

BEFORE THE
OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
STATE OF CALIFORNIA

In the Accusation Against:

HOWARD P. LEVY, D.O.,
1700 N. Via Norte
Palm Springs, CA 92262

Osteopathic Physician's and Surgeon's
Certificate No. 20A4148

Respondent.

Case No. 00-2005-001494

OAH No. L2006080309

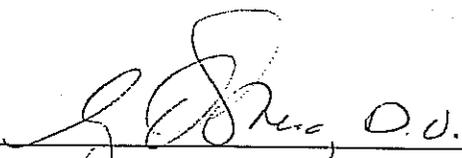
DECISION

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by
the Osteopathic Medical Board of CA as its Decision in the above-entitled matter.

This Decision shall become effective March 17, 2008.

IT IS SO ORDERED.

Date: February 13, 2008



Geraldine O'Shea, D.O., President
Osteopathic Medical Board of California

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PROPOSED DECISION

Gary Brozio, Administrative Law Judge, California Office of Administrative Hearings, heard this matter in San Diego from November 26 through 28, 2007.

Harinder K. Kapur, Deputy Attorney General, California Attorney General's Office, represented complainant Donald Krpan, Executive Director of the Osteopathic Medical Board of California.

Ronald E. Kaldor, Attorney at Law, represented respondent Howard Levy, D.O., who was present throughout the proceedings.

Respondent's request to file written closing arguments was granted. The parties timely filed the arguments in accordance with the briefing schedule ordered at the hearing.¹ The matter was submitted on January 11, 2008.

FACTUAL FINDINGS

Jurisdiction

1. On August 3, 1977, the Board issued respondent osteopathic physician and surgeon license number 20A4148. The license is active with an expiration date of

¹ The arguments were marked as OAH exhibits 1, 2, and 3, and were made a part of the record.

February 29, 2008. Apart from the Accusation filed in this case, the only former discipline on respondent's license was a public reprimand on September 15, 2005.

2. On April 19, 2005, patient P.K. complained to the Board. The complaint focused on intravenous hydrogen peroxide (IHP) treatments and treatment rendered for chronic olecranon bursitis.

3. The Board conducted an investigation which focused on the IHP treatments and treatment for bursitis. Almost no questions were raised concerning respondent's diagnosis of interstitial fibrosis or the treatment of that condition with Imuran. (Exh. 13 at 43-44.)

4. On July 20, 2006, complainant signed an Accusation seeking discipline on respondent's license for unprofessional conduct in the treatment of P.K. The Accusation alleged that respondent was grossly negligent, repeatedly negligent, and incompetent because he (1) provided patient P.K. with IHP treatments without obtaining P.K.'s written consent and without documenting P.K.'s oral consent in the chart; (2) diagnosed P.K. with interstitial fibrosis, treated him with Imuran (azathioprine), failed to record medical evidence or findings to support the diagnosis and treatment, and failed to rule out hydrogen peroxide treatment as the cause of P.K.'s condition; and (3) failed to maintain adequate records.²

Respondent and His Practice

5. Respondent practiced as a pharmacist from 1969 to 1975. He graduated from the Chicago College of Osteopathic Medicine in 1974. Thereafter, he completed a rotating internship and some portion of a residency in pediatrics. In 1985, he was board certified by the American College of Osteopathic Family Physicians.

6. From 1976 to 1996, respondent engaged in family practice in Detroit, Michigan. There, he encountered many patients with pulmonary problems, including interstitial lung disease. In 1996, respondent moved to California and began practicing in Palm Springs. In 1999, he opened his own medical practice in Yucca Valley³ where he provides family medicine to a population that is generally elderly. Besides P.K., respondent had treated other patients diagnosed with interstitial fibrosis in consultation with a pulmonologist, and he had experience with treating other patients with Imuran.

² Paragraph 13 of the Accusation was stricken at the hearing. It involved the treatment for chronic olecranon bursitis.

³ Yucca Valley is a relatively rural area in the high desert about 30 miles from Palm Springs.

Patient P.K.

7. P.K. was a man in his early 80's with multiple co-morbid diagnoses. When he began seeing respondent, P.K.'s primary problems were thrush⁴ and chronic obstructive pulmonary disease (COPD). He was on oxygen.

8. P.K. was a difficult patient. P.K. was scruffy, crusty, and rude to staff. He sometimes made racially inappropriate comments. He had burned bridges with many of the doctors in Yucca Valley. The chart contained evidence of P.K.'s problematic behavior regarding doctors. (Exh. 15 at 1071.)

9. P.K. passed away on October 7, 2007. He signed a declaration that was submitted as direct evidence.

Diagnosis of Interstitial Fibrosis and Treatment with Imuran

10. Interstitial Fibrosis and Imuran: There are some 150 different subsets or ways to classify interstitial fibrosis. In very general terms, interstitial fibrosis and interstitial lung disease broadly denote scarring of the lungs, rendering them leathery and inelastic. The cause of the scarring establishes the differential diagnosis and drives the treatment. A diagnosis of idiopathic pulmonary fibrosis (IPF) is provided when the cause of the scarring cannot be determined. There is no totally effective treatment for interstitial fibrosis, but the usual recommended treatment involves the administration of steroids, with the secondary treatment involving the administration of immune-system suppressants like Imuran.

11. Respondent's Diagnosis and Treatment: Respondent treated P.K. from February 2004 to March 2005.⁵ Respondent saw P.K. in his office about 50 times and visited P.K. at home about a dozen times. For this entire period, P.K. presented clinically with shortness of breath, which worsened over time. He was constantly using oxygen, which increased over time. He was admitted to the hospital many times as a result of shortness of breath, and he was repeatedly diagnosed with COPD.

