

**BEFORE THE  
MEDICAL BOARD OF CALIFORNIA  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA**

**In the Matter of the Accusation  
Against:**

**RICHARD LEE, M.D.**

**Case No. 06-2012-223496**

**Physician's and Surgeon's  
Certificate No. G 14329**

**Respondent**

**DECISION**

**The attached Stipulated Surrender of License and Order is hereby  
adopted as the Decision and Order of the Medical Board of California,  
Department of Consumer Affairs, State of California.**

**This Decision shall become effective at 5:00 p.m. on November 21, 2014**

**IT IS SO ORDERED November 14, 2014.**

**MEDICAL BOARD OF CALIFORNIA**

**By:**

  
**Kimberly Kirchmeyer  
Executive Director**

1 KAMALA D. HARRIS  
Attorney General of California  
2 E. A. JONES III  
Supervising Deputy Attorney General  
3 BENETH A. BROWNE  
Deputy Attorney General  
4 State Bar No. 202679  
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7 *Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:

Case No. 06-2012-223496

12 **RICHARD LEE, M.D.**  
6727 Painter Avenue  
13 Whittier, CA 90601

OAH No. 2014080438

**STIPULATED SURRENDER OF  
LICENSE AND ORDER**

14 Physician's and Surgeon's Certificate  
No. G 14329

15  
16 Respondent.

17  
18 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
19 entitled proceedings that the following matters are true:

20 PARTIES

21 1. Kimberly Kirchmeyer (Complainant) is the Executive Director of the Medical Board  
22 of California. She brought this action solely in her official capacity and is represented in this  
23 matter by Kamala D. Harris, Attorney General of the State of California, by Beneth A. Browne,  
24 Deputy Attorney General.

25 2. Richard Lee, M.D. (Respondent) is representing himself in this proceeding and has  
26 chosen not to exercise his right to be represented by counsel.

27 3. On or about January 3, 1968, the Medical Board of California issued Physician's and  
28 Surgeon's Certificate No. G 14329 to Respondent. The Physician's and Surgeon's Certificate was

1 in full force and effect at all times relevant to the charges brought in Accusation No. 06-2012-  
2 223496 and will expire on January 31, 2015, unless renewed.

3 JURISDICTION

4 4. Accusation No. 06-2012-223496 was filed before the Medical Board of California  
5 (Board), Department of Consumer Affairs, and is currently pending against Respondent. The  
6 Accusation and all other statutorily required documents were properly served on Respondent on  
7 May 29, 2014. Respondent timely filed his Notice of Defense contesting the Accusation. A copy  
8 of Accusation No. 06-2012-223496 is attached as Exhibit A and incorporated by reference.

9 ADVISEMENT AND WAIVERS

10 5. Respondent has carefully read, and understands the charges and allegations in  
11 Accusation No. 06-2012-223496. Respondent also has carefully read, and understands the effects  
12 of this Stipulated Surrender of License and Order.

13 6. Respondent is fully aware of his legal rights in this matter, including the right to a  
14 hearing on the charges and allegations in the Accusation; the right to be represented by counsel, at  
15 his own expense; the right to confront and cross-examine the witnesses against him; the right to  
16 present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel  
17 the attendance of witnesses and the production of documents; the right to reconsideration and  
18 court review of an adverse decision; and all other rights accorded by the California  
19 Administrative Procedure Act and other applicable laws.

20 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and  
21 every right set forth above.

22 CULPABILITY

23 8. Respondent admits the truth of each and every charge and allegation in Accusation  
24 No. 06-2012-223496, agrees that cause exists for discipline and imposition of civil penalties and  
25 hereby surrenders his Physician's and Surgeon's Certificate No. G 14329 for the Board's formal  
26 acceptance.

27 ///

28 ///

9. Respondent understands that by signing this stipulation he enables the Board to issue an order accepting the surrender of his Physician's and Surgeon's Certificate without further process.

## CONTINGENCY

10. This stipulation shall be subject to approval by the Medical Board of California. Respondent understands and agrees that counsel for Complainant and the staff of the Medical Board of California may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

11. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

12. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

## ORDER

IT IS HEREBY ORDERED that Physician's and Surgeon's Certificate No. G 14329, issued to Respondent RICHARD LEE, M.D., is surrendered and accepted by the Medical Board of California.

1. The surrender of Respondent's Physician's and Surgeon's Certificate and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Medical Board of California.

2. Respondent shall lose all rights and privileges as a Physician and Surgeon in

1 California as of the effective date of the Board's Decision and Order.

2 3. Respondent shall cause to be delivered to the Board his pocket license and, if one was  
3 issued, his wall certificate on or before the effective date of the Decision and Order.

