

IN THE MATTER OF
MARK R. GEIER, M.D.,

Respondent.

*** BEFORE THE MARYLAND**
*** STATE BOARD OF**
PHYSICIANS

*** Case Nos. 2007-0083, 2008-0454,**
2009-0308

* * * * *

FINAL DECISION AND ORDER

I. Procedural History

On April 27, 2011, the Maryland State Board of Physicians (the “Board”) summarily suspended the license of the respondent, Mark R. Geier, M.D., who at all times relevant to this matter has been licensed to practice medicine in the State of Maryland, because the Board concluded, pursuant to section 10-226(c)(2) of the State Government Article, that the public health, safety or welfare imperatively required such emergency action. Dr. Geier attended a post-deprivation hearing before the Board on May 11, 2011. On May 12, 2011, the Board reaffirmed that summary suspension, subject to Dr. Geier’s right to request a full evidentiary hearing before an Administrative Law Judge (“ALJ”) of the Office of Administrative Hearings. Dr. Geier requested and obtained a full evidentiary hearing, and the matter was heard before an ALJ on June 17, 20, 21, 23, 27, and 30, 2011, at the Office of Administrative Hearings in Hunt Valley, Maryland.

The parties submitted five joint exhibits. The Administrative Prosecutor submitted thirty-six exhibits and presented the testimony of two witnesses: a parent of one of Dr. Geier's patients and an expert. The ALJ accepted Linda Elizabeth Sullivan Grossman, M.D., as an expert in the following fields:

- Pediatrics
- Developmental behavioral pediatrics
- Diagnosis and treatment of children with neurodevelopmental disorders, including autism
- Generally accepted treatment of children with neurodevelopmental disorders, including autism
- Generally accepted indications for chelation
- Pharmacology related to children with autism
- Interpretation of lab studies of children with autism
- Off-label use of drugs in the area of pediatrics
- Appropriate medical documentation
- Appropriate use of billing codes
- Use of diagnostic codes.

Dr. Geier presented thirty-four exhibits and the testimony of nine witnesses, including four experts and the parents of five of his patients. The ALJ accepted James Brewster Adams, Ph.D as an expert in chelation and scientific and research knowledge applied to autistic children; Mary Norfleet Megson, M.D. as an expert in the standard of care for the diagnosis and treatment of autistic children, the use of Lupron and the efficacy and safety of Lupron in autistic children, and the off-label use of drugs for autistic children; Georgia Davis, M.D. as an expert in the standard of care in the treatment of autistic children, the efficacy and safety of the use of Lupron for treating autistic children, and the appropriateness of off-label use of drugs in the treatment of

autistic children; and Jerald Kartzinell, M.D. as an expert in the standard of care in the treatment of autistic children, the efficacy and safety of the use of Lupron for the treatment of autistic children, and the efficacy and appropriateness of off-label use of drugs with autistic children.

The ALJ issued her proposed decision on September 26, 2011, a copy of which is attached to and incorporated into this Final Decision and Order as Attachment 1. The ALJ proposed that Dr. Geier's license be summarily suspended until the resolution of the charges against his license.

Both the Administrative Prosecutor and Dr. Geier filed exceptions with the Board and responded to the other party's exceptions. The Board held a hearing on the exceptions on December 21, 2011. This Final Decision and Order is the Board's final ruling on the summary suspension issue, *i.e.*, whether the public health, safety or welfare imperatively requires emergency action, within the meaning of Md. Code Ann., State Gov't § 10-226(c) (2), to prohibit Dr. Geier's continued practice of medicine pending the resolution of the case on the merits. In making this decision, the Board has considered the entire record in this case, including the written exceptions filed by both parties and the oral arguments made by both parties at the Exceptions Hearing.

II. Findings of Fact

The Board adopts the Findings of Fact made by the ALJ and incorporates them by reference into this Final Decision and Order.

III. Conclusions of Law

With the exception of the conclusion regarding the credibility of Parent A, the Board adopts the ALJ's conclusions of law discussed at pages 39 through 63 of the Proposed Decision.¹

IV. The Exceptions

Both the Administrative Prosecutor and Dr. Geier filed exceptions to the ALJ's Proposed Decision. After careful consideration of the parties' written submissions and the arguments at the exceptions hearing, the Administrative Prosecutor's exception regarding the testimony of Parent A is sustained. Her other exception, and all of Dr. Geier's exceptions, are overruled.

A. The ALJ mischaracterized Parent A's testimony.

Parent A testified about the two appointments that her son, Patient C, had at Genetics Centers of America – one in 2005 and one in 2008. In 2005, she and her son met with both Dr. Geier and his son, David Geier. In 2008, she and her son met with David Geier in an office. She testified that she recalled “David Geier saying that [her] son was like a high-testosterone kid right off the bat. Just looking at him” Hearing Transcript at 83. Parent A characterized David Geier's statement as a diagnosis. *Id.*

¹ The ALJ dismissed the allegations regarding the Internal Review Board and Dr. Geier's credentials. *See* Proposed Decision at 48-49. Apparently, the issues of the Internal Review Board and Dr. Geier's credentials were not fully litigated. In fact, it appears that these issues were essentially dropped by the Administrative Prosecutor because they were not relevant to the issue of summary suspension. The Board itself concludes that these issues were not relevant to the summary suspension issue, and the Board will not consider these issues or make any findings on them in this final decision. The Board thus adopts the ALJ's conclusion on these issues only to the extent that these issues should be disregarded because they are not relevant to the summary suspension issue.

After this exchange, Parent A testified that David Geier took her and her son into another room for the purpose of performing a sonogram. *Id.* at 84. After they entered the other room, Parent A explained that “someone came into the room. I don’t know what she was” *Id.* On cross-examination, Parent A confirmed that “an unnamed female,” David Geier, her son, and she were in the room where the sonogram was to be performed. *Id.* at 113. On cross-examination, Dr. Geier’s attorney did not ask Parent A about David Geier’s remarks about her son, or about her characterization of those remarks as a diagnosis. *See id.* at 109-18.

The ALJ discounted Parent A’s testimony because she “did not find Parent A to be a reliable reporter.” Proposed Decision at 57-58. According to the ALJ, Parent A admitted on cross-examination that there was a fourth person in the treating room and that David Geier had made an observation, not a diagnosis. Neither finding is supported by the actual testimony given by Parent A. Parent A actually was consistent in her testimony, both direct and cross, that four persons were in the room where the sonogram was performed; and Parent A was not even asked on cross examination about her characterization of David Geier’s remarks about her son. Under these circumstances, the Board rejects the ALJ’s findings that Parent A’s testimony should be discredited because of these perceived inconsistencies. Although this erroneous characterization of Parent A’s testimony is not in any way critical to the case, the Board wishes to correct this error for the record. The Board finds no reason to discredit Parent A’s testimony.

B. The ALJ correctly ruled that proof of two peer reviews is not needed for a summary suspension.

Section 10-226(c)(2) of the State Government Article authorizes a unit of state government to “order summarily the suspension of a license if the unit . . . finds that the public health, safety, or welfare imperatively requires emergency action” and gives the licensee prompt notice and an opportunity to be heard. Md. Code Ann., State Gov’t § 10-226(c)(2) (2009). Nothing in that statute, or in the Board’s regulations dealing with summary suspensions at COMAR 10.32.02.05, imposes any requirement of the use of peer reviewers. Dr. Geier’s contention to the contrary is overruled.²

C. The ALJ properly accepted Dr. Grossman as an expert witness.

Dr. Grossman is a board certified pediatrician and developmental behavioral pediatrician. In the view of the ALJ, she has experience and training that qualify her to testify about the diagnosis and treatment of children with neurodevelopmental disorders, including children with autism, chelation therapy, interpretation of laboratory testing of children with autism, the off-label use of drugs in pediatric practice, appropriate medical documentation, and the use of diagnostic codes and billing codes. The Board agrees, based on its own experience and medical knowledge, that Dr. Grossman is eminently

² The use of peer reviewers is a required procedure in some cases arising under a different statute, the Medical Practice Act. *See, e.g.*, Md. Code Ann., Health Occ. § 14-404(a) (22) & (40). Even in the context of the Medical Practice Act, however, the use of peer reviewers is only a pre-charge procedure. “The peer review panel does not determine whether the accused physician ... is ‘guilty’ of anything, only whether there is sufficient basis for the filing of charges.” *Board of Physician Quality Assurance v. Levitsky*, 353 Md. 188, 206 (1999).

qualified to serve as an expert in this matter. The Board thus declines to disturb the ALJ's ruling accepting her as an expert witness.

The ALJ correctly identified the standard for accepting a person as an expert: Does that person have information that would be helpful to the ALJ as fact finder, taking into consideration the witness' training and experience? *See* Md. Code Ann., State Gov't § 10-213(b) (ALJ may give probative effect to evidence that reasonable and prudent individuals accept). The ALJ also correctly distinguished between the admissibility of Dr. Grossman's expert testimony and the weight to be given that testimony. *See Wantz v. Afzal*, 197 Md. App. 675, 690 (2011). Based on the Board's review of the record in this matter, as well as the ALJ's Proposed Decision, the Board concludes that Dr. Grossman has the necessary experience, education, and training to assist the Board in its assessment of the need for emergency action.

D. The ALJ correctly determined that Dr. Geier's practice raises "a substantial likelihood of a risk of serious harm to the public health, safety, or welfare."

Dr. Geier objects to the ALJ's Proposed Decision because (1) Dr. Grossman did not use the "right" words in stating her opinion of the risks posed by Dr. Geier's practice; (2) the ALJ allegedly misunderstood the patients' records; and (3) the ALJ established an inappropriate standard for treatment of children with autism and the medical records documenting that treatment. These claims have no merit.

As the ALJ noted, Dr. Grossman consistently expressed her concerns about the risk that she believed Dr. Geier's practice posed to his patients. Proposed Decision at 46-47. The ALJ acknowledged that Dr. Grossman did not always respond to questions about risk by repeating the words of the applicable regulation, but the ALJ refused to dismiss the Board's summary suspension for that reason. *See* Proposed Decision at 48 ("I am *assisted* in this determination by the expert witness, not controlled by the witness.") (emphasis in original). The Board agrees that the Administrative Prosecutor offered ample evidence through the testimony of Dr. Grossman, Dr. Geier's sworn statement, and his patients' medical records to prove the necessity of the Board's Order for Summary Suspension. Thus, although Dr. Grossman did not always use the precise words of the Board's regulations, the ALJ correctly denied Dr. Geier's motion for judgment.

Furthermore, the ALJ did not "misunderstand" the patients' medical records, as Dr. Geier contends. For example, Dr. Geier claims that the ALJ erroneously criticized Dr. Geier for failing to determine the Tanner Stage of his patients so that he could properly interpret laboratory tests. His argument fails to acknowledge that his own experts testified about the importance of Tanner Staging before the administration of Lupron. *See, e.g.,* Transcript at 951 (Dr. Megson determines Tanner Stage before administering Lupron); Transcript at 1005, 1015 (Dr. Kartzinel testified that Tanner Staging is important to include in a workup); Transcript at 1076-77 (Dr. Kartzinel uses Harriet Lane Textbook on Pediatrics to determine Tanner Stage). Similarly, Dr. Geier

contends that the ALJ erred in her evaluation of Dr. Geier's chelation treatment, but fails to recognize that the ALJ's findings rely at least in part on the testimony of Dr. Geier's own expert. *See* Proposed Decision at 28-32. The Board agrees with the ALJ's evaluation of the evidence presented.

Finally, Dr. Geier accuses the ALJ of establishing a new and unwarranted standard for the medical care of children with autism. Again, Dr. Geier fails to acknowledge that the ALJ relied to some extent on the testimony of his own expert witnesses, and on his own sworn statement, to make her findings regarding the standard of care and the deficiencies in Dr. Geier's practice. *See, e.g.*, Proposed Decision at 8 ¶ 18, 10 ¶ 19(i), 11 ¶ 20. After consideration of this entire record, The Board agrees with the ALJ's assessment of all of the evidence presented in this lengthy proceeding.

The ALJ concluded that "allowing [Dr. Geier] to continue practicing medicine while formal charges are pending raises a substantial likelihood of risk of serious harm to the public health, safety, or welfare." The Board entirely agrees. For Dr. Geier to practice medicine at this time would constitute a danger to the patient community.³

E. The remaining exceptions are overruled.

To the extent that any of the parties' exceptions are not discussed explicitly in this Final Order and Decision, the Board overrules them.

³ Lupron treatment carries a very high risk of skin abscesses and infections, and it is contraindicated in patients with a history of seizures. Dr. Geier nevertheless prescribed it for Patient B, who had a history of uncontrolled seizures. Nor did Dr. Geier perform all of the necessary diagnostic procedures before prescribing Lupron. Nor did Dr. Geier physically examine Patient B until almost three years after he began prescribing for him. *See* Proposed Decision at 33, 37-38. This is only one example of the truly risky behavior that Dr. Geier engaged in with these patients.

V. Order

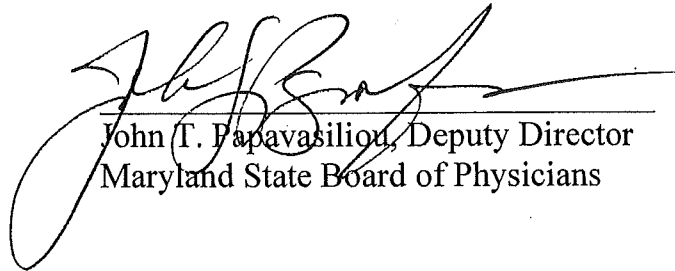
Based on the above Findings of Fact and Conclusions of Law, it is hereby **ORDERED** as follows:

The Board's **ORDER FOR SUMMARY SUSPENSION** is **UPHELD**; and it is further

ORDERED that the summary suspension of Dr. Geier's license to practice medicine is **CONTINUED** pending the resolution of the formal charges against his license; and it is further

ORDERED that this Final Decision and Order shall be considered a **PUBLIC DOCUMENT** pursuant to Md. State Gov't Code Ann. § 10-611 *et seq.* (2009).

SO ORDERED this 22nd day of March, 2012.



John T. Papavasiliou, Deputy Director
Maryland State Board of Physicians

NOTICE OF RIGHT TO APPEAL

Pursuant to section 14-408(a) of the Health Occupations Article of the Maryland Annotated Code and the applicable regulations, Dr. Geier has the right to appeal this decision to the Board of Review of the Department of Health and Mental Hygiene within thirty days of the date of this order at:

Maryland State Department of Health and Mental Hygiene
Board of Review
c/o Carlean Rhames-Jowers, Liaison
201 West Preston Street, 5th floor
Baltimore, MD 21201

If Dr. Geier files an appeal, the Board is a party and should be served with a copy of the notice of appeal. In addition, Dr. Geier should send a copy to the Board's counsel, Thomas W. Keech, Esq. at the Office of the Attorney General, 300 West Preston Street, Suite 302, Baltimore, Maryland 21201. The Administrative Prosecutor is not involved in the appeal process and need not be served or copied on pleadings filed in the appeal.

.....

STATE BOARD OF PHYSICIANS

v.

MARK R. GEIER, M.D.,
License # D24250,

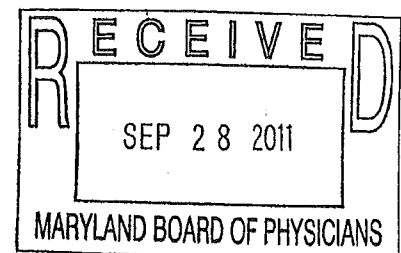
RESPONDENT

* BEFORE GEORGIA BRADY,
* AN ADMINISTRATIVE LAW JUDGE
* OF THE MARYLAND OFFICE
* OF ADMINISTRATIVE HEARINGS
* CASE NO: DHMH-SBP-72-11-19949
* SBP CASE NOS: 2007-0083, 2008-0454,
* 2009-0308

* * * * *

PROPOSED DECISION¹

STATEMENT OF THE CASE
ISSUES
SUMMARY OF THE EVIDENCE
STIPULATIONS OF FACT
FINDINGS OF FACT
DISCUSSION
CONCLUSIONS OF LAW
PROPOSED DISPOSITION



STATEMENT OF THE CASE

The Maryland State Board of Physicians (Board) summarily suspended the Respondent's license to practice medicine in the State of Maryland on April 27, 2011, on the grounds that the public health, safety, or welfare imperatively required such action. Md. Code Ann., State Gov't section 10-226(c)(2) (2009). The Respondent appealed on May 16, 2011.

