

COMMONWEALTH OF MASSACHUSETTS

Suffolk, ss.

Division of Administrative Law Appeals

Board of Registration in Medicine,
Petitioner

v.

Docket Nos. RM 10-434; RM-14-197

Rahim Shafa, M.D.,
Respondent

Appearance for Petitioner:

Pamela Meister, Esq.
Karen A. Robinson, Esq.
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Board of Registration in Medicine
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Appearance for Respondent:

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Administrative Magistrate:

Kenneth J. Forton, Esq.

RECOMMENDED DECISION

On July 7, 2010, the Petitioner, the Board of Registration in Medicine, issued a Statement of Allegations ordering the Respondent, Rahim Shafa, to show cause why he should not be disciplined for engaging in conduct that places into question his competence to practice medicine and for engaging in conduct that undermines the public confidence in the integrity of the medical profession during his treatment of Patients A

through E. On that same date, the Board issued an order to use pseudonyms and to impound and referred the matter to the Division of Administrative Law Appeals. DALA received these documents on July 14, 2010. Dr. Shafa filed his Answer to the Statement of Allegations on September 29, 2010. There ensued a lengthy series of discovery motions and arguments.

On April 16, 2014, the Board issued a second Statement of Allegations ordering Dr. Shafa to show cause why the Board should not discipline him for engaging in conduct which calls into question his competence to practice medicine, for violating a rule or regulation of the Board, for engaging in misconduct in the practice of medicine, and for engaging in conduct that undermines the public confidence in the integrity of the medical profession during his treatment of Patient F. On that same date, the Board issued an order to use a pseudonym and to impound and referred the matter to DALA. DALA received these documents on April 22, 2014. Dr. Shafa filed his Answer to the second Statement of Allegations on May 19, 2014. I joined the two appeals in a pre-hearing conference on June 6, 2014.

I held the first day of the evidentiary hearing at The Medfield Public Library, 468 Main Street, Medfield, Massachusetts on December 10, 2014, after allowing the Board's motion to do so to accommodate Patient A who presented a doctor's note stating that he was unable to travel to Boston. The hearing continued at DALA, One Congress Street, 11th Floor, Boston, Massachusetts on the following dates: December 11, 2014; December 15, 2014; December 16, 2014; December 18, 2014; December 19, 2014; December 22, 2014; December 23, 2014; January 20, 2015; January 21, 2015; January 22, 2015; and January 23, 2015. Forty-two exhibits were entered into evidence during the hearing, and

twelve witnesses testified: Patient A, Patient A's Sister, Patient D's Ex-Wife (Patient E's Mother), Patient E, Patient F's Mother, Andrew Clark, M.D., Rahim Shafa, M.D., Allan Giesen, D.O., Carl Salzman, M.D., Mark Green, M.D., Marian Ead, R.N., and Laurence Westreich, M.D.

The record closed on December 18, 2015 with the submission of post-hearing briefs.

FINDINGS OF FACT

Based on the testimony and evidence presented, I make the following findings of fact:

1. Rahim Shafa, the Respondent, was born in 1957. He graduated from the National University of Iran in 1982. He has been licensed to practice medicine in Massachusetts since 1992 and specializes in psycho-pharmacology. He became certified by the American Board of Psychiatry and Neurology in Adult Psychiatry in 1997 and by the American Society of Addiction Medicine in Addiction Medicine in December 2012. He is a sole practitioner and maintains private offices in Milford and Natick, Massachusetts. (Ex. 34; Shafa V: 748-50; Shafa XI: 1725.)¹

2. Dr. Shafa completed his internship at Jefferson Medical School from 1990 to 1991, his residency at Boston University Medical Center from 1991 to 1994, and a fellowship in psycho-pharmacology and clinical research at Massachusetts Medical Health Center from 1994 to 1998. Dr. Shafa was an on-call physician from approximately 1993 to 2003 for various hospitals. As on-call physician, he was responsible for all psychiatric care, including care of patients with substance abuse. Substance abuse

¹ Citations to the hearing transcripts will follow the following format: [Name of Witness] [Transcript Volume]: [Page Number(s)].

services included inpatient detoxification and partial hospitalization. He took three courses related to addiction psychiatry through the American Academy of Addiction Psychiatry, and he attended the Academy's annual meeting and symposium from 2008 to 2011. He completed a weeklong mini-fellowship focusing on Pediatric Bipolar Disorder, Progressive Development Disorder, and Attention Deficit Hyperactivity Disorder ("ADHD") in 2004. He became a member of the American Society of Addiction Medicine in August 2004; He completed a weekend-long mini-fellowship focusing on bipolar disorder in 2005 and attended the Society's annual conference in 2006 and 2009. Dr. Shafa was a Staff Psychiatrist for Leonard Morse Hospital (now MetroWest Hospital) from 1997 to 2010 and treated patients in the geriatric, adult, and children's units. Dr. Shafa was Medical Director (Community Psychiatry) at the Wayside Youth and Family Support Network, a psychiatric nonprofit organization, from 1999 to 2001. (Ex. 34; Ex. 39; Ex. 42; Shafa V: 745-55; Shafa VI: 1049-51; Shafa XI: 1633-42.)

3. Massachusetts Mental Health Center is a well-respected psychiatric hospital, known for its research, teaching, and clinical facilities and for treating indigent and refractory patients. (Clark IV: 599-600; Shafa V: 746-47; Salzman VIII: 1220.)

Standard of Care

4. The standard of care in psychiatry is patient-specific. A psychiatrist must review the patient's physical symptoms, current medications and substance use, treatment history, prior response to treatment, willingness to consider alternatives, and financial resources, and then exercise reasonable care and judgment to determine the best course of action. (Clark III: 394, 458; Salzman VIII: 1226-27, 1239.)

5. Refractory patients, or treatment-resistant patients, are individuals who have undergone unsuccessful treatment regimen(s) in the past. They commonly move from one treatment provider to another. They may present with comorbidity, the presence of more than one condition. Dr. Shafa frequently works with refractory patients. (Clark IV: 597-99, 601-03; Salzman VIII: 1225-26.)

6. An unsuccessful patient outcome, taken alone, does not indicate that a physician violated the standard of care. (Clark IV: 601.)

7. Psychiatrists commonly prescribe medications for an off-label purpose. Off-label prescriptions do not conform to the FDA-approved usage. Prescribing a medication for an off-label use does not violate the standard of care. FDA-approved usage of a medication is intended to produce few side effects but may not be the most effective use for a refractory patient. (Clark IV: 597; Shafa VI: 1055; Salzman VIII: 1228-30; Green IX: 1428.)

8. Drug companies typically focus on the effect of a particular drug on a particular condition, and clinical trials frequently rule out patients with comorbidities. Studies on refractory patients are less common. Accordingly, psychiatrists occasionally must treat refractory patients less conventionally. (Clark III: 463; Clark IV: 601-03.)

9. Psychiatrists “hardly ever, if ever” conform their practice to FDA or PDR recommended dose ranges. (Salzman VIII: 1229-30.)

10. It is not unusual for a psychiatrist to prescribe multiple psychiatric medications for a patient, at times on high doses. This could result in a “cocktail of medications that look at first blush as if they don’t make any sense at all.” (Clark III: 458, 460; Salzman VIII: 1249.)

11. Merely prescribing a high dosage of a medication does not violate the standard of care. (Clark IV: 604; Salzman VIII: 1238.)

12. When prescribing medication, generally psychiatrists “start low and go slow” to determine whether the medication is effective and/or causing adverse side effects, because some medications may take weeks or months to become fully effective. (Ex. 2; Clark III: 405-06, 612.)

13. When prescribing medications, psychiatrists also must balance the risks of side effects with the potential benefit. (Clark III: 455-56.)

Classes of Psychiatric Medications

14. Antidepressant medications are effective for treating depression, anxiety, and panic attacks. They are generally well tolerated and have few side effects. Pamelor (nortriptyline) is an antidepressant. (Clark III: 398.)

15. Selective serotonin reuptake inhibitors (“SSRIs”) constitute a subclass of antidepressants and include Prozac (fluoxetine), Lexapro (escitalopram), and Celexa (citalopram). (Clark III: 398, 444; Shafa V: 836.)

16. Atypical anti-psychotic medications are highly effective drugs used for various psychiatric disorders, including schizophrenia and bipolar disorder. Weight gain is a common side effect. Zyprexa (olanzapine), Abilify (aripiprazole), Risperdal (risperidone), Geodon (ziprasidone), and Seroquel (quetiapine) are atypical anti-psychotics. (Clark III: 416-21.)

17. Mood stabilizer medications are commonly used to treat bipolar disorder, and many mood stabilizers were originally developed as anticonvulsive medications. It is not uncommon for more than one mood stabilizer to be prescribed at one time. Depakote

(divalproex sodium), Lamictal (lamotrigine), Lithium citrate (Lithium citrate), Tegretol (carbatrol), Topamax (topiramate), and Trileptal (oxcarbazepine) are mood stabilizers. (Clark III: 428-32, 530; Shafa V: 825-26; Salzman VIII: 1234, 1236, 1267-68.)

18. Benzodiazepines are most commonly used for anxiety and panic disorder. They are very effective, but have several side effects. They are also frequently abused by patients, who take more than they are prescribed. When taken with alcohol, the risks of intoxication or blackouts increase because both act on the same neurotransmitter system in the central nervous system. Ativan (lorazepam), Klonopin (clonazepam), and Xanax (alprazolam) are benzodiazepines. (Clark III: 398-400, 464.)

19. Stimulants are commonly used to treat ADHD. Ritalin (methylphenidate), Adderall XR (amphetamine), and Concerta (methylphenidate) are stimulants. (Shafa V: 865; Giesen VII: 1146.)

Witnesses

20. Andrew Clark, M.D. graduated from the University of Michigan Medical School in 1986 and has been licensed to practice medicine in Massachusetts since 1988. He is board certified in Pediatrics, Psychiatry, and Child and Adolescent Psychiatry. The Massachusetts Department of Mental Health has named him a Designated Forensic Psychiatrist. Dr. Clark has a private practice in Adult and Forensic Psychiatry in Cambridge, Massachusetts. He spends approximately 40 to 60 percent of his time on forensic psychiatry and approximately 20 to 40 percent of his time on patient care for adults and children. (Ex. 15; Clark III: 380-87.)

21. Forensic Psychiatry is a subspecialty of psychiatry that deals with the intersection of psychiatry and the law. (Clark III: 383.)

22. Dr. Clark did not meet or examine Patients A through F. He reviewed their medical records and provided his opinion based on the records only. (Ex. 16; Clark III: 388.)

23. Carl Salzman, M.D. graduated from State University of New York, Upstate Medical Center School in Syracuse, New York in 1963. He has been licensed to practice medicine in Massachusetts since 1969. He is board certified in Psychiatry and Neurology. He has been employed with the Massachusetts Mental Health Center since 1969 and has a private practice in Boston, Massachusetts. He is affiliated with Beth Israel Deaconess and McLean Hospital and is a Professor at Harvard Medical School. He has authored approximately 300 articles, although not any in the last ten years. (Ex. 25; Salzman VIII: 1219-22.)

24. Dr. Salzman has provided clinical supervision to Dr. Shafa since approximately 2008 but did not provide supervision for Dr. Shafa for Patients A or D. In clinical supervision, the supervisor and supervisee discuss the supervisee's patients, their diagnoses, their medications, and any challenges that the supervisee faces in treating the patients. Psychiatrists are not required to consult other psychiatrists. Dr. Shafa pays Dr. Salzman for supervision, as is typical. (Shafa VI: 756-57; Salzman VIII: 1223-24.)

25. Allan Giesen, D.O. graduated from the University of New England with a degree in Osteopathic Medicine in 1994. He is not board certified in general psychiatry. He performed his residency in General Psychiatry at the University of New Mexico and completed a Fellowship in Child and Adolescent Psychiatry at Stanford University. He is currently employed with the South Shore Mental Health Center (Bayview Associates) in Plymouth, Massachusetts, the Home for Littler Wanderers in Plymouth, Massachusetts,

and Catholic Charities in Danvers, Massachusetts. He is clinically-oriented and has not published articles in peer-reviewed journals. Approximately 95 percent of his current patients are children. The youngest child with bipolar disorder whom he has treated was five years old. (Ex. 23; Giesen VII: 1061-65, 1071-73, 1156.)

26. The Home for Little Wanderers is the oldest social service agency in the United States. It provides residency programs that support children in the custody of the Department of Children and Families (formerly known as the Department of Social Services). (Giesen VII: 1064.)

27. Dr. Giesen reviewed the medical records for Patients B, C, and E and provided his opinion based on the records only. (Giesen VII: 1071.)

28. Mark Green, M.D. received his medical degree in 1993 from University College London in the United Kingdom. He completed a psychiatry residency at Cornell New York Hospital from 1995 to 1999. He also completed a fellowship in Addiction Psychiatry at Weill Medical College of Cornell University from 1999 to 2000. He is board certified in psychiatry and addiction psychiatry by the American Board of Psychiatry and Neurology and is licensed to practice medicine in Massachusetts. He has been published eleven times and has presented on the treatment of opiate and mixed general addictions at several conferences. He currently owns a clinic called Psychgarden, LLC that provides general psychiatry and addiction treatment in Belmont, Massachusetts. Approximately 80 percent of his time is devoted to patient care, and approximately 80 percent of his patients seek treatment for addiction. He also served as an Instructor at Harvard Medical School from 2005 to 2011. (Ex. 19; Green IX: 1304-05, 1309-10, 1312-13, 1315.)

29. Board certification from the American Board of Psychiatry and Neurology requires the completion of a board-approved fellowship with a mandated exposure to addiction patients in various settings and an examination. Board certification from the American Board of Addiction Medicine requires a written examination but does not require a fellowship like the American Board of Psychiatry and Neurology does. (Green IX: 1317.)

30. Addiction psychiatry involves assessment, diagnosis, and treatment of addiction, including assessment of intoxication, withdrawal, and the impact of addiction on patients. Addiction psychiatrists assess the accuracy of urine drug tests and the frequency of drug use, and then work with friends, family, and other treaters to determine the extent of the patient's addiction. From this information, the addiction psychologist arrives at a treatment plan, which usually includes medical and nonmedical treatments. (Green IX: 1305-08.)

31. Dr. Green reviewed Dr. Shafa's clinical record for Patient F, the complaint to the Board, and correspondence between an attorney and Dr. Shafa about Patient F's records and provided his opinion on Dr. Shafa's care of Patient F based on those records. (Green IX: 1317-18.)

32. Laurence Westreich, M.D. received his medical degree in 1988 from the University of Minnesota. He is board certified in general psychiatry and addiction psychiatry by the American Board of Psychiatry and Neurology. He completed his residency in general psychiatry at Beth Israel Medical Center in New York from 1989 to 1992. He also completed a fellowship in addiction psychiatry at New York University Medical Center, Bellevue Hospital from 1992 to 1994. Dr. Westreich was the Director of

the Alcohol Inpatient Unit at Bellevue Hospital in New York from 1993 to 1995, and he was the Director of the Dual Diagnosis Inpatient Unit at Bellevue Hospital from 1995 to 1998. He has a private practice that treats patients with addiction and dually diagnosed (both an addiction and some mental illness) patients, some of whom have substance abuse issues. He serves as adjunct faculty at New York University School of Medicine and served as President of the American Academy of Addiction Psychiatry at the time of his testimony. He has published papers on dual diagnoses, detoxification treatment, treatment of addiction, and forensic aspects of addiction psychiatry. (Ex. 26; Westreich XII: 1761-66.)

33. Dr. Westreich is an expert in his field. (Green IX: 1428.)

34. The American Academy of Addiction Psychiatry is a professional organization for academic and clinical addiction psychiatrists. Members meet once a year for an annual meeting and participate in educational and research-based activities. (Westreich XII: 1765.)

35. Dr. Westreich reviewed Patient F's medical records, Dr. Green's analysis, and medical literature and conference posters. He provided his opinion based on that information. (Westreich XII: 1768.)

36. Marian Ead, R.N. is a clinical investigator in the Enforcement Division of the Massachusetts Board of Registration in Medicine. She began working for the Board in January 2008. She was educated and trained as a nurse in clinical and supervisory capacities. She received a certification in medical and legal consulting from the Medical Legal Institute of Texas in 1999. The Board provided her with training in interview and interrogation techniques. As a clinical investigator, Ms. Ead interviews complainants,

witnesses, and physicians who are being investigated. She typically has between 30 and 50 open cases at any one time. (Ead XI: 1574-78, 1625.)

37. Cases usually begin with a complaint, an allegation made against a physician for an action that the Board would consider a violation of its regulations. In the majority of Ms. Ead's cases, the physician has had an opportunity to respond to the complaint at some point. The response may be a written response or in-person interview. If the expert review determines that the physician did not provide substandard care, then the Board may not offer the physician an opportunity to respond to the complaint. During an investigation, the Board can subpoena documents and view a physician's prescriptions. (Ead XI: 1579-82.)

38. The Board may initiate its own investigation. (Ead XI: 1626.)

39. Once the Board completes the investigation, it recommends to the Complaint Committee either that the case be closed or that discipline be initiated. The Complaint Committee is made up of Board members. (Ead XI: 1580, 1583-84.)

Patient A

40. Patient A began treatment with Dr. Shafa on November 19, 2002, when he was 45 years old. (Ex. 22: 5-21.)

41. Patient A's sister is a psychiatric nurse. (Patient A's Sister I: 176; Shafa V: 760.)

42. When Dr. Shafa began treating Patient A, he was employed by the Holliston, Massachusetts school system as an aide for a student with special needs. He had been employed there since 1999. (Ex. 3; Patient A I: 29.)

43. Patient A sought Dr. Shafa's assistance because he had been called for jury duty and did not believe he would be able to perform the required duties. Dr. Shafa wrote a letter to excuse Patient A from jury duty for medical reasons. (Ex. 22: 23; Patient A I: 30, 36.)

44. Patient A's symptoms were consistent with panic disorder. His panic attacks began in his late 20s. His symptoms included sweating, feeling physically off-center, being unable to sit, and feeling dizzy. His condition was especially present when driving. (Ex. 22: 15-19; Patient A I: 73-74; Clark III: 394; Shafa V: 762-65; Salzman VIII: 1232-33.)

45. Dr. Shafa initially diagnosed Patient A with Panic Disorder, Post-Traumatic Stress Disorder, Generalized Anxiety Disorder, Agoraphobia, and possibly Alcohol Abuse. (Ex. 22: 18.)

46. Generalized Anxiety Disorder is a psychiatric illness where an individual has an ongoing feeling of apprehension or worry. Panic disorder is a type of anxiety disorder where an individual faces sudden panic attacks, often accompanied by physical symptoms. A panic attack in a certain place can create an apprehension toward that place. Patient A had a panic attack in his late 20s while in a car. (Ex. 22: 15-16; Patient A I: 74; Clark III: 391-93; Shafa V: 764-65.)

47. Patient A also presented with several physical problems: obesity, hypertension (high blood pressure), hypercholesterolemia (high cholesterol), migraines, arthritis, knee and back pain, and a benign essential tremor. He has had surgery for kidney stones and multiple surgeries for a club foot. He also had knee surgery in 2012.

His primary care physician prescribed Lisinopril for his blood pressure and Lipitor for his cholesterol. (Ex. 22: 18, 60.)

48. Dr. Shafa's initial assessment of Patient A was comprehensive and careful. (Clark III: 394-95.)

49. Patient A is considered to be a refractory or treatment-resistant patient. He sought treatment from two medical professionals before seeking treatment from Dr. Shafa, one in New Hampshire and one in Massachusetts. He did not respond to previous treatments. He had been on psychiatric medication for approximately ten years. (Patient A I: 31, 82; Shafa V: 801; Salzman VIII: 1232-33.)

50. Patient A had taken a benzodiazepine in the past. He underwent the detoxification process and understood that he needed to do so because abruptly stopping benzodiazepines could cause side effects. Dr. Shafa did not know that Patient A had been detoxed from benzodiazepines in the past. (Patient A I: 103, 149-50; Shafa V: 765.)

51. At his first visit on November 19, 2002, Patient A was taking 40mg/day of Prozac, 50mg/day of Pamelor, and 1mg/day of Klonopin. Patient A's primary care physician, Dr. Siddiqui, had recently raised his dosages of Prozac and Klonopin to those levels, but Patient A had not responded to the increased medication. (Ex. 22: 14-19; Shafa V: 766.)

52. During Patient A's initial three visits, Dr. Shafa lowered Patient A's Pamelor dosage to 25mg/day because Dr. Shafa believed Pamelor was ineffective for Patient A's migraines. He increased his dosage of Prozac to 80mg/day, increased the dosage of Klonopin to 1.5mg/day, and added Depakote to treat Patient A's anxiety and

migraines. Although using Depakote for these purposes is uncommon, clinical studies support it. (Ex. 22: 22; Ex. 28; Clark IV: 608-11; Shafa V: 768-71; Salzman VIII: 1235.)

53. The combination of a benzodiazepine and an antidepressant (SSRI) is a common treatment for panic disorder. (Shafa V: 766; Salzman VIII: 1237.)

54. Patients suffering from severe panic disorder are often prescribed multiple medications, sometimes at high dosages. (Salzman VIII: 1249.)

55. Patient A disclosed drinking approximately a six-pack of beer on the weekends and occasionally drinking alcohol on weekdays. Dr. Shafa discussed with him the potential negative side effects of combining alcohol and benzodiazepines. (Ex. 22: 17, 19; Shafa V: 767-68.)

56. At the second visit on November 27, 2002, Patient A indicated that his migraines were better and that the panic decreased from "10/10 to 7/10" on a scale of 10/10 to 1/10. At the third visit on December 29, 2002, Patient A indicated that his tremor had worsened and Dr. Shafa added Trileptal with the intention of decreasing Patient A's tremor. Trileptal has fewer side effects than Depakote and is commonly used in the Boston area. (Ex. 22: 22, 24-25; Shafa V: 772-73; Salzman VIII: 1236.)

57. A patient's level of Depakote should be measured routinely. (Clark III: 430-31; Salzman VIII: 1243.)

58. During his visit on December 29, 2002, Patient A informed Dr. Shafa that he was having difficulty being in supermarkets. (Ex. 22: 24; Shafa V: 774-75.)

