State Medical Board of Ohio

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September 14, 2022

Phillip DeMio, M.D.
320 Orchardview Avenue, Suite 2
Seven Hills, OH 44131

RE: Case No. 19-CRF-0001

Dear Dr. DeMio:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of R. Gregory Porter, Esq., Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on September 14, 2022, including motions approving and confirming the Report and Recommendation as the Findings and Order of the State Medical Board of Ohio, and adopting an Amended Order.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Any such appeal must be filed in accordance with all requirements specified in Section 119.12, Ohio Revised Code, and must be filed with the State Medical Board of Ohio and the Franklin County Court of Common Pleas within (15) days after the date of mailing of this notice.

THE STATE MEDICAL BOARD OF OHIO

Kim G. Rothermel, M.D.
Secretary

KGR:jam
Enclosures

CERTIFIED MAIL NO. 91 7199 9991 7039 4222 4724
RETURN RECEIPT REQUESTED

Cc: James M. McGovern, Esq.
By U.S. Regular Mail

Mailed 10-6-2022

CERTIFICATION

I hereby certify that the attached copy of the Entry of Order of the State Medical Board of Ohio; Report and Recommendation of R. Gregory Porter, State Medical Board Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on September 14, 2022, including motions approving and confirming the Findings of Fact, Conclusions and Proposed Order of the Hearing Examiner as the Findings and Order of the State Medical Board of Ohio, and adopting an amended Order; constitute a true and complete copy of the Findings and Order of the State Medical Board in the matter of Phillip DeMio, M.D., Case No. 19-CRF-0001, as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.

(SEAL)

Kim G. Rothermel, M.D.
Secretary

September 14, 2022
Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF	*	
	*	CASE NO. 19-CRF-0001
PHILLIP DEMIO, M.D.	*	

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio September 14, 2022.

Upon the Report and Recommendation of R. Gregory Porter, State Medical Board Hearing Examiner, designated in this Matter pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated herein, and upon the modification, approval, and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

It is hereby ORDERED that:

> The license of Phillip DeMio, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

This Order shall become effective immediately upon the mailing of the notification of approval by the Board.

Kim G. Rothermel, M.D.
Secretary

(SEAL)

September 14, 2022
Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

In the Matter of	*	
		Case No. 19-CRF-0001
Phillip DeMio, M.D.,	*	
		Hearing Examiner Porter
Respondent.	*	

REPORT AND RECOMMENDATION

Basis for Hearing

In a Notice of Opportunity for Hearing dated January 9, 2019 ("Notice"), the State Medical Board of Ohio ("Board") notified Phillip DeMio, M.D., that it had proposed to take disciplinary action against his certificate to practice medicine and surgery in Ohio based upon his care and treatment of 16 patients identified on a confidential Patient Key. The Board alleged that Dr. DeMio's treatment of Patients 1 through 16 during the time period of in or around March 2012, through in or around September 2016, constituted:

- "Failure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as that clause is used in Ohio Revised Code Section ("R.C.") 4731.22(B)(2);

- "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in R.C. 4731.22(B)(6); and/or

- "[V]iolating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in R.C. 4731.22(B)(20), to wit:

    - Ohio Administrative Code Rule ("Rule") 4731-11-02, General Provisions, as in effect from September 30, 2008, through December 30, 2015. Furthermore, pursuant to Rule 4731-11-02(F) as in effect at that time, any violation of Rule 4731-11-02 also constitutes a violation of R.C. 4731.22(B)(2) and 4731.22(B)(6);

    - Rule 4731-11-02, General Provisions, as in effect from December 31, 2015, through August 30, 2017. Furthermore, pursuant to Rule 4731-11-02(E) as in effect at that

time, any violation of Rule 4731-11-02 also constitutes a violation of R.C. 4731.22(B)(2) and 4731.22(B)(6);

- Rule 4731-11-11, Standards and Procedures for Reviews of "Ohio Automated Rx Reporting System" (OARRS), as in effect from November 30, 2011, through December 30, 2015;

- Rule 4731-11-11, Standards and Procedures for Reviews of "Ohio Automated Rx Reporting System" (OARRS), as currently in effect from December 31, 2015; and/or

- Rule 4731-21-02, Utilizing Prescription Drugs for the Treatment of Intractable Pain, as in effect from November 30, 2008, through August 30, 2017. Furthermore, pursuant to Rule 4731-21-05 as in effect at that time, any violation of any rule in Chapter 4731-21 also constitutes a violation of R.C. 4731.22(B)(2) and 4731.22(B)(6).

Accordingly, the Board advised Dr. DeMio of his right to request a hearing and received his written request on February 6, 2019. (State's Exhibits ("St. Exs.") 22A, 22B, 22C)

Appearances

Dave Yost, Ohio Attorney General, and Kyle C. Wilcox and Melinda Snyder, Assistant Attorneys General, on behalf of the State of Ohio. Daniel S. Zinsmaster, Gregory A. Tapocsi, and Andrew S. Good, Esqs., on behalf of Dr. DeMio.

Hearing Date: December 14 through 18, 2020, and January 20 through 22, 2021

PROCEDURAL MATTERS

1. Due to the Covid-19 pandemic, the hearing was held remotely using videoconferencing software.

2. At the end of the hearing, the hearing record was held open to give the parties an opportunity to submit written closing arguments. The written closing arguments were timely received, and have been admitted to the record as State's Exhibit 30 and Respondent's Exhibit K. The record closed on March 5, 2021.

3. Complainant information was redacted from State's Exhibit 14a at page 136.

SUMMARY OF THE EVIDENCE

All exhibits and the transcript of testimony, even if not specifically mentioned, were thoroughly reviewed and considered by the Hearing Examiner prior to preparing this Report and Recommendation.

Direct Testimony of Dr. DeMio

1. Phillip DeMio, M.D., obtained his medical degree in 1984 from Case Western Reserve University. Following graduation, Dr. DeMio entered a pathology residency at University Hospitals of Cleveland. In 1985 he changed his residency to internal medicine at Mt. Sinai Medical Center in Cleveland. Subsequently, in 1986, Dr. DeMio again changed his residency to emergency medicine at Mt. Sinai and completed the program in 1989. Dr. DeMio served as Chief Resident in 1989. (Hearing Transcript ("Tr.") at 19-21, 1108-1109, 1117-1118; Respondent's Exhibit ("Resp. Ex.") A)

2. Dr. DeMio was first licensed to practice medicine and surgery in Ohio in February 1987. His license is currently active. Dr. DeMio further testified that he was also licensed in Massachusetts but has allowed that license to expire. (Tr. at 21-22; Ohio eLicense Center, <*https://elicense.ohio.gov/oh_verifylicense*>, search terms "DeMio" and "Phillip," accessed July 1, 2022)

3. Dr. DeMio was certified by the American Board of Emergency Medicine in 1991 and he last recertified in 2011. Dr. DeMio testified that the last time he had practiced emergency medicine fulltime was about five months prior to the hearing when the ER where he had been working closed. Since then, he has worked "ad hoc" shifts in the ER when another physician is needed due to staff shortages. (Tr. at 22-24, 1144-1146; Resp. Ex. A)

4. Dr. DeMio acknowledged that he had never completed a residency or fellowship in pediatrics, and that he also has never had any residency training in immunology. Moreover, he acknowledged that he had no residency training in neurology, aside from rotations as an intern and resident. He testified similarly with respect to infectious diseases. When asked about behavioral health disorders Dr. DeMio indicated that he had some training in that area while training in emergency medicine. He indicated that behavioral health issues are common for ER patients. (Tr. at 24-26)

5. . From about 1990 to 1998, Dr. DeMio operated a practice under his own name as an urgent care and family health care center, seeing people of all ages for acute issues and for primary care. He worked in his practice six days a week, and during this time he also worked Sundays in the ER at Mt. Sinai. When his mother became ill, he decided to go back to working in emergency medicine exclusively, so that he could spend some of his time helping care for her, and he sold his practice to another physician. (Tr. at 1135-1136, 1138; Resp. Ex. A at 3)

6. Dr. DeMio said that, during the time he was operating his private practice, he began using integrative principles, such as recommending fish oil as an anti-inflammatory for people with joint problems or neck and back pain, and making sure people were getting the right nutrition, and limiting salt in their diets to help manage hypertension. He said that it was a small part of his practice, but it quickly gained in popularity with patients, explaining that he would try the integrative principles first, and then blend those interventions with

conventional treatments for conditions such as diabetes or hypertension. (Tr. at 1139-1141)

7. Around this same time, Dr. DeMio was also working in occupational rehabilitation medicine at Deaconess Hospital, where he often saw patients who worked in physical labor jobs and had injuries or conditions related to their work. He said that he blended integrative medicine approaches into his work there, too. In addition to using physical therapy, he made sure his patients understood the importance of a good diet, and he recommended the use of supplements such as herbals, fish oil, and magnesium. Dr. DeMio recalled that he also saw patients who worked in industries where they were exposed to toxic substances, as well as some who worked as veterinarians or techs at the Cleveland Zoo, where they were in close proximity to animals. (Tr. at 1142-1144; Resp. Ex. A)

8. In his testimony, Dr. DeMio acknowledged, "There's some friction out there between integrative and conventional doctors * * * and it's a very intense thing, to say the least." (Tr. at 1176) Although he said that he has a good relationship with most conventional medicine physicians, Dr. DeMio said that he believes the antagonism is the result of an uninformed basis for the criticism by the conventional physicians. He emphasized that he uses conventional modalities in his practice, and that he uses conventional modalities in his practice at the ER at Summa "99.9 percent" of the time. (Tr. at 1176-1177)

Whole Health and Wellness

9. In 2004, Dr. DeMio opened his current private medical practice, Whole Health and Wellness, in Seven Hills, Ohio, near Cleveland. At first, he operated the practice with the help of only an office manager, but he later added an additional administrator. In 2007, he also opened an office in Worthington, Ohio, near Columbus, which quickly became very busy. He later relocated the Worthington office to Westerville, after the space he was using was sold to a new landlord. Dr. DeMio said that he was splitting his time equally between the two offices, seeing anywhere from four to seven patients per day at one office or the other. At the time of the hearing, he estimated that he had about 500 or 600 total patients, of which about half were pediatric patients and half were adults. This is approximately the same number of patients he had during the time period relevant to this matter, from 2012 through 2016. He said that most of his patients are from Ohio, but some come to him from surrounding states and Canada. (Tr. at 27-28; 1224-1230)

10. Dr. DeMio testified that he has no other physicians or nurses in his practice. He employs an administrative director and an administrative assistant, both of whom were working out of the Seven Hills office at the time of the hearing. Dr. DeMio testified that his practice is full-time, five days per week, and that he sometimes sees patients on Saturdays. Most of his time is spent at the Cleveland office, but he sees patients at his Westerville office approximately one or two days every other week. (Tr. at 27-29)

11. When asked why he has two offices, Dr. DeMio testified:

> I originally expanded to Worthington. We were getting a lot of patients from the Columbus area coming up to Cleveland. I just thought out of respect for them it would be easier for them if I spent some of my time down here, and so we opened an office in Worthington.
>
> I thought the access for them would be easier. They have sick family members, the travel is a couple hours.

(Tr. at 29)

12. Dr. DeMio is not an in-network provider with any insurance company, and new patients or their parents sign a statement to that effect during the intake process. In Dr. DeMio's chart for **Patient 1**, for example, a form titled Financial Responsibility and Assignment of Benefits, signed by the patient on July 1, 2013, includes the following statements:

> I understand that the doctor here is not an in-network provider with any insurance companies, and that the office operates as a fee-for-service office, and that all services must be paid by me directly to the doctor in full at the time of service. I understand that neither the doctor nor his staff submits bills or any other information to any insurance companies. If I desire, I will submit the receipt for the services to my insurance company so that I can receive reimbursement, if any, from them directly to me. I also agree to pay a $50.00 fee for each returned check.
>
> * * * **Patients with Medicaid/Medicare will NOT get reimbursed.**
> * * * I fully understand that all deposits are non-refundable, no matter when the appointment is canceled, and by signing below, I certify that I have read the Policies and Procedures for New and Follow Up appointments.

(St. Ex. 1 at 2)

13. Dr. DeMio testified that his patients pay either in cash or with a credit card. He agreed that if he submitted claims for many of the services he provides, such as chelation therapy, there would be "a very minimal chance" that he would be reimbursed by any insurer. (Tr. at 55-56)

14. Dr. DeMio testified that he bases his fees on the amount of time he spends working with a patient. Dr. DeMio testified that he charges $399.00 per hour. He charges the same rate for patient visits and for activities such as reviewing a patient's lab reports and talking on the phone. (Tr. at 61-62)

15. Dr. DeMio stated that he has testified as an expert in various court proceedings. When asked if he had ever testified before the U.S. Court of Federal Claims, Dr. DeMio responded that he had. When asked if that court ever found that Dr. DeMio lacked expertise in the area about

which he was testifying, Dr. DeMio became evasive and never answered the question directly. (Tr. at 56-60)

Dr. DeMio's Interest in Autism Spectrum Disorder ("ASD")

16. Dr. DeMio has a special interest in autism and ASD because his son, Daniel, was born in 2000 and was diagnosed with autism shortly before his second birthday. (Tr. at 1182-1184) Dr. DeMio recalled, "He didn't have autism, you know, from the start. And then he got very sick, you know, as a toddler and developed autism." (Tr. at 1184) Dr. DeMio said that his son always had physical symptoms including vomiting, gagging, and constipation, as well as severe rashes, and that he was a "scrawny" child who did not grow like other kids. (Tr. at 1183)

17. Dr. DeMio testified that he and his wife had hoped to have several children, but that because their son's care requires so much of their time and attention, they have not had other children. At the time of the hearing, Dr. DeMio's son was about 20 years old, and was living in the family's home in Medina, where they care for him with the help of other caregivers, at a cost of about $210,000 per year. Daniel is nonverbal, and although Dr. DeMio said that his son has times when he is happy, there are also times when he is self-injurious and has to wear a helmet to protect himself. He requires "two-on-one" care in case a caregiver has to use the bathroom or take a meal break, and it also takes two people to assist him with getting into a car. Dr. DeMio said that they try to prompt Daniel to go on outings so that he stays mainstreamed and does not become isolated and withdrawn. Dr. DeMio stated that his son needs to be prompted to eat, and he needs diaper changes most of the time. Sometimes there are more challenging incidents, such as a time when Daniel injured himself putting his head through a car window. (Tr. at 1148, 1183, 1188-1192)

18. Dr. DeMio testified that his son's condition caused him to be more interested in learning about treatments for ASD. He recalled that when he and his wife sought care for their son, they felt that many doctors were dismissive of him because he had an autism disorder, and as they became part of the community of ASD parents, they found that other families had had similar experiences. (Tr. at 1194-1195) Dr. DeMio testified that one of the conventional doctors they consulted told them that there were treatments available, but that that physician could not offer them because they were not considered "conventional medicine." He added, "[B]ut he basically told me to go seek all of them and do them." (Tr at 1194)

19. This sent Dr. DeMio on a quest to learn everything he could about ASD over the next two years. He testified that he went to every conference he could find about treatment options for ASD patients, many of which were offered by the Autism Research Institute. He became involved with numerous other organizations devoted to finding help for people with ASD, including the Autism Society of America, the U.S. Autism and Asperger's Association, and the American Academy of Alternative Medicine. Through these associations, Dr. DeMio found other physicians who were seeing some improvements in their ASD patients or at least stabilizing them, through the use of vitamins, herbal supplements, and dietary changes. He admitted that not all patients saw improvements with these treatments, but he maintained that

some did. (Tr. at 1197-1198) Eventually, he became a member of the "think tanks" of these groups, which researched available treatments. (Tr. at 1199)

20. Dr. DeMio testified that some of his patients' parents began asking him to share what he knew about ASD with them, so he opened his office and began treating patients with autism in late 2004. Most of the ASD patients Dr. DeMio sees have already had a formal diagnosis, but he stated that, once in a while, he finds a patient who has a learning disability, rather than ASD. Dr. DeMio testified that when he makes or confirms a diagnosis of ASD, he primarily uses the criteria of Dr. Leo Kanner, a pediatric psychiatrist from Johns Hopkins. He also performs a physical exam of the child, and observes the child's behavior and mood, and he relies on the history provided by the child's parents and any testing that has already been done. Aside from the behavioral features of ASD, Dr. DeMio testified that ASD patients also tend to have medical symptoms, including swollen tonsils, vomiting, and allergic reactions. (Tr. at 32, 1197, 1200-1201, 1204-1205)

21. Dr. DeMio stated that he was familiar with the term, "DAN doctors," and he described it as an acronym for a network of physicians working to "Defeat Autism Now." He said that the organization was founded by Dr. Bernard Rimland, a psychologist who had a son with autism in the late 1950's, so that parents and physicians could network and exchange information. (Tr. at 165-166) Although he said he does not refer to himself as a "DAN doctor," Dr. DeMio explained that Dr. Rimland started the movement to treat autism as a biomedical disorder that can be treated: "[H]e developed Defeat Autism Now," which basically became the father organization of the biomedical treatment movement, the type of thing that I'm involved with autism." (Tr. at 166-167) Dr. DeMio concluded:

> And so I consider myself to have gone through a lot of that training and experience, and I became part of some of their teaching and all that kind of stuff.

(Tr. at 167)

22. Dr. DeMio agreed at the outset of his testimony that he had never done a residency or fellowship in pediatrics or immunology, and that he had no formal training in behavioral health, mental health, or autism treatment, except for that which was part of his emergency medical training. He explained that at the time he was doing his residency, there was no training available for ASD, as developmental pediatrics was not a specialty then. (Tr. at 24-26, 1124-1125) He recalled, "I think one time I might have been told to look down the hall on my rotations, there's a person with autism, you're never going to see it again. * * * So there really was, there was almost nothing." (Tr. at 1125)

23. Despite the lack of formal training in ASD-related disorders, Dr. DeMio testified that he believes he is an expert in the treatment of autism:

> Q. [By Mr. Wilcox:] You believe you are an expert in treating autism, Doctor?

A. Yes, sir, I do.
Q. And you believe you've developed this expertise over the years not through formal training, recognized training programs?
A. I have had training programs with this.
Q. * * * Have you received formal residency training, institutional-backed training, or are you just referring to other methods of training where you received -- gone to meetings or societies or readings?
A. It's more in the category of the latter.

(Tr. at 34-36)

24. Dr. DeMio testified that he has spoken on many occasions regarding the treatment of autism spectrum disorder ("ASD"), but he is never paid for presentations that he makes about autism. He acknowledged that some of his presentations appear on YouTube, including his discussions of how hard it was for his family after learning that their son had autism. (Tr. at 31-32, 1718-1719)

25. Dr. DeMio testified that he has diagnosed patients with Autism Spectrum Disorder, and that he does this primarily by doing a physical exam and taking a history from parents or other caregivers, as well as reviewing any testing the patient may have had. (Tr. at 32) When asked if he used the criteria in the Diagnostic and Statistical Manual of Mental Disorders ("DSM-5") to make his diagnosis, he agreed, "[A] lot of people use that. It is widely used." (Tr. at 31) However, when he was asked if he has ever claimed that the DSM-5 was not based in science, Dr. DeMio conceded, "I don't think they use the science that's there as part of their criteria." (Tr. at 34)

26. Following some discussion, Dr. DeMio testified that he believes the DSM-5 is based on behavior, not biology, explaining, "So if you do scientific statistics on behavior, and behavioral criteria, then that's where the science is in there, and consensus of doctors who have pulled together and various other people, psychologists, who pull together criteria." (Tr. at 35) Dr. DeMio was also asked if he had previously stated that the DSM-5 is a nonscientific collection of symptoms, and he elaborated that is it not biological, explaining, "I mean that it does not retrieve or incorporate significant biological ongoings that are commonly present in persons with autism." (Tr. at 35)

27. Dr. DeMio pushed back against a suggestion on cross-examination that he did not use a standardized method to diagnose or assess a patient's autism symptoms. He testified that he observes "neuro-behavioral symptoms of autism" such as a patient's social function, language, interaction with others, eye contact, and relationship-forming skills, and he evaluates whether patients are restricted by their symptoms, how disruptive their symptoms are, and whether they are able to function as they should at their age. (Tr. at 1715-1717, 1736-1738) However, when Dr. DeMio was asked if he recorded any of that criteria in the patients' records, he responded, "I may not have always done that." (Tr. at 1717)

28. Dr. DeMio believes that autism is a medical biological condition rather than a mental health condition, and that it can be treated medically. He testified that integrative medicine offers "a good 300 treatments" for ASD, in addition to the therapies offered by conventional medicine, but he added that not every treatment is right for each patient. (Tr. at 31-32, 1186-1187) He emphasized that treatment needs to be individualized to each patient, which he said involved, "ferreting through all of your child or your issues, and that's what we [d]o." (Tr. at 1187) Dr. DeMio stated that his practice, Whole Health and Wellness, offers functional medicine treatments. He explained that "integrative medicine blends concepts of conventional medicine and alternative medicine, and that functional medicine "digs deeper" to look for the underlying causes of a patient's condition. (Tr. at 1152-1153) He pointed out that many hospital systems now have alternative and integrative medicine departments, including Summa Health and The Cleveland Clinic. (Tr. at 1157)

29. When asked whether ASD is caused by toxic elements in the body, Dr. DeMio replied "[s]ometimes." (Tr. at 31-32) In addition, he testified that it can sometimes be caused by Lyme disease:

> Q. [By Mr. Wilcox:] Do you believe that [L]yme disease could potentially cause autism, or autism symptoms?
> A. I think that happens sometimes.
> Q. You believe that happens sometimes?
> A. Yeah, sometimes. I don't think it's often.

(Tr. at 32)

30. The State's pediatric expert, Bradley Jackson, M.D., testified that although the medical community's understanding of autism has changed in the last 20 years so as to now recognize a spectrum of disabilities that result from it, unfortunately there have been no significant new treatment modalities for autism since 2014. He said that the only approved medication to treat autism is Risperdal, which can be used to manage aggressive behavior in some autism patients. (Tr. at 448-451)

31. Dr. Jackson testified that any other biomedical treatments for autism are only speculative, adding, "[T]here's no particular entity that has established any specific medicine labeled specifically for autism." (Tr. at 450) Dr. Jackson testified that anything beyond the use of Risperdal is still in the study phase, but that none of the studies to date has been sufficient to change the standard of care for the management of autism during the time of these cases, which range from 2012 to 2016. (Tr. at 450-451)

Dr. DeMio's Use of Chelation to Treat ASD

32. Dr. DeMio sometimes treats patients for heavy metal toxicity using chelation, because he said it can draw heavy metals out of the body. He explained that chelation can be used to remediate lead toxicity in kids who eat paint chips, or iron toxicity in a child who eats their mother's prenatal vitamins, and that when used for that purpose, chelation is usually an

inpatient IV treatment, to remove the excess lead or iron. Dr. DeMio said that if a patient has very high levels of a single metal like lead, he might chelate them using the calcium disodium form of EDTA or DMSA, sometimes sulfur or nitrogen, and, on occasion, DMPS. With chronically ill patients who have a variety of metals, he said that he would try more natural treatments to make them healthier, rather than prescribing more potent chelators. (Tr. at 36, 40-41, 1368-1369; 1709-1710)

33. Dr. DeMio explained that he does not chelate all of his patients, even if they do have heavy metal toxicity, but that he sometimes has to "make their body healthy enough for that" first. (Tr. at 1709) He testified that chelation is a therapy that can be used to treat autism in some cases by removing toxic heavy metals from a patient's body:

> Q. [By Mr. Wilcox:] And chelation therapy is basically therapy that you use to try to draw toxic metals out of the body; is that an accurate description?
> A. That's one of the things it does, yes.
> Q. And do you believe that that's a treatment that should be used for pediatric patients who may have Autism Spectrum Disorder?
> A. For some of the kids, yeah; and adults.
> Q. And you've used that over the years in treating pediatric patients, you've used chelation therapy?
> A. I have for some, yes.

(Tr at 36)

Dr. DeMio said that chelation can present a risk of removing the nutritious metals at the same time as the harmful ones, and that the goal is to "let the good metals shine by helping the body get rid of the toxic metals." (Tr. at 1370, 1372)

34. Dr. DeMio's website includes a statement under a tab titled, "Autism Spectrum Disorders are Treatable" that says, "Increasingly evidence shows that autism is a metabolic, GI, immune and nutritional disorder which is often the result of toxins such as mercury, vaccines, and those that may be in the environment," and at the hearing he agreed that that statement "does sound familiar." (Tr. at 1720; St. Ex. 28) Dr. DeMio testified that this evidence came from some of the presentations he had attended:

> Q: * * * [By Mr. Wilcox:] Do you have any scientific support, scientific evidence, studies that ASD symptoms are caused by heavy metal intoxication?
> A. There are information sources out there that show that that sometimes is the case, as in the opinions of people who have presented that.
> Q. Okay. But by information sources, are you talking about anecdotal evidence?
> A. I think there's been research looking for a connection in some cases, and I think sometimes it's anecdotal, sometimes it's not anecdotal, about the issue of metals, toxic and otherwise, heavy metal toxins, and autism. So that's

> been brought up by people who have presented that in publications and at conferences.

(Tr. at 1722-1723)

35. Dr. DeMio testified that when he considers whether to use chelation therapy, he first takes a history and conducts a physical of a pediatric patient, to look at their symptoms. He does toxicology testing that looks at both nutritious metals and toxic metals, and then he makes a decision about whether the metals are likely to be contributing to the symptoms that the child has. If so, he discusses the use of chelation with the patient or their parents before starting the treatment. (Tr. at 38-39)

36. At the hearing, Dr. DeMio explained the type of symptoms he attempts to treat with chelation, and he described how he administers the chelating agents, once he has made a decision that chelation will benefit a patient:

> Q. [By Mr. Wilcox:] And what kind of symptoms are you addressing with chelation therapy?
> A. Symptoms that may be based on toxicity of toxic metals, or metal deficiencies of good metals, if I can say, the nutritional.
> Q. And what are the symptoms, can you explain that?
> A. Well, abdominal symptoms such as GI symptoms, abdominal pain, nausea, vomiting, diarrhea, pain episodes, that's one. And neurologic symptoms, because the brain and the nerves and the spinal cord are very sensitive to toxicity, to toxic metals, and so neurologic symptoms can be present in a person. And then we look at other testing that we have done, make a determination as to whether or not there is some likelihood that there is a contribution to their symptoms from the state of their tests and what their body is doing. You can also have skin symptoms and pains in their joints and bones; eye symptoms sometimes.
> Q. And how is the chelation therapy – how do you go about administering it?
> A. We have a choice of one, the other, or a combination of herb supplements, natural substances that are out there, so-called bioidentical, those are natural substances. And then there are some drugs. And more often than not we use the natural substances, and then there's some drugs.
> Q. What drugs would you prescribe for this therapy?
> A. They include EDTA, and we use the calcium disodium form. And they also include DMSA, which is the letters for the long name for that medication. And then DMPS is something that we have used on and off, that's really not used much at all.
> Q. And how are these -- how is ETDA – how is that drug administered?
> A. Transdermal. Can be made into a cream you rub on the skin, and that's generally once or twice a month on dose, one or twice a month. Can be used IV, which is its original form of use for heavy metal toxicity.
> Q. And do you--

> A. I'm sorry, I don't do the oral form.
> Q. And what is the DMSA, how do you administer that?
> A. I usually do it as a transdermal, can be made into a cream. Sometimes oral.

(Tr. at 39-41)

Dr. DeMio added that if he prescribes a cream, it must be prepared at a compounding pharmacy. He testified that he has never had any financial interest in the compounding pharmacies that he uses or in the compounds used for the chelation therapy. (Tr. at 41-42)

37. Dr. DeMio said that he sometimes uses glutathione as "a natural chelating agent." (Tr. at 106) During his testimony, he explained the nature of glutathione and its use in his pediatric patient population:

> It's an antioxidant. It's anti-inflammatory. It's been shown to -- it's a bioidentical substance. It's what we all have in our bodies. And if I may say so, without sounding harsh, if we don't have that in our bodies we're dead.
>
> And so it's been shown that kids that have medical problems, like [Patient 7], have near certain low levels of that throughout the body, and that's very serious and you can get very sick from it. And there can be marked improvement when we supply that to a child, when we have administered that to them. So it's a nutritionally fundamental substance in our bodies."

(Tr. at 105-106)

38. When Dr. DeMio was asked if he knew the position of the American Academy of Pediatrics about the use of chelation for ASD symptoms, he offered, "I don't know if I've seen that recently, or if I have. I mean, I assume it's in writing or something like that." (Tr. at 1724) The Assistant Attorney General pressed Dr. DeMio about the Academy's position, given that he holds himself out as an autism expert, and that six of the pediatric patients in this case were treated with chelation for autism symptoms. (Tr. at 1723-1725) Dr. DeMio explained in response that he was trying to treat the heavy metal toxicity rather than the autism:

> Q. [By Mr. Wilcox:] So what is their position?
> A. I think they don't think it has anything to do with autism, and I think they come at it from an angle that somehow they got the understanding that there are people who hold it out as an autism treatment. I don't do that, it's a medical treatment for people with metal toxicity. That's what chelation is, that's what it always was, that's what it is and that's what I do with it. I don't view it as an autism treatment.
>
> * * *
>
> Sometimes there is heavy metal intoxication in autism, and it seems to be associated with the kid being sick from -- and heavy metal toxicity is an

> illness. So we make them healthier by treating whatever we can, and sometimes the autism will get better as a part of that. But I'm aiming at metal toxicity, not autism itself.

(Tr. at 1725-1727)

39. Despite this, when the Assistant Attorney General read the following statement from Dr. DeMio's website Dr. DeMio agreed, "I think it does say that":

> Heavy metals and other toxins have wide sweeping effects on the cell nucleus, metabolism, the immune system, GI function, and the brain. Therefore, detoxification such as chelation and other techniques can help to improve global areas of your child's cognition and behavior as well as motor function, including muscle tone, and fine movements. Other areas such as sensory integration also benefit. Many chelators are available through Dr. DeMio such as DMSA, DMPS, TTFD (allithiamine) glutathione, along with lipoic acid, a brain chelator also known as dioic acid.

(Tr. at 1727)

40. On cross-examination, Dr. DeMio agreed that some of the pediatric patients in case did not have high levels of toxic metals on lab testing, but he nonetheless decided to use chelation. He explained why he used chelation in those cases:

> Q. [By Ms. Snyder[1]:] So some of the patients that we looked at had toxic metal levels that were in the reference range, but you decided for those patients, because of whatever specific characteristics for those patients, they still needed to have chelation. What are the characteristics, what are the standard criteria that you use when levels come back in the reference range to determine yep, that patient still needs chelation?
> A. You mean the drugs, the chelating drugs?
> Q. Yes.
> A. Yeah, so if they hadn't responded to other treatments, and we have ruled out other causes, and we have done some of the more natural herbal treatments and some of the other things I had talked about, and they still have severe enough symptoms, then we can use these, I don't want to say watered down, but lower level dosing regimens than you would use at poison control centers when I've worked there.
>
> * * *
>
> Q. What constitutes those severe symptoms?
> A. Well, if they can't function and they have neurologic symptoms and they can't talk and they are six years old and not toilet trained, and they are not

[1] Assistant Attorney General Kyle Wilcox cross-examined Dr. DeMio with respect to his treatment of the adult patients and general aspects of his practice, while Assistant Attorney General Melinda Snyder cross-examined him about his care of the pediatric patients at issue in this case.

> able to communicate, and if they have brain dysfunction or GI dysfunction, those are among the most common and intense symptoms from heavy metals.

(Tr. at 1711-1712)

41. Dr. DeMio conceded that when he was using chelation between 2012 and 2016, he was aware of at least one study that concluded that the risks of chelation outweighed the benefits for autism patients, citing work by Dr. Stephanie Cave, a Louisiana physician who conducted a study along with another physician. (Tr. at 1718) However, at a different point in his testimony, when Dr. DeMio was asked if he knew of any studies that assessed the effectiveness of chelation therapy, he testified that he did not know what a "peer reviewed study" was:

> Q. [By Mr. Wilcox:] Would you agree that there are no peer reviews -- peer reviewed scientific studies that recommend or approve of chelation therapy for treatment of autism?
> A. I don't know what's out there in the last few years, but I don't know what you mean peer reviewed. I mean, there have been studies done.
> * * *
> Q. You don't know what a peer reviewed study is, Doctor?
> A. I don't know what you mean by peer reviewed.
> Q. You tell me what a peer reviewed study is.
> A. I'm trying to answer the question to the best of my ability. That's a question you kindly asked me, and I just want to know what you mean by it, if I may ask for clarification.
> Q. If you don't know what a peer reviewed study is, then we'll move on.

(Tr. at 37)

42. When asked if he was aware that the National Institute of Mental Health canceled a proposed double-blind study that planned to treat 120 pediatric patients with chelation therapy out of concern that it was too dangerous, Dr. DeMio replied, "I'm aware of some of their activity of chelation, and I may not be aware of their particulars in that decision, so I may be aware of some of them." (Tr. at 38) Dr. DeMio agreed that the National Institute of Mental Health has studied chelation and autism, but when pressed on whether it was found to be too dangerous to provide chelation therapy to pediatric patients, Dr. DeMio testified, "By their criteria of chelation, that may be. I'd have to see in front of me what it is you're referring to, if I may say so." (Tr. at 38)

43. In contrast to Dr. DeMio's testimony, the State's pediatric expert, Dr. Jackson, testified that there is no scientific evidence or support for the proposition that heavy metals, particularly mercury, cause autism in children. Because there is no etiology tying the presence of heavy metals to autism, Dr. Jackson said that chelation is not recognized by the American Academy of Pediatrics, nor by any other certifying organization, as a treatment for autism. (Tr. at 451-453)

Dr. DeMio's Use of Hyperbaric Oxygen Chambers

44. Another therapy that Dr. DeMio sometimes recommends for his patients, including children, is hyperbaric oxygen treatment ("HBOT") used by prescription, which he described as a "megadose [of] oxygen to treat a disorder." (Tr. at 42-43) He added, "[W]e all utilize oxygen as living creatures, and it's a heightening of the dose of oxygen, or the amount that you get." (Tr. at 42)

45. At the hearing, Dr. DeMio agreed that his website touts the use of hyperbaric oxygen to treat autism and other disorders:

> Q. [By Mr. Wilcox:] So on your website it says, "Many illnesses from autism to dementia, from lyme disease to Epstein Barr Disease, and chronic fatigue to attention deficit hyperactivity disorder, have a final common pathway of damage to the cells' mitochondria. HBOT" -- which is hyperbaric [oxygen] treatment, * * * -- "is a potential treatment for major support in healing for many patients with these maladies." Does that sound like what your website says?
> A. That sounds familiar, yeah. I'll agree to that.

(Tr. at 42-43)

46. At the hearing, Dr. DeMio said that he has used hyperbaric chambers to treat his pediatric patients for conditions that included "immune disorders, GI problems, and neurological disorders that are biologically-based." (Tr. at 44) Patients can come into the office for the HBOT treatment, or they can rent a hyperbaric oxygen chamber along with the necessary oxygen unit that goes with it from Dr. DeMio, or his office can recommend two companies that sell the units, if the patient or their family wants to buy one. (Tr. at 44-45) He said that the cost of renting a hyperbaric chamber varies depending on the size of the unit, but that it was generally "a few hundred dollars a month," while the cost of purchasing a unit ranges from about $5,000 to $7,000 for the larger chamber. (Tr. at 45-47)

47. Dr. DeMio agreed that he treats some of his ASD patients using HBOT, but he said that there must be some other indication for its use, as ASD alone is not a reason to treat the patient with hyperbaric oxygen. (Tr. at 44) During his testimony, he described the type of therapy he uses, and the nature of the hyperbaric chambers:

> [T]here are two kinds. There are the kinds that are very high dose, and I don't use those. And then there are smaller versions that are not as high a dose, it's a lower dose, and those are a cylindrical shaped chamber that looks like a miniature submarine. It's around nine feet long, a little shy of three feet around, and it's just sort of a cylindrical shape.

> It's made out of rubberized canvas, and then there's a big long zipper like a taco on the top of it, and you can get inside. There's a mattress on the bottom, and then it's pressurized so that that heightens the amount of oxygen that your body takes up, and that's the idea.
>
> So that's why it has that name, hyperbaric, increased pressure, so it will allow your body to accept more oxygen than it usually would from the normal pressure that we're at here standing like in the room.
> Q. [By Mr. Wilcox:] And do you prescribe this to treat pediatric patients who may have ASD or Autism Spectrum Disorders?
> A. Well some of them, yes.

(Tr. at 43-44)

48. When asked how his patients obtain hyperbaric chambers and whether he provides them, Dr. DeMio stated:

> We do [provide them]. They can come to the office and get treatments. Most people don't end up doing that. If they do it's -- we do a training in the office because we want to make sure they understand how to use it, they are comfortable, and that it's not going to be difficult for them or that they are not going to have side effects that are unpleasant or that we don't want them to have.
>
> So we insist they get some training -- if they are going to get hyperbaric through us, through me, in other words, that's what we do.
>
> And then if they want to do it through us, then we provide them with a chamber that they take home. It's portable.

(Tr. at 45)

49. Dr. DeMio testified that he can rent a hyperbaric chamber to his HBOT patients or help them buy one. Dr. DeMio estimated that the rental fee is a few hundred dollars per month and the cost to buy one is around $5,000 – $7,000. (Tr. at 45-47) When he was asked how many people fit into the hyperbaric chamber, Dr. DeMio replied, "[U]sually one person, or one smaller person and one adult that chaperones them. We have had two adults in there on occasion." (Tr. at 46)

50. Dr. DeMio testified that he believed there were at least two other doctors in the Cleveland area that provide HBOT to pediatric patients, as well as a "Dr. Cole" in Columbus, who provides it for pediatric patients. (Tr. at 47-49) He added that Dublin Hyperbaric is a company in the Columbus area that provides this treatment, but he added, "Those are not the type of chambers that I have used." (Tr. at 48)

Diagnosis and Treatment of Lyme Disease by Dr. DeMio

51. Dr. DeMio treated some of the patients in these cases for Lyme disease, including pediatric patients. He acknowledged that he has not had formal training in the treatment of Lyme disease, except he said that during his training under Dr. Phil Lerner, an infectious disease specialist at Mt. Sinai, sometimes there was a suspicion that a patient with chronic joint pain could possibly have Lyme disease. (Tr. at 1125-1126) He offered:

> They didn't want to operate on somebody, in other words, if it was an infection and they could be treated by, you know, the infectious disease people or the pediatricians or an internist or something. So it came up frequently, and I was very interested.

(Tr. at 1127)

52. Many years later in his practice, about 6-8 years before the time of the hearing, Dr. DeMio recalled that he began getting patients who thought they had Lyme disease and needed diagnosis and confirmation. (Tr. at 1206) He explained that when he examined all of the testing these patients had had, "[O]n further testing [they] clearly did not have anything else, and the only specific thing on their prior tests was Lyme." (Tr. at 1206)

53. Because he wanted to be able to respond to these patients, Dr. DeMio tried to broaden his base of knowledge and experience. He went to conferences of the International Lyme and Associated Diseases Society ("ILADS,") and he located another physician who was a leader in this field, Dr. Richard Horowitz, in Hyde Park, New York. Dr. DeMio testified that he went to Dr. Horowitz's clinic and stayed there several weeks observing his practice, in an area that is considered tick-endemic. He also underwent ILADS training, which involved attending accredited conferences, where he said attendees sometimes spoke with patients about their symptoms. (Tr. at 1206-1210)

54. Dr. DeMio testified that symptoms of Lyme and the co-infections that can accompany Lyme disease are very non-specific, and the patients he sees have typically had chronic symptoms for a long period of time. He stated that when a patient comes to him with a suspicion of Lyme disease, he reviews any testing the patient has had as well as the response to any treatment. (Tr. at 1210-1212) He added that he does his own testing, explaining, "You always have to want to reconfirm it and * * * make sure it's not something else." (Tr. at 1211)

55. Dr. DeMio testified that there are multiple ways to contract Lyme disease, including being bitten by ticks, mosquitoes, and spiders, or even contracting it through congenital or sexual transmission:

> Q. [By Mr. Wilcox:] And lyme disease is a disease that is spread by certain types of ticks; is that correct?
> A. Yes.

> Q. Is there any other way that lyme disease is spread?
> A. It's also, in a lesser frequency by far, congenital, and also can be spread sexually as well. * * * Congenital at birth from being infected while you're in utero, during a pregnancy before you're born.
> * * *
> Q. So you believe that lyme disease is spread by spiders and mosquitos?
> A. Can be, yeah.
> Q. What type of spiders spread lyme disease, Doctor?
> A. I think the ones that are in buildings that we sometimes occupy, homes, things like that.
> Q. Okay. You don't know what type of spiders -- because the CDC says that ticks are the only thing that spread -- and in fact, black legged ticks are the insects that spread lyme. So what other -- what types of spiders or species of spiders, I guess, spreads lyme disease, according to you?
> A. Common house spiders, recluse spiders. I think they have all been -- they can carry it and I think they can transmit. * * * the recluse spider is a house spider, but it doesn't show its face as often as some other spiders that you see in the house. Spiders that bite people are able to transmit.

(Tr. at 77-78)

56. Dr. DeMio elaborated that spiders can get Lyme disease "from biting an animal that has the Lyme in them," and that the Anopheles mosquitoes that live in hot, humid areas are the ones that seem to be able to carry Lyme disease. (Tr. at 78) At another point in his testimony, said that he had learned through working with entomologists at seminars that fire ants can also carry Lyme disease, although he said it is "far and away" the deer ticks that usually transmit it, and that the other transmission routes are rare. (Tr. at 1706-1707)

57. As rebuttal evidence, the State submitted a copy of the CDC's position on the transmission of Lyme disease, which states there is no evidence that it is spread through mosquitoes, flies, fleas, or lice. (Tr. at 1708-1709; 1807; St. Ex. 27) During cross-examination, Dr. DeMio asserted that there is disagreement about this among the entomologists he knows:

> Q. [By Ms. Snyder:] So the CDC has a position statement online about the transmission of lyme disease, and I'm just going to read you a portion of it. * * * "There is no credible evidence that lyme disease can be transmitted through air, food, water, or from the bites of mosquitos, flies, fleas, or lice." Do you agree with that statement?
> A. I think if it happens, it's very rare. So there's the competent vector statement that entomologists make, meaning whether or not they think a bug can transmit a germ like that, and so the entomologists I've talked to are on the fence about that.
> They think that there is not certain evidence for the transmission commonly for those other bugs, and I agree with them. So I agree with that statement that it's virtually never -- I mean, it's just -- that's different than the lyme

> germ being found in all these different bugs, so I'm not saying they are the same two statements.

(Tr. at 1708-1709)

58. Dr. Jackson, the State's pediatric expert, testified that Lyme disease is spread by ticks, specifically the black-legged tick, which is also sometimes called the "deer tick." When he was asked if mosquitoes, spiders, or other insects can spread Lyme disease, Dr. Jackson said that *The Red Book*, the infectious disease reference guide used by the American Academy of Pediatrics, does not recognize any other vector for Lyme disease than the tick, nor does the CDC. (Tr. at 456-458)

59. Dr. Jackson said that getting a good history, such as whether the patient lives in an area or has traveled to an area where there is a higher possibility of Lyme disease, is important to support the potential diagnosis of that condition. He testified that there are several lab tests for Lyme disease, such as the Western blot and a variety of ELISA tests, and he explained that a test that shows the IgM antibody shows an acute infection that requires treatment with a 10-14 day course of antibiotics, as recommended by *The Red Book*. He distinguished a test for the IgG antibody, which shows whether the patient has ever had a past infection. Dr. Jackson said that most practitioners would use multiple testing methods before reaching a Lyme diagnosis, adding that if the infection is in a convalescent state that has been treated, the patient may have some lingering effects but does not need the same treatment as that for an active infection. If he were in doubt about the diagnosis, Dr. Jackson said that he might have to consult with an infectious disease specialist. (Tr. at 458-461, 464-465, 467)

60. On cross-examination, Dr. Jackson agreed that the CDC has a position on the treatment of post Lyme disease syndrome when symptoms persist longer than six months, and agreed that in the late phase of Lyme disease, patients can have chronic inflammatory conditions, such as arthritis. He also agreed that if a patient's symptoms do not resolve, the patient may have to be re-treated. (Tr. at 636-638)

Expert Testimony Presented

Tricia Croake-Uleman, M.D.

61. At the hearing, the State presented the testimony of two physicians who were recognized as expert witnesses, without objection. (Tr. at 254, 444) Tricia Croake-Uleman, M.D. reviewed the charts of the five adult patients that this case concerns, wrote an expert report about those cases, and testified at the hearing about her opinions.
Dr. Croake-Uleman has been board-certified in family medicine since 2002, but after practicing family medicine for about ten years years, she trained in interventional pain management in Arizona through the American Society of Interventional Pain Physicians, where she learned pain management techniques including epidurals and facet joint injections, in addition to treating pain with medications. She then returned to Ohio in 2010 and began her practice, Southwest Ohio Pain Management in Mason, Ohio, which

is now known as Southwest Ohio Health Partners and Regenerative Medicine. Dr. Croake-Uleman is a diplomate with the American Academy of Pain Medicine, and she practices interventional pain management as well as sports medicine at her clinic and ambulatory surgery center. She also teaches regenerative medicine injections to doctors through her affiliation with the International Academy of Regenerative Therapies. (Tr. at 240-248, 253-254, 250-251; St. Exs. 18, 18A)

62. Dr. Croake-Uleman testified that she sees primarily adult patients with pain related to headaches, back and neck pain, pelvic pain, and neuropathy. She testified that she has prescribed opioid medications including Vicodin, Percocet, and tramadol for patients, but that she tends to use other treatment modalities, instead. Even when patients come to her already on opioid pain medications, Dr. Croake-Uleman testified that she tries to use other treatments such as physical therapy, epidurals, or facet injections to improve her patients' quality of life without using narcotics. (Tr. at 247-249) She testified, "I try to use a lot of other modalities, which is one of the main reasons I went into interventional pain, because I found that there's a lot of ways you can keep people off opioids, and that's kind of been my emphasis with treating." (Tr. at 247) Dr. Croake-Uleman testified that she is familiar with the Board's rules for prescribing pain medications for intractable pain, as well as the requirements concerning the use of the Ohio Automated Rx Reporting System ("OARRS,") and she agreed that all Ohio practitioners of every specialty area must follow those rules. (Tr. at 248-249)

63. On cross-examination, Dr. Croake-Uleman agreed that she had never treated a patient for Lyme disease, although she said that some of her patients that she treated for pain management might have had Lyme as one of their diagnoses. (Tr. at 310, 356) She later clarified that she had had patients who said they had Lyme disease, but she offered, "[I]t would be a small percentage. * * * [I]t's not something I treat. I don't treat Lyme disease, I would be treating either the pain or, you know, they happen to have a sports injury kind of thing." (Tr. at 320)

64. On cross-examination, Dr. Croake-Uleman also conceded that while she is a member of the American Society of Interventional Pain Physicians, she is not board-certified in pain management by the American Board of Medical Specialties. Her only board-certification is in family medicine, which she has held since 2002. (Tr. at 333-335)

65. Also on cross-examination, Dr. Croake-Uleman was asked if she was familiar with "the fifth vital sign." (Tr. at 340) Dr. Croake-Uleman testified that she was aware that some practitioners considered pain to be "the fifth vital sign," but she stated that she believed the term was coined by Purdue Pharma, explaining that it represented a more aggressive approach to the treatment of pain using opiate medications. (Tr. at 340-342) Dr. Croake-Uleman agreed that, during an earlier era, prescribers "absolutely did" feel pressure to treat pain, but she added, "That's part of why the opioid epidemic became what it did." (Tr. at 341) She stated that, over time, there has been a more conservative approach to prescribing opioid pain medications. (Tr. at 343)

66. Finally, with respect to use of OARRS, Dr. Croake-Uleman could not remember when physicians were required to start using that system, but she said that she was taught to use it during her residency. (Tr. at 344-345) When she was asked if Dr. DeMio was required by law to check OARRS reports of patients before prescribing opiates to them, she responded, "I don't know if that was a law, but that was definitely a standard of care that you would expect somebody to be doing who is giving chronic opioids." (Tr. at 348) When Dr. Croake-Uleman was pressed on whether a prescriber has to check OARRS before every prescription or if it was required only when there were "red flags," she offered the following:

> I would get an OARRS any time you're using them for longer than an acute setting. * * * It's an easy thing to do. You get online and you look at it. It's very quick and easy to do, it's not a difficult task.

(Tr. at 349)

Dr. Croake-Uleman testified that, in her practice, her staff prints out a copy of the OARRS report for her, and she looks at it when she sees a patient, and then puts it in the patient's file. She added that she keeps track of the dates that she checked OARRS to be sure she was doing it regularly. (Tr. at 349)

Bradley Jackson, M.D.

67. The State's other expert, Bradley Jackson, M.D., reviewed the charts of the eleven pediatric patients that this case concerns, wrote an expert report about those cases, and testified at the hearing about his opinions of Dr. DeMio's care of those patients. Following his graduation from medical school in 1988, Dr. Jackson did a pediatric internship and residency at Children's Hospital Medical Center in Cincinnati, Ohio. He has been board-certified in pediatrics since 1993 and he has worked in various settings, including working as the chief of child medicine for Bethesda Practice Group, a partner in his own private practice group, and a staff physician with Lincoln Heights Health Center where he saw primarily Medicaid patients whom he described as the sickest patients with the fewest resources. (Tr. at 423- 441; St. Ex. 19A) Dr. Jackson described that position as one that covered the "gamut of pediatric illnesses." (Tr. at 431) He testified that he held hospital privileges throughout his career, and he has been an assistant professor of pediatrics with Cincinnati Children's Hospital Medical Center, where he trained medical students and residents. (Tr. at 433-435, 440-441) At the time of the hearing, Dr. Jackson was employed as the medical director of Anthem Insurance's Medicaid division, and was also serving as the primary lead medical director for Johns Hopkins Hospital System and Children's National Hospital Medical Center, and was not actively practicing clinical pediatrics. (Tr. at 429-430, 440-441; St. Ex. 19A)

68. On cross-examination, Dr. Jackson agreed that he has not had any specialized training in the treatment of Lyme disease or Autism Spectrum Disorder, except to the extent that Lyme disease is included within the scope of infectious diseases, and he said that a

significant number of his patients in his pediatric practice have had diagnoses of ASD. Dr. Jackson conceded that he had never practiced alternative medicine in his career as a pediatrician. He said that "alternative medical treatment" to him meant the integrative use of other modalities of medicine, with holistic or integrative therapeutic interventions that may not be part of the standard of care that most medical providers use. He also conceded that alternative medicine uses some modalities that have been proven effective, even if they are not yet part of mainstream medicine. (Tr. at 612-617, 621)

69. In addition, Dr. Jackson agreed on cross-examination that he reviewed the charts of the pediatric patients only for the time period of 2012 through 2016, and that he based his opinions about Dr. DeMio's care upon the records during that span of time. At some points in his cross-examination about the care of specific patients, Dr. DeMio was asked about tests or treatments done in 2010 or 2011 that were included in the patient charts, and in those cases, Dr. Jackson stated that he did not review the records from before 2012, when the allegations in the Notice began. (Tr. at 624-625, 685-686)

Nosson Goldfarb, M.D.

70. Nosson Goldfarb, M.D., was called as an expert witness by Dr. DeMio to offer testimony about the treatment of both the adult and pediatric patients involved in this case. He testified that he did not know Dr. DeMio personally or professionally, except for hearing his name in association with a compounding pharmacy in Cleveland. Dr. Goldfarb has been continuously licensed in Ohio since 1994. He completed a pediatric residency at The Cleveland Clinic in 1996, and then did a two-year fellowship there in pediatric and adult allergy and immunology. Dr. Goldfarb then worked as a pediatric and adult immunologist for Ohio Permanente for five years, where he was the chief of the allergy and immunology department by the end of his tenure there. (Tr. at 746-754, 1015-1017; Resp. Ex. B)

71. By 2003, Dr. Goldfarb had developed an interest in integrative medicine, and he and a colleague "put [their] shingle up," and began The Center for Advanced Wellness. (Tr. at 759-760) A short time later, Dr. Goldfarb took a position with The Preventive Medicine Group, a practice that specialized in integrative treatments for nutrition, weight loss, chronic disease, hormone therapies, detox, and allergies. Dr. Goldfarb testified that he learned about integrative treatments for Autism Spectrum Disorder from a pediatrician there, Dr. Derek Lonsdale. In June 2007, Dr. Goldfarb decided to open his own practice, so that he could be his own boss. While getting that practice off the ground, he also took a position in a Cleveland office of the Fibromyalgia and Fatigue Centers, a national company that trains doctors to treat fibromyalgia and chronic fatigue syndrome using an integrative approach. He continued working there until 2013, when the company went out of business. (Tr. at 759-768)

72. Since March 2011, Dr. Goldfarb has practiced at his own clinic, Integrative Medicine and Wellness, where half of the practice is devoted to integrative medicine treatment of fibromyalgia, chronic fatigue immune deficiency syndrome, hormone therapies for men

and women, sleep disorders, and a weight loss program. The other half of the practice consists of a medically assisted treatment ("MAT") program that uses integrative, holistic approaches to treat opiate addiction patients. Dr. Goldfarb estimated that he sees 5-10 patients per day in his integrative medicine role, and that he spends 1½ to 2 hours on each initial patient visit, and 30-45 minutes with patients for follow-up visits. He does not treat acute issues, but requires his integrative medicine patients to have their own primary care doctors. In addition, Dr. Goldfarb is the medical director of two med-spas, in which he meets quarterly with the nurse practitioners who run those programs, to review their charts and their prescribing, in collaboration with them. (Tr. at 768-776)

73. Dr. Goldfarb was board-certified in pediatrics in 2003, but he explained that he elected not to recertify in 2013, because pediatrics was not the main focus of his practice, because it was time-consuming to study for the recertification exam, and because he did not need certification since he does not have hospital privileges anywhere. (Tr. at 777-778) He added, "[M]y patients don't really have any – they don't care if I'm board-certified or not." (Tr. at 779) Dr. Goldfarb still sees some pediatric patients in his integrative medicine practice, and he said that he uses his allergy and immunology training throughout that part of his practice. (Tr. at 777-778) Dr. Goldfarb was recognized as an expert witness, despite the State's objection on the grounds that the 16 patient cases at issue here involved Dr. DeMio's treatment of pediatric and pain management patients, which it contended Dr. Goldfarb did not have expertise or board-certification in. (Tr. at 782-789)

74. Like the State's experts, Dr. Goldfarb also reviewed Dr. DeMio's charts in the cases of both the adult and pediatric patients, wrote an expert report, and testified at the hearing about the care Dr. DeMio provided to these patients. (Tr. at 790-791) In his testimony, Dr. Goldfarb distinguished between "integrative medicine" and "alternative medicine:"

> Integrative medicine is combining or integrating conventional medical concepts with alternative or complimentary medical concepts. * * * Alternative would be anything that's not necessarily accepted in the conventional medical approach.

(Tr. at 756-757)

He stated that the integrative approach begins with a strong foundation of medical training, and he pointed out that integrative medicine is an evolving field, as some techniques, such as acupuncture, started out as alternative treatments, but have gained acceptance as "complementary" treatments to conventional medicine. (Tr. at 757-758)

75. Dr. Goldfarb testified that he believed that only another integrative medicine physician could evaluate Dr. DeMio's practice of integrative medicine, and that physicians who do not practice in this area, such as Dr. Croake-Uleman, were not equipped to offer opinions about whether Dr. DeMio's practice met the standard of care. On cross-examination, however, he agreed that the American Board of Medical Specialties does not recognize

integrative medicine as one of its specialty areas. (Tr. at 1024-1025, 1027-1028) Dr. Goldfarb was unable to name any professional association that has established standards in integrative medicine:

> Q. [By Mr. Wilcox:] When you say you review based on a similar physician, and in this case an integrative medicine physician, who sets the standard for integrative medicine?
> A. I don't think there is a -- there is no overarching body of association or organization that does that. It would fall within the realm of the general practice of medicine.

(Tr. at 1027)

When he was asked how much he was paid as a consultant in integrative medicine for this case, Dr. Goldfarb stated that he was paid $750 per hour. (Tr. at 1017-1018)

76. On cross-examination, Dr. Goldfarb testified that he has seen only a "handful" of pediatric patients since starting his practice in 2011. (Tr. at 1074) He estimated that he had 200 to 300 patients at the time of his testimony, and that fewer than 10 of them were pediatric patients. He said that he has treated those pediatric patients for issues concerning fatigue, weight loss, GI problems, allergies, and sometimes fibromyalgia pain. (Tr. at 1073, 1076)

77. Dr. Goldfarb conceded on cross-examination that he has never treated a child with an autism spectrum disorder. (Tr. 1096) He testified, "I actually never -- I actually didn't personally treat autism, I was only involved in some of my colleagues who treated autism. * * * It's not an area that I have experience -- clinical experience in in terms of actual treatment." (Tr. at 1096)

78. When pressed on whether he or Dr. DeMio had any training in treating ASD patients, Dr. Goldfarb testified that Dr. DeMio's training to treat pediatric patients with autism came from his background in emergency medicine:

> Q. [By Ms. Snyder:] So I guess in your opinion, what made Dr. DeMio qualified to treat autistic patients if he has no formal training in pediatrics or behavioral health?
> A. Well, emergency medicine includes pediatrics, so we learn -- in emergency medicine you have to learn how to treat pediatric patients.

