BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Petition to Revoke Probation Against: **HEIDI L. MEDEIROS** **4226 Valley Avenue** **Martinez, CA 94553** **Pharmacy Technician License No. TCH 25025** Respondent.	Case No. 3837 **DEFAULT DECISION AND ORDER** [Gov. Code, §11520]

FINDINGS OF FACT

1. On or about December 17, 2010, Complainant Virginia Herold, in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, filed Petition to Revoke Probation No. 3837 against Heidi L. Medeiros (Respondent) before the Board of Pharmacy. A copy of the Petition to Revoke Probation is attached as exhibit A.

2. On or about February 4, 1998, the Board of Pharmacy issued Pharmacy Technician License Number TCH 25025 to Heidi L. Medeiros (Respondent). The License was in effect at all times relevant to the charges brought herein and will expire on April 30, 2011, unless renewed.

3. In a disciplinary action titled "In the Matter of Accusation Against Docs Pharmacy Inc., Robert Eugene Horwitz, Jamey Phillip Sheets, Heidi L. Medeiros, Margo N. Cantrell," Case No. 2427, the Board of Pharmacy issued a Decision and Order, effective March 31, 2002, in which Respondent's Pharmacy Technician License was revoked. However, revocation was stayed, and Respondent's License was placed on probation with terms and conditions for five (5) years. A copy of that Decision and Order is attached as exhibit B.

4. On or about December 30, 2010, Respondent was served by Certified and First Class Mail with copies of: Petition to Revoke Probation No. 3837; a Statement to Respondent; a Notice of Defense (2 copies); a Request for Discovery; and Discovery Statutes (Gov. Code, §§ 11507.5, 11507.6, 11507.7) to Respondent's address of record, 4226 Valley Avenue, Martinez, CA 94553. Pursuant to Business and Professions Code section 136 and/or 4100, and/or California Code of Regulations, title 16, section 1704, Respondent's address of record, and any changes thereto, are required to be reported and maintained with the Board of Pharmacy (Board).

5. Service of the Petition to Revoke Probation was effective under Government Code section 11505, subdivision (c) and/or Business and Professions Code section 124.

6. On or about January 26, 2011, the copies of the aforementioned documents served by Certified Mail were returned by the U.S. Postal Service marked "Unclaimed."

7. Government Code section 11506 states, in pertinent part:

> (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense, and the notice shall be deemed a specific denial of all parts of the accusation not expressly admitted. Failure to file a notice of defense shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

8. Respondent failed to file a Notice of Defense within 15 days after service upon her of the Petition to Revoke Probation, and therefore waived her right to a hearing on the merits of Petition to Revoke Probation No. 3837.

9. California Government Code section 11520 states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence . . . .

10. Pursuant to its authority under Government Code section 11520, the Board finds Respondent is in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Investigatory Evidence Packet in this matter, as well as taking official notice of all the investigatory reports, exhibits and statements contained therein on file at the Board's offices regarding the allegations contained in Petition to Revoke Probation No. 3837, finds that the charges and allegations in Petition to Revoke Probation No. 3837, are separately and severally true and correct by clear and convincing evidence.

DETERMINATION OF ISSUES

1. Based on the foregoing findings of fact, Respondent Heidi L. Medeiros has subjected her Pharmacy Technician License No. TCH 25025 to discipline.

2. The agency has jurisdiction to adjudicate this case by default.

3. The Board of Pharmacy is authorized to revoke Respondent's Pharmacy Technician License based upon the following violations in the Petition to Revoke Probation supported by the evidence contained in the Default Decision Investigatory Evidence Packet in this case:

a. In violation of Term and Condition 5 of the probation imposed by the Decision and Order of the Board in Case No. 2427, Respondent failed to timely submit quarterly reports;

b. In violation of Term and Condition 7 of the probation ordered in Case No. 2427, Respondent failed to timely submit compliant employer acknowledgments;

c. In violation of Term and Condition 8 of the probation ordered in Case No. 2427, Respondent failed to timely make cost recovery payments to the Board;

d. In violation of Term and Condition 11 of the probation ordered in Case No. 2427, Respondent failed to timely notify the Board of her change(s) in employment;

e. In violation of Term and Condition 12 of the probation ordered in Case No. 2427, Respondent failed to maintain consistent employment as a Pharmacy Technician; and

f. In violation of Term and Condition 6 of the probation ordered in Case No. 2427, Respondent failed to cooperate with Board staff ensuring her compliance with probation.

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ORDER

IT IS SO ORDERED that Pharmacy Technician License No. TCH 25025, heretofore issued to Respondent Heidi L. Medeiros, is revoked.

Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondent. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective on May 11, 2011.

It is so ORDERED April 11, 2011.

STANLEY C. WEISSER, BOARD PRESIDENT
FOR THE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

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DOJ Matter ID:SF2010202629

Attachments:
Exhibit A: Petition to Revoke Probation
Exhibit B: Decision and Order in Case No. 2427

Exhibit A

Petition to Revoke Probation

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Supervising Deputy Attorney General
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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Petition to Revoke Probation Against: **HEIDI L. MEDEIROS** **4226 Valley Avenue** **Martinez, CA 94553** **Pharmacy Technician License No. TCH 25025** Respondent.	Case No. 3837 **PETITION TO REVOKE PROBATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Petition to Revoke Probation solely in her official capacity as the Executive Officer, Board of Pharmacy, Department of Consumer Affairs.

2. On or about February 4, 1998, the Board of Pharmacy issued Pharmacy Technician License Number TCH 25025 to Heidi L. Medeiros (Respondent). The License was in effect at all times relevant to the charges brought herein and will expire on April 30, 2011, unless renewed.

3. In a disciplinary action titled "In the Matter of Accusation Against Docs Pharmacy Inc., Robert Eugene Horwitz, Jamey Phillip Sheets, Heidi L. Medeiros, Margo N. Cantrell," Case No. 2427, the Board of Pharmacy issued a decision, effective March 31, 2002, in which Respondent's Pharmacy Technician License was revoked. However, revocation was stayed, and Respondent's License was placed on probation with terms and conditions for five (5) years. A copy of that decision is attached as exhibit A and is incorporated by reference.

JURISDICTION AND STATUTORY PROVISIONS

4. This Petition to Revoke Probation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated. Section 4402(e) of the Code provides that any non-pharmacist license issued by the Board may be canceled if not renewed within 60 days after expiration, and any license canceled in this fashion may not be reissued but will instead require a new application to seek reissuance.

FACTUAL BACKGROUND

8. On or about April 16, 2002, pursuant to Term and Condition 5 of the Decision and Order imposing probation on Respondent's License, Respondent appeared in person at the Board offices for an initial probation meeting and interview. During that meeting, all of the terms and conditions were explained to Respondent. She signed a declaration acknowledging that the Board staff had "fully explained" all of the terms to her, agreeing that she "thoroughly underst[ood]" all the terms, and agreeing that any failure to comply could result in further disciplinary action.

9. On or about October 11, 2002, following service of Respondent's initial suspension period of 90 days pursuant to Term and Condition 1 of the Decision and Order, Board staff sent a letter to Respondent explaining that pursuant to Term and Condition 2 of the Decision and Order, her License was suspended and that it would remain suspended until such time as she submitted satisfactory proof of certification by the Pharmacy Technician Certification Board (PTCB).

10. On or about February 11, 2005, Board staff sent Respondent another letter, reiterating the ongoing suspension of her license pursuant to Term and Condition 2 for failure to submit the required proof of PTCB certification, and further reiterating her obligation to nonetheless comply with other terms and conditions of probation, including her obligation to pay cost recovery (Term and Condition 8), and her obligation to submit quarterly reports (Term and Condition 5).[1] The letter set a deadline for the submission of Respondent's first quarterly report of April 10, 2005.

11. On or about January 25, 2006, Respondent sent a letter to the Board stating: that she planned to return to practice under her License on or about February 6, 2006; and that she had not to that point been practicing under her License for the three prior years. Respondent asked that she be permitted to pay cost recovery at a rate of $100 per month, before the 20th of each month. Along with her letter, Respondent submitted proof of her certification by the PTCB.

12. On or about February 10, 2006, Board staff sent Respondent a letter acknowledging receipt of the proof of certification by the PTCB, informing Respondent that the suspension was lifted, and authorizing her to return to work. The letter also enclosed the forms and documents necessary for Respondent to comply with Term and Condition 7 (Notice to Employers).

13. On or about March 1, 2006, Board staff sent Respondent another letter, approving her requested payment plan of $100 per month, and requiring Respondent to begin making payments.

