

Nevada State Board of Pharmacy

431 W. PLUMB LANE • RENO, NEVADA 89509 (775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444 E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

July 14, 2014

AMENDED AGENDA

♦ PUBLIC NOTICE ♦

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, July 23, 2014 at 9:00 am. The meeting will continue, if necessary, on Thursday, July 24, 2014 at 9:00 am or until the Board concludes its business at the following location:

> Hilton Garden Inn 7830 S Las Vegas Boulevard Las Vegas

Please Note

The Nevada State Board of Pharmacy may address agenda items out of sequence to accommodate persons appearing before the Board or to aid in the efficiency or effectiveness of the meeting;

The Nevada State Board of Pharmacy may combine two or more agenda items for consideration; and

The Nevada State Board of Pharmacy may remove an item from the agenda or delay discussion relating to an item on the agenda at any time.

Public comment is welcomed by the Board, but will be heard during the public comment item and may be limited to five minutes per person. The president may allow additional time to a given speaker as time allows and in his or her sole discretion.

Prior to the commencement and conclusion of a contested case or a quasi judicial proceeding that may affect the due process rights of an individual the board may refuse to consider public comment. See NRS 233B.126. Please be aware that <u>after</u> the quasi-judicial board or commission had rendered a decision in the contested case and assuming this happens before adjournment, then you may advise the board or commission that it may **entertain public comment on the proceeding at that time.**

♦ CONSENT AGENDA ♦

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

- 1. Public Comments and Discussion of and Deliberation Upon Those Comments: No vote may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken. (NRS 241.020)
- 2. Approval of June 11-12, 2014, Minutes for Possible Action
- 3. Applications for Out-of-State Pharmacy Non Appearance for Possible Action:
 - A. Factor Support Network Pharmacy, Inc. Camarillo, CA
 - B. LogisMedix Davie, FL
 - C. New Life Pharmacy, LLC Sandy, UT
 - D. PraxisRx Pharmacy Tampa, FL
 - E. RXpress Pharmacy Fort Worth, TX

Applications for Out-of-State Compounding Pharmacy – Non Appearance for Possible Action:

- F. Ability Pharmacy, Inc. Fort Worth, TX
- G. Amber Pharmacy Omaha, NE
- H. Ardon Health, LLC Portland, OR
- I. Carefree Compounding & Wellness Phoenix, AZ
- J. Lane Drugs Brooklyn, NY
- K. Life-Q, LLC Nashville, TN
- L. Mesa Pharmacy VII Irvine, CA
- M. Omro Pharmacy Omro, WI
- N. One Stop Rx, LLC Tulsa, OK
- O. Professional Center 205 Pharmacy Portland, OR
- P. Renner Pharmacy Richardson, TX
- Q. ScriptSite Pharmacy San Francisco, CA
- R. Synergy Rx San Diego, CA
- S. TCS Labs LLC St. Petersburg, FL

Applications for Out-of-State Wholesaler – Non Appearance for Possible Action:

- T. Abbott Laboratories, Inc. North Chicago, IL
- U. Breg, Inc. Carlsbad, CA
- V. Emerson Ecologics LLC Colonial Heights, VA
- W. MicroPort Orthopedics Inc. Arlington, TN
- X. Pharmacyclics, Inc. Sunnyvale, CA
- Y. Smith & Nephew, Inc. Memphis, TN

Applications for Out-of-State MDEG – Non Appearance for Possible Action:

- Z. C.R. Bard, Inc. Covington, GA
- AA. Datascope Corp. Mahwah, NJ
- BB. Edwards LifeSciences Technology SARL, LLC Amasco, PR
- CC. Maquet Medical Systems USA Dayton, NJ
- DD. Wilmington Medical Supply Inc. Wilmington, NC

Applications for Nevada Pharmacy – Non Appearance for Possible Action:

- EE. Atlas Specialty Pharmacy Henderson
- FF. Montevista Hospital Las Vegas
- GG. Speedee Pharmacy Las Vegas
- HH. THC of Nevada Las Vegas

Application for Nevada MDEG – Non Appearance for Possible Action:

II. Prosthetic Consulting Technologies – Carson City

Applications for Nevada Wholesaler - Non Appearance for Possible Action:

- JJ. ASD Specialty Healthcare, Inc. Reno
- KK. Integrated Commercialization Solutions, Inc. Reno
- LL. TheraCom, L.L.C. Reno

♦ REGULAR AGENDA ♦

4. Discipline for Possible Actions: <u>Note</u> – The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties.

А. В. С.	Asha K. Greco, R.Ph Target Pharmacy T-826 Christopher G. Southwick, R.Ph	(14-018-RPH-S) (14-018-PH-S) (14-017-RH-S)
D.	Advanced Isotopes of Nevada	(14-017-PH-S)
E.	Brenton S. Underwood, R.Ph	(14-031-RPH-S)
F.	Amirose De Guzman, R.Ph	(14-013-RPH-S)
G.	CVS/pharmacy #5942	(14-013-PH-S)
H.	Brian Wickson, R.Ph	(14-039-RPH-S)
Ι.	CVS/pharmacy #5792	(14-039-PH-S)
J.	Christopher Gifford, R.Ph	(14-038-RPH-S)
K.	CVS/pharmacy #2955	(14-038-PH-S)
L.	Vicky L. Blackwell, R.Ph	(14-037-RPH-S)
М.	CVS/pharmacy #5113	(14-037-PH-S)
N.	Forouzan Lewis, R.Ph	(13-072-RPH-S)
О.	CVS/pharmacy #2928	(13-072-PH-S)
Ρ.	Kenya M. Peoples, PT	(14-040-PT-S)
Q.	Ronique Dailey, PTT	(14-041-PTT-S)
R.	Charles A. Walker, R.Ph	(14-027-RPH-O)
S.	Brian Chambers, R.Ph	(14-021-RPH-O)

5. Requested Appearance for Possible Action:

Scott Stolte, Dean – Roseman University

6. Request for Authorization to Register as a Pharmaceutical Technician in Training - Appearance for Possible Action:

Cynthia Butler

7. Request for a Pharmaceutical Technician License - Appearance for Possible Action:

Robert C. Thomas

- 8. Requests for a Pharmacist License Appearance for Possible Action:
 - A. Joseph M. Rothkopf
 - B. Joseph E. Steidl
- 9. Request for a Controlled Substance License Appearance for Possible Action:

James R. Eells, MD

10. Application for Nevada MDEG – Appearance for Possible Action:

Amador Medical LLC – Las Vegas

- 11. Applications for Out-of-State Compounding Pharmacy Appearance for Possible Action:
 - A. ARJ Infusion Services Lenexa, KS
 - B. Aureus Pharmacy Pittsburgh, PA
 - C. B & H Pharmacy Provo, UT
 - D. Focus Rx Holbrook, NY
 - E. Inventive Infusion Solutions, LP San Antonio, TX
 - F. JCB Laboratories Wichita, KS
 - G. Rancho Sante Fe Pharmacy Rancho Sante Fe, CA
- 12. Presentations for Possible Action:
 - A. Maple Pharmacy John Quick
 - B. National Prescriber Log Exchange (NPLEx)
- 13. Preview of Red Flag Video for Possible Action
- 14. Appearance Request for Possible Action:

Steven Holper, MD

15. Budget – Fiscal Year 2014-2015 for Possible Action

- 16. General Counsel Report for Possible Action:
 - A. Update on Maryanne Phillips, MD
 - B. Update on Affiliated Monitors, Inc. Mike's Pharmacy
- 17. Executive Secretary Report for Possible Action:
 - A. Financial Report
 - B. Temporary Licenses
 - C. Staff Activities
 - 1. Presentations:
 - a. CE in Carson City
 - b. Washoe County Social Services
 - D. Reports to Board
 - 1. Collaborative Efforts:
 - a. Medi-Spa (BOME)
 - b. Unlicensed Practice (Metro, BOME)
 - c. BON: PMP Efforts
 - 2. Coalition Meeting on Prescription Drug Abuse
 - 3. Meeting with Department of Agriculture, Feed Stores and Veterinary Board
 - E. Board Related News
 - 1. Dental Board Regulation on PMP
 - F. Activities Report

WORKSHOP for Possible Action

<u>Thursday, July 24, 2014 – 9:00 am</u>

18. **Proposed Regulation Amendment Workshop** – The purpose of the workshop is to solicit comments from interested persons on the following general topics that may be addressed in the proposed regulations.

Amendment of Nevada Administrative Code (NAC) 453.540 Schedule IV. Addition of Tramadol to Schedule IV.

19. Next Board Meeting:

September 3-4, 2014 – Reno

20. Public Comments and Discussion of and Deliberation Upon Those Comments: No vote may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken. (NRS 241.020)



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MINUTES

Hyatt Place 1790 E Plumb Lane Reno, Nevada

June 11 & 12, 2014

Board Members Present:

Kam Gandhi Leo Basch Kevin Desmond Tallie Pederson Kirk Wentworth Jack Dalton Cheryl Blomstrom (June 12, 2014)

Board Members Absent:

Cheryl Blomstrom (June 11, 2014)

Board Staff Present:

Larry Pinson Dave Wuest Joe Depczynski Keith Marcher

Paul Edwards

Shirley Hunting

President Gandhi called the meeting to order at 9:00 a.m.

1. Public Comment

No public comment.

2. Approval of April 16-17, 2014, Minutes

Board Action:

Motion: Leo Basch moved to approve the Minutes.

Second: Jack Dalton

Action: Passed Unanimously

- 3. Applications for Out-of-State Pharmacy Non Appearance
 - A. Advanced Pharmacy Greenville, SC
 - B. Biocure LLC Houston, TX

- C. Complete Medical Homecare, Inc. Lenexa, KS
- D. EZ Scripts Holland, OH
- E. Guardian Pharmacy San Bernardino, CA
- F. JustRx Lake Mary, FL
- G. Raindrop Pharmacy Inc. Manhattan Beach, CA
- H. Western Stockmen's Pharmacy Caldwell, ID
- I. White Drug #61 Fargo, ND

Applications for Out-of-State Compounding Pharmacy

- J. Aspirar Pharmacy Cary, NC
- K. Bellevue Pharmacy Maryland Heights, MD
- L. BiologicTx Los Angeles, CA
- M. Caprock Discount Drug Lubbock, TX
- N. Enclara Health West Deptford, NJ
- O. Hall's IV & Institutional Pharmacy, Inc. Fort Worth, TX
- P. Haoeyou Pharmacy Palmdale, CA
- Q. IV Solutions of Lubbock Lubbock, TX
- R. Lenoxhill Pharmacy, Inc. New York, NY
- S. Little York Pharmacy Houston, TX
- T. MedEnvious Healthcare Miami, FL
- U. Old City Pharmacy Philadelphia, PA
- V. Pharmacy Solutions Ann Arbor, MI
- W. Pharmetrics Specialty Group of Florida Sunrise, FL
- X. Pinnacle Pharmacy, LLC Southside, AL
- Y. Prime Pharmacy Solutions, LLC Slidell, LA
- Z. Soothe Compounding Pharmacy Bradenton, FL
- AA. Tru-Valu Drugs Lake Worth, FL
- BB. Villa Pharmacy, LLC Winter Haven, FL
- CC. VLS Pharmacy, Inc. Brooklyn, NY

Applications for Out-of-State Wholesaler – Non Appearance

- DD. Amatheon, Inc. Miami, FL
- EE. Apotheca Supply, Inc. Decatur, AL
- FF. AustarPharma, LLC Edison, NJ
- GG. Boston Scientific Corporation Lowell, MA
- HH. Breg, Inc. Plainfield, IN
- II. Diversified Pharmaceutical Ingredients LLC Tulsa, OK
- JJ. Epic Fulfillment Inc. Broomfield, CO
- KK. E.R. Squibb & Sons, LLC Tampa, FL
- LL. FFF Enterprises, Inc. Kernersville, NC
- MM. Gebauer Company Cleveland, OH
- NN. H-2 Pharma, LLC Montgomery, AL
- OO. RGH Enterprises, Inc. Durham, NC
- PP. Smith & Nephew, Inc. Lawrenceville, GA

- QQ. Smith & Nephew, Inc. Mansfield, MA
- RR. Smith & Nephew, Inc. Memphis, TN
- SS. Unit Dose Services, LLC Dania Beach, FL

Applications for Out-of-State MDEG – Non Appearance

- TT. Allied Home Medical Inc. Smithville, TN
- UU. Alliqua Biomedical Inc. Langhorne, PA
- VV. Matheson Tri-Gas, Inc. Santa Rosa, CA
- WW. Rehab Medical, Inc. Indianapolis, IN
- XX. RGH Enterprises, Inc. Durham, NC
- YY. Sound Health Medical Supply Tacoma, WA
- ZZ. UPS Supply Chain Solutions, Inc. Louisville, KY

Applications for Nevada Pharmacy – Non Appearance

- AAA. Affinity Surgery Center, LLC
- BBB. Campus Pharmacy Mojave Las Vegas
- CCC. Campus Pharmacy Reno Reno
- DDD. Coram CVS/specialty Infusion Services Henderson
- EEE. Nevada Surgical Suites Las Vegas
- FFF. Sunset Ridge Surgery Center, LLC Las Vegas

Applications for Nevada MDEG – Non Appearance

- GGG. Bennett Medical Services Winnemucca, NV
- HHH. Saint Mary's Medical Equipment Reno

Jack Dalton disclosed that he is acquainted with the managing pharmacist for Campus Pharmacy Mojave (Item BBB). Mr. Dalton stated that he has no knowledge of Campus Pharmacy, and his vote will be unbiased.

Leo Basch recused from participation in the matter of Item FFF (Sunset Ridge Surgery Center) due to his position as the managing pharmacist for the surgery center. Mr. Basch also recused from participation in Item AAA (Affinity Surgery Center) due to his association with a physician at Affinity Surgery Center.

President Gandhi disclosed that he is affiliated with Sunset Ridge Surgery Center (FFF). As the meeting facilitator, he will not be casting a vote.

Items AAA, BBB and FFF will be carved out and voted on separately.

Board Action:

<u>Motion:</u> Kirk Wentworth found the Consent Agenda application information to be accurate and complete and moved for approval with the exception of Item

AAA – Affinity Surgery Center, Item BBB – Campus Pharmacy Mojave, and Item FFF - Sunset Ridge Surgery Center.

Kevin Desmond Second:

Action: Passed Unanimously

Board Action:

Kirk Wentworth moved to approve the applications for AAA – Affinity Motion: Surgery Center, Item BBB - Campus Pharmacy Mojave, and Item FFF -Sunset Ridge Surgery Center.

Kevin Desmond Second:

- Action: Passed Unanimously
- **Discipline Cases** 4.

•	A	—	B. /	
Α.	Andrew	۲.	iviann,	R.Ph

73.		
В.	Alexandria W. Park, R.Ph	(13-070-RPH-B-N)
-		(40.070 DULN)

C. Walgreens #02474 (13-070-RPH-A-N) (13-070-PH-N)

Tallie Pederson recused from participation in this matter due to her employment with Walgreens.

Andrew Mann, pharmacist, Alexandria Park, pharmacist and Bree Donnelly, pharmaceutical technician appeared and were sworn by President Gandhi prior to answering questions or offering testimony.

Ms. Donnelly was subpoenaed to appear as a witness and is not named as a respondent in this case.

William Stilling was present as counsel representing Mr. Mann, Ms. Park and Walgreens #02474.

Mr. Edwards stated that this case involves two allegations; a misfilled prescription and failure to adequately provide counseling. Mr. Edwards explained that the Respondents verified and dispensed clomipramine 50 mg capsules (an antidepressant) in error, rather than the prescribed clomiphene 50 mg tablets (fertility drug). Mr. Edwards noted that the Respondents admit to the allegations involving the misfilled prescription, but dispute the allegation that adequate counseling did not occur.

Mr. Edwards called witness Julia Page Hensen. Ms. Hensen appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

President Gandhi admitted Exhibits 1 through 6 into the record.

Both counselors posed questions to Ms. Hensen. Ms. Hensen explained that when she picked up her prescription at the pharmacy's drive through window, the gentleman at the window said to take two capsules per day. He did not say the name of the medication, what the medication was used for, nor did he explain any side effects. Ms. Hensen said that after ingesting two capsules as directed, she experienced severe adverse effects. She reported the incident to Walgreens. Ms. Hensen presented a copy of Ms. Park's business card and a document that included an image of the original prescription and also listed the names of the individuals involved in the misfill. Both documents were given to her by Ms. Park at the time Ms. Hensen attempted to obtain a copy of Walgreens' incident report regarding the misfill (Exhibits 4 and 5).

Ms. Hensen responded to questions by both counselors regarding the package insert (Exhibit 3). She stated that the package insert was stapled to the prescription bag. She did not read it until after she ingested the medication and began to feel ill. Ms. Hensen said that she does not always read the package inserts because she trusts the pharmacist.

Mr. Stilling called witness Bree Donnelly. Ms. Donnelly addressed questions posed by both counselors and Board Members.

Ms. Donnelly said that she does not recall this particular incident. She explained what she has generally observed as Mr. Mann's normal counseling procedure. She indicated that Mr. Mann usually says the name of the drug, how to take the drug, what it's used for, any special instructions, and he asks if the patient has any questions. Ms. Donnelly testified that although her initials appeared on the prescription label, the prescription was filled and verified after she had left for the day. She explained that her initials appeared because she did not sign off the computer when she left. Her initials would continue to appear until someone else signed in. Upon questioning, Ms. Donnelly stated that the computer system does have a pop-up box which alerts the user to look-alike sound-alike drugs. At the time of this incident, she was not familiar with the pop-up box. There are no warning labels on the shelves for drugs that look and sound alike and are located next to each other.

Mr. Stilling called Mr. Mann. Mr. Mann addressed questions posed by both counselors and Board Members.

Mr. Mann said that he has no recollection of the events surrounding the dispensing and counseling for this prescription. He explained that when he counsels patients, he states the name of the drug, general indication, directions for use and any other pertinent information. The procedure for filling prescriptions requires the hardcopy to follow in the filling process, which did not occur in this case. Mr. Mann had nothing to refer to other than the incorrect input. Mr. Mann said that he is not aware of Walgreens' policy on counseling.

Mr. Stilling called Ms. Park. Ms. Park addressed questions posed by both counselors and Board Members.

Ms. Park testified that she vaguely recalls having a conversation with Ms. Hensen regarding the misfilled prescription. Ms. Park asked Ms. Hensen if Mr. Mann provided counseling. Ms. Park alleges that Ms. Hensen indicated that during counseling, Mr. Mann said the name of the drug. Ms. Park stated that Walgreens has a patient counseling policy and procedure in place. Pharmacists are required to acknowledge, by signing off, that they have reviewed the policy.

Mr. Stilling and Mr. Edwards each offered closing statements.

Mr. Edwards said that Board Staff recognizes that Mr. Mann did counsel the patient. The patient's testimony indicates that the counseling provided was inadequate to satisfy the minimum requirements of NRS 639.266 and NAC 639.707. Mr. Mann's counseling merely consisted of restating the instructions on the prescription label. There was no discussion of product name, description of the drug, intended use, expected responses, contraindications, side effects and/or proper storage. If the patient had been told that the erred drug was used to treat depression versus infertility, the error would have been detected.

Mr. Stilling said that the Respondents admit that a dispensing error occurred. He contends that counseling was provided and did meet the standard of care expected in pharmacies. The final product review conducted by Mr. Mann was to compare the computer image of the product against the actual product in the prescription bottle, not the initial check for review of the entire data entry process. That verification was conducted the prior day by Ms. Park. Mr. Stilling requested that the charges regarding the dispensing error and insufficient counseling against Mr. Mann be dismissed. He also asked that the charges of negligence and unprofessional conduct against Walgreens #02474 be dismissed. Walgreens #02474 admits culpability under the governing statutes as owner of the pharmacy where the error occurred.

Mr. Edwards recommended a finding of guilt for Mr. Mann, Ms. Park and Walgreens #02474 in the First Cause of Action regarding the misfill. Mr. Edwards recommended a finding of guilt for Mr. Mann and Walgreens #02474 in the Second Cause of Action regarding inadequate counseling. Mr. Edwards stated that he will move for dismissal of the Third Cause of Action if Walgreens #02474 is found responsible in the First and Second Causes of Action.

The Board discussed Walgreens #02474 responsibility in the First and Second Causes of Action. Walgreens #02474 had policies and procedures in place at the time of the incident; however, the pharmacist failed to follow the policy. There was agreement that Mr. Mann should be charged in the First and Second Causes of action since he wrote the prescription and was also involved in the verification process.

Board Action:

Motion: Leo Basch moved to find Andrew Mann and Alexandria Park guilty in the First Cause of Action.

Second:	Kevin Desmond

Ayes: Basch, Desmond, Wentworth Nays: Dalton

Action: Motion Carried

Board Action:

Motion: Leo Basch moved to find Andrew Mann guilty in the Second Cause of Action.

Second: Kevin Desmond

Action: Passed Unanimously

Board Action:

<u>Motion:</u> Leo Basch moved to find Walgreens #02474 guilty under strict liability as owner of the pharmacy in the Third Cause of Action.

Second: Kevin Desmond

Action: Passed Unanimously

Mr. Edwards offered penalty recommendations in the three Causes of Action.

Board Action:

Motion: Kirk Wentworth moved to accept Mr. Edward's penalty recommendations in the First Cause of Action. Mr. Mann and Ms. Park shall each pay a fine of \$1,000.00 and an administrative fee of \$49.00 to cover the cost of processing fingerprint cards. Mr. Mann and Ms. Park shall each complete one unit of continuing education (CE) on error prevention within ninety (90) days.

Second: Leo Basch

Ayes:Basch, Desmond, WentworthNays:Dalton

Action: Motion Carried

Board Action:

- <u>Motion:</u> Kirk Wentworth moved that Mr. Mann shall pay a fine of \$750.00 in the Second Cause of Action. Mr. Mann shall complete one hour of CE on counseling within ninety (90) days.
- Second: Kevin Desmond
- Action: Passed Unanimously

Board Action:

Motion: Kirk Wentworth moved that Walgreens #02474 shall pay a fine of \$2,000.00 and an administrative fee of \$500.00 in the Third Cause of action.

President Gandhi offered a friendly amendment to include a Board Staff review of Walgreens' counseling policy and procedures to ensure that they are in compliance with counseling regulations.

Mr. Wentworth accepted the friendly amendment.

Second: Kevin Desmond

Because of the other issues identified during testimony, Mr. Pinson recommended a more extensive review of the policy and procedures.

Mr. Wentworth and Mr. Desmond accepted Mr. Pinson's recommendation.

Ayes:Wentworth, DesmondNays:Basch, Dalton

President Gandhi offered a Nay vote.

Action: Motion Failed

Board discussion ensued.

Board Action:

<u>Motion:</u> Kirk Wentworth moved that in the Third Cause of Action, Walgreens #02474 shall pay an administrative fee of \$500.00, and receive a letter advising communication with pharmacy staff regarding the issues identified in this incident, and the actions to correct them. A meeting will be scheduled at the Board Office to include Board Staff, the district manager and pharmacy manager to review Walgreens' policies and procedures.

Second: Leo Basch

Action: Passed Unanimously

D. Delane M. Blair, PT (14-020-PT-N)

Mr. Edwards advised the Board that Ms. Blair was not present.

Mr. Edwards moved to have Exhibits 1 through 5 admitted. President Gandhi accepted the Exhibits into the record.

Mr. Edwards explained that Board Staff received notification from CVS Caremark's director of pharmacy regulatory compliance that Ms. Blair was terminated from her employment as a pharmaceutical technician at CVS Pharmacy #9842. Ms. Blair was terminated for diversion of controlled substances. During an interview with CVS Caremark Loss Prevention personnel, Ms. Blair admitted to diverting approximately 25,200 hydrocodone/acetaminophen tablets, 18,000 alprazolam tablets, and three bottles of promethazine. Ms. Blair sold the drugs for personal financial gain.

Mr. Edwards stated that Board Staff served the Accusation on Ms. Blair by certified mail on March 4, 2014, at the address she had on record with the Board Office. He presented a copy of the certified mail receipt and the certified mail return receipt (Exhibit 1). Mr. Edwards also provided a copy of the letter sent regular mail to Ms. Blair advising her of the Hearing (Exhibit 2).

Mr. Edwards stated that the evidence provided supports a finding of guilt.

Board Action:

<u>Motion:</u> Kevin Desmond moved to find Delane Blair guilty of the alleged violations in the First Cause of Action.

Second: Tallie Pederson

Action: Passed Unanimously

Mr. Edwards recommended revocation of Ms. Blair's pharmaceutical technician registration.

Board Action:

<u>Motion:</u> Kevin Desmond moved to revoke Delane Blair's pharmaceutical technician registration for a minimum of not less than one year.

Second: Kirk Wentworth

Action: Passed Unanimously

E. Brian T. Vu, R.Ph (14-030-RPH-N)

Brian Vu, pharmacist, appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Kevin Desmond disclosed that he is acquainted with Mr. Vu through meetings that they both attended at Renown Medical Center when Mr. Vu was employed there. Mr. Desmond indicated that his participation in this matter will be unbiased.

Jack Dalton recused from participation in this matter. Mr. Dalton and Mr. Vu have engaged in discussions during the time that they were both employed by Walmart.

Mr. Edwards moved to have Exhibits 1 and 2 admitted. President Gandhi accepted the Exhibits into the record.

Mr. Edwards explained that in September 2012, the Board entered a Findings of Fact, Conclusions of Law and Order (Order) in the case of Brian Vu (Case No. 12-040-RPH-N). The Board entered the Order based on the results of a random audit conducted by Board Staff which identified that Mr. Vu completed zero units of the required thirty (30) continuing education units (CEUs) for the biennial period November 1, 2009 to October 31, 2011. In that Order, the Board ordered Mr. Vu to complete thirty (30) CEUs for the renewal period of November 1, 2009 to October 31, 2011, and seventy-five (75) CEUs for the renewal period of November 1, 2011, through October 31, 2013, for a total of one-hundred and five (105) CEUs. The Order also indicated that Mr. Vu's CEUs for the renewal period ending October 31, 2013, would be audited to verify that he had complied with the Order. The results of that audit revealed that Mr.Vu completed only 84.5 of the 105 CEUs ordered by the Board.

Mr. Vu testified that he failed to complete the required 30 CEUs in 2012, but attested on his renewal application that he had completed them. Mr. Vu was served with an Accusation and hearing notice, but he did not attend the hearing. He stated that his behavior during that period was due to a maturity issue. Mr. Vu's employer at that time terminated his employment as a result.

Mr. Vu explained that he misinterpreted the 2012 Board Order to mean that he was required to only complete 75 hours. He thought he satisfied the Order by submitting documentation of completion of the 75 hours plus an additional 9.5 hours. Mr. Vu

asked the Board to consider that he was not being negligent as this was an interpretation issue by him.

Board Action:

Motion:	Leo Basch moved to find Brian Vu guilty of the alleged violations in the First Cause of Action.
Second:	Tallie Pederson
Aves:	Basch, Pederson, Desmond

Nays: Wentworth

Action: Motion Carried

Mr. Edwards recommended that Mr. Vu pay an administrative fee of \$500.00; makeup the deficient 20.5 hours; complete 30 hours for the current renewal period; complete 60 additional hours as a penalty; and retake the law exam. Mr. Vu's CEUs will be audited for the period ending October 31, 2015, to verify that the has complied with the Board Order.

Board Action:

Motion: Kirk Wentworth moved to accept Mr. Edwards' recommendation.

Second: No Second was offered.

Action: Motion Failed

Board discussion ensued.

Board Action:

- Motion: Leo Basch moved that Mr. Vu shall complete the deficient 20.5 hours of CEUs, plus an additional 30 CEUs as a penalty (total 50.5 CEU hours), within thirty days of the Board Order. Mr. Vu shall also complete the required 30 CEUs for the period ending October 31, 2015. Mr. Vu shall pay an administrative fee of \$250.00. Mr. Vu's CEU's will be audited for the period ending October 31, 2015, to verify that he has complied with the Board's Order.
- Second: Tallie Pederson

Action: Passed Unanimously

Mr. Basch clarified that the CEUs that Mr. Vu has completed since November 1, 2013, may be applied to the 50 CEU hours due within thirty days of the Board's Order.

F. Mark R. Crumby, R.Ph (14-029-RPH-N)

Mark Crumby, pharmacist, appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Kevin Desmond recused from participation due to his employment with Renown Medical Center where Mr. Crumby is also employed.

Mr. Edwards moved to have Exhibits 1 through 3 admitted. President Gandhi accepted the Exhibits into the record.

Mr. Edwards explained that in October 2013, Mr. Crumby checked the box on his pharmacist renewal application that he had completed the required CEUs. Board Staff conducted a random audit of CEUs for the biennium ending October 31, 2013. Results of the audit identified that Mr. Crumby did not complete any CEUs for the renewal period ending October 31, 2013.

Mr. Crumby testified that he had completed free web-based CEUs offered by various universities, which were sponsored by pharmaceutical companies. He stated that he has been unable to locate the hard-copy certificates, and did not archive them electronically. Mr. Crumby stated that he did take the law CE through the *Pharmacist Letter* link on the Board's website, but the printed certification indicated zero contact hours. He said he takes full responsibility and apologized to the Board.

Ms. Pederson said that when she completed the law CE through the *Pharmacist Letter*, her certification also indicated zero hours.

The Board agreed to credit Mr. Crumby's unit of law CE.

Mr. Edwards recommended a finding of guilt due to Mr. Crumby's lack of ability to prove that he had completed the required CEUs.

Board Action:

- <u>Motion:</u> Kirk Wentworth moved to find Mark Crumby guilty of the alleged violations in the First Cause of Action.
- Second: Jack Dalton

Action: Passed Unanimously

Mr. Edwards offered penalty recommendations.

Board Action:

- Motion: Tallie Pederson moved to accept Mr. Edwards' recommendation. Mr. Crumby shall pay an administrative fee of \$500.00 within sixty (60) days of the Board Order. Mr. Crumby shall makeup the deficient twenty-nine (29) hours of CEUs, plus an additional sixty (60) CEUs as a penalty. Mr. Crumby shall complete the written law examination within ninety (90) days of the Board Order. Mr. Crumby shall also complete the required 30 CEUs for the period ending October 31, 2015. Mr. Crumby's CEU's will be audited for the period ending October 31, 2015, to verify that he has complied with the Board's Order.
- Second: Leo Basch

Action: Passed Unanimously

G. Sheldon Borson, R.Ph.

(14-026-RPH-O)

President Gandhi disclosed that he worked for the same company (Albertsons/Sav-On) as Mr. Borson, but at no time did he supervise Mr. Borson or the pharmacy in which Mr. Borson was employed.

Mr. Edwards advised the Board that Mr. Borson was not present. Mr. Borson did submit a response in the form of a letter. Copies of Mr. Borson's letter were distributed to the Board Members.

Mr. Edwards moved to have Exhibits 1 through 3 admitted. President Gandhi admitted the Exhibits into the record.

Mr. Edwards explained that Mr. Borson disclosed on his pharmacist renewal application that he has been the subject of a board citation or administrative action and disciplined by the California State Board of Pharmacy (California Board).

In October 2013, the California Board adopted a Stipulated Settlement and Disciplinary Order (California Order). In the California Order, Mr. Borson admitted to charges that he diverted approximately one-hundred thirty-seven (137) different dangerous drugs and controlled substances with an estimated value of over \$150,000 from his employer Albertsons/Sav-On Pharmacy. Mr. Edwards summarized the allegations in the California Board's Accusation (Exhibit 3).

The California Board revoked Mr. Borson's pharmacist license, however, the revocation was stayed. Mr. Borson's license was placed on probation for a period of nine years with substantial terms and conditions. Mr. Edwards summarized the California Board's Decision and Order (Exhibit 2).

Mr. Edwards recommended that discipline be taken against Mr. Borson's Nevada pharmacist license to parallel the California Order.

Based on the information provided, the Board found the facts in this matter to be alarming and of great concern, and opted for a stricter penalty.

Board Action:

- Motion: Leo Basch moved to find Sheldon Borson guilty in the First Cause of Action.
- Second: Kevin Desmond

Action: Passed Unanimously

Board Action:

- <u>Motion:</u> Leo Basch moved to revoke Sheldon Borson's Nevada pharmacist license.
- Second: Jack Dalton
- Action: Passed Unanimously
 - H. Charles A. Walker, R.Ph (14-027-RPH-O)

Mr. Edwards explained that this matter is a parallel action against Mr. Walker's Nevada pharmacist license. Mr. Walker was the subject of an administrative action and discipline in California after he admitted to substance abuse.

Mr. Walker responded to the Accusation verbally to Mr. Edwards. Mr. Walker does not work in Nevada and is near retirement. He expressed his desire to surrender his Nevada pharmacist license. Mr. Edwards sent Mr. Walker a written statement to that effect for his signature, but it has not been received by the Board Office to date.

