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McGeorge Law Review

Volume 37 | Issue 2

Article 3

1-1-2006

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Code Section Affected

Business and Professions Code § 2234.1 (amended).
AB 592 (Yee); 2005 STAT. Ch. 304.

"I started getting sick in 1988; I became too ill to work in 1991. It was not until the year 2000 that I was finally diagnosed with [persistent] Lyme disease. . . . [E]ven then I had to fight to educate my physician in order to be treated with long-term antibiotics."

—Melissa Kaplan[1]

I. INTRODUCTION

In 1978, a hiker from Sonoma County experienced the first reported human case of Lyme disease in California.[2] Between 1994 and 2003, over 850 cases of Lyme disease were reported to the State Department of Health Services from fifty-four of the fifty-eight California counties.[3]

Despite being the most frequently reported vector-borne disease in California,[4] doctors estimate patients severely underreport symptoms and doctors themselves frequently misdiagnose the disease.[5] Melissa Kaplan's letter represents more than fifty individual letters from proponents of Chapter 304, which describe the plight that Lyme disease patients in California must endure before receiving appropriate medical care or even a proper diagnosis of their disease.[6] The National Academy of Science's Institute of Medicine ("IOM") has reported that a new best practice can

1. Letter from Melissa Kaplan, to Assembly Member Leland Y. Yee, Cal. State Assembly (Apr. 4, 2005) (on file with the *McGeorge Law Review*).

2. *An Update on the Epidemiology of Lyme Disease in California*, ACTION REPORT (Med. Bd. of Cal.), Oct. 2001, at 6 [hereinafter *Epidemiology Update*] (on file with the *McGeorege Law Review*).

3. *See* CAL. DEP'T OF HEALTH SERVS., VECTOR-BORNE DISEASES IN CALIFORNIA, 2003 ANNUAL REPORT 15 (Aug. 2004) (charting the reported Lyme disease cases by county of residence in California from 1993-2003).

4. *Epidemiology Update*, *supra* note 2.

5. *See Lyme Disease: The Hidden Epidemic: Hearing Before the Senate Heath and Human Servs. Comm.*, (Feb. 25, 2004) (testimony of Raphael Stricker, M.D.) [hereinafter Stricker Testimony] (testifying on the state of Lyme disease in California).

6. *See, e.g.*, Letters from Judith Ain et al., to Assembly Member Leland Y. Yee, Cal. State Assembly, & Tracy Rhine, Consultant, Assembly Bus. and Prof. Comm. (Multiple dates) (on file with the *McGeorge Law Review*) (expressing support for Chapter 304 and describing individual experiences receiving diagnosis and treatment for the disease).

take up to seventeen years to reach the average doctor.[7] Lyme disease patients are a current, prime example of those who suffer as a result of this lag time. With Chapter 304, the California Legislature hopes to accelerate the process of reaching California patients with the new best practice for treating persistent Lyme disease.[8]

II. LYME DISEASE BACKGROUND

Infectious ticks transmit Lyme disease to humans by their bite.[9] Lyme disease was first discovered in Lyme, Connecticut in 1975[10] and has ever since divided the medical community.[11] The controversy rests between two very different schools of medical thought, which advocate two different standards of care for Lyme disease treatment.[12]

The dominant school believes that Lyme disease is "hard to catch and easy to cure"[13] and that persistent Lyme disease is either very rare or does not exist at all.[14] The dominant school, therefore, treats Lyme disease with antibiotics for a term of no greater than thirty days.[15] The clinical guidelines of the Infectious Diseases Society of America (IDSA) embrace this traditional school of thought and standard of care.[16]

In contrast, the emerging school of thought believes that Lyme disease is underreported,[17] is "[not] hard to catch and [not] easy to cure,"[18] and often fails to respond to the dominant standard of care.[19] The emerging school of thought believes that the thirty-day antibiotic regimen (the dominant standard of care) is

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7. CAL. BUS. & PROF. CODE § 2234.1(c) (amended by Chapter 304); *see The Chasm in Quality: Select Indicators from Recent Reports*, INST. OF MED., http://www.iom.edu/subpage. asp?id=14980, (last visited June 17, 2005) (on file with the *McGeorge Law Review*) ("[T]he lag between the discovery of more effective forms of treatment and their incorporation into routine patient care averages 17 years.").

