

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

In the Matter of the Accusation Against:

JAMEY PHILLIP SHEETS  
579 Aleta Place  
Pleasant Hill, CA 94523

License No. RPH 50062

Case No. 2427

OAH No. N2001080761-A

Respondent.

**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.<sup>1</sup>

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

Jamey Phillip Sheets was present and represented by John F. Martin, Esq., Station Plaza, 3100 Oak Road, Suite 230, Walnut Creek, California 94596.

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.

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<sup>1</sup> 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 April 13, 1998, the Board issued Pharmacist License Number RPH 50062 to Jamey Phillip Sheets (respondent). The pharmacist license was in full force and effect at all times relevant to this matter and will expire on June 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. Respondent 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. Complainant makes three broad allegations against respondent. First, complainant contends that respondent committed acts of gross negligence relating to the betamethasone that was compounded on May 11, 2001. Complainant believes that such acts constituted an extreme departure from the standard of care and that they bear most directly on how the Serratia contamination occurred.

Second, complainant contends that respondent committed acts of gross negligence that generally relate to how parenteral, sterile and non-sterile medications were compounded at Doc's Pharmacy. Twenty separate allegations are made in this regard and they cover matters such as the supervision of pharmacy technicians when they were compounding medications, sterile/aseptic techniques followed at Doc's Pharmacy, documentation for and labeling of compounded prescriptions, staff training, and a number of other pharmacy practices detailed in Accusation paragraph 27.

Third and finally, complainant alleges that respondent violated additional pharmacy laws and regulations as specified in Accusation paragraphs 28 through 48. There is some overlap with previous allegations relating to compounding, but there are also separate allegations relating to matters such as pharmacy policies and procedures, preparation of cytotoxic drugs, general labeling requirements and representations made to the Board on a pharmacy self-assessment form. These allegations largely fall under the category of violation of provisions of the law or regulations governing pharmacy under Business and Professions Code section 4301, subdivisions (j) and (o). They do not necessarily involve gross negligence.

The order of factual findings and discussion will essentially track the Accusation, addressing specific allegations in same order pled, followed by consideration of respondent's professional background and experience, as well as matters raised by him in mitigation and by way of explanation of his activities and involvement at Doc's Pharmacy.

### Compounding of Betamethasone (Accusation Paragraphs 13 – 26)

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. Pharmacy technician Heidi Medeiros 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 Medeiros used the autoclave alone, unsupervised by either respondent or Horwitz. 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, Medeiros 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 Medeiros to use the pouches setting. This authorization was never documented, and there is no evidence that respondent was ever advised of this change.

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 Medeiros. These instructions were easily accessible to respondent. 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. Medeiros 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.

Both respondent and Horwitz were responsible for ensuring the integrity of drug products compounded at Doc's Pharmacy and for overseeing all compounding activities of pharmacy technicians such as Medeiros. The obligation and scope of a pharmacist's supervisory responsibilities will be discussed in detail in later sections.

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. Medeiros 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 respondent and others at Doc's Pharmacy did not know this. Respondent now understands that "cold sterilization" is not sterile technique, but questions whether such was common knowledge. At the time, he deferred to Horwitz who had explained to him that using "cold sterilization" saved the pharmacy half of what sterile vials would cost. Sterile vials cost \$1.50 each versus \$.50 each for non-sterile vials.

13. Respondent was aware that "cold sterilization" was used at Doc's Pharmacy. He never questioned the practice and notes that he had never been taught otherwise and that he had never observed anything in clinical settings to suggest that it was poor practice. He was certainly aware that betamethasone was being compounded for parenteral (epidural) use, and, therefore, proper aseptic and sterile technique was paramount. He knew that the formula required the compound to be autoclaved as a final step. Had the product been autoclaved after transfer to the 10 ml vials "cold sterilization" would probably be a non-issue. But "cold sterilization" was essentially used in lieu of autoclaving. It should be common knowledge to a pharmacist engaged in compounding that isopropyl alcohol spray is no substitute for autoclaving a compound intended for parenteral injection.

Under all these circumstances 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. "Cold sterilization" was practiced on his watch and under his supervision. As one of two pharmacists on site, respondent was 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 transferred into smaller vials that were not autoclaved. As a pharmacist and for the same reasons already discussed, he was ultimately responsible for this practice and for ensuring the integrity of drug products compounded at Doc's Pharmacy.