I held a hearing in this matter on June 17, 20, 21, 23, 27 and 30, 2011, at the Office of Administrative Hearings (OAH), 11101 Gilroy Road, Hunt Valley, Maryland. The Respondent was

¹ Referred to in this document as the "Decision."

represented by Joseph A. Schwartz, III, Esquire, and J. Steven Wise, Esquire. Victoria H. Pepper, Assistant Attorney General was the Administrative Prosecutor who represented the State of Maryland.

Procedure in this case is governed by the contested case provisions of the Administrative Procedure Act, the Rules of Procedure of the Board, and the Rules of Procedure of the OAH. Md. Code Ann., State Gov't §§ 10-201 through 10-226 (2009 & Supp. 2011); Code of Maryland Regulations (COMAR) 10.32.02; and COMAR 28.02.01.

The Respondent made a Motion for Judgment (Motion) at the end of the State's case. For reasons explained on the record and pursuant to my authority under COMAR 28.02.01.12B(5), (6) and E(2)(b) and 28.02.01.11A(2) and B(11), I declined to rule from the bench on that Motion, finding good cause to issue a ruling in writing. Due to the large number of out-of-town witnesses waiting to testify in the Respondent's case, and also because my authority in this matter is limited to issuing a Proposed Decision, I proceeded to hear the case so that a complete record, including the Motion, would be presented to the Board. I informed the parties that I would rule on the Motion in this Decision, based solely upon the evidence admitted as of the time the Motion was made.

ISSUES

(1) Should all or part of the Order for Summary Suspension be dismissed, pursuant to the Motion, on the following grounds:

a. Do sections 14-401(e) and 14-404(a)(22) of the Health Occupations Article of the Maryland Code² require the State to obtain and produce two peer reviewers to establish the standard of care in a summary suspension proceeding? If so, and if the State failed to do so, should a portion or all of the Order for Summary Suspension be dismissed?

² (2009 & Supp. 2011). Sections of the Health Occupations Article of the Maryland Code will hereafter be referred to as "HO § ____."

b. Is Dr. Grossman, the peer reviewer presented by the State and its only expert witness, a “peer” of the Respondent? If not, and if peer review is required to establish “standard of care,” did the State fail to meet the requirements of HO sections 14-401(e) and 14-404(a)(22) to obtain and produce a “peer” review to establish standard of care, and, thus, should the entire Order for Summary Suspension be dismissed?

c. If the State’s expert testified only as to whether individual patients faced a “significant risk of harm,” did it meet its burden, pursuant to COMAR 10.32.02.05B(7)(a) and COMAR 10.32.02.02B(14), to establish that the Respondent’s license should be summarily suspended? If not, should the entire Order for Summary Suspension be dismissed?

d. Did the State provide sufficient evidence to carry its burden to prove that the Respondent operated a flawed Internal Review Board? If not, should paragraphs 157 through 162 of the Order for Summary Suspension be dismissed?

e. Did the State provide sufficient evidence to carry its burden to prove that the Respondent misrepresented his credentials? If not, should paragraphs 163 through 170 of the Order for Summary Suspension be dismissed?

(2) Did the Board carry its burden to prove that the Respondent’s use of his license presented a substantial likelihood of risk of serious harm to the public health, safety or welfare, justifying summary suspension of his license?

SUMMARY OF THE EVIDENCE³

Exhibits

The Exhibit List appended to this Decision identifies all admitted exhibits.

Testimony

The State presented the following witnesses:

Parent A, mother of Patient C, who testified by videoconference from Virginia

Linda Elizabeth Sullivan Grossman, M.D., who was admitted as an expert in the following areas:

- Pediatrics
- Developmental Behavioral Pediatrics
- Diagnosis and Treatment of Children with Neurodevelopmental Disorders, Including Autism
- Generally Medically Accepted Treatment of Children with Neurodevelopmental Disorders, Including Autism
- Generally Medically Accepted Indications for Chelation
- Pharmacology Related to Children with Autism
- Psychopharmacology Related to Children with Autism
- Interpretation of Lab Studies of Children with Autism
- Off-Label Use of Drugs in the Area of Pediatrics
- Appropriate Medical Documentation
- Appropriate Use of Billing Codes
- Use of Diagnostic Codes

The Respondent did not testify but called the following witnesses on his behalf:

Father of Patient B

Mother of Patient A, who testified by video-conference from Nigeria

³ One of the bases for the Board's decision to summarily suspend the Respondent's license was information accumulated from the Respondent's medical records relating to nine patients, identified as Patient A through Patient I. At the beginning of the hearing, the State noted that it would not be relying upon or offering any evidence with regard to Patient D.

In this Decision, I refer to the remaining patients collectively as "the Patients," or by each individual's designation, as for example, Patient A or Patient B. I refer to the Patients' medical records held by the Respondent collectively as "the Records" or by reference to each individual record as, for example, Patient A Record.

The State produced three large binders of exhibits for this hearing but did not offer all the exhibits therein contained. The Respondent produced one large binder of exhibits for this hearing but did not offer all the exhibits contained therein. Although I retained the entire contents of all four exhibit binders in preparation for subsequent related hearings, I reviewed and considered during my deliberations only the exhibits admitted into evidence.

Mother of Patient F

Mother of Patient E

Mother of Patient H

James Brewster Adams, Ph.D., who was admitted as an expert in the following areas:

- Chelation
- Scientific and Research Knowledge as it applies to Autistic Children

Mary Norfleet Megson, M.D., who was admitted as an expert in the following areas:

- Standard of Care for Diagnosis and Treatment of Autistic Children
- Use of Lupron and Efficacy and Safety Thereof in Autistic Children
- Off-Label Use of Drugs for Autistic Children

Georgia Davis, M.D., who testified from Illinois by videoconference, and who was admitted as an expert in the following areas:

- Standard of Care in the Treatment of Autistic Children
- Efficacy and Safety of the Use of the Drug Lupron for Treatment in Certain Autistic Children
- Appropriateness of Off-Label use of Drugs in the Treatment of Autistic Children

Jerald Kartzinell, M.D., who testified from Irvine, California by videoconference, and who was admitted as an expert in the following areas:

- Standard of Care in the Treatment of Autistic Children
- Efficacy and Safety of the Use of the Drug Lupron for Treatment of Children with Autism
- Efficacy and Appropriateness of the Off-Label use of Drugs with Children with Autism

STIPULATIONS OF FACT

The parties stipulated to the following facts:

A. At all times relevant hereto, the Respondent was and is licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on September 20, 1979.

B. The medical records requested by the Board were properly and fully transmitted by the Respondent to the Board for Patients.

C. The use of certain drugs “off-label” is not per se illegal or a breach of the standard of care.

FINDINGS OF FACT

I find the following facts by a preponderance of the evidence:

1. The Respondent is a Maryland resident. State’s Ex. 8 at 11.
2. The Respondent graduated from medical school at George Washington University in 1978 and completed one year of residency at Johns Hopkins Hospital in obstetrics and gynecology in 1979. State’s Ex. 8 at 12.
3. The Respondent attended a one-year program in genetics at Columbia University in 1970 - 1971, received a Ph.D. in genetics from George Washington University in 1973, and completed a two-year fellowship in genetics at the National Institutes of Health (NIH) in 1974. State’s Ex. 8 at 12.
4. The Respondent was a founding member of the American Board of Medical Genetics and was certified by that Board as a geneticist in 1987. State’s Ex. 8 at 12 – 13.
5. The Respondent has been a board-certified epidemiologist since 2007. State’s Ex. 8 at 13.
6. The Respondent is the founder and president of the Genetic Centers of America which is an umbrella organization that operates two companies in Maryland: the Genetic Consultants of Maryland, in Rockville, and the Genetic Center of Baltimore, in Owings Mills. State’s Ex. 8 at 14 – 15.
7. The Genetic Consultants of Maryland sees high-risk obstetrical patients for genetic counseling, sonography and amniocentesis, adult patients for evaluation of their risk for BRCA

breast cancer, and juvenile patients with neuro-developmental disorders, such as autism. State's Ex. 8 at 18.

8. The Respondent works with his partner, John Young, M.D., as well as Jessica Sank, a Board-certified MS-genetic counselor, two sonographers, two office managers, and his son, David Geier. State's Ex. 8 at 13 – 16, 52.

9. David Geier's responsibilities at the Genetic Centers of America include holding juvenile patients while the Respondent gives the patient an injection, assisting in scheduling patients, taking notes for the Respondent during patient interviews and calling in prescriptions ordered by the Respondent for patients. State's Ex. 8 at 52 - 53, 74.

10. Autism is generalized term for a variety of neuro-developmental disorders that range in severity across a spectrum. This variety of disorders, referred to in their entirety as Autism Spectrum Disorder (ASD), have symptoms that substantially impact a child's functioning in multiple spheres, including language and social interaction. Typical symptoms also include stereotypic movements, and unusual preoccupations with certain objects. Tr. 147 (Grossman).

11. Twenty-one percent of children with autism have attention deficit hyperactivity disorder and fifteen percent have epilepsy. Approximately ten percent have psychiatric problems. Slightly over four percent have aggressive behaviors as the result of Opposition-Defiant Disorder or Conduct Disorder. Tr. 185-86 (Grossman).

12. The Respondent's patients with autism typically have been diagnosed with autism prior to entering into his care. *See, e.g.*, State's Ex. 8 at 18; State's Ex. 11 at 10444; State's Ex. 12 at 10706; State's Ex. 13 at 10902; State's Ex. 15 at 11076; State's Ex. 16 at 11160; State's Ex. 18 at 11595; State's Ex. 19 at 11887; *but see* Patient G, State's Ex. 17 at 11481. [diagnosed by previous physician with Pervasive Developmental Delay, Not Otherwise Specified (PDD-NOS)].

In-Person, Telephonic, or Skype Evaluations/Consultations with Patients and/or their Physicians

13. The Respondent has performed genetic counseling and has evaluated patients' genetic profiles over the telephone. State's Ex. 8 at 55.

14. The Respondent has participated in clinical evaluations of children who have previously been diagnosed with autism, while another of the children's doctors is present by telephone or Skype. State's Ex. 8 at 57; *see also* Tr. 1019, 1037 – 1038 (Davis).

15. These evaluations and/or consultations may be initiated by either the child's parent or physician, or both. State's Ex. 8 at 58.

16. During these evaluations and/or consultations, the Respondent may ask that laboratory tests be performed on the children, might make a recommendation for other tests or treatments, or might ask questions to assist the other physician in treatment of the patient. State's Ex. 8 at 58.

17. None of the Records contain any notation reflecting that another doctor was on the telephone or otherwise present while the Respondent evaluated the Patients. *See generally* State's Exs. 11, 12, 13, 15, 16, 17, 18, 19.

Patient Evaluations

18. The standard of quality medical care for patients with autism requires that a physician perform a careful evaluation (Evaluation) of a patient prior to prescribing medication or otherwise initiating treatment. Tr. 404 – 405 (Dr. Grossman); Tr. 1055 – 1057 (Dr. Kartzinell); *see also* Tr. 950 (Dr. Megson); Tr. 1014, 1037-1043 (Dr. Davis).

19. An Evaluation of a juvenile patient with autism consists of the following components:

- a. Visual observation of the patient's appearance and behavior;
- b. A complete history to assist in making or confirming a diagnosis, and to determine symptoms and risk factors for treatment, considering medical history, current and prior treatments and success or lack of success of those treatments, symptoms of the patient's move toward or through puberty, and the existence of any conditions that are commonly co-morbid with autism, including;
 - i. Bowel disease, including constipation, diarrhea, reflux disease, and inflammatory bowel disease;
 - ii. Epilepsy or other seizure disorders;
 - iii. Endocrine issues, such as hypothyroidism, diabetes, growth hormone deficiency, and increased hormone production;
 - iv. Autoimmune issues;
 - v. Anemia;
 - vi. Inflammatory markers;
 - vii. Psychological problems;
 - viii. Sleeping problems;
 - ix. Tantrums; and
 - x. Self-stimulatory behaviors ("stimming")
- c. A complete physical examination to assist in developing or confirming a diagnosis, to identify symptoms, and to determine risk factors for treatment; the examination should include but not be limited to assessment of:

i. Weight and height;
ii. Evaluation of vital signs such as respiration, blood pressure, and pulse;

iii. Heart;
iv. Lungs;
v. Abdominal examination; and
vi. Genitalia, to determine pubertal status under the Tanner staging criteria.

d. Documented identification of the symptoms to be treated;
e. Documented identification of any further evaluation through laboratory tests, x-rays, sonograms, MRIs or other means that is either recommended or necessary to support a possible diagnosis and to rule out causes unrelated to autism, such as tumors;

f. A clearly stated rationale for each proposed treatment;
g. A documented treatment plan, considering the use of commonly-accepted treatments first, before trying alternative treatments;

h. Documentation of the physician's explanation to the patient's parent(s) of specific risks, benefits, and side effects associated with proposed treatments, particularly unusual treatments, and steps to take if the parents observe any of these side effects;

i. Development and documentation of a plan for carefully monitoring the patient's response to treatment, utilizing multiple sources of information to recognize and report improved and worsened symptoms, side effects of treatment, and dangerous outcomes of treatment. Tr. 404 – 405 (Grossman); Tr. 1055 – 1057 (Kartzinel); *see also* Tr. 950 (Megson); Tr. 1014-1015, 1037-1043 (Davis); *see also* Tr. 289 (Grossman).

Components of an Evaluation: Visual Observation of the Patient's Appearance and Behavior

20. Personal observation by the physician of how a patient with autism interacts with other people and things provides the physician with critical information necessary to properly identify a patient's symptoms and ultimately to diagnose the patient. *See* State's Ex. 8 at 73 – 74.

21. A physician interacting with a patient by Skype is unable to observe the patient's appearance, behavior, and interaction with other persons and things as fully as a physician who evaluates the patient in-person. *See* Tr. 539.

22. The Respondent was physically present in the same room at the same time with the following Patients, and was able to personally observe them prior to initiating treatment:

- a. Patient A, on June 11, 2007. *See* State's Ex. 11 at 10354.⁴
- b. Patient C, on July 1, 2005. Tr. 70 – 73.
- c. Patient E, on May 2, 2007. State's Ex. 15 at 10913-10914.⁵
- d. Patient F, on March 11, 2008. State's Ex. 16 at 11097, 11064.⁶

23. The Respondent initiated treatment of the following Patients without first observing them in person:

- a. Patient B, on March 22, 2006. *See* State's Ex. 12 at 10525; *see also* Tr. 280, 718 – 719.

⁴ My finding that the initial contact between Patient A and the Respondent was in the Respondent's office with all parties physically present is based upon the Respondent's billing record, which shows that he sought compensation for hands-on tests performed during this visit including multiple ultrasounds and actinotherapy. State's Ex. 11 at 10354. I note that none of the witnesses or the Records defined actinotherapy, discussed why it was prescribed, or described any of the positive or negative results of such therapy.

⁵ My finding that the initial contact between Patient E and the Respondent was in the Respondent's office with all parties physically present is based upon the Respondent's billing record which shows that he sought compensation for hands-on tests performed during this visit, including echography, ultrasounds, and actinotherapy. I note that none of the witnesses or any of the Records defined "echography," discussed why it was prescribed, or described any of the positive or negative results of such therapy.

⁶ My finding that the initial contact between Patient F and the Respondent was in the Respondent's office with all parties physically present is based upon the Respondent's billing record which shows that he sought compensation for hands-on tests performed during this visit, including ultrasounds. *See also* State's Ex. 16 at 11164, ultrasound screens labeled "Genetic Consultants of Maryland."

- b. Patient G, on or about March 28, 2008. State's Ex. 17 at 11327.⁷
- c. Patient H, on March 9, 2008. State's Ex. 18 at 11494.⁸
- d. Patient I, on March 21, 2006. State's Ex. 19 at 11668 – 11670; Tr. 396.⁹

24. The Respondent's pre-treatment Evaluations of Patient B, Patient G, Patient H, and Patient I were deficient because each lacked an in-person visual observation of these Patients' appearance and behavior.