59. On January 12, 2003, Dr. Shafa increased Patient A's Klonopin dosage to 2mg/day during the week and 4mg/day on the weekends. The increased Klonopin was

meant to encourage "challenges," such as attempting to visit malls. (Ex. 22: 26-27; Shafa V: 773-74.)

60. Patient A continued treatment with Dr. Shafa every two weeks from January through March 2003. Patient A reported that his tremors were better. He went to a grocery store and had a panic attack, probably brought on by walking through the refrigerator and freezer sections of the market; he reported he had difficulty with cold temperatures. Dr. Shafa discussed relaxation techniques to reduce the panic. (Ex. 22: 26-35; Shafa V: 776-77.)

61. Dr. Shafa increased the dosage of Klonopin to 6mg/day with "emergency" dosages of .5mg to be taken if necessary. Dr. Shafa raised the Trileptal dosage to 1200mg/day and Depakote dosage to 2000mg/day to help with the panic and switched Patient A to a lower weekly dosage of Prozac. (Ex. 3; Ex. 22: 33-38; Shafa V: 780-82.)

62. A dosage of Klonopin of 2mg/day is considered standard. A dosage of Klonopin between 6mg/day and 10mg/day is considered higher than average. For certain patients, a high dosage of Klonopin may be within the standard of care. Dr. Shafa does not normally prescribe high dosages of Klonopin. (Clark III: 411-12; Shafa V: 770, 778-79, 806, 812; Salzman VIII: 1238.)

63. Dr. Salzman has treated a patient who was taking a dosage of 20mg/day of Klonopin. (Salzman VIII: 1238.)

64. On March 23, 2003, Patient A reported that his panic attacks had "dropped by 50%." Patient A also indicated that he tried Risperdal, which Dr. Shafa prescribed if Klonopin was not working. Dr. Shafa noted that Patient A "was not excited about it" and that he did not try it again. (Ex. 22: 39; Shafa V: 780-83.)

65. Patient A visited Dr. Shafa on April 7, 2003 and May 4, 2003. Patient A expressed that he felt sedated and shaky. He disclosed that his relationship with his girlfriend ended earlier in April. (Ex. 22: 44-48.)

66. Patient A visited the Emergency Room on May 27, 2003, complaining of double vision and dizziness. His blood test revealed an above-range level of Trileptal and a low level of Depakote. The attending physician spoke with Dr. Shafa and told Patient A to stop taking Trileptal until he saw Dr. Shafa. (Ex. 22: 49-52; Patient A I: 42; Shafa V: 784-85; Salzman VIII: 1243-44.)

67. High levels of an anticonvulsant medication could cause confusion, disorientation, forgetfulness, or memory impairment. The Emergency Room records noted that Patient A was alert and oriented. (Salzman VIII: 1246-47.)

68. Patient A's reported symptoms to the ER doctors were similar to the ones he reported for his panic attacks. The ER record notes that Patient A "has had this episode in the past." The ER record also indicates that Patient A had low blood pressure and that he was taking a narcotic and a blood pressure medication. (Ex. 22:15; Clark IV: 627; Salzman VIII: 1240-41, 1245.)

69. Taking more than the recommended dosage of a narcotic can cause unsteadiness or sedation. Blood pressure medication or low blood pressure can cause dizziness. (Salzman VIII: 1244-45.)

70. Dr. Shafa lowered Patient A's Trileptal dosage the next day to 600mg/day. (Ex. 22: 53-54; Shafa V: 787.)

71. Patient A visited Dr. Shafa three times in June, twice in July, and twice in August, 2003. On June 8, Patient A reported that he had an incident of over-sedation with

Trileptal. He expressed that he was interested in moving and was looking for a new job. On July 9, Dr. Shafa recorded that all was well with Patient A. On July 27, Patient A indicated that he felt 60-70% better since the beginning of treatment. On August 29, Patient A expressed that he was no longer planning on leaving Holliston because he wanted to keep his employer-provided health insurance. (Ex. 22: 55-67.)

72. During these months, Dr. Shafa lowered Patient A's dosage of Depakote to 1500mg/day. Dr. Shafa began him on 5mg/day of Zyprexa Zydis to allow Patient A to challenge himself by visiting more crowded spaces. Zyprexa Zydis is fast-acting and could treat a panic attack quickly. On August 29, 2003, Patient A reported that the Zyprexa worked well. (Ex. 22: 55-67; Shafa V: 787-90; Salzman VIII: 1236.)

73. It is not unusual to prescribe a low dosage of an atypical anti-psychotic, such as Zyprexa, to treat anxiety. A common side effect of Zyprexa is weight gain. (Clark III: 416-19; Salzman VIII: 1236.)

74. In or around August 2003, Patient A tore the cartilage in his knee. Patient A's Orthopedist referred him to Dr. Shafa for pain management, perhaps because Patient A was already seeing Dr. Shafa for psychiatric medication and any pain medications must be managed with the psychiatric medications that he was taking. Patient A visited Dr. Shafa on September 3, 2003, and Dr. Shafa prescribed pain medication. (Ex. 22: 69; Shafa V: 792.)

75. In September 2003, Patient A stopped working at the middle school and began working at the high school in the same school system. (Patient A I: 113-14.)

76. On September 14, 2003, Dr. Shafa noted that Patient A had gained weight and developed edema (swelling) in his feet. Patient A reported that he was experiencing almost no panic. (Ex. 22: 71; Shafa V: 756-96.)

77. Blood pressure medication, such as Lisinopril, and anti-inflammatory medications could cause edema or weight gain. Zyprexa, Prozac, and high dosages of Trileptal or Klonopin could cause weight gain. A knee injury could limit mobility and lead to edema. (Clark III: 424-27; Shafa V: 795-97.)

78. Patient A visited Dr. Shafa on September 28 and October 24, 2003. He reported that his anxiety was in check and that he had less anxiety at work. He was still having issues with visiting large stores. Dr. Shafa lowered his Trileptal dosage to 300mg/day and Depakote dosage to 500mg/day, relatively low dosages for both medications. (Ex. 22: 74-79; Clark III: 435; Shafa V: 797-98.)

79. Patient A next saw Dr. Shafa on December 14, 2003. He reported that he felt better and that his driving had improved. His knee pain compromised his balance. (Ex. 22: 80; Shafa V: 799-800.)

80. Patient A moved to a new residence in December 2003. (Patient A I: 121.)

81. Patient A visited Dr. Shafa on January 18, 2004 in a worsened condition. He stated that the anxiety returned after he moved to a new house. On January 25, 2004, he expressed that "the panic is all back." On January 25, Patient A explained that the panic was "like electricity," he felt like he was floating on air, and he felt dizzy. (Ex. 22: 82-85; Patient A I: 37; Shafa V: 806.)

82. External changes can contribute to a relapse in a panic disorder. Refractory patients commonly have relapses. (Shafa V: 801, 803; Salzman VIII: 1259.)

83. During his January visits, Dr. Shafa increased Patient A's Zyprexa dosage to 15mg/day because he believed it to be effective. He discontinued Trileptal and added 10mg/day of Lexapro with the intention to switch Patient A from Prozac to Lexapro. Dr. Shafa prescribed additional Klonopin, if needed, to assist with panic attacks. Patient A was prescribed up to 8mg/day of Klonopin. Patient A took an additional dose of Prozac without consulting Dr. Shafa. (Ex. 3; Ex. 22: 82-89; Shafa V: 800-01, 805-08.)

84. Serotonin syndrome is caused by excessive levels of serotonin in the central nervous system, which could be caused by high dosages of more than one SSRI medication. Symptoms include feeling ill, sweating, elevated blood pressure, and occasionally confusion or poor memory. It can lead to death. (Clark III: 444.)

85. When a patient's condition worsens or the patient is in crisis, it is not unusual for a physician to make several medication changes at one time. Three options for treatment when a patient is in crisis are to increase dosage, add another medication, or switch medications. Sometimes, it may be appropriate to do all three. (Clark III: 406; Salzman VIII: 1248.)

86. Patient A visited Dr. Shafa on February 1, February 8, February 11, and February 13, 2004. His tremors worsened, his sleep was erratic, and he had difficulty with bright light. Dr. Shafa recommended that Patient A fill out a chart documenting when his attacks occurred and their severity. (Ex. 22: 90-102; Shafa V: 810-812.)

87. During those visits, Dr. Shafa increased Patient A's Klonopin dosage to 8mg/day and provided "emergency" .5mg dosages of Klonopin, for a maximum of 10mg/day. Dr. Shafa increased his Zyprexa dosage to 30mg/day, his Lexapro dosage to 20mg/day, and his Depakote dosage to 1500mg/day. He prescribed Ativan and Carbatrol.

He also added Xanax because Xanax and Klonopin match the same receptors, and Dr. Shafa wanted to decrease Patient A's Klonopin dosage without triggering benzodiazepine withdrawal symptoms. Dr. Shafa noted that Patient A expressed past success with Xanax. (Ex. 22: 90-102; Shafa V: 812-18.)

88. Patient A visited the Emergency Room on February 19, 2004, complaining of dizziness, fatigue, blurry vision, dry mouth, difficulty moving his hands, and balance problems. Intake records indicated Patient A was alert and cooperative. (Clark IV: 637-38; Shafa V: 818-19; Salzman VIII: 1250-51.)

89. The hospital performed a urine test, and the result for benzodiazepines was negative. A urine drug panel that tests negative for benzodiazepines indicates that the patient has not taken benzodiazepines for at least a few days. Dr. Shafa had prescribed Patient A high dosages of benzodiazepines at the time of the ER visit. (Ex. 3; Ex. 22: 102; Patient A I: 152; Clark IV: 639; Shafa V: 820.)

90. Abruptly discontinuing a benzodiazepine causes withdrawal effects, which can be serious. Benzodiazepine withdrawal can cause feelings of unsteadiness, vision issues, feelings of floating, or panic attacks. To avoid withdrawal effects, patients undergo a detoxification process when terminating the use of benzodiazepines. (Clark III: 399; Shafa V: 817; Salzman VIII: 1253.)

91. Patient A visited Dr. Shafa on February 20, February 22, February 25, February 29, and March 7, 2004. On February 20, he admitted that he had stopped taking all benzodiazepines. Patient A had had swollen feet, tremors, cold sweats, whole body shakes, and poor short-term memory. Dr. Shafa ceased Patient A's Lexapro prescription.

On February 25, Patient A noted that he was doing better since stopping Lexapro. (Ex. 22: 102-118; Shafa V: 822-26.)

92. Dr. Shafa considered Patient A to be in crisis and revisited his diagnosis. Dr. Shafa believed that bipolarity type II was a plausible diagnosis and began prescribing Lithium on February 29. Dr. Shafa based his decision on Patient A's family history and his non-responsiveness to treatment. Patient A disclosed at his visits on March 5, 2003 and January 18, 2004 that his family had a history of depression and anxiety. His father attempted suicide, his sister was on anti-depressant medication, his cousin had substance abuse issues, and his parents previously used acupuncture to treat anxiety. Dr. Shafa also believed bipolarity was a possibility since Patient A's anxiety and panic disorders did not appear to be responding to SSRI medications. On March 7, Patient A reported that the Lithium was helping his depression. (Ex. 22: 35, 82, 113-118; Shafa V: 823-29.)

93. It is always reasonable for a psychiatrist to consider another diagnosis, and in these circumstances it was within the standard of care for Dr. Shafa to consider bipolarity and panic disorder. (Salzman VIII: 1255-57.)

94. Medication can interfere with the assessment of a patient's symptoms. (Salzman VIII: 1276.)

95. Individuals with bipolarity are often misdiagnosed with anxiety or depression. Bipolar disorder type II is a variant of Bipolar disorder type I and relatively unusual. Patients present with hypomania (elevated mood) but do not present with the mania associated with type I. Psychiatrists should look at family history when evaluating for bipolarity. (Clark IV: 437-38, 607; Salzman VIII: 1275-76.)

96. Patient A took medical leave from work in February 2004. Dr. Shafa provided a note dated February 25, 2004 for Patient A to give to his employer. (Ex. 22: 111; Patient A I: 43, 49-50; Shafa V: 827.)

97. In March 2004, Patient A met with Dr. Horan, a behavioral therapist. Dr. Horan spoke with Patient A and Dr. Shafa about ceasing Patient A's dosage of any benzodiazepines in order to ensure that any cognitive behavioral therapy would be more effective. (Ex. 22: 122; Patient A I: 49-50, 76; Shafa VI: 830.)

98. Patient A met with Dr. Shafa on April 7, April 21, April 25, and April 28, 2004. Patient A was suffering from tremors, sedation, restlessness, lack of balance, and poor concentration. He was unable to drive and was not going to work. On April 25, Patient A expressed that he felt "ten times worse." (Ex. 22: 122-134; Shafa VI: 827-29.)

99. During those visits, Dr. Shafa lowered Patient A's Lithium dosage and added Klonopin. (Ex. 22: 122-134.)

100. Dr. Shafa explained the problems with mixing alcohol and Patient A's medications, and Patient A agreed to abstain from alcohol. (Ex. 22: 126; Shafa V: 809.)

101. Patient A visited Dr. Shafa on May 19, May 26, and June 9, 2004. He reported that his anxiety and concentration was better but that his tremor was causing him difficulties. On June 9, Dr. Shafa noted that Patient A looked better. During these visits, Dr. Shafa lowered the dosages of Depakote and Klonopin. He also switched Patient A from Klonopin to Xanax, with a prescription of Klonopin, as needed. (Ex. 22: 140-42.)

102. Patient A had his last visit with Dr. Shafa on July 14, 2004. Dr. Shafa noted that he was physically better, his balance was improved, he was not shaky, and his

face was brighter. Patient A filled out social security disability paperwork with Dr. Shafa. He terminated his care after that visit. (Ex. 22: 143-46; Shafa V: 831.)

103. Patient A switched the management of his medication to a nurse practitioner associated with Dr. Horan, and notified Dr. Shafa. (Patient A I: 66; Shafa V: 831.)

104. The Board received Patient A's complaint on July 8, 2005. (Ex. 1.)

105. Patient A did not return to his job with the Holliston school system after his medical leave. He has held three jobs since ceasing treatment with Dr. Shafa. He has been unemployed since his knee surgery in 2012. (Patient A I: 50, 68, 71.)

106. Patient A still suffers from panic attacks and anxiety. He is receiving social security disability benefits. He is currently seeking treatment from Dr. Horan. He takes 2mg/day of Klonopin, 60mg/day of Prozac, Primidone, and Verapamil. (Patient A I: 26-28, 63, 66.)

Patients B and C

97. Patients B and C are sisters. Patient B began treatment with Dr. Shafa when she was five years old, and Patient C began treatment when she was three years old. Patient B was treated from November 2003 to September 2006, and Patient C was treated from May 2005 to September 2006. They have one other sister and two brothers. (Ex. 22: 153, 206, 262, 337; Shafa V: 860.)

98. When conducting its investigation, the Board did not interview Patients B and C, their mother, grandmother, social worker, or foster parents. (Clark IV: 664-65.)

99. Patients B and C had MassHealth health insurance that paid for therapy and psychopharmacology. Dr. Shafa is a MassHealth provider. (Shafa V: 861.)

100. Dr. Shafa had difficulty finding psychotherapy for Patients B and C because fewer providers wanted to treat children covered by MassHealth. (Shafa V: 861-63.)

101. Patients B and C's mother and/or grandmother typically brought them to visit Dr. Shafa, frequently with the other siblings who would typically wait in the waiting room. Both the mother and grandmother would report the patients' symptoms to Dr. Shafa, and he would provide updates to the mother and grandmother. Dr. Shafa "had no reason to believe that there might be any reason that they didn't want to help." (Shafa V: 889-90; Shafa VI: 969-71.)

102. Patients B and C's father has bipolar disorder and ADHD, and their mother has had depression. Their father is a convicted level III sex offender, which is the most dangerous sex offender classification. G.L. c. 6, § 178K(2)(c)A provides that a Level III designation indicates that the "risk of re-offense is high and degree of dangerousness posed to the public is such that a substantial public safety interest is served by active dissemination" (Ex. 22: 153, 161; Clark III: 509; Shafa VI: 977-99.)

103. Dr. Shafa did not record whether their mother still suffered from depression. He also did not record how the father's bipolar disorder manifested or whether he lived in the house with Patients B and C. (Ex. 22: 153; Shafa VI: 971-72; Giesen VII: 1176-77.)

104. When both parents present with a mood disorder, including bipolar disorder or depression, the child has an increased risk of also presenting with a mood disorder. (Clark IV: 659-70; Giesen VII: 1073, 1076.)

105. The Department of Social Services (“DSS”) does not provide information with treatment providers on closed cases. If a case is ongoing or a child is in DSS custody, DSS normally can share information with the treatment provider. DSS did not provide information to Dr. Shafa about Patients B and C or about their new treatment provider. (Shafa VI: 1020; Giesen VII: 1075, 1179.)

106. Psychiatric treatment of children under age five is a specialized field. A board certification in child and adolescent psychiatry is not required to treat children. Treating children without a board certification in child and adolescent psychiatry does not fall below the standard of care. (Clark III: 504; Clark IV: 658; Giesen VII: 1066-67.)

107. Treating children and adolescents is different from treating adults because children present symptoms in a different manner and for different reasons than adults. When diagnosing a child patient, psychiatrists should consider the child’s environment and her relationship with her caregiver, whether there has been trauma, whether the parents suffer from mood disorders, whether the parents are experiencing marital difficulties, and whether the child may have been in foster care. (Ex. 33: 214; Clark III: 474-75, 482; Giesen VII: 1060-62, 1165.)

108. When diagnosing a child, it can be beneficial to consult with parents or guardians, the child’s primary care physician (PCP), the child’s DSS social worker if he or she has one, or other psychiatrists. But none of these are requirements. (Clark III: 493-94; Giesen VII: 1075, 1153-54.)

109. Treating a young child with atypical anti-psychotic medications could be considered a risk, although not below the standard of care. Little data exists that supports

the usage of anti-psychotic medications for preschool or elementary school-aged children. (Clark III: 484-85.)

110. It is within the standard of care and common practice to prescribe off-label medications for children. During the period that Patients B and C were treated, FDA-approved medications for children were uncommon, although they are now a bit more common. (Shafa V: 902; Giesen VII: 1068.)

111. When medicating a child, the goal is to obtain a stable mental state. A psychiatrist should always explain potential benefits and adverse reactions to the parent or guardian and to the child, if she is old enough. (Giesen VII: 1068-70.)

112. During the period that Patients B and C were treated, physicians were required to obtain informed consent from patients or their guardian(s) after discussing potential benefits and side effects of medication. The current standard for informed consent also involves obtaining a written medical record. (Giesen VII: 1070.)

113. Ideally, child patients would receive therapy and psycho-pharmacology. Children with mood disorders likely need intense behavioral and parental intervention. (Ex. 32: 120; Clark III: 484-85, 510-11; Giesen VII: 1166-68.)

114. Patients B and C would have benefitted from therapy. However, therapy alone may not have treated their mood disorder symptoms. (Shafa VI: 915-18; Giesen VII: 1097.)

115. Early onset bipolar disorder affects children under 10. Psychiatrists should consider environmental, developmental, temperamental, and social factors when diagnosing early onset bipolar disorder. Patients with early onset or juvenile bipolar

disorder, present with mania or euphoria, depression, grandiosity, changes in energy, unstable moods, and interrupted sleep. (Shafa V: 867-69; Giesen VII: 1168-69.)

116. Diagnosing juvenile bipolar disorder was common and “trendy” in Boston during Dr. Shafa’s treatment of Patients B and C. It was a relatively new diagnosis in child psychiatry. A research group at Massachusetts General Hospital spearheaded the approach and led research in the area. In more recent years, it has become more controversial, and there is more concern about diagnosing bipolarity in children because of the side effects of treatment. (Clark III: 477-78; Giesen VII: 1084-86.)

Patient B

117. Dr. Stephen Simonian treated Patient B before Dr. Shafa; he suspected that Patient B had ADHD. He prescribed Benadryl for sleep and later added Ritalin at 5mg/day for hyperactivity. Dr. Simonian did not diagnose Patient B with bipolar disorder. Dr. Simonian noted that she would wake up in the middle of the night and do “strange things such as cutting her hair or cutting the cat’s fur.” He also explained that her father had ADHD and bipolar disorder and that he was not living with the family. Dr. Shafa and his colleague, Dr. Xiangyang Li, assumed Dr. Simonian’s practice in Fall 2003. Dr. Shafa then assumed the care of Patient B. (Ex. 22: 152; Shafa V: 864-65, 965, 1051.)

118. Patient B’s first visit to Dr. Shafa was on November 3, 2003. She presented with mood instability, lack of fear or boundaries, grandiosity, boldness, and disregard for rules. She told adults what to do, which is unusual for a five-year old. She had gory nightmares about blood and vampires and had an imaginary friend who killed herself. She had extreme changes in her appetite, was impulsive, cried without reason,

and put her pet ferret into the toilet. She was alert and oriented, spoke fluently, and talked to herself. She understood who she was, where she was, and what time of day it was. (Ex. 22: 153; Shafa V: 870-72; Shafa VI: 972-73.)

119. Dr. Shafa diagnosed her with bipolar disorder, mixed and ADHD. A bipolar diagnosis is supported by the record. (Ex. 22: 153; Clark III: 502; Shafa V: 865; Giesen VII: 1074.)

120. Other explanations for her symptoms could be abuse or neglect, disruptive attachments, or impaired relationships with caregivers. (Clark III: 502.)

121. Dr. Shafa prescribed neurological testing, an EEG, and an MRI. MassHealth did not cover neurological testing, but Patient B received an EEG and MRI on November 12, 2003 at Milford-Whitinsville Regional Hospital in Milford, Massachusetts. Both tests came back as normal. Patient B's MRI revealed that she had a pineal cyst, which is generally not of concern. (Ex. 22: 154-57, Clark III: 486-87; Shafa V: 877.)

122. Dr. Shafa ordered the EEG and MRI to rule out a brain tumor or other neurological disorder; these tests were appropriate, as the normal results helped Dr. Shafa conclude that Patient B did not suffer from these troubles. Giesen VII: 1078-79.)