Mr. Edwards requested that his matter be continued to the July 2014 meeting. If Mr. Walker's statement is not received by the July meeting, the matter will be heard at the next meeting.

President Gandhi moved to continue the matter.

I. Darek T. Jones, R.Ph (14-028-RPH-O

Darek Jones, pharmacist, appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Hal Taylor was present as counsel representing Mr. Jones.

Mr. Edwards presented a Stipulation and Order regarding Mr. Jones for the Board's consideration. Mr. Jones admits to the allegations in the Notice of Intended Action and Accusation. Mr. Jones disclosed on his Nevada pharmacist license renewal application that he has been disciplined in California for diversion of controlled substances from two of his employers. Mr. Jones also admitted to being convicted in June 2010 for driving under the influence of alcohol and/or drugs.

Mr. Taylor stated that Mr. Jones is in compliance with the California Board's Order.

Mr. Edwards recommended that Mr. Jones' Nevada pharmacist license be placed on probation with terms and conditions as outlined in the Stipulation and Order. Mr. Jones shall pay an administrative fee of \$500.00.

Board Action:

Motion: Kirk Wentworth moved to accept the Stipulation and Order as presented.

Second: Jack Dalton

Action: Passed Unanimously

J. Brian E. Chambers, R.Ph (14-021-RPH-O)

Mr. Edwards moved to have Exhibit 1 admitted. President Gandhi admitted Exhibit 1 into the record.

Mr. Edwards advised the Board that Mr. Chambers was not present. Mr. Edwards explained that Mr. Chambers disclosed on his pharmacist renewal application that he has been the subject of a board citation or administrative action and disciplined by the California State Board of Pharmacy (California Board). Mr. Chambers submitted a request to the Board Office to voluntarily surrender his Nevada pharmacist license (Exhibit 1). Mr. Edwards presented a written agreement signed by Mr. Chambers surrendering his Nevada pharmacist license.

Mr. Marcher commented that if the Board desires this to be a public disciplinary matter, and reportable to disciplinary databanks, Board Staff may want to clarify with the Respondent that surrendering his license is considered a disciplinary action, and not accepted in lieu of discipline. Mr. Marcher said that the Attorney General's Office has established a policy and procedure in the cases of voluntary surrender of an individual's license in disciplinary cases. The policy has been adopted by other boards.

Mr. Marcher suggested that this Board may want to consider adopting the policy. Mr. Edwards and Board Staff agreed.

Mr. Edwards requested that the Board reject Mr. Chambers' written agreement and continue this matter to the July 2014 meeting.

Board Action:

Motion: Kirk Wentworth moved to reject Mr. Chambers' agreement.

Second: Tallie Pederson

Action: Passed Unanimously

President Gandhi moved to continue this matter until the July 2014 meeting.

5. Request for Intern Registration – Appearance

Brianne L. Chin

Brianne Chin appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Ms. Chin said that in October 2013, she was arrested for driving under the influence of alcohol or drugs. Ms. Chin explained that she had been to a restaurant with friends and consumed one glass of wine. Ms. Chin offered to drive her friends home and was pulled over by police for having four people in the back of her car. The officer questioned her, and she admitted to consuming one glass of wine. She failed a Breathalyzer test with a blood alcohol level of .089 and was arrested. The charges were later dropped and no complaint was ever filed in court.

Ms. Chin stated that she is scheduled to do a six month rotation in Sparks, Nevada. She has been on the Dean's List for two semesters, and her goal is to protect the public and improve the pharmacy profession. Ms. Chin said that she does not have a drug or alcohol problem, and will never put herself in that situation again.

Ms. Chin answered questions to the Board's satisfaction.

Board Action:

- <u>Motion:</u> Tallie Pederson moved to approve Brianne Chin's Intern Pharmacist Application.
- Second: Kevin Desmond
- Action: Passed Unanimously

- 6. Requests for Pharmaceutical Technician Registration Appearance
 - A. Scott Kearney

Scott Kearney and Colin Hodgen, Clinical Director of PRN-PRN, appeared and were sworn by President Gandhi prior to answering questions or offering testimony.

Mr. Edwards reminded the Board that Mr. Kearney appeared at the June 2013 and the September 2013 meetings. At the June 2013 meeting, the Board tabled action on Mr. Kearney's Pharmaceutical Technician in Training application pending a PRN-PRN evaluation. In September, the Board moved to deny Mr. Kearney's application until he successfully completed one year of PRN-PRN without any violations.

Mr. Kearney referenced a letter of support that was provided to the Board from Mr. Hodgen. Mr. Kearney said that he has been sober for thirty months and has recently completed his first year with PRN-PRN. He stated that he has changed and has no desire to use drugs or alcohol. Mr. Kearney said that he has a strong support system of family and friends. Mr. Kearney will potentially be employed by Walgreens Pharmacy #2658, if his application is approved.

Mr. Hodgen stated that Mr. Kearney is motivated and focused on his recovery. Mr. Kearney has tested negative on all biochemical tests. He attends meetings regularly and provides support for other members. Mr. Hodgen said that Mr. Kearney is a delight to work with, and he feels confident in Mr. Kearney's ability to do a great job.

The question on the application regarding treatment for alcohol or drug abuse was not answered on Mr. Kearney's application. He verbally answered "yes"; the application will be amended by Board Staff.

Mr. Kearney answered questions to the Board's satisfaction.

Board Action:

<u>Motion:</u> Kirk Wentworth moved to approve Scott Kearney's Pharmaceutical Technician in Training Application.

Second: Tallie Pederson

President Gandhi offered a friendly amendment that Mr. Kearney request that the managing pharmacist, where he will be employed, contact the Board Office acknowledging that he is aware of Mr. Kearney's situation and participation in PRN-PRN.

Mr. Wentworth and Ms. Pederson accepted the friendly amendment.

Ayes: Wentworth, Pederson, Dalton, Desmond

Nays: Basch

Action: Motion Carried

B. Jessica E. Marsh

Jessica Marsh appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Ms. Marsh explained that seven years ago she was arrested in California for possession of a controlled substance and for being under the influence of methamphetamine. She regularly used methamphetamine for five years prior to her arrest. The court offered Ms. Marsh a deferred entry of judgment in exchange for completion of a drug treatment program. Ms. Marsh completed the program and the case was dismissed. Ms. Marsh stated that she has been sober for seven years. She currently resides in California, and has worked in pharmacies for ten years; three years as a cashier and seven years as a pharmaceutical technician. Her long-term goal is to move to Nevada and attend the pharmay program at Roseman University. Ms. Marsh said that she has a strong support system including her family, friends and coworkers. Ms. Marsh sporadically attends drug treatment meetings at this time.

Ms. Marsh addressed questions to the Board's satisfaction.

Board Action:

<u>Motion:</u> Kirk Wentworth moved to approve Jessica Marsh's Pharmaceutical Technician Application pending Ms. Marsh's relocation to Nevada and a positive evaluation by PRN-PRN.

Second: Leo Basch

President Gandhi clarified the Motion. Ms. Marsh may be evaluated by PRN-PRN or the Pharmacist Recovery Program (PRP) in California. If the PRN-PRN or PRP recommendation is that Ms. Marsh enter into a five year treatment contract, Ms. Marsh will be required to participate in the program for a minimum of one year, without any violations, before her application is considered. Upon the successful completion of one year in the program, Ms. Marsh will be required to appear before the Board with support from a representative of the treatment program.

Action: Passed Unanimously

7. Appearance

Presentation of Expedited Licensure for Veterans: Caleb S. Cage – Director of Military and Veterans Policy Office of the Governor

Mr. Pinson commented that in 2012, Governor Sandoval signed an Executive Order which provided for reciprocity for veterans and their spouses. Mr. Pinson stated that all 50 states now have reciprocity for pharmacists. Mr. Pinson also has statutory authority to issue licenses for qualified pharmacists until the reciprocity process is completed. Board Staff has and continues to expedite the processing of licensure for veterans.

Caleb Cage presented an overview of Governor Sandoval's 2014 "Year of the Veteran" proclamation. The goals of the proclamation are to focus on veteran's issues, and develop and implement best practices for addressing those issues for veterans and their families. In May of 2014, Governor Sandoval signed an Executive Order requiring professional licensing bodies to establish reciprocity opportunities for veterans. The Order also requires each licensing body to capture the number of service members and veterans holding or seeking licensure in Nevada, and to report the data to the Nevada Department of Veterans Services.

Mr. Pinson stated that Board of Pharmacy applications will be modified to include a section to capture the required data.

8. Application for Nevada Pharmacy – Appearance

PharMerica – Henderson

Roland Werner, pharmacy director, appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Mr. Edwards explained that PharMerica has purchased Spectrum Pharmacy (Spectrum) and will be moving into Spectrum's existing facility. Spectrum was disciplined by this Board in April 2014 for a compounding error. The Board Order placed restrictions on the products that Spectrum was allowed to compound. Board Staff has major concerns regarding PharMerica taking over Spectrum with the same staff, and potentially the same issues.

Mr. Werner stated that PharMerica will not provide non-sterile compounding, and will not expand Spectrum's current product line. PharMerica currently compounds oral vancomycin and pink swizzles, and will continue to compound products currently provided by Spectrum. Commercially available products, oral capsule and troches will not be compounded. PharMerica contracts with a local certified compounding pharmacy to prepare other compounds and TPNs for their nursing home patients. Mr. Werner said that training on PharMerica policies and procedures and the computer system will be provided by him and PharMerica trainers. Mr. Werner offered to provide Board Staff with a list of products currently compounded by Spectrum and PharMerica.

President Gandhi stated that the application has the box checked for "Name Change" only. President Gandhi asked Mr. Werner to clarify the application. Mr. Werner responded that the application is for a location and ownership change. Board Staff will amend the application.

Mr. Werner addressed questions to the Board's satisfaction.

Mr. Wuest pointed out that PharMerica will be moving into the Spectrum location on Saturday, June 14th, which will not allow time for a pre-inspection.

Because there has been no inspection issues with the existing facility, the Board agreed the inspection can be conducted the following week.

Board Action:

- Motion: Cheryl Blomstrom moved to approve PharMerica's Application for Nevada Pharmacy. PharMerica may continue to compound vancomycin and pink swizzles. Mr. Werner will provide Board Staff with a list of products that are currently compounded by PharMerica and Spectrum Pharmacy. Board Staff is authorized to review and approve or deny products on the lists. The pharmacy can be inspected post-licensure.
- Second: Kirk Wentworth

Action: Passed Unanimously

- 9. Applications for Out-of-State Compounding Pharmacy Appearance
 - A. Advanced Infusion Solutions Ridgeland, MS

President Gandhi recused from participation in this matter due to his acquaintance with Mr. Mathew. Leo Basch presided as Acting President over this matter.

Koshy Mathew, Vice President of Pharmacy Services, appeared and was sworn by Acting President Basch prior to answering questions or offering testimony.

Mr. Mathew presented a letter from Charles Bell, Jr., President/PIC of Advanced Infusion Services, authorizing Mr. Mathew to represent the company.

Mr. Mathew explained that Advanced Infusion Services will provide patient specific traditional compounding services to home infusion patients. Products include TPNs, topical pain management, IV antibiotics and IV fluids. The pharmacy is USP 795 and 797 compliant. Products are lab tested for sterility, potency and endotoxins. Surface

testing is conducted weekly. Pharmacists are required to complete the Critical Point thirty-two module compounding training program. Pharmacists and technicians receive initial and ongoing training. Advanced Infusion Services is currently licensed to ship to forty-eight states. Mr. Mathew provided a copy of their inspection which was conducted by NABP on April 18, 2014. Mr. Mathew also provided a copy of their Mississippi Board of Pharmacy inspection dated February 12, 2013.

The application for Advanced Infusion Services did not have the "Parenteral" box checked under the "Services Provided." Mr. Mathew authorized Board Staff to amend the application.

Mr. Mathew answered questions to the Board's satisfaction

Board Action:

- <u>Motion:</u> Kirk Wentworth moved to approve Advanced Infusion Services Application for Out-of-State Pharmacy.
- Second: Jack Dalton
- Action: Passed Unanimously
 - B. American Custom Compounding Pharmacy LLC Dallas, TX

Vy Tran, pharmacist in charge, and Matthew Gundelfinger, owner, appeared and were sworn by President Gandhi prior to answering questions or offering testimony.

Ms. Tran explained that American Custom Compounding Pharmacy provides nonsterile and sterile compounding services primarily for age management and hormone replacement therapy. The pharmacy is 795 and 797 compliant. Products are patient specific, and lab tested for potency, sterility and endotoxins. Pharmacists and technicians are IV certified through TRINU Healthcare in Texas.

Mr. Gundelfinger said that the pharmacy was recently inspected. The Texas State Board of Pharmacy has a separate inspection and license for sterile compounding. A copy of American Custom Compounding Pharmacy's Community Sterile Compounding license was provided in the Board book.

Ms. Tran and Mr. Gundelfinger answered questions to the Board's satisfaction.

Board Action:

Motion: Cheryl Blomstrom moved to approve American Custom Compounding Pharmacy's Application for Out-of-State Pharmacy.

Second: Leo Basch

Action: Passed Unanimously

C. Aureus Pharmacy – Pittsburgh, PA

Rescheduled to the July 2014 meeting at the applicant's request.

D. Focus Rx – Holbrook, NY

Rescheduled to the July 2014 meeting at the applicant's request.

10. Application for Nevada MDEG – Appearance

Desert Rose Medical Supplies, LLC – Las Vegas

Marc Dickerson, President, appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Mr. Dickerson explained that Desert Rose Medical Supplies (Desert Rose) will focus on orthotic products, primarily, braces for back, knee, wrist and ankle. Michelle Rains is the administrator and will be onsite during business hours. Desert Rose will expand its product line to include non-DME products at a future date. Inventory from the previous owner is currently being dissolved.

Mr. Dickerson said Desert Rose was acquired by the current owners in November 2013. The business is currently operating under the previous owner's MDEG license. Mr. Dickerson indicated that he was not aware that the business required licensure by this Board. When the facility was inspected approximately six weeks ago, the Board Inspector informed Mr. Dickerson that he was required to submit the application.

The application indicated that Desert Rose was applying as a "New MDEG." Mr. Dickerson authorized Board Staff to modify the application to indicate "Ownership Change."

President Gandhi requested that Mr. Dickerson provide a copy of Desert Rose's current inventory.

Board Action:

Motion: Kirk Wentworth moved to approve Desert Rose Medical Supplies' Application for Nevada MDEG. Mr. Dickerson will submit a copy of Desert Rose Medical Supplies current inventory.

Second: Cheryl Blomstrom

Action: Passed Unanimously

11. Discussion and Determination

MDEG Dispensing

Mr. Pinson stated that dispensing practitioners are required to register with the Board prior to dispensing medications out of their practices. Board Staff has been asked if the same parameters would apply for practitioners who want to purchase MDEG products from a wholesaler to stock and dispense to patients. Should physicians be permitted to dispense such products without registering as an MDEG dispensing practitioner.

The Board discussed issues regarding certification, qualification and training to fit and/or size devices, as well as issues concerning self-referrals and walk-in patients.

The Board directed Board Staff to present this matter to the MDEG Committee for their recommendations and report back to the Board.

12. Personnel Review

Mr. Pinson reported that Kris Mangosing has been hired as a part-time employee. Kris was originally hired to work with the PMP on the CDC study which is near completion. In addition to other duties, Kris will be cross trained in licensing.

A. Personnel Evaluation

Larry Pinson commended his entire staff commenting on their hard work and efficiency. He cited several attributes and accomplishments of all members of the staff.

Mr. Pinson noted that the Legislature did not approve salary increases again this session. Staff has not received a pay increase for six years.

B. Executive Secretary Evaluation

President Gandhi commended Mr. Pinson's hard work and leadership. Mr. Pinson's leadership is reflected in the quality of work produced by Board Staff and their responsiveness to serve the public. President Gandhi commented that Mr. Pinson's presentation style is impressive. He provides excellent content and education with a great delivery.

13. General Counsel Report

Mr. Edwards reported that he submitted an appeal to the District Court in the Maryanne Phillips' case. He anticipates an answer from the court next week.

14. Executive Secretary Report

Mr. Pinson shared a D-Day 70th Anniversary article on Bill Farr who served as the Public Member on the Board in the nineties.

A. Financial Report

Mr. Pinson presented the financials to the Board's satisfaction. The Budget will be presented at the next meeting.

B. Temporary Licenses

No temporary licenses were issued since the last meeting.

- C. Staff Activities
 - 1. Presentations:
 - a. "Project Echo" through UNR School of Medicine

Mr. Pinson recently presented to this group. Lisa Adams, in conjunction with Dr. Pohl, also presented to this group and provided an opportunity to sign up with the PMP. b. NABP Annual Meeting

Mr. Pinson gave a presentation at the NABP meeting. He thanked the Board Members that attended and supported him.

c. APRN Association

Mr. Edwards presented to this group on June 7, 2014.

- D. Reports to Board
 - 1. Collaborative Efforts:
 - a. St. Kitts (Accutane)
 - b. Nevada Board of Nursing Medi-Spas
 - c. Massachusetts Board of Pharmacy -- Compounding
 - d. Nevada Board of Medical Examiners Hispanic Clinic
 - e. Nevada Board of Veterinary Examiners Nye County
 - 2. Coalition Meeting on Prescription Drug Abuse

Liz MacMenamin, Retail Association of Nevada and Mr. Wuest provided an update. Issues were pared down to define the group's focus including PMP access and the disposal of unused prescription medications. Ms. MacMenamin reported that the April drug take-back program in northern Nevada reported over 177,000 doses of drugs. There was discussion regarding educating southern Nevada about the drug take-back program. The take-back program will be expanded to include the disposal of sharps devices; e.g.; needles, syringes, etc.

3. Immunization Report

Mr. Pinson distributed the Immunization Report for the Board's information.

- E. Board Related News
 - 1. Pharmacy Job Market

Mr. Pinson presented a *Medscape* article related to the future of pharmacy jobs for the Board's information.

2. California SB 493

Mr. Pinson presented an article on SB 493 for the Board's information.

3. Zohydro

Mr. Pinson commented that Massachusetts has passed a regulation that Zohydro is illegal if it's not manufactured in an abuse deterrent formulation.

F. Activities Report

Mr. Pinson reported that a meeting of the Legislative Advisors was held in May. President Gandhi and Ms. Blomstrom participated. The group discussed pharmacy related legislative issues that may involve the Board. The group will meet again when the BDR's are released.

Mr. Edwards informed the Board that representatives from Appriss will be at the July meeting in Las Vegas to present an overview of the NPLEx system. The presentation will also be scheduled for northern Nevada.

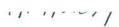
15. Next Board Meeting:

July 23-24, 2014 – Las Vegas

16. Public Comment

No public comment.

Blank



To whom it may concern,

My name is Cynthia L. Butler (Blake),

_, I am hereby requesting a hearing to re-acquire my

pharmacy technician license.

ulles

Cynthia L. Butler



Board Action:

<u>Motion:</u> Joe Kellogg moved, based on evidence presented, to find Mr. Cronshaw guilty of the alleged violations.

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Second:	Bob Wood	
Action:	Passed Unanimously	
Motion:	Joe Kellogg moved to revoke Mr. Cronshaw's pharmaceutical technician registration.	
Second:	Bob Wood	
Action:	Passed With One Negative Vote	
F.	Cynthia Blake, PT	(03-027-PT-S)

It was noted that Ms. Blake was not present for hearing.

Geri Raj, managing pharmacist for K-Mart #3592, appeared and was sworn by President Pinson prior to answering questions or offering testimony.

Mr. Ling questioned Ms. Raj regarding the circumstances of this matter. Ms. Raj testified that she received a telephone call from a physician asking who at that pharmacy was filling prescriptions for one of his patients without his authorization. Ms. Raj stated that she determined Ms. Blake had filled the prescriptions and questioned her. Ms. Raj was unable to find hard copies. It was found that the patient had her prescription filled by Ms. Blake and had taken the same prescription to another pharmacy and had it filled second time using the same prescription. Ms. Raj made a report to the district pharmacy manager. Ms. Raj again checked with the physician in this matter and asked him to please check with this medical staff to ensure that no one in his office had approved any refills for his patient. The physician found that no one from his office had authorized refills for his patient and signed a statement to that effect. This patient paid cash for her prescriptions.

Mr. Ling determined that he had proven the First Cause of Action. The Second Cause of Action, repeated negligence, was charged because of Ms. Blake's failure to renew her license and worked unlicensed for nine months.

Board Action:

Motion: Ray Seidlinger moved, based on evidence presented, to find Ms. Blake guilty of the alleged violations.

Second:	Marcie Ranick	
Action:	Passed With One Negative Vote	
Motion:	Ray Seidlinger moved to revoke Ms. Blake's pharmaceutical technician registration.	
Second:	Bob Wood	
Action:	Passed With One Negative Vote	
G.	Andres M. Estrada Jr, PT	(03-050-PT-S)

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F.

Andres Estrada appeared and was sworn by President Pinson prior to answering questions or offering testimony.

NOTE: Marcie Ranick recused from participation in this case as she is employed by Walgreens.

Mr. Ling had no opening statement and commended Mr. Estrada for his honesty with his Answer and Notice of Defense.

Mr. Estrada testified that he had gone to a concert and made a poor choice by using marijuana. He has gone to PRN-PRN and is in the process of signing a contract. Mr. Estrada plead for his license and gave various places where he regularly volunteers his time in the pursuit to help others.

Mr. Ling recommended the standard PRN-PRN contract and Order.

Larry Espadero testified that Mr. Estrada had contacted him and that he will do Mr. Estrada's evaluation next week.

Board Action:

Motion:	Joe Kellogg moved, based on evidence presented, to find Mr. Estada guilty of the alleged violations.
Second:	Bob Wood
Action:	Passed Unanimously
Motion:	Joe Kellogg moved to remand Mr. Estrada to the standard PRN-PRN Order.
Second:	Bob Wood

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

ORDER DENYING REQUEST FOR REINSTATEMENT

CYNTHIA BLAKE, P.T., Certificate of Registration #PT00182

Case No. 03-027-PT-S

Respondent.

This matter was originally heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on October 15, 2003 in Reno, Nevada. The Board was represented by Louis Ling, General Counsel, and Ms. Blake did not appear and represent herself. On November 13, 2003, the Board issued Findings of Fact, Conclusions of Law, and Order. The Board's Order revoked Ms. Blake' pharmaceutical technician registration and banned her from employment in any business registered by the Board in any capacity until she had been reinstated by the Board and that she return her registration certificate within 10 days of her receipt of the Order and her failure to do so results in a fine of \$1,000 per day until the registration certificate is received by the Board office.

On January 24, 2012, Ms. Blake sent an email requesting an appearance before the Board seeking reinstatement of her pharmaceutical technician registration. On April 2, 2012, a notice of appearance was sent to Ms. Blake's last known address scheduling her appearance before the Board on April 19, 2012 at 10:30 a.m. Ms. Blake did not appear for her hearing as scheduled. As it is Ms. Blake's to burden to prove to the Board that is in the public's interest to reinstate her registration and she did not appear,

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the Board declined to reinstate Ms. Blake's pharmaceutical technician registration PT 00182.

Signed and effective this $\frac{154}{15}$ day of May, 2012.

Beth Foster, President Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

CYNTHIA BLAKE, P.T., Certificate of Registration #PT00182,

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Case No. 03-027-PT-S

Respondent.

THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on October 15, 2003 in Reno, Nevada. The Board was represented by Louis Ling, General Counsel to the Board. Respondent Cynthia Blake did not appear at the hearing. Based on the presentation of the General Counsel and the public records in the possession and control of the Board, the Board issues the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. Board staff demonstrated that Ms. Blake had been properly served with the Notice of Intended Action and Accusation in this matter and that she had responded to Board staff after receiving it. No explanation was tendered for Ms. Blake's absence, nor did she request a continuation of the matter. Board staff presented the testimony of Geri Raj, managing pharmacist for Kmart #3592. Based upon the testimony of Ms. Raj and the presentation by the General Counsel, the Board finds the following to be the facts of this matter.

2. On March 28, 2003, Board staff received a notice that Ms. Blake had been terminated from her employment as a pharmaceutical technician from Kmart #3592.

3. Ms. Raj testified regarding the basis for Ms. Blake's termination was that on February 18, 2003, Dr. Nader Abelsayed had contacted the managing pharmacist for Kmart #3592 to inquire from whom his patient, MB, was getting prescriptions for Lortab. Ms. Raj checked the pharmacy's computer and found that MB's prescription had been filled five times between December 2002 and February 2003. Dr. Abelsayed had indicated his concern because neither he nor any member of his staff had approved refills of Patient MB's Lortab prescriptions. When Dr. Abelsayed asked Mr. Raj to pull the hard copy of the prescription, Ms. Raj was unable to located any hard copy of the prescription.

4. As a result of her call with Dr. Abelsayed, Ms. Raj spoke with Ms. Blake regarding MB's Lortab prescriptions. Ms. Blake admitted to Ms. Raj that she, Ms. Blake, had filled one of MB's prescriptions on February 13, 2003 without having the hard copy based upon MB's representation that she would bring the hard copy with her when she picked up the prescription. MB did not bring the prescription with her, so no hard copy was ever received for that prescription and placed into the pharmacy's records. Ms. Blake dispensed the prescription to MB without ringing the transaction through the pharmacy's cash register. Ms. Raj detailed her efforts to work with Ms. Blake to find the missing prescriptions and to otherwise resolve the concerns raised by Dr. Abelsayed, but ultimately Ms. Raj was unable to resolve the pharmacy's records show that Ms. Blake was responsible for the orders for which no written order could be located and which Dr. Abelsayed disavowed.

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CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter because Ms. Blake is a pharmaceutical technician registered by the Board.

2. In creating five false and fraudulent prescriptions for controlled substances for MB without authorization of MB's physician, Ms. Blake violated NRS 453.321(1), 453.331(1)(f), and 639.210(4) and (12) and NAC 639.945(1)(g), (h), and (i).

3. In being repeatedly negligent as evidenced by the prior disciplinary action against Ms. Blake, Ms. Blake violated NRS 639.210(4) and (16) and NAC 639.945(1)(d).

ORDER

Based upon the foregoing, the Board hereby orders the following:

1. Ms. Blake's pharmaceutical technician's registration (#PT00182) is revoked.

Ms. Blake may not be employed in any business or facility licensed by this Board in any capacity unless and until her registration as a pharmaceutical technician has been reinstated.

2. Ms. Blake shall return to the Board's Reno office her wallet card within 10 days of her receipt of this Order. Her failure to do so will result in a fine of \$1,000 per day until the wallet card is received by the Board office.

Signed and effective this 13th day of November, 2003.

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Larry L. Pinson, President Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,) CASE NOS. 14-018-RPH-S
) 14-018-PH-S
Petitioner,)
V.) NOTICE OF INTENDED ACTION
) AND ACCUSATION
ASHA KATHYRN GRECO, R.PH.)
Certificate of Registration No. 16908) NEVADA STATE BOARD OF PHARMACY
-) OF PHARMACT
TARGET PHARMACY #T-826	
Certificate of Registration No. PH01360) MAR 1 2 2014
-)
Respondents.	

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Asha Greco, Certificate of Registration No. 16908, was a registered pharmacist with the Board, and Respondent Target Pharmacy #T-826, Certificate of Registration No. PH01360 (Target #T-826), was a pharmacy registered with the Board.

II.

Venus Vedadi is a pharmacy student at Roseman University. On or about January 16, 2014, the Board became aware that Ms. Vedadi had not renewed her intern pharmacist registration, which expired on October 31, 2012. Despite the expiration of her intern pharmacist registration, Ms. Vedadi continued to complete her pharmacy rotations, and worked at her assigned pharmacy practice sites without a valid intern pharmacist registration.

III.

Ms. Vedadi completed a rotation at Target #T-826 during the time period of January 6, 2014 through February 14, 2014.

IV.

At the Board's request, Roseman University and the managing pharmacist at Target #T-826 provided Ms. Vedadi's work records. From the records provided, Board Staff ascertained that Ms. Vedadi had worked approximately five (5) days without a current intern pharmacist registration.

FIRST CAUSE OF ACTION

V.

As managing pharmacist for the pharmacy in which Ms. Vedadi worked without a current intern pharmacist registration, Asha Greco violated Nevada Revised Statute (NRS) 639.220(1) and Nevada Administrative Code (NAC) 639.945(1)(i) and/or (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (11), (12) and/or (15), or alternatively, under NRS 639.255, as well as NAC 639.955.

SECOND CAUSE OF ACTION

VI.

In owning and operating the pharmacy in which Ms. Vedadi worked without a current intern pharmacist registration, Target Pharmacy #T-826 violated NRS 639.220(1) and NAC 639.945(1)(i), (j) and/or (2), which violations are grounds for discipline pursuant to NRS 639.210(4), (11) and/or (12), or alternatively, under NRS 639.255, as well as NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this _____ day of March, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

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)

)

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

CASE NO. 14-018-RPH-S

v.

ASHA KATHYRN GRECO, R.PH. Certificate of Registration No. 16908

Respondent

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, April 16, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this 12 day of March, 2014.

2. hson, Pharm.D., Executive Secretary

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 14-018-RPH-S
)	
Petitioner,)	
V.)	ANSWER AND
)	NOTICE OF DEFENSE
ASHA KATHYRN GRECO, R.PH.)	
Certificate of Registration No. 16908)	
)	
Respondent	/	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

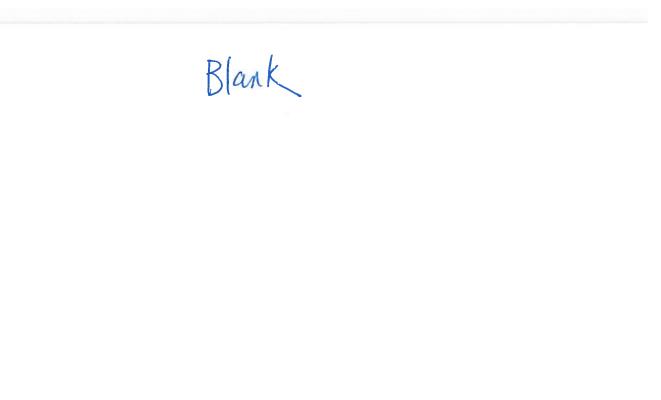
1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ______ day of ______, 2014.

ASHA KATHYRN GRECO, R.PH.



Nevada State Board of Pharmacy) Petitioner) v.)) Target Pharmacy #T-826 (No. PH01360)) Respondent) Case No. 14-018-PH-S

ANSWER AND NOTICE OF DEFENSE

Respondent Target Pharmacy #T-826 (No. PH01360) above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That its objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against it, is hereby interposed on the following grounds:

Petitioner fails to allege facts to support violations of the statutes and regulations cited in the First and Second Causes of Action.

2. That, in answer to the Notice of Intended Action and Accusation, Respondent Target admits, denies, and alleges as follows:

- A. Admits the allegations set forth in paragraphs "I" and "IV" of the Notice of Intended Action and Accusation.
- B. Admits the portion of paragraph "II" of the Notice of Intended Action and Accusation which asserts that Ms. Venus Vedadi is a pharmacy student at Roseman University. Respondent Target denies knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph "II".
- C. Denies the allegation set forth in paragraph "III". While Ms. Vedadi was assigned to a pharmacy rotation at Target Pharmacy #T-826 to run from January 6, 2014 to February 14, 2014, Ms. Vedadi only worked January 6, 7, 8, 14, and a partial day on January 15th before it was discovered that her registration was "not renewed" and she was asked not to return to the store.
- D. Denies the following allegations set forth in paragraph "VI" of the Notice of Intended Action and Accusation, the Second Cause of Action directed to Respondent Target:
 - Violation of NRS 639.220(1): At all times material to the Board's accusation, Target Pharmacy #T-826 was managed by a registered pharmacist, approved by the Board, who was responsible for compliance by the pharmacy and its personnel

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with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy;

- 2. Violation of NAC 639.945(1)(i): At all times material to the Board's accusation. Target Pharmacy #T-826 acted in a competent, skillful, and appropriate manner:
- 3. Violation of NAC 639.945(1)(j): At all times material to the Board's accusation, Target Pharmacy #T-826 did not knowingly aid or abet a person not licensed to practice pharmacy in the State of Nevada: and
- 4. Violation of NAC 639.945(2): At all times material to the Board's accusation, Target Pharmacy #T-826 was responsible for the acts of all personnel in its employ.
- E. Denies any and all allegations not heretofore previously admitted or denied.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein sate, are true and correct to the best of my knowledge.