14. Respondent was employed as a Pharmacy Technician from in or about February 2006 to in or about November 2006. During this time Respondent failed to submit paperwork required by Term and Condition 7 (Notice to Employers). Upon leaving that employment, Respondent did not submit a notification to the Board pursuant to Term and Condition 11.

15. Respondent submitted one quarterly report pursuant to Term and Condition 5, on or about April 25, 2006. She has not submitted another quarterly report, since or prior to that date.

16. Respondent's last payment toward cost recovery pursuant to Term and Condition 8 was received on or about August 3, 2006. The balance outstanding is $4,145.00.

17. Respondent has not practiced under her License since in or about November 2006.

[1] The letter also referenced Term and Condition 12 (Tolling of Probation), which prohibits a period of tolling due to non-practice in excess of three consecutive years.

FIRST CAUSE TO REVOKE PROBATION

(Failure to Timely Submit Quarterly Report(s))

18. At all times after the effective date (March 31, 2002) of the Decision and Order imposing probation on Respondent's License, Term and Condition 5 of that Order required that Respondent report to the Board quarterly, on a schedule as directed by the Board or its designee, either in person or in writing, as directed. No quarterly report was submitted to the Board by Respondent in 2002, 2003, 2004, 2005, 2007, 2008, 2009, or 2010, despite transmission by Board staff of one or more non-compliance letter(s) documenting Respondent's failure to submit. The only quarterly report submitted by Respondent was received on or about April 25, 2006. This failure to timely submit quarterly report(s) subjects Respondent's License to revocation.

SECOND CAUSE TO REVOKE PROBATION

(Failure to Timely Submit Compliant Employer Acknowledgment(s))

19. At all times after the effective date (March 31, 2002) of the Decision and Order imposing probation on Respondent's License, Term and Condition 7 of that Order required that Respondent notify her employer(s) of the decision in Case No. 2427, and that within 30 days (or within 15 days of undertaking new employment) she cause such employer(s) to submit a written acknowledgment of the decision in which her direct supervisor, pharmacist-in-charge, and owner each report that they have read the decision in Case No. 2427 and terms and conditions thereof. During her employment in and/or between February and November 2006, Respondent failed to timely submit written acknowledgment(s) from her employer(s). This failure to timely submit written acknowledgment(s) subjects Respondent's License to revocation.

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THIRD CAUSE TO REVOKE PROBATION

(Failure to Timely Pay Cost Recovery)

20. At all times after the effective date (March 31, 2002) of the Decision and Order imposing probation on Respondent's License, Term and Condition 8 of that Order required that Respondent pay to the Board its costs of investigation and prosecution totaling $4,645.00, making payments as arranged with the Board. Respondent made no payments in 2002, 2003, 2004, or 2005. After approval of her request to make payments of $100.00 per month, Respondent made five monthly payments, with her last payment received on or about August 3, 2006. No payment on the outstanding balance of $4,145.00 has been received since that time. This failure to make timely payment(s) toward cost recovery subjects Respondent's License to revocation.

FOURTH CAUSE TO REVOKE PROBATION

(Failure to Timely Submit Notification(s) of Change in Employment)

21. At all times after the effective date (March 31, 2002) of the Decision and Order imposing probation on Respondent's License, Term and Condition 11 of that Order required that Respondent notify the Board within 10 days of any change in employment (or mailing address). At no time has Respondent timely notified the Board within 10 days of a change in employment, including her departure from employment as a Pharmacy Technician in November 2006. This failure to timely notify the Board of such change(s) subjects Respondent's License to revocation.

FIFTH CAUSE TO REVOKE PROBATION

(Failure to Maintain Employment as a Pharmacy Technician)

22. At all times after the effective date (March 31, 2002) of the Decision and Order imposing probation on Respondent's License, Term and Condition 12 of that Order required that Respondent not have more than three consecutive years of non-practice as a Pharmacy Technician at any time during probation. Respondent was out of practice for more than three years prior to February 2006, and/or for more than three years following November 2006. This/these failure(s) to maintain employment as a Pharmacy Technician subject Respondent's License to revocation.

SIXTH CAUSE TO REVOKE PROBATION

(Failure to Cooperate with Board Staff)

23. At all times after the effective date (March 31, 2002) of the Decision and Order imposing probation on Respondent's License, Term and Condition 6 of that Order required that Respondent cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with probation.. The failure(s) to cooperate with Board staff, as described in paragraphs 8-22 above, subject Respondent's License to revocation.

OTHER MATTERS – EXTENSION OF PROBATION

24. At all times after the effective date (March 31, 2002) of the Decision and Order imposing probation on Respondent's License, Term and Condition 14 of that Order required:

> **14. Violation of Probation.**
>
> If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, the Board shall have continuing jurisdiction, and the period of probation shall be extended, until the petition to revoke probation or accusation is heard and decided.
>
> If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

25. Pursuant to the operation of Term and Condition 14 of the probation order applicable to Respondent's License, probation is automatically extended by the filing hereof, and/or by Respondent's failure to comply with the terms and conditions of probation, until such time as this Petition to Revoke Probation is heard and decided, or until the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation.

PRAYER

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

1. Revoking the probation that was granted by the Board of Pharmacy in Case No. 2427, and imposing the disciplinary order that was stayed, thereby revoking Pharmacy Technician License No. TCH 25025, issued to Heidi L. Medeiros;

2. Revoking or suspending Pharmacy Technician License No. TCH 25025, issued to Heidi L. Medeiros;

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

DATED: 12/17/10

Virginia Herold

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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Exhibit B

Decision and Order in Case No. 2427

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	
HEIDI L. MEDEIROS P. O. Box 2961 Martinez, CA 94553	Case No. 2427 OAH No. N2001080761-B
License No. TCH 25025	
Respondent.	

DECISION

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

This Decision shall become effective on March 31, 2002.

IT IS SO ORDERED March 1, 2002.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By: Steve Litsey
STEVE LITSEY
Board President

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: HEIDI L. MEDEIROS P. O. Box 2961 Martinez, CA 94553 License No. TCH 25025 Respondent.	Case No. 2427 OAH No. N2001080761-B

PROPOSED DECISION

This matter was heard before Administrative Law Judge Jonathan Lew, State of California, Office of Administrative Hearings on November 26 – 30, and December 3, 2001, in Oakland, California. [1]

Complainant was represented by W. Lloyd Paris, Deputy Attorney General.

Heidi L. Medeiros was present and represented by David J. Van Dam, Esq., Shuering, Zimmerman & Scully, LLP, 400 University Avenue, Sacramento, California 95825.

Submission of the case was deferred pending receipt of additional documents relating to pharmacy technician registration forms, cost certification and opposition to same. Registration forms were received, marked and admitted into evidence as Exhibit 109. Cost certification documents were received, marked and admitted into evidence as Exhibit 110. Opposition to complainant's certification of costs was received on December 14, 2001, and marked collectively as Exhibit D for identification.

The case was submitted for decision on December 14, 2001.

FACTUAL FINDINGS

1. Patricia F. Harris (complainant) brought the Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

[1] The Accusation named three respondents including pharmacist Jamey Phillip Sheets and pharmacy technicians Heidi L. Medeiros (N 2001080761-B) and Margo N. Cantrell (N 2001080761-C). Separate decisions will address allegations relating to each individual.

2. On February 4, 1998, the Board issued Pharmacy Technician License Number TCH 25025 to Heidi L. Medeiros (respondent). The Pharmacy Technician License was in full force and effect at all times relevant to this matter and will expire on April 30, 2003, unless renewed.

3. On February 23, 1999, the Board issued Pharmacy Permit Number PHY 44031 to Doc's Pharmacy Inc. Robert Eugene Horwitz (Horwitz) was the Pharmacist-in-Charge, President, Secretary and 51 percent shareholder of Doc's Pharmacy from February 23, 1999. Jamey Phillip Sheets (Sheets) was a 49 percent shareholder of Doc's Pharmacy from February 23, 1999. Horwitz recently agreed to surrender to the Board both the pharmacy permit for Docs Pharmacy and his individual pharmacist license. Doc's Pharmacy and Horwitz had been named as co-respondents in the Accusation against respondent.

Background

4. On May 11, 2001, three 100 ml vials of betamethasone were compounded at Doc's Pharmacy. This is a steroid that is administered parenterally to treat inflammation. Because it is injected into patients, it must be sterile. An employee at Doc's Pharmacy transferred betamethasone from the 100 ml vials that had been prepared on May 11 into smaller 10 ml vials. It is not clear when this transfer occurred or who did it, but it was per standard procedure followed at Doc's Pharmacy. These smaller 10 ml vials were then sent to different health care facilities in Contra Costa County. Between May 22 and May 31, 2001, a total of 38 patients at the Sierra Surgical Center in Walnut Creek were injected with this betamethasone. Of these patients thirteen were hospitalized, three have died, and the rest received follow up care. The three deaths were caused by complications secondary to acute bacterial meningitis.