4 4. If Respondent ever files an application for licensure or a petition for reinstatement in  
5 the State of California, the Board shall treat it as a petition for reinstatement. Respondent must  
6 comply with all the laws, regulations and procedures for reinstatement of a revoked license in  
7 effect at the time the petition is filed, and all of the charges and allegations contained in  
8 Accusation No. 06-2012-223496 shall be deemed to be true, correct and admitted by Respondent  
9 when the Board determines whether to grant or deny the petition.

10 5. If Respondent should ever apply or reapply for a new license or certification, or  
11 petition for reinstatement of a license, by any other health care licensing agency in the State of  
12 California, all of the charges and allegations contained in Accusation No. 06-2012-223496 shall  
13 be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of  
14 Issues or any other proceeding seeking to deny or restrict licensure.

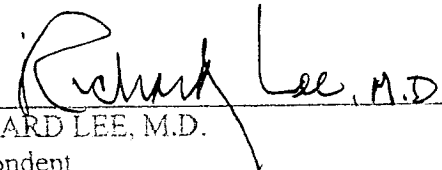
15 6. Respondent shall pay the Board civil penalties in the amount of fifty thousand dollars  
16 (\$50,000.00). Payment shall be within thirty days of the effective date of the Decision and Order  
17 unless a payment plan is coordinated between Respondent and the Board or Board representative.  
18 Full payment shall be completed within three years of the effective date of the Decision and  
19 Order. Payment of the civil penalties shall be made to: Medical Board of California, P.O. Box  
20 15588, Sacramento, CA 95852.

21 ACCEPTANCE

22 I have carefully read the Stipulated Surrender of License and Order. I understand the  
23 stipulation and the effect it will have on my Physician's and Surgeon's Certificate. I enter into  
24 this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and  
25 agree to be bound by the Decision and Order of the Medical Board of California.

26  
27 DATED:

6 OCTOBER 2014

28   
RICHARD LEE, M.D.  
Respondent

1 ENDORSEMENT

2 The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted  
3 for consideration by the Medical Board of California of the Department of Consumer Affairs.

4 Dated: October 20, 2014

Respectfully submitted,

5 KAMALA D. HARRIS  
6 Attorney General of California  
7 E. A. JONES III  
8 Supervising Deputy Attorney General

9 *Beneth A Browne*

10 BENETH A. BROWNE  
11 Deputy Attorney General  
12 *Attorneys for Complainant*

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**Exhibit A**

**Accusation No. 06-2012-223496**

1 KAMALA D. HARRIS  
Attorney General of California  
2 E.A. JONES III  
Supervising Deputy Attorney General  
3 BENETH A. BROWNE  
Deputy Attorney General  
4 State Bar No. 202679  
California Department of Justice  
5 300 So. Spring Street, Suite 1702  
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7 *Attorneys for Complainant*

FILED  
STATE OF CALIFORNIA  
MEDICAL BOARD OF CALIFORNIA  
SACRAMENTO MAY 29 2014  
BY                      ANALYST

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

11 In the Matter of the Accusation Against:

12 RICHARD LEE, M.D.  
6727 Painter Ave.  
13 Whittier, CA 90601

Case No. 06-2012-223496

**A C C U S A T I O N**

14 Physician's and Surgeon's Certificate No.  
15 G14329

16 Respondent.

17  
18 Complainant alleges:

19 **PARTIES**

20 1. Kimberly Kirchmeyer (Complainant) brings this Accusation solely in her official  
21 capacity as the Executive Director of the Medical Board of California, Department of Consumer  
22 Affairs.

23 2. On or about January 3, 1968, the Medical Board of California issued Physician's and  
24 Surgeon's Certificate Number G14329 to Richard Lee, M.D. (Respondent). The Physician's and  
25 Surgeon's Certificate was in full force and effect at all times relevant to the charges brought  
26 herein and will expire on January 31, 2015, unless renewed.

27 **JURISDICTION**

28 3. This Accusation is brought before the Medical Board of California (Board),



1 Department of Consumer Affairs, under the authority of the following laws. All section  
2 references are to the Business and Professions Code unless otherwise indicated.

3 4. Section 2229 of the Code states, in subdivision (a):

4 "Protection of the public shall be the highest priority for the Division of Medical Quality,<sup>[1]</sup>  
5 the California Board of Podiatric Medicine, and administrative law judges of the Medical Quality  
6 Hearing Panel in exercising their disciplinary authority."

7 5. Section 2227 of the Code provides that a licensee who is found guilty under the  
8 Medical Practice Act may have his or her license revoked, suspended for a period not to exceed  
9 one year, placed on probation and required to pay the costs of probation monitoring, or such other  
10 action taken in relation to discipline as the Board deems proper.

