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

In the Matter of the Statement of Issues Against:	Case No. 3163
ROBERT EUGENE HORWITZ,	OAH No. 2008050495
Respondent.	

DECISION

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

This decision shall become effective on November 14, 2008.

It is so ORDERED on October 15, 2008.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
KENNETH H. SCHELL
Board President

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

In the Matter of the Statement of Issues Against: ROBERT EUGENE HORWITZ, Respondent.	Case No. 3163 OAH No. 2008050495

PROPOSED DECISION

This matter was heard before Steven C. Owyang, Administrative Law Judge, State of California, Office of Administrative Hearings, in Oakland, California, on August 5, 2008.

Joshua A. Room, Deputy Attorney General, represented complainant Virginia Herold, Executive Officer, Board of Pharmacy, Department of Consumer Affairs.

Respondent Robert Eugene Horwitz was present and represented himself.

The matter was submitted for decision on August 5, 2008.

FACTUAL FINDINGS

1. On July 17, 2007, respondent Robert Eugene Horwitz submitted an application to the Board of Pharmacy for registration as a pharmacy technician. The board denied the application on November 19, 2007. Respondent appealed.

2. Respondent was previously licensed as a pharmacist and previously disciplined by the board.

3. On July 26, 1966, the board issued respondent Pharmacist License No. RPH 24532. On November 21, 2001, respondent stipulated to the surrender of that license in settlement of disciplinary charges that had been brought against him in Case No. 2427. From February 23, 1999, until the surrender of his license respondent was the pharmacist-in-charge, president, secretary, and 51 percent shareholder of Docs Pharmacy Inc. in Walnut Creek.

4. On August 15, 2001, in board case number 2427, the board filed an accusation charging respondent and his co-respondents with numerous violations of the Pharmacy Law.

5. On November 21, 2001, respondent and his attorney executed a stipulation in settlement of the accusation in case number 2427. Respondent admitted "that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation," and gave up his right to contest those charges. In the signed stipulation, respondent further agreed "that in any future proceedings between those respondents and the Board, that the allegations contained in Accusation No. 2427 shall be deemed admitted." Respondent agreed to surrender pharmacist license number RPH 24532, so as to lose all rights and privileges as a pharmacist in California. The board subsequently issued a decision and order, effective March 31, 2002, adopting the stipulation as its decision, and accepting the surrender of respondent's license.

6. Among the allegations admitted by respondent pursuant to the stipulated decision and order, are the following:

a. On or about February 23, 1999, the board issued pharmacy permit number PHY 44031 to Docs Pharmacy Inc. At the time of its initial permit issuance and thereafter until the date of the accusation, respondent Horwitz served as pharmacist-in-charge, president, secretary and 51 percent shareholder of Docs Pharmacy Inc.

b. Respondents Docs, Horwitz and Sheets[1] (respondents) exhibited gross negligence when, in May 2001, they compounded three 100ml vials of betamethasone, a steroid, that were sent to six different health care facilities in Contra Costa County, which vials were contaminated with a bacteria called *serratia marcescems* (serratia).

c. Respondents compounded the betamethasone in a laminar hood, in 100ml vials then taken next door to a doctor's office to be autoclaved. Respondents did not keep records of their use of the autoclave to sterilize the compounded betamethasone, the autoclave was not set at a temperature for sterilizing liquids, and the manufacturer's specifications for the autoclave stated it was not to be used to sterilize compounded medications.

d. After the 100ml vials were autoclaved, they were returned to the pharmacy. When a need for the betamethasone arose, respondents transferred the betamethasone from these 100ml vials to smaller 10ml vials without autoclaving or sterilizing the smaller vials or their rubber stoppers or crimped aluminum caps.

e. The dates on the 10ml vials did not correspond to the date that the betamethasone was compounded, but to the date(s) of transfer.

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[1] Sheets was another pharmacist at Docs Pharmacy.

f. Respondents failed to properly label and document the material(s) used to compound the betamethasone. Some ingredients were made at the pharmacy and stored in non-sterile containers without proper labeling.

g. Respondents failed to comply with record-keeping and labeling requirements regarding the betamethasone compounding.

h. A total of 38 patients received the betamethasone compounded by respondents in May 2001. Of these, 13 were hospitalized and three died.

i. Subsequent retrieval and testing of the vials of betamethasone compounded by respondents confirmed that each vial was contaminated with serratia. Testing of the surfaces at respondents' pharmacy confirmed contamination with serratia, on the sink drain board, the sink handles, and the interior of the homogenizer. One stock material used to compound the betamethasone was also contaminated with serratia.

