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BEFORE THE STATE MEDICAL BOARD OF OHIO

TIM R. VALKO, M.D.
3130 Executive Parkway, 8th Floor
Toledo, Ohio 43606

Appellant,

vs.

STATE MEDICAL BOARD OF OHIO
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Appellee.

Case No. _____

Judge _____

Board Case No. 17-CRF-0096

APPEAL FROM THE ENTRY OF ORDER OF MARCH 11, 2020 AND MAILED MARCH 26, 2020

NOTICE OF APPEAL

Appellant, Tim R. Valko, M.D., by and through counsel, and pursuant to Ohio Revised Code § 119.12, timely submits this Notice of Appeal from the Entry of Order of Appellee, the State Medical Board of Ohio ("Board"), which permanently revokes Dr. Valko's certificate to practice medicine and surgery in the State of Ohio. The Board's Entry of Order is dated March 11, 2020, and was mailed March 26, 2020. The grounds for this appeal are that the Board's Entry of Order dated March 11, 2020, is not supported by reliable, probative, and substantial evidence and is not in accordance with the law.

A copy of the Board's Entry of Order is attached as "Exhibit A."

Respectfully submitted,

DINSMORE & SHOHL LLP

/s/ Daniel S. Zinsmaster
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Counsel for Appellant Tim R. Valko, M.D.

STATE MEDICAL BOARD OF OHIO
RECEIVED:
March 27, 2020

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 27th day of March, 2020, the foregoing Notice of Appeal was filed electronically with the State Medical Board of Ohio (HearingUnit@med.ohio.gov), a copy filed electronically with the Franklin County Court of Common Pleas, and an additional copy served by electronic mail upon the following:

Kyle C. Wilcox, Esq.
Melinda R. Snyder, Esq.
Assistant Attorneys General
Ohio Attorney General's Office
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30 East Broad Street, 26th Floor
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/s/ Daniel S. Zinsmaster
Daniel S. Zinsmaster (0079687)

STATE MEDICAL BOARD OF OHIO
RECEIVED:
March 27, 2020

State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

March 11, 2020

Tim R. Valko, M.D.
3130 Executive Parkway, 8th Floor
Toledo, OH 43606

RE: Case No. 17-CRF-0096

Dear Doctor Valko:

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 March 11, 2020, including motions modifying the Findings of Fact and Conclusions of the Hearing Examiner, 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, MD/smc
Kim G. Rothermel, M.D.
Secretary

KGR:jam
Enclosures

CERTIFIED MAIL NO. 91 7199 9991 7038 7157 6259
RETURN RECEIPT REQUESTED

Cc: Daniel S. Zinsmaster and Heidi W. Dorn, Esqs.
CERTIFIED MAIL NO. 91 7199 9991 7038 7157 6536
RETURN RECEIPT REQUESTED

mailed 3/26/2020

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 March 11, 2020, including motions modifying the Findings of Fact and the Conclusions of the Hearing; and adopting an amended Order; constitute a true and complete copy of the Findings and Order of the State Medical Board in the matter Tim R. Valko, M.D., Case No. 17-CRF-0096, 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.

Kim G. Rothermel, M.D.
Secretary

(SEAL)

March 11, 2020
Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF	*	
	*	CASE NO. 17-CRF-0096
TIM R. VALKO, M.D.	*	

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on March 11, 2020.

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.

AMENDED FINDING OF FACT 1.L.ii

1.1.ii. On July 28, 2011, Patient 15's mother reported that, since the last visit, Patient 15 had experienced what she believed to be side effects from Prozac. She further reported that she discontinued Patient 15's afternoon dose, reducing his daily dose of Prozac from 80 mg to 40 mg. At that visit, Dr. Valko left Patient 15's Prozac at the lower dose of 40 mg and added BuSpar 10 mg twice per day to help prevent possible serotonin syndrome. Dr. Barzman criticized using BuSpar for that purpose when Dr. Valko could have lowered the dose of Prozac. Nevertheless, the hearing examiner found that it was an appropriate use of BuSpar when the doctor added it to a lower dose of Prozac to prevent possible serotonin syndrome. However, the Board, as a panel of experts equipped with the necessary knowledge and experience to interpret the technical and ethical requirements of its profession, finds otherwise.

Patient 15 had been on 80 mg per day of Prozac. The dose was decreased from 80 mg per day to 40 mg per day, and then BuSpar 10 mg twice per day was initiated to compensate for the decrease in the dose of the Prozac. That in itself is not necessarily problematic; however, this change does not reduce the risk of serotonin syndrome because BuSpar is a serotonergic drug. Although the dose of Prozac was lowered, BuSpar was added into the mix leaving the risk of serotonin syndrome for the most part unchanged. Accordingly, it is not accurate to find that Dr. Valko's change of medication lowered the risk of serotonin syndrome.

AMENDED FINDING OF FACT 2.I.ii

2.i.ii To clarify and expand upon the current proposed finding, GeneSight testing performed after the relevant time period indicated that Patient 9 is a fast metabolizer of stimulant medication and other drugs. However, the evidence also established that Dr. Valko prescribed doses of stimulant medication to Patient 9 that ranged as high as ten times the maximum recommended dose for his age. That is way beyond the degree of dose increase that one would contemplate to compensate for rapid metabolism. Accordingly, the Board finds that Patient 9 being a rapid metabolizer in no way justified such large doses of stimulant medication, and finds that this prescribing was inappropriate.

AMENDED CONCLUSIONS OF LAW

(**Amended to include Finding of Fact 1.l.ii as a violation**)

The acts, conduct, and/or omissions of Tim R. Valko, M.D., as described in Findings of Fact 1, 1.a.i. and 1.a.ii., 1.b. in its entirety, 1.c.i. and 1.c.ii., 1.d. in its entirety, 1.e.i. and 1.e.iii., 1.f. in its entirety, 1.g. in its entirety, 1.h., 1.i., 1.j in its entirety, 1.k. in its entirety, and 1.l in its entirety; 2, 2.a. in its entirety, 2.b.i. and 2.b.ii., 2.c. in its entirety, 2.d. in its entirety, 2.e. in its entirety, 2.f. in its entirety, 2.g.i. in its entirety, 2.h. in its entirety, 2.i.i. and 2.i.ii., 2.j. in its entirety, 2.k. in its entirety, 2.l., 2.m., 2.n., and 2.o.i. through 2.o.iii., individually and/or collectively, constitute a "[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 those clauses are used in R.C. 4731.22(B)(2).

The treatment of Patient 15 with large doses of stimulant medication, as set forth in Finding of Fact 2.o.i., extended beyond September 29, 2015, and continued through July 2016. Pursuant to R.C. 4731.225, the Board is authorized to impose a civil penalty for this violation. The Board's fining guidelines for this violation are as follows: Minimum Fine $2,500; Maximum Fine $18,000.

It is hereby ORDERED that:

A. **PERMANENT REVOCATION**: The license of Tim R. Valko, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

B. **FINE**: Within thirty days of the effective date of this Order, Dr. Valko shall remit payment in full of a fine of two thousand five hundred dollars ($2,500.00). 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.

EFFECTIVE DATE OF ORDER: This Order shall become effective immediately upon the mailing of the notification of approval by the Board.

Kim G. Rothermel, M.D.
Secretary

(SEAL)

March 11, 2020
Date

STATE MEDICAL BOARD
OF OHIO

RECEIVED:
February 12, 2020

BEFORE THE STATE MEDICAL BOARD OF OHIO

In the Matter of	*	
		Case No. 17-CRF-0096
Tim R. Valko, M.D.,	*	
		Hearing Examiner Porter
Respondent.	*	

REPORT AND RECOMMENDATION

Basis for Hearing

In a notice of opportunity for hearing dated July 12, 2017 ("Notice"), the State Medical Board of Ohio ("Board") notified Tim R. Valko, 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 15 patients identified on a confidential Patient Key. The Board alleged that Dr. Valko's prescribing of medications to Patients 1 through 15 during the time period from in or around January 2005 through in or around August 2016 constitutes a "[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 Ohio Revised Code Section ("R.C.") 4731.22(B)(2).

Accordingly, the Board advised Dr. Valko of his right to request a hearing and received his written request on August 4, 2017. (State's Exhibits ("St. Exs.") 19A, 19B)

Appearances

Dave Yost, Ohio Attorney General, and Melinda Ryans Snyder and Kyle C. Wilcox, Assistant Attorneys General, on behalf of the State of Ohio. Daniel S. Zinsmaster and Heidi W. Dorn, Esqs., on behalf of Dr. Valko.

Hearing Date: September 24 through 27, 2018

PROCEDURAL MATTERS

1. With the agreement of the parties, page 51 of State's Exhibit 5, which consisted of EKG results from a patient not named in this matter, was redacted from the exhibit. (Hearing Transcript at 687)

2. At the close of the hearing, the record was held open to give the parties an opportunity to submit written closing arguments. The documents were timely and were marked by the hearing examiner; the State's closing argument was marked State's Exhibit 20 and the

Respondent's closing argument was marked Respondent's Exhibit N. Both exhibits were admitted to the hearing record, which closed January 11, 2019.

3. During his review of the record, the hearing examiner found patient names in Respondent's Exhibit A, which was admitted to the record as a public exhibit. Consequently, the hearing examiner sealed Respondent's Exhibit A, redacted the patient names from a copy of that exhibit, and marked the redacted exhibit Respondent's Exhibit A-1. Respondent's Exhibit A-1 was admitted to the record without objection as a public exhibit.

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.

Background Information

1. Tim R. Valko, M.D., obtained his medical degree in 1987 from the University of Toledo Medical College.[1] From July 1987 through June 1991, Dr. Valko participated in and completed a four-year residency in adult psychiatry at the University of Toledo Medical College, and then, from July 1990 to June 1992, he participated in and completed a two-year fellowship in child and adolescent psychiatry at the same institution. (Respondent's Exhibit ("Resp. Ex.") D) With respect to the 1990 through 1991 overlap, Dr. Valko explained, "[Y]our fourth year of residency is considered to be electives so you can combine your fourth year [of residency] and first year of the fellowship so you make it a five-year program." (Hearing Transcript ("Tr.") at 552) In addition, Dr. Valko served as Chief Resident in his adult psychiatry residency from 1989 to 1990, and in his child and adolescent psychiatry fellowship from 1991 to 1992. (Resp. Ex. D)

2. Dr. Valko was certified in adult psychiatry by the American Board of Psychiatrist and Neurology ("ABPN") in 1994. Further, Dr. Valko was certified in child and adolescent psychiatry by the ABPN in 1996 and he recertified in 2005. (Resp. Ex. D) However, his certification in adult psychiatry expired in 2004 and his certification in child and adolescent psychiatry lapsed in December 2015. To briefly summarize Dr. Valko's explanation, he testified that recertifying in child and adolescent psychiatry used to include recertification in adult psychiatry as well. However, Dr. Valko testified that the ABPN changed that evidently around 2004-2005 and determined that when Dr. Valko recertified in child and adolescent psychiatry around 2005 that did not renew his adult certification. When asked why he didn't recertify in child and adolescent psychiatry in 2015, testified that "it was a moving target" and the ABPN kept changing the rules. (Tr. at 25-29)

[1] Dr. Valko noted that, at the time, it was called the Medical College of Ohio. (Hearing Transcript at 20)

3. Dr. Valko was first licensed to practice medicine and surgery in Ohio in August 1989. His license is currently active. Dr. Valko testified that he is licensed in no other states. (Tr. at 29; Ohio eLicense Center, <*https://elicense.ohio.gov/oh_verifylicense*>, search terms "Valko" and "Tim," accessed August 28, 2019)

4. Dr. Valko testified that he holds hospital privileges at Toledo Children's Hospital. (Tr. at 41)

5. Dr. Valko testified that he has his own private psychiatry practice located in Toledo, Ohio, called Valko and Associates, and has had that practice since January 2004. Prior to starting that practice Dr. Valko had started and was the Medical Director of the Department of Adolescent Behavior Services at Toledo Children's Hospital. (Tr. at 29-31, 553-561; Resp. Ex. D)

   In addition to his private practice, Dr. Valko serves as a Clinical Assistant Professor at the University of Toledo College of Medicine, the Ohio University College of Osteopathic Medicine, the Kansas City University of Medicine and Business, and the Des Moines University College of Medicine. (Resp. Ex. D) Dr. Valko is also involved in volunteer work for various organizations that serve the special needs community, including the Mental Health Recovery Services Board of Lucas County. (Tr. at 569-570, 573; Resp. Ex. D)

Valko and Associates

6. Dr. Valko testified that when he started Valko and Associates in 2004 he had one employee, a social worker. Dr. Valko testified that the practice filled up with patients within a couple of months and he had to add additional employees. By 2013, he had around 22 or 23 employees and the practice had over 3,000 patients. He has since added more providers and around 500 to 1,000 more patients, about half of whom are adults and half are children and adolescents. Dr. Valko testified that his practice currently has 29 employees including 11 therapists, three nurse practitioners, and two physician assistants. Dr. Valko is currently the only physician although he is trying to recruit another psychiatrist. (Tr. at 33-36, 562-566)

   Dr. Valko testified that his practice has an excellent reputation in the community, and that he receives patient referrals from a number of sources. (Tr. at 567-569) Dr. Valko testified that "[t]hey send us their more difficult patients because that's what we have a reputation to deal with. (Tr. at 568)

7. Dr. Valko testified that he sees about 30 patients on a typical day. He testified that for medication follow-up visits take about 15 minutes. If it is his first visit with a patient after the patient has already been seen in his practice it takes 30 minutes. (Tr. at 574)

8. Dr. Valko testified that his patients' ages run from three to 92 years old. Patients 18 years of age and under are seen with a parent or guardian if at all possible. Dr. Valko further

testified that he treats many different disorders including many patients with severe Attention-Deficit Hyperactivity Disorder ("ADHD") patients, Obsessive Compulsive Disorder ("OCD"), Tourette's Syndrome, disruptive mood disorders, and patients on the autism spectrum. (Tr. at 574-576)

9. Dr. Valko testified that his practice accepts public and private insurance. (Tr. at 573)

10. Dr. Valko testified regarding his understanding of the minimal standard of care:

> I was not sure what they were using as the minimal standard of care because people always say it's what most doctors would do, which I don't know how people know what most doctors do since most doctors don't publish.
>
> I looked at what the American Academy of Child Psychiatry considered the minimal standard of care, and it would be what is considered that 95 percent of all physicians will do. But yet it also goes on to state, even though five percent of the physicians may not do that, it doesn't mean they don't meet the minimal standard of care, but that is what they're basing the minimal standard of care on.

(Tr. at 593-594)

Dr. Valko added that he tries to practice well above the minimal standard of care. (Tr. at 594)

State's Expert Witness – Drew H. Barzman, M.D.

11. Drew H. Barzman, M.D., obtained his medical degree in 1997 from the State University of New York at Buffalo, School of Medicine. From 1997 to 2001 Dr. Barzman participated in a residency in psychiatry at Duke University Medical Center. From 2001 to 2002 Dr. Barzman participated in a fellowship in forensic psychiatry at the University of Cincinnati. Finally, from 2002 to 2004, Dr. Barzman participated in a residency in child and adolescent psychiatry at Cincinnati Children's Hospital where he served as Chief Resident from 2003 to 2004. (St. Ex. 18; Tr. at 266-269)

Dr. Barzman was certified in Psychiatry by the ABPN in 2002, and obtained subspecialty certification in Forensic Psychiatry in 2003 and in Child and Adolescent Psychiatry in 2004. Dr. Barzman recertified in all of those fields in 2011. (St. Ex. 18; Tr. at 270-271)

Dr. Barzman Residency Probation

12. On his January 2001 application for an Ohio medical license, Dr. Barzman answered "Yes" to the following questions on his application:

> 2. Have you ever been warned, censured, disciplined, had admissions monitored, had privileges limited, had privileges suspended or terminated, been put on

> probation, or been requested to withdraw from or resign privileges at any hospital, nursing home, clinic, health maintenance organization, or other similar institution in which you have trained, been a staff member, or held privileges, for reasons other than failure to maintain records on a timely basis, or failure to attend staff or section meetings?
>
> * * *
>
> 4. Have you ever resigned from, withdrawn from, or have you ever been warned by, censured by, disciplined by, been put on probation by, been requested to withdraw from, dismissed from, been refused renewal of a contract by, or expelled from, a medical school, clinical clerkship, externship, preceptors hip, residency, or graduate medical education program?

(Resp. Ex. G at 7)

13. In his explanation concerning his affirmative answers to questions 2 and 4, Dr. Barzman stated, "In my PGY-2 and PGY-3 years at Duke University Medical Center, I struggled with knowledge and skills in several areas and successfully underwent a course of remediation. With the benefit of time and additional clinical experience, I have caught up with my class." (Resp. Ex. G at 6)

14. Also, on his Federation Credentials Verification Service application, Dr. Barzman answered "No" to the question, "Were you ever placed on probation," and "Yes" to the question, "Were any limitations or special requirements imposed on you because of academic incompetence, disciplinary problems, or for any other reasons." He explained, "I successfully underwent a course of remediation. With the benefit of time & additional clinical experience, I caught up with my class." (Resp. Ex. G at 34)

15. In a Verification of Postgraduate Medical Education, Grace Thrall, M.D., Director of Residency Education for Duke University Medical Center, indicated that Dr. Barzman had been placed on probation and stated, "Probation for 6 months in PGY-2 year. Received additional supervision & training until knowledge and skills improved." (Resp. Ex. G at 32)

16. At the hearing, Dr. Barzman acknowledged that he had gone through remediation while in his residency but did not recall that it had been characterized as probation. Dr. Barzman testified that he did well enough that he went back to his original class and graduated on time. (Tr. at 427-429)

Dr. Barzman's Practice

17. Dr. Barzman currently serves as an Associate Professor of Psychiatry at Cincinnati Children's Hospital Medical Center and at the University of Cincinnati, as the Founding Director of the Child and Adolescent Forensic Psychiatry Service at Cincinnati Children's

Medical Center, and as the Medical Director of the Cincinnati Children's Hospital Medical Center School-Based Service. (St. Ex. 18)

18. Dr. Barzman holds an active medical license in Ohio and was initially licensed in March 2001. In addition, he is licensed to practice medicine in Kentucky. (St. Ex. 18; Ohio eLicense Center, <https://elicense.ohio.gov/oh_verifylicense>, search terms "Barzman" and "Drew," accessed November 7, 2019)

19. Dr. Barzman testified that he practices at Cincinnati Children's Hospital where he sees both inpatients and outpatients. He further testified, "I did a lot of outpatient for ten years up until four years ago. And that practice was primarily -- those ten years was mostly ADHD, disruptive behavior disorders, and we would -- disorders, depression." (Tr. at 272) Dr. Barzman further testified that his outpatient practice today is rather small, and that he currently spends about one-half day per week seeing outpatients. Moreover, Dr. Barzman testified that he is one of several child and adolescent psychiatrists as well as APRNs at the main hospital who see patients. (Tr. at 272-274)

20. Dr. Barzman testified that he holds privileges at Cincinnati Children's Hospital. (Tr. at 275)

21. Dr. Barzman testified that he spends about 70 to 75 percent of his professional time doing patient care. (Tr. at 275)

22. Dr. Barzman testified that he has prior experience testifying in court in both civil and criminal proceedings; however, he has never before testified in a Board hearing. (Tr. at 275)

23. Dr. Barzman testified that as of 2018 he was seeing around 15 to 20 outpatients. When asked if that is his typical outpatient load Dr. Barzman replied:

> No, I had more. So I did a lot of outpatient work the first, about ten years after residency, so I would see a lot of outpatients in different outpatient clinics.
>
> I transferred over about four years ago to inpatient. I did more outpatient last year as well, and kind of this urgent care model, patients would come in in crisis, but you continue to follow them. And I still have some of those patients. So I did a bunch of that type of work last year.

(Tr. at 433-434)

24. Dr. Barzman estimated that he spends 30 percent or less of his professional time working on forensic psychiatry. (Tr. at 431-432)

Standard of care

25. Dr. Barzman testified that he is familiar with the standards in Ohio that are applicable to the selection or administration of drugs or other modalities for the treatment of psychiatric illnesses. Dr. Barzman further testified that the standard of care is established based on what is generally accepted in practice, set at a minimum level or above. When asked what he looks at to determine what is generally established, Dr. Barzman testified that he looks at "safety, effectiveness, what's generally accepted in the community." Moreover, he testified that he also looks at what had been recommended for the drug by the manufacturers and the FDA. (Tr. at 276, 444-446)

26. When asked to define "a reasonable degree of medical certainty" Dr. Barzman replied, "So that means more likely than not, and that's consistent with level of certainty with a clinical opinion." (Tr. at 425)

Dr. Barzman's Testimony Concerning Dr. Valko's Treatment of Patients 1 – 15, In General

27. Twelve of the fifteen patients identified in this matter are juveniles who suffered from psychiatric conditions that included Attention Deficit Hyperactivity Disorder ("ADHD"). Dr. Barzman testified that ADHD is a diagnosis characterized by poor attention, as well as "impulsivity, hyperactivity, having problems at school, at home, and there's not another reason, you know, causing those issues." (Tr. at 282) Dr. Barzman testified that a number of medications are available to treat ADHD, and that they are either methylphenidate-based or Adderall-based. Dr. Barzman testified that the following ADHD medications are methylphenidate-based: Ritalin, Concerta, Metadate, Focalin, and Daytrana. Dr. Barzman further testified that Adderall and Vyvanse are Adderall-based. Moreover, Dr. Barzman testified that both methylphenidate and Adderall are stimulants in the same class of drugs and are used for the same reasons; however, they have different mechanisms. Dr. Barzman added that they are all Schedule II controlled substances. (Tr. at 281-282, 286-288, 291-292)

28. Dr. Barzman testified concerning the potential side effects of stimulant medications as including "poor appetite, poor sleep. Those are the most common. Headaches. Other side effects may be change in heart rate. Some kids, on rare occasion, might develop some psychosis. So that's in general." (Tr. at 288) When asked if stimulants could inhibit a child's growth, Dr. Barzman testified that they could inhibit growth indirectly by suppressing the child's appetite which "might slow down the growth a little bit," but that there is no independent effect on growth caused by stimulants. (Tr. at 289) With respect to cardiac side effects, Dr. Barzman testified, "So if the patient has a history of --personal history of cardiac problems, or even a family history, it's important to watch out for any cardiac symptoms. So there can be -- it can be anywhere from mild to severe in terms of cardiac issues." (Tr. at 289)

29. When asked if a physician should do any physical examination or family history prior to prescribing a stimulant to treat ADHD, Dr. Barzman replied:

> It's important to have a physical exam, and that could be through the pediatrician, which mostly kids do have that, and where he'd be aware of those cardiac issues, and then a family history of any sudden death, prolonged QT syndromes, something severe in the family, because there may be something undetected or silent in the child that we don't know about, so that's the way we -- what we're supposed to be doing.

(Tr. at 289-290)

Dr. Barzman further testified that, if the family has a history of cardiac arrhythmia, an EKG performed by a cardiologist should be obtained before considering what medication to prescribe. (Tr. at 291)

Dr. Valko's Testimony Concerning Patients 1 – 15, In General

30. Dr. Valko testified that he does not see many patients who have a single disorder, such as depression. He testified that the majority of his practice is treating complicated patients. Dr. Valko further testified that simpler patients, such as ADHD patients who are well controlled on medication, are usually referred back to their primary care physician or pediatrician for continued care and advised that they can always contact his office if there's an issue. (Tr. at 578-580) Dr. Valko further testified that most of these patients have issues that are affecting all aspects of their lives, including school, peers, and home and family. (Tr. at 595-596)

31. Dr. Valko testified that he always obtains a thorough family history from his patients, including cardiac issues. However, unless he receives a report of problems, he does not document it. Dr. Valko testified that "[y]ou document the things you have to worry about, not the things you don't have to worry about." When asked how he knows that he inquired about that issue without documenting it, Dr. Valko replied that he knows because he asks that question for all his patients. (Tr. at 51-53)

32. Dr. Valko agreed that many of the patients reviewed in this case were receiving large doses of stimulant medication. (Tr. at 596) When asked how he determines an ADHD patient's starting dose of stimulant medication, Dr. Valko testified, "If they've never been seen before and are not on a stimulant when they come to me, then I generally start them at the lowest possible dose and work our way up and titrate them over time. If they come to me on a stimulant and they feel they're not working, then we titrate that dose up or actually switch to a different stimulant or a different medication." (Tr. at 597)

33. Dr. Valko added that there are a number of factors that affect the dosing of stimulants, including the severity of the condition being treated, the patient's age, weight, tolerance to the

medication, other medications prescribed, the timing of the medication, and how much he trusts the family and the patient to do the necessary follow-up and take the medication appropriately. (Tr. at 598) Moreover, Dr. Valko testified that feedback is important, as well as safety:

> Looking at how are they responding to the medication, going through all those things you need to look at. Are they having any heart problems? Are they having any dizziness if they stand up too quick? You're looking at the physical issues that can occur with the medication, as well as the goal of the medication and what it's supposed to do.
>
> It doesn't matter if it's a stimulant, nonstimulant, an antidepressant, neuroleptic, you have to go through all these aspects of the side effect to make sure that they're not having any problems. If they are, we need to address for whatever is going on.

(Tr. at 599-600)

34. Dr. Valko testified that he always attempts to get prior treatment records for his patients, but typically does not receive them. (Tr. at 59-60, 589)

Patient 1

12/20/10 Initial Assessment

35. Patient 1 is a male born in 2004. On December 21, 2010, he saw Christine Buffington, M.S.W., LISW-S, an independent licensed social worker at Dr. Valko's practice, on referral from Patient 1's pediatrician. His pediatrician had been treating Patient 1 for ADHD, and she referred Patient 1 to Dr. Valko for a medication assessment because she was uncomfortable increasing his medication further, from Ritalin 20 mg three times per day. Patient 1's school reported that he is easily distracted and unable to maintain attention and concentration in the classroom. He is frequently sent to the office to have a quiet place to calm down. Patient 1's mother confirmed the hyperactivity and added that he sometimes becomes oppositional when his medication wears off. Mother also reported that he behaves well in school when the medications are working but not when the medications wear off. The initial diagnosis identified in Axis I was "314.01 Attention Deficit Hyperactivity Disorder, Combined Type." (St. Ex. 1B at 1; Tr. at 61)

36. Dr. Valko testified that Ms. Buffington performed the initial diagnostic assessment. Dr. Valko noted that he also signed the initial assessment "to make sure they seem complete to the best of her ability. I can't guarantee the diagnosis until I see the patient." (Tr. at 61; St. Ex. 1B at 3)

1/10/11 – First visit with Dr. Valko

37. Dr. Valko first saw Patient 1 on January 10, 2011. He weighed 44 pounds at that visit. Patient 1's mother expressed dissatisfaction with Patient 1's current dose of Ritalin and said that it lasted only about three hours. She further advised that, when not on medication, Patient 1 was a "Tasmanian devil on speed" and that "'mornings with him are 'hellish.' However, she reports that he is not oppositional at school, and is in fact, extremely polite." (St. Ex. 1B at 20) The progress note further states:

> We discussed treatment options and decided to put [Patient 1] on Concerta twice a day and a short-acting Ritalin in the evening. [Patient 1's] mom reports that Concerta had worked wonderfully for him in the past, but stopped working after a few months. She said the effects of the medication usually kicked in after 45 minutes and then lasted about 5 hours. I explained that the evening Ritalin dose should be enough to calm [Patient 1] down but not to overmedicate him.
>
> I went over [Patient 1's] medications with him and made him aware of the possible side effects of decreased appetite and insomnia. Mom reports that his current appetite is very good; he "eats like a horse." She will monitor his behavior at home to see how he does on his new medication regimen, and she understands to contact our office with any questions or concerns

(St. Ex. 1B at 20)

Dr. Valko confirmed the diagnosis of ADHD Combined and prescribed Concerta 36 mg with instructions to take two tablets in the morning and two tablets at noon for a total daily dose of 144 mg, Ritalin 20 mg with instructions to take one tablet at 6:00 p.m., and recommended Melatonin OTC 3 mg as needed for sleep. Patient 1 was to return for a follow-up visit in two weeks. (St. Ex. 1B at 20)

Testimony of Dr. Barzman

38. Dr. Barzman testified that Concerta is a long-acting version of Ritalin.[2] Dr. Barzman testified that the medications Dr. Valko prescribed at his first visit with Patient 1 are appropriate for a diagnosis of ADHD; however, the combined dosages of Ritalin and Concerta (164 mg) are higher than recommended. Dr. Barzman further testified that the maximum recommended daily pediatric dose of methylphenidate, as determined by the maker as well as the FDA, is not to go above 2 milligrams per kilogram of body weight per day up to a maximum of 60 milligrams per day. Dr. Barzman added that was also the standard of care in 2011. (Tr. at 313-314, 316-317)

[2] Notice is taken that the generic name for both Concerta and Ritalin is methylphenidate. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a682188.html>, accessed December 23, 2019)

Dr. Valko's initial visit note indicates that Patient 1 weighed 44 pounds. (St. Ex. 1B at 20) Administrative notice is taken that 44 pounds equals approximately 20 kilograms (44/2.205).

39. When asked how the FDA determines a maximum recommended daily dose of a medication, Dr. Barzman replied that safety studies are conducted, most likely by the manufacturer, and the data from those studies is approved by the FDA. (Tr. at 314)

40. Noting that Patient 1's mother reported that Patient 1's medication wore off after about three hours, Dr. Barzman testified that the standard of care is to listen to and rely on what the parents are saying unless there is a concern about the parent's credibility. Dr. Barzman testified that there is no indication that there is an issue with Patient 1's mother's credibility as far as he can tell. (Tr. at 315-316; St. Ex. 1B at 20)

When asked what he does when a medication is wearing off more quickly than normal, Dr. Barzman testified that possible solutions would include changing the type of stimulant prescribed or adding a non-stimulant medication to the patient's regimen. Dr. Barzman further testified that increasing the dose might help during the time period that the medication is effective but may not make the medication last longer. Therefore "it is a matter of dosing it more times throughout the day." (Tr. at 315-316)

1/25/11 visit

41. On January 25, 2011, Patient 1's mother reported that Patient 1 was calm and "acting like himself" the first day he took the Concerta but, every day after that, it worked less and less effectively. Dr. Valko increased the dose of Concerta to 108 mg[3] twice per day, a daily dose of 216 mg, and left the Ritalin and Melatonin unchanged. Patient 1 was to return in one week. (St. Ex. 1B at 37)

1/31/11 Visit

42. On January 31, 2011, mother reported that his medications were helping, but she told Dr. Valko that she had discontinued his Ritalin 20 mg because it interfered with his sleep. Dr. Valko moved Patient 1's dose of Ritalin 20 mg to the morning and maintained the same dose of Concerta.[4] (St. Ex. 1B at 44)

2/14/11 Visit

43. On February 14, 2011, Dr. Valko noted that Patient 1's mother reported "that things are going poorly and that none of the medicines see[m] to be helping. She presented a shattered camera that [Patient 1] had broken." She further reported that Patient 1 had been more aggressive toward others and more destructive. She denied any adverse effects of his

[3] Concerta 36 mg x three tablets. (St. Ex. 1B at 37)
[4] Dr. Valko prescribed Concerta 54 mg x 2 twice per day. (St. Ex. 1B at 44)

medication. Dr. Valko discontinued Ritalin and started Risperdal 0.5 mg twice per day. He noted that he discussed the side effect profile of Risperdal including tardive dyskinesia ("TD") and extrapyramidal symptoms ("EPS"). Concerta was unchanged. (St. Ex. 1B at 45)

Testimony of Dr. Barzman

44. Dr. Barzman testified that Risperdal was started to control Patient 1's aggressive behavior toward others, as well as his disruptive behavior. Dr. Barzman criticized Dr. Valko for not discussing metabolic concerns or labs for a second-generation antipsychotic such as Risperdal. Moreover, Dr. Barzman expressed concern that Concerta may had been contributing to Patient 1's aggression and that Dr. Valko should have considered lowering the Concerta dose. (Tr. at 317-318; St. Ex. 17 at 1)

45. Dr. Barzman testified that second generation antipsychotics[5] include Seroquel, Risperdal, and Clozaril. Dr. Barzman testified that each medication has its own side effect profile, Clozaril in particular, although there are some side effects that are common among all of them. Dr. Barzman testified that patients taking those medications should be monitored for weight gain, changes in glucose, metabolism, and cholesterol. In addition, the QTC interval can be prolonged. Dr. Barzman testified that that side effect is often mild and insignificant, "but if it's prolonged too far over a certain number [as measured by EKG], that can put the patient at risk for a significant event, some sort of problem." Moreover, Dr. Barzman testified that this can occur in any patient, not just those who already have an irregular heartbeat. (Tr. at 292-294)

Dr. Barzman testified that in order to monitor the patient's cholesterol and metabolism it is best to obtain baseline labs and, ideally, repeat them every six months. However, Dr. Barzman testified that, "in reality, it's sometimes hard to get those labs, and they end up being every year." Moreover, Dr. Barzman testified that the standard of care for prescribing such medications requires the physician to obtain such baseline labs. (Tr. at 295)

2/28/11 Visit

46. On February 28, 2011, Patient 1's parents noted that Patient 1 still seemed hyperactive in the morning but calmed down after his noon dose of Concerta. He was described as having been collecting shiny objects and hiding them under his bed. Dr. Valko advised that hoarding behavior is often seen with ADHD and that can be looked into once his ADHD is brought under control. The parents denied adverse effects of Patient 1's medications including TD and EPS symptoms. Dr. Valko increased Patient 1's dose of Risperdal to 1 mg twice per day and added Ritalin 30 mg in the morning to improve Patient 1's attentiveness in the morning. (St. Ex. 1B at 48)

[5] Dr. Barzman testified that the terms "neuroleptic" and "antipsychotic" are synonymous. He further testified that "neuroleptic is an earlier term for antipsychotics." (Tr. at 293)

3/9/11 Telephone Call from Patient 1's Mother

47. A note on the medication flowsheet indicates that Patient 1's mother had called to report that Patient 1's school was making him do jumping jacks because he has too much energy. (St. Ex. 1B at 219)

3/17/11 Visit

48. On March 17, 2011, mother reported that Patient 1 is doing better but still having anger issues. He had thrown rocks at a couple of kids for "covering his favorite slide." She reported giving Patient 1 an extra dose of Ritalin at 4:00 p.m. to help him get his work done. She asked if that change could be made. Dr. Valko increased Patient 1's Ritalin to 30 mg three times per day for a total daily dose of 90 mg, increased Risperdal to 2.5 mg per day by adding a 0.5 mg dose at bedtime. Concerta 108 mg twice per day remained unchanged. (St. Ex. 1B at 49)

March 25 and April 6, 2011 Telephone Calls

49. A note dated March 25, 2011, indicates that Dr. Valko spoke to Patient 1's mother and authorized an increase in Ritalin to 40 mg three times per day. A second note dated April 6, 2011, indicates that Dr. Valko again spoke to Patient 1's mother and authorized a further increase in Ritalin to 50 mg three times per day. (St. Ex. 1B at 219)

4/12/11 visit

50. On April 12, 2011, Patient 1's mother reported among other things that his school had reported seeing no difference in Patient 1's performance through all of the medication changes "and therefore [Patient 1's] mother experimented while he was home sick. She found [Patient 1] to be grumpy and moody while on Concerta, but with Ritalin alone, he is happy and cheerful. She has also been giving [Patient 1] 60 mg of Ritalin TID and not using the evening dose of Risperdal." Dr. Valko discontinued Concerta and increased Ritalin to 100 mg three times per day, with an as-needed fourth dose of 100 mg for sports and evening extracurricular activities, a total daily dose of 300 mg or 400 mg. Dr. Valko also stressed the importance of Patient 1 being tested for learning disabilities. Patient 1 weighed 46 pounds at that visit. (St. Ex. 1B at 50)

4/26/11 Visit

51. Dr. Valko next saw Patient 1 and his mother on April 26, 2011. Mother reported that Patient 1 was on spring break and was more active than normal. She also reported that she has begun giving Patient 1 an increased amount of Ritalin—110 mg three times per day—and that it made him calmer. Dr. Valko approved of and prescribed that dose along with an extra dose as needed for a total daily dose of 330 mg or 440 mg. Risperdal was left unchanged. Patient 1 weighed 48 pounds at that visit. (St. Ex. 1B at 52)

Testimony of Dr. Barzman

52. Dr. Barzman testified that he is concerned with prescribing 330 to 440 milligrams of Ritalin per day to Patient 1 primarily because of safety issues. Dr. Barzman testified that there haven't been any studies regarding the safety of such dose ranges in children. (Tr. at 320-321)

53. With respect to the mother increasing Patient 1's daily dose of Ritalin to 110 mg three times per day on her own volition, Dr. Barzman testified:

> Unfortunately we run into this where parents tend to take matters into their own hands and adjust medicine.
>
> On the bright side, it looks like he was doing better, and there may have been discussion that's just not documented about not letting the mom adjust the medication, but just making sure that that's -- if it was done, documented.

(Tr. at 325-326)

When asked if the standard of care requires a physician to place limits on a parent's ability to modify medications, Dr. Barzman replied, "Yeah. I mean, that's -- the parent should understand that, it would be obvious. So it's a matter of reviewing it again." (Tr. at 326)

54. Dr. Barzman also testified that later, at a December 11, 2011 visit, Dr. Valko did inform Patient 1's mother not to alter dosing. (Tr. at 474-475; St. Ex. 17 at 1-2) Dr. Barzman testified that he has had parents of his outpatients change patients' dosing without permission. Dr. Barzman further testified that he discusses that issue with the parents and establishes guidelines "like Dr. Valko did on 12-1-11." (Tr. at 475)

Testimony of Dr. Valko

55. Dr. Valko acknowledged that Patient 1's mother made medication changes on her own initiative but stated that he and Patient 1's mother "have a very good working relationship." (Tr. at 67)

4/29/11 Blood Test Report

56. Results from a blood sample collected from Patient 1 on April 22, 2011, indicates that no amphetamine/methamphetamine metabolites or methamphetamine were detected in Patient 1's blood. The report is dated April 29, 2011. (St. Ex. 1B at 53-54) A note on the medication flowsheet indicates that Dr. Valko had called and spoken with Patient 1's mother on April 29, 2011, concerning the negative levels. (St. Ex. 1B at 220) However, Dr. Barzman noted that the blood screen tested only for Adderall-based medication which Patient 1 had not been taking at that time. (Tr. at 530-531; St. Ex. 1B at 45-52)

Testimony of Dr. Valko

57. Referring to a note dated April 29, 2011, Dr. Valko testified, "Whenever we get a lab back, I try to contact the family about the results, unless they're completely normal. Then I won't make the phone call. If they call me about it, I would go over the labs with them. I always go over the labs at the next appointment." (Tr. at 615; St. Ex. 1B at 220)

5/2/11 Telephone Call

58. A note dated May 2, 2011, states, "returned call; mother increased meds to 120 mg and sees no gains. will need to explore options; will make appointment for Thursday." (St. Ex. 1B at 220) When asked why that happened, Dr. Valko testified:

> Because the mother commented that he wasn't doing any better, and I wasn't going to allow additional medication changes to occur between appointments. So, therefore, we made an appointment for three days later, which was the first time they could come in to see me, I believe, most likely so the parents could stay, if I need them to, to go over what the other options are.

(Tr. at 616)

Dr. Valko added that this was his typical practice. If a parent had called with an issue or a medication change they felt was necessary, he tried to get them in as soon as possible. (Tr. at 616)

5/5/11 visit

59. In his May 5, 2011 progress note, Dr. Valko noted the written comments of several of Patient 1's teachers stating that Patient 1 participates but frequently interrupts, was energetic, unfocused, and was not improving in reading or comprehension.[6] The mother reported that the anger issues had faded but she was concerned about his school performance. Dr. Valko noted that he had measured Patient 1's amphetamine serum level "which returned as 0." (St. Ex. 1B at 55) Dr. Valko further noted:

> Although he has shown improvement on Ritalin, his metabolism is processing the medication quickly and his school performance has not improved. Thus, I will change [Patient 1] to Adderall 20 mg iv (four) TID.[7]

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[6] The letters from teachers/school personnel praise Patient 1 for his kindness and courtesy but note that he is struggling with reading and being able to retain information such as counting to 25 or remembering his computer password. (St. Ex. 1B at 57-60)

[7] Notice is taken that the generic name for Adderall is amphetamine and dextroamphetamine. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a601234.html>, accessed December 23, 2019)

> I reviewed Adderall and its side effects with [Patient 1] and his mother. She is fearful of his emotional issues returning; she understands that these would appear in the first week if this side effect were to occur. I also increased the Risperdal to 1 mg TID. [Patient 1] and his mother denied any other symptoms including stiff neck, stiff jaw, EPS, or TD symptoms. [Patient 1] will return in 1 weeks time to follow-up on these changes.

(St. Ex. 1B at 55)

Dr. Valko discontinued Concerta and Ritalin, added Adderall 80 mg three times per day for a total daily dose of 240 mg, and increased Risperdal to 3 mg per day.[8] (St. Ex. 1B at 55)

Testimony of Dr. Barzman

60. At the hearing, Dr. Barzman testified, "The total dose [of Adderall] is 80 milligrams three times a day, which is way above what's been studied. So although it may -- it looks like there's labs on efficacy, make sure it works, but in terms of safety in that dose range -- and so that would be my concern." (Tr. at 319)

61. Dr. Barzman testified that Adderall 1 mg is equivalent to Ritalin 2 mg. (Tr. at 318-319) Accordingly, 240 mg of Adderall is equivalent to 480 mg of Ritalin.

5/9/11 Telephone Contact

62. The medication flowsheet documents a May 9, 2011 telephone call from Patient 1's mother reporting that Adderall had upset Patient 1's stomach and he became moody and lethargic. She tried lowering the dose to 60 mg with the same results so she restarted him on Ritalin. Dr. Valko discontinued Adderall, restarted Ritalin 110 mg three times per day. (St. Ex. 1B at 220, 227)

5/16/11 visit

63. In his May 16, 2011 progress note, Dr. Valko noted that Patient 1 had recently started on Adderall, that his mother had called the office reporting that he had had stomach pain and irritability, and that Dr. Valko was advised that she had discontinued the Adderall and restarted him on Ritalin. At that visit, Dr. Valko prescribed Risperdal 2.5 mg per day split between two doses of 1 mg and one dose of 0.5 mg, Ritalin 360 mg per day split between three doses and permitting a fourth dose of 120 mg as needed.[9] (St. Ex. 1B at 61)

Testimony of Dr. Barzman

64. With reference to Patient 1's May 16, 2011 visit, Dr. Barzman stated in his report, "Questions: Why such a high dose of Ritalin? Where are vital signs? Why Risperdal as well?" (St. Ex. 17

[8] The medication list at the top of the progress note erroneously states that Dr. Valko discontinued Risperdal when, in fact, he discontinued Ritalin. (St. Ex. 1B at 55)
[9] With a fourth dose the daily dose of Ritalin would be 480 mg.

at 2) At the hearing, Dr. Barzman acknowledged that Risperdal can be prescribed for aggression issues: "I think that Risperdal -- it's not prescribed for ADHD, but it can be prescribed for aggression related to some other diagnosis, like a disruptive behavior disorder, mood disorder." (Tr. at 476) However, Dr. Barzman acknowledged that the February 14, 2011 progress note "notes he was wrestling and made boxing motions towards his little brother. Shattered a camera, and has been more aggressive towards others as well as more destructive. So there's -- there's descriptions in here about aggression." (Tr. at 476; St. Ex. 1B at 45)

Testimony of Dr. Valko

65. Dr. Valko acknowledged that the FDA recommended maximum daily doses for both Adderall and Ritalin are 60 mg. (Tr. at 66)

66. Dr. Valko testified that "if you look at the story of this patient, up until this time he was very agitated and angry, and as Dr. Barzman said, Risperdal is routinely used to treat agitation and irritability you can have with ADHD. So with the ADHD medication, we also added the Risperdal." (Tr. at 617) When asked why he had added Risperdal to the patient's medication regimen of Ritalin, Dr. Valko testified:

> One is that this young man was on an excessive dose -- I shouldn't say excessive -- a high dose of Ritalin. It wasn't excessive because he was not having any adverse effects from the medication, and we were monitoring that very closely. But he was on what would be considered a high dose of Ritalin. I tried to use other medications in combination with a stimulant so to not even have to go any higher with the Ritalin.