123. After the EEG and MRI, Dr. Shafa prescribed Seroquel at 25mg/day. (Ex. 22: 154; Shafa V: 875-76.)

124. Seroquel is an atypical anti-psychotic. It is commonly prescribed off-label for juvenile bipolar disorder and is generally well-tolerated by children. It is commonly prescribed to patients with sleep difficulties. Possible side effects include Parkinson symptoms, cognitive dulling, muscle spasms, weight gain, sedation, white blood

abnormality, liver enzyme dysfunction, and tardive dyskinesia. (Clark III: 498, 516; Clark IV: 678, 695-96; Giesen VII: 1078.)

125. Patient B's second visit was on October 14, 2004 when she was six years old. Dr. Shafa reported that she didn't listen, talked about death, lied frequently, and argued with teachers and other adults. She was aggressive towards her siblings, and encouraged her three-year-old sister to jump off a bureau. She also bit herself and blamed someone else. (Ex. 22: 161; Shafa V: 878.)

126. It is not typical for a six-year-old to argue with a parent and a teacher because they are adults who play different roles in the child's life. (Giesen VII: 1076-77.)

127. Patient B's mother and grandmother informed Dr. Shafa that Patient B had been removed from her home by DSS and placed in foster care and that Patient B had recently returned home. Dr. Shafa could not obtain additional information from DSS because the case had been closed. (Ex. 22: 161; Shafa V: 878.)

128. It can be traumatic when DSS places a child into foster care, and the child may have problems adjusting. (Giesen VII: 1177-78.)

129. Patient B's mother informed Dr. Shafa that Patient B's father had pled guilty to a level III sex offense. Her mother informed Dr. Shafa that Patient B was not the victim but did not provide additional information. (Ex. 22: 161; Shafa VI: 977-79.)

130. Dr. Shafa prescribed 25mg/day of Seroquel, with extra dosages of Seroquel to help Patient B sleep, if necessary. The additional dosages of Seroquel would not exceed a total dosage of 200mg/day. Dr. Shafa discussed the side effects with Patient B's mother. (Ex. 22: 162; Shafa V: 878, 881-82.)

131. A dosage of 25mg of Seroquel is appropriate for Patient B's symptoms and is not concerning. (Giesen VII: 1077, 1099-1100.)

132. Physicians may prescribe adults dosages up to 800mg/day of Seroquel. Dosages of 100mg/day to 200mg/day are not unusual for children or adolescents, and physicians occasionally prescribe children dosages of 400-600mg/day. The maximum dosage of Seroquel recommended on the label for children and adolescents aged 10-17 with bipolar mania is 600mg/day. Higher dosages of Seroquel may increase the risk of adverse side effects. (Ex. 31; Clark III: 517; Clark IV: 674-75; Giesen VII: 1099-1100.)

133. Patient B visited Dr. Shafa on November 4, 2004. Dr. Shafa noted that she was sleeping better, her mood was more relaxed, she felt calmer, and she was less mean to her siblings. Her mother reported that she had increased Patient B's Seroquel dosage to 50mg/day. Patient B felt shaky when she took 75mg/day, but her mother did not report other adverse side effects. (Ex. 22: 164; Clark IV: 679; Shafa V: 882-83.)

134. Dr. Shafa spoke with Patient B's PCP on November 9, 2004. Dr. Shafa noted that Patient B had some academic skills loss, her school was not helpful with tutoring, she had been in foster care once, and it was unclear whether she had been victimized. (Ex. 22: 164; Shafa V: 883.)

135. Dr. Shafa concluded that Patient B was not abused. (Shafa VI: 981-82.)

136. Patient B visited Dr. Shafa on January 15, 2005. She was doing well. Dr. Shafa noted that she was calm when her environment was calm and hyperactive when her environment was chaotic. Dr. Shafa did not report any negative side effects from the medications. (Ex. 22: 166; Clark IV: 681; Giesen VII: 1081.)

137. Patient B visited Dr. Shafa on February 24, March 21, and May 10, 2005. She was less distracted and more focused. Her sleep had improved. She was taking dosages between 25mg/day and 75mg/day of Seroquel. Dr. Shafa had prescribed the higher dosage to be taken in case she was anxious. (Ex. 22: 168-72.)

138. Patient B visited Dr. Shafa on June 25, 2005. She had shoplifted and had bad dreams afterward. She was having difficulty sleeping. Dr. Shafa increased her dosage of Seroquel to 75mg/day. She was not experiencing negative side effects. (Ex. 22: 174; Shafa V; 891-92.)

139. She visited Dr. Shafa on July 21, August 27, September 17, October 22, and December 8, 2005. She was sleeping well, her attention was better, and she was not experiencing adverse side effects. She still had some nightmares. (Ex. 22: 176-88.)

140. Patient B visited Dr. Shafa on January 24, March 7, April 4, and May 27, 2006. She was doing well. During this period, he gradually increased her dosage to 200mg/day of Seroquel to help with sleep. 200mg/day of Seroquel is a moderate dosage for a child. (Ex. 190-99; Shafa V: 879; Giesen VII: 1079.)

141. Dr. Shafa filled out a form for the Massachusetts Department of Transitional Assistance verifying that Patient B had a disability. He was trying to help her mother obtain money to help with her children, but the application was ultimately unsuccessful. (Ex. 22: 200; Shafa V: 887-80.)

142. Patient B visited Dr. Shafa on July 1 and July 31, 2006. Her sleep had improved, she was more cooperative, and she was doing well overall. She remained on 200mg/day of Seroquel. (Ex. 22: 202-05.)

143. In August 2006, Patient B was put into foster care again. Patient B's foster mother wrote a letter dated September 20, 2006. The letter stated that Patient B had lived in the foster home since August 11, that she was pleasant, and that she was doing well. The foster mother noted that she was having a hard time waking up Patient B in the morning. (Ex. 22: 208-09.)

144. Children may be more quiet and well-behaved when first entering a new environment, although not always. (Giesen VII: 1082, 1189-90.)

145. On September 21, 2006, Dr. Shafa filled out a Medication Information Request form for DSS that Patient B's mother had provided him. He listed Patient B's diagnosis as bipolar mixed, her medication as 200mg/day of Seroquel, and the potential side effects of her medication as extrapyramidal symptoms ("EPS"), metabolic syndrome, or tardive dyskinesia ("TD"). Extrapyramidal symptoms could include muscle stiffness. Metabolic syndrome could affect weight, cholesterol, blood pressure, or blood sugar. Tardive dyskinesia is involuntary movement. He also listed a potential risk of rebound psychosis if the medication was stopped. (Ex. 7; Ex. 22: 210-11; Shafa VI: 1002-07.)

Patient C

146. Patient C first visited Dr. Shafa on May 16, 2005. She had also been present in the examination room for several of Patient B's visits, where Dr. Shafa observed her to be active and disruptive. (Ex. 22: 322; Shafa V: 894-95.)

147. Dr. Shafa noted that she was aggressive, assaultive to adults, oppositional, and destructive. She bit her siblings, head butted others, hit classmates, and laughed at adults who tried to stop her. She had good and bad days, she did not accept punishment

or limits, she would not sleep without her mother, and she threatened to hurt or kill others. Dr. Shafa diagnosed her as bipolar mixed. (Ex. 22: 322-23.)

148. Her symptoms were consistent with a behavioral disorder, such as bipolar disorder. (Clark III: 519; Giesen VII: 1083-84.)

149. Dr. Shafa prescribed 2.5mg/day (a half-tablet) of Abilify every morning for a week and then an increased dosage of 5mg/day. He discussed the side effects with Patient C's mother. He informed her that the side effects were similar to Seroquel, and that Patient C may feel queasy so Patient C should eat before taking the pills. (Ex. 22: 323; Shafa V: 898-901.)

150. Abilify is an atypical anti-psychotic that is used often in child and adolescent psychiatry for juvenile bipolar disorder. It normally does not cause as many issues with weight gain as other atypical anti-psychotics. It is generally well-tolerated. Potential side effects could include weight gain, akathisia (motor restlessness), or metabolic symptoms. (Clark III: 512-15; Shafa V: 898-901.)

151. Dr. Shafa had reservations about medicating such a young child, but he believed she needed treatment because she was already causing problems. (Shafa V: 901.)

152. At Patient C's first visit, Dr. Shafa had her mother fill out a Kutcher Adolescent Depression Rating Scale and a Mood Disorder Questionnaire. Normally, these are for older children aged 12 to 18. Psychiatrists use scales to assist with a diagnosis, and they could be filled out by the patient or a parent. They are commonly used in academic settings. Not every question would be relevant for a three year old, but

Dr. Shafa allowed Patient C's mother to answer all of the questions. (Ex. 22: 324-32; Clark: III; 505-07; Clark IV: 689; Shafa V: 897-98; Giesen VII: 1088-89.)

153. Patient C visited Dr. Shafa on June 25, 2005. She was less mean and aggressive, was more lovable in school, and could sleep at night by herself. She was sleepy on Abilify, and it still took time to get her attention. (Ex. 22: 320.)

154. Sleepiness was the only negative side effect Patient C experienced on Abilify. Dr. Shafa did not note other negative side effects in her medical record. (Clark IV: 692; Shafa V: 903-04; Giesen VII: 1090-91.)

155. Patient C had visits on July 5, July 21, and August 27, 2005. She met with Dr. Li on August 27. She was not as aggressive. She was not experiencing negative side effects from her medications. Dr. Shafa increased her dosage to 7.5mg/day during this period. (Ex. 22: 311-18.)

156. Dr. Shafa tried to help Patient C obtain disability status. She had an appointment with a Dr. Garcia on August 8, 2005, a state-appointed psychiatrist, to evaluate whether she qualified for disability status. The disability request was ultimately declined, and Dr. Shafa was unable to obtain the records from her visit with Dr. Garcia. (Ex. 22: 313; Shafa VI: 915-18.)

157. Patient C visited Dr. Shafa on September 17, 2005. She was getting more aggressive, she was not sleeping at night and "get[ting] into everything," she was hitting and pinching her siblings, and she would not listen to her mother. Dr. Shafa increased her dosage of Abilify to 10mg/day and added 25mg/day of Seroquel. Her dosage of Seroquel could be increased by 25mg/day every four days up to 100mg/day to help with her insomnia. (Ex. 22: 309-10; Shafa V: 904-07.)

158. It is not common to have a child on two anti-psychotic medications, but it is not necessarily below the standard of care. (Giesen VII: 1102-03.)

159. If a patient is prescribed Abilify but has issues with sleep, adding Seroquel would “make sense.” (Giesen VII: 1094-95.)

160. The usage of two anti-psychotic medications is not listed as a treatment algorithm in the Treatment Guidelines for Children and Adolescents with Bipolar Disorder (“Treatment Guidelines”), published by the Journal of the American Academy of Child and Adolescent Psychiatry in 2005. Treatment algorithms in the Treatment Guidelines include monotherapy, the combination of a mood stabilizer and atypical anti-psychotic, and the combination of two mood stabilizers and an atypical anti-psychotic, among others. (Ex. 33: 219-29; Clark III: 518.)

161. The Treatment Guidelines were “not intended to serve as an absolute standard of medical or psychological care.” The treating clinician is in the best position to determine an appropriate treatment plan because he can monitor the symptoms and the effectiveness of treatment. (Ex. 33: 213-14; Giesen VII: 1093-94.)

162. The authors of the Treatment Guidelines did not include those whom Dr. Giesen considered to be the national leaders in childhood bipolar disorder. (Ex. 33: 213, 232; Giesen VII: 1181-82.)

163. Patient C visited Dr. Shafa on October 22 and December 8, 2005. She was not exhibiting aggression, and she was doing well in school. Dr. Shafa did not note any side effects. Dr. Shafa continued her dosage of 10mg/day of Abilify and 25mg/day of Seroquel. (Ex. 22: 306-08; Clark IV: 696.)

164. Patient C visited Dr. Shafa on January 24, 2006. Dr. Shafa noted that she was obnoxious, she was not listening, and she was mean to people. She kicked a dog, and she gave her teacher a hard time. She exhibited this behavior all day. Dr. Shafa increased her dosage of Abilify to 20mg/day. (Ex. 22: 299; Shafa V: 909.)

165. Doubling a dosage of Abilify is a large increase for a small child. Patient C did not appear to exhibit negative side effects after the dosage was increased. (Clark III: 524-25; Clark IV: 696.)

166. Patient C visited Dr. Shafa on March 7 and May 27, 2006. She was no longer going to school, she had difficulty falling asleep and woke up early, and she was very aggressive and bold. She would wake up in the middle of the night hungry, likely a side effect of the medication. On May 27, Dr. Shafa provided a note to the Social Security office, explaining that he was treating Patient C. He increased her dosage of Abilify to 30mg/day. Patient C was four years old (almost five) at this time. (Ex. 22- 290-92, 297; Clark III: 526; Clark IV: 698; Shafa VI: 918-19; Giesen VII: 1092.)

167. The maximum FDA and PDR recommended dosage for Abilify is 30mg/day. It is not an uncommon dosage for adolescents, but it is a high dosage for children under five. The PDR does not distinguish between the maximum dosage for children and adults. (Clark III: 513-14; Clark IV: 690; Giesen VII: 1092.)

168. Dr. Giesen has prescribed 30mg/day for a child and has treated a child patient on 60mg/day. (Giesen VII: 1100.)

169. Patient C visited Dr. Shafa on July 1, 2006. She was doing better, sleeping well, and concentrating better. Dr. Shafa prescribed 30mg/day of Abilify and 150mg/day of Seroquel. (Ex. 22: 284-85.)

170. Dr. Shafa filled out part of a Request for Medical Information for DSS on July 15, 2006. The other portion was filled out by Patient C's PCP. Dr. Shafa noted that she was doing well on her medications and indicated that her PCP may consider further developmental evaluation. (Ex. 276-83; Shafa VI: 990-91.)

171. Patient C visited Dr. Shafa on July 31, 2006. Dr. Shafa noted that she was very hyperactive, uncooperative, destructive, and sneaky. She would destroy things and hide in the house. She was having difficulties sleeping, and she would not listen. Dr. Shafa increased her dosage of Seroquel to 200mg/day to help with her insomnia. (Ex. 22: 272-73; Shafa VI: 908, 993-94.)

172. Patient C's mother visited Dr. Shafa on September 21, 2006. She described an incident in August, during which Patient B and C's father had barged into the house, where he was not then living, while the children were home, terrifying the children. After that incident, both children were placed in foster care. During the children's time in foster care, the parents were required to complete certain "tasks" so that DSS could determine whether it was possible for the children to return home. Dr. Shafa tried to obtain information from DSS but was unable to. (Ex. 22: 262; Shafa VI: 995-98.)

173. Patient C's foster mother wrote an undated letter stating that Patient C was a "nice little girl," that she was behaving well, and that she sometimes needed redirection. (Ex. 22: 265.)

174. Patient C's foster mother stopped giving Patient C her Abilify because it was not initially provided when Patient C arrived. At the September 21 visit, Dr. Shafa

restarted her prescription of Abilify at a low dosage and started monitoring Patient C again. (Ex. 22: 262-63, 265.)

175. On September 21, Dr. Shafa filled out a Medication Information Request form for DSS that Patient C's mother provided him. He listed Patient C's diagnosis as bipolar disorder mixed, her medication as 5mg/day of Abilify and 200mg/day of Seroquel, and the potential side effects of her medications as EPS, metabolic syndrome, or TD. Dr. Shafa did not recommend any testing to monitor side effects. (Ex. 7; Ex. 22: 266-67; Shafa VI: 1007-09.)

176. On November 10, 2006, the Juvenile Court Department, Worcester Division, appointed Nicholas Morana, Esq. as guardian ad litem for Patients B and C. Mr. Morana requested the treatment plan and an affidavit from Dr. Shafa, outlining why Patients B and C needed to continue treatment with atypical anti-psychotic medications. Mr. Morana provided Dr. Shafa with an affidavit to fill out. Dr. Shafa did not fill out the affidavit because he received a call from DSS informing him that he no longer was the treatment provider for Patients B and C. (Ex. 22: 214-22; Shafa VI: 1013, 1017.)

177. On November 21, 2006, Dr. Shafa received a summons to appear before the Juvenile Court Department, Worcester Division on December 5, 2006 to testify about Patients B and C. On December 1, 2006, Dr. Shafa wrote a letter to the Clerk Magistrate of the Juvenile Court, requesting that he be excused from appearing in court. Dr. Shafa has written similar letters in the past. He did not appear in court, but there is no evidence that he was excused from appearing. (Ex. 22: 223, 226; Shafa VI: 1013-17, 1019.)

178. Mr. Morana contacted the Board of Registration in Medicine by letter dated January 3, 2007, at the request of Judge Carol Erskine of the Juvenile Court

Department, Worcester Division. He expressed that he had "grave concerns" about Patients B and C's treatment because they were on high dosages of anti-psychotic medications. No medical opinion was included with the complaint. (Ex. 6; Ex. 8; Ex. 9; Ex. 10.)

Patient D

179. Patient D first visited Dr. Shafa on December 4, 2003 when he was 44 years old. Dr. Shafa had been treating his daughter, Patient E, before Patient D sought treatment. (Ex. 22: 342; Shafa V: 834.)

180. Patient D complained of sudden crying, anxiety attacks, a racing heart, insomnia, and high energy. He had manic depression and a history of anxiety and depression. When he was eighteen, Patient D was diagnosed with bipolar disorder and was hospitalized. His mother had bipolar disorder and alcoholism, his daughter was bipolar, and his father had cirrhosis of the liver. Patient D worked as a computer programmer, and his work performance had declined. After his mother's death, he reported that he had no motivation to do anything. Dr. Shafa noted that he was cooperative, fluent, and coherent. He also noted that his mood was fair, he had fair judgment, and he had no evidence of psychosis. (Ex. 22: 342; Shafa V: 835-36.)

181. He was taking 60mg/day of Celexa, Lipitor, Lisinopril, metoprolol, and nitroglycerin. He reported that his work performance had improved since starting Celexa. (Ex. 22: 342; Patient E's Mother II: 247-48; Shafa V: 835.)

182. Patient E is Patient D's daughter. Patient E's mother is Patient D's ex-wife. (Ex. 22: 342.)

183. Patient D had a heart attack before he began seeing Dr. Shafa. (Ex. 22: 342.)

184. Patient D sought treatment from medical professionals in the past. He had tried Lithium previously, but it did not affect him. Clonidine and Ativan made him drowsy, and Trazodone made him feel "foggy." Ipaxil worked, but he stopped taking it after his heart attack. (Ex. 22: 342; Patient E's Mother II: 247-48.)

185. Patient D had a history of substance abuse. He admitted that he was an alcoholic and that he would binge drink 24 beers. He started drinking after his mother's death and lost his driver's license because of drinking. He smoked six marijuana cigarettes a day. He abused DayQuil in the past and once tried cocaine to stay awake. He stopped drinking after a DUI conviction because his wife said she would leave him if he did not stop drinking. He had been sober for five years but had a relapse three weeks earlier. He was attending Alcoholics Anonymous ("AA") meetings. At his initial visit, he indicated that he had some craving for alcohol. (Ex. 22: 342; Shafa V: 835.)

186. Dr. Shafa continued Patient D's prescription of Celexa and added Zyprexa Zydis. (Ex. 22: 342-43; Shafa V: 836.)

187. Patient D visited Dr. Shafa on January 14, 2004. He had been sober for 60 days. He reported that he could not sleep when he took Zyprexa. He had stopped taking Celexa. Dr. Shafa prescribed 50mg/day of Topamax, 40mg/day of Celexa, Risperidone, and Klonopin to be taken as needed for anxiety. Dr. Shafa warned Patient D about mixing a benzodiazepine, such as Klonopin, with alcohol. (Ex. 22: 344-45; Shafa V: 836-38.)

188. Prescribing a benzodiazepine to a recovering alcoholic is controversial. It was not an unreasonable risk for Dr. Shafa to prescribe a low dosage of Klonopin. In

certain circumstances, it may be appropriate for a family member to monitor a patient's benzodiazepine intake. Patient D's wife agreed to monitor his Klonopin usage. (Clark III: 539-40; Salzman VIII: 1265-66.)

189. Patient D visited Dr. Shafa on March 10 and June 11, 2004. He had stopped taking Risperidone and Topamax. On March 10, he reported no complaints, and his sleep had improved. On June 11, he indicated he was trying to quit smoking and was having difficulties. He reported that he was sad and aggravated. His wife reported that he was insecure and had "a negative outlook on everything." Dr. Shafa continued his prescription of 40mg/day of Celexa and added 5mg/day of Abilify. (Ex. 22: 346-48.)

190. Patient D visited Dr. Shafa on September 8, 2004. He reported he felt numb and had lost ambition. He was feeling insecure about his relationship with his wife. He did not take the 5mg/day of Abilify because he could not wake up. Dr. Shafa prescribed Lamictal. He gave Patient D a starter pack that started at 25mg/day and incrementally increased to 100mg/day. Dr. Shafa gave Patient D a prescription for 100mg/day to fill after he completed the starter pack. (Ex. 12; Ex. 22: 350-51; Shafa V: 853-54; Shafa VI: 1047.)

191. Lamictal is an anticonvulsant medication used as a mood stabilizer for bipolar patients. It was appropriate for Dr. Shafa to prescribe Lamictal for Patient D. (Salzman VIII: 1267-68.)

192. Stevens-Johnson Syndrome ("SJS"), or toxic epidermal necrolysis, is a rare side effect for Lamictal. SJS causes a serious rash that, untreated, could lead to admission into a burn unit. It has approximately a 20% mortality rate. It is also a side effect for Tylenol and penicillin, but Lamictal carries a heightened risk. It is very

important to engage in the informed consent process when prescribing Lamictal because of the severity of SJS. The Lamictal insert includes warnings, but patients do not always read them. (Clark III: 531-34; Shafa V: 855-57; Shafa VI: 1048-49; Giesen VII: 1123; Salzman VIII: 1269.)

193. Lamictal includes a warning outlined in a black rectangle on the box about the risk of SJS. The FDA issues these "black box" warnings about specific side effects of medications but not for every drug. Black box warnings do not define the standard of care and do not provide a reason not to prescribe a medication to a patient. (Salzman VIII: 1294, 1270-71.)

194. Informed consent is not always recorded in a physician's records.
(Salzman VIII: 1269-70.)

195. The FDA has a strict dosing regimen when starting Lamictal to mitigate the risk of SJS because the risk of the rash is thought to be highest when a patient begins taking it. The patient starts taking 25mg/day for the first two weeks, then increases to 50mg/day for two weeks, and then ultimately increases to 100mg/day. (Ex. 29; Clark III: 532; Clark IV: 652-53; Shafa V: 853-57.)