11 6. Section 2234 of the Code, states:

12 "The board shall take action against any licensee who is charged with unprofessional  
13 conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not  
14 limited to, the following:

15 "(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the  
16 violation of, or conspiring to violate any provision of this chapter.

17 "(b) Gross negligence.

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

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

23 "(2) When the standard of care requires a change in the diagnosis, act, or omission that  
24 constitutes the negligent act described in paragraph (1), including, but not limited to, a  
25 reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the

26  
27 <sup>1</sup> Pursuant to Business and Professions Code section 2002, the "Division of Medical  
28 Quality" or "Division" shall be deemed to refer to the Medical Board of California.

1 applicable standard of care, each departure constitutes a separate and distinct breach of the  
2 standard of care.

3 "(d) Incompetence.

4 "(e) The commission of any act involving dishonesty or corruption which is substantially  
5 related to the qualifications, functions, or duties of a physician and surgeon.

6 "..."

7 7. Section 2242 of the Code states:

8 "(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022  
9 without an appropriate prior examination and a medical indication, constitutes unprofessional  
10 conduct.

11 "..."

12 8. Section 2242.1 of the Code states:

13 "(a) No person or entity may prescribe, dispense, or furnish, or cause to be prescribed,  
14 dispensed, or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the  
15 Internet for delivery to any person in this state, without an appropriate prior examination and  
16 medical indication, except as authorized by Section 2242.

17 "..."

18 9. Section 4022 of the Code states:

19 "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self-use in  
20 humans or animals, and includes the following:

21 "(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without  
22 prescription," "Rx only," or words of similar import.

23 "..."

24 "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on  
25 prescription or furnished pursuant to Section 4006."

26 10. Section 2236 of the Code states:

27 "(a) The conviction of any offense substantially related to the qualifications, functions, or  
28 duties of a physician and surgeon constitutes unprofessional conduct within the meaning of this

1 chapter [Chapter 5, the Medical Practice Act]. The record of conviction shall be conclusive  
2 evidence only of the fact that the conviction occurred.

3 “(b) The district attorney, city attorney, or other prosecuting agency shall notify the  
4 Division of Medical Quality of the pendency of an action against a licensee charging a felony or  
5 misdemeanor immediately upon obtaining information that the defendant is a licensee. The notice  
6 shall identify the licensee and describe the crimes charged and the facts alleged. The prosecuting  
7 agency shall also notify the clerk of the court in which the action is pending that the defendant is  
8 a licensee, and the clerk shall record prominently in the file that the defendant holds a license as a  
9 physician and surgeon.

10 “...

11 “(c) The clerk of the court in which a licensee is convicted of a crime shall, within 48 hours  
12 after the conviction, transmit a certified copy of the record of conviction to the board. The  
13 division may inquire into the circumstances surrounding the commission of a crime in order to fix  
14 the degree of discipline or to determine if the conviction is of an offense substantially related to  
15 the qualifications, functions, or duties of a physician and surgeon.

16 “(d) A plea or verdict of guilty or a conviction after a plea of nolo contendere is deemed to  
17 be a conviction within the meaning of this section and Section 2236.1. The record of conviction  
18 shall be conclusive evidence of the fact that the conviction occurred.”

19 11. Section 2237 of the Code states:

20 “(a) The conviction of a charge of violating any federal statutes or regulations or any statute  
21 or regulation of this state, regulating dangerous drugs or controlled substances, constitutes  
22 unprofessional conduct. The record of the conviction is conclusive evidence of such  
23 unprofessional conduct. A plea or verdict of guilty or a conviction following a plea of nolo  
24 contendere is deemed to be a conviction within the meaning of this section.

25 “(b) Discipline may be ordered in accordance with Section 2227 or the Division of  
26 Licensing may order the denial of the license when the time for appeal has elapsed, or the  
27 judgment of conviction has been affirmed on appeal, or when an order granting probation is made  
28 suspending the imposition of sentence, irrespective of a subsequent order under the provisions of

1 Section 1203.4 of the Penal Code allowing such person to withdraw his or her plea of guilty and  
2 to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation,  
3 complaint, information, or indictment.”

4 12. Section 2238 of the Code states:

5 “A violation of any federal statute or federal regulation or any of the statutes or regulations  
6 of this state regulating dangerous drugs or controlled substances constitutes unprofessional  
7 conduct.”

8 13. Section 2264 of the Code states:

9 “The employing, directly or indirectly, the aiding, or the abetting of any unlicensed person  
10 or any suspended, revoked, or unlicensed practitioner to engage in the practice of medicine or any  
11 other mode of treating the sick or afflicted which requires a license to practice constitutes  
12 unprofessional conduct.”