(Tr. at 617)

6/6/11 Telephone Call from Patient 1's Mother

67. A note on the medication flowsheet indicates that Patient 1's mother had called on June 6, 2011, stating that Ritalin had stopped working so she switched Patient 1 back to Adderall. (St. Ex. 1B at 220)

6/22/11 Visit

68. On June 22, 2011 Patient 1's mother reported that he was continuing to do poorly and that she switched him back to Adderall. She reported that he does better at Adderall 30 mg but was concerned that he had developed a facial tic. Also, she reported that the medication did not seem to last very long. Dr. Valko noted that they discussed using Nuvigil and imipramine, and they decided to try Nuvigil. Dr. Valko discontinued Ritalin and Adderall and prescribed Nuvigil 150 mg in the morning. Risperdal and Melatonin were left unchanged. (St. Ex. 1B at 62)

Testimony of Dr. Barzman

69. Dr. Barzman testified that Nuvigil is a medication prescribed to patients with narcolepsy or sleep apnea to keep them awake. Dr. Barzman testified concerning Patient 1's June 22, 2011 visit in which Dr. Valko discontinued Ritalin and Adderall and added Nuvigil 150 mg per day in response to a report that patient was experiencing tics. Dr. Barzman had made a comment in his report concerning that prescription but at the hearing testified that the Nuvigil prescription was not below the minimal standard of care. (Tr. at 477-478; St. Ex. 17 at 2)

6/23/11 Note

70. A note on the medication flowsheet dated June 23, 2011, states that Patient 1's insurance denied payment for Nuvigil. (St. Ex. 1B at 220)

7/12/11 and 7/14/11 Telephone Calls from Patient 1's Mother

71. A series of phone contacts with Patient 1's mother began on July 12, 2011, when she reported that she was "overwhelmed." She also reported that she was giving Patient 1 Adderall 70 mg, that Patient 1 stopped experiencing tics, and that he was more impulsive. Dr. Valko prescribed Ativan 0.5 mg twice per day. On July 14, she called and indicated that Ativan had not helped. She stated she "will hold medication for the next three days." (St. Ex. 1B at 220)

7/18/11 Visit

72. On July 18, 2011, Dr. Valko noted that Patient 1's mother had given Patient 1 Concerta 54 mg to help him focus for a baseball game and that Patient 1 has been doing well on that. Dr. Valko noted that he would continue that medication and dose but expressed concern that Patient 1 had previously received Concerta and it lost its effectiveness. The discussed that possibility that he might take longer to metabolize medication and that would explain why expected results from medications have not been obtained. Dr. Valko prescribed Concerta 54 mg in the morning. Dr. Valko also prescribed Clonidine 0.1 mg with instructions to give Patient 1 one-half pill at bedtime as needed if the Concerta quits working. Patient 1 weighed 48 pounds at that visit. (St. Ex. 1B at 64)

73. Throughout this time, Patient 1's diagnosis has been ADHD Combined. (St. Ex. 1B at 1-64)

Treatment through January 2013

74. For several years Patient 1 continued to have difficulty which Dr. Valko continued to address via different medications and combinations of medications, including Ritalin, Concerta, Clonidine, Tenex, Abilify, Prozac, Depakote, Vyvanse, and Seroquel, as well as

counseling. During the bulk of this time Dr. Valko utilized Tenex,[10] Clonidine, and Depakote in addition to stimulants. Additionally, by January 10, 2013, Dr. Valko added Axis I diagnoses of OCD, Asperger's Syndrome, and Mood Disorder NOS[11] to the already-existing diagnosis of ADHD Combined. (St. Ex. 1B at 64-135)

Testimony of Dr. Barzman

75. Dr. Barzman testified that Clonidine and Tenex are non-stimulant alpha agonists used to treat ADHD. Dr. Barzman testified that he found those medications and the dosages prescribed by Dr. Valko to be reasonable. (Tr. at 313, 323) However, he criticized Dr. Valko prescribing Vyvanse 140 mg in the morning beginning in January 2012 as too high a dose.[12] Dr. Barzman testified that the FDA recommended maximum daily dose for Vyvanse is 70 mg. (Tr. at 322-323)

2/26/14 and 4/23/14 Visits

76. On February 26, 2014, Patient 1's mother reported that that things at school had not improved and that Patient 1 continued to have "inconsistent behavior hour to hour." Dr. Valko added Saphris 5 mm SL twice per day "to try to help his focus at school." (St. Ex. 1A at 83-84)

On April 23, 2014, Dr. Valko discontinued Saphris on a report that the patient stopped taking it after a couple of days because it made him sick and caused vomiting during school. (St. Ex. 1A at 92-93)

Testimony of Dr. Barzman

77. In his report, Dr. Barzman stated, "Saphris is not indicated for poor attention as it's an antipsychotic medication." (St. Ex. 17 at 3) When asked at the hearing if there are any diagnoses listed for Patient 1 that Saphris would be indicated to treat, Dr. Barzman noted that Mood Disorder NOS "could be a potential diagnosis for Saphris." (Tr. at 478)

Testimony of Dr. Valko

78. Dr. Valko started Patient 1 on Saphris SL at his February 26, 2014 visit, noting that Patient 1 did not like the taste. He scheduled a follow-up visit for the following week. (St. Ex. 1A at 83-84) Dr. Valko testified that the medication does taste very bad and that most people can't tolerate the ten minutes after using it they have to wait before getting something to drink. (Tr. at 619)

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[10] Notice is taken that the generic name for Tenex is guanfacine. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a601059.html>, accessed January 17, 2020)
[11] Not Otherwise Specified. (Tr. at 97-98)
[12] Notice is taken that the generic name for Vyvanse is Lisdexamfetamine. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a607047.html>, accessed January 17, 2020)

1/14/15 visit

79. On January 14, 2015, Dr. Valko prescribed Concerta 216 mg per day split between two doses, and Ritalin 40 mg as needed. (St. Ex. 1A at 4-7)

80. Dr. Barzman testified that the safety of Concerta 216 mg per day has not been studied. (Tr. at 324)

81. Dr. Valko acknowledged that the FDA maximum recommended daily dose for Concerta is 72 mg. (Tr. at 72)

Dr. Valko's References to Medical Literature

82. Dr. Valko testified that he has relied upon research that supports his position that you can utilize dosages that go above what are considered to be recommended doses:

> [A]s long as it's in the patient's best interest and as long as you're following all the safety protocol and monitoring for issues and checking, are you having any problems, increased difficulty, the appetite? Is it affecting your sleep? Are you having any extrapyramidal symptoms because you're on a neuroleptic? Are you checking for all these things constantly at every appointment?

(Tr. at 626-627)

As authority, Dr. Valko referenced a November 1, 2011, FDA Drug Safety Communication that indicated there was "[n]o association between stimulants and adverse cardiovascular effects" in children and young adults. (Tr. at 628-629; Resp. Ex. A at 5; Resp. Ex. B at 145-147) Dr. Valko testified that he also relied upon an article titled "ADHD Medications and Risks Of Serious Cardiovascular Events in Young And Middle-Aged Adults," published in the Journal of the American Medical Association in December 2011. Dr. Valko testified that that article compared the use of ADHD meds compared to patients on other meds or no meds and did not find any increased risk of serious cardiovascular issues.[13] (Tr. at 630; Resp. Ex. A at 6) In addition, Dr. Valko testified that he relied on an article titled "Drug Therapy in ADHD," published in 1996 in the Southern Medical Journal. Dr. Valko testified concerning this article that "they did studies showing medication levels, which were considered to be up to seven or eight times higher than the recommended daily dose, and said that they noted that anytime they had an above-the-normal dose, they were able to improve what they were trying to treat by nearly -- by up to almost 100 percent." (Tr. at 631; Resp. Ex. A at 6) Moreover, Dr. Valko referenced an American Academy of Child and Adolescent Psychiatry ("AACAP") Official Action Paper titled "Practice Parameter for the Use of Stimulant Medications in the Treatment of Children, Adolescents,

[13] The Hearing Examiner could not find the referenced article in the record.

and Adults," published in the Journal of the AACAP in February 2002. (Tr. at 632; Resp. Ex. A at 6; Resp. Ex. M) Dr. Valko testified that that paper:

> talked about higher doses than recommended should be closely monitored and at the higher doses, there's a greater reduction of the symptoms, and there's no -- this is really important here. That there's no evidence of a global "therapeutic" window, that each patient has his unique dose-response. So this is how this American Academy is trying to say you treat the patient. You just don't treat by what the book says. In other words, if you just treat the patient by the book, you're going to mistreat the patient.

(Tr. at 632) Finally, Dr. Valko referenced an AACAP Official Action Paper titled "Practice Parameter for the Assessment and Treatment of Children and Adolescents with [ADHD]," published in the Journal of the AACAP. No publication date was noted. Dr. Valko said that this paper stated, "The primary care clinician should titrate doses of medication for ADHD to achieve maximum benefit with minimum adverse effects." (Resp. Ex. A at 7)

Dr. Barzman Conclusions

83. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of his patients. (Tr. at 327) Dr. Barzman acknowledged that his conclusions were primarily based on the high doses of stimulants he had prescribed, and "some lab concerns as well." (Tr. at 309, 470-471) In addition, Dr. Barzman noted that Dr. Valko failed to set limits with the mother. (Tr. at 309-311)

    Dr. Barzman agreed that Dr. Valko included lab work in Patient 1's chart that was performed shortly before the patient came to Dr. Valko's office, but noted that they did not include "the usual metabolic labs that we look at, which is glucose and lipid panel." (Tr. at 471; St. Ex. 1B at 18)

84. Dr. Barzman acknowledged that, compared to medical documentation from other physicians that he has reviewed, the documentation provided by Dr. Valko is very detailed. (Tr. at 484)

Dr. Valko Conclusions

85. Dr. Valko testified that Patient 1 continues to be his patient. (Tr. at 613)

86. Dr. Valko testified concerning his treatment of Patient 1:

> Patient 1 is one of two children adopted by this family who came to us due to the fact that he has ongoing -- multiple ongoing issues at home and at school

> and with peers. He came to us -- gees, I'm not sure of the exact day. I apologize. It was quite some time ago.
>
> Initially the diagnosis probably was ADHD and some obsessive-compulsive issues, and over time and working with the family, I discovered he really meets the criteria of autistic spectrum disorder, as well as having disruptive mood dysregulation disorder, which some people consider the precursor to bipolar disorder.

(Tr. at 613)

With respect to the evolving diagnoses, Dr. Valko testified:

> The nice thing about psychiatry is it is constantly evolving. The moment new information comes out, new ways of looking at things, there's more information from a family, a different way of asking a question and getting a totally different response and realizing you missed something. So the diagnoses is not -- it should never be stagnant. It should always be evolving with your viewing and your knowledge of the patient.

(Tr. at 614)

87. Dr. Valko testified that he had frequent contact with Patient 1's mother and that she called frequently. He further testified that these calls were documented in the medication flowsheet. (Tr. at 615)

88. When asked whether Patient 1 would be considered an average patient compared to the general patient population, Dr. Valko testified:

> In the general population he's not an average patient. He would be considered an extremely difficult patient. If he didn't have the support of his parents and how supportive they were and how hard we worked together, this is a kid that would have ended up in the system in a group home. He was that aggressive, that violent, and that poorly controlled."

(Tr. at 625)

Letter of Support from Patient 1's Mother

89. In a May 9, 2018 letter, Patient 1's mother stated, in part, that she is aware that Patient 1:

> has been prescribed by Dr. Valko a higher than usual dose of Methylphenidate (Concerta). We have been working with Dr. Valko for many years and have tried a wide variety of medications to help my son cope with his [ADHD]. His ADHD is so severe, it has impacted him in every aspect of his life. * * *

> The 'cocktail' of medications he is on now and have been on for several years has been a blessing. * * * It is our hope as he is maturing, that we will be able to one day reduce his medication, but at this time we feel that it is imperative that we stay at this dose. We have full confidence in Dr. Valko and know that he is doing what is in the best interest for our child.

(Resp. Ex. F at 1)

Patient 2

11/7/08 Initial Assessment

90. Patient 2, a male born in 2004, first came to Dr. Valko's office on November 7, 2008, when he was three years old and was seen by Jeff Campey, M.Ed., LPC. The initial visit note indicates that Patient 2 had previously been seen by a doctoral student at another practice who "recommended that he be further evaluated due to concerns of anxiety, restlessness and inattentiveness." His preschool teacher reported that he will talk and walk around when he is supposed to sit in a "reading circle." Mother reported that his concentration is good if he is interested in something, but he "is active at home and will not sit to watch television or a movie." He misplaces toys and has difficulty keeping his hands to himself. He throws a fit if he is told no or cannot find something he's looking for. She also reported that when Patient 2 is upset "he will cry, hit, kick, bite, and spit at her. He is also "rough on the dog" and pulls its ears and tail. (St. Ex. 2B at 2) The note further stated:

> His mother reported that he goes to bed in his own room with a night light but awakens and comes to her room every night. His mother reported that he has difficulty transitioning to bedtime and that she will often rock or hold him to help him relax. She reported having him go to bed at 8 pm but reported that it is usually an hour or so until he falls asleep. She reported that he will have to touch her ear before she goes to sleep and will often do this to her and others when he is feeling anxious. His mother reported that he is infatuated with skateboards. Regarding his anxiety, she reported that he will be withdrawn in new situations and generally does not approach peers to play, and will often chew on things at preschool and occasionally at home.

(St. Ex. 2B at 2)

91. Mr. Campey listed the following diagnoses under Axis I:

> Anxiety Disorder NOS (300.00)
> ADHD Combined Type (314.01 Provisional)
> R/O[14] Obsessive Compulsive Disorder ("OCD")

[14] Rule out. (Tr. at 113)

(St. Ex. 2B at 3)

92. According to Mr. Campey's progress note, a preliminary diagnostic sheet was received from Patient 2's previous provider but that "further information will be requested." (St. Ex. 2B at 3)

12/19/08 – First visit with Dr. Valko

93. Dr. Valko first saw Patient 2 on December 19, 2008. By that visit Patient 2 was four years old. Dr. Valko noted that the patient was very active at the appointment. Dr. Valko further noted that Patient 2 exhibited anxiety and possibly obsessions along with ADHD but that the mother was most concerned about the ADHD symptoms. Dr. Valko continued the Axis I diagnoses from the initial assessment. He documented a discussion with the mother concerning treatment options and was told that Patient 2 cannot swallow pills. He prescribed Vyvanse 30 mg with instructions to take one each morning and noted that that is the lowest dose. (St. Ex. 2B at 12)

Testimony of Dr. Barzman

94. Dr. Barzman testified that the notation "R/O OCD" indicates that OCD is suspected but is not yet a confirmed diagnosis. (Tr. at 331-332)

Testimony of Dr. Valko

95. Dr. Valko testified that "Vyvanse is an Adderall product, and Adderall products can be used in four year old children." Dr. Valko acknowledged that the FDA insert for Vyvanse indicates that it is approved for children six and up for treatment of ADHD. However, Patient 2 could not swallow pills which "was a limiting factor on what we could and could not use." Dr. Valko noted that Vyvanse comes in a capsule that can be opened and sprinkled into food or liquid. (Tr. at 78)

96. Dr. Valko testified that, although it's not documented, he always assesses patients for a history or a family history of cardiac issues. Dr. Valko stated that he does not perform physical examinations; however, he now obtains a blood pressure at every visit. He acknowledged that, in 2008, he did not obtain a blood pressure. (Tr. at 87-88)

97. In addition to ADHD, Dr. Valko testified that Patient 2 was also reported from the beginning to have obsessions. He testified, "Obsessions can just be thoughts that are repetitive, and compulsions are actions that you take to help relieve some of the anxiety you have from your obsessions." (Tr. at 89) Dr. Valko testified that he had continued to note "R/O OCD" in the diagnosis because, as a psychiatrist, "you have to keep a lot of things in the back of your head." He testified that Patient 2 wasn't quite four years old when he first saw him and was exhibiting ADHD, anxiety, and OCD symptoms. He further testified that

> you also then have to think, in the back of your head, do they have autism. Because those are all issues in autism, and you see those things run together.

> So you try to use a lot of rule out diagnoses, just sort of keep things in the back of your head, like hey, I need to go check back on this and see what's going on.
>
> Sometimes it comes to fruition, sometimes it does not. Sometimes if you look at all my documentation I don't update it as quickly as I should have.

(Tr. at 89-90)

12/22/08 Telephone Call

98. A note on the medication flowsheet states that Patient 2's mother had called and reported that Patient 2 "had puffy eyes" and was whiny on the Vyvanse. Dr. Valko advised that if he is still whiny the next day to discontinue the medication. (St. Ex. 2B at 134)

12/31/08 Visit

99. At Patient 2's next visit on December 31, 2008, Dr. Valko noted that the mother had stopped the Vyvanse because Patient 2 became very agitated, cried, was not eating well, and could not sleep. Following that Patient 2 "returned to his baseline, which is very hyper and impulsive." Dr. Valko discontinued Vyvanse and instead prescribed Ritalin 5 mg each morning. (St. Ex. 2B at 14)

1/15/09 Visit

100. At his next visit on January 15, 2009, Dr. Valko noted the mother's report that she had not seen much improvement and that the medication helps for only two hours. Dr. Valko increased the dose of Ritalin to 10 mg each morning. (St. Ex. 2B at 15)

2/5/09 Visit

101. Patient 2 was next seen by Dr. Valko on February 5, 2009. Mother reported he was doing better. She also reported that "[s]he had been giving [Patient 2] ½ the dose in the AM and the second ½ after school." Dr. Valko changed the medication regimen to Ritalin 5 mg twice per day. (St. Ex. 1B at 18)

10/21/09 Visit

102. Several months and many visits later on October 21, 2009, Patient 2 was prescribed Focalin XR 20 mg[15] with instructions to take one dose every morning and a second dose at 1:30 p.m., and Focalin 10 mg at 5:00 p.m., for a daily dose of 50 mg. At that time Patient 2

[15] Notice it taken that the generic name for Focalin is dexmethylphenidate. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a603014.html>, accessed January 7, 2020)

weighed 54 pounds. The Axis I diagnoses remained the same. (St. Ex. 2B at 31; Tr. at 83-84)

7/12/10 Visit

103. On July 12, 2010, Dr. Valko added Prozac 20 mg to help Patient 2 with anxiety, and continued Focalin and Focalin XR. (St. Ex. 2B at 39)

104. Dr. Barzman noted in his report that Prozac 20 mg "seems to be a high dose for his age." (St. Ex. 17 at 6) However, at the hearing, Dr. Barzman noted that Patient 2 would have been six or seven years old at that point, and that he "could see other psychiatrists potentially starting around that dose, too." (Tr. at 330)

8/3/10 Visit

105. At Patient 2's next visit on August 3, 2010, Dr. Valko doubled the dose of Prozac to 40 mg based on a report that he had no ill effects from previous dose of 20 mg. (St. Ex. 2B at 40)

106. Dr. Barzman testified, "Just looking at the note, I didn't see the rationale for increasing it. And there is the diagnosis of anxiety disorder NOS. It looks like it just wasn't documented there about the reason to increase it." (Tr. at 331) Dr. Barzman further testified that 40 mg seems like a high dose, but "we do go to higher levels for OCD with Prozac." (Tr. at 331)

5/16/11 and 6/8/11 Visits

107. Several months and numerous visits later on May 16, 2011, Dr. Valko discontinued Concerta and prescribed, among other things, Focalin 20 mg three times per day, along with Prozac 60 mg in the morning and Risperdal 0.25 mg twice per day. (St. Ex. 2B at 64)

108. On June 8, 2011, Patient 2's mother reported that both she and Patient 2's teacher had seen huge improvements in Patient 2's cooperation and concentration and that the only times he had outbursts were when his medications were wearing off. She told Dr. Valko "that he seems to be wound up during the morning and evening." Dr. Valko prescribed Focalin 20 mg four times per day (rather than three) for a total daily dose of 80 mg, Prozac 60 mg in the morning, and Risperdal 0.25 mg with instructions to take one tablet twice per day. (St. Ex. 1B at 68)

Testimony of Dr. Barzman

109. In his report, Dr. Barzman stated that it was unclear why Dr. Valko increased Patient 2's Focalin as the progress note indicated that he was doing well. (St. Ex. 17 at 7) At the hearing, however, Dr. Barzman testified that it appeared that the later dose was added to improve focus during morning and evening. (Tr. at 332-333) When asked if the dose was appropriate, Dr. Barzman replied, "[I]t sounds like it's helping. But on the safety standpoint, it's a concern just because that dosing hasn't been studied." (Tr. at 333)

Dr. Barzman testified that, to his best recollection, the maximum recommended daily dose of Focalin in 2011 and at present is 20 milligrams per day. (Tr. at 334)

10/21/11 and 12/15/11 Visits

110. A few months later on October 21, 2011, Dr. Valko prescribed Focalin 25 mg[16] in the morning, 11:00 a.m., 2:00 p.m., and 5:00 p.m. for a total daily dose of 100 mg, which was an increase of 20 mg from the previous visit. This was based on a report from Patient 2's mother that the previous dose of Focalin was not as helpful at home and school as she and the school would like. In addition to Focalin, Dr. Valko prescribed Prozac 60 mg in the morning and Risperdal 0.25 mg twice per day. (St. Ex. 2B at 77)

111. A December 15, 2011 progress note states among other things that Patient 2 was having more difficulty at school, "becoming more obsessed about things," and "seems to be more obsessed the better he can focus. Mother stated that being unable to follow through with his obsessions has caused some difficulties with agitation." (St. Ex. 2B at 79) The diagnoses on December 15, 2011, include for the first time "OCD" rather than "R/O OCD." Dr. Valko continued Focalin at 25 mg four times per day, discontinued Prozac and added Zoloft 150 mg every morning, and increased Risperdal to 0.5 mg twice per day. (St. Ex. 2B at 77, 79)

Testimony of Dr. Barzman

112. Dr. Barzman criticized Dr. Valko for the large dose of Focalin prescribed and for making two medication changes at the same time. In addition, Dr. Barzman testified that stimulants can cause obsessions or anxiety. (Tr. at 334) However, later during the hearing, Dr. Barzman acknowledged that Patient 2 had a diagnosis of OCD and that he had been speculating as to the basis for Patient 2's obsessions. (Tr. at 488)

Testimony of Dr. Valko

113. In his written report, Dr. Barzman stated in reference to the December 15, 2011 progress note, "Concerns: Perhaps, high dose of stimulant caused obsessions; making two medication changes at once." (St. Ex. 17 at 7) With respect to that criticism, the following exchange took place:

> Q. [By Mr. Wilcox] * * * Stimulant medications can cause, as a side effect, obsessions?
>
> A. [By Dr. Valko] I'm not sure where that's coming from.
>
> Q. So do you disagree with that?

[16] Two tablets of Focalin 10 mg and one tablet of Focalin 5 mg. (St. Ex. 2B at 77)

A. Sometimes if you're on too high of a dose of a stimulant you can become anxious, but I don't know where the literature is, and I couldn't find the literature that showed that it caused obsessions, because I'm not sure where that came from.

And he came to us with obsessions prior to me starting a stimulant, which is a common theme among all these records.

Q. So an example of an obsession, let's say, would it be something like he or she becomes fixated on a certain toy and has to know where it is, and, you know, has to have it in their possession at all times? Is that something that's an obsession? Give us an example in this case.

A. In many cases it could be an object that they have to have. I have an autistic kid right now that I'm treating that has to touch the ground and lick it with his fingers, and I mean, obviously not a very safe obsession because there's concerns about picking up all sorts of diseases.

Q. Yeah.

A. And he's also an autistic kid who has a lot of other things going on. So it can come -- the one thing with children and adolescents is that their obsessions change. It's like a moving target.

You think you have something under control, but if you ask the questions correctly, there's probably something that took its place. Not until you're in a young adulthood do usually the obsessions stay consistent.

(Tr. at 92-93)

3/1/12 and 7/16/12 Visits

114. On March 1, 2012, Dr. Valko increased Patient 2's Focalin to 30 mg four times per day for a daily dose of 120 mg on a report from Patient 2's mother that he can no longer focus or concentrate, discontinued Zoloft, and restarted Prozac at 60 mg in the morning. Risperdal was unchanged at 0.5 mg twice per day. (St. Ex. 2B at 96)

115. Several visits later on July 16, 2012, based on a report from mother that "right now he is 'okay at focusing,' but she feels he may have some trouble when school starts." Dr. Valko also increased Patient 2's Focalin to 40 mg four times per day for a daily dose of 160 mg, increased Risperdal to 0.75 mg twice per day, and continued Prozac at 60 mg in the morning. (St. Ex. 2B at 102)

11/5/12 Visit

116. At Patient 2's next visit on November 5, 2012, Patient 2's mother reported that he had become more aggressive toward her following her breakup with Patient 2's father; however, he was not having problems at school. Dr. Valko discontinued Prozac and added Lexapro 30 mg in the morning, increased Risperdal from 1.5 mg to 2.5 mg per day split between one dose of 1 mg and one dose of 1.5 mg per day, and continued Focalin 160 mg per day split among four doses. (St. Ex. 2B at 109)

Dr. Barzman's Report

117. In his report, Dr. Barzman stated that Patient 2 had been behaving more aggressively toward mother, "[h]ence, Prozac was changed to Lexapro. He was started on Lexapro 30 mg/day which is above maximum dose and I do not understand why the change to Lexapro." (St. Ex. 17 at 8) (Emphasis omitted)

Testimony of Dr. Valko

118. Dr. Valko testified that Dr. Barzman had criticized him for discontinuing Prozac and starting Lexapro without cross-titrating the medications. Dr. Valko testified that he had not believed that to be necessary because the two medications are so closely related. Dr. Valko testified that he prescribed Patient 2 a dose of Lexapro that was equivalent to the dose of Prozac the patient had been taking at that time. (Tr. at 635-636; St. Ex. 2B at 109)

12/7/12 Visit

119. On December 7, 2012, Dr. Valko continued Lexapro 30 mg per day and Risperdal 2.5 mg per day, and increased Focalin to 170 mg per day split among one dose of 50 mg in the morning and three additional doses of 40 mg. Dr. Valko stated in the progress note that he increased the morning dose based upon a report that Patient 2 was showing some aggression in the morning. Dr. Valko also indicated that they would consider increasing the other three doses to 50 mg in the future. (St. Ex. 1B at 111)

120. Dr. Barzman testified that Dr. Valko prescribed Focalin 180 mg (it was actually 170 mg per day) and testified that he has never encountered a patient who was being prescribed that level of Focalin. (Tr. at 336)

1/4/13 Visit

121. At Patient 2's next visit on January 4, 2013, his mother reported that Patient 2 behaved well early in the day but that his behavior got worse later in the day. Dr. Valko increased Focalin to 200 mg per day split among four doses of 50 mg. The form of the progress note used by Dr. Valko also changed at this time to include more information. (St. Ex. 2B at 112)

Testimony of Dr. Barzman

122. Dr. Barzman testified that a patient can become tolerant of a medication. When asked what should be done if a patient becomes tolerant to 30 milligrams of Focalin, Dr. Barzman replied:

> It's a common problem, so one idea is if they can -- if there's not a safety issue, that there can be kind of a drug holiday.[17]
>
> But another idea would be if they need a stimulant, changing to a different stimulant, so the Ritalin, Adderall, work a little different.
>
> But you may come across a situation where they can't tolerate Adderall, they can only tolerate Focalin, for example. So it's a tough situation, because patients often do become tolerant to the medicine, and that's why you keep on increasing the doses.

(Tr. at 337)

When asked whether it's appropriate to continue increasing the doses as the patient becomes more and more tolerant, Dr. Barzman replied, "No, the limit is because of the safety. We don't know about the long-term safety or the short-term safety of these doses." (Tr. at 337)

2/1/13 and 3/1/13 Visits – Testimony of Dr. Barzman

123. Dr. Barzman noted that on February 1, 2013, Dr. Valko prescribed, among other things, Wellbutrin XL 150 mg twice per day.[18] Patient 2 was eight years old at that time. Dr. Barzman testified that Wellbutrin XL is a long-acting version of the medication and is meant to be taken once per day. At Patient 2's next visit on March 1, 2013, Dr. Valko doubled the dose of Wellbutrin to 300 mg twice per day for a daily dose of 600 mg. Patient 2 weighed 102 pounds at that visit. Dr. Barzman testified that that is "too much based on what's recommended for this medication." Dr. Barzman testified that one of the side effects of Wellbutrin is seizures and that the risk is dose-dependent. (Tr. at 339-340; St. Ex. 2A at 46-47, 51-52)

Dr. Barzman acknowledged that he saw nothing in the record to indicate that Patient 2 suffered from seizures; nevertheless, "this is a general issue for patients even without seizures. Obviously if you have a history of seizures, you're more prone. But it could still be a risk." (Tr. at 488)

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[17] Dr. Barzman testified that a medication holiday is where a child is taken off ADHD medications during the off-school summer months, if the child can tolerate that. (Tr. at 338)

[18] Dr. Valko also weaned Patient 2 from Lexapro. (St. Ex. 2B at 118)

In addition, Dr. Barzman testified that the Wellbutrin dose for pediatric patients is 3 to 6 milligrams per kilogram of body weight up to a maximum recommended dose of 450 mg per day. (Tr. at 340-341; St. Ex. 1A at 51)

Rapid Metabolism

Testimony of Dr. Barzman

124. When asked if he has ever treated a patient who is a rapid metabolizer, Dr. Barzman replied:

> I haven't ever labeled a patient as a high metabolizer. I do think something similar would be whether they are very sensitive to medication, or more tolerant.
>
> But I haven't increased the doses dramatically based on whether they are tolerant or not, or if the medication is not effective.

(Tr. at 342-343)

Dr. Barzman's Conclusion Regarding Patient 2

125. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 2. (Tr. at 343)

Dr. Valko's Conclusions regarding Patient 2

126. Regarding Patient 2, Dr. Valko testified:

> So Patient 2, again, is a very difficult patient. He came to our practice as a young child and continues to be at our practice. He's still a patient of ours. He struggles with impulse control even to this day, even though he tries not to. He's very obsessive-compulsive, and gets anxiety symptoms affecting the way he interacts with peers and school.
>
> I wouldn't put him in on the spectrum, even though it hits a lot of the criteria for the spectrum, but his social skills are better than I would expect for somebody on the autism spectrum.

(Tr. at 633-634)

127. Noting that Dr. Barzman had criticized him for prescribing medication that may have caused side effects such as obsession, Dr. Valko testified that "Patient 2 was very

obsessive, very compulsive right from the very first time we met him, and there were real issues that were there before, during, and when his stimulant medication was being adjusted." (Tr. at 634-635)

128. Dr. Valko testified that he agrees with Dr. Barzman that the standard of care requires a physician to show documentation as to why a medication is being prescribed. However, Dr. Valko believes that he did that throughout the patient records that were reviewed. (Tr. at 637-638)

129. Dr. Valko testified that Patient 2 underwent GeneSight testing after the Board had subpoenaed the medical records, and presented a GeneSight report that is dated December 12, 2017. The report shows that Patient 2 had a significant drug/gene interaction with Lexapro, Prozac, Celexa, and a number of other antidepressants; a significant drug/gene interaction with Risperdal, Abilify, and other antipsychotics; and a moderate drug/gene interaction with Adderall, Vyvanse, Focalin, Ritalin, Concerta, Metadate, and Daytrana. (Tr. at 638-644; Resp. Ex. C at 1-18)

Noting that the GeneSight testing occurred after the State had subpoenaed Patient 2's medical records, Dr. Valko testified, "This helps to explain why he seems to be struggling with his impulse control on what would have been considered to be normal doses of stimulants and why it was necessary for him to have the higher dose of that stimulant." (Tr. at 645)

Letter of Support from Patient 2's Mother

130. Patient 2's mother stated in an undated letter that Patient 2 has been seeing Dr. Valko for about nine years. She stated that she and Dr. Valko have worked together to help Patient 2, and that he has always answered any questions or concerns regarding his medications. Dr. Valko always asks about side effects of the medication prescribed. She noted that many medications were tried over the years, most with bad side effects, and that the medications that he tolerates best are metabolized fast. She further stated that Dr. Valko always does blood work to be sure Patient 2 is healthy. She trusts Dr. Valko and the treatment plan. (Resp. Ex. F at 2)

Patient 3

8/22/07 Initial Assessment

131. Patient 3, a male born in 2000, first visited Dr. Valko's practice on August 22, 2007, and was seen by Heather Simon, M.A., PCC. Mother and step-father reported that Patient 3 had been treated for ADHD since he was three years old. During the previous few months his behavior has become "physically aggressive in his interactions with others." He had a history of such behavior three years previously when he was first assessed but they disappeared after treatment was initiated for the ADHD. At the time of his initial assessment Patient 3 was being prescribed Ritalin 5 mg twice per day. (St. Ex. 3 at 1-2) The initial assessment note further states:

> [Mother] stated that the current physical aggression began towards the end of the school year in 2007 when he "punched" another boy in the nose on the bus. They stated that since that time he has kicked his pregnant babysitter in the stomach, poked this same babysitter in the upper chest with a screwdriver, and kicked others several times. [Mother] stated that he has teased his sister while holding a knife that he was going to throw the knife at her. [Mother] stated that he is no longer allowed to use a knife and that after he made the same threat with a fork he had to eat with a spoon. They stated that he becomes very angry and that he has a difficult time accepting consequences. They stated that he has a difficult time settling himself down when he gets angry. [Mother] stated that she feels that some of this behavior is connected to recent changes in his life. She stated that about the time of the first incident he was not getting as much time with her in the mornings because his sister was home more. Then his mother had a new baby at the end of July.[19] They reported that [Patient 3] has threatened to squeeze his friend's toad and kill it. They stated that he did not do this but they were concerned that he had threatened this. They also stated that some of his friends do not want to play with him after this incident. They reported the following symptoms of ADHD when he is not on medication: difficulty sustaining attention, not seeming to listen when spoken to, not following through on instructions, avoiding tasks that require sustained mental effort, losing things necessary for tasks, being easily distracted, forgetful in daily activities, fidgeting, running and climbing excessively, difficulty doing things quietly, often being "on the go," talking excessively, and interrupting. His parents stated that he has not had difficulty staying seated at school but this writer noted that during the school year he was on his medication. During the assessment, he had a difficult time staying seated and got out of his seat constantly.

(St. Ex. 3 at 1)

The note further stated that Patient 3's sister had witnessed one occasion of violent behavior by Patient 3's biological father upon the mother and the ensuing response by the police, and she had talked about the incident so many times that Patient 3 thought he witnessed it also although he was actually asleep when it happened. There had been further violent and/or menacing behavior by the biological father upon the stepfather and the note indicates that Patient 3 had witnessed some of this. However, the note also states that the biological father has not been abusive toward the children. (St. Ex. 3 at 1-2)

The progress note indicates that Patient 3's Axis I diagnoses were "[ADHD] Combined Type 314.01" and "Disruptive Behavior Disorder, NOS 312.9." (St. Ex. 3 at 3)

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[19] The note indicates that Patient 3's brother was about a month old at the time of the initial assessment. (St. Ex. 3 at 2)

9/19/07 – First visit with Dr. Valko

132. Dr. Valko first saw Patient 3 on September 19, 2007. He noted that Patient 3 was there with his mother and was able to sit in the chair and read a book, but interrupted "on an almost continuous basis." (St. Ex. 3 at 6) Mother noted that Patient 3 was doing very well on his Ritalin but that, even when given at lunchtime, it does not seem to last the day. She told Dr. Valko that she had some Ritalin LA 10 mg at home, and they discussed trying it over the weekend. Dr. Valko confirmed the diagnoses of ADHD Combined and Disruptive Behavior Disorder NOS. (St. Ex. 3 at 6)

Testimony of Dr. Valko

133. Dr. Valko testified that he often uses diagnoses such as disruptive behavior disorder or the very similar intermittent explosive disorder when the patient is aggressive, agitated, and has mood swings and Dr. Valko is seeing the possibility of bipolar disorder. (Tr. at 97) Dr. Valko further testified:

> I prefer using a diagnosis such as disruptive behavior disorder well before I will ever call anybody bipolar disorder, mainly for the reason that most kids outgrow a disruptive behavior disorder or intermittent explosive disorder.
>
> But if you give them a diagnosis of bipolar disorder, you have just given them a lifelong mental health disorder with no cure.
>
> And in today's insurance climate, as it was way back when this was happening, the last thing you want to do is inappropriately or prematurely give somebody a diagnosis that may not be correct, and then it would stick with them forever.
>
> And with the whole new age of pre-existing illness -- and if I had given somebody a bipolar disorder and they had outgrown it, shame on me.

(Tr. at 97-98)

134. Dr. Valko described Patient 3:

> Patient 3, once again, came to us because of his inability to focus, his poor impulse control, and right from the very get-go, his aggression and agitation. The mother was overwhelmed and just hopeful that our office, we would be able to help her with this.
>
> They had difficulties with medications, noting that the medications seem to not work for a very long period of time. Dr. Barzman yesterday, I think, made a comment that it's supposed to last all day. But the follow-up to that is a lot of times it doesn't. I mean, most of these long-term medications they say last

> 8 to 12 hours, and you sort of wonder who that is with, because it's sure not with the more difficult psychiatric patients. That would be ideal.

(Tr. at 647-648)

Dr. Valko noted that Patient 3 "burned through his medication pretty quick" based on reports from Patient 3's mother and his school. (Tr. at 648)

4/13/09 Visit

135. Nearly two years and many visits after his initial visit, on April 13, 2009, Patient 3 was being prescribed Ritalin 10 mg in the morning and Ritalin LA 20 mg at 1:30 p.m. At this visit, Dr. Valko discontinued Ritalin and added Adderall XR 20 mg in the morning. (St. Ex. 3 at 42)

136. In his report, Dr. Barzman stated, "Could have raised Ritalin." (St. Ex. 17 at 9; emphasis omitted) When asked at the hearing if that meant it was below the minimal standard of care or a "musing," Dr. Barzman replied, "Just something to consider, but I wouldn't say it's necessarily below the standard of care." (Tr. at 493)

6/4/09 Entry on Medication Flowsheet

137. On June 4, 2009, Dr. Valko discontinued Adderall XR and added Metadate CD 40 mg in the morning. (St. Ex. 3 at 198)

6/18/09 Visit

138. At Patient 3's June 18, 2009 visit, Patient 3's mother reported that he was still struggling with focus, concentration, and had very poor impulse control. She further advised that Metadate had not been helpful. Dr. Valko discontinued Metadate and added Focalin XR 15 mg with instructions to take two tablets every morning, a daily dose of 30 mg. (St. Ex. 3 at 49)

Testimony of Dr. Valko

139. Dr. Valko testified that Metadate is a "Ritalin product" and a CNS stimulant. Dr. Valko noted that he had replaced the Metadate with Focalin, another CNS stimulant that is supposed to have fewer side effects than Ritalin. (Tr. at 99-100) When asked how he chooses from among the numerous CNS stimulants available, Dr. Valko replied:

> It is an art, it's not a science. It's just not possible to be a science. You have to do the best you can with the information that's provided.
>
> I mean, this is obviously a very difficult patient who is having struggles in all areas, and you try to listen to what's going on and you try to find a medication

> that they can tolerate, they can swallow, or can be broken up or crushed if they can't swallow.
>
> And you hope that a slight change in the formula versus -- plain Ritalin versus the Ritalin that has been fragmented to make the Focalin,[20] may be a little bit more helpful.

(Tr. at 100-101)

When asked if he had any detailed pharmacological training to make such medication decisions, Dr. Valko testified that many of the medications available today became available after he finished his residency. However, Dr. Valko testified that he researches medications diligently, reads a lot of journals, and takes "well over 100 hours of CEUs a year to keep up on my meds. Again, I teach. If I can't explain it to a student who then has to take their shelf exam on the meds, then I haven't been a very good mentor for them." (Tr. at 101-103)

7/9/09 Visit

140. At Patient 3's next visit on July 9, 2009, Patient 3's mother reported that he was less agitated on Focalin XR but that it wore off after four hours. In addition, she reported it was not very helpful controlling his impulsivity. Dr. Valko increased Focalin XR to 15 mg three tablets every morning and three more tablets at 1:30 p.m. for a total daily dose of 90 mg. This was a threefold increase over the previous daily dose. Patient 3 weighed 68 pounds on July 9, 2009. (St. Ex. 3 at 49, 54)

Testimony of Dr. Barzman

141. Dr. Barzman testified that 90 mg is a large daily dose of Focalin considering Patient 3's weight, "[s]o just from a safety standpoint, it just hasn't been studied, that dose range." (Tr. at 346) Moreover, Dr. Barzman testified that increasing Focalin from 30 mg per day to 90 mg per day was "a large and rapid titration." (Tr. at 347) When asked for an appropriate way to titrate Focalin, Dr. Barzman replied:

> So with Focalin, depending on how the patient is doing, if they are still not doing well, they could go by 5 -- depending on the age and weight, 5 milligrams a week, or 10 milligrams a week. And what's the other question?
>
> Q. [By Ms. Snyder] Well, first, why do you titrate it that way?
>
> A. Just to make sure that they are not going to have side effects, or that they can tolerate it. Also we want the lowest effective dose. It's possible that a lower dose could be more effective.

[20] As noted previously, Ritalin is methylphenidate and Focalin is dexmethylphenidate.

Q. And why do you want the lowest effective dose?

A. From a safety standpoint. And also, we talked before about building up a tolerance. So it's for safety and not building up a tolerance.

Q. So is it your opinion that Dr. Valko titrated the Focalin too quickly from one month to the next?

A. So he went from 30 milligrams to 90? Yes.

(Tr. at 347-348)

142. Dr. Barzman testified in general, not with specific reference to Patient 3, that stimulants can cause negative behavior in patients such as irritability, aggression, anxiety, and agitation. Dr. Barzman acknowledged that he did not see those behaviors in Patient 3 around the time of the July 9, 2009 visit. (Tr. at 348-349)

Testimony of Dr. Valko

143. Dr. Valko was asked about the increase in the Focalin XR from 30 mg per day to 90 mg per day. Dr. Valko acknowledged that he tripled the daily dose of Focalin XR but that he had increased the dose only from 30 mg to 45 mg then added a second dose. Dr. Valko testified that the 30 mg dose was not that helpful. A single dose of Focalin XR 45 mg did help but lasted only about four hours, so Dr. Valko added a second dose in the afternoon to get Patient 3 through another four hours. (Tr. at 104-106)

7/20/09 Visit

144. A July 20, 2009 progress note indicates that when Patient 3 increased his dose of Focalin he experienced hives "so his mother appropriately stopped the Focalin." He had not experienced hives on lower doses previously prescribed. Dr. Valko noted that they discussed options, and "mother would like to return to the Ritalin LA, which partially worked for him. She was hopeful we could increase the dose, of which I am in agreement." Dr. Valko discontinued Focalin XR and prescribed Ritalin LA 30 mg with instructions to take one tablet in the morning and one tablet at 1:30 p.m. for a total daily dose of 60 mg. Patient 3 weighed 74.5 pounds at that visit. (St. Ex. 3 at 55)

8/3/09 Visit

145. An August 3, 2009 progress note indicates that Patient 3 was doing well on the Ritalin but that it lasted only about three hours. When the medication wore off Patient 3 experienced behavioral issues and impulsivity. Dr. Valko noted, "We reviewed options, with a decision to do to a short acting Ritalin and give it more frequently. We will start giving the medication every three hours. I will continue with the current dose, but mother understands that this may be too much. The short acting though should last about three hours, the same as the long

lasting was lasting." Dr. Valko prescribed Ritalin 20 mg with instructions to take 1-½ tablets three times per day, up from two, for a total daily dose of 90 mg. Patient 3 weighed 74 pounds at that visit. (St. Ex. 3 at 57)

8/11/09 Visit with Mr. Eble

146. In his progress note dated August 11, 2009, Mr. Eble, one of Dr. Valko's therapists, noted that he met with Patient 3 and his mother. The note includes the following:

> Mom has a list that she made and indicated that she forgot to mention several things last time, including that [Patient 3] beat up his sister and the police were called. She had a days worth of issues journaled, which she read to me and mentioned that she did not remember to talk about this last time because [Patient 3] had a few good days just before they saw me last.

(St. Ex. 3 at 58)

5/27/10 Visit

147. Several months later, on May 27, 2010, Dr. Valko noted, among other things, "We have discussed [Patient 3] with Daniel Eble, PCC and with [Patient 3's] mother and understand the disruptive and increasingly violent and damaging behavior that he is pursuing including throwing things at people, intentionally lying and deceiving, and playing with fire in his room." Dr. Valko left Ritalin unchanged at 90 mg per day split among three doses and added Risperdal 0.25 mg twice per day. Patient 3 weighed 76 pounds at that visit. (St. Ex. 3 at 76)

Testimony of Dr. Barzman

148. In his report, Dr. Barzman criticized Dr. Valko for not obtaining metabolic labs prior to starting Risperdal. (St. Ex. 17 at 10)

Testimony of Dr. Valko

149. Dr. Valko testified that Risperdal is a second-generation neuroleptic.[21] Dr. Valko further testified that it has side effects that must be monitored and requires metabolic blood panels. Moreover, Dr. Valko testified that it does not appear that he had established a baseline metabolic panel when he started Risperdal and acknowledged that he should have. (Tr. at 107-108)

[21] Dr. Valko testified that the term "neuroleptic" is more accurate than "antipsychotic" because such medications are approved to treat more than just psychoses. Both terms are used interchangeably in this report. (Tr. at 110)

11/29/10 Visit

Report of Dr. Barzman

150. With respect to Patient 3's November 29, 2010 visit, at which Dr. Valko prescribed Ritalin 40 mg three times per day, and Risperdal 0.5 mg twice per day, Dr. Barzman noted in his report that no EKG had been ordered with respect to the high-dose stimulant prescribing. (St. Ex. 3 at 89; St. Ex. 17 at 10; see, also Tr. at 367-369)

1/18/13 Visit

151. Over two years and many visits later, in late 2012, Patient 3 had been receiving Ritalin 60 mg five times per day for a daily dose of 300 mg, Risperdal 4.5 mg per day split among two doses of 2 mg and one dose of 0.5 mg, and Prozac 40 mg in the morning. At Patient 3's January 18, 2013 visit, the last visit documented in the chart, his mother described increased agitation, including an incident where Patient 3 slapped another child on the bus and was suspended from school. During another incident, his teacher asked him to clean his desk which he refused to do because he had supposedly cleaned it earlier. The teacher continued to insist and Patient 3 responded by trying to leave the classroom, and "[e]ventually three teachers had to stop him from leaving the room." Dr. Valko further documented, "To try to better address his agitation, I discussed with them adding Saphris 5 mg QAM and 10 mg QHS, and dropping the morning and evening dose of Risperdal." (St. Ex. 3 at 190-191, 200)

Testimony of Dr. Barzman

152. Dr. Barzman testified that, in his report, he criticized Dr. Valko for prescribing two second-generation antipsychotics, Risperdal and Saphris, at the same time. Dr. Barzman testified that had thought at the time that the two medications were being prescribed at the same time. However, Dr. Barzman testified that this appears to be a patient who was cross-titrated and withdrew his criticism. (Tr. at 351; St. Ex. 3 at 190-191; St. Ex. 17 at 12)

Testimony of Dr. Valko

153. Regarding Patient 3's January 18, 2013 visit, Dr. Valko confirmed that he was cross-titrating Risperdal and Saphris. (Tr. at 658-659; St. Ex. 3 at 190-192)

154. Dr. Valko testified that he had ordered labs at Patient 3's January 7, 2013 visit, and reordered them on January 18, 2013 because they had not obtained them yet. (Tr. at 653-654; St. Ex. 3 at 189-192) When asked what he does when a patient does not obtained ordered labs, Dr. Valko replied:

> It's, once again, a lot of education with the parents because this is a minor. He's not responsible for his own labs. We try to educate. We try to help. You do the best you can. I am not going to discharge this patient from my

> practice because the mom can't follow through with getting labs. You just keep asking for them.