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. Respondent was ultimately responsible as one of two pharmacists responsible for ensuring the integrity of drug products compounded at Doc's Pharmacy.

17. Betamethasone Laboratory Analysis. Doc's Pharmacy began compounding betamethasone in February 2001. As demand increased and as orders were made for as many as 50 vials a time, respondent determined that it was important to validate the product by having a sample tested for accuracy and acceptable bio-equivalency. A batch of betamethasone was compounded on April 4, 2001, and sent for laboratory analysis to Analytical Research Laboratories in Oklahoma City. The test results were reported back on May 4, 2001. The two active ingredients, betamethasone sodium phosphate and betametasone acetate, varied from the labeled concentration by minus 11.7 percent and minus 31.3 percent, respectively.

The standard of practice is to allow for plus or minus 5 percent from the labeled amount. If the product is off more than this, then the product is essentially mislabeled. The concentrations from this analysis suggest that the betamethasone compounded at Doc's Pharmacy was sub-potent. No quality assurance program was in place at Doc's Pharmacy to address a matter such as a sub-potent compound. Neither Horwitz nor respondent did anything to change the procedures or formula for making betamethasone after receiving this report. Respondent spoke briefly to Horwitz about the laboratory analysis, and he understood that Horwitz would be contacting PCCA to look into it. Respondent avers that his responsibility was not in the compounding lab and that he personally would not have made betamethasone after that point until the issue was addressed. Doc's Pharmacy continued to use the same formula and procedure when compounding betamethasone after May 4.

The continued use of the same formula for betamethasone after it was determined to be sub-potent and without any apparent or documented quality assurance review was an extreme departure from the standard of care, or gross negligence. There was a continued risk that the medication being compounded and distributed was sub-potent and not as represented on the label.

#### **Additional Compounding Violations** (Accusation Paragraph 27(a) – (t).)

18. 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.

19. 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.

Pharmacy technician Medeiros 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. Medeiros 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. A supervising pharmacist has a responsibility to intervene and correct these practices, and the failure to do so constituted gross negligence.

20. 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.

21. 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. Respondent 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.

22. Chemotherapy Drugs. Doxyrubicin and other chemotherapeutic preparations including azathioprine, chlorambucil and methimazole were kept at Doc’s Pharmacy for animal use. The doxyrubicin was kept in a refrigerator in a glass bottle. It should have been placed in a sealed plastic container in case the vial broke. Respondent explains that it was obtained from another pharmacist who had died, and transfer of the service that this pharmacist had been providing for a customer was made to Doc’s Pharmacy. It was intended for animals with cancer, and the doxyrubicin was typically added to an intravenous bag once a month and sent to veterinarians for slow drip administration.

Chemotherapy drugs were kept in the absence of required equipment, policies and procedures. For example, 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 consumer on how to dispose of any cytotoxic residue. When these preparations were compounded, it was done without the use of a vertical-flow biological safety cabinet. This created a potential health risk for Doc’s Pharmacy personnel, and possible contamination of other products being compounded.

Given the potential risks involved, it was an extreme departure from the standard of care, or gross negligence, for these chemotherapy drugs to be stored and compounded at Doc’s Pharmacy as they were. As a pharmacist respondent was aware of and was responsible for these practices at Doc’s Pharmacy.

23. Training. There was a demonstrated lack of training and knowledge with respect to maintaining the integrity and sterilization of compounded medications. There was no documented in house training for the compounding of medications. Respondent and the pharmacy technicians lacked sufficient knowledge, training and experience to compound medications. Respondent and at least two pharmacy technicians attended a PCCA course in Texas on compounding oral and parenteral medications. This was within the past four years. Sterile and aseptic technique were not included in this training. Other than wall certificates for this PCCA course, there were no other records kept concerning training of pharmacy technicians. There was no organized training program and no annual evaluation of sterile/aseptic techniques at Doc's Pharmacy. Horwitz initially provided direct one-to-one training to Medeiros, and, thereafter, training was provided to her on the spot, as needed. She was the primary compounding pharmacy technician. Training was not documented.