Components of an Evaluation: Obtaining a Complete Medical History of a Patient

25. The Respondent may obtain a complete medical history of a patient either through his own interview of the patient or the patient's family or through review of records created by other treating physicians; the other physician's records provided to the Respondent may include lab reports, medical histories and notes of physical examinations, prior and/or current treatments and the results of prior/current treatments. State's Ex. 8 at 58 – 59.

⁷ My finding that the Respondent's first contact with Patient G and his parents was not an in-person contact is based upon the Respondent's billing record which shows that none of the first few dates of services (March 25, 28, 30, 2008) were billed as in-person visits, that the Respondent did not seek payment for any hands-on tests, and that the services provided on these dates are described as "psychiatric diagnostic exam eval," a long phone consult, and "management." State's Ex. 17 at 11327. Moreover, documents in Patient G Record relating to these dates include documents bearing a fax letterhead, indicating they were not submitted to the Respondent in person. See State's Ex. 17 at 11488 – 11490; see also Tr. 356 in which Dr. Grossman testifies as to the absence of any evidence in the file that Patient G was personally presented to the Respondent before the Respondent began to treat him. My finding that March 28, 2008 was the date of the first direct (although still not in-person) contact between the Respondent and Patient G and Patient G's parent(s) is based upon the date of the document typically used by the Respondent to take a history of a patient. See State's Ex. 17 at 11484.

⁸ My finding that the Respondent's first several contacts with Patient H and/or her parent(s) were by some means other than an in-person visit is based upon the Respondent's billing record which shows that he billed to the Patient's insurer all his services from March 9, 2008 through May 23, 2008 as either a "psych diag eval," a long phone consult, or as "management." See State's Ex. 18 at 11494 – 11495; also see State's Ex. 18 at 11589 – 11598, the form the Respondent typically uses for his initial intake of a patient, dated March 14, 2008 – a service billed as a long phone consult; State's Ex. 18 at 11494; see also State's Ex. 18 at 11588, an Autism Treatment Evaluation Checklist (ATEC) typically received by the Respondent in an initial visit with a patient, which contains a fax letterhead. See also Tr. 1089-90.

⁹ My finding that the Respondent's contacts with Patient I were by some means other than an in-person visit is based upon the Respondent's billing records which show that he billed to the Patient's insurer all his services from March 21, 2006 through March 5, 2007 as either long phone consults, "management," or collecting and interpreting physiological data. See State's Ex. 19 at 11668 – 11670.

26. The Respondent receives patient records from other physicians in hard copy, typically via fax or hand-delivery by the patient's parents. Tr. 1042 (Davis); Tr. 1062 (Kartzinel); *see e.g.*, Tr. 1093 – 1094 (mother of Patient H, testifying that during her conferences with him she made a binder of results from prior laboratory testing available to the Respondent).

27. A physician documents his or her review of such records by either noting the review in the patient file record or by initialing the prior records as having been reviewed. *See* Tr. 567 (Grossman).

28. If the Respondent has recent records of a patient that include a comprehensive history and physical examination, and he has reviewed those records, he may choose not to redo these components of an Evaluation without violating the standard of quality medical care. Tr. 1068 (Kartzinel); *see* Tr. 1003 – 1005 (Davis).

29. The Records for Patient B, Patient F, Patient H and Patient I contain medical records received from other doctors who treated these Patients. *See* State's Ex. 12 at 10710 – 10725; State's Ex. 16 at 11169 – 11207; State's Ex. 18 at 11613 – 11665; State's Ex. 19 at 11930 – 12093.

30. The Records for Patients F, H and I lack verification that the Respondent reviewed any prior medical records. *See generally* State's Ex. 16, 18, 19.

31. The Respondent reviewed Patient B's medical records from birth through approximately age two-and-one-half in connection with an agreement he made to submit an affidavit in a vaccine injury lawsuit brought on behalf of Patient B. Patient B's Record does not indicate that the Respondent used these or other prior medical records of Patient B in his treatment of Patient B. *See* State's Ex. 12 at 10635 – 10658; *see generally* State's Ex. 12.

32. The Records for Patients A, C, E and G do not contain any medical records from other physicians. *See generally* State's Ex. 11, 13, 15, 17.

33. With the exception of the prior medical records in Patient B's Record, and with a single exception to review a test performed upon Patient G,¹⁰ the Records do not contain verification that the Respondent reviewed any prior medical records for the Patients that may have been submitted to him by email, fax, or in any other manner. *See generally* State's Ex. 11, 13, 15, 17.

34. Some Records show that the Respondent sent copies of lab test reports to other physicians, but except for Patient B Record none document any consultations by the Respondent with those physicians regarding lab tests or anything else. *See generally* State Ex. 11, 13, 14, 15, 16, 17, 18, and 19.

35. Patient B's Record contains a single notation of a consultation with one of Patient B's physicians, Dr. Corbier, a pediatric neurologist. The Respondent had this conversation over a year after he began treating Patient B and did not rely on any information gained during this conversation as part of his Evaluation of Patient B. *See* State's Ex. 12 at 10744; Resp. Ex. 38.

36. The Respondent received some information about the Patients' prior histories through interviews of the Patients' parents; each of the Patient Records documents information the Respondent obtained during those interviews. *See* State's Ex. 11 at 11438 – 11447; State's Ex. 12 at 10700 – 10709; State's Ex. 13 at 10902 – 10903; State's Ex. 15 at 11075 – 11077; State's Ex. 16 at 11159 – 11162; State's Ex. 17 at 11475 – 11484; State's Ex. 18 at 11475 – 11484; State's Ex. 19 at 11881 – 11890.

¹⁰ Patient G Record contains a single notation reflecting that the Respondent reviewed information from Patient G's gastroenterologist after a specific test was performed on Patient G. *See* State's Ex. 17 at 11468.

37. The Respondent's interview of a juvenile patient's parent(s) takes approximately one hour to an hour-and-a-half. During that interview, the Respondent asks about family history, medical histories of both parents, the history of the mother's pregnancy with the patient, and the medical, behavioral and developmental history of the patient. State's Ex. 8 at 28 – 29.

38. None of the summaries of the information the Respondent received during his intake history from the Patients' parents, or the prior medical records that may have been submitted to the Respondent and are contained in the Records, contain a complete medical history of the Patients with a review of all the relevant physical systems, an evaluation of the Patients' heart or lungs, results of a physical examination of the Patients' abdomens, or a Tanner Stage level of the Patients. *See generally* State's Ex. 11, 12, 13, 15, 16, 17, 18, 19.

39. The Respondent's Evaluation of each of the Patients was deficient because it did not include a complete medical history taken by the Respondent or a review by the Respondent of a complete medical history provided to him by the Patients' other medical providers.

Components of an Evaluation: Performing a Complete Physical Examination of a Patient

40. If the Respondent is performing his Evaluation of a patient in collaboration with another doctor who is present during that Evaluation by telephone or Skype, the other doctor may orally provide some of the necessary information such as current height, weight, and blood pressure, thus obviating the need for the Respondent personally to obtain that data. Tr. 1042 (Davis).

41. The Respondent conducted a truncated physical examination of Patients A, B, C, E, F, H, and I, limited to a review of their pubertal status (genitals, observation of hair), their

height and weight, and in some cases their blood pressure, pulse, and respiration rate. *See* Patient A Record, State's Ex. 11 at 10438 - 10447; Patient B Record, State's Ex. 12 at 10707; Patient C Record, State's Ex. 13 at 10902 - 10293; Patient E Record, State's Ex. 15 at 11075 - 11077; Patient F Record, State's Ex. 16 at 11133, Patient H Record, State's Ex. 18 at 11541, and Patient I Record, State's Ex. 19 at 11702.

42. The Respondent did not perform any physical examination of Patient G. Patient G Record, State's Ex. 17 at 11469; *see generally* State's Ex. 17.

43. The Respondent's Evaluation of each of the Patients was deficient because it did not include either a complete physical examination of the Patient performed by the Respondent or a review by the Respondent of a recent complete physical examination record of the Patient provided to him by the Patients' other medical providers.

44. None of the summaries of the information the Respondent received during his intake history from the Patients' parents, or the summaries of the information the Respondent personally obtained from his examination of the Patients that are contained in the Records, or the prior medical records that may have been submitted to the Respondent and are contained in the Records, contain the results of a recent complete physical examination of the Patients, a complete medical history of the Patients with a review of all the relevant physical systems, an evaluation of the Patients' heart or lungs, results of a recent physical examination of the Patients' abdomens, or a Tanner Stage level of the Patients. *See generally* State's Ex. 11, 12, 13, 15, 16, 17, 18, 19.

Components of an Evaluation: Identifying and Documenting the Symptoms to be Treated

45. The Records contain generalized descriptions of the Patients' symptoms as of the Respondent's first contact with them. *See* Patient A Record, State's Ex. 11 at 10438 - 10447; Patient B Record, State's Ex. 12 at 10707; Patient C Record, State's Ex. 13 at 10902 - 10293; Patient E Record, State's Ex. 15 at 11075 - 11077; Patient F Record, State's Ex. 16 at 11133, 11159 - 11162; Patient H Record, State's Ex. 18 at 11541, 11589 - 11598; Patient I Record, State's Ex. 19 at 11702, 11881 - 11890.

46. The Respondent asked the parents of Patients B, C, E, F, G, H, and I to complete an Autism Treatment Evaluation Checklist (ATEC) as part of his initial Evaluation. *See* State's Ex. 12 at 10699; State's Ex. 13 at 10896 and 10905; State's Ex. 15 at 11074; State's Ex. 16 at 11158; State's Ex. 17 at 11463; State's Ex. 18 at 11588; State's Ex. 19 at 11891.¹¹

47. The ATEC is a standardized questionnaire seeking subjective ratings on seventy-seven aspects of a child's speech/language/communication, sociability, sensory/cognitive awareness, and health/physical behaviors. *See e.g.* State's Ex. 11 at 10437; *see also* State's Ex. 8 at 39.

48. Having a patient's parent complete the ATEC provides baseline information about a patient's performance/symptoms in each of these areas and helps the Respondent identify symptoms to be treated. *See* State's Ex. 8 at 39.

49. Completion of ATECs by persons other than the parents would provide additional insight into the validity of the parents' perspectives on the Patients. It also would provide additional information as to the nature and frequency of behaviors in different environments,

¹¹ Neither the single ATEC form in Patient A Record nor testimony from the parent of Patient A established who completed the ATEC form in that Record. *See* State's Ex. 11 at 10437; *see generally* Tr. 802 - 829.

thus indicating whether the behaviors might be caused, aggravated, or ameliorated by different environments. State's Ex. 8 at 39.

50. The Respondent did not obtain ATECs from any of the Patients' teachers, physicians, or other care providers. State's Ex. 8 at 39; *see generally* State's Ex. 12, 15, 16, 17, 18, 19.

51. Although the Respondent obtained an ATEC from the parents of Patients B, C, E, F, G, H, and I, the Respondent did not identify in any standardized routine way which of the behaviors discussed on those forms were the symptoms he was targeting for treatment. *See generally* State's Ex. 12, 15, 16, 17, 18, 19.

52. The Respondent's Evaluation of each of the Patients was deficient because it did not include a specific detailed identification of the presenting symptoms he was targeting for future treatment.

Components of an Evaluation: Evaluating with Lab Tests, X-Rays, Sonograms, and Other Tests

53. The Respondent routinely ordered ultrasound tests of the Patients' abdomens and necks to determine whether the Patients had tumors in these areas that may have caused symptoms of concern. Tr. 197, 200, 470; *see generally* State's Ex. 11, 12, 13, 15, 16, 18, 19.

54. All the Records, except Patient G Record, contain ultrasound test results. Patient A Record, State's Ex. 11 at 10449 - 10452; Patient B Record, State's Ex. 12 at 10554 - 10556¹²; Patient C Record, State's Ex. 13 at 10894 - 10895; Patient E Record, State's Ex. 15 at 11078 - 11081; Patient F Record, State's Ex. 16 at 11160 - 11168; Patient H Record, State's Ex. 18 at

¹² The Respondent did not perform these tests on Patient B until June 10, 2009, over three years after his first contact with him on March 22, 2006. *Compare* State's Ex. 12 at 10525 *with* State's Ex. 12 at 10544. Moreover, while the thyroid test was done on that date, the documents verifying completion of the test do not state whether the test showed Patient B's thyroid to be normal or abnormal. State's Ex. 12 at 10544 - 10546.

11607 - 11608¹³; State's Ex. 19 at 11813 – 11816, 11700-11701;¹⁴ *but see generally* Patient G Record, State's Ex. 17.

55. The Respondent performed Wood's Lamp tests upon Patients A, B, E, H, and I to determine if they had tubular sclerosis, a neurological condition that may have caused some of the symptoms demonstrated by these Patients. *See* Patient A Record, State's Ex. 11 at 10436; Patient B Record, State's Ex. 12 at 10727;¹⁵ Patient E Record, State's Ex. 15 at 11076; Patient H Record, State's Ex. 18 at 11541; Patient I Record, State's Ex. 19 at 11827;¹⁶ *see also* Tr. 371.

56. The Respondent routinely orders an extensive laboratory work-up on each patient's blood, urine, and sometimes stools, in the following areas: genetic testing, including scans for syndromes that have been associated with autism, including but not limited to chromosome abnormalities, Fragile X Syndrome, Prader-Willi Syndrome, Angelmans Syndrome, and single nucleotide polymorphisms; general health screening; testing for the presence of heavy metals; and Amino Acid testing. State's Ex. 8 at 29 – 32.

57. The Records contain multiple reports of blood, urine, stool, and genetic lab tests ordered by the Respondent for the purpose of initial evaluation. *See generally* State's Ex. 11, 12, 13, 15, 16, 17, 18, 19.

¹³ The ultrasound report in Patient H Record is missing the name of the patient being tested; based upon its inclusion in that Record, I have concluded that the patient was Patient H. *Id.*

¹⁴ The Respondent ordered two sets of ultrasound testing on Patient I. The first set was performed on March 26, 2007, one year after the Respondent's first contact with Patient I on March 21, 2006. *Compare* State's Ex. 19 at 11668 *with* State's Ex. 19 at 11813 – 11816. The second set was performed on June 5, 2008. State's Ex. 19 at 11700 – 11701. Patient I Record does not contain an explanation for why these tests were repeated. *See generally* Patient I Record, State's Ex. 19.

¹⁵ The Respondent did not perform this test until June 10, 2009, over three years after his first contact with Patient B on March 22, 2006. *Compare* State's Ex. 12 at 10525 *with* State's Ex. 12 at 10727.

¹⁶ The Respondent did not perform this test until March 25, 2007, approximately one year after his first contact with Patient I on March 21, 2006. *Compare* State's Ex. 19 at 11668 *with* State's Ex. 19 at 11827. The Respondent's notes from an interview with Patient I's parent(s) state that Patient I may have had Wood's Lamp testing on an earlier date; however, the Respondent's notation with regard to the result of this testing -- "nl" -- is too ambiguous to confirm if the test was done and, if so, the result. *See* State's Ex. 19 at 11890.

58. A patient's hormonal levels, including his or her levels of free testosterone, total testosterone, DHEA, DHEA-S, androstendione, estrogens, luteinizing hormone (LH) and follicle stimulating hormone (FSH), are a key factor in a physician's decision to prescribe and continue Lupron therapy. *See* Tr. 36 (Respondent); Tr. 1075 (Kartzinel); State's Ex. 12 at 10678 (defining "androgens").

59. Because normal levels of DHEA, DHEA-S, androstendione, and androstane diol glucuronide differ based upon a patient's age and stage of puberty, results of laboratory tests for these hormones are interpreted by referring to guidelines based upon patients' ages and Tanner Stages. *See e.g.*, Patient A Record, State's Ex. 11 at 10421 – 10423.

60. The Respondent had to know a patient's age and Tanner Stage to be able to accurately interpret the significance of levels of those hormones in that patient. Tr. 565 (Grossman); *see* Tr. 1076 – 1077 (Kartzinel); Tr. 1005, 1015 (Davis); *see e.g.* Tr. 562 (Grossman).

61. The Respondent relied heavily upon the results of multiple lab test reports as part of his decision to initiate and continue Lupron therapy. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

62. The Respondent did not determine the Tanner Stage level of any of the Patients, and thus could not accurately interpret whether the Patients' levels of DHEA, DHEA-S, androstendione, and androstane diol glucuronide were normal or abnormal. Tr. 565 (Grossman).

