IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, JANE DOE 1, JANE DOE 2, and JANE DOE 3,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive,

Defendants.

Case No. 1:25-cv-11916-BEM

PLAINTIFFS' OPPOSITION TO EMERGENCY MOTION TO INTERVENE

The Emergency Motion to Intervene as Defendants and Counterclaim Plaintiffs (ECF No. 248, and their Memorandum in Support, ECF No. 249) of proposed intervenors Children's Health Defense ("CHD"), Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller (collectively, the "Proposed Intervenors") should be denied for three reasons: (1) none of the Proposed Intervenors have standing to intervene in this lawsuit; (2) none of the Proposed Intervenors satisfy the requirements for intervention as a matter of right under FED. R. CIV. P.

24(a)(2); and (3) none of the Proposed Intervenors satisfy the factors for permissive intervention under FED. R. CIV. P. 24(b)(1).

I. NONE OF THE PROPOSED INTERVENORS HAVE STANDING TO INTERVENE IN THIS CASE.

"[A]n intervenor of right must demonstrate Article III standing when it seeks additional relief" beyond the claims and relief already sought in the case. *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017). Further, the First Circuit has acknowledged that permissive intervention "must be supported by independent jurisdictional grounds." *Moosehead Sanitary Dist. v. S.G. Phillips Corp.*, 610 F.2d 49, 52 n.5 (1st Cir. 1979). Here, the Proposed Intervenors' counterclaims seek additional relief not only beyond the relief sought in Plaintiff's Administrative Procedures Act ("APA") claims, but also ***against*** Plaintiffs. Therefore, to intervene under either FED. R. CIV. P. 24(a) or (b), the Proposed Intervenors must establish that they have standing to bring such claims. They have failed to do so.

A. Children's Health Defense[1]

1. Associational Standing

To have standing, a party must allege a "personal stake in the outcome of the controversy to warrant *his* invocation of federal-court jurisdiction." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009) (emphasis in original). Associations have associational standing to sue on behalf of their members if (1) the members have standing to sue in their own right; (2) the interests the organization seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted, nor the relief requested requires the individual members to participate in the lawsuit. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977); *Am. Pub. Health Ass'n v. Nat'l*

[1] CHD has attempted intervention in three other lawsuits, and intervention was denied in all three. *See Cellco P'ship, v. County of Monmouth*, 2024 WL 4579506 (D.N.J. Oct. 25, 2024); *Couris v. Lawson*, No. 23-55069 (9th Cir. Mar. 22, 2024) (WestLaw); *McDonald v. Lawson*, No. 22-56220 (9th Cir. Mar. 22, 2024) (WestLaw).

Insts. of Health, 786 F.Supp.3d 237, 251 (D. Mass. 2025); *see also Mass. Lobstermen's Ass'n, Inc. v. Nat'l Marine Fisheries Serv.*, 2024 WL 2194260, at *5 (D. Mass. Apr. 16, 2024), *rev'd on other grounds*, *sub nom. Mass. Lobstermen's Ass'n, Inc. v. Menaches*, 127 F.4th 398 (1st Cir. 2025). To establish associational standing, an organization must "make specific allegations establishing that at least one identified member ha[s] suffered or would suffer harm." *Summers*, 555 U.S. at 498.

The Proposed Intervenors moving papers contain no specific allegations and cite to no declarations that identify at least one member of CHD who will suffer harm if the injunctive relief that Plaintiffs request in this case is granted. CHD thus fails to establish associational standing.

2. Organizational Standing

Organizational standing exists when the challenged conduct causes "concrete and demonstrable injury to the organization's activities" together with a "consequent drain on the organization's resources" which is "more than simply a setback to the organizations' abstract social interests." *Am. Ass'n of Univ. Professors v. Rubio*, 780 F.Supp.3d 350, 379 (D. Mass. 2025) (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)). If the members of an organization are injured, the organization has standing even if it has not suffered an independent injury. 13A Charles Alan Wright, Arthur R. Miller & Edward H. Cooper *Fed. Practice and Procedure* § 3531.9.5 (3d ed.).

The Proposed Intervenors moving papers allege only that: "CHD publishes books, daily news, and educational programming on vaccine safety, competing directly with AAP [American Academy of Pediatrics] in the market for vaccine-related health information. If the prior schedule is restored by judicial order, CHD's competing publications are delegitimized. CHD is also a plaintiff in both the *Shaw* and *Thomas* actions, whose outcomes will be directly affected by this Court's ruling." ECF No. 249 at 4. CHD does not explain what it means by "delegitimized" or

how a ruling in this case will affect the outcomes in the *Shaw* and *Thomas* cases, let alone how imminent an "outcome" is in those cases. These conclusory allegations are too speculative and are insufficient to establish organizational standing. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 401 (2013) (holding that plaintiffs failed to establish standing where their "theory of future injury is too speculative to satisfy the well-established requirement that threatened injury must be 'certainly impending'" (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990))).

B. Andrea Shaw and Shanticia Nelson

The allegations stated in Proposed Intervenors' moving papers regarding the deaths of Ms. Shaw and Ms. Nelson's children, while sad, fail to establish standing in this case. They assert that their children died after their "reported concerns were overridden by AAP's contraindication framework," and that "[i]f this Court restores the prior schedule, it judicially validates the protocol under which their children died and directly prejudices their pending RICO claims." ECF No. 249 at 3. They fail to define what "AAP's contraindication framework" is or what causal connection exists between "AAP's contraindication framework" and any injury they may suffer arising out of this case. Moreover, their motion is devoid of any factual allegations as to how an injunction in this case prejudices their pending RICO claims against AAP.

Food & Drug Administration v. Alliance for Hippocratic Medicine, 602 U.S. 367 (2024), is on point. There, anti-abortion doctors who did not use or prescribe mifepristone, a drug that can terminate a pregnancy, sued to make mifepristone "less available *for others*." *Hippocratic Med.*, 602 U.S. at 373 (emphasis in original). The Supreme Court held that the plaintiffs lacked standing to sue and rejected plaintiffs' theories of injury in spite of their "sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone." *Id.* at 396. The Supreme Court reaffirmed in *Hippocratic Medicine* the longstanding doctrine that

"plaintiffs attempting to show causation generally cannot rely on speculation about the unfettered choices made by independent actors not before the courts." *Id*. at 383; *see also Clapper*, 568 U.S. at 409 (quoting *Monsanto Co. v. Geertson Seed Farms,* 561 U.S. 139, 149 (2010)); *Summers,* 555 U.S. at 493; *Lujan v. Defs. Wildlife,* 504 U.S. 555, 560–561 (1992).

Neither Ms. Shaw nor Ms. Nelson have established an imminent, concrete injury that can be fairly traceable to any action by either Defendants or Plaintiffs at issue in this case. That a favorable ruling for the Plaintiffs in this case will somehow prejudice their RICO claims currently pending in the District of Columbia district court (Case No. 1:26-cv-00171) is quintessential "speculation about the unfettered choices made by independent actors not before" this Court. *See Hippocratic Med.*, 602 U.S. at 383.

C. Dr. Paul Thomas and Dr. Kenneth Stoller

Attached hereto as Exhibit A is a March 2, 2023 Agreed Order between the Washington Medical Commission and Dr. Paul Thomas in which Dr. Thomas agreed to an indefinite suspension of his medical license. The Agreed Order provided that Dr. Thomas could "petition for reinstatement . . . only after reinstatement of his Oregon medical license." Ex. A at 3.

Dr. Thomas entered into an Interim Stipulated Order with the Oregon Medical Board (attached hereto as Exhibit B) on June 3, 2021, in which "he agreed to voluntarily limit his practice to acute care; refrain from engaging in consultations or directing clinic staff with respect to vaccination protocols questions, issues, or recommendations; and refrain from performing any research involving patient care pending the completion of the Board's investigation." Ex. B at 1. Then, on "November 21, 2021, the Board issued an Amended Complaint and Notice of Proposed Disciplinary Action in which the Board proposed to take disciplinary action . . . by imposing the maximum range of potential sanctions . . . which include the revocation of license . . . ." *Id*. Dr.

Thomas agreed to settle the charges by agreeing to surrender his Oregon medical license and "agree[ing] to never reapply for a license to practice medicine in Oregon." *Id*. at 3.

Attached hereto as Exhibit C is a February 16, 2021 Order and Decision from the Medical Board of California revoking Dr. Stoller's Physician's and Surgeon's Certificate to practice medicine in California. His California license was revoked after a hearing on allegations that he:

> issued letters for 10 children between 2016 and 2018 exempting those children from vaccinations that otherwise would have been mandatory under California law for them to congregate with other children in settings such as school or day care. Complainant alleges further that because these vaccination exemptions had no medical basis, they constitute medical negligence and incompetence.

Ex. C at 2.

In comparison to these public records, the Proposed Intervenors moving papers assert that:

> Dr. Thomas published a vaccinated-versus-unvaccinated study—the very methodology the IOM recommended—and had his license suspended shortly thereafter. Dr. Stoller used genetic testing to identify at-risk children and had his license revoked for deviating from ACIP guidelines. If the prior schedule is restored, the individualized clinical approach for which both physicians lost their licenses will once again constitute professional misconduct.

ECF No. 249 at 4.

The documents explaining why these doctors lost their licenses indicate that Proposed Intervenors' moving papers misrepresent the reasons Drs. Thomas and Stoller lost their licenses. Moreover, the allegations of alleged harm to Drs. Thomas and Stoller if this Court sets aside the January 5, 2026 CDC Immunization Schedule change (the "January 5 Action") are conclusory and speculative. Drs. Thomas and Stoller offer no explanation as to how the preliminary injunctive relief of setting aside the January 5 Action will somehow affect their status of having no license to practice medicine in Oregon, Washington, and California. Conversely, they offer no explanation as to how a decision not to set aside the January 5 Action will help them get their license back,

which is a necessary prerequisite for them to be put in a position where they may be exposed to professional misconduct charges for taking an "individualized clinical approach."

Drs. Thomas and Stoller essentially assert a conscience injury, like the doctors in *Hippocratic Medicine*. Here, as in *Hippocratic Medicine*, their theory of causation is entirely attenuated, speculative, and insufficient to establish that they have standing to intervene in this case. Indeed, Dr. Thomas' agreement never to apply for a license to practice medicine in Oregon again breaks any chain of causation. And Dr. Stoller offers no evidence that he has attempted to get his medical license back. *See Hippocratic Medicine*, 602 U.S. at 390 (noting that the doctors failed to establish Article III standing because "[t]he doctors have not shown that FDA's actions likely will cause them any injury in fact. The asserted causal link is simply too speculative or too attenuated to support Article III standing.").

As a matter of law, none of the Proposed Intervenors have standing to intervene in this case.

II. PROPOSED INTERVENORS FAIL TO SATISFY THE FACTORS FOR INTERVENTION AS A MATTER OF RIGHT.

"On timely motion, the court must permit anyone to intervene who . . . claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." FED. R. CIV. P. 24(a)(2). In the First Circuit, "[a] party that desires to intervene in a civil action under Rule 24(a)(2) must satisfy four conjunctive prerequisites: (1) a timely application for intervention; (2) a demonstrated interest relating to the property or transaction that forms the basis of the ongoing action; (3) a satisfactory showing that the disposition of the action threatens to create a practical impairment or impediment to its ability to protect that interest; and (4) a satisfactory showing that existing parties

inadequately represent its interest." *Public Service Co. of New Hampshire v. Patch*, 136 F.3d 197, 204 (1st Cir. 1998) (citing *Conservation Law Found. v. Mosbacher*, 966 F.2d 39, 41 (1st Cir. 1992)) (denying intervention as of right where parties were merely interested in the outcome of a case); *see also Geiger v. Foley Hoag LLP Ret. Plan*, 521 F.3d 60, 64 (1st Cir. 2008) (citing *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 637 (1st Cir. 2008)). "An application for intervention as of right must run the table and fulfill all four of these preconditions. The failure to satisfy any one of them dooms intervention." *See Public Service Co.*, 136 F.3d at 204 (citing *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 637 (1st Cir. 2008)).

The Proposed Intervenors fail to satisfy the second, third, and fourth prongs of the Rule 24(a)(2) test. Therefore, their request to intervene as a matter of right must be denied. *See Public Service Co.*, 136 F.3d at 204.

a. The Proposed Intervenors have not identified a demonstrated interest relating to the property or transaction that forms the basis of the ongoing action.

To satisfy the requirements of FED. R. CIV. P. 24(a)(2), the Proposed Intervenors must demonstrate an interest relating to the basis of the ongoing action. "While the type of interest sufficient to sustain intervention as of right is not amendable to precise and authoritative definition, a putative intervenor must show at a bare minimum that it has a significantly protectable interest that is direct, not contingent." *Public Service Co.*, 136 F.3d at 205. "It is settled beyond peradventure, however, that an undifferentiated, generalized interest in the outcome of an ongoing action is too porous a foundation on which to premise intervention as of right." *Id.*

The Proposed Intervenors have not demonstrated a directly protectable interest relating to the basis of the ongoing action, but have rather demonstrated a fundamental misunderstanding as to the basis of the ongoing action. Proposed Intervenors contend that the central question of this litigation is "whether the childhood immunization schedule is evidence-based, safe as

administered, and lawfully mandated." *See* ECF No. 249 at 7. In fact, the fundamental basis of this Action is whether Defendants have properly adhered to applicable processes and procedures in reaching specific final agency actions in compliance with the APA and the Federal Advisory Committee Act ("FACA").