(Tr. at 1088)

Dr. Goldfarb later stated that Dr. DeMio's expertise in the area of ASD was the result of his work in the field, offering, "It's not that emergency medicine is what qualifies, it's that when a physician has a particular interest in a field, you learn about it." (Tr. at 1089-1090)

79. When he was asked what definition that he believed Dr. DeMio was using to diagnose "autism," Dr. Goldfarb responded, "I would assume he's using the DSM definition," but he agreed that he did not see anywhere in the patient charts that showed that Dr. DeMio evaluated patients under the DSM criteria. He testified that many of the patients who came to Dr. DeMio already had a diagnosis of autism, and he said that a doctor does not have to confirm that diagnosis before starting treatment for autism. Instead, he said that past history is usually relied upon for diagnosis. (Tr. at 1091-1093) When he was asked whether he would rely on a diagnosis that was relayed by a parent, Dr. Goldfarb explained that it would depend what the diagnosis was. In the case of a patient with autism, Dr. Goldfarb testified that the diagnosis could come from a combination of the patient's history, combined with a physical exam, any lab results, and any collateral information such as from the child's school. (Tr. at 1092-1094) He added, "[T]here's no test to diagnose autism spectrum disorder." (Tr. at 1093)

The Board's Rules for Treatment of Intractable Pain

80. Dr. DeMio acknowledged that he treated each of the five adult patients in this case for pain, over a period of several years between 2012 and 2016, and that he prescribed opiates and benzodiazepines to them during that time. Dr. DeMio agreed during his testimony that he was familiar with the Board's rules for the treatment of intractable pain in 2012, and he agreed that he was treating Patients 1-5 for intractable or long-term pain "some of the time." (Tr. at 66-67, 74-75)

81. When he was asked what the Board's rules required him to do when treating patients for intractable pain, Dr. DeMio offered the following explanation:

> Q. [By Mr. Wilcox:] Can you just summarize for the Board what those rules require doctors to document and perform?
> A. Well, my understanding then, and still now about that, is to make sure that you do a history, physical, look over their prior treatment, what diagnosis they have, any treatable causes of pain that would be able to be used without any pain medication of any kind, to do that. Do any other testing that needs to be done to investigate the diagnosis, and then to use the pain medications, including opiates, if that's necessary.
> They have to be followed closely and carefully, and to do what you can to make sure there's not addiction and risks to that kind of treatment, that the risk is low, and then you follow them.

(Tr. at 67)

Dr. DeMio then elaborated on what he meant by "following a patient closely and carefully:"

> Knowing that patient thoroughly, having a good relationship with them, being familiar with what their body's response is to that, what their risks

> and benefits are. How they are doing, monitoring them, making sure these things help them, that they are doing some good for them. Possibly -- I'm sorry. Constantly being able to know and make basically a continued decision that they need that ongoing treatment with things like opiates and those kinds of things.

(Tr. at 68)

82. Dr. DeMio agreed on cross-examination that one of his patients was not seen for seven months but still received monthly prescriptions for opioids. (Tr. at 68) Although he agreed that patients should be seen face to face in order to assess them, he conceded, "There are times when that – which I did not see them face-to-face, that's right, over periods of some time." (Tr. at 69)

Use of OARRS

83. At the hearing, Dr. DeMio did not remember when he began accessing the OARRS, and he testified that he did not know if he had an OARRS account between 2012 and 2016. (Tr. at 70-71) He agreed during his testimony that between 2012 and 2015, the OARRS rule required the prescriber to check OARRS when starting a patient on a controlled medication, and the rule required the prescriber to print the OARRS report and put it in the patient's chart every time a new prescription was written. (Tr. at 71-72)

84. Dr. DeMio testified on cross-examination that the purpose of the rule was to take good care of the patient, to make sure the patient was not getting multiple prescriptions for controlled substances from different prescribers, and to make sure the patient is safely using the medication by monitoring for the risk of addiction and side effects. (Tr. at 72) He agreed that checking the OARRS report is part of the standard of care, offering, "I think it is because of the law, sure." (Tr. at 73)

85. Nonetheless, Dr. DeMio acknowledged that he did not note on any of the charts of Patients 1 through 5 that he ever checked their OARRS reports, stating, "I don't think I did, no." (Tr. at 71) Dr. DeMio asserted that there were other ways to monitor patients' use of controlled substances than OARRS:

> The best way to do it is ask them, but also ask family members and make contact with -- usually phone calls with other providers. Again, they would usually tell me about the other providers, and we have asked that, you know, in the beginning. I'm sure you've seen, and I can show you in their intake forms and -- what diseases they have, and what specialists they have and doctors, and all that kind of thing. So that's included in that.
>
> And then if there's any reason to believe, on examining them and having encounters with them, that they are having negatives and bad effects, you

> know, those are among the ways of knowing about other prescriptions and what they are taking, what they are doing.

(Tr. at 73-74)

He also conceded that there was no indication that he had ever done any urine drug screens of patients receiving controlled substances for pain. (Tr. at 71, 73)

86. The State's expert, Dr. Croake-Uleman disagreed, maintaining that using OARRS and following the Board's rules for the treatment of intractable pain are part of a physician's standard of care, and that if the physician does not do those things, the care falls below the minimum standard. She said that she found nothing in the charts of Dr. DeMio's five adult patients in this case to show that he ever checked their OARRS reports or that he followed the Board's rules for treating intractable pain. (Tr. at 255-257)

87. The Respondent's expert, Dr. Goldfarb, agreed that Dr. DeMio was required to follow the Board's rules for the treatment of intractable pain and the OARRS rule during his treatment of Patients 1 through 5 between 2012 and 2016, and that those rules make up part of the standard of care. He further agreed that Dr. DeMio did not check the OARRS report of these patients, and that he therefore violated the rules in that respect. (Tr. at 1026-1029)

88. Dr. Goldfarb agreed that in some cases, Dr. DeMio continued to prescribe controlled substances for the adult patients without seeing them for several months at a time, but he testified, "My understanding of the rule is that the patient should be seen at appropriate intervals. It's not defined." (Tr. at 1029) Dr. Goldfarb was directed to Patient 5 as an example of a patient who was continually prescribed opiate pain medications without being seen for roughly one year. (Tr. at 1029-1030; St. Ex. 5) When he was pressed on how often a physician should see a patient who is getting monthly opioid prescriptions, Dr. Goldfarb stated that he believed the patient should be seen at least annually, and asserted that other types of encounters can be used to monitor the patient:

> Q. [By Mr. Wilcox:] Okay. We'll get into that in more specifics, but if it was a one-year period and that patient was receiving opioids during that one year on a monthly basis, do you believe that that is sufficient to comply with the Board's rules for treatment of intractable pain?
> A. As long as there's other encounters, then I would say yes.
> Q. Well, when you say other encounters, you mean nonpersonal visits, either telephone visit or conversation?
> A. Yes.
> Q. So it's your testimony to the State Medical Board that if a physician is prescribing monthly long-term opioids, they do not have to lay eyes on or physically examine that patient for periods up to one year?
> A. I would say that they should be seen at least yearly.

> Q. Yearly? Can you explain how you as a physician would be able to evaluate a patient's level of function without laying eyes on that patient?
> A. I believe the most important part about evaluation is history. And if I remember correctly, Patient 5 was receiving IV therapy and care, and it was nurses going to her home.

(Tr. at 1030-1031)

89. Similarly, with respect to Patient 5, Dr. Goldfarb testified that he did not believe that the standard of care required Dr. DeMio to do periodic urine screens of that patient:

> Q. [By Mr. Wilcox:] * * * [W]hen prescribing long-term opioids -- and we'll use like Patient 5 as an example -- a patient that is getting monthly Fentanyl patches and additional opioids, and I believe a Benzodiazepine for multiple years, a patient like that, do you believe the standard of care did not require a periodic urine and drug screen?
> A. My opinion is, is that for similar physicians, and it was not absolutely required as a minimum -- minimum standard.
> Q. Between 2012 and 2016; is that correct?
> A. That is correct.

(Tr. at 1033-1034)

90. Dr. Goldfarb agreed that he did not see evidence in any of the adult patients' charts to show that Dr. DeMio ever conducted a urine drug screen or checked their OARRS reports, or had them sign pain contracts. He testified that he did not believe the standard of care required Dr. DeMio to have an opioid treatment contract with any of the five adult patients, and that he also did not believe it was below the minimal standard of care for Dr. DeMio not to use OARRS or conduct urine screens, because he was not a physician who primarily practiced pain management or addiction medicine. (Tr. at 1034, 1036-1037)

91. Dr. Goldfarb emphasized that he was relying heavily on the trusting relationship that Dr. DeMio had with his patients in this case. (Tr. at 1032-1033) With respect to the requirement for urine drug screening, Dr. Goldfarb offered, "My understanding of the rule is that it's up to the discretion of the physician, it's not absolutely required." (Tr. at 1033) Dr. Goldfarb maintained that a physical examination of a patient being treated for chronic pain would provide "minimal benefit" unless there was some new complaint or a change in the patient's condition that warranted it. (Tr. at 1034-1035) He stood by his statement in his expert report in which he wrote, "A physical exam provides very little if any benefit in the ongoing assessment of pain in patients [being treated for intractable pain], since there is often no objective evidence to evaluate pain." (Tr. at 1034-1035; Resp. Ex. C at 6)

92. Although Dr. Goldfarb testified that there were no signs that any of the adult patients were abusing their medications, he reluctantly agreed that a letter from Patient 1's insurance company notified Dr. DeMio that the patient was receiving narcotics from two other doctors, and that in that case, the trusting relationship with this patient did not suffice:

> Q. [By Mr. Wilcox:] And obviously that trusting relationship between Patient 1 and Dr. DeMio broke down, would you say, because the patient did not confide that she was receiving opioids from other providers?
> A. Yes.
> Q. And would you agree with me that is why the standard of care requires checking OARRS?
> A. Yes.

(Tr. at 1039)

93. Dr. Goldfarb testified that he believed a question on Dr. DeMio's intake form that asked simply, "Drugs/Alcohol?" was a sufficient inquiry into the patient's history in order for him to make a decision to prescribe narcotics for a patient. He testified that the rules requiring a physician to do a thorough drug and alcohol assessment before treating a patient with narcotics for intractable pain were not clear about what that meant. He added that a pharmacist could contact Dr. DeMio if it were discovered that a patient was receiving multiple narcotics prescriptions from his or her doctors, but he nonetheless agreed that that did not resolve Dr. DeMio from his responsibility to use OARRS. (Tr. at 1039-1042; St. Ex. 1 at 633)

Dr. DeMio's Care of Adult Patients 1 through 5

94. Many of the five adult patients whose care is at issue in this case all received monthly prescriptions of opioid pain medications, and some were also prescribed benzodiazepines. Dr. DeMio agreed that he never checked the OARRS report and never did a urine screen of any of the patients during the time period in question, from 2012 to 2016:

> Q: [By Mr. Wilcox:] * * * When you treated these five patients during this time frame, basically 2012 to 2016, I believe, did you -- you said you didn't check the OARRS, but did you at any time, you know, run a urine screen to see if these patients were either taking the medications as prescribed, or perhaps checking to see if they were taking medications that they shouldn't have been taking? Did you ever document or run urine screens for the patients?
> A. I did not, no.
> Q. And that's for all five of the patients during that time frame, Doctor?
> A. Right.

(Tr. at 234)

95. Dr. DeMio agreed that opioids and benzodiazepines can have drastic side effects for some people, and that one of the ways to check for side effects is to document patients' vital signs. (Tr. at 233-234) With respect to the physical exams he conducted on the adult patients, Dr. DeMio testified, "The pulse would be something I would check periodically. I mean, I didn't see it written much, if any, any time there." (Tr. at 232) He said that he was able to tell a patient's pulse when he had his hands on the patient for an exam, but he stated, "The other ones I didn't do very frequently." (Tr. at 233) He added, "And then if at all, I don't think I frequently did blood pressure. I mean, sometimes I would on occasion, but I don't think I have those in there frequently; not every time that they came in." (Tr. at 232-233)

Patient 1 (HF)

96. Patient 1 is a female born in 1947. She was 66 years old when she began seeing Dr. DeMio on or about July 1, 2013. She continued seeing him for three years, through June 2016. At the time of her first appointment, she signed disclaimers stating that even though her primary insurance was through Medicare/Medicaid, she understood that she would not receive reimbursements for any consultation or treatment with Dr. DeMio, and that she understood that he was a "fee for service" provider, who was not an in-network provider with any insurance companies. (St. Ex. 1 at 1-3; Tr. at 220-221)

97. Patient 1 wrote on her intake form that she wanted to see Dr. DeMio to get better because her memory was terrible, she had spinal stenosis and joint pain, neck pain, fibromyalgia, and language problems. (St. Ex. 1 at 631-635) She listed several surgeries, including a right hip replacement that left her with nerve pain, the removal of her gallbladder and "1/2 thyroid," a hernia repair, and a procedure for peritonitis. (St. Ex. 1 at 631) Dr. DeMio testified that he treated Patient 1 for pain in her spine, neck, back, shoulders, and possibly headaches too. (Tr. at 220-221)

98. Patient 1's file also includes the patient's handwritten letter to Dr. DeMio in which she provided the following information in support of her belief that she had Lyme disease:

> Dear Dr. DeMio,
> After I was bitten I had a terrible rash the next day all over my body but not on my face.
> The rash was large oval, red, raised, hot itchy blotches. They were approx. 4 in. x 2 in. and we saw them in a Lyme booklet sent to us by a Lyme USGA.
> I went to Dr. Chris Husner for pain treatments as the pain was terrible. Then I went to him for cavitation removal. All of this was to control or get rid of pain. Pain was all over my body.
> One day he said he thought I had Lyme Disease. He did a urine antigen test and it came back highly positive. I had the hyperbaric treatments at his wife's clinic which joined his.

(St. Ex. 1 at 510)

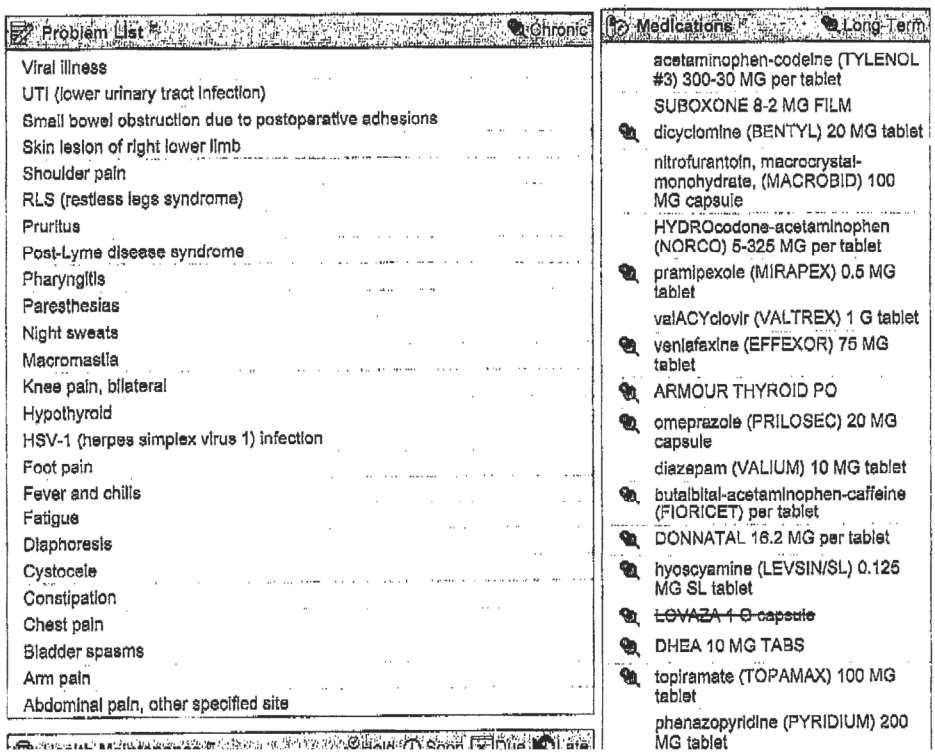
99. The patient also wrote that she was sending some test results, and that she was taking cortisol prescribed by a holistic doctor at the time she had her rash, but that the "Lyme doctor" thought that it may have affected the results of her testing. Patient 1 wrote that she believed she had neurologic involvement because she had numbness and tingling in her feet, arms, and hands, as well as nerve pain in both legs, that her joints "seem to go marching in different directions," and that she had taken numerous falls. (St. Ex. 1 at 511) She ended her letter by writing that she looked forward to seeing Dr. DeMio at her first appointment. (St. Ex. 1 at 510)

100. Dr. DeMio recalled that he saw Patient 1 for her first appointment on August 29, 2013, and that she quickly asked him to treat her for Lyme disease, recalling, "She came right to it and said she wanted Lyme treatment, that that was her major issue, and that she had symptoms from that that included pain and some other things." (Tr. at 1563) Dr. DeMio stated that Patient 1 described having had what sounded to him like a PCR test in the 1990's, which he said was a "pretty definitive" test, after she had been bitten four years earlier. (Tr. at 1563-1564)

101. At Dr. DeMio's first encounter with Patient 1, he conducted a physical exam, abbreviated "PE" in his records, and noted the areas where she complained of pain, particularly in her neck and her back. His plan of treatment after that visit was to "resume Valtrex after Enhansa," followed by a methyl B12 injection and folinic acid, with consideration of IV therapy, amino acids, and glutathione if she did not see enough improvement. Dr. DeMio testified that his notes of that visit indicate that he spent 3 hours, 10 minutes with her, but that he charged her for 2 hours, 28 minutes, because some of their conversation related to golf. (St. Ex. 1 at 239-240; Tr. at 1565-1567)

102. Based on the information she provided at intake, Dr. DeMio testified that he believed Patient 1 had chronic Lyme disease. He added that she had been in a wheelchair and on oxygen as a result, and that she had been treated for Lyme in the past, but had never had a significant work-up to check for possible co-infections. (Tr. at 1563-1567; St. Ex. 1 at 238-240) He explained, "That's sometimes why patients haven't gotten better, because that hasn't been treated. That's actually very common." (Tr. at 1564)

103. Dr. DeMio testified that, about a month after he began seeing Patient 1, he got a fax from her primary care doctor, Clarke Baxter, M.D. that provided more information about the patient's medical history. It included the following list of conditions, and medications that had been prescribed for her, including several controlled substances, such as Suboxone as well as various other narcotics. (Tr. at 1570-1572; St. Ex. 1 at 622)



Problem List — Chronic

- Viral illness
- UTI (lower urinary tract infection)
- Small bowel obstruction due to postoperative adhesions
- Skin lesion of right lower limb
- Shoulder pain
- RLS (restless legs syndrome)
- Pruritus
- Post-Lyme disease syndrome
- Pharyngitis
- Paresthesias
- Night sweats
- Macromastia
- Knee pain, bilateral
- Hypothyroid
- HSV-1 (herpes simplex virus 1) infection
- Foot pain
- Fever and chills
- Fatigue
- Diaphoresis
- Cystocele
- Constipation
- Chest pain
- Bladder spasms
- Arm pain
- Abdominal pain, other specified site

Medications — Long Term

- acetaminophen-codeine (TYLENOL #3) 300-30 MG per tablet
- SUBOXONE 8-2 MG FILM
- dicyclomine (BENTYL) 20 MG tablet
- nitrofurantoin, macrocrystal-monohydrate, (MACROBID) 100 MG capsule
- HYDROcodone-acetaminophen (NORCO) 5-325 MG per tablet
- pramipexole (MIRAPEX) 0.5 MG tablet
- valACYclovir (VALTREX) 1 G tablet
- venlafaxine (EFFEXOR) 75 MG tablet
- ARMOUR THYROID PO
- omeprazole (PRILOSEC) 20 MG capsule
- diazepam (VALIUM) 10 MG tablet
- butalbital-acetaminophen-caffeine (FIORICET) per tablet
- DONNATAL 16.2 MG per tablet
- hyoscyamine (LEVSIN/SL) 0.125 MG SL tablet
- ~~LOVAZA 1 G capsule~~
- DHEA 10 MG TABS
- topiramate (TOPAMAX) 100 MG tablet
- phenazopyridine (PYRIDIUM) 200 MG tablet

(St. Ex. 1 at 622)

104. Dr. DeMio's intake form included a question that asked simply, "Drugs/Alcohol?" In response to this, Patient 1 wrote that she used to have an occasional drink 20-25 years ago, but that she had a bad reaction to it once, and that she no longer drank at all because she did not like the taste of alcohol. She added that she "never took drugs." (St. Ex. 1 at 633-634) In Dr. DeMio's testimony, he offered this as evidence that he asked about Patient 1's drug and alcohol history before he ever saw her as a patient. (Tr. at 1558-1560)

105. Dr. DeMio also pointed out during his testimony that Patient 1 was already on various pain medications that had been prescribed by her primary care doctor, including Suboxone, acetaminophen with codeine, Valium, and hydrocodone, before he ever saw her. He acknowledged that her medication list provided by her primary care doctor included both opioids, benzodiazepines, and barbiturates, as well as some non-narcotic pain medications such as Topamax. He testified that Dr. Baxter's records showed she was being treated for post-Lyme disease syndrome and bilateral knee pain, as well as restless leg syndrome and shoulder pain, and that she had allergies to morphine and to NSAIDs. (Tr. at 1568, 1572-1574, 1588; St. Ex. 1 at 221, 622)

106. Dr. DeMio asserted that Patient 1 had chronic, longstanding medical conditions that caused pain that had been diagnosed before he began treating her, and he drew attention to imaging and test results in her records that documented those conditions. These included a March 27, 2013 CT scan of Patient 1's pelvis and abdomen that was done to

rule out a possible bowel obstruction. Dr. DeMio pointed out that the findings included chronic right-sided sacroiliitis, which would cause pain to radiate down her lower back, hips, and legs. In addition, he directed attention to an x-ray taken on March 30, 2013 after her right hip replacement surgery, which showed degenerative changes present in the lumbar spine and left hip, which suggested to him that she would have pain with walking or standing. (Tr. at 1574-1579; St. Ex. 1 at 624, 627-628)

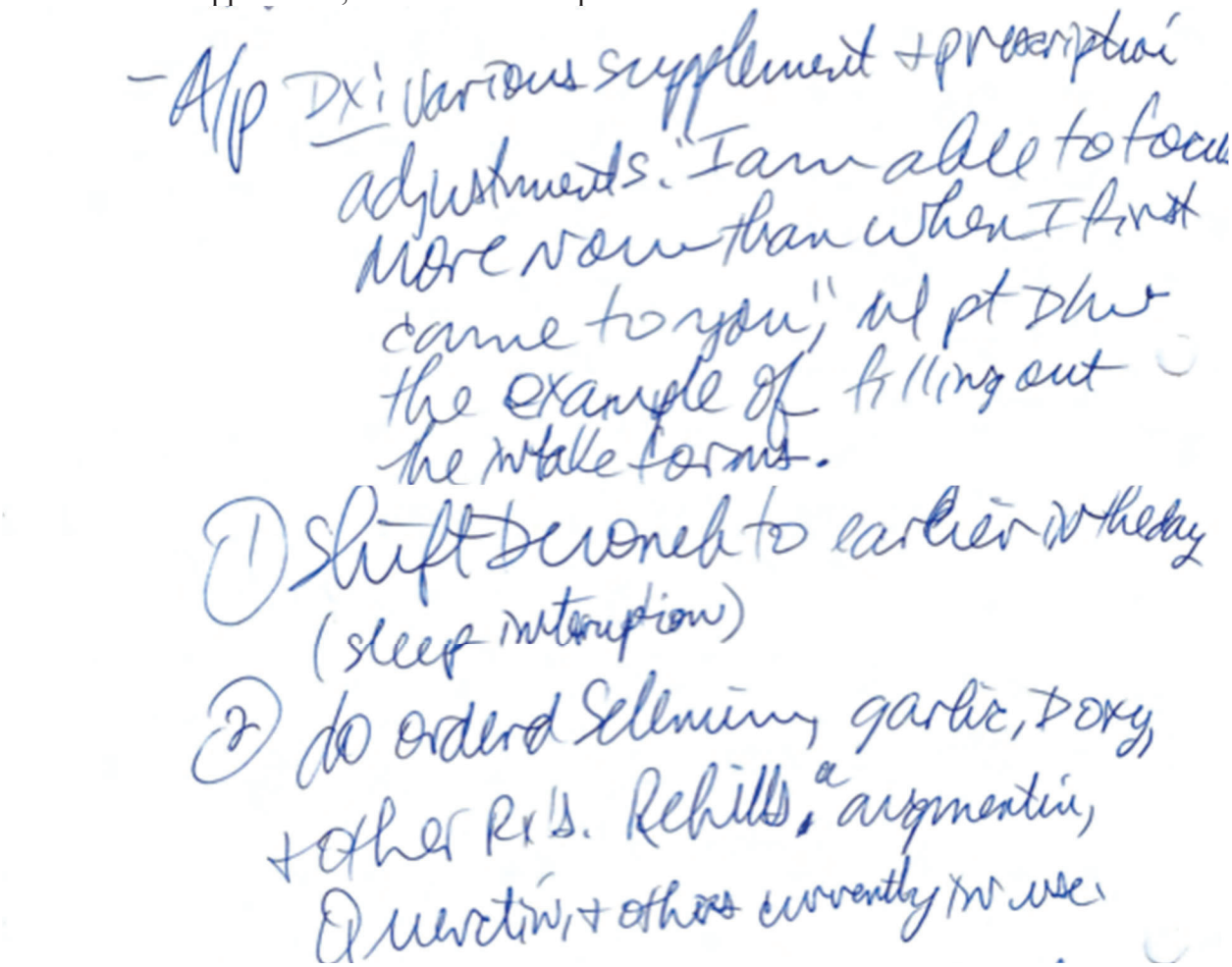
107. Dr. DeMio also called attention to an April 2014 CT scan of Patient 1's abdomen and pelvis that showed multilevel spondylosis, facet arthritis in the spine, and bilateral, degenerative changes in the sacroiliac joints. He also referred to a November 2015 MRI of Patient 1's cervical spine, which showed she was still exhibiting problems in her back and her neck that were the source of her chronic pain. He added that her file included a March 2014 lab report from Christ Hospital's lab, showing that she had normal liver and kidney functions as of the date of that test. (Tr. at 1579-1583; St. Ex. 1 at 154, 184-185, 200)

108. Dr. DeMio agreed that during the three years he treated Patient 1, he prescribed Tylenol with codeine for her, as well as Valium. He recalled that this was to treat pain in the patient's neck, spine, back, shoulders, and possibly to treat headaches, too. He conceded that there was no mention anywhere in his record of Patient 1's care of an OARRS report being checked. (Tr. at 221-222) Although he could not recall when he registered for an OARRS account, he stated, "I'm sure it was before the allegations [in the Notice] came." (Tr. at 222) Dr. DeMio stated that he had only a "handful" of adult patients that he was treating for pain. (Tr. at 222)

109. Dr. DeMio believes that the medical information that was available to him from prior imaging studies and Patient 1's primary care physician demonstrates that she had already had chronic pain work-ups with previous providers, which gave him the information he needed to prescribe pain medications for her. Dr. DeMio also emphasized that Dr. Baxter, the doctor who saw Patient 1 before he began treating her, also believed it was appropriate to prescribe pain medications for her, based on these conditions. (Tr. at 1577-1579)

110. Dr. DeMio testified that he believed Patient 1 did have improvement in her conditions as a result of the treatments he prescribed. He called attention to his progress note on February 20, 2014, in which she reported during a phone call that her brain function was better, as she had been able to do tasks and play games that she had not been able to do before. She also reported that she had no night sweats or chills, and that her pruritis (itching) was gone. In addition, Dr. DeMio recalled that he discussed her labs with her during that phone call, and that she sounded calm, bright, and alert. He also noted that when she had an office appointment on June 25, 2014, she reported that she was able to focus and could fill out her own medical forms at the office, rather than having her husband fill them out for her. Dr. DeMio stated that all of those things told him that Patient 1 was becoming more active and functional than she had previously been. (Tr. at 1584-1587; St. Ex. 1 at 299-300)

111. By the visit on June 25, 2014, Dr. DeMio adjusted some of Patient 1's medications and herbal supplements, but his notes are quite difficult to read:



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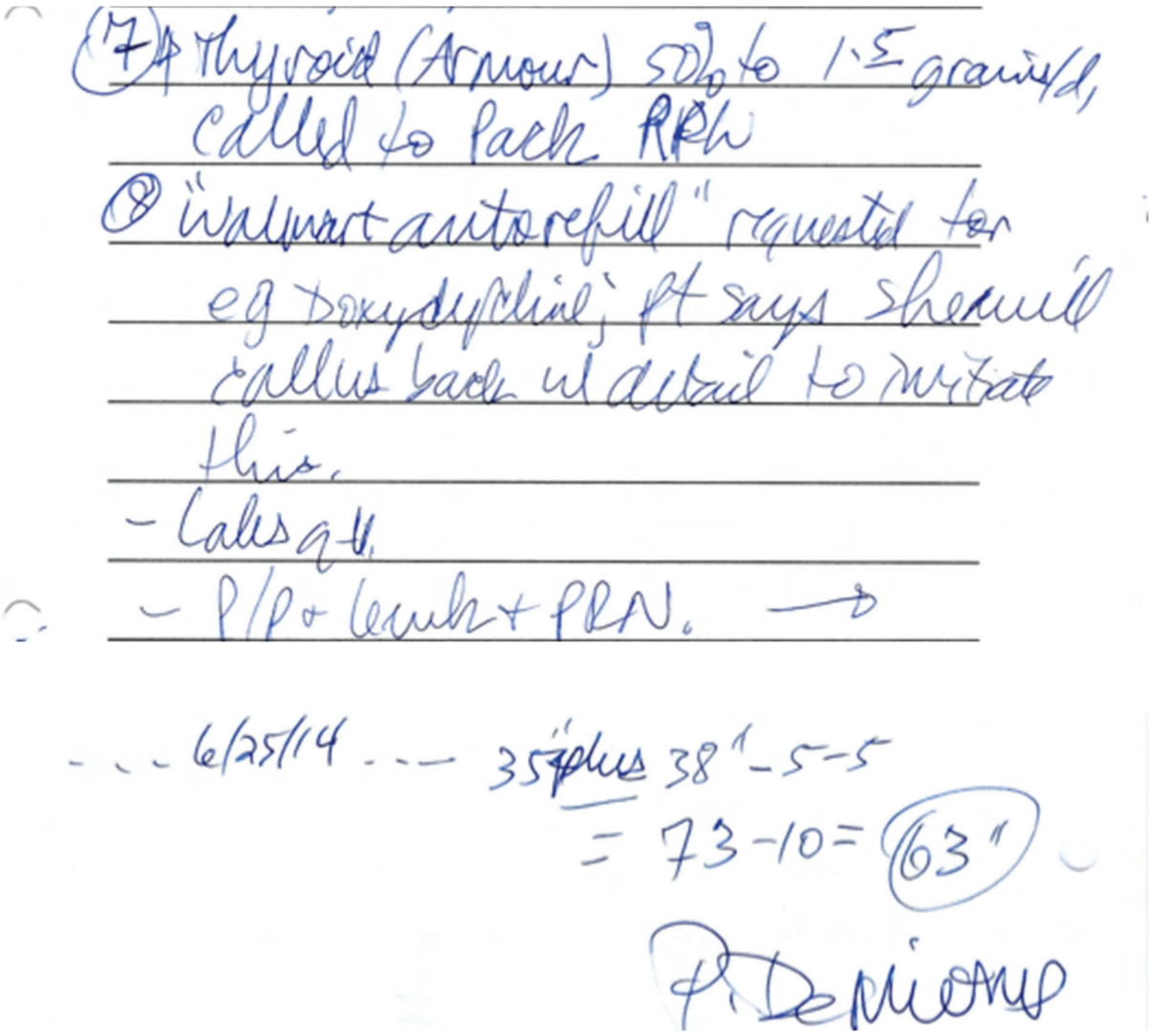


(St. Ex. 1 at 333-335)

112. Dr. DeMio testified that he gave consideration to other treatments, aside from controlled substances, to address the causes of Patient 1's pain. He noted that he prescribed venlafaxine (Effexor) and Neurontin for her, as well as allopurinol, which he said can help with joint pain when the pain is from gout. (Tr. at 1588-1590; St. Ex. 1 at 91) He added that he prescribed various antibiotics and herbal supplements, as well, to treat this patient's pain, which were not addressed by the expert report of Dr. Croake-Uleman:

> [S]he's also on a large number of multiple different treatments from me that are herbal supplements, other things that try to support the patient. Antibiotics. We're trying to get at the cause of her pain and her lack of function and mobility and cognitive dysfunction, so we're -- we're doing those things, and not one of those other things outside of the prescription [Dr.

> Croake-Uleman] criticized are narcotics, they are not benzodiazepines, they are not opiates.

(Tr. at 1588)

113. Dr. DeMio noted that he could not prescribe NSAIDs for Patient 1 to treat her pain, because the records that he received from Dr. Baxter, her primary care physician, indicated that she was allergic to NSAIDs. However, he did suggest that she try HBOT as another modality that might offer her some relief from her shoulder and Lyme-related pain, though he acknowledged that his notes did not show whether she actually tried the HBOT treatment. (Tr. at 1589-1592; St. Ex. 1 at 510)

114. Dr. DeMio maintained that he assessed Patient 1 for pain at each in-person visit, specifically asking how her pain and functioning were, and if she had any side effects such as sedation from any of the medications she was taking. He added that before he prescribed a controlled substance for this patient, he always discussed the risks and benefits with her. Dr. DeMio explained that he prescribed Valium for Patient 1 most of the time to treat her restless leg syndrome, which was preventing her from getting a good night's sleep. He pointed out that there was only one time shown in his records when he concurrently prescribed opiate and benzodiazepine medications, on July 1, 2015, when he prescribed 90 Valium 10 mg tablets and 60 acetaminophen with codeine tablets. He agreed with his counsel's calculation that on that occasion, his prescription amounted to only 9 MED units of codeine. (St. Ex. 1 at 107; Tr. at 1592-1596)

Testimony of Dr. Croake-Uleman about Dr. DeMio's Care of Patient 1

115. The State's expert, Dr. Croake-Uleman, testified that it was below the standard of care for Dr. DeMio to prescribe acetaminophen with codeine for Patient 1, in the absence of a definitive diagnosis and treatment plan. (Tr. at 259-260) First, she explained that she did not see that a complete physical exam documented on the initial visit, in order to try to find the source of the patient's pain, explaining, "[Y]ou want to try to focus on the source what you think the source of the pain is to figure out if there's some other modality you can use to help alleviate the pa[in] without going directly to narcotics." (Tr. at 259-260) In this case, Dr. Croake-Uleman testified that she could not discern the reason why Dr. DeMio prescribed acetaminophen with codeine for Patient 1, because although he noted that she had pain, he did not specify the purpose for the use of that medication, nor the details of her treatment plan in his chart. Dr. Croake-Uleman testified that the chart also did not document the patient's vital signs at her office visits or doing a physical exam, even though some of the progress notes were lengthy. She said that it was important to do an exam, and to check the patient's blood pressure, pulse, oxygenation, and respirations, in order to make sure the patient was not being compromised by any of the medications she was on. (Tr. at 260, 267, 371, 375-378)

116. In addition, Dr. Croake-Uleman testified that the standard of care required Dr. DeMio to check the patient's OARRS report, which would show if she was getting any other

controlled substances prescribed by other doctors. She emphasized that when a patient is being prescribed long-term pain medications, that patient should be getting them from only one physician. In this case, she said that she saw nothing in the patient's record to show that Dr. DeMio had ever checked her OARRS report. (Tr. at 261-262) Dr. Croake-Uleman added that physicians who prescribe chronic pain medications are supposed to have patients sign a contract stating that they will not get pain medications from any other prescribers, adding, "You just want to make sure they are not again getting multiple medications that could either cause detriment to their health, or perhaps they are diverting them, selling them, whatever." (Tr. at 262)

117. Dr. Croake-Uleman also testified that nothing in Dr. DeMio's chart for Patient 1 showed that he ever conducted a urine drug screen while he was prescribing controlled substances for her, and that this was below the standard of care for the following reasons:

> [F]irst of all I can make sure that the patient is taking their medications and not diverting it. And then on the other hand you can make sure they are not using any illicit drugs or getting scheduled medications from somewhere else that could potentially be seen in the urine.

(Tr. at 261)

She maintained that anytime a patient is being prescribed pain medications on a protracted basis, it is important for the physician to order urine drug screens of the patient, and that it is below the standard of care if this is not done. (Tr. at 260-261)

118. In the case of Patient 1, Dr. Croake-Uleman said that these safeguards were of particular importance, because this patient's prior medical records indicated that she had taken Oxycontin, as well as Suboxone, but did not indicate why. She stated that patients generally use Suboxone in order to help them get off a narcotic that they have become addicted to. On cross-examination, Dr. Croake-Uleman maintained that Suboxone was not used to treat pain, but that it was instead used to wean people off narcotics. She also called attention during cross-examination to a note in Patient 1's chart that she had been on OxyContin, and that she was using Suboxone to come off the OxyContin, after the practitioner prescribing it roughly three years ago had some kind of licensing issue. (Tr. at 264-265, 383-386; St. Ex. 1 at 238, 638)

119. Dr. Croake-Uleman also stated that, in Dr. DeMio's records, he noted that Patient 1 had used "LDN," which she said was usually an abbreviation for low dose naltrexone (Vivitrol). (St. Ex. 1 at 239; Tr. at 264-265) She maintained that it was not appropriate to prescribe narcotics for a patient on naltrexone, explaining, "The problem with low dose naltrexone is that it blocks the receptors so that the narcotics can't even work." (Tr. at 266) Dr. Croake-Uleman concluded that the patient's use of Suboxone was of such concern that she stated, "If they had been on Suboxone, I would not give them narcotics or opioids." (Tr. at 265) She queried on cross-examination, "[W]hy would you be on low dose Naltrexone when it's competitively binding with the receptors, and you're using

narcotics also. That doesn't make sense to me. You don't use the two together." (Tr. at 382)

120. Dr. Croake-Uleman also called attention to a drug utilization review that had been conducted by United Healthcare, which notified Dr. DeMio of the insurance company's concern that four different physicians, Dr. Baxter, Dr. Wu, Dr. DeMio, and Dr. Plettner, were prescribing narcotics for Patient 1 during the time period from November 1, 2015 through January 31, 2016. This was the time period when Dr. DeMio was prescribing Valium and acetaminophen with codeine for Patient 1. (Tr. at 263-267; St. Ex. 1 at 492-493)

121. Dr. Croake-Uleman wrote in her expert report that there was a period of seven months, from December 15, 2015 to July 18, 2016, when Dr. DeMio did not see Patient 1 but nonetheless continued to prescribe controlled substances for her during that time. She wrote that, because he did not see her, he could not check her vital signs and assess her pain and functioning. In addition, Dr. Croake-Uleman wrote that the risk of harm with narcotic use increases in patients 65 or older and in those with a history of substance abuse or mental health conditions, concurrent benzodiazepine use, and sleep-disordered breathing, and that she found indications of all of these in Patient 1's chart. (St. Ex. 18 at 3-4)

122. Finally, Dr. Croake-Uleman noted that at the end of this patient's treatment, Patient 1 admitted to Dr. DeMio that she had been giving some of her medications to family members who requested them and, at that point, he stopped prescribing acetaminophen with codeine for her. (Tr. at 266-267; St. Ex. 18 at 5) Dr. Croake-Uleman summarized the reasons for her opinion that it was below the standard of care for Dr. DeMio to prescribe controlled substances for Patient 1 in this case:

> [T]hrough the chart review I found multiple deficiencies and failure to maintain the minimum standard of care. Then prescribing narcotics for a protracted amount of time without establishing a diagnosis of intractable pain. He also prescribed Benzodiazepines with narcotics, which is a concerning practice, especially without discussion around it with the patient and really looking into how the patient is doing. There were a lot of benign modalities that could have been used instead of narcotics.
>
> There was lack of physical exams, there was lack of periodic review of systems, and I didn't see any documentation of the function of the patient while on these meds. There were no urine drug screens done, and this can help to assess whether or not the patient is taking the appropriate medications and to see whether or not they are using illicit drugs or other unknown prescribed narcotics or scheduled medications.
>
> And then the OARRS reports were not pulled. Intractable pain rules were not followed. So narcotics were prescribed over the phone without the

> patient being evaluated. And then the other concern was the documentation was very -- was almost illegible, a lot of times illegible, and just basically below the standard of care.

(Tr. at 258-259)

123. On cross-examination, Dr. Croake-Uleman agreed that she believed Dr. DeMio spent an above-average amount of time with his patients, and that Patient 1's notes showed that he had in-person visits with her as well as telephone consultations. (Tr. at 367-368) She also acknowledged that Patient 1's intake form could "potentially" indicate a diagnosis of intractable pain. (Tr. at 374) Dr. Croake-Uleman disagreed with a suggestion that Patient 1 had meaningful improvement during her treatment with Dr. DeMio, testifying, "I can't say that I saw meaningful improvements." (Tr. at 379) She also suggested that the patient could have been telling Dr. DeMio that she was feeling much better, so that he would continue prescribing narcotics to her, and she emphasized that this illustrates the need to use tools such as OARRS and urine drug screens when prescribing narcotics to a patient:

> Q. [By Mr. Good:] And so in this record you did not see any instances of where the patient was telling Dr. DeMio that Patient HF's life was so much better because of what he was doing?
> A. I can't say for certain that there wasn't something put in there like that, but overall I did not see that. It seemed like the patient was, you know, asking for more meds, and I believe this is a patient that was even diverting them. * * * My concern with that is if, you know -- I guess that's why I feel like urine drug screens and the OARRS and the pain contracts are so important, because in a patient that is diverting meds, they know how to play the game, too, and that's my concern from my standpoint.

(Tr. at 379)

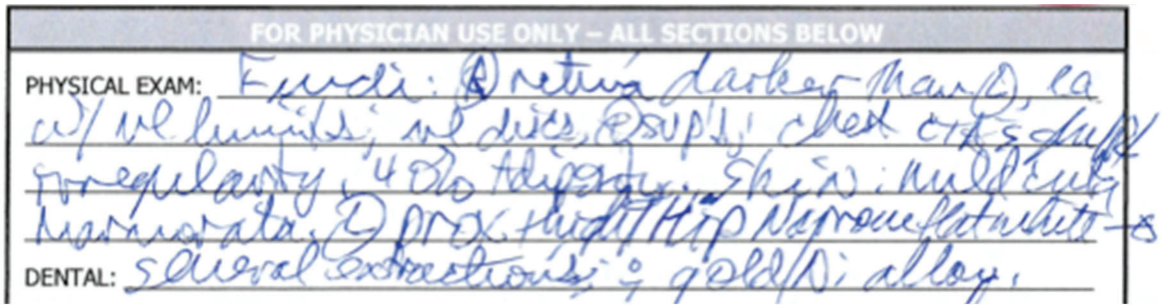
Testimony of Dr. Goldfarb about Dr. DeMio's Care of Patient 1

124. Dr. Goldfarb emphasized at the outset of his testimony that Patient 1 was a very complex patient, who had multiple pre-existing conditions that were consistent with intractable pain, including fibromyalgia, spinal stenosis, degenerative disc disease, and Lyme disease, as noted on her intake form. He stated that any of those conditions would support a diagnosis of intractable pain, and noted that Patient 1 had been prescribed OxyContin for protracted pain in the past, before she ever saw Dr. DeMio. (Tr. at 922-924, 927-928; St. Ex. 1 at 631)

125. Dr. Goldfarb pointed out, however, that Dr. DeMio was not merely treating this patient for pain or neuropathy, but that he treated her for restless leg syndrome, gastrointestinal symptoms, hormone deficiencies, and inflammation, using a combination of medications, hormones, and supplements. (Tr. at 923-925) He concluded, "Although pain was a

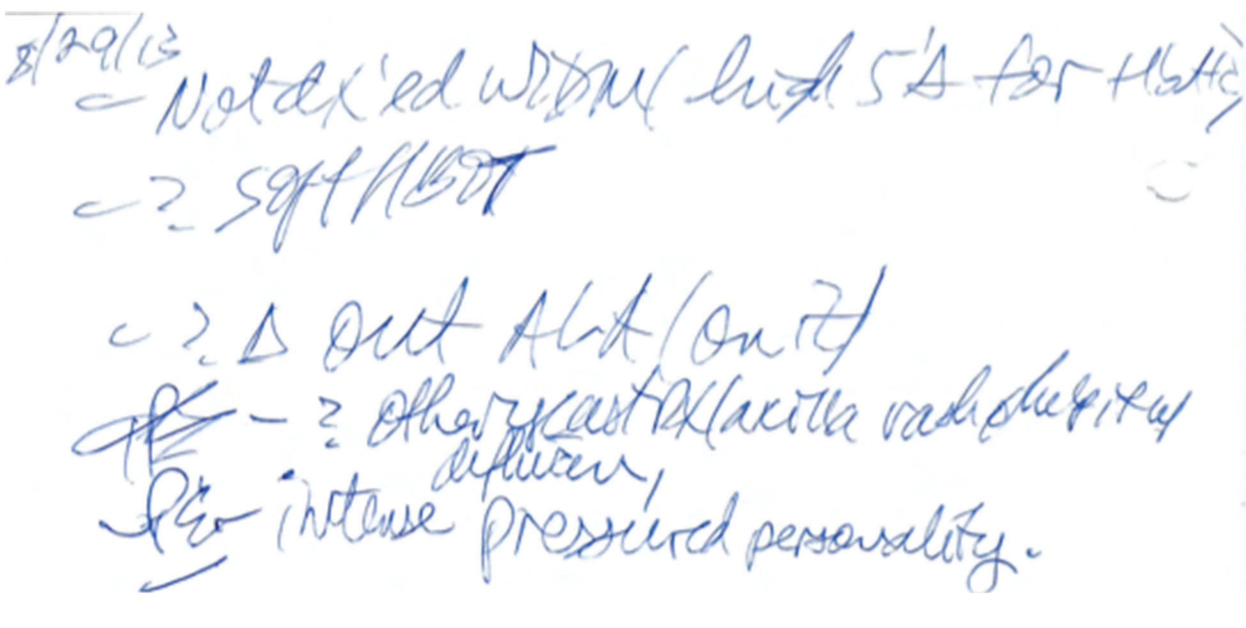
significant part of her medical history of what she needed to be dealt with, it wasn't by any means * * * the majority of her treatment." (Tr. at 926)

126. Dr. Goldfarb called attention to a "For Physician Use Only" section of Patient 1's intake form, which he said shows that Dr. DeMio performed a physical exam of this patient at this visit. (Tr. at 930-931) That section is shown below:


FOR PHYSICIAN USE ONLY – ALL SECTIONS BELOW
PHYSICAL EXAM:
DENTAL:

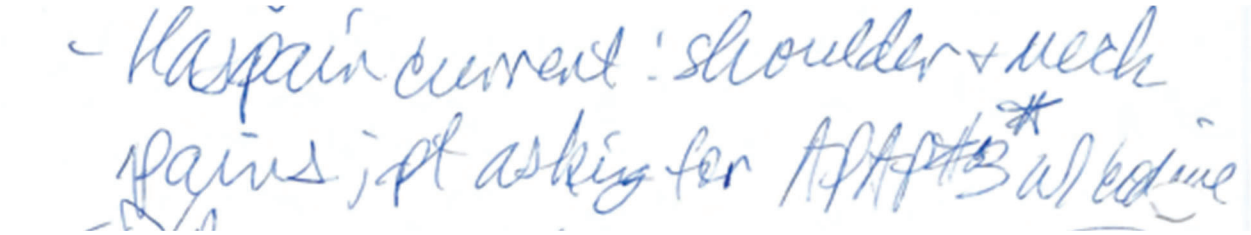
(St. Ex. 1 at 635)

Dr. Goldfarb testified that Dr. DeMio's notation of "PE" in the notes of his first appointment with Patient 1 showed that he had conducted a physical examination, as shown below in the notes of that visit:



(St. Ex. 1 at 240)

127. Later in the notes of Patient 1's first visit, Dr. DeMio noted that she was "asking for" acetaminophen ("APAP") with codeine, for her shoulder and neck pain:



(St. Ex. 1 at 240)

128. In any event, Dr. Goldfarb testified that Patient 1's complaints of pain were well-supported by her prior imaging studies of her spine and pelvis that Dr. DeMio had in the patient's chart, and that Dr. DeMio even ordered an additional MRI of the patient's lumbar spine in November 2015. (Tr. at 943-944, 947, 950-953; St. Ex. 1 at 154-155, 184-185, 627-628) He explained that that information would necessarily give a more definitive understanding of her level of pain than a physical exam:

> [P]hysical exam does not offer -- doesn't typically offer meaningful information on a patient such as this. The chronic changes and -- that we're talking about here, and disk degeneration and all the other things that we see on the radiological reports, those aren't changing, those are not getting better. So exactly what would come up on a physical exam that actually would change that, I don't see as being meaningful.

(Tr. at 958-959)

Dr. Goldfarb added that Patient 1's records showed a chronic progression of her fibromyalgia, degenerative disk disease, neuropathy, and Lyme disease, concluding, "[T]hose are chronic disorders that tend to get worse, not better." (Tr. at 950)

129. Dr. Goldfarb testified that it was evident from the records that Dr. DeMio spent a great deal of time with Patient 1. He added up a total of over 40 hours that Dr. DeMio spent with this patient, ranging from one to three hours per month, over 66 encounters. Dr. Goldfarb testified that this showed Dr. DeMio had developed a trusting relationship with Patient 1, which supported the decision to prescribe controlled substances for her. He also pointed out that Dr. DeMio had asked Patient 1 about her drug and alcohol history on the intake form that was presented to her before her initial appointment, and therefore, he believed Dr. DeMio had taken that history early on in his treatment of this patient. (Tr. at 924-925; St. Ex. 1 at 633)

130. As a result of that trusting relationship, Dr. Goldfarb did not believe it was below the standard of care for Dr. DeMio to prescribe controlled medications in response to a phone call from Patient 1. He said that patients with complex conditions often call their doctors to relate symptoms that are bothering them, and that it appeared that Dr. DeMio called the patient back and spoke to her every time. (Tr. at 958-960; St. Ex. 1 at 107) He concluded, "I would not call that below standard with a patient such as this where there's been meaningful improvement and a longstanding relationship." (Tr. at 958)

131. Dr. Goldfarb testified that it was not necessary for Dr. DeMio to ask the patient to sign a pain contract, maintaining that it was not the standard of care at that time for physicians who did not specialize in pain management to do that. While he acknowledged that a pain contract is a good idea, he said that most physicians were not using pain contracts during the time that Dr. DeMio treated Patient 1, unless they were physicians who practiced specifically in the area of pain management. (Tr. at 954)

132. With respect to the fact that Patient 1's records indicated the prior use of Suboxone, Dr. Goldfarb testified that this did not necessarily mean that Patient 1 had a history of addiction, especially because it had been prescribed for her at the same time that other opiates were being prescribed for her. (Tr. at 963-964) He offered that it may have been used as an additional medication to treat her pain without causing euphoria, explaining, "[T]he active ingredient [in Suboxone] is an opiate called buprenorphine, and buprenorphine happens to be a very good pain medication." (Tr. at 962)

133. Dr. Goldfarb agreed that Suboxone is sometimes used to help a patient with a history of substance abuse wean off pain medications that she has been on, but he said that that was not shown in Patient 1's history:

> [T]here's no indication of an addiction anywhere in the report or in her history. So the use of Suboxone in and of itself does not preclude further prescription of opiates because there's no history of addiction or abuse.

(Tr. at 963)

134. In addition, Dr. Goldfarb testified that he believes Dr. DeMio tried to treat Patient 1's pain through the use of other modalities besides scheduled drugs. After pointing out that Dr. DeMio could not prescribe NSAID medications for this patient because her history said she was allergic to NSAIDs, Dr. Goldfarb offered that Dr. DeMio prescribed anti-inflammatory protocols that would help with pain, including low-dose Naltrexone, and curcumin, as well as other supplements. In addition, the chart shows the use of Mirapex for restless leg syndrome and Topamax, which he said can be used to address nerve pain. Dr. Goldfarb added that Patient 1 was already on some of the other alternative treatments for pain, such as Effexor, which he said can decrease pain in fibromyalgia patients, and he pointed out the Neurontin prescription and the HBOT treatment that Dr. DeMio recommended, which he said can also be used to treat pain. (Tr. at 931-932, 938-939, 960-962; St. Ex. 1 at 102)

135. Dr. Goldfarb also testified that Dr. DeMio had a reasonable basis to believe that Patient 1 had chronic pain at the point he first began seeing her, since the patient had written a letter saying that she had severe pain and had previously been treated for it, and based on the records he received from her other treatment providers. Those included records showing that Dr. Baxter was treating her for bilateral knee pain, foot and arm pain, abdominal pain, chest pain, shoulder pain, restless leg syndrome, and post-Lyme disease

syndrome, although he was unclear what the latter condition was. The records also showed that Patient 1 had already received prescriptions for multiple narcotics from other doctors that were being used to treat her pain. Dr. Goldfarb concluded that within five weeks of the time he started seeing Patient 1, Dr. DeMio had enough information to support the diagnosis of intractable pain. (Tr. at 932-938, 941, 947; St. Ex. 1 at 510-511, 586, 622)

136. Dr. Goldfarb testified that he believes Dr. DeMio prescribed a "relatively minimal" amount of narcotics for Patient 1 over the nearly three years that he treated her. (Tr. at 949) He explained:

> Over the two-and-a-half years that he was taking care of her I only found eight prescriptions for opiates, and none of them were more than 30 days. So even though she meets the criteria for intractable pain, he didn't actually treat her for long-term -- long term with opiates, which is basically -- well, I take that back, there was one period he did for three months. That was the only time.
>
> So eight prescriptions, none of them more than 30 days over two-and-a-half years does not seem excessive in any way, especially given the morphine equivalent stuff he used.

(Tr. at 949-950)

137. Dr. Goldfarb agreed that today, it is "definitely frowned upon" for a physician to prescribe an opiate and a benzodiazepine, and he cautioned, "Benzodiazepines are very difficult to get off of, they cannot be stopped quickly if you've been on them for a while because there is a possibility of seizure." (Tr. at 964) However, he said that it was not necessarily contraindicated to prescribe both a benzodiazepine and an opiate in Patient 1's case because she had previously been on those concurrently without any problems. He also reiterated that the only time Dr. DeMio prescribed both for Patient 1 concurrently was on July 1, 2015 when he prescribed both Valium and acetaminophen with codeine. In that case, he stated that there was a morphine equivalency dose of only 9. (Tr. at 964-967; St. Ex. 1 at 107)

138. Dr. Goldfarb also disagreed with some of the other criticisms of Dr. DeMio's treatment of Patient 1. He said that the records did, in fact, show indications that she was having meaningful improvements while on the pain medications that Dr. DeMio prescribed, as the notes documented that she had less pain and had improvements in her sleep, her appetite, and her cognition, and was able to do more things independently. (Tr. at 954-957)

139. Ultimately, Dr. Goldfarb disagreed with Dr. Croake-Uleman's opinion that Dr. DeMio's prescribing of controlled substances for Patient 1 was below the standard of care, offering the following summary:

> Given the degree of pain that this patient was suffering, and the medical problems and the myriad of sources of pain and how much she was suffering, I would say that this amount of narcotics over that period of time, it isn't at all a lot.
>
> Many patients in such a situation would be on continuous opiates, which wouldn't surprise me. And the dosing is actually relatively low. I would think anything under 40 milliequivalents, maybe 50 milliequivalents is a low opiate dose. So it doesn't strike me as being excessive in any way, and it doesn't -- it's not commensurate with Dr. Uleman's report. It sounds from her report that he's overprescribing opiates, and I don't see that in this record.

(Tr. at 953-954)

Patient 2 (JH)

140. Patient 2 is a female born in 1972. She was 41 years old when she first consulted Dr. DeMio on or about August 29, 2013. She continued seeing him for three years, through July 2016. At the time of her first appointment, this patient also signed disclaimers stating that even though her primary insurance was through CareSource, she understood that she would not receive reimbursements for any consultation or treatment with Dr. DeMio, and that she understood that he was a "fee for service" provider, who was not an in-network provider with CareSource or with any insurance companies. Patient 2 paid $830.50 for her initial consultation with Dr. DeMio on August 29, 2013. (St. Ex. 2 at 1-3, 6, 340-343; Tr. at 224-225, 1607-1608)

141. On the intake form, when Patient 2 was asked why she wanted to see Dr. DeMio, she wrote:

> I believe I have lyme disease. After a steroid shot in November '12, started having swelling in hip, after more steroids my health has declined more, whole Rt. side of body effected [*sic*].

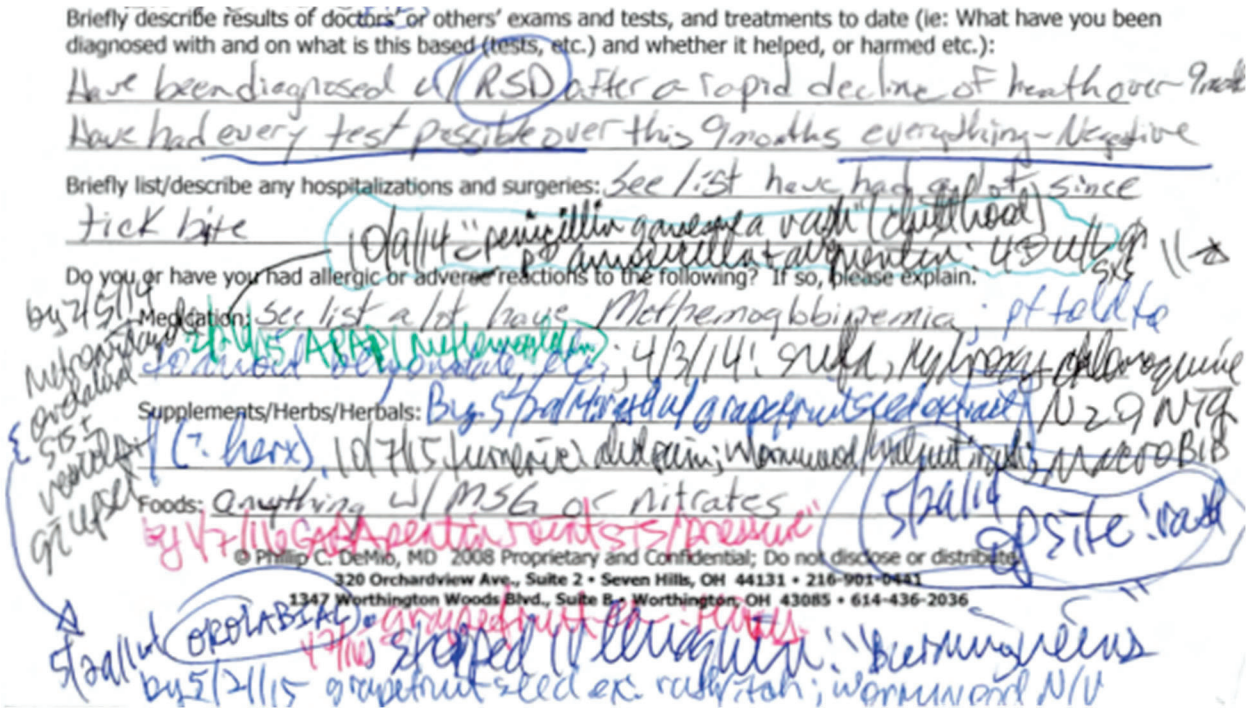
(St. Ex. 2 at 557)

In response to a question on the intake form about whether she had ever been bitten by a tick, the patient wrote:

> I was bite behind Rt. ear approximately 13 yrs ago in Ohio. Live beside park. Had a 50 cent size knot for about 2 ½ months.