12. The significant chart entries show the following:

On February 26, 2004, P.K. had a chest x-ray taken at the Hi-Desert Medical Center. The findings were "severe COPD with mild-to-moderate basal fibrosis." Respondent explained that this x-ray confirmed scarring of the lower lungs.

On March 3, 2004, a chest x-ray resulted in the impression that P.K. had "[m]oderate COPD with basal fibrotic changes that are stable." P.K.'s heart was normal.

⁴ P.K. had a yeast infection of the oral cavity.

⁵ Respondent testified about the treatment he rendered to P.K. His memory was generally good and his testimony appeared credible. There was no meaningful evidence to contradict his description of the treatment history.

On March 10, 2004, a chest x-ray resulted in the impression that P.K. had "superimposed infiltrates" in the posterior lower lung base especially on the right side." Respondent explained that this x-ray interpretation could indicate scarring or pneumonia.

A progress note from March 18, 2004, reflected respondent's impression that P.K. had "pulmonary fibrosis."

On May 15, 2004, P.K. was admitted to the hospital with shortness of breath. A chest x-ray taken that day. The impression was possible pulmonary metastasis. There was continued evidence of scarring on both lung bases.

On May 17, 2004, P.K. underwent a CT Scan of the chest. The impression was COPD and "minimal scarring both lung bases." Respondent spoke with the doctor who made the findings, and the doctor told him that P.K. had "interstitial lung disease" and "atelectasis fibrosis" (collapse of the lung space). Respondent noted these impressions in his own handwriting on the CAT Scan results, but the notation did not reflect the fact that respondent spoke to the doctor who interpreted the CAT Scan. (Exh. 15 at 1088.)

In June and July 2004, P.K. continued having shortness of breath, coughing, and other breathing difficulties. His oxygen use increased.

By August 2, 2004, P.K.'s breathing difficulties worsened, and respondent sent him to the hospital, where P.K. stayed for three weeks. When he was discharged, P.K. continued to have shortness of breath.

On a progress note dated September 27, 2004, respondent wrote that his impression that P.K. had "interstitial fibrosis hypoxemia."

On December 9, 2004, P.K. received the first of two intravenous hydrogen peroxide (IHP) treatments.

On December 20, 2004, P.K. went to the hospital with pneumonia not related to interstitial fibrosis.

On December 22, 2004, P.K. received his second and last IHP treatment.

A progress note from December 30, 2004, indicated respondent's impression that P.K. had "interstitial pneumonitis."

P.K.'s breathing problems continued through January 2005. On January 28, 2005, P.K. came to respondent complaining that he had chest pain and was feeling badly. Respondent prescribed 25 milligrams of Imuran once daily for a week. On January 29, 2005, P.K. had another x-ray. The impression was COPD and "[m]inimal parenchymal density at both lung bases, right greater than left, raised the possibility of atelectasis or consolidation at

the left lung bases.” Respondent’s handwritten notes reminded him to be sure P.K. had begun the Imuran treatments.

13. On March 11, 2005, respondent’s relationship with P.K. abruptly ended. Respondent made a house call because P.K. allegedly could not get to respondent’s office. When respondent arrived, P.K. said he had gone to see another doctor and that doctor said respondent was “killing” P.K. Faced with P.K.’s bogus request for a home visit and the affront to his treatment, respondent told P.K. he was not going to make house calls in the future. P.K. responded by calling respondent a “kike.” Respondent, who is Jewish, took great offense. An argument ensued, and P.K. threatened to report respondent to the Board. P.K. also told respondent that he refused to take the Imuran.

14. Subsequent Events: On March 24, 2007, P.K. was admitted to the hospital, and a biopsy of his right lower lung was taken. P.K. was diagnosed with “moderately differentiated adenocarcinoma with papillary and acinar regions.” Dr. Levy subsequently contacted the pathologist and asked whether there was sufficient lung tissue other than the tumor to determine whether P.K. had interstitial fibrosis. The pathologist reexamined the biopsy material and saw “multiple cores of tissue, many with non tumorous fibrous connective tissue” that was “consistent with interstitial fibrosis.” The pathologist could not make a conclusive diagnosis because it was possible the fibrosis was related to the tumor rather than scarring.

15. The Board’s Expert – Dr. Kleinman: The Board’s expert was Dr. Leonard Kleinman, a family practitioner. Dr. Kleinman received his medical degree from USC. He completed a residency in family practice. He was board certified in family practice and preventative medicine. He had treated many elderly patients with multiple symptoms, and he had seen approximately 25 cases of idiopathic pulmonary fibrosis. *He admitted that he was not an expert in lung disease.*

16. Dr. Kleinman believed that respondent diagnosed P.K. with IPF. A diagnosis of IPF means that the cause of the scarring on the lung tissue cannot be determined and there is evidence of a disease process causing functional limitations. Thus, a diagnosis with IPF is largely a diagnosis of exclusion. Based on his review of P.K.’s chart and relevant literature, Dr. Kleinman concluded that P.K.’s chart did not include sufficient testing to meet the evidence-based guidelines for a diagnosis of IPF, which, in addition to x-rays and a CT Scan, required a pulmonary functioning test, the ruling out of other causes, and sufficient expertise.⁶ Nor did the chart contain sufficient detail about respondent’s thought process in reaching that diagnosis, which included respondent’s failure to rule out the IHP therapy as the cause of P.K.’s condition. Dr. Kleinman also believed that the diagnosis and treatment of IPF was outside the scope of a family practitioner and required consultation with a pulmonologist before treating with Imuran, a drug that suppresses the immune system and had potential adverse side effects if not indicated. Although Dr. Kleinman admitted that Imuran had a role in treating IPF, he believed that using a potent drug that lowers immune

⁶ The gold standard for a diagnosis is a lung biopsy, but all the experts agreed that it was not practical in P.K.’s case.

response when there are doubtful indications constituted an extreme departure from the standard of care.