8. *See* CAL. BUS. & PROF. CODE. § 2234.1(c) (amended by Chapter 304) (stating the legislative intent behind section 2234.1).

9. *See* MERRIAM-WEBSTER DICTIONARY 754 (1997) (defining "tick" as "any of a large group of small blood-sucking arachnids").

10. Raphael B. Stricker, Andrew Lautin & Joseph J Burrascano, *Lyme Disease: Point/Counterpoint*, 3 EXPERT REV. OF ANTI-INFECTIVE THERAPY 155 (2005).

11. *Id.*

12. *Id.* at 155-56.

13. *Id.* at 155.

14. *Id.*

15. *See* Gary P. Wormser et al., *Practice Guidelines for the Treatment of Lyme Disease: Guidelines from the Infectious Diseases Society of America*, 31 CLINICAL INFECTIOUS DISEASES S1, S1-S14 (Supp. 2000) (stating the guidelines for treating Lyme disease but not recognizing persistent Lyme disease as requiring more than thirty days of antibiotic treatment).

16. *Id.*; Stricker et al., *supra* note 10, at 155.

17. Stricker et al., *supra* note 10, at 155.

18. *See* Raphael B. Stricker & Andrew Lautin, *The Lyme Wars: Time to Listen*, 12 EXPERT OPINION ON INVESTIGATIONAL DRUGS 1609 (2003) (describing testimony made before members of Congress by one of the nation's foremost experts on the treatment of Lyme disease, Dr. Joseph Burrascano of New York).

19. Stricker et. al., *supra* note 10, at 155.

effective only if administered shortly after the tick bite occurs.[20] This standard of care causes a problem because many, if not the majority, of people infected are not aware of the tick bite when it occurs and seek medical care only when symptoms later emerge.[21] When the disease is left untreated for weeks or months, it can result in a persistent debilitating form of Lyme disease that requires prolonged antibiotic treatment, lasting much longer than the thirty-day treatment course recommended by the dominant view.[22] In many cases, curing the disease requires ten or more years of treatment.[23] The evidence-based guidelines published by the International Lyme and Associated Diseases Society (ILADS) recognize the emerging school of thought.[24] However, the overwhelming majority of physicians and the Medical Board of California do not embrace these guidelines.[25] Dr. Herbert Dörken, Legislation Advocate for the California Lyme Disease Association (CLDA), describes the controversy: "Basically what we have are 'Lyme Wars' between those biased to 30 days of short-term treatment and those who on examination hold that longer-term care is essential."[26]

The lack of recognition of persistent Lyme disease prior to the enactment of Chapter 304 made the majority of physicians reluctant to diagnose it or administer treatment to patients because of potential disciplinary action by the Medical Board of California.[27] The CLDA has stated that the lack of recognition of persistent Lyme disease poses a serious problem for the effective treatment of Lyme disease patients.[28] Dr. Therese Yang's situation exemplified this problem. She is a California physician who treats persistent Lyme disease; because she recognized persistent Lyme disease and administered long-term antibiotic treatment, Medical Board of California charged her with treating an infection that does not exist.[29] The disinclination of California physicians to diagnose and treat

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20. *See* Stricker & Lautin, *supra* note 18, at 1610 (stating that the disease often goes undetected due to a patient's failure to recognize that he or she has been bitten by a tick).

21. *Id.*

22. Stricker et. al., *supra* note 10, at 155.

23. *See* AMY TAN, OPPOSITE OF FATE 393 (2003) (describing author Amy Tan's experience with Lyme disease).

