>Therapy with low-dose methotrexate (≤ 0.4 mg/kg/week), azathioprine (≤ 3.0 mg/kg/day), or 6-mercaptopurine (≤ 1.5 mg/kg/day) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, or other conditions</p> <p>Health-care providers of patients with chronic diseases or altered immunocompetence</p> <p>Contacts of patients with chronic diseases or altered immunocompetence</p> <p>Unknown or uncertain history of varicella in a U.S.-born person</p> |
| <p>Abbreviations: DT = diphtheria and tetanus toxoids; DTP = diphtheria toxoid, tetanus toxoid, and pertussis; DTaP = diphtheria and tetanus toxoids and acellular pertussis; GBS = Guillain-Barré syndrome; HBsAg = hepatitis B surface antigen; Hib = <i>Haemophilus influenzae</i> type b; HIV = human immunodeficiency virus; HPV = human papillomavirus; IIV = inactivated influenza vaccine; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MenACWY = quadrivalent meningococcal conjugate vaccine; MMR = measles, mumps, and rubella; MPSV4 = quadrivalent meningococcal polysaccharide vaccine; PCV = pneumococcal conjugate vaccine; PPSV23 = pneumococcal polysaccharide vaccine; Td = tetanus and diphtheria toxoids; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis.</p> <p>(a) Antibacterial drugs might interfere with Ty21a oral typhoid vaccine, and certain antiviral drugs might interfere with varicella-containing vaccines and LAIV4.</p> <p>(b) Hepatitis B vaccination should be deferred for infants weighing $< 2,000$ g if the mother is documented to be HBsAg negative. Vaccination should commence at chronological age 1 month or at hospital discharge. For infants born to HBsAg-positive women, hepatitis B immune globulin and hepatitis B vaccine should be administered within 12 hours after birth, regardless of weight.</p> <p>(c) An exception is Guillain-Barré syndrome within 6 weeks of a dose of influenza vaccine or tetanus-toxoid-containing vaccine, which are precautions for influenza vaccines and tetanus-toxoid containing vaccines, respectively.</p> <p>(d) MMR and varicella vaccines can be administered on the same day. If not administered on the same day, these vaccines should be separated by at least 28 days.</p> <p>(e) HIV-infected children should receive immune globulin after exposure to measles. HIV-infected children can receive varicella and measles vaccine if CD4+ T-lymphocyte count is $> 15\%$. (54).</p> <p>(f) Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin or IGRA testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for at least 4 weeks after the vaccination. If an urgent need exists to skin test or IGRA, do so with the understanding that reactivity might be reduced by the vaccine.</p> <p>(g) If a vaccinee experiences a presumed vaccine-related rash 7-25 days after vaccination, the person should avoid direct contact with immunocompromised persons for the duration of the rash.</p> | |

REFERENCES

1. McLean HQ, Fiebelkorn AP, Temte JL, Wallace GS. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2013;62(RR-4):1-34.
2. National Vaccine Advisory Committee. Standards for child and adolescent immunization practices. *Pediatrics.* 2003;112(4):958-963.
3. Rubin L, Levin M, Ljungman P, et al. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. *Clin Infect Dis.* 2014;58(3):e44-100. DOI: 10.1093/cid/cit684
4. Kroger A, Atkinson W, Pickering L. General immunization practices. In: Plotkin S, Orenstein W, Offit P, eds. *Vaccines.* 6th ed. China: Elsevier Saunders; 2013:88-111.
5. CDC. Diphtheria, tetanus, and pertussis: recommendations for vaccine use and other preventive measures. Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR Recomm Rep.* 1991;40(RR-10):1-28.
6. CDC. Addition of history of intussusception as a contraindication for rotavirus vaccination. *MMWR Morb Mortal Wkly Rep.* 2011;60(41):1427.
7. Siber GR, Werner BG, Halsey NA, et al. Interference of immune globulin with measles and rubella immunization. *J Pediatr.* 1993;122(2):204-211. DOI: 10.1016/S0022-3476(06)80114-9
8. Halsey NA, Boulos R, Mode F, et al. Response to measles vaccine in Haitian infants 6 to 12 months old. Influence of maternal antibodies, malnutrition, and concurrent illnesses. *N Engl J Med.* 1985;313(9):544-549. DOI: 10.1056/nejm198508293130904
9. Ndikuyeze A, Munoz A, Stewart J, et al. Immunogenicity and safety of measles vaccine in ill African children. *Int J Epidemiol.* 1988;17(2):448-455. DOI: 10.1093/ije/17.2.448
10. Lindegren ML, Atkinson WL, Farizo KM, Stehr-Green PA. Measles vaccination in pediatric emergency departments during a measles outbreak. *JAMA.* 1993;270(18):2185-2189. DOI: 10.1001/jama.1993.03510180055033
11. Atkinson W, Markowitz L, Baughman A, et al. Serologic response to measles vaccination among ill children [Abstract 422]. 32nd Interscience Conference on Antimicrobial Agents and Chemotherapy; 1992; Anaheim, CA.