13 14. Section 2220.7 of the Code states:

14 “(a) A physician and surgeon shall not include or permit to be included any of the following  
15 provisions in an agreement to settle a civil dispute arising from his or her practice, whether the  
16 agreement is made before or after filing the action:

17 “(1) A provision that prohibits another party to the dispute from contacting or cooperating  
18 with the board.

19 “(2) A provision that prohibits another party to the dispute from filing a complaint with the  
20 board.

21 “(3) A provision that requires another party to the dispute to withdraw a complaint he or she  
22 has filed with the board.

23 “(b) A provision described in subdivision (a) is void as against public policy.

24 “(c) A physician and surgeon who violates this section is subject to disciplinary action by  
25 the board.”

26 15. Section 2266 of the Code states: “The failure of a physician and surgeon to maintain  
27 adequate and accurate records relating to the provision of services to their patients constitutes  
28 unprofessional conduct.”

## FACTUAL ALLEGATIONS

16. Respondent and his business partner ("Partner") began a limited liability company ("Company") in 1986 to treat patients with alopecia androgenetica (male pattern baldness). Respondent was licensed as a physician and surgeon in 1968, but Respondent's partner was not a doctor or licensed medical professional. Respondent had learned about Rogaine, a prescription treatment for male pattern baldness, from a physician in Canada, where the product was legal, though it was not legal in the United States yet since it had not been approved by the Food and Drug Administration (FDA).<sup>2</sup>

17. Respondent had received his undergraduate degree in Chemistry, knew the ingredients in Rogaine and could make a solution for patients with the raw ingredients but felt he could not because Rogaine was patented. Respondent and his Partner began to sell kits to patients, however, so patients could make their own medications with the raw ingredient minoxidil, the base solution, and a filter. They opened three offices in Southern California.

18. At an interview with the Medical Board of California on May 18, 2013, Respondent explained that business was good until around 1990 when Rogaine was approved by the FDA and the Company was sued for patent infringement. Because Rogaine became readily available to patients from their own doctors, Respondent and his Partner were forced to close down two of their three offices. However, because Respondent and his Partner knew that the patent would expire after a few years, they sought to "hang on" until that happened. Respondent made minoxidil in various percentages, even higher than in Rogaine products that received FDA approval. Respondent compounded numerous pharmaceuticals to treat alopecia androgenetica including minoxidil, azelaic acid, spironolactone, and finasteride. Respondent formulated the products based on his own research and claimed the medications he produced were being used in

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<sup>2</sup> The FDA regulates the manufacture and sale of pharmaceuticals to ensure that medicines sold are safe and effective. Medications sold must be approved by the FDA and medications must be manufactured, prepared, propagated, compounded and processed in an establishment duly registered with the FDA or else they are "misbranded" and illegal. (Title 21, U.S.C., § 352, subd. (o)(registration requirement).

1 an "off-label manner." The Company never submitted any of its compounded medications to the  
2 FDA for approval. Nor did it ever register its compounding and manufacturing lab with the FDA.

3 19. In the mid-1990's, Respondent and his Partner started an internet site,  
4 www.minoxidil.com, and used it to sell their compounded pharmaceuticals both domestically and  
5 overseas. Respondent later stated that he was comfortable that he was providing safe and  
6 effective treatment for patients over the internet because he did not receive complaints.

7 20. In June of 2002, the Board filed an Accusation against Respondent alleging that he  
8 prescribed minoxidil and Proscar (finasteride) over the internet without conducting a good faith  
9 examination of the patient. Instead, the purchaser had simply been required to complete an online  
10 questionnaire. Respondent admitted that between September of 1999 and April of 2002, he had  
11 sold prescription medicine over the internet without a good faith examination approximately 300  
12 times. He agreed to pay a \$25,000 civil penalty for selling pharmaceuticals over the internet  
13 without a good faith examination in violation of Business and Professions Code section 2242.1.  
14 He was placed on probation for five years and was required to take coursework including  
15 prescribing practices and ethics.

16 21. In 2004, W.P. completed an online questionnaire on Respondent's website. The only  
17 recorded questionnaire information from 2004 included W.P.'s name; e-mail address; gender;  
18 major illness or surgeries (marked "none"); allergies (marked "none"); history and pattern of hair  
19 loss (marked "MPB" for male pattern baldness); family history (marked with an "x" by  
20 "paternal"); transplants or grafts (marked "no"); current medications (marked "none"); and  
21 questions (marked "none"). After the "initial consultation," W.P. was awarded "patient" status  
22 which meant that he was eligible to purchase products available through the website to promote  
23 hair growth. W.P. purchased products as a patient between 2004 and the time of the Company's  
24 closure in 2011, stating he spent over \$13,000.