24. INTERNATIONAL LYME AND ASSOCIATED DISEASES SOCIETY, EVIDENCE-BASED GUIDELINES FOR THE MANAGEMENT OF LYME DISEASE 35 (Summer 2004).

25. Stricker Testimony, *supra* note 5.

26. *See* Letter from Herbert Dörken, Legis. Advocate, Cal. Lyme Disease Ass'n, to the Assembly Bus. and Prof. Comm., Cal. State Assembly (Mar. 12, 2005) (on file with the *McGeorge Law Review*) (arguing in support of Assembly Bill 592).

27. *See* Letter from Lorraine Johnson, Executive Dir., Cal. Lyme Disease Ass'n, to Assembly Member Leland Y. Yee, Cal. State Assembly (Mar. 29, 2005) (on file with the *McGeorge Law Review*) ("Fear of action by the Medical Board [of California] has had a substantial chilling effect on the willingness of physicians within the state to treat persistent Lyme disease").

28. *Id.*

29. *See* Anne Krueger, *Santee's Dr. Yang: Saint or Sinner?*, SAN DIEGO UNION TRIB., Apr. 2, 2005, *available at* http://www.signonsandiego.com/uniontrib/20050402/news_1m2yang.htm (on file with the *McGeorge Law Review*) (describing the predicament of Dr. Therese Yang in treating patients with persistent Lyme disease, specifically Angel Vipond). Dr. Yang battles the Medical Board of California, which fails to recognize the

Lyme disease commonly results in misdiagnosis or subjects patients to extreme difficulty and expense in finding a physician who will treat persistent Lyme disease; therefore, the actual sufferers are those California residents stricken with persistent Lyme disease.[30] The CLDA sponsored Chapter 304 as a preemptive measure to protect physicians like Dr. Yang who administer treatment to patients with persistent Lyme disease from action by the Medical Board of California.[31]

Currently in California, it is estimated that fewer than forty physicians will treat Lyme disease and fewer than ten physicians specialize in the treatment of persistent Lyme disease.[32] Of those ten specialized physicians, their waiting lists consistently exceed five-hundred patients.[33] Supporters of Chapter 304 hope it will remove a major discouraging factor for physicians to treat Lyme disease,[34] will increase the number of physicians treating Lyme disease, and will increase the likelihood that a Lyme disease patient will receive appropriate treatment.[35]

III. LEGAL BACKGROUND

A. *California's Medical Practices Act*

California's Medical Practices Act ("Act"), originally enacted in 1876, authorized the state to create policy and procedures pertaining to regulation and licensing for the practice of medicine.[36] In 1937, the Act was codified in sections 2000 through 2497 of the California Business and Professions Code.[37] The Act created the Medical Board of California, which protects the public by regulating and licensing medical practices and creating disciplinary procedures for violations of the Act.[38]

Moreover, the Act provides that the Medical Board of California may take disciplinary action against a physician's license for engaging in unprofessional

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existence of persistent Lyme disease. Instead, the Board diagnoses patients as "extremely troubled . . . with a severe psychiatric illness." *Id.*

30. Statement to the Cal. Med. Bd., Div. of Med. Quality by Physicians Who Treat Persistent Lyme disease (Feb. 17, 2005) (on file with *McGeorge Law Review*).

31. *See* Letter from Herbert Dörken to the Assembly Bus. and Prof. Comm, *supra* note 26 (pronouncing the impetus behind the CLDA's sponsorship of Chapter 304).

32. Statement to the California Medical Board, *supra* note 30.

33. *Id.*; *see also* Letter from Therese H. Yang, to Assembly Member Leland Yee, Cal. State Assembly (Apr. 3, 2005) (on file with *McGeorge Law Review*) (stating that Dr. Yang has treated over 600 patients with Lyme disease, many of whom sought help from other doctors who denied the existence of Lyme disease in California); *see also* Stricker Testimony, *supra* note 5 (testifying that he currently has over 600 Lyme disease patients).

