VIRGINIA:

BEFORE THE DEPARTMENT OF HEALTH PROFESSIONS

IN RE: **MARK ROBIN GEIER, M.D.**
License No.: 0101-048672

ORDER

In accordance with Section 54.1-2409 of the Code of Virginia (1950), as amended, ("Code"), I, Dianne L. Reynolds-Cane, M.D., Director of the Virginia Department of Health Professions, received and acted upon evidence that the license of Mark Robin Geier, M.D., to practice medicine in the State of Maryland was summarily suspended by an Order for Summary Suspension of License to Practice Medicine dated April 4, 2011. A certified copy of the Order for Summary Suspension of License to Practice Medicine is attached to this Order and is marked as Commonwealth's Exhibit No. 1.

WHEREFORE, by the authority vested in the Director of the Department of Health Professions pursuant to Section 54.1-2409 of the Code, it is hereby ORDERED that the license of Mark Robin Geier, M.D., to practice medicine and surgery in the Commonwealth of Virginia be, and hereby is, SUSPENDED.

Upon entry of this Order, the license of Mark Robin Geier, M.D., will be recorded as suspended and no longer current. Should Dr. Geier seek reinstatement of his license pursuant to Section 54.1-2409 of the Code, he shall be responsible for any fees that may be required for the reinstatement and renewal of his license prior to issuance of his license to resume practice.

Pursuant to Sections 2.2-4023 and 54.1-2400.2 of the Code, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public inspection and copying upon request.

D. Reynolds-Cane MD

Dianne L. Reynolds-Cane, M.D., Director
Department of Health Professions

ENTERED: 6-9-11

COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

CERTIFICATION OF DUPLICATE RECORDS

I, Dianne L. Reynolds-Cane, M.D., Director of the Department of Health Professions, hereby certify that the attached Order for Summary Suspension of License to Practice Medicine dated April 27, 2011, regarding Mark Robin Geier, M.D., are true copies of the records received from the Maryland State Board of Physicians.

D. Reynolds-Cane MD Date: 6-9-11

Dianne L. Reynolds-Cane, M.D.

IN THE MATTER OF	*	BEFORE THE
MARK R. GEIER, M.D.	*	MARYLAND STATE
Respondent	*	BOARD OF PHYSICIANS
License Number: D24250		Case Numbers: 2007-0083, 2008-0454 & 2009-0308

* * * * * * * * * * * *

ORDER FOR SUMMARY SUSPENSION OF LICENSE TO PRACTICE MEDICINE

The Maryland State Board of Physicians (the "Board") hereby **SUMMARILY SUSPENDS** the license of Mark R. Geier, M.D., (the "Respondent") (D.O.B. 05/03/1948), license number D24250, to practice medicine in the State of Maryland. The Board takes such action pursuant to its authority under Md. State Govt Code Ann. § 10-226(c)(2009 Repl. Vol.) concluding that the public health, safety or welfare imperatively requires emergency action.

INVESTIGATIVE FINDINGS

Based on information received by, and made known to the Board, and the investigatory information obtained by, received by and made known to and available to the Board, including the instances described below, the Board has reason to believe that the following facts are true:[1]

1. 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,

[1] The statements regarding the Respondent's conduct are intended to provide the Respondent with notice of the basis of the suspension. They are not intended as, and do not necessarily represent a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent in connection with this matter.

PENGAD 800-631-6989
COMMONWEALTH'S EXHIBIT
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1979. The Respondent also holds active licenses in the following states: California, Florida, Hawaii, Illinois, Indiana Kentucky, Missouri, New Jersey, Virginia and Washington.

2. The Respondent is certified by the American Board of Medical Genetics as a Genetic Counselor. In an interview with Board staff, the Respondent falsely claimed to be a board-certified geneticist and a board-certified epidemiologist. *See* Section IX, (Misrepresentation of Credentials).

I. The Respondent's Practice

3. The Respondent is president of Genetic Centers of America with offices located in Rockville and Owings Mills, Maryland. Genetic Consultants of Maryland, according to the Respondent, is "under the umbrella" of Genetic Centers of America. When interviewed by Board staff, the Respondent stated that his current practice includes genetic counseling of high-risk obstetric patients, evaluation of adults for risk of cancer and "genetic work-ups" of children with neuro-developmental disorders.

4. The Respondent also practices under the name "ASD Centers LLC." "ASD" is the abbreviation for Autism Spectrum Disorder. ASD Center, LLC's motto is, "First do no harm." The Respondent advertises the services provided by ASD as follows:

> The ASD Centers, LLC nationwide network, announces a new combined genetic, biochemical, heavy metal, and hormonal evaluation/treatment for patients diagnosed with an autism spectrum disorder (ASD). ASD Centers, LLC founder and medical director, Mark Geier, MD, PhD, FABMG,[2] FACE[3] has provided innovative genetic services

[2] FABMG is the abbreviation for Fellow of the American Board of Medical Genetics.
[3] FACE is the abbreviation for Fellow of the American College of Epidemiology.

> for over 28 years, and is a leader in researching and helping to treat patients diagnosed with an ASD. The ASD Centers, LLC is excited to now offer innovative evaluation/treatment protocols, which have successfully helped over 500 patients diagnosed with ASD.
>
> Researchers from Genetic Consultants studying the biochemistry of ASD have made a major break-through in the treatment of the disorder.
>
> Evaluations of more than 600 patients diagnosed with an ASD have revealed most have clinical symptoms and laboratory results consistent with high testosterone (the male hormone) and other androgens.
>
> Published peer reviewed clinical trials and treatment of over 300 patients diagnosed with an ASD showed significant clinical improvements following successful administration of testosterone lowering medications. This treatment resulted in rapid and remarkable improvements in autistic symptoms in many patients diagnosed with ASD with few adverse side effects.

5. In or around 2006, the Respondent established the Institute of Chronic Illness ("ICI") of which he is President. His son, an unlicensed individual,[4] is the "Founder and Vice-President" of the ICI. Both the Respondent and his son are members of the Institutional Review Board ("IRB") of ICI. The mission of an IRB is to protect the rights and welfare of human research subjects. One of the patients whose care was reviewed, Patient I, was enrolled in the "Geier Experimental Protocol" for the Treatment of Regressive Autism." The Consent Form states that the ICI IRB approved the study. As set forth in Section VIII below, the IRB fails to meet federal and State regulatory criteria.

[4] The Respondent's son has a Bachelor of Arts degree in biology from the University of Maryland Baltimore County,

II. The Respondent's Treatment Protocol

6. The Respondent treated autistic children in seven (7) of the nine (9) cases reviewed.[5] Autism is a heterogeneous syndrome with a broad range of behavioral symptoms and severity. These behavioral symptoms include but are not limited to: disorder of neural development characterized by markedly impaired social interaction, verbal and non-verbal communication and a pattern of restricted and repetitive behavior.[6]

7. In 2005, the Respondent and his son published in the journal *Medical Hypotheses*[7] an article entitled, *The potential importance of steroids in the treatment of autistic spectrum disorders*[8] *and other disorders involving mercury toxicity.* The Respondent wrote in pertinent part:

> Recently emerging evidence suggests that mercury, especially from childhood vaccines, appears to be a factor in the development of the autistic disorders, and that autistic children have higher than normal body-burdens of mercury. In considering mercury toxicity, it has previously been shown that testosterone significantly potentiates mercury toxicity, whereas estrogen is protective. ...We put forward the medical hypothesis that autistic disorders, in fact, represent a form of testosterone mercury toxicity, and based upon this observation, one can design novel treatments for autistics directed towards higher testosterone levels in autistic children....It is hoped that by devising therapies that address the steroid pathways, in addition to the current treatments

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[5] The parent of Patient C, below, did not return after an initial assessment by an individual she identified as the Respondent's son. The Respondent's contact with Patient D was limited to review of laboratory test results to prepare an expert report for litigation.

[6] *See* American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition,* Diagnostic criteria for Autistic Disorder (299.0).

[7] *Medical Hypotheses* is a journal which, according to its Aims and Scope statement, publishes "interesting and important theoretical papers that foster the diversity and debate upon which the scientific process thrives...[it] exists today to give novel radical ideas and speculations in medicine open-minded consideration, opening the field to radical hypotheses which would be rejected by most conventional journals."

[8] The term 'autistic spectrum disorder' refers to a spectrum of conditions that includes autism and other conditions characterized by qualitative impairments of social communication and interaction.

that successful *(sic)* lower heavy metal body burdens of mercury, *(sic)* will work synergistically to improve clinical outcomes.