(St. Ex. 2 at 557) (Reprinted as in original)

XX. The remainder of the intake form asked the patient about any prior diagnoses, hospitalizations, or surgeries, and any medications/supplements taken, but it is exceedingly difficult to read, as Dr. DeMio apparently made notes on it:



(St. Ex. 2 at 557)

142. At the hearing, Dr. DeMio recalled that he did ultimately diagnose Patient 2 with Lyme disease. He explained that she had complex regional pain syndrome, and that previous providers had attempted to treat this with steroids and corticosteroids; however, he said that when someone with an infection takes steroids, the infection only gets worse. In addition to Lyme disease, Dr. DeMio testified that Patient 2 also had a chronic form of methemoglobinemia, a class of diseases in which the blood does not effectively carry oxygen and turns a blue/brown color. (Tr. at 1604-1607) He explained that this can be caused by exposure to toxins:

> [A] lot of substances in foods and drugs and in toxins, and a lot of situations can cause the methemoglobin to build up. It will turn the red blood sour and she can't get oxygen. It's like not breathing, it's like suffocating.

(Tr. at 1606-1607)

143. Dr. DeMio saw Patient 2 for her first appointment on August 29, 2013. At the hearing, he recalled that she complained of chronic pain, and acknowledged that when she was asked about drug or alcohol use on her intake form, Patient 2 wrote that she drank alcohol

on occasion for pain. Dr. DeMio identified his notation about this on the bottom of her office visit notes of that visit, explaining, "I said social alcohol fine, not for pain," and recalled that he instructed the patient and her husband that she was not to use alcohol to control pain. (Tr. at 1607-1609; St. Ex. 2 at 340-343, 559)

144. At her initial appointment, Dr. DeMio prescribed twice weekly vitamin B-12 injections for Patient 2. He testified that he treated this patient for Lyme and Lyme-associated diseases, as well as immune issues, metabolic issues, and neurologic issues. (Tr. at 1620; St. Ex. 2 at 190)

145. Dr. DeMio saw Patient 2 for a follow-up appointment about six weeks later, on October 11, 2013. Shortly after that visit, he prescribed additional medications including allithiamine cream, nebulized glutathione and the equipment needed for it, as well as Enhansa, and Graham Slam topical cream. (St. Ex. 2 at 184-189) A short time later, on October 24, 2013, Dr. DeMio began prescribing Duragesic (fentanyl) transdermal patches for her. She was also using IV doxycycline, acyclovir, Rocephin, and she was on oral Quercetin, an anti-inflammatory herbal supplement that Dr. DeMio testified is useful with Lyme disease. (St. Ex. 2 at 184) He believes the medications were helping her because, at a visit on December 12, 2013, he noted that she reported she was "getting around a whole lot quicker and easier." (St. Ex. 2 at 353; Tr. at 1615-1617) Dr. DeMio added that she was not having loose bowel movements, so there was no sign of a C. diff infection, and the patient reported she had stopped using a cane and that people who knew her said they could see a difference in her. (Tr. at 1615-1617)

146. Dr. DeMio testified that his abbreviation "PE" in the notes of his December 2013 visit with Patient 2 show that he did a physical examination, which showed that she had normal circulation and cardiovascular function, and that she was alert, with less reliance on her cane and more independence. He believes this shows she was having meaningful improvement because of his treatments. (Tr. at 1617-1618; St. Ex. 2 at 354)

147. By the time of Patient 2's visit on January 3, 2014, Dr. DeMio was prescribing Duragesic patches and Valium for her. (St. Ex. 2 at 176) In February 2014, he added Ultra Low Dose Naltrexone, as well as Malarone, sumatriptan, and Lamisil. (St. Ex. 2 at 165, 168, 171) By mid-2014, Dr. DeMio discontinued Patient 2's IV doxycycline and Rocephin, but changed her to Invanz and Zithromax IV antibiotics. Then, in late 2014, he changed to the use of IV doxycycline, acyclovir, and cefazolin. (St. Ex. 2 at 116-118, 141)

148. Dr. DeMio agreed that he continued prescribing the Duragesic patches and Valium for most of the three years that he saw Patient 2, and in 2015, he also prescribed hydrocodone tablets for her. (St. Ex. 2 at 102; Tr. at 223-224) He explained that he was prescribing these medications for pain including headache and joint pain. (Tr at 224) Dr. DeMio said that because she was a patient with chronic pain, it was not always necessary to examine the patient each time he saw her, and that he instead asked the patient about her pain symptoms:

> [F]or some patients if it's chronic pain and there's no overt finding of a physical palpable observable swelling, discoloration, deformity, looseness, these kinds of things, then on follow-up it's a matter of doing that, you know, when it's necessary. But really you have to ask the patient if they are hurting there, that's what pain is, and how it's helping them function. So sometimes you don't look at or feel those areas again and again and again for a chronic patient.

(Tr. at 1610)

However, Dr. DeMio maintained that he did conduct physical examinations as needed for Patient 2 that were orthopedic and neurologic in nature. (Tr. at 1610-1615; St. Ex. 2 at 393-394)

149. Dr. DeMio also testified that he used or recommended various other treatments in addition to his prescriptions for Duragesic patches, Valium, and hydrocodone to treat Patient 2's pain. These included the use of Neurontin (gabapentin), and two herbal supplements, Cat Claw and White Willow, which the patient said were very helpful. He also recommended other herbals including astragalus and Ashwagandha for neural inflammation, and chlorella, an oral seaweed supplement, to balance minerals in her body. He said that he also recommended aloe and oil of oregano, Vitamin B-12 shots, and zinc and magnesium supplements. In addition, Dr. DeMio testified that he put Patient 2 on Savella, a very low risk drug to treat her methemoglobinemia, and after finding her to have hypothyroidism in later visits, he put her on a thyroid hormone. (Tr. at 1619-1624; St. Ex. 2 at 462-463) His notes show that in May 2015, he was also prescribing antiparasitics that included ivermectin and mebendazole. (St. Ex. 2 at 421)

150. Dr. DeMio testified that he also recommended a silver vitamin mineral product, and he added, "She had made her own silver. There are silver products that are like herbs and vitamins. Some of the patients do that because the silver vitamin mineral preparations are very expensive." (Tr. at 1622)

151. Dr. DeMio asserted that he also discussed with Patient 2 the possible use of physical therapy, or a consultation with a pain management physician, Dr. Pellegrino, that he referred her to for possible hip injections. However, Dr. DeMio had told her that Dr. Pellegrino would screen her for street drug use and would reject patients with positive marijuana screens. He recalled that the patient said that she did not want to see Dr. Pellegrino because she was still using some street marijuana for nausea. Dr. DeMio referred to one of his office visit notes with the patient in May 2014 in which he discussed with her the states where medical marijuana use was legal, including Michigan. He also pointed out that in his progress notes of the January 7, 2016 visit, he instructed Patient 2 again not to use street cannabis, and she agreed to stop. (Tr. at 1620-1629; St. Ex. 2 at 379, 450) Dr. DeMio said that he tried other treatments to help with Patient 2's nausea, including Zofran, and he summarized, "[W]e talked about the dronabinol for pain and nausea, and that was the best I could do for her at that point until

she saw the pain management doctor." (Tr. at 1629) On January 7, 2016, Dr. DeMio prescribed, among other things, Dronabinol [dose illegible] with instructions to take 1 to 2 tablets twice per day as needed for pain and nausea and to continue with her "baseline pain & nausea other meds." (St. Ex. 2 at 453)

152. Dr. DeMio asserted that he had received records of Patient 2's treatment by other providers, which supported the diagnosis of chronic pain. He referred to the record of her May 9, 2013 consultation at the Cleveland Clinic, in which Vicoprofen was prescribed for her, and to imaging results of x-rays of her hip, lumbar spine and full-body bone scan at the Clinic. In addition, the patient's record contains the results of some June 13, 2013 imaging of her cervical spine at The Ohio State University's Wexner Medical Center. Dr. DeMio asserted that Patient 2 was seeing a neurologist at the Wexner Medical Center, despite the fact that the State's expert criticized him for not referring her to a neurologist. (Tr. at 1630-1633; St. Ex. 2 at 297, 299-300, 309)

153. On cross-examination, Dr. DeMio testified that he believed Patient 2's chronic pain warranted the use of long-term fentanyl patches, as well as Valium, a benzodiazepine, and hydrocodone for breakthrough pain, responding, "[Y]es, I think what I used was warranted for her." (Tr. at 224-225) When he was pressed about his decision to continue prescribing opioid pain medications for Patient 2 over the course of three years, Dr. DeMio maintained that he believed his treatment was appropriate at the time, even if in hindsight, it did not comply with the Board's rules for the treatment of intractable pain:

> Q. [By Mr. Wilcox:] Do you believe you met the standard of care for providing essentially three years of monthly opioids for this patient?
> A. I did at the time. And I obviously know that there are some more specific rules about that. And so in terms of meeting those rules, those were sometimes not what I did. But in terms of standard for helping a person with pain and doing treatments that I thought were helpful to her after going through other tests and treatments, or for having had those in the past, yeah, I do think I did use those appropriately.

(Tr. at 225-226)

154. Dr. DeMio conceded during his testimony, "Looking back and applying [the intractable pain rules], that's right, I don't think every one of those rules got followed by me." (Tr. at 226) He explained, "I didn't obey some of the rules some of the times because I just wasn't familiar that they were hard and fast rules." (Tr. at 226)

Testimony of Dr. Croake-Uleman about Dr. DeMio's Care of Patient 2

155. Dr. Croake-Uleman testified that there was no clearly-defined reason in the chart to show why Dr. DeMio prescribed narcotics, including monthly fentanyl patches, for Patient 2 from late 2013 to mid-2016, and that there was also no treatment plan that she could find in the chart:

> [T]he treatment plan should explain what the source of the pain is, what modalities have been tried to treat the source of the pain, and justify using a narcotic, you know. And with that you want to make sure that you're seeing the patient improve with the use of that narcotic, and that the benefits outweigh the risks of using that medication.

(Tr. at 272)

156. Dr. Croake-Uleman referred to a note of a phone call between Dr. DeMio and Patient 2 in November 2013 that appeared in the chart, in which the patient complained of anxiety and insomnia. Dr. DeMio then called in a prescription for Valium because the patient said it had worked in the past. Dr. Croake-Uleman said that it was important to see the patient and have a discussion of the risks and benefits of Valium, and to discuss the source of her anxiety. She added that she would not start with Valium for a patient who needs help with anxiety, but that she would first try a non-scheduled medication to see if it helped. (Tr. at 273-274; St. Ex. 2 at 352)

157. Dr. Croake-Uleman also took issue with the fact that Dr. DeMio was prescribing both Valium, a benzodiazepine, and patches containing fentanyl, an opioid, at the same time for this patient, because she explained, "[A]nytime you use a benzodiazepine with a narcotic you increase the risk of addiction and side effects, basically." (Tr. at 274) In addition, Dr. Croake-Uleman pointed to the fact that Patient 2's chart indicates that she was using marijuana. She said that the concurrent use of marijuana, along with fentanyl and Valium, was concerning because she said that the literature indicates that a patient who uses illicit drugs is at higher risk of abusing prescription medications. (Tr. at 275-276)

158. Dr. Croake-Uleman was critical of the fact that there were long periods of time when Dr. DeMio did not physically see Patient 2, but he nonetheless prescribed opioids and benzodiazepines for her without reassessing her at an office visit. On some of these occasions, Dr. DeMio wrote in the chart that he had talked to her on the phone, but Dr. Croake-Uleman emphasized that it was important to see the patient in person while prescribing fentanyl patches and Valium. (Tr. at 270-272) She explained:

> We need to assess how the patient is doing. You need to see if there are signs, you know, of drug abuse, addiction, are there signs of them being a danger to themselves as far as are they, you know, falling because they are intoxicated on these medications. So basically it's just an assessment to make sure that the patient is actually improving with these medications instead of declining with these medications.

(Tr. at 271-272)

159. Dr. Croake-Uleman testified that Dr. DeMio should have checked the OARRS report before prescribing for Patient 2, and that he also should have required Patient 2 to submit to urine drug screens while he was prescribing the controlled drugs for her between 2013 and 2016. She said that the screens could have been used to confirm that she was taking the Fentanyl and Valium and not diverting it, and to look for other drugs that she might be taking by another provider's script, as well as illicit street drugs the patient might have been taking at the same time. She clarified that the Board's rules did not specifically require the use of urine drug screens, but that the standard of care in this case did. (Tr. at 274-275, 277)

160. Dr. Croake-Uleman rejected a suggestion that Dr. DeMio did not need safeguards such as the OARRS report or the urine drug screens because he had a trusting relationship with this patient, explaining:

> [I]f somebody is addicted to drugs, you can't have a level of trust, or narcotics or whatever, you can't have a level of trust there. * * * [T]he concern is that if they want their medication that they are potentially addicted to, they are going to put on a show. So there can seem like there's a level of trust there. So it's subjective, basically, versus you can have objective data from the urine drug screen and the OARRS reports.

(Tr. at 276-277)

161. Dr. Croake-Uleman summarized the following reasons for her opinion that Dr. DeMio's care of Patient 2 did not meet the minimum standard of care in this case:

> [T]here were multiple deficiencies in failure to maintain the standard of care that included completing medication reviews despite concerning patient symptoms, and the narcotics were prescribed for a protracted amount of time without following the Board's intractable pain rules.
>
> The patient admitted to illicit drug use, but Dr. DeMio continued to prescribe narcotics and benzodiazepines despite this. And then there also needed to be a discussion of the concerns for the illicit drug abuse, and also there's concerns when you use benzodiazepines with narcotics, and none of that was addressed. There were limited physical exams and review of systems, and I didn't see a documentation of the function of patient on these narcotics.
>
> In my review there were more benign treatments that could have been done in lieu of the narcotics, and then the other concern was there are long periods of time that the narcotics -- he continued to prescribe the narcotics without seeing the patient. And there were high doses of narcotics prescribed, and when you get to a certain dose you really need to make sure that you're referring out to a specialist, a pain management specialist,

> to make sure that you're doing what is correct for the patient, and what is in the patient's best interest.
>
> There weren't urine drug screens or OARRS reports pulled. And the documentation illegible or portions illegible and difficult to read is below the minimal standard of care.

(Tr. at 269-270)

162. On cross-examination, Dr. Croake-Uleman agreed that some modalities other than narcotics had been attempted for Patient 2, as the chart showed that she had previously tried PT and hip injections, without relief. Although she agreed that Dr. DeMio prescribed Neurontin, a non-narcotic medication, she explained that Neurontin requires titrating up to the effective dose, and in this case, she did not see that he had tried to titrate up the dose. Dr. Croake-Uleman stated that in addition to trying other medications, Dr. DeMio also could have sent Patient 2 for imaging or tried cognitive behavioral therapy ("CBT") for her anxiety. She agreed, however, that Valium can be also used to treat muscle spasms, in addition to anxiety. (Tr. at 387-389)

163. Also on cross-examination, Dr. Croake-Uleman pushed back against a suggestion that prescribing opiates and benzodiazepines together would meet the minimal standard of care, so long as the patient consented, after an explanation of the risks and benefits. (Tr. at 389-390) She testified that this would not meet the minimum standard of care, and that she would not prescribe opiates and benzodiazepines together:

> Q. [By Mr. Good:] Well, my question is, if it's in your clinical judgment that Benzodiazepines and opiates being used concurrently would be beneficial to the patient, and in conversation relating to the risks and benefits of that medication, and the patient consents, is it okay for the physician to move forward with prescribing those medications so long as it's within the minimal standard of care?
> A. So I don't think that's the minimal standard of care. I think there's two points here. I think getting the risks and benefits from the patient is -- giving them the risks and benefits, that's very important to the due diligence. But I would not prescribe a Benzodiazepine with a narcotic.

(Tr. at 390)

Testimony of Dr. Goldfarb about Dr. DeMio's Care of Patient 2

164. Dr. Goldfarb testified that he believed Dr. DeMio had multiple bases on which to treat Patient 2 for intractable pain, even based strictly on the information that she included on her intake form, assuming that it was all true. He noted that Patient 2 was seeking treatment for chronic Lyme disease, as well as a tic disorder, of which she said she would email a video. (Tr. at 973-977; St. Ex. 2 at 557-558) Dr. Goldfarb explained that this

patient had "multiple diagnoses associated with chronic intractable pain such as RSD, Lyme disease, neuropathy, and she suffered from insomnia and anxiety." (Tr. at 973)

165. Dr. Goldfarb stated that Dr. DeMio treated Patient 2 with nutritional support, antibiotics, pain control medications, gabapentin, muscle relaxants, and medical marijuana, over the course of her treatment. He testified that Dr. DeMio prescribed diazepam (Valium) for her for the problems she was having with her sleep and with anxiety. (Tr. at 973)

166. Dr. Goldfarb testified that Dr. DeMio did, in fact, conduct a fairly extensive physical examination of Patient 2 at her initial office visit. They discussed her exposure to pesticides and chemicals as a child growing up on a tobacco farm, and the fact that she had had a lot of pain and nausea, and various types of shots and IVs over the years. They also discussed Patient 2's history of a tick bite that she described as being the size of a pencil eraser, after which her health declined rapidly, and they discussed her methemoglobinemia, and the side effects she had from the medication for that condition. Dr. DeMio also went over with her all of the medications and supplements that she was taking, and whether she felt they were helping with her symptoms. (Tr. at 978-980, 982-983; St. Ex. 2 at 340-343, 558-559, 561)

167. Dr. Goldfarb said that after Patient 2's initial visit, Dr. DeMio continued to do physical exams at office visits, which show that he was actively assessing and monitoring her progress. (Tr. at 974-976; St. Ex. 563-564) However, he said that if there were no changes to her condition after the initial visit, it would not be as important to conduct a thorough physical exam, explaining, "[P]hysical evaluation is not really helpful, unless it was a new complaint or something different." (Tr. at 983-984)

168. Dr. Goldfarb pointed out that Dr. DeMio also had the benefit of multiple x-rays and MRIs that documented several different painful conditions, when he first began seeing her, some of which were taken just a few months before her initial visit. He referred to imaging of Patient 2's hip, pelvis, and lumbar and thoracic spine on May 9, 2013 at the Cleveland Clinic, which showed that she had a compression deformity of the T12 vertebra as well as levo-scoliosis. (Tr. at 984-986; St. Ex. 2 at 297-301) She also had an MRI of the cervical spine done on June 14, 2013, which showed a prominent arthritic process at C5 and C6, and she had a full body bone scan on May 10, 2013 that found evidence of an acute bony process. Dr. Goldfarb testified that those tests showed that Patient 2 already had significant problems with both her cervical and her lumbar spine at the time she began seeing Dr. DeMio. (Tr. at 987-988; St. Ex. 2 at 302, 309-310)

169. Additionally, Dr. Goldfarb found that Patient 2's chart showed evidence of documented neurological conditions at the time she began seeing Dr. DeMio. She had had an MRI of the brain on May 29, 2013, and an electromyogram study at the Wexner Medical Center on June 18, 2013. Although the electromyogram indicated normal results, Dr. Goldfarb testified that the MRI study indicated that she had wrist reflexes and a tremor, as well as myelopathy, a disorder involving nerve conduction. He concluded that because these

were recent diagnostic tests, there was no need for Dr. DeMio to repeat them. (Tr. at 989-990; St. Ex. 2 at 311, 315-316)

170. Dr. Goldfarb also believes that Dr. DeMio took a drug and alcohol history from Patient 2, pointing out that the intake form asked about her history of drug and alcohol use, and that he discussed this with her at his initial encounter with her. (Tr. at 974-976, 983-983; St. Ex. 2 at 340-343, 557-559)

171. Dr. Goldfarb agreed that Dr. DeMio recommended medical marijuana for Patient 2 to treat pain and nausea, after advising her to stop using "street cannabis." (Tr. at 1005-1006; St. Ex. 2 at 453, 460) However, Dr. Goldfarb disagreed that the patient's use of any type of marijuana created a higher risk of drug abuse. (Tr. at 1004-1006) He added that he believed her close relationship with Dr. DeMio reduced the chance of any substance abuse:

> [M]arijuana is -- in our society is ubiquitous. It's inaccurate to claim that JH's use of marijuana to help control the pain is a drug abuse and that she would be considered at a high risk of abusing other drugs. She was also very honest with him about it, and she indicates that they had a very good longstanding working relationship, and that that does not indicate to me a high risk of abuse or addiction.

(Tr. at 1005)

172. Dr. Goldfarb also pointed out indications in Patient 2's chart that show that Dr. DeMio did consider the use of other treatment modalities, in addition to pain medications. These included gabapentin, baclofen and several natural anti-inflammatories and supplements for joint pain. In addition, Dr. Goldfarb referred to an entry in the chart in which Dr. DeMio at least considered the use of physical therapy for this patient. He stated that even Dr. Croake-Uleman's report noted that Patient 2 had previously tried physical therapy and hip injections, but got no relief. Dr. Goldfarb also referred to a report in the chart from Ohio Pain and Rehab Specialists from July 2016, which said that Patient 2 had an allergy to sulfa drugs. He explained that NSAIDs contain sulfa, so Dr. DeMio would not have been able to use NSAIDs for Patient 2's pain and inflammation, as they were contraindicated here. (Tr. at 990-995; St. Ex. 2 at 394-395, 491; St. Ex. 18 at 6) Despite this, Patient 2's list of medications as of her June 2, 2016 consultation with a pain management physician include ibuprofen 200 mg. capsules once a day. (St. Ex. 2 at 492)

173. Dr. Goldfarb testified that Patient 2 showed evidence of improvement in her condition while she was under Dr. DeMio's care. He pointed out that the notes of her visit on December 12, 2013 said that she reported getting around quicker and easier, and did not always have to use a cane by that time, even though he said that she previously used a wheelchair. He noted that she had increased independence and fewer headaches. (Tr. at 995-998; St. Ex. 2 at 353-354) By the time of her May 29, 2014 office visit, Patient 2 was no longer having the "ICTI," which Dr. Goldfarb explained was a

movement disorder involving tics. The notes said that she was more active and that she wanted to change the timing of her IV therapy, because she was getting out more. She later reported that she believed the Diflucan was helping, and that she was able to wear tennis shoes for the first time in years. (Tr. at 995-998; St. Ex. 2 at 377-378, 410)

174. With respect to Dr. DeMio's prescribing of controlled substances for Patient 2, Dr. Goldfarb testified that the chart showed these were also helping her. In the notes concerning a phone call on February 4, 2014, the patient and her spouse reported that her ICTI seizures/tics had improved with the Valium, and that it was also helping her sleep. In a progress note on January 18, 2015, Dr. DeMio noted that the patient had called and told him the Valium and Duragesic patches were helping with her pain, and that she had better range of motion in her hip, whereas before, she could not lie down on her right side due to hip pain. He testified that this shows that Dr. DeMio was monitoring her progress, and that the medications he prescribed were helping with her pain, nausea, anxiety, and sleep. (Tr. at 999-1004; St. Ex. 2 at 359, 394, 403, 460)

175. Dr. Goldfarb testified that Dr. DeMio conducted a more detailed examination of Patient 2 after she had what appeared to be a seizure incident, which he said was a longstanding problem rather than an acute issue. He suggested that Dr. DeMio's note indicating, "Herx" suggested that he believed this was a Herxheimer reaction, after which he did a differential diagnosis and adjusted her medications. (Tr. at 1011-1013; St. Ex. 2 at 398) Dr. Goldfarb explained that this could have been a reaction to the Lyme disease treatment she was receiving from Dr. DeMio as her body was detoxified, because shivering and shaking are signs of a Herxheimer reaction:

> Classically that is a reaction to a treatment for spirochete infections. * * * [I]t has become more broadly known as just a reaction to treatment, not -- not as a direct result of the medication, but of the die-off effect or classic effect of * * * the organisms that are being killed.

(Tr. at 1012)

176. Although Dr. Goldfarb conceded that benzodiazepines and opioids are not usually prescribed together today, he stated that it was more accepted at the time that Dr. DeMio prescribed them for Patient 2. (Tr. at 1001-1002) He explained:

> [I]t's become frowned upon now, the concurrent use of opiates and benzodiazepines, and even now it's not absolutely contraindicated. But during the time of this review it was fairly well accepted to be using these medications, and that in and of itself does not indicate substandard care. And she had tolerated it for many years and was significantly improved.

(Tr. at 1002)

177. Finally, Dr. Goldfarb pointed out that Dr. DeMio eventually did refer Patient 2 to a pain specialist, Dr. Pellegrino, who saw her on June 2, 2016. (Tr. at 1006-1007; St. Ex. 2 at 491-492) In Dr. Pellegrino's summary of that visit, he noted, "She states that the pain has been worse since November of 2013. The pain is constant. The pain is located in multiple areas of her body." (St. Ex. 2 at 491) At that visit, Dr. Pellegrino prescribed Lyrica for pain, and noted that while he would continue her current pain medications for another month, at the next visit, he would begin weaning her off of them by gradually decreasing her hydrocodone for breakthrough pain. (St. Ex. 2 at 494) Dr. Goldfarb pointed out that Dr. Pellegrino was willing to extend her pain medications, albeit for a short time, and that the notes of this visit did not criticize Dr. DeMio's decision to prescribe opiates along with a benzodiazepine. He added that after Patient 2 began seeing Dr. Pellegrino, Dr. DeMio stopped prescribing for her. (Tr. at 1008-1010; St. Ex. 2 at 494)

178. On cross-examination, Dr. Goldfarb agreed that Dr. DeMio prescribed fentanyl patches, hydrocodone, and Valium for Patient 2 "essentially monthly" from late 2013 through June 2016, and he agreed that the synergistic effects of prescribing opiates with benzodiazepines was already well-known in the medical community during those years. (Tr. at 1043-1045)

179. Dr. Goldfarb testified that a physical exam of the patient would have provided very little benefit to Dr. DeMio in his treatment of Patient 2 because it would show her condition at only "a point in time," and would not otherwise provide significant information. (Tr. at 1045-1046) Similarly, he maintained even when pressed by the Assistant Attorney General, that the standard of care did not require him to take or record the patient's vital signs:

> Q. [By Mr. Wilcox:] Is your testimony to the members of the State Medical Board then that you don't believe the recording -- the taking and recording of vital signs is required by the standard of care when prescribing drugs monthly, Fentanyl patches, Vicodin, and Valium?
> A. I don't -- I would say it's not absolutely required.
> Q. So the standard of care does not require it?
> A. I'd say no.

(Tr. at 1048)

Patient 3 (JM)

180. Patient 3 is a female born in 1951. She was 62 years old when she first consulted Dr. DeMio on or about December 15, 2013. She continued seeing him for 2 ½ years, until June 10, 2016. Like the other patients, at the time of Patient 3's first appointment, she also signed disclaimers stating that she understood that she would not receive reimbursements for any consultation or treatment with Dr. DeMio, and that she understood that he was a "fee for service" provider who was not an in-network provider

with any insurance company. Patient 2 paid $891.75 for her initial consultation with Dr. DeMio on January 31, 2014. (St. Ex. 3 at 1-6; Tr. at 227)

181. Dr. DeMio recalled that when Patient 3 came to him, she was on "heavy duty hemotoxic treatment" for rheumatoid arthritis, which had been diagnosed by a rheumatologist. (Tr. at 1637-1638) He testified that the treatment had helped her, but that it carried some risk. Patient 3 reported that while she was in treatment with the rheumatologist, she asked that physician if she should be tested for Lyme disease, and at that point, the rheumatologist discharged her from his practice. The patient reported that her inquiry had ruined her relationship with the rheumatologist, so she came to Dr. DeMio to be evaluated for Lyme disease. (Tr. at 1637-1638; St. Ex. 3 at 561)

182. On the intake form, when Patient 3 was asked why she wanted to see Dr. DeMio she wrote, "Daily life is a struggle. I need effective treatment for my Lyme disease, rheumatoid arthritis, fibromyalgia, and frequent sinus infections." (St. Ex. 3 at 561) Dr. DeMio first saw Patient 3 in his office on or about January 31, 2014, and she provided him with a lengthy list of the medications and supplements she was taking. Those included hydrocodone with acetaminophen and cyclobenzaprine, a muscle relaxant that Dr. DeMio acknowledged was on the OARRS list. Dr. DeMio testified that he discussed Patient 3's medications with her each time he saw her in his office, and he added that he also asks patients for the pharmacy that they use, so he can call the pharmacy or request a list of their medications. He said that he often calls and talks to the pharmacist about his patients' medications. (Tr. at 1638-1640; St. Ex. 3 at 568)

183. Over the course of treating Patient 3 for 2 ½ years, Dr. DeMio prescribed various antibiotics, as well as Buspar, hydroxychloroquine, Vicodin, tramadol, Tylenol #3, Vicoprofen, and ultra-low dose Naltrexone for her. (St. Ex. 3 at 69-146) Dr. DeMio testified that he discussed with Patient 3 the fact that some of those medications could be sedating, referring to his note stating that he went over "sedation precautions" with her. He said that he advised her to be careful when she sat up or got up out of bed, and to be cautious on ladders. (Tr. at 1643-1645; St. Ex. 3 at 376)

184. During cross-examination, Dr. DeMio testified that he prescribed the Vicoprofen, a combination drug containing both Vicodin and ibuprofen, for Patient 3, explaining, "If you have a lot of pain and it's inflammatory, and it hasn't been controlled by non-opiates, but you also need an anti-inflammatory component, it's helpful to have it all in one pill." (Tr. at 227)

185. With respect to his prescribing of controlled substances for Patient 3, Dr. DeMio asserted that he asked her about her drug and alcohol history when she first came to him. He referred to the intake form, in which Patient 3 was asked, "Drugs/Alcohol?" and in response wrote, "no." He testified that he also would have asked her about this at his first visit with her. (Tr. at 1637-1638; St. Ex. 3 at 563) Dr. DeMio added that he was criticized by the State's expert for prescribing Vicodin and Vicoprofen for this patient who had non-alcoholic fatty liver disease, when those medications contain NSAIDs.

However, he pointed out that the orthopedist he referred Patient 3 to, Dr. VanSteyn at Orthopedic One, allowed her to take NSAIDs such as Aleve. Dr. DeMio also pointed out that he referred Patient 3 back to her gastroenterologist, Dr. Romeo, with whom she already had an established relationship. (Tr. at 1640-1642; St. Ex. 3 at 25, 358)

186. Dr. DeMio testified that each time he saw Patient 3, he reviewed the medications she was taking, whether prescribed by him or by another provider, to discuss the effect they were having as well as any side-effects:

> [W]e do every time. I want to know if the medications I'm doing and other people are doing are helping, if they are maintaining the gains that they have had, and if there's any negatives, if they have any problems with it or with the obtaining of it. * * * [W]e talked to them every single time they come in.

(Tr. at 1640)

187. On cross-examination, however, Dr. DeMio acknowledged that he was not familiar with the Board's rules for intractable pain when he treated this patient. He also agreed that he "think[s] that's correct" that he did not document any check of Patient 3's OARRS report in her chart. (Tr. at 227-228)

188. Dr. DeMio testified that Patient 3 had "lots of improvement" as she continued treatment with him. (Tr. at 1645) He stated that she was able to get off the methotrexate that she was taking for her arthritis, and that she reported being more active, having less pain, and generally feeling better. In addition, he referred to an office visit note dated May 24, 2014, in which he noted that the patient estimated that her condition improved by about 40%, and he found moderate improvements in her cognition, pain, and energy. (Tr. at 1645-1646; St. Ex. 3 at 308)

189. Dr. DeMio offered into evidence a letter written by Patient 3. In it, she wrote that she was 69-years old at that time, and that she was on permanent disability. She related that she was diagnosed with Lyme disease by a doctor in Dayton, and that she found Dr. DeMio through a computer search for doctors who specialized in treating Lyme disease. Patient 3 wrote that finding Dr. DeMio was a blessing, and that early on, he did bloodwork that found she had "Q fever," which had to be reported to the county. She believed this was also the bloodwork that confirmed her Lyme diagnosis. The patient wrote that Dr. DeMio ultimately referred her to a pain management specialist, but that her health improved greatly under his care. (St. Ex. J-1 at 15-16)

Testimony of Dr. Croake-Uleman about Dr. DeMio's Care of Patient 3

190. Dr. Croake-Uleman took issue with several aspects of Dr. DeMio's prescribing of narcotics for Patient 3, noting that over the course of her treatment, he prescribed Tylenol No. 3, tramadol, and Vicodin, which he later changed to Vicoprofen ES during

the time between October 2014 and October 2015. She stated that Vicoprofen ES is a stronger narcotic than Vicodin because it contains 7.5 mg. of hydrocodone, as compared to Vicodin, which contains only 5 mg. Dr. Croake-Uleman testified that it was problematic that Dr. DeMio did not document the reasons that he prescribed those medications in the patient's chart. (Tr. at 279-281, 284-285) Although she stated that Patient 3's chart indicated that she was recovering from a lumbar fracture and an L2 fracture, and that she had joint pain and fibromyalgia, Dr. Croake-Uleman testified that fibromyalgia is a "diagnosis of exclusion," in which the patient has pain throughout her body, and there is no explanation what is causing it. (Tr. at 281)

191. Dr. Croake-Uleman testified that the first time Dr. DeMio prescribed any controlled substances for Patient 3, he wrote scripts for Vicodin and Tylenol No. 3, in response to a telephone conversation with the patient. (Tr. at 282-284; St. Ex. 3 at 296-297) Dr. Croake-Uleman explained:

> I would not recommend prescribing narcotics over the telephone. * * * [Y]ou want to make sure that the patient -- that -- if you are going to prescribe a narcotic they need to come in and be evaluated in order to follow the intractable pain rules.

(Tr. at 284)

Later, on cross-examination, Dr. Croake-Uleman reiterated that she would never prescribe a narcotic based on a phone call with a patient. She testified that this was below the standard of care, and that even if she were prescribing a narcotic for acute use for only 3-7 days, she would want the patient to come to the office to be seen. (Tr. at 392-393)

192. Dr. Croake-Uleman testified that Dr. DeMio did not follow the Board's rules for the treatment of intractable pain in his treatment of Patient 3. She said that there was nothing in the patient's records to show that he ever checked her OARRS report while prescribing narcotics for her, and nothing to show that he ever did any urine screens to make sure she was taking the medications he was prescribing and no other drugs. (Tr. at 281-282, 284

193. Dr. Croake-Uleman referred to a drug utilization review in Patient 3's chart, in which CVS/Caremark notified Dr. DeMio of the need for caution in prescribing cyclobenzaprine HCL (Flexeril), a muscle relaxant, for this patient because it is poorly tolerated by elderly patients and can predispose them to anticholinergic side effects such as sedation, which can cause falls and fractures. Dr. Croake-Uleman added that she could tell Dr. DeMio had reviewed this letter because he had initialed it. She testified that even though Patient 3 had a history of falls, there was no documentation in the chart to show that he had discussed this risk with her. Additionally, Dr. Croake-Uleman said that this risk could have been magnified by the fact that Dr. DeMio was also prescribing Vicodin and tramadol for Patient 3 during this same timeframe. (Tr. at 285-286, 393-394; St. Ex. 3 at 440)

194. Dr. Croake-Uleman summarized the reasons for her opinion that Dr. DeMio's care of Patient 3 did not meet the minimal standard of care:

> I found multiple deficiencies in failure to maintain the minimal standard of care in the chart work. There was a poor evaluation of physical status, vital signs, pain and function assessment. There was lack of medication review despite concerning patient symptoms.
>
> Narcotics were used even though there was concern with her falling, and she also had sleep apnea. You need to watch using narcotics when somebody has sleep apnea because it can worsen that.
>
> * * *
>
> The narcotics were used for a protracted amount of time and didn't follow the Board's intractable pain rules. There's no urine drug screen done, no OARRS reports pulled, and the documentation was incomplete and often illegible.

(Tr. at 278-279)

Testimony of Dr. Goldfarb about Dr. DeMio's Care of Patient 3

195. Although he testified at length about the care Dr. DeMio provided for Patient 1 and Patient 2, with respect to Patient 3, Patient 4, and Patient 5, Dr. Goldfarb agreed that there was "a lot of overlap" in his opinions, which he did not restate during his testimony about this patient. He testified that for this adult patient, he believed Dr. DeMio met the minimal standard of care, and he noted that Patient 3's chart showed that she had meaningful improvement while under Dr. DeMio's care. (Tr. at 1013-1014)

196. On cross-examination, Dr. Goldfarb conceded that when he calculated the amount of time Dr. DeMio spent with his patients, he did not distinguish between in-person office visits and phone consultations. (Tr. at 1048-1049) When he was asked if there was a difference in what a doctor could tell from a telephone discussion versus a patient visit, he responded, "In some ways yes, in some ways, no." (Tr. at 1049) Dr. Goldfarb did agree that a physician can sometimes get information about a patient's symptoms or the side effects of opioids simply by looking at the patient, because powerful opioids can affect how a patient looks and acts. (Tr. at 1049)

197. Dr. Goldfarb also agreed on cross-examination that Dr. DeMio prescribed long-term opioids, including Vicoprofen, Vicodin, and tramadol, for Patient 3 in 2015 and 2016, without checking the patient's OARRS reports or doing any drug screens. He explained that he believed a drug screen would not be dispositive because some drugs stay in a patient's system for only three or four days, and would not necessarily show up at the time the patient was tested. The Assistant Attorney General pressed Dr. Goldfarb on how he could know if a patient who was getting long-term narcotics was taking the

medications prescribed and was also not taking other drugs that they were getting either from another doctor or from the street, if he did not check OARRS and did not subject the patient to any screens. (Tr. at 1049-1051) Dr. Goldfarb agreed that the only other way the physician could get that information would be to ask the patient:

> Q. [By Mr. Wilcox:] Okay. So when I asked if there were any other tools besides the urine drug screen and the OARRS, is the only other tool to just ask the patient?
> A. Yes.

(Tr. at 1051-1052)

Patient 4 (SP)

198. Patient 4 is a female born in 1951. She was 60 years old when she first consulted Dr. DeMio on or about March 25, 2012. She continued seeing him for about four years, until July 22, 2016. At her first appointment, this patient, like the others, signed disclaimers stating that she understood that she would not receive would not receive insurance reimbursements for any consultation or treatment with Dr. DeMio, and that she understood that he was a "fee for service" provider, who was not an in-network provider with any insurance companies. Patient 4 indicated on her intake form that she had heard about Dr. DeMio's office from a Lyme disease support group. Patient 4 paid $660 for her initial consultation with Dr. DeMio on May 3, 2012. (St. Ex. 4 at 1-3, 5, 1287; Tr. at 1647-1648)

199. On the intake form, when Patient 2 was asked why she wanted to see Dr. DeMio, she wrote: "I travel far (P.A.) for medical treatment. I heard Dr. DeMio is Lyme literate & an excellent doctor. I desire to hear about his opinions." (St. Ex. 4 at 1287) The patient wrote that she became ill in 2006 and had seen "13+ doctors," who told her she "couldn't possibly have so many symptoms." (St. Ex. 4 at 1287) In response to a question on the form about whether she had ever been bitten by a tick, Patient 4 wrote that she had had three bites on their farm: one on the back of her head; one in the crease of her upper left leg; and one near her right arm pit. She indicated that she had had IV therapy for Lyme disease. (St. Ex. 4 at 1287, 1297)

200. Dr. DeMio recalled that Patient 4 lived in Central Ohio, and that the long trips to her doctor in Pennsylvania were difficult for her, so she wanted to find a doctor who could treat Lyme disease closer to her home. (Tr. at 1647-1648; St. Ex. 4 at 1287) He testified that she had severe headaches and neuropathic pain, and he believed there was a "high likelihood" that those symptoms were attributable to Lyme disease. (Tr. at 228-229)

201. Dr. DeMio testified that he saw Patient 4 at her first appointment in early May 2012, and that he conducted a physical examination. He said that by this time, Patient 4 had already seen multiple providers, including Dr. Joseph, her doctor in Pennsylvania; as well as a neurologist and another specialist at Grant Medical Center; and a surgeon who had put in

a port line. A few months after Dr. DeMio began seeing this patient, she had a CT scan of her abdomen and pelvis at Grant, which appears in the chart. In March 2013, Dr. DeMio himself ordered a CT scan of her abdomen and flank to evaluate a supraumbilical abdominal wall mass and pain. (Tr. at 1649-1650; St. Ex. 4 at 357, 670, 1299-1300)

202. Dr. DeMio testified that he treated Patient 4 for Lyme disease and diffuse pain, which was thought to be from nerve and joint damage. (Tr. at 1653) Over a period of four years, he prescribed morphine IR, lorazepam (Valium), and buspirone, as well as several antibiotics, a thyroid medication, and progesterone. He ordered a PICC line for long-term antibiotic administration. In May 2015, he added Vicoprofen and Dronabinol to her regular prescriptions, which continued into mid-2016. (St. Ex. 4 at 209-356)

203. On cross-examination, Dr. DeMio agreed that he began writing prescriptions for morphine for Patient 4 in December 2012 or January 2013, although he said that he believed her previous doctor had already prescribed it for her before he began treating her. (Tr. at 229) When he was asked if he wrote monthly prescriptions for morphine and Ativan for Patient 4 in 2013, 2014, and 2015, he agreed, "That sounds right." (Tr. at 229) Dr. DeMio also agreed that he did not follow the Board's rules for the treatment of intractable pain with Patient 4. (Tr. at 230)

204. Dr. DeMio testified that he referred Patient 4 to a pain management specialist, Gladstone McDowell, II, M.D., as shown by his referral on June 11, 2012. Dr. McDowell noted in his evaluation that Patient 4 had been diagnosed with Lyme disease after positive tests in 2008 by Dr. Joseph, her provider in Pennsylvania, and that she was started on morphine by his prescription. Dr. McDowell wrote that Patient 4 described having pain that averaged a 10/10 with all activities as well as at rest, and that the pain was constant, stabbing, burning, discomfort of her entire torso and extremities with numbness in her and arms and hands. Dr. McDowell's letter indicated that he checked Patient 4's OARRS report, and found several controlled substances prescribed for her, including most recently from Dr. DeMio. (St. Ex. 4 at 136-139) Dr. McDowell concluded with the following impressions and recommendations:

> IMPRESSION: Diffuse total body pain with history of Lyme disease. I am unable to elicit enough objective criteria for fibromyalgia but I would agree this is in the differential diagnosis. My concern is she needs a full neurologic evaluation for the ataxia and weakness and I would also recommend an MRI of the brain and cervical spine with contrast to rule out demalinating disorder or cervical spine disk or foraminal disease.
>
> I would suggest the use of a sustained release Morphine product rather than immediate release and certainly 30 mg every 8 hours would be a reasonable starting point with titration from there. I believe membrane stabilizing agent like Gabapentin or Lyrica are also reasonable and she indicates failure of these previously but does not know how high a dose she was on and

> Gabapentin often takes a longer time to achieve a steady state. Lyrica generally the dose can be increased every 2-3 days and titrated fairly rapidly. I would also suggest a baseline pain psychology consultation to establish a degree of depression/anxiety currently present and consider whether they are better agents than the Benzodiazepines.

(St. Ex. 4 at 137-138)

205. Dr. DeMio pointed out that Dr. McDowell agreed with the use of morphine for pain, and even suggested that 30 mg every 8 hours would be a reasonable starting point – a higher amount than what he had prescribed for this patient. In response to this evaluation, Dr. DeMio said that he followed the recommendation to use a sustained release morphine product rather than immediate release one that he had prescribed; he kept the dose the same and did not increase it to 30 mg every 8 hours. (Tr. at 1651-1652; St. Ex. 4 at 136-138; 901)

206. Dr. DeMio testified that he did consider treatment modalities other than pain medications. He testified that he recommended the use of aspirin and talked with the patient about following an anti-inflammation diet. He said that he recommended physical therapy, and that Patient 4 did have someone come to her home several times for physical therapy. Dr. DeMio recalled that he also recommended HBOT and aquatic therapy. (Tr. at 1653-1654)

207. Dr. DeMio testified that he also talked to Patient 4 and her family about the use of Vicoprofen, given her history of increased BUN and creatinine levels with ibuprofen use, in the context of all of her treatments. He pointed to a note in her chart from an office visit on February 6, 2013, in which he wrote that she had stopped taking Advil, and that her BUN and creatinine levels had decreased to normal. He submits that this demonstrates that he was speaking with her about her BUN and creatinine levels earlier in her treatment. (Tr. at 1654-1656; St. Ex. 4 at 823)

208. Dr. DeMio also asserted that he had asked Patient 4 about her drug and alcohol history on the initial intake form, in which she was asked, "Drugs/alcohol?" and she responded, "No." He said that he would have asked about this during his initial visit with her and that he would have noted any red flags in her progress notes. (Tr. at 1648-1649; St. Ex. 4 at 1297) Dr. DeMio also pointed to a note early in his treatment of Patient 4, in which he wrote that he discussed the possibility of addiction with her at an office visit on August 23, 2012. (Tr. at 1656-1657; St. Ex. 4 at 788)

209. Finally, Dr. DeMio testified that Patient 4 had clinically significant improvements while he was treating her. He pointed to a note of Patient 4's December 15, 2012 office visit, in which she and her husband reported that the Lyme treatment had decreased her pain, and that she had decreased her use of morphine from 6 tablets per day to 4 per day, and was mobile and active. He also noted that she had a hyperbaric oxygen chamber and was using it. At another visit a couple years later, on November 7, 2014, Patient 4 reported

that it was the first time in three years that she felt as though she had made big improvements. She told Dr. DeMio that she had increased energy and mobility, less diaphoresis and night sweating, and decreased painful tingling sensation in her skin. (Tr. at 1657-1659; St. Ex. 4 at 814, 973)

210. Dr. DeMio also pointed to a progress note from May 21, 2015, in which the patient called him at night and told him she was in pain with abdominal symptoms. He testified that he met her at his office and did an IV treatment using her existing port, as well as a heparin flush to make sure there were no clots in the port. He noted in his record that by 10:29 p.m., she was sitting up and was feeling much better, and that she thanked him emphatically and left the office with much less assistance than she usually needed. Dr. DeMio submits that this also shows she made improvements under his care. (Tr. at 1661-1664; St. Ex. 4 at 1070)

Testimony of Dr. Croake-Uleman about Dr. DeMio's Care of Patient 4

211. In her testimony at the hearing, Dr. Croake-Uleman agreed that Patient 4 had a complicated case, and that the patient had seen more than one pain management specialist. She referred to tests ordered by one such provider in 2010 before Dr. DeMio began seeing her, as well as his referral to Capital City Pain Care in November 2012, where Patient 4 saw Dr. Sarah Blake on November 29, 2012. (Tr. at 288-292; St. Ex. 4 at 104, 128-129, 136) After evaluating Patient 4, Dr. Blake made the following recommendations, including the recommendation that she wean off MS Contin and try physical therapy or a TENS unit for help with her pain:

> PLAN:
> RECOMMENDATIONS: At this time, I have ordered a cervical MRI to assess her for any kind of cervical pathology. I've ordered an EMG nerve conduction study bilaterally to assess her for any kind of Lyme disease-induced neuropathy. I'd like her to detoxify off the MS Contin. It's causing her to have urinary retention and constipation and I think it's exacerbating depression. [Patient 4] and I have discussed a taper where she would drop her dose by one pill per day each week until off. I've made a referral to physical therapy for strengthening and stretching as well as a TENS unit.
>
> She's going to follow up in my office upon completion of the cervical MRI and EMG and we will assess her at that time. I'd like to replace her pain medication with something like a muscle relaxer. I've also talked to [Patient 4] about detoxifying herself off some of the other medications such as Ativan and pursuing things like supplements such as high-dose vitamin C. She seems to understand.

(St. Ex. 4 at 129)

212. Dr. Croake-Uleman testified that despite those recommendations from the pain specialist, at Patient 4's December 15, 2012 office visit, Dr. DeMio noted that the patient declined to have the MRI and EMG that the pain specialist recommended. Further, she noted that instead of weaning Patient 4 off the morphine, Dr. DeMio continuously prescribed morphine and Ativan during the years 2013, 2014, 2015, and part of 2016. During some of that time, he also prescribed Vicoprofen and Dronabinol, a prescription marijuana product containing THC. Dr. Croake-Uleman stated that she was not able to tell what pain Dr. DeMio was treating with those drugs, as it was not documented in the record. In her expert report, Dr. Croake-Uleman wrote that Patient 4 declined to try physical therapy that was recommended by the pain specialist, and that Dr. DeMio did not refer her for an evaluation to see whether injections or surgery might help remediate her degenerative disc disease or her cervical spondylosis with cord compression. (Tr. at 292-294; St. Ex. 4 at 812; St. Ex. 18 at 11)

213. Dr. Croake-Uleman also testified that there was a problem with prescribing morphine, an opiate, at the same time as Ativan, a benzodiazepine. She explained that the patient had seen a neurologist who recommended that she try other medications such as Lexapro and Lyrica. (Tr. at 295) However, she said that that recommendation was also not followed, concluding, "The patient didn't want to do that, and so it was not done." (Tr. at 295)

214. Dr. Croake-Uleman emphasized that Dr. DeMio had referred Patient 4 to the neurologist and the pain management specialists because those areas were outside of his scope of practice; but when those physicians made recommendations for this patient, he did not implement them. (Tr. at 295-296) She reasoned that it made no sense for Dr. DeMio to disregard the opinions of the specialists after he gave a referral for Patient 4 to see them, and she added that the patient should not have been given the choice whether to follow the recommendations or to stay on narcotics for several more years:

> You're asking an expert opinion because it's beyond your scope of care, so it doesn't make a whole lot of sense to go against that when you've gone to a specialist. Doesn't make sense, when it's not in your scope of care, to not follow that specialist's recommendations. * * * I would follow the specialist's recommendation. And patients are going to get mad at you because they want their medications, but you have to do what is in their best interest.

(Tr. at 296)

215. Dr. Croake-Uleman concluded that Dr. DeMio's care of Patient 4 was below the minimal standard of care because he did not follow the Board's rules for the treatment of intractable pain; because he did not order any urine screens while he was prescribing narcotics for her; and because he did not check the patient's OARRS report while he was prescribing for her. She also testified that Dr. DeMio's documentation of this patient's care was incomplete and often illegible. (Tr. at 287, 295-296)

216. On cross-examination, Dr. Croake-Uleman agreed that Dr. DeMio had referred Patient 4 to several other specialists, including Dr. John Block in August 2013 for gastric issues; and to four specialists in pain management: Dr. Bruce Massau; Dr. Salama Sherif, Dr. Gladstone McDowell, and Dr. Sarah Blake. In addition, she agreed that he recommended she see a gynecologist, a dentist, and an eye specialist. (Tr. at 395-399, 401-402; St. Ex. 4 at 124-128, 134)

217. Dr. Croake-Uleman also agreed that Dr. Blake's assessment found that Patient 4 had peripheral neuropathy, cervical degenerative disc disease and cervical spondylosis with outward compression, diagnoses which could each be a basis for a diagnosis of intractable pain. However, Dr. Croake-Uleman reiterated that Dr. Blake wanted Patient 4 to come off the MS Contin, because she believed it was causing her to have urinary retention and constipation, and was exacerbating her depression, and suggested that she do a trial of muscle relaxers. When she was asked if Dr. DeMio could have found that the benefits of the MS Contin outweighed the risks, Dr. Croake-Uleman said that she would have called the specialist to discuss those recommendations. Although she did not know if Dr. DeMio had ever called Dr. Blake, she said that it was not documented in the chart that he did. (Tr. at 399-401; St. Ex. 4 at 128)

218. Also on cross-examination, Dr. Croake-Uleman agreed that Patient 4 had already been taking lorazepam and clonazepam – both benzodiazepines – as well as morphine, an opiate, when he began seeing her in May 2012. She further agreed that Dr. McDowell's report dated August 6, 2012 said that he had checked Patient 4's OARRS report and found no issues, as all of her scripts were being filled at Kroger and there seemed to be no issues with multiple prescribers. Dr. Croake-Uleman maintained, however, that she would still want to see the OARRS report, if she were prescribing for this patient. (Tr. at 402-405; St. Ex. 4 at 136-138)

219. Dr. Croake-Uleman agreed on cross-examination that Dr. DeMio did an initial exam of Patient 4, but she criticized him for not recording any vital signs and not ordering any imaging or sending her to an orthopedist for a consultation about the cause of her pain. She pointed out that in Dr. McDowell's report, he wrote that she would benefit from a full neurological evaluation for ataxia and weakness and recommended an MRI of her brain and cervical spine to rule out demyelinating disease, but she never saw that done in the chart. (Tr. at 405-407; St. Ex. 4 at 137)

Testimony of Dr. Goldfarb about Dr. DeMio's Care of Patient 4

220. Dr. Goldfarb did not provide detailed testimony about Dr. DeMio's care of Patient 4, instead agreeing that there was a "lot of overlap" in his opinions about the care of this patient as well as the other adult patients. (Tr. at 1013-1014) He testified that for this adult patient, he believed Dr. DeMio met the minimal standard of care, and he noted that Patient 4's chart showed that she had meaningful improvement while under Dr. DeMio's care. (Tr. at 1013-1014)

221. On cross-examination, Dr. Goldfarb agreed that Patient 4 received prescriptions for morphine and Ativan from Dr. DeMio. He emphasized that Dr. DeMio did refer Patient 4 for consultations with pain management specialists, but he said that she was unwilling to follow their recommendations because she felt as though they were condescending to her, and did not take her concerns seriously. For that reason, Dr. DeMio continued to prescribe for her. (Tr. at 1052-1053; Resp. Ex. C at 16)

222. Dr. Goldfarb agreed on cross-examination that Dr. DeMio did not conduct any urine screens and did not check Patient 4's OARRS report while he was prescribing narcotics for her. Finally, he agreed that Dr. DeMio was treating all five of his adult patients for intractable pain, and that even if Dr. DeMio was not a pain specialist, he still had a duty to meet the minimum standard of care for prescribing pain medications for these patients. (Tr. at 1054)

Patient 5 (A.T.K.)