DATED this 4th day of April , 2014. MM T Mill Mull

Service Group Manager, Halthan Compliance

QBI26092653.1

NEVADA STATE BOARD OF PHARMACY,) CASE NOS. 14-017-RPH-S) 14-017-PH-S
Petitioner,)
V.) NOTICE OF INTENDED ACTION
) AND ACCUSATION
CHRISTOPHER GLEN SOUTHWICK, R.PH.)
Certificate of Registration No. 11480) NEVADA STATE BOARD OF PHARMACY
ADVANCED ISOTOPES OF NEVADA)
Certificate of Registration No. PH02453) MAR 1 2 2014
Respondents.	
A	

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Christopher Southwick, Certificate of Registration No. 11480, was a registered pharmacist with the Board, and Respondent Advanced Isotopes of Nevada, Certificate of Registration No. PH02453 was a pharmacy registered with the Board.

II.

Venus Vedadi is a pharmacy student at Roseman University. On or about January 16, 2014, the Board became aware that Ms. Vedadi had not renewed her intern pharmacist registration, which expired on October 31, 2012. Despite the expiration of her intern pharmacist registration, Ms. Vedadi continued to complete her pharmacy rotations, and worked at her assigned pharmacy practice sites without a valid intern pharmacist registration.

III.

Ms. Vedadi completed a rotation at Advanced Isotopes of Nevada during the time period of August 19, 2013 through September 27, 2013.

At the Board's request, Roseman University and the managing pharmacist at Advanced Isotopes of Nevada provided Ms. Vedadi's work records. From the records provided, Board Staff ascertained that Ms. Vedadi had worked approximately twenty-one (21) days without a current intern pharmacist registration.

FIRST CAUSE OF ACTION

V.

As managing pharmacist for the pharmacy in which Ms. Vedadi worked without a current intern pharmacist registration, Christopher Southwick violated Nevada Revised Statute (NRS) 639.220(1) and Nevada Administrative Code (NAC) 639.945(1)(i) and/or (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (11), (12) and/or (15), or alternatively, under NRS 639.255, as well as NAC 639.955.

SECOND CAUSE OF ACTION

VI.

In owning and operating the pharmacy in which Ms. Vedadi worked without a current intern pharmacist registration, Advanced Isotopes of Nevada violated NRS 639.220(1) and NAC 639.945(1)(i), (j) and/or (2), which violations are grounds for discipline pursuant to NRS 639.210(4), (11) and/or (12), or alternatively, under NRS 639.255, as well as NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this <u>12</u> day of March, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

NEVADA STATE BOARD OF PHARMACY,) Petitioner,) v.) CHRISTOPHER GLEN SOUTHWICK, R.PH.) Certificate of Registration No. 11480)

Respondent

CASE NO . 14-017-RPH-S

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, April 16, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

IV.

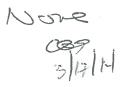
Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless. DATED this

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,)	
)	CASE NO. 14-017-RPH-S
Petitioner,)	
V.)	
)	ANSWER AND
CHRISTOPHER GLEN SOUTHWICK, R.PH.)	NOTICE OF DEFENSE
Certificate of Registration No. 11480)	
)	
Respondent	1	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").





-1-

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

Sec. 9.

See Attacted Statement & Cirriculum 029 3/18/14

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 17 day of March, 2014.

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CHRISTOPHER GLEN SOUTHWICK, R.PH.



Advanced Isotopes of Nevada 1090 E Desert Inn Rd #102 Las Vegas, NV 89109 March 18, 2014

Nevada State Board of Pharmacy 431 W. Plumb Lane Reno, NV 89509

This statement shall serve as response to the Answer and Notice of Defense case no. 14-017-RPH-S & 14-017-PH-S.

Venus started her rotation at Advanced Isotopes of Nevada LLC on August 19, 2013 and finished on Sept 25, 2013. One of the items covered during first day orientation is license verification (see attached Nuclear Pharmacy Rotation curriculum). I accept the original, or a copy of the original as proof of licensure. If the intern does not have it with them I will access the Nevada B.O.P website and print a copy for our records.

Venus presented a copy of an intern license which I looked at, thought to be her valid Nevada intern license, and posted it on our wall with our other licenses. No check of the Nevada B.O.P. website was performed.

At the end of her rotation the copy of her intern license was either given back to her or put in the shred bin for destruction. Therefore I have no way to verify if this was an expired NV intern license, or an active CA intern license which also may have been presented.

On Jan 23, 2014 a representative from Roseman University called to inform me of Venus's expired intern license and a pending investigation by the Nevada B.O.P.

Going forward I will access the Nevada B.O.P website only for all licensure verification prior to the students/employee's start date and will keep copies. Additionally I will have the intern/employee sign and date the orientation form as proof we have discussed their licensure on their first day of employment. If active licensure cannot be verified, the intern/employee will not be allowed to start work and I will inform the Nevada B.O.P.

Christen 50

Chris Southwick R.Ph. Advanced Isotopes of Nevada LLC Pharmacy Manager

1090 E. Desert Inn Rd. Suite 102 Las Vegas NV 89109 Phone: 702-476-8600 Fax: 702-750-1376

Intern Name:	
×	
Signature:	
Date:	

Nuclear Pharmacy Rotation

Advanced Isotopes of Nevada

Week #1:

5- J.

- Introductions and Layout
- License Verification
- Hours of Operation
- R.A.T. Module, BBP Testing, DOT/Hazmat Training, HIPPA, Hep B Vaccine
- ALARA
- Daily equipment QA
- Dose wrapping and shipping
- Delivery of Doses
- Supply stocking.
- Returned dose breakdown and decontamination

Week #2:

- Radiopharmaceutical QC
- Mo99/Tc99m Generator
- Radioactive decay physics/math
- RAM shipping module (Generator Return)
- Data Entry & Order Taking
- Daily set up

Week #3:

- Practice Dose Drawing
- Radiopharmaceuticals (Systems/Target Organs)
- I-131 Room & Capsule Compounding
- Customer ALARA Services
- Mid Term Eval

Week #4:

- Practice Dose Drawing
- Blood Labeling

• P.E.T. Overview

Week #5

N - 2 - 5 - 5

- Kit Prep Calculations
- Practice Dose Drawing
- Radiopharmaceutical Ordering & Inventory Management

Week #6

- Kit Prep
- Dose Drawing
- Final Evaluation

NEVADA STATE BOARD OF PHARMACY,)	
)	CASE NO. 14-017-PH-S
Petitioner,)	
V.)	
)	ANSWER AND
ADVANCED ISOTOPES OF NEVADA)	NOTICE OF DEFENSE
Certificate of Registration No. PH02453)	
)	
Respondent	_ /	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ______ day of ______, 2014.

Print or Type name

For ADVANCED ISOTOPES OF NEVADA



Advanced Isotopes of Nevada 1090 E Desert Inn Rd #102 Las Vegas, NV 89109 March 18, 2014

Nevada State Board of Pharmacy 431 W. Plumb Lane Reno, NV 89509

This statement shall serve as response to the Answer and Notice of Defense case no. 14-017-RPH-S & 14-017-PH-S.

Venus started her rotation at Advanced Isotopes of Nevada LLC on August 19, 2013 and finished on Sept 25, 2013. One of the items covered during first day orientation is license verification (see attached Nuclear Pharmacy Rotation curriculum). I accept the original, or a copy of the original as proof of licensure. If the intern does not have it with them I will access the Nevada B.O.P website and print a copy for our records.

Venus presented a copy of an intern license which I looked at, thought to be her valid Nevada intern license, and posted it on our wall with our other licenses. No check of the Nevada B.O.P. website was performed.

At the end of her rotation the copy of her intern license was either given back to her or put in the shred bin for destruction. Therefore I have no way to verify if this was an expired NV intern license, or an active CA intern license which also may have been presented.

On Jan 23, 2014 a representative from Roseman University called to inform me of Venus's expired intern license and a pending investigation by the Nevada B.O.P.

Going forward I will access the Nevada B.O.P website only for all licensure verification prior to the students/employee's start date and will keep copies. Additionally I will have the intern/employee sign and date the orientation form as proof we have discussed their licensure on their first day of employment. If active licensure cannot be verified, the intern/employee will not be allowed to start work and I will inform the Nevada B.O.P.

(Won G. Sont

Chris Southwick R.Ph. Advanced Isotopes of Nevada LLC Pharmacy Manager

1090 E. Desert Inn Rd. Suite 102 Las Vegas NV 89109 Phone: 702-476-8600 Fax: 702-750-1376 Intern Name:_____

Signature: _____

Date: _____

Nuclear Pharmacy Rotation

Advanced Isotopes of Nevada

Week #1:

- Introductions and Layout
- License Verification
- Hours of Operation
- R.A.T. Module, BBP Testing, DOT/Hazmat Training, HIPPA, Hep B Vaccine
- ALARA
- Daily equipment QA
- Dose wrapping and shipping
- Delivery of Doses
- Supply stocking.
- Returned dose breakdown and decontamination

Week #2:

- Radiopharmaceutical QC
- Mo99/Tc99m Generator
- Radioactive decay physics/math
- RAM shipping module (Generator Return)
- Data Entry & Order Taking
- Daily set up

Week #3:

- Practice Dose Drawing
- Radiopharmaceuticals (Systems/Target Organs)
- I-131 Room & Capsule Compounding
- Customer ALARA Services
- Mid Term Eval

Week #4:

- Practice Dose Drawing
- Blood Labeling

• P.E.T. Overview

Week #5

- Kit Prep Calculations
- Practice Dose Drawing
- Radiopharmaceutical Ordering & Inventory Management

Week #6

- Kit Prep
- Dose Drawing
- Final Evaluation

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	JUN 1 3 2014	
-	FILED	

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

Respondent.

 \mathbf{v}_{\bullet}

BRENTON S. UNDERWOOD, R.PH. Certificate of Registration No. 18014, CASE NO. 14-031-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because Respondent Brenton Underwood, Certificate of Registration No. 18014 (Mr. Underwood), is a registered pharmacist with the Board.

II.

During the 2013 renewal period, Mr. Underwood checked the box on his pharmacist license renewal application indicating that he had completed the required thirty (30) continuing education units (CEUs) between November 1, 2011, and October 31, 2013.

III.

After the renewal ended, Board Staff conducted a random audit of CEUs for the biennium ending October 31, 2013.

IV.

Board Staff's continuing education (CE) audit findings identified that Mr. Underwood did not complete any CEUs for the biennial period November 1, 2011, to October 31, 2013.

-1-

FIRST CAUSE OF ACTION

V.

By failing to complete the required CEUs during the biennial period November 1, 2011, to October 31, 2013, and by indicating on his renewal application that he had completed 30 CEUs during the biennial period November 1, 2011, to October 31, 2013, when he completed zero hours of CEUs, Brenton Underwood violated Nevada Revised Statute (NRS) 639.281 and Nevada Administrative Code (NAC) 639.330, 639.390, and/or 639.945(m), which violations are grounds for action pursuant to (NRS) 639.210(1), (4), (9), (10), (12) and/or (17), and 639.2174 and NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this (3) day of June, 2014.

inson, Pharm.D., Executive Secretary

Nevada State Board of Pharmacy

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

NEVADA STATE BOARD OF PHARMACY,)
Petitioner,)) CASE NO. 14-031-RPH-S
V.)
BRENTON UNDERWOOD, R.PH.	 STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION
Certificate of Registration No. 18014) AND ACCUSATION
) RIGHT TO HEARING
Respondent.	/

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

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IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless. DATED this **[3** day of June, 2014.

Lary L. Pirson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

	NEVADA STATE BOARD OF PHARMACY
BEFORE THE NEVADA STATE BO	DARD OF PHARMACY JUL - 1 2014
NEVADA STATE BOARD OF PHARMACY,	FILED
Petitioner,) CASE NO. 14-031-RPH-S
V.)
BRENTON UNDERWOOD, R.PH. Certificate of Registration No. 18014))) ANSWER AND) NOTICE OF DEFENSE
Respondent.	/

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

None.



2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I do not deny that at this time, for the biennial period November 1, 2011 to October 31, 2013, I am unable to provide proof of completion of 30 CEUs. At the time of renewal I was under the impression that I was exempt from meeting the full requirements, pursuant to NAC 639.335(1a), due to my receipt of a degree in pharmacy conferred by an accredited school or college of pharmacy occurring in November 2010. For the aforementioned biennial period I did complete 1 CEU in Nevada Law and 3 CEUs in Immunization to meet requirements as an immunizing pharmacist. Upon receipt of this notice of intended action and accusation, and review of NAC 639.330, it has come to my attention that I did not appropriately comply with the necessary continuing education requirements for reregistration. I accept full responsibility for my actions resulting in my non compliance, and accept whatever disciplinary action the board feels to be appropriate. I would like to include that for the current biennial period starting November 1, 2013, I have completed over 40 hours of CEUs. Although I understand this has no bearing on the requirements for the previous biennial period, I hope it will serve as a reflection of my dedication to continuing my education as a Pharmacist, and my commitment to the health and safety of the public.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 29^{th} day of June, 2014.

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BRENTON UNDERWOOD, R.PH.

NEVADA STATE BOA OF PHARMACY	RD
JUN 1 3 2014	
FILED)

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

AMIROSE DE GUZMAN, R.PH. Certificate of Registration No. 16884

CVS PHARMACY #5942 Certificate of Registration No. PH02020

Respondents.

NOTICE OF INTENDED ACTION AND ACCUSATION

14-013-PH-S

CASE NOS. 14-013-RPH-S

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Amirose De Guzman, R.Ph., Certificate of Registration No. 16884, was a registered pharmacist with the Board, and Respondent CVS Pharmacy #5942, Certificate of Registration No. PH02020 (CVS #5942), was a pharmacy registered with the Board.

II.

During the annual inspection of CVS #5942 on February 12, 2014, the Board Inspector discovered that pharmacy employee Angeli Domingo was working as a pharmaceutical technician without a valid Nevada pharmaceutical technician registration.

III.

Board Staff conducted an investigation and determined that from August 2013, to February 2014, Ms. Domingo worked at multiple CVS pharmacies in Nevada as an unregistered pharmaceutical technician. The Board Investigator requested Ms. Domingo's work records from Michael Forbrook, CVS Pharmacy District Supervisor. From the records provided, Board Staff ascertained that during the period of September 4, 2013, to February 19, 2014, Ms. Domingo worked approximately nineteen (19) days at CVS #5942 as an unregistered pharmaceutical technician.

V.

Respondent Ms. De Guzman was the managing pharmacist for CVS #5942 during the period in which Ms. Domingo worked as an unregistered pharmaceutical technician.

FIRST CAUSE OF ACTION

VI.

As managing pharmacist for the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, Amirose De Guzman violated Nevada Administrative Code (NAC) 639.240(1), NRS 639.220(1) and NAC 639.945(1)(i) and/or (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (12) and/or (15), or alternatively, under NRS 639.255, as well as NAC 639.955.

SECOND CAUSE OF ACTION

VII.

In owning and operating the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, CVS Pharmacy #5942 violated NAC 639.240(1), NAC 639.945(1)(i), (j) and (2), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (12), or alternatively, under NRS 639.255, as well as NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this (3) day of June, 2014.

Larry L. Pincon, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

NEVADA STATE BOARD OF PHARMACY,)
) CASE NO . 14-013-RPH-S
Petitioner,)
V.)
) STATEMENT TO THE RESPONDENT
AMIROSE DE GUZMAN, R.PH.) NOTICE OF INTENDED ACTION
Certificate of Registration No. 16884) AND ACCUSATION
_) RIGHT TO HEARING
Respondent.	1

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless. DATED this <u>13</u> day of June, 2014.

L. Pigson, Pharm.D., Executive Secretary

Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 14-013-RPH-S
Petitioner,)	
V.)	
) /	ANSWER AND
AMIROSE DE GUZMAN, R.PH.)]	NOTICE OF DEFENSE
Certificate of Registration No. 16884)	
)	
Respondent.	/	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ______, 2014.

AMIROSE DE GUZMAN, R.PH.

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	NEVADA STATE BOARD OF PHARMACY	2
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NEVADA STATE BOARD OF PHARMACY,

Answer and Notice of Defense

Petitioner,

Respondents.

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AMIROSE DE GUZMAN, R.PH. Certificate of Registration No. 16884

CVS PHARMACY #5942 Certificate of Registration No. PH02020; Case No. 14-013-RPH-S

Case No. 14-013-PH-S

COMES NOW Respondent CVS Pharmacy #5942 ("CVS") by and through its counsel, Michael W. Dyer, of Dyer, Lawrence, Flaherty, Donaldson & Prunty, and hereby responds to the Notice of Intended Action and Accusation, filed on June 13, 2014, by Petitioner, the Nevada State Board of Pharmacy ("Board"). This Response will serve as CVS's Answer and Notice of Defense pursuant to NRS 639.244. CVS hereby declares:

1. That a hearing on the Notice of Intended Action and Accusation is requested.

2. That, in answer to the Notice of Intended Action and Accusation, CVS admits, denies and avers as follows:

1.

CVS admits that the Board has jurisdiction over the matter.

11.

CVS does not contest the allegations in Paragraph II.

- 1 -

CVS hereby admits that Angeli Domingo ("Ms. Domingo") worked as an unregistered pharmaceutical technician at four CVS pharmacies in Nevada for a total of sixty-seven (67) days. CVS affirmatively states that at the time Ms. Domingo began working in the Nevada CVS pharmacies, Ms. Domingo was a registered pharmaceutical technician for CVS in Florida, who was working in Nevada as a "fill-in" or "floater" on a temporary basis, and her "home store" for payroll purposes remained in Florida. Because Ms. Domingo's home store remained in Florida, CVS's payroll system did not prompt a request for confirmation of Ms. Domingo's Nevada license. The result was that the burden of confirming Ms. Domingo's Nevada license status fell entirely on the managing pharmacist.

CVS further states that as a result of the Domingo situation, it has instituted a corrective policy requiring managing pharmacists to check the licenses of all pharmaceutical technicians not assigned to their stores and to print out a copy of the Nevada license before allowing such pharmaceutical technicians to work as a temporary fill-in or floater.

IV.

CVS does not contest the allegations in Paragraph IV.

CVS does not contest the allegations in Paragraph V

111.

FIRST CAUSE OF ACTION

VI.

Ms. De Guzman is no longer employed by CVS. CVS therefore has no response to the First Cause of Action, other than acknowledging that Ms. De Guzman allowed Ms. Domingo to work in the pharmacy of CVS #5942, and that Ms. Domingo did not have a valid license during the entire time she was allowed to work at CVS #5942.

SECOND CAUSE OF ACTION

VII.

CVS does not contest the allegations contained in Paragraph VII and does not contest that a basis for imposing discipline on CVS #5942 exists. However, CVS does not concede that NAC 639.945(1) or (2) categorically authorize the discipline of a pharmacy due to an employee's actions on a theory of strict or vicarious liability. CVS further states that corrective action has been taken to ensure that the managing pharmacist of each CVS pharmacy ensures that pharmaceutical technicians are properly licensed before working.

WHEREFORE CVS requests a hearing before the Nevada State Board of Pharmacy regarding the Notice of Intended Action and Accusation filed by Petitioner.

Dated this $\underline{7}^{\mu}_{\mu}$ day of July, 2014.

DYER, LAWRENCE, FLAHERTY, DONALDSON & PRLINTY

Michael . Dyer

Casey A/Gillham Attorneys for CVS #5942

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N	EVADA STATE BOARD OF PHARMACY	
	JUN 1 3 2014	
	FILED	

CASE NOS. 14-039-RPH-S

AND ACCUSATION

14-039-PH-S

NOTICE OF INTENDED ACTION

BEFORE THE NEVADA STATE BOARD OF PHARMACY

)

)

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

BRIAN WICKSON, R.PH. Certificate of Registration No. 12725

CVS PHARMACY #5792 Certificate of Registration No. PH01877

Respondents.

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Brian Wickson, R.Ph., Certificate of Registration No. 12725, was a registered pharmacist with the Board, and Respondent CVS Pharmacy #5792, Certificate of Registration No. PH01877 (CVS #5792), was a pharmacy registered with the Board.

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During an annual inspection of non-party CVS #5942 on February 12, 2014, the Board Inspector discovered that pharmacy employee Angeli Domingo was working as a pharmaceutical technician without a valid Nevada pharmaceutical technician registration.

III.

Board Staff conducted an investigation and determined that from August 2013, to February 2014, Ms. Domingo worked at multiple CVS pharmacies in Nevada as an unregistered pharmaceutical technician.

IV.

The Board Investigator requested Ms. Domingo's work records from Michael Forbrook, CVS Pharmacy District Supervisor. From the records provided, Board Staff ascertained that Ms. Domingo worked on October 29, 2013, (one day) at CVS #5792 as an unregistered pharmaceutical technician.

V.

Respondent Mr. Wickson was the managing pharmacist at CVS #5792 on the day Ms. Domingo worked as an unregistered pharmaceutical technician.

FIRST CAUSE OF ACTION

VI.

As managing pharmacist for the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, Brian Wickson violated Nevada Administrative Code (NAC) 639.240(1), NRS 639.220(1) and NAC 639.945(1)(i) and/or (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (12) and/or (15), or alternatively, under NRS 639.255, as well as NAC 639.955.

SECOND CAUSE OF ACTION

VII.

In owning and operating the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, CVS Pharmacy #5792 violated NAC 639.240(1), NAC 639.945(1)(i), (j) and (2), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (12), or alternatively, under NRS 639.255, as well as NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this ______ day of June, 2014.

Larry L. Puson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy -2-

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

NEVADA STATE BOARD OF PHARMACY,)) CASE NO . 14-039-RPH-S
Petitioner,)
v. BRIAN WICKSON, R.PH. Certificate of Registration No. 12725) STATEMENT TO THE RESPONDENT) NOTICE OF INTENDED ACTION) AND ACCUSATION) RIGHT TO HEARING
Respondent.	/

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless. DATED this <u>13</u> day of June, 2014.

L. Pinton, Pharm.D., Executive Secretary

Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 14-039-RPH-S
Petitioner,)	
v.)	
)	ANSWER AND
BRIAN WICKSON, R.PH.)	NOTICE OF DEFENSE
Certificate of Registration No. 12725)	
)	
Respondent.	/	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

The CVS employee Angel: Doming represented herself As A certified registered NV technician proor to work as a pharmacy technician at CVS \$792 (Desert Inn/EAstern), I requested a pharmacy technician thru the CVS district office and Angeli Domingo responded stating she was a pharmacy technician available to work Oct. 29,2013 (one day) for a 10 Am-4Pm or 10 Am to 6PM shift.



2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies

and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 27th day of June, 2014.

Wichson **BRIAN WICKSON, R.PH.**

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NEVADA STATE BOARD OF PHARMACY,) CASE NO. 14-039-PH-S Petitioner,) v.) V.) CVS PHARMACY #5792) Certificate of Registration No. PH01877) Respondent. /

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2014.

Print or Type name

For CVS PHARMACY #5792

	NEVADA STATE BOARD OF PHARMACY
	JUL - 7 2014
BEFORE THE NEVADA STATE BOAR	
NEVADA STATE BOARD OF PHARMACY,	ANSWER AND FILED
Petitioner,	NOTICE OF DEFENSE
v.	
BRIAN WICKSON, R.PH. Certificate of Registration No. 12725	Case No. 14-039-RPH-S

CVS PHARMACY #5792 Certificate of Registration No. PH02020; Case No. 14-039-PH-S

Respondents. _____/

COMES NOW Respondent CVS Pharmacy #5792 ("CVS") by and through its counsel, Michael W. Dyer, of Dyer, Lawrence, Flaherty, Donaldson & Prunty, and hereby responds to the Notice of Intended Action and Accusation, filed on June 13, 2014, by Petitioner, the Nevada State Board of Pharmacy ("Board"). This Response will serve as CVS's Answer and Notice of Defense pursuant to NRS 639.244. CVS hereby declares:

1. That a hearing on the Notice of Intended Action and Accusation is requested.

2. That, in answer to the Notice of Intended Action and Accusation, CVS admits, denies and avers as follows:

Ι.

CVS admits that the Board has jurisdiction over the matter.

11.

CVS does not contest the allegations in Paragraph II.

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III.

CVS hereby admits that Angeli Domingo ("Ms. Domingo") worked as an unregistered pharmaceutical technician at four CVS pharmacies in Nevada for a total of sixty-seven (67) days. CVS affirmatively states that at the time Ms. Domingo began working in the Nevada CVS pharmacies, Ms. Domingo was a registered pharmaceutical technician for CVS in Florida, who was working in Nevada as a "fill-in" or "floater" on a temporary basis, and her "home store" for payroll purposes remained in Florida. Because Ms. Domingo's home store remained in Florida, CVS's payroll system did not prompt a request for confirmation of Ms. Domingo's Nevada license. The result was that the burden of confirming Ms. Domingo's Nevada license status fell entirely on the managing pharmacist.

CVS further states that as a result of the Domingo situation, it has instituted a corrective policy requiring managing pharmacists to check the licenses of all pharmaceutical technicians not assigned to their stores and to print out a copy of the Nevada license before allowing such pharmaceutical technicians to work as a temporary fill-in or floater.

IV.

CVS does not contest the allegations in Paragraph IV.

V.

CVS does not contest the allegations in Paragraph V

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FIRST CAUSE OF ACTION

VI.

Mr. Wickson is no longer employed by CVS. CVS therefore has no response to the First Cause of Action, other than acknowledging that Mr. Wickson allowed Ms. Domingo to work in the pharmacy of CVS #5792, and that Ms. Domingo did not have a valid license during the entire time she was allowed to work at CVS #5792.

SECOND CAUSE OF ACTION

VII.

CVS does not contest the allegations contained in Paragraph VII and does not contest that a basis for imposing discipline on CVS #5792 exists. However, CVS does not concede that NAC 639.945(1) or (2) categorically authorize the discipline of a pharmacy due to an employee's actions on a theory of strict or vicarious liability. CVS further states that corrective action has been taken to ensure that the managing pharmacist of each CVS pharmacy ensures that pharmaceutical technicians are properly licensed before working.

WHEREFORE CVS requests a hearing before the Nevada State Board of Pharmacy regarding the Notice of Intended Action and Accusation filed by Petitioner.

Dated this 7th day of July, 2014.

DYER, LAWRENCE, FLAHERTY, DONALDSON & PRUNTY

W. Dver Michael

Casey Al/Gillham Attorneys for CVS #5792

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CASE NOS. 14-038-RPH-S

AND ACCUSATION

14-038-PH-S

NOTICE OF INTENDED ACTION

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CHRISTOPHER GIFFORD, R.PH. Certificate of Registration No. 17858

CVS PHARMACY #2955 Certificate of Registration No. PH01668

Respondents.

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Christopher Gifford, R.Ph., Certificate of Registration No. 17858, was a registered pharmacist with the Board, and Respondent CVS Pharmacy #2955, Certificate of Registration No. PH01668 (CVS #2955), was a pharmacy registered with the Board.

II.

During an annual inspection of non-party CVS #5942 on February 12, 2014, the Board Inspector discovered that pharmacy employee Angeli Domingo was working as a pharmaceutical technician without a valid Nevada pharmaceutical technician registration.

III.

Board Staff conducted an investigation and determined that from August 2013, to February 2014, Ms. Domingo worked at multiple CVS pharmacies in Nevada as an unregistered pharmaceutical technician.

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The Board Investigator requested Ms. Domingo's work records from Michael Forbrook, CVS Pharmacy District Supervisor. From the records provided, Board Staff ascertained that during the period of August 9, 2013, to February 17, 2014, Ms. Domingo worked approximately forty-six (46) days at CVS #2955 as an unregistered pharmaceutical technician.

V.

Respondent Mr. Gifford was the managing pharmacist at CVS #2955 during the period in which Ms. Domingo worked as an unregistered pharmaceutical technician.

FIRST CAUSE OF ACTION

VI.

As managing pharmacist for the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, Christopher Gifford violated Nevada Administrative Code (NAC) 639.240(1), NRS 639.220(1) and NAC 639.945(1)(i) and/or (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (12) and/or (15), or alternatively, under NRS 639.255, as well as NAC 639.955.

SECOND CAUSE OF ACTION

VII.

In owning and operating the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, CVS Pharmacy #2955 violated NAC 639.240(1), NAC 639.945(1)(i), (j) and (2), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (12), or alternatively, under NRS 639.255, as well as NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this _____ day of June, 2014.

Larry L. Vinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

CHRISTOPHER GIFFORD, R.PH. Certificate of Registration No. 17858

v.

Respondent.

CASE NO. 14-038-RPH-S

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

)

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

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IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this 13^{A} day of June, 2014.

Larry L. Pincon, Pharm.D., Executive Secretary

Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CHRISTOPHER GIFFORD, R.PH. Certificate of Registration No. 17858 CASE NO. 14-038-RPH-S

ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

Respondent.

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2014.

CHRISTOPHER GIFFORD, R.PH.

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NEVADA STATE BOARD OF PHARMACY		
JUL - 7 2014		
FILED		

NEVADA STATE BOARD OF PHARMACY,

Answer and Notice of Defense

Petitioner,

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CHRISTOPHER GIFFORD, R.PH. Certificate of Registration No. 17858 Case No. 14-038-RPH-S

CVS PHARMACY #2955 Certificate of Registration No. PH02145;

Case No. 14-038-PH-S

Respondents.

COMES NOW Respondents Christopher Gifford and CVS Pharmacy #2955 ("Respondents") by and through their counsel, Michael W. Dyer, of Dyer, Lawrence, Flaherty, Donaldson & Prunty, and hereby respond to the Notice of Intended Action and Accusation, filed on June 13, 2014, by Petitioner, the Nevada State Board of Pharmacy ("Board"). This Response will serve as Respondents' Answer and Notice of Defense pursuant to NRS 639.244. Respondents hereby declare:

1. That a hearing on the Notice of Intended Action and Accusation is requested.

2. That, in answer to the Notice of Intended Action and Accusation, Respondents admit, deny and aver as follows:

Ι.

Respondents hereby admit that the Board has jurisdiction over the matter.

Ш.

Respondents do not contest the allegations in Paragraph II.

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Respondents hereby admit that Angeli Domingo ("Ms. Domingo") worked as an unregistered pharmaceutical technician at four CVS pharmacies in Nevada for a total of sixty-

seven (67) days. Respondents affirmatively state that at the time Ms. Domingo began working in the Nevada CVS pharmacies, Ms. Domingo was a registered pharmaceutical technician for CVS in Florida, who was working in Nevada as a "fill-in" or "floater" on a temporary basis, and her "home store" for payroll purposes remained in Florida. Because Ms. Domingo's home store remained in Florida, CVS's payroll system did not prompt a request for confirmation of Ms. Domingo's Nevada license. The result was that the burden of confirming Ms. Domingo's Nevada license status fell entirely on the managing pharmacist.

Respondents further state that as a result of the Domingo situation, CVS has instituted a corrective policy requiring managing pharmacists to check the licenses of all pharmaceutical technicians not assigned to their stores and to print out a copy of the Nevada license before allowing such pharmaceutical technicians to work as a temporary fill-in or floater.

IV.

Respondents do not contest the allegations in Paragraph IV.

V.

Respondents do not contest the allegations in Paragraph V.

FIRST CAUSE OF ACTION

VI.

Respondents do not contest the allegations contained in Paragraph VI.

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SECOND CAUSE OF ACTION

VII.

Respondents do not contest the allegations contained in Paragraph VII and do not contest that a basis for imposing discipline on CVS #2955 exists. However, Respondents do not concede that NAC 639.945(1) or (2) categorically authorize the discipline of a pharmacy due to an employee's actions on a theory of strict or vicarious liability. Respondents further state that corrective action has been taken to ensure that the managing pharmacist of each CVS pharmacy ensures that all pharmaceutical technicians are properly licensed before working.

WHEREFORE Respondents request a hearing before the Nevada State Board of Pharmacy regarding the Notice of Intended Action and Accusation filed by Petitioner.

Dated this $\underline{\underline{///}}_{4}$ day of July, 2014.

DYER, LAWRENCE, FLAHERTY, DONADDSON & PRUNTY

By Michael W/Dyer

Casey A. Gillham Attorneys for Respondents Christopher Gifford and CVS #2955

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CASE NOS. 14-037-RPH-S

AND ACCUSATION

14-037-PH-S

NOTICE OF INTENDED ACTION

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

VICKY L. BLACKWELL, R.PH. Certificate of Registration No. 18312

CVS PHARMACY #5113 Certificate of Registration No. PH01951

Respondents.

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Vicky Blackwell, R.Ph., Certificate of Registration No. 18312, was a registered pharmacist with the Board, and Respondent CVS Pharmacy #5113, Certificate of Registration No. PH01951 (CVS #5113), was a pharmacy registered with the Board.

II.

During an annual inspection of non-party CVS #5942 on February 12, 2014, the Board Inspector discovered that pharmacy employee Angeli Domingo was working as a pharmaceutical technician without a valid Nevada pharmaceutical technician registration.