17. Dr. Kleinman admitted that P.K.'s x-rays showed "fibrotic changes," but they had been present a long time, the hospital was using the diagnosis of COPD, and there was insufficient evidence to warrant a diagnosis of IPF. Dr. Kleinman admitted that the diagnosis of lung disease was a "very difficult area," which seemed the most important basis for his opinion that a primary care physician should not diagnose and treat lung disease without consultation. Dr. Kleinman did not know whether Imuran was indicated to treat fibrosis with other causes. His opinions were based on his research for this case rather than on his own training and experience in the area of lung disease. In short, Dr. Kleinman was beyond his area of expertise in this portion of the testimony.

18. Respondent's Expert – Dr. Lin: Respondent's expert was Dr. Sam Lin. Dr. Lin graduated from medical school at New York Medical College in 1996. Thereafter, he completed his internship in family practice at UCLA. He also completed a one-year fellowship in sports medicine. He is board certified in family practice with a specialty in sports medicine. He operated a private, ambulatory office in La Quinta, California. *He had treated patients with interstitial fibrosis, but he had no real expertise in the area of lung disease. Neither did he have experience in treating patients with Imuran.*

19. Dr. Lin testified that a family practitioner could diagnose interstitial fibrosis if the doctor had enough information and adequate knowledge about lung disease. He stated that family practitioners begin treatment after seeing symptoms and do not need to confirm a diagnosis with a specialist. He stated that there was adequate evidence in the chart to suspect some other cause for P.K.'s condition other than COPD, and to reasonably support treatment with Imuran. He believed that respondent's experience in occupational medicine in Detroit, and his experience with Imuran, gave him sufficient knowledge about lung issues to diagnose and treat P.K.'s condition. It was not below the standard of care for respondent to render treatment without consultation because respondent had reason to believe P.K. had interstitial fibrosis, and because respondent was comfortable treating lung diseases, was familiar with Imuran, and was seeing P.K. exceedingly often and could monitor his progress. Moreover, treatment with Imuran was indicated because P.K. was tolerant to steroids.

20. Respondent's Testimony: Respondent testified that a family practitioner could diagnose and treat interstitial fibrosis and if the practitioner had experience in the field, he could treat without consultation.

Respondent believed that his diagnosis and treatment were indicated. Clinically, P.K. had shortness of breath for months and his condition was worsening. He made many trips to the hospital because he couldn't breathe. The x-rays and CT Scan were consistent with a diagnosis of interstitial fibrosis, and in addition, they ruled out a heart condition for P.K.'s chest pain, which increased the likelihood that fibrosis was the cause. Respondent suspected that P.K. had interstitial fibrosis in addition to COPD because his condition continued to worsen.

21. Respondent consulted two pulmonologists before rendering treatment. Respondent first consulted Dr. Gharghoury, who was the only pulmonologist in Yucca Valley. Dr. Gharghoury refused to see P.K. because of former conflicts. Dr. Gharghoury even refused to view P.K.'s x-rays. Thus, respondent consulted Dr. Rattibarn in Corona. Dr. Rattibarn said that, if respondent suspected interstitial fibrosis, he could start P.K. on a small dose of Imuran and gradually build up while watching the blood work and monitoring the side effects. Respondent would have liked to have had more work up, but he knew that P.K. would not cooperate or go to Palm Springs for assessment. Respondent had experience with Imuran from other patients, so he felt comfortable putting P.K. on a very low dose (one-tenth of the recommended dose) to see how he would respond. P.K. wanted to breathe better, so he agreed to try Imuran. Respondent knew that he would be monitoring P.K. closely. P.K. discontinued treatment with Imuran shortly thereafter.

22. Respondent complained that Dr. Kleinman was talking about a diagnosis of IPF (a specific diagnosis ruling out all other causes) when respondent only diagnosed P.K. with interstitial fibrosis (a general diagnosis without determination of cause). In any event, respondent stated that the treatment for either condition was the same, with the primary choice being steroids and the secondary choice being immune suppressants like Imuran. Respondent felt that P.K. was not a good candidate for steroids because he had thrush, a history of diabetes, and he had stopped taking steroids previously for COPD.

23. Evaluation: There was a lack of qualified expert testimony to prove that respondent violated the standard of care under any of the theories under consideration. None of the experts were qualified to state that respondent misdiagnosed P.K. with interstitial fibrosis, that respondent diagnosed P.K. with insufficient information, that respondent's training and experience were insufficient for him to render treatment, or that treatment with Imuran was not indicated. Moreover, respondent's reasons for diagnosing P.K. with interstitial fibrosis and treating him with Imuran became apparent for the first time in testimony because the chart was so bad and because this issue was not meaningfully addressed in the interview with the Board investigators. (Exh. 13 at 43-44.) Dr. Kleinman's testimony, which was based only on the review of the records, never took into consideration the facts respondent testified to at the hearing. There was no reason to doubt the explanation respondent gave at the hearing. After respondent testified, complainant did not present any rebuttal testimony. Thus, there was no testimony from a qualified pulmonologist who considered all the relevant evidence. And while Dr. Kleinman's testimony raised serious questions, his admitted lack of expertise in pulmonology seriously undercut his testimony and rendered it insufficient to carry complainant's burden of proof.

24. Concerning the question of consultation, respondent testified that he consulted with two pulmonologists before treating with Imuran. He also started P.K. on a very low dose to monitor his progress, but P.K. stopped using the drug before a meaningful assessment could be made. There was no evidence to refute this testimony, which again meant that complainant failed to prove a violation of the standard of care on the clear-and-convincing-evidence standard.