63. The Respondent's Evaluation of each of the Patients was deficient because he did not obtain sufficient information from the Patients to be able to accurately interpret the results of the lab tests he ordered for those Evaluations.

Components of an Evaluation: Developing and Documenting a Treatment Plan

64. A physician's treatment decisions regarding children with autism must be made in partnership with the patient's parent(s) after both parties are fully informed of the benefits, risks and potential adverse side effects of each proposed treatment. Tr. 184-85.

65. In order to adequately discuss a proposed plan of treatment with parents, a physician must develop a detailed treatment plan that sets out the benefits, risks and potential adverse side effects of each proposed treatment. *See* Tr. 184-85.

66. Some of the Records contain brief treatment plans that were created only *after* the Respondent initiated treatment of the Patients. *See* Patient B Record, State's Ex. 12 at 10726¹⁷; Patient G Record, State's Ex. 17 at 11428¹⁸; *but see* Patient B Record, State's Ex. 12 at 10678 (setting out the steps in the Geier Clinical Study Protocol in an undated document).

67. In one case, the Respondent created a detailed treatment plan but included a diagnosis of toxic encephalopathy,¹⁹ for which he offered no explanation, rationale, or defined treatment. Patient H Record, State's Ex. 18 at 11541; Tr. 371.

68. In some cases, the Respondent discussed his treatment plan with the Patient's parent but failed to document that plan in the Patient's Record. *See* Tr. 877-878 (Patient E's

¹⁷ This document is undated, but from its location in Patient B Record, I conclude that it was created after the Respondent received results from March 25, 2009 laboratory tests.

¹⁸ This treatment plan was faxed to another of Patient G's physicians after the Respondent initiated treatment of Patient G; no other treatment plan exists in Patient G Record. *Compare* June 20, 2008 treatment plan, State's Ex. 17 at 11428 *with* the Respondent's June 3, 2008 issuance of six prescriptions for Patient G, including two prescriptions for Lupron. State's Ex. 17 at 11466 - 11467.

¹⁹ Encephalopathy is a condition of the brain resulting in abnormal functioning such as confusion, change in level of consciousness, excessive sleeping or excessive irritability. Tr. 360 - 361.

mother); *see* Tr. 851-852 (Patient F's mother); *see generally* Patient E Record, State's Ex. 15, Patient F Record, State's Ex. 16.

69. The Respondent did not create a written or verbal treatment plan for Patient I. *See generally* Patient I Record, State's Ex. 19.

70. Over the course of his treatment of each Patient, the Respondent frequently added, modified or deleted treatment therapies without updating his treatment plan for that Patient or fully explaining or documenting why medications or therapies were being added, modified, or deleted. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

71. Despite differing information received about the Patients from their respective parents, the Respondent diagnosed all but Patient C with precocious puberty and prescribed for them a nearly-identical course of treatment: twice-monthly intramuscular injections and daily subcutaneous injections of Lupron Pediatric Depot; most also received daily melatonin drops, daily methyl-B12 + folinic acid, and Aldactone or Androcur. The Respondent also prescribed every-other-day chelation therapy, using rectal suppositories of DMPS, for all but Patients C, E and F. *See generally* State's Ex. 11, 12, 13, 15, 16, 17, 18, 19.

72. The Respondent's initial and continuing Evaluations of the Patients were deficient because his explanations and documentation of treatment plans were incomplete, because he failed to explain why medications were being added, modified, or deleted, and because he failed to include a rationale as to why specific therapies were chosen over others.

*Components of an Evaluation: Providing a Full Explanation
of the Risks and Benefits of Prescribed Treatments*

73. Patient H Record contains a summary statement that the Respondent advised Patient H's parent(s) of the risks and benefits of a particular proposed treatment, but it lacks any indication of what information the Respondent provided to the parent(s) about specific risks,

benefits, and potential adverse side effects of treatment or about what the parent(s) should watch for that would demonstrate improvement, lack of improvement, or adverse side effects. *See* Patient H Record, State's Ex. 18 at 11541, 11517.²⁰

74. The Respondent advised the parents of Patient I of the risks, benefits and potential adverse side effects of chelation treatment with the drug DMSA, but the Respondent prescribed a different drug for chelating Patient I – the drug DMPS – not the drug DMSA. *See* Patient I Record, State's Ex. 19 at 11840 – 11841, 11818, 11821, 11730.²¹

75. Although DMSA and DMPS are similar, DMSA is a drug that has been approved by the United States Food and Drug Administration (FDA) for chelation therapy; DMPS is not an FDA-approved drug for chelation. As such, it is critical that parents whose children are proposed for treatment using DMPS be informed in writing that DMPS is an experimental drug and equally important that the patient's medical record include written consent by the parents to DMPS treatment of their child. Tr. 742-43, 759 (Adams).

76. The Respondent had a lengthy discussion with the parents of Patient E and Patient F about treatment of their child, but failed to document whether that discussion included any specific list and specific descriptions of the risks and benefits of treatment or the adverse side effects that these parents should watch for as a result of treatment. *See* Tr. 877-878 (Patient

²⁰ Patient H's mother testified that "we also talked about some of the risks of Lupron, you know, the bone density, that kind of thing, and we discussed the risk, the benefits." Tr. 1096. This testimony fails to verify exactly what the Respondent told Patient H's mother and, thus, I cannot conclude that the discussion was sufficient to have fully informed Patient H's mother about all the risks/benefits/potential adverse side effects of the Respondent's recommended treatment.

²¹ I note that this document refers to the side effects of DMSA, a chelating agent similar but not identical to DMPS, the chelating agent the Respondent prescribed for Patient I. The State did not refute Dr. Adams' testimony that DMSA and DMPS are similar medications, differing primarily in the heavy metal to which each attaches in a child's body. The reference to DMSA, rather than to the prescribed DMPS, is concerning, but I have insufficient evidence to establish that the insertion of this word, rather than DMPS, renders the risks/benefits and adverse side effects listed in the document incorrect. *See* Tr. 742-43, 759 (Adams).

E's mother); Tr. 853 (Patient F's mother: "we discussed everything."); *see generally* Patient E Record, State's Ex. 15; Patient F Record, State's Ex. 16.

77. Patient A Record contains detailed information about the medication(s) the Respondent prescribed for Patient A, but it contains no notation that this information was provided to the Patient's parent(s). *See e.g.*, Patient A Record, State's Ex. 11 at 10397 – 10402 (Physician's Desk Reference printout regarding Lupron).

78. The Respondent provided the parents of Patient B with copy of a document entitled "Geier Clinical Study Protocol." This document, which was faxed to the parents on July 11, 2006, describes the treatment the Respondent recommended for Patient B, but it does not provide a specific identification of the risks and benefits of such treatment, nor a list of the adverse side effects the parents were to watch for. State's Ex. 12 at 10678, 10743; Tr. 287.

79. The Respondent did not provide any information to the parent(s) of Patient G regarding the risks and benefits of the treatment he prescribed for Patient G or about adverse side effects the parent(s) should have watched for. *See generally* Patient G Record, State's Ex. 17; Tr. 365.

80. The Respondent's Evaluation of Patients A, B, E, F, G and H was deficient because he failed to provide his partners in the development of treatment of each of these Patients – the Patients' parents – with a detailed explanation of the risks and benefits of Lupron, chelation, or other therapies and/or he failed to provide a detailed explanation to the Patients' parent(s) of adverse side effects to watch for during the course of these treatments.

81. The Respondent's Evaluation of Patient I was deficient because he failed to inform his partner in the development of treatment of Patient I – Patient I's parent(s) – that the drug he proposed to use to chelate Patient I, DMPS, was experimental and not FDA-approved.

Components of an Evaluation: Developing and Implementing a Careful Monitoring Plan,
Including Reports from Multiple Sources, for Responses to Treatment

82. The Respondent had three methods for monitoring the Patients' responses to treatment: monthly lab testing, completion of multiple ATECs, and parent-completed logs. *See e.g.*, Patient A Record, State's Ex. 11 at 10405; Patient B Record, State's Ex. 12 at 10678; Patient G Record, State's Ex. 17 at 11428; *see also* Tr. 1022 (Davis); *see generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

Monitoring through Laboratory Testing

83. The Records contain multiple reports of lab tests ordered by the Respondent for the purpose of monitoring his treatment of the Patients. *See generally* State's Ex. 11, 12, 13, 15, 16, 17, 18, 19.

84. The Records do not contain any systematic or regular notation verifying that the Respondent consistently or even routinely reviewed the lab testing he ordered as part of his monitoring plan for the Patients. Tr. 566-567; *see generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

85. Because the Respondent's Lupron treatment was designed to reduce high levels of DHEA, DHEA-S, Androstenedione and Testosterone, because appropriate levels of these androgens can only be measured by reference to a Tanner scale level, and because the Respondent did not determine any of the Patients' Tanner scale levels, the Respondent was unable to fully monitor the Patients' response to Lupron treatment by reliance on laboratory testing. State's Ex. 8 at 36; *see* State's Ex. 12 at 10678 (defining "androgens")

86. Monitoring a Patient's response to treatment by means of laboratory testing does not give a physician a complete picture of the Patient's response to treatment; the physician

must have supplementary methods of determining a Patient's response to treatment. Tr. 1077 (Kartzinel).

Monitoring Through a Parent Log

87. The Respondent's treatment of the Patients was targeted toward (a) remediation of negative behaviors in the Patients, such as aggression, sleeping problems, screaming, crying, and tantrums, and (b) improvement of positive behaviors such as increased attention span, lengthened periods of calm, increased verbalization, loving emotions, and eye contact. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

88. Negative behaviors in autistic children can be caused by pain that they do not have the communication skills to identify or express, or by stimulation they find uncomfortable or overwhelming, or because such behaviors gain them attention. Tr. 188-89 (Grossman).

89. Remediation of these behaviors and encouragement of positive behaviors can be accomplished by determining the frequency of the behaviors, the timing, and the environment(s) in which the behaviors occur. Careful logs of the children's behaviors are key to determining the cause and remediation of negative behaviors and to developing a plan for encouraging positive behaviors. Tr. 189 (Grossman).

90. The Respondent, through his professional experience treating children with autism with Lupron and chelation, could have gained important information about how the Patients were responding to such treatment or about signs of the development of adverse side effects, through a review of logs of the Patients' behavior.

91. None of the Records contain detailed references to the timing, frequency, or the environments in which the Patients' negative or positive behaviors occurred; thus, it would not be possible to determine whether these behaviors were caused, improved, or aggravated solely

by the therapies or could be remediated by the therapies administered to the Patients by the Respondent, rather than being caused or remediated by some other factor. *See* Tr. 662; *see generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

92. None of the Records contain copies of any of the logs the Respondent encouraged the Patients' parents to keep. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

93. The Records contain second-hand reports of vague comments about the Patients received by their parents from third parties, but they do not contain direct reports from any of the Patients' teachers, care providers, physicians, therapists, or other sources that might have provided a neutral observation of the impact of the therapies administered. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

94. The Records do not evidence the Respondent's knowledge of the Patients' reaction to the therapies he recommended outside of his receipt of intermittent, frequently vague information from the Patients' parents. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

95. Although the Respondent targeted his therapies toward improving positive behaviors and decreasing negative behaviors, the Respondent is not a behavioral or developmental pediatrician, nor does he have any formal training in pediatric behaviors. *See* State's Ex. 8, 8A.

96. The Respondent's intermittent receipt of vague and generalized reports about the Patients' conditions from their parents was insufficient to give the Respondent a complete picture of the Patient's response to treatment.

Monitoring Through Multiple ATECs

97. Completion of ATEC forms by the Patients' parents after administration of Lupron therapy could have given the Respondent a tool for comparing the Patients' behaviors

before and after administration of Lupron; this information would have enabled the Respondent to monitor the efficacy of Lupron treatment in a more objective manner. State's Ex. 8 at 38 – 39; Tr. 766 (Adams).

98. The Respondent obtained second ATEC evaluations only from the parents of Patients B and G.²² See State's Ex. 12 at 10548; State's Ex. 16 at 11373 – 11375.

99. The Respondent did not obtain second ATEC evaluations from the parents of Patients A, E, F, H, or I. See State's Ex. 11, 15, 17, 18, 19.

100. The Respondent did not obtain ATEC evaluations from any of the Patients' teachers, therapists, or other care-providers. See generally State's Ex. 11, 12, 15, 16, 17, 18, 19.

101. The Respondent monitored the Patients' response to his therapies only through the Parents' brief, mostly vague reports and through the results of laboratory testing he could not accurately interpret. See generally State's Ex. 11, 12, 15, 16, 17, 18, 19.

102. The Respondent's monitoring plan for each Patient was inadequate to carefully monitor the Patient for response to treatment and to protect the Patient from adverse side effects.

103. The Respondent's monitoring plan was an insufficient platform upon which to make safe modifications of therapies.

Therapies Prescribed by the Respondent to the Patients: Chelation

104. One of the treatments the Respondent uses for children with autism is chelation: removal of heavy metals, such as lead, mercury, or cadmium, from their bodies. Chelation is administered in pill or suppository form. State's Ex. 8 at 33 – 35.

²² Patient C record also contains two ATEC evaluation forms; however, because Patient C never accepted any treatment from the Respondent, the second ATEC evaluation was, like the first, simply an intake tool. See State's Ex. 13 at 10895, 10905.

105. Because chelation therapy causes the movement of heavy metals throughout the body, it carries the risk of causing serious damage to organs such as the brain. Tr. 748 (Adams).

106. Initiating chelation therapy when the patient does not actually have a higher-than-normal level of mercury or lead may cause a decrease in the patient's intellectual functioning. Tr. 758 (Adams).

107. A physician determines whether chelation is called for by prescribing an initial three-day round or "challenge" of chelation. If the administration of the chelation drug produces a high rate of excretion of a heavy metal, determined by lab testing, the challenge is considered successful and chelation is appropriate. If the administration of the chelation drug does not cause a high rate of excretion of a heavy metal, chelation is unnecessary and should not be continued. Tr. 756-61, 768, 777 (Adams).

108. Initiating chelation therapy is appropriate only after a successful challenge. Tr. 776-777 (Adams).

109. A hallmark of the presence of higher-than-normal levels of mercury and lead in the body of an autistic child is excretion of high levels of coproporphyrins after a round of chelation. Tr. 761 (Adams).

110. After a successful chelation challenge, the normal course of chelation therapy is three days of chelation and eleven days off from chelation. Tr. 774 (Adams).

111. Chelation strips a patient's body of essential minerals as well as undesirable amounts of lead or mercury. In order to counteract this effect, patients should be advised to take mineral supplements during administration of chelation therapy. Tr. 751 (Adams).

112. Continuing chelation for more than three sequential days tends to strip the patient's body of essential minerals, even with mineral supplements; therefore chelation should not be continued for more than three days, without an intervening eleven-day rest period. Tr. 774 (Adams).

113. The Respondent advises a parent to provide the patient child with extra vitamins during chelation therapy to ensure that the patient's bodies are not depleted of the necessary amount of essential minerals, such as zinc. State's Ex. 8 at 34-35.

114. The Respondent's initial order of chelation for Patients A, B, G, H, and I was for an unlimited period of time, on an every-other-day basis – far more than the three days appropriate for a chelation challenge. *See generally* State's Ex. 11, 12, 17, 18, 19.

115. The Respondent did not conduct a chelation challenge with Patients A, B, G, H and I before prescribing a course of chelation.

116. The Respondent first prescribed chelation therapy to Patients A, B, G, H, and I on the following dates:

- a. Patient A: March 19, 2008. State's Ex. 11 at 10453;
- b. Patient B: July 3, 2007. State's Ex. 12 at 10744;
- c. Patient G: December 9, 2008. State's Ex. 17 at 11471-72;
- d. Patient H: January 28, 2009. State's Ex. 18 at 11505;²³
- e. Patient I: July 24, 2007. State's Ex. 19 at 11791, 11821.

²³ The Respondent prescribed DMPS for Patient H in January 2009; the next note regarding chelation is from August 28, 2009, when Patient H's mother informed the Respondent that Patient H was refusing to submit to the chelation suppositories. State's Ex. 18 at 11502. Because there are no notes between these dates indicating the Patient H was not taking the prescribed chelation therapy, I conclude that she received this treatment between these two dates.

117. The Respondent prescribed chelation therapy to Patient A at a time when the Respondent knew he would be unable to monitor Patient A's response or any adverse side effects to chelation because Patient A was leaving the country. Patient A Record, State's Ex. 11 at 10362.