223. Patient 5 is a female born in 1979. She was 33 years old when she first consulted Dr. DeMio on or about December 5, 2012, writing on her intake form that she found Dr. DeMio through a "Lyme forum," called M.D. Junction. She continued seeing him for 3½ years, until July 15, 2016. Like the other patients, at the time of Patient 5's first appointment, she signed disclaimers stating that she understood that she would not receive reimbursement for any consultation or treatment with Dr. DeMio, and that she understood that he was a "fee for service" provider who was not an in-network provider with any insurance company. Patient 5 paid $742.00 for her initial consultation with Dr. DeMio on January 4, 2013. (St. Ex. 5 at 7-12; Tr. at 297)

224. Dr. DeMio recalled that Patient 5 had a positive Western blot test for Lyme disease in May 2012 from the Igenix lab. He testified that she had been treated for Lyme, but then began getting sicker in the five months before she consulted him. Dr. DeMio related that Patient 5 had fibromyalgia, and that she was starting to fall and pass out, causing her to become disabled. (Tr. at 1664-1665; St. Ex. 5 at 677)

225. Over the course of his treatment of Patient 5, Dr. DeMio prescribed numerous antibiotics to be administered by PICC line; as well as antiparasitics including Malarone, mebendazole, and hydroxychloroquine; Vitamin B-12 injections and nebulized glutathione; an antidepressant; and ultra-low dose Naltrexone ("ULDN"). (St. Ex. 5 at 73 -184)

226. Beginning in late 2013, Dr. DeMio prescribed narcotics to Patient 5, beginning with Vicoprofen, and then adding 75 microgram Duragesic (fentanyl) patches that he continuously authorized from October 2013 through June 2016. Over that span of time, Dr. DeMio also prescribed Valium and sometimes hydrocodone or Vicoprofen, as well. (Tr. at 230-231; St. Ex. 5 at 73-184)

227. On cross-examination, Dr. DeMio agreed that he provided fentanyl patches for Patient 5 on a long-term basis, and he agreed that it was probably correct that he prescribed both fentanyl and Vicoprofen for her every month in 2015 and much of 2016. (Tr. at 230-231) When he was asked what he was treating with those prescriptions, Dr. DeMio offered, "She has painful spasms of the muscles, she has muscle pains." (Tr. at 231) He agreed that he did not follow the Board's rules for the treatment of intractable pain in his treatment of Patient 5, and when he was asked if he ever checked this patient's OARRS report anytime between 2013 and 2016, Dr. DeMio stated, "I don't think I did." (Tr. at 232)

228. Dr. DeMio testified that he considered modalities other than controlled substances to treat Patient 5's pain, including antibiotics and herbal supplements to treat Lyme disease. He said that he also recommended HBOT, but he believed the cost of hyperbaric oxygen was too much for her. In addition, Dr. DeMio testified that he prescribed hydrocortisone for Patient 5, explaining that it was a bio-identical adrenal hormone that acts as an anti-inflammatory agent and helps relieve pain. Referring to a test in the patient's chart, he said that he had done a test for this hormone and was waiting on the lab to come back, while he planned how to treat it. (Tr. at 1666-1667; St. Ex. 5 at 463) Dr. DeMio said that the hydrocortisone was to replenish the patient's hormone levels, explaining, "When that hormone is low you can get very sick, have low energy, your blood pressure can get low, you can pass out, you can have a lot of the symptoms that she had." (Tr. at 1667)

229. Dr. DeMio stated that he was criticized by the State's expert for not discussing the sedation effects of some of the medications he prescribed, but he asserted that he had done this, pointing to a list of her medications and supplements that he maintained he discussed with her at her office visit on May 3, 2013. He said that he would have addressed the possibility of sedation when he saw her at that appointment. Dr. DeMio also referred to another entry in the patient's chart, showing "PTD/W," which he testified indicates that he discussed opiate and non-opiate treatments with Patient 5 at her office visit on July 26, 2013, as part of his informed consent process. (Tr. at 1667-1668; St. Ex. 5 at 384-385, 399)

230. Dr. DeMio presented a letter written by Patient 5 in which she wrote that she had "Lyme disease as well as Addison's Disease, Grave's Disease, Bartonella, Babesiosis, chronic urinary tract infections, and chronic migraines, to name a few." (Resp. Ex. J-1 at 5) She recounted that for years she knew she was more tired and sickly than other people her age, but that no one could explain what her diagnosis was, other than possibly fibromyalgia and chronic fatigue. The patient wrote that in December 2012, she passed out while driving and subsequently had to take medical leave from work. Patient 5 was then diagnosed with Lyme disease by a family doctor, and she sought treatment with Dr. DeMio. She wrote that her Lyme disease had previously gone undiagnosed, partly because she never had the "bullseye rash," which she wrote that many patients never get. She added, "It has been a nightmare, all from a tick bite that I don't even remember." (Resp. Ex. J-1 at 5) Patient 5 wrote that Dr. DeMio eventually referred her to a pain management specialist, but with respect to Dr. DeMio, she wrote, "He wouldn't over

prescribe medications of any type, or put anyone at unnecessary risk." (Resp. Ex. J-1 at 5)

Testimony of Dr. Croake-Uleman about Dr. DeMio's Care of Patient 5

231. At the hearing, Dr. Croake-Uleman testified that for most of 2015 and 2016, Dr. DeMio was prescribing fentanyl patches as well as Vicoprofen and Valium at the same time for Patient 5. She said that she would expect to see the patient's history and vital signs in the chart, as well as a treatment plan and a consideration of the risks versus benefits of those medications, but she did not see that in the patient's record. In addition, Dr. Croake-Uleman testified that, from her review of the chart, she could not tell why those medications were being prescribed for Patient 5. She added that she did not find in the chart any notes about whether the patient was improving on those medications, any side effects she might have had, or a physical assessment that would look for any signs of addiction or abuse. (Tr. at 298-300)

232. On cross-examination, Dr. Croake-Uleman agreed that there were some indications in the chart that Patient 5 had decreased joint pain and fewer headaches, and the patient reported that the Vicodin and fentanyl helped with her pain. However, she said that other notes in the chart said this patient also had weakness and daytime somnolence, and that she had taken some falls, so there were mixed reports of her results. Dr. Croake-Uleman said that those aspects would cause concern about the narcotics that she was being prescribed. (Tr. at 408-409)

233. In her expert report, Dr. Croake-Uleman wrote that Dr. DeMio went for long periods of time without seeing Patient 5, including a span of eight months from January 2, 2014 to August 1, 2014; a span of over a year from August 1, 2014 to September 17, 2015; and a span of almost another year from September 17, 2015 to July 15, 2016, and that during those extended periods, he continued prescribing opioids for her. She emphasized that because he was not seeing her for office visits, he could not have done a physical evaluation, taken her vital signs, or assessed her pain and functioning. In addition, Dr. Croake-Uleman wrote in her report that the patient's complaints of dizziness, foggy thinking, falling, and daytime somnolence could have been caused by the many medications that Dr. DeMio was prescribing for her. (St. Ex. 18 at 13-14)

234. Dr. Croake-Uleman agreed on cross-examination that Dr. DeMio ran a lot of labs for Patient 5, but she noted that this patient had a history of elevated BUN and creatinine levels in December 2013 and March 2014, as well as a slightly elevated result in May 2016. (Tr. at 409-411; St. Ex. 5 at 191-362)

235. Dr. Croake-Uleman testified that she found multiple deficiencies in Dr. DeMio's care of Patient 5, leading her to the conclusion that he did not meet the minimum standard of care in his treatment of this patient:

> The Board's intractable pain rules were not followed. Opioids were prescribed in addition to Benzodiazepines for extended periods of time without assessing the patient.
>
> There were limited exams. No vital signs. * * * [H]e continued to prescribe narcotics with a lack of medication review despite the concerning symptoms of the patient and repetitive falls.
> There was no urine drug screen done, no OARRS report pulled, and then the documentation was again incomplete and difficult to read.

(Tr. at 297)

Testimony of Dr. Goldfarb about Dr. DeMio's Care of Patient 5

236. Dr. Goldfarb did not provide detailed testimony about Dr. DeMio's care of Patient 5. He explained that there was a "lot of overlap" in his opinions about the care of this patient as well as the other adult patients. (Tr. at 1013-1014) He testified that for this adult patient, he believed Dr. DeMio met the minimal standard of care, and he said he believed that Patient 5's chart showed that she had meaningful improvement while under Dr. DeMio's care. (Tr. at 1013-1014)

237. On cross-examination, Dr. Goldfarb agreed that there were several long periods of time when Dr. DeMio did not see Patient 5 at all, but continued to prescribe fentanyl patches as well as Vicodin and Valium for her, including a span of eight months from January to August 2014; a span of 13 months from August 2014 to September 2015; and a span of 11 months from September 2015 to July 2016. However, he testified that during those times, Patient 5 was having regular visits by her home healthcare staff. (Tr. at 1055-1056, 1059-1060)

238. While Dr. Goldfarb did not contend on cross-examination that a home healthcare provider could take the place of a physician, he offered, "What I'm saying is that the nurses who were seeing this patient were doing vitals and a form of assessment that was communicated to Dr. DeMio, that's what I'm saying." (Tr. at 1056) When he was asked to show an example of the assessment communicated to Dr. DeMio by home healthcare, Dr. Goldfarb referred to the 60-day summary report from December 2015. He conceded that several values, such as blood pressure, were expressed only as ranges over the 60-day period, and there was only one respiration reading recorded, but Dr. Goldfarb nonetheless maintained that this showed the home healthcare staff was checking Patient 5's vital signs. (Tr. at 1056-1060; St. Ex. 5 at 237) And although her blood pressure range varied widely from 98/60 to 130/78, he testified, "That's a wide range, but within normal – it's normal." (Tr. at 1060)

Dr. DeMio's Care of Pediatric Patients 6 through 16

239. Many of the pediatric patients that are relevant to this case had diagnoses that included an autism spectrum disorder. (Tr. at 50) Some of the issues and treatments that were common among most or all of the pediatric cases are discussed below, including Dr. DeMio's explanations, as well as the testimony about those topics by Dr. Jackson, the State's expert in pediatrics, and Dr. Goldfarb, the Respondent's expert. A discussion of the individual patient cases follows.

Off-Label Prescribing

240. Dr. DeMio testified that prescribing medications is "a big part" of what he does in his practice, and that he sometimes prescribes medications "off label," i.e., using the medication to treat a different condition than it has FDA approval for. (Tr. at 1164-1165) He offered several examples, such as prescribing Pepcid, an ulcer medication, for anaphylaxis because it is also an antihistamine. Similarly, he said that, until recently, aspirin was routinely used off-label to prevent and treat heart attacks, because it was known to be a blood thinner. Dr. DeMio asserted that when off-label prescribing is used judiciously, looking at the risks and benefits of that medication, it is within the standard of care. (Tr. at 1164-1170)

241. Dr. DeMio said that off-label prescribing is prevalent in pediatrics because many medications are studied only on adult populations. However, he agreed that additional caution is needed when prescribing off-label for a pediatric patient, because the difference in how children metabolize medications requires adjusting the dosages. (Tr. at 1167-1170) Dr. DeMio related that the American Academy of Pediatrics views off-label prescribing as "just a part of bread and butter practice every day for the needs of the kids." (Tr. at 1170-1171) As an example specific to the pediatric population, he offered that amoxicillin is routinely used off-label to treat strep throat in nearly every pediatric practice because it effectively kills the strep infection, and kids find it more palatable than penicillin. (Tr. at 1170-1171)

Dr. DeMio's Use of Vaccines; Belief that Vaccines Can Contribute to Autism

242. Dr. DeMio testified that he makes frequent use of vaccines in his medical practice and offered that he had a "refrigerator full of them" at the time of the hearing. (Tr. at 1173-1174) As examples, he said that he uses the hepatitis vaccines, and was trying to get the COVID vaccine, and he added, "We have done the MMR vaccine." (Tr. at 1174) However, Dr. DeMio testified that "some of them have things that we are really against in them," and he stated that some vaccines still have mercury in them. (Tr. at 1174-1175) He related that when he ordered flu vaccines recently, he specifically requested a formulation that did not have mercury in it, but some of the vaccines that were sent nonetheless contained mercury, and he lamented, "I'm going to have to eat those because I'm not giving those to our patients." (Tr. at 1175)

243. Dr. DeMio believes that childhood vaccines can sometimes cause autism, as he explained in the following exchange on cross-examination by the Assistant Attorney General:

> Q. [By Mr. Wilcox:] Do you believe there's a link between childhood vaccines and Autism Spectrum Disorders?
> A. I think sometimes.
> Q. So you believe there are cases of autism that are the result of -- or Autism Spectrum Disorders that are the result of child vaccinations?
> A. I do, sometimes.
> Q. And that's based on a theory that mercury is present in the vaccine; is that correct?
> A. No.
> * * * [technical difficulty interrupted testimony]
> Q. Okay. How does the vaccine cause autism, if you could explain that to us?
> A. It seems that the multitude -- it's just an association with the vaccines that are done on some kids that lead to -- them to have a medical decompensation, part of whose result is that whole set of things that you just read off that I've said on my website; immune system, brain, gastrointestinal, metabolic. Those occur in association for some kids with -- from vaccinations, and that manifests clinically for some of them with autism.

(Tr. at 50-51)

244. Dr. DeMio vehemently disagreed with a suggestion by the Assistant Attorney General that vaccines no longer contain mercury, responding, "[G]osh no, it's still there." (Tr. at 51-52) He explained that mercury still sometimes shows up as an ingredient in various vaccines:

> Q. [By Mr. Wilcox] So you do not believe that metals like mercury in the vaccine, or that were once used as a preservative in the vaccine, is responsible, is that what you're telling us?
> A. [By Dr. DeMio] I'm hearing a couple things in there. Are you asking me if they were used before and they are not used now, or -- that seems to be part of your question.
> Q. Yeah. So you would agree that mercury is no longer part of the vaccines that are used for child immunology as of –
> A. No, gosh no, it's still there.
> Q. It's still there.
> A. Yes, sir.
> Q. So in 2001, mercury containing preservatives was not stopped as a preservative in these vaccines?

> A. It's a moving target. It has been shifted from some vaccines where they don't have it, and then a couple years later it will show up in that same brand and type of vaccine again.
> And there are several vaccines out there, and different companies may make more than one version of the -- of a given vaccine, and so there's still mercury in the vaccine schedule. All those vaccines you give your kid by the time they are 19, there's still mercury in that schedule.
> Q. And you believe that could be a contributing factor to autism in some children?
> A. I think the vaccines, the way that they are, have an association with autism spectrum etiology, to try to answer the best I can.
> Q. So that I read that as you say there's a link between the mercury and vaccines and a child developing Autism Spectrum Disorder, or symptoms thereof?
> A. I'm using the word association, I don't know if that's what you mean by link.
> Q. Okay. They are probably the same thing, I'm guessing.
> A. I'm happy to answer as best I can if you'd like to talk more about that.

(Tr. at 51-53)

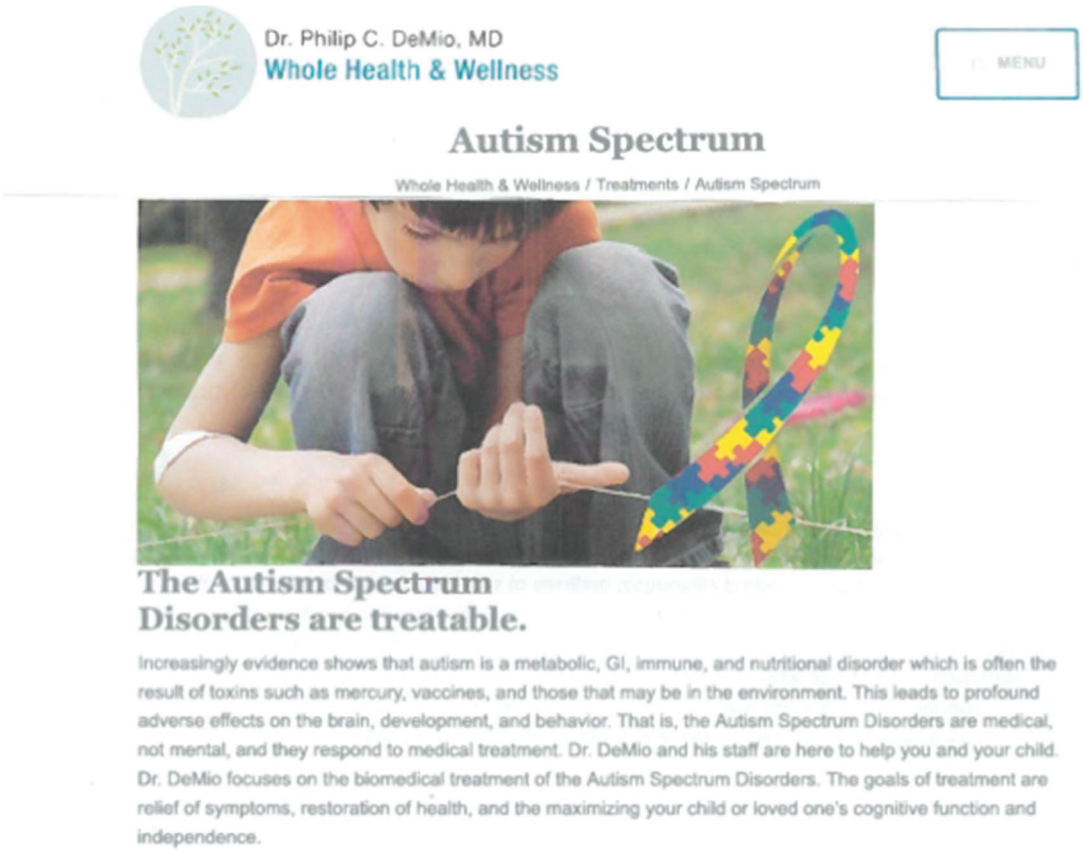
However, Dr. DeMio agreed with a suggestion by the Assistant Attorney General that several studies have disproven the possibility of a link between childhood vaccines and autism:

> Q. [By Mr. Wilcox:] And would you agree with me there have been several studies that say that there is no such link between vaccinations and autism?
> A. I would agree that there are several studies that have concluded pretty much that, just the way you said it, yes.

(Tr. at 52-53)

245. At the hearing, when the Assistant Attorney General read the following statement from Dr. DeMio's website, concerning the link between autism and toxins, including those found in vaccines, he agreed that this statement appears on his website.[2] (Tr. at 49; St. Ex. 28)

[2] The hearing examiner has omitted some of the spacing, but no content, to make the image more compact.


Dr. Philip C. DeMio, MD
Whole Health & Wellness

MENU

Autism Spectrum

Whole Health & Wellness / Treatments / Autism Spectrum

The Autism Spectrum Disorders are treatable.

Increasingly evidence shows that autism is a metabolic, GI, immune, and nutritional disorder which is often the result of toxins such as mercury, vaccines, and those that may be in the environment. This leads to profound adverse effects on the brain, development, and behavior. That is, the Autism Spectrum Disorders are medical, not mental, and they respond to medical treatment. Dr. DeMio and his staff are here to help you and your child. Dr. DeMio focuses on the biomedical treatment of the Autism Spectrum Disorders. The goals of treatment are relief of symptoms, restoration of health, and the maximizing your child or loved one's cognitive function and independence.

(St. Ex. 28)

246. The State's expert, Dr. Jackson, testified that he was aware of conjecture that the MMR vaccine causes autism, particularly in association with thimerosal, a mercury-based preservative that is sometimes used in multi-dose vials of vaccines. However, he said that the studies in the United States and in Europe have all concluded that there is no association between the MMR vaccine and autism in children. (Tr. at 452) He clarified later in his testimony that Thimerosal is very rarely used because most vaccines are now packaged as single-doses, without the need to preserve remaining doses in a larger vial:

> I did mention earlier about Thimerosal that was used as a preservative in vaccines. [T]hat is very minimally used these days, as most vaccines are single dose vials that preservatives aren't needed, but there's no tie in causality with that in any other disease, much less autism.

(Tr. at 543)

247. Additionally, Dr. Jackson testified that there is no scientific basis that a child's diet is associated with autism, and that there is only anecdotal evidence of diet changes helping in the management of autism symptoms:

> When you have an individual who has an issue with social dysfunction or even sensory integration dysfunction, they have certain dietary habits that may be different. But there is no established data to suggest that autistic children have a different, I should say, probably gastrointestinal and/or any immunologic deficiency than the general population. And there's no studies to affirm that or to confirm that.
>
> Therefore, saying management of those areas can help in the management of autism, if it is, it's anecdotal, but nothing that is evidence based and sound to bring out to the general public for use.

(Tr. at 453-454)

Pediatric Patient 6 (AL)

248. Patient 6 is a male born in June 1999. He was 15 years old when he began seeing Dr. DeMio in February 2015. He had also been treated for rheumatoid arthritis at Children's Hospital in Columbus. On the intake form, his parent wrote that they found Dr. DeMio through an internet search and a referral from a chiropractor. The parents signed a statement acknowledging that Dr. DeMio's services would not be covered by any insurance or Medicare/Medicaid, and for the initial visit on February 25, 2015, the family paid $934.80. (Tr. at 1296-1298; St. Ex. 6 at 1-7)

249. Dr. DeMio testified that he diagnosed Patient 6 with Lyme disease as his primary diagnosis and subsequently treated him for it. He agreed on cross-examination that the patient had had a Western blot IgM antibody test that was negative for Lyme disease on May 6, 2013, and that he had different test to check for the C6 peptide antibody in his blood on February 26, 2015, a few days after he began seeing Dr. DeMio. The C6 peptide test was also negative. (Tr. at 82-87, 1292-1293; St. Ex. 6 at 114, 123-124, 206-209) However, Dr. DeMio explained that he found the result to be on the borderline, explaining, "[T]he result is 0.9, and then they go on to say that if it's 0.9 or less they call that negative." (Tr. at 85) He later added, "[I]t doesn't rule out lyme per the fact that it's not higher than that number." (Tr. at 1299-1300)

250. Dr. DeMio pointed out that Patient 6 also had a positive IgG test for the Lyme antibody on January 29, 2015 just before his first office visit. (Tr. at 1295-1296; St. Ex. 6 at 209) He explained that an IgM test for Lyme can show a recent infection, while the IgG test shows a long-term response to an antibody that was made after a previous Lyme infection in the body that the immune system still recognizes. (Tr. at 1292-1295) Dr. DeMio explained that the IgM test can show a negative result over time after an infection, but that the IgG test will remain positive in a patient who has had Lyme disease, indicating a chronic condition:

> [W]hen you only see IgG, it usually means that the immune system has been recognizing that germ and it has been a long time. So in this case, for example, it means it's chronic, that he's chronically infected with lyme.

(Tr. at 1295)

Dr. DeMio said that there were various tests for Lyme disease, including the enzyme-linked immunosorbent assay, ("ELISA") the Western blot and the recently-developed "immunoblot," the IgM, the IgG, and the C6 peptide test. He said that the ELISA test was generally thought of as a screening test; if it picks up anything, one of the other tests was needed to confirm the result. (Tr. at 1310-1314) Dr. DeMio testified, "[T]he screening test for lyme and for some other diseases, but lyme more than any other disease I know, can miss the lyme, it doesn't always pick it up." (Tr. at 1312-1313)

251. Dr. DeMio agreed that he treated Patient 6 with antibiotics and other medications for Lyme disease based on the IgG test result, even though the IgM test and the C6 peptide test for it were negative. He prescribed Bactrim, as well as allithiamine, a transdermal medication that is a form of Vitamin B-1, also known as thiamine. (Tr. at 86-87; St. Ex. 6 at 49, 55) Although Dr. DeMio said that thiamine has chelating properties, he explained that he was using it in this case for its anti-inflammatory properties:

> [R]eally it's a form of the vitamin thiamine, it's anti-inflammatory. It does have some detoxifying properties, but it has a very good ability to get into the cell and deliver thiamine there. * * * [p. 88] So this releases thiamine deep inside the cells where the cells need it the most when you're in a condition like this young man.

(Tr. at 87-88)

252. Dr. DeMio agreed on cross-examination that he prescribed multiple anti-infection medications for Patient 6, maintaining that they were needed because this patient had multiple infections. (Tr. at 86) In addition to various antibiotics, Dr. DeMio prescribed hydroxychloroquine as an anti-inflammatory medication to help with the patient's arthritis and to treat the Lyme disease:

> It's anti-inflammatory for people with arthritis, and it helps with that. It's also anti-lyme, and it has the ability to also be a germ killer for other germs; some of them, not all of them. And then it's also an alkalinizer. We hear about these properties that some medications have. It's an alkalinizer, so he was appropriate for all those kinds of drugs. It does help lyme. It helps lyme and arthritis, if I were to pick my top two reasons in his case we were using it.

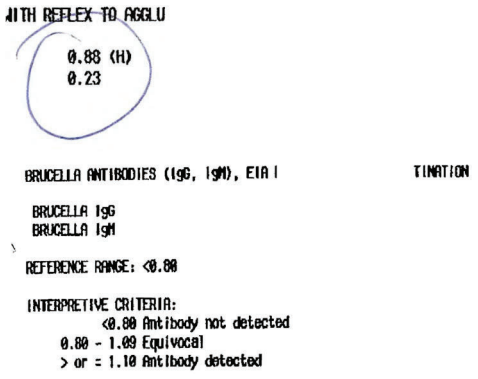
(Tr. at 89; St. Ex. 6 at 58-59, 67)

In addition, Dr. DeMio recalled, "We used and herbals and immune stabilizers, vitamin mineral support, anti-inflammatory drugs, and anti-inflammatory herbals, among the things that we did." (Tr. at 86)

253. Dr. DeMio was criticized by the State's expert for the fact that the patient's lab work showed a negative test for B. burgdorferi, which Dr. Jackson testified meant that the patient did not have Lyme disease, but Dr. DeMio testified, "The test itself does not stand alone." (Tr. at 1298-1299; St. Ex. 6 at 121) Dr. DeMio explained that B. burgdorferi is "about the most adaptable germ that there is out there," and that its many different strains can lie dormant for a while, during which time it can develop protections against the immune system and against antibiotics, infecting every organ and system of the body. (Tr. at 1301-1302)

254. Dr. DeMio testified that Patient 6 needed multiple antibiotics to treat his various infections, including Lyme disease and Brucella, an infection resulting from a staph germ, which he believed also emanated from the Lyme infection. He explained, "[W]hen you get a tick bite, you might not get lyme, but you could get a staph infection, you can get Brucella, too. In one way or another he became vulnerable to it, he got exposed to it and he's got the infection. (Tr. at 1320-1321; St. Ex. 6 at 117)

255. Patient 6's Brucella test from March 2015 shows a result of 0.88, which is in the "equivocal" range, but was flagged as high, though still below the 1.10 level that would indicate the antibody:


ITH REFLEX TO AGGLU

0.88 (H)
0.23

BRUCELLA ANTIBODIES (IgG, IgM), EIA I TINATION

BRUCELLA IgG
BRUCELLA IgM

REFERENCE RANGE: <0.80

INTERPRETIVE CRITERIA:
<0.80 Antibody not detected
0.80 - 1.09 Equivocal
> or = 1.10 Antibody detected

(St. Ex. 6 at 117)

Dr. DeMio testified "I think this means he has the infection. It's very unusual to see IgG and IgM together, unless that germ is really still there. * * * It means his immune system has not gotten rid of this germ * * *" (Tr. at 1320) He explained that Brucella is a very slow-growing bacteria, so prolonged antibiotic treatment is needed, usually with doxycycline. (Tr. at 1321-1322) Dr. DeMio added:

> We're seeing multiple infections here, so there's a – there's a greater chance of success when you use multiple antibiotics when you aim at multiple germs that have different antibiotics that kill them.

(Tr. at 1319)

256. Patient 6 was also being treated by Dr. Charles Spencer, a rheumatologist, at Nationwide Children's Hospital in Columbus. Dr. Spencer's notes indicate that he believed based on the results of imaging tests that Patient 6 had spondyloarthropathy, but the family believed, based on Dr. DeMio's diagnosis, that he had chronic Lyme disease. (St. Ex. 6 at 209-218) The notes of the patient's visit with Dr. Spencer on February 26, 2015 include Dr. Spencer's summary showing frustration with the Lyme disease diagnosis:

> He has been evaluated by Dr. DeMio in Worthington and diagnosed to have possible chronic Lyme – he is starting amoxacillin [*sic*] and azithromycin plus other antibiotics. The folks are open to the Lyme approach and diagnosis – maybe antibiotics will eliminate it all – better than chronic arthritis, right?!.

(St. Ex. 6 at 217)

257. Dr. DeMio agreed on cross-examination that Dr. Spencer did not believe Patient 6 had Lyme disease, and was not willing to treat him for arthritis as long as he was continuing the treatment for chronic Lyme disease. He admitted, however, that he had never spoken with Dr. Spencer, but was relying on the information that Patient 6's mother had relayed to him. Although Dr. DeMio agreed that Dr. Spencer had training in rheumatology that he did not have, Dr. DeMio disagreed with Dr. Spencer's opinion and maintained that Patient 6 had Lyme disease. (Tr. at 79-83, 90; St. Ex. 6 at 135-137)

258. Dr. DeMio believes that his treatment of Patient 6 for Lyme disease was beginning to show results by the time of his office visit on April 23, 2015. During that visit, his mother reported that they were "seeing their old son back," and that he had markedly reduced tremors and seizures, and that he had started laughing again, and that he had more energy, no longer needing naps in the afternoon. (Tr. at 82-83, 1327-1328; St. Ex. 6 at 141) At the hearing, he offered into evidence a letter from Patient 6's parents, stating that he was fully functioning and was doing well in academics and in sports after his treatment with Dr. DeMio. Dr. DeMio stated that he was still seeing Patient 6 at the time of the hearing. (Tr. at 1340-1341; Resp. Ex. J-1 at 3-4)

259. Over the course of treating Patient 6, Dr. DeMio also treated him for a thyroid deficiency after some lab work done on July 30, 2015. (Tr. at 1330-1332; St. Ex. 6 at 92-93, 98) The lab report showed in part, the following results:

T3, FREE	3.2		2.3-4.2	PG/ML

Test performed at Clinical Pathology Laboratories, Inc.
9200 Wall St. Austin, TX 78754
CLIA Number 45D0505003 CAP Accreditation Number 21525-01

T3, REVERSE	11.8			ng/dL

Reference Interval for ages 0-17 years not established.
INTERPRETIVE INFORMATION: Triiodothyronine, Reverse - LC-MS/MS

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/cs

Test performed at ARUP Laboratories
500 Chipeta Way, Salt Lake City, UT 84108
CLIA Number 46D0523979

TOTAL T3	82	(L)	84-172	ng/dl
FREE T4	0.83		0.80-1.80	ng/dl
THYROID ANTIBODIES				
ANTI-TPO ANTIBODY	1		<9	IU/ML

(St. Ex. 6 at 92)

260. Dr. DeMio testified that Patient 6's T3 and T4 levels were low for a teenager: "The T3 is frankly low, and the T4 is near the bottom. The reverse T3 tells you it's not because it's being turned over too fast, and he needs thyroid hormone is what that basically means." (Tr. at 1331) At the next visit on August 21, 2015, Dr. DeMio prescribed thyroid medication for Patient 6. (Tr. at 1332; St. Ex. 6 at 51)

261. In addition, Dr. DeMio testified that Patient 6 had a lot of GI and immune system issues, which can be the result of deficiencies in nutritious metals such as copper and zinc, or from toxicities such as lead, cadmium, mercury, and gadolinium. After testing him for toxic and nutritious metals in his blood and urine, Dr. DeMio concluded that Patient 6 was deficient in several nutritious metals such as chromium, and that he also had certain heavy metal toxicities. (Tr. at 1332-1334; St. Ex. 6 at 100-101, 159) He explained, "[T]he blood and the urine show that he's very likely toxic from these toxic metals, and so he needs treatment for those things, and that makes it more likely that he will get better." (Tr. at 1334)

262. Dr. DeMio began prescribing glutathione cream as a natural chelating agent and a low-risk medication that helps detoxify and balance the body, and also prescribed supplements to give the patient nutritional support. (Tr. at 1333-1336; St. Ex. 6 at 49) Dr. DeMio described the benefits of glutathione for Patient 6:

> That medication is something that helps metals move around, and it's got sulfur, a lot of sulfur in it, and metals get moved around with several things, but the biggest train that moves the metals and takes it from here to there, whether it's a good metal you want to bring in to help you absorb

> your nutritional metals better, and to get rid of the toxic metals and move them out of your tissues and out of your body, is something with sulfur usually.
>
> This is a natural substance that's present in small amounts in nature and in our diets sometimes, and so it's a mega dose to apply that substance to the body so the bad stuff moves out and the good stuff moves in. And on the back end it turns into the vitamin thiamine when it's inside your tissues, so it gives support to the tissues like white blood cells for your immune system, nerves and brain tissue, GI tract, so -- the liver. So it has a lot of benefits. * * * I used it to help his body use its own machinery to work better, so we could have a natural way to treat this, and to nourish him on the back end.

(Tr. at 1335-1336)

Testimony of Dr. Jackson about Dr. DeMio's Care of Patient 6

263. Dr. Jackson testified that Patient 6 was a 16-year old boy who had a previous diagnosis of rheumatoid arthritis from Nationwide Children's Hospital in 2013. When Patient 6 first saw Dr. DeMio in February 2015, Dr. DeMio diagnosed him with Lyme disease, as well as a nutritional deficiency and an immune deficiency. Dr. Jackson stated that he could not find evidence in the patient's chart to support those diagnoses. (Tr. at 468-469; St. Ex. 6 at 7)

264. With respect to Lyme disease, Dr. Jackson testified that he could not discern how Dr. DeMio reached that diagnosis. He began by explaining that if a parent told him there was a prior diagnosis of Lyme disease, he would want to know which doctor made the diagnosis so that he could get their prior records, in order to make sure it was appropriately diagnosed and to find out what treatment the patient had had for it. Dr. Jackson said that it is not true that a patient who has Lyme disease will always have it. (Tr. at 471-473, 476) In fact, he said that if the patient is adequately treated for it in the acute phase of the disease, "your symptoms should resolve and the only thing you may have is a marker of its past, but not anything present." (Tr. at 478)

265. Dr. Jackson pointed out that the patient's chart shows a May 2013 Western blot test for Lyme disease from Nationwide Children's Hospital. That test showed a negative result for the IgM antibody, which he said would indicate an acute infection if positive. Although it showed a positive result for the IgG antibody, Dr. Jackson explained that this is indicative of a past infection, as that antibody will remain after the acute infection has resolved. The same results occurred when the patient was tested almost two years later at Nationwide Children's Hospital, in early February 2015. (Tr. at 475-476, 489-492; St. Ex. 6 at 206, 215) Dr. Jackson reasoned that these test results did not show a current Lyme infection, but only the antibodies from a past infection:

> In this case here, if you go down on that same page, the IgM Western blot test is negative. What that suggests to me, back in 2013 this patient was probably treated adequately, that the acute antibody was negative, but the long lasting IgG was present. * * * [I]f we recheck those tests in 2015, I bet you you're still going to see possibly an IgG.
>
> But if the IgM is negative, which means there's no recurrence of the infection, and are the symptoms of swelling, inflammation, you know, what we may see, is from some other source, and maybe not the lyme disease. So there is not -- there's not any information to suggest that this is going to be a lingering entity

(Tr. at 478-479)

266. Dr. Jackson noted that the labs that Dr. DeMio ordered for Patient 6 did not include any tests for Lyme disease, but that he still prescribed 1500 mg. of amoxicillin as well as 500 mg. of Zithromax on February 25, 2015, with each prescription authorizing two refills. (Tr. at 473-474, 479-480, 495; St. Ex. 6 at 68-69, 121) He characterized this as an "astounding" dose. (Tr. at 474) Dr. Jackson offered:

> It looks like 60 days of -- is that 1,500 maybe milligrams of Amoxicillin, which is an extremely high dose. And two months of treatment is far beyond the standard that we have in the Red Book or CDC, even if you use Hippocrates, which is a dosing regimen guide for medications. But first of all, the length of treatment is, I use the word astounding, and then the dosing, I'm not clear on as to whether or not that's an appropriate level or not.

(Tr. at 474)

267. Dr. Jackson testified that he could not see any reason for Dr. DeMio to prescribe the amoxicillin and Zithromax, as he noted that there was a negative strep test, and no test showing an active infection of Lyme or any other acute disease. Although he noted that there was a lab test for mycoplasma, a bacterial respiratory infection, the results again showed a positive result for only the IgG antibody, evidencing a past infection. Dr. Jackson said that a person who had had a mycoplasma infection in the past would continue to have antibodies to it, just as someone who had had chickenpox or tuberculosis in the past would have lasting antibodies. He said that mycoplasma is so common that much of the population would test positive for having had this type of infection in the past, and that no treatment was needed for it in this patient's case, as it did not indicate an acute infection. (Tr. at 483-485, 488, 495-495; St. Ex. 6 at 104-105, 107-108)

268. Dr. Jackson explained that the high doses of antibiotics prescribed here were not harmless:

> [T]here are risks that can come with this type of treatment, which is in a bacterial resistance or allergic reactions, severe or otherwise. * * * [W]hen you get a type of reaction, antibody reaction, when it's not indicated, you might risk not being able to use this medication again, particularly when it's not indicated. * * * And so you can be -- you can do more harm than good by treating when it's not medically indicated.

(Tr. at 497-498)

269. Dr. Jackson also opined that a positive antibody test for HHV-6 does not require treatment with Valtrex or any other medication. Calling attention to the lab results for herpes simplex virus I and II, Dr. Jackson explained that Type I manifests itself as a cold sore, and Type II manifests as genital herpes. He said that Type 6 or "HHV-6" is associated with roseola infantum, a common benign childhood rash, which does not require treatment. (Tr. at 485-486, 500-501; St. Ex. 6 at 60, 107) Dr. Jackson testified that the patient's history would tell whether there was a Type I or Type II infection, concluding, "[I]f they don't have cold sores, or even * * * an infection in the genitourinary region, then it's not significant." (Tr. at 486)

270. Dr. Jackson also disagreed with Dr. DeMio's decision to prescribe one month of hydroxychloroquine 200 mg, an anti-parasitic, for Patient 6. He said that that medication would typically be used to treat malaria or another parasitic infection, but he said that none of the labs in this case showed a parasitic infection. He noted that there was a lab test for Rocky Mountain Spotted Fever, a tick-borne illness, but he said it was negative for both the IgM and the IgG antibodies, showing that the patient had neither a current or past infection of that disease. And, although he was not sure why the patient was screened for Babesia microti because he had no symptoms that would suggest that diagnosis, Dr. Jackson noted that that lab was also negative. (Tr. at 483-485, 489, 498-499; St. Ex. 6 at 67, 106, 109)

271. Again, Dr. Jackson testified that there were risks in prescribing hydroxychloroquine in the absence of any evidence showing a parasitic infection, and that there was no other reason to use it:

> [I]t's not indicated for that, it has a specific indication, and that there are complications that can occur with it, cardiac or other things. So there's no evidence out there to suggest that this can be used for the treatment outside of what it's been designed for, which is typically antiparasitic, and malaria being one of those.

(Tr. at 499)

272. On cross-examination, Dr. Jackson would not agree with a suggestion that Patient 6's lab results for the brucella antibodies showed a bacterial infection that should be treated with antibiotics. (Tr. at 658-660; St. Ex. 6 at 117) He stood by his testimony that it did not: "This does not tell me that there's an acute infection, and that does not mean you need to treat. * * * [Y]ou're suggesting that this positive test means you treat. I would say that is incorrect." (Tr. at 660) Similarly, with respect to a note from another provider about a new onset rash that Patient 6 had, Dr. Jackson maintained that this was likely a viral rash, and that it did not need treatment, because most viral rashes resolve on their own without treatment. (Tr. at 660-662; St. Ex. 6 at 199) He added that antibiotic treatment would not be appropriate, either, reiterating, "Antibiotics are not used for viruses." (Tr. at 662)

273. Finally, Dr. Jackson said that there was nothing in Patient 6's chart to support prescribing Vitamin B-12 injections or the thyroid medication that Dr. DeMio prescribed, because there were no labs to suggest that he was Vitamin B-12 deficient, or that he had any abnormal thyroid functions. He denied a suggestion that a history of fatigue and a family history of hypothyroidism would justify prescribing thyroid hormone replacement, explaining that that history could justify *testing* for thyroid deficiency, but that a lab test was needed to diagnose hypothyroidism because not everyone in a family necessarily inherits that gene. (Tr. at 500-502, 504-505; St. Ex. 6 at 39, 66) In the case of this medication, as well, he maintained that using thyroid medication in the absence of a thyroid disorder was not harmless:

> There are inherent risks and problems with using hormone therapy for any indications that are not supported by labs that suggest a deficiency. Particularly in the pediatric population, even at 15, these individuals are still growing, and you can impair their growth and can cause more symptoms. The reverse, you can probably cause hyperthyroidism or shut down your primary thyroid functioning with exogenous sources of hormones that are not indicated.

(Tr. at 504)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 6

274. Dr. Goldfarb disagreed with Dr. Jackson and found that Dr. DeMio met the standard of care in his treatment of Patient 6. He testified that Patient 6 had been diagnosed with Lyme disease two years before he saw Dr. DeMio and it had not resolved in that time, and, in fact, he characterized Patient 6 as being in Stage 3 Lyme disease. He said that Dr. DeMio treated this with anti-infective and anti-inflammatory medications, and with supplements, nutritional support, and thyroid replacement medication. (Tr. at 808-810)

275. Dr. Goldfarb agreed that a positive IgM on the Western blot indicates an active infection and that a positive test for the IgG antibody is like the "long term memory" of an infection. (Tr. at 813) However, he said that at some point, the IgM and the IgG will overlap, leaving uncertainty about how recent the infection is:

> At some point during the time that the IgM is still present, the IgG, which is a different antibody, will start being produced. So there will typically be an overlap at some point in time. That might last, let's say a few weeks or so, and then the IgG will continue to increase, and it will stay positive.
>
> * * *
>
> So when you see a negative IgM and a positive IgG you really have no idea whether this happened, let's say two months ago, or two years ago, or ten years ago, we don't know that. But that's what the test itself indicates. In this particular case you can definitely say that this patient was certainly infected with lyme.

(Tr. at 813-814)

276. Dr. Goldfarb testified that, in the 1990's, the CDC tried to establish criteria to diagnose Lyme disease and, amid disagreement, they said that if the patient has "5 of the 10 bands" such as those shown on this patient's testing, then it is a positive test. (Tr. at 814-815; St. Ex. 6 at 206) Although he maintained that this patient met the criteria for being positive for Lyme under those criteria, he cautioned that medicine is very complex, and even some well-informed practitioners and researchers do not agree with the CDC's criteria. (Tr. at 814-816)

277. Dr. Goldfarb also said that the patient's symptoms figure in to the diagnosis, and because Lyme is a complex disorder, the physician has to look at the "whole picture" to make a diagnosis. (Tr. at 816) He explained that lab testing was not definitive with Lyme disease:

> The laboratory tests can be helpful, it can be confirmatory, but it's not necessarily definitive, and it's not necessarily indicative of that there is or is not a current lyme disease entity or process going on. It needs to be looked at in a whole picture.

(Tr. at 816)

278. Referring to the February 26, 2015 lab test that Dr. Jackson said was negative for Lyme titers, Dr. Goldfarb agreed that the test was negative. (Tr. at 816-819; St. Ex. 6 at 114) However, he said that did not necessarily mean the patient does not have Lyme disease:

> [T]his is one test looking at B[orrelia] burgdorferi. You can still have lyme disease with this particular test being negative, which I think is what the position of ILADS is, it's a clinical diagnosis. There's a previous -- there is another test that actually does show that lyme was present.

(Tr. at 818-819)

279. Dr. Goldfarb explained that there are multiple antigens of the B burgdorferi bacteria, which are shown by the bands on the test results. The bands look at different protein sizes, which show different components to the organisms. (Tr. at 819-820) Dr. Goldfarb testified that, as the different species of bacteria grow and replicate, the infection goes through different phases, including a cystic phase where it "hides out," even though it is still growing and replicating. (Tr at 820-821) As a result, he contended that Lyme disease was still present in this patient, offering, "[T]he body can't really detect it, but it's still there." (Tr. at 820) Dr. DeMio said that this dormant phase can last for months or even years, and even if the infection is treated early, if it is not completely eradicated, it could "rear its ugly head in the future." (Tr. at 821)

280. Dr. Goldfarb testified that Patient 6's lab tests also showed positive results for co-infections that present along with Lyme disease. Referring to the lab results from a test for toxoplasma, Dr. Goldfarb said that the IgG test was positive, adding, "[M]any practitioners who subscribe to the ILADS protocols feel like this needs to be treated as well as the Lyme." (Tr. at 822; St. Ex. 6 at 115) He stated that Patient 6 also had a lab test that showed a possible co-infection of Brucella, which can cause brucellosis. (Tr. at 822-823; St. Ex. 6 at 117)

281. Dr. Goldfarb testified that Patient 6's mother reported that he had been diagnosed with arthritis by a doctor at Nationwide Children's Hospital before he began seeing Dr. DeMio, and that Dr. DeMio noted that in the patient's chart. (Tr. at 824-826) He noted that the patient was taking indomethacin, an NSAID, as noted in his rheumatology follow-up on February 26, 2015, (Tr. at 824-825; St. Ex. 6 at 217) However, Dr. Goldfarb testified, "[R]eally it was lyme arthritis * * * and it was subsequently rectified, or clarified." (Tr. at 825)

282. Since the patient did not get relief from his arthritis with indomethacin, Dr. Goldfarb said that it was reasonable for Dr. DeMio to try to treat it with hydroxychloroquine, instead. Dr. Goldfarb testified that hydroxychloroquine is a well-established treatment option that can be used as an anti-inflammatory medication for arthritis patients. He added that Dr. DeMio took care to monitor for ophthalmological side effects such as retinal problems that hydroxychloroquine can cause, and that he made an appropriate referral to an ophthalmologist for a baseline exam. (Tr. at 828-829) Dr. Goldfarb concluded, "[S]ince he already had tried Indomethacin, * * * and did not get relief, I think going to a different class using a well-accepted anti-inflammatory medication for arthritis is reasonable." (Tr. at 828)

283. Dr. Goldfarb also testified that it was reasonable for Dr. DeMio to treat Patient 6 for hypothyroidism, even without a lab test showing such a thyroid hormone deficiency. (Tr. at 829-830) He stated, "[T]ypically speaking, I would order thyroid studies, but there are enough indicators that he had hypothyroid symptoms." (Tr. at 829) Dr. Goldfarb explained that thyroid studies are not the sole indicator of hypothyroidism, and that this patient had a positive family history for thyroid disease, concluding, "So

given his condition, I think that it was certainly reasonable to use a low dose of thyroid * * *." (Tr. at 830) Dr. Goldfarb pointed out that Dr. DeMio monitored the patient's thyroid levels after starting him on that medication, to make sure that he wasn't getting too much. He pointed out that while Patient 6 was on the thyroid medication, his TSH increased, according to testing done on July 30, 2015. (Tr. at. at 830-832; St. Ex. 6 at 92-93)

284. Dr. Goldfarb also testified that the patient's test for toxic and essential elements test on July 30, 2015 showed some mineral deficiencies in chromium and manganese, and that his iron was "on the low end," as well. (Tr. at 832; St. Ex. 6 at 100) He said that Dr. DeMio appropriately prescribed calcium and chromium to address those deficiencies, and he noted that at an August 21, 2015 office visit, the family said they "had their son back," showing that Dr. DeMio's care brought significant improvement to Patient 6's condition. (Tr. at 832-833; St. Ex. 6 at 157-159)

285. In summary, Dr. Goldfarb testified that all the different medications that Dr. DeMio prescribed for Patient 6 were justified, because Lyme disease has so many different components:

> Q. [By Mr. Tapocsi] I believe that you mentioned in your report that this result supports the use of long time antibiotic, antivirals, and anti-yeast medications. Can you please explain that rationale?
> A. Yeah. Again, when we're looking at treatment of lyme, because it's so complicated, and there are multiple infections that are associated with it, so there may be viruses associated, there could be mold and yeast associated with it, there could be other bacterial infections, so the approach is that in order to have complete resolution of this problem, you may need to treat all the different infections, not just lyme, not just the lyme species, but also the other co-infections or associated infections that can be contributing to any of the symptoms. So we see that there's certainly a viral infection here, and that would fit the criteria of using antiviral medications.

(Tr. at 827-828)

286. Dr. Goldfarb also testified that Dr. DeMio spent "an inordinant amount of time" with Patient 6, as he calculated an average of 58 minutes per visit, according to the ICD and CPT codes that were indicated in the chart. (Tr. at 810) He said that this reflects the complexity of this patient's condition, as well as Dr. DeMio's dedication to his patients. (Tr. at 810-811)

Pediatric Patient 7 (BG)

287. Patient 7 is a male born in 2004 from Taylorsville, Kentucky. He was 7 years old when he began seeing Dr. DeMio in July 2011. His parent wrote that the family learned of

Dr. DeMio through the Indiana Biomedical Kids Yahoo Group. (Tr. at 90-92; St. Ex. 7 at 1-6)

288. Dr. DeMio testified that Patient 7 had already been diagnosed with Asperger's syndrome by a psychologist in Kentucky when he began seeing this patient. He testified that he recommended that he make a dietary change to go gluten-free and casein-free, because he said that about 85% of kids with autism and Asperger's get some improvement with that change, as it works with the brain chemistry, particularly the endorphins. However, Dr. DeMio said that some of the notes on the bottom of his first progress note were cut off when copies were made, and that recommendation was later abbreviated as "GF/CF." (Tr. at 1349-1355; St. Ex. 7 at 182-184, 276)

289. Dr. DeMio diagnosed Patient 7 with multiple conditions during the course of his treatment, including heavy metal intoxication, encephalopathy, Lyme disease, hormonal imbalance and hypothyroidism. (St. Ex. 7) At the hearing, he described encephalopathy as a broad term that suggests "some type of cognitive derangement," and he characterized it as a "grab bag diagnosis." (Tr. at 511) He testified that it could result from binge drinking, or from a hypoxic event at birth, for example, but he said that it was not synonymous with autism, adding that it just means "there's something that's affecting the global executive functioning" of the patient. (Tr. at 512) At a later point in his testimony, he added examples of other causes of encephalopathy, including yeast in the GI tract:

> It can be [from] infections, like viral is one of the causes. It can be toxic, or metabolic where the living chemistry in the body is affected, so if somebody hasn't had their dialysis for many days, they have a lot of waste products that build up, they can become deliriously confused and so on. And those are things that -- examples of that type of manifestation. You can have an encephalopathy from a head injury from getting in a pedestrian/motor vehicle accident, and your brain is never the same, so you don't act the same and speak the same and all of that. * * * [There can also be] yeast in the GI tract in some settings, and it can lead to materials that it produces that are toxic to the brain. If there's a GI problem it can affect the brain, and some of those can be chronic and some of those can be temporary, those different examples. And inflammation and infections, that's the big one. That particular category is more like encephalitis, but encephalitis is only one example of encephalopathy, they are not the same thing.

(Tr. at 1356-1357)

290. Dr. DeMio diagnosed Patient 7 with encephalopathy in May 2014, after a phone conversation with the patient's mom. He explained during his testimony that there have been studies of the brains of children with ASD or Asperger's who died in car crashes, which have shown that children with those disorders have a very high rate of brain inflammation. (Tr. at 98-99, 1357-1358; St. Ex. 7 at 225) Dr. DeMio explained, "And

the more severe they were, the more of it they had. It wasn't every kid. That's what's we suspect clinically in a lot of our cases." (Tr. at 1358)

291. Dr. DeMio said that he does not diagnose encephalopathy in every ASD patient, but that he does so only where there is a medical basis for it. He explained that he would not make such a diagnosis in the case of a high-functioning person whose autism did not greatly impact their life. But he said that, in a patient who has a more severe disability, such as one who rocks in a corner or bangs their head showing signs of pain, or if Motrin relieves their symptoms, that suggests to him that there is brain inflammation. (Tr. at 101, 1358)

292. Dr. DeMio explained that "encephalopathy" in this patient's case meant "medical abnormalities in the patient's body that lead to abnormal brain function." (Tr. at 102) He testified about how he reached the diagnosis of encephalopathy in this case:

> Q. [By Mr. Wilcox:] What specific criteria did you use to diagnose encephalopathy?
> A. He's got abnormal brain function and there's a medical basis for it.
> Q. Did you do a neurological exam of the patient?
> A. I'm sorry, did you say that day?
> Q. Yeah.
> A. I don't have one written in there, no. I mean, I was going by what the mom is telling me. * * * You know, that's an encounter. There's a series of questions and exchanges, and it's an ongoing history and she's giving me what physically is happening with that child, and telling me about it. She sees him every day, that kind of thing.

(Tr. at 100-101)

293. Dr. DeMio implied that it was through interacting with Patient 7 and getting a history from his mother that he was able to reach the conclusion that this patient had encephalopathy:

> He's got this dysphoric baseline, okay? And it's very intense in the sense that just the whole family just feels like -- I use the words walking on eggs, that's just abnormal. And I had seen him prior and had a whole workup and physical exam and follow-up with him and his mom and parents and the whole thing.
>
> And so he's the type of kid that I know that there's an encephalopathic problem, there's something that's organic going on with his central nervous system, and that's what encephalopathy is.

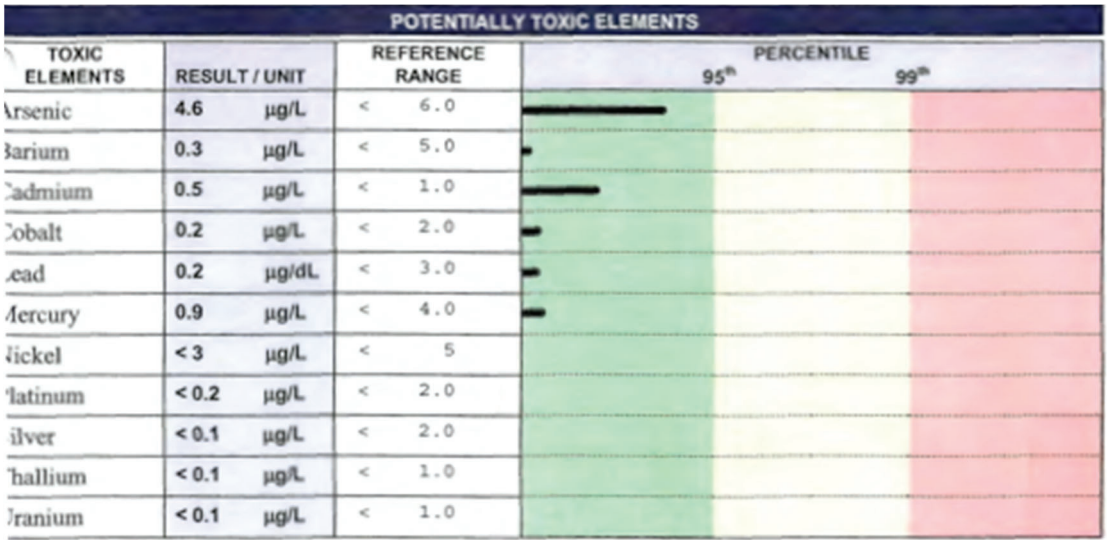
> So it's based on knowing the patient and getting some feedback from the mom at that point. And then I went through a series of things that I thought would help that.
>
> And I can clarify for you, because it got cut off on the bottom. Part one of that -- the ending of the note where I refer to the antibiotic Zithromax, it's a positive streptozyme which is a type of test that can give you an idea of what can lead to encephalopathy.
>
> And so that one was positive, so that's why I chose that antibiotic. And then we talked about other issues and things that may help those symptoms, and the basis of the encephalopathy. That's when I discussed the other things with her.

(Tr. at 99-100)

He also pointed out that in the notes of his April 2, 2015 telephone conversation with Patient 7's mother, he discussed a psychiatric evaluation the patient was having with the patient's mother, and she was going to let him know if any diagnoses or recommendations changed. (Tr. at 1355; St. Ex. 7 at 236-238)

294. Dr. DeMio agreed on cross-examination that he also diagnosed Lyme disease in Patient 7, and that he prescribed azithromycin to treat it. (Tr. at 97; St. Ex. 7 at 225-226) He explained, "He's positive for Rocky Mountain Spotted Fever, which I refer to as RMSF. And the Igenix Lab somehow was botched. That's a laboratory that does some blood counts for tick borne illnesses and things." (Tr. at 97)

295. Dr. DeMio also diagnosed Patient 7 with heavy metal intoxication, based on the results of some bloodwork that was done on August 15, 2011. (Tr. at 1360; St. Ex. 7 at 159)

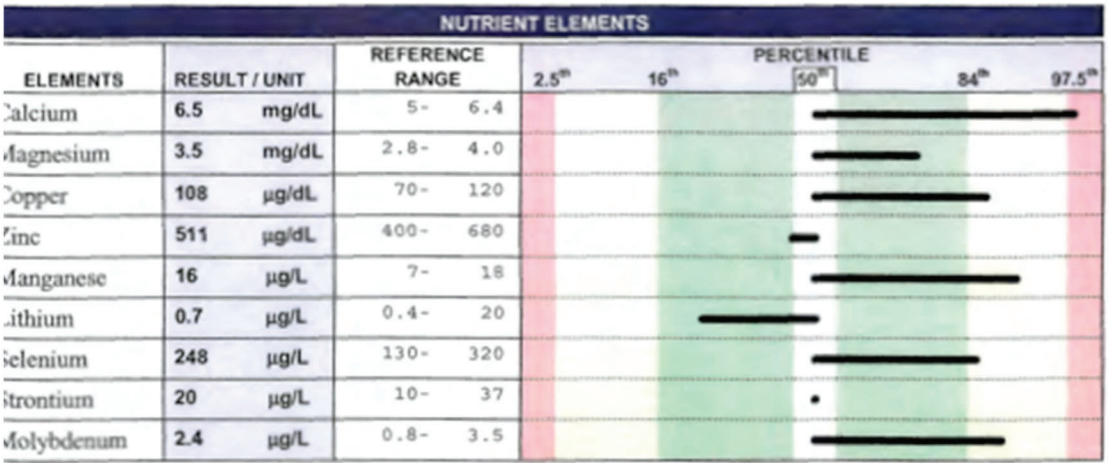


POTENTIALLY TOXIC ELEMENTS

TOXIC ELEMENTS	RESULT / UNIT	REFERENCE RANGE	PERCENTILE 95th 99th
Arsenic	4.6 µg/L	< 6.0	
Barium	0.3 µg/L	< 5.0	
Cadmium	0.5 µg/L	< 1.0	
Cobalt	0.2 µg/L	< 2.0	
Lead	0.2 µg/dL	< 3.0	
Mercury	0.9 µg/L	< 4.0	
Nickel	< 3 µg/L	< 5	
Platinum	< 0.2 µg/L	< 2.0	
Silver	< 0.1 µg/L	< 2.0	
Thallium	< 0.1 µg/L	< 1.0	
Uranium	< 0.1 µg/L	< 1.0	

(St. Ex. 7 at 159)

He testified that the bloodwork also showed high levels of the nutritious metals, as shown below:



NUTRIENT ELEMENTS				
ELEMENTS	RESULT / UNIT		REFERENCE RANGE	PERCENTILE 2.5th 16th 50th 84th 97.5th
Calcium	6.5	mg/dL	5- 6.4	
Magnesium	3.5	mg/dL	2.8- 4.0	
Copper	108	µg/dL	70- 120	
Zinc	511	µg/dL	400- 680	
Manganese	16	µg/L	7- 18	
Lithium	0.7	µg/L	0.4- 20	
Selenium	248	µg/L	130- 320	
Strontium	20	µg/L	10- 37	
Molybdenum	2.4	µg/L	0.8- 3.5	

(St. Ex. 7 at 159)

296. In interpreting the test results, Dr. DeMio said that the patient had high levels of at least six toxic heavy metals, adding, "[T]hat's to say the least, very unusual." (Tr. at 1360) With respect to the nutritious metals, he said that Patient 7 was also high in several of those, even though he was not taking all of them as supplements, and he explained, "[T]here just is not even an infinitesimal chance you'd be high in all of those at one time." (Tr. at 1362) He concluded that this showed heavy metal intoxication, explaining, "And plus this young man is symptomatic, so that is highly suggestive of heavy metal toxicity for him in conjunction with his clinical state." (Tr. at 1362)

297. Additionally, Dr. DeMio pointed to lab results from August 8, 2012, as evidence of lead toxicity that he believed was preventing the patient from having sufficient levels of iron, as the results showed that Patient 7 had low levels of red blood cells. (Tr. at 1382-1383; St. Ex. 7 at 134) He testified that this test result actually suggested lead toxicity rather than anemia:

> [Y]our body thinks it doesn't have iron because the lead is pushing it out of the way, so one of the ways is to check the kid for lead. And then the other thing is to make sure they are getting enough iron both to replete an iron and to compete with any toxins -- toxic metals to improve them. You can give all the iron in the world, but if they don't detoxify it with the other metal, the iron won't get into the driver's seat.