(Tr. at 654)

Dr. Barzman Conclusions regarding Dr. Valko's Treatment of Patient 3

155. Dr. Barzman testified that Patient 3 was a six-year-old with ADHD and Disruptive Behavior Disorder NOS when Dr. Valko began treating Patient 3 in 2007. (Tr. at 343-344) Dr. Barzman further testified that his overall concerns with Dr. Valko's treatment of Patient 3 were the lack of monitoring labs for the antipsychotic and the high dosing of stimulants. (Tr. at 344)

156. Dr. Barzman was asked what the standard of care requires concerning labs when a physician prescribes Risperdal. He replied:

> Well, there's side effects outside of the labs, too, to monitor, which include the movement disorder issues.
>
> But in terms of labs, we're looking for anything along the lines of weight gain, glucose levels, lipid levels, and something -- it could be hemoglobin A1C or insulin levels, to see any warnings of diabetes.
>
> Q. [By Ms. Snyder] So does a standard of care require that a physician obtain labs prior to prescribing?
>
> A. No. In reality, it can be around the time of prescribing, a baseline. So you start the medicine, but also obtain the labs the same week, or around that time. And then, again, depending on the patient's history, then that set of labs can be obtained further along.

(Tr. at 345)

157. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 3. (Tr. at 352)

158. Dr. Barzman was asked if he would continue to prescribe medication if the patient reported that he or she is unable to financially afford to obtain testing that had been ordered. Whereupon the following exchange took place:

> Q. [By Ms. Snyder] And what do you do if a patient doesn't follow through with the labs?

A. Depending on the situation, I would tell them that -- if they call in for a refill, I tell them here is one more week. If you don't get the labs we're going to look at stopping the medication, and really kind of putting a limit on that.

Q. Is it a safety issue, in your opinion?

A. It depends on the situation -- well, not getting labs. It is important to get the labs to monitor how the patient is doing in terms of glu- --when I say metabolic labs, I mean glucose, lipids.

But it becomes an issue if they really need the medicine for significant symptoms and they are still not getting the labs. That's where it becomes really hard.

(Tr. at 301-302)

Dr. Valko Conclusions Regarding Patient 3

159. In response to criticism in Dr. Barzman's report that he did not obtain an EKG for his prescribing of stimulants to Patient 3, Dr. Valko referenced an article he had identified in his report titled "Practice Parameter for the Assessment and Treatment of Children and Adolescents with Attention-Deficit Hyperactivity Disorder" published by the American Academy of Child and Adolescent Psychiatry in February 2002. (Resp. Ex. A at 21; Resp. Ex. M) Dr. Valko testified that the article does not mention concern about EKG monitoring when the dose is below "three and a half times what the FDA recommended dose is." (Tr. at 656-657)

That article referenced by Dr. Valko also includes the following:

> Deciding on both a minimum and maximum dose. For children and adolescents, minimum effective doses should be used to initiate therapy. A minimum starting dose of either 5 mg of MPH[22] or 2.5 mg of AMP[23] in children and adolescents, given in the form of an immediate-release tablet. These doses should be started on a 2 or 3 times daily basis because of their very short duration of action. The maximum total daily doses are calculated by adding together all doses taken during a given day. The *Physician's Desk Reference* (PDR) states that the maximum total daily dose is 60 mg for MPH and 40 mg for amphetamines. Children weighing less than 25 kg generally should not receive single doses greater than 15 mg of MPH or 10 mg of DEX/AMP. The consensus from practice is that doses may go higher than the PDR-recommended upper limits on rare occasions. Experts often limit the upper range to a total daily dose of 40 mg of AMP or 25 mg for a single dose of MPH, when MPH is given in multiple doses throughout the day. If the top

[22] Methylphenidate.
[23] Amphetamine (presumably referring to Adderall and Vyvanse).

> recommended dose does not help, more is not necessarily better. A change in drug or environmental or psychosocial intervention may be required.

(Resp. Ex. M at 28S – 29S; footnotes added, italics in original)

Patient 4

March 4, 2008 Initial Assessment

160. Patient 4, a male born in 1998, first visited Dr. Valko's practice on March 4, 2008. He had been referred by his pediatrician for a medication assessment and was seen by Jeff Campey, M.Ed., LPC. The chief complaint states:

> [Patient 4], age nine, is brought for assessment by his mother, * * *. He was referred for medication assessment by his pediatrician, Dr. Burlingame. [Mother] reported that [Patient 4] is prescribed medication for ADHD but still exhibits many symptoms of inattentiveness; however, she is more concerned about his easily becoming angry and frequently whining. She reported that he will become intensely angry and state that he wishes he were dead or that he wants to kill others. She reported that he sometimes becomes physical with his two-year-old brother and 16-year-old brother. She reported that he is more irritable and often has a negative attitude. She reported that [Patient 4] has told her that he is not able to control what his brain is doing. [Mother] identified seeing [Patient 4] as always exaggerating how he feels and what happens.
>
> [Patient 4] identified his general mood as unhappy and related seeing people take things out on him that are not his fault, "I asked them to stop but they don't." [Patient 4] identified having difficulty falling asleep at night. His mother reported that he goes to bed at eight but will repeatedly identify things to do to delay going to bed. His mother reported that she has tried multiple interventions to decrease this behavior but nothing has worked. She reported that [Patient 4] is usually asleep by 9:00 p.m. She reported that [Patient 4] has a minimal appetite and is a picky eater. Despite his current medication, [mother] reported that [Patient 4] will often rushed [sic] to complete his school work and make careless mistakes, not pay attention to detail, start and not finish his work, frequently lose or misplace his belongings, is easily distracted, has difficulty sustaining attention, and tries to avoid task[s] that require sustained concentration; she reported that he is sometimes forgetful. [Mother] reported that [Patient 4] is often fidgety but does not seem to be as restless with the medication. She reported that he is generally impatient and is verbally impulsive especially when upset. She reported that occasionally he seems to do things without thinking.

> [Mother] also expressed concern about [Patient 4] taking things that don't belong to him and then lying about it. She reported seeing him as having to have what others have and will do what ever he has to get it. She reported that [Patient 4] is defiant and will do something that he wants despite knowing there will be a consequence. She reported that he is very competitive and becomes upset when he loses. She reported that he blames other and usually does not take responsibility for his behavior. His mother identified being at her "wits end" with [Patient 4's] behaviors and not knowing what to do.

(St. Ex. 4B at 1)

The progress note indicates that Patient 4 was currently receiving Concerta for ADHD and had previously received Adderall.[24] (St. Ex. 4B at 2-3)

At his initial visit, his Axis I diagnoses were:

> ADHD Combined Type (314.01
> Depressive Disorder NOS (311.00)
> Oppositional Defiant Disorder ("ODD")
> R/O Reading Disorder

(St. Ex. 4 at 3)

3/19/08 – First visit with Dr. Valko

161. Dr. Valko first saw Patient 4 on March 19, 2008. Patient 4's mother reported that Patient 4 is impulsive and has trouble paying attention in school. Patient 4 reported that "on Monday" he was chased, tripped, and hit by other children at school, but his mother believes that he was actually the aggressor. (St. Ex. 4 at 11) In addition:

> His mother reports that after this incident on Monday [Patient 4] was sent to the school counselor where he reportedly made the counselor believe that his parents were separated, kept him up all weekend working on chores until 5 am, and that his dad stepped on his head. His mother reports that none of these are true. [Patient 4] reportedly also told the school counselor that he wanted to kill himself and that "I can snap my neck" while demonstrating this with his hands.

(St. Ex. 4 at 11)

Patient 4's mother also related that Patient 4 takes items that do not belong to him, and that she has had him banned from the school store "and if anything is ever missing she

[24] The next visit note indicates that Dr. Valko discontinued Adderall and added Concerta, so Adderall may actually have been Patient 4's then-current medication. (St. Ex. 4B at 11)

informed the school to check with [Patient 4] first." She further stated that Patient 4 has been increasingly emotional particularly when his medication begins to wear off. Also, his appetite has decreased and he has trouble sleeping. He weighed 59 pounds at that visit. (St. Ex. 4 at 11)

Dr. Valko continued the diagnoses of ADHD Combined, Depression NOS, and ODD. He did not include R/O Reading Disorder. Dr. Valko discontinued Adderall and prescribed Concerta 54 mg to be taken each morning. (St. Ex. 4 at 11)

Testimony of Dr. Barzman

162. Dr. Barzman testified that Dr. Valko's dosing of Concerta was reasonable at that visit. (Tr. at 355-356; St. Ex. 4B at 11)

Testimony of Dr. Valko

163. Dr. Valko testified that the maximum FDA recommended daily dose of Concerta is 72 milligrams. (Tr. at 115)

3/24/08 Baseline Blood Profile

164. Dr. Valko testified that he obtained a baseline blood profile for Patient 4.[25] The chart includes a report for a sample collected on March 24, 2008, that includes a metabolic panel. (Tr. at 117-120; St. Ex. 4B at 14)

Dr. Valko noted that he later changed his progress notes to include the dates of labs, medication levels, and medical reports as a reminder so those would be "more in [his] face, to be honest."[26] (Tr. at 121)

Testimony of Dr. Barzman

165. Dr. Barzman acknowledged that labs were obtained around March 2008 but did not include a lipid panel, hemoglobin A1C, or insulin. (St. Ex. 4B at 14; Tr. at 496)

Further Testimony of Dr. Valko

166. Dr. Valko testified that Patient 4 was terrified of needles and it took a while to get labs on him. (Tr. at 663-664; St. Ex. 4B at 3)

167. Dr. Valko testified that Patient 4's baseline labs were reported on March 24, 2008. (Tr. at 664; St. Ex. 4B at 14) Dr. Valko further testified:

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[25] Dr. Valko referred to it as a comprehensive metabolic panel. (Tr. at 120)
[26] See, for example, State's Exhibit 4 at pages 225 – 227, a progress note dated January 11, 2013.

> [Dr. Barzman] had commented the baseline labs, my baseline labs, did not include hemoglobin A1c, triglycerides, or cholesterol. I don't order those routinely at the very beginning. Those are more specialized labs for me and much more expensive to the family.
>
> My baseline labs are a comprehensive metabolic profile which looks at electrolytes. It looks at blood sugar. It looks at kidney functions, looks at liver functions. It looks at the basic thyroid function, and it looks at the CBC. I'm trying to rule out any major medical issues that could be causing agitation, anxiety, inability to focus and concentrate.

(Tr. at 664)

Subsequent Visits through 6/12/08

168. Dr. Valko continued Concerta 54 mg at Patient 4's next visit on March 27, 2008, but on April 30, 2008, he discontinued Concerta and prescribed Adderall XR 30 mg in the morning. Dr. Valko noted the mother's concern that Patient 4 made some gains on Concerta but that it made him very emotional. He continued to have problems in school. The mother asked about bipolar disorder but agreed that he should not be formally diagnosed with that condition. (St. Ex. 4 at 15-16)

169. On May 21, 2008, Dr. Valko added Prozac 20 mg in the morning for depressive symptoms. (St. Ex. 4 at 24)

170. On May 29, 2008, Dr. Valko discontinued Prozac and added Wellbutrin SR 150 mg in the morning based on mother's report that Patient 4 had had an emotional breakdown the afternoon of his first dose of Prozac. She stopped giving him Prozac after that one dose. (St. Ex. 4 at 25)

171. In his June 12, 2008 progress note, Dr. Valko noted that Patient 4's mother had stated that "the Wellbutrin seems to be taking all of the emotion out of her son. 'No smile, no emotion. He's very blasé.'" She expressed concern that he won't enjoy himself on their upcoming vacation because he will be too sedated. Dr. Valko continued the diagnoses, discontinued Adderall and Wellbutrin, and prescribed Vyvanse 70 mg in the morning. (St. Ex. 4 at 31)

6/23/08 Visit

172. Dr. Valko next saw Patient 4 on June 23, 2008. At that time Patient 4 reported that he had had a good time during the family vacation, an assessment that was contradicted by his mother. She indicated that Patient 4 was difficult throughout and that she took him off the Vyvanse and put him back on the Adderall, "but it didn't make a difference." (St. Ex. 4 at 32) Dr. Valko discontinued Vyvanse and added Risperdal 0.5 mg with instructions to take

one-half tablet twice per day. The progress note further states, "I explained that it is FDA approved in kids for ADHD * * *." (St. Ex. 4 at 32)

Testimony of Dr. Barzman

173. Dr. Barzman noted that Dr. Valko prescribed Risperdal at that visit and stated in the progress note that Risperdal "is FDA approved in kids for ADHD." However, Dr. Barzman testified that Risperdal has not been approved by the FDA to treat ADHD. He further testified that it has been studied as treatment for aggression in kids with ADHD, but that it is not been approved by the FDA to treat ADHD. (Tr. at 356; St. Ex. 4B at 32)

174. When asked if Patient 4 had any diagnoses for which Risperdal would be indicated, Dr. Barzman testified that aggression related to oppositional defiant disorder, which is one of Patient 4's diagnoses, would support prescribing Risperdal. (Tr. at 495)

Testimony of Dr. Valko

175. Dr. Valko acknowledged that he was in error when he stated that Risperdal was FDA approved for children with ADHD. It is approved for "agitated ADHD in autistic patients, not just for ADHD." (Tr. at 116, 663) Dr. Valko noted that Patient 4 was eventually diagnosed with autism but not at this time. (Tr. at 116)

Dr. Valko further testified that not including "agitation" as one of Patient 4's symptoms was an error, and that "[i]t wasn't as thorough of a note as it should have been." (Tr. at 663)

6/30/08 Visit

176. At Patient 4's June 30, 2008 visit, Patient 4's mother reported among other things that he was not focusing and was very lethargic, and was always cold and shivering. Dr. Valko increased the Risperdal to 0.5 mg twice per day. (St. Ex. 4B at 33-34)

10/18/10 Visit

177. More than two years and many visits later, on October 18, 2010, Dr. Valko first placed Patient 4 on Lamictal "in hopes it will help us to eliminate the Risperdal." At that time the patient was also receiving Metadate CD 80 mg in the morning, Methylphenidate 20 mg at 3:30 p.m., Paxil 30 mg once per day,[27] and Risperdal 0.25 mg twice per day. Patient 4's mother reported that he had been misbehaving in school, becoming more emotional at times, and that his focus and overall behavior was getting worse. Dr. Valko added "Lamictal 25 mg BID X 2 weeks then 50 mg – 25 mg." Patient 4's diagnoses remained ADHD Combined, Depression NOS, and ODD. (St. Ex. 4B at 92)

[27] Paxil had been added to Patient 4's regimen on July 21, 2010. (St. Ex. 4B at 86)

Dr. Barzman Report and Testimony

178. Dr. Barzman questioned in his report why Lamictal was added and for what diagnosis. (St. Ex. 17 at 16) At the hearing, Dr. Barzman acknowledged that Lamictal is an appropriate medication to treat mood disorders. (Tr. at 498)

179. In addition, Dr. Barzman stated in his report that Paxil is not supposed to be given to children. (St. Ex. 17 at 16) Dr. Barzman testified that guidance on Paxil came out around 2003 to 2005 published in the UK. Dr. Barzman further testified that information from the UK is considered reliable even though it comes from outside the US. (Tr. at 499)

Testimony of Dr. Valko

180. When asked why he had added Lamictal to Patient 4's medication regimen, Dr. Valko testified that he had added it as a mood stabilizer. He acknowledged that he "definitely should have added a mood disorder at this time because a lot of the students seem to be strictly OCD and ADHD. It seemed more of a mood disorder." (Tr. at 669)

181. Dr. Valko testified that Lamictal is an anticonvulsant medication that can also be used to treat mood disorders. Dr. Valko further testified that Lamictal has a very serious but rare side effect that he referred to as "a flesh eating rash." He testified that it can cause "a low white count. In a matter of days you could have your skin fall off and end up in the burn unit." (Tr. at 127) Dr. Valko testified that he has never personally seen this but has heard about it. Moreover, Dr. Valko testified, "[s]o when I have my patients and I put them on Lamictal, I always use the very graphic flesh eating rash, and the kids -- it's amazing. I mean, they don't forget that." (Tr. at 127)

Dr. Valko further testified that his progress note reflects that he had reviewed the side effects and benefits of Patient 4's medication, which included Lamictal.

182. With respect to Dr. Barzman's criticism that Paxil was not to be given to children, Dr. Valko replied that it was still indicated for children in 2010. Dr. Valko testified that there have since been "some controversial studies that feel that Paxil may possibly increase suicidal ideations in children and adolescents, and there is equal number of studies that it does not." (Tr. at 129) Dr. Valko opined that the FDA came down on the side of caution and recommended that it not be used for that age group. (Tr. at 130) Dr. Valko added that "[t]here's some official guidelines or nonofficial guidelines that have come out saying that it's no better than a placebo, and yet there are a lot of patients in the past that have shown gains on the Paxil, so it's a judgment call on that one." (Tr. at 670-671)

9/22/11 Visit

183. Skipping ahead approximately one year and several visits, when Patient 4 saw Dr. Valko on September 22, 2011, his medications from the previous visit had been:

- Metadate CD 80 mg (50 mg and 30 mg) in the morning
- methylphenidate 20 mg at noon
- Lamictal 100 mg twice per day
- Lexapro 20 mg

(St. Ex. 4 at 137) His diagnoses remained unchanged at the previous visit. (St. Ex. 4 at 137)

On September 22, 2011, Patient 4 complained that his "brain fell asleep" but only on the right side. Mother expressed concern that it may have been a migraine. She further related that Patient 4 had been "on a 'roller coaster with his meds' for some time" and that "his medication has changed frequently in the last few appointments, and while he was 'making progress' before, he regressed this summer at Boy Scout camp two months [earlier]." Patient 4 discussed the camp and Dr. Valko documented that he was still troubled by an incident wherein "another boy there ended up mooning him." Patient 4 became tearful and distressed relating the event. (St. Ex. 4B at 141)

Dr. Valko discontinued Patient 4's methylphenidate 20 mg and increased Metadate CD from 80 mg in the morning to 100 mg in the morning and left Lamictal and Lexapro unchanged. He ordered a blood draw for a Lamictal level and ordered "a sleep-deprived EEG be done for [Patient 4] to address his 'brain falling asleep.'" (St. Ex. 4B at 141) Dr. Valko also asked Patient 4's mother to monitor OCD and PTSD behaviors due to Dr. Valko's concern that Patient 4 "is still ruminating on the summer camp events that occurred two months ago." (St. Ex. 4B at 142) Finally, Dr. Valko documented the following Axis I diagnoses:

ADHD, combined
R/O PTSD
R/O OCD
Depression, NOS
ODD

(St. Ex. 4B at 142)

10/11/11 Visit

184. On October 11, 2011, Patient 4's mother repeated her comment that the patient had been on a "roller coaster with his meds." She was having difficulty with his behavior and his inattention remained a problem. She further related that consequences no longer seem effective controlling his behavior. He does not do his homework and he obsesses over things that shouldn't concern him. She reported that he had had an EEG done. Dr. Valko increased Metadate CD to 150 mg in the morning, increased Lamictal to 300 mg per day, and continued Lexapro at 20 mg per day. Patient 4's diagnoses remained unchanged from the September 22, 2011 visit. (St. Ex. 4B at 184)

Testimony of Dr. Barzman

185. Dr. Barzman testified that Metadate CD 150 mg was a high dose,[28] and that he could not understand why Patient 4 was receiving Lamictal for the diagnoses he had. Dr. Barzman testified that Lamictal is prescribed to treat mood disorders such as pediatric bipolar disorder. Moreover, Dr. Barzman reiterated that Lamictal can cause a fatal rash. (Tr. at 362-363)

Testimony of Dr. Valko

186. Dr. Valko acknowledged that the FDA-recommended maximum dose for Metadate CD is 60 mg. (Tr. at 122-123)

187. Dr. Valko testified that the EEG ruled out seizures that could possibly have caused his explosive episodes. (Tr. at 124)

188. With respect to Lamictal, Dr. Valko acknowledged that he should have diagnosed Patient 4 with a mood disorder sooner than he did. (Tr. at 127)

10/5/12 Visit

189. Approximately one year later, on October 5, 2012, Dr. Valko noted that Patient 4 was misbehaving in school, although he was doing fairly well academically. Up to that time Patient 4 was receiving Vyvanse 210 mg in the morning, Lamictal 200 mg in the morning and 300 mg at bedtime for a daily dose of 500 mg,[29] and Lexapro 20 mg in the morning. On October 5, 2012, Dr. Valko continued those medications and added Saphris 5 ml SL at bedtime, and Adderall 40 mg at 4:00 p.m. (St. Ex. 4B at 222)

Dr. Barzman's Report

190. In his report Dr. Barzman criticized Dr. Valko for, among other things, adding Adderall 40 mg per day to the Vyvanse 210 mg per day Patient 4 was already receiving. (St. Ex. 17 at 18)

Testimony of Dr. Valko

191. When asked for his rationale in prescribing both Adderall and Vyvanse, Dr. Valko replied that he added the shorter-acting Adderall in the afternoon "to try to help him with his early evenings." (Tr. at 124-125) Dr. Valko acknowledged that the FDA-recommended maximum daily dose of Vyvanse is 70 milligrams. (Tr. at 125-126)

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[28] Dr. Barzman testified that the maximum dose of Metadate CD that has been studied is 60 mg per day. (Tr. at 362)
[29] GeneSight testing performed in late 2017, well after the relevant time period, indicated that Patient 4 was not a fast metabolizer of mood stabilizers such as Lamictal or Tegretol. (Resp. Ex. C at 22)

10/10/12 and 10/11/12 Telephone Calls

192. Patient 4's mother called and said that Patient 4 was crying constantly, was very emotional, and "cussed out his teacher" after starting Saphris. Dr. Valko recommended they discontinue Saphris. (St. Ex. 4B at 300)

10/17/12 Visit

193. At Patient 4's October 17, 2012 visit, Patient 4's mother reported concern with his "obsessive stealing as well as his ongoing impulsive actions." However, she reported that he was no longer experiencing explosive episodes and she believed his overall mood was stable. Dr. Valko recommended increasing Adderall to treat his impulsive behaviors, and increasing Lexapro to help with his obsessive behaviors. (St. Ex. 4B at 223) He prescribed:

- Vyvanse 70 mg to take three in the morning, a total daily dose of 210 mg
- Adderall 20 mg to take three at 4:00 p.m., a total daily dose of 60 mg
- Lamictal 100 mg, to take two in the morning and three at bedtime, a total daily dose of 500 mg
- Lexapro 20 mg twice per day, a total daily dose of 40 mg

(St. Ex. 4B at 223)

Dr. Barzman's Report

194. In his report, Dr. Barzman opined that Patient 4's obsessive stealing may have resulted from the high dose of stimulants he was taking. Dr. Barzman also stated that the maximum FDA recommended daily dose of Lexapro was 20 mg and Dr. Valko prescribed 40 mg. (St. Ex. 17 at 18)

6/12/13 Visit

195. Several months and several visits later, Patient 4 was receiving total daily doses of Vyvanse 210 mg, Adderall 60 mg, and Lamictal 600 mg.[30] Lexapro and Risperdal[31] had been discontinued at his March 21, 2013 visit. (St. Ex. 4B at 277, 279) On June 12, 2013, Patient 4 and his mother reported that Patient 4 continued to be irritable and would then lose control over his emotions. Simple tasks overwhelmed him. In addition, he was still struggling with focus and attention. Dr. Valko discontinued the Vyvanse, Adderall, and Lamictal for the summer and added Tegretol 200 mg at bedtime. Dr. Valko documented the same diagnoses of ADHD Combined, Depressive Disorder NOS, and ODD for which he had been treated for some time. (St. Ex. 4B at 282-283)

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[30] Lamictal was increased to 600 mg per day on February 20, 2013, following a blood test that indicated his "level was low (7.9)." (St. Ex. 4B at 301)

[31] Risperdal had been added in January 2013. (St. Ex. 4B at 225)

Testimony of Dr. Barzman

196. Dr. Barzman testified that his main concern with this visit was Dr. Valko's rational for prescribing Tegretol. Dr. Barzman testified that Tegretol is a mood stabilizer that is used to treat mood disorders; however, the patient was not diagnosed with a mood disorder. (Tr. at 282-283, 363-364; St. Ex. 4B at 282)

Testimony of Dr. Valko

197. Dr. Valko acknowledged that, in hindsight, he should have diagnosed Patient 4 with a mood disorder by this time. (Tr. at 672)

5/13/15, 6/24/15, and 7/6/15 Visits

198. Approximately two years and many visits later, on May 13 and June 24, 2015, Dr. Valko prescribed Abilify 2.5 mg in the morning to Patient 4, among other things. Each of the progress notes indicates that Patient 4 is allergic to Abilify which causes him to experience an oculogyric crisis. (St. Ex. 4A at 51-70) Abilify was discontinued on July 6, 2015. (St. Ex. 4A at 64) In fact, the August 5, 2015 progress note indicates that he had experienced an oculogyric crisis. (St. Ex. 4A at 67)

Testimony of Dr. Barzman

199. Dr. Barzman questioned why Dr. Valko had prescribed Abilify to Patient 4 when the progress notes indicated that Patient 4 had an allergy to that medication which caused him to experience oculogyric crisis. Dr. Barzman testified that an oculogyric crisis causes "the eyes [to] go backwards and get stuck there, kind of like looking up. And it's very uncomfortable." (Tr. at 354) Dr. Barzman added that it is treatable. Dr. Barzman further testified that that is a potential side effect of several antipsychotic medications. (Tr. at 354-355)

Dr. Valko's Report

200. In his report, Dr. Valko noted that he had retried Abilify with Patient 4 years after he had originally tried it with the hope that, with age and over time, he may have been able to tolerate it. (Resp. Ex. A at 25)

10/21/15 and Subsequent Visits

201. By September 17, 2015, Dr. Valko was prescribing Daytrana Patch 30 mg one patch per day, Daytrana Patch 15 mg one patch per day, and Ritalin 20 mg at 4:00 p.m. (St. Ex. 4A at 82-87)

202. Several visits later on July 22, 2016, on a report that Daytrana was no longer effective, Dr. Valko discontinued Daytrana and Ritalin and added Concerta 54 mg in the morning. (St. Ex. 4A at 107-112)

203. On August 19, 2016, the last visit documented in Patient 4's chart, Dr. Valko increased Patient 4's Concerta to 72 mg in the morning. (St. Ex. 4A at 113-118)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 4

204. Dr. Barzman testified that Patient 4 was a male patient who was nine years old when he first saw Dr. Valko, and was diagnosed with ADHD Combined Type, Depressive Disorder NOS, and Oppositional Defiant Disorder. Dr. Barzman testified that his concerns had included "the high doses of stimulants and no EKG. Dr. Valko did not explore if stimulants were causing obsessiveness. Not clear why Tegretol was prescribed for ADHD or why add Abilify for irritability if this patient had oculogyric crisis from Abilify." (Tr. at 353-354)

205. In his report, Dr. Barzman stated that Dr. Valko "failed to maintain minimal standards applicable to the selection or administration of drugs" with respect to Patient 4. (St. Ex. 17 at 22)

Dr. Valko's Conclusions Regarding Patient 4

206. Dr. Valko testified that he first saw Patient 4 when he was about ten years old, and that he is still his patient. Dr. Valko noted that Patient 4 is a college student now. (Tr. at 661) Dr. Valko further testified:

> Over time as we -- a brief summary is that over time we saw he actually truly met the diagnosis for the autism spectrum disorder. His social skills initially I thought were secondary to his bad compulsive issues and ADHD and OCD. But when you look at that, you get that a little bit under control, he still has almost no social skills.
>
> As he has gotten older, he hasn't been able to maintain employment. He has not been able to maintain school because he just struggles with his mood and with his -- he's doing a lot better on his obsessions, been actually doing a lot better with his ADHD, but it's his mood disorder, which we initially didn't call out. And I never really gave him a formal mood disorder diagnosis, but I think as we watched him age, the mood became more of an issue, so a multi-complex patient.

(Tr. at 661-662)

207. Dr. Valko testified that Patient 4's mother was a school teacher and was very involved in his treatment. Dr. Valko further testified that he had frequent communications with her between appointments. (Tr. at 665)

Letter of Support from Patient 4's Mother

208. In an August 28, 2018[32] letter, Patient 4's mother stated:

> My son, [Patient 4], has been in Doctor Timothy Valko's care since he was in the 5th grade. In that time we have tried a variety of medications at various concentrations. At every appointment, Dr. Valko would review the medication, the side effects, the pros and cons of all the medications. Dr. Valko has answered all our questions and has even been available to answer questions or administration of medications by phone after the appointment was over. At no time did Dr. Valko pressure me into administering more medication that what was necessary. Nor did he pressure me into medication that I was not comfortable in giving to my children. I was made aware of that fact medications were being used for other than what they would be normally be prescribed for.
>
> I have complete confidence in Dr. Valko and will continue to recommend his services and that of his staff.

(Resp. Ex. F at 3)

Patient 5

12/15/10 Initial Assessment

209. Patient 5, a male born in 2002, first visited Dr. Valko's practice on December 15, 2010, when he was eight years old. He was seen by Kristine Buffington, M.S.W., LISW-S. The Chief Complaint/History of Illness states:

> [Patient 5] is an 8 year old Caucasian male who is diagnosed with Autism and ADHD. He was accompanied to this appointment by his mother * * *. His mother reports that immediately after getting his immunizations at the age of two, [Patient 5] dramatically changed immediately. He lost his interest in engaging with other people and started becoming agitated and hyperactive. He lost some of his language skills and started developing rituals with his toys. (See developmental history for more information.) His symptoms were well controlled in the past. However, he has developed new symptoms that are out of the scope of his pediatrician's practice, so Dr. Gladieux, MD referred him to this clinic. About one month ago his mother discovered that

[32] The letter is dated August 28, 2019, but this appears to be a typographical error. (Resp. Ex. F at 3)

> [Patient 5] had welts on his back. He explained to his mother that he had voices talking on his back and they were arguing with the voices in his head. He told his mother that he had tried to dig the voices out of his back. He said the voices are better in his back, but the voices in his head are still bothering him. He said the voices in his head call him names and tell him to do mean things, "like farting in other kid's faces." He said the voices also tell him to go to the bathroom 6 times a day. He is having problems with feeling agitated all of the time. He used to be able to "not explode" and keep himself in control at school. However, now he is becoming explosive and demonstrating behavior problems at school. Dr. Gladieux and his mother feel he is experiencing a psychotic break. He is also having trouble falling asleep. [Patient 5's] mother reported that they recently left [Patient 5's] father because of domestic violence, and she feels this also may in part be causing some of [Patient 5's] deterioration.

(St. Ex. 5 at 1)

Other notes indicate that his parents are separated and that his mother was a victim of emotional and sexual abuse by her husband. Patient 5 also has a 21-year-old sister who lives with the family, a 17-year-old sister, and a16-year-old special-needs brother who suffers from cerebral palsy and functions at the level of an 11-month-old. Patient 5's mother stays at home to care for Patient 5's brother. (St. Ex. 5 at 1)

Patient 5's pediatrician had previously diagnosed him with ADHD and autism. His current medications were Risperidone[33] 1 mg to take 1-½ tablets in the morning and one at night, and Vyvanse 30 mg in the morning. (St. Ex. 5 at 1-3)

Axis I diagnoses were: 299.00 Autistic Disorder, 298.9 Psychotic Disorder NOS, and 314.9 ADHD NOS per history. (St. Ex. 5 at 3)

12/28/10 – First visit with Dr. Valko

210. Dr. Valko first saw Patient 5 on December 28, 2010. Mother reported that Patient 5 is constantly moving from 6 a.m. until 11:00 p.m. or midnight every day. She stated that he sometimes urinates in his clothing "because he is too busy to go to the bathroom." She reported that he had told her that "he can't think because his head is too busy." Mother was especially concerned about Patient 5's aggression and that "he had been hurting his older [disabled] brother" whom she characterized as "defenseless," and had started to act aggressively in school.[34] She reported as at the first visit that Patient 5 had been harming himself "to beat the voices out of his back." In addition, she reported that he is obsessive, washes his hands often, and repeatedly asks where his father is. She noted that she was recently divorced and that the father promises a lot of things to the family but does not

[33] Dr. Valko testified that Risperdone is the same medication as Risperdal. (Tr. at 133)
[34] Patient 5 was in the 2nd grade. (St. Ex. 5 at 1)

follow through. (St. Ex. 5 at 4) Dr. Valko recommended that they increase Patient 5's dose of Risperdal, and further documented:

> I explained to [Patient 5's] mother that if we decrease his anxiety, we can hopefully quiet the voices that he says he's hearing. In an effort to do this, I will start him today at 20 mg of Prozac, and eventually increase him to 60-80 mg per day. I explained that it will probably take about 10 weeks for Prozac to take full effect. We will discontinue Vyvanse, as it hasn't been doing him very much good. I recommended that [Patient 5] not begin psychotherapy at this time and that he wait until his medications are under control.

(St. Ex. 5 at 4-5)

Dr. Valko diagnosed:

> Autism (299.0)
> ADHD, NOS
> R/O Psychotic Disorder, NOS
> OCD

(St. Ex. 5 at 5) Dr. Valko discontinued Vyvanse and prescribed Risperdal M-tab 1 mg three times per day, for a total daily dose of 3 mg, an increase of 0.5 mg; and Prozac 20 mg in the morning. (St. Ex. 5 at 5)

Testimony of Dr. Valko

211. Dr. Valko described Patient 5:

> So Patient 5, probably one of the more complicated patients we've had come to the office. He came to us with autism spectrum disorder, was definitely on the spectrum in all areas. The obsessions were intense. The inability to focus was intense. The impulsivity got him into trouble, even as a child, in every area. Mom had to actually pull him out of the school district and try to homeschool him. It was that or being expelled from three different school districts in the area. Has Tourette's, which is a complication, and has anxiety disorder as well.
>
> * * *
>
> The Tourette's can be a limiting factor on how you treat some things because certain medications can make the Tourette's worse and certain medications can make the Tourette's better.

(Tr. at 678-679)

212. Dr. Valko noted that he had included a diagnosis of Psychotic Disorder NOS because patients can recover from that, and "if you have a schizophrenia diagnosis at that age, it's with you for life." Dr. Valko further testified that there is no cure for schizophrenia. He added that he is "terrified to call someone schizophrenic at this age." (Tr. at 680)

1/10/11 Visit

213. At Patient 5's next visit on January 10, 2011, his mother reported that, although she did not previously think that Vyvanse was having much effect, she now believes that it had been helping him to be less hyperactive. She reported that his behavior had gotten worse over the previous two weeks following the last visit, he had been very agitated, which was also reported by his teachers who told her "that he is always touching something or someone." They have also told her that they had noticed an increased tremor in his handwriting. Dr. Valko restarted Vyvanse 30 mg twice per day, and increased Patient 5's Prozac from 20 mg to 40 mg. (St. Ex. 5 at 6)

1/31/11 Visit

214. At Patient 5's next visit on January 31, 2011, Dr. Valko noted that Patient 5, although polite, was unable to sit still. Mother reported that "things haven't improved much" and that "[h]e now says that he hears god in his room. He says god doesn't scare him but that the other voices that are in his head are scary." Dr. Valko increased Patient 5's Prozac to 40 mg twice per day for a total daily dose of 80 mg, and increased Vyvanse to 60 mg twice per day, a total daily dose of 120 mg. (St. Ex. 5 at 7)

215. In his written report, Dr. Barzman expressed concern that the dose of Vyvanse was too large and that Prozac had been increased to 80 milligrams per day in the space of one month. (St. Ex. 17 at 22)

2/14/11 Visit

216. At the next visit on February 14, 2011, Dr. Valko increased Vyvanse to 100 mg twice per day, a total daily dose of 200 mg per day. Risperdal M-tab and Prozac were continued unchanged. (St. Ex. 5 at 8)

Testimony of Dr. Barzman

217. Dr. Barzman testified that, "based on safety studies, the top limit [for Vyvanse] was 70 milligrams" per day. (Tr. at 367)

218. Dr. Barzman criticized Dr. Valko for not obtaining an EKG for the large dose of Vyvanse as well as not screening Patient 5 for cardiac symptoms. (St. Ex. 17 at 23; Tr. at 367-368) Dr. Barzman testified that his criticism regarding the EKG issue does not concern an initial screening before prescribing Vyvanse, it concerns not obtaining an EKG prior to prescribing the very large doses of Vyvanse. Dr. Barzman further testified:

> [B]ecause it's an unstudied dose level it would be -- I'd be more hypervigilant about, you know, looking at the EKG, and also screening for any problems with heart rate or any cardiac issues.
>
> What we discussed before was different in terms of screening initially before starting medication. This is more about going into doses that haven't been studied before, and doing additional screening; more like screening for cardiac symptoms, and then also getting the EKG.

(Tr. at 368) Whereupon Dr. Barzman was asked:

> Q. [By Ms. Snyder] So what would the standard of care require with respect to screening at a dose like this?
>
> A. Well, since I haven't seen doses like this, I don't know what other people would do. I don't know if they use these doses, but I would -- I don't know if there's a set guideline for the high dose.
>
> Q. So there is no standard of care of this dose?
>
> A. Yes, because it's not something -- not a dose that's been used. That's my knowledge in short.

(Tr. at 368-369)

219. When asked how frequently a psychiatrist should obtain an EKG on a patient taking high doses of stimulants, Dr. Barzman replied:

> Well, in the case of if it's a high dose stimulant, they have been on steady state dosing for a while, and there's no onset of new symptoms, an EKG comes back, look at doing it, at most, once a year. But I'm not sure. I mean, there's no set guidelines for the high dose stimulants, on how often you do it.

(Tr. at 503)

Testimony of Dr. Valko

220. Dr. Valko acknowledged that the FDA maximum recommended dose for Vyvanse is 70 milligrams. (Tr. at 134-135)

2/28/11 Visit

221. At the next visit on February 28, 2011, mother reported that Patient 5's behavior was deteriorating. Dr. Valko discontinued Prozac and added Zoloft 100 mg twice per day. He

changed the dosing schedule for Vyvanse but left the total daily dose at 200 mg. Risperdal was left unchanged. (St. Ex. 5 at 9)

8/29/11 Visit

222. Patient 5 continued with this regimen until his visit on August 29, 2011, when Dr. Valko increased his daily dose of Risperdal from 3 mg per day to 4 mg per day. Mother had reported that Patient 5 was having frequent "blow ups" at home which included "hitting the neighbor kid with his golf club 3x, ramming his scooter into his mom's van, and smashing his leapster into the TV when asked to take a bath." (St. Ex. 5 at 13)

223. In his report, Dr. Barzman stated with respect to the increase in Risperdal on August 29, 2011, that he found no evidence that fasting metabolic labs were obtained. (St. Ex. 17 at 23)

9/8/11 Visit

224. On September 8, 2011, Patient 5's mother reported that he was less violent following the increase in Risperdal but he remained very high energy and hyperactive. Dr. Valko continued Risperdal and Zoloft unchanged, discontinued Vyvanse, and added Focalin XR 40 mg in the morning. (St. Ex. 5 at 14)

9/15/11 Visit

225. On September 15, 2011, Patient 5's mother was on the verge of tears and reported that Focalin XR was not helping his concentration or impulsivity at all. She stated that it can take from 40 to 90 minutes to get him to take his medications, and he became so angry on one occasion that he kicked one of his sisters, leaving marks. Dr. Valko left Risperdal and Zoloft the same, discontinued Focalin XR, and added Daytrana Patch 60 mg[35] in the morning. (St. Ex. 5 at 15)

226. In his report Dr. Barzman opined that the dose of Daytrana was too large. (St. Ex. 17 at 23)

227. Dr. Valko testified that he had prescribed Daytrana "because the Focalin didn't seem to be as helpful as we would have liked." Dr. Valko testified that Daytrana delivers the medication slowly through the skin. He has parents place the patch on the patient two hours before the patient gets up which helps to ameliorate the morning struggle with an unmedicated child. (Tr. at 683-684)

[35] Notice is taken that the generic name for Daytrana is methylphenidate transdermal patch. (U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a606014.html>, accessed January 7, 2020)

9/15/11 Telephone Call

228. Patient 5's mother called Dr. Valko's office later that day and reported, "Daytrana patch recalle [sic]." Dr. Valko authorized Focalin XR 40 mg with instructions to take two tablets in the morning for a total daily dose of 80 mg. (St. Ex. 5 at 164)

9/29/11 Visit

229. The September 29, 2011 progress note indicates that Patient 5's mother had been unable to obtain Daytrana from their pharmacy. At the September 29 visit, mother reported that Focalin was helping a little but that it is still a struggle to get him to take his meds and he still had violent outbursts; he kicked his sister after being told he could not have a waffle, and he threw a neighbor's skateboard after the neighbor's mother told him he could not use it. Dr. Valko maintained Patient 5 on Risperdal and Zoloft as before and increased Focalin XR to 120 mg (40 mg x3) in the morning. He indicated that they would research where Patient 5 could obtain Daytrana if the Focalin XR does not help. (St. Ex. 5 at 16, 164)

10/12/11 Visit

230. On October 12, 2011, to improve Patient 5's ability to think during the day and his "violent tendencies," Dr. Valko added Clonidine 0.1 mg twice per day to Patient 5's regimen, which at that time was Risperdal M-tab 4 mg per day, Zoloft 200 mg per day, and Focalin XR 120 mg per day. (St. Ex. 5 at 17)

231. Patient 5 continued on this regimen through February 17, 2012. (St. Ex. 5 at 17-20)

2/17/12 Visit

232. On February 17, 2012, Dr. Valko doubled Patient 5's Focalin XR to 240 mg per day split between two doses to address continued inability to focus, and increased Clonidine to 0.3 mg per day split among two daytime doses and one nighttime dose to help with sleep. (St. Ex. 5 at 20)

233. Dr. Barzman testified that he was concerned about the high dose of Focalin XR prescribed. However, Dr. Barzman testified with respect to Clonidine that it had been prescribed to help Patient 5 sleep and that it is commonly used for that purpose. (Tr. at 369-370)

234. Dr. Valko testified that he prescribed Clonidine "as a way of trying to hopefully have a lower level of a stimulant" and to control tics. He also testified that it can be used off-label to treat ADHD. Dr. Valko further testified that Clonidine is used more by child and adolescent psychiatrists than adult psychiatrists. (Tr. at 681)

3/19/12 Visit

235. On March 9, 2012, Patient 5's mother reported that he was doing well in school and at home but continued "to have meltdowns twice a day." She also noted that he was "having

mood swings since his Focalin was increased last visit" but "they prefer him to have improved attention so they can deal with the mood swings." Dr. Valko increased Clonidine to 0.4 mg per day split among doses of 0.1 mg in the morning, 0.2 mg at 1:00 p.m., and 0.1 mg at bedtime to help with the meltdowns, and he continued the other medications unchanged. (St. Ex. 5 at 21)

5/7/12 Visit

236. On May 7, 2012, it was reported that Patient 5 continued to have meltdowns in the morning and in the afternoon. Dr. Valko added one Focalin 10 mg in the morning to get Patient 5 moving quicker. He also encouraged mother "to give less Focalin XR (40 mg) since he may be increasing his vocal tics." In addition, he added an additional Risperdal M-Tab 0.5 mg in the morning to address behavior issues and vocal tics for a total daily dose of 4.5 mg. Finally, Dr. Valko added "Vocal Tic" to Patient 5's Axis I diagnoses. (St. Ex. 5 at 22)

6/8/12 Visit

237. On June 8, 2012, it was noted that mother did not give the additional Focalin 10 mg in the morning due to concern with vocal tics and a belief that they were worsening, and Dr. Valko agreed that was a good decision. Dr. Valko continued Patient 5's medications but doubled Patient 5's daily dose of Clonidine to 0.6 mg. (St. Ex. 5 at 23)

7/5/12 Visit

238. At Patient 5's July 5, 2012 visit, Patient 5's mother reported that Patient 5 "is distracted with the home schooling" (but later in the note Patient 5 was documented to be doing well in school and seemed to enjoy all his classes) and she did not believe that Focalin was helping with his ADHD. Dr. Valko further documented that "[s]he is also worried about all the medications he is on and she would like him to be taking less. She wanted him to go off Risperdal and Clonidine. She was educated about the dangers of switching medications too quickly and the need to slowly go down on medications, etc." Dr. Valko reduced Clonidine back down to 0.4 mg per day, reduced Patient 5's daily dose of Focalin XR to 200 mg, discontinued Focalin 10 mg, and added Daytrana 30 mg patch in the morning. Zoloft and Risperdal were left unchanged. (St. Ex. 5 at 24)

Additional Medication Changes Through December 2012

239. On July 23, 2012, Dr. Valko decreased Focalin XR 40 mg to twice per day for a daily dose of 80 mg, and increased Daytrana Patch 30 mg to two patches in the morning for a daily dose of 60 mg. Mother reported that he gets less upset taking Daytrana. (St. Ex. 5 at 26)

240. On August 9, 2012, Dr. Valko increased Risperdal to 5 mg per day split among doses of 2 mg in the morning, 2 mg at 1:00 p.m., and 1 mg at 7:00 p.m. He also increased Clonidine to 0.6 mg per day split among three doses. Finally, he discontinued Focalin XR. (St. Ex. 5 at 28)

241. On August 22, 2012, Dr. Valko discontinued Risperdal and added Abilify Suspension 10 mg twice per day, hoping that it would be easier for Patient 5 to take liquid rather than pills. He also decreased Clonidine to 0.2 mg at bedtime based on mother's belief that it was not helping Patient 5 during the day. Dr. Valko continued Zoloft and Daytrana Patch unchanged. (St. Ex. 5 at 29)

242. Based upon Patient 5's mother's report that Abilify did not seem to be helpful and that it took up to 90 minutes for Patient 5 to get a single dose down, on September 6, 2012, Dr. Valko discontinued Abilify Suspension and reinstituted Risperdal M-Tab 6 mg per day split among three doses. (St. Ex. 5 at 31)

243. On September 19, 2012, Patient 5's mother reported he was having trouble concentrating and falling asleep at night and was having behavioral issues. She also expressed concern about the number of medications he was on and asked about lowering or removing Zoloft. Dr. Valko counseled against that due to the risk of increasing his obsessions and compulsions. Dr. Valko increased Clonidine to 0.3 mg per day split between a 0.1 mg dose in the morning and a 0.2 mg dose at bedtime. (St. Ex. 5 at 32)

244. On October 8, 2012 Dr. Valko left the medications unchanged. (St. Ex. 5 at 34)

245. On November 5, 2012, mother reported that Patient 5 was coughing and that his motor tics were increasing in frequency. Dr. Valko lowered Daytrana Patch to 20 mg with instructions to apply two patches in the morning for a daily dose of 40 mg, and increased Clonidine to 6 mg per day split among three doses. Other medications were unchanged. (St. Ex. 5 at 35)

12/12/12 Visit

246. On December 12, 2012, Dr. Valko documented, among other things, "[Patient 5] states he is hearing voices telling him to commit aggressive acts. This week he hit [male name] in the lip, bit him, slapped him, and threw a remote at him. [Patient 5] also tried to hit his sister's boyfriend. [Patient 5's] mother says the Daytrana is not working because he keeps taking the patches off." Dr. Valko discontinued Daytrana Patch and added Adderall XR 30 mg with instructions to take two in the morning for a total daily dose of 60 mg. Other medications were continued unchanged. (St. Ex. 5 at 36)

12/19/12 Telephone Call

247. On December 19, 2012, Patient 5's mother called and reported that Patient 5 was not doing well, and was violent and very aggressive. Dr. Valko increased Adderall XR to 90 mg (30 mg x 3) in the morning. (St. Ex. 5 at 167)

12/20/12 Telephone Call

248. On December 20, 2012, Patient 5's mother called and said that there were no gains from the additional Adderall although he had about four good hours of focusing. Dr. Valko increased Adderall to 90 mg twice per day for a daily dose of 180 mg. (St. Ex. 5 at 167)

12/21/12/ Visit

249. On December 21, 2012, Patient 5's mother reported:

> Recently [Patient 5] has been misbehaving at home and tells his mother "my brain is crazy" when he is asked to describe his emotions and why he is misbehaving. [Patient 5's] behaviors include being unable to tolerate being told "no", refusing to adhere to his schedule, pitching fits when he is given negative consequences, hitting, screaming, biting and kicking family members. Mom states that she has also been noticing that [Patient 5] is cruel to the family dog and he is aggressive with his soon-to-be stepbrother at his father's house. [Patient 5's] behavior reportedly does not change with positive or negative consequences. Mom called earlier in the week about these issues and was told to increase [Patient 5's] Adderall dose to be taken twice daily; this worked and [Patient 5] was much calmer after his AM dose of Adderall kicked in, but the medication wears off around 10 AM. For now [Patient 5] will continue on Adderall [XR] 30 mg 3 tab PO BID, and if problems persist a third dose may be added. [Patient 5's] family was advised about possible side effects, and they agreed to watch out for them. At the moment [Patient 5] eats very well, having as many as 7 small meals in a day. [Patient 5] will also be taken for an EKG in 1 week to confirm that he is tolerating the medication and having no cardiac issues from it.