196. From 2004 to 2007, pharmacies did not provide starter packs. The incremental dosages were only available from doctors who prescribed the drug. Dr. Shafa started his patients on these packs when he prescribed Lamictal. (Ex. 12; Clark IV: 649-51; Shafa VI: 853-54.)

197. Patient D visited Dr. Shafa on December 8, 2004 and January 3, March 2, and March 23, 2005. Patient D reported that he was weepy at times, that his concentration was good, and that he was doing fine overall. Dr. Shafa increased his Lamictal dosage to

150mg/day and continued to prescribed .5mg/day of Klonopin, to be taken as needed.
(Ex. 22: 352-58.)

198. On May 18, 2005 Patient D reported his anxiety was better and that he was doing well. He disclosed that he abused Klonopin, and Dr. Shafa discontinued the prescription of Klonopin. Dr. Shafa increased his Lamictal dosage to 200mg/day and continued 40mg/day of Celexa. (Ex. 22: 359-60; Shafa V: 845, 848.)

199. A patient may abuse Klonopin to attain a sense of euphoria. (Shafa V: 846-48.)

200. On August 10, 2005 Patient D reported that he was doing well. Dr. Shafa continued the same medications. On October 14, 2005, Patient D reported that he felt depressed and sluggish. He was sleeping well but had low energy. (Ex. 22: 361-63.)

201. On November 9, 2005 Patient D reported that he was petrified all the time, had poor memory, was tired, and was depressed. He slept well. He had bursts of energy and felt like he was "treadmilling." Patient D had started taking more Lamictal than he was prescribed. Dr. Shafa increased his Lamictal dosage to 300mg/day, tapered his Celexa prescription to discontinue it, and added .25mg of Risperidone, to be taken as needed. (Ex. 22: 366, 368.)

202. On November 23, 2005 Patient D reported that he felt "300% better." He had lost his job but was neither depressed nor euphoric. He had improved memory and was looking for a job. He had some withdrawal from Celexa. Dr. Shafa increased his Lamictal dosage to 400mg/day and continued the Risperidone prescription. (Ex. 22: 369-70.)

203. Patient D visited Dr. Shafa on January 18, 2006. He reported that the Risperidone had helped with his anxiety. He reported that his mood was good, but that his depression continued and his interest in sex was gone. Dr. Shafa added Abilify to replace the Risperidone because Dr. Shafa did not want to take him off Risperidone abruptly. (Ex. 22: 371, 373; Shafa V: 844-45.)

204. On February 8, 2006 Patient D reported that he was not sleeping well. He felt that the walls were closing in on him, and he had a headache that would not go away. Dr. Shafa prescribed Zyprexa to help with sleep. Dr. Shafa prescribed 15mg/day of Abilify and 400mg/day of Lamictal. In a follow-up visit on February 15, 2006 Patient D reported that he was sleeping okay. Dr. Shafa prescribed 20mg/day of Abilify, 400mg/day of Lamictal, and 20mg/day of Zyprexa. (Ex. 22: 374-77.)

205. On April 21, 2006, Patient D reported that he was back to himself and that everything was fine. Dr. Shafa decreased his Zyprexa dosage to 15mg/day, increased the Abilify dosage to 30mg/day, added 200mg/day of Seroquel for insomnia, maintained a Lamictal dosage of 400mg/day, and told Patient D to discontinue the Risperidone. (Ex. 22: 378-80.)

206. Depending on the patient and the severity of his illness, it may be within the standard of care to prescribe more than one anti-psychotic at the same time. It was appropriate in Patient D's case because Dr. Shafa was in the process of switching medications for Patient D. It is common for a physician to prescribe more than one medication when decreasing the dosage of one and starting another. A physician may prescribe up to four anti-psychotics at one time, but only for a brief period. (Shafa V: 841-42; Salzman VIII: 1266-67.)

207. Patient D called the office on June 10, 2006 because of bad depression. He could not come in for an appointment, so Dr. Shafa prescribed 20mg/day of Prozac. On June 22, Patient D reported that the Prozac helped, but he could not tolerate Seroquel. He was anxious about an upcoming trip, and Dr. Shafa prescribed .5mg Klonopin to help with the anxiety. Patient D promised not to abuse the Klonopin, and Patient D's wife agreed to administer the Klonopin pills. Dr. Shafa increased his prescription of Lamictal to 500mg/day. He also prescribed 15mg/day of Zyprexa, 20mg/day of Prozac, and 30mg/day of Abilify. (Ex. 22: 385-87; Patient E's Mother II: 314; Shafa V: 850-51.)

208. Patient D visited Dr. Shafa on July 27, September 28, and December 21, 2006. He was doing well, and his depression was okay. He had stopped his medication for two weeks because of financial issues in September, and Dr. Shafa provided samples of Lamictal and Zyprexa to restart his medications. Dr. Shafa prescribed 600mg/day of Lamictal, 15mg/day of Zyprexa, and .5mg of Klonopin, to be taken as needed. (Ex. 22: 388-93; Clark III: 534-35.)

209. On February 16, 2007, Dr. Shafa's office received a call from the UMass emergency room because Patient D was experiencing intense sobbing, felt anxious and depressed, and was unable to work. Patient D visited Dr. Shafa on February 18, 2006. He reported that he could not stop crying, was afraid of everything, had interrupted sleep, and could not interact with his children. (Ex. 22: 396.)

210. Patient D reported he was taking .5mg of Klonopin, 600mg/day of Lamictal, and no Prozac or Abilify. His wife reported that he was taking 20mg/day of Prozac, 30mg/day of Abilify, 600mg/day of Lamictal, .5mg/day of Klonopin, and Zyprexa. (Ex. 22: 396-97; Patient E's Mother II: 313-14.)

211. Patient D visited Dr. Shafa on March 5 and March 15, 2006. On March 5, he reported he could not go to work because of his depression. On March 15, he reported his depression was better, but his anxiety was worse. Dr. Shafa increased his Zyprexa dosage to 20mg/day. (Ex. 22: 399-400.)

212. On April 19, 2006 Patient D reported that Klonopin was the only thing helping his anxiety. He reported that he had constant anxiety and that he cried less only when he was on Klonopin. He was in a car accident, and he had a poor recollection of the past week. His wife wanted to divorce him because of his Klonopin abuse. Dr. Shafa stopped his Klonopin prescription and started Xanax extended release. Xanax extended release does not peak in the blood as easily and is less likely to be abused. (Ex. 22: 402-03; Patient E's Mother II: 252-54; Clark III: 543-44; Shafa V: 852.)

213. Patient D visited Dr. Shafa on May 3, 2006. He reported that he was very depressed and that his anxiety made his heart beat fast. He was unable to wake in the morning because of his Zyprexa dosage. Dr. Shafa increased his dosages of Prozac to 40mg/day and Xanax to 6mg/day. He also prescribed 300mg/day of Seroquel and 20mg/day of Zyprexa. (Ex.22: 404-05.)

214. Patient D was admitted to UMass Hospital in the summer of 2007 for two weeks because he was abusing Xanax extended release. He quit his job while he was in the hospital. Dr. Shafa did not know that Patient D had abused Xanax. Patient D's wife discussed Patient D's Klonopin abuse with Dr. Shafa but did not discuss the Xanax abuse because she was ready to end her marriage with Patient D. His wife sought a divorce in the summer of 2007 because of his Xanax abuse, and his drug abuse affected his

relationship with his daughter, Patient E. (Patient E II: 203; Patient E's Mother II: 232, 251, 255-59, 315-16; Clark III: 544-45; Clark IV: 647; Shafa V: 853.)

215. Patient D did not abuse alcohol while being treated by Dr. Shafa. (Shafa V: 838-39.)

216. The Board received Patient D's complaint on June 19, 2008. Patient D said he was treated by Dr. Shafa from June 2006 to May 2007. He stated that Dr. Shafa prescribed him Zyprexa, Symbian, Seroquel, Klonopin, Fluoxetine, Clonazepam, Abilify, Alprazolam, and Lamictal. He claimed that he was once prescribed the highest possible dosage of Klonopin. He stated that he went to the hospital in 2007, and the doctor told him the medications he was on were "solid alcohol." He said he was still not drinking and not on any medication. (Ex. 11.)

217. Patient D died of cancer in July 2012. (Patient E II: 203; Patient E's Mother II: 232.)

Patient E

218. Patient E, who was 7 years old when she began treatment with Dr. Shafa, visited MetroWest Medical Center in Natick, Massachusetts on November 15, 2002 because she made statements at school about killing herself and she assaulted another student. Hospital records indicate that she was hitting herself in the head and chest and had a history of head banging when frustrated. She presented as cooperative, stable, and logical. She denied suicidal ideation. She had a history of tantrums and outbursts, and she frequently made statements about killing herself. Her parents were concerned about her symptoms and expressed the possibility that she was bipolar because their family had an extensive history of mood disorders. They wanted to take her home from the hospital and

requested a referral. The hospital referred them to Dr. Shafa. (Ex. 22: 414-26; Patient E's Mother: 265.)

219. Patient E had outbursts before seeing Dr. Shafa. She would engage in destructive behavior, screaming, and kicking. She was violent towards others and was unable to communicate. She hid under her desk at school, and school officials had to remove children from the classroom for their protection. (Patient E II: 211, 215; Patient E's Mother II: 269.)

220. Dr. Shafa received a copy of the hospital intake form from MetroWest. (Shafa VI: 923.)

221. Patient E first visited Dr. Shafa on November 17, 2002. Her chief complaint was "I want to kill myself." She was frustrated and angry, and she had been getting into fights with other children. She presented as highly active, compulsive, and aggressive. She had issues with sleep, concentration, and attitude. She was too sexually preoccupied and talked about sex or social issues in a manner not appropriate for her age. She had been hugging and kissing flirtatiously since she was four years old. (Ex. 22: 427-28; Clark IV: 554; Shafa VI: 923-24, 1021-22.)

222. Her symptoms were alarming and uncommon for a seven-year-old. Suicidal thoughts in a seven-year-old child are rare. Hypersexuality in a prepubescent child is unusual. In the absence of sexual abuse, it is typically diagnosed as bipolar disorder. (Shafa VI: 923; Giesen VII: 1107-08.)

223. Patient E's paternal grandmother had bipolar disorder, her maternal aunt has depression, and her father had a heart attack when she was 6 years old. Also, her father's cousin had died recently. (Ex. 22: 427-28.)

224. Patient E's parents filled out an ADHD symptom checklist. (Ex. 22: 430.)

225. Dr. Shafa diagnosed Patient E with ADHD, mourning/grief, and ruled out bipolar disorder. "Rule out" means that the physician is considering a diagnosis and will seek further information to confirm it. (Ex. 22: 427; Clark IV: 554-55; Shafa VI: 924-25; Giesen VII: 1109.)

226. Patient E had been receiving treatment from a Dr. Rather at Staffier Associates. She was taking 10mg/day of Adderall. (Ex. 22: 424, 431; Shafa V: 822.)

227. Dr. Shafa prescribed .1mg/day of Clonidine to dampen her aggression and excitability, to help with sleep, and to abate her irritability. Clonidine was a mild intervention and safe medication to address Patient E's impulsivity. Dr. Shafa discussed potential side effects of Clonidine, including weight gain, with her parents. (Ex. 22: 432; Patient E's Mother II: 937; Shafa VI: 925; Giesen VII: 1110.)

228. Patient E visited Dr. Shafa with her mother, her father, or both parents present. Her parents would typically provide an update on Patient E's symptoms. Patient E sometimes contributed. (Patient E's Mother II: 235; Shafa VI: 923, 1045.)

229. Patient E visited Dr. Shafa on November 24, 2002. She was fighting less and was less agitated. She had a better week although some children at school complained that she hit them. She was stealing items from school. She was tired on the low dosage of Clonidine. Patient E visited Dr. Shafa in December 2002. She was more attentive and was finishing her assignments. Dr. Shafa continued the same medications. (Ex. 22: 436-37.)

230. On January 16, 2003, Dr. Shafa noted that she was doing well in school and that there was some improvement. She had some issues with sleep. On February 20,

Dr. Shafa noted that she was not irritable, and school had been uneventful. She had thrown a temper tantrum and was only partially happy. Her listening had improved when she took both Clonidine and Adderall. (Ex. 22: 439, 441.)

231. Patient E's principal wrote a letter dated March 20, 2003 at the request of Patient E's mother, detailing a violent outburst by Patient E, who had a disciplinary issue and became upset with her peers. She wrote "I am not talking, my life is shit" on the board. She threatened to hit a teacher, and she punched and hit the principal. She threatened to shoot both herself and the teacher. The principal described her behavior as dissociative, although she was eventually calm and remorseful. (Ex. 22: 459; Shafa VI: 925-26.)

232. Patient E would dissociate occasionally. When a patient dissociates, she detaches from her immediate surroundings and, in some circumstances, her physical or emotional experience. The patient appears to go "somewhere else." (Patient E's Mother II: 237; Clark IV: 712.)

233. Patient E visited Dr. Shafa on March 20, 2003. She communicated only by writing notes in response to Dr. Shafa's verbal and written questions. Her notes said "I'm crap," "I will not go to the hospital," "My life is shit. I am bad girl," and "You do not want to get to know me." She was pacing, rambling, agitated, and more impulsive. She talked about taking a gun or knife to her chest. Dr. Shafa recommended she be hospitalized, but her mother refused. Dr. Shafa's plan was to discontinue Adderall to decrease her agitation, add Risperidone, continue Clonidine, and have Patient E come to the office the next day. (Ex. 22: 22: 442-57, 460; Shafa VI: 931, 933-34.)

234. Risperidone could address her mood disorder symptoms. It was appropriate, despite her Clonidine prescription, because Clonidine would address her impulsivity but not her depressive and agitated state. (Giesen VII: 1116.)

235. Dr. Shafa recommended hospitalization, because if Patient E was hospitalized the attending physicians could monitor her eating, sleeping, and behavioral patterns. They could monitor her social and biological triggers more in-depth than Dr. Shafa could with only outpatient visits. Her mother refused to hospitalize her. (Shafa VI: 934-35.)

236. Dr. Shafa diagnosed her with bipolar disorder mixed with psychotic features. A bipolar diagnosis was appropriate because she presented with significant mood and behavioral disturbances. She had suicidal ideation and aggression. She also had significant family history of mood disorders. (Ex. 22: 460; Clark IV: 559-62.)

237. Frequently, Patient E would communicate only by notes, and still does occasionally. (Patient E II: 219.)

238. Patient E visited Dr. Shafa on March 21, 2003. Her father, Patient D, explained that he noticed many of his own bipolar symptoms in her. He detailed the family history of bipolarity in her family. He described how Patient E would go into a "fantasy world." Patient E's paternal grandmother and Patient D had been hospitalized for bipolar disorder. (Ex. 22: 463; Patient E's Mother II: 282-83; Shafa VI: 936.)

239. Patient E visited Dr. Shafa on March 23, 2003. She was doing better and was not suicidal. She became sedated on Risperidone. Dr. Shafa provided a medical excuse note to excuse Patient E's absence from school while she was adjusting to her new medications and requested school work that she could do at home. He wanted school

work for her to focus on and agreed not to hospitalize her only if she remained under her parents' observation. (Ex. 22: 463-64; Shafa VI: 936-37.)

240. Patient E visited Dr. Shafa on March 30, 2003. Her impulse control was better, her patience was good, she was not depressed, and she was more relaxed. She was still stealing, however. (Ex. 22: 466-67.)

241. Patient E visited Dr. Shafa on April 3, 2003. She could not sit still and had issues with sleep. She was having nightmares. Dr. Shafa added Lamictal and Trileptal to help with her mood and aggression. He started her on a dosage of 25mg/day of Lamictal, increasing the dosage weekly by 25mg until she was taking 100mg/day. The Lamictal starter pack was not available when Dr. Shafa began prescribing Lamictal for Patient E. He started her on a dosage of 75mg/day of Trileptal, increasing until she was taking 150mg/day. (Ex. 22: 467, 469; Shafa VI: 938, 1027, 1029.)

242. Lamictal was not FDA approved for bipolarity until Summer 2003. Dr. Shafa prescribed Lamictal off-label for Patient E. (Shafa VI: 1027.)

243. Lamictal is frequently used for symptoms of depression and maintain mood. It is appropriate to prescribe Lamictal for a child. Trileptal treats anxiety and agitation, and it can stabilize acute moods. Both medications address different symptoms, although they are both mood stabilizers. Lamictal is not very therapeutic until the dosage is 100mg/day. Trileptal could treat her impulsivity until the Lamictal becomes effective. Antidepressants may not have treated Patient E's bipolar symptoms. (Shafa VI: 939; Giesen VII: 1121-22.)

244. Dr. Shafa explained Lamictal orally to Patient E's mother so that she would be aware of potential adverse side effects. He did not document that he obtained

informed consent from her mother. Patient E's mother does not remember receiving warnings about Lamictal. (Patient E's Mother II: 238; Shafa VI: 939-40, 1028-29.)

245. Around the time of Patient E's treatment, it was not uncommon for a child around her age to be diagnosed with bipolar disorder and to be placed on four or five medications at one time. Child psychiatrists in the Boston area were diagnosing juvenile bipolar more often and were medicating children more. Generally, the practice was to add one medication at a time. (Ex. 32: 118; Clark IV: 565-68.)

246. Child psychiatrists have limited medication options. All medications have adverse side effects that must be weighed against the dangerousness of the child's behavior. (Giesen VII: 1123-24.)

247. Patient E visited Dr. Shafa on April 6, April 30, and May 14, 2003. She had severe separation anxiety from her mother, was fighting with other children, and was having frequent nightmares. She was unfocused, irritable, impulsive, and anxious. Dr. Shafa increased her Trileptal dosage to 300mg/day. (Ex. 22: 470-79.)

248. Dr. Shafa received a fax from Patient E's school nurse. Dr. Shafa had asked her to monitor Patient E for potential side effects. (Ex. 22: 478-79; Shafa VI: 953.)

249. Patient E visited Dr. Shafa on May 30, June 22, and July 16, 2003. She was having difficulty focusing and sitting still. She had poor impulse control, difficulty sleeping, and poor social skills. She was overwhelmed with other people and was not enjoying her life. During this period, Dr. Shafa increased her Lamictal dosage to 125mg/day, increased and then decreased her Trileptal dosage, added Strattera, and maintained her Clonidine dosage. (Ex. 22: 480-487; Shafa VI: 1036.)

250. She visited Dr. Shafa on August 15, September 17, October 15, and November 13, 2003. She was doing well, her eating habits improved, she was sleeping well, and her mood was improving. She had gory nightmares about her brother being skinned alive, being kidnapped, being eaten by a guinea pig, and a tiger chopping off her brother's head. Dr. Shafa increased her Clonidine and Lamictal dosages and decreased her Strattera dosage. (Ex. 22: 493-505.)

251. The gory nightmares were a possible symptom of psychotic features. (Giesen VII: 1128.)

252. During that period, she was on five medications, which is unusual but not unheard of. Dr. Shafa was still trying to stabilize her mood. Lamictal treated her depression, Trileptal treated her impulsivity and insomnia, Risperdal treated her mood disorder and agitation, Clonidine treated her sleep and impulsivity issues, and Strattera treated her ADHD and depression. There were no reports of adverse side effects. (Giesen VII: 1126-29.)

253. In 2004, Patient E visited Dr. Shafa in January, March, June, September, and December. She was doing well and was stable overall. She expressed that people did not like her. She still had dreams about family members dying in gory and violent ways. By December, she became more withdrawn and could not stay focused. Dr. Shafa increased her Risperidone dosage twice. By the end of the year, she was still on five medications: Lamictal, Trileptal, Risperidone, Strattera, and Clonidine. (Ex. 22: 512-28; Shafa VI: 944.)

254. Dr. Shafa has rarely prescribed five medications to a nine-year-old. Because Patient E was not responding to medication, Dr. Shafa gave greater weight to

Patient E's "genetic loading," a predisposition of mood disorder due to family history when diagnosing her and choosing treatment. (Shafa VI: 945-46.)

255. On February 3, 2005, Dr. Shafa filled out a form for Patient E's medical insurance requesting additional visits. He indicated that she had made minimal progress and was diagnosed with bipolar disorder with psychotic features. (Ex. 22: 539; Clark IV: 557-58.)

256. Patient E visited Dr. Shafa on February 11 and 23, 2005. She was swinging from mania to depression. She was having frequent nightmares and was irritated easily. She would cry at school and was delusional. Dr. Shafa discontinued Strattera and increased her Risperdal, Lamictal, and Trileptal dosages. (Ex. 22: 530-32.)

257. She visited Dr. Shafa on March 2 and 23, 2005. She was having dreams of being naked, but she was having fewer bad dreams. She was restless, hyperactive, and hypersexual. She had interrupted sleep and could not do her homework. She went to the hospital on March 9 after saying she wanted to kill herself. Dr. Shafa added Abilify to treat her depression, starting at 2.5mg/day for a week, and then increasing to 5mg/day. On March 23, Dr. Shafa noted that her anger decreased since starting Abilify. Her father reported that she was sweet and cooperative in the morning, but she would have melt downs in the afternoon. She could not focus on homework and was constantly distracted. Dr. Shafa increased her Abilify to 15mg/day on March 23. (Ex. 22: 534-38; Clark IV: 715.)

258. Patient E was showing manic and severe depressive symptoms. (Giesen VII: 1131.)

259. Abilify was not FDA-approved to treat juvenile bipolarity during Patient E's treatment, but it is now. (Giesen VII: 1132-33.)

260. Patient E visited Dr. Shafa on May 18, 2005. Her mood was stable, and she was not having outbursts of anger. Dr. Shafa continued the same medications: .3mg/day of Clonidine, 750mg/day of Trileptal, 15mg/day of Abilify, 3mg/day of Risperidone, and 300mg/day of Lamictal. Dr. Shafa referred her to a behavioral therapist, Dr. Douglas Counts. (Ex. 22: 541-43.)

261. Patient E visited Dr. Shafa on August 10 and October 19, 2005. She was having difficulty focusing, but her mood was good and anger in control. She bounced from one project to another and felt that no one understood her. Her mother believed that she did better on Strattera. Dr. Shafa started her on Rocalin on August 10, but noted that she had mood swings on Rocalin at her visit on October 19. At her October visit, Dr. Shafa noted that Patient E was suspended from school and had fought with a girl in the bathroom. He increased her Lamictal and Abilify dosages. Dr. Shafa noted that she would start seeing a therapist in October. (Ex. 22: 544-50.)