(Tr. at 1383)

298. Dr. DeMio recalled that Patient 7's history did not suggest an unusually high exposure to toxic metals, and he reasoned, "[C]hances are he didn't get a toxic exposure higher than the average person of all of those metals, he is just not dealing with the background amounts in all likelihood." (Tr. at 1361-1362) He testified that sulfur can help "get rid of" the toxic metals, and he also suggested supplementing with zinc and small amounts of "natural lithium." (Tr. at 1362)

299. In this case, Dr. DeMio did not order any chelating agents for Patient 7, although he noted that he did prescribe glutathione cream, which he said he did not know if he was using as a chelator. (Tr. at 105, 1374-1375; St. Ex. 7 at 84) He explained that he orders chelation "a third or less" of the time for patients, and he said that he had looked through the chart and had not seen any other treatment for heavy metal toxicity for this patient. (Tr. at 104-105, 1369) Dr. DeMio said that when he does use chelation, the goal is "to be healthier with the medical basis of what is causing their Asperger's or autism or whatever," and he added, "It's a medical treatment, it's not really a behavioral treatment." (Tr. at 1374)

300. Dr. DeMio also treated Patient 7 for vitamin deficiencies, which he said were shown in his August 15, 2011 and March 19, 2012 lab results. (St. Ex. 7 at 150, 158) He stated that this report showed the patient's Vitamin D level was 26.4 ng/mL, below the recommended levels of 32-100, and he treated it in this case with Vitamin D supplements that the patient took with meals. Dr. DeMio said that if the Vitamin D level got any lower, it could lead to calcium deficiency and rickets. He testified that he has gluten-free, casein-free supplements that patients can buy from his office, or he can give them an information sheet so they can buy the supplements over the counter. He emphasized that no one is ever coerced to buy supplements from him. Dr. DeMio also said that the August 2012 lab report showed the patient was low in chromium, and he believed that he addressed that with supplements, as well, though he could not be sure from his chart. (Tr. at 1375-1376, 1381)

301. Finally, Dr. DeMio treated Patient 7 for hypothyroidism. He explained that thyroid problems are much more common in children with developmental disabilities because they tend to have abnormal thyroid glands. As a result, he said that many of them have low thyroid levels from birth. In this case, Dr. DeMio prescribed 15 mg per day of Nature Thyroid, a thyroid supplement to treat hypothyroidism in Patient 7. (Tr. at 106-107, 1384-1388; St. Ex. 7 at 63-65) Pointing to the lab results from February 26, 2015, Dr. DeMio explained that the high TSH level showed "it's trying to kick the thyroid in the pants to make more thyroid hormone out of the thyroid g[l]and in the neck." (Tr. at 1385)

TSH		4.47 H	0.50-4.30 mIU/L
T4, FREE	1.1		0.9-1.4 ng/dL
THYROID PANEL			
T3 UPTAKE	30		22-35 %
T4 (THYROXINE), TOTAL	7.1		4.5-12.0 mcg/dL
FREE T4 INDEX (T7)	2.1		1.4-3.8
T3 REVERSE, LC/MS/MS	13		8-25 ng/dL

(St. Ex. 7 at 115)

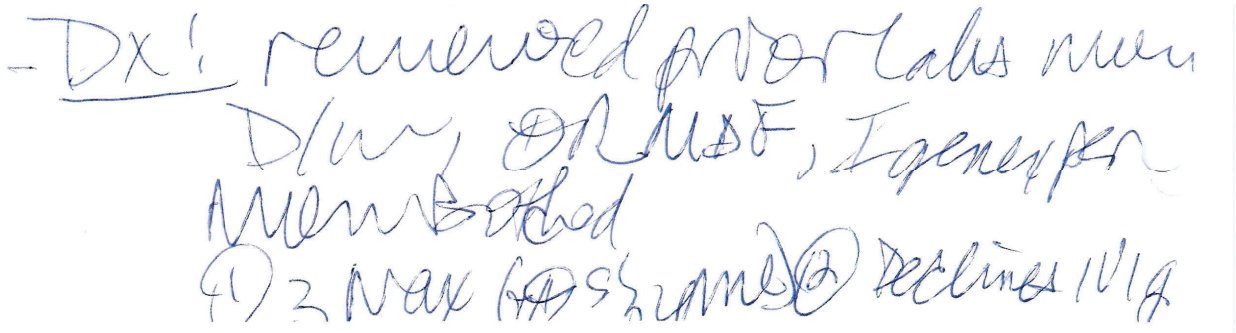
302. Dr. DeMio referred to a subsequent lab two months later, which showed that the TSH had dropped into the normal range, and the T3 was still normal, as well. (Tr. at 1386-1387; St. Ex. 7 at 113) He concluded, "So the TSH normalized and we have normal T3. That confirms what we diagnosed – what I diagnosed in that first test in the patient." (Tr. at 1387) Dr. DeMio said that Patient 7 made "a lot of improvement" under his care, and that his mom later "took it from there" and followed up with other providers. (Tr. at 1388) Patient 7 was discharged as a patient as of July 17, 2014. (Tr. at 104-105)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 7

303. The State's pediatric expert, Dr. Jackson, opined that Dr. DeMio's care of Patient 7 fell below the minimal standard of care because there was little or no documentation to support his diagnoses and treatment plan for this patient and, in particular, because he treated Patient 7 with a hormone supplement where there was no diagnostic evidence of a deficiency. (Tr. at 521)

304. Dr. Jackson testified that Dr. DeMio diagnosed Patient 7 with encephalopathy, a nutritional disorder and a metabolic disorder, and that he made the diagnosis of encephalopathy without ever doing a comprehensive mental status exam or referring the patient out for such an exam by another practitioner. He noted that Patient 7 had a prior diagnosis of Asperger's, made by another provider. Dr. Jackson said that even if there had been a baseline mental status exam, there should have been another one done to see if his functioning had improved, worsened, or stayed the same. (Tr. at 507-508, 511-513; St. Ex. 7 at 22) He stated that there was no such exam done even after Dr. DeMio noted that the patient's mother called and reported dysphoria in the patient, which he said described a cognitive status suggesting that the patient was "not with it." (Tr. at 508; St. Ex. 7 at 225-226)

305. Referring to the notes of a telephone consultation with Patient 7's mother in May 2014, Dr. Jackson said that it appeared that Dr. DeMio diagnosed Rocky Mountain Spotted Fever, as he wrote, "RMSF." (Tr. at 514-515; St. Ex. 7 at 225) That portion of the note is shown below:



(St. Ex. 7 at 225)

However, Dr. Jackson said that there was no subjective or objective information that would support that diagnosis based on this telephone call. (Tr. at 516) He elaborated:

> But there's nothing in the history that would suggest there was any type of insect bite, much less tick bite, or any symptoms that would suggest that is a part of your differential, much less your primary diagnosis.

(Tr. at 515)

306. Similarly, Dr. Jackson testified that Dr. DeMio diagnosed Patient 7 with a hormone imbalance and hypothyroidism, but there were no labs that supported that diagnosis. He called attention to the lab report on January 20, 2015, which showed only a marginally elevated TSH, the thyroid stimulating hormone, but he said that the more important tests on that report showed normal functioning. These included the free thyroid level which showed normal functioning and the T3 uptake, which he said ruled out hypothyroidism, as well as the T4, which also was not abnormal here. (Tr. at 517-518; St. Ex. 7 at 65, 115-118) Looking at the January 2015 lab report of Patient 7's thyroid hormone levels, Dr. Jackson concluded, "So in totality, thyroid functioning is normal here." (Tr. at 518) He compared Dr. DeMio's treatment to giving insulin to someone who is not a diabetic just to lower the patient's glucose level. (Tr. at 520)

307. Dr. Jackson testified that a physician should be especially careful when using thyroid medications in pediatric patients, because it treats them with a hormone that could affect their growth and development. He stated that when a doctor treats a pediatric patient for this disorder, additional labs should be ordered to monitor that the treatment is not in excess of what is needed. However, Dr. Jackson said that he saw only one time when Patient 7's thyroid hormone levels were checked, and that there were no rechecks in the chart. He added that he was not aware of any holistic practice that suggests additional thyroid would benefit a patient. (Tr. at 519-521)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 7

308. Dr. Goldfarb opined that it was reasonable for Dr. DeMio to treat Patient 7 for ASD, encephalopathy, and nutritional deficiencies using nutritional support, antibiotics, antifungals, anti-inflammatories, hormone supplements, and mood stabilizers. (Tr. at 834-835) He explained that patients diagnosed with ASD often have conditions that make them appropriate patients for these diagnoses and treatments:

> I think that in all of these patients nutritional and mineral deficit is sort of -- sort of -- it's sort of part and parcel of the ASD picture. And encephalopathy is -- as I said in my report, is any brain dysfunction. So encephalopathy is certainly an appropriate diagnosis for every encounter. So I would basically say that each of these diagnoses is certainly appropriate.

(Tr. at 836)

309. Dr. Goldfarb maintained that Dr. DeMio did not diagnose Patient 7 with heavy metal toxicity and did not prescribe any chelation treatment for him. While he saw that Patient 7 was treated with glutathione which he said has "chelating properties," he said that in this patient, it was used as an anti-oxidant, rather than a chelator. (Tr. at 837-839) He offered:

> [A]ll the patients were put on glutathione, and glutathione I think is reasonable as an antioxidant for all these complex patients. * * * "[I]t's a ubiquitous antioxidant, and extremely safe, and I wouldn't have any problems giving glutathione to anyone.

(Tr. at 838-839)

310. Dr. Goldfarb also testified that Patient 7's lab results showed that he was deficient in certain vitamins and minerals. Although some of the labs that he testified about were prior to 2012, Dr. Goldfarb said that the patient's lab results on August 8, 2012 showed low hemoglobin and hematocrit numbers, indicating that he was anemic, and that by December 6, 2013, those numbers were still low. (Tr. at 839-842; St. Ex. 7 at 124, 134) He qualified his statements by explaining that when a patient's test result showed a level at the very low end of the reference range, he would still consider a test result to be relatively low. (Tr. at 840)

311. Dr. Goldfarb also disagreed with Dr. Jackson's opinion that Dr. DeMio should have had a mental status or mental health exam done of this patient, because of Dr. DeMio's expertise in treating autism patients. (Tr. at 842-843) He explained:

> [Dr. DeMio] is very well versed in taking care of pediatric patients with ASD, and that would automatically mean that these patients have mental health concerns, social -- psychosocial concerns, these are all part and parcel of patients and families with ASD. He's been doing this for many years.
>
> So given his level of expertise in treating these patients, then -- and having to deal with their unique mental health concerns, I think it's completely reasonable for him to be able to make an assessment without necessarily having to refer those patients to a mental health specialist.

(Tr. at 842-843)

He concluded, "But to refer to a mental health specialist out of hand just because a patient has ASD, I don't think is necessary or warranted." (Tr. at 843) Dr. Goldfarb pointed out, however, that Dr. DeMio noted that this patient could be referred for a psychiatric evaluation before February 2015, which he said showed that Dr. DeMio

recognized that Patient 7 might need a higher level of care at some point. (Tr. at 843-844; St. Ex. 7 at 238)

312. Finally, Dr. Goldfarb testified that he believed it was appropriate for Dr. DeMio to treat Patient 7 for hypothyroidism, based on the labs and on the patient's family history. (Tr. at 844-845) He referred to the lab report from November 13, 2014, which he said showed that the TSH was "a little bit elevated, even though it falls in the reference range," and he added, "I think the reference range is too broad for this particular – for thyroid generally."[3] (Tr. at 844; St. Ex. 7 at 118)

313. Dr. Goldfarb testified that the November 2014 lab, coupled with a history consistent with low thyroid meant that Dr. DeMio met the standard of care in treating this patient for a thyroid condition. He noted that, by the time of Patient 7's January 16, 2015 lab, the TSH was still high, indicating that the thyroid function remained low. Dr. Goldfarb said that Dr. DeMio prescribed one quarter grain of Nature Thyroid and continued to monitor the patient's condition. He said that Dr. DeMio ran another lab two months later on March 20, 2015, which showed that his TSH was coming down. Dr. Goldfarb asserted that this showed that Dr. DeMio's treatment was appropriate. (Tr. at 844-845; St. Ex. 7 at 111-115)

Pediatric Patient 8 (BT)

314. Patient 8 is a male from Harbor Springs, Michigan, born in 2004. He was 3½ years old when he began seeing Dr. DeMio in or about September 2007. The intake form stated that his family became aware of Dr. DeMio from the mothering.com discussion list. Dr. DeMio recalled that Patient 8's parents brought him in because he suffered from severe food intolerances that resulted in an increasingly narrow diet, and he showed sensory processing problems that his mom thought could be related to his diet. Dr. DeMio agreed that, between 2014 and 2016, he entered diagnosis codes for Patient 8 that represented enteric infections, encephalopathy, and an anxiety disorder. (Tr. at 109, 111-112, St. Ex. 8 at 1-5)

315. Dr. DeMio explained that an enteric infection is an infection in the GI tract, and he compared it to a splinter in the skin that gets a staph infection. He pointed to the results of a May 10, 2015 fecal analysis that he said showed three types of strep germs: alpha hemolytic strep, gamma hemolytic strep, and enterococcus, as well as two types of E. Coli germs: Enterobacter and Citrobacter. He added that the result showed that he also had Clostridium growing. Dr. DeMio testified that this showed an enteric infection. (Tr. at 112, 1390-1391; St. Ex. 8 at 145) In addition, he said that the column on the right in the lab report[4] showed that he had dysbiotic flora, Citrobacter freundii complex, and testified, "That germ is not supposed to be there in a healthy person. It's widely known as pathological, it makes people sick. It's an infection." (Tr. at 1392; St. Ex. 8 at 145)

[3] The November 13, 2014 lab report indicates that Patient 7's TSH level was 3.19 with a reference range of 0.50 – 4.30 mIU/L. (St. Ex. 7 at 118)
[4] The right column is labeled "Dysbiotic flora." (St. Ex. 8 at 145)

316. Dr. DeMio testified that it is challenging to treat those infections and restore the GI tract to a healthy state because "[y]ou can't really 'disinfect' the GI tract." (Tr. at 1393) Dr. DeMio said that he first tried to make the GI tract stronger through the use of probiotics and herbal supplements, including oil of oregano and coconut oil. He directed attention to his office visit note from June 8, 2015, in which he documented that the patient was having problems with anxiety and defecation. (Tr. at 1393-1395) Dr. DeMio said that his plan of treatment was to use "OIG," an oral immunoglobin, which he described as a biologic antibody type substance, as well as three different probiotics that would be rotated to "throw a curve ball to the germs" and boost the patient's immune system. (Tr. at 1397-1397)

317. Dr. DeMio said that Patient 8 was also using Digest, a digestive enzyme, as well as metronidazole, an antimicrobial, which he prescribed on June 17, 2014. He testified that one of the potential side effects from the use of metronidazole is that it can kill the "good germs" and some kids can become dysphoric because it is metabolically active. However, he said that this patient did not have any dysphoria, and he added that metronidazole is a gentle medication that is "pretty low risk." (Tr. at 1398-1399; St. Ex. 8 at 117) To guard against those risks, Dr. DeMio said that he recommended some herbal supplements to stabilize his mood and 5HTP for anxiety, and advised the parents to call if they observed any changes in their child that would warrant changing course in his treatment. (Tr. at 1400-1401)

318. On cross-examination, Dr. DeMio could not recall if Patient 8 had ever seen a gastroenterologist. (Tr. at 112) When he was asked whether he had any training in gastroenterology, Dr. DeMio maintained that his training came from national meetings he attended:

> Q. * * * Do you have training and expertise in the area of gastroenterology?
> A. Well, for the patients I treat, yes. I mean, we have our national meetings and we go over our cases and work with each other and develop policies and do work on those areas, yes.

(Tr. at 113)

319. When Dr. DeMio was pressed on where he saw evidence of an enteric infection in the patient's stool analysis, he maintained that the lab report from May 2015 showed an enteric infection:

> Q. [By Mr. Wilcox:] And does this indicate an enteric infection to you?
> A. Yes, it does.
> Q. And tell us where you glean that information from, Doctor, on which page.

> A. Start with page 145. If you look at the upper left-hand corner[5] there are a variety of bacteria mentioned there, enterococcus is abnormal. It's a strep germ. And then you have other strep germs in the middle;[6] you have two of them. You have the alpha hemolytic strep and you have the gamma hemolytic strep. Those are abnormal, they shouldn't be there. [Entero]bacter is an abnormal bacteria germ, should not be there as a result on that test.
> Q. Okay. Are these things -- are those things that you circled on there that you're referring to?
> A. I did circle those, yeah. It doesn't look like I circled the [Enter]obacter. I circled the strep, and I usually do that while I'm talking to the parents because those are all variations of strep germs there that I circled. The enterococcus, alpha hemolytic strep, gamma hemolytic strep, those are the abnormal streps that are there.
> Q. So to you, you read that as an infection that must be treated in this child, is that what you're telling us?
> A. Well, in the totality of his presentation on that there, yes.

(Tr. at 115-116)

Dr. DeMio said that he also listens to the parents about the patient's swallowing, digestion, and bowel movements, and how foods affect them, as part of taking a history and physical, and that that information also assists him in diagnosing an enteric infection. He added that the patient can also make dietary changes to see if their symptoms improve, which could indicate a food allergy. (Tr. at 113-115; St. Ex. 8 at 145-148)

320. Patient 8 was also having hyperbaric oxygen treatments to treat this condition, as his family had purchased an HBOT chamber from Dr. DeMio earlier in their relationship, before the relevant time period that began in 2012, and it appears that it was being used for treatment related to the enteric infection. (Tr. at 116-117, 1403-1409; St. Ex. 8 at 340-350)

321. Dr. DeMio explained, "[W]e use [HBOT] therapeutically for our kids' problems, for the immune system, the GI tract, brain function. And in young kids the parents would go in this chamber for an hour or more at a time." (Tr. at 1405) He explained the particular purpose for HBOT for Patient 8's GI problems:

> It's a form of increasing the amount of oxygen that is delivered to the patient. We thrive on oxygen, our cells thrive on it. It's the single most important thing moment to moment for ourselves, for our body tissues, for everything from the brain to the immune system. So the GI tract, and we

[5] The left column is labeled "Expected/Beneficial flora." (St. Ex. 8 at 145)
[6] The middle column is labeled "Commensal (Imbalanced) flora." (St. Ex. 8 at 145)

> have used it for brain, immune and GI treatments, and this young man was appropriate for all three.

(Tr. at 1404)

322. Dr. DeMio also prescribed Acyclovir, an antiviral, to treat herpes viruses that he said he diagnosed, based on information he obtained from the patient's parents that a previous physician had diagnosed HHV-6, human herpes virus Type 6. (Tr. at 117-118; St. Ex. 8 at 269) When pressed on how he made that diagnosis, Dr. DeMio explained:

> Well, the HHV-6 was a prior doctor, so either I -- the only thing I can think of off the top of my head, and I can look for you, too, was either it would be either or both of the parents relating that to me -- usually HHV-6 they are not going to say.

(Tr. at 120)

323. On cross-examination, Dr. DeMio disagreed with a suggestion that HHV-6 is very common among the population and does not require treatment. He also noted that the patient had a positive test for CMV, the cytomegalovirus, another type of herpes virus, as well as positive results for the Epstein-Barr virus and roseolovirus. Dr. DeMio did not agree with suggestions that those are "very common" viruses that do not necessitate treatment. (Tr. at 120-121; St. Ex. 8 at 208-209) He agreed, however, that the labs that showed those results had been done in 2011 by another physician, Dr. Kenneth Bock in New York, and he agreed that he did not see a positive EPV test in 2015. Dr. DeMio testified that, as of the time of the hearing, he was still treating Patient 8. (Tr. at 121-123, 1390; St. Ex. 8 at 206-211)

Dr. Jackson's Testimony concerning Dr. DeMio's Care of Patient 8

324. Dr. Jackson testified that Patient 8 was 3-years old when he first saw Dr. DeMio, and that Dr. DeMio used diagnosis codes to indicate that his diagnoses included abnormal blood constituents, encephalopathy – unspecified, an enteric infection, and a metabolic disorder. Dr. Jackson testified that "ha[d] no idea" what "abnormal blood constituents" meant, as he had never used that diagnosis in his practice. (Tr. at 522; St. Ex. 8 at 16-17)

325. Dr. Jackson testified that a diagnosis of an enteric infection means there is a confirmed infection in the gut area, either viral, bacterial, fungal, or parasitic. He explained that vomiting alone does not necessarily indicate an enteric infection, and that if such an infection has not already been diagnosed by some other source, it can be diagnosed through a culture or sometimes using antigens for some types of infections. (Tr. at 522-525)

326. In this case, Dr. Jackson said that the notes in Patient 8's chart did not support a diagnosis of an enteric infection because they lacked a chief complaint, a history of past illness or

present illness, a medication list, allergies, a detailed review of symptoms, documentation of a physical exam or any lab data to demonstrate that this was the correct diagnosis. Dr. Jackson said that he was looking for some good objective or subjective information that Dr. DeMio could have based this diagnosis on, but he could not find anything to support the belief that this patient had an enteric infection. (Tr. at 525-528; St. Ex. 8 at 309-310)

327. Dr. Jackson acknowledged that the lab report of "beneficial flora" and "imbalanced flora" appears to indicate some type of culture that was done, but he testified that he was not familiar with this type of test, and he said, "[S]everal of these can be considered normal flora, but not necessarily significant enough to need to treat." (Tr. at 530, 534-535; St. Ex. 8 at 173) He stated that "dysbiosis" refers to some derangement in the bacterial flora, which was not shown on this report. (Tr. at 530)

328. When Dr. Jackson was presented with a section of Dr. Goldfarb's report that stated that enteric infections are often treated empirically without laboratory confirmation, Dr. Jackson said that he did not agree with that position. Moreover, Dr. Jackson said that in Patient 8's case, there were laboratory tests done, and those tests showed normal results. He sharply disagreed with a suggestion that ASD patients are assumed to have dysbiosis, maintaining that there was no evidence-based information to support that statement. (Tr. at 532-535) He concluded, "[I]n this case here I don't see anything that suggests the need to treat." (Tr. at 534)

329. Dr. Jackson disagreed with Dr. DeMio's decision to prescribe Acyclovir and Valtrex for Patient 8 on June 17, 2014, because he said there was nothing in the medical record that showed any diagnosis that needed to be treated, nor any history to support the need for an antiviral medication, "much less [an] antiherpetic medication." (Tr. at 535; St. EX. 8 at 118)

330. Responding to Dr. Goldfarb's report, which concluded that the patient's high titers for the Epstein-Barr virus ("EBV") supported the use of Acyclovir, Dr. Jackson again disagreed. He explained that EBV is synonymous with mononucleosis, and maintained that the EBV titers in the chart were drawn in 2011, and Dr. DeMio did not treat him with the antiviral until 2014. Dr. Jackson also emphasized that there is no antiviral treatment for mononucleosis, explaining that even if there were labs showing an active infection, there are some immunoglobins that can help with the inflammatory process, but there is no approved antiviral treatment for it. He added that even if there were an effective antiviral treatment for mononucleosis, this patient tested positive for EBV in 2011, so he would not still need treatment for it in 2014. (Tr. at 536-537; St. Ex. 8 at 118)

331. Dr. Jackson also disagreed with Dr. Goldfarb's statement in his report that this patient's positive Western blot test in April 2011 would be a valid reason to use an antiviral medication to treat a chronic infection that was a co-infection with Lyme disease. He did not agree that patients with Lyme often have chronic viral infections as co-infections, and he disagreed that it was common to treat Lyme with antivirals as well as antimicrobials.

Dr. Jackson maintained that this was not common, and that, even if it were, it would not be an appropriate treatment three years after the positive test. (Tr. at 537-538)

332. Finally, Dr. Jackson found no reason for oxytocin to be prescribed for Patient 8, which the medical record shows Dr. DeMio prescribed. He testified that oxytocin is an exogenous replacement for a hormone produced by the pituitary gland, and that it is often used in labor and delivery to help augment uterine contractions, but he said that he knew of no use for that medication in the pediatric population. (Tr. at 538; St. Ex. 8 at 119) Dr. Jackson explained:

> [T]here is no practical application in the pediatric population. You won't find any particular resources to suggest that there's any indication for oxytocin from any -- I should say any disease entity for the use of oxytocin in any form, IV or in nasal spray, in the pediatric population, unless there's pregnancy and the need to induce contractions.

(Tr. at 539)

333. Dr. Jackson testified that he did some research and found that there is some off-label use of oxytocin to improve the mental status or behavior of patients who have been diagnosed with autism. (Tr. at 539) However, he added:

> [B]ut there is no strong evidence, much less any studies that have shown any effectiveness or indication to use this, even in integrative medicine, suggested this particular medicine will help with symptoms consistent with autism or anything else.

(Tr. at 539)

For these reasons, Dr. Jackson testified that Dr. DeMio's care of Patient 8 did not meet the minimum standard of care. (Tr. at 540)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 8

334. In his testimony, Dr. Goldfarb emphasized that Patient 8 had already had 24 different diagnoses from other providers by the time he first came to see Dr. DeMio. Some of those diagnoses included hyperactivity and a sensory processing disorder diagnosed by his school district; as well as leaky gut, dysbiosis, chronic diarrhea, Lyme disease and EBV by other providers. Dr. Goldfarb believes that Dr. DeMio appropriately treated Patient 8 with nutritional supplements, antioxidants, antibodies for dysbiosis, antivirals for EBV, and mood stabilizers. (Tr. at 846-847)

335. Dr. Goldfarb testified that treating an enteric infection in the GI tract is often diagnosed based on symptoms alone without laboratory confirmation, in the same way that a sinus infection can be diagnosed based on the patient's symptoms. (Tr. at 848) He stated:

"[O]ften times enteric infections are very similar, history is consistent with a gastrointestinal infection, and sometimes we'll just treat them without doing laboratory tests, so that's empiric treatment." (Tr. at 848)

336. Dr. Goldfarb testified that in this case, there was a comprehensive stool analysis and parasitology report from lab work done on May 10, 2015, which he said showed dysbiotic flora as well as hemolytic strep, Enterobacter, and Citrobacter. (Tr. at 848-849; St. Ex. 8 at 145-151) When he was asked if that test demonstrated an enteric infection, Dr. DeMio suggested that it could:

> Well, it could be that these -- this hemolytic strep and Enterobacter and gamma hemolytic strep could possibly be, yeah, enteric infections, and then -- any infection of the gastrointestinal tract is called an enteric infection.

(Tr. at 849-850)

337. Dr. Goldfarb also said that the dysbiotic flora was considered an enteric infection. And, referring to a similar test done in October 2011, he said that those results also showed a significant overgrowth of different bacteria in the GI tract. Comparing the two lab reports, he said that they showed that the patient still had a positive test for Citrobacter, as well as dysbiotic flora, four years after the first test. (Tr. at 850-852; St. Ex. 8 at 145-151, 201)

338. Dr. Goldfarb testified that, in June 2014, between the two tests, Dr. DeMio prescribed two months' worth of metronidazole, an anti-fungal. (Tr. at 850-852; St. Ex. 8 at 117)

339. Dr. Goldfarb explained that there is a connection between the neurological system and the GI tract, offering:

> [W]henever there's a significant neurologic component to illness and making sure diet and nutrition is adequate and it's supportive, as well as removing toxins, and infections are a potential toxin, it's part and parcel of treating in an integrated holistic in these neurologic disorders.

(Tr. at 854)

340. Dr. Goldfarb testified that patients whose diagnoses include ASD often required the GI tract to be "cleaned up," even without testing to confirm an infection, explaining as follows:

> I do not believe that you need specifically to have laboratory confirmation before treating this -- these types of patients with these types of symptoms, especially if there's a history of having dysbiotic flora. Dysbiosis is extremely common in ASD, and it is often times necessary to make sure

> the gut is -- what we call clean up the gut, because of the significant gastrointestinal neurologic connection. So ASD is a neurologic condition. Gastrointestinal symptoms can contribute to that, so cleaning it up is part and parcel of a way of approach.

(Tr. at 853)

341. Dr. Goldfarb concluded that he did not believe there were significant risks to the metronidazole that Dr. DeMio prescribed, although he said that it could promote further imbalance of the gut flora and worsen his diarrhea. (Tr. at 854-855) However, he said he believed it was more likely that the antifungal medication would "get rid of the pathological organisms and help promote the rebalancing of the gut." (Tr. at 855) He added that he saw no indication in the chart that Patient 8 had any adverse reaction from the medication. (Tr. at 855)

Patient 9 (DF)

342. Patient 9 is a male born in 2007 from South Charleston, West Virginia. He was about 15 months old when his parents first sought a consultation with Dr. DeMio in December 2008. (St. Ex. 9 at 1-5) Dr. DeMio recalled, "The mom was concerned that he wasn't able to be a healthy eliminator, in her words, and she meant to help his own natural detoxification." (Tr. at 124-125) In addition, he said the patient's mother reported that he was strong-willed, and that he was not talking yet, and the parents believed this was biologically-based. (Tr. at 125)

343. Based on lab results that Patient 9 had done on May 20, 2010, that was ordered by Dr. DeMio, Patient 8 had heavy metal toxicity. (Tr. at 1410-1411; St. Ex. 9 at 220) Referring to that report, he explained:

> There are several that are high, cadmium, cesium, which is toxic because it's a heavy metal, it's radioactive, and barium is elevated, that's actually very toxic, and a lot of times it should be given even more credit for that. And then there's the presence of one, two, three, four, five, six, seven, eight, nine, ten other metals there that are also toxic substances simultaneously from one urine test. It shows he has toxicity when you compare it to what -- the possible ways you can get it and correlate it with his clinical state.

(Tr. at 1411)

344. To treat the heavy metal toxicity, Dr. DeMio said that he prescribed glutathione transdermal cream on July 12, 2010. He described it as a sulfur substance that helps with metal detoxification, adding that he initially prescribed a low dose of the transdermal cream, and later went up to an inhaled version of glutathione that was administered with a nebulizer. He said that this is still a low-risk treatment, but that it is more effective when

nebulized. Dr. DeMio referred to records in the chart where he documented medications utilized by earlier providers, pointing out that they had provided EDTA, DMPS, and DMSA as chelators before he began treating the patient. (Tr. at 125-126, 1412-1413; St. Ex. 9 at 87-89, 253)

345. Dr. DeMio continued to treat the heavy metal toxicity and, on September 30, 2011, he prescribed transdermal EDTA in the calcium disodium form based on lab results from June 7, 2011. (Tr. at 1413-1414; St. Ex. 9 at 76, 83, 214) The lab report for potentially toxic metals on that date shows the following results:

POTENTIALLY TOXIC ELEMENTS			
TOXIC ELEMENTS	RESULT µg/g	REFERENCE RANGE	PERCENTILE 95th 99th
Arsenic	0.004	< 0.010	
Cadmium	0.001	< 0.002	
Lead	0.027	< 0.050	
Mercury	0.001	< 0.010	
Thallium	< 0.0001	< 0.0005	

(St. Ex. 9 at 214)

346. Dr. DeMio testified on cross-examination that the EDTA cream he prescribed was to treat heavy metal toxicity in Patient 9, explaining, "It's to remove toxic heavy metals from the body, and it helps to distribute the good ones, too." (Tr. at 127) When he was pressed on cross-examination about whether everyone has trace elements of these metals in their body, Dr. DeMio maintained that that was not the case:

> Q. [By Mr. Wilcox:] Well, Doctor, wait a minute. You could run this test on anybody and they would show small levels of these elements, correct?
> A. No, that's not true, not everybody has them.
> Q. You're telling me not everybody has a small amount of le[a]d, mercury, and these elements tested for in the blood?
> A. That's what I'm telling you. * * *

(Tr. at 128)

When he was directed to some earlier test results that showed results that were within the "reference range," Dr. DeMio maintained that this patient still needed chelation to remove the toxic metals, explaining, "That's not normal; it's called reference." (Tr. at 129-130; St. Ex. 9 at 217)

347. On cross-examination, Dr. DeMio was asked what information led him to the determination that Patient 9 needed chelation therapy, and he offered the following:

> Q. [By Mr. Wilcox:] What about this patient made you come to that decision that this patient needed chelation therapy?

> A. That the entirety of his workup led to this being a phenomenon with these metals that has a likelihood to have the basis of leading to some or all of his symptoms, that there's a higher likelihood than the average child with the problems he had that treating these would help him.

(Tr. at 131)

348. Dr. DeMio testified that he did not recall Patient 9 being diagnosed with autism, but his mother reported that he was not talking at normal levels for a child his age, and she said that he had regressed in his communication skills after he got his vaccinations. He also acknowledged that the child had been evaluated for speech therapy and communication issues at a young age by his school district. When he was directed to that report, which the Assistant Attorney General suggested showed normal communication skills, Dr. DeMio disagreed, explaining that the report showed two different levels for his receptive and expressive language, which he said was abnormal. (Tr. at 132-134; St. Ex. 9 at 361)

349. Dr. DeMio referred to a subsequent heavy metals test from March 27, 2012, which he said showed that the chelation was working:

TOXIC METALS

		RESULT / UNIT	REFERENCE INTERVAL	PERCENTILE 95th	PERCENTILE 99th
Arsenic	(As)	0.005 µg/g	< 0.010		
Cadmium	(Cd)	0.001 µg/g	< 0.002		
Lead	(Pb)	0.023 µg/g	< 0.050		
Mercury	(Hg)	0.001 µg/g	< 0.010		
Thallium	(Tl)	< 0.0001 µg/g	< 0.0005		

(St. Ex. 9 at 199)

Referring to these results, Dr. DeMio explained:

> The lead has gone down, the arsenic has gone up, and the other two metals have stayed the same. And that's consistent with, and in this case it means that he has pulled out some lead and reduced it, and we're in the middle of pulling out arsenic out of his body, and the other two haven't gone down, and they are still coming up.

(Tr. at 1417)

Dr. DeMio also pointed to the results of urine testing for toxic metals, done six months later on September 3, 2012, which he said showed ten different metals that were being excreted from the patient's body in his urine. (Tr. at 1417-1418; St. Ex. 9 at 175)

350. Dr. DeMio further testified that the child improved intellectually and in his social skills as a result of this treatment, offering, "Intellectually he moved ahead. * ** [O]ne of the

parents said emotionally, their words, he was immature and whiny and got upset. So these things had all improved though with the EDTA." (Tr. at 1419)

351. At the hearing, Dr. DeMio presented a letter from Patient 9's parents, who wrote that they believed Dr. DeMio offered a biomedical approach to treat the underlying cause of their son's issues, instead of focusing only on his symptoms. They wrote that Dr. DeMio put into place a plan to address "the biomedical issues that formed the root of [their] son's diagnosis," and that he did blood, urine, and stool testing to determine his nutritional deficiencies and to identify the toxins that were not being eliminated from his body. (Resp. Ex. J-1 at 8) The parents wrote that they believed this approach helped their child's condition improve, and that he was at that time participating in a high school international baccalaureate program that had selective admissions. (Resp. Ex. J-1 at 7-8)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 9

352. Dr. Jackson testified that Dr. DeMio's care of Patient 9 fell below the standard of care because the patient was treated with chelation for heavy metal toxicity even though none of his lab reports showed that he had such a disorder. Dr. Jackson explained that chelation is sometimes warranted to remove heavy metals from the body, for example, in patients with sickle cell anemia who may have iron overload from frequent blood transfusions, or in patients with hemochromatosis, where heavy metals accumulate in certain organs. (Tr. at 541-544) He stated, "Those levels are easy to document, and there's certainly clinical information to support the toxicity and chelating therapy which requires an inpatient hospitalization to have that done." (Tr. at 543)

353. Dr. Jackson testified that some amounts of the heavy metals shown on the lab reports in this case are naturally present in the body, and do not represent anything abnormal:

> [T]oxicity is defined as those that are above a normal standard level of presence. So we all have iron in our body, we all have a measurable amount of mercury, as well as in lead, only because this is an environment that we're in. Treatment might only be indicated if there are symptoms and/or abnormal levels in the body.

(Tr. at 542)

354. Dr. Jackson testified that where toxicity is found, the primary intervention is to remove the patient from the source of the toxic metal. He explained, for example, that babies are screened for lead exposure at the age of 9-12 months because they could be exposed to lead water pipes or lead-based paint and that, in such cases, the appropriate action would be to remove that source of contamination from their environment rather than using chelation. (Tr. at 542-543, 546-547)

355. In Patient 8's case, however, Dr. Jackson firmly maintained that neither of the two tests for heavy metals showed any toxicity, as both the November 2012 test and the

December 2014 test showed levels that were within the reference ranges for each of the metals tested. (Tr. at 544-545; St. Ex. 9 at 131, 138) Dr. Jackson explained:

> [E]verything appears to be within a normal range. That being said, I'll point out a couple that we typically see chelating for, would probably be like lead and mercury. What this tells you is that there is the presence of those in the system, but they are not in any intoxicating levels that warrant any type of treatment. So that's what I would gain or gather from this particular testing. But all of these are all within normal limits.

(Tr. at 545)

Dr. Jackson rejected a suggestion in Dr. Goldfarb's report that Patient 8 had positive results showing toxic amounts of both lead and mercury, explaining, "[A]ll of those metals were present. The question is were they outside the range of being abnormal to be considered a toxicity." (Tr. at 551)

356. In this case, Dr. Jackson believed that Dr. DeMio used glutathione cream as a chelator to remove the heavy metals that he believed were present in Patient 8's body, as that medication was prescribed after the urine labs from 2012 and 2014. He stated that he believed Dr. DeMio used it as an antioxidant to help in a detoxifying process, as antioxidants can help metabolize those elements. However, Dr. Jackson said that he knew of nothing that proved it was effective to draw out toxic metals, and he maintained that it was not warranted here anyway. (Tr. at 547-552; St. Ex. 9 at 82)

357. Finally, Dr. Jackson noted that Patient 8 also suffered from a rash and noted that the use of glutathione over a period of years might have been a potential source for that. (Tr. at 552-554)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 9

358. Dr. Goldfarb disagreed with Dr. Jackson's testimony, explaining that he found many lab tests in the chart that did show heavy metal toxicity. Some of those tests were before 2012-2016, the relevant time period stated in the Notice. However, Dr. Goldfarb testified that the labs done in July 2012 and in September 2012 also showed evidence of heavy metal toxicity. Dr. DeMio said that compared to the tests done in 2010 and 2011 which showed the presence of barium, cadmium, cesium, lead, and mercury, the test done later in September 2016 showed only one element – nickel – that was outside the reference range, and that this lab demonstrated that there was a 50% reduction in lead and mercury in the patient's body, due to Dr. DeMio's use of EDTA, a chelating agent, in September 2011. (Tr. at 856-861; St. Ex. 9 at 175, 189, 201, 217, 220)

359. Dr. Goldfarb also testified that a urine screen was not necessarily a dispositive test to rule out the presence of heavy metals, because of the use of "provoking agents." (Tr. at 857)

He implied that any heavy metals that are present may not be apparent if the urine screen did not use a provoking agent:

> [I]n an unprovoked urine tox screen, which this is, the presence of heavy metals may very well be significant because we're not really measuring the full extent of what could be present in the body because it doesn't naturally come out. So the presence of any heavy metal can be significant, especially lead and mercury because those are the most toxic.

(Tr. at 858)

360. Dr. Goldfarb acknowledged that the patient's mother called on November 13, 2012 and reported that Patient 9 had a rash, but he said that was not an indication that the chelation should necessarily have been stopped. He said that rashes are relatively common, and that this patient had had them multiple times in the past. Dr. Goldfarb added that the family was communicating with Dr. DeMio about the rash so that he could monitor the patient for it. Dr. Goldfarb noted that in a May 30, 2013 note, Dr. DeMio wrote that the patient's mother had commented how much better the patient was doing since he had been in Dr. DeMio's program. (Tr. at 861-863; St. Ex. 9 at 302, 315) In this case, he concluded, "[I]t's reasonable to continue using a medication that is beneficial despite a side effect." (Tr. at 382)

Patient 10 (DP).

361. Patient 10 is a female born in 1997 from Medina, Ohio. She was almost 17 years old when Dr. DeMio was first consulted for her care in February 2014. Her mother wrote on the intake form that they learned of Dr. DeMio's practice through the Igenix lab. She signed the disclaimer acknowledging that Dr. DeMio was not an in-network provider with any insurer, and paid $738 for Patient 10's first visit on February 24, 2014. (St. Ex. 10 at 1-7)

362. Dr. DeMio recalled that Patient 10 came to him for treatment of Lyme disease, relating that she had had a positive test for it, and her parents thought that Lyme disease could be the cause of the symptoms she was having. Dr. DeMio ordered tests for "LADs," Lyme-associated diseases" spread by ticks and bugs, but acknowledged that he did not order a test specifically to detect Lyme disease at that time. On September 16, 2014, he wrote a school excuse note, explaining Patient 10 was being treated for chronic Lyme disease, and that because the disease and the treatment are very hard on the patient, he was requesting time for her to go home to rest during part of the school day. (Tr. at 136-137; St. Ex. 10 at 212, 347)

363. Dr. DeMio testified that he prescribed Malarone, an anti-parasitic drug, for Patient 10 to treat Babesia and toxoplasma, both parasitic diseases. He further testified that he did not prescribe it to treat malaria. (Tr. at 138-139, 1429-1430; St. Ex. 10 at 96) Dr. DeMio conceded on cross-examination that Patient 10 did not have a laboratory diagnosis of a

parasitic infection, but he said that he treated her for the condition anyway, because he believed that was the cause of her symptoms, and he wanted to do a trial of the medication for it to see if it would help. (Tr. at 139) He gave the following explanation on cross-examination:

> Q. [By Mr. Wilcox:] How did you confirm that she had that toxoplasma?
> A. So I think in her case – and I can look in more detail, but just to be as efficient as possible, I think in her case the parasitic treatment was empirical. Plus I saw some eye findings that were suggestive of toxoplasmosis as well. And many of our patients have those that are otherwise not detected by other means.
> Q. You said -- you started your answer off with it's empirical?
> A. I did say that, yes.
> Q. Explain that to us, what you mean by that.
> A. That the physician, and me in this case, was highly suspect or convinced that that's what the patient has, and they needed a trial of treatment for that, that it's reasonable in the process of doing the treatment.
> Q. So you suspected this may be a parasitic infection, but you didn't have evidence that it was in a positive blood test, but you treated it with this medication, the antiparasitic, is that what --
> A. I think that's -- that was the case. I mean, like I say, I can look further in the chart and go into the detail. I think that was the way we did that in this case, yes.

(Tr. at 140-141)

364. Dr. DeMio pointed to the lab report from a test for B. burgdorferi that the patient had had in January 2014, just before he began seeing her. When the Assistant Attorney General pressed Dr. DeMio on cross-examination about whether this test showed a negative result, he maintained that it showed an "equivocal" result, and that this test helped convince him that Patient 10 needed to be treated for Lyme disease. (Tr. at 145-147; St. Ex. 10 at 362) The lab report of that test is shown below:

TEST NAME	RESULT	UNITS
IFA, B BURGDORFERI G/M/A	40	

REVISED 1/11/11

The Lyme Immunofluorescence Assay (IFA) detects antibodies (IgG, IgM, IgA) against B. burgdorferi. Seroconversion usually occurs 2-3 weeks after infection and may remain elevated in case of persistent disease. Cross-reactions with other Borrelia and other spirochetes occur. A positive or equivocal result is preliminary and should be confirmed with IgG and IgM Western blot.

INTERPRETATION (TITER):

<40	NEGATIVE
40	EQUIVOCAL
= OR >80	POSITIVE

(St. Ex. 10 at 362; poor quality original)

365. Dr. DeMio explained that it was primarily changes in Patient 10's lifestyle that led him to believe she needed treatment for Lyme disease:

> She had a sudden change in her life from being an extremely successful student and gymnast and highly achieved in every aspect of life, and she just fell into marked fatigue, very severe loss of cognitive function. She had been just a highly achieved student. Joint aches. These were all new onsets. Hormonal dysfunction, and inability to physically and cognitively make it through the day even, is what they told me. Struggling in life. I mean, her quality of life was poor and she just couldn't function through school and just daily life. She ended up giving up all of her sports that she was doing.

(Tr. at 148)

366. Dr. DeMio testified that he believed Patient 10 had a parasitic infection from protozoans, one-celled parasites, that are very hard to detect on lab tests. He explained that many patients who are bitten by ticks get these infections, particularly Babesia and toxoplasma, and he said that those infections can cause the symptoms that Patient 10 was having. (Tr. at 1429-1430)

367. As evidence that his diagnosis was correct, Dr. DeMio pointed to his March 31, 2014 office visit note, in which the patient reported improvement in her joint pain. (Tr. at 1430-1431; St. Ex. 10 at 224-225) He explained:

> So we had given her treatment for lyme, which is bacterial, and that had improved. And so my diagnosis was lyme and associated diseases, which includes some bacterial diseases, and those things had improved to some degree, the joints. And then -- so some of the remaining disorders that are very commonly present in the patients are the co-infections, and they include the parasites.

(Tr. at 1431)

368. Dr. DeMio also prescribed Valtrex to treat the herpes virus HHV-6 in Patient 10. Referring to the lab results from February 26, 2014, Dr. DeMio said that this test showed a very high HHV-6 result, adding, "I rarely would see it that high. And I see a lot of these test results are positive, and so this is a very high one of HHV-6 IgG positive." (Tr. at 1431-1433; St. Ex. 10 at 182, 226) The result is shown below, along with the interpretive information stating that a result higher than 1.11 indicates a positive IgG antibody to HHV-6, which may indicate a current or past infection:

Herpesvirus 6 IgG Ab H 14.71
Reference range: <=0.89
Unit: IV
(NOTE)
INTERPRETIVE INFORMATION: Herpesvirus 6 (HHV-6) Ab, IgG

0.89 IV or less ..... Negative: No significant level of detectable HHV-6 IgG antibody.
0.90 - 1.10 IV ..... Equivocal: Questionable presence of HHV-6 IgG antibody. Repeat testing in 10-14 days may be helpful.
1.11 IV or greater .. Positive: IgG antibody to HHV-6 detected, which may indicate current or past infection.

(St. Ex. 10 at 182)

369. Dr. DeMio also treated Patient 10 for anxiety. Referring to his notes in the patient's chart, Dr. DeMio recounted that he received a call from the patient's mom on August 18, 2014, who asked if Patient 10 could use Ativan for anxiety, because the anxiety was interrupting her mornings. He testified that he did not prescribe Ativan for Patient 10, but that he prescribed Buspar 30 mg., a mild, non-controlled medication, for her instead. He said that Buspar is very effective at controlling anxiety, and yet it is non-addictive and has no black box warning, so it is a safer medication. Although Dr. DeMio said that he discussed the risks and benefits of that medication with the patient, he said that he did not document that discussion in her chart. (Tr. at 1433-1438; St. Ex. 10 at 247-249)

370. Dr. DeMio explained that Patient 10 had been taking an herbal supplement, Larix, as well as herbal supplemental silver, and he explained that he directed the patient to stop taking those, because they could have been contributing to her anxiety. (Tr. at 1434-1435) He testified, "Sometimes those will kill germs and cause – and cause an upheaval of release of things that are toxic that cause people to get anxiety." (Tr. at 1435)

371. Responding to criticism about prescribing an anxiety medication on the basis of a telephone call from the patient's mother, Dr. DeMio maintained that it was appropriate in this case, because the mother had been to all of Patient 10's appointments, and he knew her very well, as he also knew the patient:

> She knows the patient, I know the patient, and she reported completely all the different symptoms. * * * we described characteristics of the anxiety on page 247, and we had a discussion about the issue medically and about the options for treatments, and the risks and benefits. And it's very complete, it's very safe, so I think it's good care and it's above the standard of care, frankly. It's a patient I know very well.

(Tr. at 1439-1440)

372. Dr. DeMio emphasized that Patient 10's anxiety was not a chronic issue but was episodic, and was not severe enough to require hospitalization. (Tr. at 1440-1441) He stated that

he prescribed the Buspar for occasional issues with anxiety and sleep interruption, and he added that he monitored her in follow-up, recalling, "I don't think she ever ended up using it." (Tr. at 1441) Dr. DeMio explained that he did not believe it was necessary to refer Patient 10 to a mental health professional for an evaluation because her mom already had a psychologist for her that she could go to for counseling. (Tr. at 1440-1441)

373. Similarly, Dr. DeMio testified that he did not believe he should have referred Patient 10 for a pelvic exam, in connection with his prescribing of Valtrex and his treatment of any hormonal issues. He said that he does not have the equipment and supplies at his office to do a pelvic exam, and that he did not believe she needed to be seen by a gynecologist at that time for her symptoms. (Tr. at 1443-1444) He related, "I really strongly disagree with that. * * * [T]hat would be like the three year old with diarrhea getting a rectal exam." (Tr. at 1443-1444) However, he drew attention to a note about his referral of Patient 10 at a later time on June 30, 2016 to Dr. Leah Adkins, a gynecologist in Columbus, where she made an appointment to be seen for an exam, and communications from Dr. Adkins's staff about the referral. (Tr. at 1444-1445; St. Ex. 10 at 29, 337)

374. Dr. DeMio also identified letters by Patient 10 and her mother, which were admitted into evidence. In one letter, Patient 10 wrote that when she was a junior in high school, she became so sick that she had to drop out of sports. Her family consulted various doctors, including an infectious disease specialist, who suggested that there was nothing physically wrong, and that she might simply be depressed. The patient wrote that she had to travel in order to find a "Lyme literate doctor." She said that under Dr. DeMio's care, her symptoms improved and she was at that time a college student, but that without Dr. DeMio, she did not believe she would have been able to finish high school. The patient credited Dr. DeMio with saving her life. (Resp. Ex. J-1 at 17)

375. Patient 10's mother wrote that her daughter was diagnosed with Lyme disease in 2014 by the Igenix lab test, and that she was treated by Dr. DeMio, whom she described as an expert in the treatment of Lyme disease. The patient's mother wrote that they had no idea the patient had Lyme disease because they had never seen a tick or a tick bite on her. (Resp. Ex. J-1 at 18-20) She concluded that her daughter's health had greatly improved since she began seeing Dr. DeMio, and she offered, "I can't say enough about the positive changes in my daughter's health. Just look at her lab results and see her numbers, there is no guesswork involved just scientific data." (Resp. Ex. J-1 at 20)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 10

376. Dr. Jackson disagreed in his report with Dr. DeMio's treatment of Patient 10 for a thyroid disorder and Lyme disease because there was a lack of documentation to support those diagnoses. With respect to Lyme disease, Dr. Jackson's report noted that her Lyme titers (IgG) Western blot testing on January 14, 2014 was negative/normal, and the Borrelia burgdorferi ABS titers documented on February 27, 2014 were negative. Similarly, he noted that the patient's thyroid studies on April 10, 2014, July 1, 2014, and August 14, 2014 were normal. Dr. Jackson's testimony at the hearing focused on his view that

Dr. DeMio inappropriately diagnosed and treated a mental health disorder in this case. (Tr. at 557; St. Ex. 19 at 8-9)

377. Dr. Jackson identified the progress note of an August 18, 2014 telephone call from Patient 10's mother as the first time Dr. DeMio made the diagnosis of anxiety, and he emphasized that the diagnosis was made in a non-face to face encounter, with symptoms described over the phone by the parent. Although there was evidence presented by other witnesses that Dr. DeMio did not make a true diagnosis of anxiety, Dr. Jackson maintained that in the note of that telephone call, Dr. DeMio used the ICD diagnosis code 308.0, which corresponds to Anxiety Disorder. However, he said there was a difference between feeling anxious on a certain day and having an actual anxiety disorder. (Tr. at 558-559; St. Ex. 10 at 11, 247; Resp. Ex. C at 29)

378. Dr. Jackson testified that after diagnosing Anxiety Disorder over the telephone, Dr. DeMio prescribed Buspar, an anti-psychotic, to manage it. He stated that Buspar is not a first-line treatment for anxiety or depression, because most anti-psychotics carry a black box warning that they can cause a patient to have suicidal ideations and that they need to be used judiciously. In this case, Dr. Jackson testified that there was nothing in the chart to show that Dr. DeMio warned the patient's mom about this possible effect. He concluded that there was not an appropriate work-up here to support the prescribing of Buspar for Patient 10. (Tr. at 560-563; St. Ex. 10 at 83)

379. In addition, Dr. Jackson testified that Patient 10, a teenager, was old enough to answer questions about her condition, and that a mental status exam was warranted to determine if medication was needed or if counseling might have been a better option than medication. He stated that the literature supports the use of counseling as an intervention for anxiety, but that in Patient 10's case, there was no referral to a behavioral health specialist. He noted that the patient's mother called about a year later, on June 15, 2015, relating that the patient had extreme anxiety and could not sleep, so the condition had either worsened or resurfaced. (Tr. at 562-566; St. Ex. 10 at 280) In either case, Dr. Jackson said that there should have been a referral to a mental health treatment provider, explaining, "[W]hen you start getting extreme cases you have to say what we're doing is not working, you need to find the most available specialist or counselor to go beyond your scope of management." (Tr. at 566)

380. In his report, Dr. Jackson stated that, in his opinion, Dr. DeMio's care of Patient 10 fell below the minimal standard of care, and that Dr. DeMio failed to employ acceptable scientific methods in the selection of drugs or other modalities for the treatment of disease. (St. Ex. 19 at 9)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 10

381. Dr. Goldfarb testified that Patient 10 came to Dr. DeMio with a diagnosis of Lyme disease, and he primarily treated her for that disorder and its co-infections, but that he also gave her thyroid replacement, nutritional support, and treatment for sleep and

anxiety issues. Referring to the lab report of January 14, 2014 from another provider's office, Dr. Goldfarb testified that this report was indicative of the Lyme disease diagnosis. (Tr. at 863-864; St. Ex. 10 at 364) Although he testified that the CDC requires five positive bands in the test results, this particular test was from the Igenix lab which uses different criteria. Under those criteria, he said that "only one double starred band for intermediate double starred bands in a negative report may indicate clinical significance." (Tr. at 565)

382. With respect to Dr. DeMio's diagnosis of an anxiety disorder, Dr. Goldfarb contended that he did not see anywhere in the patient's chart where Dr. DeMio made an actual diagnosis of an anxiety disorder. He explained that there is a difference between anxiety disorder that is an extreme condition that persists over a long period of time, and this patient's two isolated incidents of anxiety. Dr. Goldfarb believed that this patient's chart does not indicate an anxiety disorder. Because there was no indication in this case that Patient 10 had a prolonged state of anxiety, he opined that it was not necessary for her to be referred for a mental health assessment. He added that many people suffer from anxiety, but that does not mean that every time someone is anxious, that person needs to be sent for a mental health assessment. (Tr. at 866-867)

383. Dr. Goldfarb had no disagreement with Dr. DeMio's decision to prescribe Buspar for Patient 10. He explained that he found this appropriate, because of Dr. DeMio's expertise and because Buspar is not a controlled substance. (Tr. at 867-868) He offered the following testimony, comparing prescribing Buspar instead of a mental health referral to recommending OTC ibuprofen instead of ordering a CT scan:

> [Buspar] can help relieve anxiety on an acute basis, and it's certainly a reasonable thing to give someone something to help calm them and help them sleep, and see if this is an ongoing problem. I don't think it would be much different than a parent called and said my child has a headache. That does not warrant a CT scan or a neurologic evaluation necessarily. You can try some Tylenol or Motrin or some other medication and see a response, and then if it's persistent, then follow up.

(Tr. at 868)

384. Dr. Goldfarb also agreed that Dr. DeMio was justified in prescribing Buspar based on the information relayed to him over the telephone by Patient 10's mother. He explained that Dr. DeMio saw Patient 10 often – roughly 30 times in 2 ½ years – so he knew her very well by the time he prescribed this medication. He also pointed out that the patient had been seen in his office shortly before this phone call, and was seen again relatively soon after it. Under those circumstances, he testified that it was reasonable for Dr. DeMio to prescribe Buspar. (Tr. at 868-869)

385. Similarly, Dr. Goldfarb testified that Dr. DeMio's prescription of Vitamin B-12 shots was a reasonable choice, because anything affecting the neurological system can be affected

by a patient's B-12, and it is a cofactor in multiple metabolic reactions, including depression and anxiety. He said that Vitamin B-12 is a water-soluble vitamin, and he had never heard of anyone having toxicity from it. (Tr. at 871-873; St. Ex. 10 at 335) Dr. Goldfarb concluded, "It's extremely safe, it's over-the-counter, and basically I'd say there's no risk to it." (Tr. at 873) Even though he conceded that this particular Vitamin B-12 order was prescribed by injection, he said that it was still very safe for her, given her history. (Tr. at 873)

386. Finally, Dr. Goldfarb agreed with Dr. DeMio's treatment of a hormonal imbalance in Patient 10, a girl who was about 17 years old. Although he was presented with Dr. Jackson's opinion that her thyroid levels were normal, Dr. Goldfarb maintained that thyroid studies are only one aspect of evaluating a patient's thyroid status, and that Patient 10's history showed other signs of thyroid disorder, including menstrual irregularities, which he said are often associated with low thyroid levels. He testified that when thyroid studies are the only tool used to evaluate a patient's thyroid status, thyroid disorders are undertreated. In addition, Dr. Goldfarb said that he did not believe a referral for a pelvic exam was necessary in Patient 10's case because he said menstrual irregularities are fairly common in young women, and that would not warrant subjecting her to an invasive and potentially traumatic pelvic exam. (Tr. at 869-870)

Patient 11 (HR)

387. Patient 11 is a male from Louisville, Kentucky, who was born in 2010. He was 3 ½ years old when his parents first sought treatment with Dr. DeMio in March 2014. His mother wrote on the intake form that she became aware of Dr. DeMio's practice through "Mother Warriors by Jenny McCarthy." (St. Ex. 11 at 1-2)

388. Dr. DeMio recalled that Patient 11 had been diagnosed with ASD, and his parents wanted him evaluated for possible medical treatment to remediate his autism symptoms. (Tr. at 148-149; St. Ex. 11) Dr. DeMio testified that he wrote in his initial progress note that he may want to "detox later," meaning that he wanted to "remind [him]self that this patient had a vaccine associated regression." (Tr. at 149; St. Ex. 11 at 214)

389. On cross-examination, Dr. DeMio elaborated that he was considering detoxification from the reaction he believed this patient was having to a vaccine:

> Q. Detoxification from what?
> A. Reactions in the body associated with vaccines, adverse type of a -- a shift in the body that we see in some kids who get sick after they have a vaccination.
> Q. And what are you detoxifying the child for, what agents?
> A. It includes the entire response that people can have to a toxin that has a toxin effect in the body, and metals are one, and there's a host of a toxicity to the immune system, to the GI tract, to the neurochemistry in the brain, the way the brain communicates and regulates itself and functions, and to

> the basic cell function. So there's a host of things we do that's part of detoxification, a conglomerate of things.