25. Concerning the allegations about recordkeeping, there was no doubt that the chart was inadequate to explain respondent's reasons for the diagnosing interstitial fibrosis and treating the condition with Imuran. As discussed for fully below, respondent's failure to adequately record the reasons for the diagnosis and treatment was negligent and violated statutory-record-keeping requirements.

Consent for Intravenous Hydrogen Peroxide Treatments

26. Informed Consent: Respondent became interested in IHP treatment when one of respondent's patients said that it had helped his bronchitis. Respondent inquired about the treatment with another alternative-medicine doctor and decided to offer the treatment at his office. On October 6, 2004, the doctor experienced in IHP treatment participated in a seminar at respondent's office. Several patients were present including P.K. A brochure regarding the treatment was given to the participants. At the seminar, P.K. asked for IHP treatment.

27. The brochure was entitled "A Closer Look at Intravenous Hydrogen Peroxide H₂O₂." Including the cover, it was 11 pages long. It went into significant detail about IHP treatment. (Exh. 8 at 276-286.) As relevant to this case, the section dealing with informed consent told the reader that he or she will have to "sign a permit" before receiving IHP treatment because "the bulk of doctors in the USA consider peroxide *non-customary, experimental, unnecessary, weird, strange, or unusual* therapy." (Emphasis in original.) Other portions of the brochure mentioned that some physicians considered the treatment to be experimental.

28. After the seminar, respondent took two courses in providing IHP treatment and ordered the peroxide. He began giving IHP treatments in December 2004.

29. On December 6, 2004, respondent again discussed the IHP treatment with P.K. Respondent gave P.K. the brochure a second time and went over it page by page. Respondent explained that there were no guarantees, but the treatment might help P.K.'s infections and thrush problem. P.K. agreed to undergo the procedure, but respondent did not obtain P.K.'s written consent nor did he record P.K.'s oral consent in the chart. Respondent never told P.K. that the treatment was experimental.⁷

30. P.K. received IHP treatments on December 9 and 22, 2004. On these two days, the chart reflected the concentration and amount given. The chart also contained entries on October 14, 2004, December 6, 2004, and January 24, 2005, reflecting the notation "H₂O₂ Tx," which was respondent's shorthand for IHP treatment. Respondent explained that the treatment was not given on these three days. These entries merely reflected his plan to

⁷ P.K. declaration did not contradict this fact, nor did respondent's statements to the Board investigators contradict this fact. Noting in the record supported the conclusion that respondent called IHP treatments "experimental."

provide the treatment in the future. If the treatment had been provided, the chart would have reflected the concentration and amount.⁸

31. Sometime after receiving the second IHP treatment, P.K. decided to discontinue the treatment. Respondent said that P.K. did not want to spend the two hours in his office necessary to perform the procedure. Respondent denied that P.K. ever reported side effects from the IHP treatments.

32. On March 23, 2007, P.K. signed a declaration regarding the IHP treatments. According to the declaration, respondent recommended IHP as a "breakthrough treatment" for his yeast infection. Respondent gave P.K. a pamphlet, told P.K. the treatment was safe, and said it would "cure everything in [P.K.'s] blood." P.K. said that the treatments caused nausea and blurry vision and did not help his yeast infection. P.K.'s declaration stated that "[t]he pamphlet indicated that this treatment was experimental," and that it made him "feel like a guinea pig." The declaration did not say that respondent termed the treatment "experimental."

33. Dr. Kleinman: Dr. Kleinman testified that IHP was a complementary and alternative medicine (CAM) that may have a role in treating bronchitis and lung infections, but there was minimal scientific evidence to support it. He admitted that there was no clear standard for whether a doctor must have written consent before treating a patient with CAM. He thought that written consent was required in this case because the pamphlet described the treatment as "experimental," and this characterization required the consent similar to that in "research trials." In other words, the pamphlet's use of the word "experimental" made IHP therapy "experimental CAM" requiring written consent.

34. Dr. Kleinman admitted that, absent the characterization of the treatment as "experimental," written consent may not have been necessary. Nevertheless, it would have been necessary to record P.K.'s oral consent in the chart. Respondent's failure to do so was an ordinary departure from the standard of care. Since no consent was documented, Dr. Kleinman assumed that P.K. did not receive adequate informed consent, which would have constituted an extreme departure from the standard of care.

35. Dr. Lin: Dr. Lin testified that, in family practice, informed consent is required but need not be written. He had no experience regarding the standard of care for CAM treatments, but he testified that the standard of care was the same for all other treatments given in family practice.

36. Respondent: Respondent was interviewed on August 17, 2005. The statements respondent gave in the interview were consistent with his testimony at the hearing. Respondent has a general informed-consent form, but he did not obtain a general consent form from P.K. The record does not contain a written consent form for P.K.'s IHP treatments.

⁸ In the investigation, respondent also stated that P.K. received the treatment twice. At the hearing, however, both experts read his chart entries to mean P.K. received the treatment five times.

37. Evaluation: P.K. received the information necessary to provide informed consent at the seminar on October 6, 2004, and in his discussion with respondent on December 6, 2004. P.K. orally agreed to receive IHP treatments, and he received two IHP treatments on December 9 and 22, 2004. P.K. did not sign a written consent to receive IHP treatments, but the evidence failed to establish that the standard of care required written consent. Dr. Kleinman's attempt to characterize IHP therapy as "experimental," based solely on the wording in the pamphlet, was unconvincing. IHP therapy constitutes CAM and it is used by a respected minority of competent practitioners. Based on Dr. Kleinman's own testimony, it is unsettled whether written consent is necessary for treatment with CAM. Thus, complainant failed to prove, by clear and convincing evidence, that the standard of care required written consent.

