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of the State of California
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6 Attorneys for Complainant

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

11 In the Matter of the Accusation Against:
12 DOCS PHARMACY INC
112 La Casa Via, #100
Walnut Creek, CA 94598
License No. PHY 44031
13 ROBERT EUGENE HORWITZ
1080 Coco Lane
14 Walnut Creek, CA 94598
License No. RPH 24532
15 JAMEY PHILLIP SHEETS
16 579 Aleta Place
Pleasant Hill, CA 94523
17 License No. RPH 50062
18 HEIDI L. MEDEIROS
P. O. Box 2961
19 Martinez, CA 94553
License No. TCH 25025
20 MARGO N. CANTRELL
21 2942 Filbert Street
Antioch, CA 94509
22 License No. TCH 16559
23 Respondents.

Case No. 2427

OAH No. N2001080761

**STIPULATED SETTLEMENT
AGREEMENT ONLY WITH
RESPECT TO RESPONDENTS
DOCS PHARMACY INC AND
ROBERT EUGENE HORWITZ**

24
25 IT IS HEREBY STIPULATED AND AGREED by and between the Docs
26 Pharmacy Inc and Robert Eugene Horwitz, who are represented by Lee Archer, Esq., and the
27 Complainant, who is represented by W. Lloyd Paris, Deputy Attorney General that the following
28 matters are true:

1 PARTIES

2 1. Patricia F. Harris (Complainant) is the Executive Officer of the Board of
3 Pharmacy. She brought this action solely in her official capacity and is represented in this matter
4 by Bill Lockyer, Attorney General of the State of California, by W. Lloyd Paris, Deputy
5 Attorney General.

6 2. DOCS PHARMACY INC (also referred to herein as Respondent "Docs")
7 and ROBERT EUGENE HORWITZ (also referred to herein as "Respondent Horwitz") are
8 represented in this proceeding by attorney Lee Archer, whose address is ARCHER & NORRIS,
9 2033 North Main Street, Suite 800, Walnut Creek, California 94596-3728.

10 3. On or about July 26, 1966, the Board of Pharmacy issued Pharmacy issued
11 Pharmacist License No. RPH 24532 to ROBERT EUGENE HORWITZ. The Pharmacist
12 license issued to Respondent Horwitz was in full force and effect at all times relevant to the
13 charges alleged in the Accusation and will expire on January 31, 2003, unless renewed.

14 4. On or about February 23, 1999, the Board of Pharmacy issued Pharmacy
15 Permit No. PHY 44031 to DOCS PHARMACY INC. The Pharmacy Permit was in full force
16 and effect at all times relevant to the charges alleged in the Accusation. Respondent Horwitz has
17 been the Pharmacist-in-Charge, President, Secretary and 51% shareholder of Respondent Docs
18 since February 23, 1999.

19 JURISDICTION

20 5. Accusation No. 2427 was filed before the Board of Pharmacy (Board),
21 Department of Consumer Affairs, and is currently pending against Respondent Docs and
22 Respondent Horwitz. The Accusation, together with all other statutorily required documents
23 were properly served on Respondent Docs and Respondent Horwitz on August 15, 2001.
24 Respondent Horwitz, individually and on behalf of Respondent Docs, timely filed his Notice of
25 Defense contesting the Accusation. A copy of Accusation No. 2427 is attached as exhibit A and
26 incorporated herein by reference.

27 ADVISEMENT AND WAIVERS

28 6. Respondent Horwitz has carefully read, fully discussed with counsel, and

[8262 ON TX/XX] 01:01 WED 10/12/11

1 17. Respondent Docs shall lose all rights and privileges and cease to operate
2 as a Pharmacy in California as of the effective date of the Board's Decision and Order.

3 18. Respondent Horwitz shall cause to be delivered to the Board Respondent
4 Docs's Pharmacy permit on or before the effective date of the Decision and Order.

5 ACCEPTANCE

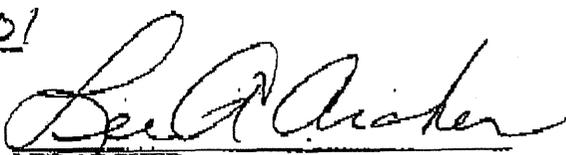
6 I have carefully read the above Stipulated Surrender of License and Order and
7 have fully discussed it with my attorney, Lee Archer. I understand the stipulation and the effect
8 it will have on my Pharmacist License No. RPH 24532 and Pharmacy Permit No. PHY 44031
9 issued to DOCS PHARMACY INC. I enter into this Stipulated Surrender of License and Order
10 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
11 Board of Pharmacy.

12 DATED: 11/21/01

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14 
15 ROBERT EUGENE HORWITZ,
16 Individually and on behalf of Docs Pharmacy Inc.
17 Respondent

18 I have read and fully discussed with Respondent ROBERT EUGENE HORWITZ
19 the terms and conditions and other matters contained in this Stipulated Surrender of License and
20 Order. I approve its form and content.

21 DATED: Nov 21, 2001

22 
23 LEE ARCHER
24 Attorney for Respondent

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ENDORSEMENT

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

DATED: 1/29/02.

BILL LOCKYER, Attorney General
of the State of California



W. LLOYD PARIS
Deputy Attorney General

Attorneys for Complainant

DOJ Docket Number: 03583110-SF2001AD0765
Stipulation for surrender 10/12/01

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

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2942 Filbert Street
Antioch, CA 94509
License No. TCH 16559

Respondents.