(Tr. at 149-150)

390. Dr. DeMio testified that he prescribed oxytocin nasal spray for Patient 11 to improve his coping abilities and help his brain function, through its neurotransmitter effects. He conceded that oxytocin is not FDA-approved for this use, but he explained that it was an off-label use for it. Later in his testimony on direct exam, Dr. DeMio said that Patient 11 had developed encephalopathy, a pathology of the brain that was clinically apparent. (Tr. at 150-151, 1448-1449; St. Ex. 11 at 62) On cross-examination, Dr. DeMio was asked if he knew of any studies that supported the use of oxytocin for this purpose in children:

> Q. [By Mr. Wilcox:] And you're prescribing this off label to a three year old child again for what purpose?
> A. It's to help his brain chemistry become more normal like it should be. * * * And for that to make him healthier, to make things better for him; quality of life, physical health, those kind of things.
> Q. And what clinical evidence is there that oxytocin is used to help brain development in three year old children?
> A. There is evidence in the basic science literature, and there's also clinical work that has been done. And then there's the work of those of us who come together at the national conferences and present these types of things, and those are the things that are part of the basis for knowing that that has potential help.
> Q. Any double blind studies, scientific studies, show oxytocin is beneficial to a three year old for this purpose, or is it just anecdotal evidence?
> A. I don't know if there's been a double blind study in three year olds, there may be. And I've seen studies about this over the years, probably many years, so there's work that this has been used for patients in a setting virtually identical to this with success. A drug company, for example, was looking at this, and they stopped their study and I don't think -- I guess they didn't want to put more money into it or whatever. So I think the market was small.

(Tr. at 151-152)

391. Later on direct exam by his counsel, Dr. DeMio stated that a drug company had done studies that showed promising improvements with the use of oxytocin for this purpose, though he could not remember the name of the company. (Tr. at 1449-1450) He suggested that the study was later dropped, offering, "I think they gave it up at the end because it didn't have enough of a broad population and enough improvement that I don't think they were going to pursue it for that reason." (Tr. at 1450)

392. Dr. DeMio testified that oxytocin is naturally produced by the pituitary gland, and that it is primarily used in obstetrics to augment labor and help deliver a baby. (Tr. at 151) He added that it has a calming effect on people, and helps them feel more connected to others, helping them feel "more brotherly love" so that they don't self-isolate, as kids with ASD tend to do. (Tr. at 1450-1452) In the case of Patient 11, he explained that he prescribed it to calm the patient and reduce upset and uncontrolled behavior: "[M]any of our children with autism have low levels of that substance. * * * [G]iving oxytocin helps a lot of those people to gain that control." (Tr. at 1451)

393. Dr. DeMio also provided chelation therapy for Patient 11 for removal of heavy metals. However, he agreed on cross-examination that the results of urine screens done on April 27, 2014 and November 5, 2014 showed results that were all within normal limits. (Tr. at 152; St. Ex. 11 at 177, 185) He nonetheless would not agree that those screens did not indicate heavy metal toxicity. (Tr. at 153)

394. Dr. DeMio testified that he prescribed Nystatin, a gentle anti-fungal medication, to treat candida parapsilosis or "yeast" found in a stool analysis done on April 27, 2014. He explained that there is a gut/brain connection and treating yeast in many of his pediatric patients can help with mood and behavioral issues. He also advised the parents to change the child's diet to a low-carb and low-sugar one, and to use probiotics. (Tr. at 153-154, 1454-1456; St. Ex. 11 at 162-167)

395. Finally, Dr. DeMio testified that he prescribed mebendazole, which he described as a "parasite killing drug for the worm – the larvae, the worm-like parasites" that he believed Patient 11 had. (Tr. at 153) He agreed that the stool analysis did not show a parasitic infection, and he did not identify any other lab test that did show one. (Tr. at 154-157; St. Ex. 11 at 162) Later in his testimony, on direct exam by his own counsel, Dr. DeMio gave the following explanation for why he prescribed mebendazole to Patient 11:

> Mebendazole is antiparasitic, and so it's for parasites. Many of our kids will respond to that. I'm happy to look back at notes and things to see if there's something more specific, but many of our kids empirically, with a broadly dysfunctioning GI tract, which is just exactly what this test shows, the hardest germs to detect on this test are parasites.
>
> They look for two parasites on this test, and there are a variety of parasites that they look for, and those two parasites are not present, and that's good. You look under the microscope to see if there's a large number of easily seen parasites. But other parasites, mostly in the multicellular category, they are not protozoans, different than what they tested for, respond to Mebendazole.

(1457-1458)

396. Dr. DeMio testified that Patient 11's condition improved under his care, and he called attention to the notes of his June 3, 2016 office visit with this patient, in which his parents reported that he had become toilet-trained and was able to write sentences and go to the grocery store without "melt-downs." He related that they told him the child had graduated from the use of a stroller, and that he had seen a movie and wanted to see another one, though he still had a few issues with light and sounds. (Tr. at 1458-1460; St. Ex. 11 at 274-278)

397. Dr. DeMio also identified a letter written by Patient 11's mother, a high school science teacher, in which she described her child's improvements under Dr. DeMio's care. She wrote that Dr. DeMio had treated their family with the utmost respect and had given her son the best care of any physician she had ever known. She wrote that she had a bachelor's degree in molecular biology and chemistry, as well as a master's degree in physics education, and that her husband had a bachelor's degree in biochemistry, so they understood much of the biological information presented to them through Dr. DeMio's treatment. The mother wrote that her son was initially diagnosed with autism savant syndrome, and that he was developing a love of music and reading and was taking swimming lessons. However, she wrote that, after he was evaluated by a team of nine medical professionals at Nationwide Children's Hospital, they were told that he would never be potty-trained and would likely have to live in a group home. (Tr. at 1460-1461; Resp. Ex. J-1 at 10-14)

398. Unwilling to accept that assessment, Patient 11's mother wrote that she joined a parents' group and began learning about autism-specific physicians. By the time they waited for an appointment, her son's condition had worsened. On the day they first saw Dr. DeMio, the mother related that her son had bitten someone in his social group and had urinated through his clothes. She wrote that Dr. DeMio was the first doctor who ever was willing to listen to her son's entire story, and that after the appointment, she felt hopeful for the first time. (Resp. Ex. J-1 at 10-14)

399. Patient 11's mother wrote that, under Dr. DeMio's care, her son's growth and development seemed to improve. She related that Dr. DeMio was the first to give them a prognosis that was not all "doom and gloom," and that the family quit the ABA therapy that they had begun because it was only making her son untrusting of adults and preventing him from learning new skills. The parent wrote, "The biggest hurdle was H.R.'s heavy metal load," relating that Dr. DeMio used a transdermal form of DMSA and that with this agent, "chelation turned out to be a miracle." (Resp. Ex. J-1 at 12) She wrote that her child began writing letters and telling stories, and that he became potty-trained. His sensory issues were not as inhibiting, and his eye contact improved. Dr. DeMio then introduced them to HBOT, which she wrote, "could help [Patient 11] grow capillaries to deliver the other therapies into deeper tissues." (Resp. Ex. J-1 at 13)

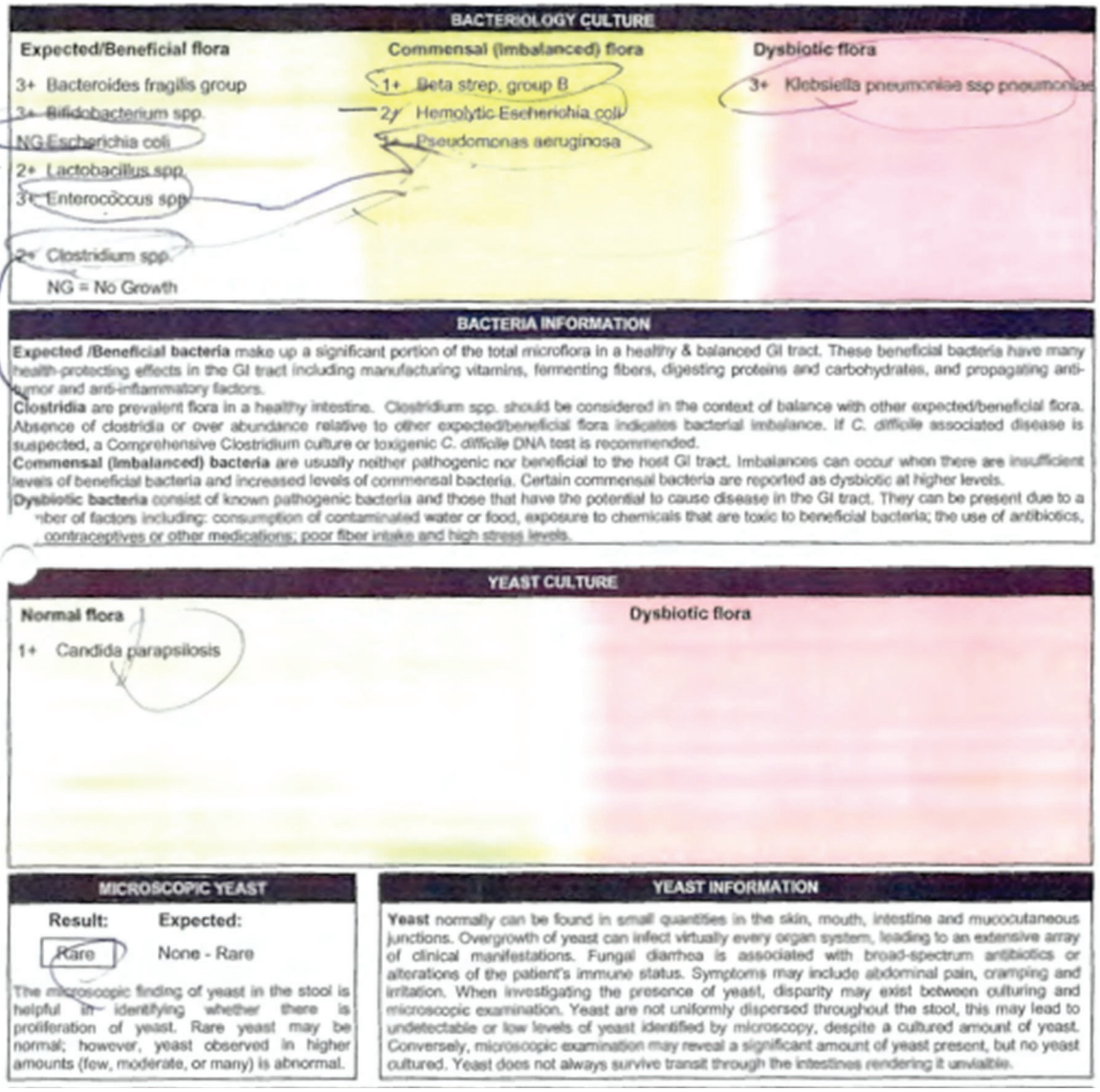
400. The patient's mother wrote that, by the time of her letter, her son was making friends in their homeschool group, was fully independent in hygiene and dressing, and had learned to ride a bike. She added that he had become an accomplished pianist and loved musical

theatre, and that he was in a 6th grade level or higher in every subject. The mother wrote that none of this would have been possible without Dr. DeMio's care, and she believes her son was living up to his potential because of the early medical interventions of Dr. DeMio. (Resp. Ex. J-1 at 13)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 11

401. Although Dr. Jackson's expert report also took issue with Dr. DeMio's treatment of heavy metal toxicity in Patient 11, his testimony primarily focused on his disagreement with Dr. DeMio's treatment of Patient 11 with Nystatin, Anfluterison B, and mebendazole. He stated that those medications were prescribed to treat nutritional mineral deficiencies, candida infections, and immune deficiency. (Tr. at 568-569; St. Ex. 19 at 10)

402. Referring to the results of an April 27, 2014 stool analysis which was presented as the evidence supporting the prescribing of those medications, Dr. Jackson testified that many of the things identified on this report indicated normal conditions that did not require treatment in this 3-year old boy:



BACTERIOLOGY CULTURE

Expected/Beneficial flora	Commensal (imbalanced) flora	Dysbiotic flora
3+ Bacteroides fragilis group	1+ Beta strep, group B	3+ Klebsiella pneumoniae ssp pneumoniae
3+ Bifidobacterium spp.	2+ Hemolytic Escherichia coli	
NG Escherichia coli	2+ Pseudomonas aeruginosa	
2+ Lactobacillus spp.		
3+ Enterococcus spp.		
2+ Clostridium spp.		

NG = No Growth

BACTERIA INFORMATION

Expected /Beneficial bacteria make up a significant portion of the total microflora in a healthy & balanced GI tract. These beneficial bacteria have many health-protecting effects in the GI tract including manufacturing vitamins, fermenting fibers, digesting proteins and carbohydrates, and propagating anti-tumor and anti-inflammatory factors.
Clostridia are prevalent flora in a healthy intestine. Clostridium spp. should be considered in the context of balance with other expected/beneficial flora. Absence of clostridia or over abundance relative to other expected/beneficial flora indicates bacterial imbalance. If *C. difficile* associated disease is suspected, a Comprehensive Clostridium culture or toxigenic *C. difficile* DNA test is recommended.
Commensal (imbalanced) bacteria are usually neither pathogenic nor beneficial to the host GI tract. Imbalances can occur when there are insufficient levels of beneficial bacteria and increased levels of commensal bacteria. Certain commensal bacteria are reported as dysbiotic at higher levels.
Dysbiotic bacteria consist of known pathogenic bacteria and those that have the potential to cause disease in the GI tract. They can be present due to a number of factors including: consumption of contaminated water or food, exposure to chemicals that are toxic to beneficial bacteria; the use of antibiotics, contraceptives or other medications; poor fiber intake and high stress levels.

YEAST CULTURE

Normal flora	Dysbiotic flora
1+ Candida parapsilosis	

MICROSCOPIC YEAST

Result:	Expected:
Rare	None - Rare

The microscopic finding of yeast in the stool is helpful in identifying whether there is proliferation of yeast. Rare yeast may be normal; however, yeast observed in higher amounts (few, moderate, or many) is abnormal.

YEAST INFORMATION

Yeast normally can be found in small quantities in the skin, mouth, intestine and mucocutaneous junctions. Overgrowth of yeast can infect virtually every organ system, leading to an extensive array of clinical manifestations. Fungal diarrhea is associated with broad-spectrum antibiotics or alterations of the patient's immune status. Symptoms may include abdominal pain, cramping and irritation. When investigating the presence of yeast, disparity may exist between culturing and microscopic examination. Yeast are not uniformly dispersed throughout the stool, this may lead to undetectable or low levels of yeast identified by microscopy, despite a cultured amount of yeast. Conversely, microscopic examination may reveal a significant amount of yeast present, but no yeast cultured. Yeast does not always survive transit through the intestines rendering it unviable.

(St. Ex. 11 at 162)

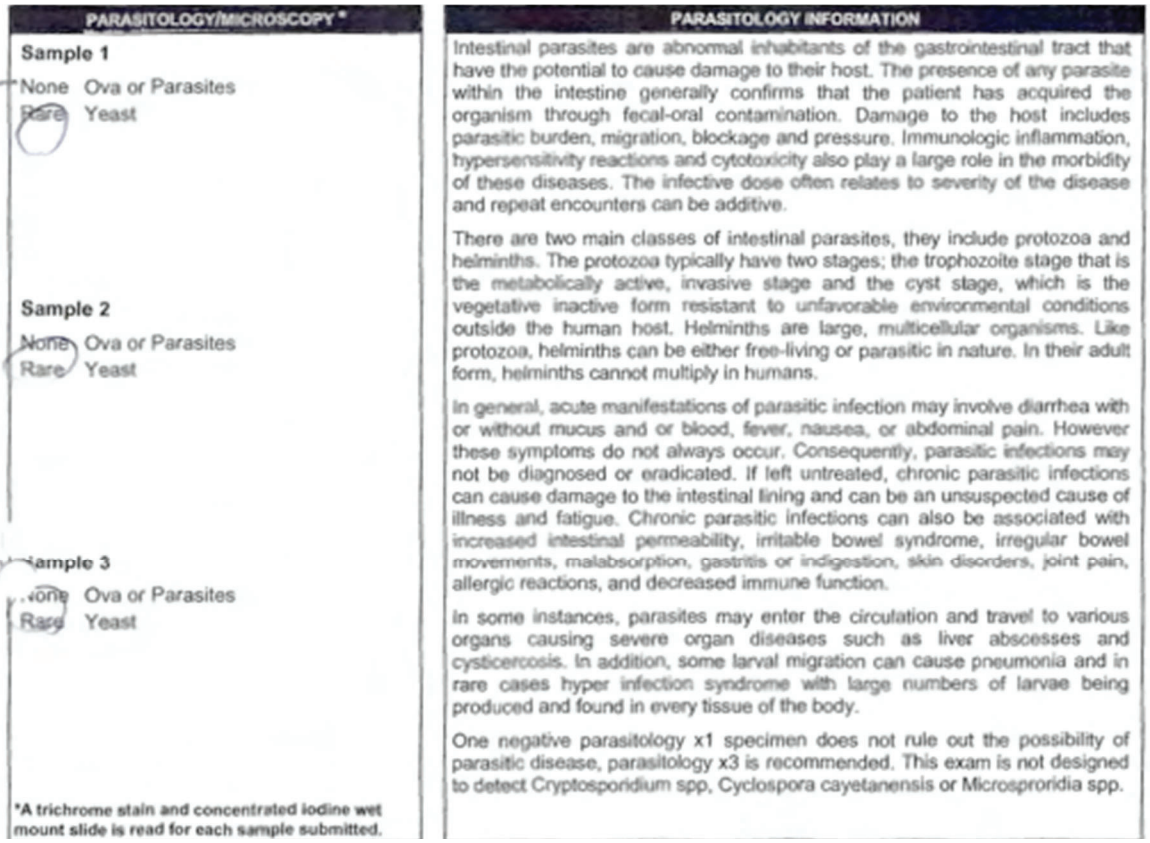
403. Moreover, Dr. Jackson testified that none of the medications Dr. DeMio prescribed are generally used to treat any of the conditions that he diagnosed in Patient 11:

> Q. [By Ms. Snyder:] * * * Does this stool analysis support Dr. DeMio's use of Nystatin, Anfluterison B, or Mebendazole?
> A. None of those are considered appropriate treatments for any of those items that are listed. Now, I would only mention that in that if you go down on the list of the yeast culture, that candida is a fungus -- or I should say is a yeast infection, that's considered normal flora.
> And there is nothing else that would suggest the indication for Anfluterison B, which is used in most cases for systemic fungal infections.

> In my experience we have used this with patients in the hospital, particularly those who have peritoneal dialysis and systemic fungal infections are those who are on chemotherapy who are immunocompromised who might require this usually in the form of IV use. So that's a far fetch for using something for a normal yeast infection. Nystatin can be used in indications if this is an overgrowth beyond what is considered normal flora. So Nystatin might be appropriate, but there's nothing in the history that suggests that there was any type of fungal infection that required Nystatin, much less Anfluterison B. Mebendazole is typically used for treatment of like pin worms. I have nothing to suggest that there is a history of pin worms, much less anal itching, pruritus, or anything -- testing that would suggest the presence of intestinal worms to require the use of that medication.

(Tr. at 569-570)

404. Dr. Jackson also pointed out that, while mebendazole could be used to treat a parasitic infection, the second page of the stool analysis report specifically showed the *absence* of any parasites in this patient:



PARASITOLOGY/MICROSCOPY*

Sample 1

None Ova or Parasites
Rare Yeast

Sample 2

None Ova or Parasites
Rare Yeast

Sample 3

None Ova or Parasites
Rare Yeast

*A trichrome stain and concentrated iodine wet mount slide is read for each sample submitted.

PARASITOLOGY INFORMATION

Intestinal parasites are abnormal inhabitants of the gastrointestinal tract that have the potential to cause damage to their host. The presence of any parasite within the intestine generally confirms that the patient has acquired the organism through fecal-oral contamination. Damage to the host includes parasitic burden, migration, blockage and pressure. Immunologic inflammation, hypersensitivity reactions and cytotoxicity also play a large role in the morbidity of these diseases. The infective dose often relates to severity of the disease and repeat encounters can be additive.

There are two main classes of intestinal parasites, they include protozoa and helminths. The protozoa typically have two stages; the trophozoite stage that is the metabolically active, invasive stage and the cyst stage, which is the vegetative inactive form resistant to unfavorable environmental conditions outside the human host. Helminths are large, multicellular organisms. Like protozoa, helminths can be either free-living or parasitic in nature. In their adult form, helminths cannot multiply in humans.

In general, acute manifestations of parasitic infection may involve diarrhea with or without mucus and or blood, fever, nausea, or abdominal pain. However these symptoms do not always occur. Consequently, parasitic infections may not be diagnosed or eradicated. If left untreated, chronic parasitic infections can cause damage to the intestinal lining and can be an unsuspected cause of illness and fatigue. Chronic parasitic infections can also be associated with increased intestinal permeability, irritable bowel syndrome, irregular bowel movements, malabsorption, gastritis or indigestion, skin disorders, joint pain, allergic reactions, and decreased immune function.

In some instances, parasites may enter the circulation and travel to various organs causing severe organ diseases such as liver abscesses and cysticercosis. In addition, some larval migration can cause pneumonia and in rare cases hyper infection syndrome with large numbers of larvae being produced and found in every tissue of the body.

One negative parasitology x1 specimen does not rule out the possibility of parasitic disease, parasitology x3 is recommended. This exam is not designed to detect Cryptosporidium spp, Cyclospora cayetanensis or Microsproridia spp.

(St. Ex. 11 at 163)

405. Dr. Jackson also disagreed with Dr. DeMio's decision to prescribe oxytocin nasal spray for Patient 11 for the same reasons that he previously described in his testimony related to other patients. (Tr. at 571) He said that in certain populations, oxytocin may act as a mood stabilizer, but he maintained, "[O]xytocin has no indication in the pediatric population." (Tr. at 372)

406. Dr. Jackson opined that Dr. DeMio's care of Patient 11 fell below the minimal standard of care, and that he failed to employ acceptable scientific methods in the selection of drugs or other modalities for the treatment of disease. (St. Ex. 19 at 11)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 11

407. Dr. Goldfarb agreed with Dr. DeMio's treatment of Patient 11, explaining that this patient came to him with a diagnosis of ASD, with his family seeking out Dr. DeMio specifically because of his expertise in this disorder. He testified that the patient was treated with nutritional support, natural and synthetic chelating agents, and hyperbaric oxygen. Dr. Goldfarb disagreed with the criticism that Dr. DeMio did not state a "chief complaint" for every visit, explaining that this would be reasonable for acute care visits, but not for a patient who is being treated for a chronic condition. (Tr. at 873-875) He offered, "[S]ometimes his assessment and plan includes 13 different items, so if there's 13 different issues to be taken care of, then I think requiring a chief complaint does not make sense." (Tr. at 875)

408. Dr. Goldfarb testified that Dr. DeMio prescribed oxytocin for Patient 11 only once, on March 17, 2014, to see if it would help calm him and that this was reasonable. He said that it is an accepted off-label use of that medication in ASD patients, and reiterated that a lot of what is done in pediatrics is "off label." Dr. Goldfarb stated that this use of oxytocin has been studied, and that the literature was split about whether to prescribe oxytocin for ASD patients for a potential calming effect, as some reports showed no effect, while others showed a positive effect. (Tr. at 875-878; St. Ex. 11 at 62) He concluded, "I think that it's reasonable for a trial of this medication in a patient with ASD to help calm, to help mood and social interactions," and in fact, he noted that a subsequent office visit note stated that the parents found that the patient seemed calmer. (Tr at 878-879; St. Ex. 11 at 225)

409. Dr. Goldfarb also agreed with Dr. DeMio's treatment of Patient 11 for yeast issues, based on the stool analysis results from April 27, 2014, shown above. He pointed out that the test showed the presence of candida, as well as elevated yeast and fungal markers shown on an additional lab report of that test. (Tr. at 879-881; St. Ex. 11 at 162-167, 195) Dr. Goldfarb testified that ASD patients often require treatment for yeast issues, even though he appeared to acknowledge that this report showed normal flora:

> [T]ypically speaking, many ASD patients will be treated empirically for candida, which is a yeast. This particular test is showing it's part of the

normal flora, but ASD patients often times have yeast issues and are treated empirically.

(Tr. at 880)

410. Finally, Dr. Goldfarb approved of Dr. DeMio's use of chelation, based on the results of an April 27, 2014 urine screen:

Toxic Metals; Urine

TOXIC METALS		RESULT µg/g creat	REFERENCE INTERVAL	WITHIN REFERENCE / OUTSIDE REFERENCE
Aluminum	(Al)	18	< 100	
Antimony	(Sb)	< dl	< 0.7	
Arsenic	(As)	14	< 120	
Barium	(Ba)	6.5	< 8	
Beryllium	(Be)	< dl	< 1	
Bismuth	(Bi)	< dl	< 2	
Cadmium	(Cd)	0.2	< 0.5	
Cesium	(Cs)	11	< 15	
Gadolinium	(Gd)	< dl	< 0.5	
Lead	(Pb)	0.7	< 3	
Mercury	(Hg)	0.9	< 4.5	
Nickel	(Ni)	10	< 18	
Palladium	(Pd)	< dl	< 0.2	
Platinum	(Pt)	< dl	< 0.1	
Tellurium	(Te)	< dl	< 0.5	
Thallium	(Tl)	0.7	< 1	
Thorium	(Th)	< dl	< 0.1	
Tin	(Sn)	0.3	< 15	
Tungsten	(W)	< dl	< 1	
Uranium	(U)	< dl	< 0.05	

(St. Ex. 11 at 185)

411. Dr. Goldfarb testified that Dr. DeMio prescribed a DMSA chelating agent a few months later, on July 23, 2014, because the lab report showed the presence of lead and mercury. He maintained that there was no universally accepted lower level of toxicity for those elements, and that the results also showed relatively increased barium, cesium, thallium, and nickel. (Tr. at 881-882; St. Ex. 11 at 57, 185)

412. Dr. Goldfarb drew attention to the results of a follow-up test done September 2, 2014, which showed that both the lead and mercury had decreased. He said that Dr. DeMio wrote one final two-month DMSA prescription for Patient 11 on January 13, 2016, and that a lab done four months later on April 10, 2016 showed that the mercury level had become undetectable. (Tr. at 882-884; St. Ex. 11 at 46, 114, 180) Dr. Goldfarb conceded that the April 2016 test showed that although the mercury level had decreased, the lead level had increased, but he said this could be the result of using a provoking agent, and

maintained that this test nonetheless represented that Dr. DeMio's treatment was effective:

> [Y]ou expect to see more on this test as a provoking agent than you would without a provoking agent. So the provoking agent of DSMA with no mercury is very significant. The fact that the lead increased some is not unexpected. * * * That means that it's a successful chelation therapy for this patient.

(Tr. at 884)

Patient 12 (IJG)

413. Patient 12 is a male born in 2005. The intake registration form indicated that Patient 12 and his family live in Granada, Spain, and DeKalb, Illinois. He was 9 ½ years old when his family sought consultation with Dr. DeMio in July 2015, bringing him to his first appointment in September 2015. Dr. DeMio testified that Patient 12 had already had a diagnosis of Psychiatric Abnormal Neurologic Disorder After Strep or "PANDAS," which was related to him by the child's parent. Dr. DeMio testified that this is an autoimmune disorder that can affect a child's immune system, causing brain dysfunction resulting in neurobehavioral symptoms such as extreme upset when in social situations or symptoms that mimic OCD, such as watching the same movie or video game over and over. Dr. DeMio recalled that Patient 12 presented with the neurobehavioral symptoms of PANDAS, as well as the clinical presentation of strep, and lab results that confirmed the diagnosis. (Tr. at 158, 1462-1468; St. Ex. 12 at 1, 63, 92, 145)

414. Dr. DeMio recalled that at the time of his first visit in September 2015, Patient 12 was already on amoxycillin to treat PANDAS. However, he said that it was a subclinical dose, so he changed his medication to Augmentin, which he characterized as amoxicillin with a "booster." In addition to the PANDAS autoimmune disorder, Dr. DeMio diagnosed Patient 12 at his first visit with encephalopathy, as well as a bacterial infection and a metabolic disorder. (Tr. at 158, 1468-1469; St. Ex. 12 at 7, 92-94)

415. At Patient 12's next office visit in October 2015, Dr. DeMio also diagnosed him with Lyme disease. (Tr. at 158; St. Ex. 12 at 8, 94-100) On cross-examination, Dr. DeMio agreed that a Western blot test done on August 11, 2015 showed negative results for Lyme disease for both the IgM and IgG antibodies:

IGENEX IGM RESULT	NEGATIVE
CDC/NYS RESULT	NEGATIVE

(St. Ex. 12 at 74)

IGENEX-IGG-RESULT	NEGATIVE
CDC/NYS-RESULT	NEGATIVE

(St. Ex. 12 at 75)

However, Dr. DeMio pointed out that the instructions on the bottom of the page say that the presence of only one double star band, or indeterminate double star bands may be clinically significant, and that the lab recommends the test be done through another method 4-6 weeks later. (Tr. at 1474-1475; St. Ex. 12 at 74-75)

416. Despite those results, Dr. DeMio agreed that between September 2015 and 2016, he prescribed various antibiotics, including Augmentin, amoxicillin, and azithromycin for the purpose of treating Lyme disease. He explained at the hearing that people with PANDAS can have co-infections with other conditions such as Lyme disease, and that when they have simultaneous co-infections, the symptoms can be worse and more chronic. (Tr. at 160-161, 1470-1473; St. Ex. 12 at 34-38) He concluded that this patient needed all three antibiotics as the treatment for "all the different germs." (Tr. at 1470)

417. At the appointment on October 9, 2015, Dr. DeMio also prescribed Nystatin, an anti-microbial to kill yeast in Patient 12's digestive tract, Vitamin B-12 shots, and glutathione, taken with a nebulizer. (Tr. at 1471-1473; St. Ex. 12 at 34-38) He testified that he also wrote a note to himself in the chart that if the patient was still having problems at his next visit, he would consider prescribing oxytocin nasal spray. At the next visit on January 15, 2016, Dr. DeMio did prescribe the oxytocin nebulized at 40 units per milliliter, after discussing it with both parents, because he explained that the patient was still having the mood and behavioral issues. He said that oxytocin is a low-risk medication, and that the risks were limited to some patients finding that it gets them "more wound up." Dr. DeMio stated that other pediatricians will prescribe oxytocin for children, but he could not think of any off the top of his head. (Tr. at 162-165, 1475-1476; St. Ex. 12 at 99, 105)

418. Also at Patient 12's January 15, 2016 office visit, Dr. DeMio noted that his hyperkinetic behavior was reduced. At this visit, he recommended Lithium Orotate, 1 to 3 capsules per day, after discussing the risks and benefits with his parents, to treat the remaining biologically-based mood and behavior issues. (Tr. at 1479; St. Ex. 12 at 16-17, 105-106) He explained that Lithium Orotate is an over-the-counter medication that is a "much lower than the amount and much different type, a milder type than what the psychiatric prescription is," and he added that lithium naturally occurs in foods that are high in potassium such as bananas and potatoes. (Tr. at 1479-1480) He reasoned:

> Lithium is part of what we use to keep ourselves calm, and at that dose, the repleted amount that's in our bodies, it's not sedating. I thought that was -- that's often a good choice in this situation, so that's why I chose it.

(Tr. at 1479)

Dr. DeMio emphasized that the lithium orotate he recommended and the lithium that can be prescribed to treat bipolar disorder are "two different things," and that he was not intending to treat bipolar disorder. (Tr. at 1480, 1482) He added:

> [I]t's a much lower dose. The minimum you'd give a person like this would be like 150, more like 300 milligrams of lithium carbonate, for example. That's the prescription. You might give 600 milligrams a day of that, and I'm giving, the most, 15, 1-5, milligrams of Lithium Orotate.

(Tr. at 1480)

He agreed, however, that he had written "lithium" in his notes, rather than "lithium orotate." (Tr. at 1482)

419. With respect to the diagnosis of encephalopathy, Dr. DeMio testified that Patient 12 had "a variety of findings on his history and physical exam, and on lab testing for things that would support the fact that he had brain dysfunction." (Tr. at 161-162) He explained that the patient had learning disabilities and visual spatial problems, and he was in a very low cognition percentile in terms of his processing speed. Dr. DeMio explained that the oxytocin was prescribed to treat this encephalopathy. (Tr. at 161-162, 164)

420. Dr. DeMio also prescribed a nebulized form of glutathione for Patient 12, for treatment of heavy metal toxicity. When he was directed to the results of a November 25, 2015 blood test for heavy metal toxicity, he agreed that he could not tell from those results if the patient had heavy metal toxicity. (Tr. at 168, 170-172; St. Ex. 12 at 30, 34, 64) He explained that he would have to take the test into consideration as "part of the whole workup," along with his findings about the patient's symptoms. (Tr. at 170) Dr. DeMio explained:

> Q. [By Mr. Wilcox:] You can't tell that by looking at it?
> A. I can tell you what the test result is, and I'd have to go back and match it up with the symptoms. If he were completely without symptoms that I could assign to a reasonable likelihood that it had some contribution to his symptoms, after having orally looked for other potential causes and weighing all the different ways that something could contribute to some symptoms, then -- such as GI symptoms and neurologic symptoms, then I put it in context.
> Q. So just so the Medical Board knows, this is a doctor -- this is basically a jury of doctors. You're telling us that this screen right here doesn't indicate to you one way or another whether this patient has significant toxicity levels of these heavy metals?
> A. It's not standalone, is what I'm trying to say. I'd have to compare to where I was at with that patient at that time.

(Tr. at 168-169)

421. At one point in his testimony, Dr. DeMio expressed uncertainty about why he prescribed the glutathione, agreeing that he sometimes uses it to draw out toxic heavy metals from a patient's body, but stating that he could not find a treatment note to show why he was using it in this case. (Tr. at 172-173; St. Ex. 12 at 104-106) He was pressed on the reason during cross-examination:

> Q. [By Mr. Wilcox:] * * * [W]hat precisely did you document in your record was the rationale for prescribing those particular substances?
> A. I use Glutathione for other reasons, meaning in this case he had several mineral deficiencies, the Glutathione helps the body deliver that. And he is in a position to have a high likelihood of depleted low Glutathione. He's got several reasons to believe that that is low or it's -- that it's depleted. And so it's a replenishing of a bioidentical substance that our bodies have.

(Tr. at 175)

When Dr. DeMio was asked where in the chart it showed that Patient 12 was deficient in any of the nutritious metals, he offered the blood metals test, as one example, explaining that it showed he was low in selenium, chromium, boron, and zinc, which he believed may have contributed to Patient 12's symptoms. He agreed that it was important to document in a patient's chart why a medication is prescribed. (Tr. at 174-176; St. Ex. 12 at 71)

422. Dr. DeMio was criticized by the State's expert for putting Patient 12 at risk of getting a C. difficile ("C. diff.") infection through the use of the various antibiotics. (Tr. at 1482-1486; St. Ex. 19) Dr. DeMio maintained that this is a risk he keeps in mind when he prescribes and, in this case, he also prescribed saccharomyces boulardii, a "cousin of brewer's yeast," which he described as "a good guy yeast that fights the C. diff, and keeps it to a zero, to a minimum." (Tr. at 1483) He explained that C. diff is an opportunistic infection that patients with a weakened immune system are at high risk of. He offered examples of an elderly debilitated patient, a person with HIV, or a chronically-ill person in a hospital setting where they might be exposed to C. diff., who would be at high risk of that infection. Dr. DeMio said that Patient 12 was not at high risk for a C. diff infection and that, in any event, he prescribes probiotics, herbal supplements, and oral immunoglobins to lower the risk of that infection as much as possible. He added that he watches his patients carefully and tests them for C. diff if they have any signs of it. In this case, he said that Patient 12 never got a C. diff infection, and he offered an August 10, 2015 urine test showing that he was not in a high range for clostridial bacteria markers of C. diff, as evidence that he was monitoring that risk. (Tr. at 1483-1486; St. Ex. 12 at 76)

423. Finally, Dr. DeMio testified that he prescribed Zoloft for Patient 12, not to treat depression, but to manage his OCD symptoms that he was having because of the PANDAS diagnosis. (Tr. at 1492-1494) He explained:

> Q. [By Mr. Wilcox:] What were you using Zoloft for then for this patient?
> A. Basically for OCD, or the PANDAS. We were having trouble controlling it with all these different herbals, antibiotics, it was back and forth. We'd helped the strep part of it, then we would have the clostridial part, then he had the rash from yeast. So we had to go -- it wasn't intentional to make things ying yang, but he had to go on and off Nystatin and these kinds of things, so I added that in for him. I offered that to the parents as one of the treatments.

(Tr. at 1493)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 12

424. In his expert report, Dr. Jackson wrote that Patient 12 was diagnosed with an autoimmune disorder, PANDAS, as well as encephalopathy and Lyme disease, but that there was no diagnostic testing to support the diagnosis of Lyme disease, nor an assessment to support the diagnosis of encephalopathy. At the hearing, he testified that the patient's caregiver related the diagnosis of PANDAS, but he maintained that there was nothing in the chart to support that diagnosis, other than the fact that the patient's caregiver told Dr. DeMio about it. (Tr. at 572, 706-708; St. Ex. 12 at 92, 145; St. Ex. 19 at 12-13)

425. Dr. Jackson also opined that Patient 12 was at risk of getting a C. difficile infection due to Dr. DeMio's prescription of multiple antibiotics for him. He explained that some of the bacteria in the intestines are actually beneficial, and that they can be killed off by the long-term use of antibiotics leaving the patient open to C. diff as an opportunistic infection. On cross-examination, Dr. Jackson acknowledged that certain risk factors predispose a patient to a C. diff infection, including HIV or an otherwise weakened immune system, cancer, or a recent stay in a hospital that could increase a patient's exposure to the infection. He also acknowledged that, in this case, Patient 12 had none of those risk factors and that he did not, in fact, develop a C. diff infection. (Tr. at 710-712; St. Ex. 19 at 12-13)

426. Dr. Jackson wrote in his expert report that he disagreed with Dr. DeMio's decision to prescribe oxytocin and lithium to treat encephalopathy in Patient 12 because there was no physical examination or mental status evaluation to support that diagnosis. On cross-examination, he agreed that lithium is FDA approved for the management of bipolar disorder, and that it is not a controlled substance. While he also agreed that it could have a calming effect on a patient, he stated that that would be an off-label use of it. (Tr. at 708-710; St. Ex. 19 at 12-13)

427. Dr. Jackson opined in his report that Dr. DeMio's care of Patient 12 fell below the minimal standard of care, and that he failed to employ acceptable scientific methods in the selection of drugs or other modalities for the treatment of disease. (St. Ex. 19 at 13)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 12

428. Dr. Goldfarb agreed with Dr. DeMio's treatment of Patient 12 for PANDAS based on his previous diagnosis, and said that it was considered a co-infection of Lyme disease. He testified that Dr. DeMio treated Patient 12 with antibiotics for those infections, and that he also provided nutritional support, a natural chelating agent for heavy metal toxicity, mood stabilizing medications, and antifungal medications to treat yeast. Dr. Goldfarb testified that PANDAS is curable with treatment, and that the neurological symptoms usually resolve with treatment, but that if the patient has another strep infection, the PANDAS condition could return. (Tr. at 885-887)

429. Dr. Goldfarb testified that Dr. DeMio appropriately prescribed lithium off-label to treat PANDAS in Patient 12's case, explaining:

> [M]ood stabilization in patients who have hyperarousal state is warranted. And this patient doesn't have – doesn't have ASD specifically. Lithium has been used in ASD disorders, so it's being used in conditions outside of bipolar disorder. And it is -- given the fact that it's a mood stabilizer, it would be warranted in a patient that has a hyper-aroused state.

(Tr. at 888-889)

430. Dr. Goldfarb also testified that it was appropriate for Dr. DeMio to prescribe Nystatin for Patient 12 to treat yeast and fungal overgrowth in the GI tract that he said were shown on an August 10, 2015 lab report. He agreed that, when the GI tract has the normal balance of flora, the risk of a C. diff infection is kept in check, but that antibiotic use can disrupt that balance and kill off the good bacteria as well as the bad, raising the risk of a C. diff infection. However, Dr. Goldfarb said that this was more common in elderly or immunocompromised patients, and that it was rare for pediatric or healthy adult patients. (Tr. at 889-892; St. Ex. 76-77)

431. Dr. Goldfarb said that Dr. DeMio appropriately addressed the risk of C. diff by prescribing probiotics that were given along with the antibiotics, and adding that some of his other prescribed medications would help keep C. diff in check as well:

> All the patients' records show the use of probiotic products, given with the antibiotics. Some of the other antiyeast medications, antiparasitic medications, other things can also kind of keep this from getting out of hand.

(Tr. at 892)

Dr. Goldfarb added that some of the other medications and supplements that were prescribed also helped address that risk:

> [H]e used oregano oil, which is a natural anti-infective type of supplement, saccharomyces boulardii is a probiotic and Metronidazole and Nystatin are antiparasitic and antifungal [medications]. So these are things that would be used to kind of keep that risk low.

(Tr. at 893)

Finally, Dr. Goldfarb pointed out that the chart showed no indication that Patient 12 ever developed a C. diff infection. (Tr. at 893)

Patient 13 (KH)

432. Patient 13 is a female from Granville, Ohio, born in 2000. She was 13 ½ years old when she first saw Dr. DeMio at an appointment in May 2014. After signing the disclaimers that none of Dr. DeMio's services would be reimbursed by insurance, the patient's family paid $1,027.05 for her first appointment on May 9, 2014. (St. Ex. 13 at 1-7)

433. Dr. DeMio identified a March 2014 letter in Patient 13's chart from her previous physician, Dr. Larry Everhart, along with some results from an MSA Meridien test. Dr. Everhart wrote that Patient 13 was being treated for Lyme disease as well as a Babesia infection, and that she had severe fatigue and pain in her back and knees. (Tr. at 1494-1495; St. Ex. 13 at 199-201)

434. Dr. DeMio testified that Patient 13 had a surgical history after a car rolled over her foot when she was in the fifth grade. She needed an initial foot surgery, followed by a second surgery to remove pins. He said that she had also had a concussion and a tick bite around this same time, and that she had had a fracture in her back as well as spondylosis. As a result of these conditions, Patient 13 was already on numerous medications for pain and muscle spasms, including Lyrica, tramadol, Valium, and prednisone, an anti-inflammatory drug to help with her joint pain. (Tr. at 1495-1496; St. Ex. 13 at 208-210)

435. Dr. DeMio recalled that Patient 13 was homebound and disabled when he began seeing her, and that her mother sought treatment for her for arthritis, fibromyalgia, and chronic fatigue that had been diagnosed by other providers before he began treating this patient. At his first visit with Patient 13 on May 9, 2014, Dr. DeMio prescribed herbs and supplements, as well as Vitamin B-12 shots. (Tr. at 179, 1497-1498; St. Ex. 13 at 124-131)

436. At the next visit on June 9, 2014, Dr. DeMio prescribed two months' worth of mebendazole, a medication for a parasitic infection. He also prescribed tramadol and Lyrica for her, which he said were for pain from arthritis. He believed she had previously seen a rheumatologist, who had made that diagnosis. Dr. DeMio agreed that he also treated Patient 13 for a metabolic or nutritional deficiency, although when he was directed to her lab results showing her CBC, thyroid test, and immune function tests, he

agreed that none of those values indicated a nutritional or metabolic deficiency. (Tr. at 179-182; St. Ex. 13 at 67, 71, 99-100)

437. With respect to his prescribing of tramadol for Patient 13, Dr. DeMio said that tramadol was at one time a non-controlled substance, and he was not sure when it became controlled. He called attention to the "Start Talking" form in her chart that is required when opioids are prescribed for a minor, demonstrating that the parents signed to indicate that they have discussed the risks of addiction. He also had the patient's mother sign a Start Talking form when he prescribed Lyrica, which he said is a controlled substance but is not an opiate. Dr. DeMio acknowledged that at an August 7, 2014 office visit, he instructed Patient 13 to increase her tramadol to four times a day on days when she had breakthrough pain, which he recalled usually happened when her Lyme disease flared up, coinciding with her menstrual cycle. He added that she was also taking Zoloft, which can interact with tramadol, but he said that fortunately, there was no interaction in this case. (Tr. at 1498-1501; St. Ex. 13 at 195, 197)

438. Dr. DeMio agreed that he treated Patient 13 for Lyme disease, using several different kinds of antibiotics, as well as some vitamins and herbal supplements. However, he agreed that this patient had several different tests for Lyme disease – a Lyme IgM Western Blot test on May 28, 2014; and a Lyme IgG Western Blot test on May 28, 2014, as well as a Multiplex PCR urine test for B. burgdorferi on June 2, 2014; and a Lyme Dot-Blot assay panel on June 2, 2014 – and all of those tests were negative. (Tr. at 183-184; St. Ex. 13 at 111-114)

439. On cross-examination, Dr. DeMio explained why he treated Patient 13 for Lyme even though her lab tests for it were negative:

> Q. [By Mr. Wilcox:] Why does a patient who has negative testing get several types of antibiotics?
> A. You can have lyme with a negative test, and I think she did. I'm convinced of it. I was highly suspect. I was pretty convinced she already did. Another provider has diagnosed her with that. She had arthritis, there was not rheumatoid. Those are among the things. And then I was very much convinced that she needed a trial of that. I mean, I thought that was really the most likely major phenomenon, an infection of some kind. She had had a rash that was consistent with that.

(Tr. at 184)

Dr. DeMio added that on the intake form, he asks if the patient has ever been bitten by a tick, and in this case, Patient 13's mom said she had had a tick bite in July 2013. He could not remember if he received any records from Dr. Everhart that showed a previous diagnosis of Lyme disease. (Tr. at 184-185; St. Ex. 13 at 204)

440. Dr. DeMio also began treating Patient 13 for HHV-6, prescribing Valtrex 1,000 mg on March 26, 2015. He referred to a May 15, 2014 lab test that showed she had this particular herpes virus, and although he agreed that it is a benign virus that is commonly associated with roseola, he said that he still treated her with Valtrex for HHV-6. (Tr. at 186-187; St. Ex. 13 at 58, 88) He explained that in her case, it was more likely that this virus was contributing to her symptoms:

> Q. [By Mr. Wilcox:] So why treat something like that if it's common in almost everyone?
> A. Well, she's not a three year old with roseola and a benign form of it, which most people who get it, get it at childhood, and it usually has a benign course.
> In a person with chronic symptoms there's a higher likelihood, and in this case a much higher likelihood, that it is contributing to and is part of the basis of her medical problems and her difficulty functioning, her pain, her immune systems function.
> And so it's a very immune suppressant germ, so that -- and it can affect the brain and it does a lot of things that are not good, and so when people have continued symptoms, that's a stronger consideration.

(Tr. at 187-188)

441. Dr. DeMio testified that he did not agree that any of his prescribing put Patient 13 at risk of opportunistic infections, offering that he did not think she had any abnormal exposure to infections, nor would that increase her risk. He asserted, "[T]here's nothing about the treatment that I gave her, or that anybody else I know that gave her, that would expose her to infections." (Tr. at 1503)

442. Dr. DeMio testified that he was still seeing Patient 13, who was an adult at the time of the hearing. He introduced into evidence a letter from her, in which she wrote that when she first saw Dr. DeMio, she was barely able to walk, and had stopped going to school due to pain, fatigue, and loss of brain function. She believed she was dying. The patient wrote that, although Dr. DeMio was the ninth doctor who diagnosed her with Lyme disease, he was the first one who could actually help her. She wrote that she endured intense pain during her teen and pre-teen years, and added that, without adequate pain medication, she would have killed herself. The patient wrote that she is now living a full, healthy life as a college student, and that she would not be alive right now if not for Dr. DeMio. (Tr. at 1503-1504; St. Ex. J-1 at 9)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 13

443. Dr. Jackson testified that Patient 13 came to Dr. DeMio with diagnoses of arthritis and complex Lyme disease, and that Dr. DeMio treated her with multiple antibiotics, as well as two medications for pain, Lyrica and tramadol. (Tr. at 573-574, 577; St. Ex. 13 at 71)

444. Dr. Jackson disagreed with Dr. DeMio's prescribing of Bactrim, amoxicillin, Biaxin, cefuroxime, and Tindamax to treat infections. (Tr. at 577-578) Although he said that antibiotic treatment would be appropriate for an acute case of Lyme disease, he maintained that there was no lab test to show such an infection, explaining, "[W]e had no confirmatory information in the notes to suggest the need to treat." (Tr. at 578)

445. Dr. Jackson also disagreed with Dr. DeMio's decision to prescribe tramadol in September 2014. He testified that tramadol is an opioid pain medication that was used along with Lyrica to treat the patient's arthralgia. He stated that Lyrica can be used for fibromyalgia and other musculoskeletal pain, and sometimes for diabetic neuropathy and, rarely, to treat seizure disorders, but there was nothing in the chart to show that this patient had fibromyalgia, a seizure disorder, or any neuropathies. (Tr. at 573-575; St. Ex. 13 at 71)

446. Dr. Jackson said that those pain medications raised concern about potential opioid dependency in this 13-year old patient, particularly where there was nothing in the chart to show a pain level that warranted these drugs:

> [T]here's nothing there to grade, if not assess the level of pain to warrant that level of treatment. It seems like an extreme direction to use in the management of pain, not knowing how significant the pain level is to warrant that level of treatment.

(Tr. at 574)

He added that there were no labs in the chart to show the extent of the arthritis or severity of the arthralgia, such as an elevated ESR level to show inflammation. (Tr. at 575-576)

447. Dr. Jackson noted that Dr. DeMio continued to prescribe Lyrica in February and March 2015 without appropriate indication for it. He stated that, in the absence of an exam that showed pain points that required pain management, he would not prescribe tramadol or Lyrica for this patient. (Tr. at 575-577; St. Ex. 13 at 202)

448. Finally, Dr. Jackson testified that he saw nothing in Patient 13's chart to show that Dr. DeMio had counseled her and her family about the risk of becoming addicted to tramadol. He added that prescribers during that time were required to have a consent form about the use of any opioid medications in the chart as well as an OARRS check, and he did not see that. Dr. Jackson added that around 2014 or 2016, there were rules put into place about how many days this medication could be prescribed. (Tr. at 576-577)

449. Dr. Jackson opined in his report that Dr. DeMio's care and treatment of Patient 13 fell below the minimal standard of care, and that he failed to employ acceptable scientific methods in the selection of drugs or other modalities for the treatment of disease. (St. Ex. 19 at 15)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 13

450. Dr. Goldfarb testified that Patient 13 came to Dr. DeMio with diagnoses of non-rheumatoid arthritis, fibromyalgia, chronic fatigue, and chronic Lyme disease, and she was treated with nutritional support, anti-infectives, anti-inflammatory supplements, and pain medications. (Tr. at 893-894) He called attention to a letter in the chart from her previous physician, Dr. Everhart, who wrote that she had been diagnosed with "chronic Lyme disease complicated by dysbiosis." (Tr. at 894-895; St. Ex. 13 at 199) Dr. Goldfarb explained that dysbiosis was a parasitic co-infection with Lyme disease:

> [I]t's a parasitic infection, and parasites can affect the gut and cause gastrointestinal problems, but it can also be systemic, and it can lead to arthritis. And we typically think of dysbiosis as a potential co-infection with Lyme, or in other words, an associated infection concept.

(Tr. at 895)

451. Dr. Goldfarb identified the patient's March 6, 2014 lab results as the ones showing a diagnosis of Babesiosis, with a positive result for four different species of that parasite. (Tr. at 895-896; St. Ex. 13 at 200) He said that Dr. DeMio appropriately prescribed mebendazole for this infection, explaining, "[I]n order to completely treat the Lyme disorder we need to treat the parasite as well, so that would be an indicator for using the mebendazole." (Tr. at 896-897)

452. Dr. Goldfarb testified that Lyme disease has different phases as the organism causing it replicates, and that one of the phases is a dormant state. However, he said that it can only be eradicated when it is in the active, replication phase when the body actually recognizes the infection. Therefore, he said that long-term therapy is often needed to completely treat Lyme disease. Dr. Goldfarb added that in Patient 13's case, he could tell that she had an ongoing, longstanding infection because she had already been diagnosed with chronic fatigue syndrome and fibromyalgia, demonstrating that her Lyme infection had progressed over time. (Tr. at 897-898)

453. Dr. Goldfarb also agreed with Dr. DeMio's treatment of the herpes virus HHV-6 in this case, although for that particular infection, he conceded, "probably everyone has it." (Tr. at 898-899) He explained that in most people, the virus is self-limiting and does not require treatment, but he said that for chronic Lyme patients, treatment is warranted:

> [T]here has been work done, research done on showing a correlation between HHV-6 and chronic fatigue and fibromyalgia. So there's a thought that when that's present, and you find the evidence of previous infection with HHV-6, a course of antiviral medications is a warranted approach to treating those types of patients.

(Tr. at 889-900)

454. Dr. Goldfarb opined that Dr. DeMio was justified in treating Patient 13's pain with Lyrica and tramadol without referring her out to a pain specialist. He explained that Dr. DeMio was well-versed in treating fibromyalgia, and there was a documented source of pain that had responded to these medications that she was treated with before this patient came to Dr. DeMio. He added that she had seen a rheumatology specialist who had diagnosed her with non-rheumatoid arthritis, and she had a history of trauma, which may have contributed to her pain and arthritis. (Tr. at 900-901) Dr. Goldfarb concluded, "[A] course of some kind of pain management would certainly be okay in this situation," adding that if that course of treatment did not work, it would be reasonable to refer her out. (Tr. at 901) He maintained, "[N]ot every patient that presents with pain needs to go to a specialist in order to receive pain medications." (Tr. at 900)

Patient 14 (SW)

455. Patient 14 is a female born in 2011. She was three years old when she first saw Dr. DeMio in October 2014. Dr. DeMio testified that Patient 14's grandmother, who was a nurse, had custody of her. He said that the child's mother had been addicted to opiates and possibly other substances during her pregnancy, and Patient 14 had gone through withdrawal after she was born. Patient 14's aunt worked for Dr. DeMio's office, and he agreed to see her without charging the family for his treatment, writing "no charge" on the bottom of the intake form. (Tr. at 189, 1505-1507; St. Ex. 14 at 1-6, 86-89, 154-160)

456. Dr. DeMio testified that the child had "extreme difficult, unimaginable meltdowns," with screaming, as well as self-injurious behaviors and aggression towards her aunt. (Tr. at 1507-1509; St. Ex. 14 at 155) He said that he was shown a video in which she had rapidly changing mood swings, and injured her own face and legs, and he said the family reported that she had an unusual odor that they suspected could have been caused by a medical issue. Dr. DeMio recalled that the family wanted him to evaluate the child for biological issues that could have been causing her developmental issues. (Tr. at 189, 1507-1509)

457. Patient 14 was first seen in Dr. DeMio's office on October 14, 2016, and he continued treating her for 15 months, until January 15, 2016. He noted in her chart that she had some blindness and a severe lazy left eye that had been diagnosed by an eye specialist, as well as reactive airway disease. In addition, he noted that she had been exposed in utero to opiates and marijuana, and to group B strep. (Tr. at 1507-1510; St. Ex. 14 at 85-86, 155)

458. Because of Patient 14's exposure to chemical substances in utero, Dr. DeMio said that he knew from the start that he did not want to use any controlled substances in her treatment, and her grandmother agreed. His plan of treatment included recommending a gluten-free, casein-free diet, and using digestive enzymes, because he said that her urine test showed abnormalities in her GI tract and a metabolic abnormality in her folic acid.

(Tr. at 1510-1514; St. Ex. 14 at 88-93) Dr. DeMio said that he also wanted her to use glutathione, and he wanted to "vaccine-exempt her." (Tr. at 1511)

459. Dr. DeMio's plan of treatment for Patient 14 also included using herbals and other supplements, including a curcumin supplement (Enhansa), theanine, and Vitamin B-12, as well as oxytocin, used off-label as a calming agent, and probiotics. He also prescribed Acyclovir, an anti-viral medication, and recommended supplements of lithium orotate, zinc, and magnesium. In addition, Dr. DeMio referred Patient 14 for a speech-language evaluation through Nationwide Children's Hospital, and he later referred her to the psychiatry department there for an evaluation when she was four years old. (Tr. at 189-192, 1515-1516, 1534; St. Ex. 14 at 24, 125, 145-146; St. Ex. 14A at 55-56)

460. Dr. DeMio also prescribed a thyroid medication for Patient 14, on the basis of blood work done on January 27, 2015. On cross-examination, he agreed that all of the values on that lab report were within normal limits except for her T4 at 6.9, slightly lower than the reference range of 7.3-15 u.g./dL. Dr. DeMio explained that this report showed that she had lower than normal thyroid hormones for a child her age, so he prescribed a thyroid medication and OTC iodine to treat hypothyroidism. (Tr. at 196-198; St. Ex. 14 at 33, 69) At the hearing, he explained his rationale for that prescribing decision:

> Thyroid hormone is made of iodine. Sometimes those numbers are low not because the thyroid gland itself can't work, it just needs the right fuel and material. And I had already provided that for her. So it means that that is a true reading of the inability of the thyroid gland to put out enough of that particular hormone in the normal range. It's got enough iodine and it still ain't doing it.