118. The first lab test after Patient B began chelation on July 3, 2007 showed high levels of excretion of coproporphyrins, an indication that Patient B had higher-than-normal levels of lead or mercury in his body. State's Ex. 12 at 10631 – 10634, July 23, 2007 lab test report.

119. After beginning chelation on December 9, 2008, Patient G underwent lab testing on December 17, 2008, but the Respondent did not request any coproporphyrin testing on that date. *See* State's Ex. 17 at 11376 – 11389. The results of the next lab testing, on February 4 – 5, 2009, showed Patient G's coproporphyrin levels within normal ranges. State's Ex. 17 at 11365 – 11372. By mid-March, 2009, one of Patient G's two coproporphyrin tests was slightly high. State's Ex. 17 at 11346 – 11352. The Respondent failed to request any coproporphyrin testing in June, but by July 2009, both of Patient G's two coproporphyrin tests were well above normal ranges, indicating that he had higher-than-normal levels of lead or mercury in his body. State's Ex. 17 at 11340-11345, 11337 – 11339.

120. Although the Respondent began to treat Patient H with chelation on January 28, 2009, he neither monitored the results of chelation through lab tests nor documented that chelation had been stopped until August 2009. *See* State's Ex. 18 at 11502; *see generally* State's Ex. 18.

121. After beginning chelation on July 24, 2007, Patient I underwent lab testing on August 4, 2007, but the Respondent did not request any coproporphyrin testing on that date. *See* State's Ex. 19 at 11783 – 11786. By September 2007, both of Patient I's two coproporphyrin tests were well above normal ranges, indicating that he had higher-than-normal levels of lead or mercury in his body. State's Ex. 19 at 11773 – 11781. Patient I's coproporphyrin test results continued to

demonstrate higher-than-normal levels throughout the remainder of 2007 and 2008, with the exception of one normal reading in April 2008. State's Ex. 19 at 11679 – 11685, 11686 – 11691, 11703 – 11708, 11709 – 11713, 11731 – 11736, 11743 – 11747, 11748 – 11759,

122. By prescribing chelation therapy for Patients A, B, G, H and I without a chelation challenge to determine whether their bodies contained excessive levels of lead or mercury, and thus whether they needed chelation, the Respondent placed these Patients at risk of serious harm.

123. The Respondent continued chelation therapy of Patient A and Patient H when he was aware that he was unable to monitor whether chelation was necessary or efficacious and thereby placed both of these Patients at risk of serious harm.

124. The Respondent prescribed chelation therapy for Patients A, B, G, H, and I without appropriate rest breaks to permit their bodies to recover from the stresses of chelation and thereby placed these Patients at risk of serious harm.

Therapies Prescribed by the Respondent to the Patients: Lupron

125. The Respondent prescribed Lupron injections to the Patients, both subcutaneous and intramuscular. State's Ex. 8 at 36.

126. The Respondent first prescribed Lupron for Patient A on September 10, 2007 when he was nearly ten years old. State's Ex. 11 at 10392. The Respondent based this determination on a July 9, 2007 lab report from which he deduced that Patient A's results on testing for LH, free testosterone, total cholesterol, HDL and LDL, and DHEA were high. State's Ex. 11 at 10390; *see* State's Ex. 11 at 10407 - 10435.

127. On July 9, 2007, Patient A's LH, free testosterone, and cholesterol readings were above the normal range, but the Respondent could not have determined that Patient A's DHEA

level was high because he had not determined Patient A's Tanner Stage level. *See* State's Ex. 11 at 10407 – 10435.

128. Because at least one of the factors upon which the Respondent rested his August 1, 2007 decision to prescribe Lupron was unreliable, his decision to treat Patient A with Lupron was questionable.

129. The Respondent first prescribed Lupron for Patient B on July 10, 2006 when he was nearly six-and-a-half years old. State's Ex. 12 at 10745, 10531.

130. Record B does not set out a specific basis for the Respondent's decision to prescribe Lupron for Patient B. *See generally* State's Ex. 12.

131. Because the Respondent did not detail in Patient B's Record the specific basis for prescribing Lupron to Patient B, his decision to treat Patient B with Lupron was questionable.

132. The Respondent first prescribed Lupron for Patient E on August 1, 2007 when she was nearly nine-and-a-half years old. State's Ex. 15 at 11043 – 11045, 10919.

133. The Respondent based his determination to prescribe Lupron for Patient E, in part, upon lab testing of Patient E's free testosterone, DHEA and androstenedione levels on June 20, 2007. *See* State's Ex. 15 at 11047-11048, 11058 – 11068.

134. While Patient E's free testosterone level exceeded normal levels on June 20, 2007, the Respondent could not have determined whether Patient E's DHEA or androstenedione levels were high because he had not determined her Tanner Level. *See* State's Ex. 15 at 11059, 11063, 11067.

135. Because at least two of the factors upon which the Respondent rested his August 1, 2007 decision to prescribe Lupron to Patient E were unreliable, his decision to treat Patient E with Lupron is questionable.

136. The Respondent first prescribed Lupron for Patient F on May 27, 2008 when she was nearly eight years old. State's Ex. 16 at 11139, 11102.

137. The Respondent based his determination to prescribe Lupron for Patient F, in part, upon lab testing of Patient F's LH, serum testosterone, free testosterone, percent free testosterone, androstenedione and DHEA²⁴ levels on May 12, 2008. *See* State's Ex. 16 at 11139, 11149 – 11156.

138. Patient F's LH, serum testosterone, free testosterone, and percent free testosterone results were all high for her age. The Respondent did not determine Patient F's Tanner level and so could not specifically determine how abnormal her androstenedione and DHEA levels were; the results of tests for these androgens were so high for her age, however, that the Respondent could have determined that these results were abnormally high regardless of Patient F's Tanner scale level. *See* State's Ex. 16 at 11149 – 11156.

139. Patient F Record evidences a reliable reason for the Respondent's decision to prescribe Lupron to reduce the level of androgens in Patient F's body.

140. The Respondent first prescribed Lupron for Patient G on June 23, 2008 when he was approximately eight-and-one-half years old. State's Ex. G at 11487, 11339.

141. The Respondent based his determination to prescribe Lupron for Patient G, in part, on "high androgens." State's Ex. 17 at 11428.

142. Test results from the only samples taken from Patient G prior to June 23, 2008, show that all of his androgens were within normal levels except for his percent free testosterone and his DHEA. State's Ex. 17 at 11452 – 11462 (April 15, 2008).

²⁴ The Respondent's note refers to elevated levels of "HDEA"; as the lab test report does not refer to any report on "HDEA," however, I have concluded that this was a typographical error and that the Respondent intended to refer to DHEA. *See* State's Ex. 16 at 11139, 11149 – 11156.

143. The Respondent could not have determined whether Patient G's DHEA level was high, because he had not determined Patient G's Tanner Level and because all but one of Patient G's other androgen levels were within normal levels. Therefore the factors upon which the Respondent rested his June 23, 2008 decision to prescribe Lupron to Patient E were unreliable, and his decision to prescribe Lupron to Patient G is questionable.

144. The Respondent first prescribed Lupron for Patient H on July 16, 2008 when she was nearly nine years old. State's Ex. 18 at 11496, 11505, and 11569.

145. The Respondent based his determination to prescribe Lupron for Patient H on elevated levels of dihydrotestosterone, 17-OH progesterone, DHEA, and prolactin. State's Ex. 18 at 11541.²⁵

146. Although Patient H's 17-OH progesterone and prolactin levels were high, the Respondent could only have found that Patient H's level of dihydrotestosterone was high by determining whether she was prepubertal; since he did not, he could not have reliably concluded that her dihydrotestosterone levels were high. See State's Ex. 18 at 11543 – 11568.

147. The Respondent could only have found Patient H's level of DHEA to be elevated if he determined her Tanner Level; since he did not, he could not have reliably concluded that her DHEA level was high. *Id.*

148. Because the Respondent could not have determined whether Patient H's dihydrotestosterone and DHEA levels were high, two of the factors upon which the Respondent presumably rested his July 16, 2008 decision to prescribe Lupron to Patient H were unreliable and his decision to prescribe Lupron to Patient H is questionable.

²⁵ The Respondent listed several test readings in his treatment plan ordering administration of Lupron and other medications. He did not explain what symptom or test readings he was targeting for treatment with each medication. I have concluded that the listed hormones were relevant to his decision to treat Patient H with Lupron based upon similar decisions reflected in other Patient charts.

149. The Respondent first prescribed Lupron for Patient I on June 12, 2006 when he was nearly ten years old. State's Ex. 19 at 11831, 11822, and 11921.

150. Patient I Record does not contain a specific explanation for the Respondent's decision to prescribe Lupron. *See generally* State's Ex. 19.

151. Because the Respondent has not specified the basis for his determination to prescribe Lupron for Patient I, his decision to prescribe Lupron to Patient I is unreliable.

152. A serious side-effect of Lupron therapy is the risk of skin infections at the injection site; this risk is increased by the number of shots of Lupron administered to the Patient. Tr. 513.

153. The side-effect most frequently observed with administration of Lupron is injection-site soreness. State's Ex. 8 at 37.

154. Because the Patients received two injections of Lupron Depot each month and received at least one injection of Lupron subcutaneously each day, they were at a very high risk of skin infections and skin abscesses. Tr. 513.

155. The Records do not contain specific direction to the Patients' parents to watch for signs of skin infections at the injection sites. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

156. Another serious although not common side-effect of Lupron is exacerbation of seizures. Because seizure disorders are commonly co-morbid with autism spectrum disorders, it is important for a physician prescribing Lupron to determine whether his patient has a history of seizures. Such a history makes prescribing Lupron contraindicated. Tr. 505.

157. The Respondent prescribed Lupron to Patient B despite his history of having uncontrolled seizures. *See* State's Ex. 12 at 10654, 10658, 10745; Tr. 717.

158. The Respondent monitored the Patients on Lupron through monthly laboratory tests of the patient's androgen and estrogen levels, and by asking the Patients' parents to complete ATEC checklists identifying increased or diminished behaviors. State's Ex. 8 at 37 - 42.

159. The Respondent did not ask the Patients' teachers, therapists, or other care providers to complete ATEC checklists based on their observations of the Patients; he failed to obtain first-hand neutral observations of the Patients' baseline behaviors prior to treatment with Lupron and failed to obtain first-hand neutral observations of changes in the Patients' behaviors after initiation of treatment with Lupron. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

160. The Respondent did not obtain any subsequent ATEC checklists from the parents of Patients A, E, F, H, or I after initiation of his treatment of those Patients, and thus had no standardized method of monitoring the effect of Lupron therapy on those Patients. *See* State's Ex. 11, 15, 16, 18, 19.

161. The Respondent obtained a second ATEC checklist from the parents of Patient B after initiation of Lupron therapy, but only after nearly three years of that treatment and, thus, he did not use this tool as a way of monitoring progress with Lupron. *See* State's Ex. 12 at 10548.

162. The Respondent obtained a second ATEC checklist from the parent(s) of Patient G approximately one year after initiating Lupron therapy, and may have used this as a tool for monitoring Patient G's progress with Lupron. *See* State's Ex. 17 at 11373 – 11375.

Treating a Patient Before In-Person Contact With That Patient

163. The Respondent first prescribed medication for Patient B on July 10, 2006, nearly three years prior to the date he first physically examined him on June 10, 2009. The Respondent continued to treat Patient B, prescribing medications for him and modifying the doses of those

medications, during the three-year period before he saw Patient B in person. *Compare* State's Ex. 12 at 10525 *with* State's Ex. 12 at 10734, 10745, 10554-10556.

164. The Respondent first prescribed medication for Patient G on June 3, 2008, nine months before he first saw Patient G in person on March 1, 2009. The Respondent developed a treatment plan, prescribed medications, and modified the doses of those medications before he ever physically saw or examined Patient G. *See* State's Ex. 17 at 11466, 11469; *see generally* State's Ex. 17.

165. The Respondent first prescribed medication for Patient I on June 21, 2006, over nine months before he first saw Patient I in person on March 25, 2007. The Respondent developed a treatment plan, prescribed medications, and modified the doses of those medications before he ever physically saw or examined Patient I. *See* State's Ex. 19 at 11670, 11822; *see generally* State's Ex. 19.

166. Prescribing medications for Patients B, G, and I before ever physically seeing them placed those Patients at risk of serious harm.

167. The Respondent added medications, or increased or lowered the dosage of already prescribed medications, to Patients A, B, E, F, G, H, and I without performing additional physical examinations of those Patients. *See generally* State's Ex. 11, 12, 15, 16, 17, 18, 19.

168. The Respondent's Evaluation of Patients A, B, E, F, G, H, and I was deficient because the monitoring plan for each Patient was inadequate and insufficient to both protect the Patients from adverse side effects and to make well-grounded decisions about the efficacy of or modifications to therapies administered to them.

169. The missing components of the Respondent's Evaluations and monitoring plans prevented the Respondent from being able to accurately assess whether Patients A, B, E, F, G, H,

and I needed the therapies and treatments he prescribed for them, and from being able to accurately assess the risks and benefits to each Patient of each of those prescribed therapies and treatments.

170. The Respondent's monitoring plans for Patients A, B, E, F, G, H, and I lacked critically important information necessary to assess whether the Patients could be or were suffering adverse side effects from the treatments and therapies he prescribed.

171. The missing components and deficiencies in the Respondent's initial Evaluations and ongoing monitoring of Patients A, B, E, F, G, H, and I posed a risk of serious harm to each of these Patients.

172. The missing components and deficiencies in the Respondent's initial Evaluations and his inadequate monitoring of the Patients make it substantially likely that the Respondent's evaluation and monitoring of other patients would be similarly defective and present a substantial likelihood of risk of serious harm to the health, safety, or welfare of the public.

DISCUSSION

I. Motion for Judgment.

The Respondent made a Motion for Judgment at the close of the State's case-in-chief. The Respondent presented its Motion both in writing and orally. Due to the complexity of the issues raised in the Motion, the late hour at which the Motion was presented, and the schedules of witnesses waiting to testify on behalf of the Respondent, the parties agreed that the Administrative Prosecutor would respond to the Motion on the following day. The parties and I further agreed that the Respondent would not be considered to have withdrawn its Motion by presenting evidence prior to either the Administrative Prosecutor's or my response to the Motion. *See* COMAR 28.02.01.12E(3).

OAH Rules of Procedure permit a party to move for judgment on any or all of the issues at the close of the evidence offered by the opposing party. COMAR 28.02.01.12E(1). Under that rule, I am permitted to decline to render judgment until the close of all the evidence. After hearing the Respondent's argument on the Motion, I indicated that I was likely to choose to decline to render judgment until the close of the evidence and, after hearing the Administrative Prosecutor's argument on the following day, I chose to do so for reasons explained on the record. COMAR 28.02.01.12E(2)(b). I rule on the Motion in this Decision, considering only the evidence in the State's case in chief.

A. State's obligation to obtain and produce two peer reviews to establish the standard of care

The Respondent argued that, under sections 14-401(e) and 14-404(a)(22) of the Health Occupations Article, the State is required to obtain and produce two peer reviewers for each allegation that a physician has failed to meet appropriate standards for the delivery of quality medical care. The Respondent further argued the State had failed to produce evidence that it had met this requirement. The Respondent pointed out that the State's case-in-chief included only one peer review report and the testimony of a single reviewer, Dr. Grossman. The Respondent contended that this evidence was insufficient to prove that the Board had followed mandatory procedures prior to issuance of the Order for Summary Suspension and had failed to carry its burden to establish "the standard of care." The Respondent relied upon the proposed decision of Administrative Law Judge Geraldine Klauber in the case of *Maryland Board of Physicians v. Lee-Bloem, M.D.*, OAH Case No. DHMH-SBP-71-08-08596 (Sept. 11, 2008) as support for its position that, in the absence of a standard that at least two peer reviewers agreed upon, there is no established

“standard of care.”²⁶ The Respondent urged me to recommend dismissal of the Order for Summary Suspension because its allegations centered around a “standard of care” that the State had failed to establish.

In response, the State encouraged me to focus only upon the issue at hand, namely, “whether the Board was correct in suspending the Respondent because his practice raised the substantial likelihood of serious harm to public health, safety or welfare.” Tr. 836. The State disagreed that it was required, in this hearing, to produce two peer reviewers or to establish that it had obtained two peer reviews²⁷ and argued that its expert, Dr. Grossman, had produced sufficient evidence of the risk of serious harm posed by the Respondent to justify summary suspension of his license.