5. County health officials conducted an extensive investigation and impounded betamethasone compounded at Doc's Pharmacy from three locations – Sierra Surgery Center, Diablo Valley Surgery Center and Diablo Orthopedic. All of the 24 vials removed from the Sierra Surgical Center tested positive for a bacteria known as Serratia marcescens (Serratia). Twenty-three of the vials had been used for surgery. One vial remained sealed and it was also contaminated with Serratia.

All ten vials of betamethasone taken from Diablo Valley Surgical Center were contaminated. These ten vials were sealed. A single vial from Diablo Orthopedic Medical Group tested positive for Serratia.

In addition, a county senior microbiologist collected and cultured environmental samples from the work area inside Doc's Pharmacy where the betamethasone was compounded. Serratia was cultured from the interior of a homogenizer and from a stock solution of carboxymethylcellulose. Both were used in the compounding of betamethasone. A sink drain board and sink handles near the compounding area also tested positive for Serratia.

Other batches of betamethasone compounded at Doc's Pharmacy, but not on May 11, were also tested. No Serratia was cultured from these betamethasone samples.

Allegations

6. The Accusation contains three allegations relating to respondent. First, complainant contends that respondent committed acts of gross negligence relating to procedures that she used in compounding medications, including the contaminated betamethasone. Second, complainant contends that respondent failed to work under the direct supervision of a registered pharmacist when compounding medications, and that pharmacists were not fully aware of all her activities in the preparation and dispensing of medications. Third, complainant alleges that respondent violated pharmacy laws and regulations relating to the labeling of parenteral products and the wearing of proper name tags identifying herself as a pharmacy technician.

Compounding of Betamethasone

7. Doc's Pharmacy obtained a suggested formula for betamethasone repository injections from Professional Compounding Centers of America (PCCA), a supplier of bulk pharmaceuticals and technical assistance to compounding pharmacists. This formula contained a list of all the ingredients needed to prepare a specific amount of betamethasone together with specific instructions to be followed in compounding this medication. This information was then added to a computer database maintained at Doc's Pharmacy, and every time this, or any other medication was compounded at Doc's Pharmacy, a pharmacist or pharmacy technician would retrieve the formula from the computer and print a hard copy. This printed document was known as the "Formula Log," and it served multiple purposes. The formula log indicates when the log was printed and by whom, the quantity to be compounded, the lot number of the compounded medication, identification and quantity and lot number of all ingredients, and compounding instructions. A block stamp was typically added to the formula log to serve as a checking procedure for compounded medications. This was to be initialed after certain steps were completed, and it listed three checking categories: "Label to Log," "Filled By" and "Checked By," and an adjacent line for initials.

8. Autoclave Setting. The betamethasone compounded on May 11, 2001, was prepared per standard procedures followed at Doc's Pharmacy. Respondent prepared a total of 300 ml. It was poured into three 100 ml vials that were taken next door to a physician's office to be autoclaved. It was off the pharmacy premises and respondent used the autoclave alone, unsupervised by either Horwitz or Sheets. Autoclaving was essentially the final step after all ingredients were combined, and it was intended to sterilize the compounded betamethasone. The formula log references only one activity to take place after autoclaving – shaking the compound while cooling.

Both the PCCA and formula log specified the autoclave temperature, pressure and time settings to be used for betamethasone. It was to be autoclaved at 115° C, 15 pounds per square inch (psi) for 20 minutes. There were no notations on the formula log to indicate that

a pharmacist had authorized any variance from these settings or that any discretion could be exercised in autoclaving the betamethasone.

9. The autoclave used by Doc's Pharmacy had four programmed settings, one each for unwrapped objects, pouches, liquids and packs. The temperature, pressure and time could not be independently set. Earlier in April 2001, respondent had noticed discoloration of a batch of betamethasone after it had been autoclaved on the liquids setting. She raised this matter with Horwitz and even provided him with a sheet that detailed the temperature, pressure and time for each of the four settings. She insisted that Horwitz call PCCA to obtain the correct autoclave setting, and she believes that he did so. Horwitz gave verbal authorization to respondent to use the pouches setting. This authorization was never documented.

The pouches' setting provided that the betamethasone would be autoclaved at 132° C, 27 psi for 15 minutes. This varied from the PCCA and formula log settings by increasing the temperature and pressure, but by also decreasing the autoclave time by 5 minutes.

10. The written instructions for use of the autoclave were available and seen by both Horwitz and respondent. These instructions were easily accessible to pharmacy technicians. On the first page, and in bold type, under the column for items to be sterilized it read: "**Not recommended for sterilization of liquids intended for direct patient contact.**"

11. The standard of care for autoclaving compounded medications is to use an autoclave that can be set to the exact settings specified in the PCCA and formula log. The autoclave used on May 11 could not be set to the specifications required for compounding betamethasone. The temperature and pressure were higher than needed, and the time was too short. Different settings may be used only after running tests with a positive control (live bacteria) in order to test the effectiveness of the different setting. This was not done in this case. If a decision is made to vary the settings from that specified by the PCCA and formula log, it must also be documented in writing and this was never done. Only a pharmacist can make such a decision, not a pharmacy technician.

Importantly, the operating instructions highlighted the fact that the autoclave was not to be used for sterilizing liquids intended for direct patient contact. It was an extreme departure from the standard of care or gross negligence to use this particular autoclave to sterilize the betamethasone. It was also gross negligence to employ the pouches' setting on this autoclave to sterilize this compound without first testing that setting with a positive control and then culturing it for bacteria.

No records of the autoclaving process were maintained at Doc's Pharmacy. Respondent used sterilization strips with each product that she autoclaved. To her credit she initiated this procedure on her own, but she tossed the test strips after autoclaving. Doc's Pharmacy had no procedure regarding the use of sterilization test strips.

12. Cold Sterilization. After the betamethasone was autoclaved and cooled, it was transferred to smaller 10 ml vials. These smaller vials were not sterile. Although sterile bottles could easily be obtained for this purpose, Doc's Pharmacy purchased less expensive non-sterile vials and employed a process of "cold sterilization" instead. This is a method by which isopropyl alcohol was squirted into and outside the 10 ml vials and their rubber stoppers and aluminum caps, and these items were then placed atop sterile gauze to dry under a laminar flow hood. Horwitz was a proponent of this method, and he instructed pharmacy technicians in this technique. Respondent explained that she would typically clean the hood area and then spray each vial four times with isopropyl alcohol until the smell pervaded the entire hood. The vials, stoppers and caps were then left to dry under the hood.

Isopropyl alcohol may be useful as a disinfectant, but it is not a sterilizing agent. It was an extreme departure from the standard of care or gross negligence to use isopropyl alcohol to sterilize the 10 ml vials. Joanne Whitney, Ph.D., Pharm.D. testified as an expert witness on behalf of complainant. She is the Director, Drug Product Services Laboratory, Department of Clinical Pharmacy, School of Pharmacy, University of California, San Francisco. She opines that pharmacy technicians and most certainly pharmacists should know that isopropyl alcohol is not a sterilizing agent. She expressed shock that pharmacists and pharmacy technicians at Doc's Pharmacy did not know this.

13. Respondent was introduced to and instructed in compounding by Horwitz. She received no formal instruction in aseptic/sterile technique. In September or October 1998, Horwitz began teaching her laminar airflow hood technique and "cold sterilization" as part of her compounding work. She never questioned the practice, and she had never been taught otherwise by Horwitz or Sheets. She never observed anything in pharmacy settings to suggest that it was poor practice. It should be common knowledge to a pharmacy technician engaged in compounding that isopropyl alcohol spray is no substitute for autoclaving a compound intended for parenteral injection.

It was an extreme departure from the standard of care, or gross negligence, for respondent to rely upon isopropyl alcohol spray to ensure the sterility of a compounded medication. However, "cold sterilization" was also practiced by both pharmacists on site and they, not respondent, were ultimately responsible for ensuring the integrity of drug products compounded at Doc's Pharmacy.

14. Failure to Autoclave 10 ml Vials. After the 100 ml vials of betamethasone were transferred into the smaller vials, they were not autoclaved. The PCCA formula called for filling 20 of the 5 ml serum vials and then crimping and sealing them. The final step was autoclaving these smaller vials at 115° C, 15 psi for 20 minutes. As previously discussed, the practice at Doc's Pharmacy was to autoclave the 100 ml vials, and then aliquot the betamethasone into 20 smaller vials. This would have been acceptable if sterile 10 ml vials had been used to begin with. Because sterile vials were not used, the standard of care would be to autoclave the betamethasone in the smaller vials as the final step. The failure to do so was a significant deviation from the PCCA formula and an extreme departure from the

standard of care or gross negligence. Respondent was aware that the betamethasone was typically transferred into smaller vials that were not autoclaved.