(St. Ex. 5 at 37)

On December 21, 2012, Patient 5 was taking Risperdal M-Tab 6 mg per day, Zoloft 200 mg per day, Clonidine 0.6 mg per day, and Adderall XR 180 mg per day. His Axis I diagnosis remained the same throughout his treatment with Dr. Valko: Autism (299.0), ADHD NOS, R/O Psychotic Disorder NOS, and OCD.

Testimony of Dr. Barzman

250. Dr. Barzman criticized the high dose of Adderall. He further testified that the FDA recommended maximum daily dose of Adderall XR was 30 mg, so 180 mg per day was six times the maximum recommended dose. Dr. Barzman added that an EKG was ordered for the first time at the December 21, 2012 visit. (Tr. at 370)

Testimony of Dr. Valko

251. When asked why he had waited until the December 21, 2012 visit to order an EKG for Patient 5, Dr. Valko replied that he is not sure but that he probably thought it would be a good idea because the patient was on a higher dose of Adderall. (Tr. at 135-136)

Dr. Valko testified that Patient 5 obtained the EKG in April 2013 and the results were within normal limits. (Tr. at 140; St. Ex. 5 at 160-161)

Subsequent Visits

252. By May 9, 2013, the last visit documented in State's Exhibit 5, Patient 5 was still having serious behavioral issues including pushing an air conditioner out of the window. At that time, Dr. Valko was prescribing Clonidine 0.2 mg three times per day, "Adderall XR 30 mg iii po TID vs. Vyvanse 70 mg ii po TID," Lexapro 30 mg in the morning, and Zyprexa 10 mg three times per day. (St. Ex. 5 at 47)

253. Dr. Valko testified that he tries to obtain labs on his patients about once per year; however, compliance can be difficult with children due to the fasting requirement. Dr. Valko further testified that his practice started documenting things a new way beginning in 2013 which makes it easier to document how they order and reorder labs "until they finally get it for us." (Tr. at 686)

Patient 5 Additional Information

254. Dr. Valko testified that he still sees Patient 5. (Tr. at 132)

GeneSight Testing

255. Dr. Valko testified that he had obtained GeneSight testing on Patient 5 in July 2018. Dr. Valko further testified that the report indicates that he is a fast metabolizer and has reduced therapeutic response to stimulants. (Tr. at 691; Resp. Ex. C at 53) Dr. Valko believes that this testing serves to justify "a lot of why we were where we were at when it comes to dosing." (Tr. at 691) The report does state that the "COMT genotype is associated with reduced therapeutic response to" Adderall, Focalin, Dexedrine, Vyvanse, Ritalin, Concerta, Metadate, and Daytrana. It also states that lower doses of Clonidine may be required. (Resp. Ex. C at 53)

256. Dr. Valko testified that, prior to the availability of pharmacogenetic testing, determining whether a patient was a fast metabolizer was made by taking a family history and by observing the effects of medication on the patient. If the patient was taking a drug in the morning that is supposed to last eight hours but seems to wear off at lunchtime, it may have been because the patient was a fast metabolizer. Dr. Valko added that, for children who had suffered Shaken Baby Syndrome or Fetal Alcohol Syndrome, "their brain doesn't use

the medications the same way, so you have to really think outside the box on how to help." (Tr. at 692)

Dr. Valko added that, generally, if fast metabolizers have side effects from their medication they tend to be brief and limited." (Tr. at 693)

Dr. Barzman Conclusions Regarding Dr. Valko's Treatment of Patient 5

257. Dr. Barzman testified that he had concluded with respect to Dr. Valko's treatment of Patient 5 that the stimulant doses were high, non-stimulant medications were increased quickly, and that he could find no labs or EKGs in the record for over two years. (Tr. at 365)

258. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 5. (Tr. at 370-371)

Letter of Support from Patient 5's Mother

259. In an August 28, 2018 letter, Patient 5's mother stated:

> Dr Valko has been following my son, [Patient 5], since he was diagnosed with autism and ADHD 12 years ago. [Patient 5] has been a difficult case and has many subsequent diagnosis due to his autism and OCD and life situations. Dr. Valko listens to [Patient 5], makes sure he knows his medications and what they are for, keeps up on his labs and answers all of my questions. He makes sure that [Patient 5] is comfortable but not sleepy.
>
> I have never had any concerns with what Dr. Valko has given [Patient 5] because he always explained what he was giving him and why. He has always been available to answer my questions, even if it meant he had to return a phone call at 8 or 9 in the evening after office hours.
>
> We have taken [Patient 5] to other doctors for consultations and for brief periods of time for treatment. It didn't go well. Nobody listened to us, or [Patient 5] the way Dr. Valko has or had the same level of concern for his well being.
>
> That being said, when [Patient 5] needs a stern talking to, he gets that too. What we always get is the truth. If something can be helped, he does his best and if it can't, he tells us that too. I always appreciate his straightforward honesty in all situations. [Patient 5's] case is not easy as he is dealing with so many issues.
>
> We could never find another doctor with as much integrity, honesty, and true love for children. It is difficult to find doctors to have both compassion and a

> down-to-earth bedside manner as well as such high standards for medical care and knowledge of autism in the area. I would not want another doctor to treat my son again.

(Resp. Ex. F at 4)

Patient 6

5/23/07 Initial Assessment

260. Patient 6, a male born in 1997, first visited Dr. Valko's practice on May 23, 2007, and was seen by Heather Simon, M.A., PCC. (St. Ex. 6 at 13)[36] The description of the chief complaint includes the following:

> [Patient 6] presented as a well-groomed, 9 year old, Caucasian male. He attended the session with his mother * * *. They stated that for about the last year he has been in treatment with Dr. Corp. They stated that he was diagnosed with ADHD and Oppositional Defiant Disorder. They also stated that his therapist Mike Drewer has expressed concern about depression. They reported that when he is not on medication for ADHD he fails to pay attention to details, has difficulty sustaining attention, does not listen when spoken to, does not follow through tasks, has difficulty organizing, loses things necessary for a task, avoids homework, is easily distracted, is forgetful, squirms, does not remain seated, is on the go, talks excessively, difficulty being quiet, interrupts, has difficulty waiting his turn, and blurts out answers to questions. They stated that he sleeps well after taking his medication but has difficulty getting to sleep when not on medication. They reported that he does not eat a lot and on the meds he has lost 3-5 pounds even though he has grown taller. They reported that he loses his temper often, argues with adults, defies rules, deliberately annoys others, blames other for his misbehavior, is often angry, and is often spiteful. His mother stated that he has been more aggressive in the last few weeks as evidenced by his pushing his 3 year old brother down. They reported that he has been aggressive in the past. They reported that he has depressed or irritable moods. It was difficult to assess if he met the criteria for Major Depressive Disorder because of his other symptoms. Further assessment needs to be done in this area. He appeared to meet at least some criteria for anxiety but it was difficult for this writer to determine if these symptoms were related to anxiety or depression. [Patient 6] stated that he does worry and has difficulty controlling his worry sometimes.

(St. Ex. 6 at 13)

[36] The page numbers referenced in State's Exhibit 6 are the larger page numbers in the bottom right corner of each page.

The initial assessment further states that he lives with his mother and father and a three-year-old brother. The mother reported that the father "can be emotionally and verbally abusive by calling [Patient 6] names and cussing at [Patient 6]." The note further indicates that mental illness affects both parents' families, and includes depression, ADHD, schizoaffective disorder, and bipolar disorder, and that the mother suffers from ADHD and depression. (St. Ex. 6 at 15)

At the time of his initial assessment Patient 6 was taking Concerta 54 mg and Risperdal 1 mg. (St. Ex. 6 at 15) The initial assessment note lists the following Axis I diagnoses:

ADHD, Combined Type 314.01
Oppositional Defiant Disorder 313.81
R/O Depressive Disorder NOS 311
R/O Generalized Anxiety Disorder 300.02

(St. Ex. 6 at 17)

Blood Test

261. Dr. Valko ordered and obtained a comprehensive metabolic panel on May 28, 2007. (St. Ex. 6 at 19)

5/30/07 – First Visit with Dr. Valko

262. According to the medication flowsheet, Dr. Valko first saw Patient 6 on May 30, 2007; unfortunately, the hearing examiner was unable to find the progress note for that visit. The medication flowsheet indicates that Dr. Valko continued Risperdal 1 mg at bedtime, discontinued Concerta, and added Focalin XR 15 mg to take two tablets twice per day for a daily dose of 60 mg. (St. Ex. 6 at 593)

6/7/07 Visit

263. Dr. Valko next saw Patient 6 on June 7, 2007. He noted that Patient 6 is responsible enough to take his medication without prompting, but becomes "difficult to manage when it wears off and he becomes explosive again." He swears at his mother and yells at his brother. Dr. Valko noted that he "is full of aggression." Dr. Valko confirmed the diagnoses from Patient 6's initial visit, increased Patient 6's Risperdal to 1.5 mg per day from 1 mg, and noted he would "change the dosing schedule of Focalin XR" but continue the daily dose of 60 mg per day. Patient 6 weighed 62 pounds at that visit. (St. Ex. 6 at 21)

Dr. Barzman's Report

264. In his report, Dr. Barzman offered the following comments concerning Patient 6's June 7, 2007 visit:

> Meds are Focalin XR 30 mg BID and Risperdal 1.5 mg po QAM and 1 mg po QHS; ADHD and ODD; Continued to have aggression and Risperdal was increased and the dosing schedule of Focalin XR was changed. His weight is 62 # so Focalin XR dose was high and it was possible that he was aggressive due to Focalin XR dose.

(St. Ex. 17 at 41; Emphasis omitted)

Testimony of Dr. Valko

265. Dr. Valko testified with response to Dr. Barzman's criticism regarding Focalin that the aggression symptoms, which included "explosive behaviors," were present prior to the patient receiving Focalin. (Tr. at 144) Dr. Valko further testified, in hindsight, that he wished he had considered a mood disorder for Patient 6 earlier in his treatment. (Tr. at 144-146)

2/14/08 Visit

266. The February 14, 2008, progress note states, among other things, "[Patient 6's mother] states that he told his grandmother "F you Bitch" while she was babysitting and that grandma just ignored him. I recommend that next time they slap him and send him to his room." (St. Ex. 6 at 65)

Testimony of Dr. Barzman

267. Dr. Barzman testified that he was concerned that Dr. Valko had documented a suggestion that Patient 6's parents slap him and send him to his room after saying "F you Bitch" to his grandmother. Dr. Barzman found that to be problematic and not an appropriate treatment modality. (St. Ex. 6 at 27; Tr. at 375-376)

Testimony of Dr. Valko

268. Dr. Valko testified that he never recommends or condones capital punishment. (Tr. at 700) When asked about the February 14, 2008 progress note, he testified:

> This is something I should have caught when I was typing it out. It was a pretty intense appointment. He used some extremely vulgar language to his mother and grandmother. And, you know, I was surprised. If your kid told you that, I think your first response is to think -- I mean, like, you would actually go into that pose, like, Wow, you don't say that to me. At least if I ever said that to my mother, I probably wouldn't have two teeth left. I didn't say they should slap. It should be I thought they would have slapped. I mean, I'm surprised they didn't.

(Tr. at 700)

9/3/08 Visit

269. On September 3, 2008, Dr. Valko increased Patient 6's Risperdal from 1.5 mg per day to 2 mg per day, stating that "[w]e decided to increase the dose of Risperdal to help [Patient 6] make better decisions and think more clearly." (St. Ex. 6 at 93)

Testimony of Dr. Barzman

270. Dr. Barzman testified that Risperdal is not indicated to improve decision making and clarity of thought. He acknowledged that Risperdal may be indicated for aggressiveness. (Tr. at 506-507)

9/30/08 Visit

271. On September 30, 2008, after Dr. Valko had been treating Patient 6 for a little over one year, he prescribed daily doses of Vyvanse 100 mg, Risperdal 2 mg, Zoloft 200 mg, and Riluzole 50 mg. Patient 6's diagnoses at that time were ADHD Combined, ODD, OCD, rule out Depression NOS, and rule out Generalized Anxiety Disorder. (St. Ex. 6 at 101)

Testimony of Dr. Barzman

272. Dr. Barzman expressed concern that the high dose of Vyvanse could cause mood swings. Dr. Barzman testified that Vyvanse has been studied up to 70 mg per day. (Tr. at 374)

273. Dr. Barzman testified that he learned from reviewing this case that Riluzole is a medication to treat ALS and that is being used off-label to treat OCD. Dr. Barzman testified that he is unfamiliar with the drug and does not use it in his practice. Dr. Barzman further testified that although Riluzole is not FDA-approved for use in children there was an "open label study on it." (Tr. at 372-373, 505-506) Dr. Barzman testified that an open-label study is not double-blinded, so the physician, patient, and parents know if the patient is receiving the drug. (Tr. at 373)

When asked what steps are required for a physician to provide a medication for off-label use, Dr. Barzman testified, "Simply telling them that the medication has not been studied, it's being used off-label, it was developed for this reason, which was for ALS, and now it's being used off-label, it's not FDA approved for OCD, and then just documenting it." (Tr. at 373)

Testimony of Dr. Valko

274. Dr. Valko testified that Riluzole was first developed to treat Lou Gehrig's disease. (Tr. at 147) He further testified that "[t]he NIH did a study with Riluzole for people with and without autism that were having obsessive compulsive disorder. We were part of that study, our office was." (Tr. at 147)

10/7/08 Visit

275. On October 7, 2008, Dr. Valko increased Patient 6's daily dose of Vyvanse to 140 mg, and increased Riluzole to 50 mg twice per day. Risperdal 2 mg and Zoloft 200 mg were left unchanged. (St. Ex. 6 at 115)

276. Dr. Barzman expressed concern about the high dose of Vyvanse without obtaining an EKG. (Tr. at 374)

277. Dr. Valko acknowledged that Vyvanse 140 mg per day is twice the FDA recommended maximum daily dose of that drug. (Tr. at 147) Dr. Valko further testified that Patient 6 had not been experiencing side effects from Vyvanse other than his father noting that he thought Patient 6 seemed a little tired. Dr. Valko testified that this was not a side effect he would expect from Vyvanse. Otherwise, Dr. Valko believes that Patient 6 tolerated Vyvanse "exceptionally well." (Tr. at 701-702)

3/4/10 Visit

278. About 18 months later, as of March 4, 2010, Patient 6's diagnoses were ADHD Combined, Mood Disorder NOS, ODD, OCD, R/O Depression NOS, and R/O Generalized Anxiety Disorder NOS. At that visit Dr. Valko noted that Patient 6 was doing rather well and was not having mood fluctuations. He also noted that Patient 6 was struggling with his last period of the day in school and added Ritalin 20 mg at 1:30 p.m. to treat that. Dr. Valko further noted that "[o]bsessions continue to be an issue, but mother and [Patient 6] feel that they are better than off medication." Finally, Patient 6's medication regimen consisted of the following daily doses: Vyvanse 140 mg, Ritalin 20 mg, Risperdal 4 mg, Zoloft 100 mg, Riluzole 100 mg, and Depakote 750 mg. (St. Ex. 6 at 213)

Testimony of Dr. Barzman

279. Dr. Barzman criticized Dr. Valko for the high dose of stimulants and for not obtaining metabolic labs when prescribing Risperdal. (Tr. at 375)

Testimony of Dr. Valko

280. When asked what the various medications were prescribed for, Dr. Valko testified that the Vyvanse and Ritalin were prescribed to treat ADHD, the Risperdal and Depakote were prescribed to treat Mood Disorder NOS, Risperdal was prescribed to treat OCD and also contributes to the treatment of the Mood Disorder, and Riluzole was prescribed for OCD. (Tr. at 154-155)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 6

281. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ

acceptable scientific methods in the selection of drugs in the treatment of Patient 6. (Tr. at 376)

Dr. Valko's Conclusions Regarding Patient 6

282. Dr. Valko testified that Patient 6 was a complex patient with multiple psychiatric issues. In addition to that his parents were going through a difficult divorce. He came to Dr. Valko because his previous physician had died. (Tr. at 696)

Patient 7

9/8/08 Initial Assessment

283. Patient 7 is a male born in 2002. He was seen for an initial assessment in Dr. Valko's practice by Daniel Eble, M.Ed., PCC, on September 8, 2008, when he was six years old. He was at that time being treated by the family's primary care physician for ADHD. He also had anxiety about going to school[37] to the point where he was vomiting before and at school, and cried at school wanting to go home. He had difficulty sleeping. He has an older brother with ADHD. Mother stated that she has some ADHD traits and severe OCD for which she takes Prozac. Mother also reported a history of depression and substance abuse in her family. Patient 7's medications at that time were Singulair 5 mg, Albuterol for "anxiety induced asthma," Zoloft 25 mg per day for three weeks, and Vyvanse 30 mg. (St. Ex. 7A at 1-3) He was given the following Axis I diagnoses:

> ADHD, by history (314.01)
> Separation Anxiety Disorder (309.21)
> R/O OCD
> R/O Generalized Anxiety Disorder
> R/O Depressive Disorder NOS (311)

(St. Ex. 7A at 3)

9/16/08 – First visit with Dr. Valko

284. Dr. Valko first saw Patient 7 on September 16, 2008 with Patient 7's mother and father. Patient 7 cried and covered his face during the visit and stayed by his mother's side with his head in her lap. The parents reported that he had recently developed problems being away from his parents and getting him to school every morning is difficult. Parents reported that Patient 7 "has some severe obsessions in addition to his anxiety" and that "this has caused some significant dysfunctions within the family." They also reported that they had not seen any significant improvement since Patient 7 began taking Zoloft and Vyvanse. Dr. Valko continued the same diagnoses except for R/O OCD and instead diagnosed OCD. Dr. Valko discontinued Zoloft and added Prozac 20 mg in the morning

[37] Patient 6 was in the first grade. (St. Ex. 7A at 2)

based on mother's report that Prozac had been helpful for her own obsessions, and increased Vyvanse to 50 mg in the morning. In addition, Dr. Valko noted that Patient 7 also uses Singulair, Proair inhaler, and takes Melatonin 3 mg to aid sleep. (St. Ex. 7A at 4)

Dr. Barzman's Report and Testimony

285. In his report, Dr. Barzman commented concerning Patient 7's September 16, 2008 visit:

> It would have been better to stop Vyvanse to see if the obsessions get better. In addition, should review the psychiatric side effects from Singulair which may be causing problems. Instead switched Zoloft to Prozac and increased Vyvanse to 50 mg/day. Weight is 50#. Diagnoses are ADHD, CT; Separation Anxiety Disorder, and OCD. Prozac 20 mg is a large starting dose for a 6 year old.

(St. Ex. 17 at 45-46)

Nevertheless, Dr. Barzman testified that he found the Vyvanse dose prescribed at this visit to be appropriate. (Tr. at 378)

286. In his report and during the hearing Dr. Barzman identified Singulair as having possible psychiatric side effects and that that should have been reviewed. (St. Ex. 17 at 45-46; Tr. at 377-378) However, Dr. Barzman later testified that his comments concerning Patient 7 receiving Singulair do not concern a minimal standard of care issue. Dr. Barzman further testified, "I'll just say in my experience most people don't address it, so I think it would be above the minimum standard of care to actually address Singulair." (Tr. at 509-510)

10/1/08 Visit

287. At Patient 7's next visit on October 1, 2008, Patient 7's mother reported that he was doing much better in school with his anxiety and no longer missed his mother during the day but had increased difficulties with his ability to focus. Mother further reported that Patient 7 seemed to obsess at times particularly with regard to a deceased grandfather whom he never met. Dr. Valko increased Vyvanse to 70 mg in the morning and Prozac to 40 mg in the morning. (St. Ex. 7A at 6)

288. Dr. Barzman indicated in his report that he was concerned about Dr. Valko increasing both Vyvanse and Prozac at the same time. He further stated, "It's too soon to increase Prozac and it's not clear if Vyvanse is causing OCD symptoms. Increasing Vyvanse may worsen OCD." (St. Ex. 17 at 46)

289. Dr. Valko disagreed with Dr. Barzman's criticism and testified that "[t]he Vyvanse was increased because he was still struggling with his impulse control. The Prozac was increased because of his ongoing intensive obsessions." (Tr. at 163)

12/7/09 Visit

290. Skipping ahead 14 months and many visits to Patient 7's December 7, 2009 visit, Dr. Valko documented that Patient 7 reported being able to focus and concentrate at school, and his father stated that things had been going well overall with some instances of impulsivity but not enough to warrant a change in medication. At that time Patient 7 was receiving the following daily doses of medications, in addition to Singulair, ProAir, and melatonin: Focalin XR 80 mg split between two doses, Prozac 60 mg in the morning, and Risperdal 2 mg split between two doses. (St. Ex. 7A at 22)

291. Dr. Barzman criticized Dr. Valko in his report for obtaining no metabolic labs or EKG. (St. Ex. 17 at 47)

292. Dr. Valko acknowledged that a daily dose of Focalin XR 80 mg is above the FDA recommended dose. (Tr. at 164)

    Dr. Valko further testified that he had added Risperdal to Patient 7's regimen in April 2009 "because [Patient 7's] thinking process was so bad on his OCD, and we were concerned about that." (Tr. at 165; St. Ex. 7A at 14)

5/13/10 Visit

293. On May 13, 2010, Dr. Valko increased Patient 7's Focalin XR to 60 mg twice per day for a total daily dose of 120 mg. In addition, Patient 7 was taking daily doses of Prozac 60 mg and Risperdal 2 mg. Patient 6 weighed 61.5 pounds at that visit. (St. Ex. 7A at 24)

294. Dr. Barzman testified that the maximum recommended daily dose of Focalin XR in 2010 was 30 mg per day, but that off-label the maximum dose could be up to 50 mg per day. (Tr. at 378-379)

6/1/10 Visit

295. On June 1, 2010, Dr. Valko's progress note indicates that Dr. Valko increased Patient 7's daily dose of Risperdal to 3.5 mg twice per day based upon out-of-control behavior. (St. Ex. 7A at 25)

296. In his report, Dr. Barzman expressed concern that Patient 7's "behaviors may be poor due to high dose of stimulant. It appears raising Risperdal is to treat the likely side effect of Focalin XR (high dose)." (St. Ex. 17 at 48)

297. Dr. Valko disagreed with Dr. Barzman's criticism that Risperdal was being used to treat a side effect of high doses of Focalin XR. When asked why, Dr. Valko replied:

> Well, as we had discussed just a little while ago, the Risperdal was added because the obsessions were so intense.

> And he had OCD and anxiety starting before we even increased the dose of the stimulants, so that was baseline for Patient 7. And so adding a stimulant did not make it any worse, it just didn't make it any better. We're treating two different issues here.

(Tr. at 167-168)

Dr. Valko added that he has not in his experience seen a CNS stimulant cause an increase in obsessive behavior. (Tr. at 168)

11/23/10 Visit

298. On November 23, 2010, in an attempt to better control Patient 7's impulsive behaviors, Dr. Valko discontinued Risperdal and added Saphris 5 mg SL twice per day. In addition, Patient 7 was prescribed Focalin XR 90 mg twice per day and Prozac 60 mg in the morning. (St. Ex. 7A at 28)

299. With respect to prescribing Saphris to Patient 7, Dr. Valko testified:

> Saphris is a neuroleptic. It's similar to Risperdal. It's similar to Zyprexa, except it's one of the medications you can use when kids aren't taking the meds very well because it's sublingual. Again, this is a medication where you can't drink ten minutes before or after the dosing, and it has to be kept under the tongue until it's completely absorbed.
>
> It's a way of trying to ensure the patient is getting the medication. If you have a very difficult patient, that's one of the ways of doing it.

(Tr. at 712-713)

2/18/11 Visit

300. On February 18, 2011, Patient 7's mother reported among other things that he was still impulsive, was "written up" on the school bus and told he would not be allowed to ride the bus if the offending behavior was repeated, and his teacher said she "is at her 'whit's end.'" His handwriting had deteriorated to "chicken scratch" and he quit baseball "because he won't leave the house to play sports." Dr. Valko discontinued Concerta and Saphris, added Focalin XR 90 mg twice per day, and increased Risperdal to 2 mg twice per day. He weighed 71 pounds at that visit. (St. Ex. 7A at 34)

301. In his report, Dr. Barzman stated, "The concerns are making more than one change and starting at such a high dose of Focalin XR while his weight is 71# (32 KG)." (St. Ex. 17 at 49; emphasis omitted)

11/28/11 Telephone Call

302. Several months later, a November 28, 2011 note on the medication flowsheet indicates that Dr. Valko reviewed Patient 7's "intense OCD" with the parents. He discontinued Zoloft and added Paxil 40 mg twice per day. (St. Ex. 7A at 120)

Testimony of Dr. Barzman

303. Dr. Barzman testified:

> So I was concerned about the use of Paxil. And I had noticed muscles aches in shoulders, and transient tremors. I'm just wondering if these were side effects to Abilify and Focalin XR, so I would say the main concern was the use of Paxil.
>
> Q. [By Ms. Snyder] Why was that a concern?
>
> A. Because there was information sent out that Paxil was no better than placebo in children, and that there might be an increase in suicidality with the use of Paxil. This was back in 2004, 2005.
>
> Q. So -- and correct me if I'm using the wrong terminology. Does that mean that Paxil was not indicated for children?
>
> A. It depends on -- I don't know that the FDA made a specific ruling or withdrew Paxil, but there definitely -- there were statements made, and this information was known by child psychiatrists, the Paxil is not really used in this age group.
>
> Q. And tell me about the muscle aches in the shoulders and transient tremors in the right arm. What is your concern about that?
>
> A. I mean, it's possible that tremors could potentially be from one or both medications, but normally you'd see a tremor in both arms if it's from a medication.
>
> Muscle aches in shoulders, that's not something we typically see with side effects of these medications unless there's stiffness, and I don't know if there was any stiffness.

(Tr. at 380-381)

Dr. Barzman added that these symptoms do not indicate tardive dyskinesia. (Tr. at 381)

Testimony of Dr. Valko

304. Dr. Valko testified that Paxil was tried only after trying two other serotonin reuptake inhibitors. (Tr. at 713-714)

12/5/11 Visit

305. According to the December 5, 2011 progress note, the last visit documented in Patient 7's medical records, Dr. Valko noted among other things that Patient 7's OCD symptoms were "bad right now," and Patient 7 complained of muscle aches in his shoulders and "a transient tremor in [his] right arm." Dr. Valko prescribed, among other things, Focalin XR 30 mg with instructions to take three tablets every four hours[38] and continued Paxil. (St. Ex. 7A at 42, 120)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 7

306. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 7. (Tr. at 381)

Dr. Valko's Testimony Regarding Patient 7

307. Dr. Valko acknowledged that he had "used higher than normal doses of medications" in his treatment of Patient 7. (Tr. at 172) Dr. Valko further testified that Patient 7 was a difficult patient. (Tr. at 713)

Patient 8

5/27/09 Initial Visit

308. Patient 8 is a male born in 2000 and is the brother of Patient 7. He first visited Dr. Valko's practice on May 27, 2009, and was seen for his initial assessment by Sue Rutledge-Hehl, LISW, MSW. Patient 8's complaints were that he had trouble sleeping, resists going to bed, and has many fears, including fears of having nightmares or something happening to his parents. He also had problems staying focused during the day. He had no history of physical aggression. He previously had been diagnosed with ADHD and was receiving Adderall 20 mg from his primary care physician. The parents had not sought to increase the dose out of concern about his weight. He was given Axis I diagnoses of Anxiety Disorder NOS 300.00 and ADHD 314.01. (St. Ex. 8A at 1-2; Tr. at 155-156)

[38] The medication flowsheet indicates that Focalin XR 90 mg was to be taken three times per day. (St. Ex. 7A at 120)

5/28/09 – First Visit with Dr. Valko

309. Dr. Valko first saw Patient 8 on May 28, 2009. At that time the mother reported that Patient 8 attends Catholic school and had developed anxiety related to school prayers. She reported that they had prayed for orphans, and Patient 8 "dwelled and dwelled on this to the point of not sleeping." He also has nightmares about monsters that wake him up. This leads to Patient 8 being sleepy in school. Mother was also concerned that she has trouble getting him to eat and gain weight. His recorded weight is 53.5 pounds. Dr. Valko continued the diagnoses of ADHD Combined, Anxiety Disorder NOS (300.00), and added R/O OCD. He discontinued Adderall and added Focalin XR 30 mg in the morning, and Clonidine 0.1 mg at bedtime. (St. Ex. 8A at 3)

310. Dr. Valko testified that he had prescribed Clonidine to help Patient 8 sleep. He testified that clonidine is an old antihypertensive medication that causes drowsiness as a side effect. Dr. Valko further testified that is has fewer adverse effects compared to other sleep aids. (Tr. at 176-177)

7/29/09 Visit

311. Three visits later, on July 29, 2009, Patient 8's mother reported continuing problems with concentration. Dr. Valko increased Patient 8's Focalin XR to 40 mg in the morning and continued Clonidine 0.3 mg at bedtime. He weighed 50 pounds at that visit. (St. Ex. 8A at 6)

312. Dr. Barzman testified that Focalin XR 40 mg per day was a large dose for the patient's weight. (Tr. at 382) Dr. Barzman also believes that the large dose of Focalin XR could be a factor causing insomnia and obsessions. (Tr. at 382-383)

8/26/09 Visit

313. On August 26, 2009, Dr. Valko confirmed an Axis I diagnosis of OCD. (St. Ex. 8A at 8)

9/23/09 Visit

314. A few visits later, on September 23, 2009, Dr. Valko continued Focalin XR 40 mg and Prozac 20 mg, but discontinued Clonidine and added Risperdal 0.5 mg at bedtime based on a concern that Patient 8 was not gaining weight. He weighed 51 pounds at that visit. The note indicates that Risperdal will have the same effect as Clonidine for treating OCD diagnoses but may also help him put on weight. (St. Ex. 8A at 9)

Dr. Barzman's Report

315. In his report, Dr. Barzman expressed concern with respect to Risperdal that no baseline metabolic labs were obtained. (St. Ex. 17 at 26)

12/7/09 Visit

316. Several visits later, on December 7, 2009, Patient 8 was receiving daily doses of Focalin XR 60 mg in the morning, Prozac 20 mg in the morning, and Risperdal 2 mg split between two doses for diagnoses of ADHD Combined, Anxiety Disorder NOS, and OCD. (St. Ex. 8A at 13)

6/1/10 Visit

317. Several visits later, on June 1, 2010, Patient 8 received daily doses of Focalin XR 80 mg in the morning, Prozac 20 mg in the morning, and Risperdal 3 mg split between two doses. Dr. Valko noted that Patient 8 had continuing difficulty going to sleep, and was not showing any improvement in his behavior and focus at school or at home. (St. Ex. 8A at 16)

318. Dr. Barzman expressed concern in his report that "the high dose of Focalin XR may be causing the anxiety and obsessive thinking." (St. Ex. 17 at 26, emphasis omitted)

319. Dr. Valko acknowledged that 80 milligrams of Focalin XR per day exceeds the FDA guidelines. (Tr. at 180)

4/15/11 Visit

320. Nearly a year and multiple visits later, on April 15, 2011, Patient 8 continued to have issues focusing in school, at least for part of the day, and teachers had reported that he has some compulsions while he takes tests. Dr. Valko prescribed a daily dose of Focalin XR 90 mg twice per day, Prozac 80 mg in the morning, and Risperdal 1.5 mg twice per day. Dr. Valko advised mother that "the compulsions might get worse with the increased Focalin, so this should be monitored." (St. Ex. 8A at 25) An Axis III diagnosis of R/O Tourette's had been added on June 9, 2010 for "his vocal and motor tic." (St. Ex. 8A at 17)

321. Dr. Barzman expressed concern about the safety of prescribing a "very high" dose of 180 milligrams of Focalin XR per day. Dr. Barzman further testified that the FDA maximum recommended dose of Focalin is 30 mg per day. Moreover, Dr. Barzman testified that he has never seen anyone prescribe that dose of Focalin before. He opined that such a high dose could create or exacerbate behavior issues in a patient. (Tr. at 383-384)

5/13/11 Visit

322. At Patient 8's next visit on May 13, 2011, Dr. Valko discontinued Focalin XR noting "still poor concentration" and added Concerta 162 mg (54 mg x3) in the morning. Prozac and Risperdal continued unchanged. Patient 8 weighed 64 pounds at that visit. (St. Ex. 8A at 26)

Telephone Contacts

323. On May 19, 2011, Dr. Valko returned mother's call and was informed that Patient 8 was not doing well and was spending most of his time at the school nurse's office and mother

has had to pick him up from school. Dr. Valko told her to increase Concerta to four 54 mg tablets in the morning (216 mg) and call him the following Monday if there is no change. (St. Ex. 8A at 91)

324. On May 23, 2011, Dr. Valko prescribed Focalin XR 30 mg with instructions to take three tablets twice per day, a daily dose of 180 mg, on a telephone report that Patient 8 was "still in 'a daze'" and mother believed that Focalin had been more helpful. Presumably Concerta was discontinued. (St. Ex. 8A at 91)

7/6/11 Emergency Appointment

325. On July 6, 2011, at the parents' request, Patient 8 was seen for an emergency appointment. He was nine years old at that time. The progress note states, in part:

> Parents started the beginning of the appointment by asking [Patient 8] to sit outside so they could discuss his recent issues. Last night he spray painted and set on fire a near by girl's house. He also "keyed" and punctured three tires. Parents state it is a girl that he "likes" but do not know why he did it. When they asked [Patient 8], he does not know either. They state [Patient 8] also has a glazed over eyes often. They also state that there has been an increase in the lying, acting up, and he has been acting like a "punk". Parents state he has not been eating or sleeping either. They said he has been acting completely out of his normal character.
>
> The parents are waiting to get a second opinion at Cleveland Clinic. We discussed stopping some of his medications and restarting on different medications. Both parents agree this is a good idea. We will D/C the Focalin starting today. The parents will decrease the dose to ½ PO for three days then stop.[39] We will keep the Prozac the same. We discussed that this could make his impulsions worse, but they are willing to try. The parents are going to monitor his progress. We discussed with [Patient 8] what we were going to do and that he needed to try his hardest to control his impulsions. He agreed.

(St. Ex. 8A at 27) In addition, Patient 8 was to taper the Risperdal by taking half of his normal dose for three days and then stop. He was maintained on Prozac 80 mg in the morning. (St. Ex. 8A at 27)

7/8/11 Telephone Contact

326. On July 8, 2011, Patient 8's father called and reported that Patient 8 was not doing well. Dr. Valko prescribed Focalin XR 30 mg with instructions to take two tablets in the morning and at 11:30 a.m., a daily dose of 120 mg. He also discontinued Risperdal. (St. Ex. 91 at 91)

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[39] Patient 8 had been receiving a daily dose of Focalin XR 180 mg at that time. (St. Ex. 8A at 27)

7/11/11 Visit

327. On July 11, 2011, Dr. Valko continued Focalin XR and Prozac as before and added Abilify 5 mg in the morning and 5 mg at 11:30. (St. Ex. 8A at 28)

328. Dr. Valko testified that Patient 8 "was still struggling with many difficulties and still hyperfocused with his obsessions, the goal was to try to see if using a different neuroleptic, such as Abilify, would be more helpful for him than the Risperdal." (Tr. at 716)

Dr. Valko further testified why he prescribed Abilify 5 mg twice per day:

> I don't know why this didn't get transcribed. There's equivalent dosing of neuroleptics, what Dr. Barzman calls antipsychotics. It's well accepted that certain doses of some meds are equal to other meds. He was on 3 milligrams of Risperdal.
>
> In general, 1 milligram of Risperdal is equivalent to 4 milligrams or 5 milligrams of Abilify. So I went from 3 milligrams of Risperdal, which would have been 12 to 15 milligrams of Abilify, but I went to 10. So it was actually a slightly lower dose, but a split dose.
>
> I almost always split my doses when it comes to neuroleptics with kids and young adults, because if you're older, you don't break down your medicines as fast. It can last a day. But kids seem to burn through it a little faster, so I split the dose half in the morning and half in the evening.

(Tr. at 718-719)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 8

329. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 8. (Tr. at 385)

Dr. Valko's Conclusions Regarding Patient 8

330. Dr. Valko described Patient 8:

> So this is the brother of Patient 7. And the parents brought him to our office because, as they stated -- and I remember cases like this because they felt we were actually listening to the family and trying to help the family and not letting things -- trying to catch everything we could do.

> They were also having difficulties with the younger brother and were hopeful that we might be able to help with both brothers. It should be noted there is a family history of obsessive-compulsive in this family, and so it may explain a lot of the obsessions and anxiety this patient is also exhibiting.

(Tr. at 715)

Patient 9

3/13/07 Initial Assessment

331. Patient 9 is a male born in 2000. He was first seen in Dr. Valko's practice on March 13, 2007, by Heather Simon, M.A., PCC. The initial assessment note indicates that Patient 9 had been treated for ADHD with a variety of medications none of which proved effective. His primary care physician had recommended that he see a psychiatrist for a medication assessment. His mother reported a host of ADHD symptoms such as difficulty paying attention, difficulty organizing, difficulty waiting his turn, among many others, that affect him both at home and in school.[40] Mother reported an incident where Patient 9 hit another child in the face with a ball before gym class. She reported that his father was recently placed on Adderall XR for ADHD-like symptoms, and that she takes Paxil for fibromyalgia. (St. Ex. 9B at 2)

The note states as follows concerning medication history: "Concerta, Adderall XR – used until 2 weeks ago – had control of impulses but had mood swings would cry a lot then begin kicking and hitting, Ritalin – had no impulse control, Strattera, Daytrana." (St. Ex. 9B at 3)

The Axis I diagnosis listed was ADHD Combined Type 314.01. (St. Ex. 8B at 3)

4/11/07 – First Visit with Dr. Valko

332. Dr. Valko first saw Patient 9 on April 11, 2007. He noted that Patient 9 was extremely active and distracted throughout the visit despite being corrected by his mother. He further documented:

> His mother states that [Patient 9] also has a large appetite and is obsessive about particulars such as constantly picking at loose skin and scabs on himself and others, and irresistibly having to pick dried glue off all of the glue bottles at school. His mother also states that [Patient 9] frequently eats the food off of his siblings plates without permission. She says [Patient 9] does not eat food with plastic still on it or food that is not prepared.

(St. Ex. 9 at 18)

[40] He was in kindergarten. (St. Ex. 9B at 2)

The note further indicates that Patient 9 had previously taken Concerta 40 mg unsuccessfully and that the only medication that had had any significant effect was Daytrana. However, the Daytrana patch leaves an area of red and irritated skin that can take weeks to clear up. Moreover, the mother reported that, even on Daytrana, he does not function well in school or at home. Dr. Valko diagnosed Patient 9 on Axis I with ADHD Combined and R/O OCD.[41] Dr. Valko prescribed Concerta 54 mg in the morning. (St. Ex. 9B at 18)

5/9/07 Visit

333. On May 9, 2007, Risperdal 0.25 mg twice per day was added "to help with his emotions, behavior, and concentration." Dr. Valko also added R/O Asperger to the Axis I diagnoses. (St. Ex. 9B at 22)

5/23/07 Visit

334. On May 23, 2007, Patient 9's mother advised that Patient 9 "is obsessive with spinning, trains and the color red." He confirmed an Axis I symptom of OCD in addition to ADHD Combined and R/O Asperger's Syndrome. Dr. Valko increased Concerta to 72 mg in the morning, and increased Risperdal to 0.5 mg twice per day. (St. Ex. 9B at 24)

335. In his report Dr. Barzman had stated that Patient 9 "is likely becoming obsessive due to Concerta." (St. Ex. 17 at 28) Dr. Barzman testified that "[i]t's not -- obviously not a hundred percent, but there is that --that possibility." (Tr. at 511-512) Noting that Patient 9 was later diagnosed with Asperger's, Dr. Barzman acknowledged that that could be the basis for the patient's obsessions. (Tr. at 512)

7/26/07 Visit

336. On July 26, 2007, Dr. Valko noted that Patient 9 was very active during the appointment and that Patient 9 talked to him on a continuous basis interrupting his mother, and "did not seem to have any concept that there were others in the room." (St. Ex. 9B at 25) Mother reported that Patient 9 is not doing well and his impulsivity seemed to be getting worse. She also reported that the Risperdal "is also not as helpful." Dr. Valko increased Patient 9's Concerta dose to 108 mg in the morning. He weighed 93 pounds at that visit. (St. Ex. 9B at 25)

337. Dr. Barzman testified that the dose of Concerta was high. (Tr. at 387; St. Ex. 17 at 28)

09/13/07 Visit

338. On September 13, 2007, Dr. Valko confirmed an Axis I diagnosis of Asperger's Syndrome. (St. Ex. 9B at 29)

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[41] He also diagnosed "R/O Prader-Willi" on Axis III but that possible diagnosis was eliminated by Patient 9's third visit. (St. Ex. 9B at 18, 20, 22)

2/11/09 Visit

339. Approximately 18 months and many visits later, on February 11, 2009, Patient 9's mother reported, among other things:

> [Patient 9] has been increasingly irritable, agitated, and blows up frequently. His mother reports that she had taken him off of his medications last year after a teacher advised her to do so. He began to do poorly at school and acted out much more. He was kicked out of school. His mother is currently trying to home school him, with little success. Even when they are doing fun activities, he cannot stay focused. She is apologetic and feels somewhat guilty that he[r] son is now behind to taking him off of his medications. I apologized that the teacher had given her that advice, and told her I will help things back in order. However, I told her if other physicians and outsiders are involved in his psychiatric care it will be difficult to be successful.