8. In 2004, the National Academy of Science's Institute of Medicine ("IOM") [9] published a report entitled, "Immunization Safety Review – Vaccines and Autism." ("IOM Report") The IOM Report rejected a causal relationship between vaccines containing thimerosal, a preservative containing mercury, and autism.[10] The report specifically rejected the Respondent's and his son's studies that reported findings of such an association concluding, "the studies by Geier and Geier ...have serious methodological flaws and their analytic methods were nontransparent making their results uninterpretable, and therefore noncontributory with respect to causality."[11]

9. Notwithstanding the rejection of the Respondent's studies by the IOM, the Respondent developed a treatment protocol wherein autistic children are injected with anti-androgens, including Lupron (leuprolide), to decrease the amount of sex hormones the child's body produces. Under the Respondent's protocol, a child receives daily subcutaneous injections

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[9] The National Academy of Science is a "private, nonprofit, self-perpetuating society of distinguished scholars, created by congressional charter in 1863 to advise the federal government on scientific and technical matters." *Blackwell v. Wyeth,* 408 MD 575, 597, fn17 (2009)(rejecting the Respondent's epidemiological studies purporting to show a causal link between thimerosal-containing vaccines and mercury because his "credentials as a medical doctor and genetic counselor are not a foundation sufficient for him to offer [such] an opinion...") *Id. at 605.* The *Blackwell* court noted that IOM reports "are highly regarded in the relevant scientific community, and their reliability has been recognized by numerous courts..." *Id.* at 604.

[10] In 2001, IOM published a report finding that evidence was "inadequate to accept or reject a causal relationship between exposure to thimerosal from childhood vaccines and the neurodevelopmental disorders of autism, ADHD and speech and language delay." As a precautionary measure, thimerosal was removed from all childhood vaccines in 2001.

[11] IOM Report at page 65, citing studies described at pages 55 – 62.

("SQ") of Lupron, typically administered by a parent, and bi-weekly intra-muscular ("IM") injections administered in the Respondent's office.

III. Lupron

10. Lupron is a potent anti-androgen; that is, it reduces the amount of testosterone the body produces.

11. It is used to treat adult males with metastatic prostate cancer and adult females with endometriosis and uterine fibroids.

12. Lupron is also used to chemically castrate sex offenders.

13. The only medically accepted use of Lupron in children is precocious (or "premature") puberty. In this context, Lupron delays the progression of puberty by inhibiting the release of the Gonadotropin Releasing Hormone ("GnRH"), which affects the development of ovaries and testicles. Lupron is not approved for the treatment of autism.

14. With regard to administering Lupron to autistic children, the Respondent has been quoted as saying, "If you want to call it a nasty name, call it chemical castration. If you want to call it something nice, say you are lowering testosterone."[12]

15. Adverse side effects of Lupron in children include, but are not limited to, risk of bone and heart damage. Lupron is not recommended for individuals with heart disease, kidney disease, asthma or seizure as it may worsen those conditions. Autistic children are prone to seizures. No clinical studies have been completed in children to assess the full reversibility of fertility suppression.

[12] Trine Tsouderos, *"Miracle Drug" Called Junk Science,* Chicago Tribune, May 21, 2009.

16. The Respondent was reported to have stated in a 2006 radio interview[13] that Lupron is "99% natural" and "if you give it to kids whose normal level of testosterone is zero, and you lower these kids to zero, there are virtually no side effects." The Respondent also stated: "If you demonstrate that a child has precocious puberty the treatment under mainline medicine, has been for 20 years, is Lupron. Now the only difference is that we get a side effect. The side effect is that they not only lose their precocious puberty, they lose a good deal of their autism."

17. The cost of Lupron therapy ranges from $5,000 to $6,000 a month. The Respondent has stated that health insurance covers the cost when precocious puberty is diagnosed.

IV. Precocious (premature) puberty

18. The Respondent misdiagnosed six (6) of the nine (9) autistic children whose care is reviewed herein with precocious puberty.

19. The American Academy of Pediatrics has defined precocious puberty as the onset of sexual maturation before age eight (8) in girls and age nine (9) in boys.[14]

20. Precocious puberty is a relatively rare condition. It may be caused by tumors, central nervous system injury or genetic abnormalities.

21. There are no evidence-based publications in the medical literature to support the use of hormonal treatment in children with autism. The

[13] June 23, 2006, Radio Liberty.

[14] The Respondent is aware of the age component of the precocious puberty diagnosis. In a 2007 Patent Application, his definition of precocious puberty included the age criterion. United States Patent Application 20070254314, Inventors: Mark .R. Geier & [son], *Methods of treating autism and autism spectrum disorders,* ¶0107 (Nov. 1, 2007)

Respondent relies on his own studies, which have been discredited by the IOM.

22. The standard of quality care for the treatment of precocious puberty begins with an accurate diagnosis. The standard of quality care for the diagnosis of precocious puberty, in addition to the age criteria, includes: an x-ray of the child's left hand and wrist to assess skeletal maturation and accelerated bone growth, the result of a sex hormone effect. Unless history and examination suggest an abnormality, no further evaluation is required for children with pubertal milestones that are within one (1) year of population standards.

23. When further evaluation is necessary, the standard of quality care requires: height and weight measurements; physical examination of genitalia (and breasts for girls); measurement of serum levels of gonadotropins and gonadal and adrenal steroids; pelvic and adrenal ultrasound to rule out a steroid-secreting tumor and a computed tomography ("CT") scan of the head to rule out an intracranial tumor.

V. Chelation

24. The Respondent has stated that precocious puberty in children with autism is the result of an excessive level of mercury in the child's blood. In the 2006 radio interview, the Respondent discussed his theory:

> If you look at these children, most of them have signs and symptoms of precocious puberty. That's what [my son] and I have discovered. We discovered that the mercury upsets the pathway that has to do with testosterone, and the testosterone pathway interacts with the glutathione pathway, which is the pathway for

> eliminating mercury. Most of these kids have precocious puberty and they can be treated...They have high testosterone, they masturbate at age six, they have mustaches, they're aggressive, and you can treat them by lowering their testosterone and removing mercury, and we've had unbelievable success...And a number of doctors now are joining us, but they would join us a lot better if the authorities would actually tell the truth about what happened to the children.

25. In some instances, the Respondent's treatment protocol includes chelation therapy. The Respondent prescribed chelation therapy to three (3) patients described herein and recommended it for three (3) patients. Chelation therapy is the administration of chelating agents to remove heavy metals from the body. For the most common forms of heavy metal intoxication – those involving lead, arsenic or mercury – the standard of care dictates the use of DSMA.[15] Chelation therapy is not risk-free; it is associated with potential adverse side effects such as bone marrow suppression, shock, low blood sugar, convulsions, cardiac arrhythmias, respiratory arrest, and liver and kidney failure, which can be fatal.

26. In the cases reviewed, the Respondent prescribed rectal DMPS[16] suppositories for chelation. DMPS is not approved by the U.S. Food and Drug Administration ("FDA") and is considered an experimental drug in the United States.

27. With regard to chelation therapy, the 2004 IOM Report states:

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[15] The abbreviation for dimercaptosuccinic acid.

[16] The abbreviation for dimercapto-propane-sulfonic acid.

> [t]he committee found no scientific evidence ..that chelation is an effective therapy for ASD or is even indicated in these circumstances. Chelation therapy is currently indicated only for high-dose, acute mercury poisonings...Moreover, chelation therapy has serious risks; for example, some chelation therapies might cause the release of mercury from soft-tissue stores, thus leading to increased exposure of the nervous system to mercury. [citation omitted] **Because chelation therapy has potentially serious risks, the committee recommends that it be used only in carefully controlled research settings with appropriate oversight by Institutional Review Boards protecting the interests of the children who participate.**

2004 IOM Report at 149 (emphasis in original)

VI. Procedural History

Board Case Number 2007-0083[17]

28. On or about August 15, 2006, the Board received a written complaint from an individual who was neither a patient of the Respondent nor a parent of a patient. The complainant alleged that the Respondent promotes the use of Lupron as a treatment for autism in children. The complainant alleged that the Respondent, *inter alia*:

    a. Practices outside of the scope of his expertise and the prevailing standard of care for autism;

    b. Experimented on children without a rational scientific theory or the supervision of a qualified review board; and

    c. Failed to provide appropriate informed consent regarding the potential side effects of Lupron and similar drugs.