15. Labeling/Recordkeeping. Labeling is the cornerstone of and is basic to the practice of pharmacy. General labeling practices at Doc's Pharmacy will be considered in a later section, but with regard to the betamethasone compounded on May 11, 2001, the dates on the 10 ml vials did not correspond to the date that the betamethasone was actually compounded. Rather, the dates corresponded to a date the betamethasone was put into the smaller vials after May 11. This is an issue in terms of setting the correct expiration date, which runs from the date a medication is compounded, and it is also an issue in terms of being able to trace a medication back to the corresponding formula log and related compounding history. There was added confusion in this case because the formula log for the betamethasone compounded on May 11 was dated May 9, 2001. This corresponded to the date that the formula log was retrieved from the pharmacy's database, not to when it was actually compounded. Because the formula log served as Doc's Pharmacy's primary documentation for compounded medications, it was initially assumed that the contaminated betamethasone was prepared on May 9.

There were also labeling issues around the stock materials used to compound the betamethasone. Some of the ingredients came directly from a manufacturer or supplier such as PCCA. Other ingredients were made at the pharmacy. Stock materials were not properly labeled. They were often missing the date materials were prepared, storage conditions, the person who prepared it, lot numbers, expiration dates, or the source of a particular ingredient.

The failure to properly label the betamethasone vials with the date that it was actually compounded, and the failure to provide all necessary labeling information on certain stock materials used to compound the betamethasone constituted extreme departures from the standard of care, or gross negligence.

16. There were also numerous recordkeeping violations. The standard of care is to record the log numbers and expiration dates of all ingredients used in the compounding of betamethasone. This is necessary for several reasons. It may become necessary to trace where an ingredient came from or where it was used if a problem arises or in the case of a product recall. Importantly, the expiration date of a compounded medication is generally the lesser of 180 days, or the expiration date of any one of the ingredients used. The betamethasone formula log used by Doc's Pharmacy had a column for ingredient lot numbers. For the ten ingredients used to make betamethasone no lot numbers were listed. Either a "NA" or "None" was entered in the column for lot number. It was impossible to determine from the formula log what the lot numbers or expiration dates for the ingredients were, and there was no separate documentation of this information elsewhere at the pharmacy. While some ingredients may not have an expiration date, it is certain that others did, and it is this total absence of recordkeeping that is troubling. Doc's Pharmacy did maintain a drug movement report which confirmed where the betamethasone had been sent, and this report was used by county health officials to recover the contaminated vials.

The failure to maintain records of the lot numbers and expiration dates of ingredients used to compound the betamethasone was an extreme departure from the standard of care or gross negligence.

Additional Compounding Violations

17. Supervision of Pharmacy Technicians. Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is on the premises at all times and is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records. A pharmacy technician may compound medications only under the immediate, personal supervision and control of a pharmacist and within the pharmacist's view. (Cal. Code Regs., tit. 16, § 1793.7, subd. (c).) Pharmacists are not required to stand over the shoulder of pharmacy technicians while they are compounding. However, they need to be in the same room and situated so that they can continually make certain that everything is going correctly. Pharmacists should ensure that pharmacy technicians are properly attired, and that they are using proper sterile/aseptic technique under the laminar flow hood, using the right equipment, products and solvents. If incorrect procedures are being used the pharmacist needs to be able to intervene. During important compounding steps, the pharmacy technician must stop to have a pharmacist check critical weights or volumes. The pharmacist must ultimately sign off on the compounded medication and by so doing verifies that every single step was done correctly. If a pharmacist is away from the compounding area for any length of time, the pharmacy technician should stop compounding until a pharmacist is available to provide supervision. The compounding area must be within the pharmacist's line of sight at all times.

The compounding area at Doc's Pharmacy was in the far back of the store and not within line of sight of most areas of the pharmacy. A set of storage shelves stood between the dispensing and compounding areas so that a pharmacist working in the front area would not be able to observe or supervise a pharmacy technician compounding in the back. Pharmacists often worked in the front of the pharmacy, and Horwitz admitted that technicians could not be supervised when he was in the front. Autoclaving was done off the pharmacy premises next door. Pharmacy technicians were routinely allowed to go off the premises unsupervised during this part of a compounding procedure. The autoclave was not within sight of a pharmacist within Doc's Pharmacy.

It was established that pharmacy technicians at Doc's Pharmacy routinely compounded parenteral medications outside the direct supervision of a pharmacist. They were often alone and not within a pharmacist's line of sight. Pharmacists never supervised autoclaving. This was an extreme departure from the standard of care, or gross negligence.

18. Laminar Flow Hood Technique. Sterile aseptic technique is critical for all work under a laminar flow hood. The hood itself should be wiped down frequently and a cleaning record maintained. Individuals working under the hood should wear no jewelry – no earrings, rings, necklaces or bracelets. Gloves must be worn, preferably sterile. Hands

should remain under the hood, and, if taken out repeatedly, the gloves should be washed and dried with alcohol before going back in, or new gloves worn. Long sleeve or loose clothing that might harbor particles should not be worn. Gowns may be worn over such clothing as well as a cap for hair.

Respondent demonstrated the technique that she used under the laminar flow hood. A Board investigator also observed her in the compounding area on June 6, 2001, as she was setting up to work in the laminar flow hood. She put her hands into and out of the laminar flow hood area more than three times, and she did not do anything to her hands between the time they were in and out of the hood. Doc's Pharmacy provided clean, but not sterile gloves. Respondent initially washed her hands before putting the gloves. She kept her ring on, visible underneath a glove. She wore a long sleeve denim shirt. This was the uniform provided by Doc's Pharmacy, and it was not covered with a gown. No documentation was kept to show when the parenteral compounding area was cleaned.

It was an extreme departure from the standard of care, or gross negligence, to wear jewelry while compounding, to place hands into and out of the laminar flow hood without washing and to wear a long sleeve denim shirt while compounding parenteral medications. It constitutes a failure to use aseptic sterile technique.

19. Labeling of Stock Solutions/ Labeling Generally. Reference is made to Finding 15. Stock solutions were not labeled consistently with the date of preparation, expiration date, lot number or storage indications. A stock solution of carboxymethylcellulose was stored in a refrigerator in a plastic container that allowed entry with a plastic syringe. It was not a sterile product. There was no expiration date, preparation date, storage instruction or indication of who had prepared the product. There were also vials of insulin meant for cats that were unlabeled, vials in a bag with no labels and a tray containing vials that were not labeled. A Board inspection in June revealed improperly labeled vials and suppositories stored in a refrigerator. The medications were missing names, lot numbers and expiration dates. Labeling practices for compounded medications were at times confusing, inaccurate or inconsistent. For example, when a compounded prescription was refilled, it was assigned a lot number that corresponded to the original prescription number even though the re-fill prescription was compounded from a different batch.

The above examples appear to be representative of labeling/recordkeeping practices for compounded medications and stock solutions at Doc's Pharmacy. Were they but isolated instances, it would be simple negligence. But Board inspectors repeatedly encountered improperly labeled bottles, and it was an extreme departure from the standard of care, or gross negligence, for this degree of poor labeling to occur. Ultimate responsibility for these practices rests with the supervising pharmacists.

20. Formula Logs. Reference is made to Finding 7. Doc's Pharmacy used the formula log as its primary means of documenting the preparation of compounded medications. The formula log dates were computer generated and corresponded to when the log was retrieved from the computer. It did not necessarily correspond to the dates the

medication was compounded. For example, the formula log for the bethamethasone compounded on May 11 was actually dated May 9, 2001. (Finding 15.) From the face of the formula log it appeared that pharmacy technicians, and not pharmacists, did the final sign off for some compounded medications. Under the block stamped "COMPOUNDED MEDICATION CHECKING PROCEDURE" pharmacy technicians would initial the line for "checked by," thereby suggesting that a pharmacy technician, and not a pharmacist, approved the final product. Pharmacy technician initials also appeared on the printed portion of the formula log under "Auth'd By" and to an outside observer this created confusion over whether this meant that a pharmacy technician authorized a particular compounded medication. In fact, "Auth'd By" only meant that the formula log was retrieved from the computer by that individual.