III.

Board Staff conducted an investigation and determined that from August 2013, to February 2014, Ms. Domingo worked at multiple CVS pharmacies in Nevada as an unregistered pharmaceutical technician.

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IV.

The Board Investigator requested Ms. Domingo's work records from Michael Forbrook, CVS Pharmacy District Supervisor. From the records provided, Board Staff ascertained that Ms. Domingo worked on November 5, 2013, (one day) at CVS #5113 as an unregistered pharmaceutical technician.

V.

Respondent Ms. Blackwell was the managing pharmacist at CVS #5113 on the day Ms. Domingo worked as an unregistered pharmaceutical technician.

FIRST CAUSE OF ACTION

VI.

As managing pharmacist for the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, Vicky Blackwell violated Nevada Administrative Code (NAC) 639.240(1), NRS 639.220(1) and NAC 639.945(1)(i) and/or (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (12) and/or (15), or alternatively, under NRS 639.255, as well as NAC 639.955.

SECOND CAUSE OF ACTION

VII.

In owning and operating the pharmacy in which Ms. Domingo worked without a Nevada pharmaceutical technician registration, CVS Pharmacy #5113 violated NAC 639.240(1), NAC 639.945(1)(i), (j) and (2), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (12), or alternatively, under NRS 639.255, as well as NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this _____ day of June, 2014.

Lary L. Vinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

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NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

VICKY BLACKWELL, R.PH. Certificate of Registration No. 18312

Respondent.

CASE NO. 14-037-RPH-S

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

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IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless. DATED this <u>13</u> day of June, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE B	OARD OF PHARMACY
NEVADA STATE BOARD OF PHARMACY, Petitioner,) FILED) CASE NO. 14-037-RPH-S
v. VICKY BLACKWELL, R.PH. Certificate of Registration No. 18312) ANSWER AND) NOTICE OF DEFENSE) /
Respondent.	/

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

I OTBJECT ON THE GROWNDS OF THE FACT THAT I WAS NOT THERE ON THE DAY IN QUESTION. MY EXPLANATION is ON THE FOLLOWING PAGE. 2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies

and alleges as follows:

Ms. Angeli Domingo workED AT My STORE FOR I day ON 11-5-2013. We had A call out, so I utilized the name my supervisor, MR. Forbrook, had given during A visit prior than 11-5-13.

I was scheduled OFF on the day in Question. Ms. Domin60's contact INFORMATION was used AND I was unaware she was unlicensed. My understanding OF CUS's policy is that Ms. Domingo's home store IS Responsible FOR MAINTAINING technicians license status in General, AND therefore would not have checked her status until Ms. Domingo ARRIved to work.

As Pharmacy Mgr. FOR Store #5113, I make sure that all techs licenses are verified and my only mistake was not Beinb present the day Ms. Down worked. IF I would have Been Present during her shift, I would have verified her license status im mediately and dismissed her accordinly. I would like to request a Araring For THIS MATTER. IF The Nevada State BOARD would allow, I would also like to request that the hearing take place AFTER July He, 2014 due to a 6 month advanced, planned vacation.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of

Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ ___, 2014.

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NEVADA STATE BOARD OF PHARMACY,) CASE NO. 14-037-PH-S
Petitioner,)
V.) ANSWER AND) NOTICE OF DEFENSE
CVS PHARMACY #5113)
Certificate of Registration No. PH01951)
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Respondent.	_ /

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2014.

Print or Type name

For CVS PHARMACY #5113



NEVADA STATE BOARD OF PHARMACY,)
)
Petitioner,) CASE NO. 13-072-RPH-S
v.) CASE NO. 13-072-PH-S
FOROUZAN LEWIS, R.PH.) NOTICE OF INTENDED ACTION
Certificate of Registration No. 17733,) AND ACCUSATION
CVS PHARMACY #2928)
Certificate of Registration No. PH01674,	ý
- .)
Respondents.	/

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the alleged conduct, Respondent Forouzan Lewis, R.Ph. (Ms. Lewis), Certificate of Registration No. 17733, was a registered pharmacist with the Board, and Respondent CVS Pharmacy #2928 (CVS #2928), Certificate of Registration No. PH01674, was a pharmacy registered with the Board.

II.

In November 2013, Patient JS was discharged from St. Rose Dominican Hospital with written prescriptions for five different medications. One of the prescriptions was for insulin lispro (Humalog®) with instructions to inject five (5) units before meals. The patient tendered the prescriptions to CVS #2928, and picked them up on November 17, 2013. Patient counseling was performed at the time the prescriptions were dispensed.

III.

Later that evening, JS' wife, CS, began to prepare the Humalog® injection to administer to JS. CS noticed that the instructions on the prescription label were to inject fifty (50) units of Humalog® before meals. CS recalled that during her husband's hospitalization, the dose of Humalog® administered by hospital staff was significantly less than fifty units.

IV.

CS attempted to telephonically contact CVS #2928 to verify the dosage, but there was no answer. She then called the nurse's station at St. Rose Dominican Hospital. A nurse verified that the instructions in JS' patient chart were to administer five (5) units of Humalog® three times per day.

V.

CS contacted CVS #2928 the next day and requested verification of the instructions on JS' Humalog® prescription. A male pharmacist confirmed that the instructions on the Humalog® prescription label that was dispensed to JS were incorrect.

VI.

CS asked the pharmacist to replace the Humalog®. The pharmacist indicated that he would call the doctor. CS alleges that she never received further contact from CVS #2928.

VII.

Pharmaceutical technician Darilyn Vertido (Ms. Vertido) initiated the processing of filling JS' prescription for Humalog®. When interviewed by the Board Investigator, Ms. Vertido explained that during data entry into the pharmacy computer system, she misread the information on the prescription and input "INJECT 50 UNITS BEFORE MEALS" instead of the prescribed "inject 5 units before meals."

VIII.

Ms. Lewis was the verifying and dispensing pharmacist for JS' prescriptions. In a written

statement, Ms. Lewis indicated that the Humalog® prescription was handwritten. During verification, she read the prescription as "50 units" instead of "5 units." Ms. Lewis explained that the "U" following the "5" on the written prescription looked like a "0" (zero).

IX.

In the written statement, Ms. Lewis indicated that 50 units "is not an out of range dose." There was no drug utilization review alert on the computer screen regarding the dosage. She therefore completed the verification and dispensed the medication.

FIRST CAUSE OF ACTION

Х.

By filling and dispensing JS' prescription for Humalog® with instructions to inject fifty (50) units before meals, rather than with instructions to inject five 5 units before meals as prescribed, Forouzan Lewis violated Nevada Administrative Code (NAC) 639.945(1)(d) and/or (i), which violations are grounds for action pursuant to Nevada Revised Statute (NRS) 639.210(4), (11) and/or (12), and NRS 639.255.

SECOND CAUSE OF ACTION

XI.

As the owner of the pharmacy in which the foregoing violations, or any one of them, occurred, Respondent CVS Pharmacy #2928 is responsible and therefore subject to discipline pursuant to NAC 639.945(1), (d), (i) and/or (2), which violations are grounds for action pursuant to NRS 639.210(4), (11) and/or (12), and NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent. Signed this <u>19</u> day of June, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary

Nevada State Board of Pharmacy

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

NEVADA STATE BOARD OF PHARMACY,)
Petitioner,)) CASE NO. 13-072-RPH-S
v.) CASE IVO. 13-072-IVI II-5
FOROUZAN LEWIS)) STATEMENT TO THE RESPONDENT
Certificate of Registration No. 17733) NOTICE OF INTENDED ACTION
Respondent.) AND ACCUSATION / RIGHT TO HEARING

TO THE RESPONDENT ABOVE-SAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. It is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada. The hour of the hearing will be set by letter to follow.

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Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless. DATED this <u>19</u> day of June, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary 2.

Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,)	
Petitioner,)	CASE NO. 13-072-RPH-S
rennoner,	Ś	CASE NO. 15-0/2-RI II-5
V.)	
)	
FOROUZAN LEWIS, R.PH.)	ANSWER AND
Certificate of Registration No. 17733)	NOTICE OF DEFENSE
)	
Respondent.	/	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ____ day of June, 2014.

FOROUZAN LEWIS, R.PH.

NEVADA STATE BOARD OF PHARMACY,)
Petitioner,)) CASE NO. 13-072-PH-S
V.)
)
CVS PHARMACY #2928) ANSWER AND
Certificate of Registration No. PH01674) NOTICE OF DEFENSE
5)
Respondent	ĺ

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ____ day of June, 2014.

Print or Type name

Authorized Representative For CVS Pharmacy #2928



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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

KENYA MARIE PEOPLES, PT Certificate of Registration No. PT13478,

Respondent.

CASE NO. 14-040-PT-S

NOTICE OF INTENDED ACTION AND ACCUSATION

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3), and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because Respondent Kenya Marie Peoples (Ms. Peoples), Certificate of Registration No. PT13478, was a registered pharmaceutical technician with the Board at the time of the events alleged herein.

II.

On or about May 16, 2014, Board Staff received notification from CVS Caremark's District Pharmacy Supervisor that CVS terminated Ms. Peoples' employment as a pharmaceutical technician at CVS Pharmacy #2929. CVS terminated Ms. Peoples' employment for diversion of controlled substances.

III.

During an interview conducted by CVS Caremark Loss Prevention personnel, and in a written statement, Ms. Peoples admitted to diverting approximately two-hundred and twenty (220) alprazolam 2 mg. tablets in early May, 2014.

IV.

Ms. Peoples alleges that a family member threatened to harm her and her family if she did not obtain alprazolam for him.

FIRST CAUSE OF ACTION

V.

By diverting controlled substances, namely, two-hundred and twenty (220) alprazolam 2 mg. tablets, Kenya Marie Peoples violated Nevada Revised Statute (NRS) 453.331(1)(d) and/or NRS 453.336(1), and/or Nevada Administrative Code (NAC) 639.945(1)(g) and/or (h), which violations are grounds for action pursuant to NRS 639.210(1), (4), (11), and/or (12), as well as NRS 639.255.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this **13** day of June, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

CASE NO. 14-040-PT-S

v.

KENYA MARIE PEOPLES, PT Certificate of Registration No. PT13478

Respondent.

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. Should you desire a hearing, it is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Board within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada. The hour of the hearing will be set by letter to follow. IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this 13 day of June, 2014.

Larry L. Pingon, Pharm.D., Executive Secretary

Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOA	ARD OF PHARMAC NEVADA STATE BOARD
NEVADA STATE BOARD OF PHARMACY,) CASE NO. 4-040-PT-S
Petitioner,) JUL - 3 2014
v.)
KENYA MARIE PEOPLES, PT) ANSWER AND NOTICE LED
Certificate of Registration No. PT13478) OF DEFENSE
Respondent.)) /

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies

Do not contest - No Contest and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 29 day of June, 2014.

Kenya Pupels, KENYA MARIE PEOPLES, PT

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

RONIQUE DAILEY, PTT Certificate of Registration No. PT15474,

Respondent.

CASE NO. 14-041-PTT-S

NOTICE OF INTENDED ACTION AND ACCUSATION

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3), and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because Respondent Ronique Dailey, PTT (Ms. Dailey), Certificate of Registration No. PT15474, was a registered pharmaceutical technician in training with the Board at the time of the events alleged herein.

II.

On or about May 19, 2014, Board Staff received notification from a Walgreens' Loss Prevention Manager indicating that Walgreens terminated Ms. Dailey from her employment as a pharmaceutical technician in training at Walgreens #5479 (Walgreens). Walgreens terminated Ms. Dailey's employment for diversion of controlled substances.

III.

During an interview conducted by the Walgreens' Loss Prevention Manager, and in a written statement, Ms. Dailey admitted to diverting one-hundred and fifty-seven (157) oxycodone 30 mg. tablets on or about May 10, 2014.

Ms. Dailey alleges that an individual, to whom her uncle owed money, threatened her and her uncle if she did not obtain and provide the oxycodone to him as payment for her uncle's debt.

FIRST CAUSE OF ACTION

V.

By diverting controlled substances, namely, one-hundred and fifty-seven (157) oxycodone 30 mg. tablets, Ronique Dailey violated Nevada Revised Statute (NRS) 453.331(1)(d) and/or NRS 453.336(1), and/or Nevada Administrative Code (NAC) 639.945(1)(g) and/or (h), which violations are grounds for action pursuant to NRS 639.210(1), (4), (11), and/or (12), as well as NRS 639.255.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this <u>1</u>⁹ day of June, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

CASE NO. 14-041-PTT-S

v.

RONIQUE DAILEY, PTT Certificate of Registration No. PT15474

Respondent.

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. Should you desire a hearing, it is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Board within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, July 23, 2014, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada. The hour of the hearing will be set by letter to follow. IV.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this <u>19</u> day of June, 2014.

PL

Larry L. Pirson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,) CASE NO. 14-041-PTT-S
)
Petitioner,)
V.)
)
RONIQUE DAILEY, PTT) ANSWER AND NOTICE
Certificate of Registration No. PT15474) OF DEFENSE
)
Respondent.)
	/

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of ______, 2014.

RONIQUE DAILEY, PTT



NEVADA STATE BOARD OF PHARMACY,)
Petitioner, v.)) CASE NO. 14-027-RPH-O)
CHARLES A. WALKER, RPH Certificate of Registration No. 07397	 NOTICE OF INTENDED ACTION AND ACCUSATION
Respondent.) /

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because Charles A. Walker, Certificate of Registration No. 07397 (Mr. Walker), is a pharmacist licensed by the Board.

II.

On or about November 5, 2013, the Board Office received a renewal application for Respondent Walker's pharmacist license. Mr. Walker disclosed on the application that he has been the subject of a board citation or an administrative action in California, and the subject of discipline for violation of pharmacy or drug laws since the last renewal period.

III.

Mr. Walker was disciplined in California after he admitted to smoking Marijuana for several months between June 2008 and February 2010.

IV.

The California Board revoked Mr. Walker's pharmacist license effective June 22, 2012; however, the revocation was stayed. Mr. Walker's license was placed on probation for a period of three years with terms and conditions.

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FIRST CAUSE OF ACTION

V.

In receiving discipline against his license in California for actions that would be grounds for discipline, suspension or revocation of his license in Nevada, respondent Mr. Walker is subject to discipline to parallel the California action pursuant to Nevada Revised Statute (NRS) 639.210(14) and/or NRS 639.255. The unlawful use of marijuana is grounds for discipline of Mr. Walker's Nevada license pursuant to NRS 453.336(1), which is grounds for action pursuant to NRS 639.210(1), (4), (11), and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license of Respondent Mr. Walker.

Signed this 7th day of May, 2014.

Lary L. Pinson, Pharm.D., Executive Secretary

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

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NEVADA STATE BOARD OF PHARMACY,

v.

CHARLES A. WALKER, RPH Certificate of Registration No. 07397

Respondent.

Petitioner,

CASE NO. 14-027-RPH-O

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. Should you desire a hearing, it is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Board within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, June 11, 2014, as the date for a hearing on this matter at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada. The hour of the hearing will be set by letter to follow.

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this ² day of May, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

CASE NO. 14-027-RPH-O

v.

CHARLES A. WALKER, RPH Certificate of Registration No. 07397

Respondent.

ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ____ day of May, 2014.

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CHARLES A. WALKER, RPH.



NEVADA STATE BOARD OF PHARMACY,)
Petitioner,)) CASE NO. 14-021-RPH-O
v.)
BRIAN EARL CHAMBERS, RPH Certificate of Registration No. 10906	 NOTICE OF INTENDED ACTION AND ACCUSATION
Respondent.) /

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because Brian Earl Chambers, Certificate of Registration No. 10906 (Mr. Chambers), is a pharmacist licensed by the Board.

II.

On or about October 21, 2013, the Board Office received a renewal application for Respondent Chambers' pharmacist license. Mr. Chambers disclosed on his application that he has been the subject of a board citation or an administrative action in Idaho, and the subject of discipline and criminal action for violation of pharmacy or drug laws since the last renewal period.

III.

On May 31, 2012, the Idaho State Board of Pharmacy (Idaho Board) adopted a Stipulation and Consent Order (Case No. BOP 12-016) regarding Mr. Chambers. In the Stipulation and Consent Order, Mr. Chambers admitted to the charge that he diverted controlled substances from his employer. The Idaho Board placed conditions on Mr. Chambers' continued licensure including terms and conditions for five (5) years or until his successful completion of the PRN Program.

V.

In November 2012, Mr. Chambers pled guilty and was convicted in the District Court of the State of Idaho, in and for the County of Ada (Case CR-FE-2012-0010447), on two counts of Fraud by Computer and one count of Petit Theft for the diversion of controlled substances and adjusting inventory counts in a pharmacy computer. Mr. Chambers was sentenced to five years of supervised probation.

FIRST CAUSE OF ACTION

VI.

By stipulating to the facts and penalties set forth in the Stipulation and Order in Idaho Case No. BOP 12-016 regarding the diversion of controlled substances, and receiving discipline for the same, respondent Mr. Chambers is subject to discipline pursuant to Nevada Revised Statute (NRS) 639.210(1), (4), (6), (7), and (11) and/or NRS 639.255.

SECOND CAUSE OF ACTION

VII.

By being convicted of fraud by computer in Idaho Case No. CF-FE-2012-00010447, respondent Mr. Chambers is subject to discipline pursuant to NRS 639.210(1), (4), (6), (7), and (11) and/or NRS 639.255 and Nevada Administrative Code (NAC) 639.945(1)(g), and (h) and NRS 453.331(d).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license of respondent Mr. Chambers.

Signed this <u>7</u> day of May, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

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NEVADA STATE BOARD OF PHARMACY,

v.

BRIAN EARL CHAMBERS, RPH Certificate of Registration No. 10906

Respondent.

Petitioner,

CASE NO. 14-021-RPH-O

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, Larry L. Pinson, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. Should you desire a hearing, it is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Board within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

III.

The Board has reserved Wednesday, June 11, 2014, as the date for a hearing on this matter at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada. The hour of the hearing will be set by letter to follow.

-1-

Failure to complete and file your Notice of Defense with the Board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the Board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this <u>7</u> day of May, 2014.

Larry L. Pinson, Pharm.D., Executive Secretary Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,)	
Petitioner,))	CASE NO. 14-021-RPH-O
V.)	
BRIAN EARL CHAMBERS, RPH Certificate of Registration No. 10906)))	ANSWER AND NOTICE OF DEFENSE
Respondent.) /	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

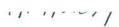
2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ____ day of May, 2014.

BRIAN EARL CHAMBERS, R.PH.

Blank



To whom it may concern,

My name is Cynthia L. Butler (Blake),

_, I am hereby requesting a hearing to re-acquire my

pharmacy technician license.

ulles

Cynthia L. Butler



Board Action:

<u>Motion:</u> Joe Kellogg moved, based on evidence presented, to find Mr. Cronshaw guilty of the alleged violations.

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Second:	Bob Wood		
Action:	Passed Unanimously		
Motion:	Joe Kellogg moved to revoke Mr. Cronshaw's pharmaceutical technician registration.		
Second:	Bob Wood		
Action:	Passed With One Negative Vote		
F.	Cynthia Blake, PT	(03-027-PT-S)	

It was noted that Ms. Blake was not present for hearing.

Geri Raj, managing pharmacist for K-Mart #3592, appeared and was sworn by President Pinson prior to answering questions or offering testimony.

Mr. Ling questioned Ms. Raj regarding the circumstances of this matter. Ms. Raj testified that she received a telephone call from a physician asking who at that pharmacy was filling prescriptions for one of his patients without his authorization. Ms. Raj stated that she determined Ms. Blake had filled the prescriptions and questioned her. Ms. Raj was unable to find hard copies. It was found that the patient had her prescription filled by Ms. Blake and had taken the same prescription to another pharmacy and had it filled second time using the same prescription. Ms. Raj made a report to the district pharmacy manager. Ms. Raj again checked with the physician in this matter and asked him to please check with this medical staff to ensure that no one in his office had approved any refills for his patient. The physician found that no one from his office had authorized refills for his patient and signed a statement to that effect. This patient paid cash for her prescriptions.

Mr. Ling determined that he had proven the First Cause of Action. The Second Cause of Action, repeated negligence, was charged because of Ms. Blake's failure to renew her license and worked unlicensed for nine months.

Board Action:

Motion: Ray Seidlinger moved, based on evidence presented, to find Ms. Blake guilty of the alleged violations.

Second:	Marcie Ranick		
Action:	Passed With One Negative Vote		
Motion:	Ray Seidlinger moved to revoke Ms. Blake's pharmaceutical technician registration.		
Second:	Bob Wood		
Action:	Passed With One Negative Vote		
G.	Andres M. Estrada Jr, PT	(03-050-PT-S)	

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F.

Andres Estrada appeared and was sworn by President Pinson prior to answering questions or offering testimony.

NOTE: Marcie Ranick recused from participation in this case as she is employed by Walgreens.

Mr. Ling had no opening statement and commended Mr. Estrada for his honesty with his Answer and Notice of Defense.

Mr. Estrada testified that he had gone to a concert and made a poor choice by using marijuana. He has gone to PRN-PRN and is in the process of signing a contract. Mr. Estrada plead for his license and gave various places where he regularly volunteers his time in the pursuit to help others.

Mr. Ling recommended the standard PRN-PRN contract and Order.

Larry Espadero testified that Mr. Estrada had contacted him and that he will do Mr. Estrada's evaluation next week.

Board Action:

Motion:	Joe Kellogg moved, based on evidence presented, to find Mr. Estada guilty of the alleged violations.
Second:	Bob Wood
Action:	Passed Unanimously
Motion:	Joe Kellogg moved to remand Mr. Estrada to the standard PRN-PRN Order.
Second:	Bob Wood

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

ORDER DENYING REQUEST FOR REINSTATEMENT

CYNTHIA BLAKE, P.T., Certificate of Registration #PT00182

Case No. 03-027-PT-S

Respondent.

This matter was originally heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on October 15, 2003 in Reno, Nevada. The Board was represented by Louis Ling, General Counsel, and Ms. Blake did not appear and represent herself. On November 13, 2003, the Board issued Findings of Fact, Conclusions of Law, and Order. The Board's Order revoked Ms. Blake' pharmaceutical technician registration and banned her from employment in any business registered by the Board in any capacity until she had been reinstated by the Board and that she return her registration certificate within 10 days of her receipt of the Order and her failure to do so results in a fine of \$1,000 per day until the registration certificate is received by the Board office.

On January 24, 2012, Ms. Blake sent an email requesting an appearance before the Board seeking reinstatement of her pharmaceutical technician registration. On April 2, 2012, a notice of appearance was sent to Ms. Blake's last known address scheduling her appearance before the Board on April 19, 2012 at 10:30 a.m. Ms. Blake did not appear for her hearing as scheduled. As it is Ms. Blake's to burden to prove to the Board that is in the public's interest to reinstate her registration and she did not appear,

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the Board declined to reinstate Ms. Blake's pharmaceutical technician registration PT 00182.

Signed and effective this $\frac{154}{15}$ day of May, 2012.

Beth Foster, President Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

CYNTHIA BLAKE, P.T., Certificate of Registration #PT00182,

ν.

Case No. 03-027-PT-S

Respondent.

THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on October 15, 2003 in Reno, Nevada. The Board was represented by Louis Ling, General Counsel to the Board. Respondent Cynthia Blake did not appear at the hearing. Based on the presentation of the General Counsel and the public records in the possession and control of the Board, the Board issues the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. Board staff demonstrated that Ms. Blake had been properly served with the Notice of Intended Action and Accusation in this matter and that she had responded to Board staff after receiving it. No explanation was tendered for Ms. Blake's absence, nor did she request a continuation of the matter. Board staff presented the testimony of Geri Raj, managing pharmacist for Kmart #3592. Based upon the testimony of Ms. Raj and the presentation by the General Counsel, the Board finds the following to be the facts of this matter.

2. On March 28, 2003, Board staff received a notice that Ms. Blake had been terminated from her employment as a pharmaceutical technician from Kmart #3592.

3. Ms. Raj testified regarding the basis for Ms. Blake's termination was that on February 18, 2003, Dr. Nader Abelsayed had contacted the managing pharmacist for Kmart #3592 to inquire from whom his patient, MB, was getting prescriptions for Lortab. Ms. Raj checked the pharmacy's computer and found that MB's prescription had been filled five times between December 2002 and February 2003. Dr. Abelsayed had indicated his concern because neither he nor any member of his staff had approved refills of Patient MB's Lortab prescriptions. When Dr. Abelsayed asked Mr. Raj to pull the hard copy of the prescription, Ms. Raj was unable to located any hard copy of the prescription.

4. As a result of her call with Dr. Abelsayed, Ms. Raj spoke with Ms. Blake regarding MB's Lortab prescriptions. Ms. Blake admitted to Ms. Raj that she, Ms. Blake, had filled one of MB's prescriptions on February 13, 2003 without having the hard copy based upon MB's representation that she would bring the hard copy with her when she picked up the prescription. MB did not bring the prescription with her, so no hard copy was ever received for that prescription and placed into the pharmacy's records. Ms. Blake dispensed the prescription to MB without ringing the transaction through the pharmacy's cash register. Ms. Raj detailed her efforts to work with Ms. Blake to find the missing prescriptions and to otherwise resolve the concerns raised by Dr. Abelsayed, but ultimately Ms. Raj was unable to resolve the pharmacy's records show that Ms. Blake was responsible for the orders for which no written order could be located and which Dr. Abelsayed disavowed.

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CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter because Ms. Blake is a pharmaceutical technician registered by the Board.

2. In creating five false and fraudulent prescriptions for controlled substances for MB without authorization of MB's physician, Ms. Blake violated NRS 453.321(1), 453.331(1)(f), and 639.210(4) and (12) and NAC 639.945(1)(g), (h), and (i).

3. In being repeatedly negligent as evidenced by the prior disciplinary action against Ms. Blake, Ms. Blake violated NRS 639.210(4) and (16) and NAC 639.945(1)(d).

ORDER

Based upon the foregoing, the Board hereby orders the following:

1. Ms. Blake's pharmaceutical technician's registration (#PT00182) is revoked.

Ms. Blake may not be employed in any business or facility licensed by this Board in any capacity unless and until her registration as a pharmaceutical technician has been reinstated.

2. Ms. Blake shall return to the Board's Reno office her wallet card within 10 days of her receipt of this Order. Her failure to do so will result in a fine of \$1,000 per day until the wallet card is received by the Board office.

Signed and effective this 13th day of November, 2003.

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Larry L. Pinson, President Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY 431 W Plumb Lane ≈ Reno, NV 89509 ≈ 775/850-1440

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PHARMACEUTICAL TECHNICIAN APPLICATION

Registration Fee: <u>\$40.00</u> - (non-refundable money order or cashier's check only, no cash)

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ROB THOMAS

March 28, 2013 Nevada State Board of Pharmacy 431 Plumb Lane, Reno, NV 89509

Dear State Board,

I had received my license in 1999 in Nevada when I was 19 after completing the 500 hours as a tech in training where I was then promoted to work in Minneapolis Mn. I scored 2nd highest in nationwide exam for pharm techs in the same year. In 2003 I was convicted in federal court of conspiracy to distribute methamphetamine and MDMA in which I served 5 years and 6 months, I went through a 9 month drug rehabilitation program and successfully completed, it I was released in 2007 and completed 1 year of aftercare at Bridge Counseling in Las Vegas, and again completed the program with accolades. Then unfortunately Dec 29 of 2008 I was stopped and charged with a DUI in which I completed all classes and requirements that satified the courts. I am unable to find all the necessary documentation pertaining to the cases because the time that has passed, but if they are necessary I will see what other means I have in findig the information. I have worked very hard to work past my past record and last year graduated from College of Southern Nevada with an Associate in Science in the field of Medical Laboratory Technician and am working towards my Bachelor as well. I also was certified as a personal fitness trainer and continually try to better myself and learn new subjects. I now have an opportunity to get back into the pharmacy which is a job I loved and am asking if I have the support of the Board to apply. I can and would accept any conditions that may be placed on me if necessary because I have no qualms about proving myself and my abilities. I'm applying also for the limited entry program to continue with my BS degree and they require working in the health fields as extra weight towards acceptance of my application. So I ask that you would please accept my application to get back into the field so I again can continue to learn as much as possible and use the skills I've been granted to succeed. Also, when I was in the pharmacy I scored second highest for pharmacy technicians and the only one to get higher was a pharmacy student, that was when I was 19, so allowing me back into the field is beneficial to me and the field. Thank you for your time and I hope I have proven that I am more then the mistakes of my young adult life.

Sincerely yours,

Rob Thomas

PT02499

July 2013 Board Meeting

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12. Application for Pharmaceutical Technician Registration – Appearance

Robert C. Thomas

Robert Thomas appeared and was sworn by President Gandhi prior to answering questions or offering testimony.

Mr. Thomas explained that in 2003, he was convicted in federal court for conspiracy to distribute methamphetamine and Ecstasy. He served five years and six months in prison. Mr. Thomas said that he was living in a drug dealer's house, and he was also using methamphetamine. Until the trial, he was not aware of the extent of the illegal activities which had taken place in the house where he was living. Mr. Thomas successfully completed a nine month drug rehabilitation program while in prison. He was released from prison in 2007, and completed one year of aftercare at Bridge Counseling. On New Year's Eve 2008, he was charged with a DUI. Mr. Thomas said that he has a strong family support system and is committed to his sobriety.

The Board expressed concern that Mr. Thomas had a commitment to control his addiction then relapsed one year following his release from prison. He currently is not participating in a support program.

Board Action:

<u>Motion:</u> Cheryl Blomstrom moved to table Robert Thomas' Pharmaceutical Technician Application pending an evaluation by PRN-PRN. Mr. Thomas will be required to appear with Mr. Espadero at a future Board meeting with the results of the PRN evaluation

Second: Jack Dalton

Action: Passed Unanimously

Blank

NEVADA STATE BOARD OF PHARMACY 431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

APPLICATION BY RECIPROCATION AS A PHARMACIST

If you are requesting licensure by reciprocation (i.e.you have a current pharmacist license from another state and wish to transfer license information and only need to take the Nevada MPJE), complete this application:

Total Fee: \$330.00 (non-refundable, money order or cashier's check only. no cash)

Money Order or Cashier's Check made payable to: Nevada State Board of Pharmacy

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Mailing Address: <u>A2SS</u> City: <u>Colorado SPC1</u>	9.5	State:)	Zip Code:	80919
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Graduation Date: (109/1/	6				
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Laws	MPJE		-		

Page 1 of 2

Other states where you a	are (or were) licensed as a pl	harmacist or print '	'none"
State Lic #	Is the license active? Stat	te Lic#	Is the license active?
-NV 030310)_Yes 🕁 No 🗖		Yes 🗆 No 🗖
C10 15014	Yes		Yes 🗆 No 🗖
**Attach separate sheet i	if needed		
			Yes No
abuse, or physical conditionfunctions of your license?.1. Been charged, arrested2. Been the subject of an3. Had your license subject	d for any mental illness, includin on that would impair your ability d or convicted of a felony or mis administrative action whether c cted to any discipline for violation of the numbered questions (1-	to perform the esse demeanor in <u>any</u> st completed or pendin on of pharmacy or d	ntial
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Action:	2) 41 1200)		
	Date: Case #:	County	Court
Action: /	1		
	FEDERALLY MANDAT		<u>ITS</u>
In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this questions as part of all applications. 4. Are you the subject of a court order for the support of a child?Yes □ Nod <u>4a. If you marked Yes, to the question 4,</u> are you in compliance with the court order?Yes □ No □			
application are true, accurate and corr concerning the prevention of transmiss Pharmacy, it's agents, servants and er reputation, as it may deem necessary,	rect. I attest to knowledge of and compliance sion of infectious agents through safe and ap mployees, to conduct any investigation(s) of r , proper or desirable.	with the guidelines of the Ce opropriate injection practices. my business, professional, s	I HEIEDY AUTIONZE THE NEVADA STATE DOUTS OF

authorization.