29. The Board designated this complaint as Board Case Number 2007-0083.

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[17] The names of patients and other individuals discussed herein are confidential. The Respondent may obtain them from the Administrative Prosecutor.

Board Case Number 2008-0454

30. While conducting its investigation of Case Number 2007-0083, the Board, on or about January 15, 2008, received a complaint from a pediatrician ("Physician A") who had referred one of his patients ("Patient A," below) to the Respondent for genetic evaluation and counseling. Physician A complained that the Respondent performed an inappropriate evaluation, made an incorrect diagnosis and treated Patient A inappropriately. Specifically, Physician A reported that the Respondent, whom he noted is not board-certified in either pediatric medicine or pediatric endocrinology, misdiagnosed Patient A with an endocrinological problem based on normal results of laboratory studies. Physician A further reported that the Respondent administered Lupron to Patient A for a "non-existent endocrine problem," and that his evaluation was "excessive and not based on any evidence-based evaluation algorithms."

31. The Board designated Physician A's complaint as Board Case Number 2008-0454.

Board Case Number 2009-0308

32. On October 8, 2008, the Board received a complaint from the mother of a former patient of the Respondent ("Patient C, below). Patient C's mother ("Parent A") alleged that the Respondent's son, was her only contact at a May 19, 2008 appointment at Genetic Centers of America. Parent A knew both the Respondent and his son, having met them both at a July 2005 consultation. Parent A reported that the Respondent's son, after asking

very few questions regarding Patient C's medical history and symptoms, told her that her son seemed to be a "typical high-testosterone kid" whose growth would be stunted if his testosterone production continued at its current pace. Parent A reported that she and her son did not see the Respondent at this visit.

33. According to Parent A, the Respondent's son performed an ultrasound examination on Patient C, attempting to examine his neck and abdomen by tapping him with the ultrasound wand while Patient C was moving around the room. Parent A further reported that the Respondent's son ordered an extensive number of laboratory studies of Patient C, noting "insomnia" and "metabolic disorder" as diagnoses.

34. The Board designated Parent A's complaint as Board Case Number 2009-0308.

35. On October 26, 2010, the Board referred eleven (11) patient records, including those of Patients A and C, to a peer review organization for review of the Respondent's practice. The peer reviewers declined to offer an opinion in two (2) of the cases because the care provided was beyond the scope of their expertise.

36. On January 25, 2011, the Board received the results of the peer review.

Summary Statement in Support of Summary Suspension

The Respondent misdiagnosed autistic children with precocious puberty and other genetic abnormalities and treated them with potent hormonal therapy ("Lupron Therapy" or "Lupron Protocol"), and in some instances, chelation

therapy, both of which have a substantial risk of both short-term and long-term adverse side effects. The Respondent's treatment exposed the children to needless risk of harm.

The Respondent, in addition to being a physician, is certified as a genetic counselor. His assessment and treatment of autistic children, as described herein, however, far exceeds his qualifications and expertise.[18] The extensive and expensive batteries of laboratory studies the Respondent initially orders, many of which he orders to be repeated on a monthly basis, are outside the standard of quality care for a work-up for an autistic patient or to determine the underlying cause of autism. The Respondent failed to conduct adequate physical examinations of any of the patients and in several instances, began his

[18] The Respondent is often called upon by plaintiffs to provide expert testimony before the Court of Federal Claims and other tribunals regarding the causation of alleged vaccine-related injuries, including autism. Since 1993, his testimony has been called into question. *See e.g. Marascalco v. Sect'y HHS,* 1993 WL 277095 (Fed.Cl.) (holding that the Respondent's affidavit as "intellectually dishonest" and "nothing more than an egregious example of blatant, result-oriented testimony[.]"); *Raj v. Sect'y HHS,* 2001 WL 963985 (Fed.Cl.) (Respondent "wholly unqualified to testify regarding the two major issues in this case [whether plaintiff had sustained encephalopathy or infantile spasms as a result of a vaccination]..because he is neither board certified nor has formal training in pediatrics or pediatric neurology[;]"); *Bruesewitz v. Sect'y HHS,* 2002 WL 31965722 (Fed.Cl.)(rejecting the Respondent's affidavits and report as "not credible" because he was not qualified to diagnose neurological diseases); *Thompson v. Sect'y HHS,* 2003 WL 21439672 (Fed.Cl)(rejecting the Respondent's comments that statistical significance in data is not meaningful as being "speculative," "not reach[ing] the level of evidentiary reliability" and lacking "intellectual rigor;" *Piscopo v. Sect'y HHS,* 66 Fed.Cl. 49 (2005)(noting that the Respondent's opinions have been "increasingly criticized in other vaccine cases" for offering expert opinions outside of his areas of training, education and experience); *Doe 2 v. Ortho-Clinical Diagnostics, Inc.,* 440 F.Supp.2d 465, 471 – 2)(2006)(noting that "in more than 10 ...cases [before the National Vaccine Injury Compensation Program of the U.S. Court of Federal Claims], particularly in some of the more recent cases, [the Respondent]'s testimony has either been excluded or accorded little or no weight based upon a determination that he was testifying beyond his expertise." The *Doe 2* Court further held: "Moreover, [the Respondent]'s conclusion that the peer-reviewed literature he has relied upon supports his theory that autism can be caused by thimerosal is flatly contradicted by all of the epidemiological studies available at this time.") *Id.* at 474; *Redfoot v. B.F. Ascher & Co.,* 2007 WL 1593239 (N.D.Cal.)("there is no evidence that [the Respondent] has either the training or the background to diagnose autism or to treat autism in any child."); *Blackwell v. Wyeth,* 408 Md. 575 (2009)(Court of Appeals upheld trial court's exclusion of the Respondent as an expert in epidemiology, *inter alia,* because he was not qualified in that field).

Lupron Protocol based merely on a telephone consultation with the child's parent and the results of selected laboratory tests he ordered. The Respondent's omission of a comprehensive physical examination constitutes a danger because his treatment is based on a diagnosis that requires documentation of sexual development beyond that expected for the age of the child. Moreover, his treatment may constitute more of a risk to a child with an underlying medical condition.

The Respondent failed to provide adequate informed consent to the parents of the autistic children he treated. In one (1) instance, he misrepresented that his treatment protocol had been approved by a federally approved IRB.

There are no evidence-based studies to support either the Respondent's Lupron Protocol or his administration of chelation therapy to autistic children; he relies in large part on his own studies which have been wholly discredited by the Institute of Medicine and denounced by the American Academy of Pediatrics.

The Respondent's treatment of autistic children with his Lupron Protocol and chelation therapy is not limited to Maryland. Indeed, in a recent article in the *Chicago Tribune,* the Respondent stated his intent to open clinics all over the United States, "[w]e plan to open everywhere. I am going to treat as many as I can."[19] [20]

[19] Trine Tsoudersos, *"Miracle Drug" Called Junk Science,* Chicago Tribune, May 21, 2009.
[20] In a December 2008 note, the Respondent documented that he had informed Patient G's parents, who reside in Washington state, that he was opening an office in Seattle and provided them with information to schedule their next appointment at that location.

The Respondent endangers autistic children and exploits their parents by administering to the children a treatment protocol that has a known substantial risk of serious harm and which is neither consistent with evidence-based medicine nor generally accepted in the relevant scientific community.

VII. Patient-Specific Findings

Patient A

37. Patient A is a male born in October 1997. On June 11, 2007, an associate of Physician A referred Patient A to the Respondent for "genetic testing and counsel."

38. Patient A initially presented to the Respondent on June 11, 2007; Patient A was then nine (9) years, eight (8) months old. According to the Respondent's note, Patient A had been diagnosed with autism when he was four (4) years old, after receiving the usual childhood vaccinations and four (4) additional vaccinations required for entry to the United States.[21]

39. Patient A's mother completed an "Autism Treatment Evaluation Checklist" ("ATEC").[22] On the ATEC form, Patient A's mother reported, *inter alia* that self-injurious, aggressive and destructive behaviors were "not a problem" for Patient A.

40. The Respondent completed a "Neurodevelopmental Disorder Assessment" form at Patient A's initial visit. Notwithstanding Patient A's

[21] Patient A and his parents are not citizens of the United States.
[22] The ATEC is a listing of twenty-five (25) behaviors and abilities; the individual who completes the form is asked to indicate from three (3) descriptive phrases for each behavior that best describes the patient.

mother's report that aggression was not a problem with Patient A, the Respondent noted in the "Precious *(sic)* Puberty Evaluation" section of the form that Patient A, "bites and punches others; hits head with hands." The Respondent failed to document an adequate history of Patient A's aggressive behavior; for example, he failed to note the frequency of the behavior and under what circumstances it occurred.