Actual practice at Doc's Pharmacy was to have a pharmacist approve all compounded medications before it was dispensed. The final check by a pharmacist was not documented anywhere in particular. Although the formula log was left on a counter for a pharmacist to review and sign, Horwitz would often initial only the medication label, and leave no initial on the formula log or anywhere else to document the fact of his review. Sheets was more careful about reviewing and approving compounded medications, but it was still difficult to determine from the face of formula logs whether a final review and authorization was done by him. His initials on a formula log would not necessarily mean that he conducted a final check. For example, initials on the formula log often indicated that a pharmacist checked the quantity of active ingredients prior to a pharmacy technician compounding them. This is called a "scale check" and it was done early in the compounding process.

The formula logs were very confusing to outside observers. It was difficult to tell whether a pharmacy technician or a pharmacist had authorized the medication as being "checked," and it was often impossible to tell from the formula log which pharmacist had responsibility for supervising and approving the preparation of a given compounded medication.

It would be an extreme departure from the standard of care to have a pharmacy technician approve a compounded medication. Although the formula log suggests as much, this did not, in fact, occur. One is basically left with very confusing and poor documentation of the pharmacist's involvement in the checking procedure. It was a departure from the standard of care for this to be so.

Additional Violations of Pharmacy Law

21. The Board may take disciplinary action against a pharmacy technician who is guilty of unprofessional conduct. Unprofessional conduct includes the violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs. (Bus. & Prof. Code, § 4301, subd. (j).) It also arises from violation of any provision or term of Chapter 9 of the Business and Professions Code or applicable federal and state laws and regulations governing pharmacy, including regulations established by the Board. (Bus. & Prof. Code, § 4301, subd. (o).)

Respondent engaged in unprofessional conduct insofar as she failed to comply with the following matters required by statutes or regulations:

a. Supervision of Pharmacy Technicians. The performance of duties by a pharmacy technician must be under the direct supervision and control of a pharmacist, and any pharmacist responsible for a pharmacy technician must be on the premises at all times, and the pharmacy technician must be within the pharmacist's view. (Bus. & Prof. Code, § 4115, subd. (f).) A pharmacy technician must work under the direct supervision of a pharmacist and in such a manner that the pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records. (Cal. Code Regs., tit. 16, § 1793.7, subd. (c).) Reference is made to the matters set forth in Finding 17. Pharmacy technicians were not adequately supervised during the preparation of compounded medications. Pharmacy technicians were not supervised during compounding activity when autoclaving occurred outside the pharmacy.

b. Labeling of Parenteral Products. Pharmacies that compound parenteral products, in addition to existing labeling requirements, must also include the telephone number of the pharmacy, name, concentration of all ingredients and instructions for storage and handling on the medication' label. Labeling practices at Doc's Pharmacy were inconsistent and sometimes nonexistent where vials were found to be unlabeled. Reference is made to Findings 15 and 19. The procedures used by Doc's Pharmacy to label work in progress and finished products were below accepted pharmacy standards.

The recordkeeping for drugs compounded for future furnishing was most confusing. For example, a formula log for betamethasone dated May 17, 2001, for three 100 ml bottles was printed. There are handwritten check marks and calculations alongside all ingredients. The block for "Compounded Medication Checking Procedure" is completely initialed on all three lines. On paper there is every indication that betamethasone had been compounded on that date. Yet, this never occurred. A tray of unmarked vials of betamethasone was discovered at the last moment. It had been compounded earlier in May and it was dispensed instead of making a new batch. Although the May 17 batch was never made, everything in the records indicated otherwise. The matter could only be clarified through the memory of a pharmacy technician.

c. Name Tags. A pharmacy technician must wear identification clearly identifying her as a pharmacy technician. (Cal. Code Regs., tit. 16, § 1793.7, subd. (d).) This prevents a consumer from confusing a pharmacy technician with a pharmacist, and helps a technician from being placed in the awkward position of having to answer questions that should be addressed to a pharmacist. The practice of wearing nametags was followed at Doc's Pharmacy, but on at least one occasion respondent and pharmacy technicians Cantrell were observed without a name tag.

Respondent's Background and Experience

22. Respondent graduated from high school in 1990, and she took community college and business school classes through 1992. She received a certificate for medical office work and then completed pharmacy technician training through employment with Thrifty/Payless pharmacies. She began work at Thrifty's on August 6, 1994. She worked at the Palos Verdes store in Walnut Creek with duties consisting of answering phones, prescriptions, making labels and pulling medications corresponding to the labels. This was largely clerical work. She did no compounding and she received no training in sterile/aseptic technique. On March 15, 1997 she started work at Doc's Pharmacy.

23. Doc's Pharmacy. Respondent became registered as a pharmacy technician based on certification by employing pharmacists, including Horwitz, that she had completed at least 1,500 hours performing duties as a pharmacy clerk-typist within the past three years. She received her certificate in February 1998, and, thereafter, Horwitz began providing her on the job training in compounding medications. She learned to generate and then follow formula log sheets. Horwitz would oversee all her training and work product. She learned to compound capsules, suspensions and lotions. She also took a PCCA course in April 1998, but she does not recall being instructed in aseptic or sterile technique as a part of that course, or at any other time.

Horwitz was well known and respected in the area of compounding pharmacy. He was recipient of the 1998 PCCA "Compounder of the Year." PCCA has close to 6000 members and Horwitz was a recognized expert on the subject of compounding. Horwitz was responsible for educating all pharmacy technicians who engaged in compounding at Doc's Pharmacy.

24. Matters in Mitigation. Respondent compounded the betamethasone on May 11, but left the batch in the three 100 ml bottles after they were autoclaved. She did not aliquot the betamethasone into the 10 ml vials, and she does not know who did so because she went on vacation after she made the batch. She does acknowledge following the same "cold sterilization" procedures at issue on other occasions when she had prepared and then aliquotted betamethasone into smaller vials. With regard to the different autoclave settings, it was respondent who brought the matter to the attention of Horwitz. She specifically asked him to confirm with PCCA whether one of the four different settings (pouches) was appropriate for sterilizing betamethasone. She proceeded to use the pouches' setting only after Horwitz authorized her to do so. On her own she routinely used autoclave strips, and she also adopted the practice, on her own, of cleaning and wiping down the compounding area with isopropyl alcohol before compounding a new product. Respondent would have Horwitz check active ingredients during scale checks, and she would press him to sign off on any compounded medications when final checks were needed. She was not aware until this case that she was supposed to be in a pharmacist's line of sight during compounding.

25. Respondent left Doc's Pharmacy in July 2001. She is unemployed but has an offer to work with UCSF poison control as a pharmacy technician.

Respondent has been cooperative with Board investigators and has been forthright about her own involvement. She performed her work as a pharmacy technician exactly as she was trained to do. Horwitz was the pharmacist in charge, and he was clearly the one most responsible for all that occurred. He established all of the pharmacy practices challenged in this case. He was responsible for the daily operations of Doc's Pharmacy and ultimately for the pharmacy's compliance with all pharmacy laws. Doc's Pharmacy is now closed. Horwitz is no longer practicing pharmacy. Protection of the public health and safety is furthered by these actions.

Respondent received all of her training in compounding from Horwitz. She had never worked in compounding before, and, therefore, she had nothing with which to compare the practices at Doc's Pharmacy as she encountered them. Mostly out of deference to and respect for Horwitz, she never thought to challenge established compounding procedures or to push hard for improved quality controls. She never completed a formal accredited pharmacy technician program. It was not unreasonable for someone in her position to accept what was taught by Horwitz to be the standard of practice in compound pharmacy.

26. Respondent is a dedicated pharmacy technician who has diligently observed all that she has been instructed to do. With additional education and restrictions on her pharmacy practice, including a prohibition against compounding any parenteral medications, she will present no danger to the public health or safety.

It will, therefore, not be contrary to the public interest to issue respondent a probationary license at this time.

27. Cost Recovery. The Board has incurred the following costs in connection with the investigation and prosecution of this case:

Inspector's Costs – 264.75 hours @ $65/hour	$17,208.75
Legal Analyst's Costs – 115.5 hours @ $53/hour	6,121.50
Attorney General's Costs – 71.5 hours @ $106/hour	7,579.00
149.25 hours @ $112/hour	16,716.00
Total Costs	$47,625.25

The Deputy Attorney General spent 150.75 hours in obtaining an interim suspension order and defending a writ of mandate. Hours billed exclusively to the preparation and prosecution of the accusation totaled 70.00. Mr. Paris notes that the prior work on the

interim suspension order greatly facilitated this work. It is reasonable to include the time spent preparing for and obtaining an interim suspension order as part of the investigation and prosecution of this case. The work overlaps to a degree with the preparation of a case for administrative hearing and Mr. Paris acknowledges as much. However, it is not reasonable to include time defending a writ of mandate. Although such was not specifically itemized, it is reasonable to reduce the 150.75 hours by 25 percent. Attorney General costs will be reduced by 37.6875 hours @ $112/hour = $4221. Legal analyst time should also be reduced a proportionate amount or 19.72 hours @ $53/hour = $1045.