25 22. In June of 2005, Respondent petitioned the Board for early termination of his  
26 probation. At a hearing regarding his petition, Respondent acknowledged that he still limited his  
27 practice of medicine to the treatment of alopecia androgenetica (male pattern baldness). He  
28 testified that the reason the Board disciplined him was his furnishing prescription medication to

1 patients who he had not personally examined. His legal violation (prescribing over the internet  
2 without conducting an appropriate prior examination of the patient), Respondent testified, "was  
3 an error of judgment rather than a willful disobedience or self profiting act." The Board denied  
4 Respondent penalty relief, finding that he failed to make a sufficient showing of rehabilitation and  
5 he had failed to complete paying civil penalties as required.

6 23. Respondent made his products available to people who contacted him about hair loss  
7 conditions, primarily male pattern baldness. At an interview with the Board on May 18, 2013, he  
8 stated that he screened patients by an internet questionnaire and excluded patients with certain  
9 medical conditions like heart disease from purchasing his products. He claimed he did not  
10 directly prescribe these products, but let patients who he approved based on their internet  
11 questionnaire, select medications based on their evaluation of information about the products that  
12 he provided on his website. After initial consultation (completing the internet questionnaire),  
13 patients could make purchases of whichever medications they chose for as long as they liked.  
14 Patients were able to contact Respondent by e-mail if they had questions or problems and  
15 Respondent stated he answered them promptly. The patients received no regular follow-up or  
16 periodic review. Patients were not requested to provide any updated medical information over  
17 time.

18 24. Patient medical records of W.P. consisted of e-mail correspondence between W.P.  
19 and the Company including the "new patient consultation" e-mail sent to W.P. dated October 7,  
20 2004, e-mail correspondence between W.P. and Respondent dated May 25, 2009, regarding  
21 concern about a product, and e-mails between W.P. and Respondent dated March 31, 2011; April  
22 1, 2011 (including a letter from patient W.P.); April 4, 2011; and April 9, 2011. Patients'  
23 purchasing history and e-mail correspondence was retained by the Company. The "new patient  
24 consultation" e-mail provided information about medications, how to use them, what could be  
25 expected, how to place orders with the Company and listed patient information from the patient  
26 questionnaire. Respondent did not develop or record any treatment plans or state objectives of  
27 treatment. He dispensed medication as ordered over the internet based solely on an internet  
28 questionnaire.

1        25. Between January of 2009 and the Company's closure in April of 2011, Respondent  
2 had over 14,000 patients to whom he sold pharmaceuticals through his website based solely on  
3 their responses to internet questionnaires.

4        26. In February of 2011, the FDA audited the Company's business and learned that it was  
5 selling misbranded products developed and compounded by Respondent using his own formulas.  
6 Respondent had not registered the Company with the FDA and did not seek or obtain approval to  
7 sell its hair growth drugs. On or around March 29, 2011, the Company was required to send an  
8 "urgent recall" notice letters to over 14,000 patients regarding the 16 pharmaceutical products he  
9 sold, informing them they were unapproved by the FDA, they may be potential health hazards  
10 and advising them to destroy the product and return the packaging for a refund. The medications  
11 that Respondent had already compounded but not sold were quarantined by the FDA and  
12 disposed of.

13        27. In or around April of 2011, Respondent and his non-doctor Partner drove a truck with  
14 their formulas/recipes, equipment and \$100,000 worth of raw materials to Utah and delivered  
15 them to two unlicensed individuals (the "Utah Partners"). Respondent's Partner trained them  
16 how to create the prescription medications from the raw materials using the equipment. The raw  
17 materials, after compounded into the prescription medications, would retail at about \$1,000,000.  
18 Respondent was to receive 25% of the Utah Partners' profits. Respondent referred his prior  
19 patients to the new website from which Utah Partners sold the prescription medications.

20        28. In a letter from W.P. to Respondent dated April 1, 2011, W.P. requested \$5,000 in  
21 exchange for W.P.'s agreement to not sue Respondent and to not report Respondent to the  
22 Medical Board of California for selling misbranded drugs over the internet. On or about April 9,  
23 2011, Respondent accepted the offer and wrote a check for \$5,000 that he sent to patient. On or  
24 about April 11, 2011, the check was cashed.

25        29. An FDA Enforcement Report dated May 25, 2011, listed the Company's 16  
26 products subject to recall, stated the recall was ongoing, and noted that the drugs were "marked  
27  
28



1 without an approved New Drug Application or Abbreviated New Drug Application.”<sup>3</sup> The report  
2 listed the volume of products in commerce as 57,999 bottles. It listed 75 countries in addition to  
3 the United States where the products were distributed.