(St. Ex. 9B at 73)

Dr. Valko added Seroquel 50 mg three times per day for a total daily dose of 150 mg to Patient 9's regimen of daily doses of Prozac 80 mg and Imipramine 100 mg.[42] Dr. Valko noted that he is "hopeful that [Seroquel] will help him focus and with its sedative properties that it will decrease his outbursts."[43] Patient 9's Axis I diagnoses were ADHD Combined, OCD, and Asperger's Syndrome. (St. Ex. 9B at 73)

Testimony of Dr. Valko

340. Dr. Valko testified that, looking back, he should have diagnosed Patient 9 with a mood disorder by this time, which he added later. (Tr. at 185-186)

341. Dr. Valko testified that Patient 9's mother had previously discontinued his medications so he had not been taking stimulants for a while. Dr. Valko added that they had not been helpful and that "[t]hey were lasting maybe an hour or two hours max." Moreover, Dr. Valko testified that Patient 9 was a fast metabolizer, and that this was supported by later GeneSight testing. Dr. Valko further testified that GeneSight indicated that he was a fast metabolizer of Prozac and other antidepressants as well as Seroquel and other antipsychotics, and that that means "[y]ou almost have to double the normal dosage." (Tr. at 723-724; Resp. Ex. C at 57, 59)

The GeneSight report dated September 27, 2017, indicates that there is also gene-drug interaction with Tegretol and with ADHD stimulant and non-stimulant medications. The

[42] Dr. Valko testified that Imipramine is a nonstimulant prescribed off-label for ADHD to try to assist Patient 9 with focus. (Tr. at 723)
[43] Patient 9 had not been prescribed a stimulant since Concerta was discontinued on January 8, 2008. (St. Ex. 9B at 42-73)

report indicates that higher doses of Adderall and Vyvanse may be required and that Patient 9 might have a reduced response to Focalin, guanfacine, and methylphenidate. (Resp. Ex. C at 60, 71)

3/25/10 and 6/14/10 Visits

342. More than one year later and many visits later, on March 25, 2010, Dr. Valko prescribed Concerta 270 mg (54 mg x 5) in the morning, Zoloft 100 mg twice per day, and Intuniv 4 mg at bedtime.[44] (St. Ex. 9B at 115)

343. At Patient 9's next visit on June 14, 2010, Patient 9's mother reported that Patient 9's attention tends to wane in the afternoon and evening making after-school sports activities difficult. Dr. Valko added a second dose of Concerta 270 mg at 1:30 p.m. for a total daily dose of 540 mg. Zoloft 200 mg per day was left unchanged, and Intuniv was reported to be ineffective and was discontinued. (Tr. at 187; St. Ex. 9B at 124)

344. Dr. Barzman testified that the FDA maximum recommended daily dose for Concerta is 72 mg per day. Dr. Barzman testified that Concerta 540 mg per day has not been studied and that he has never seen a patient receive that dose before. (Tr. at 387-388)

345. When asked whether Concerta 540 mg per day was a large dose for a 10-year-old child, Dr. Valko replied, "Once again, I'm not looking at the age of the child, the weight of the child, I'm looking at what works and what does not work for that child. And it's considered above the FDA guidelines." (Tr. at 187)

7/12/10 Visit

346. At Patient 9's next visit on July 12, 2010, Patient 9's mother reported that their insurance would not approve the second daily dose of Concerta. In response, Dr. Valko discontinued the afternoon dose of Concerta and added Focalin XR 60 mg at 1:00 p.m. (St. Ex. 9B at 129)

11/15/10 and 12/20/10 Visits

347. On November 15, 2010, in addition to other prescriptions, Dr. Valko started Patient 9 on Clonidine 0.1 mg at bedtime. (St. Ex. 9B at 138) Per the medication flowhseet, Dr. Valko increased Clonidine to 0.2 mg on November 29, 2011. (St. Ex. 9B at 264) At Patient 9's next visit on December 20, 2010, Dr. Valko increased Patient 9's Clonodine to 0.8 mg per day, split among two doses of 0.2 mg, one in the morning and the second at noon, and one dose of 0.4 mg at bedtime. (St. Ex. 9B at 139)

[44] Notice is taken that the generic name for Intuniv is guanfacine. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a601059.html>, accessed January 28, 2020)

Testimony of Dr. Barzman

348. Dr. Barzman testified that the dose of Clonidine 0.8 mg was high and should have been titrated up over a longer period of time. (Tr. at 388-390) He further testified, "My concern with the dosing of the Clonidine is * * * that it can cause a drop in blood pressure, drop in heart rate. Overdose can be very serious, so that was the concern with that one." (Tr. at 390)

3/28/11 Visit

349. On March 28, 2011, Dr. Valko added BuSpar 20 mg twice per day to Patient 9's regimen of Celexa 40 mg twice per day; Concerta 270 mg in the morning; Focalin XR 90 mg at 1:00 p.m.; Clonidine 0.2 mg in the morning, 0.4 mg at 1:00 p.m. and 0.6 mg at bedtime for daily dose of 1.2 mg. Dr. Valko indicated in the progress note that BuSpar was added to help with Patient 9's anxiety. (St. Ex. 9B at 156)

Testimony of Dr. Valko

350. Dr. Valko testified that BuSpar is a non-addicting antianxiety medication "that sometimes can help other medications that are onboard" such as "serotonin reuptake inhibitors when you're looking at helping with [OCD]" without increasing the dose of the SSRI. (Tr. at 729-730)

3/8/12 and 5/23/12 Visits

351. Approximately one year later, on March 8, 2012, Patient 9 was prescribed Concerta 270 mg in the morning and Focalin XR 90 mg at 1:00 p.m., both unchanged from a year earlier; Clonidine 0.2 mg in the morning, 0.4 mg at 1:00 p.m., and 0.6 mg at bedtime for a total daily dose of 1.2 mg; and Tegretol 100 mg at 4:00 p.m. and 200 mg at bedtime, a daily dose of 300 mg. Patient 9's Axis I diagnoses remained unchanged—ADHD Combined, OCD, and Asperger's Syndrome. (St. Ex. 9B at 202)

352. At Patient 9's next visit on May 23, 2012 visit, mother reported that Patient 9 continued to struggle with attention and concentration and had meltdowns during the day after the Concerta wore off after lunch. Dr. Valko suggested short-acting Ritalin three times per day to help with focus during afternoons and evenings. Dr. Valko discontinued Focalin XR and added Ritalin 60 mg at 10:30 a.m., 1:30 p.m., and 4:30 p.m., a daily dose of 180 mg, and left the other medications unchanged.[45] (St. Ex. 9B at 209)

Testimony of Dr. Valko

353. When asked about the dosage of stimulants and any side effects, Dr. Valko testified:

[45] The progress notes for this visit and the next visit include Cogentin in the medication list. This appears to be an error as prescriptions for Cogentin are not mentioned in the bodies of the notes or on the medication flowsheet during this time period. (St. Ex. 9B at 209, 210, 269-270)

> The dosage is high. I always will admit these dosages are high. It is above what is considered normal dosages. As per the American Academy of Child and Adolescent Psychiatry, they say you're supposed to treat the best you can for the patient and make sure that you do the best you can, no matter what the dose, assuring there are no adverse effects and side effects. So he was still eating. He was still sleeping. He had no cardiac complaints and no cardiac issues.
>
> As you saw, we later discovered he was a fast metabolizer for all of these medications, so, therefore, mom was giving these meds -- at one point I think she was giving them six times a day because she's able to figure -- she has an alarm set on her phone, and this is when he gets his next dose, hoping to get it in him before the two, two and a half hours of the stimulant wears off.

(Tr. at 730-731)

7/17/14 Visit

354. By July 17, 2014, two years and numerous visits later and the latest visit included in the charts, Patient 9 is 14 years old. He is taking daily doses of Concerta 108 mg, Ritalin 360 mg split among five doses, Clonidine 1.2 mg split among three doses, Tegretol 800 mg split among four doses, and Klonopin 1.5 mg split among three doses. (St. Ex. 9A at 21)

355. Dr. Valko acknowledged that the dose of Ritalin exceeded the FDA-recommended maximum daily dose of 60 mg. (Tr. at 192)

Dr. Barzman Conclusions Regarding Dr. Valko's Treatment of Patient 9

356. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 9. (Tr. at 390)

Dr. Valko's Conclusions Regarding Patient 9

357. Dr. Valko testified that Patient 9 is still his patient. (Tr. at 183, 719)

358. Dr. Valko described his treatment of Patient 9:

> Patient 9, you have to love him because if you don't, you go crazy. Patient 9 is the oldest of four siblings who all come to my office all on the autism spectrum. Mom homeschools all four kids. She's a godsend. Patient 9, he tries so hard to be the most loveable, wonderful kid in the world, but as soon as something changes that doesn't go with his obsessions, he will beat the

> living crap out of you and destroy whatever is right in front of him, not caring if it's his own handheld game or whatever. If that obsession isn't done the way it's supposed to be, things are just destroyed.
>
> * * *
>
> So Patient 9 had been on multiple medications before he came to us. He was on Concerta, Adderall XR, which made him emotional, Strattera, Daytrana, Ritalin. When he came to us, he was on the Daytrana patch. He is on the autism spectrum. He's OCD, ADHD. He's disruptive.
>
> I still call him a disruptive mood, dysregulation disorder. He meets every criteria for bipolar. He's over 18 now. Mom and I were having a discussion because mom's got a guardian. I'm actually formally calling him bipolar disorder because he is bipolar. But before we went there, his depression was so intense, but then he would get so agitated and then truly manicky.
>
> So he is a little bit -- not a little bit. He's a lot of everything, except -- and when he gets really manicky, he can get psychotic, but the psychosis is only with the mania, so he's not schizophrenic.

(Tr. at 719-721)

359. Dr. Valko testified that Patient 9 was not a typical patient and was, in fact, an extreme patient considering his difficulties with medications and his mother having three other special-needs kids at home. (Tr. at 731)

Patient 10

4/3/07 Initial Assessment

360. Patient 10 is a male born in 1997. He was first seen in Dr. Valko's practice on April 3, 2007, by Heather Simon, M.A., PCC, when he was nine years old. At that time, he had been treated by his pediatrician for ADHD and oppositional issues since he was five. Patient 10's mother reported that the pediatrician had been unwilling to continue Patient 10's medications unless he saw a psychiatrist. At that time he was receiving Concerta 54 mg, and had previously tried Adderall, Strattera, and Guanfacine (which he may have still been taking as the note states, "[Mother] reported that he had been off this for about 2 weeks because his prescription ran out"). Patient 10 was in third grade in a severely behaviorally handicapped ("SBH") class. (St. Ex. 10A at 5-6)

In addition to ADHD symptoms he also was aggressive and destroyed property such as stuffed animals. Mother reported "that within the last six months he has lost his temper often, argues with adults at home, defies rules, deliberately annoys others, is easily

annoyed, blames others for his misbehavior, and is angry. She stated that this has been an issue for him at school and at home." (St. Ex. 10A at 5)

Mother reported that she lives with her boyfriend of eight years (who is not Patient 10's father), two daughters from an earlier relationship ages 16 and 10 who are Patient 10's half-sisters, Patient 10, and the 18-month-old daughter of her and her boyfriend. Patient 10's biological father sees him irregularly and at one time was on SSI because he heard voices. (St. Ex. 10A at 5)

Mother reported that her boyfriend "is great with the kids"; however, she has not married him "because he does not feel safe to her." Before Patient 10 was able to talk he bit the boyfriend who responded by hitting Patient 10 in the face leaving his face black-and-blue. (St. Ex. 10A at 5) She also reported that a few months prior to seeing Dr. Valko:

> [Lucas County Children Services] came to the home because of a report about [boyfriend] choking [Patient 10]. She stated that there were no bruises and that [boyfriend] has not touched [Patient 10] in this way since that time. While [mother] related these reports [Patient 10] made a comment about [boyfriend] telling [Patient 10] that when [boyfriend] was young he hurt some kids that were picking on him and that one of them ended up in a wheelchair. [Patient 10] appeared to identify with not trusting [boyfriend].

(St. Ex. 10A at 5)

Mother also reported that Patient 10 had seen another psychiatrist and a counselor but had stopped seeing them the previous year. Mother reported that she did not like the counselor because, during one appointment, he had insisted upon meeting with mother and her boyfriend outside Patient 10's presence. While Patient 10 was in the waiting room, "his sister pushed him into a table and he ended up needing stitches on his face."[46] She blamed the counselor for this and never went back. (St. Ex. 10A at 6)

Under the heading Legal History Ms. Simon documented:

> [Mother] reported that she has called the police several times when [Patient 10] has threatened his sister or herself with a knife or scissors. She stated that at these times he was taken to Kobacker. She reported that the last time he threatened his sister was last week. [Mother] stated that she stopped him and did not indicate that she called the police.

(St. Ex. 10A at 7)

At the initial assessment Patient 10 was diagnosed on Axis I with ADHD Combined Type 314.01 and Oppositional Defiant Disorder ("ODD") 313.81. (St. Ex. 10A at 7)

[46] Presumably this was one of his older half-sisters.

April 10 and 24, 2007 Counseling Sessions

361. The progress note from Patient 10's April 10, 2007 counseling session with Ms. Simon indicates that he had taken some knives from boyfriend's collection and hidden them in his room. Patient 10 reported that he had not planned on doing anything with the knives. Ms. Simon told Mom and boyfriend to put a lock on the room door where the knives are kept so Patient 10 could not get in. (St. Ex. 10A at 8)

362. Two counseling sessions later, on April 24, 2007, Ms. Simon again met with mother and boyfriend. Among other things, the progress note indicates that Patient 10 had become increasingly aggressive at school and the school reported that he had threatened to kill several classmates. Ms. Simon asked whether the knives had been locked up yet. They had not, but mom and boyfriend reported hiding them where Patient 10 cannot find them. Ms. Simon encouraged them to lock them up as soon as possible because of Patient 10's threatening statements. (St. Ex. 10A at 10)

5/1/07 – First Visit with Dr. Valko

363. Patient 10 first saw Dr. Valko on May 1, 2007. Mother reported that Patient 10:

> had been off the Tenex that was prescribed to him by his primary care physician and his vocal and motor tics are back. She also feels as if he is still not able to concentrate. He has been getting mostly Unsatisfactories in school. His mother states that [Patient 10] has threatened his sister with a knife before and he has issues with becoming angry easily. She states that [Patient 10] has difficulty falling asleep. She also reports that he does not eat very well at school or at home.

(St. Ex. 10A at 11)

Dr. Valko diagnosed ADHD Combined on Axis I and R/O Tourette's on Axis III. He added Risperdal 0.5 mg twice per day to the Concerta 54 mg in the morning that Patient 10 was already taking. (St. Ex. 10A at 11)

Testimony of Dr. Barzman

364. Dr. Barzman testified that Tourette's "can be a combination of vocal and motor tics." Dr. Barzman further testified that research has indicated that stimulants do not cause or worsen tics. (Tr. at 391)

Testimony of Dr. Valko

365. Dr. Valko testified that Patient 10 came to his office with a diagnosis of ADHD and he subsequently added a diagnosis of ODD. Later, he added OCD. (Tr. at 733) When asked to describe ODD Dr. Valko testified:

> [T]here's oppositional defiant disorder and conduct disorder. Oppositional defiant disorder is when the kid says no, stomps his feet, and runs away. Conduct disorder is when a kid says no and hits you with a baseball bat. That's my simple, down-and-dirty explanation. It's a kid who refuses to follow direction but doesn't cause any major destruction and is not actively trying to harm someone or their surroundings.

(Tr. at 734)

5/31/07 Visit

366. Dr. Valko next saw Patient 10 on May 31, 2007. Mother reported that she has noticed an improvement with Risperdal but could not identify any specific examples. Patient 10 agreed that things were better. The diagnoses and medications were left unchanged. (St. Ex. 10A at 17)

7/3/07 Counseling Session

367. At a counseling session on July 3, 2007, Patient 10 (who was not quite 10 years old) was not doing very well and his mother reported that he was being defiant and not listening. "She reported that the previous night he was out late and did not call to say where he was until after 10 pm." Ms. Simon discussed the seriousness of this situation one-on-one with the mother, suggested a book for her to read, and offered individual therapy to focus on these issues. (St. Ex. 10A at 19)

8/21/07 – 10/07 Visits

368. Dr. Valko next saw Patient 10 on August 21, 2007. Mother expressed concerns about Patient 10's medications and indicated they were not as helpful as she would have liked. She wanted to increase Patient 10's Concerta but Dr. Valko declined due to Patient 10's tics. He also declined to explore herbal options as they had not been sufficiently studied. Dr. Valko discussed Patient 10's obsessive behavior, which the mom and boyfriend were initially reluctant to discuss, but acknowledged that "[h]e apparently is obsessed over various objects." Dr. Valko increased Patient 10's Risperdal to 1 mg twice per day and left Concerta unchanged at 54 mg in the morning. Dr. Valko also added rule-out OCD to Patient 10's Axis I diagnoses. (St. Ex. 10A at 20)

369. Dr. Valko next saw Patient 10 on September 18, 2007, and mother discussed his ADHD symptoms. Dr. Valko increased Patient 10's dose of Concerta to 72 mg in the morning. Risperdal was left unchanged. (St. Ex. 10A at 21)

370. The next progress note from Dr. Valko is undated but probably referenced a visit in late October 2007. He continued to experience ADHD symptoms and was doing poorly at school, and the mother reported that, when he does not get what he wants, he walks out of the school. Dr. Valko increased Concerta to 108 mg in the morning and left Risperdal unchanged. (St. Ex. 10A at 22)

11/26/07 Visit

371. On November 26, 2007, Dr. Valko increased Patient 10's Risperdal to 1.5 mg in the morning and 1 mg at bedtime for a daily dose of 2.5 mg and continued Concerta at 108 mg in the morning. Patient 10 weighed 73 pounds at that visit. (St. Ex. 10A at 23)

Testimony of Dr. Barzman

372. Dr. Barzman testified that the dose of Concerta was large considering the patient's weight, and Risperdal was increased. Dr. Barzman further testified that Patient 10 was reported to be more irritable and to have a low frustration tolerance, which could be a side effect of Concerta. Dr. Barzman testified that "it is challenging to disentangle what is what, but it may be a matter of seeing if lowering the dose could help. Then it's possible the ADHD symptoms may get worse, so it's a matter of trial and error." (Tr. at 392; St. Ex. 10A at 23)

Testimony of Dr. Valko

373. In relation to Dr. Barzman's criticism that Patient 10's OCD was likely caused by the high doses of stimulants being prescribed, Dr. Valko testified that he had considered a diagnosis of OCD back on August 21, 2007. Dr. Valko testified that, at that time, Patient 10 was taking only 54 milligrams of Concerta, well below the FDA maximum daily dose. Dr. Valko testified that he observed Patient 10 for that diagnosis for a long time before giving him a formal diagnosis of OCD on February 4, 2010. (Tr. at 735-736; St. Ex. 10A; St. Ex. 17 at 54; Resp. Ex. C at 75-76)

4/3/08 Visit

374. By April 3, 2008, Patient 10's diagnoses remained ADHD Combined and R/O OCD on Axis I, and R/O Tourette's on Axis III. He was prescribed Concerta 108 mg in the morning and Risperdal 1.5 mg in the morning and one mg at bedtime. (St. Ex. 10A at 28)

07/1/08 Letter

375. A July 1, 2008 letter to Lucas County Children Services from Dr. Valko indicates that Patient 10 had not been seen since April 3, 2008 because his mother refused to pay his bill.

At that time Patient 10 had no appointments scheduled with Dr. Valko's practice. (St. Ex. 10A at 29)

7/21/08 Visit

376. Patient 10 was next seen by Dr. Valko on July 21, 2008 and was still having problems with behaviors and impulsivity. Dr. Valko noted that he could not increase Concerta because of Patient 10's tics, but increased Patient 10's Risperdal to 3 mg daily split between a morning dose and a 4:00 p.m. dose. (St. Ex. 10A at 30)

10/21/08 Visit

377. Two visits later on October 21, 2008, Patient 10's mother reported that he had been acting up at home and in school. The progress note states, in part:

> [Patient 10] says he can concentrate and do okay at school, but once he gets home his medication wears off and he starts to yell at his babysitter, his parents, destroys things, hides things, gets knives out of the kitchen and cannot stay out of trouble. * * *
>
> During the appointment he was arguing and yelling at his mother, throwing snide comments at her whenever she said anything he disagreed with. He was pointing at her and was easily agitated. We discussed increasing his Concerta and will do so before changing the Risperdal in hopes to control some of his concentration and behavior problems.

(St. Ex. 10A at 32)

Dr. Valko increased Patient 10 dose of Concerta to 144 mg in the morning (36 mg x 4). (St. Ex. 10A at 32)

Subsequent Visits

378. On December 23, 2008, the boyfriend (referred to as "dad" in the progress note) reported that Patient 10 was doing well in school but not at home where he is very hyperactive and out of control. Dr. Valko added Ritalin 40 mg at 4:00 p.m. (St. Ex. 10A at 34)

379. Dr. Barzman testified that the Concerta and Ritalin doses were large and questioned whether Patient 10 "was more labile because of the high doses." (Tr. at 393) However, Dr. Barzman testified that Concerta and Ritalin are frequently prescribed together, Concerta being the longer-lasting medication and Ritalin given later in the day. (Tr. at 393)

380. Patient 10 saw Dr. Valko again on March 31, 2009. "Dad" reported that he had asked for the appointment because he was afraid Patient 10 was running out of medication. He reported that Patient 10 becomes angry when he does not get his way and "will use

profanity, stomp, and throw objects down the stairs. He also blows up at school. His defiant actions are directed toward mom and dad and his teacher." Dr. Valko noted that he increased Patient 10's dose of Risperdal to 2 mg twice per day "to assist with his moodiness. [Dr. Valko's] goal is that he will think before he acts." He also recommended that he see a therapist on staff to work on Patient 10's defiant behavior and provide assistance with parenting skills for the parents. He also recommended no TV or video games within two hours of going to bed to address Patient 10's complaint of difficulty falling asleep. (St. Ex. 10A at 36)

381. In his progress note for Patient 10's April 21, 2009 visit, Dr. Valko noted, "Throughout the appointment he was very dis-respectful towards his mother. Mother did not seem to be overwhelmed with this, but I did address this issue. Mother noted that he has been more physically abusive towards her by hitting and kicking as well." He was also reported to be having some behavioral issues at school. Dr. Valko left Patient 10's medications unchanged. (St. Ex. 10A at 41)

May 2009 Hospitalization

382. On May 21, 2009, Patient 10 was admitted to Toledo Children's Hospital, and was discharged on May 26, 2009. (St. Ex. 10B at 186-187) The Discharge Summary states, in part:

> HISTORY OF PRESENTING ILLNESS: [Patient 10] is an 11-year-old male who was admitted to the hospital because of acute suicidal ideation with plans to jumping out of the window.[47] The patient is very stressed after he was told that he had to go to karate classes, which he refused to go. He has a long history of behavioral problems. The patient has been on medications for a very long time. He was started on prevalently high doses of Concerta 144 mg per day, 40 mg of Ritalin, and Risperdal. It is unclear if these were the causes of his aggression.
>
> HOSPITALIZATION COURSE: The patient was admitted to Adolescent Behavioral Medicine Unit of Toledo Children's Hospital for stabilization and safekeeping. His medications were appropriately reviewed downwards. His Concerta was restarted at a dose of 72 mg. Family meeting was held to discuss the stressors and how to keep him safe. His laboratory test showed no abnormality including urinary drug screen. He was appropriately also physically examined and no abnormality. Family meeting is discussed how to keep him safe in community and how to de-escalate him. A follow up plan was also made.

[47] In addition to the issues related to suicidal ideation, the Emergency Center Report stated that Patient 1 "has been physically abusive to the mother. He was so violent that stepfather had to pull him off the mother today. Child has been having behavior issues for over 2 years, according to mom it has just gotten out of hand. She couldn't take it today." (St. Ex. 10B at 194)

> DISCHARGE MEDICATIONS: Concerta 72 mg p.o. q.a.m., Ritalin 40 mg at 4 p.m., and Risperdal 2 mg p.o. b.i.d.

(St. Ex. 10B at 186)

In addition, Patient 10's Axis I diagnoses "on admission and discharge" were "Mood disorder, not otherwise specified, rule out bipolar disorder and [ADHD], combined type." The plan was for Patient 10 to follow up with Dr. Valko. An appointment was scheduled for later that day. (St. Ex. 10B at 186)

May 26, 2009 and Subsequent Visits

383. Dr. Valko saw Patient 10 on May 26, 2009, and was made aware of the hospitalization. Dr. Valko noted that the hospital had reduced Patient 10's dose of Concerta to 72 mg in the morning and Dr. Valko maintained him at that dose, in addition to Ritalin 40 mg per day and Risperdal 4 mg per day. The plan was for Patient 10 to continue seeing the therapist. Stepfather reported that Patient 10 seems to improve for a few weeks following medication changes "but then he seems to adapt to it such it's like he's not on anything at all." (St. Ex. 10A at 43)

384. Dr. Valko next saw Patient 10 and his mother on June 9, 2009. He noted that Patient 10 "was very argumentative and rude with his mother having hit her once while walking down the hall and arguing back or making snide remarks at everything she said." (St. Ex. 10A at 45) In addition, Dr. Valko documented:

> His mom said she checked her family history and found out there is a history of depression and she thinks she's got that as she "can't take it anymore." I noticed during the appointment that she didn't speak to [Patient 10] without raising her voice which would cause him to raise his voice in return. When asked if they are always like that she said, "yes," and that she yells at him "to prevent being physically abusive since she was abused as a child." She tells me that [Patient 10] has been terrible and learned nothing while in the hospital being very argumentative, disobedient, hitting, etc. [Patient 10] explained that he just forgot about the appointment and said he forgets about a lot of things. I'm concerned that he still isn't able to focus as well as he should be. His dose of Concerta was decreased while in the hospital because it made him "too hyper" and was always jumping around. He says he's noticed a difference with the lower dose. I'm going to stop the Concerta as it evidently isn't working very well for him, and start Vyvanse 70mg. The side effect of possible upset stomach was explained. He has been taking his medications at varying times and I told them he should have his morning medicine by 8 a.m. and the afternoon medicine around 5 p.m. They both understood this and said they would comply. I told them these problems weren't created in a day and won't go away quickly and that they needed to get in and see the therapist to work through things.

(St. Ex. 10A at 45)

Dr. Valko discontinued Concerta, added Vyvanse 70 mg in the morning, and continued Ritalin and Risperdal. (St. Ex. 10A at 45)

385. Dr. Valko next saw Patient 10 on June 18, 2009. Patient 10 indicated that the Vyvanse wears off in the afternoon at which time he gets angry more easily. Stepfather reported that Patient 10's attitude was improved but that he is still impulsive and more hyperactive. Dr. Valko increased Patient 10's Vyvanse to 100 mg twice per day for a total daily dose of 200 mg, and discontinued Ritalin. Risperdal was maintained at 4 mg per day. (St. Ex. 10A at 46)

386. At Patient 10's next visit on July 22, 2009, Dr. Valko noted that Patient 10 was doing well on his medications and had not had any more blow-ups. He left the medications unchanged. (St. Ex. 10A at 47)

387. Patient 10 next saw Dr. Valko on September 16, 2009, accompanied by his mother. Dr. Valko noted that his attitude was poor and that he kept interrupting his mother and "muttering to himself quietly." Dr. Valko further noted:

> I noticed that mom would often respond to his interruptions while she was talking to me, and I made her aware of how this only further empowers [Patient 10] to be disrespectful. He is having a lot of trouble at school, as evidenced by the poor scores on his behavior sheet. He has not been following directions or paying attention and has been acting out. Mom says she feels like he just isn't trying. He blames the teachers for his problems. She has threatened to take away his Xbox and internet privileges if does not get above 85% on his behavioral scores, and he responded by saying he would just have one of his friends hack the system.

(St. Ex. 10A at 48)

Dr. Valko increased Patient 10's Vyvanse to 120 mg twice per day for a total daily dose of 240 mg to try to help with Patient 10's behavior, and continued Risperdal at 4 mg per day. (St. Ex. 10A at 48)

388. Patient 10's behavior had improved to some extent by his next visit on November 9, 2009, and Dr. Valko continued his medications unchanged. (St. Ex. 10A at 49)

389. Patient 10 next saw Dr. Valko on February 4, 2010, accompanied by his mother. Dr. Valko noted that Patient 10 appeared to be in a good mood at first but became angrier as his mother spoke. He argued and constantly interrupted her with "condescending remarks, including telling his mother to shut up." (St. Ex. 10A at 50) Dr. Valko further noted:

> His mother informs me that he went to Juvenile on Saturday and disrespected the police officers who took him in. * * * She tells me how [Patient 10] doesn't like school, he says how he doesn't have any friends, and the teacher

> hates him. She goes on to say he is currently being punished by not being able to play X-Box. She says how he has been arguing more and he is always trying to get out of going to school. During the session, I observe [Patient 10] trying to tie his shoes for ten minutes.

(St. Ex. 10A at 50)

At that visit, Dr. Valko confirmed OCD as an Axis I diagnosis. He increased Patient 10's dose of Vyvanse to 140 mg twice per day for a daily dose of 280 mg to help with Patient 10's focus and hyperactivity. He also added Prozac 20 mg in the morning to help with Patient 10's obsessions. Risperdal was maintained at 4 mg per day. (St. Ex. 10A at 50)

390. At Patient 10's next visit on February 16, 2010, he was better behaved and reported doing better at school. Mother agreed, reported that his mood and attitude had improved, and opined that "going to court played a large part in his turnaround." Dr. Valko increased Patient 10's Prozac to 40 mg in the morning, believing that it would help with his obsessions, and maintained the Vyvanse and Risperdal unchanged. (St. Ex. 10A at 52)

391. At a March 11, 2010, visit with the counselor the major topics were the serious conflict between Patient 10 and the mother and Patient 10's upcoming juvenile court appearance. The offense he was going to court for was not described in the progress note. (St. Ex. 10A at 53-54)

392. At Patient 10's next psychiatric visit on March 29, 2010, he was seen by a different psychiatrist at Dr. Valko's practice, Dr. Hysell. Patient 10's mother was present. Among other things he complained of chest pain and shortness of breath. They discussed his use of the computer until late and his problems sleeping at night but with long naps in the evening. Also, they discussed Patient 10's behavior problems in school, and mother's desire to send him to military school but feared "he would learn bad behaviors." Mother (or possibly Patient 10) remarked, "I can see why parents kill their kids." Patient 10 reported he did not like Mother's significant other. He said that adults yell. Moreover, Dr. Hysell noted, "He worries about Mom getting hurt but he reports he is not going to come to her defense next time." (St. Ex. 10A at 55)

Among her recommendations, Dr. Hysell noted that Patient 10 should be put on a regular sleep schedule at night and not be allowed to take long naps, to decrease Vyvanse based on Mother's feeling that it's not working, to start Seroquel to address mood and tics, and "EKG to be done ASAP. Mom was informed to get it done ASAP since he complains of pain and SOB. She should go today." (St. Ex. 10A at 55)

Patient 10's dose of Vyvanse was decreased to 140 mg in the morning and 100 mg in the afternoon for a daily dose of 240 mg, and Seroquel 50 mg at 4:00 and 8:00 p.m. was added, for a daily dose of 100 mg. (St. Ex. 10A at 55-56)

April 26, 2010 Visit

393. Patient 10's next and last visit to Dr. Valko was on April 26, 2010. Dr. Valko noted that he had "significant psychomotor agitation," frequently interrupted his mother, and tried to draw her into arguments. Mother had a written list of behavioral problems, including breaking car windows, not taking his medications while staying at friends' houses, and getting straight Fs in school. His Xbox had been taken away and he continually brought that up during the appointment. He had been missing a lot of school and mother had "Great difficulty every morning getting him on the bus." Dr. Valko suggested that she file truancy charges when he refuses to go to school, and to file charges when he breaks things, but noted, "She did not commit to this." Dr. Valko further documented, "We reviewed his medications. After a lengthy discussion, a decision was made to change the Risperdal to Seroquel to see if this would be more helpful with his escalating behaviors." Patient 10 weighed 99 pounds at that time. (St. Ex. 10A at 4, 57)

Dr. Valko prescribed his previous daily dose of Vyvanse 240 mg, left Prozac unchanged, discontinued Risperdal, and increased Seroquel to 300 mg twice per day for a daily dose of 600 mg. (St. Ex. 10A at 4, 57)

Testimony of Dr. Barzman

394. Dr. Barzman testified:

> So the Risperdal is stopped, and Seroquel is started. I just think my concern would be the risk for any withdrawal effects of stopping the Risperdal.
>
> Even though they are both antipsychotics, unless there's some major, urgent reason for some reaction that we need to stop the Risperdal right now, it's best to do a cross titration.
>
> And then since Seroquel doesn't bind as strongly to Dopamine receptors, I wonder if this could lead to some withdrawal dyskinesia.
>
> Q. [By Ms. Snyder] And what is withdrawal dyskinesia?
>
> A. It presents similar to tardive dyskinesia. It's from withdrawal to the medication, but it should go away.

(Tr. at 394)

Dr. Barzman further criticized prescribing Vyvanse 280 mg per day as too high, and noted that it has not been studied at that dosage level. (Tr. at 394) Dr. Barzman further testified that it could be dangerous at that dosage: "Dangers would be like cardiovascular system could be in danger. You could look at problems with the heart, so tachycardia, other issues. Seizures." (Tr. at 395)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 10

395. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 10. (Tr. at 395)

Dr. Valko's Conclusions Regarding Patient 10

396. Dr. Valko emphasized how very difficult Patient 10 was to treat. Dr. Valko further testified that Patient 10's violent behavior would change ODD to a Conduct Disorder. (Tr. at 737)

Patient 11

397. Patient 11 is a male born in 2002.[48] He first visited Dr. Valko's practice on July 17, 2007, when he was five years old and was seen by Sujean Meine, LISW, MSW, LICDC. Ms. Meine documented the following as Patient 11's chief complaint.

> [Patient 11] is a five year old male Caucasian who was referred to Valko and Associates per Police Officer, Zolciak from Lucas County. [Patient 11] ran away from home and has been a behavioral problem for a long period of time. His mother * * * reports [Patient 11] has tried to choke himself and has threatened to kill his mother in her sleep and threatened to kill his fish and made threats to harm his brother and sisters. His mother reports [Patient 11] used to hurt the dogs by sticking things in their rectums, ears and noses. He has cried when a pet bug died and on the other hand has been seen tearing live bugs apart. [Patient 11] does not sleep at night and his mother reports he moves about the house sleep walking when he does sleep. During his sleep walks he eats sugar and urinates in the corner and on his dog and siblings. [Patient 11's] mother reports she has received negative reports from his pre-school but no reports of violent behaviors like he demonstrates at home. He reportedly has put his hand through glass three times recently when things did not go his way.

(St. Ex. 11A at 5)

In addition, Patient 11's mother reported that his biological father is serving a life term in prison and that there are four generations of men incarcerated on his paternal side. In addition, she reported that "[h]is developmental stages were all accelerated for his age." (St. Ex. 11A at 5) In addition, the mother reported that he "threatens suicide daily if things do not go his way." (St. Ex. 11A at 6) Ms. Meine found that the mother's reports seemed

[48] The year of birth is erroneously listed on the first few progress notes as 1992. (St. Ex. 11A)

to contradict her observation of Patient 11 who appeared shy, quiet, and cooperative throughout the assessment, sat still in a chair, and "responded appropriately to all questions asked." (St. Ex. 11A at 5-6)

At the time of the initial assessment he was taking Xoponex and Pulmocort for asthma as well as melatonin 3 mg at bedtime. (St. Ex. 11A at 6)

Ms. Meine documented an Axis I diagnosis of Adjustment Disorder Unspecified 309.90. (St. Ex. 11A at 6)

7/19/07 – First Visit with Dr. Valko

398. Dr. Valko first saw Patient 11 on July 19, 2007. Dr. Valko's progress note states, in part, as follows:

> [Patient 11] sat quietly but fidgeted in his seat. He was appropriately dressed and appeared to be a healthy seven-year old boy.[49] [Patient 11's] mother proceeded to give the history of [Patient 11's] destructive and explosive behavior. She reported that [Patient 11] has run away several times, frequently plays with knives, and threatens to hurt himself as well as others. Of course the knives have been taken away from [Patient 11] but he tries to find other destructive ways to cause more concern. In addition, it has been recommended that [Patient 11] be locked in his room in order to prevent him from any further harm to himself or others. It is evident that [Patient 11's] mother has made every attempt with disciplinary action but has had no success to this date. There was an incident in [Patient 11's] daycare in which he literally, bit off a "chunk of a young girl's cheek, causing her permanent disfiguration." [Patient 11] appeared apathetic during the entire appointment as we discussed his behavior.
>
> [Patient 11's] mother stated that he "has been like this his whole life," referring to his angry outbursts and aggression. She noted that he throws temper tantrums in which she is able to control with discipline but then there is the extreme opposite in which he loses control and cannot be reasoned with in any manner. [Patient 11's] mother added that his biologically [sic] father is serving a life sentence in prison but didn't elaborate.
>
> I discussed the possibility of [Patient 11] having a seizure disorder. We also discussed the diagnosis of Intermittent Explosive Disorder. This has never been ruled out yet so it is something to seriously consider. I requested that [Patient 11] have an EEG done to determine if this is indeed a likely cause for his behavior. In addition, we agreed to initiate a trial of Depakote [125 mg to take one in the morning and two at bedtime], as noted above. This medication

[49] According to the records, Patient 11 was born in early 2002 and was five years old at this visit. (St. Ex. 11A at 8)

> will hopefully better manage [Patient 11's] angry outbursts, rage and aggressive behavior. We discussed target symptoms, benefits and potential adverse effects of this medication. [Patient 11's] mother will monitor him for these aspects and will call me if [Patient 11] has any complications with this medication.

(St. Ex. 11A at 8)

Dr. Valko diagnosed "Intermittent Explosive Disorder (312.34)" on Axis I and "R/O Seizure Disorder" on Axis III. He prescribed Depakote 375 mg per day. (St. Ex. 11A at 8)

Testimony of Dr. Valko

399. Dr. Valko testified that Patient 11 was referred to him by the police who told Patient 11's mother that he might be able to help Patient 11. Dr. Valko noted that it is "being polite" to characterize Patient 11's behavior as extreme, as the initial visit note indicates. Dr. Valko further testified that Patient 11's mother was most concerned about Patient 11's explosive rage, and the threats and damage he caused to his surroundings. Dr. Valko testified that he first diagnosed Patient 11 with Intermittent Explosive Disorder, which is "similar to what people would consider to be bipolar disorder or mood dysregulation disorder." (Tr. at 746) Dr. Valko further testified that the appropriate treatment for that is a mood stabilizer, and he initially prescribed Depakote. He testified that he tries to get a blood level of 85 to 110 mcg/mL for a patient with that diagnosis. (Tr. at 744-748)

8/6/07 Visit

400. At Patient 11's next visit on August 6, 2007, his mother reported that his behavior was much improved on the Depakote. He still became angry at times but he was no longer aggressive and no longer did things like break glass or strike out at others. She had not yet obtained an EEG but Dr. Valko noted that it "may be irrelevant except to assure that this was not a seizure disorder." Patient 11's medication regimen was left unchanged. The sole diagnosis was Intermittent Explosive Disorder on Axis I. (St. Ex. 11A at 9)

10/10/07 Visit

401. At Patient 11's next visit on October 10, 2007, Dr. Valko documented, in part:

> [Patient 11] was see[n] with his mother who was present throughout the entire appointment. He announced that he has not been doing well, and in fact, mother stated that he may be asked to leave his school (he is in kindergarten). Mother stated that his rage has been intense to the point where he attempted to strangle another student. She is very overwhelmed about school and home. Unfortunately the Depakote has not been helpful with a therapeutic dose (level was 100).

> After reviewing the various options, a decision was made to have a trial of the medication Risperdal. They were educated concerning the target symptoms as well as potential adverse effects, including possible appetite changes, EPS and TD. Mother was very agreeable to a trial. She will have benadryl at home if necessary.
>
> Mother understands that we are starting at a very low dose. She also understands that if she has any questions or concerns, to contact this office.

(St. Ex. 11A at 11)

Dr. Valko discontinued Depakote and added Risperdal 0.25 mg twice per day. Patient 11 was to return in one week. (St. Ex. 11A at 11)

Dr. Barzman's Report

402. In his report, Dr. Barzman noted that Risperdal was started but no metabolic labs were ordered. (St. Ex. 17 at 54)

Subsequent Visits through 1/29/08

403. At his next visit on October 18, 2007, Patient 11's mother reported that his behavior had improved a great deal, that he had no explosive outbursts at home "with no holes in the wall all week," had not been to the principal's office all week, and even earned a sticker for good behavior. Dr. Valko continued the Risperdal unchanged. He added an Axis I diagnosis of ADHD Combined to the previous diagnosis of Intermittent Explosive Disorder. (St. Ex. 11A at 12)

404. On November 13, 2007, Dr. Valko increased Patient 11's dose of Risperdal to 0.5 mg in the morning and 0.75 mg at bedtime and added DDAVP 0.1 mg at bedtime on a report that Patient 11 "got in the habit of urinating on family members, especially his sisters, in the middle of the night." Dr. Valko also noted that it would be helpful for his agitation and concentration issues as well as bedwetting. The mother was instructed to have his sisters' room locked at night to prevent this behavior. (St. Ex. 11A at 13)

405. Two visits later, on January 29, 2008, Patient 11's mother reported that Patient 11 was falling asleep at kindergarten and did not like his teacher because she would not let him take naps. In addition, Dr. Valko documented, "Mom states that [Patient 11] is having one explosive outbreak everyday following his evening dose of Risperdal. It can last up to 25 minutes. She says he screams 'I'm going to kill myself,' 'I'm going to kill you,' and bangs his head against a wall, etc." (St. Ex. 11A at 15)

Dr. Valko increased Patient 11's Risperdal to 0.5 mg three times per day for a daily dose of 1.5 mg, added Concerta 18 mg in the morning, and continued DDAVP unchanged. (St. Ex. 11A at 15)

4/30/08 Visit

406. On April 30, 2008, Patient 11's mother reported that he was doing better, that Risperdal had helped with Patient 11's rage and impulsiveness, but that he was still having "breakthroughs." Dr. Valko noted that "[h]e had four days in a row of breakthrough; for example, he suddenly bit his chaperone on a field trip because she wasn't giving him enough attention. He then realized what he did and apologized." Risperdal 3 mg per day, Concerta 18 mg in the morning, and DDAVP 0.1 mg at bedtime were left unchanged. (St. Ex. 11A at 17)

1/6/09 Visit

407. Nine months later on January 6, 2009, Patient 11 was being prescribed Concerta 54 mg in the morning and Risperdal 1.0 mg four times per day. Mother reported noticing "a great benefit with the Concerta"; however, when Patient 11 comes home from school and the Concerta wears off he "goes back to his old self." Dr. Valko increased the Concerta dose to 54 mg twice per day for a total daily dose of 108 mg. Patient 11 weighed 50 pounds at that visit. (St. Ex. 11A at 22)

Testimony of Dr. Barzman

408. Dr. Barzman testified that he was concerned about the high dose of Concerta prescribed on January 6, 2009. (Tr. at 396)

Testimony of Dr. Valko

409. Dr. Valko testified that he added a second dose of Concerta because "the Concerta was actually helping with some of his impulse issues that were leading to his, you know, major aggression issues, so to try to help the mom with that, we added a second dose in the afternoon." (Tr. at 748-749)

410. Dr. Valko acknowledged that a daily dose of Concerta 108 mg exceeds the FDA recommended daily dose. (Tr. at 209-210)

3/4/09 Visit

411. On March 4, 2009, Dr. Valko discontinued the afternoon dose of Concerta and added Ritalin 10 mg at 4:00 p.m. with the hope that it would affect "his appetite less." (St. Ex. 11A at 23)

6/2/09 Visit

412. At Patient 11's visit on June 2, 2009, he was taking Risperdal 1 mg three times per day and Concerta 108 mg in the morning.[50] Patient 11 weighed 50 pounds at this visit. Patient 11's mother reported that Concerta was not having much effect and that Patient 11 was extremely active and talkative. She asked that something be done because "she can't take him like this all summer." Dr. Valko suggested increasing Patient 11's dose of Concerta and mother agreed. (St. Ex. 11A at 25)

6/18/09 Visit

413. At Patient 11's next visit on June 18, 2009, Dr. Valko increased Concerta to 144 mg in the morning (2 x 54 mg + 36 mg). He continued Risperdal 1 mg three times per day, Prozac 20 mg in the morning. Dr. Valko also added OCD as an Axis I diagnosis. (St. Ex. 11A at 26) According to the medication flowsheet, Dr. Valko also added Cogentin 0.5 mg twice per day. (St. Ex. 11A at 3)

Dr. Barzman's Report

414. In his report, Dr. Barzman stated that Prozac had been added to address Patient 11's many obsessions and compulsions; "[h]owever, obsessions and compulsions may be increased due to increased Concerta." (St. Ex. 17 at 55)

8/27/09 Visit

415. Patient 11 next visited Dr. Valko on August 27, 2009. At that time he appeared very hyperactive in the office. Dr. Valko further documented:

> Mother is very overwhelmed due to the fact that he is still stealing, only eating crunchy foods, has multiple obsessions, and overall is not listening.
>
> We reviewed all of his medications. Risperdal does not seem to be helping much, so we will lower the Risperdal. On occasion he has a stiff jaw from the Risperdal, so hopefully this will no longer occur. We will substitute Focalin for Concerta, hoping that we can increase the dose to help with [h]is obsessions but not interfere with his appetite. We will also increase his Prozac [to 40 mg in the morning] due to his obsessions.
>
> We reviewed all of his medications, including the target symptoms as well as potential adverse effects. Mother seemed to understand the risks and benefits, and will monitor appetite, sleep, as well as for EPS or TD. She will also work

[50] Ritalin was also listed on the progress notes for this visit and the next; however, according to the medication flowsheet, it was prescribed only once, on March 4, 2009. (St. Ex. 11A at 2-4)

> with the school to monitor how he is doing with his ability to focus and concentrate.