262. Patient E visited Dr. Shafa on November 23, 2005. She had received an award at school, but she slapped someone 30 minutes later, and the school suspended her. She was restless, argumentative, and assaultive towards her parents. She would convince herself that she was the victim and change the story. Her mother reported her behavior as having good days and bad days. She had had a major melt down and was suspended from school at the end of September. (Ex. 22: 553-54.)

263. Dr. Shafa increased her Abilify dosage to 30mg/day and increased her Trileptal dosage to 900mg/day. He maintained her dosage of Lamictal at 400mg/day, Clonidine at .3mg/day, and Risperidone at 3mg/day. (Ex. 22: 553-55.)

264. Patient E's mother gave permission for Dr. Shafa to release Patient E's medical records to her school so that school officials could understand her condition. (Ex. 22: 556-57; Shafa VI: 955.)

265. Patient E visited Dr. Shafa on January 18, 2006. She was happier, she was not fighting in school, and she was getting along with other children better. She had trouble staying focused and sitting still. Her mother believed she was doing better. Dr. Shafa ordered blood tests. (Ex. 22: 568-69; Patient E's Mother II: 296.)

266. LabCorp in Worcester, Massachusetts performed blood and liver function tests for Patient E on February 1. Dr. Shafa highlighted that she had a high prolactin (a hormone) level and made a note that she was on Risperidone. Liver function tests would ensure that the anti-psychotic medications she was on were not harming her liver. (Ex. 22: 563-66; Giesen VII: 1136.)

267. Patient E visited Dr. Shafa on February 8 and 15, 2006. She was having tantrums easily despite the increase in Abilify. She was having a growth spurt. She was confrontational to teachers and adults, and her school suspended her. Dr. Shafa increased her Abilify dosage to 45mg/day. (Ex. 22: 571-78.)

268. Patient E visited Dr. Shafa on April 21, 2006. Her mood was still cycling. She was restless in the evening and had some bad dreams. Dr. Shafa increased her dosage of Abilify to 60mg/day. He also prescribed 600mg/day of Carbatrol because he believed

both to be medically necessary. Actna denied his request to fill Abilify and Carbatrol prescriptions at such high dosages. (Ex. 22: 580-91.)

269. 60mg/day is an unusually high dosage of Abilify. Dr. Giesen has treated one other child on that dosage. Dr. Clark found only once case of a schizophrenic woman on a dosage of 75mg/day of Abilify. (Clark IV: 570; Giesen VII: 1136-37.)

270. Patient E visited Dr. Shafa on June 15 and 22, 2006. She still had rage and was snappy and demanding. She would leave class frequently and had hit a child and teacher. She was very hyperactive and had punched her father. Dr. Shafa decreased her Abilify dosage to 30mg/day because the additional Abilify had not made a significant difference in her behavior. (Ex. 22: 594-96.)

271. Patient E visited Dr. Shafa on July 27, 2006 after returning from a family vacation. She had fainted three times: once at the airport, once at Disney, and once in Boston. She had gone to the hospital, and no problem was found. The ER doctor gave her salt tablets and water, which suggests that she was dehydrated. She was emotionally stable. Dr. Shafa prescribed 30mg/day of Abilify, 1200mg/day of Carbatrol, 4mg/day of Risperidone, .3mg/day of Clonidine, and 400mg/day of Lamictal. (Ex. 22: 599-605; Clark IV: 720-21.)

272. Patient E visited Dr. Shafa on September 28 and December 21, 2006. She was doing okay, and her anger and anxiety were in check. In November, Patient E's mother called to notify Dr. Shafa that Patient E had stopped taking Carbatrol. Dr. Shafa prescribed Trileptal in November and increased her dosage in December. At her visit on December 21, she was unable to sit still, her temper was explosive, and she was oppositional and defiant. She assaulted her mother during the session. Dr. Shafa

prescribed 450mg/day of Lithium for a period, then increased to 900mg/day. Patient E was taking Lithium, 1200mg/day of Trileptal, 400mg/day of Lamictal, .3mg/day of Clonidine, and 4mg/day of Risperdal. (Ex. 22: 607-12.)

273. Lithium is a robust treatment for mood disorder. The combination of Lithium and Lamictal would address the depressive symptoms of a bipolar patient. (Giesen VII: 1142.)

274. Patient E switched schools in sixth grade because she needed additional psychological help. She had to be restrained at school because she had outbursts. (Patient E II: 224-26.)

275. Around December 2006 and January 2007, Patient E's mother and father were having marital issues. They argued frequently. Patient E's father filed for bankruptcy around that time. (Patient E's Mother II: 296-97.)

276. Patient E visited Dr. Shafa on January 4 and 9, 2007, having taken a turn for the worse. She punched, kicked, and slapped the vice principal and was suspended. Lithium had not made a difference, and she was worse every day. She was dramatic, flamboyant, and hyperactive. Dr. Shafa ordered blood work, and Patient E went to BioLab in Milford, Massachusetts for blood analysis on January 4 and 25, 2007. Dr. Shafa increased her Lithium on January 9 but decreased it after her blood work came back on January 25. (Ex. 22: 614-22; Clark IV: 722.)

277. On February 1, 2007 Dr. Shafa spoke with Jill Carroll, a counselor at Patient E's school. Ms. Carroll expressed concern that Patient E would flunk the year. Patient E had no friends, and the school was worried about her being a danger to other

students. She had no respect for classroom rules and school authorities. She would drool, she was tired, and she was irrational. (Ex. 22: 623; Shafa VI: 947-48.)

278. Patient E appeared to be suffering from drooling as a side effect of the medication. Her tiredness could have also been a side effect of her medication. (Clark IV: 577-78; Shafa VI: 948; Giesen VII: 1139.)

279. She visited Dr. Shafa on February 1, 2007. She was very hyperactive, she could not focus in class, and she could not control herself. Dr. Shafa decreased her Lithium dosage and increased her Risperidone and Carbatrol dosages. Patient E was on 60mg/day of Abilify because Dr. Shafa was hoping to stabilize her by giving her the high dosage. (Ex. 22: 625-26; Shafa VI: 949-51.)

280. Dr. Shafa reviewed data from Europe that suggested that higher dosages of Abilify could address Patient E's symptoms. Dr. Shafa discussed this information with Patient E's mother before increasing her dosage of Abilify to 60mg/day. Patient E's mother consented to increasing the Abilify dosage. (Shafa VI: 949-51.)

281. Dr. Shafa discussed hospitalizing Patient E with her mother several times, but her mother refused. (Patient E's Mother II: 267-68; Shafa VI: 951.)

282. Psychiatrists can commit patients who are an imminent danger to themselves or to others, under G.L. c. 123, § 12. Patient E was not in such danger. Parents are often able to manage their children. Dr. Shafa's decision not to commit Patient E was appropriate. (Clark IV: 585-86; Giesen VII: 1198.)

283. In early 2007, Patient E appeared to her mother as a different child. She could not hold a conversation and had no personality. She could not focus and was doing

poorly in school. She had no friends, and her siblings stopped liking her. (Patient E's Mother II: 239-40.)

284. Patient E visited Dr. Shafa on February 17, 2007. She was upset about her father's depression. Her mother reported slight improvement. Patient E had been drooling for months and was called "drooly girl" at school. Dr. Shafa increased her Risperidone dosage to 8mg/day. Patient E was taking Risperidone, 600mg/day of Lamictal, 60mg/day of Abilify, .3mg/day of Clonidine, and 1200mg/day of Carbatrol. Her mother called February 20, 2007, stating that she had given Dr. Shafa the wrong report of Patient E's dosage of Lamictal. Patient E became nauseated when taking 600mg/day of Lamictal, so Dr. Shafa decreased her dosage to 400mg/day. (Ex. 22: 627-30; Shafa VI: 951.)

285. Raising the dosage of Risperidone could worsen Patient E's drooling. (Clark IV: 579.)

286. High dosages of anti-psychotics can cause drooling, but Patient E's behavior required intervention with medication that would likely cause adverse side effects. Dr. Shafa wanted to reduce Patient E's Abilify dosage, and he found her behavioral stability to be more important than stopping her drooling. (Shafa VI: 952; Giesen VII: 1141.)

287. Avoiding overmedication and undermedication for children with severe mood disorders is very difficult because there is a delicate balance that is difficult to find. If the child is overmedicated, she could be sedated or drooling. If the child is under-medicated, she could experience dangerous mood disorder symptoms. "Ideally you get a patient to a euthymic place where they are no longer agitated, [or] depressed, and not doing dangerous behaviors." (Giesen VII: 1139-41.)

288. Dr. Shafa was in contact with Patient E's school at various times throughout her treatment. (Patient E's Mother II: 286-88; Shafa VI: 952.)

289. Patient E visited Dr. Shafa on March 15, 2007. She was still manic, and her medications were not helping. She slept well at night but was not doing well overall. Dr. Shafa discontinued Risperidone, decreased her Abilify dosage to 30mg/day, and started Zyprexa at 10mg/day for mood stabilization. (Ex. 22: 631-32; Giesen VII: 1143.)

290. Patient E's last visit with Dr. Shafa was on March 22, 2007. She was doing better on Zyprexa. She had stomachaches and headaches. She was having difficulty waking up in the morning. Dr. Shafa noted that she claimed to have gained 20 pounds since September. (Ex. 22: 633.)

291. Weight gain of 20 pounds in an adolescent girl is concerning to Dr. Shafa and probably to the girl. The medication or puberty could have caused her weight gain. (Clark IV: 573-75; Giesen VII: 1143-45.)

292. Patient E's mother was concerned about Patient E's weight gain since she began treatment. (Shafa VI: 941.)

293. Patient E's situation was very extreme, making her a challenging patient to treat. (Clark IV: 719; Shafa VI: 953-54.)

294. Patient E was hospitalized from April 4, 2007 to April 12, 2007 at MetroWest Medical Center. Her mother admitted her because she continued to have mood instability despite being on multiple medications and because Patient E's PCP opined that she was on too many medications. Clinicians described her as appearing overmedicated. While hospitalized, she participated in group therapy and generally appeared agitated. The notes indicated that she was labile and restless. She had extreme

mood swings, she was distracted, and her cognition worsened over her stay. On April 11, the group therapy note indicated that she looked a little better. (Patient E II: 201; Patient E's Mother II: 241-42; 299-300; Clark IV: 579-80; Giesen VII: 1146-48, 1192-93, 1203-09.)

295. Her diagnosis at discharge was mood disorder not otherwise specified, rule out anxiety disorder, ADHD, Oppositional Defiant Disorder, and rule out learning disorder. The hospital recommended behavioral treatment and psycho-educational testing. (Clark IV: 5850.)

296. Dr. Shafa's diagnosis of bipolar mixed and mood disorder not otherwise specified would not be a meaningful difference from the hospital's diagnosis. Mood disorder not otherwise specified was a catchall diagnosis at the time. (Clark IV: 582; Giesen VII: 1149-50.)

297. Oppositional defiant disorder typically presents in late preschool or early elementary school years. It presents as stubbornness and difficulty with authority. It is sometimes a precursor to a conduct disorder or mood disturbance and is fairly common in child psychiatry. ODD as a diagnosis is usually limited when situational factors exist (e.g., parents having marital difficulties) (Clark IV: 581; Giesen VII: 1192.)

298. At discharge, Patient E was taken off all anti-psychotics by the hospital doctors. She was still taking Lamictal and Clonidine. She was also taking Tegretol and Concerta. (Patient E's Mother II: 305; Giesen VII: 1145-46.)

299. Dr. Shafa did not receive professional supervision for Patient E's treatment. (Shafa VI: 1047.)

300. Patient E terminated treatment with Dr. Shafa. On January 31, 2008, Dr. Shafa released Patient E's medical records to her new medical provider. (Ex. 22: 634-35.)

301. The Board received Patient D's complaint on behalf of Patient E on June 19, 2008. The complaint stated that Patient E was diagnosed with bipolar disorder, but she has since been diagnosed with mood disorder and ODD. It stated that she was on some medications for sleeping and mood disorder. It also stated that she had difficulty with male doctors and any prescription medications. (Ex. 13.)

302. Patient E saw a psychotherapist while being treated by Dr. Shafa. (Patient E's Mother II: 289.)

303. After terminating treatment with Dr. Shafa, Patient E still suffered from various symptoms. She attended a therapeutic school until she was a sophomore in high school. She suffered from depression and began cutting herself in eighth grade, around the time her mother had surgery. She still suffers from outbursts and separation anxiety. She has been hospitalized two to three more times since terminating treatment with Dr. Shafa and has been in psychotherapy. A few weeks before Patient E testified, her mother called the police after she assaulted her stepfather. She takes 40mg/day of Prozac and .5mg/day of Clonazepam as needed for anxiety disorder. (Patient E II: 205, 213, 221-22, 229-30; Patient E's Mother II: 243, 285, 290-92, 308, 319-20.)

304. Patient E is a refractory patient. (Clark IV: 725-26.)

Patient F

305. Patient F visited Dr. Shafa in September 2009 to treat an opiate addiction. He was 22 years old. His mother accompanied him. (Patient F's Mother II: 343; Green IX: 1319, 1339-40.)

306. Patient F's mother drove him to all of his visits with Dr. Shafa. She normally remained in the waiting room. (Patient F's Mother II: 325, 333.)

307. Patient F's mother brought Patient F to Dr. Shafa because she had been told about Dr. Shafa's treatment and had researched online about naltrexone and disulfiram implants. She wanted Patient F to see Dr. Shafa because other treatments had not worked. (Patient F's Mother II: 349; Green IX: 1431; Ead XI: 1618-19.)

308. Patients seeking addiction treatment often look for one specific treatment option offered by a physician, like a particular prescription or treatment that the doctor is authorized to dispense. (Westreich XII: 1796.)

309. In August 2004, Dr. Shafa was featured in the MetroWest Daily News in an article about treating opiate addiction with a naltrexone pellet. Dr. Shafa treated patients that came to him after reading the article. Dr. Shafa did not advertise his practice. (Ex. 40; Shafa XI: 1649-50.)

310. Dr. Shafa's clinic used to be called Assisted Abstinence Addiction Clinic. He provided pharmacological treatment and some counseling. The primary drugs he prescribed were Suboxone and naltrexone. (Shafa XI: 1647-49.)

311. It is common for implant patients to have prior knowledge of the treatments they seek before seeing Dr. Shafa. (Shafa XI: 165-57.)

312. Patient F was snorting approximately 400mg/day of Oxycontin. He had been abusing the drug for two years, and it was costing him \$250-\$300 per day. He said that he liked opiates because they made him relax and relieved his anxiety. He also indicated he had a long history of being around bad people, which prevented him from staying off drugs. He had obtained methadone from the street to try to detoxify himself

from the drug. Patient F had experienced withdrawal symptoms; they included a racing heart. (Green IX: 1339-40, 1457-58; Shafa XI: 1658-59, 1664, 1727-28; Westreich XII: 1777.)

313. Dr. Shafa asked whether Patient F used tobacco, marijuana, alcohol, cocaine, crystal meth, Adderall, Special K [ketamine], or LSD. Patient F had tried cocaine when he was 18 but did not like it because it made him hyperactive. He first used tobacco when he was 13. He did not like it, but it calmed him. He also consumed less than a gram of marijuana daily to keep him calm. He started drinking alcohol when he was 18. He did not have any DUI convictions and had not tried Adderall, Special K, or LSD. He did not have a history of intravenous drug use. He had never been to inpatient treatment (detoxification, rehabilitation). He had never attended AA or Narcotics Anonymous ("NA") meetings. He had received psychotherapy in the past and suffered from social anxiety. (Green XI: 1460-63, 1466-67; Shafa XI: 1660, 1662-63.)

314. His maternal grandmother was addicted to pills. His mother's family had a history of anorexia and bulimia. (Green XI: 1464; Shafa XI: 1664-65.)

315. Patient F filled out a mood disorder questionnaire. His answers fell just below the threshold for bipolar disorder, and Dr. Shafa indicated that he wanted to rule out bipolar disorder. Patient F did not fill out the questionnaire at subsequent visits. (Green IX: 1465; Shafa XI: 1665-66, 1746.)

316. Dr. Shafa took a urine sample in the office to determine whether Patient F had drugs in his system. It showed that Patient F had marijuana, methadone, and Oxycontin in his system. (Green IX: 1465-66; Shafa XI: 1667-68.)

317. Dr. Shafa had a “tough” talk with Patient F. Dr. Shafa wanted to help him understand that he needed to commit to becoming clean. He also informed Patient F that he needed to be off drugs to start naltrexone. (Patient F’s Mother II: 327; Shafa XI: 1668-70.)

318. Dr. Shafa noted in the medical record that he discussed the side effects of the naltrexone pellet with Patient F. Dr. Shafa discussed naltrexone and disulfiram with Patient F. His mother was present for the conversation. (Patient F’s Mother II: 367; Green IX: 1464-65.)

319. Dr. Shafa prescribed Comtan for Patient F to be taken as needed. Patient F did not take any Comtan because he was not interested in sobriety at the time. Dr. Shafa also recommended “soup and salt,” a home remedy for opiate withdrawal. Consuming soup and salt helps patients tolerate withdrawal symptoms and prevents some of the withdrawal side effects. (Green X: 1507-08; Shafa XI: 1681-82; 1703-04.)

320. At a patient’s initial assessment for addiction, the clinician should discuss the patient’s chief complaint, obtain information about the addictive substances the patient uses, note the patient’s mental status, obtain the patient’s medical and addiction treatment histories, assess the patient’s status, and make a treatment plan. (Green IX: 1327-28; Westreich XII: 1775.)

321. Dr. Shafa’s initial assessment was adequate. (Westreich XII: 1777-78.)

322. Dr. Shafa scheduled a follow up appointment for September 21, 2009 to implant the naltrexone pellet once Patient F did not have drugs in his system. Patient F did not return for the pellet. (Green IX: 1434; Shafa XI: 1682.)

323. Between 2009 and 2010, Patient F saw Winnie Wang, a doctor who administered Suboxone. He also received psychotherapy. Patient F was kicked out of that clinic because he was tampering with his urine tests. (Patient F's Mother II: 345-47, 366.)

324. Suboxone is an opioid agonist used to treat opiate addiction by activating opioid receptors. It is an opiate replacement that blunts the high of other opiates. Patients must abstain from using drugs for 24 hours to begin Suboxone treatment. Suboxone is not likely to be effective for cocaine addiction because the drugs affect different neurotransmitters. (Green IX: 1384-85; Shafa XI: 1644-45; Westreich XII: 1795-96.)

325. Suboxone is federally regulated, and physicians must either take an eight-hour course or complete a fellowship in order to be eligible to prescribe Suboxone. Dr. Shafa completed the course and can prescribe Suboxone to a maximum of 100 patients. He typically treats between 70 and 80 patients at any one time with Suboxone. If he gets close to the 100 patient limit, he refers patients to other treatment providers. (Green IX: 1421-22, 1552-53; Shafa XI: 1645-47.)

326. Methadone is an opioid agonist that must be taken once every 24 hours. It must be administered at a hospital or a federally licensed clinic. Methadone clinics have a reputation for being difficult places for addicts because other people use or sell drugs in the vicinity. (Westreich XII: 1795-99.)

327. Suboxone and methadone can lead to the termination of illegal opiate use. It is not necessarily a cure and may need to be taken indefinitely. Opioid agonists have been criticized because they replace one drug with another drug. They require patients to continue taking the drug, but on the other hand they keep patients stable. (Green IX: 1447; Westreich XII: 1797-98.)

328. Patient F's mother sought to involuntarily hospitalize Patient F under G.L. c. 123, § 35. Section 35 commitment is a 30-day detoxification program ordered by a judge. After Patient F finished that program, he entered another detox program at Baldpate Hospital, another addiction treatment center that helps prepare patients for naltrexone treatment. (Green IX: 1330-31, 1467-69; Shafa XI: 1685-86.)

329. Patient F's mother brought him to Dr. Shafa upon his release from Baldpate on August 11, 2010. His mother agreed to let Patient F come home only if he restarted treatment with Dr. Shafa. He was suffering from an opiate and cocaine addiction. (Patient F's Mother II: 328-29; Green IX: 1319, 1467-69; Shafa XI: 1685.)

330. Patient F's mother did not know that he was abusing cocaine and heroin. (Patient F's Mother II: 344.)

331. Dr. Shafa's nurse saw Patient F and administered two injections for Patient F: naltrexone and disulfiram. Dr. Shafa asked Patient F to return so that he could evaluate him. (Green XI: 1334; Shafa XI: 1688-89, 1693.)

332. Naltrexone is an opioid blocker; it treats opiate addiction by blocking opioid receptors. Vivitrol is a one-month extended release form of naltrexone. (Green XI: 1480-81; Westreich XII: 1795.)

333. Disulfiram is normally used to treat alcohol dependence. Health care providers to addicts have observed that it is useful for combating cocaine craving. Peer-reviewed journals have published studies about the use of disulfiram for cocaine addiction, though the studies have shown a modest benefit. It is within the standard of care to treat cocaine addiction with disulfiram. (Westreich XII: 1789-90.)

334. In theory, an extended release injection of disulfiram would ensure that the patient receives his medication every day without having to take it himself. (Green X: 1531.)

335. Dr. Shafa required Patient F to sign a form each time he came in for a disulfiram injection. By signing the form, Dr. Shafa intended to encourage his patients to take responsibility for their treatment because addicts have the tendency to blame others or be self-centered. The patient agrees to seek individual therapy, group therapy (AA/NA), call for help, and be honest. (Green IX: 1357; Shafa XI: 1690-93, 1739.)

336. Group therapy, like AA or NA, provides a social group to addicts outside of the drug-using group. Recovering addicts need emotional support to overcome the disease. (Green IX: 1348; Shafa XI: 1653.)

337. Patient F returned on August 18, 2010. He reported that he tried cocaine and heroin because he was curious to see what would happen. He explained that he had social anxiety during family gatherings. Patient F tested positive for cocaine and opiates. (Green IX: 1476; Shafa XI: 1694.)