Each intervenor has raised an interest they claim to be significantly protectable. Andrea Shaw and Shanticia Nelson claim that "[i]f this Court restores the prior schedule, it judicially validates the protocol under which their children died and directly prejudices their pending RICO claims." ECF No. 249 at 3. Drs. Paul Thomas and Kenneth Stoller claim that "[i]f the prior schedule is restored, the individualized clinical approach for which both physicians lost their licenses will once again constitute professional misconduct." *Id.* at 4. CHD claims that "[i]f the prior schedule is restored by judicial order, CHD's competing publications are delegitimized. CHD is also a plaintiff in both the *Shaw* and *Thomas* actions, whose outcomes will be directly affected by this Court's ruling." *Id.* Proposed Intervenors fail to address how these supposedly "significantly protectable" interests—which all essentially relate to an interest in what is and is not included on the CDC immunization schedule—directly relate to the basis of ***this*** action. *See Public Service Co.*, 136 F.3d at 205.

The *Public Service Co.* case is instructive. There, ratepayers and ratepayer advocates sought to intervene under Rule 24(a)(2) in a lawsuit by multiple electric utilities challenging the New Hampshire public utilities commissioners' final plan to create competition in New Hampshire's electric utility market. *Id.* at 202–04. The ratepayers and ratepayer advocates claimed that they had a "significantly protectable interest" in obtaining lower electric rates. *Id.* at 205. Even acknowledging that potential economic harm would usually warrant serious consideration as a protectable interest, the court determined that the ratepayers' and ratepayer advocates' economic

interest theory was too general to satisfy Rule 24(a)(2)'s requirements. *Id.* "After all," the court mused, "every electricity consumer in New Hampshire and every person who does business with any electricity yearns for lower electric rates." *Id.* Further, the court noted that the ratepayers and ratepayer advocates' interest in lower electric rates had an "overly contingent" quality because whether the interaction of numerous market variables would actually produce lower rates was "anybody's guess." *Id.* at 205–06. Therefore, the ratepayers' and ratepayer advocates' articulated interest was insufficient to satisfy Rule 24(a)(2).

Similarly here, Proposed Intervenors' interests in the outcome of what is and is not included on the immunization schedule are too general to satisfy Rule 24(a)(2). Their interest in what is on the immunization schedule is no different from the general interest that any provider, patient, or parent has in the CDC immunization schedule, regardless of whether they agree or disagree on the content of the schedule. Further, their interest in ***not*** returning to the status quo of the previous CDC immunization schedule is overly contingent because (1) it assumes that there were problems with the previous schedule, which is not at issue in this litigation, and (2) it assumes that the ultimate resolution of this lawsuit will require implementation of a specific immunization schedule. But this case is not about the outcome of what is reflected on the schedule—it is about whether Defendants properly complied with the APA in undertaking its final agency actions with respect to the immunization schedule and the composition of the Advisory Committee on Immunization Practices ("ACIP"). In other words, this case is not seeking any judicial approval or disapproval of a particular immunization schedule; it is challenging whether the Defendants followed the proper processes and procedures as required by the APA and FACA in making immunization schedule changes and appointing ACIP members. Further, the Proposed Intervenors provide no authority to support how the potential impacts on a completely unrelated RICO lawsuit

or on the "legitimacy" of CHD's "publications questioning the schedule's safety" serve as significantly protectable interests in the issues that form the bases of Plaintiffs' APA claims. Therefore, the Proposed Intervenors' interests cannot satisfy Rule 24(a)(2).

b. The Proposed Intervenors have not made a satisfactory showing that the disposition of this Action threatens to create a practical impairment or impediment to their ability to protect an interest relating to the basis of this Action.

In order to succeed under FED. R. CIV. P. 24(a)(2), the Proposed Intervenors must show that the disposition of this Action threatens to create a practical impairment or impediment to their ability to protect an interest relating to the basis of this Action. "Where the disposition of the case could result in a judicially enforceable order that adversely affects the would-be intervenor's significant interest, this requirement is satisfied." *See Allco Renewable Energy Ltd. v. Haaland*, 2022 WL 18033002, at *4 (D. Mass. Jan. 7, 2022) (citing *Daggett v. Comm'n Governmental Ethics & Election Pracs.*, 172 F.3d 104, 110–11 (1st Cir. 1999)). Proposed Intervenors necessarily fail this prong because, as explained above, they have not established an interest directly related to the basis of this action. Where no such interest exists, it cannot be adversely affected by a judicially enforceable order. *See id.*

Even assuming the Proposed Intervenors established an interest relating to the basis of this action, there is no practical tie between the Proposed Intervenors' purported interests and their ability to protect such interests. The Proposed Intervenors argue that if the prior immunization schedule is restored, "the schedule under which the Shaw twins and Sa'Niya Carter died will be reimposed by judicial order, directly harming the Shaw and Nelson families and prejudicing their pending RICO claims." ECF No. 249 at 4. But there is no explanation provided for *how* the schedule would harm the Shaw and Nelson families or prejudice their RICO claims; these averments are purely conclusory. Indeed, the existence of separate litigation or a different forum

for addressing the Proposed Intervenors' interests undermines their argument that the disposition of this case threatens to create a practical impairment or impediment to their ability to protect their interests.

The Proposed Intervenors also argue that restoring the prior schedule would contradict CHD's publications questioning the schedule's safety and thereby impair CHD's competitive position in the market for vaccine-related information, but the Proposed Intervenors cite no authority to support that they can have a protectable interest in having uncontradicted opinions, let alone that an order granting Plaintiffs' motion for preliminary injunction in this case would impede the Proposed Intervenors' ability to protect such interests. They also argue that restoring the schedule on a record that does not contain certain information the Proposed Intervenors would like it to include "foreclose[es] the possibility of a fully informed judicial decision." ECF No. 249 at 5.

These arguments are based on a misguided impression that this lawsuit seeks judicial review and approval of the previous CDC immunization schedule. Again, this lawsuit does not seek judicial approval or disapproval of any iteration of the CDC immunization schedule; Plaintiffs' motion for preliminary injunction seeks merely to restore the ***status quo***—i.e., to revert to the previous CDC immunization schedule—pending resolution of the claims in this lawsuit, which relate to Defendants' APA violations in failing to follow appropriate processes and procedures in making schedule changes and reconstituting the ACIP.

In short, the Proposed Intervenors have not, and cannot, demonstrate the disposition of this Action threatens to create a practical impairment or impediment to their ability to protect any protectable interest relating to the basis of this action.

c. The Proposed Intervenors have not made a satisfactory showing that existing parties inadequately represent their interest.

To satisfy the requirements of FED. R. CIV. P. 24(a)(2), the Proposed Intervenors must make a satisfactory showing that existing parties inadequately represent their interests. To satisfy the adequacy of interest requirement, the party seeking to intervene as a matter of right "must produce some tangible basis to support a claim of purported inadequacy." *Public Service Co.*, 136 F.3d at 207. In cases involving a governmental entity, there are two assumptions of adequate representation that proposed intervenors must overcome. *Mass. Food Ass'n v. Sullivan*, 184 F.R.D. 217, 222–23 (D. Mass. 1999). The first is a presumption that a government body or agency adequately represents the interests of constituents, and overcoming this presumption requires a "strong affirmative showing" that the agency is not fairly representing the applicant's interests. *Public Service Co.*, 136 F.3d at 207. The second is a presumption of adequate representation where the governmental entity and the proposed intervenor have the same ultimate goal, and overcoming this presumption requires the proposed intervenor to demonstrate, for example, "adversity of interest, collusion, or nonfeasance." *Mass. Food Ass'n*, 184 F.R.D. at 222–23; *cf. Daggett*, 172 F.3dat 111 (noting that this "trilogy" is not an exclusive list).

The Proposed Intervenors argue that the Government's opposition briefing focuses on the Secretary's legal authority and does not address interests the Proposed Intervenors seek to protect because it fails to challenge specific claims in Plaintiffs' Fourth Amended Complaint, identify children harmed by the prior schedule, or address the "enforcement infrastructure." ECF No. 249 at 5–6. In other words, the Proposed Intervenors seek to intervene based on the fact that one opposition brief to a specific motion filed by Plaintiffs did not include arguments that the Proposed Intervenors would have preferred the Government to make.

There are two key issues with this argument that prevent the Proposed Intervenors from rebutting the two presumptions in favor of adequate representation. First, as stated above, the

arguments the Proposed Intervenors would have liked the Government to make are not relevant to this case, which is an APA case arguing that the Defendants failed to follow applicable processes and procedures in making changes to the immunization schedules and reconstituting the ACIP. This case does not seek judicial determinations about what should or should not be on the CDC immunization schedules. Therefore, this is not the appropriate forum or case for the Proposed Intervenors to air their grievances regarding the former CDC immunization schedule or to advocate for their policy positions regarding any changes to the former CDC immunization schedule. Because such arguments are wholly irrelevant to the APA claims in this case, the Proposed Intervenors cannot demonstrate a lack of adequate representation as they cannot demonstrate they would add any "necessary element to the case" that the Defendants are not satisfactorily addressing. *Mass. Food. Ass'n*, 184 F.R.D. at 223–24.

Second, disagreement over what legal arguments to make is not sufficient to demonstrate inadequacy of representation. *See Pharm. Rsch. & Mfrs. of Am. v. Comm'r, Maine Dep't Human Servs.*, 201 F.R.D. 12, 14–15 (D. Me. 2001) (holding that a proposed intervenor's argument that the Plaintiffs had failed to make a specific argument regarding federal preemption in the lawsuit failed to satisfy the inadequacy of representation prong of FED. R. CIV. P. 24(a)(2) because "[w]here the would-be intervenor's interest is the same as the party's, only an extreme failure to present obvious arguments constitutes inadequate representation"); *see also Maine v. Norton*, 203 F.R.D. 22, 29 (D. Me. 2001) (holding that "potential differences in litigation strategy" were not sufficient to establish inadequate representation for Rule 24(a)(2)). This is especially true given that the Proposed Intervenors and the Defendants have the same ultimate goal: to defend Defendants' January 5 Action in response to Plaintiffs' APA claims. *Daggett*, 172 F.3d at 111; *Mass. Food Ass'n*, 184 F.R.D. at 222.

Even if there is some divergence of certain interests between the Proposed Intervenors and Defendants—such as having adverse positions in a separate case, *see* ECF No. 249 at 6—the Proposed Intervenors have not demonstrated "adversity of interest, collusion, or nonfeasance," or anything like it, between them and the Defendants ***with regard to challenging Plaintiffs' APA claims***. *See Mass. Food Ass'n*, 184 F.R.D. at 223 (noting that even apparent divergent interests based on the "traditionally adversarial relationship" between the proposed intervenor—a trade association—and the defendant commission members that regulate the proposed intervenor's members did not overcome the presumption of adequate representation because the defendants appeared "willing and able" to present all applicable defenses).

For these reasons, the Proposed Intervenors cannot satisfy the inadequacy of representation prong as they have failed to make a strong affirmative showing that the Defendants are not adequately representing their interests.

III. PROPOSED INTERVENORS FAIL TO ESTABLISH THE ELEMENTS FOR PERMISSIVE INTERVENTION.

The Proposed Intervenors cannot overcome their pleading deficiencies under FED. R. CIV. P. 24(a) by moving, in the alternative, for permissive intervention under FED. R. CIV. P. 24(b)(2). The Court may only allow intervention "upon a timely motion when an applicant's claim or defense and the main action have a question of law or fact in common." *Students for Fair Admissions, Inc. v. President and Fellows of Harvard Coll.*, 308 F.R.D. 39, 45 (D. Mass. 2015) (citation modified) (citing *Daggett v. Comm'n on Governmental Ethics & Election Practices*, 172 F.3d 104, 112–113 (1st Cir. 1999)). This critical threshold must be satisfied for the analysis to continue, in which case the court may consider "almost any factor rationally relevant" in deciding whether permissive intervention is nevertheless proper. *Daggett v. Comm'n on Governmental Ethics & Election Practices*, 172 F.3d 104, 112–113 (1st Cir. 1999). In contrast to intervention as

a matter of right under FED. R. CIV. P. 24(a), the decision to permit permissive intervention is "wholly discretionary," and should consider prejudice to the parties and/or delay in the pending action. *See id*. at 51; *President and Fellows of Harvard College*, 308 F.R.D. at 51.