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4/24/11 Date

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Original Signature, no copies or stamps accepted

Date

Page 2 of 2

e-ProfileID: C Process Date: 2/11/14 DCN: 550000080750922 Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph M Rothkopf Reporting Entity: Colorado State Board of Pharmacy

 Transaction Type: Initial Report
 Date of Action: 04/02/2001

 Action
 Basis for Action

 - 1145 - Voluntary Surrender of License
 - 19 - Criminal Conviction

A. REPORTING ENTITY	Entity Name: Address: City, State, Zip:	Colorado State Board of Pharmacy 1560 Broadway, Suite 1310 Denver, CO 80202-5146
	Country: Name of Certifier: Title or Department:	US
	Telephone: Type of Report: Related Report Number:	Initial
B. SUBJECT IDENTIFICATION INFORMATION	Subject Name: e-Profile ID: Other Name(s) Used:	Joseph M Rothkopf
INFORMATION	Gender: Date of Birth:	Male
	Work Address: City, State, ZIP: Deceased:	ხ255 Ursa Ln Colorado Springs, CO 80919 NO
	Federal Employer Identification Numbers (FEIN):	
	Social Security Numbers (SSN): Individual Taxpayer Identification Number (ITIN):	
	National Provider Identifiers (NPI): Professional School & Year of Graduation: Occupation/Field of Licensure (Code):	St John's University - NY (1976) Pharmacist
	State License Number, State of Licensure:	PHA-15014 , CO

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

1600 Feehanville Drive, Mt. Prospect, IL 60056 847/391-4400 ~ clearinghouse@nabp.net

e-ProfileID: Process Date: 2/11/14 DCN: 550000080750922 Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

No

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

C. INCIDENT REPORTED

Type of Adverse Action: Basis for Action: Reporting Entity: Action Classification Code(s): Date Action Was Taken: Date Action Became Effective: Length of Action: Monetary Penalty: Auto Reinstate?: Description:

Initial - 19 - Criminal Conviction CO - 1145 - Voluntary Surrender of License 04/02/2001 04/02/2001 Permanent

Pharmacist permanently surrenders his Colorado pharmacist license as part of the disposition of his criminal case. He is charged with four felony charges in Case 00 CR 799 in Grand Junction, Colorado: two counts of Obtaining a Schedule IV Controlled Substance by Fraud and Deceit and two counts of Distribution of a Schedule IV Controlled Substance.

STATE OF COLORADO

Case No. RG PH

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER REGARDING THE LICENSE TO PRACTICE PHARMACY IN THE STATE OF COLORADO OF JOSEPH M. ROTHKOPF, R.Ph., LICENSE NO. 15014,

Respondent.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Joseph M. Rothkopf, R.Ph. ("Respondent") to resolve case number P-20-067 by allowing Respondent to permanently relinquish his license to practice pharmacy.

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over the person of Respondent, his license to practice pharmacy and the subject matter of this stipulation pursuant to the provisions of title 12, article 22, C.R.S. (2000), otherwise known as the Drugs and Druggists Act.

2. Respondent has been licensed to practice as a pharmacist in the State of Colorado at all times relevant to this agreement.

3. Respondent's address on record with the Board is: 1049 Belford Ave., Grand Junction, CO 81501.

4. Respondent hereby admits and waives any further proof in this or any other proceeding before or initiated by the Board that the following facts are true.

5. Respondent is currently charged with four felony charges relating to his practice of pharmacy. Case 00 CR 799 in Grand Junction, Colorado contains two counts of Obtaining a Schedule IV Controlled Substance by Fraud and Deceit, § 18-18-415, C.R.S., and two counts of Distribution of a Schedule IV Controlled Substance, § 18-18-405, C.R.S.

6. While employed at City Market Pharmacy located at 425 Patterson Rd. in Grand Junction, Colorado, Respondent dispensed 100 Xanax 0.5 mg tablets on two occasions without authorization or a prescription order. These actions gave rise to Case 00 CR 799.

7. Respondent has indicated his desire to resolve this case in conjunction with the criminal case pending against him. Respondent wishes to permanently relinquish his license to practice pharmacy as part of the disposition of the criminal case.

8. The Board finds and concludes, and Respondent agrees, that based upon Respondent's request, the following outcome is just and appropriate under the circumstances.

DISPOSITION

Voluntary Surrender and Permanent Relinquishment of License

8. <u>Voluntary Relinquishment</u>. Respondent consents to the Board's entry of an order whereby his license to practice pharmacy shall be relinquished and canceled. Upon the effective date of this Stipulation and Final Agency Order, Respondent shall promptly surrender to the Board all indicia of his Colorado licensure. Respondent agrees that he will not, at any time, reapply for licensure in this state.

9. <u>Advisements and Waivers</u>. Respondent enters into this Stipulation and Final Agency Order freely and voluntarily, after the opportunity to consult with legal counsel of his own choosing.

10. <u>Acknowledgments</u>. Respondent has read this Stipulation and Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel, that he understands its legal consequences and he agrees that none of its terms or conditions are unconscionable.

11. <u>Integration and Severability</u>. Upon execution by all parties, this Stipulation and Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Stipulation and Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Stipulation and Final Agency Order shall be given full force and effect.

12. <u>Public Record</u>. Upon execution by all parties, this Stipulation and Final Agency Order shall be a public record, maintained in the custody of the Board.

2

ACCEPTED AND AGREED BY Respondent

Dated: 3/24/01

Joseph M. Rothkopf, R.Ph., # 15014 1049 Belford Ave. Grand Junction, CO 81501

Subscribed and sworn to	before me in the County of	, State of
Colorado, this <u>16</u> day of	March, 2001, by Joseph M. R.	othkopf, R.Ph.
	Dud Marie	241
	NOTARY PUBLIC	1
My Commission expires:	CARY PUBL	V
9-20-03	DAVID E.	8
	AND CECOLORING	

FINAL AGENCY CRUER

WHEREFORE, after motion and vote, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an order of the Board.

DONE AND EFFECTIVE this 2 W day of Arri , 2001.

State Board of Pharmacy

MARIN BY: / ram administrator Title:

DOCUMENT APPROVED AS TO FORM:

Stephen L. Laiche, #16427 Foster, Larson, Laiche & Giff KEN SALAZAR Attorney General

HEAN WOODFORD WALTERS, #24834*

Assistant Attorney General Regulatory Law Section

Attorneys for State Board of Pharmacy

422 White Ave., Suite 323 Grand Junction, CO 81501 Telephone (970) 245-8021 FAX: (970) 24500590

Attorney for Respondent

1525 Sherman Street, 5th Floor Denver, Colorado 80203 Telephone: (303) 866-5158 FAX: (303) 866-5395 *Counsel of Record

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Name: Joseph M Rothkopf e-ProfileID: Process Date: 2/11/14 DCN: Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph M Rothkopf Reporting Entity: New York Board of Pharmacy

 Action
 Basis for Action

 - 1135 - Suspension of License
 - 19 - Criminal Conviction

A. REPORTING ENTITY	Entity Name: Address: City, State, Zip:	New York Board of Pharmacy Cultural Education Center, Room 3035 Albany, NY 12230
	Country: Name of Certifier: Title or Department: Telephone:	US
	Type of Report: Related Report Number:	Initial
B. SUBJECT DENTIFICATION INFORMATION	Subject Name: e-Profile ID: Other Name(s) Used:	Joseph M Rothkopf
	Gender: Date of Birth:	Male
	Work Address: City, State, ZIP: Deceased:	6255 Ursa Ln Colorado Springs, CO 80919 NO
	Federal Employer Identification Numbers (FEIN): Social Security Numbers (SSN):	
	Individual Taxpayer Identification Number (ITIN): National Provider Identifiers (NPI):	
	Professional School & Year of Graduation: Occupation/Field of Licensure (Code): State License Number, State of Licensure:	St John's University - NY (1976) Pharmacist 030310 , NY

Name: Joseph M Rothkopt e-ProfileID Process Date: 2/11/14 DCN: Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

	1.92-1
Type of Adverse Action: Basis for Action:	Initial - 19 - Criminal Conviction
Reporting Entity: Action Classification Code(s):	NY - 1135 - Suspension of License
Date Action Was Taken:	02/06/1986
Date Action Became Effective:	03/24/1986
Length of Action:	3 Years, 0 Months, 0 Days
Monetary Penalty:	\$ 2500
Auto Reinstate?: Description:	No Order #4096 Basis - Criminal Conviction for Criminal Sale of a Controlled Substance in the 5th Degree, a class D felony Additional Basis - numerous violations of New York recordkeeping requirements for Controlled Substances Action - New York license is suspended for 3 years, last 2 years of suspension are stayed and license placed on probation with terms and conditions for 2 years. \$2500.00 fine levied.
	Reporting Entity: Action Classification Code(s): Date Action Was Taken: Date Action Became Effective: Length of Action: Monetary Penalty: Auto Reinstate?:



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IN THE MATTER

OF

JOSEPH ROTHKOPF (Pharmacist) ORIGINAL ORDER NO. 4096

Upon the application of JOSEPH ROTHKOPF, under Calendar No. 4096, and the vote of the Board of Regents on December 13, 1985, which application and vote are incorporated herein and made a part hereof, it is

JOSEPH ROTHKOPF, of ORDERED that the application respondent, for a consent order be granted; that respondent's license and registration to practice as a pharmacist in the State of New York be suspended for three years; that execution of the last two years of said suspension be stayed at which time respondent then be placed on probation for a period of two years under the terms set forth in the exhibit annexed hereto, made a part hereof, and marked as Exhibit "A"; and that respondent be fined \$2,500, said fine to be made payable, by certified check, to the order of the New York State Education Department, and mailed to the Executive Director, Office of Professional Discipline, New York State Education Department, 622 Third Avenue, New York, New York 10017-6756 within 30 days after the effective date of the service of this order.



IN WITNESS WHEREOF, I, Gordon M. Ambach, Commissioner of Education of the State of New York, for and on behalf of the State Education Department and the Board of Regents, do hereunto set my hand and affix the seal of the State Education Department, at the City of Albany, this (Hay of Juluary, 1986.

Vier State

Commissioner of Education

Approved December 13, 1985

No. 4096

Upon the application of JOSEPH ROTHKOPF, under Calendar No. 4096, and in accordance with the provisions of Title VIII of the Education Law, it was

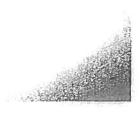
<u>Voted</u>: That the application of JOSEPH ROTHKOPF, respondent, for a consent order be granted; that respondent's license and registration to practice as a pharmacist in the State of New York be suspended for three years; that execution of the last two years of said suspension be stayed at which time respondent then be placed on probation for a period of two years under the terms set forth in the application; that respondent be fined \$2,500, said fine to be made payable, by certified check, to the order of the New York State Education Department, and mailed to the Executive Director, Office of Professional Discipline, New York State Education Department, 622 Third Avenue, New York, New York 10017-6756 within 30 days after the effective date of the service of the order of the Commissioner of Education be empowered to execute, for and on behalf of the Board of Regents, all orders necessary to carry out the terms of this vote.

EXHIBIT A

TERMS OF PROBATION

JOSEPH ROTHKOPF

- That respondent, during the period of probation, shall conduct himself in all ways in a manner befitting his professional status, and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession;
- 2. That respondent shall submit written notification to the New York State Education Department, addressed to the Executive Director, Office of Professional Discipline, New York State Education Department, 622 Third Avenue, New York, NY 10017-6756, of any employment and practice, of respondent's residence and telephone number, of any change in respondent's employment, practice, residence, or telephone number within or without the State of New York;
- 3. That respondent shall submit written proof from the Division of Professional Licensing Services (DPLS), New York State Education Department (NYSED), that respondent has paid all registration fees due and owing to the NYSED and respondent shall cooperate with and submit whatever papers are requested by DPLS in regard to said registration fees, said proof from DPLS to be submitted by respondent to the NYSED, addressed to the Executive Director, Office of Professional Discipline, as aforesaid, no later than the first three months of the period of probation;
- 4. That respondent shall submit written proof to the NYSED, addressed to the Executive Director, Office of Professional Discipline, as aforesaid, that 1) respondent is currently registered with the NYSED, unless respondent submits written proof that respondent has advised DPLS, NYSED, that respondent is not engaging in the practice of respondent's profession in the State of New York and does not desire to register, and that 2) respondent has paid any fines which may have previously been imposed upon respondent by the Board of Regents; said proof of the above to be submitted no later than the first two months of the period of probation;
- 5. That so long as the stay of execution is in effect, respondent may continue to practice respondent's aforementioned profession in accordance with the terms of probation; provided, however, that upon receipt of evidence of noncompliance with or any other violation of any of the aforementioned terms of probation, the New York State Education Department may initiate a violation of probation proceeding and/or such other proceedings pursuant to the Education Law and the Rules of the Board of Regents.



NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY

IN THE MATTER

of the

Application for the revocation of the authorization and license heretofore granted to APPLICATION FOR CONSENT ORDER

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JOSEPH ROTHKOPF

to practice as a pharmacist in the State of New York, for the cancellation of his registration as such, and for such other relief as the premises warrant.

STATE OF NEW YORK) SS: COUNTY OF)

JOSEPH ROTHKOPF, being duly sworn, deposes and says:

That on or about September 17, 1976 I was licensed to practice as a pharmacist in the State of New York, having been issued license No. 030310 by the New York State Education Department.

I am currently registered with the New York State Education Department to practice as a pharmacist in the State of New York from an address at 4 Sagamore Lane, Dix Hills, New York 11746.

JOSEPH ROTHKOPF

That I have been charged with two specifications of professional misconduct, a copy of which is annexed hereto, made a part hereof, and marked as Exhibit "A".

I admit guilt to the aforesaid two specifications of professional misconduct.

I hereby agree to the penalty that my license to practice as a pharmacist in the State of New York be suspended for a period of three years, that execution of the last two years of said suspension be stayed at which time I then be placed on probation for the two years under the terms set forth in the exhibit annexed hereto, made a part hereof, and marked as Exhibit "B", and that I be fined \$2,500.00, said fine to be made payable by certified check, to the New York State Education Department, 622 Third Avenue, New York, New York 10017-6756 within 30 days after the effective date of the service of the order of the Commissioner of Education to be issued in this matter.

I hereby make this application to the Board of Regents and request that it be granted.

JOSEPH ROTHKOPF

I understand that, in the event this application is not granted by the Board of Regents, nothing contained herein shall be binding upon me or construed to be an admission of any act of misconduct alleged or charged against me, such application shall not be used against me in any way and shall be kept in strict confidence during the pendency of the disciplinary proceeding, and such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

I agree that, in the event the Board of Regents grants my application, as set forth herein, an order of the Commissioner of Education may be issued in accordance with the same.

No promises of any kind were made to me. I am making this application of my own free will and accord and not under duress, compulsion, or restraint of any kind or manner.

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Joseph Lotthone Responden

Sworn to before me this 304 day of O John 1985 NOTARY PUBLIC JEROME SAGER NOTARY PUBLIC, State of New York No. 41-4514908 Quelified in Queens County Commission Expires March 30, 1975 NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY

IN THE MATTER

of the

Application for the revocation of the authorization and license heretofore granted to

JOSEPH ROTHKOPF

to practice pharmacy in the State of New York, for the cancellation of his registration as such, and for such other and further relief as the premises warrant.

TO: THE REGENTS REVIEW COMMITTEE

THE NEW YORK STATE EDUCATION DEPARTMENT BY ITS DIVISION OF PROSECUTION OF THE OFFICE OF PROFESSIONAL DISCIPLINE ALLEGES AS FOLLOWS:

STATEMENT

OF

____X

CHARGES

FIRST: JOSEPH ROTHKOPF, hereinafter referred to as the respondent, was authorized to practice pharmacy in the State of New York by issuance to him of license No. 030310 on September 17, 1976 by the New York State Education Department.

SECOND: Respondent is currently registered from an address at: 4 Sagamore Lane, Dix Hills, New York 11746.

SPECIFICATION OF PROFESSIONAL MISCONDUCT

THIRD: Respondent herein is charged with having been convicted of committing an act constituting a crime within the

- EXHIBIT "A"

purview and meaning of Section 6509(5)(a)(i) of the Education Law of the State of New York, in that:

On February 2, 1983, respondent was charged in the Superior Court, Nassau County, New York with three counts of Criminal Sale of a Controlled Substance in the Fifth Degree, a class D felony. The Information alleged that the respondent sold Placidyl, a Schedule IV controlled drug on three separate occasions.

On February 10, 1980, respondent pled guilty to Attempted Criminal Possession of a Controlled Substance, in the Seventh Degree, a class B misdemeanor in satisfaction of the information.

On March 25, 1980 the respondent was sentenced to one year probation and payment of a \$500 fine or thirty days in prison.

SECOND SPECIFICATION OF PROFESSIONAL MISCONDUCT

FOURTH: Respondent herein is charged with having been found to be in violation of the applicable provisions of Title VII of Article 33 of the New York State Public Health Law by Commissioner of Health within the purview and meaning of Section 6509(5)(c) of the Education Law of the State of New York, in that:

On June 24, 1983 the respondent was charged by the Department of Health with the following violations:

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1. Respondent, in violation of Section 3304 of

the Public Health Law, unlawfully dispensed controlled substances on numerous occasions between May 26, 1981 and January 19, 1983, in Great Neck, New York.

Respondent, in violation of subdivision one 2. of Section 3333 of the Public Health Law, and of Section 80.73(a) of Part 80 of the Administrative Regulations of the Health Department, Rules and controlled Schedule II dispensed unlawfully substances on prescriptions which were not written on official New York State prescription forms. On four occasions, the Respondent unlawfully dispensed the Schedule II substances Nembutal and Percodan on written prescription forms.

Respondent, in violation of subdivision 3. three of Section 3336 of the Public Health Law, and of Section 80.74(c) of Part 80 of the Administrative Regulations of the Health Department, Rules and failed to endorse the signature of the pharmacist filling a written prescription and to record the date user. On fifteen ultimate of delivery to the occasions between October 19, 1981 and January 19, 1983, the Respondent dispensed controlled substances dispensing the on date of without noting the

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prescription forms. On twenty-nine occasions during the same period, the Respondent failed to affix the signature of the dispensing pharmacist to the written prescription.

Respondent, in violation of subdivision 4. (1) (a) of Section 3337 of the Public Health Law, and of Section 80.70(a) of Part 80 of the Administrative Rules and Regulations of the Health Department, complete all required information on failed to written memoranda of telephone orders for controlled substances. On at least twenty-one occasions, the Respondent dispensed controlled substances on oral prescriptions, but did not include on the written memorandum of the order the patient's age, complete name, and/or address. On eleven of the aforesaid written memoranda, the date of the order was not recorded.

5. Respondent, in violation of subdivision two of Section 3334 of the Public Health Law, unlawfully dispensed more than a five day supply of a Schedule II substance on an emergency oral prescription. On November 8, 1982, the Respondent dispensed a seven day supply of the Schedule II substance, Percocet.

6. Respondent, in violation of subdivision two of Section 3337 of the Public Health Law, and of

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Section 80.70(b) of Part 80 of the Administrative Rules and Regulations of the Health Department, unlawfully dispensed more than a five day supply of a Schedule III substance on an oral prescription. On January 7, 1983, the Respondent dispensed a twelve day supply of Tylenol #3; on January 8, 1983, the Respondent dispensed a thirty day supply of Fiorinal.

7. Paragraph "7" of the charges was deleted.

violation of Section Respondent, in 8. 80.70(c),(d) of Part 80 of the Administrative Rules and Regulations of the Health Department, failed either to attach written follow-up prescriptions to the memoranda of oral orders or, in the alternative, to note on the memoranda that written prescriptions were not received from the prescribing practitioner. On twenty telephone orders for controlled substances filled during the period July 22, 1982 through January 15, 1983, the Respondent did not either attach a copy of a written follow-up prescription to the written memorandum of a telephone order or note written such written memorandum that the on prescription was not received.

9. Respondent, in violation of Section 80.70(e) of Part 80 of the Administrative Rules and Regulations of the Health Department, failed to

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endorse on a written follow-up prescription his signature, the date of filling, the prescription number under which it is recorded in the pharmacy prescription file, and failed to place on the back of the follow-up prescription the date of receipt, serial number and date on which the oral order was filled. A written follow-up prescription dated January 18, 1983 did not contain the signature of the dispensing pharmacist, the date of filling or the prescription number, nor was there any information recorded on the back of the follow-up.

10. Respondent, in violation of Section 80.74(d) of the Administrative Rules and Regulations of the Health Department, unlawfully dispensed controlled substances on written prescriptions which were not dated. On April 28, 1982 and on January 3, 1983, the Respondent filled prescriptions which were undated.

On January 6, 1984 the respondent was charged with the following violations:

Respondent, in violation of Section 3304(a)
 of the Public Health Law, unlawfully dispensed
 controlled substances during the period May 26, 1981
 and January 19, 1983, in Great Neck, New York.

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2. Respondent, in violation of Section 3333(1)

of the Public Health Law, and of Section 80.73(c) of the Administrative Rules and Regulations of the Health Department, unlawfully dispensed, Schedule II, controlled substances on prescriptions which were not written on official New York State prescription forms. On June 11, 1981, the Respondent dispensed 60 Nembutal 100 mg. capsules to the ultimate user, on a written, not a triplicate prescription. On six occasions during the period May 25, 1981 through Respondent dispensed the January 11. 1983 the Schedule II substance, Percodan and Percocet, on triplicate prescription forms which had not been dated by the prescribing practitioner.

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3. Respondent, in violation of Section 3334(1)(a) of the Public Health Law, and of Section 80.73(d) of the Administrative Rules and Regulations Health Department, unlawfully dispensed of the Schedule II substances to ultimate users in that all of the required information was not recorded on the written memoranda of emergency oral prescriptions. On twenty-nine occasions between May 25, 1981 and November 20, 1982, the Respondents failed to include the prescribing practitioner's DEA registration and address on written memoranda of telephone orders for the Schedule II substance, Nembutal.

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4. Respondent, in violation of Section 3334(2) of the Public Health Law, and of Section 80.73(e) of the Administrative Rules and Regulations, unlawfully dispensed more than a five day supply of a Schedule II substance on an emergency oral prescription. On eighteen occasions between May 25, 1981 and November 20, 1982, the Respondent dispensed a thirty day supply of the Schedule II substance, Nembutal on a telephone order.

5. Respondent, in violation of Section 3334(3) of the Public Health Law, and of Section 80.73(f) of the Administrative Rules and Regulations of the Health Department, failed to notify the Health Department that a prescribing practitioner had failed to deliver the original and one copy of an official New York State prescription authorizing the emergency dispensing of a Schedule II substance. On twenty nine occasions between May 25, 1981 and November 20, 1982, the Respondent dispensed the Schedule II substance Nembutal on the basis of telephoned orders, but failed to notify the Department that the required follow up triplicate prescription was not received.

6. Respondent, in violation of Section 3334(4) of the Public Health Law, and of Section 80.73(g) of the Administrative Rules and Regulations of the

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Health Department, failed to endorse a prescription calling for a Schedule II substance. On twenty nine occasions between May 25, 1981 and November 20, 1982, the dispensing pharmacist failed to sign prescriptions calling for Schedule II substances.

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Respondent, in violation of Section 7. 3337(1)(a) of the Public Health Law and of Section Rules and 80.70(a)(1) of the Administrative Regulations of the Health Department, unlawfully dispensed Schedule II substances to ultimate users in that the dispensing pharmacist failed to record the practitioner's address and DEA prescribing registration number on eighteen written memoranda of telephone orders for the Schedule IV substance Valium, filled between May 26, 1981 and January 18, 1983.

8. Respondent, in violation of Section 3337(4) of the Public Health Law and of Section 80.70(1) of the Administrative Rules and Regulations of the Health Department, failed to sign written memoranda of telephone orders calling for Valium 10 mg., filled between May 26, 1981 and January 18, 1983.

9. Respondent, in violation of Section 3343(2) of the Public Health Law, and of Section 80.106 of the Administrative Rules and Regulations of the

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Health Department, failed to keep proper records of controlled substances received and dispensed. An audit of controlled substance records for the period May 26, 1981 to January 19, 1983 revealed shortages of 301 Percodan tablets; 44 Percocet-5 tablets; 638 Phenobarbital 100 mg. capsules; 424 Valium 10 mg. tablets; and an overage of 32 Placidy1 750 mg. capsules.

10. Respondent, in violation of Section 3397(1)(b) of the Public Health Law, and of Section and Administrative Rules 80.125(a)(2) of the Regulations of the Health Department, wilfully made a false statement on a record required by Article 33 of the Public Health Law. On one occasion, Respondent altered the date written on an Official New York State prescription form. On seven occasions, the date of filling was altered on a written controlled substance prescription. On one occasion, a false serial (prescription) number was affixed to а controlled substance prescription.

On August 9, 1984 Order No. MCS-84-96 was issued by the Commissioner of Health of the State of New York, adopting the Stipulation entered into by Respondent wherein respondent admitted violating Article 33 of the New York State Public Health Law and the Administrative Rules and Regulations of the

Department of Health as set forth in the aforesaid charges dated June 24, 1983 and January 6, 1984. Paragraph "7" of the charges dated June 24, 1983 was deleted, and respondent did not admit this allegation.

In addition to respondent's admission to the aforesaid charges respondent admitted failure to keep proper records in violation of Section 3343(2) of the Public Health Law and Section 80.106(a) of the Administrative Rules and Regulations of the Department of Health, in that in audit of controlled substances for the period May 26, 1981 to June 19, 1983 revealed shortages of 301 Percodan tablets; 30 Percocet-5[.] tablets, 638 Phenobarbital, 100 mg. capsules; 424 Valium 10 mg. tablets and an overage of 32 Placidyl; 750 mg. capsules.

As a result, of the Stipulation entered into by the respondent and the Department of Health, the respondent was assessed a fine of \$7,200. The Department agreed to suspend \$2,700 of the penalty provided the respondent comply with the terms of probation.

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WHEREFORE, it is requested that the license previously granted to JOSEPH ROTHKOPF to practice pharmacy in the State of New York as a pharmacist be revoked or that such other and further relief be granted as may be just and proper.

Dated: /S day of April, 1985

Sel de la

WILLIAM L. WOOD, JR. PROFESSIONAL MISCONDUCT OFFICER

BY:/

LOUIS M. MERINGOLO Prosecuting Attorney New York State Education Department Office of Professional Discipline 622 Third Avenue -- 37th floor New York, New York 10017

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NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY

IN THE MATTER

of the

Application for the revocation of the authorization and license heretofore granted to

JOSEPH ROTHKOPF

to practice pharmacy in the State . of New York, and for the cancellation of his registration as such, or for such other relief as the premises warrant.

NOTICE OF AMENDMENT

SIRS:

PLEASE TAKE NOTICE that the petitioner hereby amends the charges previously served upon respondent, JOSEPH ROTHKOPF, on June 14, 1985 to delete paragraph Third, and to include the following paragraph, Third as follows:

FIRST SPECIFICATION OF PROFESSIONAL MISCONDUCT

THIRD: Respondent is charged with having been convicted of committing an act constituting a crime within the purview and meaning of §6509(5)(a)(i) of the Education Law of the State of New York, in that:

On February 10, 1983, respondent was charged in the Superior Court, Nassau County, New York with three

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TXHIBLE "A"

counts of Criminal Sale of a Controlled Substance in the Fifth Degree, a class D felony. The Information alleged that the respondent sold Placidyl, a Schedule IV controlled drug on three separate occasions.

On February 10, 1983, respondent pled guilty to Attempted Criminal Possession of a Controlled Substance, in the Seventh Degree, a class "B" misdemeanor in satisfaction of the information.

On March 25, 1983, the respondent was sentenced to one year probation and payment of a \$500 fine or thirty days in prison.

Dated:

day of August 1985

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JOSEPH FISCH PROFESSIONAL CONDUCT OFFICER

- By:

LOUIS M. MERINGOLO

Prosecuting Attorney Office of Professional Discipline N.Y.S. Education Department 622 Third Avenue - 37th Floor New York, New York 10017-6756 (212) 557-2196

To: Jerome I. Sager, Esq. 126 E 16 Street New York, N.Y. 10003

EXHIBIT "B"

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TERMS OF PROBATION

JOSEPH ROTHKOPF

- 1. That respondent, during the period of probation, shall conduct himself in all ways in a manner befitting his professional status, and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession;
- 2. That respondent shall submit written notification to the New York State Education Department, addressed to the Executive Director, Office of Professional Discipline, New York State Education Department, 622 Third Avenue, New York, NY 10017-6756, of any employment and practice, of respondent's residence and telephone number, of any change in respondent's employment, practice, residence, or telephone number within or without the State of New York;
- 3. That respondent shall submit written proof from the Division of Professional Licensing Services (DPLS), New York State Education Department (NYSED), that respondent has paid all registration fees due and owing to the NYSED and respondent shall cooperate with and submit whatever papers are requested by DPLS in regard to said registration fees, said proof from DPLS to be submitted by respondent to the NYSED, addressed to the Executive Director, Office of Professional Discipline, as aforesaid, no later than the first three months of the period of probation;
- 4. That respondent shall submit written proof to the NYSED, addressed to the Executive Director, Office of Professional Discipline, as aforesaid, that 1) respondent is currently registered with the NYSED, unless respondent submits written proof that respondent has advised DPLS, NYSED, that respondent is not engaging in the practice of respondent's profession in the State of New York and does not desire to register, and that 2) respondent has paid any fines which may have previously been imposed upon respondent by the Board of Regents; said proof of the above to be submitted no later than the first two months of the period of probation;
- 5. That so long as the stay of execution is in effect, respondent may continue to practice respondent's aforementioned profession in accordance with the terms of probation; provided, however, that upon receipt of evidence of noncompliance with or any other violation of any of the aforementioned terms of probation, the New York State Education Department may initiate a violation of probation proceeding and/or such other proceedings pursuant to the Education Law and the Rules of the Board of Regents.

4 m 01 m NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY _ _ _ _ _ _X IN THE MATTER of the APPLICATION FOR Application for the revocation of the CONSENT ORDER authorization and license heretofore granted to JOSEPH ROTHKOPF to practice as a pharmacist in the State of New York, for the cancellation of his registration as such, and for such other relief as the premises warrant. The undersigned agree to the above statement and to the proposed penalty based on the terms and conditions thereof. Dated: /0.30 , 1985 Dated: 10-90 , 1985 for Respondent ttorney Dated: 11/2/85 , 1985 Member of the State Board of Pharmacy Dated: Arvember 6 , 1985 Executive Secretary State Board of Pharmacy Dated: 11/25 , 1985 960 Office of Professional Discipline The undersigned, a member of the Board of Regents who has been designated by the Chairman of the Regents Committee on Professional Discipline to review this Application for a Consent Order, has reviewed said Application and recommends to the Board of Regents that the Application be granted. Dated: 11/27, 1985 Member, Board of Regents

Name: Joseph M Rothkopf e-ProfileID: Process Date: 2/11/14 DCN: Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph M Rothkopf Reporting Entity: New York Board of Pharmacy

 Transaction Type: Initial Report
 Date of Action: 02/22/1990

 Action
 Basis for Action

 - 1125 - Probation of License
 - A5 - Violation of or Failure to Comply With Licensing Board Order

A. REPORTING ENTITY	Entity Name: Address: City, State, Zip: Country: Name of Certifier: Title or Department: Telephone: Type of Report: Related Report Number:	New York Board of Pharmacy Cultural Education Center, Room 3035 Albany, NY 12230 US Initial
B. SUBJECT IDENTIFICATION INFORMATION	Subject Name: e-Profile ID: Other Name(s) Used: Gender: Date of Birth: Work Address: City, State, ZIP: Deceased: Federal Employer Identification Numbers (FEIN): Social Security Numbers (SSN): Individual Taxpayer Identification Number (ITIN): National Provider Identifiers (NPI): Professional School & Year of Graduation: Occupation/Field of Licensure (Code): State License Number, State of Licensure:	Josenh M Rothkopf Male 6255 Ursa Ln Colorado Springs, CO 80919 NO St John's University - NY (1976) Pharmacist 030310 , NY

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Name: Joseph M Rothkopf e-ProfileID: Process Date: 2/11/14 DCN: Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary



Type of Adverse Action: Initial Basis for Action: - A5 -Reporting Entity: NY Action Classification Code(s): - 112 Date Action Was Taken: 02/22 Date Action Became Effective: 03/05 Length of Action: 2 Yea Monetary Penalty: \$ 500 Auto Reinstate?: No Description: Order

 Action:
 - A5 - Violation of or Failure to Comply With Licensing Board Order

 In Entity:
 NY

 ode(s):
 - 1125 - Probation of License

 Taken:
 02/22/1990

 fective:
 03/05/1990

 Action:
 2 Years, 0 Months, 0 Days

 Penalty:
 \$ 500

 state?:
 No

 Order #10409:
 Pharmacist dispensed Synthroid 0.125 mg instead of the prescribed Synthroid .075 mg, failed to properly complete and maintain required

Synthroid .075 mg, failed to properly complete and maintain required paperwork and in so doing, violated the terms of probation of the Board Order effective March 24, 1986. New York license is now suspended for one year. Suspension is stayed and license is placed on probation with terms and conditions for a period of two years. Fine of \$500.00 levied.