Case No. 2427

OAH No. N2001080761

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this 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
Board President

1 BILL LOCKYER, Attorney General
of the State of California
2 W. LLOYD PARIS, State Bar No. 124755
Deputy Attorney General
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8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 2427

12 DOCS PHARMACY INC
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13 Walnut Creek, CA 94598
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ACCUSATION

14 ROBERT EUGENE HORWITZ
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2942 Filbert Street
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License No. TCH 16559

24 Respondents.
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1 Complainant alleges:

2 **PARTIES**

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

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

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

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

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

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

28

1 JURISDICTION

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

4 8. Section 4300 of the Code states:

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

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

9 (1) Suspending judgment.

10 (2) Placing him or her upon probation.

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

12 (4) Revoking his or her license.

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

15 9. Section 4301 of the Code states:

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

20 (c) Gross negligence.

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

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

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

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

4 11. Section 125.3 of the Code provides, in pertinent part, that the Board may
5 request the administrative law judge to direct a licentiate found to have committed a violation or
6 violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation
7 and enforcement of the case.

8 **ALLEGATIONS AGAINST RESPONDENTS DOCS, HORWITZ & SHEETS**

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

12 **A. COMPOUNDING OF BETAMETHASONE**

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

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

1 15. After the 100 ml vials were autoclaved, the betamethasone was taken back
2 to Docs Pharmacy. When a need for the betamethasone arose, betamethasone was taken from the
3 100 ml vial and transferred to smaller 10 ml vials. The smaller 10 ml vials, the rubber stoppers
4 and the crimped aluminum caps were not autoclaved or sterilized. They were only sprayed with
5 alcohol, thus failing to sterilize the smaller vials, rubber stoppers or aluminum caps.

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

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

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

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

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

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

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

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

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

18 24. A sealed vial of betamethasone taken from a third health care facility,
19 Diablo Orthopedic Medical Group in Pittsburg, was also contaminated with serratia. This vial of
20 betamethasone is dated May 16, 2001 even though it was compounded by respondents on May
21 11, 2001.

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

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

1 until a batch compounded on April 30, 2001 was sent for laboratory analysis. During the period
2 of February 5, 2001 and April 30, 2001, 165 5ml vials of betamethasone were dispensed. A May
3 4, 2001 laboratory analysis of the betamethasone compounded on April 30, 2001 showed the
4 Betamethasone Sodium Phosphate varied from the labeled concentration by minus 11.7%, and
5 the Betamethasone Acetate varied from the labeled concentration by minus 31.3%. Despite
6 having received the May 4, 2001 laboratory analysis respondents continued to use the same
7 formula when compounding betamethasone.

8 B. ADDITIONAL COMPOUNDING VIOLATIONS

9 27. In addition to the above acts of gross negligence, respondents Docs,
10 Horwitz and Sheets committed additional acts of gross negligence in violation of Code section
11 4301(c) pertaining to the compounding of the parenteral, sterile and non-sterile medications as
12 follows:

- 13 a. Failed to properly supervise its pharmacy technicians when they were
14 compounding medications. Respondents could not see the compounding area
15 unless standing directly in the area (there are shelves to block the view). The
16 autoclaving process was not supervised when it was done next door. Respondents
17 did not have an on going program to monitor personnel or equipment.
- 18 b. Allowed respondent pharmacy technicians to compound sterile medications in a
19 laminar air flow hood while wearing jewelry, long sleeve denim shirts, and non-
20 sterile gloves. Respondent pharmacy technicians were also allowed to leave,
21 touch objects outside the laminar air flow hood, and re-enter it without washing or
22 sterilizing their hands.
- 23 c. Stock solutions were not labeled consistently with the date of preparation,
24 expiration date, lot number or storage instructions.
- 25 d. Formula logs were used to document the preparation of compounded medications.
26 The formula log dates were computer generated and did not necessarily
27 correspond to the dates the medication was compounded. Respondent pharmacy
28 technicians were improperly authorized to initial the log as being "checked" when

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- 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 there 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

1 recalled.

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

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

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

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

13 **C. ADDITIONAL VIOLATIONS OF PHARMACY LAW**

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

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

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

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

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

7 32. Respondents Docs, Horwitz and Sheets are subject to disciplinary action
8 pursuant to Code section 4301(j) and (o) for having violated Health and Safety Code sections
9 111255, 111295 and 111300 for having compounded and dispensed betamethasone that was
10 contaminated with serratia. The allegations of paragraphs 13 through 27 are incorporated by
11 reference as if fully set forth.

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

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

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

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

27 37. Title 16, CCR, section 1751.6, provides that pharmacies providing
28 parenteral services shall have written policies and procedures for the disposal of infectious

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

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

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

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

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

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

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

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

1 materials and/or materials containing cytotoxic residue.

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

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

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

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

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

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

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

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

5 **ALLEGATIONS AGAINST RESPONDENTS MEDERIOS AND CANTRELL**

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

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

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

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

21 57. Respondents Mederios and Cantrell are subject to disciplinary action
22 pursuant to Code section 4301(j) and (o) for having violated Code section 4115(f), Title 16,
23 CCR, sections 1793.2 and 1793.7(c) in that they did not work under the direct supervision of a
24 registered pharmacist when compounding medications. The allegations of paragraphs 13 through
25 30 are incorporated by reference as if fully set forth.

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

1 13 through 27 and 36 are incorporated by reference as if fully set forth.

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

5 PRAYER

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

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

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

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

14 4. Revoking or suspending Pharmacy Technician License Number TCH
15 25025, issued to HEIDI L. MEDEIROS;

16 5. Revoking or suspending Pharmacy Technician License Number TCH
17 16559, issued to MARGO N. CANTRELL;

18 6. Ordering DOCS PHARMACY, ROBERT EUGENE HORWITZ, JAMEY
19 PHILLIP SHEETS, HEIDI L. MEDERIOS and MARGO N. CANTRELL to pay the Board of
20 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
21 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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