The Proposed Intervenors fail to meet the threshold requirement of showing a common question of law or fact. Proposed Intervenors fail to articulate how their claims share a common question of law or fact with the instant case; they merely state as much in one conclusory sentence *See* ECF No. 249 at 7. Rather, Proposed Intervenors focus almost entirely on purported legal issues and harms that are undoubtedly not at issue in the pending litigation before this Court. The only commonality between Proposed Intervenors' factual and legal claims and those raised in the operative complaint is the impact of the childhood vaccination schedule. But this, too, is a red herring. Plaintiffs seek adjudication of claims under the APA brought against various Defendants for failing to follow the required processes and laws that inform vaccine recommendations in this country. The case turns on whether the proper procedures were followed by Defendants.

Despite making unfounded factual assertions about the safety and efficacy of the previous childhood schedule, the Proposed Intervenors do not advance arguments relating to the propriety of the processes followed by the Defendants in reaching the final agency actions at issue. Nor do the Proposed Intervenors articulate a significant stake in the outcome beyond their general agreement with the downgraded recommendations to shared clinical decision making. The issue of whether the prior childhood schedule was safe is a wholly separately legal claim, and not one before this Court nor that properly falls under the APA. *See United States v. Puerto Rico*, 2014 WL 13064595 (1st Cir. 2014) (permissive intervention denied where proposed intervenors' interests and legal claims did not "involve a question of law or fact at issue in the main action."). Critically, the Proposed Intervenors assert no facts or law bearing on whether Defendants acted

according to the required administrative procedures, much less whether the Defendants' final agency actions contravene the APA because they were arbitrary and capricious, or contrary to the law. This is not an instance in which a party intervenes in an APA case to assert the challenged process was lawfully undertaken or defend their significant stake in the outcome. *Contrast Allco*, 2002 WL 18022002 (allowing permissive intervention where non-party intervenor had significant monetary stake in outcome of litigation and advanced arguments to defend the lawfulness of the government permitting actions being challenged), *aff'd* by *Melone v. Coit,* 100 F. 4th 21, 28–29 (1st Cir. 2024). Plaintiffs seek to undo a discrete set of agency actions in favor of full compliance by Defendants moving forward. Any benefit to the Proposed Intervenors' interests is speculative and incidental at best.

Rather, the crux of the Proposed Intervenors' claim is that the AAP has historically endorsed a childhood vaccine schedule that is unsafe and untested, and that harmed children and others. The question of the safety of past vaccine schedules is not before the Court in this matter. Nevertheless, the Proposed Intervenors are, in essence, asking the Court to permit intervention for the purpose of adjudicating whether the former childhood vaccine schedule was appropriate and safe, a self-serving determination that will bolster the Proposed Intervenors' legal claims brought in unrelated litigation not before this Court rather than inform the Court's decision whether Defendants have violated the APA in this case. And in doing so, the Proposed Intervenors concede they have no intention of addressing the critical issue of whether the Secretary had the authority to revise the childhood vaccine schedule—a question which Proposed Intervenors acknowledge Defendants squarely address in their pleadings. ECF No. 248 at 3. Put simply, the Proposed Intervenors have failed to allege a common law or fact.

While the Court need not proceed in its analysis to deny permissive intervention, it is important to note that to the extent the Proposed Intervenors' endorsement of the current childhood vaccine schedule are relevant to this case, the Defendants adequately represent such interests. *See President and Fellows of Harvard College*, 308 F.R.D. at 49–51 (citing *Daggett*, 172 F.3d at 111) (noting where the goals of applicants are ultimately the same, adequate representation is presumed). Moreover, Defendants are well positioned to defend the propriety of the Government's actions with exclusive access to the administrative record that details if, and to what extent, the prescribed administrative policies and procedures were followed. Even if there was a common question of fact raised, the Proposed Intervenors have not sufficiently shown how they would be "helpful in developing the case." *See T-Mobile Ne. LLC v. Town of Barnstable*, 969 F. 3d 33, 41 (1st Cir. 2020), citing *Daggett*, 172 F.3d at 113. To the extent the Proposed Intervenors and their counsel may have specialized expertise developed through other litigation, this expertise may be appropriately deployed through amicus briefs, or through testimonial evidence solicited by Defendants. *See Daggett*, 172 F.3d at 113.

Finally, the Court should deny permissive intervention for the additional reason that intervention in this instance "will unduly delay or prejudice the adjudication of the original parties' rights." FED. R. CIV. P. 24(b)(3); *see also Daggett*, 172 F.3d at 113 (holding that whether additional of new parties would complicate a case "that badly needed to be expedited" is a permissible under consideration under FED. R. CIV. P. 24(b)(2)). Where, as here, the APA claims largely turn on the administrative record (being compiled by the Defendants as ordered by the Court on January 22, 2026, ECF No. 182) and the legal frameworks and regulations dictating the formation of vaccine policy and recommendations, the addition of new parties that "do not appear poised to add anything of meaningful value to the litigation" would unduly hinder the efficient resolution of this case. *See*

T-Mobile, 969 F.3d at 41–42. The parties have fully briefed, argued, and had the opportunity present additional evidence before the Court on the Plaintiffs' Motion for Preliminary Injunction related to the January 5 Action. Despite its assertion it will follow the Court's existing scheduling order, Proposed Intervenors' interests appear to relate solely to this issue, which has already been presented to the Court on an expedited basis as part of the Plaintiffs' requested for preliminary injunctive relief.

Attached to Proposed Intervenors' motion to intervene is a proposed Answer, Affirmative Defenses, and Counterclaims. ECF 248-1. Their second counterclaim is a claim of "False Advertising Under the Lanham Act, 15 U.S.C. §§ 1125(a) (Against AAP)." In addition to this claim not sharing common questions of fact or law with the claims that the seven medical associations and organizations assert in the Fourth Amended Complaint in this case, this claim, if allowed, would cause undue delay and prejudice to all of the parties in this case, not just AAP. To prove their false advertising claim, Proposed Intervenors would seek discovery on the elements of proving a Lanham Act claim, namely falsity, deception, materiality, intent, dissemination, injury, and damages. See 15 U.S.C. § 1125. This in turn would lead to discovery demands for documents and depositions on how AAP's childhood immunization schedule is developed; the scientific studies, analysis, and research underlying the Red Book (AAP's authoritative guide on childhood infectious diseases); how AAP advertises and markets its Red Book; revenue and profit generated by selling the Red Book, and much, much more. Allowing Proposed Intervenors into this case to pursue discovery on counterclaims that are unrelated to the APA claims asserted herein would cause undue delay, force Plaintiffs to incur unnecessary expense to defend the counterclaims, and would further exacerbate the harm to the Plaintiffs and public health by delaying adjudication on the agency actions challenged herein.

II. CONCLUSION

For all the foregoing reasons, Plaintiffs respectfully request that this Court deny the Emergency Motion to Intervene.

Dated: February 26, 2026

Respectfully submitted,

By: */s/ James J. Oh*
James J. Oh (admitted *pro hac vice*)
Kathleen Barrett (admitted *pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
227 W. Monroe Street, Suite 4500
Chicago, IL 60606
Tel: 312.499.1400
Fax: 312.845.1998
Email: joh@ebglaw.com
kbarrett@ebglaw.com

Elizabeth J. McEvoy (BBO No. 683191)
Gianna M. Costello (BBO No. 715031)
EPSTEIN BECKER & GREEN, P.C.
One Financial Center, Suite 1520
Boston, MA 02111
Tel: 617.603.1100
Fax: 617.249.1573
Email: emcevoy@ebglaw.com
gcostello@ebglaw.com

Richard H. Hughes IV (admitted *pro hac vice*)
Robert Wanerman (admitted *pro hac vice*)
William Walters (admitted *pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
1227 25th Street, N.W., Suite 700
Washington, DC 20037
Tel: 202.861.0900
Fax: 202.296.2882
Email: rhhughes@ebglaw.com
rwanerman@ebglaw.com
wwalters@ebglaw.com

Jeremy A. Avila (admitted *pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
57 Post Street, Suite 703
San Francisco, CA 94104
Tel: 415.398.3500

Fax: 415.398.0955
Email: javila@ebglaw.com

Daniella R. Lee (admitted *pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
201 East Kennedy Blvd., Suite 1260
Tampa, FL 33602
Tel: 813.367.9454
Fax: 813.367.9441
Email: dlee@ebglaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 26th day of February 2026:

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services

c/o Leah Belaire Foley, US Attorney
Michael L. Fitzgerald
Office of the US Attorney for the District of Massachusetts
1 Courthouse Way, Suite 9200
Boston, Massachusetts 02210
michael.fitzgerald2@usdoj.gov

Jay Bhattacharya, MD, PhD, in his official capacity as Acting Director Centers for Disease Control and Prevention

c/o Isaac Belfer
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044-0386
Isaac.C.Belfer@usdoj.gov

James W. Harlow
DOJ-Civ
Consumer Protection Branch
P.O Box 386
Washington, D.C. 20044
James.w.harlow@usdoj.gov

/s/ James J. Oh
James J. Oh

EXHIBIT A

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Paul Thomas, MD
Master Case No.: M2021-378
Document: Agreed Order

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld: **NONE**

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center
P.O. Box 47865
Olympia, WA 98504-7865
Phone: (360) 236-4700
Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

STATE OF WASHINGTON
WASHINGTON MEDICAL COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: **PAUL THOMAS, MD** License No. MD.MD.60353591 Respondent.	**No. M2021-378** **STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND AGREED ORDER**

The Washington Medical Commission (Commission), through Colleen Balatbat, Commission Staff Attorney, and Respondent, represented by counsel, Troy Bundy, stipulate and agree to the following.

1. PROCEDURAL STIPULATIONS

1.1 On February 11, 2022, the Commission issued a Statement of Charges against Respondent alleging a violation of RCW 18.130.180(5).

1.2 On May 16, 2022, the Commission and Respondent entered an Interim Stipulated Order which placed limitations on Respondent's license.

1.3 The Commission is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.4 Respondent has the right to defend against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.5 The Commission has the authority to impose sanctions pursuant to RCW 18.130.160 if the allegations are proven at a hearing.

1.6 The parties agree to resolve this matter by means of this Stipulated Findings of Fact, Conclusions of Law, and Agreed Order (Agreed Order).

1.7 Respondent waives the opportunity for a hearing on the Statement of Charges if the Commission accepts this Agreed Order.

1.8 This Agreed Order is not binding unless it is accepted and signed by the Commission.

1.9 If the Commission accepts this Agreed Order, it will be reported to the National Practitioner Data Bank (45 CFR Part 60), the Federation of State Medical Boards' Physician Data Center, and elsewhere as required by law.

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1.10 This Agreed Order is a public document. It will be placed on the Department of Health's website, disseminated via the Commission's electronic mailing list, and disseminated according to the Uniform Disciplinary Act (Chapter 18.130 RCW). It may be disclosed to the public upon request pursuant to the Public Records Act (Chapter 42.56 RCW). It will remain part of Respondent's file according to the state's records retention law and cannot be expunged.

1.11 If the Commission rejects this Agreed Order, Respondent waives any objection to the participation at hearing of any Commission members who heard the Agreed Order presentation.

1.12 If the Commission accepts this Agreed Order, it will supersede the Interim Stipulated Order entered on May 6, 2022.

2. FINDINGS OF FACT

Respondent and the Commission stipulate to the following findings of fact:

2.1 On August 2, 2013, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active.

2.2 On or about June 3, 2021, an Interim Stipulated Order was filed with the Oregon Medical Board and signed by Respondent on June 2, 2021. The Interim Order required Respondent to comply with the following:

2.2a Respondent's practice is limited to patients requiring acute care.

2.2b Respondent must not engage in consultations with parents or patients relating to vaccination protocols, questions, issues, or recommendations.

2.2c Respondent must not perform any research involving patient care.

2.3 On or about October 6, 2022, a Stipulated Order was filed with the Oregon Medical Board and signed by Respondent indicating that Respondent agreed to surrender his Oregon medical license.

3. CONCLUSIONS OF LAW

The Commission hereby entersthe following Conclusions of Law:

3.1 The Commission has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 Respondent has committed unprofessional conduct in violation of RCW 18.130.180(5).

3.3 The above violations provide grounds for imposing sanctions under RCW 18.130.160.

4. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, Respondent agrees to entry of the following Agreed Order:

4.1 **Indefinite Suspension.** Respondent's license to practice as a physician and surgeon in the state of Washington is **INDEFINITELY SUSPENDED**.

4.2 **Reinstatement**. Respondent may petition for reinstatement pursuant to RCW 18.130.150 and only after reinstatement of his Oregon medical license. The Commission may agree to an order of reinstatement. If the Commission does not agree, a hearing may be held on the petition. Any order of reinstatement based on agreement or following a hearing may impose any terms and conditions listed in RCW 18.130.160 as deemed necessary by the Commission to protect the public and/or rehabilitate Respondent's practice.

4.3 **Demographic Census.** Washington law requires physicians and physician assistants to complete a demographic census with their license renewal. RCW 18.71.080(1)(b) and 18.71A.020(4)(b). Respondent must submit a completed demographic census to the Commission within **thirty (30) days** of the effective date of this Agreed Order, or at the time of renewal, whichever comes first. The demographic census can be found here: can be found here: https://wmc.wa.gov/licensing/renewals/demographic-census.