Section 14-401 of the Health Occupations Article governs the Board’s actions during investigations that may lead to disciplinary action against physicians under HO section 14-404. One key element of the investigatory process is physician peer review. HO § 14-401(e). By law, the Board is required to obtain “two peer review reports for each allegation” of a violation of the standard of quality care. *Id.* at (e)(1)(i), (ii) (referencing HO § 14-404(a)(22)).

The law distinguishes, however, between the procedure required for formal disciplinary action against a physician’s license and summary suspension of a physician’s license. Under HO section 14-405(a), which governs “Hearings,” “before the Board takes any action under § 14-404(a) . . . , [the Board] shall give the individual against whom the action is contemplated an opportunity for a hearing before a hearing officer.” This is true “[e]xcept as otherwise provided in the

²⁶ “The ordinary sense of the phrase ‘appropriate standards as determined by appropriate peer review’ indicates that under section 14-404(a)(22) it is *peer reviewers* who determine the standard(s).” *Lee-Bloem*, slip op. at 15 (Attachment 1, Respondent’s Motion for Judgment).

²⁷ The State consistently argued that it had obtained two peer reviews, citing its Order for Summary Suspension. The Order for Summary Suspension, State’s Exhibit 63, was admitted for the limited purpose of establishing that the State had issued and provided that Order to the Respondent. *See* Tr. 175. As clarified during the hearing, it was not admitted to establish the truth of all the allegations contained within it, including whether the State obtained two peer reviews. *See* Tr. 174.

Administrative Procedure Act.” *Id.* (emphasis added). COMAR 10.32.02.05, entitled “Summary Suspensions,” makes it clear that the phrase “except as otherwise provided in the Administrative Procedure Act” refers to the post-deprivation hearings in summary suspension cases because it states that “State Government Article § 10-226(c), Annotated Code of Maryland, governs consideration of summary suspension of a license.” COMAR 10.32.02.05A.

Section 10-226(c) of the State Government Article does not set out the prehearing procedure required for summary suspension hearings; it merely states:

- (2) A unit may order summarily the suspension of a license if the unit:
 - (i) finds that the public health, safety, or welfare *imperatively* requires *emergency* action; and
 - (ii) promptly gives the licensee:
 - 1. written notice of the suspension, the finding, and the reasons that support the finding; and
 - 2. an opportunity to be heard.

(Emphasis added).

The regulations governing summary suspension are silent as to which, if any, of the procedures required for hearings regarding formal charges are also required in or during preparation for summary suspension hearings. Indeed, the sole regulatory reference to fact-gathering prior to the summary suspension hearing states: “Based on information *gathered during an investigation*, the Board may determine that there is a substantial likelihood of a risk of serious harm to the public health, safety or welfare by the health provider, and vote an intent to summarily suspend the license of the respondent.” COMAR 10.32.02.05B(1) (emphasis added).

After considering the focus the governing statute has on “emergency action,” I conclude that section 10-226(c)(2) of the State Government Article is designed to permit a state agency to take action *immediately* upon its determination that summary suspension is necessary to protect

the public. I see nothing in the law that requires the agency, in this case the Board, to finish its entire investigation before concluding that an emergency situation requiring summary suspension exists. To the contrary, COMAR 10.32.02.05B(1) simply states that the Board can act on information "gathered during an investigation"; the regulation does not require the Board to *complete* its investigation before voting to summarily suspend.

Moreover, HO section 14-401(e)(1) specifically limits the requirement of obtaining two peer reviews to cases in which the Board is seeking discipline under HO section 14-404(a)(22). Hearings on allegations arising under HO section 14-404(a)(22) are governed by HO section 14-405, which, as noted above, excepts from its provisions summary suspension hearings. It should be noted that Judge Klauber's decision in the *Lee-Bloem* case addressed an alleged defect in the Board's preparation for a formal section 14-405 charges hearing; it was not a summary suspension case. *See Maryland Board of Physicians v. Lee-Bloem, M.D.*, OAH Case No. DHMH-SBP-71-08-08596 (Sept. 11, 2008).

While I am aware that the Board has filed formal charges against the Respondent under HO section 14-405, *this is not the hearing to determine those charges*. The argument presented by the Respondent may be applicable in that subsequent hearing, currently scheduled to be convened in December 2011. In this hearing, I am not required to determine whether the Respondent's conduct justifies action under HO section 14-404(a)(22) and, thus, the absence of a second peer review does not require dismissal of the Order for Summary Suspension. The Respondent's request for dismissal on this ground is denied.

B. Is Dr. Grossman the Respondent's "peer" for purposes of HO sections 14-401 and 14-404(a)(22)?

Respondent's counsel argues that the Respondent, a geneticist, is a specialist, and that the State's expert witness, Dr. Grossman, as a behavioral pediatrician, is a primary care doctor not qualified to render opinions on the medical appropriateness of the Respondent's actions.

The State disagrees, arguing that Dr. Grossman and the Respondent fall within the definition of "peers" because they are both physicians who treat children with autism. The State pointed to COMAR 10.32.02.02(b)(20), which defines "peer review" as "an evaluation according to procedures, set forth by the faculty and approved by the Board, by physicians within the involved medical specialty or specialties, of an act or acts of medical or surgical care, or other acts connected with medical or surgical practices, by an applicant or a licensee."

As discussed above, I am not making a determination under HO sections 14-404 or 14-401 in this hearing. My sole task is to determine whether the State has proved, by a preponderance of the evidence presented, that the Respondent's actions present a substantial likelihood of risk of serious harm to the public health, safety or welfare.

In making that determination, I must weigh the evidence the State presented in this case. The Respondent's argument raises an important question which must be decided: namely, is Dr. Grossman sufficiently knowledgeable about the area of medicine practiced by the Respondent to permit me to rely on her opinion of his work?

The regulations governing this hearing define the term "involved medical specialties," as used in COMAR 10.32.02.02B(20), as "the area of medical specialty which would be most normally concerned with the medical or surgical act in question and the practitioners of which area would be the most likely to be familiar with the risks and benefits of that act." COMAR 10.32.02.02B(16). The acts in question in this case are the Respondent's evaluation and

treatment of children with autism with an eye toward reducing the behavioral symptoms of those diseases. Time and time again the Respondent's notes reflect his concerns about the Patients' problems with sleeping, screaming, verbalizations, temper tantrums, and performance in school. The Respondent urged the Patients' parents to keep a close eye on them and log what happened after the administration of the Lupron shots he prescribed (for every Patient in this case except Patient C) and the chelation therapy he instituted (for Patients other than C, E, and F).

While there is no doubt that the Respondent is a geneticist, I heard no testimony and saw little evidence of his work in the field of genetics. Although the Respondent did order some genetic tests for the Patients, the bulk of his work with the Patients related to his treatment of their behavioral issues. Moreover, the Board has not relied upon the Respondent's genetic work as a basis for the summary suspension. To the contrary, the "medical acts" at issue in this case are the Respondent's attempts to modify youthful Patients' symptomatic behaviors, primarily through the administration of Lupron and chelation.

Dr. Grossman is a behavioral pediatrician who examines and treats children with autism, and who also prescribes medication based in part on their behaviors. I find that she is a practitioner in the area of the "medical acts" at issue here, and that she is "most likely to be familiar with the risks and benefits of [those] acts."

The Respondent also argued that because he is a "specialist" and Dr. Grossman is a primary care physician, she is not his peer. Because the Respondent did not support this argument with any testimony about the differences between how specialists and primary care physicians practice medicine, I have no grounds to find such a difference, particularly as it applies to this case.

The Respondent's request that I dismiss the Order for Summary Suspension on the grounds that Dr. Grossman is not a "peer" and presented unreliable testimony is denied.

C. Does Dr. Grossman's testimony as to whether the Respondent's actions with each Patient presented to that Patient a "serious risk of harm" or a "significant risk of harm" require dismissal of the Order for Summary Suspension because it failed to establish that the Respondent's actions presented a "substantial likelihood of risk of serious harm to the public health, safety or welfare"?

The Respondent argues that during the State's examination of Dr. Grossman, the State asked if the Respondent's actions represented a "significant risk of harm" or a "serious risk of harm," rather than the statutory standard, namely, whether his actions presented a "substantial likelihood of risk of serious harm." According to the Respondent, the State therefore failed to present expert testimony on this point and I must dismiss the Order for Summary Suspension. The State rejects this argument, saying that my "determination of this case is not dependent on formulaic incantations with regard to proof" and, thus, any misstatements in phrasing of the questions or answers were irrelevant in light of the bulk of the evidence in this case. Tr. 836.

At the end of her testimony regarding each Patient, the State solicited an overall opinion from Dr. Grossman as to that Patient's risk of harm from the Respondent's treatment. But along the way, the questions presented to Dr. Grossman contained varying descriptions of the standard in question. Naturally enough, her responses contained various phrases using the word "risk."

Dr. Grossman gave a multi-tiered response to questions presented to her about "exposure to risk of harm" from the Respondent's treatment of Patients A, B, and E. Tr. 275 - 76; Tr. 298; Tr. 334 - 35. In response to a question about Patient C's "possible exposure to risk of harm" as a result of the Respondent's order that he submit to laboratory testing, Dr. Grossman expressed that she thought he was at "possible exposure to risk of harm." Tr. 302. Dr. Grossman expressed an opinion that Patient F, Patient G, and Patient I were at "significant" risk of harm

from the Respondent's treatment. Tr. 347 - 348; Tr. 366; Tr. 405 - 06. Dr. Grossman was asked about Patient H's "exposure to risk of harm" but did not directly answer that question, although she was clearly worried about the risk posed to Patient H by being "given several potentially dangerous medicines without adequate monitoring and adequate assessment prior to starting ... [w]ithout adequate assessment prior to starting and adequate monitoring when she was on it."

Tr. 383. Thus, I agree with the Respondent that Dr. Grossman rarely gave a succinct answer to the question of whether the Respondent's treatment presented a "substantial likelihood of risk of serious harm" to each of the Patients.

Nevertheless, there can be no doubt that Dr. Grossman was seriously and genuinely concerned about nearly every level of the Respondent's interactions with the Patients. The complexity of this case required sometimes grueling testimony by Dr. Grossman which extended over most of three days. Counsel and I frequently had to ask her to raise her voice as she tired and to break down her testimony on complex issues into more and more discrete parts. Despite her fatigue, Dr. Grossman never wavered in her persistent concern about the risk she believed the Respondent's treatment posed to the Patients.

The Respondent asks me to focus exclusively upon testimony in which Dr. Grossman used the statutory and regulatory language of "substantial likelihood of risk of serious harm." I decline to do so. I do not judge an answer solely by the use of a specific phrase; doing so would convert my review into something like the chelation described in this case: a review, that when activated, attached itself to only one specific type of testimony and ignored everything else. As a human judge, I cast a wide gaze on the entirety of the evidence and endeavor to understand the words, their context, and what the witness is conveying and attempting to convey. While the specific words themselves are critically important, the statute and regulations do not require the

presence of the standard's language in every single response by a witness to make that response relevant and probative evidence.

I am asked to determine whether continuing to permit the Respondent to practice medicine pending a resolution of formal charges against his license posed a "substantial likelihood" of "risk of serious harm" to "the public health, safety or welfare." I am *assisted* in this determination by the expert witness, not controlled by the witness. For purposes of this Motion for Judgment, I had not only the testimony of Dr. Grossman and Parent A, but thousands of documents, including a sworn statement from the Respondent and his son. Considering all of this information, I do not find that the absence of a specific response from Dr. Grossman to a specific question phrased about "the substantial likelihood of risk of serious harm" requires dismissal of the Order for Summary Suspension. The Respondent's Motion for dismissal of the Order for Summary Suspension on this ground is denied.

D. Did the State provide sufficient evidence to carry its burden to prove that the Respondent operated a flawed Internal Review Board, as alleged in paragraphs 157 through 162 of the Order for Summary Suspension?

The Respondent argued both that he was not required by federal law to have an Internal Review Board and, that even if he was bound by such a requirement, the State failed to produce any evidence that his board operated in a flawed manner. The State did not dispute this argument in its response to the Motion. I agree with the Respondent that the State failed to produce sufficient evidence to survive a motion for judgment on the allegations related to an Internal Review Board. *See* COMAR 28.02.01.12E. *Cf.* Md. Rule 2-519. I will recommend that this portion of the Motion be granted and further recommend that paragraphs 157 through 162 of the Order for Summary Suspension be dismissed.

E. Did the State provide sufficient evidence to carry its burden to prove that that the Respondent misrepresented his credentials, as alleged in paragraphs 163 through 170 of the Order for Summary Suspension?

The State did not specifically oppose the Respondent's argument on this issue. I agree that the evidence in the State's case-in-chief is insufficient to survive a motion for judgment on allegations related to the misrepresentation of credentials. I will recommend that this portion of the Motion be granted and further recommend that paragraphs 163 through 170 be dismissed.

II. Did the Respondent's practice of medicine present a substantial likelihood of risk of serious harm to the public health, safety or welfare?

A. Legal Standard

Summary suspension of an individual's license is governed in Maryland by the Administrative Procedure Act, which permits suspension if "the public health, safety, or welfare imperatively requires emergency action" and if the licensee is given notice of the suspension and an opportunity to be heard. Md. Code Ann., State Govt. § 10-226(c)(2) (2009). The regulations governing the Board's actions in this case interpret the term "imperatively requires" as an action required "as the result of factual contentions which raise a substantial likelihood of risk of serious harm to the public health, safety, or welfare before an evidentiary hearing governed by the Administrative Procedure Act." COMAR 10.32.02.02B(14). Thus, the Board may summarily suspend the license of a health care provider if the provider's use of that license raises "a substantial likelihood of a risk of serious harm to the public health, safety, or welfare." COMAR 10.32.02.05.

The Maryland Court of Appeals interpreted this standard in *Board of Physician Quality Assur. v. Mullan*, 381 Md. 157 (2004). The case arose after the Board summarily suspended the license of Dr. Mullan based on allegations that he was treating minor patients while under the influence of alcohol. While doing so, Dr. Mullan departed from his normal practice of dictating

diagnoses and completing the patients' charts. He also failed to note in the patient charts some of the medications he had prescribed for them. The Board stipulated that the standard of medical care was not violated by these actions but concluded that summary suspension was necessary because the doctor's decision to treat patients, while knowing that he was under the influence of alcohol, presented a substantial likelihood of a risk of serious harm to the public health, safety or welfare. The Court of Appeals upheld the Board's decision to summarily suspend the doctor's license, noting that, as a pediatrician with a history of severe alcoholism, Dr. Mullen exhibited a "remarkable lack of sound judgment" for his failure to refrain from seeing patients if he could not refrain from using alcohol. "Such a lack of sound judgment is sufficient evidence for a reasonable Board to conclude the incident might repeat itself, requiring the immediate suspension of the doctor's license and posing a danger that "imperatively requires emergency action." *Mullan*, 381 Md. at 172-73. *Mullan* is significant for setting the precedent that the Board may summarily suspend a physician's license if, despite the absence of a violation of standard of care, the physician's lack of judgment places patients at risk of serious harm.

Another case involving allegations of poor documentation leading to summary suspension arose under a similar statute in the District of Columbia. *Williamson v. District of Columbia Bd. of Dentistry*, 647 A.2d 389 (D.C. 1994). In *Williamson*, the District of Columbia's Department of Consumer and Regulatory Affairs (DCRA) summarily suspended a dentist's registration to dispense controlled dangerous substances, summarily suspended his dentistry license, and issued notice of intent to permanently suspend or revoke his registration. These actions were based upon information indicating that Dr. Williamson had incomplete and inadequate documentation of his control over narcotics stored in his office. After a three day hearing on the summary suspension actions, an administrative law judge set aside the summary

suspension of Dr. Williamson's license, but sustained DCRA's summary suspension of the registration. The judge found that "summary suspension of the registration was necessary to prevent 'imminent danger to the public health and safety' as required by the statute, basing this conclusion on the fact that petitioner had not taken adequate safeguards to insure proper and documented inventory and dispensing controls of controlled substances."²⁸ *Williamson*, 647 A.2d at 393. The District of Columbia Board of Dentistry subsequently revoked Dr. Williamson's dentistry license on grounds that included the summary suspension of his registration. When Dr. Williamson appealed the revocation to the District of Columbia Court of Appeals, the D.C. Court examined the summary suspension decision and affirmed it, ruling that "summary suspension of registration arises from and focuses upon the need for prompt action and may well be based on considerations and imposed under circumstances in which the conduct of the registrant would not meet the requisite standard for license discipline." *Williamson*, 647 A.2d at 394.