The costs claimed in connection with investigator Dennis Ming were for 135.25 hours, out of which 100 hours was spent drafting reports summarizing the findings in his investigation. Investigator Jeff Smith was the primary investigator and he spent only 11 hours drafting reports summarizing the findings in his investigation. The costs claimed in connection with Mr. Ming's reports appear to be excessive and they should be reduced by 80 hours @ $65/hour = $5,200.

The allegations in this case largely involve pharmacists Horwitz and Sheets, and respondent only to a lesser degree. Apportionment of costs should therefore be made with respect to her. Pharmacy technicians Medeiros and Cantrell should account for no more than a quarter of total costs, or 12.5 percent each.

28. The $47,625.25 that the Board's seeks to recover as its costs shall be reduced by $10,466 per Finding 27. The reasonable costs of the investigation and prosecution of this case are determined to be $37,159.25. Respondent's share of cost is set at 12.5 percent of this total or $4645.

LEGAL CONCLUSIONS

1. Business and Professions Code section 4301 provides that the Board shall take action against any holder of a license who is guilty of unprofessional conduct. Unprofessional conduct includes gross negligence. (Bus. & Prof. Code, § 4301, subd. (c).)

2. Cause for disciplinary action exists against respondent under Business and Professions Code section 4301, subdivision (c), by reason of the matters set forth in Findings 7 through 20. Respondent committed acts of gross negligence that relate to the procedures and manner by which parenteral, sterile and non-sterile medications were compounded at Doc's Pharmacy.

4. Business and Professions Code section 4301, subdivision (j) provides that unprofessional conduct includes the violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs. Under subdivision (o), unprofessional conduct also includes violating or assisting in or abetting the violation of any provision of Chapter 9 of the Business and Professions Code or of applicable federal and state laws and regulations governing pharmacy.

Cause for disciplinary action exists against respondent under these sections, by reason of the matters set forth in Finding 21. Specific references are made in Finding 21 to the pharmacy laws and regulations that were violated by respondent.

5. Business and Professions Code section 125.3 provides that the Board 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. Reasonable costs in this case are determined to be $37,159.25, by reason of the matters set forth in Findings 27 and 28. Respondent's share of this should be 12.5 percent or $4645.

6. The matters set forth in Findings 22 through 26 were considered in making the following order. It would not be contrary to the public interest, health or safety to issue respondent a probationary license at this time. Respondent should be placed on five years probation with special conditions including remedial education and a prohibition against compounding parenteral medications until the Board deems it safe for her to do so.

ORDER

Pharmacy Technician License Number TCH 25025 issued to Heidi L. Medeiros is revoked; however, revocation is stayed, and respondent is placed on a probation for five (5) years upon the following terms and conditions:

1. Actual Suspension. As part of probation, respondent is suspended from the duties of a pharmacy technician for ninety (90) days beginning the effective date of this decision.

   During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, medical device retailer, food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs, controlled substances or legend drugs are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or controlled substances.

   Respondent shall not direct or control any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy or wholesaler in which she holds an interest at the time this decision becomes effective.

   During suspension, respondent shall not enter any pharmacy area nor perform any of the duties of a pharmacy technician as provided by section 4115 of the Business and Professions Code.

2. Certification Prior to Resuming Work. Respondent shall be suspended from working as a pharmacy technician until she is certified by the pharmacy technician certification board and provides satisfactory proof of certification to the Board.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, medical device retailer, food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs, controlled substances or legend drugs are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or controlled substances.

Respondent shall not direct or control any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy or wholesaler in which she holds an interest at the time this decision becomes effective.

3. Restriction on Practice. Respondent's practice of pharmacy shall be restricted so that she is prohibited from compounding parenteral medications over the period of probation. The Board, upon receipt of documentation showing that she has completed a Board approved remedial education program, may modify this condition to allow her to compound parenteral medications.

4. Obey All Laws. Respondent shall obey all federal and state laws and regulations substantially related or governing the practice of pharmacy.

5. Reporting to/Interview with the Board. Respondent shall report to the Board or its designee quarterly. The report shall be made either in person or in writing, as directed. If the final probation report is not be made as directed, probation shall be extended automatically until such time as the final report is made.

Upon receipt of reasonable notice, respondent shall appear in person for interviews with the Board or its designee upon request at various intervals at a location to be determined by the Board or its designee. Failure to appear for a scheduled interview without prior notification to Board staff shall be considered a violation of probation.

6. Cooperation with Board Staff. Respondent shall cooperate with the Board's inspection program and in the Board's monitoring and investigation of respondent's compliance with the terms and conditions of her probation. Failure to cooperate shall be considered a violation of probation.

7. Notice to Employers. Respondent shall notify all present and prospective employers of the decision in case No. 2427 and the terms, conditions and restrictions imposed on respondent by the decision.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking new employment, respondent shall cause her employer to report to the Board in writing acknowledging the employer has read the decision in this case.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify the pharmacist-in-charge and/or owner at every pharmacy at which she is to employed or used of the fact and terms of the decision in case number in advance of the respondent commencing work at the pharmacy.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacist, whether the respondent is considered an employee or independent contractor.

8. Reimbursement of Board Costs. Respondent shall pay to the Board its costs of investigation and prosecution in the amount of $4645. Respondent shall make payments as arranged with the Board.

If respondent fails to pay the costs as specified by the Board and on the date(s) determined by the Board, the Board shall, without affording the respondent notice and the opportunity to be heard, revoke probation and carry out the disciplinary order that was stayed.

9. Probation Monitoring Costs. Respondent shall pay the costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board at the end of each year of probation. Failure to pay such costs shall be considered a violation of probation.

10. Status of License. Respondent shall, at all times while on probation, maintain an active current certification/registration with the Board, including any period during which suspension or probation is tolled.

If respondent's certification/registration expires by operation of law or otherwise, upon renewal or reapplication, respondent's license shall be subject to all terms of this probation not previously satisfied.

11. Notification of Employment/Mailing Address Change. Within ten (10) days of a change in employment -- either leaving or commencing employment -- respondent shall so notify the Board in writing, including the address of the new employer; within ten (10) days of a change of mailing address, respondent shall

notify the Board in writing. If respondent works for or is employed through a pharmacy employment service, respondent shall, as requested, provide to the Board or its designee with a work schedule indicating dates and location of employment.

12. Tolling of Probation. If respondent leaves California to reside or practice outside this state, respondent must notify the Board in writing of the dates of departure and return within ten (10) days of departure or return. Periods of residency, except such periods where the respondent is actively practicing as a pharmacy technician within California, or practice outside California shall not apply to reduction of the probationary period.

Should respondent, regardless of residency, for any reason cease practicing as a pharmacy technician in California, respondent must notify the Board in writing within ten (10) days of cessation of practice or resuming practice. "Cessation of practice" means any period of time exceeding thirty (30) days in which respondent is not engaged in the practice of a pharmacy technician as defined in section 4038 of the Business and Professions Code.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a period exceeding a consecutive period of three years.

13. Tolling of Suspension. If respondent leaves California to reside or practice outside this state, or for any period exceeding ten (10) days (including vacation), respondent must notify the Board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of ten (10) days shall not apply to the reduction of the suspension period.

Respondent shall not act as a pharmacy technician upon returning to this state until notification by the Board the period of suspension has been completed.

14. Violation of Probation. If respondent violates probation in any respect, the Board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, the Board shall have continuing jurisdiction, and the period of probation shall be extended, until the petition to revoke probation is heard and decided.

If respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been met or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

15. Completion of Probation. Upon successful completion of probation, respondent's certificate will be fully restored.

DATED: January 18, 2002

JONATHAN LEW
Administrative Law Judge
Office of Administrative Hearings

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: DOCS PHARMACY INC 112 La Casa Via #100 Walnut Creek, CA 94598 License No. PHY 44031 ROBERT EUGENE HORWITZ 1080 Coco Lane Walnut Creek, CA 94598 License No. RPH 24532 JAMEY PHILLIP SHEETS 579 Aleta Place Pleasant Hill, CA 94523 License No. RPH 50062 HEIDI L. MEDEIROS P.O. Box 2961 Martinez, CA 94553 License No. TCH 25025 MARGO N. CANTRELL 2942 Filbert Street Antioch, CA 94509 License No. TCH 16559 Respondents.	Case No. 2427 **A C C U S A T I O N**

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Complainant alleges:

PARTIES

1. Patricia F. Harris ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about February 23, 1999, the Board of Pharmacy issued Pharmacy Permit Number PHY 44031 to DOCS PHARMACY INC ("Respondent Docs"). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2002, unless renewed. Respondent Horwitz has been the Pharmacist-in-Charge, President, Secretary and 51% shareholder of Respondent Docs since February 23, 1999. Respondent Sheets has been a 49% shareholder of Respondent Docs since February 23, 1999.