4.4 **Self-Reporting.** Respondent shall report in writing, by email to medical.compliance@wmc.wa.gov, within thirty (30) days of the occurrence of any of the following events:

a. Entry into any formal or informal agreement or order or issuance of any order, letter of concern, or reprimand with or by any healthcare-related license for the Respondent in another state;

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b. Denial, restriction, suspension or revocation of privileges for the Respondent in any healthcare facility;

c. Any felony or gross misdemeanor charge against the Respondent; and

d. The filing of a complaint in superior court or federal district court against Respondent alleging negligence or request for mediation pursuant to chapter 7.70 RCW.

This requirement supplements and does not supersede the reporting obligations imposed by WAC 246-16-230.

4.5 **Obey Laws.** Respondent must obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

4.6 **Costs.** Respondent must assume all costs of complying with this Agreed Order.

4.7 **Violations.** If Respondent violates any provision of this Agreed Order in any respect, the Commission may initiate further action against Respondent's license.

4.8 **Change of Address or Name.** Respondent must inform the Commission and Adjudicative Clerk Office in writing, of changes in his residential and/or business address and/or his name within thirty (30) days of such change.

4.9 **Effective Date.** The effective date of this Agreed Order is the date the Adjudicative Clerk Office places the signed Agreed Order into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective of this Agreed Order.

5. COMPLIANCE WITH SANCTION RULES

The Commission applies WAC 246-16-800, *et seq.,* to determine appropriate sanctions. There is no sanction schedule that applies to this case. WAC 246 16-800 (2)(d) provides that if the conduct is not described in a schedule, the disciplining authority will use its judgment to determine appropriate sanctions. The ultimate duration of this Agreed Order is undetermined. It is uncertain when, or if, Respondent will be granted reinstatement of his Oregon medical license.

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6. FAILURE TO COMPLY

Protection of the public requires practice under the terms and conditions imposed in this Agreed Order. Failure to comply with the terms and conditions of this Agreed Order may result in further action on Respondent's license after a show cause hearing. If Respondent fails to comply with the terms and conditions of this Agreed Order, the Commission may hold a hearing to require Respondent to show cause why the license should not be revoked. Alternatively, the Commission may bring additional charges of unprofessional conduct under RCW 18.130.180(9). In either case, Respondent will be afforded notice and an opportunity for a hearing on the issue of non-compliance.

7. RESPONDENT'S ACCEPTANCE

I, PAUL THOMAS, MD, Respondent, certify that I have read this Agreed Order in its entirety; that my counsel of record, TROY BUNDY, has fully explained the legal significance and consequence of it; that I fully understand and agree to all of it; and that it may be presented to the Commission without my appearance. If the Commission accepts the Agreed Order, I understand that I will receive a signed copy.

PAUL THOMAS, MD
RESPONDENT

Feb. 17, 2023
DATE

TROY S. BUNDY, WSBA NO. 33330
ATTORNEY FOR RESPONDENT

2.17.2023
DATE

8. COMMISSION'S ACCEPTANCE AND ORDER

The Commission accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED: 3/2/2023.

STATE OF WASHINGTON
WASHINGTON MEDICAL COMMISSION

T Murphy MD
PANEL CHAIR

PRESENTED BY:

Colleen Balatbat
COLLEEN BALATBAT, WSBA NO. 48084
COMMISSION STAFF ATTORNEY

EXHIBIT B

BEFORE THE

OREGON MEDICAL BOARD

STATE OF OREGON

In the Matter of PAUL NORMAN THOMAS, MD LICENSE NO. MD15689	STIPULATED ORDER

1.

The Oregon Medical Board (Board) is the state agency responsible for licensing, regulating and disciplining certain health care providers, including physicians, in the State of Oregon. Paul Norman Thomas, MD (Licensee) is a licensed physician in the State of Oregon.

2.

On June 3, 2021, Licensee entered into an Interim Stipulated Order with the Board in which he agreed to voluntarily limit his practice to acute care; refrain from engaging in consultations or directing clinic staff with respect to vaccination protocols questions, issues or recommendations; and refrain from performing any research involving patient care pending the completion of the Board's investigation. On November 21, 2021, the Board issued an Amended Complaint and Notice of Proposed Disciplinary Action in which the Board proposed to take disciplinary action against Licensee by imposing the maximum range of potential sanctions identified in ORS 677.205(2), which include the revocation of license, a $10,000 civil penalty per violation, and assessment of costs, for violations of the Medical Practice Act, specifically: ORS 677.190(1)(a) unprofessional or dishonorable conduct as defined in ORS 677.188(4)(a) any conduct or practice contrary to recognized standards of ethics of the medical profession or any conduct or practice which does or might constitute a danger to the health or safety of a patient or the public; ORS 677.190(9) making false or misleading statements regarding the efficacy of the licensee's treatments; ORS 677.190(13) repeated negligence and gross negligence in the practice of medicine; ORS 677.190(17) willfully violating any provision of this chapter including ORS

677.080 knowingly making a false statement or representation on a matter; and failing to comply with a Board request made under ORS 677.320 (Board investigations); and ORS 677.190(26) failing to report an adverse action.

3.

Licensee and the Board desire to settle this matter by the entry of this Stipulated Order. Licensee understands that he has the right to a contested case hearing under the Administrative Procedures Act (Oregon Revised Statutes chapter 183), fully and finally waives the right to a contested case hearing, understands and acknowledges that this order is not subject to judicial review, and acknowledges and agrees the grounds to petition for the stipulated order to be set aside under ORS 183.417(3)(b) do not exist in this case, by the signing of and entry of this Order in the Board's records. Licensee neither admits nor denies, but the Board finds that Licensee engaged in conduct as described in the November 21, 2021, Complaint and Notice of Proposed Disciplinary Action, and that this conduct violated the Medical Practice Act, to wit ORS 677.190(1)(a) as defined in ORS 677.188(4)(a); ORS 677.190(9); ORS 677.190(13); ORS 677.190(17); and ORS 677.190(26). Licensee understands that this Order is a public record and is a disciplinary action that is reportable to the National Practitioner Data Bank and the Federation of State Medical Boards. Licensee understands the terms of this Order and signs freely.

4.

Licensee and the Board agree that the Board will close this investigation and resolve this matter by entry of this Stipulated Order, subject to the following conditions:

4.1 Licensee surrenders his Oregon medical license. Licensee's Oregon medical license shall be changed to surrendered status effective 60 days from the date this Stipulated Order is signed by the Board Chair.

4.2 Licensee agrees to never reapply for a license to practice medicine in Oregon.

4.3 All of Licensee's currently pending administrative matters before the Board are closed effective the date this Stipulated Order is signed by the Board Chair.

4.4 The June 3, 2021, Interim Stipulated Order terminates effective the date this Stipulated Order is signed by the Board Chair.

4.5 Licensee must obey all federal and Oregon state laws and regulations pertaining to the practice of medicine.

4.6 Licensee stipulates and agrees that any violation of the terms of this Order shall be grounds for further disciplinary action under ORS 677.190(17).

5.

This Order becomes effective the date it is signed by the Board Chair.

IT IS SO STIPULATED this 13TH day of SEPTEMBER 2022.

[redacted]

PAUL NORMAN THOMAS, MD

IT IS SO ORDERED this 6th day of October 2022.

OREGON MEDICAL BOARD
State of Oregon

[redacted]

ROBERT M. CAHN, MD
Board Chair

EXHIBIT C

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against	
Kenneth Paul Stoller, M.D.	**Case No. 800-2017-034218**
Physician's and Surgeon's Certificate No. A41183	
Respondent	

DECISION

The attached Proposed Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on March 18, 2021.

IT IS SO ORDERED February 16, 2021.

MEDICAL BOARD OF CALIFORNIA

By: Richard E. Thorp MD
Richard E. Thorp, M.D., Chair
Panel B

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

KENNETH PAUL STOLLER, M.D.,

Physician's and Surgeon's Certificate No. A 41183

Respondent.

Agency Case No. 800-2017-034218

OAH No. 2019110039

PROPOSED DECISION

Administrative Law Judge Juliet E. Cox, State of California, Office of Administrative Hearings, heard this matter by videoconference on September 21 through 24, 2020.

Deputy Attorney General Lawrence Mercer represented complainant William J. Prasifka, Executive Director of the Medical Board of California.

Attorney Richard Jaffe represented respondent Kenneth Paul Stoller, M.D., who was present for the hearing.

The matter was held open for written closing argument. The record closed and the matter was submitted for decision on November 9, 2020.

FACTUAL FINDINGS

1. Respondent Kenneth Paul Stoller, M.D., has held Physician's and Surgeon's Certificate No. A 41183 since September 10, 1984. As of the hearing date, this certificate was active, and was scheduled to expire December 31, 2021.

2. Acting in her official capacity as Executive Director of the Medical Board of California (Board), Kimberly Kirchmeyer filed an accusation against respondent on July 29, 2019. Complainant William J. Prasifka later replaced Kirchmeyer as the Board's Executive Director.

3. Complainant alleges that respondent issued letters for 10 children between 2016 and 2018 exempting those children from vaccinations that otherwise would have been mandatory under California law for them to congregate with other children in settings such as school or day care. Complainant alleges further that because these vaccination exemptions had no medical basis, they constitute medical negligence and incompetence. Finally, complainant alleges that respondent's medical records about these children and their vaccination exemptions are not only inaccurate but also inadequate to reflect and explain his medical advice. For all these reasons, complainant seeks professional discipline against respondent.

Educational and Professional History

4. Respondent received his medical degree in 1982. He completed a residency in pediatrics in 1986.

5. Respondent was board-certified as a pediatrician between 1989 and 2011. He did not seek to renew his board certification in 2011, and testified that he did

not because the practice shift described below in Finding 7 had made board certification less valuable to him.

6. Respondent was in private practice as a pediatrician in Southern California between 1986 and 1998. In late 1998 he moved to New Mexico, where he continued practicing as a pediatrician. Between 2002 and 2005, respondent served as a clinical assistant faculty member in pediatrics at the University of New Mexico School of Medicine.

7. Soon after he moved to New Mexico, respondent's medical practice began emphasizing hyperbaric oxygen treatment for brain injuries as well as other illnesses. Since 2005, respondent has been the medical director at several hyperbaric oxygen clinics in New Mexico and California.

8. The evidence did not establish precisely when respondent moved back to California from New Mexico. When he saw the 10 patients whose treatment is at issue in this matter, respondent was a member of a private practice in San Francisco with several chiropractors and naturopaths. In that practice, respondent treated more adults than children, using primarily but not exclusively hyperbaric oxygen therapy.

9. Respondent left the private practice described in Finding 8 in part because of negative publicity relating to his vaccination exemptions. He currently is in solo practice in Santa Rosa.

10. Through his residency and experience in pediatrics, through continuing medical education during his career, and through regular attention to medical and scientific literature, respondent has studied important concepts and vocabulary in infectious disease, human genetics, and immunology. He has no formal postgraduate training in any of these subjects.

California Mandatory Immunization Laws

11. California law generally requires immunizations for children attending schools and licensed day care facilities. (Health & Saf. Code, § 120325 et seq.)[1] At a child's initial enrollment, and at certain milestones thereafter, school or day care personnel must obtain confirmation that the child has received immunizations according to regulations and schedules issued by the California Department of Public Health (CDPH). (*Id.*, § 120335; Cal. Code Regs., tit. 17, § 6000, subd. (*l*).)

12. The mandatory immunization statutes list 10 diseases or disease-causing organisms against which a child must receive immunization: diphtheria, Haemophilus influenzae type b (a bacterium, not the virus that causes influenza), measles, mumps, pertussis, poliomyelitis, rubella, tetanus, hepatitis B, and chickenpox. (Health & Saf. Code, § 120335, subd. (b).) The statutes also authorize CDPH to add additional diseases or disease-causing organisms to this list (*id.*, subd. (b)(11)), although the evidence did not establish that CDPH has done so.

13. Since January 1, 2016, California law has permitted schools and day care facilities to enroll unimmunized children only if physicians have exempted those children from immunization for medical reasons. Specifically, in lieu of confirmation that a child has received immunizations, the school or day care facility may accept:

> a written statement by a licensed physician and surgeon to the effect that the physical condition of the child is such, or

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[1] The Legislature amended these statutes effective January 1, 2020. The amendments are not relevant to the allegations against respondent.

> medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician and surgeon does not recommend immunization.

(Health & Saf. Code, § 120370, subd. (a)(1).) Physicians licensed by the Board, or by the Osteopathic Medical Board, may issue these medical exemption statements. (Cal. Code Regs., tit. 17, § 6000, subd. (f).)

14. A medical exemption that permits an unimmunized child to attend school or day care may exempt the child from immunization against only one disease, against some, or against all diseases for which immunization otherwise would be mandatory. The exemption may be either temporary, reflecting circumstances that the issuing physician expects to change over time, or permanent.