B. Findings in this Proposed Decision

On April 27, 2011 the Board issued a forty-eight page Order for Summary Suspension of the Respondent's license. The Respondent's license was thereafter summarily suspended on May 12, 2011 and this hearing convened on June 17, 2011, by agreement of the parties. On May 16, 2011, the Board issued formal charges against the Respondent's license on grounds that the parties asserted were nearly identical to those raised in the Order for Summary Suspension. The hearing on those charges will be convened on December 6, 2011 and continue through December 7, 2011.

²⁸ Summary suspension of a registration is governed in the District of Columbia by D.C. Code § 33-535(b). "It is initially imposed, simultaneously with the institution of permanent suspension or revocation proceedings under § 33-534(a), to prevent 'imminent danger to the public health or safety.'" *Williamson*, 647 A.2d at 392 – 393 (quoting D.C. Code § 33-535(b)(1)).

The parties requested that I preside over this subsequent hearing as well as over a related hearing regarding the Respondent's son, David Geier (scheduled for December 8 – 9, 2011), in order to increase the efficiency of holding three hearings with many related issues. Doing so also reduces the risk that different judges would issue different rulings based on some of the same evidence. Nevertheless, there is an inherent challenge faced by a judge presiding over three related hearings when the allegations in two are nearly identical and some of the same evidence is presented in all three, namely, that additional evidence or even the same evidence presented more clearly may convince the judge to change her mind on one or more findings of fact. While such a change may be entirely appropriate, given the additional evidence and evidence considered under similar but still slightly different issues, the change could be perceived as unfair or arbitrary, is more complicated to explain, and can unnecessarily create confusion and issues on appeal.

Being mindful of these entanglements, I take caution in this hearing to focus strictly on the limited issue presented to me, namely, did the Respondent's practice of medicine pending resolution of the formal charges against his license, present a substantial likelihood of risk of serious harm to the public health, safety or welfare. The State has presented forty-eight pages of reasons why it believed such a substantial likelihood of risk of serious harm existed. If I find that the evidences establishes the existence of a substantial likelihood of risk of serious harm based solely upon the allegations contained on pages two through four, or solely upon the allegations contained on page thirty-four, substantial likelihood of risk of serious harm has been established and the need to make findings on the remaining allegations ends. A drive to be thorough pushes toward the issuance of findings on all the allegations in the Order for Summary Suspension but, for the reasons expressed above, doing so is very likely to interfere with the

issuance of findings of fact on virtually the same questions after the more complete presentation in the subsequent cases in December. I therefore restrict my findings in this Decision in an effort to avoid that interference. I can find no prejudice to either party by doing so.

I state for the record in this matter that, with the exception of the last two issues raised in the Motion, the absence of a finding in this Decision on any specific issue raised in the Order for Summary Suspension should not be construed as a conclusion that the evidence on that issue was either sufficient or insufficient to establish a substantial likelihood of risk of serious harm to the public health, safety or welfare.

C. Evaluation of Witnesses and the Records

The Records were the primary “witness” in this hearing. Dr. Grossman, the only expert testifying in this hearing who evaluated the Records, played a key role in assisting me in understanding that witness and interpreting its testimony. The Respondent did not testify and none of the experts he presented had reviewed the Records or were called upon to provide an explanation of what was present – or absent – in them.

I found Dr. Grossman’s evaluation of the Records to be both credible and reliable. Dr. Grossman was a high-caliber witness with decades of experience in treating children and in teaching other physicians how to both treat and document the treatment of children. Dr. Grossman endeavored to provide as full an explanation of every question as she possibly could. She testified about standard medical practices and standard documentation of medical practice in medical records and, although she resisted ever backing off her opinions, it is apparent that her opinions were sound, reflected medical school teaching regarding medical record documentation, and were firmly based on standard medical practice. For the most part, Dr. Grossman’s

testimony about standard medical practices was corroborated by the Respondent's expert witnesses. I found Dr. Grossman to be a credible witness.

Because each Record was hundreds of pages long, Dr. Grossman's testimony, by necessity, tended to "cherry-pick" points. In order to ensure that her testimony was fully supported by the entirety of the Records, I conducted my own detailed review of each page of the Records, through the lens of her expert opinion. This review demonstrated that Dr. Grossman's conclusions were grounded in fact. I found her review of the Records to be reliable.

I also found the Respondent's experts to be high-caliber witnesses, each with decades of experience and research in their respective fields. Their testimony was very helpful in enabling me to understand the rationale and methods for using Lupron and chelation, and there is no question that their experience with these therapies exceeded Dr. Grossman's.

The State argued that I should disregard the testimony of the Respondent's witnesses because their relationships with the Respondent made them biased in his favor. It is true that one hallmark of the credibility of an expert witness is the witness's neutrality and it is also true that in this case all four expert witnesses agreed that they had worked with the Respondent on research projects, in referring patients to the Respondent, or, as in Dr. Davis' case, in a current business relationship. The nature of such relationships does not automatically give rise to bias: all experts have some degree of relationship with the party who presents them; I am sure that Dr. Grossman also developed a working relationship with the Administrative Prosecutor during the State's preparations for this hearing. Despite the Respondent's relationships with Drs. Adams, Davis, Megson, and Kartzinell, and despite these witnesses' obvious respect and admiration for him, I did not observe that their connections tainted their opinions with regard to the use of Lupron and chelation. While all agreed that using Lupron and chelation to treat children with

autism is outside the mainstream of traditional treatments for autism, these experts explained why they approved of such therapy in a credible and reliable manner based upon their research and direct experience with these therapies. As the State noted in its opening statement and in its closing argument, my sole task in this case is to determine whether the Respondent's actions pose a substantial likelihood of risk of serious harm. This decision was made without reaching conclusions as to either the safety of using Lupron and chelation therapy to treat the symptoms of autism in children or as to the Respondent's reputation in the medical and autism communities. The Respondent's expert witnesses were helpful to me in understanding the medical issues in this case. I deny the State's request that I disregard their testimony on the ground that they are biased.

While I found the Respondents' experts reliable and credible, for the most part, they were unable to assist me with the central question of this hearing: whether the Respondent's treatment of the Patients placed these Patients at risk of serious harm and, if so, if the Respondent's conduct carried a substantial likelihood of placing the public at risk of serious harm. This is because none of these experts had reviewed the Records the Respondent maintained for these Patients. While Dr. Kartzinel, Dr. Davis, and Dr. Megson had all referred children to the Respondent, and these doctors as well as Dr. Adams had worked with him, none testified that they had referred to the Respondent any of the Patients at issue in this case. Thus, none could testify about the Respondent's actions with these Patients.

The Respondent's expert witnesses also did not describe in detail the Respondent's treatment of any of the patients they referred to him. Dr. Davis described the general process of evaluating patients with the Respondent, but the long-distance consulting that she described (with Dr. Davis performing the physical examination and taking the vital readings of the patient,

and then conveying that information over the telephone or through a Skype internet link to the Respondent) did not occur for any of the Patients. In the absence of any documentation that such a practice was followed in their cases, I cannot assume that a similar electronic or e-collaboration actually occurred.

Dr. Davis also testified that because the Respondent lacks direct access to the electronic medical records system she maintains on her/their patients, she would send the Respondent records by fax or in some other hard-copy format. Dr. Kartzinel testified that his practice was to forward hard copies of patient records to the Respondent through the parents of the patient involved. Because I inferred that any hard copies of patient records, if received by the Respondent, likely would remain part of the Records, I relied upon the presence or absence of such information in the Records. Hypothetically, the Respondent might have reviewed information electronically, but I could not assume that he did so in the absence of any documentation to that effect. Accordingly, without the Respondent's testimony, my decision on any question posed by a review of the Records rested squarely on the shoulders of Dr. Grossman and on what the Records themselves indicated about the Respondent's treatment of the Patients.

Both parties presented parents of the Patients as witnesses. Each of these witnesses testified passionately about their concern for their children and about the challenges they have faced in caring for them. Their testimony was touching, frequently heart-rending, and, with one exception, credible. All but Parent A attested to the benefits of the therapies the Respondent provided their children. All the parents testified as to the extraordinary challenges they face in caring for their children and of their hopes for improvement. I fully accept their testimony as credible. Still, the question posed to me cannot be restricted to assessing the benefits of Lupron or chelation therapy; the question posed to me is whether the Respondent's actions or inactions

during the care of the Patients placed the Patients at risk of serious harm, and, by extension, the public.

Again, it was the Records, as supplemented by the Parents' testimonies, which spoke most clearly and thoroughly about what the Respondent either did or did not do. One parent testified that she provided the Respondent with access to her binder of previous lab tests performed on her child, Patient H; yet there is no reference in Patient H's Record of exactly what the Respondent reviewed or whether he relied on that information. One parent testified that the Respondent sent her "all" the lab reports and reviewed them with her, but while this may be true, the other Records did not reflect such thoroughness. More than one parent testified that the Respondent answered all his/her questions; but, this testimony was not sufficient detailed to demonstrate that the Respondent provided those parents with essential information about all the risks and benefits of the proposed therapies and with an adequate identification of the adverse side effects to be guarded against.

The single parent witness I did not find to be credible was Parent A. Parent A testified about two visits her and her son, Patient C, made to the Respondent's office. Parent A made a complaint to the Board about her concerns that the Respondent required far too many blood tests of Patient C, and that the Respondent had falsely billed her insurance company for nonexistent procedures. Parent A's testimony about the bills was strident but confused, primarily due to her lack of knowledge about the meaning of all the codes reflected on the bills.²⁹ Parent A also testified that, on her second visit to the Respondent's office, she and Patient C were alone in a treatment room with the Respondent's son when the Respondent's son performed a diagnosis of Patient C and a sonogram. The reliability of Parent A's recollections disintegrated on cross-

²⁹ Her assertion that the Respondent should be charged with insurance fraud is not a question I am bound to answer in this hearing, and thus I did not consider her testimony on that point.

examination when she admitted that there might have been someone else in the treating room, and when the “diagnosis” was revealed to be little more than an observation. Because Parent A and Patient C did not return to the Respondent’s office for any treatment, and because I did not find Parent A to be a reliable reporter as to what occurred in the Respondent’s office, Parent A’s testimony was not the basis for any of my findings related to the Respondent’s treatment of children with autism.

D. Application of the Standard to the Evidence

The Board has taken action in this case based, in part, upon a sworn statement from the Respondent and the Board’s review of the Records. As described in the Findings of Fact, it is apparent that the Respondent initiated and continued treatment of children with severe forms of autism without much of the basic information necessary to do so. As the United States District Court for the District of Maryland has noted, a doctor *must* possess certain critical pieces of information before proceeding to treat a patient:

First, the doctor receives information directly from the patient. This includes complaints made by the patient, the doctor’s own observations and examination of the patient, and complaints or observations made by the patient to other doctors which are communicated to him. Second, the doctor obtains information from any laboratory tests that are ordered. Third, the doctor may receive information from third parties, such as friends or relatives of the patient.

East v. United States, 745 F. Supp. 1142, 1153 (D. Md. 1990). In *East*, the Court concluded that this information was essential to permit a doctor to issue a diagnosis of a patient. In the instant case, testimony by the State’s expert, Dr. Grossman, and the Respondent’s experts Drs. Kartzinell, Megson, and Davis, reflected their unshakeable conviction that these several types of information are essential in order to evaluate a patient for further treatment, even after prior diagnosis by another physician.

The Records demonstrate that, contrary to the Respondent's statements to the Board investigator, the Respondent failed to personally observe and examine a majority of the Patients and also failed to review the records of other physicians who had. Statements by the Respondent that he collaborated with other physicians in evaluating his patients were not substantiated in the case records of these Patients. The Respondent ordered hundreds of laboratory tests on the Patients which he could not accurately read because he failed to determine the Patients' Tanner Stages. The Respondent received information from the Patients' parents but failed to obtain and review the detailed logs he asked the parents to keep. The Respondent also failed to obtain information from anyone other than the parents, despite his statement to the Board investigator that statements about his patients from persons other than the parents were vital.

In many cases, the Respondent treated children with severe autism by telephone or Skype without access to the information he would have gained from personal observation of the children and personal examination of the children; the Records demonstrate that the Respondent treated the Patients for months – even years – before ever seeing those Patients in person. The Records demonstrate that the medications and other therapies the Respondent was prescribing were far from standard mainstream treatments with established low risks and a long well-recognized history of success. Nevertheless, the Respondent's plan for monitoring the efficacy and potential adverse side effects of these unusual treatments rested upon lab test results which he had insufficient information to interpret, and upon reports from the Patients' parents that were not sufficiently detailed to provide a clear picture of what was happening with Patients living many miles away.

In his sworn statement, the Respondent noted that he asked his patients' parents to watch the children carefully and document their observations in a detailed log. Yet, the Records do not reflect what he told the Patients' parents to watch *for* and to document, and the Records do not contain any of those logs. Such logs could have contained critical information that would only have been available to the Respondent in this written form, since the Respondent was treating many of the Patients "long-distance" and did not see them or examine them in person for lengthy periods of time. The absence of specific direction to the Parents about what might be important to log seriously weakened their ability to provide the Respondent with the information a careful physician would need to determine the efficacy of treatment and to protect the Patients from adverse side effects. The absence of the logs in the Records also shows that the Respondent treated these children with a constricted base of knowledge, essentially depriving himself of information that, if reviewed directly by the Respondent – a trained and experienced physician – could have uncovered an adverse side effect the Parents might not have noticed, or could have led to important conclusions about the efficacy of the prescribed therapy.

It was the Respondent's responsibility to take every precaution to guard his patients against such adverse side effects and to continuously monitor the efficacy of his prescribed therapies. The Records do not demonstrate that he adequately shouldered that responsibility.

The Records contain hundreds of pages of results from laboratory testing that the Patients endured on a monthly or more frequent basis. The Respondent testified in his sworn statement that he initiated and modified the administration of Lupron and initiated and continued or discontinued chelation therapy based in large part upon the results of these tests. Yet, the

Records contain no consistent documentation as to whether the Respondent reviewed those monthly lab test results or how his ongoing treatment reflected their results.

The Respondent testified in his sworn statement that he administered Lupron to his patients in an effort to reduce high levels of androgens such as DHEA, DHEA-S, Androstenedione and Testosterone. A determination as to whether test results show high levels of such androgens is based upon two factors: the patients' ages and the patients' puberty levels as measured by the Tanner Scale. None of the Records contain any determination of the Patients' Tanner Scale levels. Without this information, the Respondent could not have accurately determined whether the Patients' androgens were high. Clearly the absence of Tanner Scale measurements for the Patients calls into question the appropriateness of the Respondent's decisions to initiate and continue Lupron therapy for them. If the Respondent had this information, he inexplicably failed to document it in his Patients' medical records.

The Respondent testified in his sworn statement that he orders chelation therapy for his patients on "various" schedules "every other day or a few days on and a few days off for a couple of months – three months." State's Ex. 8 at 34. Yet, the Respondent's expert on chelation, Dr. Adams, testified credibly that patients need an even longer break between rounds of chelation: three days of chelation followed by *eleven* days off. Dr. Adams also testified that chelation therapy should *only* be initiated after a patient is given a short "challenge" dose of chelation to ensure that the patient actually needs the therapy. If administered to a patient who does not need it, chelation poses serious risks of injury to the brain and other organs. It is imperative, therefore, that a physician only administer chelation on a limited basis to the patients

who actually need it. The Respondent not only skipped the challenge step necessary to ensure chelation was even necessary, but then went full force into chelation therapy on an intensive schedule (with an experimental drug not FDA-approved for that purpose) without appropriate rest breaks. In several cases, moreover, the Respondent failed to regularly monitor the effects of chelation, and in two cases he prescribed it for patients that he knew he could not monitor.

The Records demonstrate that the Respondent frequently added or deleted medications or therapies during his treatment of the Patients, but the Records only infrequently explain his rationale for doing so. In particular, the Records consistently indicate increases in Lupron doses for each Patient but do not contain medical rationales for these changes.