j. Respondents compounded betamethasone between February 5 and April 30, 2001, without prior testing or validation. A batch of betamethasone compounded on April 30, 2001, was sent for laboratory analysis, which analysis determined that the betamethasone sodium phosphate in the compound varied from the labeled concentration by -11.7 percent, and the betamethasone acetate varied from the labeled concentration by -31.3 percent. Notwithstanding these findings, respondents continued to use the same formula thereafter.

k. Among other failures, respondents failed to adequately supervise pharmacy technicians in compounding activities, allowed pharmacy technicians to compound sterile medications under non-sterile conditions, committed numerous labeling or documentation errors, compounded drugs in the absence of required equipment, policies and procedures, failed to exhibit proper training or knowledge as to maintaining integrity or sterility, and compounded using chloroform despite a 1976 FDA prohibition on use of chloroform.

l. Respondents violated laws regulating controlled substances and dangerous drugs or laws governing pharmacy (Bus. & Prof. Code, § 4301, subds. (j) and (o)) when: in violation of Health and Safety Code sections 111255, 111295, and 111300, they compounded and dispensed betamethasone contaminated with serratia; in violation of California Code of Regulations, title 16, section 1751.1, they prepared cytotoxic medications in the absence of an approved cytotoxic vertical laminar air flow hood, after having falsely represented on a pharmacy self-assessment questionnaire that they did not compound cytotoxic medications; in violation of California Code of Regulations, title 16, section 1751.2, they failed to properly label parenteral products compounded at the pharmacy; in violation of California Code of Regulations, title 16, section 1751.6, they failed to have any written policies or procedures for disposal of infectious materials and/or materials containing

cytotoxic residue; in violation of California Code of Regulations, title 16, section 1751.7, they failed to have a quality assurance program for products compounded at the pharmacy; in violation of California Code of Regulations, title 16, section 1751.8, they failed to have any written policies and procedures with respect to compounding parenteral products; in violation of California Code of Regulations, title 16, section 1716.2, they failed to meet the labeling requirements for medications compounded for future use; in violation of California Code of Regulations, title 16, section 1793.1, subdivision (g), they failed to ensure that activities of pharmacy technicians were performed completely, safely, and without risk to patients; in violation of California Code of Regulations, title 16, section 1793.7, subdivision (d), they failed to ensure that pharmacy technicians wore identification tags; in violation of California Code of Regulations, title 16, section 1751.5, they did not ensure that pharmacy personnel had proper training and competence to compound parenteral products; in violation of California Code of Regulations, title 16, section 1715, they improperly and inaccurately completed a pharmacy self-assessment form dated December 9, 1999.

7. Following the March 31, 2002, effective date of respondent's surrender of his pharmacist license, respondent submitted an application for a pharmacy technician license to the board on March 3, 2003. In a decision that took effect February 14, 2004, the board denied respondent's application.

8. On April 1, 2005, respondent submitted an application for a pharmacist license to the board. After a hearing on January 10, 2006, the board issued a decision that took effect July 14, 2006, and denied respondent's application. Among the board's Factual Findings were:

> 7. Respondent received his undergraduate degree from the University of California, Berkeley, and his doctorate in pharmacy from the University of California, San Francisco, in 1966. Respondent was owner and sole proprietor of Docs Pharmacy from 1971 until 1999, when he and Sheets began conducting the business as a "50/50" partnership. No disciplinary action was taken against respondent's pharmacist license between 1966 and 2001. A notice of violation was issued to Docs Pharmacy in 2000, but there is no evidence that any disciplinary action was taken as a result of that notice.
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> 11. Respondent has no desire to again be in charge of a pharmacy. He believes he is "not cut out" to be an administrator and therefore wants to work only in a subordinate pharmacist position. Respondent's failure to recognize that his failure was not only as an administrator, but as a pharmacist. He failed to meet the most basic requirements under federal and state law. For example, failure to

label properly, failure to have procedures and polices [*sic*] in place, failure to test equipment for accuracy, failure to properly supervisor [*sic*] subordinate staff while performing pharmacy activities. While respondent testified that he would not want to be involved again in sterile compounding, the Board is concerned that his significant failures in compounding medications overlap with the basic functions found in any pharmacy, namely record keeping, supervisor of staff, compliance with federal and state laws and regulations and so forth. Respondent believes he can still be a helpful member of a health care team and would like another chance to be a productive citizen. He testified that a number of pharmacists are willing to offer him a job but he didn't "remember who specifically."

12. From 2002 until 2004, respondent worked as a "marketing agent" for one to two dozen compounding pharmacies. He spoke to physicians about those pharmacies' abilities to compound medications for patients. The transcript differs from the Proposed Decision in that respondent did not testify "at the request of two pharmacies, he wrote sterile compounding policies for them." He testified that "a dozen or two pharmacies who specialized in compounding to explain to their local physicians what their expertise was." [Citation to transcript omitted.] Respondent also testified that he has spoken to pharmacy associations about the circumstances that resulted in the loss of his license and ways to prevent similar occurrences through more careful work. The Board does find this to be helpful to the pharmacy community and a benefit to consumers.