3. On or about July 26, 1966, the Board of Pharmacy issued Pharmacist License Number RPH 24532 to ROBERT EUGENE HORWITZ ("Respondent Horwitz'). The Pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2003, unless renewed.

4. On or about April 13, 1998, the Board of Pharmacy issued Pharmacist License Number RPH 50062 to JAMEY PHILLIP SHEETS ("Respondent Sheets"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2003, unless renewed.

5. On or about February 4, 1998, the Board of Pharmacy issued Pharmacy Technician License Number TCH 25025 to Heidi L. Medeiros ("Respondent Mederios"). The Pharmacy Technician License was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2003, unless renewed.

6. On or about July 11, 1995, the Board of Pharmacy issued Pharmacy Technician License Number TCH 16559 to Margo N. Cantrell ("Respondent Cantrell"). The Pharmacy Technician License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2002, unless renewed.

JURISDICTION

7. This Accusation is brought before the Board of Pharmacy ("Board"), under the authority of the following sections of the Business and Professions Code ("Code").

8. Section 4300 of the Code states:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

9. Section 4301 of the Code states:

The Board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(c) Gross negligence.

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of Chapter 9 (commencing with Section 4000) of the Business and Professions Code or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

10. Section 118, subdivision (b), of the Code provides that the suspension,

expiration, surrender, cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

11. Section 125.3 of the Code provides, in pertinent part, that the Board 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.

ALLEGATIONS AGAINST RESPONDENTS DOCS, HORWITZ & SHEETS

12. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(c) for committing acts of gross negligence. The circumstances are as follows:

A. COMPOUNDING OF BETAMETHASONE

13. On May 11, 2001 (although respondents' records shown May 9, 2001) respondents compounded three 100ml vials of betamethasone, a steroid that is used to treat inflamation. The batches of the drug compounded on May 11, 2001 were sent to six different health care facilities in Contra Costa County. Respondents' acts of gross negligence led to the contamination of the drug compounded on May 11, 2001 with a bacteria known as serratia marcescems ("serratia").

14. The betamethasone was compounded pursuant to a particular formula log (an instruction sheet or "recipe" sheet) which lists the materials to be compounded as well as the methodology for compounding the drug. Respondents' procedure was to compound betamethasone in a laminar hood. The betamethasone was compounded in 100ml vials which were then taken next door to a doctor's office to be autoclaved. Respondents used the autoclave in an attempt to sterilize the compounded betamethasone. A special gauge strip was used during the process of autoclaving process to determine whether the material was sterilized. Records of the autoclaving process were not kept by respondents. The autoclave was not set at the temperature for sterilizing liquids. The manufacturer's specifications for this autoclave indicate that it is not to be used to sterilize compounded medications.

15. After the 100 ml vials were autoclaved, the betamethasone was taken back to Docs Pharmacy. When a need for the betamethasone arose, betamethasone was taken from the 100 ml vial and transferred to smaller 10 ml vials. The smaller 10 ml vials, the rubber stoppers and the crimped aluminum caps were not autoclaved or sterilized. They were only sprayed with alcohol, thus failing to sterilize the smaller vials, rubber stoppers or aluminum caps.

16. The dates on the 10 ml vials did not correspond to the date the sterile 100 ml product was compounded. The date on the smaller vial was the date the betamethasone was put into the smaller vial, not the date the substance was actually compounded. In the case of the contaminated batch of betamethasone, it was compounded at Docs on May 11, 2001 pursuant to a formula log dated May 9, 2001.

17. Respondents also failed to properly label and document the stock material used to compound the betamethasone. Some of the ingredients came directly from a manufacturer. However, other the ingredients were made at the pharmacy and then stored in ordinary non-sterile containers. These containers were not properly labeled with a manufacturing date, expiration date, lot number or even the source of a particular ingredient.

18. There were numerous record keeping violations with respect to the compounding of the betamethasone. For instance, the dates on the 10 ml vials do not correspond to the date the medicine was compounded. The pharmacy is required to assign lot numbers and expiration dates to the compounded drugs. This was not done. There were no manufacturer lot numbers for the ingredients. The only records, besides prescriptions and the formula logs, kept by respondents was a drug movement report which confirmed that respondents provided the betamethasone to the three locations were sealed contaminated vials were subsequently impounded by county health officials - Sierra Surgery Center, Diablo Valley Surgery Center and Diablo Orthopedic.

19. A total of 38 patients received respondents' betamethasone by injection at the Sierra Surgical Center in Walnut Creek between May 22, 2001 and May 31, 2001. Of these patients thirteen were hospitalized, three have died, and the rest received follow up care.

20. The vials of betamethasone compounded on May 11, 2001 and distributed

by respondents to the six different health facilities were retrieved by the county health officials. Field interviews and site inspections were conducted by county health officials, the Board, and the Federal Food and Drug Administration.

21. The laboratory results performed by the county health officials show that betamethasone compounded on May 11, 2001 (pursuant to a formula log dated May 9, 2001) by respondents was contaminated with serratia. The contamination occurred during the compounding process at Docs Pharmacy as opposed to contamination at any of the three health care facilities.

22. All of the 24 vials removed from the Sierra Surgical Center tested positive for serratia. All of the vials were dated May 17, 2001. However, all vials in question were compounded by respondents on May 11, 2001, but assigned a different date when actually distributed to the health care facilities. Twenty-three of the vials had been used for surgery, but one vial remained sealed. The sealed vial was contaminated with serratia.

23. Additionally, all ten vials of betamethasone taken from Diablo Valley Surgical Center in Walnut Creek were contaminated. These vials had a date of May 18, 2001 even though they were actually compounded by respondents on May 11, 2001. All ten of the betamethasone vials taken from Diablo Valley Surgical Center were sealed.

24. A sealed vial of betamethasone taken from a third health care facility, Diablo Orthopedic Medical Group in Pittsburg, was also contaminated with serratia. This vial of betamethasone is dated May 16, 2001 even though it was compounded by respondents on May 11, 2001.

25. The swab cultures taken from Docs Pharmacy on June 7, 2001 by county health officials show contamination of serratia. The serratia at Docs Pharmacy was found on the sink drain board, sink handles and the interior of the homogenizer. Additionally, one of the stock materials used to compound the betamethasone was contaminated with serratia.

26. Respondents began compounding betamethasone in February 5, 2001. Not until a batch compounded on April 30, 2001 did respondents determine or validate if the compounding processes was accurate or if it produced a product with acceptable bio-equivalency

until a batch compounded on April 30, 2001 was sent for laboratory analysis. During the period of February 5, 2001 and April 30, 2001, 165 5ml vials of betamethasone were dispensed. A May 4, 2001 laboratory analysis of the betamethasone compounded on April 30, 2001 showed the Betamethasone Sodium Phosphate varied from the labeled concentration by minus 11.7%, and the Betamethasone Acetate varied from the labeled concentration by minus 31.3%. Despite having received the May 4, 2001 laboratory analysis respondents continued to use the same formula when compounding betamethasone.

B. ADDITIONAL COMPOUNDING VIOLATIONS

27. In addition to the above acts of gross negligence, respondents Docs, Horwitz and Sheets committed additional acts of gross negligence in violation of Code section 4301(c) pertaining to the compounding of the parenteral, sterile and non-sterile medications as follows:

a. Failed to properly supervise its pharmacy technicians when they were compounding medications. Respondents could not see the compounding area unless standing directly in the area (there are shelves to block the view). The autoclaving process was not supervised when it was done next door. Respondents did not have an on going program to monitor personnel or equipment.

b. Allowed respondent pharmacy technicians to compound sterile medications in a laminar air flow hood while wearing jewelry, long sleeve denim shirts, and non-sterile gloves. Respondent pharmacy technicians were also allowed to leave, touch objects outside the laminar air flow hood, and re-enter it without washing or sterilizing their hands.

c. Stock solutions were not labeled consistently with the date of preparation, expiration date, lot number or storage instructions.

d. Formula logs were used to document the preparation of compounded medications. The formula log dates were computer generated and did not necessarily correspond to the dates the medication was compounded. Respondent pharmacy technicians were improperly authorized to initial the log as being "checked" when

a pharmacist was unavailable.

e. When a compounded prescription was refilled it was assigned a lot number that corresponded to the original prescription number even though the re-fill prescription was compounded from a different batch.