The University of the State of Rew Block

IN THE MATTER

OF

JOSEPH M. ROTHKOPF (Pharmacist) ORIGINAL VOTE AND ORDER NO. 10409

Upon the application of JOSEPH M. ROTHKOPF, under Calendar No. 10409, which application is made a part hereof, and in accordance with the provisions of Title VIII of the Education Law, it was

VOTED (February 16, 1990): That the application of JOSEPH M. ROTHKOPF, respondent, for a consent order be granted; and that the Commissioner of Education be empowered to execute, for and on behalf of the Board of Regents, all orders necessary to carry out the provisions of this vote;

and it is

ORDERED: That, pursuant to the above vote of the Board of Regents, said vote and the provisions thereof as well as the application and the provisions thereof are hereby adopted and SO ORDERED, and it is further

ORDERED that this order shall take effect as of the date of the personal service of this order upon the respondent or five days after mailing by certified mail.

JOSEPH M. ROTHKOPF (10409)



IN WITNESS WHEREOF, I, Thomas Sobol, Commissioner of Education of the State of New York, for and on behalf of the State Education Department and the Board of Regents, do hereunto set my hand and affix the seal of the State Education Department, at the City of Albany, this adm day of

Jehronany 3990. SUW

Commissioner of Education

NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY

IN THE MATTER

of the

Disciplinary Proceeding

APPLICATION FOR CONSENT ORDER

against

JOSEPH M. ROTHKOPF

CAL. NO. 10409

who is currently licensed to practice as a pharmacist in the State of New York.

)

)

STATE OF NEW YORK

COUNTY OF

··· , . . , . .

SS:

JOSEPH M. ROTHKOPF, being duly sworn, deposes and says:

That on or about September 17, 1976 I was licensed to practice as a pharmacist in the State of New York, having been issued license No. 030310 by the New York State Education Department.

I am currently registered with the New York State Education Department to practice as a pharmacist in the State of New York from an address at: 4 Sagamore Lane, Dix Hills, New York 11746-6014.

That I have been charged with two (2) specifications of professional misconduct, a copy of which is annexed hereto, made a part hereof, and marked as Exhibit "A".

I admit guilt to each of the aforementioned two (2) specifications of professional misconduct.

JOSEPH M. ROTHKOPF

I hereby agree to the penalty that my license to practice as a pharmacist in the State of New York be suspended for one (1) year; that execution of said suspension be stayed; that I be placed on probation for two (2) years under the terms set forth in the exhibit annexed hereto, made a part hereof and marked as Exhibit "B"; and that I be fined the sum of five hundred dollars (\$500.00), said fine to be paid as set forth in said terms of probation.

16

I hereby make this application to the Board of Regents and request that it be granted.

I understand that in the event that the Board of Regents denies the application, nothing contained herein shall be binding upon me or construed to be an admission of any act of misconduct alleged or charged against me. Such application shall not be used against me in any way and shall be kept in strict confidence during the pendency of the disciplinary proceeding, and such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

I agree that in the event the Board of Regents grants my application, as set forth herein, an Order of the Commissioner of Education may be issued in accordance with the same. JOSEPH M. ROTHKOPF

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No promises of any kind were made to me. I am making this application of my own free will and accord and not under duress, compulsion, or restraint of any kind or manner.

Respondent

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Sworn to before me this day of Alexaber, 1989 14 NOTARY PUBLIC

DOROTHY W. OKUN NOTARY PUBLIC, State of New York No. 4673312 Qualified in Nassau County Commission Expires March 30, 19 Kor 30, 199

EXHIBIT "A"

JOSEPH M. ROTHKOPF

FIRST SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is charged with committing unprofessional conduct within the purview and meaning of Section 6509(9) of the Education Law of the State of New York, in that:

While Respondent was the supervising pharmacist at the retail pharmacy operated by Beth Fair Pharmacy, Inc., Bethpage, New York, the following occurred:

- a) On or about October 27, 1988, Respondent, without the knowledge or consent of the prescriber, dispensed the non-controlled drug Synthroid 0.125 mg. to a customer instead of the prescribed non-controlled drug Synthroid .075 mg., in violation of 8 NYCRR 29.7(a)(5);
- November b) 22, 1988, the aforesaid On prescription for the non-controlled drug Synthroid .075 mg. was refilled without entering on the reverse of said prescription the date of the refill and the signature or readily identifiable initials of the dispensing pharmacist, in violation of 8 NYCRR 29.7(a)(4); and

c) The daily record of all prescriptions filled and refilled at said pharmacy between October ll, 1988 and December 18, 1988 failed to include the signature or readily identifiable initials of the dispensing pharmacist(s), in violation of 8 NYCRR 29.7(a)(8).

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SECOND SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is further charged with committing unprofessional conduct within the purview and meaning of Section 6509(9) of the Education Law of the State of New York, in specific violation of 8 NYCRR 29.1(b)(14), in that:

Pursuant to Commissioner's Order No. 4096, dated February 6, 1986, <u>In the Matter of Joseph Rothkopf</u>, Respondent was placed on probation for a period of two (2) years. The effective date of said Order was March 24, 1986 and the probationary period ran from March 24, 1987 through March 23, 1989. The terms of probation included the following provision:

1. That Respondent, during the period of probation, shall conduct himself in all ways in a manner befitting his professional status, and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession.

Respondent violated Term of Probation No. 1 by failing to conduct himself in all ways in a manner befitting his professional status and by failing to conform fully to the moral and professional standards of conduct imposed by law and by his profession, as follows:

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	The allegations contained in the Fi	rst
	Specification are repeated, reiterated and realled	ged
	with the same force and effect as if more particula:	
	set forth herein at length.	
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<i>v</i> .		

EXHIBIT "B"

TERMS OF PROBATION

JOSEPH M. ROTHKOPF

- That Respondent, during the period of probation, shall act in all ways in a manner befitting Respondent's professional status, and shall conform fully to the moral and professional standards of conduct imposed by law and by Respondent's profession;
- That Respondent shall submit written notification to the New York State Education Department, addressed to the Executive Director, Office of Professional Discipline, New York State Education Department, One Park Avenue, 6th Floor, New York, NY 10016-5802, of any employment and/or practice, Respondent's residence, telephone number, or mailing address, of any change in Respondent's employment, practice, residence, telephone number, or mailing address within or without the State of New York;
- That Respondent shall pay the \$500.00 fine imposed upon Respondent, by certified or bank cashier's check, made payable to the order of the New York State Education Department, to be delivered to the Executive Director, Office of Professional Discipline, as aforesaid, no later than thirty (30) days after the effective date of the service of the Order of the Commissioner of Education to be issued in this matter;
- That Respondent shall submit written proof from the Division of Professional Licensing Services (DPLS), New York State Education Department (NYSED), that Respondent has paid all registration fees due and owing to the NYSED and Respondent shall cooperate with and submit whatever papers are requested by DPLS in regard to said registration fees, said proof from DPLS to be submitted by Respondent to the NYSED, addressed to the Executive Director, Office of Professional Discipline, as aforesaid, no later than the first three months of the period of probation;

That Respondent shall submit written proof to the NYSED, addressed to the Executive Director, Office of Professional Discipline, as aforesaid, that 1) Respondent is currently registered with the NYSED, unless Respondent submits written proof that Respondent has advised DPLS, NYSED, that Respondent is not engaging in the practice of Respondent's profession in the State of New York and does not desire to register, and that 2) Respondent has paid any fines which may have previously been imposed upon Respondent by the Board of Regents; said proof of the above to be submitted no later than the first two months of the period of probation;

DSEPH M. ROTHKOPF

- That Respondent shall make quarterly visits to an employee of the Office of Professional Discipline, New York State Education Department, unless otherwise agreed to by said employee, for the purpose of said employee monitoring Respondent's terms of probation to assure compliance therewith, and Respondent shall cooperate with said employee, including the submission of information requested by said employee, regarding the aforesaid monitoring;
 - That so long as there is full compliance with every term herein set forth, Respondent may continue to practice Respondent's aforementioned profession in accordance with the terms of probation; provided, however, that upon receipt of evidence of noncompliance with or any other violation of any of the aforementioned terms of probation, the New York State Education Department may initiate a violation of probation proceeding and/or such other proceedings pursuant to the Education Law and the Rules of the Board of Regents.

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	NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY
14	IN THE MATTER of the
	Disciplinary Proceeding APPLICATION FOR
	against CAL. NO. 10409
	JOSEPH M. ROTHKOPF who is currently licensed to practice as a pharmacist in the State of New York.
	The undersigned agree to the above statement and to the proposed penalty based on the terms and conditions thereof.
	Dated: Dec. 14, 1989 M. Authr Respondent
	Dated Decity, 1989 Attorney for Respondent
	Dated: Alic 23, 1989 Actorney for Respondent Member of the State Board of Pharmacy
	Dated: Dec. 29, 1989 Sauscance A. Mochinhen Executive Secretary State Board of Pharmacy
	Dated John J. 1990 Charles Colom Executive Director Office of Professional Discipline
	The undersigned, a member of the Board of Regents who has been designated by the Chairman of the Regents Committee on Professional Practice to review this Application for a Consent Order, has reviewed said Application and recommends to the Board of Regents that the Application be granted.
	Dated: Juny 17, 1999 Member, Board of Regents
1	

e-ProfileID: Process Date: 2/11/14 DCN: Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph M Rothkopf Reporting Entity: New York Board of Pharmacy

Transaction Type: Initial Report Date of Action: 05/07/1995

 Action
 Basis for Action

 - 1173 - Publicly Available Fine/Monetary Penalty
 - A5 - Violation of or Failure to Comply With Licensing Board Order

second states		
A. REPORTING ENTITY	Entity Name: Address: City, State, Zip:	New York Board of Pharmacy Cultural Education Center, Room 3035 Albany, NY 12230
	Country: Name of Certifier: Title or Department: Telephone:	US
	Type of Report: Related Report Number:	Initial
B. SUBJECT IDENTIFICATION	Subject Name: e-Profile ID: Other Name(s) Used:	Joseph M Rothkopf
	Gender: Date of Birth:	Male
	Work Address:	6255 Ursa Ln
	City, State, ZIP:	Colorado Springs, CO 80919
	Deceased:	NO
	Federal Employer Identification Numbers (FEIN):	
	Social Security Numbers (SSN):	
	Individual Taxpayer Identification Number	
	(ITIN):	
	National Provider Identifiers (NPI):	
	Professional School & Year of Graduation:	St John's University - NY (1976)
	Occupation/Field of Licensure (Code): State License Number, State of Licensure:	Pharmacist 030310 , NY

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Rame, Joseph M Rothkopt e-ProfileID. Process Date: 2/11/14 DCN: Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary



Type of Adverse Action: In Basis for Action: -, Reporting Entity: N Action Classification Code(s): Date Action Was Taken: 05 Date Action Became Effective: 05 Length of Action: No Monetary Penalty: \$2 Auto Reinstate?: No Description: Fil Ph

 Action:
 Initial

 Action:
 - A5 - Violation of or Failure to Comply With Licensing Board Order

 g Entity:
 NY

 Code(s):
 - 1173 - Publicly Available Fine/Monetary Penalty

 Taken:
 05/07/1995

 ffective:
 05/07/1995

 Action:
 Not Specified

 Penalty:
 \$ 250

 Istate?:
 No

 File #9105646, 9102827

 Pharmacist violated Order of Probation of New York license by failing to sign the computer generated daily records of all prescriptions filled and refilled to indicate that the records are accurate. Pharmacist reprimanded and fined \$250,00.

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File # 9105646 9102827

STATEMENT

2.2.3.1.224

TO: The New York State Office of Professional Discipline The New York State Board of Pharmacy

I wish to settle and dispose of the misconduct allegations which are pending against me, to wit: committing unprofessional conduct (violating probation in that while employed as a pharmacist at the pharmacy operated by Genovese Drug Stores, Inc., 371 Horseblock Road, Farmingville, New York, a routine inspection of said pharmacy revealed that I routinely failed to sign the computer generated daily records of all prescriptions filled and refilled to indicate that said records are accurate), in violation of Section 6509(9) of the Education Law of the State of New York, in specific violation of 8 NYCRR 29,1(b)(14) and 29.7(a)(8). For purposes of settlement I do not contest said allegations. I agree to a Censure and Reprimand and a \$250.00 fine. My check in the sum of \$250.00, payable to the New York State Education Department is enclosed.

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1600 Feehanville Drive, Mt. Prospect, IL 60056 847/391-4400 ~ clearinghouse@nabp.net e-ProfileID Process Date: 2/11/14 DCN: Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph M Rothkopf Reporting Entity: New York Board of Pharmacy

Transaction Type: Initial Report

Date of Action: 01/24/1997

 Action
 Basis for Action

 - 1173 - Publicly Available Fine/Monetary Penalty
 - H5 - Error in Prescribing, Dispensing or Administering Medication

A. REPORTING ENTITY	Entity Name: Address: City, State, Zip:	New York Board of Pharmacy Cultural Education Center, Room 3035 Albany, NY 12230
	Country: Name of Certifier: Title or Department: Telephone:	US
9	Type of Report: Related Report Number:	Initial
B. SUBJECT IDENTIFICATION INFORMATION	Subject Name: e-Profile ID: Other Name(s) Used:	Joseph M Rothkopf
·	Gender: Date of Birth:	Male
	Work Address: City, State, ZIP: Deceased:	6255 Ursa Ln Colorado Springs, CO 80919 NO
	Federal Employer Identification Numbers (FEIN): Social Security Numbers (SSN): Individual Taxpayer Identification Number	
	(ITIN): National Provider Identifiers (NPI): Professional School & Year of Graduation: Occupation/Field of Licensure (Code): State License Number, State of Licensure:	St John's University - NY (1976) Pharmacist 030310 , NY

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National Association of Boards of Pharmacy 1600 Feehanville Drive, Mt. Prospect, IL 60056 847/391-4400 ~ clearinghouse@nabp.net

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Name: Joseph M Rothkopf e-ProfileIC Process Date: 2/11/14 DCN: Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

C. INCIDENT REPORTED	Type of Adverse Action: Basis for Action:	Initial - H5 - Error in Prescribing, Dispensing or Administering Medication
	Reporting Entity: Action Classification Code(s):	NY - 1173 - Publicly Available Fine/Monetary Penalty
E Y N TO THE REAL PROPERTY OF	Date Action Was Taken:	01/24/1997
	Date Action Became Effective:	01/24/1997
	Length of Action:	Not Specified
	Monetary Penalty:	\$ 500
	Auto Reinstate?: Description:	No New York Case #9600634-9401 Pharmacist was fined \$500.00 for dispensing a drug other than the one prescribed.

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THE UNIVERSITY OF THE STATE OF NEW YORK THE STATE EDUCATION DEPARTMENT 1 Park Avenue 6th Floor New York, New York 10016

DEPUTY COMMISSIONER, OFFICE OF THE PROFESSIONS		OFFICE OF PROFESSIONAL DISCIPLINE
JOSEPH M. ROTHKOPF 4 SAGAMORE LANE		JANUARY 24. 1997

J 4 ANE DIX HILLS, NY 11746-6014

Dear Sir:

RE: 9600634 9401

As Professional Conduct Officer, I have determined that there is substantial evidence of your responsibility for the follow-ing violation(s). This determination is made pursuant to SECTION 6510 of the New York State Education Law. 8 ¹⁰¹

4.

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PENALTY VIOLATIONS

\$ 500 1. N. H Dispensing a drug other than prescribed. -----

\$ 500 TOTAL PENALTY

OPD 401 PG 1 (9/82)

NAME: JOSEPH M, ROTHKOPF FILE #: 9600634 9401

If you do not wish to contest these charges, sign your name under the first option on the enclosed form and return your check, with the form, for the total penalty indicated,

If you do not wish to contest these charges but would like to make a statement in mitigation or explanation to a Pharmacy Board Violations Committee, sign your name under the second option on the enclosed form. Please note that if you select this option, the Viola-tions Committee will not be bound by the monetary penalties set forth above. The Committee may increase the penalties (not to exceed \$500 per violation) or may decrease the penalties. In addition, or in the alternative, the Committee may issue a Censure and Reprimand for the viola-tions. The date you must appear before the Violations Committee is set forth in the second option. • So . 1685.

If you believe you are not guilty of the charges and wish to contest them, sign under the third option on the enclosed form. You will then be given a full adversary hearing in accordance with the New York State Education Law. If you select this option you will be served with a formal Notice of Hearing and Statement of Charges. If found guilty of any of these charges, you may be subject to the full range of penalties set forth in the Education Law, including possible revocation or suspension of your license to practice pharmacy in New York State and/or fines up to \$10,000 for each violation.

If no answer is received by this office within twenty days of your receipt of this letter, the matter will be automatically referred to a Violations Committee for its determination on the date indicated in the second option on the enclosed form.

CHARLES J. ADAMS PROFESSIONAL CONDUCT CONDUCT OFFIC PROFESSIONAL CONDUCT OFFICER

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OPD 401 PG 2 (9/82)

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	а		
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TOTAL: 96	00634 - 9401 500		
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Name: Joseph M Rothkoph e-ProfileID: Process Date: 2/11/14 DCN: Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph M Rothkopf Reporting Entity: New York Board of Pharmacy

 Transaction Type: Initial Report
 Date of Action: 12/20/2011

 Action
 Basis for Action

 - 1135 - Suspension of License
 - E4 - Fraud, Deceit or Material Omission in Obtaining License or Credentials

A. REPORTING ENTITY	Entity Name: Address: City, State, Zip:	New York Board of Pharmacy Cultural Education Center, Room 3035 Albany, NY 12230
	Country: Name of Certifier: Title or Department:	US
	Telephone: Type of Report: Related Report Number:	Initial
B. SUBJECT	Subject Name: e-Profile ID:	Joseph M Rothkopf
	Other Name(s) Used:	
INFORMATION	Gender:	Male
	Date of Birth:	
	Work Address:	ozoo Ursa Ln
	City, State, ZIP:	Colorado Springs, CO 80919
	Deceased:	NO
	Federal Employer Identification Numbers	
	(FEIN):	
	Social Security Numbers (SSN):	
	Individual Taxpayer Identification Number	
	(ITIN):	
	National Provider Identifiers (NPI): Professional School & Year of Graduation: Occupation/Field of Licensure (Code): State License Number, State of Licensure:	St John's University - NY (1976) Pharmacist 030310 , NY
	State License Hamsel, State of Electicate.	

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e-ProfileID: Process Date: 2/11/14 DCN: Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

1 Post 200		
C. INCIDENT REPORTED	Type of Adverse Action: Basis for Action:	Initial - E4 - Fraud, Deceit or Material Omission in Obtaining License or Credentials
	Reporting Entity: Action Classification Code(s):	NY
and Second Barbara	Action Glassification Gode(s).	- 1135 - Suspension of License
	Date Action Was Taken:	12/20/2011
	Date Action Became Effective:	12/20/2011
	Length of Action:	0 Years, 3 Months, 0 Days
	Monetary Penalty:	\$ 1000
	Auto Reinstate?: Description:	No Pharmacist admitted to having been convicted of a crime in Colorado and to having lied on his re-registration application. New York license is suspended for 24 months, with 3 months actual suspension and 21 months stayed suspension. When the pharmacist returns to practice in New York, his license will be placed on probation for 2 years. A \$1,000.00 fine was also levied.

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Profession: Pharmacist; Lic. No. 030310; Cal. No. 25850

Regents Action Date: December 20, 2011

Action: Application for consent order granted; Penalty agreed upon: 3 month actual suspension, 21 month stayed suspension, 2 years probation to commence upon return to practice in State of New York, \$1,000 fine.

Summary: Licensee admitted to having been convicted of a crime in Colorado and to having lied on his re-registration application.



THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12230

OFFICE OF THE PROFESSIONS DIVISION DF PROFESSIONAL LICENSING SERVICES Public Information Unit Tel. (518) 474-3817 EXT: 330 Fax (518) 473-0578 E-mail: DPLSDSU@MAIL.NYSED.GOV

STATE OF NEW YORK) SS: COUNTY OF ALBANY)

In accordance with the <u>Civil Practice Law and Rules Article 45</u>, I, Cathy Hanczaryk, Principal Clerk in the Division of Professional Licensing Services of the New York State Education Department, have caused this certificate to be prepared. I certify that I have legal custody of the official original records of the Division of Professional Licensing Services and I attest that the attached are true, complete and correct copies of the original documents in our files relating to the licensure of JOSEPH M. ROTHKOPF.

Witness my hand and the seal of the New York State Education Department this 20 February, 2014.

athy J

Cathy Hanczaryk, Principal Clerk Professional Licensing Services







The University of the State of New York

IN THE MATTER

OF

Joseph M. Rothkopf

PHARMACIST

X		X
STATE OF NEW YORK) SS.:	
COUNTY OF ALBANY)	

I, Michael Kinley, being duly sworn, deposes and says:

I am over the age of twenty-one years and am an employee of the New York State Education Department, Office of Professional Discipline, 80 Wolf Road, Suite 204, Albany, New York 12205-2643.

On the 21 day of December, 2011, I personally delivered to the Stuyvesant Plaza Post Office the Duplicate Original Vote of the Board of Regents and Order under Calendar No. 25850 and the Report of the Regents Review Committee or Application for Consent or Surrender, or Report of the designated Regent in a summary suspension proceeding as applicable, by Certified Mail - Return Receipt Requested to the respondent herein named at Lynbrook, NY

Certified Mail Receipt No: 7002 0860 0000 6521 6416

The effective date of the Order being the 26 day of December, 2011.

Sworn to before me this day of December, 2011 STEPHEN E. GROGAN Notary Public, State of New York Qualified in Rensselaer County, Commission Expires 8/31/



The University of the State of New York

IN THE MATTER

OF

JOSEPH M. ROTHKOPF (Pharmacist) ORIGINAL VOTE AND ORDER NO. 25850

Upon the application of JOSEPH M. ROTHKOPF, under Calendar No. 25850, which application is made a part hereof, and in accordance with the provisions of Title VIII of the Education Law, it was

VOTED (December 13, 2011): That the application of JOSEPH M. ROTHKOPF, respondent, for a consent order be granted; and that the Deputy Commissioner for the Professions be empowered to execute, for and on behalf of the Board of Regents, all orders necessary to carry out the terms of this vote;

and it is

ORDERED: That, pursuant to the above vote of the Board of Regents, said vote and the provisions thereof are hereby adopted and SO ORDERED, and it is further

ORDERED that this order shall take effect as of the date of the personal service of this order upon the respondent or five days after mailing by certified mail.

JOSEPH M. ROTHKOPF (25850)

IN WITNESS WHEREOF, I, Douglas E. Lentivech, Deputy Commissioner for the Professions, for and on behalf of the State Education Department and the Board of Regents, do hereunto set my hand, at the City of Albany, this 13th day of December, 2011.

MARCH AND THE REAL

DOUGLAS E. LENTIVECH DEPUTY COMMISSIONER FOR THE PROFESSIONS NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY

IN THE MATTER

of the

Disciplinary Proceeding

APPLICATION FOR CONSENT ORDER

against

CAL. NO.25850

JOSEPH M. ROTHKOPF

who is currently licensed to practice as a pharmacist in the State of New York.

JOSEPH M. ROTHKOPF states:

That on or about September 17, 1976 I was licensed to practice as a pharmacist in the State of New York, having been issued license number 030310 by the New York State Education Department.

I am currently registered with the New York State Education Department to practice as a pharmacist in the State of New York from an address at

That I have been charged with two (2) specifications of professional misconduct, a copy of which is annexed hereto, made a part hereof, and marked as Exhibit "A."

I admit guilt to the aforesaid two (2) specifications of professional misconduct, charging me with being convicted of committing an act constituting a crime under the law of another jurisdiction and which, if committed within this state would have constituted a crime under New York State law (Colorado crime) and unprofessional conduct (lying on re-registration).

JOSEPH M. ROTHKOPF

I hereby agree to the penalty that my license to practice as a pharmacist in the State of New York be suspended for two (2) years; that execution of the last twenty-one (21) months of said suspension be stayed; that I shall be placed on probation for a period of two (2) years, to commence upon my return to practice as a pharmacist in the State of New York, under the terms set forth in the exhibit annexed hereto, made a part hereof, and marked as Exhibit "B; and that I shall be fined one-thousand (\$1,000) dollars, said fine to be paid in the manner set forth in the aforementioned terms of probation.

I further agree to inform the Director, Office of Professional Discipline, of my return to practice as a pharmacist in the State of New York, by certified mail, return receipt requested, addressed to said Director at 195 Montague Street, Fourth Floor, Brooklyn, New York 11201-3631, at least seven (7) days before my return to practice as a pharmacist in the State of New York.

I hereby make this application to the Board of Regents and request that it be granted.

I understand that in the event that the Board of Regents denies the application, nothing contained herein shall be binding upon me or construed to be an admission of any act of misconduct alleged or charged against me. Such application shall not be used against me in any way and shall be kept in strict confidence

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JOSEPH M. ROTHKOPF

during the pendency of the disciplinary proceeding, and such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

I agree that in the event the Board of Regents grants my application, as set forth herein, an Order may be issued in accordance with the same. <u>I understand that if and when the Board</u> of Regents grants this application, the entire application shall become a matter of public record.

No promises of any kind were made to me. I am making this application of my own free will and accord and not under duress, compulsion, or restraint of any kind or manner.

AN REAL Respondent

EXHIBIT "A"

JOSEPH M. ROTHKOPF

FIRST SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is charged with being convicted of committing an act constituting a crime under the law of another jurisdiction and which, if committed within this state, would have constituted a crime under New York State law, within the meaning and purview of Section 6509(5)(a)(iii) of the Education Law of the State of New York, in that:

Respondent, on or about April 18, 2001, was convicted in the District Court, Mesa County, Colorado, of the crimes of Theft under \$100, in violation of section 18-4-401(1)(a) of the Colorado Revised Statues and Obtaining Controlled Substances by Fraud or Deceit, in violation of section 18-18-415. The conviction for Obtaining Controlled Substances by Fraud or Deceit was later dismissed after successful completion of conditions of Respondent's sentence. Respondent was found to have dispensed controlled substances without a valid prescription.

SECOND SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is charged with unprofessional conduct and filing a false report, within the purview and meaning of New York Education Law section 6509(9), in specific violation of 29.1(b)(6) in that:

A. Respondent, in and about June 2006, with fraudulent intent, caused to be submitted to the Division of Professional Licensing Services of the New York State Education Department a re-registration of his licensure as a pharmacist in the State of New York, in which Respondent represented that he had not been convicted of a crime since he last registered when, in fact, Respondent had been convicted of the aforementioned crimes as set forth in the First Specification.

EXHIBIT "B" TERMS OF PROBATION JOSEPH M. ROTHKOPF CALENDAR NO. 25850

- That Respondent, during the period of probation, shall be in compliance with the standards of conduct prescribed by the law governing Respondent's profession;
- 2. That Respondent shall submit written notification to the New York State Education Department, addressed to the Director, Office of Professional Discipline, New York State Education Department, 195 Montague Street -- Fourth Floor, Brooklyn, New York 11201-3631, of any employment and/or practice, Respondent's residence, telephone number, or mailing address, and of any change in Respondent's employment, practice, residence, telephone number, or mailing address within or without the State of New York;
- 3. That Respondent shall pay the one-thousand (\$1,000) dollar fine imposed upon Respondent, by certified or bank cashier's check, made payable to the order of the New York State Education Department, to be delivered to the Director, Office of Professional Discipline, as aforesaid, within the first six (6) months of the period of probation
- 4. That Respondent shall submit written proof from the Division of Professional Licensing Services (DPLS), New York State Education Department (NYSED), that Respondent has paid all registration fees due and owing to the NYSED and Respondent shall cooperate with and submit whatever papers are requested by DPLS in regard to said registration fees, said proof from DPLS to be submitted by Respondent to the NYSED, addressed to the Director, Office of Professional Discipline, as aforesaid, no later than the first three months of the period of probation;
- 5. That Respondent shall submit written proof to the NYSED, addressed to the Director, Office of Professional Discipline, as aforesaid, that 1) Respondent is currently registered with the NYSED, unless Respondent submits written proof that Respondent has advised DPLS, NYSED, that Respondent is not engaging in the practice of Respondent's profession in the State of New York and does not desire to register, and that 2) Respondent has paid any fines which may have previously been imposed upon Respondent by the Board of Regents, said

proof of the above to be submitted no later than the first two months of the period of probation;

6. That Respondent shall make quarterly visits to an employee of the Office of Professional Discipline, New York State Education Department, unless otherwise agreed to by said employee, for the purpose of said employee monitoring Respondent's terms of probation to assure compliance therewith, and Respondent shall cooperate with said employee, including the submission of information requested by said employee, regarding the aforesaid monitoring;

7. That upon receipt of evidence of noncompliance with or any other violation of any of the aforementioned terms of probation, the New York State Education Department may initiate a violation of probation proceeding and/or such other proceedings pursuant to the Education Law and/or Rules of the Board of Regents. NEW YORK STATE EDUCATION DEPARTMENT OFFICE OF PROFESSIONAL DISCIPLINE STATE BOARD OF PHARMACY

IN THE MATTER

of the

Disciplinary Proceeding

Against

CONSENT ORDER

APPLICATION FOR

JOSEPH M. ROTHKOPF

CAL. NO. 25850

who is currently licensed to practice as a pharmacist in the State of New York.

The undersigned agree to the above statement and to the proposed penalty based on the terms and conditions thereof.

Dated:		1	2011	ATTORNEY SIGNATURE NOT REQUIRED;
Dated:		,	2011	Attorney (for Respondent
Dated:	8/2	r	2011	Member, State Board of Pharmacy
Dated:		,	2011	Executive Secretary
Dated:	10/27	,	2011	Office of Professional Discipline

The undersigned, a member of the Board of Regents who has been designated by the Chairman of the Regents Committee on Professional Practice to review this Application for a Consent Order, has reviewed said Application and recommends to the Board of Regents that the Application be granted.

ap Desire and the Dated: October 24, 2011 Member, Board of Regents

KEC/gjt

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

APPLICATION BY RECIPROCATION AS A PHARMACIST

If you are requesting licensure by reciprocation (i.e.you have a current pharmacist license from another state and wish to transfer license information and only need to take the Nevada MPJE), complete this application:

Total Fee: \$330.00 (non-refundable, money order or cashier's check only. no cash)

Money Order or Cashier's Check made payable to: Nevada State Board of Pharmacy

Complete Name (no abbreviations):	
First: Joseph Middle:	ric Last: Steidl
Mailing Address: 11 Mallard Roc	d
City: Melrose	State: <u>1</u> . Zip Code: <u>32666</u>
	E-mail Address
	Place of Birth: Patterson, NJ
	Sex: ⊠ M or □ F
Original State of Licensure you are reciprocat State: $\int oridg Date of Issue$	ing from must be active and issued by exam; Original = July, 1978 ance: <u>correct = 9/3/13</u>
College of Pharmacy Information	
	S in Pharmacy 🗂 Other (check one)
Name of Pharmacy School: University	of Florida
Location of School:Gainesville, FT	
	opy of your FPGEC certificate to THIS APPLICATION. e college of pharmacy information
Ø Board Use Only	
	Entity #: (5403
Laws 11314 MPJE	65

Other states where you are (or were) licensed as a pharmacist or print "none" Is the license active? Is the license active? State Lic# Lic# State 700 1 Yes No 0 NONP Yes □ No □ NONP Yes 🗆 No 🗖 none Yes INO I **Attach separate sheet if needed Yes No Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?...... 1. Been charged, arrested or convicted of a felonv or misdemeanor in any state?...... 2. Been the subject of an administrative action whether completed or pending in any state?..... 3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?.... If you marked YES to any of the numbered questions (1-3) above, please include the following information and provide an expiration or documents: Case #: **Board Administrative** Date: State Action: Court County Case #: Criminal State Date: Action: 1 1 FEDERALLY MANDATED REQUIREMENTS In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this questions as part of all applications. 4. Are you the subject of a court order for the support of a child?.....Yes □ No X

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I attest to knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. I hereby authorize the Nevada State Board of Pharmacy, it's agents, servants and employees, to conduct any investigation(s) of my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, it's members, servants or employees because or by reason of the use of the authorization.

Original Signature, no copies or stamps accepted

12/12/13

Vational Association of Boards of Pharmacy 1600 Feehanville Drive, Mt. Prospect, IL 60056 347/391-4400 ~ clearinghouse@nabp.net

Name: Joseph Eric Steidl e-ProfileID Process Date: 6/24/14 DCN: Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph Eric Steidl Reporting Entity: Florida Board of Pharmacy

Transaction Type: Initial Report

Date of Action: 06/20/2001

Action	Basis for Action
- 1173 - Publicly Available Fine/Monetary Penalty	- H3 - Unauthorized Dispensing of Medication

A. REPORTING ENTITY	Entity Name: Address: City, State, Zip:	Florida Board of Pharmacy 2020 Capital Circle S.E., Bin #C04, Tallahassee, FL 32399-3254
	Country: Name of Certifier: Title or Department: Telephone:	US
	Type of Report: Related Report Number:	Initial
3. SUBJECT DENTIFICATION	Subject Name: e-Profile ID:	Joseph Eric Steidl
NFORMATION	Other Name(s) Used: Gender: Date of Birth:	Male
	Work Address: City, State, ZIP: Deceased:	2720 S Blagg Rd Pahrump, NV 89048 NO
	Federal Employer Identification Numbers (FEIN):	
	Social Security Numbers (SSN): Individual Taxpayer Identification Number (ITIN):	
	National Provider Identifiers (NPI): Professional School & Year of Graduation: Occupation/Field of Licensure (Code): State License Number, State of Licensure:	University of Florida – FL (1978) Pharmacist PS17002 , FL
	State License Mumbel, State of Licensure.	