(Tr. at 198)

461. In May 2015, Dr. DeMio also prescribed a minimal daily dose of 1/8 milligram of Risperdal, which he described as a "major tranquilizer," for Patient 14, along with benztropine, because he said that her functional status had declined since he first saw her. (Tr. at 1524-1525) He related that her aunt reported that she had increased aggression, and was throwing things, banging her head, pulling her own hair, and trying to harm a baby that was living in the household. They reported that her behavior ranged from tearful and hyperkinetic to overreactive and upset, and they felt they were in crisis. (Tr. at 199, 1521-1523; St. Ex. 14 at 104) At the hearing, he explained why he prescribed those medications:

> I had pushed several times for them at that point to go see psychiatry. And so this was a temporizing issue. This was a crisis situation, so that's why I wrote the Risperdal. And then the Benztropine is to help the Risperdal not have side effects. And then I wanted to follow up to see her in two weeks and to get some lab tests. And I described the medications, what -- you

> know, what to do with them, what to look for, when to contact me and that kind of thing.

(Tr. at 1523)

Dr. DeMio agreed during cross-examination that Patient 14 had never been diagnosed with bipolar disorder, even though Risperdal can be used to treat bipolar and other mental health disorders. He added that it is FDA-approved to treat certain symptoms of autism, including agitated, repetitive behaviors, in children as young as four years old. (Tr. at 1523-1525)

462. Another medication that Dr. DeMio prescribed for Patient 14 was Strattera, after a discussion with her grandmother. (St. Ex. 14 at 108) At the hearing, he explained why he chose to prescribe that medication over some other options:

> Well, it's a medication for focus and attention. It often slows down this hyperkinetic moment to moment, minute to minute jumping from one thing to another, this internal pestered feeling that you have to go from this to that to that. So I wanted her to have a focus attention medication to help that, and I didn't want the controlled version. The other versions are all things that are able to cause addiction and withdrawal.
>
> They are either controlled amphetamines or they can cause opiate like effects and have addiction and withdrawal even if they are not controlled. And I didn't want any of those to – for her, to be exposed to any of those. * * * [Strattera is] a noncontrolled medication for focus and attention that does not use an opiate or an alpha receptor.

(Tr. at 1528-1529)

463. Dr. DeMio recalled that he decided to prescribe Strattera in July 2015 because her grandmother reported that she was "out of control" and had oppositional defiant tendencies when there was an attempt to redirect her. (Tr. at 1526, 1530) He testified that the grandmother reported spanking her, which he noted in her chart as "mild appropriate corporal discipline," because she was trying to prepare the child for preschool and more interaction with other people. (Tr. at 1527)

464. At the hearing Dr. DeMio recounted that there was initially a third-party rejection of the authorization for Strattera for Patient 14, and he explained that the insurer wanted him to try another drug such as Adderall or Dexedrine first, which he believed was purely "a financial thing." (Tr. at 1530; St. Ex. 14 at 150) He explained that he did not want to use one of those medications because they are both controlled drugs that can be addictive. (Tr. at 1531) Dr. DeMio pointed to his note showing that he called the pharmacy at the Medicaid office and had "quite a bit of discussion" about his reasons for prescribing Strattera instead of one of the other drugs used for ADHD. (Tr. at 1532) He said that, of

the other options he discussed with the pharmacist, all of the drugs that were not controlled were not acceptable because they used alpha or opiate receptors and had the same risks of overdose and withdrawal. (Tr. at 1531-1533; St. Ex. 14 at 112-117) He reported that that discussion was productive, and the insurer then approved the use of Strattera for Patient 14. (Tr. at 1533; St. Ex. 14 at 147-150)

465. Dr. DeMio also prescribed Keppra, an anti-seizure/anti-epileptic medication, for Patient 14, even though he agreed that she did not have seizures. (Tr. at 199-200, 1537; St. Ex. 14 at 126) He explained, "[I]t's off label using it for mood and behavior, which it has an off label indication. There's studies about it, about that, and showing that it helps in situations like this." (Tr. at 1537) Dr. DeMio conceded that Keppra was not a first-line choice, but he said that for kids who have tried other medications such as Risperdal, benztropine, and Strattera, it can be helpful. (Tr. at 1538) He added, "[I]t also affects other functions of the brain, which the antiepileptics do, but it also leads to other ways of doing things in the brain for different disorders." (Tr. at 199)

466. Dr. DeMio maintained that he kept urging Patient 14's family to seek other evaluations for her, including a psychiatric examination and an evaluation with a psychologist from the county or from her school district. (Tr. at 1519) He stated that he filled out referral forms for that purpose and he emphasized, "I pushed for it every time I saw them." (Tr. at 1520) He identified notes showing that Patient 14 had seen other providers including a speech-language pathologist (abbreviated in the chart as "SLP") and a counselor at a Nationwide Children's Behavioral Health ("BHB") outreach center. In one of his notes, Dr. DeMio wrote that the family finally had an appointment in February 2016, the first available, with a psychiatry provider at Nationwide Children's, and that they would follow-up with him after that. (Tr. at 1534-1536; St. Ex. 14 at 122-127)

467. Responding to criticism by the State's expert that he did not document a comprehensive physical exam with a mental status exam, Dr. DeMio disagreed, maintaining that he observed her for long periods of time at her appointments:

> I did do mental status exams and watched her for hours when she was able to come, or did come to the office, and the first time she was there for two hours. And just the entire behavior and her interactions with people, and I have -- I mean, there's some areas there that show that in the chart.
>
> And then those types of evaluations that [the State's expert] Dr. Jackson referred to, lots of that is history that the family fills out and tells you, like screaming and yelling, upsets with minimal provocation or no provocation. It has to do with, you know, what types of responses a child like this has, and it was -- and so those evaluations are history and physical, and that's basically what I did for this child. (Tr. at 1518)

* * *

> And so the bottom line is that that -- those are telling you what her brain function is, mental status, how she responds, how she reacts, and whether she's -- what normal is or whether it's not normal.

(Tr. at 1518-1519)

468. In February 2016, Patient 14's grandmother took Patient 14 for a consultation with a physician at Nationwide Children's Hospital. The summary of that visit included the following:

> G/M is here today for a second opinion due to [Patient 14] being non responsive to multiple prescription medications in addition to supplements which were prescribed to her by Dr. DiMio, a self proclaimed expert in ADHD, autism, PANDAS and other maladies. Dr. DiMio's previous diagnoses for her at age 3 were: ADHD, OCD, ODD and PANDAS.

(St. Ex. 14A at 135)

469. At the hearing, Dr. DeMio said that he could not recall if he made those diagnoses, but he conceded that the doctor at Nationwide Children's disagreed with his treatment of this patient. However, he pointed out that later in the child's treatment at Nationwide Children's, another provider started her on Risperdal (risperidone) at .5 mg – a higher dose than what he had prescribed for her – and it was noted in her next appointment there in September 2016 that she was doing well with the change. He agreed that he did not see Patient 14 after the office visit on January 15, 2016. (Tr. at 193-195, 1507-1509, 1542; St. Ex. 14A at 361, 385-388)

470. After Patient 14's evaluation at Nationwide Children's Hospital in February 2016, the physician there made the following recommendations related to discontinuing the medications that Dr. DeMio had prescribed for her:

> 1.Immediately discontinue Oxytocin, Saccharomyces, Naltrexone, Armour Thyroid, Strattera, stop Cogentin, Propr[an]olol.
> 2. Begin to taper Keppra 100g/ml twice a day. Give 1 ml in the morning and 1 ml at bedtime for 5 days. Then stop risperidone 0.25 mg take 1/2 dose x 3 days then stop.
> 3. Memantine 2mg/ml only give once a day for 3 days.
> 4. Increase Melatonin 1/2 tab at dinnertime or 2.5 mg and 1 tab at bedtime.

(St. Ex. 14A at 136)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 14

471. Dr. Jackson testified that Dr. DeMio saw Patient 14 for about a year before she had a behavioral evaluation at Nationwide Children's Hospital in 2015. He stated that this

patient was a 3-year old girl who was reportedly having increasingly aggressive and hyperkinetic behavior which he said is commonly seen in patients with ADHD. However, Dr. Jackson testified that the treatment options are very limited in a child this young, and he saw no medications in her chart that were appropriate for her age. (Tr. at 579-581)

472. Dr. Jackson testified that Dr. DeMio had very limited information upon which to base a diagnosis of ADHD. He said that there are many different possible explanations for this behavior in a 3-year old child, and that it was important to take into account her past medical history and any information about her behavior, in order to discover any information that could shed light on the reasons for the behavior, as part of making an accurate diagnosis. Dr. Jackson added that ADHD is one possible explanation, but that some type of abuse could also give rise to the type of behavior that was described to Dr. DeMio. He also emphasized the importance of getting the diagnosis right, since ADHD could be a diagnosis that remains with the patient for life. (Tr. at 581-583)

473. Referring to Dr. DeMio's October 16, 2014 progress note in which he made the ADHD diagnosis, Dr. Jackson said that this note did not contain sufficient information to support that diagnosis made at that visit. (Tr. at 581-582; St. Ex. 14 at 88-89) He explained:

> [T]here's very cursory information here to come up with a presumed diagnosis of ADHD without any other supporting information. The physical exam is very limited. I mean, I go as far as saying does this child have any abrasions, lesions, or anything that might suggest abuse that can contribute to that behavior. And also getting a feel for the child's demeanor other than looking active, which a three year old can be, but how do you differentiate that from the norm. And so to go from there to a point of making, you know, a diagnosis is difficult.

(Tr. at 582)

Dr. Jackson agreed with Dr. DeMio's note that a school assessment for developmental delays may have been appropriate, but with respect to the ADHD diagnosis, he maintained, "I don't think you can make that diagnosis in this visit." (Tr. at 582-583)

474. Dr. Jackson was also critical of Dr. DeMio's prescribing of lithium and Risperdal for Patient 14. He said that lithium is used to treat bipolar disorder, with very few off-label uses for that drug, and that it must be used very judiciously to make sure the dosing is not at a level that could be toxic to the patient. (Tr. at 583-584) Dr. Jackson added that there can be side effects such as behavioral issues or cardiac manifestations, and he concluded that it was "certainly not indicated in the pediatric population outside of the diagnosis of bipolar disorder." (Tr. at 584)

475. Finally, Dr. Jackson disagreed with Dr. Goldfarb's conclusion in his expert report that Dr. DeMio had expertise in pediatric behavior disorders and was qualified to make

assessments of ADHD and ODD [oppositional defiant disorder.] He testified that from his understanding of Dr. DeMio's training, he had had no special training or certification that would suggest any level of expertise in pediatric behavioral health. (Tr. at 584)

476. Dr. Jackson opined in his report that Dr. DeMio's care of Patient 14 fell below the minimal standard of care, and that he failed to employ acceptable scientific methods in the selection of drugs or other modalities for the treatment of disease. (St. Ex. 19 at 17)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 14

477. Dr. Goldfarb testified that Patient 14 had a strong family history of mental health disorders, and had been born with neonatal abstinence syndrome as a result of her birth mother's substance use. He stated that Dr. DeMio's diagnoses included obsessive compulsive disorder ("OCD,") oppositional defiant disorder ("ODD,") and ADHD, and that Dr. DeMio tried many different approaches to control the patient's behavior, including prescribing lithium, oxytocin, Risperdal, Keppra, and Strattera, as well as medications for hyperthyroidism. Dr. Goldfarb testified that the patient was exhibiting behaviors that supported the diagnoses of OCD, ODD, and ADHD, and the behaviors were very difficult to control. (Tr. at 903-904, 907)

478. Dr. Goldfarb testified that there were similarities between neonatal abstinence syndrome ("NAS,") and ASD, and that biochemical processes contribute to the patient's behavioral symptoms in both cases:

> [T]here is some thought that just like in autism, there is biochemical derangement leading to neurologic symptoms, same thing would be true in NAS. Something is disrupting the normal biochemical reactions in the body that would lead to some kind of neurologic defects.

(Tr. at 905-906)

479. Dr. Goldfarb supported Dr. DeMio's decision to prescribe lithium, oxytocin, Risperdal, and Keppra for Patient 14, and he noted that on the patient's lab results from January 2015, her labs showed "a lithium level of less than .2," which he said was "quite low." (Tr. at 907-908; St. Ex. 14 at 70) Dr. DeMio said that the practitioners who saw Patient 14 at Nationwide Children's Hospital noted that she had used Adderall, Ritalin, and Concerta, which are all controlled drugs, as well as Zoloft, which caused side effects, and there was a note in her chart that the child's grandmother did not want to use amphetamines to treat ADHD. (Tr. at 908-909)

480. Dr. Goldfarb concluded that Dr. DeMio made an appropriate decision to try to treat Patient 14's condition with non-scheduled medications, and that the doctors who later saw her prescribed more dangerous drugs for her. (Tr. at 908-909) He summarized:

> Dr. DeMio was trying to be sensitive to the legal guardian's wishes and not use control[led] substances, amphetamines specifically, so he used Strattera, which is a noncontrolled medication approved for ADHD, and the practitioners at Nationwide Children's were very critical of Dr. DeMio, but in the end they ended up using these more dangerous medications, and then ended up coming back to the same medication that Dr. DeMio had used, the Risperidone. So I found that to be hypocritical.

(Tr. at 908-909)

Patient 15 (TG)

481. Patient 15 is a male born in 2006. He was almost 9 years old when his parents first sought care with Dr. DeMio in August 2015. His mother wrote on the intake form that she learned of Dr. DeMio through a Lyme disease Facebook group, and when asked about his vaccine status, she wrote, "Last vaccinations were at 3 years old. We stopped after that." (St. Ex. 15 at 65) She signed the disclaimers stating that Dr. DeMio's services were not reimbursable through any insurance provider, and paid $774.90 for Patient 15's first appointment on September 9, 2015. (Tr. at 201; St. Ex. 15 at 1-7)

482. Dr. DeMio testified that the parents brought Patient 15 to him because he had a bullseye rash, and they were concerned about Lyme disease. The parents related that Patient 15 had a history of a tick bite, and that they had actually found a tick attached to his scalp. He called attention to the pictures of the rash in the patient's chart, and he said that two other doctors had seen the child for this problem before he did. (Tr. at 203-204, 1543-1546; St. Ex. 15 at 53, 64)

483. Dr. DeMio testified that he noted that Patient 15 had had a course of doxycycline that started July 2, 2015, two months before he began seeing the patient. At his first appointment with Patient 15 on September 9, 2015, Dr. DeMio diagnosed the patient with Lyme disease and likely co-infections. He testified that he noted that the patient exhibited "brain fogginess," and that he believed there was also a likelihood of yeast buildup. (Tr. at 201-202, 1546-1547; St. Ex. 15 at 8, 49-51)

484. Dr. DeMio prescribed a one-month supply of Biaxin and cephalexin, both antibiotics, which he testified are first-line treatments for Lyme disease and its associated co-infections, adding that Biaxin also has anti-parasitic properties. He testified that he also recommended grapefruit seed extract and saccharomyces boulardii, both herbal supplements, and digestive enzymes. In addition, he recommended a gluten-free, casein-free, low-sugar diet, along with Vitamin B-12 shots and folinic acid. (Tr. at 204-207, 1547-1549; St. Ex. 15 at 18-20)

485. Dr. DeMio agreed on cross-examination that he never ordered a Western blot blood test to check if Patient 15 had Lyme disease. (Tr. at 205) He maintained that this was not below the standard of care because he had seen the picture of the child's bullseye rash:

> Q. [By Mr. Wilcox:] Is this standard of care for diagnosing lyme disease and treating it with antibacterials just based on a history of tick bites?
> A. No, I think I saw the picture of that rash when he first came, and that's a very classic looking rash. He had tick bites, he had that rash, and he had symptoms. And it says right here, so now I can tell you, I don't know if that's a picture of the original bulls-eye rash, but on the intake form he had a bulls-eye rash by the time he already saw me, and it was in association with tick bites. So I've got both of those pieces of information on there.
> Q. Okay. So based on the picture of the rash and the history given of tick bites, you prescribed the antibacterial medications to the child; is that correct?
> A. Yes.

(Tr. at 206)

486. Dr. DeMio testified that he follows the standards of the International Lyme and Associated Diseases ("ILADS") for the treatment of Lyme disease and the co-infections that are associated with Lyme disease. He said that he is one of the physicians who contributes to the ILADS standards, and that testing is only one aspect of recognizing Lyme disease. He maintained that sometimes Lyme disease and its coinfections are missed in testing. In those cases, he said that patients still need to be treated with antibiotics. (Tr. at 1549-1551)

487. Dr. DeMio also treated Patient 15 for heavy metal toxicity, on the basis of a toxic metal urine screen performed in December 2015. When he was directed to the results of that testing on cross-examination, Dr. DeMio acknowledged that the only metal that was at or above the reference range was tungsten, at .7 dl, above the reference range of .6 dl. (Tr. at 207-209; St. Ex. 15 at 30) When he was asked if he had reason to believe this patient had been exposed to a toxic amount of tungsten, Dr. DeMio explained:

> It gets into the environment, and so it can be an exposure that is just from that. And then it's used in industrial manufacturing, and it's also in a lot of products that end up coming into the home, mostly light bulbs, but there are other things that have tungsten in them. And so it can make its way into crops and animal feed and water, and so it's –"

(Tr. at 207-208)

He agreed that he would have ordinarily had a conversation with the parent about whether the family lived "near a smelting factory or someplace like that," but he did not know if he had documented any such discussion. (Tr. at 207-208)

488. Finally, Dr. DeMio treated Patient 15 with Diflucan (fluconazole) and Acyclovir for a fungal infection. When he was asked on cross-examination what particular fungal

infection he was treating in this case, he referred to a lab test done on December 14, 2015, which he said showed a positive test for a GI fungus. (Tr. at 209-211; St. Ex. 15 at 35) When Dr. DeMio was pressed on which particular value showed a GI fungus, he offered:

> Well, it's the totality of those. That section that says yeast and fungal markers above the numeral 1, and then the two of them that are high is the arabinose, which is No. 7, and the tartaric, which is No. 6.

(Tr. at 210-211)

Dr. DeMio stated that most healthy people would have zeros or very low numbers for all of the tests done on this screen, and this patient had no zeros. (Tr. at 211)

489. Dr. DeMio saw Patient 15 only twice, with the last visit occurring on January 7, 2016. (Tr. at 208-209; St. Ex. 15 at 55-59)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 15

490. Dr. Jackson testified that Patient 15 came to Dr. DeMio in September 2015 and was diagnosed with Lyme disease and arthralgia. A progress note from his first office visit on September 9, 2015 noted that he had had years of leg pain, and that he had new pain in his back and hips. (Tr. at 586; St. Ex. 15 at 49)

491. Dr. DeMio was also provided with a picture of a rash at the patient's first visit, but he said that the picture did not look to him like the bullseye rash that would indicate Lyme disease. He explained that bullseye rashes are usually flat and not itchy, with irregular borders. In contrast, he said that the rash in the pictures showed excoriation, indicating scratching. Dr. Jackson noted that he did not know if the patient had these rashes elsewhere on his body, but he added that the rash shown could have been ringworm that did not get better because it was not treated with a topical medication. (Tr. at 586-588; St. Ex. 15 at 53)

492. As additional support for his belief that Patient 15's rash was not related to Lyme disease, Dr. Jackson noted that the patient's mother reported that he had taken six weeks of doxycycline starting July 20, 2015, and it apparently had not improved. (Tr. at 589-590; St. Ex. 15 at 65) He stated:

> You have to say in your mind what other things are going to cause this that didn't get better with a frontline treatment of Doxycycline? * * * [I]f you had the appropriate diagnosis regimen for this [for] six weeks, why is it that this child didn't get better. You have to heighten your mind to say maybe it's something else.

(Tr. at 590)

Dr. Jackson concluded that Dr. DeMio's care of Patient 15 fell below the minimum standard of care, explaining, "[T]here's a lot of information that is missing that for me to assume Lyme disease would not be justified, much less treating it." (Tr. at 591)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 15

493. Dr. Goldfarb disagreed with Dr. Jackson, and offered his opinion that Dr. DeMio had appropriately treated Patient 15. He pointed out that Patient 15 already had the diagnosis of Lyme disease when he came to Dr. DeMio, and that he was treated with additional antibiotics. In addition, Dr. DeMio also treated him for heavy metal toxicity and the herpes virus HHV-6. (Tr. at 909)

494. Dr. Goldfarb pointed to the results of a September 29, 2015 lab test, which showed that Patient 15 was heterozygous for the MTHFR gene mutation, which he said supported the prescribing of folic acid and Methyl B-12. Although he said that not everyone with that gene mutation has a mental health diagnosis, he said that patients who have the gene and do have depression will benefit from the combined use of methylfolate and methyl B-12. (Tr. at 910-911; St. Ex. 15 at 23-28)

495. Dr. Goldfarb also approved of Dr. DeMio's decision to prescribe anti-fungal medications for Patient 15. He said that the lab results of December 14, 2015 showed quite a few abnormalities, including high yeast levels and fungal metabolites. He said that these can be associated with small intestinal bacterial overgrowth or "SIBO." Dr. Goldfarb concluded that this was an appropriate reason to prescribe antifungals for this patient. (Tr. at 912; St. Ex. 15 at 35-44)

Patient 16 (TK)

496. Patient 16 is a male from Meadville, Pennsylvania, who was born in 2009. He was four years old when he first saw Dr. DeMio in March 2013. His mother wrote on the intake form that she learned of Dr. DeMio through an internet search. (St. Ex. 16 at 1-6)

497. Dr. DeMio testified that Patient 16 had a diagnosis of autism from Denver Children's Hospital, and he believed that he was also diagnosed with OCD at the same time, although he said he did not recall getting those records and he did not see them in the patient's chart. He said the fact that they were not in the chart probably meant that he did not contact the patient's other providers. (Tr. at 212-213; St. Ex. 16) When he was pressed on whether he needed those records to continue treatment, Dr. DeMio said:

> If I have a reliable source of information and they are confident and I'm confident, and it all makes sense, then if I have the information I need from their prior dealings with doctors and providers and tests and all that, then I can go forward. If I need to get them for any reason, or if there's – if I need to contact the other providers, I do.

(Tr. at 213)

498. Dr. DeMio recalled that Patient 16's parents wanted him treated for "the medical aspects of autism and OCD." (Tr. at 212) His diagnoses for this patient included encephalopathy, enteric infections, a metabolic disorder, nutritional deficiency, and abnormal blood constituents. (Tr. at 214; St. Ex. 16 at 7-12)

499. Some of the notes in Patient 16's chart documented telephone encounters with the patient's mother. One note on January 5, 2016, stated that Patient 16 was doing very well, "the best he's ever been," and that his teachers were "blown away" by his improvements in language, and that she believed the supplements had really made a difference. (St. Ex. 16 at 106-109)

500. On the basis of that call, Dr. DeMio prescribed azithromycin for Patient 16, which he asked to be compounded so that it could be prepared "without the fillers and the sugars and all of that." (Tr. at 214, 1551-1553; St. Ex. 16 at 110) When he was asked on cross-examination why he prescribed azithromycin at that time, Dr. DeMio explained:

> Q: [By Mr. Wilcox:] And what's [azithromycin] prescribed for?
> A: In the A&P section I've got bacterial, one of the diagnoses for bacterial for infection, basically. And then on the top of page 108 I name various agents, lyme, bruce, short for brucella, myco short for mycoplasma, toxoplasma.

(Tr. at 215)

501. In a telephone call 20 days later on January 25, 2016, however, Patient 16's mother related that she was concerned about her child's reaction to three new "supplements" that he had started taking three weeks earlier – biotin, saccharomyces, and azithromycin. She said that his pupils appeared dilated, and that his behavior issues had gotten worse, getting him sent to the principal's office at school. Dr. DeMio testified that he returned the mother's call at around 8 p.m. that day and talked to her about what she observed, and she told him that they had not actually started the saccharomyces or the Nystatin that he ordered. (Tr. at 216-217, 1551-1553; St. Ex. 16 at 110)

502. During that call, Dr. DeMio said that he discussed with Patient 16's mother the possible causes and what they should do:

> I have a differential diagnosis here basically, was it a Herx[heimer's reaction], was it testosterone shifting, was it a yeast build up, did it involve the biotin, so we talked about those possibilities, or did it involve azithromycin, those are the possible causes.

> So I told her to stop the biotin, and if that did not help by about a week, to stop the azithromycin, and to call at any time if she wanted, but to keep our plan of followup, because we have recommendations for followup from the last visit for that. That's what our discussion was.

(Tr. at 1553)

503. On cross-examination, Dr. DeMio elaborated about how the medications and supplements that Patient 16 was taking could have contributed to Herxheimer's reaction, which could cause the symptoms he was having:

> [S]o biotin, for example, can inhibit yeast. When you inhibit yeast, they die off, and yeast can be harmful -- it's an infection. The things it does that, you know, are negative for a person are from the substances it produces, and those can be discharged when the yeast germ dies, so biotin can cause that to happen.
>
> Biotin also is used in the body and biological systems to inhibit testosterone formation, and so when that happens the body has feedback mechanisms to gear up testosterone if something happens.
>
> So sometimes you can get a reaction like that, and the kids will get that sometimes, and it can happen when you're treating with the biotin. Then shifting to the Azithromycin, it's a germ killer, and germs do things that make us sick because they produce substances that mediate the way they make us sick. When you kill the germs, more of that garbage, if you will, is released.
>
> It's a very well known phenomenon for that to happen.
> That's -- Herxheimer's reaction is one name, and other names, but it's a phenomenon that is well known to happen, and it can happen in these situations.

(Tr. at 218-219)

He added that dilated pupils are "one of these parainfectious phenomena." (Tr. at 218)

504. Dr. DeMio rejected a suggestion that an in-person visit was needed so that he could observe Patient 16, because he said he knew the patient and her mother well and he had just seen the child three weeks earlier:

> I knew this patient, and the mother is very good about telling me what is happening. I had the call with her on the 25th of January, and less than three weeks prior is the previous appointment that I had with this child.

> So it wasn't like I hadn't heard from them for months and I didn't know, you know, this child * * *.

(Tr. at 1555)

He said that, as a result of his conversation on the telephone with the patient's mother, he had made "a whole orderly list" of the possible causes and had made a differential diagnosis. (Tr. at 1555)

505. Dr. DeMio continued seeing Patient 16 for about 2 ½ years, through January 2016. (Tr. at 212) When he was asked if he ever prescribed oxytocin for Patient 16, Dr. DeMio replied, "If you see it somewhere, I'm happy to look at that," but he did not locate it in his records. (Tr. at 215-216) He agreed that if it appeared in the patient's records as one of his medications, then he would have prescribed it for the same reason it was prescribed for the other pediatric patients, "to stabilize the brain chemistry, the nerve transmitters." (Tr. at 216)

Dr. Jackson's Testimony about Dr. DeMio's Care of Patient 16

506. Dr. Jackson testified that Patient 16 was four years old and already had a diagnosis of autism from Denver Children's Hospital when he first saw Dr. DeMio. (Tr. at 591-592; St. Ex. 16 at 110)

507. Dr. Jackson was critical of Dr. DeMio's handling of a January 25, 2016 phone call by Patient 16's mother, who said that her child had "dilated eyes," shortly after he diagnosed the child with Lyme disease and PANDAS at a January 5, 2016 office visit. Dr. Jackson did not agree with Dr. DeMio's decision to prescribe medication based solely on the phone call, because he said that "dilated eyes" could indicate that the patient had been in an accident or suffered some kind of trauma, or possibly that he ingested some of his parents' medications. (Tr. at 592-594; St. Ex. 16 at 110) He said it was crucial that a patient with that physical description be examined face-to-face, for an in-depth evaluation, adding, "I can't imagine in a phone consultation being able to derive the answer in that setting." (Tr. at 594)

508. Dr. Jackson said this was especially important in light of the fact that Patient 16 had just begun taking some new medications, Nystatin and biotin, ten days earlier, as he could have been having some kind of cross-reaction to the various medications he was taking. In this case, as in the other pediatric cases, Dr. Jackson concluded that Dr. DeMio's care fell below the minimum standard of care. (Tr. at 594-596; St. Ex. 16 at 17)

Dr. Goldfarb's Testimony about Dr. DeMio's Care of Patient 16

509. Dr. Goldfarb testified that Dr. DeMio saw Patient 16 for about three years, during which time he was treated with antibiotics for suspected PANDAS, and he was also treated for suspected yeast and fungal overgrowth in the GI tract. (Tr. at 913-914)

510. As the basis for Dr. DeMio's PANDAS diagnosis, Dr. Goldfarb pointed to Patient 16's lab results from December 4, 2015. (Tr. at 914-915; St. Ex. 16 at 53) He said that these showed a positive streptozyme titer, which indicated a relatively recent strep infection, explaining, "[T]his was showing that there is a positive strep test, and if there was any neurologic symptoms, a tic, OCD, those are some of the things that could be consistent with PANDAS." (Tr. at 915)

511. Dr. Goldfarb did not disapprove of Dr. DeMio's handling of the phone call with Patient 16's mother on January 25, 2016. (Tr. at 915-915; St. Ex. 16 at 110-111) He concluded that Dr. DeMio made a differential diagnosis based on the information he had received, and appropriately adjusted the patient's medications, in response:

> It could possibly be a Herx reaction, Herxheimer reaction, which is a -- basically it's a die off reaction of treating infections, a testosterone shift, a yeast buildup from biotin, or from Zithromax. And he has a plan dealing with them. So first thing he says is to stop the biotin. He said if that's no help, by seven days stop the Zithromax. So it seemed like he addressed it, and documented it, and had a plan and an appropriate follow-up.

(Tr. at 916)

Legibility of Dr. DeMio's charts

512. Paragraph 2 of the Notice alleges, in part, that Dr. DeMio's medical documentation was inadequate, difficult to follow, and difficult to determine the dates and dosages of medications he prescribed, which contributed to his practicing below the minimal standard of care. (St. Ex. 22A)

513. All of the expert witnesses who offered testimony at the hearing agreed that Dr. DeMio's handwritten charts were difficult to read and follow. Dr. Croake-Uleman repeatedly referred to the illegible records as a reason for her opinion that Dr. DeMio's practice was below the standard of care, in discussing the cases of Patients 1 through 5. (Tr. at 253, 268-270, 278-279, 287) She testified, "[T]he documentation was very -- was almost illegible, a lot of times illegible, and just basically below the standard of care." (Tr. at 258-259) On cross-examination, Dr. Croake-Uleman reluctantly agreed that if she got records from another physician that she could not read, she could call the other doctor for clarification. (Tr. at 394-395) Dr. Jackson, the State's expert on the pediatric cases, likewise expressed, "I would say the legibility is not very good for me. Maybe not for Dr. DeMio, but for me it is difficult to read." (Tr. at 470)

514. Dr. Goldfarb, the Respondent's expert witness, also agreed that that the standard of care requires a chart to be legible enough for another physician to pick it up and follow the patient's care. He wrote in his expert report that Dr. DeMio's handwritten charts were

"extremely difficult to decipher which made the chart review exceedingly difficult." (Tr. at 1031-1032; Resp. Ex. C at 3) He agreed that more legible charts would assist other providers of care for this patient:

> His handwriting was very difficult to decipher, and I felt that it would be much easier for other practitioners to be able to figure out what he's doing, what he's thinking, and what's going on if either the handwriting were better or it was typed.

(Tr. at 808)

515. In Dr. DeMio's testimony, he also agreed that the minimal standard of care required him to thoroughly and legibly document his treatment, so that a subsequent provider for one of his patients could pick up the chart and understand the patient's treatment up to that point. Dr. DeMio testified concerned his implementation of the new KAREO EMR system that he now uses to keep patient charts, in lieu of handwritten records. (Tr. at 63-64, 1247-1248; Resp. Ex. E) He testified that in or about March 2020, he updated his records to the new system, explaining, "I just want it to be clear what we do for patients shows in the record." (Tr. at 64)

516. Dr. DeMio offered an example of a patient record into evidence, to show how his new EMR system maintains his patients' charts, and he added that his staff uses other features of the system for billing. He explained how he now dictates his "SOAP" notes, which can include any medications or referrals, and which are then transcribed and made available for him to check for accuracy before signing off on the note. The new EMR system also allows him to convey prescriptions to pharmacies electronically for patients. (Tr. at 1247-1253; Resp. Ex. E-1)

517. At the hearing, Dr. DeMio explained that he believed the expectation today is for physicians to keep typewritten records, explaining, "[T]yped out is always better." (Tr. at 1244) However, he maintained that he did not believe the charts of Patients 1 through 16 were difficult to follow:

> Q. [By Mr. Wilcox:] Would you agree with me that the documentation on the 16 charts we're going to look at today is very difficult to follow?
> A. I really don't.
>
> * * *
>
> Q. If you don't believe it's difficult to follow, why did you change your method of recordkeeping and recording in these charts?
> A. Well, I think there's an expectation out there for typed out records, is probably the biggest reason. And I want anyone who might look at the records to see the type of care that we give, so that that shows through and shines through, I think is the way to say it.
> Q. So under the prior recordkeeping system you think people would have had trouble seeing that care that you provided?

> A. I think that that may have been their view of it. Sometimes they just wouldn't accept written records before they even looked at them, if they knew they were --
> Q. I'm sorry, Doctor, I didn't understand that answer. Could you repeat that, please?
> A. I think some people, knowing that records are handwritten, don't want to have anything to do with them.
> Q. You think your handwriting is legible and easy for other doctors or clinicians to follow?
> A. I think largely it is, yeah.

(Tr. at 65-66)

518. The records in this case show Dr. DeMio's handwritten notes that he used before he put the new EMR system in place at his office. However, Dr. DeMio contended during the hearing that the records used at the hearing were in a different format than they were when he provided them to the Board, and that this made his records more difficult to follow than they would have otherwise been. He explained that when he received the subpoena for patient records, he sent copies of his paper charts, along with the binders that they were in, with tabs on the charts to distinguish between the various sections. (Tr. at 64-65, 1254-1263) Dr. DeMio testified, "[W]e have colored tabs that say this is the lab section, this is the progress note, this is referrals and specialists that other than me that see the patient, other doctors, basically." (Tr. at 1255) Dr. DeMio said that when the charts were copied, some of the pages were reduced in size and some notes in margins were eliminated, and tabs separating different sections were also removed. As a result, he said he believes that the charts presented to the Board are less organized than his original charts actually were. (Tr. at 1263)

Mitigation Evidence

Testimony of Patient 2 (JH)

519. Patient 2 is a 48-year old woman who said that she has been on disability since 2015. She testified that before she began seeing Dr. DeMio in 2013 she was on a "long road of physical illness" and felt as though she was passed from one doctor to another with no answers, all the while getting sicker and sicker. (Tr. at 1741-1743)

520. Patient 2 reported that about 20 years ago, she was bitten by a tick. (Tr. at 1743) She said that she had "a big knot on [her] head that wouldn't go away," but her family doctor had told her that Lyme disease was not in their area, so she said she took his word for it. (Tr. at 1743-1744) The patient testified that for the past 20 years, she had been "vomiting every day with no explanation" and losing weight. (Tr. at 1744) She said that she began having problems with her gall bladder, which progressed to "issue after issue," and although she went to many different specialists, she did not get any resolution of her problems. She had frequent rashes, and lost the range of motion in her leg. On many

days she said that she could not get out of bed, and she missed holidays and special events with her family. (Tr. at 1744-1745) Reflecting on the many doctors she had seen, the patient related, "Some of them wouldn't even give me the time of day, treated me like I was a psychotic person who just needed to go talk to somebody * * *" (Tr. at 1745)

521. Patient 2 recalled that, in addition to her physical challenges, she also began having neurological problems. She began stuttering and having difficulty finding words, and she said that she was having "full blown seizures," though they were not epileptic seizures. (Tr. at 1746-1747) She said that the entire right side of her body began shaking and she could not walk, "with doctors telling [her] that [she] was okay, * * * when in actuality [she] wasn't okay." (Tr. at 1746)

522. After seeing various physicians, Patient 2 decided to consult an Amish practitioner, who suggested several other possible diagnoses, including Lyme disease:

> [I]t got really bad to where I even went to the Amish doctor, because I was getting no answers. And he did his testing and his talking to me and observed how much I was shaking. He felt I had lyme disease, he felt I had very bad thyroid issues. He said I had a brain tumor. I didn't actually have a brain tumor, I had an infection within my spinal cord. Maybe that's what he was seeing, I don't know.

(Tr. at 1746)

523. Finally, in or about 2013, Patient 2's husband saw a documentary called "Under Our Skin" about a women's experience with Lyme disease, and they began to believe that her medical problems could be attributed to undiagnosed Lyme disease. (Tr. at 1743) Patient 2 said that, at her husband's urging, she began seeing Dr. DeMio, and she recalled, "[T]hat's when my life changed for the better." (Tr. at 1743) She recalled that Dr. DeMio spent about 2 ½ hours with her at the first appointment, adding that before, she had been "lucky to ever get ten minutes with anybody." (Tr. at 1748)

524. At her first appointment in August 2013, Patient 2 said that she brought her prior testing, and Dr. DeMio did more of his own testing. She said that she began seeing him every six weeks, and that he would call to check on her between appointments. She added that Dr. DeMio gave her his cell phone number and told her to call anytime, day or night. The patient stated that she has, in fact, called him at 11:00 or 11:30 p.m. (Tr. at 1748, 1750) In a letter of support, Patient 2 wrote that after doing his own testing, Dr. DeMio diagnosed Lyme disease and several other parasitic infections:

> After all of my tests came back and Dr DeMio explained how sick I was. I not only had Lyme Disease but also had several co-infections. He setup a game plan for me to treat all of the infections and parasites.

(Resp. Ex. J-5)

525. Patient 2 said that she grew up on a tobacco farm where she was exposed to chemicals at a young age, causing her to have methemoglobinemia, a rare condition in which her blood does not exchange oxygen as it normally would. (Tr. at 1748-1749) She added that it "really freaks a lot of doctors out," and that many doctors do not want to treat her because she thinks "they are afraid they are going to get sued." (Tr. at 1749-1750)

526. Patient 2 testified that she was on IV antibiotics for 20 months, and that because of the antibiotics, she got an excessive yeast growth in her mouth, as if "a rug grew on [her] tongue." (Tr at 1751) She said that Dr. DeMio took the time to culture it, in order to figure out what it was. The patient stated that Dr. DeMio takes the time to explain her diagnoses, as well as the risks and benefits of the treatments he suggests, and that he never pressured her to do any particular treatments. She testified that he has also referred her to specialists, including rheumatologists, endocrinologists, and a neurosurgeon. (Tr. at 1751-1753, 1755-1757) The patient offered, "I had so much going on between the Lyme disease itself, the infection in my spinal cord, my thyroid issues, the Bartonella, the shaking, the seizures * * *" (Tr. at 1755)

527. Patient 2 asked the Board to consider the difference in her life that Dr. DeMio's care has made:

> I had no hope before I met Dr. DeMio. In fact, everything looked pretty grim. I was telling my family I was getting my funeral arrangements made, that's how grim it was getting. I walked in to find the most caring compassionate doctor I had ever met who actually took the time, explained everything to where we understood the severity of what I was looking at, understand the severity of the treatment, and how truly sick I was * * * .
>
> [H]e was there for me to go the step forward to try to fix and do the best we could for where I was at. Without him I just don't think I'd be here, and I don't feel it's right to have somebody that cares as much as he does, it doesn't matter what time of day when it comes to his patients, he's all in or nothing.

(Tr. at 1758-1759)

The patient testified that she had gone from using a wheelchair to using only a cane, and she added:

> I'm still very sick, I'll always be sick, but I still have somewhat of a life now thanks to Dr. DeMio for caring and not just tossing me out the door because I'm too difficult and didn't want to take the time or take the time to listen or take what it took to try to get me better * * *

(Tr. at 1759)

Patient 2 identified a letter of support that she wrote, which was admitted into evidence. (Tr. at 1757; Resp. Ex. J-5)

Testimony of Joyce Miller DeMio

528. Joyce Miller DeMio is Dr. DeMio's wife of approximately 25 years. She testified at the hearing about the lengths that Dr. DeMio goes to in order to give good care to his patients, and about their son. Mrs. DeMio testified that their son was 20 years old at the time of the hearing, and she described him as "our beautiful son," and as "a delightful person to be around," despite the fact that he is "profoundly disabled." (Tr. at 1785-1786)

529. Mrs. DeMio testified that their son has multiple diagnoses including ASD, a seizure disorder, immune disorders, and a sensory integration disorder. She said that he also has apraxia and dyspraxia, and that he needed a feeding tube until he was nine years old. Mrs. DeMio said that their son requires 24/7 care and assistance with all activities of daily living, including eating, toileting, and hygiene. He lives at home with his parents, and Mrs. DeMio said that the last 20 years have been very challenging, emotionally and financially. (Tr. at 1785-1786)

530. Mrs. DeMio testified that she believes her husband practices "the true art of medicine." (Tr. at 1787) She related that she has heard from patients and colleagues that he is an extraordinary doctor, and that he is the only doctor that truly listens to patients. She testified that Dr. DeMio works 7 days a week and takes his commitment to his patients very seriously, and that he often works overnight shifts at the hospital to help support their family. (Tr. at 1786-1790)

531. Despite working long hours for his patients, Mrs. DeMio said that her husband is a devoted father to their son. She recounted that when Dr. DeMio comes home, Daniel will run to him and remove his dad's belt and tie, as a way to signal that he is home and not going back out. Mrs. DeMio testified that he and his dad are "the best of friends," and that Dr. DeMio always remains calm and loving and never loses patience with their son, even when he is aggressive or very loud. (Tr. at 1789-1790)

532. Mrs. DeMio identified a letter that she wrote, which was admitted into evidence. In the letter, she described Dr. DeMio as the "Best Father Ever," and said that from the moment of their son's diagnosis, Dr. DeMio had dedicated his life to their son's care and wellbeing, and to the wellbeing of other ASD patients. (Tr. at 1791; Resp. Ex. J-4 at 14-15)

533. In her testimony at the hearing, Mrs. DeMio said that Dr. DeMio is never "not learning," and that even when he is driving, he listens to "medical tapes." (Tr. at 1792) She characterized him as a true scholar, and as one of the kindest people she had ever met,

who has "incredible manners." (Tr. at 1792-1793) Mrs. DeMio wanted the Board to consider the following:

> I've never seen anyone who takes their oath as a physician so seriously. I've never seen anyone who is so selfless, who truly doesn't desire any rewards for what he does, not financial, not material. My husband is pure in that sense.
>
> I watched him care for his father until the day he died from emphysema. I've watched him selflessly care for our son. I've seen him take care of patients in the middle of the night if he has to.
>
> He's just really a very caring person, and I've never seen anyone like him who pursues knowledge for the pursuit of the knowledge of the art of medicine. He loves medicine.

(Tr. at 1792)

Testimony of Redacted Redacted *Ph.D.*

534. Redacted Redacted Ph.D., is not a medical doctor but holds a doctoral degree in health administration research with a focus on autism spectrum disorders. Dr. Redacted lives in a suburb of Salt Lake City, Utah, and he testified that in July 2005, he founded the United States Autism Association, which was known as the "United States Autism and Asperger's Association," until the organization's name change in 2018. (Tr. at 1763-1768)

535. Dr. Redacted also has a son with autism, and he testified that he met Dr. DeMio when Dr. DeMio's son was three years old, and his own son was 13 years old. He related that both of their children are severely affected by the disorder, and that when they met for lunch that first time, they talked for three hours about the challenges their sons had faced. (Tr. at 1768-1769)

536. Dr. Redacted related that Dr. DeMio became very involved with the United States Autism Association, and that at their 2008 conference, Dr. DeMio was named the chief medical officer, based on his wealth of knowledge in pathology, primary care, and emergency medicine. Although he confided that he believed some of the medical presenters who spoke at that conference were "looking for potential clients," he said that was not at all the case with Dr. DeMio. (Tr. at 1770-1771) Dr. Redacted said that the conference had educators and medical practitioners who spoke to those in attendance, and that they tried to make sure the organization did not "sell out to vendors." (Tr. at 1772) He maintained that Dr. DeMio's interest was genuine and authentic, adding, "[H]e was living the life that we were all living, especially with a son with severe, severe disabilities at that time." (Tr. at 1771)

537. Dr. Redacted testified that Dr. DeMio had treated his son, and they had seen improvements. He related that his son had had "screaming, yelling, and vomiting" for the first four or five years after the diagnosis of autism, and that after having a gastroenterology consult at the University of Utah, they were told nothing could be done for their son. (Tr. at 1774-1776) He stated that every practitioner they consulted told them, "[T]here's really nothing we can do, it's all behavioral, it has nothing to do with anything medical." (Tr. at 1775)

538. Dr. Redacted testified that his family traveled to see Dr. DeMio for their son's treatment, and that Dr. DeMio diagnosed severe types of the Epstein Barr virus and the Coxsackie virus, and multiple bacterial infections that he explained were "probably dormant and may have been there for a long time until stressors kicked in triggering the viruses causing major havoc on the system." (Tr. at 1776) He stated that Dr. DeMio also diagnosed both himself (Dr. Redacted and his son with chronic Lyme disease. (Tr. at 1775)

539. Dr. Redacted testified that Dr. DeMio is always willing to talk to parents at conferences, and that Dr. DeMio encourages parents to have patience and persistence, and not to blame themselves, adding that the pandemic had been especially stressful for parents of kids with autism because they thrive on routine. He concluded that Dr. DeMio has deep compassion for families, and that he had changed the lives of thousands of people for the better, including Dr. Redacted own family. (Tr. at 1779-1781)

540. At the end of his testimony, Dr. Redacted offered the notes he took from one of his conference speeches in July 2015, as well as letters of support that he and his wife had written for Dr. DeMio, and asked that the Board take them into consideration. (Tr. at 1779-1780; Resp. Ex. J-2 at 1-4, 6)

Letters of Support from Patients and Families

541. At the hearing, Dr. DeMio presented a collection of letters written by patients or their parents describing the improvements in their health that they experienced under his care. In nearly all of the letters, the patients emphasized how much time Dr. DeMio spent with them listening to their descriptions of their symptoms and gaining an understanding of their history. Another common thread was found in their characterization of Dr. DeMio as a physician who treats every patient with dignity and compassion, a quality they had not found in some of the other physicians they had consulted. (Resp. Ex. J-1)

542. Many parents wrote to describe progress that their children who had been diagnosed with autism or related disorders had made under Dr. DeMio's care or similar treatments provided by other practitioners. Theresa Wrangham, who is on the advisory board for the U.S. Autism Association, wrote that her child has autism, and that the family was told she would never be able to do basic things, but that she had graduated from college and now lived independently. Ms. Wrangham wrote about Dr. DeMio's dedication to the

community of parents of children with autism and about his humility to admit that doctors don't have all the answers about this complex diagnosis. (Resp. Ex. J-2 at 11-13)

543. Another parent of a child with an autism-related diagnosis wrote that their daughter had seen Dr. DeMio for 16 years, since she was two years old, after finding that other practitioners dismissed their concerns for their child. The parent related that her daughter had made vast improvements in her cognition, social skills, verbal and non-verbal communication, fine and gross motor skills, and activities of daily living and that she had graduated from high school in the top of her class of 500. She wrote that Dr. DeMio's treatment "is not only based solidly in current science, but also acknowledges our daughter [name redacted] as a whole and worthy person." She concluded, "To put it bluntly, Dr. DeMio's treatments work." (Resp. Ex. J-2 at 21-23)

544. Some of the parents who wrote letters in support of Dr. DeMio were also healthcare professionals themselves. One parent, who identified himself as a board-certified physiatrist in North Carolina, wrote that Dr. DeMio had treated his son and daughter for complex health conditions. He related that Dr. DeMio shows a high level of empathy for his patients, and he characterized him as an expert in nutritional based interventions to promote health and wellness. (Resp. Ex. J-2 at 10) This physician wrote that his family still travels so that Dr. DeMio can treat his children, and he added, "I can attest with certainty that he possesses an expert level of knowledge across multiple disciplines of medicine, in particular as it relates to pediatric health issues." (Resp. Ex. J-2 at 10)

545. Many other patients or parents of patients wrote to describe the debilitating symptoms that plagued their lives before they were diagnosed and treated for Lyme disease and co-infections by Dr. DeMio. In one letter, a college student majoring in electrical engineering related that he had had rheumatoid arthritis, as well as seizures and tremors and that previous doctors he saw thought he was "making up [his] symptoms" and did not believe him. He wrote that they told him Lyme did not exist in Ohio, but that once he began treatment with Dr. DeMio for Lyme and its co-infections, his health improved. That same student's parents wrote a letter saying that other doctors had told him his Lyme disease was already "cured," but that he continued to suffer until Dr. DeMio discovered through blood tests that he was still battling Lyme as well as co-infections including Bartonella. With treatment, they wrote that he transformed from a sickly pre-teen into a healthy young man who did well in school and sports, and who was at that time progressing through college. (Resp. Ex. J-1 at 1-2)

546. Another parent, a lawyer from Texas, wrote that after a tick bite, her teenage son began having symptoms so debilitating that he could not continue going to school, but that after seeing multiple specialists at Texas Children's Hospital in Houston and having every conceivable lab and imaging test, no one was able to offer a diagnosis. The parent related that a Texas physician ultimately diagnosed Lyme disease and started her son on a course of clindamycin and doxycycline, and although he had periods of improvement, his symptoms returned. (Resp. Ex. J-2 at 33-35) They later sought treatment with Dr. DeMio, who prescribed "a combination of prescription medications, supplements,

diet modifications and hyperbaric oxygen treatments." (Resp. Ex. J-2 at 34) The parent credited Dr. DeMio with giving her child a chance at a life worth living again, and wrote that he had made enough improvement that he was able to get a GED, take the ACT, and get accepted into the Culinary Institute of America, where he expected to begin culinary school in the fall of 2021. (Resp. Ex. J-2 at 33-35)

547. There were also numerous letters from Dr. DeMio's colleagues, including several physicians, some of whom had either been treated by Dr. DeMio or knew his patients. Dr. Rick Gebhart, who identified himself as an associate professor in the medical schools at Wright State University and Ohio University, wrote about his own experiences being treated for Lyme disease by Dr. DeMio. Referring to Dr. DeMio, he offered, "His methods may not be conventional, but Lyme's [*sic*] disease and autism do not conform to standards." (Resp. Ex. J-2 at 28-30) Dr. Gebhart's wife also wrote a letter in support of Dr. DeMio, attesting to the improvements in her husband's health as a result of the care he received from Dr. DeMio. (Resp. Ex. J-2 at 31-32)

548. A student at The Ohio State University College of Medicine wrote that he expected to begin his residency in 2021and that Dr. DeMio had successfully treated him for Lyme disease. He related that, during his first year of medical school, he began having severe fatigue, sleeping 12-14 hours a day, and that he had a facial droop, chest pain, and headaches, but all of his lab tests came back with inconclusive results. The student wrote that an immunologist diagnosed him with Lyme disease and recommended that he seek out a physician who specialized in the treatment of Lyme, which led him to Dr. DeMio. This student wrote that he believed he would have had to take a leave of absence from medical school, but that Dr. DeMio's treatment helped him restore his energy and recover. (Resp. Ex. J-2 at 17)

549. Another colleague, Dr. Jay Burstein, wrote that there are many diseases that medicine has an incomplete knowledge of, and he described Dr. DeMio as a vital resource for patients with complex conditions. (Resp. Ex. J-4 at 5)

550. Daniel Jones, M.D., a physician who is board-certified in neurology and sleep medicine, wrote a letter that likewise described parainfectious diseases as poorly understood and infrequently diagnosed. He wrote that he did not take lightly the notion of writing to the Board in support of another physician, but he offered that in his observation of Dr. DeMio's practice over the past 27 years, he believed that Dr. DeMio is involved with the treatment of a very difficult population of patients. (Resp. Ex. J-4 at 2) Dr. Jones added the following observation:

> I have observe[d] patients diagnosed with "autism," aphasic, learning disabled, etc. be treated by Dr. DeMio and subsequently arise to prominent success in secondary and college levels.

(Resp. Ex. J-4 at 2)

551. A registered nurse also wrote about Dr. DeMio's treatment of her Lyme disease, which she said brought relief after two years of debilitating symptoms that caused a rapid downward spiral of many aspects of her health. She concluded, "Thanks to Dr. DeMio, I got my life back." (St. Ex. J-2 at 20, 25)

Additional Information

552. At the time of the hearing, Dr. DeMio had been a licensed physician in Ohio for 34 years without any prior discipline by the Board. He was still on staff at Summa Health's hospital in Summit County at that time, although he said that several satellite facilities had closed due to the pandemic. He said that he had been working about 36 hours a week in the Emergency Department until mid-2020, but that that Department was closed even before the pandemic because the facility's volume had dropped. (Tr. at 1127, 1144-1147) As a result, Dr. DeMio said that he was working as a staff physician at Summa, and worked "ad hoc" when and if any of Summa's Emergency Departments needed a physician to cover a shift. (Tr. at 1144-1146)

553. Dr. DeMio explained that he worked at the hospital at nights and on weekends and holidays when his office was closed. He explained that it was primarily a "paycheck issue" to help support his family and provide for their son's care, especially since his wife's employer had made cutbacks. He emphasized that their son's care is of paramount importance to both him and his wife, and they want him to continue being cared for at home. At the same time, he said that working at the hospital also was a good "pulse" of the community, to help him know what infections were prevalent. (Tr. at 1147-1148)

554. Since he was no longer working regular shifts in the Emergency Department at Summa by the time of the hearing, Dr. DeMio said that he had had to tap into a line of credit. Although he said that he had covered some shifts for other emergency physicians, he said that it was "nothing compared to the 36 hours per week" that he had been working. Dr. DeMio confirmed that Summa Health is the only place where he has privileges in the Emergency Department. He testified that he had not looked for other work because of the pending Board action, as he believed no other employer would choose to bring him on staff while the Board's action was unresolved. However, he said that Summa was aware of the action and had chosen to keep him on staff as of the time of the hearing. (Tr. at 1149-1151)

555. Dr. DeMio said that he had not prescribed any controlled substances for patients who had pain in the last four years, as of the date of the hearing. He explained that he made a decision to stop taking pain patients, after giving a 90-day notice of that change to current patients, so the last time he prescribed opioid pain medications for patients of his practice was in November 2017. Dr. DeMio said that he now he refers such patients to pain management specialists, neurologists, or other providers, instead. Dr. DeMio offered into evidence an August 2017 letter that he sent to patients to notify them of this policy change. He added that he now tries to educate patients about other treatment options for the underlying causes of their pain. (Tr. at 1232-1235, 1237, 1239; Resp. Ex. D)

Dr. DeMio asserted that he had "thousands and thousands" of patient visits between 2012 and 2016, and that only a "[v]ery tiny percentage" were getting opioids for pain. (Tr. at 1233)

556. Dr. DeMio presented a February 21, 2017 letter from Ted Parran, M.D., Medical Director, Continuing Medical Education Program, Case Western Reserve University School of Medicine, that indicated that Dr. DeMio had attended and participated in the Intensive Course in Controlled Substance Prescribing offered by Case Western. Dr. Parran further stated, among other things, "Dr. DeMio was an active participant in the case discussion sessions and demonstrated skills in each of the role-play sessions." (Resp. Ex. F) Dr. DeMio also presented the brochure for the course he attended. (Resp. Ex. F-1)

557. Dr. DeMio also presented a Certificate of Credit for attending a 10-credit seminar titled Medical Record Keeping Seminar on January 24, 2020, offered by Memorial Hospital, University of Colorado, and the Center for Personalized Education for Professionals ("CPEP"). (Resp. Exs. G, G-1)

558. Dr. DeMio also introduced the State Pharmacy Board's Prescription Monitoring Program Prescriber Reports of his prescribing between 2018 and 2020, showing that during that time, he dramatically reduced the amount of pain medications that he prescribed to patients, and was no longer engaging in practices that were considered high-risk, such as prescribing opiates and benzodiazepines at the same time. Dr. DeMio explained that he now prescribes opioids only rarely through his practice in the Emergency Department, when a patient has a broken bone, for example, and then he prescribes only a few pills, generally eight or fewer. (Tr. at 1237-1240; Resp. Exs. I-1, I-2, I-3)

559. Dr. DeMio maintained that patients with ASD often have painful GI issues and headaches, while Lyme patients can also have serious intractable pain. He said that he now refers them to pain or neurology specialists for treatment of their pain, and he no longer continues to prescribe pain medications that a patient started taking through another provider's script. (Tr. at 1241-1242)

560. Dr. DeMio testified that with these changes, and the changes to upgrade his recordkeeping system through the use of EMRs, he believes he has improved his practice, and he explained that he strives to exceed the "minimum standard" of care:

> I want to do what's likely to do the best for that child and go the extra mile, be more complete, more knowledgeable, more experienced, more aware of risks and benefits than the minimum standards would be. Top level, whatever you want to call it. Honors level.

(Tr. at 1266)

FINDINGS OF FACT

1. From in or about March 2012 through in or about September 2016, Phillip DeMio, M.D., provided care in the routine course of his practice for Patients 1 through 16, as identified on a confidential Patient Key.