41. The Respondent noted in the "genital development" section of the assessment form that Patient A was "very well endowed" – the Respondent did not document any further description of Patient A's secondary sexual characteristics or Tanner Stage,[23] nor did he otherwise document his examination of Patient A's genitals.

42. On an undated "Physician Examination" form, the Respondent noted merely: "no grossly dysmorphic features"[24] and "negative Wood's Lamp test."[25] With the exception of Patient A's height and weight, the Respondent did not document any other findings of his examination.

43. The Respondent ordered his standard laboratory battery of over 40 different sets of studies, including genetic and extensive endocrinology work-ups.[26]

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[23] The Tanner Scale is the standard five-stage clinical system for describing normal pubertal development and variation.

[24] Dysmorphic features indicate possible early neurodevelopmental impairment, including autism.

[25] A Wood's lamp examination of the skin is one (1) component of the clinical evaluation of Tuberous Sclerosis Complex, a genetic disease which symptoms are sometimes similar to autism.

[26] Many of the laboratory studies that it was the Respondent's practice to order exceed the standard of care for the diagnosis of autism.

44. On September 25, 2007, the Respondent wrote a Letter of Medical Necessity to Patient A's insurance company to obtain authorization to commence Lupron therapy. The Respondent stated in pertinent part:

> I ordered laboratory testing on [Patient A] which showed that he has significantly increased testosterone metabolites in this blood and other related laboratory abnormalities... Based on these laboratory findings and my clinical findings that include beginning development of testes and penis and extremely aggressive behaviors including biting head banging *(sic)*, I have diagnosed [Patient A] with the medical condition of premature puberty and neurodevelopmental disorder. Additionally, I have concluded that [Patient A] also suffers from the related medical condition of pituitary dysfunction. I have concluded that for [Patient A] Lupron therapy is the appropriate and medically necessary treatment for his present medical conditions. It is my medical opinion that it is absolutely medically necessary that [Patient A] undergo Lupron therapy.

45. The Respondent misdiagnosed Patient A with premature puberty. Significantly, Patient A did not meet the age criteria for premature puberty.

46. In addition, the results of Patient A's laboratory studies do not support the Respondent's diagnosis. The Respondent reported that Patient A's testosterone metabolites were "significantly increased;" however, the results of Patient A's luteinizing hormone ("LH") were only marginally elevated, and his free testosterone and DHEA were within range for a ten (10) year old male.[27]

47. The Respondent failed to evaluate certain standard components to confirm his diagnosis of precocious puberty. The Respondent failed to document in a thorough and focused manner Patient A's medical history

[27] The Respondent included in the Medical Necessity Letter Patient A's cholesterol levels; these results are not relevant to a diagnosis of premature puberty.

and family history. He failed to take an x-ray of Patient A's left wrist to estimate physiologic age for comparison with Patient A's chronologic age. Although he ordered a CT scan of Patient A's head, the purpose of which would be to rule out a brain lesion, there is no indication that the scan was actually performed as Patient A's chart does not contain the results of such a procedure. In addition, the Respondent failed to confirm his diagnosis by obtaining Patient A's response to a GnRH stimulation test.[28]

48. On November 5, 2007, the Respondent started Patient A on Lupron therapy. The Respondent administered Lupron Pediatric ("Lupron") IM and noted that he, "taught Mom to give SQ 0.4 ml daily in a.m." The Respondent further noted that Patient A was to return in two (2) weeks for an IM Lupron injection and, "I future *(sic)* start Aldactone and if necessary chelation."

49. Aldactone (spironolactone) is used to treat, *inter alia,* hyperaldosternoism – the production of an excessive level of the hormone aldosterone, which regulates the amount of sodium and potassium in the body. The Respondent prescribes Aldactone "as a therapeutic intervention for increased oxidative stress/inflammation" in autistic patients.

50. On December 3, 2007, the Respondent began Aldactone and noted that he would consider "rectal DMPS if porphyrins[29] are still up."

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[28]A GnRH stimulation test confirms a diagnosis of GnRH-independent precocious puberty when gonadotropin responses to exogenous GnRH are prepubertal in a patient with no tumor or other obvious cause of early sexual development. If the response is pubertal, central nervous system lesions must be excluded.

[29] The Respondent has reported that "[m]ercury toxicity [is] associated with elevations in urinary [porphyrins]...Porphyrins need to be routinely measured in ASDs to establish if mercury toxicity is a causative factor and to evaluate the effectiveness of chelation therapy." [Respondent's son]

51. The Respondent administered Lupron IM at the December 3, 2007 visit and prescribed melatonin and vitamin B-12 drops. He noted that Patient A was "doing well but still somewhat hyper."

52. At the December 3, 2007 visit, the Respondent also wrote a standing order for ten (10) sets of labs to be done on a monthly basis, as was his standard practice.

53. The Respondent continued Patient A on Lupron, both intramuscularly and subcutaneously through March 2008, when Patient A's family left the United States.

54. By letter dated January 3, 2008, Physician A notified Patient A's mother that he had cancelled his office's referral of Patient A to the Respondent. Physician A wrote in pertinent part:

> [The Respondent] incorrectly determined that [Patient A] has an endocrinological problem and is treating him for this. [The Respondent] is neither board certified in pediatrics or pediatric endocrinology. Because of this incorrect diagnosis and treatment I have canceled our referral to him[.]

55. By letter dated January 3, 2008, Physician A notified the Respondent that his office would no longer permit the Respondent to provide treatment to Patient A through Patient A's insurance company.

56. By letter dated January 3, 2008, Physician A notified Patient A's insurance company that he was canceling his referral because the Respondent was not qualified to treat Patient A and he "believe[d] his treatment has the possibility to harm this patient."

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and M.R. Geier, *A prospective study of mercury toxicity biomarkers in autistic spectrum disorders.* J. Toxicolol. Environ Health A., 20 (2007).

57. On February 8, 2008, the Respondent noted that "Mom wants to begin Androcur to replace [Aldactone]."

58. On March 19, 2008, the Respondent noted that Patient A's parents were leaving the country and would not be able to afford IM Lupron, but would continue SQ Lupron and would "begin switch to Androcur."

59. Patient A and his mother last visited the Respondent on March 31, 2008. The Respondent noted that Patient A's mother said that Patient A was "much improved" that he observed progress. The Respondent noted that Patient A was to switch from IM Lupron to Androcur before the family leaves the United States permanently and told Patient A's mother to order Androcur from a Canadian mail order pharmacy. The Respondent also noted that Patient A was to undergo chelation with DMPS rectal suppositories and told his mother "not to do EDTA."[30]

60. The Respondent inaccurately diagnosed Patient A with precocious puberty. Patient A's age at the time of the Respondent's initial assessment disqualified him for the diagnosis. In addition, the results of the laboratory tests that the Respondent reported as abnormal to Patient A's insurance company for approval of Lupron therapy were either only slightly elevated or not part of the diagnostic battery (i.e. – cholesterol levels). The Respondent failed to conduct appropriate diagnostic tests such as GnRH and an x-ray of his left wrist to confirm his diagnosis. Patient A did not have high levels of mercury or any other heavy metal that would have warranted chelation therapy.

[30] EDTA is a chelating agent; it has not been approved by the FDA.

61. The Respondent treated Patient A with hormonal therapy and chelation therapy for conditions he did not have. These treatments do not meet the standard of quality care for treatment of autistic children; especially when the Respondent's diagnosis of precocious puberty is not substantiated by laboratory studies or clinical observations. The Respondent failed to provide adequate informed consent to Patient A's parents regarding the possible risks associated with both hormonal therapy and chelation. The Respondent needlessly exposed Patient A to the risk of harm because of his incorrect diagnosis.

Patient B

62. Patient B, a male, was six (6) years, one (1) month old when he was initially assessed by the Respondent. Patient B had been diagnosed with autism by practitioners other than the Respondent when he was two (2) years old.

63. Billing records indicate that Patient B and his family are residents of Tennessee. On March 22, 2006, they had an initial telephonic consultation with the Respondent.

64. The Respondent documented that Patient B had regressed after his twelve (12) month vaccinations, noting that Patient B was "zoned out, hyperactive, classic autistic."