34. Statement to the California Medical Board, *supra* note 30.

35. *Id.*

36. *See Ex parte* Frazer, 54 Cal. 94, 95 (1880) (acknowledging the 1876 Act and discussing its initial powers).

37. CAL. BUS. & PROF. CODE § 2000 (West 2003); *see* Sobey v. Molony, 40 Cal. App. 2d 381, 384, 104 P.2d 868, 870, (1940) (discussing the codification of the Medical Practices Act into the Business and Professions Code).

38. CAL. BUS. & PROF. CODE § 2001.1.

conduct.[39] It defines unprofessional conduct to include gross negligence, repeated negligent acts, and incompetence.[40]

Historically, the Act discouraged physicians and surgeons from treating patients by means of non-conventional methods of medical care, even though they had been determined safe and effective.[41] Physicians feared that advising patients on these methods would be considered a form of incompetence and would subject the physician to disciplinary procedures by the Medical Board of California likely resulting in loss of his or her medical license.[42]

B. Business and Professions Code Sections 2500 and 2501[43]

Business and Professions Code section 2500 acknowledges the interest of physicians and patients in non-conventional methods of medical care[44] and requires the Medical Board of California to establish policies and/or modify laws to "assure California consumers the most advanced and innovative medical care."[45] Section 2501 requires the Medical Board of California to set forth disciplinary policies and procedures to reflect emerging and innovative medical practices for licensed physicians.[46]

Due to the enactment of sections 2500 and 2501, the Medical Board of California instituted a "Non-Conventional Medicine Committee"[47] for the purpose of evaluating "alternative and complementary medicine" and its integration into the common practice of medicine.[48] After its creation, the Non-Conventional Medicine Committee investigated the current need and usage of alternative and complementary medicine and then developed the language for Business and Professions Code section 2234.1, which Senate Bill 1691 enacted.[49]

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39. *Id.* § 2234.

40. *Id.* § 2234(b)-(d).

41. ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 2100, at 3 (June 27, 2000).

42. *Id.*

43. CAL. BUS. & PROF. CODE §§ 2500-01 (as enacted by 2000 Cal. Stat. ch. 660).

44. *Id.* § 2500 (West 2003) (stating the interest and giving examples of non-conventional medical care as "including, but not limited to, biopsychosocial techniques, nutrition, and the use of natural supplements to enhance health and wellness").

45. *Id.*

46. *Id.* § 2501.

47. *See* Med. Bd. of Cal., Committees of the Medical Board of California, http://www.medbd.ca.gov/Committees.htm (last visited June 23, 2005) (on file with the *McGeorge Law Review*) (listing the members of the Non-Conventional Medicine Committee as Lorie G. Rice, M.P.H., Chair; William S. Breall, M.D; Salma Haider; Ronald L. Morton, M.D.).

48. *See* ASSEMBLY FLOOR, FLOOR ANALYSIS OF SB 1691, at 3 (Aug. 18, 2004) (stating that as a result of the enactment of SB 2100, the Medical Board of California established the Non-Conventional Medicine Committee and revised disciplinary policies and staff training).

49. *See id.* (describing the Non-Conventional Medicine Committee's involvement in the development of SB 1691).

C. Business and Professions Code Section 2234.1[50]

Prior to its amendment by Chapter 304, Business and Professions Code section 2234.1 created an exemption from discipline for physicians prescribing "alternative or complementary medicine."[51] There are four requirements to qualify for the exception: 1) the physicians must acquire informed consent before administering alternative or complementary medicine to the patient;[52] 2) the physicians must give the patient information regarding conventional treatments and the physicians' pedigrees relating to their practice of alternative or complementary medicine;[53] 3) the alternative or complementary medicine must "not cause delay in, or discourage traditional diagnosis of, a condition of the patient;" and 4) the alternative or complementary medicine must "not cause death or serious bodily injury to the patient."[54]

Section 2234.1 defines "alternative or complementary medicine" as "methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method."[55]