38. The chart did not memorialize P.K.'s informed consent. Neither did it memorialize P.K.'s attendance at the seminar, his receipt of the pamphlet on two occasions, or his discussions with respondent about the treatment. Clear and convincing evidence established that IHP therapy is CAM treatment that lacks significant scientific support. Thus, absent written consent, a patient's informed consent to IHP therapy must be recorded in the chart. Respondent's failure to adequately document P.K.'s consent was negligent and a breach of statutory-record-keeping requirements.

Failure to Keep Adequate Records

39. The Chart: Respondent's notations in P.K.'s chart were largely illegible. The experts who reviewed the chart could not decipher his writing. The records were disorganized and difficult to follow. Many important parts of a chart were missing, including the patient history and problem list. Both experts believed that respondent provided P.K. with five IHP treatments when respondent only provided two. There were almost no notes to support the diagnosis of interstitial fibrosis or the treatment with Imuran, and the chart notes were illegible. There were no notes regarding why respondent used the secondary drug for treatment of interstitial fibrosis. There were no chart notes regarding consultation with pulmonologists. There was nothing memorializing P.K.'s consent to IHP treatments and no general consent form.

40. Dr. Kleinman: Dr. Kleinman had the most expertise regarding the standard of care for record keeping. He had been keeping his own records for many years; he had conducted reviews for the Medical Board of California, he had provided quality assurance for the Los Angeles County health care system; and he had been conducting peer review since 1990.

41. Dr. Kleinman explained that adequate records were necessary to protect the patient in the event that another doctor might have to render treatment, to record the treatment history and decision making process, and to assist in enforcement. Dr. Kleinman testified that respondent's records were illegible, disorganized, and incomplete. It was impossible to decipher the thought process for diagnosing interstitial fibrosis and treatment with Imuran. There was no patient history, general consent form, or problem list. When

considered in its entirety, Dr. Kleinman believed that P.K.'s chart constituted an extreme departure from the standard of care for recordkeeping.

42. Dr. Lin: Dr. Lin conceded that a patient's chart should reflect the thought process in rendering a diagnosis, but the amount written depended on the nature of the disease and treatment. In general, records were adequate if they reflected subjective complaints, objective symptoms, and the doctor's assessment and plan (SOAP). The diagnosis and plan could evolve over several visits for a condition like interstitial fibrosis. Dr. Lin testified that a problem list was not required to meet the standard of care in a family practice, especially if the physician knows the patient "like the back of his hand." A medication list was more important than a problem list because any doctor could surmise the patient's problems given the medications prescribed in treatment. There was a medication list in P.K.'s chart but it did not include Imuran. Dr. Lin testified that legibility of entries was not so important if a physician could read most of the entries and figure out what was going on. Dr. Lin had previously monitored respondent's billing practices and was familiar with his charts. He had previously advised respondent to improve his legibility. During testimony, Dr. Lin was unable to decipher many entries in P.K.'s chart, and like Dr. Kaufman, he believed that P.K. received five IHP treatments. Dr. Lin testified that P.K.'s chart was not below the standard of care. He based his opinion on his own practice and training. He was far less qualified to render an opinion than Dr. Kaufman.

43. Respondent: Respondent testified that he did not put his thought processes in the chart because he knew P.K. well and saw him often. He put down his impressions, but did not believe he had to write a "thesis" on his course of treatment. He believed that the only purpose of the chart was to "protect him against malpractice." Respondent pointed to portions of P.K.'s chart that he believed constituted a patient history (e.g., Exh. 15 at 1071) and problem list (e.g., Exh. 15 at 1043), but not persuasive because no reasonable physician reviewing the chart could have identified them as such. It was obvious that respondent has much to learn about the standard of care for recordkeeping.

44. Evaluation: Respondent's entries into P.K.'s chart were largely illegible. This alone rendered the chart below the standard of care. Even when legible, qualified experts could not decipher what respondent did. For example, both experts thought P.K. received five IHP treatments when P.K. only received two. Many important details were missing. For example, respondent adequately informed P.K. about the IHP therapy but there was nothing in the chart regarding consent. In addition, the information in the chart was totally inadequate to support the diagnosis with interstitial fibrosis. Interstitial fibrosis is a relatively uncommon and serious condition that requires greater care in diagnosing than a common cold. It was impossible to cobble together respondent's reasoning in making this diagnosis, which only became apparent in respondent's testimony. Moreover, nothing in the chart conveyed the reason for treating P.K. with Imuran, which is considered the secondary drug of choice. The lack of a patient history, initial examination, and problem list were also concerning, especially given P.K.'s multiple co-morbid conditions. Thus, clear and convincing evidence established that P.K.'s chart, in its entirety, constituted an extreme departure from the standard of care for recordkeeping.

Costs

45. Complainant submitted cost declarations. The investigative costs were \$4,672.21 and the prosecution costs were \$19,669. These costs were reasonable given the size of P.K.'s chart and the complexity of the issues. Respondent submitted no contrary evidence or argument. He presented no evidence regarding ability to pay.

LEGAL CONCLUSIONS

Burden of Proof

1. Regarding the allegations seeking discipline, complainant had the burden to prove them by clear and convincing evidence. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856; *Reality Projects, Inc. v. Smith* (1973) 32 Cal.App.3d 204, 212.) The requirement of proof by clear and convincing evidence presents a heavy burden, far in excess of the preponderance sufficient for most civil litigation. Clear and convincing evidence requires a finding of high probability. The evidence must be so clear as to leave no substantial doubt. It must be sufficiently strong to command the unhesitating assent of every reasonable mind. (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.)

2. Regarding the costs of investigation, complainant had the burden to prove them by a preponderance of evidence. (Evid. Code, § 115.) This standard is defined as "more likely to be true than not true." (CACI § 200.)