15. Some people develop effective future immunity to some infectious diseases by living through infection with those diseases. In general, however, immunization satisfying California's school and day care requirements must occur through vaccination, which CDPH defines with reference to the "federal Advisory Committee on Immunization Practices" (ACIP). (Cal. Code Regs., tit. 17, §§ 6000, subd. (m), 6025, 6065.) The ACIP, in turn, uses the term "vaccine" specifically to refer to a "suspension of live (usually attenuated) or inactivated microorganisms (e.g., bacteria or viruses) or fractions thereof administered to induce immunity and prevent infectious disease or its sequelae." (ACIP General Best Practice Guidelines for Immunizations [ACIP Guidelines], at p. 193.)

16. Vaccines, as all evidence in this matter referred to them, are pharmaceutical products that their manufacturers may distribute in the United States only with approval from the federal government. Manufacturers have designed some vaccines to induce immunity to only one infectious microorganism or disease. Other vaccines include ingredients to induce immunity to multiple microorganisms or diseases. In addition to live or inactivated infectious microorganisms or portions of such microorganisms, most vaccines also include substances such as water and preservatives.

Respondent's Vaccination Exemptions

17. Between April 2016 and September 2018, respondent issued medical exemptions from all vaccination for 10 children (Patients 1 through 10).[2] Two of these exemptions (for Patients 2 and 3) were temporary; the other eight were for the patients' lifetimes.

18. For each of Patients 1 through 10, although respondent met the patient before issuing a medical exemption from vaccination, respondent was not the patient's regular treating pediatrician. Respondent did not consult any other physician who ever had treated any of these 10 patients before issuing exemptions to them.

19. The ACIP publishes and periodically updates its ACIP Guidelines, which cover topics that include timing and spacing of vaccine administration, evaluating contraindications and precautions for various vaccines, preventing and managing

[2] In an interview with Board investigators, respondent estimated that he had issued about 500 such exemptions between 2016 and 2019. He testified that he used a similar protocol to evaluate every request for medical vaccination exemption.

adverse reactions, addressing "altered immunocompetence" in vaccine recipients, and addressing bleeding risks in vaccine recipients.

20. Respondent did not consider the ACIP Guidelines in issuing medical exemptions from vaccination for Patients 1 through 10. To his knowledge, the ACIP Guidelines do not support temporary or lifelong medical exemption from any vaccination for any of Patients 1 through 10. Respondent's exemptions for Patients 1 to 10 rely on information about Patients 1 to 10 that the ACIP Guidelines do not deem relevant to determining whether or when a child should receive any vaccine.

21. The American Academy of Pediatrics (AAP, a professional organization for pediatricians) includes a committee on infectious diseases. This committee publishes, and updates periodically, a handbook for pediatricians about infectious disease treatment and prevention. The handbook (the AAP Red Book) recommends immunization practices, and includes advice for pediatricians about selecting vaccine products, scheduling childhood immunizations, and evaluating unusual circumstances under which pediatricians should consider departing from the practices the AAP Red Book recommends for most patients.

22. Respondent did not consider the AAP Red Book in issuing medical exemptions from vaccination for Patients 1 through 10. To his knowledge, the AAP Red Book does not support temporary or lifelong medical exemption from any vaccination for any of Patients 1 through 10. Respondent's exemptions for Patients 1 to 10 rely on information about Patients 1 to 10 that the AAP Red Book does not deem relevant to determining whether or when a child should receive any vaccine.

PATIENT 1

23. Respondent saw Patient 1 in August 2016, when Patient 1 was about four months old. Respondent stated in his interview with Board investigators that Patient 1's mother brought Patient 1 to him "because the mother wanted a medical exemption from vaccines."

24. Patient 1's mother reported that Patient 1 had a ventriculoseptal defect (VSD, an abnormal opening between the two lower chambers in his heart) and that he took medication because of this problem. She also described Patient 1 as having "digestive problems" and "weight problems," and stated that many people in her and Patient 1's father's families had "seasonal allergies." Respondent's records regarding Patient 1 do not show that he weighed or measured Patient 1, but he noted that Patient 1 "appears to not have any gross growth abnormalities."

25. Patient 1's mother did not bring or send any medical records about Patient 1 to respondent, and respondent did not obtain any from other providers. Medical records in evidence from Patient 1's regular treating medical group confirm that he was born with a VSD and that he took medication for it when he was an infant. By October 2018, when Patient 1 was about 30 months old, these records state that his VSD had "almost completely closed" and that he appeared "well-developed and well-nourished."

26. Respondent ordered laboratory testing to determine which alleles Patient 1 had for several genes that encode cell-surface proteins in the Human Leukocyte Antigen (HLA) system.

27. Respondent's medical records state that he concluded from the testing described in Finding 26 that Patient 1 likely would be "a vaccine non-responder for

multiple vaccines." The records state further that because respondent believed that vaccination for Patient 1 would offer no immunity benefit warranting Patient 1's exposure to any vaccination risks, respondent believed a medical exemption to be appropriate for Patient 1.

28. Respondent provided a report to Patient 1's mother stating that Patient 1 "has critical genes associated with Adverse Event reactions to a vaccine" and that this "medical condition is life-long." Despite the matters stated in Finding 27, the report says nothing about Patient 1's likely non-response to vaccination.

29. The report described in Finding 28 covers nine pages and includes at least 10 citations to other documents that the report characterizes as scientific publications. Its text uses specialized terminology from genetics, immunology, and medicine. Although the evidence did not establish which, if any, of the scientific statements in the report are true, most of the report is nonsense.[3]

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[3] As only one example, the report states that "hundreds of different versions (alleles) of the HLA-DQB1 gene" exist. The next sentence refers to narcolepsy and an influenza vaccine, but not to any HLA genes or alleles of those genes. The next sentence says that "[b]ased on the above, one would expect a spike in [vaccination] Adverse Events among those with the HLA-DQB1 polymorphism." Despite having just stated that polymorphism (genetic variation) at the HLA-DQB1 gene comprises hundreds of possible alleles, the report does not identify which two alleles among these hundreds of possibilities Patient 1 actually has, or which allele(s) would cause any physician or scientist to expect adverse vaccination events for any person.

30. Respondent sent Patient 1's mother a letter dated August 25, 2016, addressed "To Whom It May Concern," exempting Patient 1 permanently, on genetic grounds, from "all vaccines otherwise required for admission to school."

31. In his interview with Board investigators, and in his testimony at the hearing, respondent emphasized reasons for issuing Patent 1's medical exemption that were more consistent with his medical records described in Finding 27 (noting the likelihood that vaccination would not benefit Patient 1 because it would fail to provoke immunity in him) than with the report described in Finding 28 (describing risks to Patient 1 from immune over-response to vaccination). Despite this emphasis, respondent also testified to his strong opinion that only an irresponsible physician would have recommended vaccinating Patient 1.

32. Respondent charged Patient 1's family $550 for his services for Patient 1. The evidence did not establish how much Patient 1's family paid for the laboratory testing described above in Finding 26.

PATIENTS 2 AND 3

33. Patients 2 and 3 are siblings. Respondent saw them in September 2018, when Patient 2 was about 30 months old and Patient 3 was almost five years old.

34. The mother wrote on an intake form that when Patient 3 was six months old (in approximately June 2014), he had received several vaccinations in a single pediatrician visit and had woken up the next morning with his crib pillow "covered in blood." Respondent's own notes from his examination of Patient 3 and his in-person interview with Patient 3's mother describe Patient 3 as having woken the morning after his six-month vaccines "in a puddle of blood and vomit." Elsewhere, his notes for

Patients 2 and 3 describe the incident as "near-exsanguinatory" (loss of a significant proportion of total blood volume) and "near SIDS" (Sudden Infant Death Syndrome).

35. The mother also told respondent that Patient 3 had developed "[s]peech issues" after the event described in Finding 34. Elsewhere in his records about Patients 2 and 3, respondent characterized these concerns as "apraxia/dyspraxia."

36. The mother sent respondent copies of records showing that Patient 2 had not received any vaccinations and that that Patient 3 had received various vaccinations between December 2013 (on his birth date) and December 2014, with the last on December 19, 2014. She did not bring or send any other medical records about Patient 2 or Patient 3 to respondent, and respondent did not obtain any from any other providers.

37. Medical records in evidence from these children's regular treating pediatrician (Vyajanthi Srinivasan, M.D.) show that their mother sent an email message to Dr. Srinivasan on December 22, 2014. The email correspondence stated that Patient 3 had suffered a nosebleed during the night between December 19 and 20, and asked Dr. Srinivasan for advice. To Dr. Srinivasan's knowledge, and according to the medical records in evidence, Patient 3 did not receive treatment in June 2014 (at six months old), in December 2014 (at one year old), or at any other time for any life-threatening emergency involving either vomiting or voluminous bleeding. Dr. Srinivasan's records from a well-child examination of Patient 3 in October 2018 refer to no developmental delays or apparent neurological disorders.

38. Dr. Srinivasan does not believe that either Patient 2 or Patient 3 has, or ever has had, any medical condition warranting temporary or permanent exemption from vaccination.

39. Respondent's medical records criticize Patient 3's treating physicians for having failed to investigate Patient 3's post-vaccination "bleeding event." They state his conclusion that a temporary medical exemption from further immunization is appropriate for Patient 3 while he obtains "a genetic screen for critical polymorphisms" and possibly a "further work-up for clotting factors." In addition, respondent's records state his conclusion that a "genetic screen" is appropriate for Patient 2 because of her elder brother's medical history, and that a temporary medical exemption from further immunization is appropriate for her until he obtains the results from that testing.

40. Respondent gave the mother of Patients 2 and 3 letters dated September 27, 2018, addressed "To Whom It May Concern," exempting Patients 2 and 3 for 180 days from "all vaccines otherwise required for admission to school" pending an "Adverse Event Risk assessment."

41. Respondent advised these patients' mother to obtain further laboratory testing for Patients 2 and 3, but the evidence did not establish whether she did so. Respondent did not see Patient 2 or Patient 3 again after issuing the temporary exemptions described in Finding 40, and did not issue any permanent exemptions for them.

42. Respondent's testimony at the hearing about his reasons for issuing Patient 2's and Patient 3's medical exemptions was consistent with his medical records.

43. Respondent charged $400 for his services for Patient 2, and another $400 for his services for Patient 3.

PATIENT 4

44. Patient 4's mother consulted respondent about Patient 4 in December 2015, a few months after Patient 4's fourth birthday. She reported to respondent that Patient 4 had received no vaccinations. Patient 4's mother also reported a long list of allergies, dietary sensitivities, and mental health problems for Patient 4, herself, Patient 4's father, and their extended families.

45. Patient 4's mother did not provide any medical records about Patient 4 to respondent, and respondent did not obtain any from other providers before issuing a medical exemption to Patient 4 as described below in Finding 51.[4]

46. Respondent's medical records state that "[s]ince vaccination invariably induces genetically modulated systemic inflammation which is associated with a multitude of adverse events, a genetic screen is indicated in this child with a strong family history of auto-immune issues."

47. Respondent testified that he instructed Patient 4's mother to have Patient 4 tested using the 23andMe service, a commercially available service that uses a saliva sample to test for known variants at tens of thousands of base-pair locations on a person's chromosomes. He also gave Patient 4's mother instructions for obtaining not just a report from 23andMe but also the testing data, and for providing the data to him for further analysis. She did so.

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[4] Respondent's records regarding Patient 4 include records from an emergency room visit by Patient 4 in late 2018. The evidence did not explain why.

48. Respondent's medical records state that he concluded from the testing described in Finding 47 that Patient 4 would experience "an overreaction by this child's immune system to vaccines, especially vaccines that contain viral components." Because of Patient 4's genetic characteristics, and her "very reactive immediate family," respondent concluded that she should be medically exempt from vaccination.

49. Respondent provided a report to Patient 4's mother in April 2016 that was similar to the report described above in Findings 28 and 29 for Patient 1 in its sophisticated vocabulary and illogic, but that referred to different genes and their variants. This report states that Patient 4 "has multiple polymorphisms on two critical genes associated with Adverse Event reactions to a vaccine" and that this "medical condition is life-long." The report states that vaccination would be unsafe for Patient 4.

50. Respondent provided a second version of this report to Patient 4's mother in January 2018. The second version repeats much of the text from the first version. It is much longer (32 pages), because it includes many pages explaining respondent's views on vaccine hazards and research (summarized below in Findings 86 and 87).

51. Respondent gave Patient 4's mother a letter dated April 29, 2016, addressed "To Whom It May Concern." The letter exempts Patient 4 permanently from "all vaccines," on the ground that Patient 4's "genetic issues" put her at "high risk of adverse events to vaccination."

52. Also in January 2018, respondent sent Patient 4's mother a second version of the "To Whom It May Concern" letter dated April 29, 2016. This second version states, "I certify that all vaccines otherwise required for admission to school" are unsafe for Patient 4, and that this condition is "permanent."

53. Respondent's testimony at the hearing about his reasons for issuing Patent 4's medical exemption was consistent with his medical records and with the reports described in Findings 49 and 50.