65. Patient B's mother had completed the ATEC form on March 21, 2006 and had faxed it to the Respondent's office. She indicated that Patient B had significant problems with temper tantrums, hyperactivity, sleep problems

and stereotypic behaviors, but did not have self-injurious behaviors or aggression towards others.

66. On the Neurodevelopment Disorder Assessment form, the Respondent noted that Patient B was "very tall" without further explanation of growth spurts or the parents' heights. The Respondent documented that Patient B had no genital development without further explanation or description. In the Aggression section of the form, the Respondent noted "sometimes – squeeze, stomping."

67. In his initial consultation, the Respondent failed to document key components such as: the reason for the visit; the parents' current concerns; Patient B developmental status and a description of Patient B's behaviors and interactions. The Respondent also failed to document a diagnosis or treatment plan.

68. The Respondent initially ordered his standard battery of laboratory tests, including genetics testing, and extensive blood and urine testing. He then submitted to the laboratory a standing order for ten (10) sets of tests, to be conducted monthly.

69. The Respondent failed to assess Patient B's bone age, assess the child's growth velocity or order a GnRH test to confirm the presumptive diagnosis of precocious puberty.

70. The Respondent failed to document his diagnosis of precocious puberty except for noting the ICD-9 code[31] corresponding to that diagnosis on laboratory orders. (ICD Code 259.1)

71. At some point in time (the Respondent failed to document the date), the Respondent began Lupron therapy for Patient B. In addition to failing to document a diagnosis, the Respondent also failed to document his treatment rationale for prescribing hormonal therapy for Patient B.

72. An undated form entitled, "Geier Clinical Study Protocol" (the "Protocol") states that "absent any significant adverse reactions", IM Lupron would be administered monthly with daily SQ injections. The Respondent failed to describe the possible adverse reactions of Lupron therapy. The Protocol required patients to undergo monthly laboratory testing for: androgen levels (DHEA, DHEA-S, androstenedione and testosterone), glutathione levels, liver, kidney and thyroid function, as well as monthly CBC studies.

73. The Respondent started and discontinued chelation therapy throughout the period of review (through June 2010) even though the results of Patient B's heavy metal tests were normal. The Respondent failed to document his treatment rationale for chelation therapy.

74. The Respondent's notes of Patient B's visits are scant and do not include a physical or developmental examination of Patient B. There is no indication that the Respondent actually reviewed the periodic laboratory results or that he discussed them with Patient B's parents.

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[31] The International Classification of Diseases- Ninth Revision provides alphanumeric designations assigned to every diagnosis, description of symptoms and cause of death.

75. Included in Patient B's chart are the Respondent's notes of affidavits and depositions taken in the law suit Patient B's parents had filed against Patient B's former primary care physician ("Physician B"). Patient B's parents contend that Physician B's administration of various vaccines to Patient B caused him to develop autism.

76. Also included in Patient B's chart is a copy of the Respondent's affidavit in the law suit, which he prepared in 2007.[32] Regarding his treatment of Patient B, the Respondent wrote:

> When a child has been injured by a vaccine containing thimerosal, the sooner the child is treated, the greater the possibility of removing or reducing the extent of the vaccine injury. This is apparent in [Patient B]'s case, since during the course of [Patient B]'s treatment I have used Lupron and chelation in an effort to detoxify the amount of damage to [Patient B] and he has improved; I am further of the professional opinion that [Patient B]'s improvement by administration of the Lupron and chelation evidences the fact that the vaccines containing thimerosal, wrongly administered by Defendants, directly and proximately caused [Patient B]'s injuries and damages, and his improvement by the reduction of the levels of androgens and mercury in this system evidences its destructive and injurious effect upon the child's brain, neurological, endocrine, gastroenterological and immunological systems.

77. Among the Respondent's criticisms of Physician B in the affidavit was Physician B's "failure to provide and secure the child's parents' informed consent." The Respondent continued:

> Medical ethics and informed consent requires that the patient [or parent or guardian]...be provided full disclosure of all alternatives, risks, precautions, benefits, side effects, and adverse results to the proposed medical treatment.

[32] The Respondent had not signed the copy of the affidavit contained in Patient B's chart. The month the document was prepared is not indicated.

78. In his affidavit, the Respondent noted that there was no signed medical authorization form in [Physician B]'s medical records. The Respondent opined that:

> [Physician B]'s failure to secure a signed medical authorization consent form before the administration of vaccinations to [Patient B] constituted a deviation from the standard of care and [Physician B]'s conduct did not conform to, and fell beneath, the recognized standard of acceptable professional practice that is customarily exercised by physicians who administer childhood vaccinations including...[pediatricians and internal medicine practitioners.]

79. The Respondent failed to secure written medical authorization forms from parents of any patient referenced in this document. In addition, the Respondent failed to provide and document that he provided adequate informed consent to any of the parents of the patients referenced herein.

Patient C

80. Patient C, was ten (10) years old when he was initially evaluated by the Respondent in July 2005. Patient C had been diagnosed as autistic at age three (3), having regressed in his development when he was two (2) years old.

81. At the initial visit, the Respondent noted Patient C's mother's reports that he sexually rubbed himself; upon examination he noted some hair development on his legs and arms. He also noted that Patient C had received a DPT[33] vaccination in France, after which he had a high fever.

82. Based on his interview with Patient C's mother and his observations of Patient C, the Respondent diagnosed him with unspecified developmental

[33] The abbreviation for diphtheria, pertussis (whooping cough) and tetanus.

delay, possible precocious puberty and possible childhood heavy metal exposure (mercury). The Respondent did not document a physical examination at this visit. The Respondent ordered his typical extensive laboratory studies. Patient C's mother did not follow-up on this visit.

83. Patient C's mother returned to the Respondent's office on May 19, 2008 because of the worsening of Patient C's aggressive behaviors. According to her complaint, the Respondent was not present during this office visit, She saw only his unlicensed son.

84. The note of the visit[34] indicates that "comprehensive" abdominal and thyroid ultrasounds were performed. Patient C's physical appearance is described as suggesting "advancement from his chronological age" and that he appeared to be "potentially significantly physically aggressive to himself and/or others."

85. A portion of the "Psychological Examination" section of the note states, "It is apparent based upon examination of the DSM-IV criteria that [Patient C]'s present symptoms are compatible with a diagnosis of pervasive developmental delay – not otherwise specific *(sic)."*

86. The Impression portion of the note states: 1) PDD-NOS, 2) Sleep problems (insomnia) and 3) Unspecified Metabolic Disorder. The plan was to prepare a laboratory work-up after which a follow-up consultation would be scheduled to discuss treatment. Twenty-six (26) laboratory studies are listed.

[34] The note was typed on a "Patient Interview Form." The Respondent's name is typed at the bottom of the report, it is neither signed nor initialed.

87. According to Patient C's mother's complaint, laboratory personnel were "flummoxed by the amount of blood needed for the tests" and she instructed them to draw only as much blood as was necessary to assay some genetic conditions, urine metals and porphyrins, the latter because the Respondent's son had emphasized their importance during the visit.

88. In late July 2008, Patient C's mother received two (2) statements from Genetic Consultants of Maryland. On the bills, charges appeared for four (4) separate dates (May 19, May 22, June 17 and June 18, 2009). A charge for "Prolonged Evaluation and Management" ($150.00 each) was billed for three (3) of the dates and "Psychiatric Diagnostic Interview and Exam" ($150.00) was billed for May 19, 2008.

89. Patient C's mother did not follow-up with the Respondent or his son regarding the 2008 visit.

90. At the 2005 visit, the Respondent incorrectly included precocious puberty in Patient C's differential diagnosis; at ten (10) years of age he did not qualify for that diagnosis.

91. At the 2008 visit, an extensive and unnecessary work-up was ordered that is not part of the standard of care to assess or treat autism. Patient C's aggressive behaviors were not adequately evaluated and assessed.

Patient D

92. Patient D, a female, was three (3) years and seven (7) months old when on May 20, 2008, the Respondent consulted with her mother by

telephone. According to the "Rule 26 Report"[35] the Respondent prepared after the consultation, he had been asked to "give an opinion, to a reasonable degree of medical probability, whether or not [Patient D]'s condition was caused by an identifiable genetic disorder."

93. The Respondent did not physically examine Patient D. His report was based on information provided by her mother and incomplete laboratory results.

94. In the report, the Respondent stated that he had not been able to identify a causal genetic condition because "several very important laboratory test *(sic)* that I have ordered have not yet been reported out....I will file a supplemental report discussing all of the remaining laboratory test results when they become available."