Disciplinary Authority

3. Business and Professions Code section 3600 states that "[t]he law governing licentiates of the Osteopathic Medical Board of California is found in the Osteopathic Act and in Chapter 5 of Division 2, relating to medicine." Section 2 of the Osteopathic Act states that the Board shall enforce the portions of the Medical Practices Act in Article 12 (commencing with section 2220), Chapter 5, Division (2), which currently encompasses sections 2220 through 2319 of the Business and Professions Code.

4. Section 2234 of that Code permits a licensee to be disciplined for "unprofessional conduct," which includes gross negligence (subd. (b)), repeated acts of negligence (subd. (c)), and incompetence (subd. (d)). In addition, section 2266 of the Code states that "[t]he failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

Gross Negligence

5. Gross negligence involves very great negligence or the want of even scant care. So far as the phrase has any accepted legal meaning, "gross negligence" is an extreme

departure from the ordinary standard of care. (*Eastburn v. Regional Fire Protection Authority* (2003) 31 Cal.4th 1175, 1185-1186.)

Repeated Negligent Acts

6. Simple negligence is merely a departure from the standard of care. A difference of medical opinion does not establish negligence. Different doctors may disagree in good faith upon what might encompass proper treatment in a given situation. Medicine is not a field of absolutes. There is not ordinarily only one correct route to be followed at any given time. And, there is always a need for professional judgment as to what course of conduct would be most appropriate with regard to the patient's condition. (*Mathis v. Morrissey* (1992) 11 Cal.App.4th 332, 342.)

"Repeated negligent acts" consists of two or more negligent acts. (*Zabetian v. Medical Board of California* (2000) 80 Cal.App.4th 462.) Business and Professions Code section 2234, subdivision (c) states:

"To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care."

Incompetence

7. The term "incompetency" generally indicates "an absence of qualification, ability or fitness to perform a prescribed duty or function." (*Pollack v. Kinder* (1978) 85 Cal.App.3d 833, 837.) Incompetency is distinguishable from negligence, in that one "may be competent or capable of performing a given duty but negligent in performing that duty." (*Id.* at 838.) Thus, "a single act of negligence . . . may be attributable to remissness in discharging known duties, rather than . . . incompetency respecting the proper performance." (*Ibid.*, quoting from *Peters v. Southern Pacific Co.* (1911) 160 Cal. 48, 62 [116 P. 400].)

Cause for Discipline

8. Cause was not established to impose discipline for respondent's failure to obtain P.K.'s written consent to IHP treatments. This conclusion was based on Factual Findings 1-9, 26-38 and Legal Conclusions 1, 3-6, and 8.

9. Cause was not established to impose discipline for respondent's diagnosis of interstitial fibrosis and treatment with Imuran. This conclusion was based on Factual Findings 1-25 and Legal Conclusions 1, 3-6, and 9.

10. Cause was not established to discipline respondent for incompetence. This conclusion was based on all Factual Findings and Legal Conclusions 1, 3, 4, 7, and 10.

11. Cause was established to discipline respondent for unprofessional conduct in recordkeeping. P.K.'s chart as a whole constituted an extreme departure from the standard of care and warranted discipline under section 2234, subdivision (b). Respondent's failure to record P.K.'s consent to IHP treatment, his failure to record the decision-making process for a diagnosis of interstitial fibrosis, and his failure to record the reasons for using the secondary drug of treatment, among other inadequacies, constituted repeated acts of negligence and warranted discipline under section 2234, subdivision (c). The same evidence proved beyond any doubt that P.K.'s chart was inadequate within the meaning of section 2266. These conclusions were based on all Factual Findings and Legal Conclusions 1, 2-6, and 11.

Disciplinary Guidelines

12. California Code of Regulations, Title 16, section 1663, requires the board to "consider the disciplinary guidelines entitled 'Osteopathic Medical Board of California Disciplinary Guidelines of 1996.'" The regulation further states that "[d]eviation from these guidelines and orders, including the standard terms of probation, is appropriate where the [Board] in its sole discretion determines that the facts of the particular case warrant such a deviation--for example: the presence of mitigating factors; the age of the case; evidentiary problems."

The introduction to the Guidelines states:

"The following disciplinary penalties for selected Business and Professions Code violations are guidelines for use by administrative law judges at hearings as well as for use in the settlement of cases. Individual penalties may vary depending upon the particular circumstances of the case resulting in aggravation or mitigation of the offenses alleged. If probation is imposed as part of a penalty, the probation should include: (1) standard conditions, which will appear in all cases; and (2) the optional conditions, which will be tailored according to the nature of the offense."

Regarding gross negligence and repeated acts of negligence, the Guidelines recommend a maximum penalty of revocation and a minimum penalty of revocation stayed with a five-year period of probation.

Degree of Discipline

13. The appropriate degree of discipline in this case is revocation stayed with a five-year period of probation. Respondent must attend and complete the PACE record-keeping course, and thereafter, he must be monitored for a year to assure compliance with the standard of care. The standard conditions of probation are also appropriate. This conclusion was based on all Factual Findings and Legal Conclusions.

Costs

14. The Accusation seeks costs under Business and Professions Code section 125.3. That section provides in pertinent part:

“(a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) In the case of a disciplined licentiate that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge where the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).”

15. In *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, the California Supreme Court held that the imposition of costs for investigation and enforcement under California Code of Regulations, title 16, section 317.5 did not violate due

process. However, the court held that it was incumbent on the Board to exercise its discretion to reduce or eliminate cost awards in a manner that ensured section 317.5 did not "deter chiropractors with potentially meritorious claims or defenses from exercising their right to a hearing." The Court set forth four factors that the Board was required to consider when deciding whether to reduce or eliminate costs. These were: (1) whether the chiropractor used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed; (2) whether the chiropractor had a "subjective" good faith belief in the merits of his position; (3) whether the chiropractor raised a "colorable challenge" to the proposed discipline; and (4) whether the chiropractor had the financial ability to make payments.