Respondent does not recall much about his pharmacy school education regarding compounding. He participated in a pharmaceuticals laboratory course, but does not recall if this included training in the compounding of parenteral medications. It would be rather shocking if the only training that he received in compounding parenteral medications was the same PCCA course taken by the pharmacy technicians that he was responsible for supervising.

24. Policy and Procedures. Documented policies and procedures were not in place regarding quality assurance, disposal of waste material, preparation of chemotherapeutic drugs, disposal of cytotoxic waste, accuracy/calibration of laboratory equipment used, suitability of process water for use in compounded medications, and steps to be taken if tests proved that a compounded product was contaminated or needed to be recalled. Other than the one instance in April 2001 when a batch of betamethasone was sent out for laboratory analysis (Finding 17), there was no documentation that quality assurance or process evaluation was performed as a usual part of compounding procedure at Doc's Pharmacy. The pharmacy lacked some type of process assessment measure for the correctness, accuracy, sterility and lack of pyrogens in all classes of compounded medications. Continuous assurance of product integrity is required in the compounding of sterile products. Doc's Pharmacy failed to maintain quality assurance documentation, and the failure to do so constituted negligence.

25. Other Matters Observed. Syringes were attached to bottles of stock solutions, flavoring agents, sterilizer agents and colorizer agents. There was no record indicating when the syringe was attached to the stock solutions. An unlabeled and undated syringe may be a source of contamination if it is used repeatedly over a period of time without cleaning. The standard of care is to use syringes a single time, for any product. The failure to do so was an extreme departure from the standard of care, or gross negligence.

Canned cat food was stored on shelf directly behind the laminar flow hood. It was an agent used for flavor or coloring. There were also food products found in a refrigerator alongside medications. Generally, food should not be stored near medications for fear of cross-contamination. It was negligence to do so.

In February 2001, an eye medication (Idoxuridine) was compounded for the owner of a cat, and there was a complaint that the cat's eyes were burned as a result of using this medication. The medication apparently was not checked off by either Horwitz or respondent, and one cannot tell from the formula log who had compounded it. The product smelled of and was found on laboratory analysis to contain isopropyl alcohol. This was not an ingredient in the medication, and respondent believes it was inadvertently added when an eyedropper was used that had been soaked with alcohol and not completely dried under the hood.

On March 13, 2001, a drug containing chloroform was compounded at and dispensed from Doc's Pharmacy. The Food and Drug Administration (FDA) had directed the removal of all drugs containing chloroform in 1976. Both the Idoxuridine and chloroform incidents were departures from the standard of care or negligence.

**Additional Violations of Pharmacy Law** (Accusation Paragraphs 28 – 52.)

26. The Board may take disciplinary action against a pharmacist 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 he 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 18. Respondent failed to provide adequate supervision of pharmacy technicians during the preparation of compounded medications. He failed to supervise pharmacy technician compounding activity during autoclaving outside the pharmacy. In terms of maintenance of appropriate records, respondent failed to have in place policies and procedures that required pharmacy technicians to properly document and label compounded drugs.

b. Adulterated Drugs. A drug is adulterated if it has been produced, prepared, packaged or held under conditions whereby it may have been contaminated. (Heath & Saf. Code, § 111255.) It is unlawful for any person to adulterate or to manufacture for sale any

drug that is adulterated. (Health & Saf. Code, §§ 111295 and 111300.) Reference is made to the matters set forth in Findings 7 through 17. Respondent shared responsibility for conditions at Doc's Pharmacy leading to the compounding and dispensing of betamethasone that was contaminated with Serratia.

c. Cytotoxic Drugs. Pharmacies preparing cytotoxic drugs must be compounded within a certified Class II vertical laminar air flow hood with bag in – bag out design. (Cal. Code Regs., tit. 16, § 1751.1.) Reference is made to Finding 22. Cytotoxic medications were prepared at Doc's Pharmacy in the absence of an approved cytotoxic vertical laminar air flow hood. When respondent completed a "Community Pharmacy Self-Assessment Questionnaire" in December 1999, he represented that Doc's Pharmacy did not compound cytotoxic medications.

d. 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 20. The procedures used by Doc's Pharmacy to label work in progress and finished products were below accepted pharmacy standards.

e. Disposal of Infectious Materials/Cytotoxic Residue. Pharmacies providing parenteral services must have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residue. The pharmacy is also responsible for ensuring the return of such materials or shall communicate the proper destruction of such materials to the caregiver. (Cal. Code Regs., tit. 16, § 1751.6.) Reference is made to the matters in Findings 22 and 24. Respondent failed to ensure that written policies and procedures were in place for the disposal of infectious materials and/or materials containing cytotoxic residue.

f. Quality Assurance Program. Pharmacies are required to have a documented ongoing quality assurance program that monitors personnel performance, equipment, and facilities. <sup>2</sup> (Cal. Code Regs., tit. 16, § 1751.7.) Reference is made to Findings 17 and 24.) Respondent failed to ensure that a documented quality assurance program was in place for parenteral products.