(St. Ex. 11A at 27)

Risperdal was lowered to 1 mg twice per day, Concerta was discontinued, Focalin XR 60 mg in the morning was added, Prozac was increased from 20 mg to 40 mg, and Cogentin 0.5 mg twice per day was continued. Patient 11 weighed 51 pounds at that visit. He was to return in two weeks. (St. Ex. 11A at 3, 27)

Testimony of Dr. Barzman

416. Dr. Barzman testified that Dr. Valko made three medication changes at once on August 27, 2009, "[s]o the concern is not knowing what is causing a problem, what's helping." (Tr. at 396-397) Dr. Barzman testified that only one change should be made at a time if that is possible so you can tell if the change is helpful or problematic. Dr. Barzman further testified that Focalin 60 mg is a high dose. (Tr. at 397-398)

417. Noting that Dr. Valko had lowered Patient 11's Risperdal dose because of occasional stiff jaw, Dr. Barzman testified, "So that can be an extrapyramidal stimulant or dystonia, and lowering the Risperdal makes sense to help that." (Tr. at 397)

Testimony of Dr. Valko

418. Dr. Valko testified that Patient 11's mother reported that Risperdal had not seemed helpful, so Dr. Valko started lowering the dose. In addition, Patient 11 had occasionally experienced a stiff jaw which Dr. Valko testified was an extrapyramidal symptom of Risperdal. Dr. Valko indicated that he had prescribed Cogentin to help alleviate extrapyramidal symptoms such as a stiff jaw, stiff neck, or an oculogyric crisis. (Tr. at 213, 753-755)

Additionally, Dr. Valko "flipped from the Concerta to Focalin, because Focalin is that medication that's supposed to have less issues with appetite and sleep." (Tr. at 754)

419. When asked why he had made multiple medication changes at once, Dr. Valko testified that he had made two small changes to Patient 11's regimen—he lowered the Risperdal dose, and he changed from one Ritalin-based medication to another.[51] (Tr. at 755-756)

When asked if it is his practice to make that many changes at one appointment, Dr. Valko testified that Patient 11 was difficult, Patient 11's mother was difficult, "and you want to try to help the child do better to help stop a lot of that conflict." (Tr. at 756-757) Dr. Valko further testified that he asked them to return in two weeks because his level of

[51] Dr. Valko also doubled Patient 11's dose of Prozac from 20 mg in the morning to 40 mg in the morning. (St. Ex. 11A at 27)

Risperdal would be coming down and Dr. Valko wanted to see how he was doing on the Focalin. (Tr. at 757; St. Ex. 11A at 27)

9/8/09 Visit

420. In his September 8, 2009 progress note, Dr. Valko documented:

> [Patient 11] had started focalin and it did not work for him at all. He was very restless over the weekend and his mother expressed that he has had a lot of ticks (sic) and he continued talking for 48hrs straight. He was given 5 Benadryls and nothing worked for him. His obsessive behavior was greatly increased and after rearranging his room many times he made a mess of the house and could not be calmed down.
>
> The rest of the medications were working well. He was dressed casually and was restless in the chair. He was cooperative and pleasant and inattentive for most of the visit.
>
> I decided to discontinue Focalin, Risperdal and Cogentin and begin on Concerta again. I also added Trazodone since he is having a lot of problems sleeping. We discussed the side effects of Trazodone (priapism) and he is returning in 1 week to check on his medication.

(St. Ex. 11A at 28)

Dr. Valko discontinued Risperdal, Cogentin, and Focalin, and added Concerta 144 mg in the morning, Trazodone 50 mg with instructions to take one or two at bedtime, and continued Prozac 40 mg in the morning. (St. Ex. 11A at 28)

9/17/09 Visit

421. Patient 11 next saw Dr. Valko on September 17, 2009. This is the last visit documented in Dr. Valko's medical record. The progress note states, in part:

> [Patient 11] had an episode of "withdrawal Dyskinesia" after discontinuing the Risperdal due to his hyperactivity and lack of sleep before. It was very traumatic for his mother and since the nurse on the phone had not been very helpful, she had decided to continue the Risperdal and Cogentin and it immediately helped with symptoms and she had not stopped it since that day. [Patient 11] was able to sleep for 10 hours after taking Risperdal and [he] has been doing much better lately. He still has some obsessive behavior, however his mother does not want to begin Prozac and she believes as long she does not have experience (sic) the side effect of the withdrawal again, she will deal with the situation.

> [Patient 11] was dressed casually, had good eye contact and stayed in his chair for all the appointment. He was attentive and cooperative and denied any side effects of sleep and appetite change, EPS or TD.
>
> I am continuing the Risperdal and Cogentin to avoid any of the withdrawal symptoms and his agitation and behavioral control. I am keeping his Concerta at the same dosage [since] it has been helpful for his attention in school. They are returning in 4 weeks and they are aware to contact the office with any questions or problems.

(St. Ex. 11A at 29)

Dr. Valko prescribed Risperdal 1 mg twice per day, Cogentin 0.5 mg twice per day, and reduced Concerta to 90 mg in the morning (54 mg + 36 mg). (St. Ex. 11A at 3, 29)

Testimony of Dr. Barzman

422. Dr. Barzman testified that Patient 11 appears to have experienced withdrawal symptoms after the Risperdal was stopped, so Risperdal and Cogentin were continued. Dr. Barzman further testified that Risperdal should be weaned and not discontinued suddenly to prevent withdrawal dyskinesia. (Tr. at 398-399)

Testimony of Dr. Valko

423. Dr. Valko testified that after Patient 11 was down to 2 mg per day "a decision was made that we would try to stop it at that point, and I stopped it too soon, and I should have weaned further. So because we stopped it too quickly, he fully had what we were calling a withdrawal dyskinesia, and so therefore we increased -- we restarted the Risperdal." (Tr. at 758)

9/18/09 Note

424. A note dated September 18, 2009, on Patient 11's medication flowsheet states, "Mother called stating Pharmacy refused to fill the rest of [Patient 11's] scripts and that they felt the amount Dr. Valko was giving him was lethal. Told mom to take the script to fill it elsewhere." (St. Ex. 11A at 4)

Testimony of Dr. Valko

425. Dr. Valko acknowledged that a pharmacy had refused to fill a prescription for Patient 11 because they felt the amount prescribed was lethal, and that Dr. Valko responded that Patient 11's mother should take it to a different pharmacy. Dr. Valko testified that that would happen about once a year, and that he had encouraged pharmacists to contact his office if they have any concerns about a prescription. (Tr. at 860-861; St. Ex. 11A at 4)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 11

426. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 11. (Tr. at 399)

Dr. Valko's Conclusions Regarding Patient 11

427. Asked if there was anything else he wanted to Board to know about his treatment of Patient 11 that had not already been discussed, Dr. Valko noted that he ordered an EEG but the patient never got it. He also emphasized that the mother had been difficult in that she would stop and start meds without first discussing the changes with Dr. Valko, and would fail to follow through with labs. Dr. Valko added that he had had difficulty with Patient 11's mother canceling appointments to the point where Patient 11 would run out of medication. (Tr. at 750, 759-760)

Dr. Valko also referred to an article titled "Preschoolers with ADHD May Benefit from Stimulants," published in Psychiatric New on December 15, 2006. The article indicates that children from 3 to 5.5 years old appeared to benefit from low doses of methylphenidate. (Resp. Ex. L; Tr. at 760)

Patient 12

2/7/06 Initial Assessment

428. Patient 12 is an adult, male patient born in 1970. He was living at a facility for autistic adults and had been there since 1989. He was first seen at Dr. Valko's practice on February 7, 2006, by Sujean Meine, LISW, MSW, LICDC. Ms. Meine noted that Patient 12 had been referred to Dr. Valko by Patient 12's primary care physician. Patient 12 was noted to have diagnoses of Autistic Disorder (299.0) and PICA (307.52) on Axis I, Moderate Mental Retardation (318.00) on Axis II, Encopresis, Enuresis, Bulimia, and Weight Loss on Axis III, and to lack a major support system on Axis IV. His GAF was 35. (St. Ex. 12A at 5-6)

The initial assessment indicated that Patient 12's history included clothes tearing, general property destruction, outbursts with aggression and self-injurious behaviors, and obsessions related to food and meals. In 1991 he underwent "a small bowel resection due to an obstruction caused by ingesting pillow stuffing." The staff at Patient 12's facility was at that time concerned about Patient 12 vomiting and recently losing 15 pounds. (St. Ex. 12A at 5-6)

His current medications were listed on the medication flowsheet as Celexa 60 mg in the morning, Clozapine 50 mg twice per day,[52] Cogentin 1 mg twice per day, Remeron 30 mg at bedtime, Klonopin 1 mg in the morning and 2 mg at bedtime, Luvox 50 mg in the morning "with increase to BID," and Seroquel 400 mg twice per day. (St. Ex. 12A at 5-6)

3/2/06 – First Visit with Dr. Valko

429. Patient 12 first saw Dr. Valko on March 2, 2006. Dr. Valko documented in his progress note:

> [Patient 12] was seen with his case worker, who was present throughout the entire session. [Patient 12] was quiet through the whole session, and had poor eye contact. He would look down once he made eye contact. He kept observing around the room. Whenever he was asked a question, he would reply with "yes". He sees Dr. Pierce as his primary care physician.
>
> Case worker mentioned that [Patient 12] has OCD. He obsesses on excessive self abuse and vomiting, which happens randomly at anytime. He also regurgitates and ruminates a lot. He was started on Luvox on 2/25/06 to help with his OCD. Case worker noted that [Patient 12] had a history of PICA (ate part of pillow), but doesn't do it any more.
>
> When asked, case worker noted that [Patient 12] hasn't had an EEG for the last 6 months, and he also hasn't seen a neurologist. We recommended having an EEG on [Patient 12].
>
> Case worker stated that in spring of 2004, [Patient 12] was started with Clozaril for his vomiting, and it worked out well, but when it was started back again in 2005 it didn't work as well. Case worker noted that [Patient 12] has a lot of energy throughout the day, and he never becomes sedated. After reviewing the medication, we are going to discontinue Clozapine. We are increasing the dose of Luvox to 50mg twice a day starting on 3/11/06.
>
> We are going to discontinue weekly CBC for [Patient 12]. It was recommended to have [Patient 12] weighed weekly at his residence.

(St. Ex. 12A at 8)

His medications on March 2, 2006, were Celexa 60 mg in the morning, Cogentin 1 mg twice per day, Remeron 30 mg at bedtime, Klonopin 1 mg in the morning and 2 mg at bedtime, and Luvox 50 mg twice per day beginning on March 11, 2006. Clozapine was discontinued. (St. Ex. 12A at 8)

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[52] Notice is taken that clozapine is the generic name for Clozaril. They are used interchangeably in the hearing record and this report. (See, U.S. Nation Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/ meds/a691001.html>, accessed January 14, 2020)

Testimony of Dr. Barzman

430. Dr. Barzman initially expressed concern that Dr. Valko simultaneously prescribed two serotonin reuptake inhibitors ("SSRIs"), Celexa and Luvox, to Patient 12. However, he noted that the Luvox dose increased over a few visits and the Celexa was reduced and then discontinued. Accordingly, Dr. Barzman believes that Dr. Valko had been cross-titrating those medications to substitute Luvox for Celexa and withdrew that criticism. (Tr. at 400-402; St. Ex. 12A at 8-11)

Testimony of Dr. Valko

431. Dr. Valko testified that Patient 12 is a special-needs adult patient who resides at a facility that specializes in working with autistic adults. Dr. Valko testified that, in addition to autism, Patient 12 also had a moderate intellectual disability, meaning his IQ was 60 to 70 with 100 being average. Dr. Valko further testified that Patient 12 also had many obsessions and compulsions. He would also eat non-food objects, a condition called PICA, "defecate in places that he shouldn't, and uncontrollably. He would urinate on himself, and he would force himself to vomit multiple times during the day." Dr. Valko further testified that the vomiting was due to bulimia and not from a medication issue. (Tr. at 761-764)

Dr. Valko testified that Patient 12 first presented on a number of medications—specifically, Celexa, Cogentin, Remeron, Klonopin, and Clozapine—and "that was the concern that the [Bittersweet Farm] staff had, and the guardian had, that with all these medicines he still wasn't doing well." Dr. Valko further testified that he discussed with Patient 12's guardian making multiple medication changes and focus more on Patient 12's OCD. The hope was that, by better treating the OCD, they may alleviate Patient 12's PICA and some of his vomiting, which Dr. Valko testified may or may not have been secondary to OCD. (Tr. at 765-766)

432. Dr. Valko testified that Luvox is an SSRI, like Celexa, but it is only FDA approved to treat OCD. Dr. Valko further testified that it can take four to six weeks to get the Luvox dose up to full strength, and if Celexa was stopped too suddenly, then Patient 12's vomiting and obsessions could have worsened. (Tr. at 766)

Subsequent Visits

433. On March 29, 2006, Dr. Valko discontinued Cogentin, added Seroquel 400 mg twice per day, and increased Luvox to 50 mg in the morning and 100 mg at bedtime. (St. Ex. 12A at 9)

434. On April 12, 2006, Dr. Valko lowered Patient 12's Celexa to 40 mg in the morning and increased Luvox to 100 mg twice per day. (St. Ex. 12A at 10)

435. On May 3, 2006, Dr. Valko discontinued Celexa, increased Luvox to 200 mg in the morning and 300 mg at bedtime, and changed the dose timing (but not the daily dose) for Seroquel to 400 mg to take two at bedtime. Dr. Valko also made reference to discontinuing Lunesta, which is noted on the medication flowsheet but was not on the medication lists on the progress notes. (St. Ex. 12A at 1, 8-11)

436. On May 17, 2006, Dr. Valko increased Luvox to 300 mg in the morning and 300 mg at bedtime. (St. Ex. 12A at 12)

437. On June 28, 2006, Dr. Valko decreased Patient 12's dose of Luvox to 200 mg twice per day and added Prozac 20 mg in the morning. Patient 12 had an ongoing issue with vomiting daily which some notes indicate is voluntary. Dr. Valko noted that the Luvox did not seem to be helping. (St. Ex. 12A at 13)

438. On July 18, 2006, Dr. Valko lowered Patient 12's dose of Luvox to 100 mg and increased Prozac to 40 mg in the morning. Dr. Valko noted that he is hopeful that Prozac will help more with Patient 12's OCD symptoms. (St. Ex. 12A at 17)

439. On August 8, 2006, Dr. Valko discontinued Luvox and increased Prozac to 60 mg in the morning. (St. Ex. 12A at 18)

440. On September 5, 2006, Dr. Valko increased Patient 12's Prozac to 40 mg twice per day. Vomiting continued to be a problem, as well as obsessions. Dr. Valko added a diagnosis of OCD to Patient 12's Axis I diagnoses. He spoke to the caretaker about possibly adding Clozaril to Patient 12's regimen. (St. Ex. 12A at 19)

9/13/06 Visit

441. On September 13, 2006, Dr. Valko added Clozaril 25 mg at bedtime. Dr. Valko noted that a blood panel indicated that Patient 12's WBC was normal, although he was anemic which had been an ongoing problem. His progress note states that he discussed the target symptoms and potential adverse effects with Patient 12's staff. (St. Ex. 12A at 2, 21)

Testimony of Dr. Barzman

442. Dr. Barzman testified that Clozaril is a second-generation antipsychotic with the potential to cause agranulocytosis as a potential side effect, which is a lowering of the absolute neutrophil count, as well as seizures, myocarditis, and eosinophilia, which is an increase in the number of eosinophils. (Tr. at 292-299) Dr. Barzman further testified that he could find no indication for prescribing Clozaril to Patient 12: "I didn't see any psychosis or violence documented, or aggression, so I couldn't find the specific indication for Clozaril." (Tr. at 402-403) Dr. Barzman further testified:

> Clozaril has potential risks with it, which could be serious. So you really need a significant indication to start it.

Q. [By Ms. Snyder] And again, by "significant indication", like what?

A. So you can look at treatment resistant schizophrenia, bipolar disorder, and I've also seen it prescribed for aggression, violence within the autistic population.

Q. And when you say "aggression", what would you expect -- what level of aggression would you expect to see in a patient's record if a patient were being prescribed Clozaril?

A. Very severe, almost to the point where they need to be in like a locked facility, constant aggression, injuring themselves, injuring other people.

(Tr. at 404)

Dr. Barzman further testified that the appropriate dosing range for Clozaril is as low as 12.5 mg per day up to 900 mg per day. Dr. Barzman testified that, by March 19, 2008, Dr. Valko was prescribing 1,200 mg of Clozaril per day which Dr. Barzman characterized as a high dose for any patient. (Tr. at 405)

Testimony of Dr. Valko

443. Dr. Valko testified that he added Clozaril in September 2006 to "to try to help [Patient 12] with his thoughts so that he wouldn't force himself to vomit and bang his head against the floor." Dr. Valko further testified that the staff at Patient 12's facility had also reported that Patient 12 did better on Clozaril in the past than he was doing on Seroquel. (Tr. at 222-223)

444. Dr. Valko testified that Clozaril is a second-generation neuroleptic (antipsychotic) like Risperdal and Seroquel which, like those medications, can cause extrapyramidal symptoms, tardive dyskinesia, and increased appetite. Dr. Valko further testified that Clozaril can also cause drowsiness, and that "[a]lmost everyone on Clozapine has drooling, even from a low dose, it just seems to be inherent." Moreover, Dr. Valko testified that it can cause a low white blood cell count and patients taking Clozaril must be monitored carefully. (Tr. at 220-221) Dr. Valko testified that he had never had a patient who was on Clozaril experience a low white blood cell count, and that the primary reason for doing the blood work was regulatory. Dr. Valko testified that FDA requirements necessitate that "if you don't get the blood count they can't fill the prescription." (Tr. at 225)

Subsequent Visits

445. The following changes were made to Patient 12's medication regimen:

- On October 4, 2006, Dr. Valko noted that Patient 12 was tolerating the Clozaril well and increased the dose to 100 mg at bedtime. (St. Ex. 12A at 23)

- On October 11, 2006, Dr. Valko noted that Patient 12 was tolerating Clozaril and was having none of the anticipated adverse effects such as drooling. He increased Clozaril to 150 mg at bedtime. (St. Ex. 12A at 24)

- On October 16, 2006, Dr. Valko increased Clozaril to 200 mg at bedtime. (St. Ex. 12A at 26)

- On November 1, 2006, Dr. Valko increased Clozaril to 400 mg at bedtime. (St. Ex. 12A at 28)

- On November 8, Dr. Valko decreased Seroquel to 400 mg at bedtime and increased Clozaril to 500 mg at bedtime. He stated that he had reviewed labs which were within normal limits. (St. Ex. 12A at 29-30)

- On November 15, 2006, Dr. Valko decreased Seroquel to 200 mg at bedtime and increased Clozaril to 100 mg in the morning and 500 mg at bedtime. (St. Ex. 11A at 31)

- On November 29, 2006, Dr. Valko discontinued Seroquel, increased Clozaril to 200 mg in the morning and 600 mg at bedtime, and added Trazodone 100 mg at bedtime to aid with sleep. Dr. Valko noted that labs were normal. (St. Ex. 12A at 33)

- On December 6, 2006, Dr. Valko increased Trazodone to 200 mg at bedtime. (St. Ex. 12A at 36)

- On December 20, 2006, Dr. Valko increased Trazodone to 300 mg at bedtime. (St. Ex. 12A at 39)

- On January 3, 2006, 2007, Dr. Valko increased Clozaril to 200 mg in the morning and 800 mg at bedtime. The prescriptions for Klonopin, Prozac, and Trazodone remained unchanged. (St. Ex. 12A at 42)

- On January 10, 2007, Dr. Valko increased Clozaril to 200 mg in the morning and 1,000 mg at bedtime. (St. Ex. 12A at 3, 43)

- Following January 10, 2007, Patient 12 remained on a regimen of Klonopin 3 mg per day (1 mg in the morning and 2 mg at bedtime), Prozac 80 mg per day split between two doses, Clozaril 1,200 mg per day (200 mg in the morning and 1,000 mg at bedtime), and Trazodone 300 mg at bedtime until April 18, 2007. (St. Ex. 12A at 43-57) On April 18, 2007, Dr. Valko reduced Trazodone to 200 mg at bedtime because Patient 12's sleeping had improved. (St. Ex. 12A at 59)

- On July 11, 2007, Dr. Valko added Cogentin 0.5 mg twice per day to control Patient 12's drooling, noted previously to be an adverse effect of Clozaril. On July

25, 2007, Cogentin was discontinued and Clozaril was decreased to 200 mg in the morning and 800 mg at bedtime, a total daily dose of 1,000 mg. (St. Ex. 12A at 72-74)

- On August 22, 2007, Dr. Valko discontinued Trazodone on a report that Patient 12 was sleeping well. (St. Ex. 12A at 76) He was maintained on a regimen of Klonopin 3 mg per day, Prozac 80 mg per day, and Clozaril 1,000 mg per day until January 23, 2008, when his Clozaril was decreased to 200 mg in the morning and 600 mg at bedtime for a daily dose of 800 mg. (St. Ex. 12A at 78-89)

- On or around March 19, 2008, Dr. Valko increased Clozaril to 1,200 mg per day again (200 mg in the morning and 1,000 mg at bedtime) on a report that Patient 12 was again losing weight and hitting himself, which had been issues in the past. This was the last visit documented in Dr. Valko's medical record for Patient 12. (St. Ex. 12A at 4, 92)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 12

446. Dr. Barzman testified that he could find no record of Patient 12's cardiac history in the chart or any cardiac screening ordered by Dr. Valko. (Tr. at 405-406)

447. Dr. Barzman acknowledged that he has never initiated Clozaril in his practice, although he has continued prescribing that medication for patients who were already receiving it. (Tr. at 519-521)

448. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 12. (Tr. at 406)

Dr. Valko's Conclusions Regarding Patient 12

449. Dr. Valko testified that he prescribed clozapine to Patient 12, and that he uses that medication on his patients when it is indicated. Dr. Valko described clozapine as a second-generation neuroleptic that is FDA-approved to treat schizophrenia, depression, and other conditions. (Tr. at 43-44) Dr. Valko further testified:

> It is considered not a first line medication, but more of a second or third line medication because it can cause agranulocytosis, which is lowering your white blood count, and so therefore you have to monitor them very closely.
>
> It's a very good medication as well. You use that for people who don't do well with other medications.

(Tr. at 44-45)

When asked if clozapine can cause heart complications, Dr. Valko replied, "Pretty much every medication can do that or not do that, I think. You don't have to do an EKG with it, there's no recommended anything like that for it. Some people worry about possible seizures with it, but no, I'm not as concerned about EKG issues." (Tr. at 45) However, Dr. Valko further testified:

> I don't prescribe it freely. You have to meet criteria for it. You have to have failed other medications, and then you have to monitor them.
>
> Initially you have to see them once a week and they have to have a blood draw, CBC, to make sure the white count did not drop. You do that for the first six months, and then after -- after month 6 through 12 they have to have blood drawn every other week.
>
> Once again, you cannot even fill the medication until that is drawn. And then from one year on they have to be seen on a monthly basis with a white blood count drawn at that time.
>
> So you have to have the blood draw. The blood draw has to go to what's called -- it's a national repository of -- I don't know, it's called REMS. I have no clue what that stands for.
>
> And you have to document that they did have their blood drawn, and then it goes -- the pharmacy has to look that up to make sure the blood draw is drawn, and then they can hand the medication over.

(Tr. at 45-46)

450. Dr. Valko testified that studies indicate that you can prescribe 2,000 to 3,000 milligrams of Clozaril per day to patients with moderate mental retardation and disabilities; however, he believes the maximum dose for a schizophrenic patient to be around 900 mg. (Tr. at 226)

451. Dr. Valko testified and stated in his report that he followed the standard of care for prescribing Clozapine that Dr. Barzman described. Patient 12 had blood tests every week for the first six months, every two weeks for the second six months, and once per month thereafter. Dr. Valko further stated that Patient 12 did well except for some drooling, which is a common side effect of Clozapine, even at low doses. Dr. Valko acknowledged that Patient 12 was taking a large dose of Clozapine but that that was the amount required to control Patient 12's symptoms. (Tr. at 772-773; Resp. Ex. A at 89-90) Based on information from Patient 12's staff, when Dr. Valko tried lowering the dose, "all his self-abusive behaviors returned, so we increased the dose back up." (Tr. at 773) Finally, Dr. Valko testified that all of Patient 12's absolute neutrophil counts were normal. (Tr. at 777)

Literature Referenced by Dr. Valko Regarding Clozapine

452. In his report, Dr. Valko identified a number of articles that he believes support his Clozapine prescribing to Patient 12:

- "Treatment-Resistance to Clozapine in Association with Ultrarapid CYP1A2 Activity and the C A Polymorphism in Intron 1 of the CYPIA2 Gene: Effect of Grapefruit Juice and low-dose Fluvoxamine,": Journal of Clinical Psychopharmacology, December 2001: 21 (6):603-607.

  Dr. Valko commented in his report, "Noted the need to adjust dose for various patients depending on how they metabolized clozapine."

- "Very High Cytochrome P4501A2 activity and non-response to Clozapine," Archives of General Psychiatry, 1998: 55 (11): 1048-1050.

  Dr. Valko commented in his report, "Noted that some patients metabolized Clozapine rapidly."

- "Optimizing Treatment with Clozapine," Journal of Clinical Psychiatry, 1998:59 (supplement 3): 44-48.

  Dr. Valko commented in his report, "Noted that in study they used dosages up to 1200 mg, but unfortunately the patients did not respond and their blood levels did not increase."

- "Nonresponse to Clozapine and ultrarapid CYP1A2 activity: clinical data and analysis of CYPIA2 gene," Journal of Clinical Psychopharmacology, 2004 Paril: 24(2): 214-219.

  Dr. Valko commented in his report, "May need to use higher dosages of Clozapine to achieve therapeutic response."

- "Factors affecting Interindividual differences in clozapine response: a review and case report," Human Psychopharmacology, March 2011.

  Dr. Valko commented in his report, "Noted that patients Clozapine dosage needs to be individualized to reach a therapeutic response."

- "Updated Practice Guidelines for use of Clozapine in Adult individuals with Intellectual Disabilities," authored by Jose de Leon; no publication information given.

  Dr. Valko commented in his report, "Noted cases where dosage of clozapine had to be increased above 1000 mg per day to achieve therapeutic levels."

(Resp. Ex. A at 91)

Patient 13

453. Patient 13 is a female born in 1960. She had been referred to Dr. Valko by a clinical psychologist. In a January 18, 2005 letter to Dr. Valko the psychologist noted that Patient 13 was being treated for chronic abdominal pain by a pain specialist that was complicated by a significant history of sexual abuse. The psychologist further wrote:

> Most recently, [Patient 13] has been experiencing an exacerbation of her depressive symptoms. I believe this is largely because her pain has been worse lately. She has been taking Zoloft, but was recently changed to Effexor by her family physician, Dr. Hazimah. When I saw her today, she had only taken the Effexor for five days, so we have not seen any effect thus far.
>
> In the time that I have been working with [Patient 13], I have found that she can be difficult to work with, because she is so very well-defended. However, she has dealt with many difficult situations and is currently really struggling. I hope that you can help find a more effective medication regimen for her.

(St. Ex. 13B at 1)

1/31/05 Initial Visit with Dr. Valko

454. Patient 13 first visited Dr. Valko on January 31, 2005, complaining of depression. In his progress note for her first visit, Dr. Valko stated:

> [Patient 13] was seen independent of any family member. She is able to review with me her understanding as to why she is being seen on this date.
>
> [Patient 13] is very concerned that she continues to be depressed. Her affect and mood were very restricted throughout. She had almost no eye contact. She describes herself as being very depressed. She notes problems with sleep, interest, energy and concentration as well.
>
> [Patient 13] had a trial of the medication Zoloft, taking up to 125 mg daily. She states that this was not helpful. She recently started Effexor, taking 75 mg daily.
>
> We reviewed the various options available for her. Due to the fact that she has chronic pain, as well as depression, I am recommending a trial of the medication Cymbalta. [Patient 13] was educated concerning the target symptoms as well as potential adverse effects (including nausea). She is agreeable to a trial. She understands that if she tolerates the 30 mg, I will increase the Cymbalta during the next appointment.

> [Patient 13] will be stopping the Effexor. She was educated concerning the potential difficulties of stopping the Effexor. Hopefully she will not experience any of the withdrawal type of symptoms since she is taking only 75 mg.
>
> [Patient 13] will continue with all of her previous support.

(St. Ex. 13B at 2)

In the medication list for that visit, in addition to Cymbalta 30 mg in the morning, Dr. Valko noted that she was receiving Duragesic Patch, Morphine Pump, Vicodin 10 mg three times per day, Trazodone 100 mg at bedtime, and Klonopin 1 mg at bedtime. (St. Ex. 13B at 2)

Dr. Valko diagnosed Major Depression, Single, Moderate on Axis I. (St. Ex. 13B at 2)

Testimony of Dr. Barzman

455. Dr. Barzman testified that opiates can cause a depressed mood. (Tr. at 408, 522)

Testimony of Dr. Valko

456. When asked if depression is a possible side effect of long-term opiate use, Dr. Valko testified that he does not believe that opiate pain medications directly cause depression. He testified that the pain the patients experience can have an effect—patients in more pain can be more depressed because of their pain and vice-versa—but the medications themselves do not lead to depression. (Tr. at 232-233)

457. Dr. Valko acknowledged that he diagnosed Patient 13 with depression and stated, "That's a Workers' Comp. diagnosis. So you have to use that diagnosis." (Tr. at 233) When asked to explain, Dr. Valko testified:

> So if they have more than just major depression, which many BWC people do have, if you treat them for that it will not be covered by BWC and their medications won't be covered by BWC, and then BWC will look at are you really treating the allowed condition, are you treating something else.
>
> There are people where I have petitioned to have conditions added, and there are people where if they are going to be -- if you find another diagnosis that isn't going to be added as their allowed condition that's second to their workplace injury, then you have to not charge BWC for that appointment and charge a third party insurance if they have it.

(Tr. at 234)

458. Dr. Valko testified that Patient 13's condition arose as a result of a terrible head injury, "She was actually T-boned by a Waste Management vehicle who ran a red light and T-boned her, and she had a horrible concussion and coup and contrecoup, which means the brain hit one side of the head and hit the other side of the head." Dr. Valko testified that she was very distrustful of people, and that "it took a good two years for her and I to come to a really good understanding, and the fact that it took that long for her to actually trust me." (Tr. at 783-784)

Subsequent Visits

459. On February 10, 2005, Dr. Valko increased Patient 13's dose of Cymbalta to 60 mg, and moved the dosing schedule from morning to bedtime on a report that the medication made her drowsy. She was told that if the medication keeps her awake she should return to taking it in the morning and call the office. (St. Ex. 13B at 3)

460. On February 24, 2005, Dr. Valko increased Cymbalta to 90 mg at bedtime. Patient 13 reported that she sometimes awakens at 4:00 a.m. and cannot go back to sleep. Dr. Valko added a second dose Trazodone 100 mg to take at 4:00 a.m. as needed. (St. Ex. 13B at 4)

461. On March 10, 2005, Dr. Valko noted that Patient 13 "feels that the Cymbalta is working and would be comfortable increasing the dose." Dr. Valko increased Cymbalta to 120 mg at bedtime. (St. Ex. 13B at 5)

462. On April 21, 2005, Dr. Valko increased Patient 13's dose of Trazodone to 100 mg at bedtime and 200 mg at 4:00 a.m. as needed, a daily dose of 300 mg. (St. Ex. 13B at 12, 174)

463. Two visits later on July 11, 2005, Patient 13 reported increased outbursts of temper, including being thrown out of a grocery store a month earlier for verbally harassing another customer. Patient 13 reported that it felt "like an out of body experience." She also reported "constantly yelling at her husband." Dr. Valko added Lunesta 1 mg to be used three days every two weeks. He reduced Cymbalta to 60 mg at bedtime and left Trazodone unchanged. (St. Ex. 13B at 15)

464. At her next visit on July 26, 2005, Dr. Valko added Prozac 20 mg in the morning to her regimen based on a report of continued depression. (St. Ex. 13B at 16)

465. At the next visit on August 1, 2005, he increased Prozac to 40 mg in the morning and reduced Cymbalta to 30 mg at bedtime. He also increased Trazodone and changed the dosing schedule to 50 mg at 1:00 p.m., 100 mg at bedtime, and 200 mg at 4:00 a.m. as needed, a daily dose of 350 mg. (St. Ex. 13B at 17)

466. On August 23, 2005, Dr. Valko discontinued Cymbalta and left the Trazodone, Lunesta, and Prozac unchanged. (St. Ex. 13B at 18) Patient 13 continued on this regimen until November 29, 2005. (St. Ex. 13B at 18-31)

467. On November 29, 2005, Patient 13 reported an improved mood but was having problems staying asleep at night due to "a mixture of pain, dreams and anxiety." Dr. Valko also noted, "She became quite insistent when asking to try Ambien." She reported that it had helped her in the past. Dr. Valko discontinued Lunesta and added Ambien CR 10 mg as needed for sleep. (St. Ex. 13B at 31)

468. On January 18, 2006, Patient 13 reported that she had stopped taking Prozac a week before because of weight gain and anxiety. Dr. Valko discontinued Prozac 20 mg twice per day and added Lexapro 10 mg in the morning.[53] He increased the dose to 20 mg in the morning on January 23, 2006 and decreased Trazodone to 100 mg at bedtime and 200 mg at 4:00 a.m. as needed. On March 30, 2006, he increased Lexapro to 30 mg in the morning. On May 2, 2006, he increased Lexapro to 40 mg in the morning and increased Ambien to 12.5 mg. On June 6, 2006, he added Wellbutrin XL 150 mg at bedtime. On June 22, 2006, Dr. Valko decreased Lexapro to 20 mg and increased Wellbutrin XL to 300 mg at bedtime. He discontinued Lexapro on July 20, 2006 and modified the Wellbutrin XL prescription to Wellbutrin SR 150 mg twice per day, leaving the daily dose at 300 mg. (St. Ex. 13B at 32-36, 38-40, 45)

Dr. Barzman's Report

469. Dr. Barzman noted in his report that the maximum recommended daily dose for Lexapro is 20 mg. Dr. Barzman also questioned why Patient 13 had been instructed to take Wellbutrin at bedtime because it can cause insomnia. (St. Ex. 17 at 35-36)

Testimony of Dr. Valko

470. Dr. Valko testified that he prescribed Wellbutrin to be taken at night because, first, Patient 13 was better about taking her nighttime medications than her morning medications and missed more doses in the morning. He added that Patient 13 had come to him with sleep issues and those issues were not exacerbated by taking Wellbutrin at bedtime. He further testified that all patients are different, and that she did not report any sleep difficulties caused by the Wellbutrin. (Tr. at 782-783)

Wellbutrin, Viibryd, and Serzone Prescribing

471. Dr. Valko continued prescribing Wellbutrin SR 150 mg twice per day through February 27, 2007. On May 29, 2007, he increased Wellbutrin SR to 150 mg in the morning and 300 mg at bedtime, a daily dose of 450 mg. He continued prescribing Wellbutrin SR 450 mg per day through October 13, 2009. On January 6, 2010, he increased Wellbutrin SR to 600 mg

[53] Dr. Valko testified that Lexapro is a serotonin reuptake inhibitor antidepressant. (Tr. at 235)

at bedtime, and continued prescribing that dose through March 12, 2012, when he instructed her to decrease her dose by 150 mg every two weeks and added Viibryd. On May 7, 2012, he discontinued Wellbutrin SR and prescribed Viibryd 40 mg in the morning, among other things. Wellbutrin was briefly restarted on January 14, 2013, and Viibryd discontinued but Wellbutrin was discontinued again on March 11, 2013 and Serzone 50 mg at bedtime was added. Serzone was increased to 100 mg at bedtime on March 18, 2013, and to 200 mg on May 14, 2013. Serzone 200 mg at bedtime continued until July 10, 2013, when it was discontinued and Wellbutrin SR 600 mg at bedtime was restarted and continued through April 28, 2014. On June 23, 2014, Dr. Valko noted that Patient 13 had discontinued Wellbutrin on her own. (St. Ex. 13B at 46-138; St. Ex. 11A at 1-25)

Testimony of Dr. Barzman

472. Dr. Barzman noted that on January 3, 2014, Dr. Valko prescribed, among other things, Wellbutrin SR 600 mg at bedtime. Dr. Barzman testified that, at that high dose, he would be concerned about the increased risk of seizure. Dr. Barzman also testified that Wellbutrin can cause insomnia when taken at night. Moreover, Dr. Barzman noted that Dr. Valko was also prescribing Ambien 12.5 mg to aid sleep, so she is taking one medication to help her sleep, and one medication that is causing insomnia. (Tr. at 408-409)

Dr. Barzman further testified that Wellbutrin SR can be given twice per day, but typically not at doses over 200 mg each because of the increased risk for seizure. (Tr. at 409-410)

Testimony of Dr. Valko

473. Dr. Valko testified that Wellbutrin did not add to Patient 13's issues with insomnia and that she had wanted to take it at bedtime. He disagreed that it had been inappropriate for him to prescribe it to be taken at bedtime. (Tr. at 239-240)

474. Dr. Valko testified that he did not know what the FDA maximum recommended daily dose of Wellbutrin was in 2014 but stated that he has seen research that indicates that the average daily dose of Wellbutrin was 450 milligrams. Dr. Valko further testified that he is certain that he had read that research prior to January 2014. (Tr. at 237-239)

Subsequent Visits

475. By March 11, 2015, Patient 13's diagnosis had remained unchanged (Major Depressive Disorder) and Dr. Valko was prescribing Methylphenidate 10 mg three times per day, Ambien (zolpidem) 12.5 mg at bedtime, Xanax (alprazolam) 1 mg four times per day, and Brintellix 10 mg, to increase in two weeks to 20 mg. Among other things, Patient 13 complained of having no appetite and losing weight and reported that "her heart rate dips to 38 bpm at night," and Dr. Valko noted that it was 50 beats per minute in the office that day. The note then states that she was counseled on the severe consequences of inadequate calorie intake. (St. Ex. 12A at 94-97)

476. By June 30, 2016, the last visit documented in Patient 16's chart, Dr. Valko had added an Axis I diagnosis of ADHD and to rule out Bipolar II Disorder. She received oxycodone, presumably from her pain medicine provider, and Dr. Valko prescribed Xanax 2 mg four times per day for anxiety, Concerta 72 mg per day for focus, Trazodone 300 mg at bedtime for sleep, and Wellbutrin XL 450 mg at bedtime for depression. (St. Ex. 13A at 147-152)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 13

477. With reference to a statement in his report that Dr. Valko had refused to prescribe Lunesta on May 23, 2005, "due to concerns about causing addiction and not enough data yet," Dr. Barzman acknowledged that that shows prudence and caution on Dr. Valko's part. (Tr. at 523; St. Ex. 17 at 34)

478. In his report, Dr. Barzman stated, "Concern Serzone was stopped in US by FDA and can cause liver failure." (St. Ex. 17 at 40; emphasis omitted) However, Dr. Barzman testified that the medication is still available generically. Moreover, Dr. Barzman acknowledged that the progress notes dated March 18 and April 8, 2013, indicate that Patient 13's mood improved on that medication. (Tr. at 526; St. Ex. 13B at 150-153)

479. Dr. Barzman testified that the stimulant medications used for treating ADHD can also be used for treatment resistant depression. (Tr. at 281-282)

480. Dr. Barzman testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 13. (Tr. at 411)

Dr. Valko's Conclusions Regarding Patient 13

481. Dr. Valko testified that one recurring issue with Patient 13 was that, if she thought a new medication was helping, she would increase the dose herself without first talking to him. Dr. Valko testified that he had admonished her not to do that. For example, when she was taking Lexapro 30 mg as prescribed on March 30, 2006, she increased it to 40 mg on her own volition. At the May 2, 2006 visit she indicated that the increased dose was helping her. Dr. Valko testified that he explained the risks and benefits and prescribed the increased dose to her. (Tr. at 786-787) In his report, Dr. Valko indicated that the Lexapro was lowered a short time afterward when the higher dose ultimately proved unhelpful. (Resp. Ex. A at 94; St. Ex. 13B at 38-40)

    Dr. Valko noted that this increase took place in 2006. He testified that, in 2012, the FDA warned that medications such as Lexapro and Celexa could cause cardiac issues and recommended not to go above a certain dose. Dr. Valko further testified that this event happened six years before then and complied with the standard of care as in effect at that time. (Tr. at 787)

Letter of Support from Patient 13

482. In an August 28, 2018 letter, Patient 13 stated:

> I have been seeing Dr. Valko for many years. He has been the first doctor that has helped my depression and anxiety. He always told me the risks of my medications, also the benefits. I feel comfortable with my dosages and especially the Wellbutrin. I did not get any relief until he put me on my current dosage. I am always included in the discussions of my dosages and can always contact him if there is any problems.

(Resp. Ex. F at 5)

Patient 14

3/8/04 Initial Assessment

483. Patient 14, a male born in 1962, was first seen at Dr. Valko's practice on March 8, 2004 by Sue Rutledge-Hehl, LISW, MSW. The initial visit note indicates that Patient 14 lived in a group home and was profoundly mentally disabled with autistic traits. He was non-verbal. The note further indicates that his case workers reported that he was currently the most stable that he had been in years: "Previously, he was self abusive, pounding his head [on] the wall, he had difficulties with appetite and food, some aggression towards others, all day episodes of taking off his [clothes], and extreme anxiety." They reported that he continued to have some minimal anxiety in social settings and large crowds but was doing well overall. He had some ritual behaviors that he did on a regular basis that involve touching and counting things in a certain manner. Patient 14 had resided in a children's facility prior to moving to the adult facility. (St. Ex. 14C at 103-104)

    Patient 14 was being transferred to the care of Dr. Valko for medication management. Two years earlier he had been hospitalized because of out-of-control self-abusive behaviors. He was placed on Zyprexa and had vastly improved. In addition to Zyprexa, Patient 14 also takes Detrol and Prevacid. He was diagnosed on Axis I with OCD.[54] (St. Ex. 14C at 104)

484. It is apparent from Dr. Valko's medication flowsheet that he treated Patient 14 continuously following his initial visit in March 2004; however, the hearing examiner was unable to find any follow-up notes earlier than a January 17, 2008 progress note from Dr. Valko. However, the medication flowsheet indicates that Dr. Valko maintained Patient 14 on Zyprexa and Trazodone during that time. (St. Ex. 14C at 2-3, 106)

[54] Dr. Valko testified that Zyprexa is a second-generation neuroleptic, otherwise known as an antipsychotic. (Tr. at 245)

1/17/08 Visit

485. On January 17, 2008, Patient 14's diagnoses on Axis I were OCD (300.30) and Bipolar Disorder (by history), and his Axis II diagnosis was "profound mental retardation." Dr. Valko prescribed Zyprexa 10 mg in the morning and 15 mg at bedtime, and Trazodone 200 mg in the morning and 200 mg at 10:00 p.m. (St. Ex. 14C at 106)

Subsequent Visits through April 2010

486. According to the medication flowsheet, Dr. Valko maintained Patient 14 on Zyprexa, which gradually increased to 15 mg in the morning and 20 mg at 7:00 p.m., through April 2010. During this time he also prescribed Trazodone, Ambien, Cogentin, and Prozac. (St. Ex. 14C at 2-4)

April 13, 2010 Visit

487. On April 13, 2010, Patient 14's caseworker reported that Patient 14 had not been doing well, that he had been more manic, taking his clothes off throughout the day, not sleeping, not eating, and agitated. Dr. Valko discontinued Zyprexa and added Seroquel 200 mg in the morning, 200 mg at 4:00 p.m., and 400 mg at bedtime for a total daily dose of 800 mg. He also prescribed Trazodone 200 mg in the morning and 400 mg at 7:00 p.m., and Cogentin 2 mg twice per day. (St. Ex. 14C at 65)

Testimony of Dr. Barzman

488. Dr. Barzman testified that the FDA maximum recommended daily dose of Seroquel is 800 mg. (Tr. at 412)

Testimony of Dr. Valko

489. Dr. Valko testified that Seroquel is a neuroleptic similar to Risperdal and Zyprexa, which Patient 14 had previously taken, "that is supposed to help with thoughts, with mood, and with agitation." (Tr. at 795)

4/27/10 Visit

490. On April 27, 2010, Patient 14's caseworkers reported continued behavior issues during the day. Dr. Valko increased Seroquel to 300 mg in the morning, 300 mg at 4:00 p.m., and 600 mg at bedtime, for a total daily dose of 1,200 milligrams. Trazodone and Cogentin were continued unchanged. (St. Ex. 14C at 4, 63)

Subsequent Visits

491. At Patient 14's next visit on May 27, 2010, Dr. Valko prescribed, among other things, Seroquel XR 300 mg twice per day. (St. Ex. 14C at 38) This was later increased to 400

mg twice per day on August 16, 2010. (St. Ex. 14C at 34) He continued Patient 14 on Seroquel XR at 800 mg per day, or less, through March 19, 2012, the last visit documented in State's Exhibit 14C. (St. Ex. 14C at 5-7, 12-34)

Testimony of Dr. Barzman

492. Dr. Barzman testified that his criticism concerning Dr. Valko's treatment of Patient 14 was the large daily dose of Seroquel 1,200 mg prescribed on April 27, 2010. Dr. Barzman did not question the appropriateness of Seroquel to treat Patient 14's conditions, only for prescribing too high of a dose at that visit. (Tr. at 411-413, 526-527; St. Ex. 17 at 53) Dr. Barzman further testified that it is his opinion that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 14. (Tr. at 413)

Testimony of Dr. Valko

493. Dr. Valko testified acknowledged that the prescribed high doses of Seroquel. However, he further testified that, looking at the April 13, 2010 progress note when he discontinued Zyprexa 35 mg per day and added Seroquel 800 mg per day, the Seroquel 800 mg per day was equivalent to a lowered dose of Zyprexa. (Tr. at 246, 797)

494. Dr. Valko testified concerning some of the publications he listed in his report concerning Seroquel. He indicated that some of the publications reference Seroquel dosages exceeding 2,000 mg. (Tr. at 797-800; Resp. Ex. A at 97-98)

Patient 15

5/3/07 Initial Assessment

495. Patient 15, a male born in 1999, first visited Dr. Valko's practice for an initial assessment on May 3, 2007, by Daniel Eble, M.Ed., PCC. At that time Patient 15 was in the first grade. He had previously been seeing another practitioner for medication management and therapy. Patient 15's mother reported that Patient 15 had been having behavioral issues at home and school: "Mom shares that [Patient 15] seems to want to be in charge of his peers and tries to help the teacher which comes off as bossiness." He was being treated for ADHD and OCD. Mother reported that mornings are "awful" without his current medications and that his behaviors worsen in the evening when the medication is wearing off. (St. Ex. 15B at 19)

His then-current medications were listed as Risperdal 0.25 mg with instructions to take one-half tablet at 4:00 a.m. and 9:00 a.m. to treat bedwetting, Adderall XR 15 mg in the morning, and Lexapro 5 mg at 6:15 a.m. Mr. Eble noted Axis I diagnoses of ADHD by history (314.01) and OCD by history (300.3). (St. Ex. 15B at 20)

5/31/07 – First Visit with Dr. Valko

496. Patient 15 first saw Dr. Valko on May 31, 2007. Dr. Valko noted that Patient 15 obsessively picked at scabs on his arm and legs during the appointment. Mother reported that Adderall had been wearing off late in the school day and he becomes more difficult for the teacher to control. She reported that he is obsessive about certain things: "cereal has to be poured in a certain way, the cereal bowl and spoon must be the same color, blocks have to match in color and be lined up, must wear seamless socks." She reported that medication has improved his obsessions. (St. Ex. 15B at 18)

Dr. Valko confirmed Axis I diagnoses of ADHD Combined and OCD. Dr. Valko changed the timing of Lexapro and Risperdal to 4:00 p.m. doses to decrease morning drowsiness and aid sleep, and he continued Adderall XR 15 mg in the morning. (St. Ex. 15B at 18)

Testimony of Dr. Valko

497. Dr. Valko testified that, in Patient 15's case, he had medical records from Patient 15's prior treating psychiatrist. Dr. Valko further testified that Patient 15's mother was a nurse and was very involved in Patient 15's care. (St. Ex. 15B at 8-15)

Dr. Valko testified that Patient 15's initial diagnoses were ADHD and OCD, and later his main issues were "anxiety, secondary to obsessive compulsive disorder. And if you follow the notes we added an autism spectrum to this as well, as well as intermittent explosive disorder." (Tr. at 251)

12/31/08 Visit

498. Approximately 18 months and many visits later, on December 31, 2008, Dr. Valko was prescribing Adderall XR 25 mg in the morning, Focalin 2.5 mg with instructions to take one and one-half tablets at 3:00 p.m., and Lexapro 10 mg in the morning. At that visit mother reported that Patient 15 "seems to be doing well in school and for the majority of the time at home." Medications were left unchanged and he was to schedule a follow-up visit in 12 weeks. (St. Ex. 15B at 55)

2/16/09 Visit

499. Patient 15 was seen again on February 16, 2009. Dr. Valko noted in the chart:

> This is an earlier appointment than was scheduled and mom reports that [Patient 15] has become increasingly difficult to deal with in the afternoons. She explained that it is taking several hours to finish a few pages of homework and that his anxiety levels have begun to increase when he gets something wrong leading to screaming and yelling. She adds that even noises and looking at [Patient 15] cause him to scream. A report from his teacher noted that [Patient 15] has been completing his assignments but they lack the

> quality that they once had. Mom admits that her parenting style hasn't been the best in the past, but recently she and her husband are trying a new approach that excludes yelling.
>
> [Patient 15] was groomed and dressed appropriately for the weather. He was pleasant and his affect was spontaneous. He fidgeted and was constantly moving in his chair and several times he interrupted conversation with comments. His speech was fluent and cohesive.
>
> [Patient 15] could recall his medications and doses and he denies any adverse effects. I am switching [Patient 15] from Lexapro to Celexa [40 mg in the morning] and increasing the dose to help decrease [Patient 15's] anxiety level. I will also increase his Adderall dose to 30 mg and give that twice daily and discontinue the Focalin in an effort to help with focus after school. I will continue to monitor for target symptoms and adverse effects. Mom received scripts before she left and understands that she may contact this office if there are any questions or concerns.