16. Since regulation 317.5 and section 125.3 have substantially the same language and seek the same sort of cost recovery, it is reasonable to extend the reasoning in *Zuckerman* to section 125.3.

17. The investigative costs were \$4,672.21 and the prosecution costs were \$19,669. These costs were reasonable, but a reduction is warranted because respondent used the hearing process to obtain dismissal of two of the three allegations, because respondent had a "subjective" good faith belief in the merits of his position, and because respondent raised a "colorable challenge" to the proposed discipline. Costs in the amount of \$15,000 are appropriate, fair, and reasonable. This conclusion was based on all Factual Finding 45 and Legal Conclusions 2 and 14-17.

ORDER

Osteopathic physician and surgeon license number 20A4148, issued to Howard P. Levy, is revoked, but the revocation shall be stayed and respondent shall be placed on five-years probation on the following terms and conditions:

1. Obey all laws -

Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California, and remain in full compliance with any court ordered criminal probation, payments and other orders.

2. Quarterly reports -

Respondent shall submit to the Board quarterly declaration under penalty of perjury on the Quarterly Report of Compliance Form, OMB 10 (5/97) which is hereby incorporated by reference, stating whether there has been compliance with all the conditions of probation.

3. Probation surveillance program -

Respondent shall comply with the Board's probation surveillance program. Respondent shall, at all times, keep the Board informed of his or her addresses of business

and residence which shall both serve as addresses of record. Changes of such addresses shall be immediately communicated in writing to the Board. Under no circumstances shall a post office box serve as an address of record.

Respondent shall also immediately inform the Board, in writing, of any travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) days.

4. Interviews with medical consultants -

Respondent shall appear in person for interviews with the Board's medical consultants upon request at various intervals and with reasonable notice.

5. Cost recovery -

The respondent is hereby ordered to reimburse the Board the amount of \$ 15,000 within 90 days from the effective date of this decision for its investigative and prosecution costs. Failure to reimburse the Board's cost of its investigation and prosecution shall constitute a violation of the probation order, unless the Board agrees in writing to payment by an installment plan because of financial hardship.

6. License surrender -

Following the effective date of this decision, if respondent ceases practicing due to retirement, health reasons, or is otherwise unable to satisfy the terms and conditions of probation, respondent may voluntarily tender his/her certificate to the Board. The Board reserves the right to evaluate the respondent's request and to exercise its discretion whether to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the tendered license, respondent will no longer be subject to the terms and conditions of probation.

7. Tolling for out-of-state practice or residence, or in-state non-practice (inactive license).

In the event respondent should leave California to reside or to practice outside the State or for any reason should respondent stop practicing medicine in California, respondent shall notify the board or its designee in writing within ten days of the dates of departure and return or the dates of non-practice within California. Non-practice is defined as any period of time exceeding thirty days in which respondent is not engaging in any activities defined in Section 2051 and/or 2052 of the Business and Professions Code. All time spent in an intensive training program approved by the Board or its designee in or out of state shall be considered as time spent in the practice of medicine. Periods of temporary or permanent residence or practice outside California or of non-practice within California, as defined in this condition, will not apply to the reduction of the probationary period.

8. Probation violation/completion of probation -

If respondent violates probation in any respect, the Board may revoke probation and carry out the disciplinary order that was stayed after giving respondent notice and the opportunity to be heard. If an Accusation and/or Petition to revoke is filed against respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final. Upon successful completion of probation, respondent's certificate will be fully restored.

9. Education course -

Within 90 days of the effective date of this decision, respondent shall enroll in the PACE course for record keeping. This shall be completed during the first year of probation. This program shall be in addition to the Continuing Medical Education requirements for relicensure. Following the completion of the course, the Board or its designee may administer an examination to test the respondent's knowledge of the course. Respondent shall provide proof of attendance for both continuing medical education requirements.

10. Monitoring -

After completing the PACE course on recordkeeping, respondent's recordkeeping shall be monitored for a year. Respondent shall submit the name of the monitor to the Board for its prior approval. The monitor shall provide the Board with monthly reports confirming respondent's compliance with the standard of care. Respondent shall bear all costs of the monitoring program.

DATED: 1/25/08



GARY BROZIO
Administrative Law Judge
Office of Administrative Hearings

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8
9 **BEFORE THE**
OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 00-2005-001494

12 HOWARD P. LEVY, D.O.
13 1700 N. Via Norte
Palm Springs, CA 92262

OAH No.

ACCUSATION

14 Osteopathic Physician and Surgeon
15 Certificate No. 20A4148

16 Respondent.

17
18 Complainant alleges:

19 PARTIES

20 1. Donald Krpan (Complainant) brings this Accusation solely in his
21 official capacity as the Executive Director (A) of the Osteopathic Medical Board of California.

22 2. On or about August 3, 1977, the Osteopathic Medical Board of California
23 issued Osteopathic Physician's and Surgeon's Certificate No. 20A4148 to HOWARD P. LEVY,
24 D.O. (Respondent). The Osteopathic Physician's and Surgeon's Certificate was in full force and
25 effect at all times relevant to the charges brought herein and will expire on February 29, 2008, unless
26 renewed.

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1 meeting the legal requirements of that state or country for the practice of medicine.

2 Section 2314 shall not apply to this subdivision. This subdivision shall become operative
3 upon the implementation of the proposed registration program described in Section
4 2052.5."

5 5. Section 3600 of the Code states that the law governing licentiates of the
6 Osteopathic Medical Board of California is found in the Osteopathic Act and in Chapter 5 of
7 Division 2, relating to medicine.