13. Since the surrender of his license respondent has attended a number of continuing education programs. He attended a three-day PCCA marketing symposium in February 2002 and a three-day PCCA International seminar in April 2003. Perhaps reflective of his stated desire to abandon the area of sterile compounding, he has not taken any compounding-related continuing education since then. He has since January 2003 undertaken continuing education in such areas as opiate dependence, hormone replacement, dosage considerations and guidelines, and women's health. Including the PCCA programs, he has accumulated in excess of 70 hours of continuing education.

14. Since the surrender of his license respondent has engaged in a number of community-related volunteer activities. He has worked as an afterschool counselor for the Boys and Girls Club of Diablo Valley, helping children with homework and teaching

computer skills. He has served as a Big Brother to a 10-year-old boy whose father died of cancer. He has been a hospice volunteer with Asera Care Hospice in Concord. He has become a tutor with the Jewish Coalition for Literacy. And he has been involved in a variety of capacities at his synagogue, including working in a program to feed the homeless, serving as a member of a number of committees, and acting as assistant choir director.

Respondent submitted letters from nine pharmacists, five physicians, and three veterinarians, each of whom indicates awareness of the incident that led to the loss of respondent's license, recommending consideration be given to reinstating his license. These letter writers variously refer to respondent's knowledge, skill and professionalism, his dedication to the field of pharmacy, his willingness to share new techniques and innovations with other pharmacists, his impact in the "small niche" of pharmacy involved in compounding, his impact upon the community in which he practiced, and his integrity, compassion and character.

15. Some of respondent's continuing education hours came from attending board meetings in October 2003 and October 2004. Respondent maintains that at one of those meetings Patricia Harris, the board's executive officer, told him that if the board were to grant him a new license he might not have to retake the licensing examination; that requirement could be waived. However, he testified that Harris recently told him he would have to retake the licensing examinations. Respondent seems to see this as an indication that Harris (and by extension the board) is not treating him fairly.

16. Respondent's testimony at the hearing is revealing as to his understanding of his role in what went wrong at Doc's [*sic*] Pharmacy and his current degree of rehabilitation. When Respondent was asked, in regards to section 1751 of the regulations which were in effect at the time of the incident, "what explanation to [*sic*] you offer for the way in which your policies and procedures failed to even come close to meeting those requirements?" Respondent answered, "I don't have a good explanation for where we failed in terms of compliance. We did. There were many people who have not complied with regulations and this is – this is a case of that. We were – we were deficient in that regard." Respondent clearly has not taken the time to educate himself as to exactly what went wrong at Doc's [*sic*] Pharmacy other than to blame Sheets and his own lack of "administrative" skills. This lack of understanding, in light of

the extremely serious nature of the violations, is evidence that Respondent is currently unfit to practice safely as a pharmacist.

9. In Legal Conclusions 6 and 7 in the decision, the board stated:

> 6. In the four years since he surrendered his license respondent has undertaken a number of steps towards rehabilitation. He has volunteered in a number of projects that serve the greater community. He has undertaken continuing education courses. And he has spoken to a pharmacy association about the mistakes made at Docs Pharmacy in an effort to prevent others from making similar mistakes. Respondent recognizes the tragic consequences that resulted from Doc Pharmacy's actions, he takes some responsibility for those actions, and he is clearly remorseful for what occurred. All of this weighs in respondent's favor. On the other hand, respondent's testimony and attitude at the hearing demonstrated an arrogance or hubris that tended to undercut his rehabilitation. While taking responsibility for what occurred in 2001 because he was pharmacist-in-charge, respondent nevertheless sought to distance himself from more direct fault by blaming Sheets for changing the protocols for the compounding of betamethasone without his consent or knowledge. Sheets failure to follow the protocol was not the only violation found at Docs Pharmacy. As the pharmacist-in-charge, respondent would have been aware of these failure [*sic*] by his mere presence in the pharmacy. And respondent attacked both the prosecuting deputy attorney general – for allegedly browbeating him into surrendering his license, and the board's executive officer – for allegedly going back on her word that he would not have to retake a licensing exam if he were granted a license.
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> 7. Due to the serious nature of the acts that led to the loss of respondent's pharmacist license and the lack of insight as to what went wrong at Doc's [sic] Pharmacy as set forth above, and taking into consideration the amount of time that has passed since his failures at Docs Pharmacy, it is determined that respondent has not presented sufficient evidence of rehabilitation to warrant granting him a pharmacist license.