4 30. After the FDA shut down Respondent’s business, Respondent believed that physical  
5 patient medical records were shred. On May 29, 2012, Respondent certified that he had no  
6 patient records for W.P. In a letter to the Board dated July 17, 2012, Respondent stated that after  
7 he closed the Company, many records were shredded or destroyed and W.P.’s records may have  
8 been among them. On May 8, 2013, in an interview with the Board, Respondent explained that  
9 he gave possession and control of electronic medical records from the Company to his non-doctor  
10 business Partner. On May 9, 2013, Respondent advised the Board that he had received back and  
11 was personally maintaining possession of all of the medical records for the Company.

12 31. On or about September 26, 2012, in *United States of America v. Richard Lee, James*  
13 *Dorius, Alexander Ahn and Min Kim*, a Bill of Indictment was filed in the United States District  
14 Court, Idaho Central District, against Respondent and three co-defendants. Count I, against all  
15 four Defendants, alleged a violation of 18 U.S.C. § 371,<sup>4</sup> Conspiracy to Introduce Misbranded  
16 Drugs into Interstate Commerce. Count 2, alleged against Respondent and his California business  
17 Partner, alleged a felony violation of 21 U.S.C. § 331(a),<sup>5</sup> Introduction of Misbranded Drugs into

18 <sup>33</sup> A New Drug Application (NDA) to the FDA must demonstrate the drug’s safety and  
19 effectiveness, established with preclinical (animal) and clinical (human) data, showing how the  
20 drug behaves in the body and how it is manufactured. An Abbreviated New Drug Application  
(ANDA) is used to seek review and approval of a generic drug product. An applicant must  
21 scientifically demonstrate that its product performs in the same manner as the original drug.

22 <sup>4</sup> “If two or more persons conspire either to commit any offense against the United  
23 States, or to defraud the United States, or any agency thereof in any manner or for any purpose,  
24 and one or more of such persons do any act to effect the object of the conspiracy, each shall be  
25 fined under this title or imprisoned not more than five years, or both.

26 “If, however, the offense, the commission of which is the object of the conspiracy, is a  
27 misdemeanor only, the punishment for such conspiracy shall not exceed the maximum  
28 punishment provided for such misdemeanor.”

<sup>5</sup> “The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food,  
drug, device, tobacco product, or cosmetic that is adulterated or misbranded.”

1 Interstate Commerce, punishable by 21 U.S.C. § 333(a)(2).<sup>6</sup> Count 3 alleged against co-  
2 defendants, alleged a misdemeanor violation of 21 U.S.C. § 331(a), Introduction of Misbranded  
3 Drugs into Interstate Commerce, by the Utah partners, punishable by 21 U.S.C. § 333(a)(1).

4 32. On January 29, 2013, Respondent entered into a plea agreement in which he agreed to  
5 plead guilty to misdemeanor Introduction of Misbranded Drugs into Interstate Commerce. A  
6 Misdemeanor Information was filed against Respondent and his co-defendant Partner alleging a  
7 misdemeanor violation of 21 U.S.C. § 331(a), Introduction of Misbranded Drugs into Interstate  
8 Commerce, punishable by 21 U.S.C. § 333(a)(1). Respondent pled guilty to the violation. In a  
9 Statement in Advance of Plea, Respondent agreed to pay a \$25,000 fine and he stipulated to the  
10 following facts:

11 "From on or about January 1, 2011, to on or about October 24, 2011, in the  
12 Central Division of the District of Utah and elsewhere, I introduced and caused the  
13 introduction into interstate commerce misbranded drugs. I did this by compounding  
14 and selling, along with my co-defendants, hair treatment products over the internet  
15 that did not conform with the requirements of federal law in that they were  
16 manufactured, prepared, propagated, compounded and processed in an establishment  
17 not duly registered with the FDA as required under 21 U.S.C. § 352(o)."<sup>7</sup>

18 <sup>6</sup> "(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

19 "(1) Any person who violates a provision of section 331 of this title shall be imprisoned  
20 for not more than one year or fined not more than \$1,000, or both.

21 "(2) Notwithstanding the provisions of paragraph (1) of this section, if any person  
22 commits such a violation after a conviction of him under this section has become final, or  
commits such a violation with the intent to defraud or mislead, such person shall be imprisoned  
for not more than three years or fined not more than \$10,000, or both."

23 <sup>7</sup> "A drug or device shall be deemed to be misbranded—

24 " . . .

25 "(o) If it was manufactured, prepared, propagated, compounded, or processed in an  
establishment not duly registered under section 360 of this title, if it is a drug and was imported or  
26 offered for import by a commercial importer of drugs not duly registered under section 381(s) of  
this title, if it was not included in a list required by section 360(j) of this title, if a notice or other  
27 information respecting it was not provided as required by such section or section 360(k) of this  
title, or if it does not bear such symbols from the uniform system for identification of devices  
prescribed under section 360(e) of this title as the Secretary by regulation requires."