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<sup>2</sup> Under California Code of Regulations, title 16, section 1751.7, the Quality Assurance Program shall include at least the following:

- a. Cleaning and sanitization of the parenteral medication preparation area.
- b. Written documentation that the end product has been tested on a sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive.
- c. If the manufacturing of parenteral products is performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of product from quarantine. This process must include testing for sterility and pyrogens.
- d. The storage of compounded parenteral products in the pharmacy and periodic documentation of refrigerator temperature.
- e. Steps to be taken in the event of a drug recall.

g. Policies and Procedures for Parenteral Products. Pharmacies are required to have written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products. (Cal. Code Regs., tit. 16, § 1751.8.) Reference is made to Finding 24. There were no written policies and procedures for the production of betamethasone or any other compounded medications. The PCCA and formula logs essentially substituted for this requirement and these fell well short of what was required.<sup>3</sup> There were no formal policies and procedures for parenteral products or for the general operation of the pharmacy.

h. Compounding for Future Furnishing. When a pharmacy compounds quantities larger than required for immediate dispensing, it is required to maintain records that include the date of preparation, the lot numbers and the expiration date of the finished product. (Cal. Code Regs., tit. 16, § 1716.2.) Reference is made to Findings 15,16 and 20. Betamethasone was compounded on May 9, 2001, but the labels on the vials corresponded to the later dates when it was aliquoted into the smaller vials. This also affected the expiration dates. Lot numbers on refills referenced the original prescription number so that the same drug prepared and dispensed on different dates had the same lot number. Lot numbers for ingredients from the original manufacturer or from stock preparations were not recorded.

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.

Respondent failed to ensure that there was compliance with regulations governing labeling and appropriate recordkeeping of compounded medications intended for future use.

i. Duties of Pharmacist. A registered pharmacist is responsible for all activities of pharmacy technicians to ensure that such activities are performed completely, safely and without risk or harm to patients. (Cal. Code Regs., tit. 16, § 1793.1, subd. (g).) Reference is

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f. Written justification of the chose expiration dates for compounded, parenteral products.

<sup>3</sup> The procedures must include: a) compounding and labeling of intravenous admixtures, b) administration of intravenous therapy, c) equipment and supplies, d) training of staff, patient and caregiver, e) procedures for handling cytotoxic agents, f) quality assurance program, and g) record keeping requirements. (Cal. Code Regs., tit. 16 § 1751.8.)

made to the matters set forth in Findings 8 through 16. Respondent failed to ensure that the compounding activities of pharmacy technicians were performed completely, safely and without risk to patients.

j. 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 name tags was followed at Doc's Pharmacy, but on at least one occasion pharmacy technicians Cantrell and Medeiros were observed without a name tag.

k. Pharmacist in Charge. A pharmacist in charge is responsible for ensuring that all pharmacy personnel engaged in compounding parenteral solutions shall have training and demonstrated competence in the safe handling and compounding of parenteral solutions including cytotoxic agents. Records of training and demonstrated competence must be available for each individual. (Cal Code Regs., tit. 16, § 1751.5.) Respondent was not the pharmacist-in-charge so he was not responsible for the training of pharmacy technicians. Horwitz was.

Horwitz, as the pharmacist-in-charge, was responsible for completing a self-assessment of the pharmacy's compliance with federal and state pharmacy laws. (Cal. Code Regs., tit. 16, § 1715.) The form was completed by respondent instead of Horwitz, in anticipation of respondent's eventual assumption of pharmacist-in-charge responsibilities. Respondent represented on that form that a quality assurance program was in place when, in fact, no such program existed. Respondent also indicated that a biological safety cabinet was not applicable when such a safety cabinet was required to compound cytotoxic medications. Finally, respondent also indicated that policies and procedures were to be written for the preparation and compounding of parenteral products, but no such polices or procedures were ever written.