95. An expert report regarding genetic causation requires a full clinical examination because there are genetic conditions that cannot be identified by laboratory testing alone. The Respondent failed to conduct a physical examination of Patient D and had not planned to conduct one before submitting an expert report for possible use in federal litigation.

Patient E

96. Patient E, a female, was nine (9) years and three (3) months old when she initially presented to the Respondent on May 2, 2007.[36] According to the

[35] Federal Civil Procedure Rule 26 governs discovery in a federal case; Rule 26(b) sets out the requirements of an expert report.

[36] The vast majority of the Respondent's notes in the reviewed cases were handwritten and consisted of phrases. Several of Patient E's office notes were typed and consisted of lengthy narratives.

notes in Patient E's chart, she was diagnosed with autism at the age of two (2).

97. In the clinical examination portion of the initial note, the Respondent documented that Patient E "has significant evidence of premature puberty," citing her "obsessive masturbation behaviors" and describing her as "very bossy, persistent, aggressive and very strong." He failed to conduct an adequate physical examination; documenting only Patient E's height and weight. The Respondent noted that she had no grossly dysmorphic features and that the Woods Lamp examination was negative. He also performed an ultrasound of Patient E's thyroid and abdomen.

98. The Respondent described her developmental history and noted that, according to her mother, Patient E is hyperlexic, has acquired multiple languages and is able to type 130 words per minute.

99. In the May 2, 2007 note, the Respondent diagnosed Patient E with precocious puberty and neurodevelopmental disorder of unknown origin. His plan was to order a "specific battery of tests to evaluate her present medical condition for potential identification of the etiological basis of her present symptoms, and help design potential treatment protocol[.]"

100. On August 1, 2007, Patient E returned to the Respondent. The Respondent reviewed with her mother the results of laboratory results. He documented his assessment as follows: "[a]ssessment is that patient is presently suffering from premature puberty with associated pituitary dysfunction." The Respondent further noted *inter alia* that "the patient also

has evidence of exposure to heavy metals with elevated urinary nickel levels." Review of Patient E's laboratory studies reveals that her urinary nickel level was 9.1; however, the reference range has not been established. Patient E's nickel/creatinine ratio was slightly elevated (10.2; reference range = 0.0 – 9.9).

101. In the August 1, 2007 note, the Respondent documented that his treatment plan "is to start [Patient E] on Lupron IM and SQ therapy for treatment of her current clinical conditions...[i]n addition, patient will be monitored for continued exposure to heavy metals in urine (i.e. elevated nickel) to determine if future detoxification therapy is necessary.

102. On August 10, 2007, the Respondent completed a Prior Authorization Request for a Lupron Kit for Patient E; he noted Central Precocious Puberty as the diagnosis to support the request.

103. Over the next several months, Patient E's symptoms initially worsened and the Respondent increased her Lupron dosage. In October 2007, the Respondent noted that Patient E's Aldactone dosage had been increased; however, he neither documented when it was started nor the treatment rationale for adding it to Patient E's regimen.

104. Patient E's chart contains laboratory results through September 2009; however, the last note written by the Respondent is dated January 18, 2008 (the last previous note was dated November 7, 2007 and appears to document a telephone conversation with Patient E's mother). It is unclear

from the January 18, 2008 note whether it is documentation of an office visit or a telephone conversation.

105. In the January 18, 2008, note the Respondent failed to document a physical examination of Patient E. He noted that she was "doing well not wow on Diflucan." Diflucan (fluconazole) is an antifungal antibiotic, The Respondent failed to document either when he started Diflucan or his treatment rationale for adding it to Patient E's regimen.

106. The Respondent further documented that he was increasing Patient E's Lupron SQ dosage and was starting Methyl B12 drops, with no treatment rationale stated.

107. An entry in Patient E's "Phone Contact Sheet" indicates that as of April 2, 2010, the Respondent was continuing to prescribe Lupron and Leuprolide acetate to Patient E.

108. The Respondent failed to obtain and document that he had obtained informed consent from Patient E's mother at any time during Patient E's course of treatment with the Lupron protocol.

109. The Respondent misdiagnosed Patient E with precocious puberty and treated her with hormonal therapy that has a substantial risk of both short-term and long-term complications. Significantly, Patient E does not meet the diagnostic criteria for precocious puberty because she was older than eight (8) years old when she initially presented to him. In addition, the Respondent failed to assess Patient E's skeletal maturation by ordering an

x-ray of her left wrist and he failed to order a scan of her brain in order to rule out a tumor.

110. The Respondent's documentation of all visits after Patient E's initial visit is scant and inadequate. He failed to conduct a physical examination of Patient E at any time during her course of treatment.

111. The Respondent failed to document his treatment rationale for adding Aldactone and Diflucan to Patient E's regimen.

Patient F

112. Patient F, a female, was seven (7) years and nine (9) months old when she initially presented to the Respondent on March 10, 2008. Patient F had been diagnosed with autism at the age of three (3). The Respondent noted in his initial assessment: "[Patient F]'s mother reports that her daughter at twelve (12) months underwent a developmental regression after receiving MMR[37] vaccination...She slowly began to develop anxiety behaviors, OCD[38] behaviors and significantly lost words."

113. In the "Results of my Clinical Examination" section of the Respondent's initial assessment, he documented that Patient F has emerging breast buds and "has been showing early signs of menstruation for the past 3 months." The Respondent performed an ultrasound on Patient F's liver, kidney, spleen, adrenal glands and thyroid, the result of which were normal. He noted that she had no gross dysmorphic features. The

[37] The abbreviation for measles, mumps and rubella.
[38] The abbreviation for obsessive compulsive disorder.

Respondent failed to conduct and document a review of Patient F's systems.

114. The Respondent documented his impression that Patient F had a neurodevelopmental disorder of unknown origin. He ordered Patient F to undergo a "specific battery of tests [48 in all] to evaluate her present medical condition for potential identification of etiological basis of her present symptoms..."[39]

115. On May 7, 2008, the Respondent documented a telephone conversation with Patient F's mother. She advised that Patient F had significant breast development, developed pubic hair and significant facial hair. The Respondent noted: "Assessment is that [Patient F] is manifesting more significant symptoms of premature puberty." The Respondent deferred discussing treatment options until Patient F had undergone the laboratory testing as ordered.

116. On May 27, 2008, Patient F presented for review of her laboratory results. Based on the results, the Respondent noted that Patient F, "1) is in premature puberty with associated pituitary dysfunction; 2)...has low vitamin D; and 3) she has evidence of mitochondrial dysfunction." The Respondent started Patient F on Lupron IM and SQ and noted that she would continue with her current [Aldactone] and Carnitor dosing, the latter for mitochondrial dysfunction. The Respondent had not previously

[39] Patient E's chart contains her previous medical records from a physician in Washington, D.C. who specializes in the treatment of autism. In February 2009, one (1) month before Patient E presented to the Respondent, Patient E had undergone extensive laboratory testing. The tests ordered by the Respondent were the same as many of the tests ordered by Patient E's prior physician.

documented that Patient F was taking these medications, who had ordered them and the treatment rationale for them.

117. The Respondent also noted that he would "in future consider effects of Femara med prescribed by Dr. [C]." Femera is an oral non-steroidal aromatase inhibitor for treatment of hormonal-responsive breast cancer. The Respondent had not previously documented that Patient F was taking this medication.

118. The Respondent continued prescribing Lupron IM and SQ to Patient F throughout September 2008. During her course of treatment he added melatonin and methyl B12, and continued her Aldactone.

119. The Respondent misdiagnosed Patient F with precocious puberty and treated her with hormonal therapy that has a substantial risk of both short-term and long-term complications. Patient F did not meet the diagnostic criteria for precocious puberty because she was older than eight (8) years when she initially presented to him. The Respondent diagnosed Patient F with premature puberty in the absence of an appropriate examination. He failed to assess Patient F's bone age, assess the child's growth velocity or order a GnRH test to confirm the presumptive diagnosis of precocious puberty. He based his diagnosis in part on the results of several abnormal endocrine tests; however, it is not clear whether the tests were drawn while Patient F was on hormonal treatment with Femera, as the Respondent failed to document when this medication had been started. If

Patient F had been taking Femera, the result of the testing would have been invalid for a diagnosis of premature puberty.

120. The Respondent's documentation of visits/consultations after Patient F's initial visit was scant. He did not perform a physical examination during her course of treatment.