Before Chapter 304, section 2234.1 provided that physicians who administered alternative or complementary medical care would be protected from discipline by the Medical Board of California. However, the alternative and complementary exemption did not extend protection to physicians who administered treatment of persistent Lyme disease.[56]

IV. CHAPTER 304

Chapter 304 amends Business and Professions Code section 2234.1[57] and furthers the goal of Business and Professions Code section 2500,[58] which is to assure California consumers that the quality of medicine in the state is the most advanced and innovative it can be in terms of preserving health and providing diagnosis and treatment of illness.[59] Chapter 304 advances this goal by expanding the scope of alternative and complementary medicine to include treatment of

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50. *Id.* § 2234.1(as enacted by 2004 Cal. Stat. ch. 742).
51. *Id.* § 2234.1(a) (West 2005).
52. *Id.* § 2234.1(a)(1).
53. *Id.* § 2234.1(a)(2).
54. *Id.* § 2234.1(a)(3)-(4).
55. *Id.* § 2234.1(b).
56. ASSEMBLY FLOOR, FLOOR ANALYSIS OF AB 592, at 3 (April 15, 2005).
57. *Id.*
58. *See id.* (stating the goals of California Business and Professions code section 2500 (enacted by SB 2100)); *see also id.* § 2500 (amended by Chapter 304) (acknowledging an interest by physicians and consumers and requiring the boards—Medical Board of California and Osteopathic Medical Board of California—to establish policies and/or modify law to assure California consumers the best possible medical care).
59. ASSEMBLY FLOOR, FLOOR ANALYSIS OF AB 592, at 3 (Apr. 15, 2005).

persistent Lyme disease.[60] Thus, a physician or surgeon will not be subject to discipline for administering treatment of persistent Lyme disease so long as he or she follows the appropriate procedures enumerated in section 2234.1.[61]

Finally, Chapter 304 states the legislative intent for section 2234.1 and the reason for including persistent Lyme disease within the meaning of alternative and complementary medicine.[62] Chapter 304 also states:

> Because the National Institute of Medicine has reported that it can take up to 17 years for a new best practice to reach the average physician or surgeon, attention must be given to new developments in general medical care, as well as, the treatment of specific diseases, particularly those that are not yet broadly recognized in California.[63]

V. ANALYSIS

California follows the lead of the Rhode Island State legislature[64] by enacting Chapter 304 to protect physicians administering long term antibiotic treatment of persistent Lyme disease.[65] While the enactment of Chapter 304 will quell California physicians' apprehension about being disciplined by the Medical Board of California for treating persistent Lyme disease, it is only one step toward increasing treatment opportunities for those afflicted with this disease.

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60. CAL. BUS. & PROF. CODE § 2234.1 (amended by Chapter 304).

61. *See id.* § 2234.1(a)(1)-(4) (West 2003). "A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine if that treatment or advice meets all of the following requirements:

> (1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.
>
> (2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine he or she practices.
>
> (3) It does not cause a delay in, or discourage traditional diagnosis of, a condition of the patient.
>
> (4) It does not cause death or serious bodily injury to the patient." *Id.*

62. ASSEMBLY FLOOR, FLOOR ANALYSIS OF AB 592, at 2 (Apr. 4, 2005).

63. CAL. BUS. & PROF. CODE § 2234.1(c); *see* ASSEMBLY FLOOR, ANALYSIS OF AB 592, at 3 (Apr. 4, 2005) (stating that the CLDA sponsors the bill because it seeks to protect physicians administering long-term treatment of persistent Lyme disease).

64. *See* R.I. GEN. LAWS § 5-37.5-4 (2004) ("No physician is subject to disciplinary action by the board solely for prescribing, administering or dispensing long-term antibiotic therapy for a therapeutic purpose for a patient clinically diagnosed with Lyme disease . . . ."). The statute also lists the requirements the physician must fulfill in order to receive the exemption from discipline. *Id.*

65. *See* ASSEMBLY FLOOR, FLOOR ANALYSIS OF AB 592, at 3 (Apr. 4, 2005) (stating that the sponsor of the bill seeks to protect physicians administering long-term treatment of persistent Lyme disease).