### **Respondent's Background and Experience**

27. Education and Experience. Respondent completed a Doctor of Pharmacy program at the University of Illinois at Chicago. He worked as a hospital pharmacy technician while attending pharmacy school. Upon graduation he took and passed both the national and Illinois pharmacy examinations. Between 1994 and 1996 he worked as a clinical pharmacist and preceptor at Northwestern Memorial Hospital in Chicago. This was in a teaching hospital setting, and his duties included attending daily rounds as a clinical pharmacist on a medical team. In 1996 he worked as the clinical coordinator for the Department of Pharmacy at Chicago's Vencor Hospital, a 125-bed hospital for mechanically ventilated patients. They needed a pharmacist to start a pharmacokinetic dosing service and to train their staff, a task he accomplished over six months.

In 1996 he moved west to Overlake Hospital and Medical center in Bellevue, Washington. Between 1996 and 1998 he was a Clinical Coordinator, Department of Pharmacy where he lead a team of nine clinical pharmacists in activities including drug use evaluations, monitoring drug therapies and overseeing pharmacy services for a 35-bed oncology ward. He performed a pharmaco-economic study on Abcizimab, an angioplasty medication, examining its impact on hospital length of stay and presented the results at a 1998 pharmacy conference of the American Society of Health Systems Pharmacists (ASHP). He also helped run a pharmacy residency program for post-graduate studies.

28. Doc's Pharmacy. Respondent met Horwitz during an earlier tour of the Bay Area and maintained professional contact with him. Horwitz approached respondent in winter 1998 and asked him to consider moving to Walnut Creek to work with him and to eventually take over Doc's Pharmacy when Horwitz retired. Respondent was intrigued by the opportunity to work in retail pharmacy. He felt that he and Horwitz complemented each other rather well, respondent being focused on developing a clinical practice and Horwitz being established in retail pharmacy and compounding.

Horwitz was well known and respected in the area of compounding pharmacy. He was recipient of the 1998 PCCA "Compounder of the Year" and he was particularly proud of this fact. PCCA has close to 6000 members, and respondent knew Horwitz to be a recognized expert and highly regarded conference speaker on the subject of compounding. Not surprising, such was his reputation that within Doc's Pharmacy there was an institutional acceptance of the status quo and an atmosphere of deference to Horwitz in all manners and procedures by which drugs were compounded there. Horwitz was the undisputed expert in compounding, responsible for educating everyone who engaged in compounding at the pharmacy, including respondent. Respondent assumed that compounding practices at Doc's Pharmacy were in good order when he began working there in 1998, and he gave very little thought to challenging, let alone changing any compounding protocols. Owing to this dynamic he had a blind spot to compounding problems throughout the entire period leading up to the May 2001 tragedy. In his mind compounding was the primary responsibility of Horwitz, and respondent's involvement was as little as he could manage. He essentially limited himself to supervising and signing off on compounded medications when Horwitz was unavailable to do, so or was otherwise absent from the pharmacy. Even the Doc's Pharmacy letterhead reflected their working arrangement, characterizing Horwitz as "Compounding Specialist" and respondent as "Clinical Pharmacy Specialist."

Respondent summarized the situation as follows in a letter he sent to the Board: "Prior to coming to Doc's I had no experience in compounding or retail pharmacy for that matter. I foolishly was lead to believe that Doc's Pharmacy, being such a well-respected pharmacy and Dr. Horwitz, being so well revered by his colleagues, was following all practices to the letter of the law."

29. Matters in Mitigation. Respondent found Doc's Pharmacy to be a rather fluid and very busy pharmacy. He estimates that the pharmacy filled approximately 550 prescriptions per week, half of which were compounded medications. In a given year Doc's

Pharmacy would prepare roughly 300 prescriptions for injection. In terms of compounded medications, respondent estimates that 8000 formula logs were generated in a given year and that he may have been involved in 1000 of these. When he was involved, he made it clear to pharmacy technicians that he wanted to sign off on both the finished product and early on during the compounding process. When pharmacy technicians called for a "scale check," that would alert him to go over to the compounding area to check any critical step of the compounding procedure. He would review the label and formula log that had been printed and make sure that they matched, then do the calculations and scale measures to ensure that ingredients were properly measured and weighed. He avers that he did so religiously, notwithstanding the confusing documentation reflected on the formula logs. Before compounded medications were dispensed, he would visually examine the product for consistency and then sign the label that would go on the medication.