1 The Court accepted Respondent's plea of Guilty to Count I of the Misdemeanor Information and  
2 a pre-sentence report was ordered.

3 33. On April 16, 2013, a Judgment issued. Respondent pled guilty to Count 1 of the  
4 Misdemeanor Information, all counts of the prior indictment were dismissed, Respondent was  
5 adjudicated guilty and Respondent was sentenced to twelve months of probation.<sup>8</sup> Respondent  
6 was ordered to pay a \$25,000 fine.

7 **FIRST CAUSE FOR DISCIPLINE**

8 (Gross Negligence)

9 34. Respondent is subject to disciplinary action under section 2234, subdivision (b), of  
10 the Code in that he was grossly negligent in the care and treatment patient W.P. The  
11 circumstances are as follows:

12 35. The facts and circumstances alleged in paragraphs 19, 21, 23, 24 and 28 above are  
13 incorporated here as if fully set forth.

14 36. Respondent was grossly negligent in his care and treatment of W.P. on and after May  
15 15, 2007, each time he treated W.P. by prescribing or shipping medication to W.P., when he,  
16 taken singularly or collectively:

17 A. failed to perform a physical examination; failed to obtain and assess a thorough  
18 medical history; failed to assess W.P.'s presenting complaints; failed to assess W.P.'s current  
19 medical treatment; and failed to assess W.P.'s underlying or co-existing diseases or conditions;

20 B. failed to develop a treatment plan with objectives of treatment;

21 C. failed to create and maintain timely, accurate, legible medical records documenting  
22 physical examination findings, assessment or diagnosis, treatment plan or objectives of treatment;

23 D. Failed to perform periodic reviews of the patient's treatment and status.

24 **SECOND CAUSE FOR DISCIPLINE**

25 (Repeated Negligent Acts)

26  
27 <sup>8</sup> An Amended Judgment issued on May 23, 2013, clarifying that the probation was  
28 unsupervised.

37. Respondent Richard Lee, M.D. is subject to disciplinary action under section 2234, subdivision (c), of the Code in that he was repeatedly negligent in the care and treatment of W.P. The circumstances are as follows:

38. The facts and circumstances alleged in paragraphs 19, 21, 23, 24 and 28 above are incorporated here as if fully set forth.

39. Respondent was negligent in his care and treatment of W.P. on or after May 15, 2007, each time he shipped W.P. misbranded prescription medication, and he, taken singularly or collectively:

A. failed to perform a physical examination; failed to obtain and assess a thorough medical history; failed to assess W.P.'s presenting complaints; failed to assess W.P.'s current medical treatment; and failed to assess W.P.'s underlying or co-existing diseases or conditions;

B. failed to develop a treatment plan with objectives of treatment;

C. failed to create and maintain timely, accurate, legible medical records documenting physical examination findings, assessment or diagnosis, treatment plan or objectives of treatment;

D. Failed to perform periodic reviews of the patient's treatment and status.

E. Failed to maintain W.P.'s medical records.

### **THIRD CAUSE FOR DISCIPLINE**

(Prescribing Without Exam)

40. Respondent is subject to disciplinary action under section 2242 of the Code in that he prescribed, dispensed, or furnished dangerous drugs as defined in section 4022 of the Code without an appropriate prior examination and a medical indication, thereby committing unprofessional conduct. The circumstances are as follows:

41. The facts and circumstances alleged in paragraphs 21, 23, 24 and 25 above are incorporated here as if fully set forth.

### **FOURTH CAUSE FOR DISCIPLINE**

(Internet Prescribing Without Exam)

42. Respondent is subject to disciplinary action under Code section 2242.1 in that he, on or after May 15, 2007, prescribed, dispensed, or furnished, or caused to be prescribed, dispensed,

1 or furnished, dangerous drugs on the Internet for delivery to a person in this state, without an  
2 appropriate prior examination and medical indication. The circumstances are as follows:

3 43. The facts and circumstances alleged in paragraphs 21, 23, 25, 27, and 32 above are  
4 incorporated here as if fully set forth.

5 **FIFTH CAUSE FOR DISCIPLINE**

6 (Conviction)

7 44. Respondent is subject to disciplinary action under section 2236 in that he was  
8 convicted of an offense substantially related to the qualifications, functions, or duties of a  
9 physician and surgeon, thereby committing unprofessional conduct. The circumstances are as  
10 follows:

11 45. The facts and circumstances alleged in paragraphs 27, 30, 32, and 33 above are  
12 incorporated here as if fully set forth.