8 6. Section 3600-2 of the Code states:

9 "The Osteopathic Medical Board of California shall enforce those portions of the
10 Medical Practice Act identified as Article 12 (commencing with Section 2220), of
11 Chapter 5 of Division 2 of the Business and Professions Code, as now existing or
12 hereafter amended, as to persons who hold certificates subject to the jurisdiction of the
13 Osteopathic Medical Board of California, however, persons who elect to practice using
14 the term or suffix "M.D." as provided in Section 2275 of the Business and Professions
15 Code, as now existing or hereafter amended, shall not be subject to this section, and the
16 Medical Board of California shall enforce the provisions of the article as to persons who
17 make the election. After making the election, each person so electing shall apply for
18 renewal of his or her certificate to the Medical Board of California, and the Medical
19 Board of California shall issue renewal certificates in the same manner as other renewal
20 certificates are issued by it."

21 7. Section 2266 of the Code states: "The failure of a physician and surgeon
22 to maintain adequate and accurate records relating to the provision of services to their patients
23 constitutes unprofessional conduct."

24 8. Section 125.3 of the Code states, in pertinent part, that the Board may
25 request the administrative law judge to direct a licentiate found to have committed a violation or
26 violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation
27 and enforcement of the case.

28 ///

1 FIRST CAUSE FOR DISCIPLINE

2 (Gross Negligence)

3 9. Respondent is subject to disciplinary action under Code sections 3600,
4 3600-2 and 2234 as defined by 2234 (b) in that he was grossly negligent in connection with his
5 care, treatment and management of patient P.K. The circumstances are as follows:

6 10. Between on or about February 16, 2004, and March 11, 2005, P.K., a then
7 82-year-old male, was a patient of Respondent. Respondent saw P.K. for approximately 65
8 office visits and respondent treated P.K. on three or four home visits.

9 11. During this time, most of the care provided to P.K. by Respondent was
10 directed to five chronic medical problems which included COPD, chronic olecranon bursitis,
11 osteoarthritis of the knees, lower urinary tract symptoms and chronic oropharyngeal discomfort
12 attributed to a fungal infection (yeast).

13 12. Respondent did not believe that P.K.'s oropharyngeal discomfort or
14 respiratory distress and possible fungal (yeast) infection was being adequately treated with
15 conventional therapy and recommended to P.K. that he undergo a series of treatments by
16 intravenous infusion of hydrogen peroxide. Although Respondent knew and told his patient that
17 the use of hydrogen peroxide was experimental, he did not follow approved research protocol for
18 its use nor did he document the patient's consent to the experimental use of hydrogen peroxide.
19 Respondent treated P.K. with hydrogen peroxide on several occasions.

20 13. Patient P.K. also suffered from chronic olecranon bursitis. The olecranon
21 is located at the posterior point of the elbow and has a synovial membrane that may become
22 affected by gout, rheumatoid arthritis, sepsis, hemorrhage, or trauma. Fluid accumulated in the
23 patient's olecranon bursa and Respondent treated the condition by joint aspiration on eight
24 occasions. On or about January 10, 2005, following the seventh aspiration, Respondent sent the
25 synovial fluid to a laboratory for analysis but did not request a bacterial culture. Respondent
26 never recommended surgical removal as definitive treatment.

27 14. Between on or about January 27, 2005, and February 9, 2005, Respondent
28 diagnosed P.K. with interstitial fibrosis and treated him with Imuran (azathioprine). The medical

1 records do not contain medical evidence or findings to support the diagnosis or the use of
2 Imuran, a powerful drug with potential adverse reactions. Also, Respondent did not consider
3 that the use of experimental hydrogen peroxide might be the cause of P.K.'s condition.

4 15. The Respondent's medical records for P.K. are not adequate or accurate in
5 that they are illegible, disorganized, and incomplete. There is no initial history and physical
6 examination of the patient, no general consent form, no specific consent form for the use of
7 experimental hydrogen peroxide treatment, no report of the concentration of hydrogen
8 peroxide used when administered, and no problem list.

9 SECOND CAUSE FOR DISCIPLINE

10 (Repeated Negligent Acts)

11 16. Respondent is subject to disciplinary action under Code sections 3600,
12 3600-2 and 2234 as defined by 2234 (c) in that he was repeatedly negligent in connection with
13 his care, treatment and management of patient P. K. as set forth in paragraphs 9- 15 above which
14 are incorporated herein by reference as though fully set forth.

15 THIRD CAUSE FOR DISCIPLINE

16 (Incompetence)

17 17. Respondent is subject to disciplinary action under Code sections 3600,
18 3600-2 and 2234 as defined by 2234 (d) in that he was incompetent in connection with his care,
19 treatment and management of patient P. K. as set forth in paragraphs 9-1 5 above which are
20 incorporated herein by reference as though fully set forth.

21 FOURTH CAUSE FOR DISCIPLINE

22 (Records)

23 18. Respondent is subject to disciplinary action under Code sections 3600,
24 3600-2 and 2234 as defined by 2266 in that his medical records for patient P.K. are neither
25 adequate nor accurate as set forth in paragraphs 9-15 above which are incorporated herein by
26 reference as though fully set forth.

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1 PRAYER

2 WHEREFORE, Complainant requests that a hearing be held on the matters herein
3 alleged, and that following the hearing, the Osteopathic Medical Board of California issue a
4 decision:

5 1. Revoking or suspending Osteopathic Physician and Surgeon Number
6 20A4148, issued to HOWARD P. LEVY, D.O.

7 2 Ordering HOWARD P. LEVY, D.O. to pay the Osteopathic Medical
8 Board of California the reasonable costs of the investigation and enforcement of this case,
9 pursuant to Business and Professions Code section 125.3; and, if placed on probation, the costs
10 of probation monitoring; and,

11 3. Taking such other and further action as deemed necessary and proper.

12
13 DATED: 7-20-06

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17 DONALD KR PAN
18 Executive Director (A)
19 Osteopathic Medical Board of California
20 State of California
21 Complainant

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