Respondent avers that he did his professional best to make sure that prescriptions were filled properly and that the information conveyed was accurate. In addition to signing off on labels reflecting his personal involvement, he would also sign off on finished products that he believed had been checked earlier by Horwitz.

Respondent had no direct involvement in the compounding of the contaminated batch of betamethasone. However, he was familiar with the procedures by which betamethasone was prepared at Doc's Pharmacy, and presumably these same procedures were followed on May 11, 2001.

30. Respondent's first six months at Doc's Pharmacy were spent learning the ropes of basic retail pharmacy. By December 1998 he went into partnership with Horwitz and obtained a 15 percent share of the business. Doc's Pharmacy became incorporated in April 1999, and by late summer 2000 respondent's share of the business was 49 percent. Horwitz remained majority shareholder and served as president, treasurer and secretary of the corporation. Respondent was given a minor role as director, and his authority was quite limited – he was not even authorized to sign checks for the business.

The business itself grew as respondent branched out services into new areas such as palliative care, pain management, wound care and central nervous system deficiencies. Respondent began doing consulting work, largely in the area of natural hormone replacement therapy and nutrition. He built his practice up to 100 patients with whom he worked, and he spent up to three hours per day on the telephone providing consultation services.

Respondent left Doc's Pharmacy in August 2001. He now works in a Safeway pharmacy in Walnut Creek. Respondent learned only secondhand that Doc's Pharmacy was sold by Horwitz. He was never consulted about the sale, he does not know the sale price and he has not received any of the sale proceeds.

31. Other Matters Considered. Respondent understands that as part owner he needs "to take some responsibility," but he also insists that he cannot "be directly blamed for something that I was not even at the pharmacy when it happened." He is quick to point out

that the bulk of his time was spent consulting with patients and that he “could never claim expertise in compounding nor did I ever purport myself as such.”

Respondent somehow misses the point. He is responsible. He knows how betamethasone was compounded at the pharmacy, and that betamethasone was probably compounded on May 11 as it had always been compounded at Doc’s Pharmacy. The use of cold sterilization, improper autoclave settings, the failure to autoclave as a last step, improper supervision of pharmacy technicians while compounding and the host of other problems associated with recordkeeping, labeling and checking procedures were all routine practices at Doc’s Pharmacy. Respondent knows this, and he engaged in or supervised such activities. He was directly involved in perhaps 1000 out of 8000 formula logs each year, and this is a very significant amount. He cannot simply dismiss his involvement in compounding as not being the pharmacist with education/expertise in this area. Having undertaken to become involved at all in compounding, and having a direct awareness of pharmacy compounding procedures, he now needs to accept a larger and more direct responsibility for what happened.

Had business at Doc’s Pharmacy proceeded according to plans, Horwitz would have retired, and respondent would have become the pharmacist in charge. Compounding practices may very well have continued as before at Doc’s Pharmacy, only without Horwitz. Respondent must accept more than token responsibility for what happened and not be so quick to lay blame at the feet of Horwitz.

32. The above matters have been considered in determining what discipline should be imposed. It is appropriate that the licenses for Doc’s Pharmacy and for Horwitz have already been surrendered. Horwitz was the pharmacist in charge, and he was clearly the one most responsible for all that occurred. He established most, if not 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.

License revocation, however, is not necessary in this case. It would be unduly harsh. Respondent was only a fourth year pharmacist when he joined Doc’s Pharmacy. It was a difficult situation for him because he had never worked in retail pharmacy, and, therefore, he had little with which to compare the practices at Doc’s Pharmacy as he encountered them. Mostly out of deference to and respect for Horwitz, he never thought to challenge established compounding procedures or to push hard for improved quality controls. His pharmacy school and professional education in compounding medications were apparently deficient, almost non-existent in terms of sterile/aseptic technique. He was focused on expanding into clinical pharmacy, and he was rather comfortable trusting that Horwitz and pharmacy technicians who were engaged for years in compounding knew what they were doing.