(St. Ex. 15B at 56)

Patient 15's Axis I diagnoses at that time remained ADHD Combined and OCD. He weighed 66 pounds at that visit. (St. Ex. 15B at 56)

Testimony of Dr. Barzman

500. Dr. Barzman testified that the doses of Adderall XR and Celexa were too high for this patient, and that he "had a concern about getting an EKG for being on the stimulant and Celexa." (Tr. at 414)

501. On cross-examination, Dr. Barzman was referred to an FDA safety announcement published in or around March 2012, clarifying an earlier announcement published in or around August 2011, and which is titled, "FDA Drug Safety Communication: Revised recommendations for Celexa * * * related to a potential risk of abnormal heart rhythms with high doses." In that announcement the FDA stated that doses of Celexa greater than 40 milligrams per day should no longer be used "because it could cause potentially dangerous abnormalities in the electrical activity of the heart." (Resp. Ex. B at 139-142) Dr. Barzman acknowledged the announcements and the 2011 and 2012 dates, which postdate the February 16, 2009 visit. (Tr. at 462)

12/18/09 Visit

502. Several months later on December 18, 2009, Dr. Valko prescribed Vyvanse 80 mg, Adderall 10 mg, Celexa 40 mg, and added Wellbutrin SR 150 mg off-label to help with Patient 15's anxiety and his focusing, noting that the mother would monitor him while they

raise the Wellbutrin SR and lower the Celexa.[55] Patient 15 weighed 70.5 pounds at that visit. (St. Ex. 15B at 85)

Testimony of Dr. Barzman

503. Dr. Barzman testified that his concern was that Patient 15's anxiety could have resulted as a side effect of the stimulants he was being prescribed. However, he further testified that the dose of Wellbutrin SR prescribed at that visit was reasonable. (Tr. at 415)

Testimony of Dr. Valko

504. Dr. Valko testified that Wellbutrin is FDA approved to treat depression but can also be used off-label to treat anxiety and ADHD. Dr. Valko further testified that, at doses above 300 mg, it can help with focusing and concentration. Moreover, Dr. Valko testified that Patient 15 had an issue with tics and Dr. Valko was also looking for a way to treat ADHD without going higher on the stimulants which he said can cause tics. (Tr. at 805)

1/26/10 Visit

505. On January 26, 2010, in addition to continuing Patient 15's prescriptions for Vyvanse and Adderall, which the note said he was taking to improve concentration and focusing. Dr. Valko ordered that Celexa for anxiety and mood be tapered over a period of two weeks then stopped, and increased Wellbutrin SR to 150 mg in the morning and 300 mg at bedtime for a total daily dose of 450 mg. Patient 15 weighed 72 pounds at that visit. (St. Ex. 15B at 90)

Testimony of Dr. Barzman

506. Dr. Barzman testified that Wellbutrin SR 450 mg per day is a large dose for Patient 15's weight. Dr. Barzman testified that an appropriate dose of Wellbutrin SR is around 3 to 6 milligrams per kilogram of body weight. At 450 milligrams per day and 72 pounds, Patient 15 was taking 13 milligrams of Wellbutrin SR per kilogram. (Tr. at 417-418)

Testimony of Dr. Valko

507. With respect to Dr. Barzman's criticism that Patient 15 was on too high a dose of Wellbutrin, Dr. Valko testified that "you usually don't even see any improvement with focusing and concentration until you get above a 300 milligram dose." (Tr. at 807-808)

4/15/11 and 4/28/11 Visits

508. On April 15, 2011, Dr. Valko documented that Patient 15's mother was "tearful and visibly upset" when she entered his office. (St. Ex. 15B at 111) He further documented:

[55] Dr. Valko had begun prescribing Vyvanse 80 mg and Adderall 10 mg at the previous visit in November 2009. (St. Ex. 15B at 80, 224)

> [Patient 15] is not doing well. Mom says that things had been going well with [Patient 15] for about a week and then this s[t]opped. He does have times when he is well behaved and paying attention well, but then something will upset him and set him off. Once this happens, his teachers and his parents are not able to bring him back under control. His mother also reports that he has started blowing his nose over and over until it bleeds. He will get blood on his hands, which will be pointed out by his teachers. [Patient 15] will talk back to them and say he does not have blood on him. He is reportedly acting out a lot at home. His parents try and discipline him but are having trouble with this. At one point, [Patient 15] reportedly went to his grandmother's car and started to tear apart the dashboard. His father apparently saw him doing this and told him to stop. [Patient 15] then began to run across their yard and his father had to run after him. Mother and [Patient 15] report that father had to grab him by the arm and "drag" him back to the house to get him to stop. [Patient 15] would not cooperate. Mom informs me that [Patient 15] told his principal about this incident and said that his father slammed [Patient 15's] head against the car. There is no mark on [Patient 15's] head and no indentation on the car. Mother also said that the principal also told her that the story continued to grow as the principal was being told the story. I told Mom [that] she and Dad need to document exactly what happened - Dad's version of the story and [Patient 15's] versions, which according to Mom and the principal, kept changing. [Patient 15] is upset and crying as Mom tells this story. He interjects says (sic) that he didn't do anything wrong and it was his dad's fault. It was very apparent that [Patient 15] needed to get the last word in. I asked him if he knows that he did something wrong. He would reply with "yes, but... " every time.

(St. Ex. 15B at 111) Dr. Valko added "R/O IED" to his other Axis I diagnoses of ADHD Combined and OCD. Dr. Valko prescribed Vyvanse 100 mg at 5:30 a.m. and 100 mg at 1:15 p.m., Prozac 40 mg twice per day, and Depakote ER 250 mg in the morning and 500 mg at bedtime. (St. Ex. 15B at 111)

509. On April 28, 2011, Dr. Valko increased Patient 15's dose of Vyvanse from 100 mg twice per day to 120 mg twice per day based on mother's report that Patient 15 was still having problems with impulsivity; however, she noted that his rages had reduced and become less violent. Nevertheless, he was reported to have yelled at other children on the bus because they were being too loud and had threated to kill a classmate. Mother further noted that he was up to nine out of ten possible school suspensions and that the school had told her that "they may not be able to accommodate [Patient 15] in the public school system anymore." He was scheduled for an "IEP" meeting with the school. (St. Ex. 15B at 113)

Dr. Valko maintained Patient 15 at a daily dose of Vyvanse 240 mg through at least July 28, 2016, the last visit documented in Patient 15's chart. (St. Ex. 15A at 3-114)

6/8/11 Visit

510. On June 8, 2011, Dr. Valko reduced Depakote to 250 mg twice per day on a report that Patient 15 had developed a tremor. Dr. Valko noted that, if that is not helpful, they should consider use of Saphris off-label. (St. Ex. 15B at 140)

6/15/11 Visit

511. At Patient 15's next visit on June 15, 2011, Dr. Valko noted that he was being seen on an emergency basis due to a worsening tremor and "having more issues with explosive tendencies." Mother was also concerned about Patient 15's manic behaviors. Dr. Valko expressed surprise that the tremor continued after lowering Depakote. Dr. Valko discontinued Depakote and added Saphris 5 mg SL twice per day. Vyvanse and Prozac were left unchanged. (St. Ex. 15 at 142)

6/30/11 Visit

512. The June 30, 2011 progress note indicates that Saphris was increased to 5 mg SL in the morning and 10 mg SL at bedtime due to less frequent but intense outbursts. (St. Ex. 15B at 144)

7/28/11 Visit

513. On July 28, 2011, mother reported that she had been concerned about "serotonin syndrome" due to Patient 15 having nausea and vomiting with headaches and had discontinued Patient 15's afternoon dose, cutting his daily dose of Prozac to 40 mg from 80 mg. Dr. Valko added BuSpar 10 mg twice per day "to help prevent possible serotonin syndrome" and increased Saphris to 10 mg SL twice per day. (St. Ex. 15B at 145)

Testimony of Dr. Barzman

514. Dr. Barzman noted in his report that "[i]t is not clear that BuSpar was indicated since keeping Prozac at a lower dose or weaning off Prozac would prevent serotonin syndrome." (St. Ex. 17 at 57)

Testimony of Dr. Valko

515. In response to Dr. Barzman's criticism, Dr. Valko testified that medical literature supports prescribing BuSpar to augment serotonin reuptake inhibitors. (Tr. at 809-810; St. Ex. 15B at 145; St. Ex. 17 at 57; Resp. Ex. A at 106) One article Dr. Valko identified in his report titled "Combination/augmentation strategies for improving the treatment of depression," published in Neuropsychiatry Disease Treatment in 2005, states, in part, that "buspirone,[56] which is used

[56] Notice is taken that buspirone is the generic name for BuSpar. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a688005.html>, accessed January 15, 2020)

principally in generalized anxiety disorder, has also been shown to produce marked clinical improvement when used as an augmenting agent in depressed[57] patients who are initially unresponsive to the SSRIs * * *." However, "results from another double-blind, placebo-controlled trial failed to demonstrate any difference in the extra efficacy resulting from the addition of buspirone or placebo to their SSRI therapy. An unusually high placebo response may explain this result." (Resp. Ex. B at 104-116, quotes at 109; Footnotes added)

Another article titled "Medical Augmentation after the Failure of SSRIs for Depression," published in the New England Journal of Medicine in March 2006, offers the following conclusion: "Augmentation of citalopram[58] with either sustained-release bupropion[59] or buspirone appears to be useful in actual clinical settings. Augmentation with sustained-release bupropion does have certain advantages, including a greater reduction in the number and severity of symptoms and fewer side effects and adverse events." (Resp. Ex. B at 218-235, quote at 219; Footnotes added)

516. Dr. Valko testified that BuSpar is "considered a clean medication with minimal if any difficulties" that magnifies "the way [a patient's] Prozac works without causing" the nausea that Patient 15 was experiencing, as noted in the progress note dated July 28, 2011. (Tr. at 811; St. Ex. 15B at 145) Dr. Valko further testified that "if we had bumped up the SSRI he'd have side effects. But by adding to this, what we're actually doing is increase the Serotonin in the brain without causing side effects." (Tr. at 811) He also testified that the BuSpar decreased Patient 15's obsessions and that the effect was "monumental." (Tr. at 812)

8/19/11 Visit

517. Three visits later on August 19, 2011, mother noted that Patient 15 had a bilateral resting hand tremor and occasional shakiness in his voice which Dr. Valko opined was due to prior Depakote usage. She also reported a period of hyperfixation at a store wherein Patient 15 "wanted a net, but his mother would not get it for him. He had a temper tantrum and screamed for about a half hour, then rapidly calmed down and apologized for his behavior." Dr. Valko prescribed Vyvanse 120 mg twice per day, Prozac 40 mg, Saphris SL 10 mg twice per day, and increased BuSpar to 20 mg twice per day "to help control his anxiety and worries." Patient 15 weighed 96.5 pounds at that time. (St. Ex. 15B at 150)

Testimony of Dr. Barzman

518. Dr. Barzman testified that Vyvanse 240 mg per day is a high dose, and that the FDA maximum recommended daily dose is 70 mg. Dr. Barzman also noted that too much stimulant medication can cause the hand tremor and shakiness in the voice that Patient 15 had been experiencing. However, when apprised of Dr. Valko's testimony that Patient 15

[57] Patient 15 had not been diagnosed with depression at this time.
[58] Notice is taken that citalopram is the generic name for Celexa. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a699001.html>, accessed January 15, 2020)
[59] Notice is taken that bupropion is the generic name for Wellbutrin. (See, U.S. National Library of Medicine, MedlinePlus website, <https://medlineplus.gov/druginfo/meds/a695033.html>, accessed January 15, 2020)

had been taking that dose of Vyvanse previously without tremors, Dr. Barzman acknowledged that that makes it seem less likely that Vyvanse was the cause of that problem as he would have expected the tremor to begin almost immediately. (Tr. at 419-420; St. Ex. 17 at 57)

Dr. Barzman also testified that the high dose of Vyvanse could also have contributed to Patient 15's episode of hyperfixation reported at the August 19, 2011 visit. (Tr. at 420) Later in his testimony, he acknowledged that Patient 15's hyperfixation could also have been a symptom of Patient 15's OCD. (Tr. at 527)

Testimony of Dr. Valko

519. When Dr. Valko was asked what made him conclude that Depakote had caused Patient 15's tremor and shaky voice, as noted on the June 15, 2011 progress note, Dr. Valko replied that "Patient 15 was sensitive to a lot of different medications, and he did have a hand tremor from the Depakote, and then the Depakote was stopped over time, and then the tremor continued." Dr. Valko further testified that it dissipated over time. (Tr. at 254) When asked to comment on Dr. Barzman's concern that high-dose stimulants could have been the cause of Patient 15's tremor and shaky voice, Dr. Valko replied, "As you're well aware, this is the same dose that you just discussed with me that occurred like six months before, and he did not have a hand tremor at that time.[60] So the chances of it being from this medication dose at this time would be negligible." (Tr. at 254)

9/1/11 Visit

520. On September 1, 2011, Dr. Valko increased BuSpar to 30 mg twice per day to address Patient 15's "anxiety and worries." Dr. Valko also informed mother that she can give a smaller dose in the morning and a larger dose in the evening if that helps with morning sleepiness. (St. Ex. 15B at 152)

5/10/12 Visit

521. On May 12, 2012, Dr. Valko added Asperger's Syndrome to Patient 15's Axis I diagnoses of ADHD Combined, OCD, and R/O IED. (St. Ex. 15B at 157)

Testimony of Dr. Valko

522. Dr. Valko testified that, based on a long period of observation, Patient 15 met all the criteria of Asperger's Syndrome, which the DSM-V now refers to as autism spectrum

[60] According to the chart, Dr. Valko increased Patient 15's dose of Vyvanse to 240 mg on April 28, 2011, an increase of 40 mg over the previous dose. However, Dr. Barzman testified that he would have expected the tremor to appear almost immediately, and Patient 15 did not report a tremor ding an intervening visit on May 16, 2011. Patient 15 first complained of a tremor on June 8, 2011, approximately six weeks after the increase to 240 mg per day, at which time Dr. Valko decreased Depakote. (St. Ex. 15B at 103-140; Tr. at 419)

disorder. Dr. Valko further testified that Patient 15 "would be on the high end of the spectrum." (Tr. at 255-256)

11/5/12 Visit

523. On November 5, 2012, Dr. Valko prescribed, among other things, Lexapro 40 mg. He weighed 116 pounds at that visit. (St. Ex. 15B at 188)

Testimony of Dr. Barzman

524. Dr. Barzman testified that the maximum dose of Lexapro in 2012 was 20 mg. (Tr. at 420)

Dr. Barzman's Conclusions Regarding Dr. Valko's Treatment of Patient 15

525. Dr. Barzman opined that Dr. Valko failed to maintain minimal standards applicable to the selection or administration of drugs, or that he failed to employ acceptable scientific methods in the selection of drugs in the treatment of Patient 15. (Tr. at 421)

Dr. Valko's Conclusions Regarding Patient 15

526. Dr. Valko testified that he continues to treat Patient 15. (Tr. at 801)

Letter of Support from Patient 15's Mother

527. In an August 17, 2018 letter, Patient 15's mother stated that Patient 15 has been seeing Dr. Valko for over 12 years, and "[i]t is because of Dr. Valko and his team of therapists that my son is now entering his senior year at [school name redacted to protect patient confidentiality] here locally as an honor roll student in their Welding Program." She stated that Dr. Valko has always presented treatment options to the family and allowed the family to decide how to proceed. She further testified that Dr. Valko has required Patient 15 to know the medications he is taking and their doses and, since Patient 15 was seven years old, has included Patient 15 in his healthcare decisions. (Resp. Ex. F at 6) Moreover, she stated:

> Over the years we have trialed many different medications to help with [Patient 15's] diagnoses of ADHD, Autism, Anxiety disorder and OCD. Dr. Valko has always been very forthcoming that there is no medication that is going to completely eradicate the behaviors associated with his diagnoses. Due to [Patient 15] quickly metabolizing medications there were times where gradual increases in doses had to be made. Again, changes were always gradual and Dr. Valko has always erred on the side of caution on many occasions asking us to speak with the therapist first and try behavior modification before just increasing doses. Without the use of medications to help control some of his behaviors [Patient 15] never would have been able to attend school or function positively within society. Throughout the years we have had [Patient 15] speak with a therapist [at Dr. Valko's practice] to help him work through issues and to learn

> behavior. * * * If at any point we felt what Dr. Valko was doing was not the best or safest for [Patient 15] or that he didn't have [Patient 15's] best interest at forefront we would not have hesitated to make a change.
>
> Dr. Valko monitored [Patient 15's] health on an ongoing basis by ordering regular lab work. There were times where [Patient 15's] primary care doctor had recently order labs that Dr. Valko would not submit duplicate orders but request copies of the recent labs to review. Times where labs were delayed were not due in part to Dr. Valko, but to us as busy parents who forgot. Additionally, as a member of the medical community I was aware of what to watch for and any time I had questions or concerns I knew I could reach out to Dr. Valko and that I would hear back very quickly.
>
> Approximately 10 years ago we were at a point with [Patient 15] where he was so socially inept that he never wanted to leave the house. Additionally, he was so rigid in his thought process that functioning in mainstream was almost impossible. We had discussed the possibility that he may never be able to secure employment that would sustain living on his own. Thru therapy, behavior modification, trialing of medications and monitoring and adjusting of those doses upon growth spurts, attendance to a specialized school and the support he received there and through Dr. Valko and his therapists and staff; [Patient 15] is now entering his Senior year at [School Name] where he is an Honor Roll student in their Welding program. Upon graduation he plans to begin work as a welder while he pursues further training to be an underwater welder.

(Resp. Ex. F at 6-7)

Additionally, Patient 15's mother stated that when her younger son told her about some issues he was having with depression and attention she took him to Dr. Valko, and that "[i]f there was any iota of concern I certainly would not have chosen to have my second child placed under Dr. Valko's care. We are so very thankful for the expertise and care we have been provided by Dr. Valko and his staff." (Resp. Ex. F at 7)

Dr. Barzman's Summary

528. Dr. Barzman testified that, in his over 20 years of practicing psychiatry, he has never seen stimulants prescribed at the level that Dr. Valko prescribed to these patients. Dr. Barzman further testified that, in his opinion, prescribing doses of medication that exceed the studied level falls below the minimal standard of care because "we don't know about the safety of those dosages. (Tr. at 422)

529. Dr. Barzman acknowledged that the records he reviewed for this matter cover a substantial period of time. Dr. Barzman further acknowledged that the minimal standard of care evolves over periods of time. However, Dr. Barzman does not believe that the standard of care applicable to Patients 1 through 15 evolved during the course of their treatment.

Dr. Barzman further testified that, after he completed his report, he reviewed the FDA website and package inserts for the medications that are relevant to the 15 patients and did not find any changes to the dosage recommendations. (Tr. at 446-448)

530. Dr. Barzman testified that nothing discussed during his testimony has changed his opinion concerning the levels of medication that Dr. Valko was prescribing. (Tr. at 538)

531. When asked whether Patients 1 through 15 were typical psychiatric patients, Dr. Barzman replied, "I think they are very complicated, and I do see these patients on an inpatient event, sometimes in the urgent care setting, but they are --based on the records they do seem to be challenging. And also some of the family factors and concerns, too." (Tr. at 528)

Dr. Barzman further testified that he has the impression from reviewing Dr. Valko's charts that he is trying to alleviate his patients' dysfunction. Moreover, Dr. Barzman testified that he found no evidence in the charts that prescribed medications were being abused. (Tr. at 529)

532. Dr. Barzman testified that, in general, Dr. Valko educated his patients regarding the medications he prescribed, including the potential side effects. (Tr. at 529-530)

Dr. Valko's Summary

533. Dr. Valko testified that he believes that the care and treatment he provided to Patients 1 through 15 in this matter complied with the standard of care. (Tr. at 829) When asked whether, in hindsight, he would have done anything differently in his practice concerning the 15 patients in this case, Dr. Valko testified:

> In hindsight I should have changed my electronic records, the way I documented earlier, to show that -- to help remind me to obtain certain labs in hindsight.
>
> In hindsight, looking back at how things are being looked at, and now being a little skeptical of how agencies -- just how people look at things that you are expected to know what the new guidelines are before they happen, that you should have been prepared for that.
>
> Hindsight was I probably should have got some EKGs more frequently, which I did with the labs. Hindsight would have had the documentation for documenting -- you know, for signing off on meds earlier than we did. That would be hindsight.
>
> I mean, when it comes to educating and double-checking and checking for safety and checking for all the side effects, I think I do the -- I think I do an awesome job with that.

> Not to sound cocky, but honestly, if you would call up any one of my patients and put a six year old on the phone, they will tell you what they take, why they take it, what it's for, if they are having any side effects and if it's working. I can guarantee any one of those would do it.
>
> And I think that says a lot for how I practice, how important that whole safety is, the education issue, working as a team. I think that gives some background of where I'm coming from.

(Tr. at 830-831)

534. When asked to compare his practice to Dr. Barzman's, Dr. Valko noted first that, in his practice, although he can do inpatient work, he does not because his outpatient practice is so busy. Dr. Valko further testified that his goal is to keep patients out of the hospital, and he sees some patients weekly or biweekly, sometimes more than once per week, to keep them out of the hospital and in the least restrictive environment possible. (Tr. at 813-814) Comparing that to inpatient work, Dr. Valko testified:

> So when you're working on an inpatient unit you have sort of a snapshot of patients, which makes it really difficult.
>
> Sometimes you get information from the treating psychiatrist, sometimes you don't. Sometimes you don't even ask for the treating information, so you're sort of practicing in a void and doing the best you can with the information you have.
>
> So you treat a patient and then they are gone. And the goal in an inpatient unit is to make sure most are at maybe three, five days max, so the goal in an inpatient unit is safety, no longer suicidal, can they be released back outside without wanting to harm themselves or harm other people.

(Tr. at 814)

With respect to outpatient work, Dr. Valko testified:

> Outpatient for me, and I'm recalling it's the same for Dr. Barzman, is a continuity of care, building a relationship with my patients and their families, making sure that we all work as a team, and to move forward, as I keep calling it, on this adventure, because things pop up that mess things up, and a new stressor could hit and all of a sudden somebody spirals out of control.
>
> I need to be available. The family needs to be involved. Let's get that patient in. The last thing I want is for that patient to end up in that crisis patient unit where things could get changed without anybody's -- my knowledge and the parents are just like I don't know what to do, I'll do whatever you tell me, and then things could get better or worse.

> So in my unit, and as you can see, my office, a lot of these patients have been with me for well over a decade. I have some patients who have seen me well over two decades.
>
> I think it's that relationship that I have with my patients. The fact that I educate them, we're all looking at -- the whole goal is the same thing, the best patient care possible.
>
> What the State's trying to look at this, am I providing appropriate care for my patients, am I looking at my patients in their best interest.
>
> And I honestly believe that I do the best possible I can with that, because my goal is that -- and I think I've achieved that goal many times, is that those patients feel so comfortable with me they would refer a family member to me, and they have. Many have, over and over and over.
>
> * * *
>
> I'm sort of hyper dedicated to what I do. Sometimes I get out at 6:00, sometimes I get out at 7:00, sometimes I get out at 8:00, but like I said, I don't leave until my phone calls are done, all my families have been contacted. Dr. Barzman has a much smaller practice. He felt he saw 15 to 20 [out]patients.

(Tr. at 814-816) In contrast, Dr. Valko testified that, in 2013, his outpatient base "was a thousand." (Tr. at 816)

535. Dr. Valko testified that, when he sees a new patient, he always independently confirms any previously rendered diagnoses. (Tr. at 580-581)

Dr. Valko further testified that he determines whether a medication is working by obtaining feedback from the patient and from the parents, information from the parents about how the patient is doing in school, and by observing the patient during the appointment. If he sees a child being treated for ADHD bouncing off the walls during the appointment, he knows the medications aren't working very well. (Tr. at 581-582)

536. When asked about the mother of one of the 15 patients who seemed to be changing the amount of the patient's medications on her own, Dr. Valko replied to the effect that he makes an effort to work with and develop a relationship with the families of his young patients and to educate them. (Tr. at 37-38; 604-605) Dr. Valko further that, once that relationship is formed, "you have to do some trusting with some the parents because their best interests are their children's best interest. They are trying to help their children the best that they can." (Tr. at 37-38) When asked whether he would discharge a patient because the parent changed the patient's medication, Dr. Valko testified that he would struggle with that "because here you have a kid who is willing to try to improve upon themselves and a parent

who really isn't following the directions of what's supposed to happen. Is it really the eight-year-old's fault that mom sort of screwed up and hopefully will never do it again?" (Tr. at 605) Finally, Dr. Valko testified that he has never had to actually do that "because every time it's been addressed, it's stopped. And if it would happen again, we'd have another talk because, again, it's about the patient." (Tr. at 605)

537. Dr. Valko testified that he has made changes to his practice over time as any physician would. For example, Dr. Valko testified that he and his staff noticed that they did not always get blood work on an annual basis despite efforts to do so. Dr. Valko testified that, in response, in 2013, he changed the format of his progress notes as can be seen in the later progress notes included in the patient records. Dr. Valko testified that the new format makes it easier to see at each visit when the last labs were obtained rather than having to flip through the charts to find that information. (Tr. at 822-823)

Dr. Valko further testified that in 2014 they changed their electronic medical records system ("EMR") from a locally created system to a special EMR made for psychiatric practices. (Tr. at 826-827)

Additionally, referring to Respondent's Exhibit I which concerns patient/guardian consent, Dr. Valko testified:

> We started doing an informed consent for medication thing that every patient has to sign for every single medication, if it's within the -- the recognized standards or if it's even above.
>
> Whenever there's a medication that's considered to be beyond the FDA recommendations, the comments are in there, and it's always explained in the note, but it's also documented in this form that this is above FDA or not -- or an off-label medication.
>
> We document how this is being used. Like in Patient 15 Wellbutrin was being used as an off-label, this would say Wellbutrin, these are the dose ranges, and this is an off-label medication.

(Tr. at 827-828; Resp. Ex. I)

Medical Literature

538. An FDA safety announcement published in or around November 2011 titled, "FDA Drug Safety Communication: Safety Review Update of Medications used to treat [ADHD] in children and young adults." (Resp. Ex. B at 145-146) The announcement states, in part:

> The [FDA] is updating the public that a large, recently-completed study in children and young adults prescription with medication for [ADHD] has not shown an association between use of certain ADHD medications and adverse

> cardiovascular events. These adverse cardiovascular events include stroke, heart attack * * *, and sudden cardiac death.

(Resp. Ex. B at 145) Elsewhere it states, "Patients treated with ADHD medications should be periodically monitored for changes in heart rate or blood pressure." (Resp. Ex. B at 145) Further down it states, "In comparison to non use, there was no association of serious cardiovascular events with ADHD drug use * * *." (Resp. Ex. B at 146)

Dr. Barzman testified that he agrees with that statement. (Tr. at 463)

539. An AACAP Policy Statement that appeared in the March/April 2018 issue of American Academy of Child and Adolescent Psychiatry ("AACAP") News. The policy statement states, in part:

> Off-label medication use is part of the standard of care in the treatment of psychiatric disorders when: 1) there is a solid evidence base for the medication, 2) an off-label medication has better efficacy and/or safety evidence than an on-label one, 3) a child has symptoms that are not controlled by, or experiences unacceptable side effects due to, an on-label medication, 4) a child has a disorder or comorbid conditions for which there is no FDA-approved treatment, 5) adjunct medication is necessary for control of side effects of another medication, and/or 6) a child is below the age for which an FDA approved treatment is available.

(Resp. Ex. B at 23)

Dr. Barzman agrees with that statement and believes it would also have been true in 2012, 2008, or 2006. (Tr. at 460-461)

540. The AACAP Policy Statement also states that "[a]nother increasing use of 'off-label' medications is when youth exhibit impairment but do not meet threshold criteria for a specific disorder." (Resp. Ex. B at 23) (Footnotes omitted)

Dr. Barzman agrees with that statement and believes it would also have been true in 2012, 2008, or 2006. (Tr. at 460)

541. Dr. Valko presented a Policy Statement from the American Academy of Pediatrics that was published in Pediatrics in August 2008 titled, "Cardiovascular Monitoring and Stimulant Drugs for [ADHD]." The authors of that article reference a statement from the American Heart Association recommending routine EKGs for children before they start medications to treat ADHD. The authors expressed disagreement with that requirement, stating that the recommendation

> contradicts the carefully considered and evidence-based recommendations of the American Academy of Child and Adolescent Psychiatry and the American

> Academy of Pediatrics (AAP). These organizations have concluded that sudden cardiac death (SCD) in persons taking medications for ADHD is a very rare event, occurring at rates no higher than those in the general population of children and adolescents. Both of these groups also noted the lack of any evidence that the routine use of ECG[61] screening before beginning medication for ADHD treatment would prevent sudden death.

(Resp. Ex. K) (Original footnotes omitted; footnote added)

Dr. Barzman testified that he agrees with that statement. (Tr. at 465)

Further, under the section titled "Summary," the article states:

> Although the sudden death of a child is a tragedy, there have been no studies or compelling clinical evidence to demonstrate that the likelihood of sudden death is higher in children receiving medications for ADHD than that in the general population. It has not been shown that screening ECGs before starting stimulants have an appropriate balance of benefit, risk, and cost-effectiveness for general use in identifying risk factors for sudden death. Until these questions can be answered, a recommendation to obtain routine ECGs for children receiving ADHD medications is not warranted.

(Resp. Ex. K)

Dr. Barzman testified, "I agree. I mean, this is consistent with what I said before, with exploring personal and family history of cardiac history." (Tr. at 465-466) Dr. Barzman further testified:

> So this article is based upon the assumption that the stimulant doses are within the therapeutic range, that there hadn't been studies on large dosages of stimulants.
>
> So I do agree that if the stimulants are within the normal therapeutic range that's been studied, that EKGs are not routinely needed. It's a matter of exploring personal and family history for cardiac disease.
>
> But if they are way above the standard dosing for stimulants, then it's -- I don't think this paper applies to that.

(Tr. at 466-467)

Dr. Barzman further testified that he is unaware of any studies or journal articles concerning very high doses of stimulants in children that are 300 to 400 percent above the recommended therapeutic dose. (Tr. at 467-468)

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[61] Dr. Barzman testified that ECG and EKG are synonymous. (Tr. at 464)

542. Dr. Barzman testified that he is familiar with an NIH study concerning the use of Riluzole to treat pediatric patients for OCD with or without autism spectrum disorder but indicated that he was not familiar with the drug prior to his review for this case. Dr. Barzman further testified that he has never prescribed Riluzole nor has he seen it prescribed. Dr. Barzman acknowledged that, at the time he completed his report, he had not known what authority Dr. Valko was relying upon when he prescribed Riluzole to his patients. (Tr. at 468-470)

543. One case study provided by Dr. Valko titled "Case Report: High Dose Methylphenidate for Adult ADHD," authored by Batya Swift Yasgur, LMSW, and dated November 26, 2012, states in part that the patient's "ADHD symptoms only improved dramatically after he began treatment [using] extended-release [methylphenidate] (378mg/day)." He suffered no cardiac side effects or other psychiatric side effects. (Resp. Ex. B at 80) Further, the report states:

> The authors conclude, "To our knowledge, this is the first reported case of high-dose treatment in a patient with adult ADHD. We therefore suggest that clinicians consider these findings in their work when ADHD symptoms do not improve sufficiently with currently recommended dosages of stimulants." They advise close monitoring of clinical symptoms for potential adverse effects when using these higher dosages.

(Resp. Ex. B at 80)

A more detailed description of this case is given in an article titled "High Dose Methylphenidate Treatment in Adult [ADHD]: A Case Report, published in the Journal of Medical Case Reports in May 2012. (Resp. Ex. B at 156-163)

Additional Testimony by Dr. Valko

544. Dr. Valko testified that there is a shortage of psychiatrists, particularly child and adolescent patients, in northwest Ohio. Dr. Valko based that testimony upon information he gained during meeting he had had the week before his hearing with the head of the Department of Psychiatry at the University of Toledo Medical Center. Dr. Valko further testified:

> [O]ne of the things she wants to work with me with, other than have me more involved with the residency program, other than just teach her students, is look at a second community psychiatry residency program.
>
> So it would be based out of the community, not out of the university, and that way it would allow more people to come to Toledo to be residents.
>
> And if it's a community-based program they are more apt to become -- what is the term I want, I always love this term -- they are going to become part of the community, so the chances of them leaving are less.

(Tr. at 835-836)

545. Dr. Valko testified that Respondent's Exhibit E is a table created by his staff that shows the various dates when the Board subpoenaed the medical records for Patients 1 through 15. The dates range from July 2010 for three of the patients through August 2016. Dr. Valko noted that charts on some of the patients were subpoenaed multiple times. Dr. Valko testified that that is why some of the documents in the charts are out of order. (Tr. at 823-825; Resp. Ex. E)

546. When asked if there is anything he would like to say to the Board, clinician to clinician, Dr. Valko replied:

> So I think we're all here for the same thing; good patient care. And I understand that that is what this is all about. I do believe I have provided good patient care. I believe I provided well above the minimum standard of care for my patients.
>
> I believe the patients that we reviewed today are extremely difficult patients, and if anybody looked at, would consider them a difficult patient with multisystem issues, and that I worked as best as I can with the patients and the patients' families and support systems to try to improve the quality of life, and decrease the psychiatric symptoms in those patients.
>
> Unfortunately back in 2005, 2006, there weren't some of the testings that you can do now to help justify some of the issues that we're going through, and -- but when newer and appropriate testing came around I was quick to try to use that to help with my patient care.
>
> I just did the best I possibly could. I honestly believe I've done the best I possibly could with my patients.
>
> I realize that the dosing of some of these medications is well above what is considered above average, but I also realized I was in constant communication with my patients.
>
> We were always double-checking for potential side effects, looking at safety issues, looking at how the medications -- they were responding to the medications, and making appropriate changes when necessary with those medications, working as a team with my patients and their families and support staff.

(Tr. at 832-833)

WITNESS CREDIBILITY

1. The hearing examiner finds that, overall, Dr. Barzman is a credible and knowledgeable expert witness. He is well-trained and is Board-certified in adult psychiatry, forensic psychiatry, and child and adolescent psychiatry. There is evidence that, at one point during his residency, he had some academic struggles, but he overcame them. At this point in his career, that is not an issue. At the hearing, Dr. Barzman appeared to be very objective as evidenced by his willingness to withdraw or modify his criticism when, for example, it was shown at hearing that Dr. Valko was cross-titrating two medications rather than inappropriately prescribing the two medications simultaneously. The rationales he provided at hearing for his criticisms were, to the hearing examiner's medically untrained ear, logical, and consistent, and centered on patient safety. Dr. Barzman acknowledged without hesitation that the patients in this matter were extremely complex and very difficult to treat. Further, although Dr. Barzman's and Dr. Valko's current practices are very different—Dr. Valko exclusively treats outpatients while Dr. Barzman primarily treats inpatients—Dr. Barzman treated outpatients in the past and continues to treat a few outpatients. Nevertheless, the hearing examiner acknowledges that he found the structure of Dr. Barzman's written report to be confusing. Because of that, the hearing examiner relied almost exclusively on Dr. Barzman's testimony at hearing, and relied on the statements in his report to the extent they appeared consistent with his testimony at the hearing concerning the patient at issue or other patients, and/or when Dr. Valko acknowledged the criticism.

2. The hearing examiner finds Dr. Valko to be a knowledgeable witness. He is well-trained and held specialty Board certification in both adult psychiatry as well as child and adolescent psychiatry, although he has allowed those certifications to lapse. The Hearing Examiner also finds Dr. Valko to be forthcoming and honest with respect to his treatment of these patients, although there were a handful of times where his testimony contradicted what was actually set forth in the medical record, for example, concerning the slapping comment with regard to Patient 6. For the most part, however, Dr. Valko's testimony concerning his treatment of the patients was credible.

   For the hearing examiner, however, there is a credibility gap between Dr. Barzman's opinions and Dr. Valko's, particularly regarding dosing levels of medication. Dr. Barzman's opinions appeared grounded in scientific studies of various medications' dosing limits and centered on patient safety. Dr. Barzman's testimony leads the hearing examiner to believe that the FDA recommended maximum doses are not necessarily an absolute limit on prescribing; however, it is unsafe to exceed them by multiple factors due to concern for patient safety. Dosing levels five, six, or ten times the FDA maximum recommended daily dose have not been studied and thus could potentially lead to unpredictable and unsatisfactory results. In contrast, Dr. Valko's opinion is that, as long as the patient is being closely monitored, the medication is effective, and the patient is not suffering from side effects, then the limits set by the FDA are not as important. Dr. Valko referenced medical literature to support his position; however, the hearing examiner did not find the articles to include any clear support for prescribing very large doses of medication.

Only one article concerned dosing levels on par with Dr. Valko's, and that was a single-patient case study that concerned an adult patient. Another article referenced by Dr. Valko to support his position that EKGs are not relevant to stimulant prescribing until you get into large doses appeared to discourage large doses of stimulants, saying that more stimulant medication is not necessarily better. However, the hearing examiner is not medically trained and he invites the Board to amend this section if the Board, as a panel of experts, disagrees.