13 **SIXTH CAUSE FOR DISCIPLINE**

14 (Conviction of Charge of Violating a Statute Regulating Dangerous Drugs)

15 46. Respondent is subject to disciplinary action under section 2237 in that he was  
16 convicted of a charge of violating a federal statute regulating dangerous drugs, thereby  
17 committing unprofessional conduct. The circumstances follow:

18 47. The facts and circumstances alleged in paragraphs 27, 30, 32, and 33 above are  
19 incorporated here as if fully set forth.

20 **SEVENTH CAUSE FOR DISCIPLINE**

21 (Violation of a of a Statute Regulating Dangerous Drugs)

22 48. Respondent is subject to disciplinary action under section 2238 in that he violated a  
23 federal statute regulating dangerous drugs, thereby committing unprofessional conduct.

24 Specifically, Respondent sold misbranded drugs between June of 2007 and 2011 in violation  
25 federal statutes regulating dangerous drugs, i.e., Title 21, U.S.C., § 331, subd. (a) (lacking FDA  
26 approval of dangerous drugs prescribed); and Title 21, U.S.C., § 352, subd. (o)(compounding and  
27 manufacturing prescriptions drugs in a facility not appropriately registered with the FDA).

28 49. The facts and circumstances alleged in paragraphs 18, 25, 26, 27, 29, and 32 above

are incorporated here as if fully set forth.

#### **EIGHTH CAUSE FOR DISCIPLINE**

(Aiding and Abetting the Unlicensed Practice of Medicine)

50. Respondent is subject to disciplinary action under section 2264 in that he employed, directly or indirectly, aided, or abetted an unlicensed person or unlicensed practitioner to engage in the practice of medicine, including, taken singularly or collectively, James Dorius, Alexander Ahn and Min Kim. The circumstances are as follows:

51. The facts and circumstances alleged in paragraphs 16 – 19, 25, 26, 27, and 32 above are incorporated here as if fully set forth.

#### **NINTH CAUSE FOR DISCIPLINE**

(Civil Settlement Prohibiting Complaint to Board)

52. Respondent is subject to disciplinary action under section 2220.7 by including a provision that prohibited a patient from filing a complaint with the board in an agreement to settle a civil dispute arising from his practice.

53. The facts and circumstances alleged in paragraphs 21, 24 and 28 above are incorporated here as if fully set forth.

#### **TENTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Adequate and Accurate Medical Records)

54. Respondent is subject to disciplinary action under section 2266 in that he failed to maintain adequate and accurate records relating to the provision of services to his patients, thereby committing unprofessional conduct. The circumstances follow:

55. The facts and circumstances alleged in paragraphs 21, 23, 24 and 39 above are incorporated here as if fully set forth.

#### **ELEVENTH CAUSE FOR DISCIPLINE**

(General Unprofessional Conduct)

56. Respondent is subject to disciplinary action under section 2234 in that he committed general unprofessional conduct on or after May 15, 2007. The circumstances are as follows:

57. The facts and circumstances alleged in paragraphs 16 through 55 are incorporated

1 here as if fully set forth.

2 **DISCIPLINARY CONSIDERATIONS**

3 58. To determine the degree of discipline, if any, to be imposed on Respondent,  
4 Complainant alleges that on or about August 26, 2002, in a prior disciplinary action entitled *In the*  
5 *Matter of the Accusation Against Richard Lee, M.D.*, before the Medical Board of California, in  
6 Case No. 23-2001-125091, Respondent's license was revoked, the revocation was stayed and  
7 Respondent was placed on probation for five years and was ordered to pay a civil penalty of  
8 \$25,000 for violating Business and Professions Code sections 2242 and 2242.1 when he  
9 prescribed prescription medication for treatment of hair loss to a single patient over the internet  
10 without having appropriately examined the patient. That decision is now final.

11 **PRAYER**

12 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
13 and that following the hearing, the Medical Board of California issue a decision:

- 14 1. Revoking or suspending Physician's and Surgeon's Certificate Number G14329,  
15 issued to Richard Lee, M.D.;
- 16 2. Revoking, suspending or denying approval of Respondent's authority to supervise  
17 physician assistants, pursuant to section 3527 of the Code;
- 18 3. Ordering Richard Lee, M.D., if placed on probation, to pay the Medical Board of  
19 California the costs of probation monitoring;
- 20 4. Ordering Richard Lee, M.D., to pay civil penalties, pursuant to section 2242.1 of the  
21 Code; and
- 22 5. Taking such other and further action as deemed necessary and proper.

23  
24 DATED: May 29, 2014

  
KIMBERLY KIRCHMEYER  
Executive Director  
Medical Board of California  
Department of Consumer Affairs  
State of California  
Complainant

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