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Vational Association of Boards of Pharmacy 1600 Feehanville Drive, Mt. Prospect, IL 60056 347/391-4400 ~ clearinghouse@nabp.net

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Name: Joseph Eric Steidl e-ProfileID: Process Date: 6/24/14 DCN: Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

EPORTED	Type of Adverse Action: Basis for Action:	Initial - H3 - Unauthorized Dispensing of Medication
	Reporting Entity: Action Classification Code(s):	FL - 1173 - Publicly Available Fine/Monetary Penalty
	Date Action Was Taken:	06/20/2001
	Date Action Became Effective:	06/29/2001
	Length of Action:	Not Specified
	Monetary Penalty:	\$ 500
	Auto Reinstate?: Description:	No Case #97-11523: Pharmacist dispensed Stadol, a schedule IV controlled substance, to a pharmacy technician without a prescription. He altered the prescription on file for the medication Stadol written for the pharmacy technician to show remaining refills that were never ordered by the prescribing physician and

remaining refills that were never ordered by the prescribing physician and delivered the Stadol medication to the pharmacy technician at her home. Florida Board of Pharmacy ordered the pharmacist to pay a \$500.00 fine and costs of \$1,125.76 within 90 days. Pharmacist must also submit proof to the Board office of completing a 12-hour continuing education course in pharmacy laws and rules within 1 year.

STATE OF FLORIDA BOARD OF PHARMACY

Final Order No. DOH-01-103 FILED DATE Rv

DEPARTMENT OF HEALTH,

Petitioner,

٧S.

CASE NO.: 97-11523

JOSEPH STEIDL, R.Ph.,

Respondent.

FINAL ORDER

Respondent, Joseph Steidl, R.Ph, holds Florida license number PS 0017002 as a licensed pharmacist. Petitioner filed an Administrative Complaint seeking disciplinary action against the license. A copy of the Administrative Complaint is attached to and made a part of this Final Order.

This matter appeared before the Board of Pharmacy on June 11, 2001, meeting held in Tampa, Florida, for an informal hearing pursuant to Section 120.57(2), Florida Statutes. Petitioner was represented by Lawrence F. Kranert, Jr., Senior Attorney. Respondent was present.

FINDINGS OF FACT

Based upon the admission of the factual allegations, the Board adopts as its findings of fact paragraphs 1-6 of the Administrative Complaint.

CONCLUSIONS OF LAW

Based upon the Findings of Fact, the Board concludes the licensee has violated Section 465.016(1)(e); 465.015(2)(c); and 893.08(3)(b), Florida Statutes, and rule 64B16-27.810(2), Florida Administrative Code.

The Board is empowered by Section 465.016(2), Florida Statutes, to impose a penalty against the licensee. Therefore it is ORDERED that Respondent shall pay a FINE of \$500 and COSTS of \$1,125.76 no later than 90 days from his receipt of this Order. Respondent shall

complete (and submit proof to the Board office) a twelve (12) hour continuing education course in pharmacy laws and rules no later than one (1) year from receipt of this Order, and this course shall not count toward his pharmacy renewal requirements

Pursuant to Section 120.68, Florida Statutes, the parties are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the clerk of the agency and by filing a filing fee and one copy of a notice of appeal with the District Court of Appeal within thirty days of the date this Final Order is filed.

This Final Order shall become effective upon filing with the Clerk of the Department. DONE AND ORDERED this 2014 day of <u>JUNE</u>, 2001, by the Florida Board of Pharmacy.

JOHN D. TAYLOR, R/Ph. EXECUTIVE DIRECTOR

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by United States Mail; to Joseph Steidl, R.Ph., 111 Mallard Road, Melrose, Florida 32666 and by hand delivery/interoffice mail to Department of Health and its counsel, Lawrence F. Kranert, Jr., Senior Attorney, Agency for Health Care Administration, this ______ day of ______, 2001.

AMENDED CERTIFICATE OF SERVICE

DEPARTMENT OF HEALTH,

2

Petitioner,

٢.

Vs.

\$

CASE NO. 97-11523

(

JOSEPH E. STEIDL, R.PH.,

Respondent.

ADMINISTRATIVE COMPLAINT

STATE OF FLORIDA

DEPARTMENT OF HEALTH

COMES NOW the Petitioner, Department of Health, and files this Administrative Complaint before the Board of Pharmacy against the Respondent, JOSPEH E. STEIDL, R.PH., and in support thereof would state:

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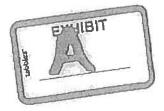
4 10 245

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1. Petitioner is the state agency charged with regulating the practice of Pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 455, Florida Statutes; and Chapter 465, Florida Statutes.

2. Pursuant to the authority of Section 20.43(3)(g), Florida Statutes, the Petitioner has contracted with the Agency for Health Care Administration, hereinafter referred to as the "Agency," to provide consumer complaint, investigative, and prosecutorial services required by the Division of Medical Quality Assurance, councils or board, as appropriate, including the issuance of emergency orders of suspension or restriction.

3. Respondent has been at all times pertinent hereto, a duly licensed pharmacist pursuant to Chapter 465, Florida Statutes, having been issued license number PS 0017002.



4. Respondent's last known address is Post Office Box 505, Florahome, Florida 32140-0505.

5. On or about July 17, 1997, an investigation was performed by agents of the Petitioner. As a result, it was discovered:

- a. In March 1997 the Respondent dispensed the medication Stadol, a schedule IV controlled substance, to a pharmacy technician known as
 B D without a prescription.
- b. The Respondent altered the prescription on file for the medication Stadol, written for the pharmacy technician known as B I to show remaining refills that were never ordered by the prescribing physician.
- c. The Respondent delivered the Stadol, a Schedule IV controlled substance, medication to the pharmacy technician at her home.

6. On March 19, 1997 the Respondent admitted to dispensing the medication to pharmacy technician B [1] [1] without a prescription.

7. The conduct of the Respondent as aforesaid is contrary to the provisions contained in Sections 465.016(1)(e) and 465.015(2)(c), Florida Statutes, by dispensing medication without first being furnished a prescription; Rule 64B16-27.810(2), Florida Administrative Code, by failing to take appropriate steps to avoid or resolve the problem of clinical abuse / misuse; Section 893.08(3)(b), Florida Statutes, by dispensing medication in other than good faith; and Section 455.624(2)(b), Florida Statutes, by intentionally violating any rule adopted by the board or department.

WHEREFORE, Petitioner respectfully requests the Board of Pharmacy to enter an Order imposing one or more of the penalties proscribed by law, together with any other and further relief deemed just under the circumstances.

SIGNED this Maday of Ma

Robert G. Brooks, M.D. Secretary, Department of Health

DEPARTMENT OF HEALTH DEPUTY CLERK CLERK Vichi R- Elison 3-10-2000 DATE

By: Nancy M. Snurkowski Chief Attorney On Behalf of the Agency for Health Care Administration

COUNSEL FOR AGENCY: Lawrence F. Kranert, Jr. Senior Attorney Florida Bar No. 0171063 Agency for Health Care Administration General Counsel's Office - MQA Practitioner Regulation P.O. Box 14229

Tallahassee, Florida 32317-4229 (850) 487-2225

LFK/rt 21/00 PCP:

STATE OF FLORIDA DEPARTMENT OF HEALTH

DOH

FILED DEPARTMENT OF HEALTH DEPUTY CLERK CLERK Melisa Nobles DATE 9/6/2011

BOAI	RD:
007.0	APR 1

BOARD OF PHARMACY

CASE NUMBER:

PS 2008-14880

COMPLAINT MADE BY;

DATE OF COMPLAINT:

June 11, 2008

COMPLAINT MADE AGAINST:

Joseph Eric Steidl, RPh P.O. Box 505 Florahome, Florida 32140

INVESTIGATED BY:

Anita M. Hill

REVIEWED BY:

Cecilie Sv Assistant General Counsel

RECOMMENDATION:

DISMISS (4099)

HOTICE OF DISMISSAL/CLOSING ORDER ON RECONSIDERATION

THE COMPLAINT: On or about October 6, 2008, an Administrative Complaint was filed with the Clerk of the Department of Health in the above-referenced case alleging that Respondent violated Section 465.016(1)(r), Florida Statutes, through violations of Rules 64B16-26.103(2)(a) and 64B16-26.603, Florida Administrative Code by failing to comply with the requirements of a continuing education audit.

THE FACTS: The Administrative Complaint alleges that Respondent failed to document and submit proof of completion of ten hours of LIVE

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continuing education credits required for the 2005 through 2007 pharmacist licensure biennium.

In response to the Administrative Complaint, Subject submitted proof of completion of the required continuing education credits.

THE LAW: Based upon the foregoing, the Department recommends that this case be closed with no further prosecution.

It is, therefore, ORDERED that this matter should be and the same is hereby DISMISSED.

DONE AND ORDERED this ale day of _____, 2011.

State Surgeon General

Michule Weine Phone BUPS Chairperson, Probable Cause Panel

Board of Pharmacy

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STATE OF FLORIDA DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

٧.

CASE NO. 2008-14880

JOSEPH ERIC STEIDL, R.Ph.,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Joseph Eric Steidl, R.Ph., and in support thereof alleges:

 Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist, within the state of Florida, having been issued license number PS 17002.

3. Respondent's address of record is 111 Mallard Road, Melrose, Florida 32666.

4. In 2008, the Board of Pharmacy conducted an audit of the continuing education credits earned by Respondent during the 2005 - 2007 licensure biennium.

5. Section 465.016(1)(r), Florida Statutes (2005,2006, and 2007), provides that violating any provision of Chapter 465, Florida Statutes, or Chapter 456, Florida Statutes, or any rules adopted pursuant thereto constitutes grounds for disciplinary action by the Board of Pharmacy.

6. Rule 64B16-26.103(1), Florida Administrative Code, provides that no biennial renewal certificate shall be issued by the Board until the applicant submits proof satisfactory to the Board that during the biennial period preceding the renewal period the applicant has participated in not less than 30 hours of approved courses of continued professional pharmaceutical education.

7. Rule 64B16-26.603, Florida Administrative Code, provides that each pharmacist shall retain documentation of participation in continuing education programs required for license renewal for not less than two years after the license is renewed for audit purposes if

and when such audit is undertaken by the Department and the Board.

8. The audit revealed that Respondent failed to document completion of ten (10) hours of Board approved LIVE continuing education nours required during the 2005-2007 biennium.

Respondent has failed to submit proof of completion of ten
 (10) hours of Board approved LIVE continuing education hours
 required during the 2005-2007 biennium.

10. Based on the foregoing, the Respondent has violated Section 465.016(1)(r), Florida Statutes (2005, 2006 and 2007), by violating a rule of the Board or Department, through a violation of Rule 64B. 5-26.103(1) and 64B16-26.603, Florida Administrative Code, by failing to submit proof satisfactory to the Board that during the biennial period preceding the renewal period the applicant has participated in not less than 30 hours of approved courses of continued professional pharmaceutical education and failing to retain documentation of participation in continuing education programs required for license renewal for not less than two years after the license is renewed for audit purposes.

er.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this lott day of October 2008.

State Surgeon General

ecilie furthe

Ana M. Viamonte Ros, M.D., M.P.H.

AT LANDER LES

Cecilie Sykes Assistant General Counsel DOH Prosecution Services Unit 4052 Bald Cypress Way, Bin C-65 Tallahassee, Florida 32399-3265 Florida Bar No. 0250340 (850) 245-4640 (850) 245-4682 FAX

DOH v. Joseph Eric Steidl, R.Ph.; DOH Case No. 2008-14880

4

PCP: Q. QUECE PCP Members: <u>Lului d</u> Hierory

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on Notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

DOH v. Joseph Eric Steidl, R.Ph.; DOH Case No. 2008-14880

Profession Code Q201 Case Number 200502546

Document Type

Clerk Discipline Filing

Vational Association of Boards of Pharmacy 1600 Feehanville Drive, Mt. Prospect, IL 60056 347/391-4400 ~ clearinghouse@nabp.net Name: Joseph Eric Steidl e-ProfileID Process Date: 6/24/14 DCN: Page: 1 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

Joseph Eric Steidl Reporting Entity: Florida Board of Pharmacy

Transaction Type: Initial Report

Date of Action: 01/12/2006

Action	Basis for Action	
- 1173 - Publicly Available Fine/Monetary Penalty	- A5 - Violation of or Failure to Comply With Licensing Board Order	

A. REPORTING ENTITY	Entity Name: Address: City, State, Zip:	Florida Board of Pharmacy 2020 Capital Circle S.E., Bin #C04, Tallahassee, FL 32399-3254
	Country: Name of Certifier: Title or Department:	US
	Telephone: Type of Report: Related Report Number:	Initial
3. SUBJECT	Subject Name:	Joseph Eric Steidl
DENTIFICATION		
NFORMATION	Other Name(s) Used: Gender:	Male
	Date of Birth:	Male
1.1	Work Address:	2720 S Blagg Rd
	City, State, ZIP:	Pahrump, NV 89048
	Deceased:	NO
	Federal Employer Identification Numbers	
	(FEIN):	
	Social Security Numbers (SSN):	
	Individual Taxpayer Identification Number	
	(ITIN):	
	National Provider Identifiers (NPI): Professional School & Year of Graduation:	University of Florida - FL (1978)
	Occupation/Field of Licensure (Code):	Pharmacist
	State License Number, State of Licensure:	PS17002, FL

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

Name: Joseph Eric Steidl e-ProfileID Process Date: 6/24/14 DCN: Page: 2 of 2

DISCIPLINARY ACTIONS ARE SUBMITTED TO NABP BY STATE BOARDS OF PHARMACY ON A VOLUNTARY BASIS, AND, ACCORDINGLY, THE FOREGOING REPORTS MAY NOT BE ALL INCLUSIVE. FURTHER, THE INFORMATION SET FORTH SHOULD BE VERIFIED WITH THE DESIGNATED DISCIPLINARY JURISDICTION AS TO THE ACCURACY AND STATUS PRIOR TO RELIANCE ON THESE REPORTS IN SUPPORT OF ANY CONTEMPLATED ACTION BY YOUR AGENCY.

Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary

: INCIDENT		
EPORTED	Type of Adverse Action: Basis for Action:	Initial - A5 - Violation of or Failure to Comply With Licensing Board Order
	Reporting Entity: Action Classification Code(s):	FL - 1173 - Publicly Available Fine/Monetary Penalty
	Date Action Was Taken:	01/12/2006
	Date Action Became Effective:	01/13/2006
	Length of Action:	Not Specified
	Monetary Penalty:	\$ 1000
	Auto Reinstate?: Description:	No Case #2005-02546: Pharmacist failed to comply with the terms of Case #97-11523 when he failed to provide proof within 1 year of completion of 12 hours of continuing education relating to the laws and rules governing the practice of pharmacy in Florida. Pharmacist is now ordered to pay a \$1,000.00 fine

and costs of \$152.56 within 30 days.

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

Final Order No. DOH-06-0103- S -MOA
FILED DATE - 1-13-06
Department of Health
AV I
By: Theresa Mckown
Deputy Agency Clerk

STATE OF FLORIDA BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

vs.

Case No.: 2005-02546 License No.: PS 17002

JOSEPH ERIC STEIDL, R.PH.,

Respondent,

FINAL ORDER

THIS MATTER came before the Board of Pharmacy (hereinafter "the Board") at a duly noticed public meeting on December 7, 2005, in Ft. Lauderdale, Florida. Petitioner filed an Administrative Complaint seeking disciplinary action against the Respondent's license to practice pharmacy. A copy of the Administrative Complaint is attached to and made a part of this Final Order. The Petitioner was represented by Deborah Loucks, Assistant General Counsel, with the Department of Health. The Respondent was not present and was not represented.

Petitioner and Respondent have stipulated to a disposition in this case. After considering the presentation of the parties and reviewing the record of the case, the Board voted to adopt the Stipulation as an appropriate settlement of the case. A copy of the settlement stipulation is attached to and made a part of this Final Order. The parties shall be governed accordingly.

Pursuant to Section 456.072(4), Florida Statutes, the Department is required to collect costs for investigation and prosecution. The evidence presented to the Board was

that the costs associated with this matter are \$152.56. Payment shall be made within thirty (30) days to the Department of Health, P.O. Box 6320, Tallahassee, FL 32324-6320.

It is therefore **ORDERED** that the Stipulation is adopted and the Respondent is hereby ordered to reimburse the Department costs in the amount of \$152.56.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this ______ day of ____ _, 2006. January

BOARD OF PHARMACY

Ribyun R. Poston

Rebecca R. Poston, R. Ph. **Executive Director** Florida Board of Pharmacy

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Mail to: Joseph Eric Steidl, R.PH., 111 Mallard Road, Melrose, Florida 32666; by interoffice mail to Reginald D. Dixon, Assistant Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; and Deborah Loucks, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin # C-65, Tallahassee, Florida 32399-

3265 this 13th day of January, 2006

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Deputy Agency Clerk

STATE OF FLORIDA DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH, BOARD OF PHARMACY,

Petitioner,

CASE NO. 2005-02546

JOSEPH ERIC STEIDL, R.PH.,

VS.

Respondent.

STIPULATION

Pursuant to Section 120.57(4), Florida Statutes, the above named parties hereby offer this Stipulation to the Board of Pharmacy as disposition of the Administrative Complaint, attached hereto as Exhibit "A," in lieu of any other administrative proceedings. The terms herein become effective only if and when a Final Order accepting this Stipulation is issued by the Board and filed. In considering this Stipulation, the Board may review all investigative materials regarding this case. If this Stipulation is rejected, it, and its presentation to the Board, shall not be used against either party.

STIPULATED FACTS

1. For all times pertinent herein, Respondent was a licensed pharmacist in the State of Florida, having been issued license number PS 17002. Respondent's address of record is 111 Mallard Road, Melrose, Florida 32666.

2. Respondent was charged by an Administrative Complaint filed by the Department and properly served upon Respondent with violations of Chapters 456 and 465, Florida Statutes. A true and correct copy of the Administrative Complaint is attached hereto and incorporated by reference as Exhibit A.

3. Respondent neither admits nor denies the factual allegations contained in the Administrative Complaint for the purposes of settlement in these administrative proceedings only.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department of Health and the Board.

2. Respondent admits that the stipulated facts, if proven true, constitute violations of law as alleged in the Administrative Complaint.

PROPOSED DISPOSITION

1. Respondent shall be present when this Stipulation is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and the disposition thereof.

2. The license of Respondent shall be reprimanded by the Board of Pharmacy.

3. The Board of Pharmacy shall impose an administrative fine of one thousand dollars (\$1,000) against the license of Respondent. Respondent shall also pay the administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed four hundred dollars (\$400). Total costs shall be assessed when the Stipulation is presented to the Board. The fine and costs are to be paid by Respondent to the **Pharmacy Compliance Officer, Department of Health, HMQ/AMS, Client Services, PO Box 6320, Tallahassee, Florida 32314-6320,** within thirty (30) days of the filing of a Final Order accepting and incorporating this Stipulation.

4. In the future, Respondent shall not violate Chapter 456, 465, 499, and/or 893, Florida Statutes, the rules promulgated pursuant thereto, or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

5. It is expressly understood that a violation of the terms of this Stipulation shall be considered a violation of a Final Order of the Board of Pharmacy for which disciplinary action may be initiated pursuant to Chapter 465, Florida Statutes.

6. It is expressly understood that this Stipulation is subject to approval by the Board and Department and has no force or effect until the Board bases an Order upon it.

7. This Stipulation is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular cause. In this regard, Respondent authorizes the Board to review and examine all -investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Stipulation. Petitioner and Respondent agree to support this Stipulation at the time it is presented to the Board and shall offer no evidence, testimony, or argument that

disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Stipulation not be accepted by the Board, it is agreed that the presentation and consideration of this Stipulation and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

8. Respondent and the Department fully understand that this Stipulation and subsequent Final Order incorporating same will in no way preclude additional proceedings by the Board and/or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint, attached hereto as Exhibit A.

9. Respondent waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

10. Respondent waives all rights to appeal and further review of this Stipulation and these proceedings.

WHEREFORE, the parties hereby request that the Board enter a Final

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Order accepting, adopting, and implementing the terms contained herein.

SIGNED this 27 day of JUMP, 2005.

Signed: /JØSEPH ERIC STEIDL, R.PH. CASE NO. 2005-02546

Sworn to and subscribed by Respondent before me this 27^{+1} day of 2005.

Notary Public My Commission Expires:

APPROVED this 10 day of angre 2005.

John O. Agwunobi, M.D., M.B.A., M.P.H. Secretary, Department of Health

Why S. Berton By: Wings S. Benton, Deputy General Counsel Department of Health

HITCA & EMITH Y COMMISSION / DD 100107

EXPIRES: Manch 2, 2007

COUNSEL FOR PETITIONER:

Deborah B. Loucks, Assistant General Counsel Florida Bar Number 0169889 Department of Health/MQA Prosecution Services Unit 4052 Bald Cypress Way, Bin C-65 Tallahassee, Florida 32399-3265 (850) 487-3908

X

STATE OF FLORIDA DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. ..

CASE NO. 2005-02546

JOSEPH ERIC STEIDL, R.PH.,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Joseph Eric Steidl, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida-Statutes; and Chapter 465, Florida-Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 17002.

3. Respondent's address of record is 111 Mallard Road, Melrose, Florida 32666.

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4. On June 29, 2001, a Final Order was filed with the Clerk of the Department of Health in the matter of the Department of Health vs. Joseph Steidl, R.Ph., Case Number 97-11523. By terms of this Final Order, the Board of Pharmacy ordered Respondent to complete twelve (12) hours of continuing education relating to the laws and rules governing to the practice of pharmacy in this state and provide proof of completion to the Florida Board of Pharmacy within one (1) year of the filing of the Final Order.

5. As of the date of the filing of this Administrative Complaint, Respondent has failed to provide proof of completion of twelve (12) hours continuing education relating to the laws and rules governing the practice of pharmacy in this state to the Board.

6. Section 465.016(1)(n), Florida Statutes (2002), provides that violating a rule of the board or department or violating an order of the board or department previously entered in a disciplinary hearing constitutes grounds for disciplinary action by the Board of Pharmacy.

7. Respondent failed to provide proof of completion of twelve (12) hours of continuing education relating to the laws and rules governing the practice of pharmacy in this state to the Board.

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8. Based on the foregoing, Respondent has violated Section 465.016(1)(n), Florida Statutes (2002), by violating an order of the board previously entered in a disciplinary hearing by failing to provide proof of completion of twelve (12) hours of continuing education relating to the laws and rules governing the practice of pharmacy in this state.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 🥼 day of	une , 2005.
	John O. Agwunobi, M.D., M.B.A., M.P.H.
s.*	Secretary, Department of Health
FILED	Céclie Sidies
DEPARTMENT OF HEALTH	Cecilie Sykes
DEPUTY CLERK	Assistant General Counsel
CLERK Neather Coleman	DOH Prosecution Services Unit
DATE 6-6-05	4052 Bald Cypress Way, Bin C-65
	Tallahassee, FL 32399-3265
	Florida Bar No. 0250340
	(850) 414-8126
	-(850)-414-1989 FAX

Joseph Eric Steidl, R.Ph., Case No. 2005-02546

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Reviewed and approved by: \underline{M} (initials) $\underline{513105}$ (date)

PCP: 5/27/85 PCP Members: alwarez + Parrado

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Joseph Eric Steidl, R.Ph., Case No. 2005-02546

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FILED
DEPARTMENT OF HEALTH
DERUTY CLERK
CLERK Theresa Mckimm
DATE 8-26-65

STATE OF FLORIDA DEPARTMENT OF HEALTH BOARD OF PHARMACY

DEPARTMENT OF HEALTH

Petitioner,

vs.

CASE NO. 2005-02546

JOSEPH ERIC STEIDL, R.PH.,

Respondent.

MOTION FOR BOARD'S FINAL ORDER BY STIPULATION

Petitioner, Department of Health, by and through its undersigned counsel, moves the above-styled cause be scheduled before the Board of Pharmacy for consideration of a Stipulation entered into between the parties as settlement of the Administrative Complaint filed in this cause.

The parties request that this matter be scheduled for hearing by the Board of Pharmacy on October 10, 2005, at the Ramada Conference Center, 2900 North Monroe Street, Tallahassee, Florida, 32303, (850)386-1027, beginning at 8:00 a.m. A copy of the entire investigative report and additional documentation in support of this motion has been provided to the Board of Pharmacy.

Respectfully Submitted,

Deborah Bartholow Loucks Assistant General Counsel Florida Bar No. 0169889 Prosecution Services Unit Department of Health 4052 Bald Cypress Way, Bin C-65 Tallahassee, Florida 32399-3265 (850)487-2225 (850)413-8417 (fax)

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided to JOSEPH ERIC STEIDL, R.PH., 111 Mallard Road, Melrose, Florida 32666 by U.S. Mail delivery on______, 2005.

Deborah Bartholow Loucks Assistant General Counsel

DBL/mt 08/22/05

FILED	
DEPARTMENT OF HEALTH	1
DEPUTY CLERK	1
CLERK Lilli Dai	he
DATE 11/14/05	\mathcal{D}
and the second sec	

STATE OF FLORIDA DEPARTMENT OF HEALTH BOARD OF PHARMACY

DEPARTMENT OF HEALTH

Petitioner,

vs.

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CASE NO. 2005-02546

JOSEPH ERIC STEIDL, R.PH.,

Respondent.

MOTION FOR BOARD'S FINAL ORDER BY STIPULATION

Petitioner, Department of Health, by and through its undersigned counsel, moves the above-styled cause be scheduled before the Board of Pharmacy for consideration of a Stipulation entered into between the parties as settlement of the Administrative Complaint filed in this cause.

The parties request that this matter be scheduled for hearing by the Board of Pharmacy on December 7, 2005, at the Bahia Mar Beach Resort, 801 Seabreeze Boulevard, Ft. Lauderdale, Florida, 33316, (954)764-2233, beginning at 8:00 a.m. A copy of the entire investigative report and additional documentation in support of this motion has been provided to the Board of Pharmacy.

Respectfully Submitted,

Deborah Bartholow Loucks Assistant General Counsel Florida Bar No. 0169889 Prosecution Services Unit Department of Health 4052 Bald Cypress Way, Bin C-65 Tallahassee, Florida 32399-3265 (850)487-2225 (850)413-8417 (fax)

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided to JOSEPH ERIC STEIDL, R.PH., 111 Mallard Road, Melrose, Florida 32666 by U.S. Mail delivery on______, 2005.

Deborah Bartholow Loucks Assistant General Counsel

DBL/mt 11/4/05

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided to JOSEPH ERIC STEIDL, R.PH., 111 Mallard Road, Melrose, Florida 32666 by U.S. Mail delivery on______, 2005.

Deborah Bartholow Loucks Assistant General Counsel

DBL/mt 11/4/05

. NEVADA STATE BOA 431 W Plumb Lane	ARD OF PHARMACY – Reno, NV 89509
CONTROLLED SUBST	TANCE APPLICATION
Registration Fee: \$80.00 (non-refu	undable money order only, no cash)
(This application can not k	be used by PA's or APRN's)
First: JAMES Middle: 103517	Last: Eells Degree: MM
Practice Name (if any): JAMES Rogert Ee	LLS MD, LTO
Nevada Address: <u>7106</u> SMOKE RANCH (This must be a practicing address, we will not issue a licens	Red Suite #: 110
PO Box:	
E-mail address:	
	e: <u>Navana</u> Zip Code: <u>89128</u>
Work Telephone (702) 796-3847	Date of Birth: 3/4/60
Fax: (702) 341-6379	Sex: 🕅 Mor 🗆 F
Practitioner License Number: <u>NV 6500</u>	Specialty: INT MENICINE
You must have a current Nevada license with you	
application. The Nevada license must remain cur registration.	Trent to keep the controlled substance
registration.	Yes No
 Been diagnosed or treated for any mental illness, include Physical condition that would impair your ability to perform 1. Been charged, arrested or convicted of a felony or misdements. Been the subject of a board citation or an administrative act 3. Had your license subjected to any discipline for violation of performance. 	rform the essential functions of your license?)这一日 eanor in <u>any</u> state?
If you marked YES to any of the numbered questions (1-3) about explanation and documentation:	ove, include the following information & provide an
Board Administrative State Date:	Case #:
Action: NONE REVIEW / /	
Criminal State Date: Case #:	County Court
Action: NV 12/1/2012 C-12-2789741	CLARK Dismicr, ELLSWORTH
It is a violation of Nevada law to falsify this application and sanctions have read this application. I certify that all statements made are true	
I understand that Nevada law requires a licensed physician who, in treasonable cause to believe, a child has been abused/neglected, to welfare services or to a local law enforcement agency.	
XIII	6/9/14
Original Signature, no copies or stamps accepted.	Date

 \mathfrak{X}

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14

Original Signature, no copies or stamps accepted.

Board Use Only: : Date Processed:

Amount:

80



JAMES R. EELLS, M.D. Board Certified Internal Medicine 1992

Exceptional Personalized Healthcare with the focus on You!

Nevada State Board of Pharmacy 431 W. Plumb Lane Reno Nevada 89509 (775) 850-1440

June 12th, 2014

Letter of Explanation

I have been a practicing physician in Las Vegas since 1992.

December 1st, 2011 I was arrested by local DEA agents for writing fraudulent prescriptions. I had become addicted to prescription medications and foolishly used a family members name to obtain medications for myself.

December 2011, at the time of my arrest, I voluntarily inactivated my medical license while going to rehab at Las Vegas Recovery Center, Dr Mel Pohl.

March 2012, as a consequence of not having an active medical license I surrendered my DEA license. June 2012 the Nevada State Medical Board re-activated my medical license with the condition that I not prescribe controlled substances and that I remain compliant with Nevada Professional Assistance Program. I have been back in private practice since June 2012.

May 2013 in agreement with District Court Judge Ellsworth the criminal charges were reduced to a single class E felony charge of possession which will be completely dropped at the end of a five year probation period. No convictions ever.

May 17th, 2014 District Court Judge Ellsworth removed the stipulation that I not re-apply for DEA license. June 6th, 2014 the Nevada State Medical Board removed condition on my license of not prescribing controlled substances.

I now come to the Pharmacy board and Drug Enforcement Agency seeking a new controlled substance and DEA license. I have taken full responsibility for my illegal foolish misconduct. I have severely learned my lesson and suffered massive consequences. I am completely and totally plugged in to Nevada Professional Assistance Program monitoring program. I have passed all random drug screens for two and a half years now. I have no inclination to ever take or abuse prescription drugs again in the future. I have never used illicit or street drugs. I've never drank alcohol. My practice is rebuilding daily. It is virtually impossible to practice without a DEA license. It is my hope that the Pharmacy Board will join with District Court Judge Ellsworth and the Medical Board and see my solid recovery and progress and approve my controlled substance and DEA licenses so I can better care for patients.

Sincerely,

1	BEFORE THE BOARD OF MEDICAL EXAMINERS		
2	OF THE STATE OF NEVADA		
3	* * * * *		
4			
5			
6	In the Matter of the License of)		
7) License No. 6500 FILED		
8	JAMES ROBERT EELLS, M.D., JUN 1 8 2014		
9	Licensee.) NEVADA STATE BOARD OF		
10	By:		
11	ORDER REMOVING PROHIBITION AGAINST PRESCRIBING CONTROLLED SUBSTANCES		
12	James Robert Eells, M.D. (Dr. Eells), License No. 6500, personally appeared in Reno		
13	before the Nevada State Board of Medical Examiners (Board) at its regularly scheduled meeting		
14	on June 6, 2014 requesting removal of the existing prohibition against prescribing controlled		
15	substances from his license to practice medicine in the state of Nevada.		
16	After considering the request and speaking with Dr. Eells, the Board enters the following		
17	order:		
18	IT IS HEREBY ORDERED that the Board's prohibition against Dr. Eells prescribing		
19	controlled substances is removed from his license to practice medicine in the state of Nevada. All		
20	other restrictions, conditions and/or turns of Dr. Eells' license to practice medicine in the state of		
21	Nevada remain the same.		
22	Failure to comply with the foregoing Order is grounds for disciplinary action pursuant to		
23	the provisions of Nevada Revised Statute 630.3065(2)(a).		
24	Dated this 6 th day of June, 2014.		
25	NEVADA STATE BOARD OF MEDICAL EXAMINERS		
26	michon f. Frie pro		
27	Michael J. Fischer, M.D., President		
28	Nevada State Board of Medical Examiners		

NEW YORK OFFICE AREA CODE 516 221-0400 254 PETTIT AVENUE BELLMORE, N.Y. 11710

NEVADA OFFICE AREA CODE 702 387-0400 602 SOUTH TENTH ST. LAS VEGAS, NV 89101

REPLY TO NEVADA OFFICE

06/16/2014

Dr. James Eells 1350 N. Town Center Dr., Apt 2047 Las Vegas, Nevada 89144

Re: State of Nevada vs. Eells: Case No.: C-12-278974-1

Dear Dr. Eells:

LAW OFFICES

Herbert Sachs

ADMITTED NEW YORK AND NEVADA BARS

Pursuant to your request, I am writing this letter to further explain the negotiation and eventual culmination of the above entitled matter.