Patient G

121. Patient G, a male, was eight (8) years and three (3) months on March 28, 2008, the date of the Respondent's initial assessment. Billing records indicate that Patient G and his family reside in Washington State.

122. All but one (1) of the Respondent's notes regarding Patient G are "consultations," apparently by telephone. With the exception of one (1) office visit, there is no indication that the Respondent personally examined this patient, including at Patient G's initial assessment.

123. On the assessment form, the Respondent noted that Patient G had been exposed to mercury from "usual childhood vaccinations up to 3 y.o." and from a broken glass thermometer when he was "young." Patient G had been diagnosed at age three (3) with Pervasive Disability Disorder – Not Otherwise Specified ("PDD-NOS").[40]

124. On March 30, 2008, the Respondent ordered his usual battery of over forty (40) laboratory tests, noting the ICD code for "insomnia, unspecified" (780.52) as the diagnosis.[41]

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[40] PDD is a diagnostic category that includes autism.

[41] Patient G's mother had noted on the ATEC form that sleep problems were a serious problem for her son.

125. The lab results indicated a low level of glutathione and high free testosterone.

126. On June 20, 2008, the Respondent documented his treatment plan for Patient G. The Respondent noted: "[t]he plan is to lower [Patient G]'s androgens and if possible raise his glutathione levels and improve his autistic symptoms." The Respondent started Lupron IM (biweekly) and SQ (daily). The Respondent noted that Patient G is "on Rx [prescription] of carnitor liquid, methyl B-12 drops and Aldactone." The Respondent wrote a prescription for these medications on May 23, 2008.[42]

127. The Respondent noted in the Treatment Plan that "[w]e may also need to add Androcur to his regiment *(sic)*." The Respondent failed to document in the Treatment Plan or thereafter his treatment rationale for adding a second anti-androgen to Patient G's regimen. He also noted that Patient G's body-burden of mercury would be monitored by "urinary porphyrin testing" to determine if chelation was necessary. The Respondent instructed Patient G's mother to keep a "detailed log" of Patient G's behaviors, as adjustments to Patient G's medications would be based on her observations and monthly laboratory testing.

128. The Respondent failed to document in his notes that he had diagnosed Patient G with precocious puberty. The only place this diagnosis appears is on a Standing Order Request (for monthly lab studies) on which the

[42] There is no indication that Patient G had been administered these medications prior to being treated by the Respondent.

Respondent wrote the ICD-9 diagnosis code for precocious puberty (259.1) among other diagnoses.

129. The Respondent failed to assess Patient G's bone age, assess the child's growth velocity or order a GnRH test to confirm the presumptive diagnosis of precocious puberty.

130. On October 31, 2008, the Respondent noted that Patient G's lab results revealed high normal androgen levels. The Respondent concluded that Patient G "is under-dosed with Lupron" and increased the dosage of Lupron SQ.

131. In Patient G's Treatment Plan, the Respondent further noted that, "patient has evidence of mercury-toxic encephalopathy with elevated mercury body-burden[,] [a]n informed consent decision was made to start rectal DMPS to lower mercury body-burden." Patient G's mother was to administer the suppositories "until urinary porphyrins are normalized." Notwithstanding the Respondent's statement regarding the "informed consent decision" to start chelation, the Respondent failed to document that he had discussed specific risk factors of chelation with Patient G's mother.

132. On December 9, 2008, the Respondent added Androcur (cyproterone), an antiandogen, to Patient G's regimen and continued all of his current medications, including Lupron.

133. On March 1, 2009, the Respondent documented that he had an "OV [office visit] with Mom" The Respondent documented Patient G's

temperature, pulse and respiration, but did not otherwise document that he conducted a physical examination. He noted "Puberty signs way ↓" without further description or explanation.

134. The Respondent's last note is dated May 19, 2009,[43] on which date he spoke to Patient G's mother by Skype. The Respondent documented that Patient G had been treated by another physician for "lympohypoplasia"[44] and was prescribed new medications. On this date, the Respondent increased Patient G's dosage of Lupron SQ but did not document his treatment rationale.

135. The Respondent prescribed chelation therapy, Lupron and Lupron in combination with Androcur to Patient G in the absence of informed consent. The Respondent failed to discuss potential risks of hormonal treatment with Patient G's parents.

136. The Respondent misdiagnosed Patient G with precocious puberty and treated him with hormonal therapy that has a substantial risk of both short-term and long-term complications.

Patient H

137. Patient H, a female, was eight (8) years and seven (7) months old on March 14, 2008 when she was initially assessed by the Respondent. Billing records indicate that Patient H and her family reside in Tennessee. The Respondent billed for a lengthy telephone call on this date; it is

[43] The results of Patient G's monthly laboratory studies through July 2009 are included in his chart.

[44] An inherited deficiency of the thymus gland characterized by enlarged lymph glands, adrenal dysfunction and susceptibility to infectious diseases.

apparent that the Respondent did not personally examine Patient H on the date of the initial assessment.

138. Patient H had been diagnosed with ASD at 23 months of age. The Respondent noted on Patient H's Neurodevelopmental Disorder Assessment form that she had regressed at nine (9) months of age after receiving hepatitis vaccinations. He also indicated that she may have had excessive environmental exposure to mercury based on her postal zip code. He noted that Patient H had fine hair on her legs and arms[45] and that breast buds were starting to appear.

139. The Respondent noted that Patient H had undergone 26 previous intravenous chelation treatments with glutathione, EDTA and DMPS, but had not had any treatments for the last four (4) weeks.[46]

140. The Respondent ordered his usual battery of 40 plus laboratory tests.

141. On June 23, 2008, Patient H presented to the Respondent's office to review the laboratory results and so that the Respondent could "suggest potential treatments." The Respondent documented Patient H's vital signs but he did not document a complete physical examination, nor did he document any clinical observations. The Respondent performed a Wood's Lamp test (negative for tuberous sclerosis) and ultrasound of Patient H's abdomen, neck and pelvis, the latter of which revealed ovarian follicles.

[45] This observation is irrelevant to the diagnosis of precocious puberty.
[46] He noted that Patient H had been treated by a DAN! (Defeat Autism Now!) trained physician.

142. In his June 23, 2008 note, the Respondent documented Patient H's lab results, including "↑ urinary porphyrins, low-normal carnitine levels, ↑ dyhydrortestosterone..." and assessed her with "toxic encephalopathy & associated ↑ body-burden of heavy metals, particular *(sic)* Hg [mercury], based on ↑ porphyrins." The Respondent also diagnosed mitochondrial dysfunction and noted *inter alia* that Patient H "had evidence of premature puberty with associated pituitary dysfunction [low] vitamin D levels and disturbance of sulfur-bearing amino acid SNPs in the MTHFR gene."[47]

143. The Respondent's treatment plan included: Lupron (IM and SQ) and Aldactone "for premature puberty;" Carnitor liquid for mitochondrial dysfunction, Vitamin D and melatonin. The Respondent also noted that chelation would be considered. The Respondent concluded: "Reviewed risks/benefits of meds and informed consent decision was made to start present meds." Patient H's chart does not contain a written informed consent form, nor any evidence that the Respondent discussed specific risk factors of chelation or hormonal therapy with Patient H's mother..

144. The Respondent inappropriately diagnosed Patient H with precocious puberty. Her pubertal development was well within age norms for girls in the United States. The Respondent prescribed hormonal therapy to her in the absence of medical justification; Patient H was too old either to be diagnosed with precocious puberty or to be prescribed medication for that condition. The Respondent failed to assess Patient H's bone age, assess

[47] SNP is the abbreviation for single-nucleotide polymorphism. MTHFR is an enzyme responsible for creating the circulating form of folate.

the child's growth velocity or order a GnRH test to confirm the presumptive diagnosis of precocious puberty.

145. The Respondent prescribed medication for carnitine deficiency in the absence of medical necessity. Patient H's carnitine level was within normal range.

146. The Respondent misdiagnosed Patient H with precocious puberty and treated her with hormonal therapy that has a substantial risk of both short-term and long-term complications.

Patient I

147. Patient I, a male, was nine and one-half (9½) years old when the Respondent initially assessed him. Patient I had been diagnosed with autism at the age of three (3).

148. Billing records indicate that Patient I and his family reside in Illinois. The Respondent initially assessed Patient I by telephone consultation on March 21, 2006.