338. Dr. Shafa discussed Substance Outpatient Addiction Program ("SOAP") and AA, but Patient F did not want to go. Dr. Shafa noted that he would continue to encourage Patient F to engage in group therapy, that he would discuss referrals for therapy and psychiatric follow-up, and that Patient F was going to see his PCP. (Green X: 1482; Shafa XI: 1696.)

339. On August 19, Dr. Shafa typed up a summary of Patient F's August 11 and 18 visits. He added more detail about Patient F's detox and sobriety history, his substance abuse history, his current drug use, the last time he used and the route he used,

their discussion about informed consent and side effects, and the medication Dr. Shafa was prescribing. (Green IX: 1478-79.)

340. Normally, physicians should record medical notes as close to the appointment as possible. It is standard to record notes within a couple days. (Green X: 1556-57.)

341. Patient F visited Dr. Shafa on September 8, 2010. He disclosed smoking cocaine. He told Dr. Shafa that he started working at a new job. Dr. Shafa gave him an injection of disulfiram. (Green IX: 1341-43; 1471.)

342. Patient F began seeing Woburn Family Practice's Dr. Kishore for the treatment of his opiate addiction because Patient F's insurance covered naltrexone. He continued with Dr. Shafa for the treatment of his cocaine addiction only. Patient F's PCP was also at Woburn Family Practice. (Green IX: 1342, 1487-88; Shafa XI: 1695-97; Ead XI: 1622.)

343. Woburn Family Practice provides internal medicine treatment. It is a primary care and addiction clinic. It provided physical exams, blood work, and group and individual therapy. Dr. Shafa shared patients with them. (Shafa XI: 165-55.)

344. It is not ideal for a patient to receive addiction treatment from different providers, but it is not below the standard of care. (Westreich XII: 1813-14.)

345. Generally, treating cocaine addiction is difficult. The response to addiction treatment depends on the patient: the form of the drug he abuses, the route he uses, genetics, availability of a social support system, and severity of cravings. (Westreich XII: 1779-80, 1814.)

346. Dr. Shafa discussed alternative treatments with Patient F. He did not record the discussion in his medical record. (Shafa XI: 1734-35.)

347. Patient F visited Dr. Shafa on October 6, 2010. He disclosed that he was on probation for assault and battery. He tried taking the keys to his sister's car from his mother. He stole his sister's car to buy cocaine. Dr. Shafa noted this in red ink because it was very significant that Patient F was beginning to face legal issues related to his addiction. Dr. Shafa spoke with his mother to see what happened. (Green IX: 1351-52; Shafa XI: 1698-1700.)

348. Patient F reported that he used drugs when he was bored or anxious, on average at least once per week. Dr. Shafa discussed his craving. His urine test came back positive for cocaine. (Green X: 1501, 1503-04, 1532.)

349. Patient F's mother bought him a Nintendo GameBoy; he sold it and used the money for drugs. Dr. Shafa recommended that she take away the four C's: computer, cash, car, credit card. She should then release them as a reward for improving. (Green IX: 1352; Shafa XI: 1701.)

350. Dr. Shafa gave Patient F another disulfiram injection and prescribed Comtan to address Patient F's craving. (Green IX: 1355.)

351. Comtan is a drug used to treat Parkinson's disease and is not typically used to treat cravings. Dr. Shafa performed a pilot study about the effectiveness of Comtan for cravings in addiction patients as part of a team from Harvard and Boston University. The study showed that 77 percent of the 36 patients were able to abstain from using cocaine while on Comtan. He performed a second study in 2013 with 253 patients. The use of Comtan significantly improved the patients' adherence to Suboxone treatment.

It was within the standard of care to use Comtan. (Ex. 40; Shafa XI: 1673-76, 1678; Westreich XII: 1793-94.)

352. Patient F visited Dr. Shafa on November 2, 2010. He reported that he was doing well but then broke down and admitted that he had “screwed up.” He said that he began working 60 hours per week, and he did cocaine when he had idle time. He said he never filled his Comtan prescription because he did not think he needed it, and he did not like it. He expressed that he was still not interested in meetings because of his social anxiety and that he could not go online for group therapy because his computer was broken. Patient F and Dr. Shafa discussed the implications of his drug use on his family, especially his mother. His urine test was positive for cocaine. (Green X: 1512-15, 1518-19; Shafa XI: 1704-06.)

353. Dr. Shafa prescribed a new medication, bromocriptine, to replace Comtan. He gave Patient F another disulfiram injection. (Green X: 1521.)

354. Bromocriptine is normally used for Parkinson’s disease. In the 1970s and 80s, it was used to treat cocaine addiction but was found to be ineffective by the 1990s. A few studies published in peer-reviewed journals suggest that while it was not effective in treating addiction to cocaine, it can decrease cocaine craving. The studies show some, albeit not overwhelming, benefit. (Green IX: 1382-83; Westreich XII: 1790-91.)

355. It was within the standard of care to prescribe bromocriptine and disulfiram to treat Patient F. (Westreich XII: 1792.)

356. Patient F fainted when he received the injection because he had not eaten breakfast or lunch that day. Patient F’s mother was asked to come into the treatment

room. He recovered after lying down. (Patient F's Mother II: 351; Shafa XI: 1701; Ead XI: 1628.)

357. Patient F signed a form authorizing his therapist, Ed Bleu, to share information with Dr. Shafa. Dr. Shafa spoke with Ed Bleu about Patient F but did not document the conversations. (Green X: 1515-17; Shafa XI: 1706.)

358. At Patient F's subsequent visit on November 24, 2010, he expressed that his cocaine use had decreased. His urine screen came back with a lower concentration of cocaine in his system than in previous sessions. Patient F expressed a desire to stop using cocaine. He tried to educate Patient F about addiction so that he would understand his triggers and recognize situations that could instigate a relapse. (Shafa XI: 1707-12.)

359. Dr. Shafa created a plan to help Patient F deal with the craving, which included taking bromocriptine. Dr. Shafa also gave a disulfiram injection. Patient F signed an additional form that was a comprehensive informed consent document. It discussed what the patient would be responsible for, particularly his own treatment. Patient F signed this form several times during his treatment. Dr. Shafa has patients sign this form only if they take disulfiram. (Shafa XI: 1711, 1737; Westreich XII: 1772-74.)

360. Patient F visited Dr. Shafa on December 15, 2010. He reported that his cravings for and use of cocaine had decreased. He also reported that he was taking 2.5mg/day of bromocriptine and that it had been helping with his depression. He got his cell phone back and would be receiving his car back at Christmas. He was proud that he was acting responsibly. His boss said that he was improving at work and had more energy. Patient F had his first negative test for cocaine. (Green X: 1523-24, 1526; Shafa XI: 1714-16.)

361. Patient F began attending group therapy meetings at Grace Chapel, which provided therapy for addicts and for family members of addicts. Patient F's mother attended the meetings. (Patient F's Mother II: 349-50; Green X: 1522-23; Shafa XI: 1713-14.)

362. Patient F visited Dr. Shafa on January 5, 2011. He reported that he was doing well and that the bromocriptine was working well. He was still seeing Ed Bleu and going to group therapy meetings at Grace Chapel. He discussed his cravings. He tested negative for cocaine. (Green X: 1526-28; Shafa XI: 1716.)

363. Patient F missed his visit on January 31, 2011 because of snow. Dr. Shafa called in a prescription of the pill form of disulfiram, Antabuse, to take until he could visit Dr. Shafa for an injection. He visited Dr. Shafa on February 9 and reported that he took the Antabuse pills as prescribed. He reported that he received his Vivitrol shot, that he liked taking bromocriptine, and that he was not doing cocaine. His test was negative for cocaine. (Green X: 1531-32; Shafa XI: 1717-18.)

364. Patient F had his last visit with Dr. Shafa on March 7, 2011, although Dr. Shafa did not know it would be Patient F's last visit. Patient F reported that he had been doing well and that his cravings came and went. After being clean for 80 days, he relapsed two days before because he had had a hard day at work. His boss yelled at him, his parents were having issues, and he did not have a good relationship with his father. He was still attending group and individual therapy, and he indicated he had people in his life that he could call if necessary. Dr. Shafa discussed with him participating actively in group therapy and getting a sponsor, someone who had gone through what he had. (Green X: 1533, 1535; Shafa XI: 1718-21.)

365. Relapse in addiction patients does not mean that treatment failed. Relapse is an expected part of improvement from addiction disorder. The physician should ask what caused the relapse and make changes to address it. (Green IX: 1439; Westreich XII: 1781, 1783.)

366. Abstinence is not required in addiction treatment, though in 2009 and 2010 this approach was controversial. Physicians can treat patients using the harm-reduction model: working with patients to diminish drug use and gradually move toward improved outcomes. Doctors can teach moderation and discuss safer injection practices because not every patient will stop using drugs. (Green IX: 1442.)

367. Patients are more likely to be successful when they are motivated and involved in the recovery process. Typically, the more a patient has to lose, such as a stronger family or a better job, the more likely the patient will stop abusing drugs. (Green IX: 1423-24; Westreich XII: 1782-83.)

368. Patient F's mother called to cancel his appointment for March 30, 2011. She was trying to obtain reimbursement, but her insurance would not pay for the visits. Patient F had signed a consent form that acknowledged that Dr. Shafa did not accept insurance and that Patient F was responsible for the payments. (Green X: 1538-39; Shafa XI: 1723; Ead XI: 1623.)

369. Insurance will often pay for modest treatment. It usually will not pay for inpatient cocaine treatment. Patient F's insurance covered treatment with Vivitrol. (Green IX: 1487; Westreich XII: 1812.)

370. Patient F missed his April 20, 2011 appointment. There is no record of Dr. Shafa contacting the patient or his other health care providers. (Green XI: 1392.)

371. Patient F went to a rehabilitation center in New Hampshire from May 8 to 25, 2011. He then moved to another treatment center in Connecticut from May 27 to June 20, 2011. (Patient F's Mother II: 358-59.)

372. Patient F died on June 22 of heroin and cocaine overdose. (Patient F's Mother II: 359-60.)

373. Patient F's mother sued the Connecticut facility because they discharged him too early. She claims that they did not wait for her to pick him up and transfer him to another facility. (Patient F's Mother II: 360-61.)

374. On February 8, 2012, Dr. Shafa's nurse wrote a discharge summary note on Patient F's medical record saying that Patient F suffered from cocaine dependency. It is not his typical practice to include a discharge summary note in his medical records. Dr. Shafa was sending the medical records to a lawyer who was hired by Patient F's parents. The discharge summary note was meant to help subsequent readers understand the medical records. (Shafa XI: 1730, 1746-47.)

375. Cocaine addiction does not have a "gold standard" for treatment. Various medications can be used to treat cocaine abuse and dependence. Some are effective, but none is very effective. Useful drugs could be desipramine, modafinil, bupropion (Wellbutrin), topiramate, or disulfiram. The FDA has not approved any treatment for cocaine addiction. (Green IX: 1365, 1372, 1428; Westreich XII: 1786)

376. Desipramine is a modestly useful anti-depressant that is useful for some patients. It can cause heart arrhythmias or be lethal in overdose. Modafinil can be helpful for cocaine dependence and craving. It is a non-stimulant treatment for narcolepsy and is useful for ADD, as well. Stephens-Johnson Syndrome is a side effect. Bupropion has

shown some effectiveness in decreasing cocaine craving, and it has few side effects.

Topiramate is an anti-convulsant medication used to treat bipolar disorder. It has been shown to be modestly effective for alcohol and cocaine cravings. (Green X: 1540; Westreich XII: 1787-88.)

377. Little funding is available for studies related to cocaine addiction. Most studies are small. (Westreich XII: 1794-95.)

378. Despite the fact that most drugs are only modestly useful, addiction clinicians must still use them because they are "so desperate to get some benefit in the struggle against cocaine." Clinicians will prescribe medications that may benefit the patient, even if the likelihood of effectiveness is low. Due to the lack of evidence in the addiction treatment field, clinicians must learn from their experience, the experience of other clinicians, academic settings, formal fellowships and lectures, professional groups, and training seminars. (Westreich XII: 1769-70, 1791-92.)

379. Addiction specialists must engage in the informed consent process with patients. They must discuss the options, including the risks and benefits of each, to determine the best treatment for the patient. (Green IX: 1387, 1399-1400; Shafa XI: 1649; Westreich XII: 1770-71.)

380. Physicians do not need to document that they obtained informed consent from patients to meet the standard of care. (Westreich XII: 1772.)

381. During Patient F's treatment, Dr. Shafa was in contact with Patient F's mother, Ed Blcu (his therapist), and the Woburn Family Practice. (Shafa XI: 1742, 1748.)

382. Dr. Shafa never ruled out bipolar disorder for Patient F. He did not want to rule it out until he was more certain about the diagnosis. To finalize the diagnosis, he

would interact with Patient F, look at the spectrum of his anxiety and mood, and determine whether he suffered from addiction, mood disorder, or both. For instance, Patient F said his social anxiety prevented him from attending group meetings, but after some treatment he was able to attend group therapy at Grace Chapel. (Shafa XI: 1746.)

383. Anxiety or bipolar disorder could affect addiction. When a patient has addiction disorder and symptoms of a psychiatric disorder, it is appropriate for the physician to watch and wait, monitoring the psychiatric symptoms as the addiction clears. It is common for patients to have a co-occurring mental illness when suffering from addiction disorder. (Westreich XII: 1763, 1814, 1818.)

384. Dr. Shafa never implanted a naltrexone or disulfiram pellet in Patient F. (Green IX: 1470.)

385. Psychiatrists are not required to complete a fellowship or obtain board certification in addiction psychiatry to treat addiction patients. (Westreich XII: 1768-69.)

386. Physicians may use a few words to trigger a memory when noting a patient's visit in medical records. Medical records serve as a guide to refresh the physician's memory about the patient's treatment. Physicians typically do not include every part of the conversation with the patient in a medical record. (Green IX: 1417-18; Westreich XII: 1805.)

387. Some of Dr. Shafa's written notes were difficult to read. Dr. Shafa's notes were consistent with those that Dr. Westreich has reviewed of other clinicians in the past. His notes were within the standard of care. (Westreich XII: 1819.)

388. The Board received the complaint from Patient F's father on March 1, 2012. Patient F's father complained that he requested Patient F's medical records from Dr. Shafa, and Dr. Shafa did not comply. (Ex. 17; Ead XI: 1589-90.)

389. On January 23, 2012, Dr. Shafa received a fax from Tracey Hardman, an attorney hired by Patient F's father, requesting Patient F's medical records. Ms. Hardman instructed Dr. Shafa to send Patient F's records to her office. Dr. Shafa sent a copy of Patient F's medical records to Ms. Hardman on February 12, 2012. Dr. Shafa's attorney responded to the Board complaint in a letter to the Board dated April 23, 2012, explaining this sequence of events. (Ex. 18; Ead XI: 1590-93.)

390. Marian Ead, R.N. was assigned as the clinical investigator for Patient F's case in May 2012. She discussed the complaint, Dr. Shafa's response, and whether to send Patient F's records to an expert with the Board's complaint counsel. (Ead XI: 1587-88, 1594-95.)

391. The Board obtained Patient F's medical records from Attorney Hardman on September 11, 2012. (Ead XI: 1597-1600.)

392. Although Patient F's father's complaint was resolved and did not include an allegation of substandard care, the Board sent Patient F's records to an expert for review for substandard care. The Board wanted to investigate Dr. Shafa's care of Patient F because Dr. Shafa had other complaints of substandard care. Ms. Hardman provided Patient F's medical records to the Board. Normally the physician provides a certified copy of the medical records. The Board requested a certified copy of the medical records from Dr. Shafa in March 2014. (Ead XI: 1601-03, 1607.)

393. Patient F's parents sued Dr. Shafa in small claims court to recover the costs for the attorney's fees they paid to obtain records from Dr. Shafa. (Ex. 27; Patient F's Mother II: 353-56.)

394. The Board sent the medical records to Maximus in June 2013. Maximus is a company that the Board contacted to provide expert reviews on cases. (Ead XI: 1608, 1611.)

395. The Board sought Dr. Green's review of Patient F's records in October 2013. Dr. Green expressed concerns with legibility. The Board did not request a transcript from Dr. Shafa of his medical records. The Board did not contact Dr. Shafa to address the concerns Dr. Green outlined in his expert report. The Board often contacts physicians to give them the opportunity to address concerns raised in an expert review of their medical records. (Green IX: 1413; Ead XI: 1612-14.)

396. After Dr. Green was concerned about the legibility of Patient F's medical records, the Board did not ask Dr. Shafa for clarification. Physicians are now encouraged to use electronic medical records. Illegible notes were a concern that led to this change in practice. (Ex. 20; Green IX: 1413-16.)

397. The Enforcement Division presented this case to the Complaint Committee on March 5, 2014. Dr. Shafa was not present at the proceeding. (Ead XI: 1616-17.)

398. Ms. Ead interviewed Patient F's father and mother on March 12, 2014. The Board did not conduct other interviews. The Board requested medical records from Dr. Shafa and did not subpoena any documents. (Ead XI: 1606-07.)

399. Ms. Ead submitted an affidavit that was written with the help of complaint counsel on March 26, 2014. The affidavit sought a summary suspension of Dr. Shafa's license from the Board. The Board denied the motion for summary suspension. (Ead XI: 1609-10.)

CONCLUSION AND RECOMMENDATION

The Board has not proven by a preponderance of the evidence that Dr. Shafa engaged in conduct that places into question his competence to practice medicine or engaged in conduct that undermines the public confidence in the integrity of the medical profession during his treatment of Patients A through E. The Board has also not proven that Dr. Shafa engaged in conduct which calls into question his competence to practice medicine, violated a rule or regulation of the Board, engaged in misconduct in the practice of medicine, or engaged in conduct that undermines the public confidence in the integrity of the medical profession during his treatment of Patient F. Dr. Shafa's treatment of Patients A through F met the standard of care. In its Closing Argument, the Board makes additional allegations and arguments, but it failed to include these in its Statement of Allegations.² Therefore, these arguments are not properly before me.

² Specifically, the Board made the following arguments. It argued that Dr. Shafa failed to consider alternatives to his treatment regimen for Patient E. The Board argues that Dr. Shafa did not consider family therapy and did not receive professional consultation about Patient E. The Board also argues that Dr. Shafa should have reconsidered his diagnosis. First, Dr. Shafa notes several times in the record that Patient E was in individual therapy. While family therapy may have benefited Patient E, merely having alternative treatments available does not mean that Dr. Shafa fell below the standard of care in this regard. Dr. Shafa knew Patient E was receiving therapy and continually maintained contact with her school throughout her treatment. He also treated both of her parents for a time and did not fall below the standard of care in this regard. Next, the Board asserted that Dr. Shafa was required to obtain professional supervision on each of his patients; he is not. Lastly, although reconsidering his diagnosis may have been beneficial, the Board did not present sufficient evidence to show that Dr. Shafa did

Statutory Basis for Discipline

In Massachusetts, physicians may be disciplined for “misconduct in the practice of medicine.” 243 CMR 1.03(5)(a)(18). Doctors are also prohibited from engaging in conduct which places into “question the physician’s competence to practice medicine,” including gross misconduct in the practice of medicine. G.L. c. 112, § 5(c); 243 CMR 1.03(5)(a)(3). The Supreme Judicial Court defined the term “misconduct” in *Hellman v. Board of Registration in Medicine*, 404 Mass. 800, 804 (1989):

“Misconduct” in general, is improper conduct or wrong behavior, but as used in speech and in law it implies that the conduct complained of was willed and intentional. It is more than that conduct which comes about by reason of error of judgment or lack of diligence. It involves intentional wrongdoing or lack of concern for one’s conduct. Whether or not an act constitutes misconduct must be determined from the facts surrounding the act, the nature of the act, and the intention of the actor.

A physician may be disciplined for misconduct during diagnosis or treatment of a patient or for misconduct “in carrying out his professional activities.” *Forziati v. Board of Registration in Medicine*, 333 Mass. 125, 130 (1955).

Additionally, the Board may discipline a physician who lacks “good moral character” or has engaged in conduct that undermines the public confidence in the integrity of the medical profession. G.L. c. 112 § 2; *Alsabati v. Board of Registration in Medicine*, 404 Mass. 547, 551 (1989) (committed plagiarism nearly ten years earlier); *Raymond v. Board of Registration in Medicine*, 387 Mass. 708, 712 (1982) (convicted of illegal arms dealing); *Levy v. Board of Registration in Medicine*, 378 Mass. 519, 527-28 (1979) (convicted of grand larceny). Such disciplinary action “is reasonably related to

not reconsider his diagnosis for Patient E. The testifying experts agreed that Patient E suffered from a severe mood disturbance, and bipolar disorder was an appropriate diagnosis.

promotion of the public health, welfare, and safety.” *Raymond*, 387 Mass. at 713. The Board may also discipline physicians for violation of a Board rule or regulation. G.L. c. 122 § 5(h); 243 CMR 1.03(5)(a)(11). The Board has issued a regulation that physicians must maintain patient records that are “complete, timely, legible, and adequate to enable the licensee or any other health care provider to provide proper diagnosis and treatment.” 243 CMR 2.07(13)(a).

Standard of Care

All physicians, including psychiatrists, must meet the standard of care, which is “the degree of care and skill of the average qualified practitioner, taking into account the advances in the profession.” *Brune v. Belinkoff*, 354 Mass. 102, 109 (1968). The standard of care is the level of care and skill that physicians in the same specialty commonly possess. *Palandijan v. Foster*, 446 Mass. 100, 105 (2006); *McCarthy v. Boston City Hospital*, 358 Mass. 639, 643 (1971). Evidence that other physicians may have treated a patient differently does not prove negligence on its own, unless such treatment does not coincide with accepted medical practice. *Grassis v. Retik*, 25 Mass. App. Ct. 595, 602 (1988). Physicians may be required to choose one treatment from other medically appropriate alternatives that fall “within a reasonable range of medical judgment, taking into account the particular patient and circumstances.” *Barrette v. Hight*, 353 Mass. 268, 276 (1967). The testifying experts in this appeal agreed that the standard of care in psychiatry is specific to the patient, and more than one type of treatment for the same illness could fall within the standard of care.³ Psychiatrists determine the appropriate

³ Some of the experts expressed this sentiment thus: “There are not a lot of really bright lines in psychiatry . . . and there are times when good clinicians engaging in a thoughtful process end up with a cocktail of medications that look as if they don’t make

treatment by assessing patients and their reactions to treatment and by balancing the risks of side effects with the potential benefit of the medication. (Clark III: 455-56.)