10. Two and one-half years have passed since the January 2006 hearing that resulted in the denial of respondent's application for a pharmacist license. Respondent now seeks registration as pharmacy technician, not licensure as a pharmacist.

11. In a statement presented at the August 5, 2008, hearing in this matter, respondent said:

I feel fortunate again to have this opportunity to present myself to you with the hopes that you will look at me in a new light, as a caring individual, and not the hubristic person the State perceived me to be when I last appeared in court. Those people who know me, family, friends, colleagues, and those with whom I worked on a professional basis, know that I am a caring and compassionate individual. It really saddens me to think that I may have given a false impression in the past. It is difficult for me to come to terms, even now, with the fact that I could have caused all of the destruction that I was responsible for doing. It still causes me sleepless nights and lasting thoughts as to my involvement in such a horrible tragedy. That is why I am now asking you both to please give me the opportunity to serve in a supportive role as a pharmacy technician, instead of as a pharmacist. I caused a tragedy in our community some 7 years ago by not being a vigilant "Pharmacist-in-charge". I hope that in this session today, the Board will take this opportunity, in this courtroom, to have a new mindset and to entertain the possibility of reassessing their view of me. I do have a lot to be proud of over my years as a pharmacist, but being a "Pharmacist-in-charge" is nowhere on that list. I have always taken the positive position in life, assuming that directions would be followed as instructed, but that role failed me because I am not the stickler for making sure that things are done by others as I had done them myself. When my pharmacy was much smaller, I did all the compounding, and there was never a problem that the Board needed to address. As we grew, we added pharmacy staff, and I directed what I wanted done and how it was to be done. Unfortunately, I was not a good leader of personnel, and did not check to see that things were done as requested. I acted more like a behind the scene administrator rather than a hands-on person in the middle of everything as I should have done. I do feel terrible for the situation I caused by not being more vigilant. That position, I have realized for some time now, is not what suites [*sic*] my type of person, and I never want to be in that type of situation again. I would be happy to follow the direction of others, knowing full well that I could do a good job in assisting a pharmacist in helping the patients of that pharmacy get top quality service and products. My coming across as hubristic, I'm sure, is a result of my not wanting to break down when I think of the harm and tragedy I caused from my carelessness. It has been over 40 years since I have taken the State Board exams, and have no desire to begin all over again at my age. I would just like to be a pharmacy technician, and, in some small way, help the public with their medications, as I have been trained to do. I realize that I would no longer be counseling patients on their drugs, but merely

> assisting the pharmacist to get appropriate, prescribed medication to each patient. My love for pharmacy is still very strong, in spite of the tragedy, and is [*sic*] some small way, I want the opportunity to redeem myself by being helpful to others within the healthcare field.
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> Judge Owyang and Mr. Room, I hope that when this day is over, you will come to a new understanding of the pain, embarrassment, shame, and anguish both the State Board and I felt with regard to this tragedy, and still do to this day. It is something that has been a wake-up call for me to finally understand myself and my limitations in society. I also hope that the Board can find it in their hearts to finally forgive me for my transgressions, and give me another opportunity to once again work productively in the healthcare industry. Thank you again judge for allowing me to say my piece in an attempt to become a participant in keeping our community healthy, and healing the sick.
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> Finally, our Judeo-Christian roots as well as our country's forefathers instilled in us mercy, compassion, forgiveness, and redemption, and so I humbly stand before you now to ask for your consideration of those lessons so deeply ingrained in us all. Thank you.

12. The acts that resulted in the surrender of respondent's pharmacist's license were extremely serious. Three people died and many others were hospitalized because Docs Pharmacy failed to take sufficient precautions to prevent a compounded medication from becoming contaminated. Respondent understands this and takes responsibility for it. He remains remorseful, embarrassed, and anguished by his conduct. He did not exhibit arrogance or hubris or attack the board, its executive officer or the deputy attorney general. As respondent stated, it has been "a wake-up call for me to finally understand myself and my limitations in society."

LEGAL CONCLUSIONS

1. Complainant established grounds to deny respondent's application for registration as a pharmacy technician under Business and Professions Code sections 480, subdivision (a)(3), and 4300, subdivision (c), in that applicant engaged in unprofessional conduct and acts by a licentiate that were grounds for suspension or revocation of a license, including gross negligence under Business and Professions Code, section 4301, subdivision (c).