Still, there is a major hurdle to overcome before persistent Lyme disease patients will have the availability of treatment that they require—insurance coverage. Because insurance companies do not cover treatment of persistent Lyme disease[66] and California does not have legislation in place requiring such coverage (as Rhode Island and Connecticut do),[67] treatment of persistent Lyme disease will be limited to patients with the financial means to support long term antibiotic treatment.[68]

VI. CONCLUSION

The California Legislature has become aware of the Lyme disease epidemic it is facing, and it has taken several strides forward to protect its citizens from this disease. The first step came in 1999 when Senate Bill 1115 established the Lyme disease Advisory Committee to provide educational materials and information regarding Lyme disease in California.[69] The next step came in April of 2005 as the Legislature enacted Resolution Chapter 20 proclaiming May fourth through May tenth as Lyme Disease Awareness week.[70] Now, Chapter 304 adds a level of protection to the physicians and surgeons of California who treat Lyme disease and in turn those who suffer from it. Before Chapter 304,

66. *See* TAN, *supra* note 23 at 393 (describing author Amy Tan's experience with Lyme disease and the fact that insurance companies, HMOs, and medical organizations do not recognize, nor cover long-term treatment of persistent Lyme disease); *see also* Letter from Therese H. Yang to Assembly Member Leland Yee, *supra* note 33 (stating that insurance companies disregard evidence based guidelines that recommend long-term treatment of persistent Lyme disease, but recognize the evidence based guidelines that say such treatment is not beneficial, and speculating that there is "an obvious conflict of interest").

67. *See* R.I. GEN. LAWS § 27-18-62 (2004) ("Every individual or group hospital or medical expense insurance policy or individual or group hospital or medical services plan contract delivered, issued for delivery, or renewed in this state on or after January 1, 2004 shall provide coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician acting in accordance with chapter 37.5 of title 5 entitled 'Lyme disease diagnosis and treatment' after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment. Treatment otherwise eligible for benefits pursuant to this section shall not be denied solely because such treatment may be characterized as unproven, experimental, or investigational in nature. Provided, however, this section shall not apply to insurance coverage providing benefits for: (1) Hospital confinement indemnity; (2) Disability income; (3) Accident only; (4) Long-term care; (5) Medicare supplement; (6) Limited benefit health; (7) Specified disease indemnity; (8) Sickness or bodily injury or death by accident or both; and (9) Other limited benefit policies."); *see also* CONN. GEN. STAT. §§ 38a-492h (2004) ("Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed or continued in this state on or after January 1, 2000, shall provide coverage for Lyme disease treatment including not less than thirty days of intravenous antibiotic therapy, sixty days of oral antibiotic therapy, or both, and shall provide further treatment if recommended by a board certified rheumatologist, infectious disease specialist or neurologist licensed in accordance with chapter 370 or who is licensed in another state or jurisdiction whose requirements for practicing in such capacity are substantially similar to or higher than those of this state.").

68. *See* Barbara L. Altwell, *Mainstreaming Complementary and Alternative Medicine in the Face of Uncertainty*, 72 U.M.K.C. L. REV. 593, 594 (2004) (discussing the growing demand for alternative and complementary medicine and the difficulty of receiving insurance coverage for non-conventional treatments).

69. CAL. HEALTH & SAFETY CODE §§ 104190-93 (West 2004).

70. RESOLUTION CHAPTER 20 (2005) (enacted by Senate Concurrent Resolution 23).

physicians who treated persistent Lyme disease were subject to disciplinary action by the Medical Board of California; after the enactment of Chapter 304 physicians no longer have to worry about such action.

While Chapter 304 accomplishes its purpose, to protect physicians who treat persistent Lyme disease from disciplinary actions, the package will not be complete until California enacts measures similar to Rhode Island and Connecticut that will protect patients who seek treatment for persistent Lyme disease from the exorbitant cost of long term antibiotics.