54. Respondent charged Patient 4's family $500 for his services for Patient 4. The evidence did not establish how much Patient 4's family paid for the laboratory testing described above in Finding 47.

PATIENTS 5 TO 10

55. All of Patients 5 through 10 lived in the same community. Their parents sought medical exemptions from respondent because these children's schools had threatened to exclude the children from continuing attendance until they presented either medical exemptions or immunization confirmations.

Initial Telephone Consultations

56. The father of Patients 5 and 6 first contacted respondent in September 2017, when Patient 5 was six years old and Patient 6 was 12. The parents told respondent on an intake form and by telephone that the children's elder sibling had many allergies or sensitivities ("dairy, sugar, metal, gluten"), which respondent's notes characterize as "post vaccine auto-immune issues." The parents reported to respondent that they were "concerned about adverse risk" if Patients 5 and 6 received vaccinations.

57. Respondent spoke by telephone with Patient 7's mother in September 2017. Patient 7 was five years old and had received some vaccinations. Patient 7's mother described Patient 7 on an intake form as "an amazing very smart child," but one with "slurred/delayed speech." Respondent's notes from the telephone call

describe Patient 7 as "dyspraxic," and also state that one of Patient 7's first cousins had experienced an adverse vaccine reaction.

58. Patient 8's parents contacted respondent in August 2017, when Patient 8 was 12 years old. They provided little information in writing to respondent before his initial telephone consultation with them. Respondent's notes from his initial telephone call with Patient 8's parents state that they told him she had developed a "severe" reaction after her first infant vaccine: "an almost immediate full body rash followed by a year of what can only be described as an encephalitic reaction—inconsolable crying that lasted a year and a four week period of esotropia [an eye turning inward toward the nose] soon after the vaccine that may have been due to a stroke."

59. Patient 9 also was 12 years old when her mother contacted respondent in September 2017. Patient 9's mother described Patient 9 as having been ill very frequently as an infant and small child, especially with respiratory problems. Patient 9's mother attributes Patient 9's poor early childhood health to prior vaccination. She brought Patient 9 to respondent because Patient 9's regular treating physician refused to issue a medical immunization exemption for Patient 9.

60. Patient 10's mother contacted respondent in September 2017, when Patient 10 was almost six years old. She stated on her written intake form for Patient 10, "I don't want to vaccinate bc of our family history," and that Patient 10 was allergic to eggs and gluten. Respondent's notes from a telephone conversation with Patient 10's parents state that they reported that Patient 10's sibling had "developed overt neuro-behavioral delays after vaccines received."

Other Providers' Medical Records

61. The parents of Patients 5 through 10 did not provide any medical records about their children to respondent, and respondent did not obtain any from other providers.

62. The parents of Patients 5, 6, and 10 did not provide any medical records about these patients' siblings to respondent, and respondent did not obtain any from other providers.

63. Patient 7's parents did not provide any medical records about Patient 7's first cousin to respondent, and respondent did not obtain any from other providers

Advice and Temporary Exemptions

64. Respondent's medical records for Patients 5 through 10 all state that he advised these patients' parents to obtain genetic testing for their children.

65. Respondent sent the parents of Patients 5 through 10 letters addressed "To Whom It May Concern," exempting Patients 5 through 10 for 180 days from "all vaccines otherwise required for admission to school" pending an "Adverse Event Risk assessment."

66. Respondent also sent the parents of Patients 8 and 10 later letters extending these patients' temporary exemptions.

Examination, Evaluation, and Permanent Exemptions

67. Each child's parents obtained testing as respondent had recommended through the 23andMe service, described above in Finding 47. They followed respondent's instructions for providing the data to him for analysis.

68. Respondent examined each of Patients 5 through 10 in person after receiving results from the testing described in Finding 67. His medical records note nothing unusual about his physical examinations of Patients 5, 6, 8, and 9. For Patient 7, respondent's physical examination summary notes "dyspraxia." For Patient 10, respondent's notes say that Patient 10's mother described Patient 10 as experiencing occasional migraines and heartburn.

69. Respondent's records state that the parents of both Patient 7 and Patient 9 are "adamant" that their children previously had experienced adverse health consequences from vaccination.

70. For each of Patients 5 through 10, respondent's records state that he concluded from the testing described in Finding 67 that the child had various "mutations" or "polymorphisms" increasing risk for poor health consequences after vaccination. For each child, respondent concluded that the child's genetic characteristics justified medical exemption from vaccination. For Patients 7, 8, and 9, respondent also cited prior health problems he attributed to immunization. In addition, for Patients 7 and 10, respondent based his conclusions on other family members' reported experiences.

71. Respondent sent nearly identical reports to each patient's parents. These reports were similar to the report described above in Finding 50 for Patient 4, but referred to a longer list of genes and their variants. Every report stated that the patient[5] "has multiple polymorphisms on critical genes associated with Adverse Event

[5] Patient 8's report referred to another child, not to Patient 8.

reactions to a vaccine" and that this "medical condition is life-long." The reports all state that "this child should avoid receiving vaccines of any type."

72. Respondent also sent his patients' parents letters, one for each patient, addressed "To Whom It May Concern." Each letter states, "I certify that all vaccines otherwise required for admission to school" are unsafe for the patient, and that this condition is "permanent."

73. Respondent's testimony at the hearing about his reasons for issuing medical exemptions for Patients 5 through 10 was consistent with his medical records and with the reports described in Finding 71.

74. Respondent charged $550 each for his services to Patients 5, 6, 7, and 9.

75. Respondent charged $600 each for his services to Patients 8 and 10.

76. The evidence did not establish how much any of these patients' families paid for the testing described above in Finding 67.

Expert Testimony

77. Dean A. Blumberg, M.D., testified on complainant's behalf, after having reviewed records about Patients 1 to 10 and issued reports summarizing his opinions. Dr. Blumberg holds a California physician's and surgeon's certificate and is board-certified in pediatrics and pediatric infectious diseases. He is a professor at the University of California, Davis, School of Medicine, and the Chief of the Division of Pediatric Infectious Disease at the University of California, Davis, Children's Hospital.

78. Dr. Blumberg's clinical research has emphasized vaccine-preventable diseases and adverse events after vaccination. He has participated as an investigator in

vaccine clinical trials, including most recently in a study of a new vaccine against the Ebola virus. Overall, Dr. Blumberg's testimony demonstrates significant relevant expertise, and is persuasive.

79. To support and explain his medical immunization exemptions, respondent presented testimony from Mary Kelly Sutton, M.D. Dr. Sutton holds a California physician's and surgeon's certificate and is board-certified in internal medicine. Dr. Sutton considers herself a "complementary" or "integrative" practitioner, with special training in "anthroposophic" medicine. Dr. Sutton has no unusual knowledge or training about pediatric infectious disease, human genetics, or immunology.

80. Like Dr. Blumberg, Dr. Sutton reviewed records about Patients 1 to 10 and prepared a report summarizing her opinions. In most instances, however, Dr. Sutton not only repeated respondent's opinions but also cited him as the source for her views. Overall, her testimony is neither expert nor persuasive.

STANDARD OF CARE FOR PEDIATRIC VACCINATION DECISIONS

81. The evidence illustrated both risks and rewards to patients from vaccination. Adverse events after vaccination do occur, and Dr. Blumberg's own clinical practice includes investigating and treating such events. On the other hand, Dr. Blumberg testified persuasively that vaccination can benefit both the individual patient (by reducing the risk of acute or chronic ill health) and the patient's community (by reducing the patient's risk of transmitting infectious disease to other vulnerable people).

82. The ACIP Guidelines and the AAP Red Book synthesize and report scientific and medical recommendations from committee members who work in

medical care and public health, taking into account both potential harms and potential benefits from vaccination. These publications recommend specific vaccines for most patients, and schedules for administering those vaccines. They also identify circumstances under which a patient should not receive a vaccine, or should not receive one or more vaccines on the usual schedule.

83. Dr. Blumberg testified that in general, the standard of care for pediatricians in giving advice and making decisions about immunization is to follow the recommendations in the ACIP Guidelines and the AAP Red Book. A physician who advises against vaccination in a manner consistent with the ACIP Guidelines or the AAP Red Book would conform to the standard of care.

84. Dr. Blumberg acknowledged that the ACIP Guidelines and the AAP Red Book do not address every circumstance a pediatrician might encounter in making decisions about which vaccines (if any) to use to immunize a patient, and about when to use them. He also acknowledged that the recommendations in these publications have changed over time to reflect new information from clinical research and new or different vaccine products that have become available. According to Dr. Blumberg, a physician may depart from the ACIP Guidelines or the AAP Red Book if the physician has information leading reasonably to the conclusion that these publications do not address a patient's circumstances fully or precisely. To do so in a manner consistent with the standard of care, however, the physician must base any such departure on medical science.

85. Respondent and Dr. Sutton testified that they do not consider either the ACIP Guidelines or the AAP Red Book to offer reliable guidance for physicians regarding vaccination. In the first place, they believe that the ACIP and AAP

overestimate both the personal and the community benefits from vaccination.[6] In the second place, they believe that these organizations underestimate the general risks to all patients from any vaccinations. In the third place, respondent and Dr. Sutton testified that they believe the ACIP and AAP underestimate the specific risks of various vaccine products; and in the fourth place, they believe that the ACIP and AAP recommendations fail to account for research showing the risks that vaccines pose to individuals with specific genetic characteristics, personal health histories, or family health histories.

86. Because respondent and Dr. Sutton do not consider the ACIP Guidelines and the AAP Red Book to offer reliable vaccination guidance, they believe that professionally responsible physicians routinely should consider factors these publications do not address in advising patients about vaccination. They both testified, moreover, that any doubts about vaccination safety or efficacy that the physician may derive from these factors should weigh against vaccination.

87. Respondent and Dr. Sutton supported their opinion testimony by asserting, without further evidence, that the ACIP and AAP have disregarded scientific

[6] Dr. Sutton testified that she believes that improvements in sanitation, nutrition, and education, rather than vaccination, explain why diseases such as poliomyelitis, diphtheria, and pertussis are no longer major public health hazards in the United States.

information that conflicts with the views summarized in Findings 85 and 86.[7] They also stated that vaccine manufacturers and governmental regulatory agencies, both in the United States and worldwide, have conspired to bring many vaccine products to market without testing them either for safety or for efficacy; to permit manufacturers to sell products that include ingredients other than those the manufacturers have disclosed and that governmental regulatory agencies have approved; and to suppress emerging information about these products' hazards. They accused the ACIP, the AAP, and physicians who follow these organizations' recommendations of prioritizing pharmaceutical companies' profits and patients' conformity to governmental regulations over either individual or public health. Their opinions are not persuasive.

88. Dr. Blumberg's opinion that the standard of care is to follow the ACIP Guidelines and the AAP Red Book derives from his personal experience in clinical practice and research, and from his observation that pediatricians across the United States rely on these publications. Dr. Blumberg's description of the standard of care, as stated in Findings 83 and 84, is persuasive.

GENETIC TESTING AS A BASIS FOR VACCINATION EXEMPTIONS

89. As he had stated in the reports described above in Findings 29, 49, 50, and 71, respondent testified that some alleles of some human genes correlate statistically with their bearers' failure to respond to vaccines by developing immunity to the target infection(s). He also stated that some alleles of some genes correlate with

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[7] For example, respondent alluded to safety studies that he said were "not known to the conventional medical community," and insisted that "most physicians do not know anything about vaccine safety."

overresponse to vaccines, in the sense that vaccination prompts a person with one or more of those alleles to develop inappropriate auto-immunity rather than immunity targeting the infectious organism(s) the vaccine's manufacturer intended. Dr. Sutton offered no independent opinion, stating instead that respondent is more knowledgeable than she is about genetic influences on immune response.

90. No independent expert testimony corroborated respondent's testimony about genetic testing's actual or potential value for predicting a patient's response to any vaccine. Moreover, although respondent stated that he had developed his opinions in reliance on scientific publications, his testimony did not demonstrate that his understanding of these publications (or of other publications building on them) is accurate or up-to-date; that his extrapolation from these publications to his patients is reasonable; or that any other medical experts in genetics or immunology draw similar conclusions. Respondent's belief that the genetic information he obtained about Patients 1 to 10 is medically relevant to any decision about whether or when these patients should receive any vaccines is not persuasive.

91. Dr. Blumberg testified that no research has identified any specific alleles of any human genes that even correlate with, let alone cause, differences among patients in their immune responses to vaccination. He testified further that because research has identified no vaccine-relevant alleles of any human genes, genetic testing provides no information that will assist a physician in predicting a patient's response to vaccination. Any recommendations about vaccination based on genetic testing are speculative and irrational. For this reason, Dr. Blumberg's opinion is that respondent's reliance on genetic analyses to issue medical vaccination exemptions for Patients 1 through 10 was an extreme departure from the standard of care.

92. Dr. Blumberg's opinion rests on his experience both as a clinician and as an academic researcher. In addition, his opinion is consistent with the ACIP Guidelines and the AAP Red Book, neither of which recommend genetic testing to evaluate a patient's potential risks and benefits from vaccination. Dr. Blumberg's opinion regarding respondent's use of genetic testing for Patients 1 through 10, as described in Finding 91, is persuasive.