f. Respondents compounded chemotherapy drugs in the absence of required equipment, policies and procedures. There was no cytotoxic safety cabinet to compound these drugs, no methodology for disposing of cytotoxic waste, no procedure on how the materials were to be prepared or information to be given to the patients on how to dispose of the cytotoxic residue.

g. A June 13, 2001 inspection revealed improperly labeled vials and suppositories stored in the refrigerator. The medications were missing names, lot numbers and expiration dates.

h. There was a demonstrated lack of training and knowledge with respect to maintaining the integrity and sterilization of any compounded medications. There was no documented in house training for the compounding of medications.

i. There was no documentation for the cleaning and sanitation of the parenteral compounding area.

j. The labeling practice for all compounded medications was confusing, inaccurate and inconsistent.

k. Syringes were attached to many liquid ingredients used for compounding medications, but the was no date on the syringe indicating when it was attached.

l. Medications were stored next to food preparations.

m. There was no documentation on steps to be taken if testing proves that a product is contaminated.

n. Respondents did not monitor or document equipment (autoclave, scales, etc.) for accuracy.

o. Respondents failed to have a written policy regarding disposal of waste material.

p. Respondents did not have a policy with respect to compounded drugs that must be

recalled.

q. On March 13, 2001, respondents compounded and dispensed a drug containing chloroform despite the fact the FDA directed the removal of all drugs containing chloroform in 1976.

r. There were no controls to assure process water was suitable for use as an ingredient in compounded medications.

s. In February, 2001 an eye medication was compounded for the owner of a cat. Respondents logs fail to indicate who compounded the medication. The compounding of this medication was not checked by a pharmacist. The cat's eyes were burned as a result of using this medication.

t. Respondents and its staff lacked sufficient knowledge, training, and experience to compound medications.

C. ADDITIONAL VIOLATIONS OF PHARMACY LAW

28. Business and Professions Code section 4115(f) provides, in part, that the performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view.

29. Title 16, California Code of Regulations ("CCR"), section 1793.7(c) provides pharmacy technicians must work under the direct supervision of a pharmacist and in such a manner that the pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

30. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Code section 4115(f) and Title 16, CCR, section 1793.7(c), in that they failed to provide adequate supervision of pharmacy technicians during the preparation of compounded medications. They failed to provide supervision of pharmacy technician activities during the sterilization process conducted in another location outside the pharmacy. They failed to have in place policies and procedures which required pharmacy technicians to properly document and label the compounded drugs.

The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

31. Health and Safety Code section 111255 provides that any drug is adulterated if it has been produced, prepared, packaged or held under conditions whereby it may have been contaminated. Health and Safety Code section 111295 provides that it is unlawful for any person to manufacture for sale any drug that is adulterated. Health and Safety Code section 111300 provides that it is unlawful for any person to adulterate any drug.

32. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Health and Safety Code sections 111255, 111295 and 111300 for having compounded and dispensed betamethasone that was contaminated with serratia. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

33. Title 16, CCR, section 1751.1 requires that pharmacies preparing cytotoxic drugs shall be compounded within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in - bag out design.

34. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1751.1 in that they prepared cytotoxic medications in the absence of an approved cytotoxic vertical laminar air flow hood. They falsely represented on a "Community Pharmacy Self-Assessment Questionnaire" dated December 2, 1999 that they did not compound cytotoxic medications.

35. Title 16, CCR, section 1751.2, provides that pharmacies which compound parenteral products shall include the telephone number of the pharmacy, name, concentration of all ingredients and instructions for storage and handling on the medication's label.

36. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1751.2 in that they failed to properly label parenteral products compounded at the pharmacy. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

37. Title 16, CCR, section1751.6, provides that pharmacies providing parenteral services shall have written policies and procedures for the disposal of infectious

45. Title 16, CCR, section 1793.1(g), provides that a registered pharmacist shall be responsible for the activities of pharmacy technicians.

46. Respondents Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1793.1(g) for failing to ensure that the activities of pharmacy technicians were performed completely, safely and without risk to patients. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

47. Title 16, CCR, section 1793.7(d) provides that pharmacy technicians must wear name tags clearly identifying themselves as such.

48. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1793.7 in that pharmacy technicians did not wear proper identification tags.

49. Title 16, CCR, section 1751.5 provides that the pharmacist in charge shall be responsible to ensure all pharmacy personnel engaging in compounding parenteral solutions shall have training and demonstrated competence. The pharmacist in charge shall be responsible to insure the continuing competence of pharmacy personnel engaged in compounding parenteral solutions.

50. Respondent Horwitz is subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1751.5 in that pharmacy personnel did not have proper training and competence to compound parenteral products. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

51. Title 16, CCR, section 1715 provides that the pharmacist-in-charge shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law.

52. Respondent Horwitz is subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1715 for improperly and inaccurately completing a self-assessment form dated December 9, 1999. The form was filled out by respondent Sheets instead of the pharmacist-in-charge, respondent Horwitz. The form indicated that a quality assurance program was in place when, in fact, no such program existed.

materials and/or materials containing cytotoxic residue.

38. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1751.6 in that they failed to have any written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residue.

39. Title 16, CCR, section 1751.7, provides that there shall be a documented on-going quality assurance program that monitors personnel, performance, equipment and facilities that compound parenteral products. The end product shall be examined on a sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications.

40. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1751.7 in that they failed to have a quality assurance program for parenteral products. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

41. Title 16, CCR, section 1751.8 provides that a pharmacy compounding parenteral substances maintain written policies and procedures that contain a minimum of seven enumerated items.

42. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1751.8 in that they failed to have any written policies and procedures with respect to compounding parenteral products. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

43. Title 16, CCR, section 1716.2, sets forth the labeling requirements of drugs that are compounded for future use.

44. Respondents Docs, Horwitz and Sheets are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 1716.2 in that they failed to meet the labeling requirements for medications intended for future use. The labeling practice was inaccurate and inconsistent. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

The form indicated that a biological safety cabinet was not applicable when, in fact, such a safety cabinet was required to compound cytotoxic medications. The form also indicated that policies and procedures were to be written for the preparation and compounding of parenteral products, but no such policies or procedures were ever written.

ALLEGATIONS AGAINST RESPONDENTS MEDERIOS AND CANTRELL

53. During the course of the investigation, Board inspectors interviewed respondents Mederios and Cantrell. These respondents were responsible for compounding medications at respondent Docs, including the contaminated betamethasone. During the course of the investigation, respondents Mederios and Cantrell demonstrated to investigators the procedures they used in compounding medications, including the contaminated betamethasone.

54. Respondents Mederios and Cantrell are subject to disciplinary action for having violated Code section 4301(c), gross negligence. The allegations of paragraphs 13 through 27 are incorporated by reference as if fully set forth.

55. Title 16, CCR, section 1793.2, provides that a pharmacy technician may perform packaging, manipulative, repetitive, or other non-discretionary tasks, while assisting, and while under the direct supervision and control of a registered pharmacist.

56. Title 16, CCR, section 1793.7(c), provides that a pharmacy technician must work under the direct supervision of a registered pharmacist and in such a relationship that the supervising pharmacist is on the premises at all times and if fully aware of all activities in the preparation and dispensing of medications, including the maintenance of appropriate records.

57. Respondents Mederios and Cantrell are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Code section 4115(f), Title 16, CCR, sections 1793.2 and 1793.7(c) in that they did not work under the direct supervision of a registered pharmacist when compounding medications. The allegations of paragraphs 13 through 30 are incorporated by reference as if fully set forth.

58. Respondents Mederios and Cantrell are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated, Title 16, CCR, section 1751.2, in that they failed to properly label parenteral products as required. The allegations of paragraphs

13 through 27 and 36 are incorporated by reference as if fully set forth.

59. Respondents Mederios and Cantrell are subject to disciplinary action pursuant to Code section 4301(j) and (o) for having violated Title 16, CCR, section 17937(d) in that they did not wear proper name tags identifying themselves as pharmacy technicians.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 44031, issued to DOCS PHARMACY INC;

2. Revoking or suspending Pharmacist License Number RPH 24532, issued to ROBERT EUGENE HORWITZ;.

3. Revoking or suspending Pharmacist License Number RPH 50062, issued to JAMEY PHILLIP SHEETS;.

4. Revoking or suspending Pharmacy Technician License Number TCH 25025, issued to HEIDI L. MEDEIROS;

5. Revoking or suspending Pharmacy Technician License Number TCH 16559, issued to MARGO N. CANTRELL;

6. Ordering DOCS PHARMACY, ROBERT EUGENE HORWITZ, JAMEY PHILLIP SHEETS, HEIDI L. MEDERIOS and MARGO N. CANTRELL to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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7. Taking such other and further action as deemed necessary and proper.

DATED: 8/15/01

PATRICIA F. HARRIS
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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