Respondent has been and continues to be very dedicated to the practice of pharmacy. These events have been more than an eye opener. He will surely take future supervisory

responsibilities more seriously, and he will hopefully take greater pains to establish and maintain the highest standards for quality assurance wherever he practices pharmacy. With additional education and restrictions on his pharmacy practice, including a prohibition against compounding any parenteral medications, respondent will present no danger to the public health or safety.

33. 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, except those few that relate directly to the duties of a pharmacist in charge, all involved respondent to some degree. Apportionment of costs will therefore not be made with respect to him. However, to the extent that the Board recovers the reasonable costs ordered and due from respondents Cantrell and Medeiros, such should be credited to the balance owing from respondent.

34. The \$47,625.25 that the Board's seeks to recover as its costs shall be reduced by \$10,466 per Finding 33. The reasonable costs of the investigation and prosecution of this case are determined to be \$37,159.25.

## 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 17. Respondent committed acts of gross negligence that relate to the procedures and manner by which the contaminated betamethasone was prepared on May 11, 2001.

3. 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 18 through 20, and 22. Respondent committed acts of gross negligence pertaining to the compounding of parenteral, sterile and non-sterile medications. Other matters set forth in Findings 21, 23 through 25 constituted simple departures from the standard of care or negligence.

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 26. Specific references are made in Finding 26 to the pharmacy laws and regulations that were violated by respondent in each instance.

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 33 and 34.

6. The matters set forth in Findings 28 through 32 were carefully considered in making the following order. Given all the circumstances in this case, 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 ninety (90) days actual suspension, remedial education and a prohibition against compounding parenteral medications until the Board deems it safe for him to do so.

## ORDER

License number RPH 50062 issued to Jamey Phillip Sheets is revoked. However, the revocation is stayed and respondent is placed on probation for five (5) years upon the following terms and conditions:

1. Actual Suspension. As part of probation, respondent is suspended from the practice of pharmacy 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 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 practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; 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 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 in which he holds an interest at the time this decision becomes effective.

2. Restricted Practice. Respondent's practice of pharmacy shall be restricted so that he is prohibited from compounding parenteral medications over the period of probation. The Board, upon receipt of documentation showing that he has completed a Board approved remedial education program, may modify this condition to allow him to compound parenteral medications.
3. Remedial Education. Within sixty (60) days of the effective date of this decision, respondent shall submit to the Board, for its prior approval, an appropriate program of remedial education related to compounding parenteral medications, quality assurance procedures, recordkeeping, basic supervision of pharmacy technicians/retail pharmacy operations and any other subjects deemed appropriate by the Board. The program of remedial education shall consist of at least 180 hours, which shall be completed within three (3) years at respondent's own expense. The period of probation shall be extended until such remedial education is successfully completed and written proof, in a form acceptable to the Board, is provided to the Board. All remedial education shall be in addition to continuing education courses used for license renewal purposes. Failure to complete the remedial education as set out hereinabove is a ground for the filing of a petition to revoke probation.

Following the completion of each course, the Board or its designee may administer an examination to test the respondent's knowledge of the course.

4. Supervised Practice. Respondent shall practice only under the supervision of a pharmacist not on probation with the Board. Respondent shall not practice until the supervisor is approved by the Board or its designee. The degree of supervision shall be as the Board directs.

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit a report to the Board in writing stating the supervisor has read this decision. If respondent changes employment, respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit a report to the Board in writing stating the supervisor has read this decision.

With ten (10) days of leaving employment, respondent shall so notify the Board in writing.

5. No Supervision. Respondent shall not supervise any ancillary personnel, including, but not limited to, registered technicians or exemptees, of any pharmacy or wholesaler licensed by the Board. The Board, upon receipt of documentation that respondent has completed a Board approved remedial education program, may modify this condition to allow him to supervise ancillary personnel.
6. Obey All Laws. Respondent shall obey all federal and state laws and regulations substantially related or governing the practice of pharmacy.
7. Reporting to 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 made as directed, probation shall be extended automatically until such time as the final report is made.
8. Interview with Board. 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.
9. 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 his probation. Failure to cooperate shall be considered a violation of probation.