While some of the Records contain information about the risks of Lupron therapy, many do not. None of the Records contain information about the risks chelation therapy poses to Patients. Some of the Respondent's notes in the Records contain a statement reflecting that the Patients' parents made an "informed consent" decision to proceed with one therapy or the other, but those notes do not go beyond that conclusory statement to explain either the basis or any details of that "informed consent" decision.

These inconsistencies between the Respondent's sworn statement and the Records he maintained of the Patients, the lack of information in the Records about treatment decisions and what led to those treatment decisions, the absence of evidence that the Respondent made decisions based on his own hands-on complete physical examinations and/or receipt of complete medical histories, the lack of evidence that the Respondent was relying on fully-informed, objective reports of the Patients' conditions, and the infrequency of in-person visits with many of

the Patients are factors which establish that the Patients were at risk of serious harm: from a constricted information base, from a deficient basis for initiating treatment, and from a flawed system of monitoring adverse side effects and efficacy. I believe that these factual considerations imperatively required emergency action. *Mullan*, 381 Md. at 172-73.

I conclude that for all these reasons, the Patients' health, safety or welfare was at risk of serious harm. Further, the existence of all these problems throughout all the Records raises a substantial likelihood that the risk of serious harm to the Patients was also posed to many other children with autism treated by the Respondent. I find that this meets the necessary standard for summary suspension of the Respondent's license: allowing him to continue practicing medicine while formal charges are pending raises a substantial likelihood of risk of serious harm to the public health, safety, or welfare.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact and Discussion, I conclude the following as a matter of law:

(1) The State failed to prove by a preponderance of the evidence that the Respondent operated a flawed Internal Review Board, as charged in paragraphs 157 - 162 of the Order for Summary Suspension;

(2) The State failed to prove by a preponderance of the evidence that the Respondent misrepresented his credentials, as charged in paragraphs 163 - 170 of the Order for Summary Suspension; and,

(3) The State has proved by a preponderance of the evidence that summary suspension of the Respondent's license to practice medicine is imperatively required to protect the public health, safety or welfare. Md. Code Ann., State Gov't § 10-226(c)(2) (2009).

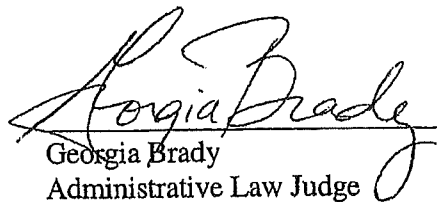
PROPOSED DISPOSITION

I **PROPOSE** that the Respondent's Motion for Judgment on the issues in paragraphs 157 through 170 of the Order for Summary Suspension be granted; and I further

PROPOSE that the remainder of the Respondent's Motion for Judgment be denied; and I further

PROPOSE that the Respondent's license to practice medicine be summarily suspended until the resolution of formal charges against his license.

September 26, 2011
Date Decision Mailed


Georgia Brady
Administrative Law Judge

GB/rbs
Doc #120841

NOTICE OF RIGHT TO FILE EXCEPTIONS

Any party may file written exceptions to this Proposed Decision addressed to the Board of Physicians, ATTENTION: Barbara K. Vona, Chief, Compliance Administration, 4201 Patterson Avenue, Baltimore, MD 21215, within fifteen days from the date of the proposed decision. Md. Code Ann., State Gov't §§ 10-216 and 10-220 (2009) and COMAR 10.32.02.03F. Any party may request a hearing on the exceptions.³⁰ Any filing with the Board must be copied to opposing counsel. Each party will have fifteen days from the date of receipt of any written exceptions to file a response with the Board. The Office of Administrative Hearings is not a party to any review process.

³⁰ Pursuant to COMAR 10.32.02.03F(2), the Board is obliged to schedule a hearing upon receiving any exceptions, however, the Board's transmittal of this case instructs the ALJ to notify the parties that they may request a hearing on exceptions.

Copies Mailed To:

Victoria H. Pepper
Assistant Attorney General
Administrative Prosecutor
Health Occupations Prosecution and Litigation Division
Office of the Attorney General
300 West Preston Street, Suite 201
Baltimore, MD 21201
vpepper@dhmh.state.md.us

Joseph A. Schwartz, III, Esquire
J. Steven Wise, Esquire
Schwartz, Metz & Wise, P.C.
10 West Madison Street
Baltimore, MD 21201
jschwartz@schwartzmetz.com
swise@schwartzmetz.com

Mark R. Geier, M.D.
14 Redgate Court
Silver Spring, MD 20905

Christine Farrelly, Supervisor
Compliance Administration
State Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

C. Irving Pinder, Executive Director
State Board of Physicians
4201 Patterson Avenue, 3rd Floor
Baltimore, MD 21215

Rosalind Spellman, Administrative Officer
Health Occupations Prosecution and Litigation Division
Office of the Attorney General
300 West Preston Street, Room 201
Baltimore, MD 21201

Paul T. Elder, M.D., Chairman
State Board of Physicians
Metro Executive Plaza
4201 Patterson Avenue, Third floor
Baltimore, MD 21215

John Nugent, Principal Counsel
Health Occupations Prosecution and Litigation Division
Office of the Attorney General
300 West Preston Street, Room 201
Baltimore, MD 21201

STATE BOARD OF PHYSICIANS

v.

MARK R. GEIER, M.D.,
License # D24250,

RESPONDENT

* BEFORE GEORGIA BRADY,
* AN ADMINISTRATIVE LAW JUDGE
* OF THE MARYLAND OFFICE
* OF ADMINISTRATIVE HEARINGS
* CASE NO: DHMH-SBP-72-11-19949
* SBP CASE NOS: 2007-0083, 2008-0454,
* 2009-0308

* * * * *

EXHIBIT LIST

Joint Exhibits

The following were Respondent's exhibits offered by the State in its case-in-chief, and admitted as Joint Exhibits:

Joint Exhibit #1 Dr. James B. Adams – Curriculum Vitae
Joint Exhibit #2 Dr. James B. Adams - Expert Opinion
Joint Exhibit #3 Dr. Georgia Davis - Expert Opinion
Joint Exhibit #4 Dr. Jerrold J. Kartzinel - Expert Opinion
Joint Exhibit #5 Dr. Mary Megson - Expert Opinion

State Exhibits

I admitted the following exhibits on behalf of the State:

State Exhibit #1 Complaint 2007-0083
State Exhibit #2 Complaint 2008-0454
State Exhibit #3 Complaint 2009-0308

- State Exhibit #4 October 19, 2006 Respondent's Response to Complaint 2007-0083
- State Exhibit #5 March 5, 2008 Respondent's Response to Complaint 2008-0454
- State Exhibit #6 January 22, 2010 Respondent's Response to Complaint 2009-0308
- State Exhibit #7 Transcript of Board staff interview of Amy Busch, March 31, 2009
- State Exhibit #8 Transcript of Board staff interview of Mark Geier, M.D., November 6, 2007
- State Exhibit #8A Mark R. Geier, M.D. – Curriculum Vitae
- State Exhibit #9 Transcript of Board staff interview of David Geier, January 19, 2010
- State Exhibit #10 July 19, 2010 Letter from Respondent's former counsel, Thomas Yost, Esquire
- State Exhibit #11 Patient A Record
- State Exhibit #12 Patient B Record
- State Exhibit #13 Patient C Record
- State Exhibit #15³¹ Patient E Record
- State Exhibit #16 Patient F Record
- State Exhibit #17 Patient G Record
- State Exhibit #18 Patient H Record
- State Exhibit #19 Patient I Record
- State Exhibit #24 Geier, D. and Geier, M., *A Prospective Assessment of Porphyrins in Autistic Disorders: A Potential Marker for Heavy Metal Exposure*, Neurotoxicity Research, 10(1), 57-64 (2006) – Offered By Respondent
- State Exhibit #25 Geier, D. and Geier, M., *A Prospective Study of Mercury Toxicity Biomarkers in Autistic Spectrum Disorders*, Journal of Toxicology and Environmental Health, Part A, 70:1723-1730 (2007)
- State Exhibit #48 Curriculum Vitae – Linda E. S. Grossman, M.D.

³¹ State Exhibits 14; 20-23; 26-47; and 61-62 were not offered.

- State Exhibit #49 January 25, 2011 Peer Review Report – Linda E.S. Grossman, M.D.
- State Exhibit #50 Carel, J. *et al.*, Consensus Statement on the Use of Gonadotropin-Releasing Hormone Analogs in Children, *American Journal of Pediatrics*, e752-e761 (2009)
- State Exhibit #51 Frazier, T., *et al.*, *Effectiveness of Medication Combined with Intensive Behavioral Intervention for Reducing Aggression in Youth with Autism Spectrum Disorder*, *Journal of Child and Adolescent Psychopharmacology*, 20:3, 167-177 (2010)
- State Exhibit #52 Curry, C., *et al.*, *Evaluation of Mental Retardation: Recommendations of a Consensus Conference*, *American Journal of Medical Genetics*, 72:468-477 (1997)
- State Exhibit #53 American Academy of Pediatrics, Committee on Children with Disabilities, *Counseling Families Who Choose Complementary and Alternative Medicine for Their Child with Chronic Illness or Disability*, *Pediatrics*, 107:3, 598-601 (2001)
- State Exhibit #54 e-Medicine Specialties > Pediatrics: Genetics and Metabolic Disease > Metabolic Diseases, *Carnitine Deficiency*
- State Exhibit #55 Myers, S., *et al.*, *Management of Children with Autism Spectrum Disorders*, *American Academy of Pediatrics*, 1162-1182 (2007)
- State Exhibit #56 McDougale, C., *et al.*, *Treatment of Aggression in Children and Adolescents with Autism and Conduct Disorder*, *Journal of Clinical Psychiatry*, 64[supp4]: 16-25 (2003)
- State Exhibit #57 Lupron (leuprolide acetate injection) Drug Information Sheet
- State Exhibit #58 Carel, J., *et al.*, *Treatment of Central Precocious Puberty with Depot Leuprolin (Abstract)*, *European Journal of Endocrinology*, 132:6 (1995)
- State Exhibit #59 Tordjman, S., *et al.*, *Plasma Androgens in Autism (Abstract)*, *Journal of Autism and Developmental Disorders*, 25:3 (1995)
- State Exhibit #60 ASD Centers: Autism Treatment Clinics – Listing of Clinics in Rockville and Baltimore, MD; Springfield, IL; Tamarac, FL; Allen, TX; Indianapolis, IN.; Pennsylvania and New Jersey; St. Louis, MO; Louisville, KY; and Seattle, WA.
- State Exhibit #63 April 27, 2011 Order for Summary Suspension of License to Practice Medicine

State Exhibit #64 DHMH Board of Physicians, May 12, 2011 Order For Summary
Suspension of License to Practice Medicine

Respondent Exhibits

I admitted the following exhibits on behalf of the Respondent:

- Respondent #3 Curriculum Vitae - Georgia Davis, M.D.
- Respondent #5³² Curriculum Vitae – Jerrold J. Kartzinel, M.D., FAAP
- Respondent #7 Curriculum Vitae – Mary Megson, M.D.
- Respondent #9 Curriculum Vitae - Mark Robin Geier
- Respondent #10 BMC Clinical Pharmacology (2009) – Safety and efficacy of oral
DMSA therapy for children with Autism Spectrum disorders: Part A -
Medical results, James B. Adams, et al.
- Respondent #11 BMC Clinical Pharmacology (2009) – Safety and efficacy of oral
DMSA therapy for children with Autism Spectrum disorders: Part B -
Behavioral Results, James B. Adams, et al.
- Respondent # 12 The Severity of Autism is Associated with Toxic Metal Body Burden
and Red Blood Cell Glutathione Levels, J. B.
Adams, et al.; Hindawi Publishing Corporation (2009).
- Respondent #13 Treatment Options for Mercury/Metal Toxicity in Autism and Related
Developmental Disabilities: Consensus Position Paper; Autism
Research Institute (2005)
- Respondent #14 A clinical trial of combined anti-androgen and anti-heavy metal
therapy in autistic disorders; David A. Geier and Mark B. Geier;
Neuroendocrinology Letters (2006)
- Respondent #15 A prospective assessment of androgen levels in patients with autistic
spectrum disorders: biochemical underpinnings and suggested
therapies; David A Geier and Mark R. Geier; Neuroendocrinology
Letters (2007)
- Respondent #16 Autism spectrum disorder-associated biomarkers for case evaluation
and management by clinical geneticists; David A. Geier and Mark R.
Geier; Expert Reviews (2008)

³² Respondent Exhibits 4, 6, and 8 were not offered for admission.

- Respondent #17 Clinical Genetics evaluation in identifying the etiology of autism spectrum disorders; G. Bradley Schaefer, M.D., et al.; Genetics in Medicine (2008)
- Respondent #18 Treatment compliance in children and adolescents initiated on ADHD medication in clinical practice (COMPLY); P. Wehmeier, et al.; European Neuropsychopharmacology (2010)
- Respondent #19 Androgenic Activity in Autism; Sylvie Tordjiman, M.D., Ph.D., et al.; American Psychiatric Association (1997)
- Respondent #20 Sex differences in the Brain: Implications for Explaining Autism; Simon Baron-Cohen, et al.; Science Magazine (2005)
- Respondent #21 Thimerosal exposure & increasing trends of premature puberty in the vaccine safety datalink; Davis A. Geier, Heather A. Young, and Mark B. Geier; Indian Journal of Medicine (2010)
- Respondent #22 Lupron Depot-Ped Package Insert; (leuprolide acetate for depot suspension)
- Respondent #23 Leuprolide Acetate Injection - Package Insert
- Respondent #24 Results of Long-Term Follow-Up after Treatment of Central Precocious Puberty with Leuprorelin Acetate: Evaluation of Effectiveness of Treatment and Recovery of Gonadal Function. The TAP-144-SR Japanese Study Group on Central Precocious Puberty; Toshiaki Tanaka, et al., Journal of Clinical Endocrinology & Metabolism (2005)
- Respondent #25 Longitudinal Follow-Up of Bone Density and Body Composition in Children with Precocious or Early Puberty before, during and after Cessation of GnRH Agonist Therapy; Inge M. van der Sluis; et al., Journal of Clinical Endocrinology & Metabolism (2002)
- Respondent #26 The Efficacy and Safety of Gonadotropin-Releasing Hormone Analog Treatment in Childhood and Adolescence: A Single Center, Long-Term Follow-Up Study; Maria Alexandra Magiakou, et al; the Endocrine Society (2010)
- Respondent #27 Treatment of central precocious puberty by GnRH analogs: long-term outcome in men; Silvano Bertelloni, et al.; Asian Journal of Andrology (2008)
- Respondent #28 Mitochondrial Disease in Autism Spectrum Disorder Patients: A Cohort Analysis; Jacqueline R. Weissman, et al; PLoS (2008)

- Respondent #29 A Prospective double-blind, randomized clinical trial of levocarnitine to treat autism spectrum disorders; David A. Geier, et al.; Medical Science Monitor (2011)
- Respondent #30 Safety of Frequent Venous Blood Sampling in a Pediatric Research Population; Sarabeth Broder-Fingert, MA, et al.; National Institute of Health (2009)
- Respondent #31 Cutting-Edge Therapies for Autism 2011-2012, Ken Siri, et al.; National Autism Association; Skyhorse Publishing (2011)
- Respondent #32 Maryland Board of Physicians Investigations – Memorandum of Interview of Mrs. Kawasaki; May 6, 2011
- Respondent #33 DSM-IV Criteria – Pervasive Developmental Disorders; American Psychiatric Association (1994)
- Respondent #34 CPT 2006, Current Procedural Terminology - American Medical Association (2006)
- Respondent #35 Institutional Review Board of the Institute of Chronic Illnesses- IRB Rules and Procedures, Record Keeping, Meetings, Categories of Proposals to the IRB, Continuing Review, Considerations of Research Design, and Changes in IRB Policy
- Respondent #36 Early Autism Detection: Are We Ready of Routine Screening?; Mona Al-Qabandi, et al., American Academy of Pediatrics (2011)
- Respondent #37 Porphyrins, Quantitative, Random Urine; Lab Corp. (2011)
- Respondent #38 Genetic Centers of America – Phone Contact Sheet for period January 1, 2007 through October 10, 2007
- Respondent #39 Use of Drugs Not Described in the Package Insert (Off-Label Uses); American Academy of Pediatrics (2002)