149. On July 29, 2006, Patient I's mother signed a "Consent for Enrollment in the Geier Experimental Protocol for the Treatment of Regressive Autism." The Consent reads in pertinent part:

> 1. I request that my child be enrolled in the Geier Experimental Protocol for the treatment of regressive autism. The Institutional Review Board (IRB) of the Institute for Chronic Illnesses (Office for Human Research Protection, US Department of Health and Human Services IRB number: IRB00005375) has approved this study protocol.

150. The Consent states that the protocol uses Lupron to lower testosterone and notes that Lupron is an FDA-approved drug for precocious puberty and "other conditions where it is helpful to lower testosterone levels."

151. The Respondent did not diagnose Patient I with precocious puberty. On various lab order forms he wrote diagnoses for: congenital malformation syndrome affecting multiple systems, not elsewhere classified (ICD code – 758.89), disturbances of sulphur-bearing amino acid metabolism (ICD code – 270.4) and toxic encephalopathy (ICD code – 349.82).

152. The Respondent started Patient I on the Lupron protocol in August 2006.

153. Patient I's chart consists mostly of reports of monthly laboratory results. The majority of the Respondent's infrequent contacts with Patient I's family were by telephone. One (1) of two (2) office visits was documented on March 25, 2007 (on a Phone Contact Sheet). The Respondent noted that Patient I was "[d]oing very well." With the exception of noting that the Wood's Lamp examination was negative (except for toe fungus), the Respondent failed to document a physical examination or review of systems. The Respondent documented, "will do porphyrins – if indicated possible chelation."

154. On August 25, 2007, the Respondent documented that a follow-up (telephone) consultation with Patient I's father regarding his son's progress on DMPS suppositories. The Respondent failed to document when he had started chelation therapy. Patient I's father reported that Patient I was "having significant increased verbalizations. He has even

observed Patient I to say and identify father ("Papa") in context for the first time." "Papa" is the only word the Respondent documented Patient I as having said. The Respondent noted his assessment that "[Patient I] is continuing to respond well to the Lupron therapy and the DMPS is apparently accelerating the rate of [Patient I]'s attempts at verbalizations."

155. On February 10, 2008, an individual other than the Respondent noted on a Phone Contact Sheet that based on a consultation with Patient I's mother and a review of Patient I's record, Carnitor would be started. The Respondent failed to document his treatment rationale for starting Carnitor.

156. The last note in Patient I's record is dated February 26, 2009, his second office visit. The Respondent documented that complaints regarding Patient I's aggression at school were returning and that chelation had been stopped. At that time, Patient I's medications included: IM Lupron bi-weekly; daily Lupron SQ, DMPS suppositories; vitamin D and methyl B-12/folonic acid. The Respondent prescribed Diflucan but failed to document his treatment rationale.

VIII. The Respondent's ICI IRB fails to meet State and Federal regulations

157. The purpose of an IRB is to protect the interests of human research subjects. In Maryland, research using human subjects may not be conducted unless it is conducted in accordance with federal regulations. Md. Health Gen'l Code §13-2002(a) and (b). Federal regulations on the protection of human subjects is defined as Title 45, Part 46 of the Code of

Federal Regulations (the "Common Rule"). The Common Rule is the baseline standard of ethics to which the institution holds its researchers.

158. An IRB is a committee that monitors all human subject research in an institution to ensure the research is ethical in design and conforms to all federal regulations. One of the main concerns of the IRB is to minimize the risks of the research and to ensure that the researchers obtain sufficient informed consent that is appropriately documented.

159. The ICI IRB is registered with the Office for Human Research Protection ("OHRP"). The address for ICI is the Respondent's home address.

160. Because IRBs have the authority to suspend or terminate approval of research that is not being conducted in accordance with the ethical principles of the IRB, federal regulations provide that no IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest.

161. An IRB must consist of at least five (5) members. The ICI IRB's members include the Respondent, his son and the Respondent's wife. The ICI IRB is inconsistent with the requirement that a member should not have a conflict of interest in the research project.

162. The IRB noted in Patient I's "Consent for Enrollment in the Geier Experimental Protocol for the Treatment of Regressive Autism" (IRB00005375) was registered with OHRP; however, it is not linked to any OHRP assurance – the mechanism whereby the IRB commits to adhering to the ethical requirements of the Common Rule.

IX. The Respondent Misrepresented His Credentials

163. On November 6, 2007, in furtherance of the Board's investigation, Board staff interviewed the Respondent. During the interview, the Respondent stated that he was a board-certified geneticist and a board-certified epidemiologist. The Respondent stated that he had been board-certified in epidemiology in 2007.

164. An inquiry to the Certification Board of Infection Control and Epidemiology revealed that the Respondent is not board-certified in epidemiology.

165. On March 9, 2011, the Board issued a subpoena to the Respondent directing him to provide "any and all" documents to support his claim that he was board-certified in epidemiology and medical genetics.

166. By letter dated March 29, 2011, the Respondent, through counsel, submitted to the Board a "Fellowship Certificate" from the American College of Epidemiology ("ACE"). The ACE is a professional association whose policy on admission is "inclusiveness." An ACE fellow is not required to have a degree in epidemiology, a degree in a "related field" is sufficient.

167. The Respondent knew, or reasonably should have known, that he was not board-certified in epidemiology.

168. By letter dated March 29, 2011, the Respondent, through counsel, also submitted to the Board a certificate issued by the American Board of Medical Genetics on September 15, 1987 certifying the Respondent as a Genetic Counselor.

169. The term "genetic counselor" is not synonymous with "geneticist." A geneticist, or medical geneticist, is a physician who evaluates a patient for genetic conditions, which may include performing a physical examination and ordering tests. A genetic counselor is an individual with a masters degree who helps to educate the patient and provides an assessment of the risk of the condition recur in the family.

170. The Respondent knew, or reasonably should have known, that he was not a board-certified geneticist.

CONCLUSION OF LAW

Based on the foregoing facts, the Board concludes that the public health, safety or welfare imperatively require emergency action in this case, pursuant to Md. State Gov't Code Ann. § 10-226 (c) (2) (i) (2009 Repl. Vol.).

ORDER

Based on the foregoing, it is this 27th day of April, 2011, by a majority of the quorum of the Board:

ORDERED that pursuant to the authority vested by Md. State Gov't Code Ann., § 10-226(c)(2), the Respondent's license to practice medicine in the State of Maryland be and is hereby **SUMMARILY SUSPENDED**; and be it further

ORDERED that a post-deprivation hearing in accordance with Code Md. Regs. tit. 10, § 32.02.05.B (7) and E on the Summary Suspension has been scheduled for **Wednesday, May 11, 2011**, at **10:00 a.m.**, at the Maryland State

Board of Physicians, 4201 Patterson Avenue, Baltimore, Maryland 21215-0095; and be it further

ORDERED that at the conclusion of the **SUMMARY SUSPENSION** hearing held before the Board, the Respondent, if dissatisfied with the result of the hearing, may request within ten (10) days an evidentiary hearing, such hearing to be held within thirty (30) days of the request, before an Administrative Law Judge at the Office of Administrative Hearings, Administrative Law Building, 11101 Gilroy Road, Hunt Valley, Maryland 21031-1301; and be it further

ORDERED that on presentation of this Order, the Respondent **SHALL SURRENDER** to the Board's Compliance Analyst, the following items:

(1) the Respondent's original Maryland License D24250;

(2) the Respondent's current renewal certificate;

(3) the Respondent's Maryland Controlled Dangerous Substance Registration;

(4) all controlled dangerous substances in the Respondent's possession and/or practice;

(5) all Medical Assistance prescription forms;

(6) all prescription forms and pads in the Respondent's possession and/or practice; and

(7) Any and all prescription pads on which his name and DEA number are imprinted; and be it further

ORDERED that a copy of this Order of Summary Suspension shall be filed with the Board in accordance with Md. Health Occ. Code Ann. § 14-407 (2009 Repl. Vol.); and be it further

ORDERED that this is a Final Order of the Board and, as such, is a **PUBLIC DOCUMENT** pursuant to Md. State Gov't Code Ann. § 10-611 *et seq.*

4/27/11
Date

Harry C. Knipp, M.D.
Vice Chair
Maryland State Board of Physicians

I HEREBY ATTEST AND CERTIFY UNDER PENALTY OF PERJURY ON 5/10/11 THAT THE FORGOING DOCUMENT IS A FULL, TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN MY OFFICE AND IN MY LEGAL CUSTODY.

DEPUTY DIRECTOR
MARYLAND BOARD OF PHYSICIANS