2. Complainant established grounds to deny respondent's application for registration as a pharmacy technician under Business and Professions Code sections 480, subdivision (a)(3), and 4300, subdivision (c), in that applicant engaged in unprofessional conduct and acts done by a licentiate that were grounds for suspension or revocation of a license, i.e., violations of laws regulating controlled substances and dangerous drugs or laws governing pharmacy as per Business and Professions Code sections 4301, subdivisions (j) and (o), and Health and Safety Code sections 111255, 111295, and 111300, as well as violations of California Code of Regulations, title 16, sections 1715, 1716.2, 1751.1, 1751.2, 1751.5, 1751.6, 1751.7, 1751.8, 1793.1, subdivision (g), and 1793.7, subdivision (d).

3. In considering whether to grant respondent's application for a pharmacy technician registration, a number of legal principles must be borne in mind. First, respondent bears the burden of proving that he is currently fit to practice safely as a pharmacy technician. Second, in exercising its licensing, regulatory, and disciplinary functions, the board's highest priority is protection of the public; when "the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." (Bus. & Prof. Code, § 4001.1.) Third, in passing upon a license application the board is required to give consideration to evidence of rehabilitation and lack thereof. Once again, however, "public protection shall take priority over rehabilitation and, where evidence of rehabilitation and public protection are in conflict, public protection shall take precedence." (Bus. & Prof. Code, § 4313.) The applicant's evidence of rehabilitation must be considered in light of the nature and severity of the acts that serve as grounds for denial and the time that has elapsed since those acts. (Cal. Code Regs., tit. 16, § 1769, subd. (a).) Finally, case law has long held that the primary purpose of administrative proceedings such as this one is protection of the public, not punishment of the licensee or applicant. (*Camacho v. Youde* (1979) 95 Cal.App.3d 161, 164.)

The acts that resulted in the surrender of respondent's license were extremely serious. Three people died and many others were hospitalized because Docs Pharmacy failed to take sufficient precautions to prevent a compounded medication from becoming contaminated. Respondent, as pharmacist-in-charge, was ultimately responsible for the failures in process and procedure that led to the contamination. Respondent understands this and takes responsibility for it. He remains remorseful, embarrassed, and anguished by his conduct. He did not exhibit arrogance or hubris or attack the board, its executive officer or the deputy attorney general. As respondent stated, it has been "a wake-up call for me to finally understand myself and my limitations in society."

Nearly a decade has gone by since the events that led to the revocation of respondent's pharmacist license. He has been through a number of proceedings before the board. The board previously recognized respondent's efforts toward rehabilitation, but remained concerned about his hubris, attacks on the deputy attorney general and board's executive officer, and lack of insight as to what went wrong at Docs Pharmacy. With the passage of time and the opportunity for additional introspection, respondent has come to understand and take responsibility for his conduct. He did not manifest hubris, blame others,

or attack the deputy attorney general, the board's executive officer, or the board. He has demonstrated sufficient rehabilitation to conclude that he may be granted registration as a pharmacy technician, under probationary terms.

ORDER

The application of respondent Robert Eugene Horwitz for registration as a pharmacy technician is hereby granted, provided:

1. That respondent must first meet all statutory and regulatory requirements for registration as a pharmacy technician. Whether respondent shall be required to take and pass all or a portion of the current licensing examination, or whether, by virtue of his prior licensure, he shall be deemed to have satisfied that requirement, is within the board's discretion. If respondent is required to take an examination, he must do so at his own expense. The examination must be taken and passed within 18 months of the effective date of this decision. Failure to pass the examination within that period shall result in denial of respondent's application.

2. That, following the satisfaction of the foregoing, respondent's registration shall be issued and shall immediately be revoked, the order of revocation shall be stayed, and respondent shall be placed on probation for a period of 10 years on the following terms and conditions:

CONDITIONS OF PROBATION

1. *Obey All Laws* – Respondent shall obey all state and federal laws and regulations substantially related to or governing the practice of a pharmacy technician. Respondent shall report any of the following occurrences to the board, in writing, within 72 hours of such occurrence:

   (a) An arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;

   (b) A plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment;

   (c) A conviction of any crime;

   (d) Discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's registration as a pharmacy technician or that is related to the practice of pharmacy or

the manufacturing, obtaining, handling or distribution or billing or charging for any drug, device or controlled substance.

2. *Reporting to the Board* – Respondent shall report to the board quarterly. The report shall be made either in person or in writing, as directed. Respondent shall state under penalty of perjury whether there has been compliance with all the terms and conditions of probation. If the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the board.

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

4. *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 comply shall be considered a violation of probation.

5. *Continuing Education* – Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacy technician as directed by the board.

6. *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 this decision. Within 30 days of the effective date of this decision, and within 15 days of respondent's undertaking new employment, respondent shall cause his direct supervisor, pharmacist-in-charge and/or owner to report to the board in writing acknowledging the employer has read this decision. If respondent works for or is employed by or through a pharmacy employment service, respondent must notify the direct supervisor, pharmacist-in-charge, and/or owner at every pharmacy of the terms and conditions of this decision in advance of respondent's commencing work at each pharmacy. "Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacy technician, whether respondent is considered an employee or independent contractor.