2. In the course of Dr. DeMio's treatment of Patients 1 (HF), 2 (JH), 3 (JM), 4 (SP), and 5 (AKT), adult patients whom he treated during the time period referenced above, Dr. DeMio practiced below minimal standards of care, including the following:

   - Dr. DeMio acknowledged that he did not review OARRS reports or obtain urine drug screens for Patients 1 through 5. Dr. Croake-Uleman testified persuasively that OARRS helps physicians ensure that their patients who receive controlled substances are not obtaining those medications from other prescribers, and urine drug screens ensure that patients are taking the medications they are being prescribed and are not taking medications or illicit drugs that they are not being prescribed. Dr. DeMio's statements that he knew the patients well and trusted them are not persuasive because, as Dr. Croake-Uleman persuasively testified, patients suffering from a substance use disorder are simply not trustworthy.

   - With respect to Patients 1 through 5, Dr. DeMio failed to complete and/or document the completion of an appropriate history and physical examination to establish a diagnosis and treatment plan, and he consistently failed to document vital signs. The State proved that such measures are necessary to comply with the standard of care.

   - With respect to Patients 1 through 5, Dr. DeMio's medical documentation was inadequate, difficult to read and follow, and difficult to determine the dates/dosages of medications.

   - With respect to Patients 1, 2, and 5, Dr. DeMio continued to prescribe controlled substance medication without seeing the patients for long periods of time.

   - With respect to Patients 1 through 5, Dr. DeMio treated the patients with controlled substances for protracted periods of time without establishing a diagnosis of intractable pain, and without following the Board's intractable pain rules.

   - With respect to Patients 1, 2, 3, 4, Dr. DeMio failed to consistently assess the patient's functional status while prescribing opioid medication on a protracted basis.

   - With respect to Patients 1, 2, 4, and 5, Dr. DeMio concomitantly prescribed opiates and benzodiazepines which Dr. Croake-Uleman convincingly opined jeopardized patient safety.

   - With respect to Patients 1 through 5, Dr. DeMio failed to consistently assess the patient's functional status while prescribing opioid medication on a protracted basis.

- With respect to Patient 4, Dr. DeMio failed to appropriately implement specialist recommendations.

3. In the course of Dr. DeMio's treatment of Patients 6 (AL), 7 (BG), 8 (BT), 9 (DF), 10 (DP), 11 (HR), 12 (IJG), 13 (KH), 14 (SW), 15 (TG), and 16 (TK), pediatric patients he treated from about January 2014 through about September 2016, Dr. DeMio practiced below the minimal standard of care, including the following:

   - With respect to Patients 6 through 16, Dr. DeMio failed to appropriately identify or document the identification of a defined chief complaint.

   - With respect to Patients 6 through 16, Dr. DeMio failed to complete, appropriately review and/or properly document completion of review of a history of present/past medical illness, medication list, allergies, a detailed review of systems and/or physical examination/assessment to support the documented diagnoses.

   - With respect to Patients 6 through 16, Dr. DeMio failed to complete and/or document the completion of diagnostic testing to support the patients' diagnoses and treatment plan.

   - With respect to Patients 6 through 16, the amount and/or type of medications and/or supplements prescribed were not supported by history, diagnosis, physical exam, and/or laboratory findings, including: prescribing thyroid medication without the presence of abnormal thyroid function studies, utilizing chelating supplements and medications in the absence of heavy metals in testing, prescribing anti-malarial medication without a confirmed diagnosis of malaria, and prescribing anti-parasitic medication without documentation of a parasitic infection. In fact, Dr. DeMio would sometimes order a test that came back either negative or within the normal range, and then treat the condition anyway. For example, Patient 11 was tested for parasites using a stool sample, and the test failed to detect a parasitic infection. Nevertheless, Dr. DeMio prescribed Mebendazole, an anti-parasitic medication, stating at the hearing that parasites can be difficult to detect.

   - With respect to Patient 10, Dr. DeMio failed to appropriately refer and/or document an appropriate referral to a behavioral health specialist.

CONCLUSIONS OF LAW

1. The acts, conduct, and/or omissions of Phillip DeMio, M.D., as described in Findings of Fact 1 through 3, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as that clause is used in R.C. 4731.22(B)(2).

1.a Pursuant to R.C. 4731.225 and Board policy, the Board is authorized to impose a civil penalty for this violation with respect to Dr. DeMio's conduct that occurred on or after September 29, 2015. The Board's fining guidelines provide as follows:

Maximum Fine: $18,000
Minimum Fine: $2,500

2. Dr. DeMio's acts, conduct, and/or omissions as described in Findings of Fact 1 through 3, individually and/or collectively, constitute a "departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in R.C. 4731.22(B)(6).

2.a Pursuant to R.C. 4731.225 and Board policy, the Board is authorized to impose a civil penalty for this violation with respect to Dr. DeMio's conduct that occurred on or after September 29, 2015. The Board's fining guidelines provide as follows:

Maximum Fine: $20,000
Minimum Fine: $3,500

3. Dr. DeMio's acts, conduct, and/or omissions, as described in Findings of Fact 1 and 2, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in R.C. 4731.22(B)(20), to wit: Utilizing Prescription Drugs for the Treatment of Intractable Pain, Rule 4731-21-02, as in effect from November 30, 2008, through August 30, 2017.

3.a Pursuant to R.C. 4731.225 and Board policy, the Board is authorized to impose a civil penalty for this violation with respect to Dr. DeMio's conduct that occurred on or after September 29, 2015. The Board's fining guidelines provide as follows:

Maximum Fine: $20,000
Minimum Fine: $4,500

4. Dr. DeMio's acts, conduct, and/or omissions that occurred on or before December 30, 2015, as described in Findings of Fact 1 and 2, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in R.C. 4731.22(B)(20), Ohio Revised Code, to wit: General Provisions, Rule 4731-11-02, as in effect from September 30, 2008, through December 30, 2015. Furthermore, pursuant to Rule 4731-11-02(F) as in effect at that time, any violation of Rule 4731-11-02 also constitutes violations of R.C. 4731.22(B)(2) and R.C. 4731.22(B)(6).

4.a Pursuant to R.C. 4731.225 and Board policy, the Board is authorized to impose a civil penalty for this violation with respect to Dr. DeMio's conduct that occurred on or after September 29, 2015. The Board's fining guidelines provide as follows:

Maximum Fine: $10,000
Minimum Fine: $1,000

5. Dr. DeMio's acts, conduct, and/or omissions that occurred on or after December 31, 2015, as described in Findings of Fact 1 and 2, individually and/or collectively, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in R.C. 4731.22(B)(20), to wit: General Provisions, Rule 4731-11-02 as in effect from December 31, 2015, through August 30, 2017. Furthermore, pursuant to Rule 4731-11-02(E) as in effect at that time, any violation of Rule 4731-11-02 also constitutes violations of R.C. 4731.22(B)(2) and R.C. 4731.22(B)(6).

5.a Pursuant to R.C. 4731.225 and Board policy, the Board is authorized to impose a civil penalty for this violation with respect to Dr. DeMio's conduct that occurred on or after September 29, 2015. The Board's fining guidelines provide as follows:

Maximum Fine: $10,000
Minimum Fine: $1,000

6. Dr. DeMio's acts, conduct, and/or omissions that occurred on or before December 30, 2015, as alleged in paragraphs (1) through (2) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(8)(20), Ohio Revised Code, to wit: Standards and Procedures for Review of "Ohio Automated Rx Reporting System" (OARRS), Rule 4731-11-11, Ohio Administrative Code, as in effect from November 30, 2011, through December 30, 2015.

6.a Pursuant to R.C. 4731.225 and Board policy, the Board is authorized to impose a civil penalty for this violation with respect to Dr. DeMio's conduct that occurred on or after September 29, 2015. The Board's fining guidelines provide as follows:

Maximum Fine: $20,000
Minimum Fine: $4,500

7. Dr. DeMio's acts, conduct, and/or omissions that occurred on or after December 31, 2015, as described in Findings of Fact 1 and 2, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in R.C. 4731.22(B)(20), to wit: Standards and

Procedures for Review of "Ohio Automated Rx Reporting System" ("OARRS"), Rule 4731-11-11 as currently effective commencing on December 31, 2015.

7.a Pursuant to R.C. 4731.225 and Board policy, the Board is authorized to impose a civil penalty for this violation. The Board's fining guidelines provide as follows:

Maximum Fine: $20,000
Minimum Fine: $4,500

RATIONALE FOR THE PROPOSED ORDER

There were a variety of issues presented in this case. With respect to the adult patients, Dr. DeMio did not dispute that he prescribed opioid analgesics to Patients 1 through 5, sometimes in conjunction with benzodiazepines, for protracted periods of time, without checking OARRS or ordering urine toxicology screens. In a couple cases he prescribed these drugs without personally seeing the patients for up to a year. His prescribing of pain medications sometimes ignored various "red flags" that would have suggested his patients were misusing the opioids he was prescribing for them or were getting controlled substances from multiple prescribers. His suggestion that the best way to find out if a patient is misusing prescription narcotics is to simply ask them ignores the realities of addiction and seems naïve.

There was also little disagreement that Dr. DeMio's medical recordkeeping was inadequate with respect to all the patients. Although Dr. DeMio maintained that he could read his charts, all of the experts, including Dr. Goldfarb, agreed that they were difficult to decipher, and would be very difficult for a subsequent treatment provider to understand. The hearing examiner also had great difficulty reading and understanding the medical records.

Other issues were very much in dispute, primarily with respect to his care of Patients 6 through 16. First, Dr. DeMio holds himself out as an expert in the treatment of Lyme disease and other tick and insect-borne diseases, nutritional disorders, and metals toxicity. However, he lacks formal residency or fellowship training in these areas other than what he received in his training as an emergency medicine physician. Further, some of the beliefs that Dr. DeMio stated as facts are contradicted by scientific authorities such as the CDC and the American Academy of Pediatrics and are not supported by medical literature.

Dr. DeMio also holds himself out as an expert in the treatment of ASD. Again, Dr. DeMio does not have any formal residency or fellowship training in the area but does have a clear personal interest in that subject as the father of an autistic child. Further, as stated in the previous paragraph, some of Dr. DeMio's beliefs concerning the diagnosis and treatment of ASD, such as his belief that vaccines contribute to autism or that heavy metal toxicity can be the cause of a patient's autism, could not be supported with any scientific evidence. Even with significant time before the hearing to locate any studies that would support those beliefs, Dr. DeMio was unable to offer evidence to support those beliefs. It appears irresponsible for a physician to advance unproven treatments or make dangerous claims such as that childhood vaccines can cause autism.

The subject matter of this case is one that profoundly affects some people in an emotional and personal way, particularly with respect to ASD. Many of the patients and parents of patients who came to Dr. DeMio believed they had been given little hope by practitioners of traditional medicine. The evidence suggests that Dr. DeMio tried to offer them treatment that would alleviate pain or, at the very least, improve some of their symptoms and help increase their social functioning. Several medical professionals either wrote or testified that medical science does not have a very comprehensive understanding of autism, and numerous parents of children with autism wrote that they felt dismissed by other doctors who could offer them no hope that their children's symptoms would ever abate or become manageable. Dr. DeMio was willing to provide treatment options through the use of supplements, hyperbaric oxygen, and nebulized oxytocin, among other things. There were a number of letters from parents of patients stating that they had been told by other healthcare professionals that their children would never be able to develop into functioning adults but that Dr. DeMio had helped them to do well and even attend college. These parents included several medical professionals. All strongly supported Dr. DeMio's continued practice. The problem is that there was no scientific evidence or medical literature presented to support the effectiveness of those treatments other than personal testimonials.

However, there was plenty of mitigating evidence presented in this case. Dr. DeMio has no prior disciplinary history. He is clearly a very dedicated and compassionate physician who wants to provide the best care that he can to his patients. The hearing examiner does not believe that Dr. DeMio was trying to enrich himself at the expense of his patients. To the contrary, the lives of Dr. DeMio and his family have been profoundly affected by ASD which may have led him off the beaten medical path in an effort to find solutions for such patients. In addition, Dr. DeMio has taken steps to remediate some of the issues addressed in this matter. He has worked to improve his medical charting and put in place an EMR system. He has also taken courses in medical recordkeeping and controlled substance prescribing. Moreover, he has since stopped prescribing controlled substance pain medication and refers patients to pain specialists when necessary. Also, Dr. DeMio wants to improve his medical practice and thus appears to be amendable to additional training. Finally, none of the issues presented in this matter concern Dr. DeMio's emergency medicine practice.

The proposed order would suspend Dr. DeMio's certificate for an indefinite period of time following a 30-day wind-down period. Requirements for reinstatement would include an assessment by the Post-Licensure Assessment System ("PLAS") sponsored by the Federation of State Medical Boards. The hearing examiner understands that PLAS can perform comprehensive assessments of a physician's practice and tailor an appropriate education program that can include any training deemed appropriate ranging from self-directed continuing medical education to additional residency or fellowship training. Following reinstatement, Dr. DeMio will be subject to probationary terms and conditions for at least three years that would include a practice plan consistent with the PLAS education program, as well as completion of courses concerning medical recordkeeping and controlled substance prescribing. The Board may consider the courses that Dr. DeMio already completed as partial or complete fulfilment of these requirements. The proposed order would also levy a civil penalty of $4,500.00, the highest minimum civil penalty applicable to this matter.

PROPOSED ORDER

It is hereby ORDERED that:

A. **SUSPENSION OF LICENSE**: Commencing on the thirty-first day following the date on which this Order becomes effective, the license of Phillip DeMio, M.D., to practice medicine and surgery in the State of Ohio shall be SUSPENDED for an indefinite period of time. During the thirty-day interim, Dr. DeMio shall not undertake the care of any patient not already under his care.

B. **FINE**: Within thirty days of the effective date of this Order, Dr. DeMio shall remit payment in full of a fine of four thousand five hundred dollars ($4,500.00). Such payment shall be made via credit card in the manner specified by the Board through its online portal, or by other manner as specified by the Board.

C. **CONDITIONS FOR REINSTATEMENT OR RESTORATION**: The Board shall not consider reinstatement or restoration of Dr. DeMio's license to practice medicine and surgery until all of the following conditions have been met:

1. **Application for Reinstatement or Restoration**: Dr. DeMio shall submit an application for reinstatement or restoration, accompanied by appropriate fees, if any.

2. **Post-Licensure Assessment Program**: Prior to submitting his application for reinstatement or restoration, Dr. DeMio shall have undergone an assessment and completed the recommended educational activities, as developed for Dr. DeMio by the Post-Licensure Assessment System ("PLAS") sponsored by the Federation of State Medical Boards and the National Board of Medical Examiners. Dr. DeMio's participation in the PLAS shall be at his own expense.

   a. Prior to the initial assessment by the PLAS, Dr. DeMio shall furnish the PLAS copies of the Board's Order, including the Summary of the Evidence, Findings of Fact, and Conclusions of Law, and any other documentation from the hearing record that the Board may deem appropriate or helpful to that assessment.

   b. Should the PLAS request patient records maintained by Dr. DeMio, Dr. DeMio shall furnish copies of the patient records at issue in this matter along with any other patient records he submits. Dr. DeMio shall further ensure that the PLAS maintains patient confidentiality in accordance with Section 4731.22(F)(5), Ohio Revised Code.

   c. Dr. DeMio shall ensure that the written Assessment Report by the PLAS includes the following:

- A detailed plan of recommended practice limitations, if any;
- Any recommended education;
- Any recommended mentorship or preceptorship;
- Any reports upon which the recommendation is based, including reports of physical examination and psychological or other testing.

Moreover, Dr. DeMio shall ensure that, within 14 days of its completion, the written Assessment Report by the PLAS is submitted to the Board.

d. Any Learning Plan recommended by the PLAS shall have been developed subsequent to the issuance of a written Assessment Report, based on an assessment and evaluation of Dr. DeMio by the PLAS. Dr. DeMio shall successfully complete the educational activities as recommended in the Learning Plan, including any final assessment or evaluation.

e. At the time he submits his application for reinstatement or restoration, Dr. DeMio shall submit to the Board satisfactory documentation from the PLAS indicating that he has successfully completed the recommended educational activities.

3. **Medical Records Course(s)**: At the time he submits his application for reinstatement or restoration, or as otherwise approved by the Board, Dr. DeMio shall submit acceptable documentation of successful completion of a course or courses on maintaining adequate and appropriate medical records. The exact number of hours and the specific content of the course or courses shall be subject to the prior approval of the Board or its designee. The Board may consider the medical recordkeeping course completed by Dr. DeMio prior to the hearing as partial or complete fulfilment of this requirement. Any course(s) taken in compliance with this provision shall be in addition to the Continuing Medical Education requirements for relicensure for the Continuing Medical Education period(s) in which they are completed.

   In addition, at the time Dr. DeMio submits the documentation of successful completion of the course(s) on maintaining adequate and appropriate medical records, he shall also submit to the Board a written report describing the course(s), setting forth what he learned from the course(s), and identifying with specificity how he will apply what he has learned to his practice of medicine in the future.

4. **Controlled Substances Prescribing Course(s)**: Before the end of the first year of probation, or as otherwise approved by the Board, Dr. DeMio shall submit acceptable documentation of successful completion of a course or courses dealing with the prescribing of controlled substances. The exact number of hours and the specific content of the course or courses shall be subject to the prior approval of the Board or

its designee. The Board may consider the controlled substance prescribing course completed by Dr. DeMio prior to the hearing as partial or complete fulfilment of this requirement. Any course(s) taken in compliance with this provision shall be in addition to the Continuing Medical Education requirements for relicensure for the Continuing Medical Education period(s) in which they are completed.

In addition, at the time Dr. DeMio submits the documentation of successful completion of the course(s) dealing with the prescribing of controlled substances, he shall also submit to the Board a written report describing the course(s), setting forth what he learned from the course(s), and identifying with specificity how he will apply what he has learned to his practice of medicine in the future.

5. **Payment of Fine**: Dr. DeMio shall have fully paid the fine as set forth in Paragraph B of this Order.

6. **Additional Evidence of Fitness To Resume Practice**: In the event that Dr. DeMio has not been engaged in the active practice of medicine and surgery for a period in excess of two years prior to application for reinstatement or restoration, the Board may exercise its discretion under Section 4731.222, Ohio Revised Code, to require additional evidence of his fitness to resume practice.

D. **PROBATION**: Upon reinstatement or restoration, the license of Dr. DeMio to practice medicine and surgery in the State of Ohio shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of at least three years:

1. **Obey the Law**: Dr. DeMio shall obey all federal, state, and local laws, and all rules governing the practice of medicine and surgery in Ohio.

2. **Declarations of Compliance**: Dr. DeMio shall submit quarterly declarations under penalty of Board disciplinary action and/or criminal prosecution, stating whether there has been compliance with all the conditions of this Order. The first quarterly declaration must be received in the Board's offices on or before the first day of the third month following the month in which Dr. DeMio's license is reinstated or restored. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.

3. **Personal Appearances**: Dr. DeMio shall appear in person for an interview before the full Board or its designated representative during the third month following the month in which Dr. DeMio's license is reinstated or restored, or as otherwise directed by the Board. Subsequent personal appearances shall occur as directed by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.

4. **Post-Licensure Assessment Program**: Dr. DeMio shall practice in accordance with the Learning Plan developed by the PLAS, unless otherwise determined by the Board.

Dr. DeMio shall cause to be submitted to the Board quarterly declarations from the PLAS documenting Dr. DeMio's continued compliance with the Learning Plan.

Dr. DeMio shall obtain the Board's prior approval for any deviation from the Learning Plan.

If, in a manner not authorized by the Board, Dr. DeMio fails to comply with the Learning Plan, Dr. DeMio shall cease practicing medicine and surgery beginning the day following Dr. DeMio's receiving notice from the Board of such violation and shall refrain from practicing until the PLAS provides written notification to the Board that Dr. DeMio has reestablished compliance with the Learning Plan. Practice during the period of noncompliance shall be considered practicing medicine without a license, in violation of Section 4731.41, Ohio Revised Code.

5. **Practice Plan and Monitoring Physician**: Within 30 days of the date of Dr. DeMio's reinstatement or restoration, or as otherwise determined by the Board, Dr. DeMio shall submit to the Board and receive its approval for a plan of practice in Ohio. The practice plan, unless otherwise determined by the Board, shall be limited to a supervised structured environment in which Dr. DeMio's activities will be directly supervised and overseen by a monitoring physician approved by the Board. The practice plan shall, as determined by the Board, reflect, but not be limited to, the PLAS Learning Plan. Dr. DeMio shall obtain the Board's prior approval for any alteration to the practice plan approved pursuant to this Order.

At the time Dr. DeMio submits his practice plan, he shall also submit the name and curriculum vitae of a monitoring physician for prior written approval by the Secretary and Supervising Member of the Board. In approving an individual to serve in this capacity, the Secretary and Supervising Member will give preference to a physician who practices in the same locale as Dr. DeMio and who is engaged in the same or similar practice specialty.

The monitoring physician shall monitor Dr. DeMio and his medical practice, and shall review Dr. DeMio's patient charts. The chart review may be done on a random basis, with the frequency and number of charts reviewed to be determined by the Board.

Further, the monitoring physician shall provide the Board with reports on the monitoring of Dr. DeMio and his medical practice, and on the review of Dr. DeMio's patient charts. Dr. DeMio shall ensure that the reports are forwarded to the Board on a quarterly basis and are received in the Board's offices no later than the due date for Dr. DeMio's declarations of compliance.

In the event that the designated monitoring physician becomes unable or unwilling to serve in this capacity, Dr. DeMio shall immediately so notify the Board in writing. In addition, Dr. DeMio shall make arrangements acceptable to the Board for another

monitoring physician within 30 days after the previously designated monitoring physician becomes unable or unwilling to serve, unless otherwise determined by the Board. Dr. DeMio shall further ensure that the previously designated monitoring physician also notifies the Board directly of his or her inability to continue to serve and the reasons therefor.

The Board, in its sole discretion, may disapprove any physician proposed to serve as Dr. DeMio's monitoring physician, or may withdraw its approval of any physician previously approved to serve as Dr. DeMio's monitoring physician, in the event that the Secretary and Supervising Member of the Board determine that any such monitoring physician has demonstrated a lack of cooperation in providing information to the Board or for any other reason.

6. **Required Reporting of Change of Address**: Dr. DeMio shall notify the Board in writing of any change of residence address and/or principal practice address within 30 days of the change.

D. **TERMINATION OF PROBATION**: Upon successful completion of probation, as evidenced by a written release from the Board, Dr. DeMio's license will be fully restored.

E. **REQUIRED REPORTING TO THIRD PARTIES; VERIFICATION**:

1. **Required Reporting to Employers and Others**: Within 30 days of the effective date of this Order, Dr. DeMio shall provide a copy of this Order to all employers or entities with which he is under contract to provide healthcare services (including but not limited to third-party payors), or is receiving training, and the Chief of Staff at each hospital or healthcare center where he has privileges or appointments. Further, Dr. DeMio shall promptly provide a copy of this Order to all employers or entities with which he contracts in the future to provide healthcare services (including but not limited to third-party payors), or applies for or receives training, and the Chief of Staff at each hospital or healthcare center where he applies for or obtains privileges or appointments.

In the event that Dr. DeMio provides any healthcare services or healthcare direction or medical oversight to any emergency medical services organization or emergency medical services provider in Ohio, within 30 days of the effective date of this Order, he shall provide a copy of this Order to the Ohio Department of Public Safety, Division of Emergency Medical Services.

Further, within 30 days of the date of each such notification, Dr. DeMio shall provide documentation acceptable to the Secretary and Supervising Member of the Board demonstrating that the required notification has occurred.

This requirement shall continue until Dr. DeMio receives from the Board written notification of the successful completion of his probation.

2. **Required Reporting to Other Licensing Authorities**: Within 30 days of the effective date of this Order, Dr. DeMio shall provide a copy of this Order by certified mail to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license, as well as any federal agency or entity, including but not limited to the Drug Enforcement Administration, through which he currently holds any professional license or certificate. Also, Dr. DeMio shall provide a copy of this Order by certified mail at the time of application to the proper licensing authority of any state or jurisdiction in which he applies for any professional license or reinstatement/restoration of any professional license.

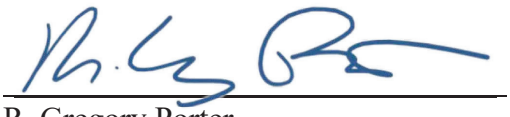
   Additionally, within 30 days of the effective date of this Order, Dr. DeMio shall provide a copy of this Order to any specialty or subspecialty board of the American Board of Medical Specialties or the American Osteopathic Association Bureau of Osteopathic Specialists under which he currently holds or has previously held certification.

   Further, within 30 days of the date of each such notification, Dr. DeMio shall provide documentation acceptable to the Secretary and Supervising Member of the Board demonstrating that the required notification has occurred.

   This requirement shall continue until Dr. DeMio receives from the Board written notification of the successful completion of his probation.

F. **VIOLATION OF THE TERMS OF THIS ORDER**: If Dr. DeMio violates the terms of this Order in any respect, the Board, after giving him notice and the opportunity to be heard, may institute whatever disciplinary action it deems appropriate, up to and including the permanent revocation of his license.

This Order shall become effective immediately upon the mailing of the notification of approval by the Board.



R. Gregory Porter
Hearing Examiner

State Medical Board of Ohio

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EXCERPT FROM THE DRAFT MINUTES OF SEPTEMBER 14, 2022 IN THE MATTER OF PHILLIP DEMIO, M.D.

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REPORTS AND RECOMMENDATIONS

Ms. Montgomery asked the Board to consider the Reports and Recommendations appearing on the agenda: Laurence Kobina Entsuah, M.D.; Phillip DeMio, M.D.; Charles Donald Mok, D.O.; Casey Prifogle, R.C.P.; James Shaw, L.M.T.; and Austin Kosier, M.D.

Ms. Montgomery asked all Board members the following questions:

1.) Has each member of the Board received, read and considered the Hearing Record; the Findings of Fact, Conclusions and Proposed Orders; and any objections filed in each of the Reports and Recommendations?

2.) Does each member of the Board understand that the Board's disciplinary guidelines do not limit any sanction to be imposed, and that the range of sanctions available in each matter runs from Dismissal to Permanent Revocation or Permanent Denial?

3.) Does each member of the Board understand that in each matter eligible for a fine, the Board's fining guidelines allow for imposition of the range of civil penalties, from no fine to the statutory maximum amount of $20,000?

ROLL CALL:	Dr. Rothermel	- aye
	Dr. Saferin	- aye
	Mr. Giacalone	- aye
	Dr. Schottenstein	- aye
	Dr. Soin	- aye
	Dr. Johnson	- aye
	Mr. Gonidakis	- aye
	Dr. Kakarala	- aye
	Dr. Feibel	- aye
	Dr. Reddy	- aye
	Dr. Bechtel	- aye
	Ms. Montgomery	- aye

Ms. Montgomery stated that in accordance with the provision in section 4731.22(F)(2), Ohio Revised Code, specifying that no member of the Board who supervises the investigation of a case shall participate in further adjudication of the case, the Secretary and Supervising Member must abstain from further participation in the adjudication of any disciplinary matters. In the disciplinary matters before the Board today, Dr. Rothermel served as Secretary and Dr. Saferin served as Supervising Member.

During these proceedings, no oral motions were allowed by either party.

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Phillip DeMio, M.D.

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Dr. Johnson moved to approve and confirm the Proposed Findings of Fact, Conclusions of Law, and Proposed Order in the matter of Dr. DeMio. Dr. Kakarala seconded the motion.

Ms. Montgomery stated that she will now entertain discussion in the above matter.

Dr. Reddy commented that he sees emotions over science in this case. Dr. Reddy stated that Dr. DeMio means well, but his methods are not acceptable medicine.

Dr. Schottenstein concurred with the Assistant Attorney General's comments. Dr. Schottenstein opined that Dr. DeMio has pretentions of knowledge and skill that he does not actually have. Dr. Schottenstein commented that Dr. DeMio perceives himself to be an expert in child psychiatry, chronic pain management, and infectious disease, three widely disparate fields with substantially different skill sets, none of which Dr. DeMio formally trained in.

Dr. Schottenstein further opined that Dr. DeMio perceives himself as not only an expert, but that his expertise is superior to that of other experts because he is practicing in a way that actual experts in those fields would never condone. For instance, Dr. DeMio recommends chelation therapy, hyperbaric oxygen, and oxytocin for patients with autism. However, in the field of child psychiatry chelation therapy is strongly discouraged because there is no evidence of efficacy and there is potential for serious harm and death. Hyperbaric oxygen therapy is not recommended as a treatment for autism, evidence to support it is insufficient, and there are potentially dangerous risks. Regarding oxytocin, a placebo-controlled trial showed no benefit for social or cognitive functioning; randomized trials showing evidence of benefit would be needed to recommend oxytocin.

Dr. Schottenstein noted the Dr. DeMio also endorses a link between vaccines and autism, which has been thoroughly debunked. There is no causal association between the MMR vaccine and autism and no causal association between thimerosal and autism. Dr. Schottenstein pointed out that there are cases of polio in this country again because physicians like Dr. DeMio scare people away from life-saving vaccines.

Dr. Schottenstein continued that patients are literally at risk of serious injury and death based on the way Dr. DeMio prescribes opioids and antibiotics. The Board's expert pediatric witness, Bradley Jackson, M.D., used the word "astounding" to describe the regime of a prescribed antibiotic. Dr. DeMio prescribes anti-viral medication when there is no scientific evidence to justify the treatment of a virus, and he also prescribes anti-parasitic medications when there is no scientific evidence of the presence of a parasite. Dr. Schottenstein stated that the science is clear in these matters, but that does not make an impression on Dr. DeMio because he is not science-based.

Dr. Schottenstein perceived that Dr. DeMio has an inherently unfalsifiable belief system in which something that cannot be proven wrong must be true. There is a substantial dependence on confirmation bias, meaning Dr. DeMio favors information that supports what he already believes. This is seen in Dr. DeMio's embrace of patient testimonials to justify his practice even though patient testimonials never qualify as evidence in the field of medicine. Dr. DeMio attempts to cloak himself in credibility by embracing like-minded physicians, national meetings, and associations that act as echo chambers but are not credible or science-based. Dr. DeMio dresses up his beliefs in science, uses medical jargon, and orders laboratory tests to suit his purposes; when the laboratory value does not confirm his belief, he is not dissuaded; he simply discounts the values as erroneous.

Dr. Schottenstein stated that Dr. DeMio has been diagnosing medical conditions out of whole cloth and treating medical conditions where the medical evidence indicates serious risk and inefficacy. That cannot be justified by claiming to practice integrative medicine, prescribing medications off-label, characterizing the treatment as complimentary or alternative, or referencing the treatment as "empirical." Characterizing one's practice and treatments in this manner cannot be used as a shield to justify practice below the minimum standards of care. Dr. DeMio is deviating from the principles of science which inform the practice of medicine. Dr. Schottenstein stated that this manner of practice can fairly be characterized as quackery and it tempts vulnerable patients away from legitimate care that is science-based, which has negative repercussions in terms of both the physical and emotional health for these individuals and for society at large.

Dr. Schottenstein stated that Dr. DeMio is fortunate that he has not hurt or killed someone thus far. One cannot prescribe dangerous treatments that actual specialists in the field shy away from because they are lacking in evidence. This manner of practice is reckless and bespeaks hubris. Dr. DeMio does not seem to understand that just because something makes sense to him does not make it true, and that is why there are studies to guide physicians' practice. Dr. Schottenstein opined that the Board needs to save Dr. DeMio from himself.

Dr. Schottenstein stated that Dr. DeMio and his defense counsel attempt to rely on their argument that there were many long-suffering patients who got better with Dr. DeMio's treatment. However, Dr. Schottenstein noted that Dr. DeMio spends a great deal of time with his patients and shows compassion towards them. Dr. Schottenstein speculated that a large part of the reason these patients feel better is because of the time Dr. DeMio spends talking and listening to them when, in some cases, no one else would. Dr. Schottenstein suspected that these counseling sessions make the patients feel better and make them feel like their children are doing better. To this day, it is not known if the patients actually had the conditions Dr. DeMio diagnosed because he ignored the laboratory values that did not fit his narrative, and it is not known if Dr. DeMio's "machine gun" approach to treatment, in which he prescribed several broad-spectrum agents, treated something that was not even on his list of diagnoses, essentially treating the patients by accident. It is also not known if the patients would have gotten better in time if they had not been treated or if there had been a placebo response. Dr. Schottenstein stated that these are difficult concepts for those not educated in scientific principles, but he was somewhat incredulous that Dr. DeMio does not seem to understand these basic and obvious flaws in his theory that he must be practicing medicine appropriately because some of his patients got better.

Dr. Schottenstein stated that this should not be turned into a referendum on alternative medicine or complimentary alternative treatment. That manner of practice has a place in the practice of medicine, but there is only one standard of care. Dr. DeMio is not before the Board today for practicing integrative medicine. Rather, Dr. DeMio is here because he is prescribing treatment for which the medical evidence indicates inefficacy and serious risk.

Regarding the Proposed Order, Dr. Schottenstein appreciated the thought of referring Dr. DeMio to a physician reentry program. However, Dr. Schottenstein stated that Dr. DeMio practices based on his belief system, and therefore he did not believe that providing Dr. DeMio with additional education would impact his practice. Dr. Schottenstein suggested amending the Proposed Order so that Dr. DeMio's license is permanently restricted and limited to his specialty, namely the practice of emergency medicine and urgent care medicine. Dr. Schottenstein noted that there have been no allegations of minimal standards violations in these areas and Dr. DeMio has testified that he practices conventional medicine in those fields. This would obviate the need for a physician reentry program. Dr. Schottenstein felt that the provision for a practice plan should remain in place. Dr. Schottenstein further suggested that the probationary period be shortened from a minimum of three years to a minimum of two years since the Board does not have minimal standards of care concerns regarding Dr. DeMio's practice of emergency medicine.

Dr. Feibel agreed with virtually all of Dr. Schottenstein's comments. However, Dr. Feibel emphasized that Dr. DeMio had practice below the minimal standards of care in a manner that, as Dr. Schottenstein noted, was reckless and bespoke of hubris with potential for severe harm and death to children. Dr. Feibel stated that Dr. DeMio's actions were unethical and dangerous, and to allow such a person to return to the practice of medicine in any circumstance would be reckless in Dr. Feibel's opinion. Dr. Feibel strongly suggested permanently revoking Dr. DeMio's medical license. Dr. Feibel, while acknowledging that every case is different, noted that the Board had previously revoked the license of a physician for their dangerous treatments for Lyme disease in adults.

Ms. Montgomery thanked Dr. Schottenstein for his thorough review of this case. Ms. Montgomery agreed with Dr. Feibel's comments, stating that Dr. DeMio's behavior was dangerous and she was not certain this matter is remediable. Ms. Montgomery had the sense that Dr. DeMio had simply been trying treatment after treatment until one worked, without any science behind his decisions. Ms. Montgomery was not certain if a change at this point in Dr. DeMio's practice could make him a safely-practicing physician, and she therefore favored permanent revocation.

Ms. Gonidakis commented that Dr. Schottenstein's proposed amendment addresses Ms. Montgomery's concerns by limiting Dr. DeMio to the practice of emergency medicine and urgent care medicine. Ms. Montgomery replied that she is more concerned with Dr. DeMio's underlying mentality and denial of the scientific method. Ms. Montgomery stated that the Board has to address Dr. DeMio's behavior as it has been presented to the Board, and she felt that Dr. DeMio deserves to lose his license.

Dr. Soin agreed that that Dr. DeMio's behavior and some of the things that were done are very challenging. Dr. Soin also appreciated the depth of the Hearing Examiner's Report and Recommendation. Dr. Soin stated that upon his initial review of this case he also favored

permanent revocation of Dr. DeMio's license. However, Dr. Soin wished to discuss five relevant points.

First, Dr. Soin noted that Dr. DeMio allegedly violated that minimal standards of care by not checking the Ohio Automated Rx Reporting System (OARRS) for his patients. Dr. Soin stated that in the time frame in question, March 2012 through 2016, the concept of checking OARRS in pain management was vastly different from what it is today. Dr. Soin recalled that when he joined the Medical Board in 2013 OARRS reports specifically stated that the report is not accurate and does not belong in the medical record. Dr. Soin stated that it was a couple of years after he joined the Medical Board that the Board began educating physicians on the process of checking OARRS. Dr. Soin agreed that Dr. DeMio should have been checking OARRS, but stated that there could be some nuance on whether that was the standard of care at that time.

Second, Dr. Soin agreed that prescribing benzodiazepines and opioids for a protracted period is not a good idea. However, in the time period of 2012 to 2016, and even today, Dr. Soin sees this occur in the referrals he receives as a pain management specialist. There can be nuance in some situations that would make such prescribing appropriate for particular patients, and Dr. Soin was therefore uncertain if that is always a breach of the minimal standards of care, though it is not necessarily recommended.

Third, Dr. Soin noted comments that Dr. DeMio is not board-certified in a specialty other than emergency medicine, never completed a residency other than emergency medicine, and never completed a fellowship. Dr. Soin pointed out that the Board's expert witness is a family practice physician, Dr. Croake-Uleman, who never completed a residency in pain management. Dr. Croake-Uleman indicated that she has received training from the American Society of Interventional Pain Physicians (ASIPP). Dr. Soin, who has served for two years as president of the ASIPP, stated that ASIPP does not offer a fellowship but does offer courses such as a recent weekend course that was six hours per day for two days. Dr. Soin stated that such a supplemental educational course would not qualify someone as an expert. Dr. Croake-Uleman also did not complete a residency in pain management and is not board-certified in pain management by the American Board of Medical Specialties. Dr. Soin found it odd and hypocritical to hold Dr. DeMio to such a standard when the Board's expert witness against him also does not meet that standard.

Dr. Soin continued that at one point Dr. Croake-Uleman stated that there is no place for prescribing low-dose naltrexone with opioids. Dr. Soin stated that, in fact, low-dose naltrexone is often used in pain management and there are numerous studies of it being used with opioids. For example, low-dose naltrexone is approved by the Food and Drug Administration (FDA), with a randomized controlled trial, to use naltrexone with opioids to treat opioid-induced constipation.

Fourth, Dr. Soin stated that things such as chelation, glutathione, and hyperbaric oxygen are not things he would recommend. However, these are things that are being done and are advertised all over Ohio in integrative medicine scenarios. Dr. Soin stated that the standard of care for such treatments is nebulous, which poses challenges when considering whether to permanently revoke a physician's license. Dr. Soin added that there is also nuance around the concept of following the science. Dr. Soin noted that when he was in medical school it was commonly known that if someone is having chest pains shooting down their arm with exertion, they should

be given an aspirin and put on oxygen, among other things. However, aspirin was not approved by the FDA for acute myocardial infarction (MI) and the FDA did not issue a statement on that topic until about 2014. Dr. Soin stated that oftentimes physicians do things without randomized controlled trials because there is some art and nuance in the ways people practice.

Fifth, Dr. Soin stated that it is very important for physicians who prescribe these medications to be doing urine drug screens. However, Dr. Soin recalled when the Medical Board's red flag guidance was issued because he helped write that guidance a couple of years after he had joined the Medical Board. Dr. Soin stated that it is challenging to apply this standard in hindsight to the 2013 to 2016 time frame.

Dr. Soin observed that Dr. DeMio has had no prior issues with the Board. Further, the Hearing Examiner determined that Dr. DeMio did not engage in this behavior for financial reasons. According to testimony, Dr. DeMio tried to help people and he had stopped controlled substances for some patients. Dr. DeMio now has integrated electronic medical records to help with issues like handwriting.

Dr. Soin commented that this is a complicated case. Dr. Soin opined that Dr. DeMio could be remediated, contribute to society, and be helpful to people. Dr. Soin opined that permanently revoking Dr. DeMio's license could be a disservice to the community. Dr. Soin favored Dr. Schottenstein's proposed amendment, including the provision to limit Dr. DeMio to emergency and urgent care medicine.

Mr. Giacalone thanked Dr. Soin for his comments, particularly those relating to controlled substances. Mr. Giacalone opined that the bigger factor is whether Dr. DeMio should continue practicing medicine. Mr. Giacalone stated that he is struggling with this case, noting that at one time blood-letting and leeches were the standard of care and then the practice of medicine evolved. However, Mr. Giacalone also questioned whether the areas of Dr. DeMio's practice are still in development or if there is now more scientific literature that may demand a different opinion. Mr. Giacalone opined that Dr. DeMio overstepped the line at least in terms of his treatment of autism, Lyme disease, and some other treatments. In Dr. DeMio's defense, Mr. Giacalone stated that Dr. DeMio was not in it for the money and he had the intention to help people.

Mr. Giacalone continued that these conditions have affected Dr. DeMio's family and that may have skewed his analysis in trying to find an ultimate solution that probably does not exist, and this ultimate solution is what Dr. DeMio's patients are also trying to find for themselves and their children, as any parent would.

Mr. Giacalone stated that alternative care therapy is acceptable, but he questioned if it was reasonable in this case and whether the benefits and risks of alternative medical treatment versus conventional care had been properly compared. Mr. Giacalone, as a pharmacist, stated that the medications prescribed by Dr. DeMio were out-of-scope for these conditions and were not approved for such use by the FDA. On the other hand, treatment utilizing medications for off-label use is not uncommon.

Mr. Giacalone stated that he generally agrees with Dr. Soin and Dr. Schottenstein to confine Dr. DeMio's practice to emergency medicine and specifically away from the treatment of autism,

Lyme disease, and the other conditions at issue in this case. Mr. Giacalone opined that as long as Dr. DeMio understands that treating those conditions is out-of-scope for him, he will probably be okay because he is a compassionate person.

Dr. Kakarala stated that this case involves patients or patient families who are very desperate, so they are willing to undergo any type of therapy or treatment so their loved one can get better. This makes the patients very susceptible to exploitation. Dr. Kakarala added that he has practiced hyperbaric medicine and that many factors have to be considered before sending a patient to a hyperbaric chamber, including chest x-rays, making certain there is no risk of tympanic membrane rupture, a significant neurological examination, sometimes prescreening CT scans of the brain, head, and neck, and possibly articular examinations depending on the patient's history. There was no documentation that any of these things were done before Dr. DeMio's patients were referred for hyperbaric treatment. Dr. Kakarala stated that life-threatening crises like pneumothoraces and pneumopericardium can result from improper referral to hyperbaric treatment.

Dr. Kakarala reiterated that hyperbaric therapy can be potentially dangerous for the wrong type of patient, especially if they are not screened properly. Anyone who does not understand that should not be prescribing that type of therapy, particularly for patients who may not have a full understanding of the risks. This is especially true when there could be repeated sessions of hyperbaric therapy. Dr. Kakarala questioned how a physician can properly inform patients of the risks when they themselves do not understand them. Dr. Kakarala noted that the risks of hyperbaric treatment do not seem to have ever been outlined for the patients.

Dr. Kakarala stated that he does not usually support the permanent revocation of licenses, but in this case he would advocate for a permanent revocation of Dr. DeMio's license.

Dr. Reddy reiterated that emotions played a significant role in this matter, both Dr. DeMio's emotions and the patients emotions. Dr. DeMio had the right intention of helping these patient with very difficult problems, but his methods were not acceptable.

Mr. Gonidakis asked whether Dr. DeMio's license should be suspended since, under Dr. Schottenstein's proposal, he would also be restricted from the practice that is source of the Board's concerns. Dr. Schottenstein felt that the suspension is appropriate based on the manner in which Dr. DeMio had practiced in these cases. Dr. Schottenstein stated that he would be glad to hear other Board members' thoughts on whether a suspension is appropriate. Dr. Soin stated that he initially had had the same thought as Mr. Gonidakis. However, Dr. Soin strongly agreed with the suspension and strongly disagreed with how Dr. DeMio had taken care of his patients. Dr. Soin felt it is important to send a message with the suspension of Dr. DeMio's license.

Dr. Johnson asked if Dr. DeMio would be able to practice telemedicine if he continues to have an active license. Dr. Schottenstein replied that he had envisioned Dr. DeMio only practicing in an urgent care or emergency department setting. Dr. Kakarala expressed concern that the same types of patients can present in an emergency or urgent care setting due to symptoms of Lyme disease, for instance, allowing opportunity for Dr. DeMio to impart the same manner of care. Dr. Soin agreed and questioned whether an emergency department or urgent care center may also have a chelation center or a hyperbaric oxygen chamber attached to it. If this is the

case, Dr. Soin felt that it should be made clear that such practice would be considered a breach of the order from a material standpoint.

Ms. Montgomery asked if Dr. DeMio would be able to open his own urgent care center under Dr. Schottenstein's proposal. Dr. Schottenstein replied that there would be nothing in the order to prevent that. Dr. Schottenstein stated that the spirit of the order would be that Dr. DeMio would practice emergency or urgent care medicine and not attempt to engage in the treatments or prescribing that had brought him to the Board's attention. Dr. Schottenstein noted Dr. DeMio's testimony that 99.9% of what he does in the emergency department is conventional medicine and there are no allegations of minimal standards concerns with Dr. DeMio's emergency medicine practice.

Dr. Feibel asked for Ms. Anderson's opinion on what it means to restrict a license to the practice of emergency medicine and what would constitute a violation of such an order. Ms. Anderson replied that if the Board adopts such an order, the staff would probably consult with experts about any practice that is alleged to be outside the scope of emergency or urgent care medicine. Ms. Anderson commented that she is unaware of any previous Board order with this specific permanent restriction.

Dr. Feibel opined that the practical application of the proposed permanent restriction is very ambiguous. Dr. Feibel appreciated Dr. Soin's insightful comments, but stated that he is basing his determination on Dr. DeMio's actions and interpretation of the record as a whole rather than what a particular expert said or opined. Dr. Feibel was worried most about Dr. DeMio's stubbornness and inability to look inward and recognize that he has a problem because he is not using science. For instance, it is fairly well elucidated that Lyme disease is caused by a tick, yet Dr. DeMio would not agree to that fact. Also, when asked the question, Dr. DeMio did not know what "peer-reviewed literature" was. Dr. Feibel did not have the feeling that Dr. DeMio recognizes his mistakes or plans to change his practice accordingly. Dr. Feibel reiterated that the Board revoked the license of another physician based on the physician's use of a machine to make diagnoses which were not based on science. Dr. Feibel opined that it is not fair to the public to continue allowing Dr. DeMio to practice when he failed to recognize that the treatments he prescribed could have seriously harmed or killed his patients.

Dr. Soin commented that he does not know what the correct answer is in this case. Dr. Soin had given this case a great deal of thought and did not sleep until at least 2:38 a.m. the previous night because he had been thinking about this case. Dr. Soin added that he, also, is concerned about the public.

Mr. Gonidakis noted that this case involves the treatment of 16 patients, which includes adult as well as pediatric patients. Mr. Gonidakis further noted that while some Board members advocate for revoking Dr. DeMio's license, Dr. Soin has called into question the analysis of the expert the Board is relying on.

Dr. Feibel stated that he is focusing on the totality of the case. Dr. Feibel found Dr. Soin's point about OARRS reports to be very valid, but still felt that Dr. DeMio's care fell below the minimal standards of care at that time. The Board members have the ability to interpret the record and to agree or disagree with the experts' opinions. Dr. Feibel reiterated that he is basing his decision not on the expert's testimony, but on the entirety of Dr. DeMio's actions and on his own

knowledge of medicine as a whole. Dr. Feibel stated that he would not want one of his family members to be treated by Dr. DeMio because he would not trust that the family member is receiving the scientifically-based standard of care. Dr. Feibel stated that all patients should expect scientifically-based care.

Ms. Montgomery thanked the Board for its very thoughtful and insightful conversation. Ms. Montgomery stated that she also does not rely solely on the Board's expert. Ms. Montgomery noted that at the hearing Dr. DeMio did not know what the term "peer-reviewed literature" meant, something that even Ms. Montgomery as a non-physician knows. Ms. Montgomery agreed with Dr. Reddy that Dr. DeMio's approach to these issues seems to be an emotional response and he seems to try whatever treatments are available until one works. Ms. Montgomery had the impression that, although Dr. DeMio seems to be well-intentioned, he is dangerous, and for this reason Ms. Montgomery did not support Dr. Schottenstein's recommendation.

Dr. Schottenstein appreciated the point that under his proposal Dr. DeMio may be able to provide longitudinal care in an urgent care setting. Dr. Schottenstein stated that he could modify his proposal to specify only emergency medicine and remove the urgent care aspects.

Dr. Schottenstein moved to amend the Proposed Order to permanently restrict and limit Dr. DeMio's medical license to the practice of emergency medicine in an emergency department; remove the requirement for the Post-Licensure Assessment Program; reduce the probationary period from a minimum of three years to a minimum of two years; and leave all other provisions of the Proposed Order, including the requirement for a practice plan and monitoring physician, in place. Mr. Gonidakis seconded the motion. A vote was taken:

ROLL CALL:	Dr. Rothermel	- abstain
	Dr. Saferin	- abstain
	Mr. Giacalone	- aye
	Dr. Schottenstein	- aye
	Dr. Soin	- nay
	Dr. Johnson	- nay
	Mr. Gonidakis	- aye
	Dr. Kakarala	- nay
	Dr. Feibel	- nay
	Dr. Reddy	- nay
	Dr. Bechtel	- abstain
	Ms. Montgomery	- nay

The motion to amend did not carry.

Dr. Feibel moved to amend the Proposed Order to a permanent revocation of Dr. DeMio's license to practice medicine and surgery. Dr. Kakarala seconded the motion. A vote was taken:

ROLL CALL:	Dr. Rothermel	- abstain
	Dr. Saferin	- abstain

Mr. Giacalone	- aye
Dr. Schottenstein	- aye
Dr. Soin	- aye
Dr. Johnson	- aye
Mr. Gonidakis	- nay
Dr. Kakarala	- aye
Dr. Feibel	- aye
Dr. Reddy	- aye
Dr. Bechtel	- abstain
Ms. Montgomery	- aye

The motion to amend carried.

In response to a question from Ms. Anderson, Dr. Feibel clarified that his amendment did not include the $4,500 fine or the 30-day wind down period that was in the Proposed Order. Therefore, those provisions are not part of the amended order.

Dr. Feibel moved to approve and confirm the Proposed Findings of Fact, Conclusions of Law, and Proposed Order, as amended, in the matter of Dr. DeMio. Mr. Giacalone seconded the motion. A vote was taken:

ROLL CALL:	Dr. Rothermel	- abstain
	Dr. Saferin	- abstain
	Mr. Giacalone	- aye
	Dr. Schottenstein	- aye
	Dr. Soin	- aye
	Dr. Johnson	- aye
	Mr. Gonidakis	- nay
	Dr. Kakarala	- aye
	Dr. Feibel	- aye
	Dr. Reddy	- aye
	Dr. Bechtel	- abstain
	Ms. Montgomery	- aye

The motion to approve carried.

State Medical Board of
Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

January 9, 2019

Case number: 19-CRF- 0001

Phillip DeMio, M.D.
320 Orchardview Ave., Suite 2
Seven Hills, OH 44131

Dear Doctor DeMio:

In accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the State Medical Board of Ohio [Board] intends to determine whether or not to limit, revoke, permanently revoke, suspend, refuse to grant or register or renew or reinstate your license or certificate to practice medicine and surgery, or to reprimand you or place you on probation for one or more of the following reasons:

(1) During the time period of during or about March 2012 through during or about September 2016, you provided care in the routine course of your practice, for the sixteen patients identified on the attached confidential Patient Key. (The Patient Key is to be withheld from public disclosure.)

(2) In the course of your treatment of HF, JH, JM, SP, and AKT, adult patients whom you treated during the time period of during or about March 2012 through during or about July 2016, you practiced below minimal standards of care, including, but not limited to:

- You failed to complete and/or document the completion of an appropriate history and physical exam to establish a diagnosis and treatment plan; you consistently failed to document vital signs;
- You failed to complete and/or document the completion of updating imaging and/or diagnostic testing to support the patients' treatment plan;
- You failed to appropriately refer and/or document appropriate referral and/or appropriately follow-up on referrals to specialists and/or appropriately implement specialist recommendations; your medical documentation was inadequate, difficult to follow, and difficult to determine the dates/dosages of medications;
- You failed to complete appropriate toxicology screening to determine compliance with medications prescribed and/or use of non-prescribed and/or illicit substances to identify possible addiction issues; you failed to consistently assess the patient's functional status while prescribing opioid medication on a protracted basis;
- You failed to consider or document consideration of non-opioid treatments; the amount and/or type and/or combinations of medications prescribed was

Mailed 1-10-19

inappropriate, including inappropriately prescribing benzodiazepines and opioids concurrently; you failed to appropriately evaluate, or document the appropriate evaluation with respect to possible adverse drug effects, and/or signs of any illegal drug and/or alcohol use or abuse; and/or

- You failed to complete and/or document completion of appropriate OARRS checks.

(3) In the course of your treatment of patients TK, DP, BT, AL, DF, BG, TG, IJG, HR, KH, and SW, pediatric patients whom you treated during the time period of during or about January 2014 through during or about September 2016, you practiced below minimal standard of care, including, but not limited to:

- You failed to appropriately identify or document the identification of defined chief complaint;
- You failed to complete, appropriately review and/or properly document completion of review of a history of present/past medical illness, medication list, allergies, a detailed review of systems and/or physical examination/assessment to support the documented diagnoses;
- You failed to complete and/or document the completion of diagnostic testing to support the patients' diagnoses and/or treatment plan;
- You failed to appropriately refer and/or document appropriate referrals to specialists;
- Your treatment and/or medical management was not appropriate for complaint/diagnosis/diagnostic testing;
- The amount and/or type of medications and/or supplements prescribed were not supported by history, diagnosis, physical exam, and/or laboratory findings, including but not limited to: prescribing thyroid medication without the presence of abnormal thyroid function studies, utilizing chelating supplements and medications in the absence of heavy metals in testing, prescribing anti-malarial medication without a confirmed diagnosis of malaria, and prescribing anti-parasitic medication without documentation of a parasitic infection.

Your acts, conduct, and/or omissions as alleged in paragraphs (1) through (3) above, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as that clause is used in Section 4731.22(B)(2), Ohio Revised Code.

Further, your acts, conduct, and/or omissions as alleged in paragraphs (1) through (3) above, individually and/or collectively, constitute a "departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.

Further, your acts, conduct, and/or omissions, as alleged in paragraphs (1) through (2) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly,

or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code, to wit: Utilizing Prescription Drugs for the Treatment of Intractable Pain, Rule 4731-21-02, Ohio Administrative Code, as in effect from November 30, 2008, through August 30, 2017.

Further, your acts, conduct, and/or omissions that occurred on or before December 30, 2015, as alleged in paragraphs (1) through (2) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code, to wit: General Provisions, Rule 4731-11-02, Ohio Administrative Code, as in effect from September 30, 2008, through December 30, 2015. Furthermore, pursuant to Rule 4731-11-02(F), Ohio Administrative Code, as in effect at that time, any violation of Rule 4731-11-02 also constitutes a violation of Section 4731.22(B)(2), Ohio Revised Code, and Section 4731.22(B)(6), Ohio Revised Code.

Further, your acts, conduct, and/or omissions that occurred on or after December 31, 2015, as alleged in paragraphs (1) through (2) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code, to wit: General Provisions, Rule 4731-11-02, Ohio Administrative Code, as in effect from December 31, 2015, through August 30, 2017. Furthermore, pursuant to Rule 4731-11-02(E), Ohio Administrative Code, as in effect at that time, any violation of Rule 4731-11-02 also constitutes a violation of Section 4731.22(B)(2), Ohio Revised Code, and Section 4731.22(B)(6), Ohio Revised Code.

Further, your acts, conduct, and/or omissions that occurred on or before December 30, 2015, as alleged in paragraphs (1) through (2) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code, to wit: Standards and Procedures for Review of "Ohio Automated Rx Reporting System" (OARRS), Rule 4731-11-11, Ohio Administrative Code, as in effect from November 30, 2011, through December 30, 2015.

Further, your acts, conduct, and/or omissions that occurred on or after December 31, 2015, as alleged in paragraphs (1) through (2) above, individually and/or collectively, constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in Section 4731.22(B)(20), Ohio Revised Code, to wit: Standards and Procedures for Review of "Ohio Automated Rx Reporting System" (OARRS), Rule 4731-11-11, Ohio Administrative Code, as currently effective commencing on December 31, 2015.

Furthermore, for any violations that occurred on or after September 29, 2015, the board may impose a civil penalty in an amount that shall not exceed twenty thousand dollars, pursuant to Section 4731.225, Ohio Revised Code. The civil penalty may be in addition to any other action the board may take under section 4731.22, Ohio Revised Code.

Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty days of the time of mailing of this notice.

You are further advised that, if you timely request a hearing, you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, permanently revoke, suspend, refuse to grant or register or renew or reinstate your certificate or license to practice medicine and surgery or to reprimand you or place you on probation.

Please note that, whether or not you request a hearing, Section 4731.22(L), Ohio Revised Code, provides that "[w]hen the board refuses to grant or issue a license or certificate to practice to an applicant, revokes an individual's license or certificate to practice, refuses to renew an individual's license or certificate to practice, or refuses to reinstate an individual's license or certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a license or certificate to practice and the board shall not accept an application for reinstatement of the license or certificate or for issuance of a new license or certificate."

Copies of the applicable sections are enclosed for your information.

Very truly yours,

Kim G. Rothermel, M.D.

Kim G. Rothermel, M.D.
Secretary

KGR/AMM/jb
Enclosures

CERTIFIED MAIL #91 7199 9991 7038 9415 8368
RETURN RECEIPT REQUESTED

cc: Daniel S. Zinsmaster
Dinsmore & Shohl, L.L.P.
191 West Nationwide Blvd., Ste. 300
Columbus, OH 43215

CERTIFIED MAIL #91 7199 9991 7038 9415 8375
RETURN RECEIPT REQUESTED

IN THE MATTER OF PHILLIP CHRISTOPHER DEMIO, MD

19-CRF-0001

JANUARY 9, 2019, NOTICE OF OPPORTUNITY FOR HEARING - PATIENT KEY

SEALED TO PROTECT PATIENT CONFIDENTIALITY AND MAINTAINED IN CASE RECORD FILE.