PATIENT A

Medication Regimen

The Board alleges that Dr. Shafa violated the standard of care because he prescribed medications for Patient A that were contraindicated when taken singly or in concert with other medications and that cause adverse side effects.

Benzodiazepines: The Board alleges that Dr. Shafa prescribed high dosages of benzodiazepines that were inconsistent with the “start low, go slow” approach. The record indicates that Dr. Shafa started Patient A on a standard dosage of Klonopin, increasing the dosage until eventually Patient A could take up to 10mg/day (8 mg/day taken regularly and 2mg/day taken on an as-needed basis). The experts and Dr. Shafa agree that between 6mg/day and 10mg/day is a higher than average dosage of Klonopin. However, Dr. Salzman testified that psychiatrists “hardly ever, if ever” conform their practice to FDA or PDR recommended dosage ranges and that he had treated a patient taking 20mg/day of Klonopin. (Salzman VIII: 1229-30.) Dr. Shafa continued to increase Patient A’s Klonopin dosage gradually and altered the dosages when his own observations and Patient A’s reports led him to infer that the medication was effective or ineffective.

The Board also alleges that Dr. Shafa’s prescription of high dosages of Xanax and Klonopin were inconsistent with the “start low, go slow” approach. However, Dr. Shafa

sense at all.” Clark III: 458. “We don’t have an objective measure scientific measure, so we go by the symptoms they present with.” Giesen VII: 1067-68. “It’s not like a heart attack Because we don’t have any biologic tests for our disorders, we don’t have any way of specifically measuring.” Salzman VIII: 1226-27.

testified that he prescribed a high dosage of Xanax for Patient A because Xanax and Klonopin are compatible drugs and because Dr. Shafa wanted to decrease Patient A's Klonopin dosage without triggering withdrawal symptoms. Additionally, Patient A was undergoing a crisis, and Dr. Shafa was adjusting his medications to abate the crisis.

The Board argues that Patient A's emergency room visit in February 2004 demonstrates that Patient A was overmedicated on Klonopin and/or Zyprexa. However, Patient A's urine drug panel tested negative for benzodiazepines (Klonopin is a benzodiazepene), and Patient A admitted that he stopped taking his prescribed benzodiazepines. Dr. Clark explained that in order for his blood test to be negative, Patient A must have stopped taking his prescribed benzodiazepines for at least a few days. The experts agreed that benzodiazepine withdrawal could cause many of the symptoms that Patient A presented with. Dr. Salzman also explained that abruptly stopping benzodiazepines after taking them for over a year would "guarantee return of panic disorder probably more severe than before." (Salzman VIII: 1253.) In this instance, it is more likely than not that Patient A was undergoing benzodiazepine withdrawal symptoms because he stopped taking his medication, which in turn triggered a panic attack.

The Board further alleges that Dr. Shafa prescribed benzodiazepines despite Patient A's disclosure of alcohol consumption, violating the standard of care. However, Dr. Shafa provided sufficient information to Patient A for him to be aware of the risks of consuming alcohol while taking his prescribed medications.

For the reasons stated, I conclude that Dr. Shafa did not provide substandard care in the treatment of Patient A with benzodiazepines.

Anti-depressants: The Board alleges that Dr. Shafa's prescription of more than one anti-depressant (SSRI) at once constituted substandard care for Patient A. The Board argues that Dr. Shafa failed to appreciate the risk of serotonin syndrome when he prescribed two SSRI medications in January 2004. Dr. Shafa began prescribing a low dosage of Lexapro in addition to Patient A's dosage of Prozac, with the intention of switching Patient A from Prozac to Lexapro. Dr. Shafa began increasing Patient A's dosage of Lexapro and stopped prescribing Prozac. When Patient A's condition worsened, Dr. Shafa ceased the prescription of all SSRIs. Once Patient A stopped taking Lexapro, he reported that he felt better. Furthermore, these medication changes occurred during a time when Patient A was in crisis. Dr. Shafa changed Patient A's medications in response to his crisis and his reported symptoms. For these reasons, Dr. Shafa did not fail to respond to Patient A's presenting symptoms while prescribing anti-depressants.

Mood Stabilizers: The Board also alleges that Dr. Shafa's treatment fell below the standard of care because he prescribed two mood stabilizers at the same time without medical reason and without monitoring side effects. Dr. Salzman credibly testified that prescribing two mood stabilizers is not uncommon, and the record indicates that Dr. Shafa monitored the side effects of the medications. For instance, Patient A complained that his tremors had worsened since starting Depakote, so Dr. Shafa decreased the dosage of Depakote and added Trileptal, a medication that has fewer side effects. As Dr. Clark explained, psychiatry involves a risk-benefit analysis, and the psychiatrist must balance the side effects with the benefits of the medication. Dr. Shafa performed this balancing analysis by changing Patient A's medications when it appeared that the side effects outweighed the potential benefits. Both Dr. Clark and Dr. Salzman describe Dr. Shafa's

approach as a “creative” approach to psychotherapy; but neither expert claimed that this approach violated the standard of care. Rather, Dr. Shafa exercised reasoned judgment based on his observations, his experience, and Patient A’s symptoms in order to find the appropriate treatment for Patient A.

The Board also asserts that Dr. Shafa did not monitor the side effects of Patient A’s Trileptal levels when Patient A visited the ER in May 2003. The Board and its expert called the Trileptal level “toxic.” However, Dr. Salzman explained it is not clear that the elevated Trileptal level is clinically significant because Trileptal is not typically measured. *See* Ex. 16; Salzman VIII: 1242.

Dr. Salzman also indicated that the most common side effect of a high level of anticonvulsant medication would be a change in mental status, but Patient A appeared alert and oriented to the ER staff. Dr. Salzman presented several alternative causes of Patient A’s symptoms. For instance: he could have been having a panic attack, he could have been experiencing dizziness from low blood pressure, or his pain medication could have caused unsteadiness or sedation. Additionally, many of Patient A’s reported symptoms were consistent with his panic attacks, and Patient A described having similar episodes in the past. There are several possible explanations for Patient A’s symptoms, and the Board did not present sufficient evidence that an elevated Trileptal level was more likely than not the cause.

For the reasons stated, Dr. Shafa did not provide substandard care in his prescription of mood stabilizers for Patient A.

Changes in Medication: The Board alleges that Dr. Shafa did not adhere to the “start low, go slow” approach in January 2004 when he made four changes in Patient A’s

medication. Although this approach is a general rule of psychopharmacology, the experts agreed that when a patient's condition worsens or a patient is in crisis, it is not unusual to make several medication changes at once. In early 2004, Patient A was in crisis, so Dr. Shafa increased dosages, added medications, and switched medications. Dr. Salzman testified that such adjustments may be appropriate when a patient is in crisis. Furthermore, the record suggests that Dr. Shafa generally increased or decreased Patient A's dosages gradually and in response to Dr. Shafa's observations and Patient A's reported symptoms.

Side Effects: The Board alleges that Dr. Shafa provided substandard care by failing to adequately assess and monitor Patient A's side effects associated with his multiple medications at high dosages. However, as discussed above, the record suggests that Dr. Shafa monitored the side effects and made changes to medications based on his own observations and on reports from Patient A.

The Board similarly alleges that Dr. Shafa failed to monitor the medications' effect on Patient A's tremors and weight. However, the record contains several instances of Dr. Shafa adjusting Patient A's medication in response to Patient A's reports that his tremors were worsening. (*E.g.*, Ex. 22: 24, 58, 138.) Additionally, Dr. Shafa opined that Patient A's weight gain and edema could be caused by one of several factors, including his knee injury, his blood pressure medication, and/or his psychiatric medications.

For the reasons stated above, Dr. Shafa did not fail to monitor Patient A's side effects in violation of the standard of care.

Bipolar Diagnosis

The Board alleges that Dr. Shafa's bipolar diagnosis is not supported by Patient A's medical and social history and that the combination of medications prescribed to Patient A had the potential to create side effects that would hinder an adequate diagnosis. Patient A was in crisis and was not responding to medication. Dr. Shafa based his diagnosis on Patient A's family history of anxiety and depression coupled with his non-responsiveness to SSRIs, a common treatment for panic disorder that is normally successful for patients. Once on Lithium, Patient A reported that the medication was helping his depression, although Dr. Shafa discontinued the Lithium once Patient A did not improve further. While Patient A's medication could have interfered with an assessment of his current symptoms, Dr. Shafa based his diagnosis on several factors after having treated Patient A for over a year. Furthermore, Dr. Shafa testified that he believed bipolarity to be plausible, but not necessarily conclusive. As Dr. Clark explained, there are not many bright lines in psychiatry. Dr. Salzman opined that it was within the standard of care to consider bipolarity and panic disorder under these circumstances. Thus, Dr. Shafa reconsidered his diagnosis in light of his experience and observations, Patient A's family and medical history, and Patient A's non-responsiveness to medication. Although treatment was unsuccessful, Dr. Shafa's diagnosis was a reasoned action that attempted to bring Patient A out of crisis and did not fall below the standard of care.

Patient A's Response to Treatment

Finally, the Board asserts that Patient A did not improve consistently while under Dr. Shafa's care, that he showed signs of overmedication, and that he was nearly

incapacitated after treatment with Dr. Shafa. However, the record, including Patient A's complaint, suggests that Patient A did improve initially. After some treatment, Dr. Shafa began decreasing the dosages of Patient A's medication, and Patient A's visits decreased. Although Patient A did not consistently improve, Dr. Shafa's care did not violate the standard of care merely because the treatment was ultimately unsuccessful.

In his testimony, Patient A denied any improvement in his condition while being treated by Dr. Shafa. I grant little evidentiary weight to this testimony for the following reasons. First, Patient A frequently commented on how he had little to no memory of the events because ten years had passed. (*E.g.*, Ex. 22: 48, 51, 78, 89, 107.) Second, his testimony lacked specificity and was self-contradictory at times. Dr. Shafa's medical records, on the other hand, provided detailed information about the changes in Patient A's symptoms and medication.

The Board argues that Patient A was overmedicated while being treated by Dr. Shafa. However, both experts explained that it is not unusual for a patient to be on several psychiatric medications at one time. Dr. Salzman explained that patients suffering from severe panic are often prescribed multiple medications, and often at high dosages. Patient A was suffering from serious panic attacks, and Dr. Shafa consequently prescribed several medications at one time, sometimes at high dosages. However, as discussed above, he made changes to the medication as he deemed appropriate based on his observations and Patient A's reports of his progress throughout the course of treatment.

The Board highlights that Patient A lost his job while being treated by Dr. Shafa. Patient A went on medical leave after his second ER visit and did not return to his position that school year. Unfortunately, because of his extended leave of absence, he

was not re-hired at the school. Since losing that job, however, he has held three jobs. He is only recently unemployed, partly due to his knee surgery in 2012, which left him unable to perform certain job duties. While being treated by Dr. Shafa, Patient A underwent several personal changes: he ended his relationship with his girlfriend, he began working at a new school, and he moved to a new house. Dr. Salzman explained that external changes could trigger a relapse in a refractory patient. In fact, Patient A himself attributed the return of his panic to his move. Considering all of the circumstances, Dr. Shafa's treatment was not more likely than not the cause of Patient A losing his job.

The experts and Dr. Shafa agreed that Patient A is a refractory patient. He had undergone unsuccessful treatment for nearly a decade when he first sought treatment from Dr. Shafa. At first, Patient A's condition temporarily improved under Dr. Shafa's care, but the treatment was ultimately unsuccessful. Patient A continued to seek treatment because he still suffers from panic attacks and anxiety. He is also still taking a benzodiazepine and anti-depressant. Unsuccessful treatment, especially of a refractory patient, does not indicate that Dr. Shafa's care fell below the standard of care. Although reasonable minds may differ on the best treatment for Patient A, the Board did not prove by a preponderance of the evidence that Dr. Shafa's treatment was inappropriate or below the standard of care.

PATIENTS B AND C

Dr. Shafa's Professional Training

The Board alleges that Dr. Shafa's treatment fell below the standard of care because he did not have specific training or certification in the diagnosis or treatment of

children's mental health conditions. Dr. Shafa did have training and experience in child psychiatry. When he treated Patients B and C, he had nearly a decade of experience at Leonard Morse Hospital, which included treatment in the children's unit. He also completed a mini-fellowship in Pediatric Bipolar Disorder, ADHD, and PDD in 2004. The Board points to Dr. Shafa's use of diagnostic scales for Patient C to demonstrate that Dr. Shafa was unqualified to treat children. However, Dr. Shafa used this as an informative tool to assist him in his diagnosis, and I conclude it was not inappropriate. Moreover, the Board's expert testified that any psychiatrist can treat children without falling below the standard of care. In fact, there is no requirement that Dr. Shafa be board certified in child and adolescent psychiatry to treat children. Thus, I conclude that Dr. Shafa did not fall below the standard of care.

Dr. Shafa's Diagnoses for Patients B and C

The Board alleges that Dr. Shafa did not investigate primary sources, such as teachers, pediatricians, or therapists when he diagnosed Patients B and C. The Board also alleges that Dr. Shafa failed to include any investigation of social and environmental factors, such as home life and any potential abuse. Although additional information from other primary sources may have been useful in a diagnosis, Dr. Giesen indicated that a psychiatrist is not required to speak with a pediatrician when diagnosing a patient. In fact, though, Dr. Shafa did speak with Patient B's PCP in November 2004. Additionally, while Dr. Clark opined that Dr. Shafa could have learned more by questioning other caregivers, the Board did not present sufficient evidence that it would be necessary to consult with other primary sources to meet the standard of care. Dr. Shafa monitored the social and environmental changes for Patients B and C as their mother and grandmother reported

them to him. He questioned their mother and grandmother about foster care and spoke with Patient B's PCP, ultimately concluding that Patient B had not been abused. He noted several changes in their home environment and tried contacting DSS several times for more information, without avail. The Board has not proven by a preponderance of the evidence that Dr. Shafa failed to investigate or inadequately investigated the girls' backgrounds.

The Board alleges that Dr. Shafa did not heed the cautionary language in the 2007 Treatment Guidelines about diagnosing children with bipolar disorder. Those guidelines were issued after Dr. Shafa ceased treating Patients B and C. In fact, Dr. Giesen testified that diagnosing bipolarity in children was "trendy" around that time. Dr. Clark similarly testified that it was a common diagnosis in the Boston area because that diagnosis was encouraged by an aggressive research group based out of Massachusetts General Hospital. Dr. Shafa testified that he was hesitant to treat Patient C with medications but felt it was necessary because she was already exhibiting very troubling symptoms, such as waking in the middle of the night and cutting her own hair or the cat's hair. Additionally, both Dr. Giesen and Dr. Clark testified that bipolarity was a plausible diagnosis for Patients B and C based on the symptoms they presented and their parents' mood disorders. The Treatment Guidelines from 2005 and 2007 indicate that children of adults with bipolar disorder have an increased risk of developing a mood disorder. (Ex. 32: 110; Ex. 33: 218.) Although the diagnosis of bipolarity in children has become more controversial in more recent years, the record establishes that it was a common diagnosis while Dr. Shafa treated Patients B and C. The Board discusses Dr. Clark's expert report, which opines that the diagnosis of childhood bipolar for two children in the same family

is statistically unlikely. (Ex. 16.) Although Dr. Clark discussed alternative causes or diagnoses that could have explained Patients B and C's symptoms, it was not clear from the record that a bipolar diagnosis for either or both children fell below the standard of care.

Additionally, the Board alleges that Dr. Shafa refused to investigate whether the children's reported behavior was accurate or possibly caused by other factors unrelated to psychological disorders. The Board argues that the letters from the foster mothers were indicative of the role of environment in Patients B and C's symptoms. I grant little evidentiary weight to the letters. The foster mothers did not testify, there was no opportunity for cross-examination, and it is unclear why they wrote these letters. Although the letters express that Patients B and C were behaving well, Dr. Giesen opined that children in a new environment occasionally behave better than they would normally. Dr. Shafa based his treatment of Patients B and C based on his own observations and by the reports of their mother and grandmother. The Board did not prove by a preponderance of the evidence that Dr. Shafa refused or failed to investigate the patients' behavior sufficiently.

The Board further alleges that Dr. Shafa did not investigate the circumstances of the children's removal from their home and whether that would be relevant to their diagnoses. Dr. Shafa testified that he tried to contact DSS several times for additional information, but that DSS would not provide him information about Patients B and C. He was able to obtain information from their mother and grandmother, and he believed they intended to help Patients B and C. They provided information that, in combination with Dr. Shafa's own observations about the patients, was sufficient to determine the

appropriate treatment for Patients B and C. Thus, I conclude that Dr. Shafa performed sufficient investigation into the circumstances surrounding the patients' foster care.

Incorporation of Psychotherapy into Treatment

The Board alleges that Dr. Shafa neglected to consider or incorporate psychotherapy treatment for Patients B and C. It is not disputed that Patients B and C would have benefitted from therapy. Moreover, Dr. Shafa made several attempts for Patients B and C to obtain therapy. He sought a disability classification so that their mother would have additional funds to seek treatment, and he tried communicating with DSS to obtain therapy. Dr. Shafa testified that it was difficult to find therapists who would treat Patients B and C. Although their MassHealth insurance covered therapy, it was not Dr. Shafa's lack of effort that resulted in their not receiving it. Dr. Giesen also opined that therapy may not have helped Patients B and C with their mood disorder symptoms. Furthermore, Dr. Clark testified that the use of medication alone for young children is a risk but would not violate the standard of care. Thus the Board did not prove that Dr. Shafa violated the standard of care in this respect.

Administration of Medication

The Board alleges that Dr. Shafa failed to treat Patients B and C through a multimodal treatment plan, instead limiting his care to the administration of anti-psychotic medications. The Board alleges that Dr. Shafa used unusually large doses of anti-psychotic medications and that he failed to test Patient B for side effects for Seroquel. Dr. Clark testified that a dosage of 100mg/day to 200mg/day is not unusual for adolescents or children, and Dr. Giesen testified that children could be prescribed up to 400mg/day or 600mg/day. (Clark III: 517; Giesen VII: 1099-1100.) Dr. Shafa started

treating Patients B and C with low dosages of medication, gradually increasing the dosage in response to their exhibited symptoms. He added an additional medication for Patient C when she needed help with sleep. Additionally, Dr. Shafa did not record any negative side effects. The Board notes that Dr. Shafa's records do not indicate that he ordered blood work or monitored the patients' weight. However, the Board did not present sufficient evidence that these failures fell below the standard of care.

The Board also alleges that Dr. Shafa provided substandard care because Patient B was on the maximum dosage of Abilify. Patient B was never prescribed Abilify. Nonetheless, I will address whether Patient C's high dosage of Abilify would be considered below the standard of care. Patient C was initially prescribed a low dosage of Abilify, which Dr. Shafa increased until she reached the maximum dosage of 30mg/day. Dr. Shafa increased her medication when her mother and/or grandmother indicated that her symptoms were worsening. She only exhibited the side effect of sleepiness on one occasion. The record indicates that Dr. Shafa gradually increased the dosage based on his own observations and Patient C's mother's report of her behavior and symptoms, generally without negative side effects. The FDA does not distinguish the maximum dosage between children and adults. Dr. Giesen testified that he had prescribed 30mg/day of Abilify to a child and had treated a child on 60mg/day.

The Board alleged that Dr. Shafa's prescription of two anti-psychotic medications at the same time for Patient C was improper. More specifically, Dr. Clark pointed out that the Treatment Guidelines from 2005 do not list two anti-psychotics as a recommended treatment algorithm. The Treatment Guidelines from both 2005 and 2007 did, however, contain the qualification that they do not represent the standard of care. The Treatment

Guidelines also corroborate Dr. Giesen's testimony that the treating clinician is in the best position to determine the appropriate treatment for a patient because the treating clinician observes the progress of the patient. (Ex. 32: 114; Ex. 33: 213-14.) Although prescribing two anti-psychotics is unconventional for a small child, it did not violate the standard of care in these circumstances.

Furthermore, Dr. Giesen testified that limited options exist for treatment of bipolarity; only anticonvulsants (mood stabilizers) and atypical anti-psychotics should be prescribed. He stressed that Dr. Shafa was in the best position to make the dosing decision because he had contact with the patients, he observed their symptoms, and he documented their progress. As discussed above, the Treatment Guidelines from 2005 and 2007 both assert that the treating clinician must make the ultimate decision and that the clinical guidelines are recommendations, not the standard of care.

Informed Consent

The Board alleges that Dr. Shafa's record does not indicate that Patients B and C's mother was informed that Patients B and C were prescribed medication that was not approved by the FDA. The experts agreed that to obtain informed consent, a psychiatrist must explain the benefits and potential adverse side effects of the medication to the parent, or the child if she is old enough. Dr. Shafa testified that he discussed the medications with the patients' mother. He explained it would be "futile" to prescribe medication without discussing it because the patient requires a "manual so that they know what to do with it." (Shafa V: 899-900.) He explained that if he did not discuss the medication with the patient, the patient is not as likely to take it. The Board did not present sufficient evidence to contradict Dr. Shafa's credible testimony.

More specifically, the Board alleges that Dr. Shafa did not inform the patients' mother that he was prescribing medications off-label. Dr. Giesen testified off-label prescriptions were common during the period that Dr. Shafa treated Patients B and C because the FDA did not approve many psychiatric medications for children. While this may be useful knowledge, the Board did not prove by a preponderance of the evidence that an explanation of off-label prescribing is a necessary component of informed consent.

The Board argues that Dr. Shafa did not engage in the informed consent process with Patients B and C's mother because he did not document it in the medical records. However, Dr. Giesen testified that the current practice of obtaining written records of informed consent has only recently been implemented. Ideally, Dr. Shafa would have noted the details of his discussion with Patients B and C's mother. However, the Board did not provide sufficient evidence that failing to maintain a written record of informed consent fell below the standard of care during the time that Dr. Shafa treated Patients B and C.

Patient B's Pineal Cyst

The Board alleges that Dr. Shafa did not follow up on the pineal cyst that appeared on Patient B's MRI. Although Dr. Shafa's records do not note follow up on this condition, Dr. Clark testified that a pineal cyst was a normal variant and not of concern. Thus, no further action was required by Dr. Shafa. I conclude that Dr. Shafa did not provide substandard care.