10. Peer Review. Respondent shall submit to peer review as deemed necessary by the Board.
11. Continuing Education. Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board.
12. Notice to Employers. Respondent shall notify all present and prospective employers of the decision in this case 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 his employer to report to the Board in writing acknowledging the employer has read the decision.

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 he is to be employed or used of the fact and terms of the decision in this case in advance of 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 respondent is considered an employee or independent contractor.

13. No Preceptorships. Respondent shall not supervise any intern pharmacist or perform any of the duties of a preceptor, nor shall respondent be the pharmacist-in-charge of any pharmacy licensed by the Board.
14. Reimbursement of Costs. Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$ 37,159.25. Respondent shall make said payments as arranged with and directed by the Board.

If respondent fails to pay the costs as specified by the Board and on or before the dates 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.

15. 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.
16. License Status. Respondent shall, at all times while on probation, maintain an active current license with the Board, including any period during which suspension or probation is toned.

If respondent's license 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.

17. Notice 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.
18. 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 respondent is actively practicing pharmacy 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 pharmacy in California, respondent must notify the Board in writing within ten (10) days of cessation of the practice of pharmacy or resuming the practice of pharmacy. "Cessation of practice" means any period of time exceeding thirty (30) days in which respondent is not engaged in the practice of pharmacy as defined in section 4052 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.

19. 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 practice pharmacy upon returning to this state until notification by the Board the period of suspension has been completed.

20. 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.

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

DATED: January 18, 2007

  
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JONATHAN LEW  
Administrative Law Judge  
Office of Administrative Hearings

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

In the Matter of the Accusation Against:

JAMEY PHILLIP SHEETS  
579 Aleta Place  
Pleasant Hill, CA 94523

License No. RPH 50062

Respondent.

Case No. 2427

OAH No. N2001080761-A

**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 LITSEV  
Board President

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6 Attorneys for Complainant

7  
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  
112 La Casa Via #100  
13 Walnut Creek, CA 94598  
License No. PHY 44031

**ACCUSATION**

14 ROBERT EUGENE HORWITZ  
15 1080 Coco Lane  
Walnut Creek, CA 94598  
16 License No. RPH 24532

17 JAMEY PHILLIP SHEETS  
579 Aleta Place  
18 Pleasant Hill, CA 94523  
License No. RPH 50062

19 HEIDI L. MEDEIROS  
20 P.O. Box 2961  
Martinez, CA 94553  
21 License No. TCH 25025

22 MARGO N. CANTRELL  
2942 Filbert Street  
23 Antioch, CA 94509  
License No. TCH 16559

24 Respondents.

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26  
27 //

28 //

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 where 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

- 1 a pharmacist was unavailable.
- 2 e. When a compounded prescription was refilled it was assigned a lot number that
- 3 corresponded to the original prescription number even though the re-fill
- 4 prescription was compounded from a different batch.
- 5 f. Respondents compounded chemotherapy drugs in the absence of required
- 6 equipment, policies and procedures. There was no cytotoxic safety cabinet to
- 7 compound these drugs, no methodology for disposing of cytotoxic waste, no
- 8 procedure on how the materials were to be prepared or information to be given to
- 9 the patients on how to dispose of the cytotoxic residue.
- 10 g. A June 13, 2001 inspection revealed improperly labeled vials and suppositories
- 11 stored in the refrigerator. The medications were missing names, lot numbers and
- 12 expiration dates.
- 13 h. There was a demonstrated lack of training and knowledge with respect to
- 14 maintaining the integrity and sterilization of any compounded medications. There
- 15 was no documented in house training for the compounding of medications.
- 16 i. There was no documentation for the cleaning and sanitation of the parenteral
- 17 compounding area.
- 18 j. The labeling practice for all compounded medications was confusing, inaccurate
- 19 and inconsistent.
- 20 k. Syringes were attached to many liquid ingredients used for compounding
- 21 medications, but there was no date on the syringe indicating when it was attached.
- 22 l. Medications were stored next to food preparations.
- 23 m. There was no documentation on steps to be taken if testing proves that a product
- 24 is contaminated.
- 25 n. Respondents did not monitor or document equipment (autoclave, scales, etc.) for
- 26 accuracy.
- 27 o. Respondents failed to have a written policy regarding disposal of waste material.
- 28 p. Respondents did not have a policy with respect to compounded drugs that must be

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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.

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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