7. *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.

8. *Status of Registration* – Respondent shall, at all times while on probation, maintain an active current registration with the board, including any period during which suspension or probation is tolled. If respondent's registration expires or is cancelled by operation of law or otherwise, upon renewal or reapplication respondent's registration shall be subject to all terms and conditions of this probation not previously satisfied.

9. *Registration Surrender while on Probation* – Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his registration to the board for surrender. The board shall have the discretion whether to grant the request for surrender or to take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the registration, respondent will no longer be subject to the terms and conditions of probation. Upon acceptance of the surrender, respondent shall relinquish his registration to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any registration from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the registration sought as of the date the application for that registration is submitted to the board.

10. *Notification of Employment/Mailing Address Change* – Respondent shall notify the board in writing within 10 days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, supervisor or owner, and respondent's work schedule if known. Respondent shall notify the board in writing within 10 days of a change in name, mailing address or phone number.

11. *Tolling of Probation* – Should respondent, regardless of residency, for any reason cease work as a pharmacy technician for a minimum of 40 hours per calendar month in California, he must notify the board in writing within 10 days of cessation of work as a pharmacy technician or the resumption of work as a pharmacy technician. Such periods of time shall not apply to the reduction of the probation period. It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a period exceeding three years. "Cessation of practice" means any period of time exceeding 30 days in which respondent is not engaged in work as a pharmacy technician. If respondent has not complied with this condition during the probationary term, and respondent has presented sufficient documentation of his good faith efforts to comply with this

condition, and if no other conditions have been violated, the board, in its discretion, may grant an extension of respondent's probation period up to one year without further hearing in order to comply with this condition.

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

13. *Completion of Probation* – Upon successful completion of probation, respondent's registration will be fully restored.

14. *Supervised Practice* – Respondent shall work as a pharmacy technician only under the supervision of a pharmacist not on probation with the board. Respondent shall not work as a pharmacy technician until his supervisor is approved by the board. The supervision shall be, as required by the board, either: Continuous - 75% to 100% of a work week; Substantial - At least 50% of a work week; Partial - At least 25% of a work week; Daily Review - Supervisor's review of respondent's daily activities within 24 hours. Within 30 days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating the supervisor has read this decision and is familiar with the level of supervision as determined by the board. If respondent changes employment, respondent shall have his new supervisor, within 15 days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read this decision and are familiar with the level of supervision as determined by the board. Within 10 days of leaving employment, respondent shall notify the board in writing.

15. *No Supervision* – Respondent shall not supervise any ancillary personnel, including, but not limited to, registered pharmacy technicians or exemptees, of any entity licensed by the board.

16. *No Ownership of Premises* – Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation

currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within 90 days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board.

DATED: August 29, 2008

STEVEN C. OWYANG
Administrative Law Judge
Office of Administrative Hearings

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

In the Matter of the Statement of Issues Against: ROBERT EUGENE HORWITZ 1080 Coco Lane Walnut Creek, California 94598 Applicant for Pharmacy Technician Registration Respondent.	Case No. 3163 **STATEMENT OF ISSUES**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Statement of Issues solely in her official capacity as Executive Officer, Board of Pharmacy, Department of Consumer Affairs.

2. On or about July 17, 2007, the Board of Pharmacy, Department of Consumer Affairs received an Application for Registration as a Pharmacy Technician from Robert Eugene Horwitz (Respondent). On or about July 12, 2007, Respondent certified under penalty of perjury the truthfulness of all statements, answers, and representations in the application. The Board denied the application on or about November 19, 2007.

JURISDICTION

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

STATUTORY PROVISIONS

4. Section 4300, subdivision (c), of the Code states:

"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

"(1) Medical or psychiatric evaluation.

"(2) Continuing medical or psychiatric treatment.

"(3) Restriction of type or circumstances of practice.

"(4) Continuing participation in a board-approved rehabilitation program.

"(5) Abstention from the use of alcohol or drugs.

"(6) Random fluid testing for alcohol or drugs.

"(7) Compliance with laws and regulations governing the practice of pharmacy."

5. Section 4301 of the Code provides, in pertinent part, that "unprofessional conduct" is defined to include, but not be limited to, any of the following:

. . .

"(c) Gross negligence.

. . .

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

. . .

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

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6. Section 480 of the Code states, in pertinent part:

"(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

. . .

"(3) Done any act which if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

"The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions or duties of the business or profession for which application is made."

. . .

7. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

PROCEDURAL/FACTUAL BACKGROUND

8. On or about July 26, 1966, the Board issued Pharmacist License Number RPH 24532 to Respondent. On or about August 15, 2001, in a case titled *In the Matter of the Accusation Against Docs Pharmacy Inc; Robert Eugene Horwitz; Jamey Phillip Sheets; Heidi L. Medeiros; Margo N. Cantrell*, Board Case No. 2427, the Board filed an Accusation charging Respondent and his co-respondents with numerous violations of Pharmacy Law.

9. The Accusation filed against Respondent and his co-respondents alleged that the respondents committed several acts of gross negligence (Bus. & Prof. Code, § 4301(c)), and several violations of the laws regulating controlled substances and/or the laws regulating pharmacy (Bus. & Prof. Code, § 4301(j), (o); Cal. Code Regs., tit. 16, § 1700 et seq.).

10. On or about November 21, 2001, Respondent and his attorney executed a stipulation in settlement of the Accusation in Case No. 2427 in which Respondent admitted "that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation," and gave up his right to contest those charges. In the signed stipulation, Respondent further agreed "that in any future proceedings between those respondents and the Board, that the allegations contained in Accusation No. 2427 shall be deemed admitted." (Stipulation, ¶ 9). By way of the stipulation, Respondent agreed to surrender Pharmacist License No. RPH 24532, so as to lose all rights and privileges as a Pharmacist in California. The Board subsequently issued a Decision and Order, effective March 31, 2002, adopting the stipulation as its decision, and accepting the surrender of Respondent's license. A signed copy of the "Stipulated Settlement Agreement Only With Respect to Respondents Docs Pharmacy Inc and Robert Eugene Horwitz," the Board's Decision and Order adopting that stipulation, and the Accusation in Case No. 2427, is attached as Exhibit A hereto and incorporated herein by reference.

11. Among the allegations in Accusation No. 2427, which are to be deemed admitted by Respondent, pursuant to the stipulated Decision and Order, are the following:

a. On or about February 23, 1999, the Board issued Pharmacy Permit No. PHY 44031 to Docs Pharmacy Inc. At the time of its initial permit issuance and thereafter until the date of the Accusation, Respondent Horwitz served as Pharmacist-in-Charge, President, Secretary, and 51% shareholder of Docs Pharmacy Inc. (Accusation, ¶ 2).

b. Respondents Docs, Horwitz and Sheets ("Respondents") exhibited gross negligence when, in May 2001, they compounded three 100ml vials of betamethasone, a steroid, that were sent to six different health care facilities in Contra Costa County, which vials were contaminated with a bacteria called *serratia marcescems* ("serratia"). (Accusation, ¶ 13).

c. Respondents compounded the betamethasone in a laminar hood, in 100ml vials then taken next door to a doctor's office to be autoclaved. Respondents did not keep records of their use of the autoclave to sterilize the compounded betamethasone, the autoclave was not set at a temperature for sterilizing liquids, and the manufacturer's specifications for the autoclave stated it was not to be used to sterilize compounded medications. (Accusation, ¶ 14).

d. After the 100ml vials were autoclaved, they were returned to the pharmacy. When a need for the betamethasone arose, respondents transferred the betamethasone from these 100ml vials to smaller 10ml vials without autoclaving or sterilizing the smaller vials, or their rubber stoppers or crimped aluminum caps. (Accusation, ¶ 15).

e. The dates on the 10ml vials did not correspond to the date that the betamethasone was compounded, but to the date(s) of transfer. (Accusation, ¶ 16).

f. Respondents failed to properly label and document the material(s) used to compound the betamethasone. Some ingredients were made at the pharmacy and stored in non-sterile containers without proper labeling. (Accusation, ¶ 17).

g. Respondents failed to comply with record-keeping and labeling requirements regarding the betamethasone compounding. (Accusation, ¶ 18).

h. A total of 38 patients received the betamethasone compounded by respondents in May 2001. Of these, 13 were hospitalized, and 3 died. (Accusation, ¶ 19).

i. Subsequent retrieval and testing of the vials of betamethasone compounded by respondents confirmed that each vial was contaminated with serratia. Testing of the surfaces at respondents' pharmacy confirmed contamination with serratia, on the sink drain board, the sink handles, and the interior of the homogenizer. One stock material used to compound the betamethasone was also contaminated with serratia. (Accusation, ¶¶ 20-25).

j. Respondents compounded betamethasone between February 5 and April 30, 2001 without performing any validation or testing of the compounding processes or the final product. During this time period 165 5ml vials of betamethasone were dispensed without prior testing or validation. A batch of betamethasone compounded on April 30, 2001 was sent for laboratory analysis, which analysis determined that the betamethasone sodium phosphate in the compound varied from the labeled concentration by -11.7%, and the betamethasone acetate varied from the labeled concentration by -31.3%. Notwithstanding these findings, respondents continued to use the same formula thereafter. (Accusation, ¶ 26).

