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2	JANE ZACK SIMON Supervising Deputy Attorney General	FILED	
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4	State Bar No. 111898	SACRAMENTO JULY 29 20 19	
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8	BEFORE THE		
9	MEDICAL BOARD OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF CALIFORNIA		
11	In the Matter of the Accusation Against:	G N 900 2017 024219	
12	Kenneth Paul Stoller, M.D.	Case No. 800-2017-034218	
13	2020 County Center Dr. Suite C Santa Rosa CA 95403	ACCUSATION	
14	Dharisiants and Comment Classes AV A 44400	·	
15	Physician's and Surgeon's Certificate No. A 41183		
16	Respondent.		
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18	PART	<u> </u>	
19	Kimberly Kirchmeyer (Complainant) brings this Accusation solely in her official		
20	capacity as the Executive Director of the Medical Board of California, Department of Consumer		
21	Affairs (Board).		
22	,		
23	2. On or about September 10, 1984, the Medical Board issued Physician's and Surgeon's		
24	Certificate Number A 41183 to Kenneth Paul Stoller, M.D. (Respondent). The Physician's and		
25	Surgeon's Certificate was in full force and effect at all times relevant to the charges brought		
26	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

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 schoolaged 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 1¹ 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.

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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

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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

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27 28 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	1.	1. Revoking or suspending Physician's and Surgeon's Certificate Number A 41183,	
2	issued to Respondent.;		
3	2.	2. Revoking, suspending or denying approval of Respondent's authority to supervise	
4	physician assistants and advanced practice nurses;		
5	3.	3. Ordering Respondent, if placed on probation, to pay the Board the costs of probation	
6	monitoring	monitoring; and	
7	4.	4. Taking such other and further action as deemed necessary and proper.	
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9	DATED:	July 29, 2019 Kully Kully	
10	KIMBERLY/KIRCHMEYER Executive Director		
11		Medical Board of California Department of Consumer Affairs State of California	
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