PATIENT D

Prescription of Lamictal

The Board alleges that Dr. Shafa prescribed a high dosage of Lamictal to Patient D that was inappropriate and unnecessarily exposed Patient D to significant health risks. More specifically, the Board argues that it was inappropriate to start Patient D on a dosage of 100mg/day because the FDA-approved starter pack requires that patients start on a dosage of 25mg/day with gradual increases over a five-week period. Although Dr. Shafa gave Patient D a prescription for 100mg/day, he also testified that he provided a sample pack for the first thirty days of Patient D's Lamictal regimen. The starter pack that is now provided by pharmacies was not available at the time; when it was prescribed to Patient D it was available only from prescribing doctors. Dr. Shafa also provided a sample pack to Patient D when Patient D stopped taking Lamictal due to financial reasons. A preponderance of the evidence supports the conclusion that Dr. Shafa followed the proper incremental dosage increases for Patient D.

Additionally, the Board argues that the dosage of 600mg/day of Lamictal was inappropriately high because it is three times the recommended dosage. Although Dr. Clark testified that 400mg/day is the maximum recommended dosage for bipolar patients (Clark III: 536), he did not testify that it would violate the standard of care to prescribe higher than the recommended dosage in the circumstances of this case. Thus, the Board did not present sufficient evidence that prescribing 600mg/day of Lamictal to Patient D violated the standard of care.

The Board also alleges that Dr. Shafa did not make a record of explaining the side effects of Lamictal to Patient D. However, Dr. Shafa credibly testified that he explained

the risks to Patient D, but did not record that fact. Dr. Salzman testified that he “almost never record[s] informed consent, but always give[s] it.” (Salzman VIII: 1269-70.) As discussed above, the practice of obtaining written informed consent was less common during the period that Dr. Shafa treated Patient D, although it is now customary. Finally, the testifying experts agreed that SJS is a rare disease. Dr. Salzman explained that the black box warning about the risk of SJS is simply an additional warning that physicians must discuss when prescribing Lamictal. Because Dr. Shafa provided these warnings, he fulfilled his duty. The Board did not prove by a preponderance of the evidence that Dr. Shafa failed to meet the standard of care by failing to record that he obtained informed consent from Patient D.

Prescription of Benzodiazepines despite Substance Abuse History

The Board also alleges that Dr. Shafa provided substandard care in prescribing benzodiazepines to Patient D, who had a history of alcohol abuse. However, the Board’s expert testified that it was not an unreasonable risk to take by prescribing a low dosage of Klonopin to Patient D. (Clark III: 359-40.) Dr. Salzman explained that it is controversial to prescribe benzodiazepines to such a patient, but it would be reasonable to prescribe them if the patient needed them and the patient had a support system, as Patient D did. (Salzman VIII: 1265.) Additionally, Dr. Shafa noted that he discussed the use of alcohol with benzodiazepines, and Patient D did not abuse alcohol while being treated by Dr. Shafa. In both instances when Patient D admitted to abusing Klonopin, Dr. Shafa stopped prescribing it. Dr. Shafa prescribed Klonopin the second time because Patient D expressed increased anxiety before a trip and his wife agreed to distribute the pills to him. The Board did not provide sufficient evidence that Dr. Shafa failed to address or consider

Patient D's substance abuse history, nor did it provide sufficient evidence that Dr. Shafa failed to monitor Patient D's usage of benzodiazepines.

Treatment with Multiple Medications

The Board alleges that Dr. Shafa's prescribing multiple atypical anti-psychotics at high doses is contrary to accepted medical practice. Specifically, the Board argues that the prescription of Abilify, Zyprexa, Risperdal, and Seroquel in early 2006 was inappropriate. However, Dr. Salzman testified that it was appropriate in Patient D's circumstances to prescribe four anti-psychotic medications because Dr. Shafa was decreasing Patient D's dosage of Zyprexa and discontinuing Risperdal to address Patient D's reported loss of libido. Dr. Clark also testified that the use of three anti-psychotics was controversial but does occur, that Dr. Shafa was in the process of adjusting Patient D's medications, and that Dr. Shafa was urging Patient D to discontinue Risperdal. (Clark III: 537-38.) Additionally, during that period, Patient D reported that he was back to himself and was feeling better. The Board did not prove by a preponderance of the evidence that Dr. Shafa's medication regimen in these circumstances fell below the standard of care.

The Board also alleges that Dr. Shafa failed to identify clearly defined signs of overmedication and/or abuse of prescription medications and continued to prescribe the medications up to a few weeks before Patient D's hospitalization. As discussed above, Dr. Shafa responded to both instances of Patient D's Klonopin abuse by ceasing Patient D's prescription. Dr. Shafa testified that he had prescribed the extended-release version of Xanax because it is less likely to be abused and that he did not know of Patient D's Xanax abuse. Patient D's ex-wife also testified that she did not inform Dr. Shafa of

Patient D's Xanax abuse because by that point she was divorcing Patient D. Dr. Shafa had increased Patient D's Xanax prescription after Patient D reported worsened anxiety and depression. A preponderance of the evidence does not support the conclusion that Dr. Shafa knew of Patient D's Xanax abuse.

PATIENT E

High Dosages and Combinations of Medications

The Board alleges that the medications and the dosages prescribed to Patient E were excessively high for a patient her age, and the combinations were inappropriate for Patient E. The Board first asserts that the high dosage of Abilify was inappropriate. Dr. Shafa began prescribing Patient E a low dosage of Abilify, gradually increasing the dosage until she was taking 60mg/day. Dr. Clark testified that this was unprecedented, but Dr. Giesen testified that he had once seen a child on that dosage. Dr. Giesen opined that, although not appropriate in all circumstances, the high dosage of Abilify was appropriate for Patient E because of the severity of her symptoms. He also opined that it may have been the safer alternative and that this was not below the standard of care. I give greater weight to Dr. Giesen's opinion than Dr. Clark's because Dr. Giesen's practice is devoted almost exclusively to children and he has more clinical experience treating children. (Giesen VII: 1136-38.) Although an unusual dosage in general, prescribing Abilify at 60mg/day in these circumstances did not fall below the standard of care.

The Board also argues that Dr. Shafa's high dosage of Lamictal was inappropriate. As with Abilify, Dr. Shafa started Patient E off at a low dosage of Lamictal, gradually increasing her until, for a brief period, she was taking 600mg/day.

For the majority of her treatment, Patient E was taking between 100 and 400mg/day of Lamictal. Dr. Clark expressed concern with Patient E taking 400 to 600mg/day of Lamictal because it was higher than the recommended dosage. (Clark IV: 573.) Dr. Clark's concern however does not rise to the level of a violation of the standard of care. Furthermore, Dr. Giesen explained several times that Lamictal was effective for treating Patient E's severe depressive symptoms. (E.g. Giesen VII: 1028, 1121, 1142.) Thus, the Board has not proved that Dr. Shafa violated the standard of care by prescribing the higher dosages of Lamictal.

The Board also argues that prescribing Lamictal and Trileptal at the same time was inappropriate. Dr. Clark testified that prescribing two medications of the same class is generally not good practice because it is difficult to determine which medication is causing any side effects. (Clark IV: 564.) However, Dr. Giesen indicated that Lamictal and Trileptal, although both mood stabilizers, treat different symptoms. He explained that Lamictal is effective for treating depressive symptoms, while Trileptal is effective for agitation and anxiety. He also explained that anti-depressant medications may not have treated Patient E's bipolar symptoms. Dr. Shafa confirmed that he prescribed both medications because Lamictal does not treat acute states, Trileptal does, and Patient E was in an acute state. Although it was not a good practice in every circumstance, the record more strongly suggests that it was appropriate in Patient E's case.

Generally, Dr. Shafa adjusted Patient E's dosages in response to her reported symptoms. For example, in August 2003, although she reported that she was doing well, she was still having gory nightmares. Dr. Shafa increased her Clonidine and Lamictal dosages, attempting to improve her mood stability. Around November 2005 and February

2007, Dr. Shafa prescribed five psychiatric medications for Patient E. Dr. Clark testified that around the time that Patient E was treated, it was not uncommon for children around Patient E's age to be diagnosed as bipolar and to be treated with four or five medications at one time. Additionally, each medication was initially prescribed at a low dosage and gradually increased or decreased in response to Patient E's symptoms and Dr. Shafa's observations.

The Board argues that Dr. Shafa's treatment fell below the standard of care because he did not obtain nor did he document that he obtained informed consent when prescribing Lamictal to Patient E. Dr. Shafa credibly testified that he discussed the medications with Patient E's mother but did not note it in the medical records. He further explained that he gradually increased Patient E's prescription of Lamictal according to the required schedule to reduce the risk of SJS, and it was his regular practice to do so. Patient E's mother testified that she did not recall receiving any warnings about Lamictal, but that does not mean that she did not receive the warnings. Further, as discussed previously, failure to document that informed consent was obtained on its own does not violate the standard of care. A preponderance of the evidence tends to prove that Dr. Shafa engaged in the informed consent process with Patient E's mother.

Side Effects Affecting Patient E

The Board alleged that the prescribed medications and dosages increased the likelihood of developing significant side effects that interfered with Patient E's efforts to learn more adaptive coping strategies. Dr. Clark expressed his concerns about using atypical anti-psychotic medications in a child of Patient E's age because of the potential cognitive or emotional effects. (Clark IV: 587.) He also expressed that Dr. Shafa could

have reduced her medications, referred Patient E to therapy, and evaluated her school setting. (Clark IV: 587-88.) Dr. Shafa did adjust her medications, lowering dosages when he believed the medication to be ineffective or her symptoms to be improving. He also made several notes about her therapy, and Patient E and her mother testified that she was receiving therapy for the majority of her treatment with Dr. Shafa. Finally, Dr. Shafa was in frequent contact with her school about her treatment. Further, Dr. Giesen explained that child psychiatrists have limited medication options, all of the medications have adverse side effects, that the psychiatrist must balance the side effects with the dangerousness of the patient's symptoms and behavior. Patient E exhibited very dangerous and violent behavior and made frequent statements about suicidal ideation. All of the testifying experts agreed that her case was very extreme and difficult to treat. The record demonstrates that it was appropriate to prescribe anti-psychotic medications to treat Patient E's symptoms.

The Board also argues that her medication regimen created serious problems for her, including inability to make friends or to hold a conversation, and a decline in her school performance. Patient E's mother testified that Patient E had no personality towards the end of her treatment with Dr. Shafa. She also testified that her daughter was "awesome" after she had been taken off of the powerful medications that Dr. Shafa prescribed. (Patient E's Mother II: 244.) Unfortunately, this assessment is not borne out by the facts; her mother had to call the police on Patient E recently because she had assaulted her stepfather. The Board additionally argues that she suffered in school because of the medication regimen she was on. Patient E was seriously struggling before she began treatment with Dr. Shafa and continued to struggle after she terminated

treatment with Dr. Shafa. She had been treated for approximately a year for ADHD and was referred to Dr. Shafa after assaulting a student and making statements about killing herself. After ceasing treatment, she remained depressed and has since been diagnosed with anxiety. She continues to exhibit violent behavior and has been hospitalized several times since ceasing treatment with Dr. Shafa. It was not proven by a preponderance of the evidence that Dr. Shafa's medication regimen caused the serious problems that Patient E was facing. The record reflects that Patient E suffered before and after Dr. Shafa's treatment. Although his treatment was ultimately unsuccessful for Patient E, it did not violate the standard of care.

The Board also alleges that Dr. Shafa disregarded clear side effects and signs of overmedication, especially in light of Patient E's inability to carry a conversation, her drooling, and her weight gain. The record reflects that Dr. Shafa did *not* ignore those side effects. Rather, he monitored Patient E's symptoms and side effects as they were reported to him by her parents and as he observed them in their sessions. He adjusted her medications in response to those reports and observations. Dr. Giesen explained that avoiding over-medication and under-medication for children with severe mood disorders is very difficult because it is more difficult to gauge dosages in a child than in an adult. (Giesen VII: 1139-40.) He explained that when the patient is overmedicated, she could be sedated or drooling. *Id.* If the child is under-medicated, the child could experience dangerous mood disorder symptoms. *Id.* "Ideally you get a patient to a euthymic place where they are no longer agitated, depressed, and not doing dangerous behaviors," he explained. *Id.* Dr. Shafa testified that he determined her safety and stability were more important than stopping the drooling. (Shafa VI: 952.) Dr. Shafa did not ignore Patient

E's side effects. Instead, he monitored them and adjusted her medications and dosages as appropriate to treat her very serious behavioral symptoms.

Finally, the Board argues that her medications caused fainting episodes and weight gain. However, the Board also conceded that Dr. Shafa treated her fainting episodes with salt tablets. Regarding her weight gain, the testifying experts agreed that her medications could have caused weight gain. However, Dr. Salzman also opined that she could be gaining weight as a result of puberty. Furthermore, Dr. Shafa testified that he discussed the issue of weight gain with Patient E's parents, discussed balancing the risks with the benefits, and they made the decision that her treatment was appropriate. (Shafa VI: 1035.) These balancing decisions did not violate the standard of care.

PATIENT F

Dr. Shafa's Assessment and Treatment of Patient F

The Board alleges that Dr. Shafa violated the standard of care by not performing a comprehensive addiction review in sessions and failing to inquire into current stressors, supports, triggers, or details of recent use. The Board argues also that Dr. Shafa failed to propose standard evidence-based strategies, such as cognitive behavioral therapy, group or individual therapy, relapse prevention, contingency management, family therapy, inpatient care, or partial hospitalization. The record reflects otherwise; in fact, this accusation has no basis in fact and is at best perplexing. Dr. Shafa discussed Patient F's substance abuse history and current drug use, medical and psychiatric history, and drug use triggers. Dr. Shafa recommended group and individual therapy for Patient F and was in contact with Patient F's mother on various occasions. Patient F attended individual and

group therapy, and his mother attended group therapy sessions with him. Furthermore, Dr. Westreich testified that Dr. Shafa performed an adequate initial assessment.

The Board also argues that Dr. Shafa failed to respond to positive toxicology reports with a change in treatment plan or medications. These allegations are similarly wholly unsupported by the record. After starting Patient F on disulfiram, Patient F was still having cravings, so Dr. Shafa added Comtan. Patient F expressed an aversion to Comtan and was still craving cocaine; so Dr. Shafa switched Patient F to bromocriptine. Patient F expressed that bromocriptine was helping. Furthermore, once taking disulfiram and bromocriptine, Patient F appeared to respond to treatment. The concentration of cocaine went down initially, and he even had some tests that were negative for cocaine. Furthermore, when Patient F relapsed and had the first positive drug test in a few months, Dr. Shafa responded by discussing the circumstances surrounding the relapse and urging him to participate more actively in group therapy. The testifying experts agreed that relapses are expected and do not indicate that treatment is unsuccessful. Dr. Shafa did not provide substandard care in this respect.

The Board alleges that Dr. Shafa ignored standard treatments for cocaine dependence in favor of treatments that did not have evidence or clinical support for their use. The Board argues that Dr. Shafa should have incorporated family therapy in Patient F's treatment. Dr. Shafa *did* recommend family therapy to Patient F, and Patient F attended group therapy at Grace Chapel with his mother. The Board also alleges that Dr. Shafa's use of disulfiram, Comtan, and bromocriptine was ineffective, that bromocriptine was not FDA-approved, and that no strong evidence existed to support its use for cocaine dependence. As discussed above, the record more strongly suggests that Dr. Shafa's

treatment with disulfiram and bromocriptine was effective for a time. Additionally, as discussed previously, most medications prescribed in psychiatry are off-label, and prescribing off-label on its own does not violate the standard of care. Finally, Dr. Westreich explained that treatment is patient dependent and that there is no gold-standard drug treatment. He also testified that the use of disulfiram and bromocriptine was within the standard of care. Dr. Green suggested alternative treatments, and Dr. Westreich testified that he would not use Comtan. Availability of other treatments or testimony that another clinician may have treated the patient differently does not mean that Dr. Shafa violated the standard of care. Dr. Westreich explained that all medications used to treat cocaine dependency are only modestly effective. Furthermore, little research exists about treating cocaine addiction. Rather, addiction specialists must rely on small-scale studies that indicate that certain drugs are relatively effective to treat the addiction. Thus, the Board did not present sufficient evidence to conclude that Dr. Shafa violated the standard of care in this respect.

The Board argues that Dr. Shafa did not provide sufficient explanation in his medical records about why he chose naltrexone over Suboxone at Patient F's initial visit. Dr. Shafa testified that he discussed alternative treatments with Patient F. His mother also testified that she took him to Dr. Shafa for the naltrexone pellet and that she was present for Dr. Shafa's conversation with Patient F about treatment with disulfiram and naltrexone. Dr. Westreich also confirmed that patients occasionally come in for a certain kind of treatment. It was not clear that providing a patient with the treatment that he requested, if it was medically indicated, would be below the standard of care. Additionally, the testifying experts agreed that doctors may not note every detail of their

conversation with the patient, instead making notes that may trigger a memory about the patient. The Board did not present sufficient evidence to conclude that Dr. Shafa fell below the standard of care in this respect.

The Board argues that it made no sense for Dr. Shafa not to use Vivitrol for Patient F because it was covered by his insurance. There was insufficient evidence presented to conclude that not accepting insurance or using drugs that are not covered by a patient's insurance would fall below the standard of care. In fact, the Board's expert testified that he also does not accept insurance at his addiction treatment clinic. (Green IX: 1406.) Thus, the Board did not prove that Dr. Shafa violated the standard of care in this respect.

Finally, the Board argues that Dr. Shafa failed to monitor Patient F's liver function. In his answer, Dr. Shafa admitted that he did not perform liver function tests. More specifically, Dr. Green testified that the PDR recommends regular liver function tests. In his amended report, he presented information stating that liver function tests should either be done biweekly or quarterly. (Ex. 21.) However, he did not elaborate or clarify further in his testimony, so it is unclear whether the regular tests were ideal or the actual standard of care. It is also not clear how often the regular tests must be taken. Therefore, the Board did not present sufficient evidence for me to come to a conclusion on this issue.

Consultations and Referrals

The Board alleges that Dr. Shafa failed to discuss Patient F's treatment with his PCP, therapist, or opiate addiction specialist and that he did not document such communications. However, Dr. Shafa testified that he was in contact with Patient F's

therapist and the Woburn Family Practice, where Patient F's opiate addiction specialist and PCP worked. Dr. Shafa admitted that he did not record the conversations in the record, although he noted the names of Patient F's other doctors. It is not clear that Dr. Shafa fell below the standard of care in this respect.

The Board argues that Dr. Shafa failed to consult with expert colleagues when treatment was not effective. First, Dr. Shafa was not required to obtain professional consultation or supervision. Second, it was not clear that Patient F's treatment was ineffective. Although his urine screens were positive for the first few visits, Patient F eventually started testing negative for cocaine. Dr. Green indicated that addicts tend to be dishonest about their drug use, but the record more strongly suggests that Patient F actually was honest about his drug use. When he was beginning to improve, he told Dr. Shafa. When he relapsed, he told Dr. Shafa. Furthermore, Dr. Shafa noted that the concentration of cocaine in urine was lower than in previous sessions in November. Despite the relapse, it was not clear that Dr. Shafa's treatment was unsuccessful.

The Board also argues Dr. Shafa failed to refer Patient F to alternative care, such as a residential treatment facility, when he continued to use cocaine. As discussed above, it was not clear that Dr. Shafa's treatment of Patient F was unsuccessful. Rather, up until his relapse that occurred before his last visit, Patient F appeared to be improving. Thus, it was not clear that a referral would either be required or even useful in his circumstances.

Informed Consent

The Board alleges that Dr. Shafa attempted to avoid responsibility for his actions through the use of the consent forms that released him from liability from any negative patient outcome. However, Dr. Shafa explained that he used the form as a way for his

patients to acknowledge that they would take responsibility for their own treatment, instead of blaming others if they were to relapse in their treatment. Dr. Westreich testified that it was standard in addiction treatment for a clinician to ensure that the patient takes responsibility for his actions. Although he does not have his own patients sign such a form, Dr. Westreich indicated that this was a more thorough manner of documenting informed consent. (Westreich XII: 1774.) Thus, Dr. Shafa did not violate the standard of care in this respect.

The Board also argues that Dr. Shafa did not sufficiently discuss the use of naltrexone or disulfiram and did not obtain informed consent from Patient F. As discussed previously, failure to document informed consent does not necessarily violate the standard of care. Dr. Shafa also testified that he discussed the risks and benefits of disulfiram with Patient F. Patient F's mother confirmed that Dr. Shafa discussed naltrexone and disulfiram with Patient F and that she was present for the conversation. Thus, the Board did not present sufficient evidence that Dr. Shafa failed to engage in the informed consent process.

Dr. Shafa's Medical Records for Patient F

The Board alleges that Dr. Shafa failed to maintain complete, adequate, and legible medical records. The Board argues that medical records should document all aspects of the patient's care. However, the testifying experts agreed that records, especially handwritten records, rarely include every aspect of the patient's care, and the physician may use key words to trigger his memory. The Board also notes that Dr. Shafa's notes were often illegible. Dr. Green testified he had difficulty reading Dr. Shafa's notes, but he also did not request clarification from the Board or Dr. Shafa about

the notes. Further, Dr. Westreich opined that Dr. Shafa's records were similar to those that he has reviewed in the past from other clinicians. He also testified that he was able to adequately ascertain Dr. Shafa's treatment regimen from the records. I conclude that Dr. Shafa's medical records were not ideal, but they were adequate and did not fall below the standard of care.

CONCLUSION

Based on the evidence presented at the hearing, the Board has not proven by a preponderance of the evidence that Dr. Shafa committed misconduct or gross misconduct in the practice of medicine. Although reasonable minds could differ on what the "best" treatment for Patients A through F would be, the Board did not prove that Dr. Shafa's treatment violated the standard of care. Additionally, the Board did not provide sufficient evidence that Dr. Shafa's conduct was intentional wrongdoing or lack of concern for the treatment of Patients A through F. Rather, the record establishes that Dr. Shafa's care involved reasoned decisions and complied with the standard of care.

Based on the foregoing reasons, I recommend that the Board refrain from imposing discipline on Dr. Shafa.

DIVISION OF ADMINISTRATIVE LAW APPEALS



Kenneth J. Forton
Administrative Magistrate

DATED: **AUG 15 2017**