PATIENT AND FAMILY HISTORY AS A BASIS FOR VACCINATION EXEMPTIONS

93. Respondent admits, as described above in Findings 20, 22, 85, and 86, that he did not follow the ACIP Guidelines or the AAP Red Book in evaluating whether his patients' personal or family health histories made vaccination unsafe for them. Although he relied most heavily on genetic testing to support the vaccination exemptions he issued to Patients 1 through 10, he did also consider aspects of personal and family health history that the ACIP Guidelines and the AAP Red Book do not identify as relevant (as summarized above in Findings 24, 44, 46, 48, 56, 57, 59, 60, 69, and 70). Neither he nor Dr. Sutton cited any laboratory or clinical research, however, supporting their opinions that these personal and family health factors increased the likelihood that these patients would experience negative consequences from vaccination.[8]

[8] With respect to Patient 1, in particular, Dr. Blumberg testified persuasively that his VSD made him more vulnerable to serious illness from infectious disease than a similar infant without a VSD, and that for this reason vaccinating Patient 1 would have decreased his risk of medical harm in infancy and early childhood.

94. Furthermore, and as described in Findings 18, 24, 25, 34 through 36, 44, 45, and 56 through 63, respondent relied in every case solely on his patients' parents' reports about their children's or their family members' medical histories. Even when those reports were extreme, inconsistent, and facially implausible, such as for Patients 3 (described in Finding 34) and 8 (described in Finding 58), respondent made no effort to investigate them further.

95. With respect to personal and family health history matters that the ACIP Guidelines and AAP Red Book do not identify as contraindications or precautions to vaccination, Dr. Blumberg's opinion as stated in Findings 83 and 84 above is that respondent committed extreme departures from the standard of care by relying on those matters to issue medical vaccination exemptions. Even as to personal or family health history matters that the ACIP Guidelines and AAP Red Book identify as potentially relevant to vaccination, however, Dr. Blumberg testified that the standard of care requires a physician to obtain complete, accurate information about those matters before relying on them to make medical decisions. He characterized respondent's uncritical acceptance of his patients' parents' statements about their children's and family members' health histories as an extreme departure from this standard.

96. In his interview with Board investigators, respondent explained that he did not seek other medical records about patients who came to him seeking medical immunization exemptions, because he did not need "to verify that this is truth or not truth." Yet in his medical records, his reports to parents, and his hearing testimony, respondent relied repeatedly on his patients' and their family members' reported environmental allergies, auto-immune disorders, neurological problems, and previous

vaccine-related health problems to justify the vaccination exemptions he issued.[9] Dr. Blumberg's assessment of respondent's reliance on unverified personal and family health histories in his medical vaccination exemptions for Patients 1 through 10 is persuasive.

OTHER BASES FOR LIFELONG, UNIVERSAL VACCINATION EXEMPTIONS

97. According to Dr. Blumberg, the majority of the vaccination contraindications and precautions in the ACIP Guidelines and the AAP Red Book are vaccine-specific. He noted that respondent's stated reason for recommending genetic analysis for Patients 2 and 3 related to a post-vaccination nosebleed by Patient 3 (as described above in Finding 34). Dr. Blumberg's opinion is that a temporary exemption from all vaccinations for Patients 2 and 3, rather than from the specific vaccine(s) that preceded Patient 3's nosebleed, was an extreme departure from the standard of care.

98. In addition, Dr. Blumberg testified that a few contraindications and precautions stated in the ACIP Guidelines and in the AAP Red Book, such as acute illness, apply to all vaccinations but are time-limited rather than lifelong. He identified no circumstance for which the ACIP Guidelines or the AAP Red Book would recommend never vaccinating a person against any of the 10 diseases identified in Finding 12. In Dr. Blumberg's opinion, respondent's issuance of lifelong medical exemptions from all vaccination for Patients 1 and 4 through 10 also was an extreme departure from the standard of care.

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[9] Dr. Sutton relied on those same health histories, filtered for her evaluation through respondent's records and reports, in developing her favorable opinion of respondent's medical judgment.

99. To explain and defend respondent's universal vaccination exemptions, respondent and Dr. Sutton relied on the general precautionary principles described in Finding 86. Likewise, because respondent emphasized genetic traits as bases for his exemptions, he concluded that the exemptions for children who had received such testing should be lifelong.

100. As stated in Finding 87, respondent's and Dr. Sutton's opinions about general vaccine safety and about genetic influences on vaccine risk are not persuasive. For this reason, Dr. Blumberg's opinion is persuasive that respondent committed extreme departures from the standard of care by issuing universal vaccine exemptions, and by making most of those exemptions lifelong.

LEGAL CONCLUSIONS

1. The Board may take disciplinary action against respondent only if clear and convincing evidence establishes cause for such action.

2. The Health and Safety Code permits only licensed physicians to exempt children from otherwise mandatory immunization. (Health & Saf. Code, § 120370, subd. (a)(1).) The statute's references to a patient's "physical condition" and "medical circumstances . . . including, but not limited to, family medical history" as potential reasons for a physician to "not recommend immunization" (*id.*) do not authorize physicians to grant medical exemptions for non-medical reasons. Instead, issuing medical immunization exemptions under Health and Safety Code section 120370 is a medical activity that physicians must perform in a manner consistent with their professional responsibilities.

First Cause for Discipline (Genetic Testing as a Basis for Exemption)

3. The Board may suspend or revoke respondent's physician's and surgeon's certificate if he has engaged in unprofessional conduct, such as gross negligence, repeated negligence, or incompetence. (Bus. & Prof. Code, § 2234, subds. (b), (c), (d).) The matters stated in Findings 83, 84, 88, 91, and 92 establish cause under this statute for discipline against respondent arising from his issuance of medical vaccination exemptions for Patients 1 through 10 in reliance on spurious genetic analyses.

Second Cause for Discipline (Unverified Patient and Family History)

4. The matters stated in Findings 83, 84, 88, 95, and 96 also establish cause under Business and Professions Code section 2234, subdivisions (b), (c), and (d), for discipline against respondent arising from his issuance of medical vaccination exemptions for Patients 1 through 10 in reliance on unverified and medically irrelevant personal and family health histories.

Third Cause for Discipline (Blanket Exemptions)

5. The matters stated in Findings 83, 84, 88, 97, 98, and 100 also establish cause under Business and Professions Code section 2234, subdivisions (b), (c), and (d), for discipline against respondent arising from his issuance of baseless lifelong medical vaccination exemptions for Patients 1 and 4 through 10, and from his issuance of baseless exemptions to all vaccination for Patients 1 through 10.

Fourth Cause for Discipline (Inadequate Records)

6. A physician's failure "to maintain adequate and accurate records relating to the provision of services to [his] patients constitutes unprofessional conduct." (Bus.

& Prof. Code, § 2266.) As described in Findings 24, 27, 34, 39, 44, 46, 48, 56 through 60, 64, 69, and 70, respondent's records regarding Patients 1 through 10 demonstrate his unprofessional conduct with respect to these patients. Further, as described in Findings 31, 42, 53, and 73, other evidence did not show respondent's records to be incomplete or false. Complainant did not establish cause for discipline against respondent arising from inadequate or inaccurate medical record-keeping.

Disciplinary Considerations

7. Business and Professions Code section 2234.1 permits a licensed physician and surgeon to rely on "alternative," rather than "conventional," medical treatments and theories. Under this statute, a physician does not act unprofessionally simply by relying on medical opinions the physician shares with only a minority, rather than a majority, of other practitioners.

8. To qualify as professionally responsible alternative medical advice or treatment, however, such advice or treatment must follow "informed consent and a good-faith prior examination of the patient," including "information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine that he or she practices." (Bus. & Prof. Code, § 2234.1, subds. (a)(1), (a)(2).) In addition, alternative medical advice or treatment must not "delay" or "discourage traditional diagnosis." (*Id.*, subd. (a)(3).) Finally, professionally responsible alternative medical advice and treatment must "provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk" of the alternative strategy. (*Id.*, subd. (b).)

9. As stated in Findings 18, 24, 25, 34 through 36, 44, 45, and 56 through 63 and in Legal Conclusion 4, respondent did not undertake a good-faith prior examination of any of Patients 1 through 10 before issuing vaccination exemptions to them. Moreover, the very purpose of respondent's exemptions was to delay or discourage vaccination for Patients 1 through 10, even though the matters stated in Legal Conclusions 3, 4, and 5 confirm that no medical reasons existed for those children not to receive vaccination. Finally, the matters stated in Findings 11, 12, and 81 confirm that vaccine avoidance for Patients 1 to 10 increased their own and their communities' susceptibility to infectious disease despite offering these patients no potential personal benefit. None of the medical vaccination exemptions at issue in this matter are professionally responsible under Business and Professions Code section 2234.1.

10. The matters stated in Findings 24, 34, 35, 37, 44, 56 through 60, and 69 show that the parents of many of the 10 children whose exemptions are at issue in this matter were medically anxious. As illustrated in Findings 23, 59, and 60, many of these parents came to respondent specifically seeking medical immunization exemptions, not seeking medical advice with a basis in science. In exchange for $400 to $600 per child, as stated in Findings 32, 43, 54, 74, and 75, respondent sold these parents (and many others, as stated in Finding 17) the exemptions they sought.

11. The Medical Board's disciplinary responsibility is to protect the public both against the personal and public health hazards that result from negligent or incompetent medical practice and against physicians who abuse their licensure by exploiting medical ignorance or parental caution for financial gain. (Bus. & Prof. Code, §§ 2220.05, 2229.)

12. Respondent's issuance of medical vaccination exemptions to Patients 1 through 10 undermined public health and welfare. In addition, the matters stated in Findings 10, 18, 29, 39, 85, 87, and 94 and in Legal Conclusions 3, 4, 5, and 10 demonstrate both respondent's contempt for medical science and his unsuitability for probation. Public safety requires revocation of respondent's physician's and surgeon's certificate.

ORDER

Physician's and Surgeon's Certificate No. A 41183, held by respondent Kenneth Paul Stoller, M.D., is revoked.

DATE: 12/04/2020

Juliet E. Cox

JULIET E. COX
Administrative Law Judge
Office of Administrative Hearings

XAVIER BECERRA
Attorney General of California
JANE ZACK SIMON
Supervising Deputy Attorney General
LAWRENCE MERCER
Deputy Attorney General
State Bar No. 111898
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3488
Facsimile: (415) 703-5480
Attorneys for Complainant

FILED
STATE OF CALIFORNIA
MEDICAL BOARD OF CALIFORNIA
SACRAMENTO July 29 20 19
BY [signature] ANALYST

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **Kenneth Paul Stoller, M.D.** **2020 County Center Dr. Suite C** **Santa Rosa CA 95403** **Physician's and Surgeon's Certificate No. A 41183** Respondent.	Case No. 800-2017-034218 **A C C U S A T I O N**

PARTIES

1. Kimberly Kirchmeyer (Complainant) brings this Accusation solely in her official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about September 10, 1984, the Medical Board issued Physician's and Surgeon's Certificate Number A 41183 to Kenneth Paul Stoller, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2019, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 2220 of the Code states:

Except as otherwise provided by law, the Board may take action against all persons guilty of violating this chapter. The Board shall enforce and administer this article as to physician and surgeon certificate holders, including those who hold certificates that do not permit them to practice medicine, such as, but not limited to, retired, inactive, or disabled status certificate holders, and the Board shall have all the powers granted in this chapter for these purposes including, but not limited to:

(a) Investigating complaints from the public, from other licensees, from health care facilities, or from the Board that a physician and surgeon may be guilty of unprofessional conduct. The Board shall investigate the circumstances underlying a report received pursuant to Section 805 or 805.01 within 30 days to determine if an interim suspension order or temporary restraining order should be issued. The Board shall otherwise provide timely disposition of the reports received pursuant to Section 805 and Section 805.01.

(b) Investigating the circumstances of practice of any physician and surgeon where there have been any judgments, settlements, or arbitration awards requiring the physician and surgeon or his or her professional liability insurer to pay an amount in damages in excess of a cumulative total of thirty thousand dollars ($30,000) with respect to any claim that injury or damage was proximately caused by the physician's and surgeon's error, negligence, or omission.

(c) Investigating the nature and causes of injuries from cases which shall be reported of a high number of judgments, settlements, or arbitration awards against a physician and surgeon.

5. Section 2234 of the Code states, in pertinent part:

The Board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.

(b) Gross negligence.

(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

(d) Incompetence.

6. Section 2266 of the Code states:

The failure of a physician and surgeon to maintain adequate and accurate records relating to

the provision of services to their patients constitutes unprofessional conduct.

OTHER STATUTES

7. Health and Safety Code section 120325 provides:

In enacting this chapter, but excluding Section 120380, and in enacting Sections 120400, 120405, 120410, and 120415, it is the intent of the Legislature to provide:

(a) A means for the eventual achievement of total immunization of appropriate age groups against the following childhood diseases:

(1) Diphtheria.