k. Among other failures, respondents failed to adequately supervise pharmacy technicians in compounding activities, allowed pharmacy technicians to compound

sterile medications under non-sterile conditions, committed numerous labeling or documentation errors, compounded drugs in the absence of required equipment, policies and procedures, failed to exhibit proper training or knowledge as to maintaining integrity or sterility, and compounded using chloroform despite a 1976 FDA prohibition on use of chloroform. (Accusation, ¶¶ 27-30).

l. Respondents also violated laws regulating controlled substances and dangerous drugs or laws governing pharmacy (Bus. & Prof. Code, § 4301(j), (o)) when: in violation of Health and Safety Code sections 111255, 111295, and 111300, they compounded and dispensed betamethasone contaminated with serratia; in violation of California Code of Regulations, title 16, section 1751.1, they prepared cytotoxic medications in the absence of an approved cytotoxic vertical laminar air flow hood, after having falsely represented on a pharmacy self-assessment questionnaire that they did not compound cytotoxic medications; in violation of California Code of Regulations, title 16, section 1751.2, they failed to properly label parenteral products compounded at the pharmacy; in violation of California Code of Regulations, title 16, section 1751.6, they failed to have any written policies or procedures for disposal of infectious materials and/or materials containing cytotoxic residue; in violation of California Code of Regulations, title 16, section 1751.7, they failed to have a quality assurance program for products compounded at the pharmacy; in violation of California Code of Regulations, title 16, section 1751.8, they failed to have any written policies and procedures with respect to compounding parenteral products; in violation of California Code of Regulations, title 16, section 1716.2, they failed to meet the labeling requirements for medications compounded for future use; in violation of California Code of Regulations, title 16, section 1793.1(g), they failed to ensure that activities of pharmacy technicians were performed completely, safely, and without risk to patients; in violation of California Code of Regulations, title 16, section 1793.7(d), they failed to ensure that pharmacy technicians wore identification tags; in violation of California Code of Regulations, title 16, section 1751.5, they did not ensure that pharmacy personnel had proper training and competence to compound parenteral products; in violation of California Code of Regulations, title 16, section 1715, they improperly and inaccurately completed a pharmacy self-assessment form dated December 9, 1999. (Accusation, ¶¶ 31-52).

FIRST CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct: Gross Negligence)

12. Respondent's application is subject to denial under sections 4300(c) and 480(a)(3) of the Code in that, as described in paragraph 11(a)-(k), above, Respondent is guilty of unprofessional conduct and/or acts which if done by a licentiate would be (and were) grounds for suspension or revocation of a license, i.e., gross negligence as per section 4301(c) of the Code.

SECOND CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct: Violation of Laws and Regulations)

13. Respondent's application is subject to denial under sections 4300(c) and 480(a)(3) of the Code in that, as described in paragraph 11(l), above, Respondent is guilty of unprofessional conduct and/or acts which if done by a licentiate would be (and were) grounds for suspension or revocation of a license, i.e., violations of laws regulating controlled substances and dangerous drugs or laws governing pharmacy as per sections 4301(j) and/or 4301(o) of the Code, including violations of Health and Safety Code sections 111255, 111295, and 111300, as well as violations of California Code of Regulations, title 16, sections 1751.1, 1751.2, 1751.6, 1751.7, 1751.8, 1716.2, 1793.1(g), 1793.7(d), 1751.5, and 1715.

RE-APPLICATION HISTORY

14. Following the March 31, 2002 effective date of Respondent's surrender of his Pharmacist License, on or about March 3, 2003 Respondent submitted an application for a Pharmacy Technician Registration to the Board. That application was denied on June 4, 2003. Respondent appealed the denial, and an administrative hearing followed. On or about January 15, 2004, with an effective date of February 14, 2004, the Board adopted a Proposed Decision in *In the Matter of the Statement of Issues Against Robert E. Horwitz*, Board Case No. 2675 (OAH No. N2003090034), denying Respondent's application for licensure as a Pharmacy Technician.

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15. On or about April 1, 2005, Respondent then submitted an application for a Pharmacist License to the Board. That application was denied on June 20, 2005. Respondent appealed the denial, and an administrative hearing followed. On or about June 14, 2006, with an effective date of July 14, 2006, the Board issued a Decision After Nonadoption in *In the Matter of the Statement of Issues Against Robert Eugene Horwitz*, Board Case No. 2910 (OAH No. N2005100729), denying Respondent's application for licensure as a Pharmacist.

PRAYER

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

A. Denying the application by Respondent to be a Pharmacy Technician;

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

DATED: 4/18/08

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

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