FINDINGS OF FACT

1. In the routine course of his practice, Tim R. Valko, M.D., provided care and treatment for Patients 1 through 15 as identified a confidential Patient Key. From in or around January 2005 to in or around August 2016, Dr. Valko inappropriately treated and/or failed to appropriately treat these patients, as follows:

    a. Patient 1:
        i. Dr. Valko failed to obtain metabolic labs with respect to prescribing Risperdal. Dr. Barzman testified persuasively that it is important to obtain a baseline metabolic lab when prescribing Risperdal. In fact, with regard to another patient, Patient 3, Dr. Valko acknowledged that Risperdal has side effects that must be monitored via metabolic blood panels. With respect to Patient 1, Dr. Valko did not obtain a baseline metabolic blood panel.
        ii. On February 26, 2014, Dr. Valko documented that he added Saphris to assist with Patient 1's focus, although the medication is not indicated for that purpose. The patient also suffered from Mood Disorder NOS, which Dr. Barzman testified would be an appropriate indication for Saphris. Nevertheless, the progress note stated that Saphris was prescribed to help Patient 1 with focus.
        iii. The evidence is insufficient to find that Dr. Valko should have done more to set limits on Patient 1's mother changing Patient 1's medication without first obtaining Dr. Valko's approval. Dr. Barzman noted at hearing that Dr. Valko did, in fact, set such limits on December 1, 2011.

    b. Patient 2:
        i. Dr. Valko failed to document a rationale for increasing Prozac from 20 mg to 40 mg on August 3, 2010.
        ii. No rationale was documented in the November 5, 2012 progress note for discontinuing Prozac and adding Lexapro. Dr. Valko testified that he did not believe that cross-titration had been necessary because the medications are closely related; however, Dr. Barzman's criticism was restricted to the lack of a documented rationale for the change, not a failure to cross-titrate.

    c. Patient 3:
        i. Dr. Valko prescribed Risperdal without obtaining metabolic labs.

ii. Dr. Valko failed to obtain an EKG as a patient-safety measure when prescribing very large doses of stimulant medication, as described in Finding of Fact 2.c.i., below. Dr. Barzman testified that the levels of medication prescribed are beyond levels that have been studied. Dr. Valko acknowledged that medical literature does not support EKG monitoring when the dose is below three and one-half time the FDA recommended maximum dose. However, during the course of treating Patient 3, he prescribed Ritalin at daily doses (300 mg) that exceeded the FDA maximum recommended daily dose of 60 mg by a factor of five, so the level prescribed was well above the threshold referenced by Dr. Valko.

iii. The evidence is insufficient to find that Dr. Valko inappropriately prescribed two antipsychotic medications simultaneously. Dr. Barzman withdrew that criticism at the hearing, noting that Dr. Valko had, in fact, been cross-titrating the two medications, which was appropriate.

d. Patient 4:

i. Dr. Valko acknowledged at the hearing that, during a June 23, 2008 visit, he had incorrectly advised Patient 4's mother that Risperdal was FDA-approved to treat children with ADHD. Dr. Barzman noted that Patient 4 did have a condition for which Risperdal could be prescribed—aggression related to ODD—but the progress note stated it had been prescribed to treat ADHD.

ii. From July through November 2010, Dr. Valko inappropriately prescribed Paxil to Patient 4, a juvenile patient. Dr. Barzman testified that Paxil is not an appropriate medication for children and that that has been known in the child and adolescent psychiatry community after studies were published in the United Kingdom around 2003 to 2005. Dr. Valko testified that the FDA did not make any recommendations with regard to prescribing Paxil to child patients before 2010. However, Dr. Barzman's opinion is deemed more persuasive, as Dr. Valko should have been aware of the UK studies by the time he prescribed the medication to Patient 4.

iii. Dr. Valko first prescribed Lamictal to Patient 4 in October 2010 without a supporting diagnosis such as a mood disorder. Likewise, Dr. Valko first prescribed Tegretol to Patient 4 in June 2013 in the absence of a supporting diagnosis such as a mood disorder. Dr. Valko acknowledged that he should have diagnosed Patient 4 with a mood disorder by the time he prescribed these medications.

iv. In May, June, and July 2015 Dr. Valko prescribed Abilify to Patient 4 despite a warning on each of those progress notes that Patient 4 had an allergy to Abilify and that it caused oculogyric crisis. In fact, Patient 4 was reported to have experienced that condition in August 2015, whereupon Abilify was discontinued. Dr. Valko's rationale that he wanted to retry the medication is not persuasive.

e. Patient 5:

i. Dr. Valko failed to obtain an EKG in connection with prescribing large, unstudied doses of Vyvanse, Daytrana, or Focalin.

ii. Dr. Valko did obtain an EKG in connection with prescribing large, unstudied doses of Adderall, which occurred after he had discontinued Vyvanse, Daytrana, and Focalin.
iii. Dr. Valko failed to obtain baseline metabolic labs in relation to August 2011 increased prescribing of Risperdal.

f. Patient 6:
i. Dr. Valko inappropriately advised the parents of Patient 6 that the next time he swears at his grandmother they should slap him and send him to his room. Such advice obviously is not related to prescribing but constitutes an "other modality" of treatment. Dr. Valko denied telling Patient 6's parent that they should have slapped him and sent him to his room; however, that contradicts the statement in the progress note.
ii. Dr. Valko's September 3, 2008 progress note indicates that Risperdal had been prescribed to improve Patient 6's decision-making and clarity of thought, which is not an indication for that medication. Risperdal is indicated for aggression, which Patient 6 certainly had; however, the progress note states that it had been prescribed for improved decision-making and clarity of thought.
iii. Dr. Valko failed to obtain an EKG in connection with an October 7, 2008 increase of Vyvanse to 140 mg.

g. Patient 7:
i. On February 18, 2011, Dr. Valko inappropriately made multiple medication changes at the same time by discontinuing Concerta and Saphris, restarting Focalin XR at 180 mg per day, and increasing Risperdal. Dr. Barzman opined persuasively that such practice makes it difficult to determine which changes may have been helpful and which were not.
ii. Dr. Valko inappropriately added Paxil to Patient 7's regimen on November 28, 2011. Dr. Valko testified that he started that medication only after trying two other selective serotonin reuptake inhibitors. The hearing examiner finds that prescribing Paxil was nevertheless inappropriate. The Board, as a panel of experts, is encouraged to amend this finding if it finds otherwise.
iii. Dr. Valko failed to obtain an EKG in connection with prescribing large, unstudied doses of stimulant medication.

h. Patient 8: Dr. Valko failed to obtain metabolic labs in relation to prescribing Risperdal to Patient 8.

i. Patient 9: On November 15, 2010, Dr. Valko started Clonidine 0.1 mg, which was subsequently increased on November 29, 2010 to 0.2 mg. At Patient 9's next visit on December 20, 2010, Dr. Valko increased Clonidine to 0.8 mg per day. Dr. Barzman opined persuasively that such a significant and rapid increase was inappropriate and could have resulted in an unsafe drop in blood pressure and heart rate.

j. Patient 11:
   i. Dr. Valko failed to obtain metabolic labs in relation to prescribing Risperdal.
   ii. On August 27, 2009, Dr. Valko inappropriately made multiple medication changes at the same time by decreasing Patient 11's Risperdal, increasing Prozac, and by discontinuing Concerta and adding Focalin, although Dr. Barzman acknowledged that Dr. Valko was justified in reducing Risperdal due to extrapyramidal symptoms (stiffness in jaw).
   iii On September 8, 2009, Dr. Valko discontinued Risperdal 2 mg per day. At the next visit it was reported that this caused the patient to experience withdrawal dyskinesia. Dr. Barzman opined that Patient 11 should had been weaned from Risperdal and Dr. Valko agreed.

k. Patient 12:
   i. Dr. Valko inappropriately prescribed Clozapine to Patient 12 without a specific indication. Dr. Barzman offered persuasive testimony that Clozapine has potentially serious side effects and requires a significant indication for use, including treatment-resistant schizophrenia or severe, constant aggression in an autistic patient to the point where the patient needs to be in a locked facility. Patient 12 is autistic but lacked any level of aggression that comes even close to that described by Dr. Barzman.
   ii. Dr. Valko prescribed large doses of Clozapine to Patient 12, which has potential cardiac-related side effects, without obtaining a cardiac history or screening.

l. Patient 15:
   i. Dr. Valko failed to obtain an EKG in relation to increasing Adderall to 60 mg per day and Celexa to 40 mg per day on February 16, 2009.
   ii. On July 28, 2011, Patient 15's mother reported that, since the last visit, Patient 15 had experienced what she believed to be side effects from Prozac. She further reported that she discontinued Patient 15's afternoon dose, reducing his daily dose of Prozac from 80 mg to 40 mg. At that visit, Dr. Valko left Patient 15's Prozac at the lower dose of 40 mg and added BuSpar 10 mg twice per day to help prevent possible serotonin syndrome. Dr. Barzman criticized using BuSpar for that purpose when Dr. Valko could have lowered the dose of Prozac. However, the hearing examiner does not find that criticism to be persuasive. Dr. Valko already lowered Prozac by ratifying the mother's decision to reduce Prozac to only one 40 mg dose per day, half of the previous dose. Further, according to the hearing examiner's understanding of Dr. Valko's testimony, he had prescribed BuSpar to augment the lowered dose of Prozac. According to supporting literature referenced by Dr. Valko, this is an appropriate use of BuSpar. Keeping the dose of Prozac lower by augmenting it with BuSpar potentially helped prevent serotonin syndrome. Accordingly, the hearing examiner finds the evidence to be insufficient to establish that this was inappropriate. The Board, as a panel of experts, is encouraged to amend this finding if it finds otherwise.

m. There are no issues under Finding of Fact 1 concerning Patients 13 and 14.

2. From in or around January 2005 to in or around August 2016, Dr. Valko prescribed excessively high doses of medications in his treatment of Patients 1 through 15. At times, the effects of the medications may have caused conditions, including but not limited to increased anxiety or obsessions, for which he prescribed additional or increased medications and/or failed to adjust prescribed medications.

a. Patient 1:

i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 1. For example, at Patient 1's initial visit with Dr. Valko on January 10, 2011, Dr. Valko began prescribing large doses of stimulant medication to Patient 1 for a diagnosis of ADHD Combined Type: Concerta 144 mg per day and Ritalin 20 mg per day. Both medications contain methylphenidate. Dr. Barzman testified that the FDA maximum recommended daily dose of Ritalin, a short-acting version of methylphenidate is 60 mg. For Concerta, a long-acting formulation, the maximum daily dose is 72 mg. At the next visit, Dr. Valko increased Concerta to 216 mg per day plus Ritalin 20 mg, a daily dose of 236 mg. By March 17, 2011, Dr. Valko was prescribing Concerta 216 mg and Ritalin 90 mg per day, a daily dose of 306 mg of methylphenidate. Patient 1's schoolwork did improve, but mother reported that Concerta made him grumpy and moody. Dr. Valko discontinued Concerta and increased Ritalin to 100 mg three times per day along with an optional fourth dose of 100 mg for after-school activities. At the next visit on April 26, 2011, Dr. Valko increased Ritalin to 110 mg three times per day with an optional fourth dose of 110 mg, a daily dose of 330 to 440 mg of methylphenidate. A few days later, on May 2, 2011, mother called and said she had increased Patient 1's doses of Ritalin to 120 mg. Patient 1 was seen with his mother on May 5, 2011, and Adderall 80 mg three times per day, a daily dose of 240 mg, was substituted for Ritalin. Patient 1 did not tolerate Adderall, and Dr. Valko restarted Ritalin at 110 mg three or four times per day, subsequently increased to 120 mg three or four times per day for a daily dose of 360 mg to 480 mg. This amount was six to eight time the FDA maximum recommended daily dose of 60 mg. In June 2011 Dr. Valko discontinued Ritalin and reduced the amount of stimulant prescribed for a time. However, by January 14, 2015, Patient 1 was back to Concerta 216 mg per day plus Ritalin 40 mg as needed.

Dr. Barzman testified that, in arriving at a maximum daily dose, the FDA relies on safety studies that are usually performed by the manufacturer. Dr. Barzman further testified that dosage levels of stimulants that Dr. Valko prescribed to Patient 1 and other patients in this matter exceeded, and in some of these patients including Patient 1, far exceeded the FDA maximum recommended daily dose. Moreover, Dr. Barzman testified that no standard of care even exists for these levels because no studies exist concerning safe prescribing at these

levels. In fact, one of the articles relied upon by Dr. Valko states that "more is not necessarily better" when it comes to prescribing stimulant medication.

Dr. Valko testified that the doses of stimulant medication he prescribed to Patient 1 were not excessive because the patients were not having any adverse effects to the medication and were being closely monitored. However, this position is not persuasive because of the safety concerns identified by Dr. Barzman of going so far beyond dosage levels that have been studied.

Dr. Valko also testified that, if the medication dose is effective but does not seem to be lasting very long it, becomes necessary to increase the frequency of dosing. Dr. Valko further testified that if a large single dose is required to control the patient's symptoms but last only a short time due to the patient's metabolism of the drug, multiple doses will be needed at that large dose. That would naturally increase the total daily dose used by the patient. However, it is the hearing examiner's understanding that the FDA maximum recommended daily dose is based on the doses that have been studied and approved by the FDA, and that exceeding that maximum dose increases the risk to the patient.

ii. The high doses of stimulants that Dr. Valko prescribed to Patient 1 may have caused an increase in Patient 1's aggressive behavior. Very early in his treatment, Patient 1 was receiving Concerta 144 mg and Ritalin 20 mg since January 10, 2011. On February 14, 2011, Patient 1 was reported to be destructive and aggressive toward others and had recently destroyed a camera. Dr. Valko discontinued Ritalin and added Risperdal 0.5 mg twice per day. However, Dr. Barzman testified that Dr. Valko should have tried lowering the dose of Concerta as that may have contributed to Patient 1's aggression.

b. Patient 2:

i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 2. For example, in December 2011, Dr. Valko prescribed Focalin 20 mg four times per day for a daily dose of 80 mg. Dr. Barzman acknowledged that the dose appeared to be helping; however, he testified that the FDA recommended maximum daily dose of Focalin is 20 mg,[62] and that 80 mg is concerning because that dosage level has not been studied. Later, Dr. Valko prescribed even higher doses of Focalin, 170 mg per day and then 200 mg per day, which Dr. Barzman testified he has never encountered before. Focalin 200 mg per day is ten times the FDA maximum recommended daily dose.

ii. The dose of Wellbutrin XL Dr. Valko prescribed on March 1, 2013—300 mg twice per day for a daily dose of 600 mg—was too high due to seizure risk even if Patient 2 had no seizure disorder. Dr. Valko lowered the dose back to 300 mg in the morning at the following visit.

[62] This is for immediate-release Focalin and is lower than the maximum dose for the Focalin XR which was prescribed to some other patients.

iii. The evidence is insufficient to find that excessive doses of stimulant medication caused Patient 2's obsessions or anxiety because Dr. Barzman retracted that criticism at the hearing as having been speculative.

c. Patient 3:
   i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 3. For example, beginning in November 2011, Dr. Valko prescribed Ritalin 60 mg four times per day, a daily dose of 240 mg, which is four times the FDA maximum recommended daily dose. Subsequently, from October 2012 through January 2013, he prescribed Ritalin at daily doses of 300 mg (60 mg five times per day), which is five times the FDA maximum recommended daily dose of 60 mg.
   ii. In June and July 2009, Dr. Valko prescribed Focalin XR 30 mg to Patient 3 and titrated it up to 90 mg at the next visit. Dr. Barzman opined that such an increase should be made more slowly in order to ensure that the patient is taking the smallest effective dose from a safety standpoint and to not build up a tolerance to the medication. Such testimony is found to be persuasive.
   iii. The inappropriate prescribing of stimulants may have caused an increase in Patient 3's negative behavior such as aggression and anxiety.

d. Patient 4:
   i. Dr. Valko prescribed excessive amounts of stimulant medication to Patient 4. For example, from October through December 2011, he prescribed Metadate CD 150 mg per day to Patient 4. From March 2012 through July 2012 Dr. Valko added a second dose of Metadate CD that increased the daily dose to 300 mg. Dr. Valko acknowledged that the FDA maximum recommended daily dose for Metadate CD is 60 mg. Further, beginning in August 2012, Dr. Valko prescribed Vyvanse 210 mg per day. Dr. Valko acknowledged that the FDA maximum recommended daily dose for Vyvanse is 70 mg per day. In October 2012 he added an afternoon dose of Adderall 60 mg to the Vyvanse. This prescribing continued through June 2013 when Vyvanse and Adderall were discontinued.
   ii. The inappropriate prescribing of stimulants may have caused an increase in Patient 4's compulsive stealing.

e. Patient 5:
   i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 5. For example, in January 2011 Dr. Valko began prescribing Vyvanse 120 mg per day. The FDA maximum recommended daily dose for Vyvanse is 70 mg. The following month, he increased Vyvanse to 200 mg per day, which continued for several months. Later, beginning in September 2011, Dr. Valko discontinued Vyvanse and prescribed Focalin XR 120 mg in the morning, which he subsequently doubled to 240 mg per day in February 2012. This continued through July 2012 when he reduced the daily dose of Focalin to 200 mg and then to 120 mg.

ii. GeneSight testing performed after the relevant time period indicated that Patient 5 is a fast metabolizer of stimulant medication. The hearing examiner does not find this to mean the stimulant prescribing was appropriate; however, the Board, as a panel of experts, is encouraged to amend this finding should it determine otherwise.

f. Patient 6:
   i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 6. For example, in October 2008, Dr. Barzman prescribed Vyvanse 140 mg per day, twice the FDA maximum recommended daily dose of 70 mg. In March 2010, Dr. Valko added Ritalin 20 mg per day. Ritalin was later discontinued but the patient was maintained on Vyvanse 140 mg for the majority of time through October 2011.
   ii. The inappropriate prescribing of stimulants may have caused an increase in Patient 6's aggressive behavior.

g. Patient 7:
   i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 7. For example, by December 7, 2009, Dr. Valko was prescribing Focalin XR 80 mg per day. In May 2010 he increased Focalin XR to 120 mg per day, well above the maximum recommended daily dose of 50 mg, and was further increased to 180 mg in November 2010. From December 2010 through January 2011, Focalin XR was discontinued and Concerta 108 mg per day was added, then Patient 7 was restarted on Focalin XR 120 mg. On December 5, 2011, Dr. Valko increased Focalin XR to 270 mg per day.
   ii. The inappropriate prescribing of stimulants may have caused an increase in Patient 7's anxiety and OCD.

h. Patient 8:
   i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 8. For example, on June 1, 2010, Dr. Valko prescribed a daily dose of Focalin XR 80 mg, above the maximum dose of 50 mg, and in April 2011 increased in to 180 mg per day. At Patient 8's next visit in May 2011 he discontinued Focalin and added Concerta 162 mg per day and increased several days later to 216 mg per day. The FDA maximum recommended daily dose for Concerta is 72 mg. A few days after that, Dr. Valko discontinued Concerta and restarted Focalin XR 180 mg per day. In July 2011 he reduced the daily dose to 120 mg.
   ii. The inappropriate prescribing of stimulants may have caused an increase in Patient 8's anxiety and obsessive behavior.

i. Patient 9:
   i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 9. For example, in July 2007, Dr. Valko prescribed Concerta 108 mg per day which was increased to 162 mg per day in December 2007. Concerta

was discontinued the following month. Dr. Valko did not prescribe stimulants to Patient 9 for over a year. In March 2009, he restarted Concerta at 162 mg per day, which was increased to 270 mg by October 2009, then to 540 mg in June 2010. Subsequently, following a brief period during which he discontinued Concerta and prescribed Focalin XR, he restarted Patient 9 on Concerta at 270 mg per day. Subsequently he added Focalin XR 90 mg to the Concerta. He continued on this regimen until mid-2012 when Ritalin 120 mg was substituted for Focalin XR.

ii. GeneSight testing performed after the relevant time period indicated that Patient 9 is a fast metabolizer of stimulant medication, antipsychotics, and antidepressants. The hearing examiner does find this to mean the stimulant prescribing was appropriate; however, the Board, as a panel of experts, is encouraged to amend this finding should it determine otherwise.

iii. The evidence is insufficient to establish by a preponderance of the evidence that the inappropriate prescribing of stimulants caused obsessions. Patient 9 presented to Dr. Valko with those issues, including obsessively picking dried glue off the glue containers at school, and was later diagnosed with Asperger's Syndrome. Dr. Barzman acknowledged that Asperger's Syndrome could have been the basis for Patient 9's obsessions.

j. Patient 10:

i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 10. For example, Dr. Valko began prescribed Concerta 108 mg to Patient 10 in October 2007 and increased it to 144 mg in October 2008. Dr. Valko continued to adjust Patient 10's stimulant medication and, by April 2010, he was prescribing Vyvanse 240 mg per day. The FDA maximum recommended daily dose for Vyvanse is 70 mg.

ii. The excessive stimulant prescribing may have lowered Patient 10's frustration tolerance causing him to be more irritable.

k. Patient 11:

i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 11. For example, in January 2009, Dr. Valko began prescribing Concerta 108 mg per day which was increased to 144 mg per day by June 2009. He reduced it to 90 mg in November 2009.

ii. The inappropriate prescribing of stimulants may have caused an increase in Patient 11's OCD.

l. Patient 12: Dr. Valko inappropriately prescribed a very high daily dose of Clozapine—1,200 mg per day—for several months in 2007.

m. Patient 13: From January 2010 through March 2012, Dr. Valko prescribed Wellbutrin SR 600 mg per day to Patient 13 creating an increased risk of seizure even in a patient who does not have a seizure disorder.

n. Patient 14: At one visit on April 27, 2010, Dr. Valko exceeded the maximum safe dose of Seroquel by prescribing a daily dose of 1,200 mg to Patient 14.

o. Patient 15:
   i. Dr. Valko prescribed excessive, unstudied doses of stimulant medication to Patient 15. For example, beginning in November 2009, Dr. Valko prescribed Vyvanse 80 mg and Adderall 10 mg. By December 2010, Dr. Valko had discontinued Adderall and began prescribing Vyvanse 200 mg per day, which was increased to 240 mg per day in April 2011. Dr. Valko maintained Patient 15 at this dose through July 2016.
   ii. On January 26, 2010, Dr. Valko prescribed a daily dose of Wellbutrin SR 450 mg to Patient 15. The appropriate daily dose of Wellbutrin SR is from 3 to 6 milligrams of Wellbutrin SR per kilogram of body weight. At Patient 15's weight of 72 pounds, 450 mg was approximately 13 mg per kg of body weight.
   iii. On November 5, 2012, Dr. Valko discontinued Prozac and added Lexapro 40 mg in the morning. The FDA maximum recommended daily dose for Lexapro is 20 mg.
   iv. On June 15, 2011, approximately two months after increasing Vyvanse to 240 mg per day in April 2011, Patient 15 reported tremors. Dr. Valko attributed the tremors to Depakote, which had been started around April 2011. Dr. Barzman opined that Patient 15's tremors had been caused by the Vyvanse. However, Dr. Barzman testified that if the increased dose of Vyvanse was the cause he would have expected the tremor to begin almost immediately. This did not seem to be the case as Patient 15 had an intervening visit on May 16, 2011 and did not report tremors. Accordingly, the evidence is insufficient to support a finding that the prescribing of stimulants may have caused or increased Patient 15's tremor.

3. The evidence supports a finding that the patients identified in this matter, especially the child and adolescent patients, Patients 1 through 11 and Patient 15, were extremely complex patients and difficult to treat.

CONCLUSIONS OF LAW

The acts, conduct, and/or omissions of Tim R. Valko, M.D., as described in Findings of Fact 1, 1.a.i. and 1.a.ii., 1.b. in its entirety, 1.c.i. and 1.c.ii., 1.d. in its entirety, 1.e.i. and 1.e.iii., 1.f. in its entirety, 1.g. in its entirety, 1.h., 1.i., 1.j in its entirety, 1.k. in its entirety, and 1.l.i.; 2, 2.a. in its entirety, 2.b.i. and 2.b.ii., 2.c. in its entirety, 2.d. in its entirety, 2.e. in its entirety, 2.f. in its entirety, 2.g.i. in its entirety, 2.h. in its entirety, 2.i.i. and 2.i.ii., 2.j. in its entirety, 2.k. in its entirety, 2.l., 2.m., 2.n., and 2.o.i. through 2.o.iii., individually and/or collectively, constitute a "[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 those clauses are used in R.C. 4731.22(B)(2).

The treatment of Patient 15 with large doses of stimulant medication, as set forth in Finding of Fact 2.o.i., extended beyond September 29, 2015, and continued through July 2016. Pursuant to R.C. 4731.225, the Board is authorized to impose a civil penalty for this violation. The Board's fining guidelines for this violation are as follows: Minimum Fine $2,500; Maximum Fine $18,000.

RATIONALE FOR THE PROPOSED ORDER

The evidence established that Dr. Valko prescribed very large doses of stimulant medication to his patients, as well as very large doses of other medications such as Wellbutrin, Clozapine, and Seroquel. The doses he prescribed have not been studied to determine if they are safe. In addition, the doses of stimulants may have caused or exacerbated other conditions such as anxiety, aggression, and OCD. Further, in some cases he prescribed Risperdal without obtaining metabolic labs, and he prescribed large doses of stimulants without obtaining EKGs. All of these issues affect patient safety. On a few occasions the records reflected conditions for which the medication prescribed is not indicated, although, overall, Dr. Valko's documentation was very good.

The evidence also included mitigating factors. Dr. Barzman readily acknowledged that these patients were extremely complex and difficult, in some cases exacerbated by complex home situations. Sometimes the medications prescribed seemed effective for only a short time and then required adjustment or a different medication. The medical records also reflect very detailed documentation concerning each patient's condition and treatment. The patients were generally seen frequently, sometimes with only two weeks and, on a few occasions, one week between visits. Also, the evidence indicates that Dr. Valko made an effort to keep these patients, some of whom were very sick, in school and/or living at home. There was no evidence of a dishonest or selfish motive in any of these cases. In addition, Dr. Valko took remedial measures by developing more detailed and informative progress notes which can be seen in the charts of patients he continued to treat in 2013 and beyond. Finally, Dr. Valko testified with conviction that he loves his work and is always looking for ways to improve his practice.

With respect to the proposed order, the hearing examiner considered but rejected placing an absolute limitation on Dr. Valko's prescribing of stimulant or other medications as it is the hearing examiner's impression that the FDA maximum recommended daily dose does not establish an absolute ceiling on physicians' ability to prescribe. However, it would be beneficial to suspend Dr. Valko's license until he is able to complete a course or courses, approved in advance by the Board, that address the prescribing of controlled substance stimulant medications, as that is the area of primary concern. Following reinstatement, Dr. Valko would be placed on probation and he would be required to maintain a log of controlled substance stimulant medications prescribed, and a monitoring physician would be required to monitor Dr. Valko's practice and review his charts. Finally, the minimum fine of $2,500.00 is recommended.

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 Tim R. Valko, M.D., to practice medicine and surgery in the State of Ohio shall be SUSPENDED for an indefinite period of time.

B. **FINE**: Within thirty days of the effective date of this Order, Dr. Valko shall remit payment in full of a fine of two thousand five hundred dollars ($2,500.00). 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. Valko's license to practice medicine and surgery until all of the following conditions have been met:

1. **Application for Reinstatement or Restoration**: Dr. Valko shall submit an application for reinstatement or restoration, accompanied by appropriate fees, if any.

2. **Controlled Substance Stimulants Prescribing Course(s)**: At the time he submits his application for reinstatement or restoration, or as otherwise approved by the Board, Dr. Valko shall provide acceptable documentation of successful completion of a course or courses dealing with the prescribing of controlled substance stimulant medication. 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. 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. Valko 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.

3. **Payment of Fine**: Dr. Valko shall have fully paid the fine as set forth in Paragraph B of this Order.

4. **Additional Evidence of Fitness To Resume Practice**: In the event that Dr. Valko 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, Dr. Valko's license shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of at least three years:

1. **Obey the Law**: Dr. Valko 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. Valko 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. Valko's license is restored or reinstated. 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. Valko 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. Valko's license is restored or reinstated, or as otherwise directed by the Board. Subsequent personal appearances shall occur as otherwise 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. **Controlled Substance Stimulants Log**: Dr. Valko shall keep a log of all controlled substance stimulants he prescribes, orders, administers, or personally furnishes. Such log shall be submitted in a format of Dr. Valko's choosing and approved in advance by the Board. All such logs required under this paragraph must be received in the Board's offices no later than the due date for Dr. Valko's declarations of compliance, or as otherwise directed by the Board. Further, Dr. Valko shall make his patient records with regard to such controlled substance stimulants available for review by an agent of the Board upon request.

5. **Monitoring Physician**: Within 30 days of the date of Dr. Valko's reinstatement or restoration, or as otherwise determined by the Board, Dr. Valko shall submit in writing 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. Valko and who is engaged in the same or similar practice specialty.

   The monitoring physician shall monitor Dr. Valko and his medical practice, and shall review Dr. Valko'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. Valko and his medical practice, and on the review of Dr. Valko's

patient charts. Dr. Valko 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. Valko's declarations of compliance.

In the event that the designated monitoring physician becomes unable or unwilling to serve in this capacity, Dr. Valko shall immediately so notify the Board in writing. In addition, Dr. Valko 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. Valko 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. Valko's monitoring physician, or may withdraw its approval of any physician previously approved to serve as Dr. Valko'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. Valko shall notify the Board in writing of any change of residence address and/or principal practice address within 30 days of the change.

7. **Tolling of Probationary Period While Out of Compliance**: In the event Dr. Valko is found by the Secretary of the Board to have failed to comply with any provision of this Order, and is so notified of that deficiency in writing, such period(s) of noncompliance will not apply to the reduction of the probationary period under this Order.

E. **TERMINATION OF PROBATION**: Upon successful completion of probation, as evidenced by a written release from the Board, Dr. Valko's license will be fully restored.

F. **VIOLATION OF THE TERMS OF THIS ORDER**: If Dr. Valko 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.

1. **Required Reporting to Employers and Others**: Within 30 days of the effective date of this Order, Dr. Valko 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. Valko 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. Valko 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. Valko 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. Valko 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. Valko 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. Valko 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. Valko 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. Valko 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. Valko receives from the Board written notification of the successful completion of his probation.

EFFECTIVE DATE OF ORDER: 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 MARCH 11, 2020 IN THE MATTER OF TIM R. VALKO, M.D.

REPORTS AND RECOMMENDATIONS

Dr. Schottenstein asked the Board to consider the Reports and Recommendations appearing on the agenda. He asked if 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 the matters of: Ajay P. Anvekar, M.D.; Tim R. Valko, M.D.; and Peter Zavell, M.D. A roll call was taken:

Dr. Rothermel	Y
Dr. Saferin	Y
Mr. Giacalone	Y
Dr. Edgin	Y
Dr. Schottenstein	Y
Mr. Gonidakis	Y
Dr. Johnson	Y
Dr. Kakarala	Y
Dr. Feibel	Y
Dr. Bechtel	Y

Dr. Schottenstein further asked if each member of the Board understands 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. A roll call was taken:

Dr. Rothermel	Y
Dr. Saferin	Y
Mr. Giacalone	Y
Dr. Edgin	Y
Dr. Schottenstein	Y
Mr. Gonidakis	Y
Dr. Johnson	Y
Dr. Kakarala	Y
Dr. Feibel	Y
Dr. Bechtel	Y

Dr. Schottenstein further asked if each member of the Board understands 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. A roll call was taken:

Dr. Rothermel	Y
Dr. Saferin	Y
Mr. Giacalone	Y

Dr. Edgin	Y
Dr. Schottenstein	Y
Mr. Gonidakis	Y
Dr. Johnson	Y
Dr. Kakarala	Y
Dr. Feibel	Y
Dr. Bechtel	Y

Dr. Schottenstein 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. In addition, Dr. Bechtel served as Secretary and/or Supervising member in the matter of Dr. Valko. The matter involving Dr. Anvekar is non-disciplinary in nature and therefore all Board members may vote.

During these proceedings, no oral motions were allowed by either party. Respondents and their attorneys addressing the Board were allotted five minutes to do so. The assistant attorneys general are subject to the same limitations.

.....

Tim R. Valko, M.D.

.....

Motion to approve and confirm the Proposed Findings of Fact, Conclusions, and Order in the matter of Dr. Valko:

Motion	Dr. Johnson
2nd	Dr. Kakarala

Dr. Schottenstein stated that he will now entertain discussion in the above matter.

Dr. Schottenstein stated that the Food and Drug Administration (FDA) approves medication, but it does not regulate the practice of medicine. State medical boards regulate the practice of medicine, and in that respect it is ultimately the Board's judgment whether off-label prescribing is below the minimal standards of care. Dr. Schottenstein opined, with regret, that Dr. Valko's prescribing was grossly negligent and fell below the minimal standards of care. Dr. Schottenstein stated that it is not persuasive to equate this level of prescribing with the off-label prescribing that is very common in the medical field.

Dr. Schottenstein continued that a physician has a duty to care for his patients, and he opined that Dr. Valko violated that duty by deviating so substantially from the standard of practice in a way that cannot be explained away by describing his prescribing as "off-label." Dr. Schottenstein commented that by the defense counsel's definition, every case in which a physician practices below minimal standards could be conceptualized as off-label, and every

such case could also be explained as individualizing the treatment as Dr. Valko testified. Dr. Schottenstein noted the defense argument that ten different psychiatrists may look at a patient and develop ten different approaches to treat that patient; however, what is left out of that remark is that all ten of those approaches, even if they are different from one another, should exercise caution and prudence and be consistent with what most practicing psychiatrists would consider reasonable. Dr. Schottenstein opined that the average, reasonable psychiatrist would react to this amount of prescribing with incredulity and a feeling of fear for the welfare of the patients.

Dr. Schottenstein noted that Dr. Valko justified his prescribing, in part, by saying that his patients are complex. However, Dr. Schottenstein stated that the complexity of the patients' presentation would never justify this kind of prescribing. Dr. Schottenstein stated that he has been practicing child psychiatry for over 20 years, just as the State's expert Drew H. Barzman, M.D., has, and he has never seen anything like the prescribing in this case. Not only were these very high doses, but frequently the medications were started at a very high level and then may be doubled or tripled, or stopped abruptly without any gradual taper. Dr. Schottenstein saw this pattern not only with stimulants, but also anti-psychotics, anti-depressants, and alpha-agonists. In many cases, Dr. Valko did not seem inclined to try small dose increases first to see if they would be effective.

Dr. Schottenstein stated that he looked through the articles that Dr. Valko referenced to bolster his claim that his prescribing was legitimate, including the article from the Southern Medical Journal reference in the defense counsel's closing argument. Dr. Schottenstein opined that it would be very challenging to find a psychiatrist who would look at those articles and feel that they sufficed as justification for Dr. Valko's prescribed dosages or the aggressiveness of dose changes. Dr. Schottenstein opined that the articles provided by Dr. Valko in no way justified this level or prescribing, nor is there substantial peer review to justify it.

Dr. Schottenstein stated that patients can develop serious reactions to stimulant medications, including dependency, psychosis, mania, and aggression. In patients prone to cardiovascular issues, one may see hypertension, myocardial infarction, stroke, and arrythmia, and those adverse reactions may be dose-related. Dr. Schottenstein also pointed out substantial concerns about Dr. Valko's prescribing of non-stimulants. Dr. Schottenstein stated that one does not, as Dr. Valko did, increase Clonodine from 0.2 mg per day to 0.8 mg per day, which is twice the FDA recommended maximum dose, all at once. Dr. Schottenstein also stated that one does not, as Dr. Valko did, put a patient on 13 mg per kg per day of Wellbutrin when the recommended maximum dose is 6 mg per kg per day. Dr. Valko also prescribed a patient 1200 mg per day of Clozapine when the recommended maximum dose is 900 mg per day. Dr. Schottenstein noted that another psychiatrist had previously come before the Board whose arguably aggressive prescribing of Clozapine led to the death of a patient; that physician also justified his prescribing by pointing to the complexity of the patient.

Dr. Schottenstein stated that Dr. Valko's manner of practice is heedless of the risks of these medications. Dr. Schottenstein opined that instead of portraying a picture of being appropriately aggressive with a complex patient, this prescribing paints a picture of someone who is flailing and does not know what he is doing. Dr. Schottenstein noted Dr. Valko's testimony that he does not pay attention to the body weight of his patients, but just pushes the dosage as long as

there is no obvious adverse event. Dr. Schottenstein stated that the whole point is to avoid the adverse event in the first place by being mindful of things like age and weight when prescribing.

Dr. Schottenstein commented that in his testimony, Dr. Valko did not appear to appreciate the fact that stimulant medications are Schedule II drugs, meaning they have a high potential for abuse which could lead to psychological or physical dependence. There are severe restrictions on the ways in which these drugs can be used because they have the highest potential for abuse among drugs allowed for medical use, in the same category as opioids. Dr. Schottenstein stated that there is risk of abuse, dependency, diversion, and societal harm with Dr. Valko's manner of prescribing. Dr. Schottenstein opined that it is not reasonable to justify this level of prescribing based on a few cherry-picked articles that basically consist of non-blinded case reports with low sample sizes, especially with drugs that are this potentially dangerous to individual patients as well as to society at large. Dr. Schottenstein stated that when prescribing these medications, one should proceed in a way that reflects the consensus of the practitioners in the field.

Given the fact that stimulants are drugs of abuse, Dr. Schottenstein wondered if Dr. Valko was not mindful of the possibility of stimulant intoxication and dependency. Dr. Schottenstein further wondered, when Dr. Valko prescribes a stimulant dose that is ten times higher than the FDA recommended maximum, if he contemplates the possibility that the patient will become intoxicated from the stimulant and that regular stimulant intoxication can provoke severe behavioral reactions such as anxiety, agitation, psychosis, and increased psychomotor activity, which have all been seen in Dr. Valko's patients. Dr. Schottenstein questioned what the difference would be between the doses prescribed by Dr. Valko and the dose one would take if one was inclined to abuse these medications. Dr. Schottenstein stated that the doses prescribed by Dr. Valko look like dosages of abuse, the kind of doses one would take in order to get high, and these doses are being prescribed to children.

Regarding Dr. Valko's explanation that his patients are complex, Dr. Schottenstein stated that, if anything, a physician should proceed even more cautiously when a patient is complex because there is arguably a great risk of adverse reactions. Dr. Schottenstein commented that by Dr. Valko's logic, there is no such thing as a minimal standard of care in a complex patient and that the complexity itself justifies a medication regimen that is so excessive that it is experimental and unstudied. Dr. Schottenstein stated that the complexity of the patient is not justification to violate the standard of care, and that standard was violated repeatedly in this case.

Dr. Schottenstein noted that Patient 10 was admitted to a psychiatric hospital and one of his admitting diagnoses was medication-induced psychosis. Dr. Schottenstein stated that the term "medication-induced" refers to the high dose of stimulants that Dr. Valko prescribed to Patient 10. The admitting physician's notes stated the following:

> I believe that agitation has been made worse by the unusual level of medications that have been prescribed from Dr. Valko's office.

Dr. Schottenstein also quoted from later in the note:

> We'll reduce the dose of Vyvanse to more reasonable levels and will reduce some of the other mediations. It is possible in the end that the patient may not

> have medication-responsive symptoms and that he may need more behavioral therapy.

Dr. Schottenstein observed that this subsequent psychiatrist is approaching Patient 10 in a spirit of humility and he understands that medication management may be inadequate to fully address Patient 10's symptoms. Dr. Schottenstein further observed that the subsequent psychiatrist is not contemplating medication dosing that is orders of magnitude higher than the recommended dose range.

Dr. Schottenstein had noticed the pattern in many of these patients in which the prescribing of high dosages of stimulants would precede a subsequent need for anti-psychotic or anti-depressant medication to control agitation or anxiety. Dr. Barzman had also recognized this pattern and expressed at times his concern that stimulants could be provoking aggression, anxiety, obsessive-compulsive features, and behavior disturbance, and that Dr. Valko should have considered lowering the dosage of stimulants. While one could argue that these patients were prone to those symptoms to begin with, Dr. Schottenstein stated that the pattern was such that several patients were medicated with these substantial doses of stimulants before requiring medication for agitation or anxiety, and then received additional diagnoses to justify those additional medications after the fact.

Dr. Schottenstein stated that he does not have the sense that Dr. Valko entertains evidence that is contrary to his belief that hyperaggressive doses and dose changes of medications are legitimate interventions in challenging patients. When a patient has a bad reaction to high dosages or abrupt dose changes, Dr. Valko explains it away with another diagnosis and another medication. Dr. Schottenstein noted that Dr. Valko testified that he had not been inclined to get his own expert for his hearing because he felt he could answer the questions himself; Dr. Schottenstein opined that Dr. Valko would have been hard-pressed to find an expert who would have felt this kind of prescribing was justified.

Dr. Schottenstein quoted from Patient 11's medical record:

> Mother called stating pharmacy refused to fill the rest of [Patient 11's] scripts and that they felt the amount Dr. Valko was giving him was lethal.

Dr. Schottenstein commented that if he ever received a call like that, it would scare him and he would call the pharmacist to learn what had so concerned the pharmacist, and he would then rethink his prescribing. However, Dr. Valko just told the patient to fill the prescription at another pharmacy; Dr. Valko also added that that happens about once a year, a statement that Dr. Schottenstein could not quite believe. Dr. Schottenstein then quoted from the initial psychiatric assessment from Patient 11's subsequence child psychiatrist:

> The patient's mother says that her pharmacist actually refused to fill these prescriptions because it seemed to be in unusually high dosages. ... The patient's pharmacist as well as the patient's mother's psychiatrist told her to come to our clinic because of the fact that the patient was being over-medicated by Dr. Valko. ... The patient's mother says that each time she went for a visit, the patient would come back with another additional medication, and it came to the point where the patient was on six medications.

Dr. Schottenstein commented that Patient 11 was a seven-year-old child and had been treated over the preceding four years by Dr. Valko. The subsequent outpatient psychiatrist's plan referred to the fact that Patient 11 presented on "multiple psychotropic medications at unusually high dosages." The outpatient psychiatrist had to explain to Patient 11's mother that Patient 11 had likely experienced an irreversible event with regard to what he thought was likely Tardive dyskinesia "as a result of unusually high dosages and excessive dosage of anti-psychotic medications at a young age." The outpatient psychiatrist's note continued:

> The patient's mother was urged to contact authorities and file complaints with requisite board members, and most likely I will have to make a report to the State Medical Board of Ohio because of significant malpractice and making significant departure from usual and customary medical services as they are delivered to a four-year-old.

Dr. Schottenstein opined that this outpatient psychiatrist seeing Dr. Valko's patient was more than just concerned, he was appalled at the nature of the care provided to this child by Dr. Valko. The outpatient psychiatrist did not entertain the possibility that the complexity of the patient's presentation justified the kind of treatment he received from Dr. Valko, he did not excuse that treatment by conceptualizing it as off-label, and he did not think back to reputable journal articles that would legitimize the treatment because there are no such articles.

Dr. Schottenstein continued that the notes on Patient 11 show that a pharmacist, Patient 11's mother's psychiatrist, Patient 11's primary care physician, and Patient 11's subsequent outpatient child psychiatrist all expressed significant concern about this level of medication dosing.

Dr. Schottenstein stated that there was no acknowledgement in Dr. Valko's testimony that his level of prescribing had been concerning. Rather, it was the opposite, because despite the fact that multiple patients experienced what appears to be obvious adverse effects from Dr. Valko's medical management and his medical practice is so obviously below the minimal standards of care, Dr. Valko and his defense counsel made the case that everything has been appropriate and that the Board should take no further action. Dr. Schottenstein asked where was Dr. Valko's insight, his humility, his self-reflection, and his ability to acknowledge that he may have been wrong.

Dr. Schottenstein quoted from the defense counsel's closing argument:

> Although the dosages of some of the medications were above FDA guidelines, Dr. Barzman testified that the medications were effective for the patients and there were no adverse effects.

Dr. Schottenstein stated respectfully that that is not what Dr. Barzman said. The defense counsel went on to say the following:

> Additionally, the reliable literature indicates that Dr. Valko's prescribing was appropriate.

Dr. Schottenstein stated respectfully that that is just not true.

Despite statements about the complexity of the patients, references to off-label prescribing, and journal articles, Dr. Schottenstein stated that this kind of prescribing is just not okay. Dr. Schottenstein characterized Dr. Valko's prescribing as negligent and stated that Dr. Valko hurt his patients. Further, Dr. Schottenstein considered Dr. Valko's failure to take responsibility for his prescribing to be an aggravating factor in this case and made him doubt Dr. Valko's ability to be remediated.

Dr. Schottenstein suggested amending Finding of Fact 1(l) regarding Patient 15. The Hearing Examiner found that Dr. Valko had appropriately used BuSpar when he added it to a lower dose of Prozac to prevent possible serotonin syndrome. Specifically, Patient 15 had been on 80 mg per day of Prozac, and the dose was reduced to 40 mg per day with the addition of BuSpar 10 mg twice per day. Dr. Schottenstein stated that these changes were fine, but it arguably would not reduce the risk of serotonin syndrome because BuSpar is a serotonergic drug. Dr. Schottenstein suspected that this had little to no effect on the risk of serotonin syndrome. Dr. Schottenstein felt that this Finding of Fact should be amended to reflect this and that Conclusion of Law be amended to include Finding of Fact 1(l)(ii) as a violation.

Dr. Schottenstein also suggested amending Finding of Fact 2(i)(ii) regarding Patient 9. The Hearing Examiner found that the stimulant prescribing in this case was appropriate because GeneSight testing showed that Patient 9 was a rapid metabolizer. Dr. Schottenstein stated that Patient 9 was put on a dose that is ten times the maximum recommended dose for his age and was far beyond the dose increase that one would contemplate to compensate for a rapid metabolism. Dr. Schottenstein stated that being a rapid metabolizer in no way justifies such a large dose of stimulant medication, and he therefore found this prescribing to be inappropriate. Dr. Schottenstein suggested amending this Finding of Fact accordingly.

Dr. Schottenstein was respectful of the Hearing Examiner's Proposed Order, but he felt it did not go far enough. Dr. Schottenstein asked the Board to consider amending the Proposed Order to permanently revoke Dr. Valko's license. Mr. Giacalone agreed.

Motion to amend the Findings of Fact and Conclusions of Law as discussed by Dr. Schottenstein, and to amend the Proposed Order to permanent revocation of Dr. Valko's medical license while keeping the Proposed Order's fine of $2,500:

Motion	Mr. Giacalone
2nd	Dr. Kakarala

Mr. Giacalone stated that as a pharmacist and as someone who understands the FDA's approval process regarding safety and effectiveness, he found the doses of medication in this case to be eye-popping, especially in children. Mr. Giacalone also did not understand why the process of titration appeared to be non-existent as medications were changed in what appeared to be a helter-skelter fashion. Mr. Giacalone stated that although the changes in medication were well-intentioned given that the patients' psychiatric conditions were extremely complex, he could not follow Dr. Valko's logic in the doses prescribed or the changes in medication without even providing some transition point to see if the changes made were effective or not. Mr. Giacalone stated that Dr. Valko tried to get results, which is something to be applauded, but Mr.

Giacalone stated that he was not sure that the changes that Dr. Valko made were in the best interest of the patients. Dr. Schottenstein agreed, stating that this case is not only about high doses and that Dr. Valko's prescribing seemed haphazard and desultory.

Dr. Feibel stated that he was also most concerned about Dr. Valko's lack of willingness to accept responsibility. Because of this, Dr. Feibel was inclined to support the amendment to permanently revoke Dr. Valko's license.

Vote on Mr. Giacalone's motion to amend:

Dr. Rothermel	Abstain
Dr. Saferin	Abstain
Mr. Giacalone	Y
Dr. Edgin	Y
Dr. Schottenstein	Y
Mr. Gonidakis	Y
Dr. Johnson	Y
Dr. Kakarala	Y
Dr. Feibel	Y
Dr. Bechtel	Abstain

The motion to amend carried.

Motion to approve and confirm the Proposed Findings of Fact, Conclusions, and Order, as amended, in the matter of Dr. Valko:

Motion	Dr. Johnson
2nd	Dr. Kakarala
Dr. Rothermel	Abstain
Dr. Saferin	Abstain
Mr. Giacalone	Y
Dr. Edgin	Y
Dr. Schottenstein	Y
Mr. Gonidakis	Y
Dr. Johnson	Y
Dr. Kakarala	Y
Dr. Feibel	Y
Dr. Bechtel	Abstain

The motion carried.

State Medical Board of
Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

July 12, 2017

Case number: 17-CRF- 0096

Tim R. Valko, M.D.
3130 Executive Parkway
8th Floor
Toledo, Ohio 43606

Dear Doctor Valko:

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 register or reinstate your certificate to practice medicine and surgery, or to reprimand you or place you on probation for one or more of the following reasons:

(1) In the routine course of your practice, you provided care and treatment for Patients 1 through 15 as identified on the attached Patient Key **(Key is confidential and to be withheld from public disclosure).** During the time period of in or around January 2005 to in or around August 2016, you inappropriately treated and/or failed to appropriately treat and/or failed to appropriately document your treatment of these patients.

(2) During the time period of in or around January 2005 to in or around August 2016, you prescribed excessively high doses of medications in treatment of Patients 1 through 15. At times, the effects of the medications may have caused conditions, including but not limited to increased anxiety or obsessions, for which you prescribed additional or increased medications and/or failed to adjust prescribed medications.

Your acts, conduct, and/or omissions as alleged in paragraphs (1) and (2) 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 those clauses are used in Section 4731.22(B)(2), Ohio Revised Code.

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.

Mailed 7-13-17

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 register or reinstate your certificate 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 a certificate to an applicant, revokes an individual's certificate to practice, refuses to register an applicant, or refuses to reinstate an individual's 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 certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate."

Copies of the applicable sections are enclosed for your information.

Very truly yours,

Kim G. Rothermel, M.D.
Secretary

KGR/CDP/bjr
Enclosures

CERTIFIED MAIL #91 7199 9991 7036 6914 3421
RETURN RECEIPT REQUESTED

IN THE MATTER OF TIM ROBERT VALKO, M.D.

17-CRF-0096

JULY 12, 2017, NOTICE OF OPPORTUNITY FOR HEARING - PATIENT KEY

SEALED TO PROTECT PATIENT CONFIDENTIALITY AND MAINTAINED IN CASE RECORD FILE.