(2) Hepatitis B.

(3) Haemophilus influenza type b.

(4) Measles.

(5) Mumps.

(6) Pertussis (whooping cough).

(7) Poliomyelitis.

(8) Rubella.

(9) Tetanus.

(10) Varicella (chickenpox).

(11) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

(b) That the persons required to be immunized be allowed to obtain immunizations from whatever medical source they so desire, subject only to the condition that the immunization be

performed in accordance with the regulations of the department and that a record of the immunization is made in accordance with the regulations.

(c) Exemptions from immunization for medical reasons.

(d) For the keeping of adequate records of immunization so that health departments, schools, and other institutions, parents or guardians, and the persons immunized will be able to ascertain that a child is fully or only partially immunized, and so that appropriate public agencies will be able to ascertain the immunization needs of groups of children in schools or other institutions.

(e) Incentives to public health authorities to design innovative and creative programs that will promote and achieve full and timely immunization of children.

8. Health and Safety Code section 120370 provides, in pertinent part:

(a) If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician does not recommend immunization, that child shall be exempt from the requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician's statement.

FACTUAL ALLEGATIONS

9. At all relevant times, Respondent Kenneth P. Stoller, M.D., was a physician and surgeon with a specialization in pediatrics at his office in San Francisco, California.

10. In 2015, the California Legislature amended Health and Safety Code section 120325 to eliminate personal beliefs as a basis for exemption from required immunizations for school-aged children. As a consequence, school-aged children not subject to any other exception were

required to have immunizations for 10 vaccine-preventable childhood illnesses as a condition of public school attendance.

11. Beginning in 2016, Respondent began issuing medical exemptions to school-aged children.

12. Patient 1, a 4-month old male, was seen by Respondent on or about August 9, 2016. Patient 1[1] had a medical history significant for a congenital heart defect, and reports of vomiting, shortness of breath and difficulty gaining weight. Respondent's records state a history of present illness (HPI) as the parents' concern about an adverse event from immunization (AEFI). Respondent did not document an examination or record vital signs. His plan was to test for HLA DRB1/DQB1 genes. Based on subsequent testing, Respondent concluded that the HLA-DRB1*13 allele was absent and that the child had an HLA DRB1 03 allele, which genetic polymorphisms Respondent concluded would likely make him a vaccine non-responder to the vaccines for measles and hepatitis B. Albeit he had not identified any vaccine contraindication or precaution, as defined by the Centers for Disease Control and Prevention and/or the American Academy of Pediatrics, Respondent issued a medical exemption for Patient 1 that was global, i.e. applying to all vaccines, and permanent in duration.

13. Patient 2, a 2.5-year old female, was seen by Respondent on September 27, 2018. The examination documented for Patient 2 was within normal limits and her medical history was unremarkable for any contraindications or precautions for any vaccines. Nevertheless, Respondent issued a temporary medical exemption based upon the history of a sibling who reportedly had an AEFI after his 6-month immunizations and had thereafter developed a learning disability. Although the temporary exemption stated that the child would be undergoing an "Adverse Event Risk Assessment," no further testing or evaluation was performed and/or documented.

14. Patient 3, the 4.5 year old male sibling of Patient 2, was also seen by Respondent on September 27, 2018. The parents reported that they believed Patient 3 had developed dyspraxia/apraxia after receiving a set of six immunizations at age 6 months. They reported that

[1] Patients' names are redacted to protect privacy.

the morning after he received the vaccines, Patient 3 was found lying in "a puddle of blood and vomitus." Respondent described the reported event variously as "near SIDS," "near exsanguitory" and an "acute encephalitic response" or AEFI. Respondent did not obtain the child's pediatric records, nor did he investigate further. Respondent's plan was to perform genetic testing, however, such testing is not documented and apparently was not done. Respondent issued a temporary exemption from all required vaccinations.

15. Patient 4, a 4-year old female, was seen by Respondent on December 14, 2015. At that time, the child's mother reported that the child had not had any immunizations and that the mother was concerned that the child might have a genetic predisposition to adverse reactions to vaccinations, based upon a family history of autoimmune illnesses and relatives with neurodevelopmental issues and autism. Respondent did not obtain or review any past medical records. On or about April 29, 2016, Respondent issued a medical exemption letter for Patient 4. In that document, Respondent stated that Patient 4 "has genetic issues" and as a result, "she is at high risk of adverse events to vaccination so that vaccinations are not considered safe." As with Patient 1, discussed above, the exemption is permanent and barred administration of any and all vaccines. In his "Adverse Event Risk Assessment Report," Respondent stated that the basis for his conclusion that vaccines were unsafe for the child was that "the patient has the IRF1/MTHFR/IL-4 polymorphism." In a subsequent interview, Respondent acknowledged that genetic polymorphisms are not recognized by the CDC as medical contraindications to vaccination.

16. Patient 5, a 6-year old female, was seen by Respondent on December 18, 2017. Prior to that visit, as was his custom and practice, Respondent conducted a telephone interview with the child's father. In that interview, the HPI was stated as the parent's concern that the child would be at risk of an adverse vaccine reaction based upon a sibling with "post vaccine auto-immune issues including but not limited to chronic joint pain and allergies to various foods, gluten and metals." Respondent's plan was to perform genetic testing, for which the parents were instructed to purchase "23 and Me" a direct-to-consumer ancestry and genetic testing product. Respondent then interpreted the raw data to conclude that the child had multiple polymorphisms on multiple

genes which he stated were related to adverse risks from vaccinations. Respondent issued a permanent exemption from all vaccinations for the child, which stated that "vaccination is not considered safe due to [Patient 5's] specific genetics."

17. Patient 6, a 12-year old male child and sibling of Patient 5, underwent the same evaluation as his sister and received a permanent and global exemption from all vaccinations based upon genetic polymorphisms.

18. Patient 7, a 5-year old female, was seen by Respondent on January 3, 2018. Prior to that visit, in a telephone consultation, the child's parents had attributed the child's dyspraxia and speech delay to previous vaccinations and requested a genomic assessment. Respondent concluded that the child had polymorphisms on 8 of 12 genes associated with adverse event following immunization (AEFI), specifically IRF1 and SCN1A and "a cousin with documented AEFI (VAERS)." No medical documentation relating to the cousin is contained in Respondent's chart. The exemption is permanent and applies to all required vaccines.

19. Patient 8, a 12-year old female, was seen by Respondent on December 7, 2017. That was preceded by an August telephone consultation with the child's parents. which Respondent summarized as a discussion of her prolonged encephalitic reaction and "stroke" related to a Hepatitis B vaccine. Patient 8 was given a permanent exemption from all vaccinations based upon her "unusual history" and on polymorphisms on HLA DRB1 AND SCN1A genes.

20. Patient 9, a 12-year old female, was evaluated by Respondent on January 3, 2018. The visit was preceded by a September 13, 2017 telephone call from the child's mother in which the mother stated that the child needed an exemption within ten days or "she can't go to school." In a telephone consultation that took place on the following day, Respondent made note that the child has "immediate family members with multiple autoimmune diseases and who seems to have gone thru a multiple year period of having very compromised health post vaccination including but not limited to multiple URI/LRI, asthma, atopia and otitis infections." A temporary exemption was issued as to all vaccines and, after testing, a permanent and global exemption was issued based on double mutation on the HLA DQB1 and double mutation on the IRF1 gene, which

Respondent stated "play such a strong roll [sic] in having untoward immune reactions to foreign substances and biotoxins."

21. Patient 10, a 5-year old female, was seen on March 8, 2018. During an earlier telephone consultation, Patient 10's mother had requested that the child be screened for genetic risk from vaccines and she related a family history of "auto-immune issues" and an older sibling who developed "overt neuro-behavioral delays" after receiving vaccines. The mother complained that the school nurse "sees it as her job to protect the community from unvaccinated children." The same at-home genetic test resulted in findings of multiple polymorphisms and Respondent opined that the child was at increased risk of an AEFI and should be permanently exempted from all required vaccinations.

FIRST CAUSE FOR DISCIPLINARY ACTION

(Gross Negligence/Repeated Negligent Acts/Incompetence)

22. Respondent Kenneth Paul Stoller, M.D. is subject to disciplinary action pursuant to section 2234 and/or 2234(b) and/or 2234(c) and/or 2234(d) in that Respondent engaged in unprofessional conduct and was grossly negligent and/or repeatedly negligent and/or incompetent in his care and treatment of the patients described in paragraphs 12 and 15 through 21 above, which are incorporated herein.

23. Respondent routinely performed genetic testing for the purpose of determining whether a child should be exempted from required vaccinations. Genetic testing in order to determine vaccine response or risk for adverse events following immunization is not recommended by the Centers for Disease Control and Prevention (CDC) or the American Academy of Pediatrics (AAP). The standard of care for a primary care provider and specialist is to follow national standards for pediatric vaccination practices and immunization recommendations from the CDC, issued through the Advisory Committee on Immunization Practices, and the American Academy of Pediatrics, as summarized in The Red Book. Genetic variations in the population are normal and to be expected. While some differences exist, at the present time, no allele serves as a marker that accurately predicts vaccine response. A permanent

exemption for all vaccines based on the polymorphisms described by Respondent is not supported by medical and scientific evidence and constitutes grounds for disciplinary action pursuant to the statutes set forth in paragraph 22.

SECOND CAUSE FOR DISCIPLINARY ACTION

(Gross Negligence/Repeated Negligent Acts/Incompetence)

24. Respondent Kenneth Paul Stoller, M.D. is subject to disciplinary action pursuant to section 2234 and/or 2234(b) and/or 2234(c) and/or 2234(d) in that Respondent engaged in unprofessional conduct and was grossly negligent and/or repeatedly negligent and/or incompetent in his care and treatment of the patients described in paragraphs 12 through 21 above, which are incorporated herein.

25. Respondent routinely obtained and relied upon unverified patient and family histories, including but not limited to autoimmune disorders, asthma, gluten sensitivity, inflammatory bowel disease, Hashimoto's disease and other conditions not generally accepted to constitute precautions or contraindications to vaccines. The standard of care for a primary care provider and specialist is to follow national standards for pediatric vaccination practices and immunization recommendations from the CDC, issued through the Advisory Committee on Immunization Practices, and the American Academy of Pediatrics, as summarized in The Red Book. The conditions described in Respondent's records are not considered precautions or contraindications for routine immunizations by the CDC or AAP. The histories obtained by Respondent are typically scant and insufficiently documented as accepted diagnoses. To document an existing or family history of a condition or reaction without specification of the condition, the person who had the condition and their relation to the patient, and the specific vaccine or vaccine component that the condition or reaction related to, is not standard medical charting. In some cases, Respondent recorded a history of potentially very serious events, such as near SIDS, near exsanguination or acute encephalitis, but he did not obtain the pertinent medical records or otherwise investigate. Respondent's provision of medical exemptions based on conditions not generally accepted as medical precautions or contraindications, his inadequate documentation of patient and family histories and failure to obtain records and/or investigate

potentially very serious events fall below the standard of care and constitute grounds for discipline pursuant to the statutes set forth in paragraph 24 above.

THIRD CAUSE FOR DISCIPLINARY ACTION

(Gross Negligence/Repeated Negligent Acts/Incompetence)

26. Respondent Kenneth Paul Stoller, M.D. is subject to disciplinary action pursuant to section 2234 and/or 2234(b) and/or 2234(c) and/or 2234(d) in that Respondent engaged in unprofessional conduct and was grossly negligent and/or repeatedly negligent and/or incompetent in his care and treatment of the patients described in paragraphs 12 through 21 above, which are incorporated herein.

27. Respondent routinely issued exemptions that applied to all vaccines. There is no component that is common to all vaccines. A severe reaction to an earlier dose of a specific vaccine may be a contraindication for another dose of that vaccine or to a dose of a related vaccine that also contains the same constituents, but not to all vaccines. Similarly, a moderate or severe acute illness might be a temporary precaution, resulting in deferral of immunization, but not a permanent, global contraindication to all vaccines. Respondent's issuance of vaccine exemptions which are not specific to a particular vaccine and are permanent and global falls below the standard of care and constitutes grounds for discipline pursuant to the statutes set forth in paragraph 26 above.

FOURTH CAUSE FOR DISCIPLINARY ACTION

(Inadequate Records)

28. Respondent Kenneth Paul Stoller, M.D. is subject to disciplinary action pursuant to section 2266 in that Respondent failed to maintain adequate and accurate records. As stated above, Respondent's records contain only scant and vague patient and family histories, lack vaccine-specific evaluations, contain diagnoses not supported by the findings or by medical science and omit reference to prior medical records and/or primary care physicians.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate Number A 41183, issued to Respondent.;

2. Revoking, suspending or denying approval of Respondent's authority to supervise physician assistants and advanced practice nurses;

3. Ordering Respondent, if placed on probation, to pay the Board the costs of probation monitoring; and

4. Taking such other and further action as deemed necessary and proper.

DATED: July 29, 2019

KIMBERLY KIRCHMEYER
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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