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. A41183 Respondent	Case No. 800-2017-034218

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

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[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

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[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]

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[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

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

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

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

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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