Although the Plea Agreement is silent, it was the understanding between the Office of the District Attorney, me as your counsel and the judge that until such time as the probationary period of five years expires you will not have been adjudicated guilty of any criminal charge, including the Alford plea referred to in the Plea Agreement, that at the time of expiration of the probationary period you will be adjudicated under the civil commitment statute which specifically requires the omission of any reference to any crime that has been committed.

In short, you would be able to respond negatively to any inquiry as to your criminal history. In other words, if someone where to ask you if you were ever convicted of a crime the answer would be no.

If you have any further questions or comments please feel free to contact this office at any time.

Sincerely,

HS/db

1 2 3 4 5 6 7	GPA STEVEN B. WOLFSON Clark County District Attorney Nevada Bar #001565 JAY P. RAMAN Chief Deputy District Attorney Nevada Bar #010193 200 Lewis Avenue Las Vegas, NV 89155-2212 (702) 671-2500 Attorney for Plaintiff DISTRI	CT COURT JNTY, NEVADA	
8			
9	THE STATE OF NEVADA,		
10	Plaintiff,	CASE NO:	C-12-278-974-1
11		DEPT NO:	V
12	JAMES ROBERT EELLS, #1717257		
13	Defendant.		
14			s
15	GUILTY PLE	A AGREEMENT	
16	I hereby agree to plead guilty, purs	uant to <u>North Caroli</u>	ina v. Alford, 400 U.S. 25
17	(1970), to: POSSESSION OF CONTROLI	LED SUBSTANCE	(Category E Felony - NRS
18	453.336),, as more fully alleged in the chargi	ng document attache	d hereto as Exhibit "1".
19	My decision to plead guilty by way of the Alford decision is based upon the plea		
20	agreement in this case which is as follows:		
21	The State agrees to retain the right to	argue at rendition o	f sentence. The Defendant
22	agrees to stipulate to forfeit any and all prop	erty and firearms sei	zed in connection with this
23	case.		10 ×
24	I agree to the forfeiture as set forth	in the Stipulation t	for Compromise of Seized
25	Property which is attached hereto and incorpo	orated herein by refer	rence as Exhibit "2". I
26	understand and agree that, if I fail to intervie	w with the Departme	ent of Parole and Probation
27	(P&P), fail to appear at any subsequent hear		
28	by affidavit review, confirms probable cause	against me for new	criminal charges including
			P:\WPDOCS\INF\120\12080503.doc

reckless driving or DUI, but excluding minor traffic violations, that the State will have the unqualified right to argue for any legal sentence and term of confinement allowable for the crime(s) to which I am pleading guilty, including the use of any prior convictions I may have to increase my sentence as an habitual criminal to five (5) to twenty (20) years, life without the possibility of parole, life with the possibility of parole after ten (10) years, or a definite twenty-five (25) year term with the possibility of parole after ten (10) years.

7 Otherwise I am entitled to receive the benefits of these negotiations as stated in this8 plea agreement.

CONSEQUENCES OF THE PLEA

9

By pleading guilty pursuant to the <u>Alford</u> decision, it is my desire to avoid the possibility of being convicted of more offenses or of a greater offense if I were to proceed to trial on the original charge(s) and of also receiving a greater penalty. I understand that my decision to plead guilty by way of the <u>Alford</u> decision does not require me to admit guilt, but is based upon my belief that the State would present sufficient evidence at trial that a jury would return a verdict of guilty of a greater offense or of more offenses than that to which I am pleading guilty to.

17 I understand that as a consequence of my plea of guilty by way of the Alford decision the Court must sentence me to imprisonment in the Nevada Department of Corrections for a 18 minimum term of not less than one (1) year and a maximum term of not more than four (4) 19 20 years. The minimum term of imprisonment may not exceed forty percent (40%) of the maximum term of imprisonment. I understand that I may also be fined up to \$5,000.00. I 21 understand that the law requires me to pay an Administrative Assessment Fee. I also 22 understand that a conviction of any violation of NRS Chapter 453, the Uniform Controlled 23 Substance Act, requires that I pay a controlled substance analysis fee. 24

I understand that, if appropriate, I will be ordered to make restitution to the victim of the offense(s) to which I am pleading guilty and to the victim of any related offense which is being dismissed or not prosecuted pursuant to this agreement. I will also be ordered to reimburse the State of Nevada for any expenses related to my extradition, if any.

I understand that I am eligible for probation for the offense(s) to which I am pleading
 guilty. I understand that, except as otherwise provided by statute, the question of whether I
 receive probation is in the discretion of the sentencing judge.

I also understand that I must submit to blood and/or saliva tests under the direction of the P&P to determine genetic markers and/or secretor status.

I further understand that if I am pleading guilty to charges of Burglary, Invasion of the Home, Possession of a Controlled Substance with Intent to Sell, Sale of a Controlled Substance, or Gaming Crimes, for which I have prior felony conviction(s), I will not be eligible for probation and may receive a higher sentencing range.

I understand that if more than one sentence of imprisonment is imposed and I am
eligible to serve the sentences concurrently, the sentencing judge has the discretion to order
the sentences served concurrently or consecutively.

I also understand that information regarding charges not filed, dismissed charges, or
charges to be dismissed pursuant to this agreement may be considered by the judge at
sentencing.

I have not been promised or guaranteed any particular sentence by anyone. I know
that my sentence is to be determined by the Court within the limits prescribed by statute.

I understand that if my attorney or the State of Nevada or both recommend any
specific punishment to the Court, the Court is not obligated to accept the recommendation.

I understand that if the State of Nevada has agreed to recommend or stipulate a 20 particular sentence or has agreed not to present argument regarding the sentence, or agreed 21 not to oppose a particular sentence, or has agreed to disposition as a gross misdemeanor 22 when the offense could have been treated as a felony, such agreement is contingent upon my 23 appearance in court on the initial sentencing date (and any subsequent dates if the sentencing 24 is continued). I understand that if I fail to appear for the scheduled sentencing date or I 25 commit a new criminal offense prior to sentencing the State of Nevada would regain the full 26 27 right to argue for any lawful sentence.

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I understand if the offense(s) to which I am pleading guilty to was committed while I 1 was incarcerated on another charge or while I was on probation or parole that I am not 2 eligible for credit for time served toward the instant offense(s). 3 I understand that if I am not a United States citizen, any criminal conviction will 4 likely result in serious negative immigration consequences including but not limited to: 5 6 1. The removal from the United States through deportation; 7 2. An inability to reenter the United States; 8 The inability to gain United States citizenship or legal residency; 3. 9 An inability to renew and/or retain any legal residency status; and/or-4. 10 5. An indeterminate term of confinement, with the United States Federal Government based on my conviction and immigration status. 11 12 Regardless of what I have been told by any attorney, no one can promise me that this 13 conviction will not result in negative immigration consequences and/or impact my ability to 14 become a United States citizen and/or a legal resident. 15 I understand that P&P will prepare a report for the sentencing judge prior to 16 sentencing. This report will include matters relevant to the issue of sentencing, including my 17 criminal history. This report may contain hearsay information regarding my background and 18 criminal history. My attorney and I will each have the opportunity to comment on the 19 information contained in the report at the time of sentencing. Unless the District Attorney 20 has specifically agreed otherwise, then the District Attorney may also comment on this 21 report. 22 23 WAIVER OF RIGHTS By entering my plea of guilty, I understand that I am waiving and forever giving up 24 the following rights and privileges: 25 26 The constitutional privilege against self-incrimination, including the right to refuse to testify at trial, in which event the prosecution would 1. 27 not be allowed to comment to the jury about my refusal to testify. 28 The constitutional right to a speedy and public trial by an impartial jury, 2. free of excessive pretrial publicity prejudicial to the defense, at which 4

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1 2	trial I would be entitled to the assistance of an attorney, either appointed or retained. At trial the State would bear the burden of proving beyond a reasonable doubt each element of the offense(s) charged.
3	3. The constitutional right to confront and cross-examine any witnesses who would testify against me.
4	4. The constitutional right to subpoena witnesses to testify on my behalf.
5	5. The constitutional right to testify in my own defense.
6	6. The right to appeal the conviction with the assistance of
7	agreed upon as provided in NRS 174 035(3). Lunderstand this unter
8	conviction including any challenge based on appeal of this
 9 10	to challenge my conviction through other post-conviction remedies including a habeas corpus petition pursuant to NRS Chapter 34.
11	VOLUNTARINESS OF PLEA
12	I have discussed the elements of all of the original charge(s) against me with my
13	attorney and I understand the nature of the charge(s) against me.
14	I understand that the State would have to prove each element of the charge(s) against
15	me at trial.
16	I have discussed with my attorney any possible defenses, defense strategies and
17	circumstances which might be in my favor.
18	All of the foregoing elements, consequences, rights, and waiver of rights have been
19	thoroughly explained to me by my attorney.
20	I believe that pleading guilty and accepting this plea bargain is in my best interest,
21	and that a trial would be contrary to my best interest.
22	I am signing this agreement voluntarily, after consultation with my attorney, and I am
23	not acting under duress or coercion or by virtue of any promises of leniency, except for those
24	set forth in this agreement.
25	I am not now under the influence of any intoxicating liquor, a controlled substance or
26	other drug which would in any manner impair my ability to comprehend or understand this
27	agreement or the proceedings surrounding my entry of this plea.
28	
	5

1	My attorney has answered all my questions regarding this guilty plea agreement and			
2	its consequences to my satisfaction and I am satisfied with the services provided by my			
3	attorney.			
4	DATED this 4477 day of November, 2012.			
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6				
7	JANAES ROBERT EELLS Defendant			
8	AGREED TO BY:			
9				
10	JAY P. RAMAN Chief Deputy District Attorney			
11	Chief Deputy District Attorney Nevada Bar #010193			
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JUN 1 2 2014

Nevada State Board of Medical Examiners

MINUTES

OPEN SESSION BOARD MEETING

Held in the Conference Room at the Offices of the Nevada State Board of Medical Examiners 1105 Terminal Way, Suite 301, Reno, Nevada 89502

and videoconferenced to

the Conference Room at the Offices of the Nevada State Board of Medical Examiners/Nevada State Board of Dental Examiners 6010 S. Rainbow Boulevard, Building A, Suite I, Las Vegas, Nevada 89118

FRIDAY, MARCH 7, 2014 - 8:30 a.m.

Board Members Present Michael J. Fischer, M.D., President Theodore B. Berndt, M.D., Vice President Valerie J. Clark, BSN, RHU, LUTCF, Secretary-Treasurer Sue Lowden Bashir Chowdhry, M.D. Wayne Hardwick, M.D. Ann Wilkinson Rachakonda D. Prabhu, M.D.

> *Board Members Absent* Beverly A. Neyland, M.D.

LAS VEGAS OFFICE Board of Medical Examiners Building A, Suite 2 6010 S. Rainbow Boulevard Las Vegas, NV 89118 Phone: 702-486-3300 Fax: 702-486-3301 RENO OFFICE
 Board of Medical Examiners Suite 301
 1105 Terminal Way Reno, NV 89502
 Phone: 775-688-2559
 Fax: 775-688-2321 was taken on the motion and it passed, with all other Board members voting in favor of the motion.

Agenda Item 4

CONSIDERATION AND ACTION REGARDING PROPOSED AMENDMENTS TO NEVADA ADMINISTRATIVE CODE CHAPTER 630

(a) Consideration of Amendment to Nevada Administrative Code Chapter 630, Amending NAC 630.230 to Add Language Which Makes It Prohibited Professional Conduct to Utilize, or Allow Another Under a Licensee's Direction or Authority to Utilize, a Single-Use Medical Device in More Than One Instance, or on More Than One Patient; or Utilize, or Allow Another Under a Licensee's Direction or Authority to Utilize, a Single-Use Medical Device in a Manner Inconsistent With the Manufacturer's Packaging Instructions or Directions Included With the Medical Device

Mr. Cousineau explained that staff would like to have some additional disciplinary authority beyond the current standard of care model used in instances where it is learned a licensee has engaged in some kind of unsafe or improper injection practice or in any instance where a licensee has used a single-use medical device in multiple instances or with multiple patients. Staff is requesting authority to proceed with the regulatory adoption process to add a new section under prohibited professional conduct which would make it a violation of the Nevada Administrative Code, and therefore a violation of statute, to engage in the administration or use of a single-use medical device in more than one instance or on more than one patient, or in a manner that is inconsistent with the manufacturer's packaging instructions, and add a definition of "single-use medical device."

Discussion ensued regarding the fact that the FDA has guidelines which address this issue, but they are not mandates, and that is why staff deemed it appropriate to create a mandate via regulation.

Dr. Fischer moved that the Board authorize staff to proceed with the regulatory adoption process. Mrs. Lowden seconded the motion and it passed unanimously.

Agenda ltem 5

CONSIDERATION OF REQUEST OF JAMES EELLS, M.D. FOR REMOVAL OF CONDITION ON HIS MEDICAL LICENSE

Dr. Eells was present in Las Vegas.

Dr. Fischer explained that Dr. Eells had appeared before the Board on June 8, 2012, to request a change in license status from Inactive to Active. He was issued an Active-status license with conditions that he complete his contract with NPAP and be prohibited from prescribing any controlled substances. Dr. Eells was now requesting that the Board release him from the condition prohibiting him from prescribing controlled substances. Dr. Fischer asked Dr. Eells to explain why the Board should grant his request.

Dr. Eells stated that he was much better off than he had been two years ago. Since then, he had re-established his practice and everything was going well. From a personal standpoint, he was doing well and he was actively participating with the NPAP. He said it was extremely difficult to practice without a DEA license. He had learned his lesson and had a completely

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane □ Reno, NV 89509 □ (775) 850-1440 APPLEATEDN FOR NEVADA MedealDevee, Equipment & Gases (MDEG) \$500.00 Fee made payable to: Nevada State Board of Pharmacy (non_refundable and not transferable money order or cashler's check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

Ownership Change New MDEG □ Name Change □ Location Change (Please provide current license number if making changes: MP or MW □/Publicly Traded Corporation □ Pages 1,2,3,4 Partnership - Pages 1,2,3,6 Non Publicly Traded Corporation
Pages 1,2,3,5a,5b □ Sole Owner □ Pages 1,2,3,7 Please check box for type of ownership and complete correct part of the application. GENERAL INFORMATION to be completed by a types of ownership Amador Medical MDEG Name: 32 Kasteh Jma Ke Kanch Physical Address: This must be a business address, we can not issue a license to a home address Mailing Address: 7320 Smoke Ranch Rol Ste H State: NVZip Code: 89128 City: LOS 2 Fax: Telephone: E-mail: DAYS AND HOURS THAT THE FACEEV WELL BE REGULARLY OPERATENG Wed: 9 to 5 Thu: 9 to 5 Mon: 9 to 5 Tue: 9 to 5Sat: On call Sun: on call 9 to 5Eri: Holidays: oncal MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required) Amado >onal Name: TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE) □ Medical Gases** Assistive Equipment Parenteral and Enteral Equipment** X Respiratory Equipment** X Orthotics and Prosethics □ Life-sustaining equipment** □ Diabetic Supplies Other: **If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact. Name: Telephone: _ 702 237 9984 Page 1 1010673

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider	numbers registered	to the business or its owner:
Elot an modificate and modificate provider	nambere regieterea	

1)	Do any shareholders hold an interest ownership or have management in		
- 55	any type of business or facility which are licensed by the State of Nevada		
	or another political jurisdiction?	Yes 🗆	No 🗗

2)	Are you or have you in the last year been associated with any person,	
	business or health care entity in which MDEG products were sold,	
	dispensed or distributed?	Yes 🗆 No 🗔

3) Are any of the owners health professionals? If yes, please check the box and list name.

Practitioner	Name:	
Advanced Practitioner of Nursing	Name:	
Physician 🛽 Assistant	Name:	
Physical Therapist	Name:	
Occupational Therapist	Name:	
Registered Nurse	Name:	
Respiratory Therapist	Name:	

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1)	Has the corporation, any owner, shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes 🗆 No 🗹
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes 🗆 No 😡
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry?	Yes 🗆 No 🗹
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	Yes 🗆 No 🗔
5)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	Yes 🗆 No 🔽

If the answer to questions 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may-deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Print Name of Author	ized Person	5-1-14 Date	
Board Use On ₽	Received: 5/27/14-	Amount: <u>\$500,00</u>	

Page 3	3
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APPLICATION FOR NEVADA MDEG LICENSE

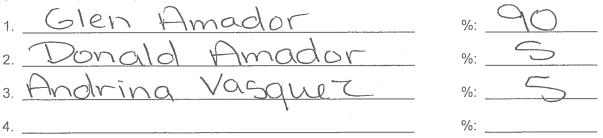
OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: NEVAda
Parent Company if any:NA
LL Corporation Name: Amador Medical LLC
Mailing Address: 7320 Smoke Ranch Rd # H
City: Las Vegas State: NV Zip: 89128
Telephone: 1022398556 Fax: 658/039
License Contact Person: Donald Amador

Ownership Information
Complete Section 1 or 2

Do not use N/A In this section Section 1 or 2 must be completed

<u>Section 1:</u> List the corporations four largest shareholders: (Name and percentage of ownership)



<u>Section 2:</u> If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation:

Registration number issued:

Stock Exchange: _____

hclude with the application for a public traded corporation

List of officers and directors.

<u>Certificate of Corporate status</u> (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of States office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

\$1Date 4 28 2014

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Mudical Devices EC Amador Mudical Walture of Licenses	20 Smoke Ranch Ral #1
Name and Address of Establishment for Whic	n License Is Requested
If applicable, Name Under Which It Is	Now Operated
1. PERSONAL INFORMATION: Amador-JUanz Donal Last Name First Name	C/l Middle Name
Alias (es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)	,
	= 3111 LV NIV 89145
Present Residence Address-Street or RFD City	State/Zip
Present Business Address	State/Zip
Occupation	Phone:
Date of Birth (Oity, County, State)	Caraguna
97	M
Age Sucial Security Number Br. Br. Tol 17	U Med 5811
Color of Eyes Color of Hair Complexion Weig	ht Build Height
Scars, tattoos or distinguishing marks and/or characteristics	
Are you a citizen of the United States? Yes D No X If alien, regi	stration N
If naturalized, certificate NoDat	9
Place(If r	naturalized, document must be verified.)
2. MARITAL INFORMATION:	
Single Married Separated Divorced Wide	owed 🗆 Engaged 🗆
	Applicant's initialDA

λ.	Current Ma	Da			City, County a	and State
	Spouse's fu	ll name (Maiden)			S.S. No	
	Date of Birth	۱	Place o	f Birth		
	Resident ad	dressStreet		Citv	State	Zip
		Residence				
		nployer				
		employer Street		City	State	Zip
B. F	Previous Marri	ages: If ever legally se	eparated, divorced, or	annulled, indica	te below:	
	of Spouse		Date of Place of Marriage	Nature		y unty and State
ame		UI Declee	Of Mainage	/0101	00	
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		s. current address and				
	List of name		telephone numbers of City	of previous spou	ses: Zip	
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FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name_____

Address

Contact person_____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation, Name (Maiden) Birth Date Address Occupation

Father Ivan Rene Amada	or Arrieta	Desea	sect)
Mother	ita Juarez E	SPINOZA	
Father-in-Law	Nicar	DUPIO	A)
Mother-in-Law		U	

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Glen Amo	dor		Amador Medical
Spouse Emilie Ar	nador		

Spouse

Spouse

Spouse

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate /
Grammar		in the h	lice polle	
School	194	MILLAUOL P	MARALIA	Yes 🕑 No 🗆
High		monduri	1 Viccircution	
School	1011	MAGUL	MUMAGAU	Yes 🗹 No 🗖
College	N			
University	K A	ALMANNE	2. 1. 1.	Yes 🛛 No 🗹
Other	10 (1, NICATOR	10 Yes D No D
Type of degr	ree obtained, if any		<u> </u>	J
Colleae or u	niversity where obtained			
			* * * * * * * * * * * * * * * * * * * *	
			Applicant	's initial DA

А.	Have you ever served in any armed for	ces? Yes 🗆 N	10 2		
	Branch	Date of entry-activ	ve service		
	Date of separation	Type of discharge)		
	Rating at separation	Serial nur	mber		
	While in the military service were you ev special or general court martial? regardless of where they occurred-foreig	Yes 🗆 No 🗆 If yes, fur	which resulted in sun nish details on page	nmary act 10. (List	tion, a trial all incident
В.	Have you registered for the draft?	Yes 🗆 No 🗹			
	CountyState	D	ate registered		
з. A	RRESTS, DETENTIONS, LITIGATIONS A	AND ARBITRATIONS: (In	clude those arrests	in which	ı you were
A.	not convicted.) Have you ever been arrested, detained, violation for any reason whatsoever, reg Yes D No D If yes, give details in spa	ardless of the disposition o	f the event? (Except	minor tra	
		ce provided below. List an	cases without excep		
ate of	, · · · · · · · · · · · · · · · · · · ·	Location-City and State			Agency
B.	Arrest Age Charge	Location-City and State	Deposition/Date	Arresting	you were
В.	Arrest Age Charge Has a criminal indictment, information or arrested or in which you were named as page 10.	Location-City and State	Deposition/Date ned against you, but ′es □ No ☑ If yes.	Arresting for which furnish d	you were etails on
В. С.	Arrest Age Charge Has a criminal indictment, information or arrested or in which you were named as page 10. Have you ever been questioned or depo or committee? Yes □ No ☑	Location-City and State complaint ever been retur an unindicted co-party? Y sed by a city, state, federa	Deposition/Date ned against you, but ′es □ No ⊡∕ If yes. I or law enforcement	Arresting for which furnish d agency, o	you were etails on commissio
В. С. D.	Arrest Age Charge Has a criminal indictment, information or arrested or in which you were named as page 10. Have you ever been questioned or depo or committee? Yes D No D Have you ever been subpoenaed to app commission? Yes D No D	Location-City and State	Deposition/Date ned against you, but 'es □ No ⊡ If yes. I or law enforcement ral, state or county g	Arresting for which furnish d agency, o rand jury,	you were etails on commissio board or
В. С. Е.	Arrest Age Charge Has a criminal indictment, information or arrested or in which you were named as page 10. Have you ever been questioned or depo or committee? Yes □ No □ Have you ever been subpoenaed to app commission? Yes □ No □ Have you ever been subpoenaed to test Yes □ No □	Location-City and State complaint ever been retur an unindicted co-party? Y sed by a city, state, federa ear or testify before a fede ify for any civil, criminal or	Deposition/Date ned against you, but 'es □ No ☑ If yes. I or law enforcement ral, state or county g administrative proce	for which for which furnish d agency, o rand jury, eding or h	you were letails on commissio board or nearing?
В. С. D.	Arrest Age Charge Has a criminal indictment, information or arrested or in which you were named as page 10. Have you ever been questioned or depo or committee? Yes □ No □ Have you ever been subpoenaed to app commission? Yes □ No □ Have you ever been subpoenaed to test Yes □ No □ Have you ever been subpoenaed to test Yes □ No □ Have you ever been subpoenaed to test Yes □ No □	Location-City and State complaint ever been retur an unindicted co-party? Y sed by a city, state, federa ear or testify before a fede ify for any civil, criminal or ord expunged or sealed by	Deposition/Date ned against you, but 'es □ No ☑ If yes. I or law enforcement ral, state or county g administrative proces	Arresting for which furnish d agency, o rand jury, eding or h	you were etails on commissio board or nearing?
В. С. D. Е.	Arrest Age Charge Has a criminal indictment, information or arrested or in which you were named as page 10. Have you ever been questioned of depo or committee? Yes □ No ☑ Have you ever been subpoenaed to app commission? Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever had a civil or criminal rec If yes, when? Have you ever received a pardon or defendence	Location-City and State complaint ever been retur an unindicted co-party? Y sed by a city, state, federa ear or testify before a fede ify for any civil, criminal or ord expunged or sealed by city, county and st erred prosecution for any c	Deposition/Date ned against you, but 'es □ No ☑ If yes. I or law enforcement ral, state or county g administrative proce a court order? Yes ate riminal offense? Yes	Arresting for which furnish d agency, o rand jury, eding or h	you were letails on commissio board or nearing?
В. С. Е. F.	Arrest Age Charge Has a criminal indictment, information or arrested or in which you were named as page 10. Have you ever been questioned of depo or committee? Yes □ No ☑ Have you ever been subpoenaed to app commission? Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever been subpoenaed to test Yes □ No ☑ Have you ever had a civil or criminal rec If yes, when? Have you ever received a pardon or defendence	Location-City and State complaint ever been retur an unindicted co-party? Y sed by a city, state, federa ear or testify before a fede ify for any civil, criminal or ord expunged or sealed by city, county and st erred prosecution for any c city, county and st ur spouse's family ever bee	Deposition/Date ned against you, but 'es □ No ☑ If yes. I or law enforcement ral, state or county g administrative proce a court order? Yes ate	Arresting for which for which furnish d agency, o rand jury, eding or h No No No No No No No No No No	you were etails on commissio board or nearing?

Applicant's initial _____ ∫ ∧____ Page 4

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
 Yes □ No □ (Other than divorces)
 If yes, give details below. List all cases without exception, including bankruptcies:

J. Has any general pathership, business venture, sole proprietorship or closely held corporation (whi associated with // f as an owner, officer, director or partner) been a party to a lawsuit, arbitration or b Yes Name of Entity Type of Entity. Approximate Date(s) of Lawsuit/Arbitration/Bankruptey Residences you have had for the last 25 years: anth and Year (From To) Street and Number City State or County	laintiff/Defendant or laimant/Respondent	Court and Case Date Filed Number	City, County and State	Disposition/Date
Approximate Date(s) of Name of Entity Curve of	amanartoopontoon			Disposition/Date
associated with if as an owner, officer, director or partner) been a party to a lawsuit, arbitration or b Yes No If yes, complete the following: Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy RESIDENCES: t all residences you have had for the last 25 years: th and Year From-To) Street and Number City State or County		· · · · · · · · · · · · · · · · · · ·		
Approximate Date(s) of Name of Entity RESIDENCES: t all residences you have had for the last 25 years: Th and Year Trom-To) Street and Number City State or County				
associated with if as an owner, officer, director or partner) been a party to a lawsuit, arbitration or b Yes No If yes, complete the following: Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy Residences you have had for the last 25 years: th and Year From-To) Street and Number City State or County				
associated with if as an owner, officer, director or partner) been a party to a lawsuit, arbitration or b Yes No If yes, complete the following: Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy RESIDENCES: t all residences you have had for the last 25 years: th and Year From-To) Street and Number City State or County				
Name of Entity Type of Entity Lawsuit/Arbitration/Bankruptcy Name of Entity Lawsuit/Arbitration/Bankruptcy RESIDENCES: Image: Comparison of the last 25 years: t all residences you have had for the last 25 years: Image: City Th and Year Street and Number From-To) Street and Number City State or County	J. Has any general associated with <i>i</i> Yes □ No I	partnership, business venture, so t as an owner, officer, director or p f yes, complete the following:	le proprietorship or closely held partner) been a party to a lawsu	d corporation (while you w iit, arbitration or bankrupt
Name of Entity Type of Entity Lawsuit/Arbitration/Bankruptcy Lawsuit/Arbitration/Bankruptcy			Approxima	ate Date(s) of
t all residences you have had for the last 25 years: nth and Year From-To) Street and Number City State or County	Name of Entity	Type of Entity	Lawsuit/A	rbitration/Bankruptcy
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Ith and Year From-To) Street and Number City State or County	RESIDENCES:			
anth and Year From-To) Street and Number City State or County	t all residences vou ba	ve had for the last 25 years:		
Trom-To) Street and Number City State or County State or County		-		
	-rom-ro)	Street and Number	City	State or County
	5			
		and the second secon		
Applicant's initial				-

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8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
0.9/90//	Amador Medical LL	C Current
Director	Description of Duties Operations Mat.	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees,

Name of Where Employed Street	Olive Otate 7's Talash		
	City State Zip Teleph	one Years H	Known
Name TILLAFIR A Home II	LATING LOG IN LO		
Employer Manployed Business	DITISTON MALL M	<u> </u>	
Name VACA Home	UD PIRALES COVE		
Employed MM PLOYEO Business	NIX		(+ -)
Name FLMAMOLO Home 73	300 Prates Cou	18 # 1081.)
Employer HT YUUY SUV VI (Business)	JA		_ `
Name FUILLI' HO SMUTHOME 75	300 Pirates Cove .	#1081	. 5)
Employer III & OF LV Business			(
ALCOLOG SI.	18 SAMUL SIDE	PCT.	(5)
Name 18571Ca Home ON	70 -00000000000000000000000000000000000		()
Employer V 12 CA 1100 Business			
	ox or other such depository, access to a	any depository or do you	use any other
person's depository? Yes D No If yes, complete the following:			
		·····	
Box Number or Type of Depository	Location City and State	Authorized Users	
C			
	occupational or professional license in	any state, including but	not limited to
the following: Liquor Lawyer	Race horse/race dog owner	Securities dealer	Insurance
	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant Pilot Yes □ No ⊠	Sports promoter	Trainer or manager	Educator
If yes, state type, where and yea	rs held		
12. Have you ever applied for a city,	county of state business, venture or inc	dustry license or held a fi	nancial
interest in a licensed business or	industry OUTSIDE the State of Nevad	a? Yes 🗆 No 🔽	
interest in a licensed business or If yes, state type, when and wher	industry OUTSIDE the State of Nevad e and give names and locations of the	a? Yes □ No ↓ businesses in which you	were
interest in a licensed business or If yes, state type, when and wher	industry OUTSIDE the State of Nevad	a? Yes □ No ↓ businesses in which you	were
interest in a licensed business or If yes, state type, when and wher involved, the names and address	industry OUTSIDE the State of Nevad e and give names and locations of the	a? Yes □ No ↓ businesses in which you	were
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interest in a licensed business or If yes, state type, when and wher involved, the names and address	industry OUTSIDE the State of Nevad re and give names and locations of the s of all partners and the agency respons	a? Yes □ No ↓ businesses in which you	were Isiness,

13.	Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes D No A
14.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes 🔲 No 🕰
lf yes t	o the above, state where, when and for what reason:
15.	Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability?
16.	Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes D No
17.	Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances?
18.	Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes D No Z
19.	Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes □ No ↓

	Date of photograph 5112014
	Applicant's initial

STATE OF NEVADA

SS.

COUNTY OF CLARK

I, <u>Donal</u> <u>Amades - Surac</u>, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

05 Subscribed and Sworn to before me this day of 1014 MA \sim Notary Public



Applicant's initial Page 9

Blank

NEVADA STATE BOARD OF PHARMACY 431 W Plumb Lane – Reno, NV 89509 APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

 ✓ New Pharmacy or □Ownership Change (Provide current license number if making changes: PH_____

 Check box below for type of ownership and complete all required forms.

 □ Publicly Traded Corporation – Pages 1,2,3,7
 □ Partnership - Pages 1,2,5,7

 ✓ Non Publicly Traded Corporation – Pages 1,2,4,7
 □ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership					fownership
Pharmacy Name:	ARJ Infusion Sei	rvices			
Physical Address: 10049 Lakeview Aver			nue, Ler	ıex	(a KS 66219
Mailing Address:	10049 Lakeview	Avenu	le		
City: Lenexa					Zip Code: 66219
Telephone: (866) 451-8804	Fax: (877) 45	51-	8955
Toll Free Number:	(866) 451-8804		(Required	l pe	er NAC 639.708)
F-mail info@arj	infusion.com	\	Nebsite:	w۱	ww.arjinfusion.com
					License Number: 1-10863 [KS]
	E OF PHARMACY	AND	<u>5E</u>	KVI	CES PROVIDED
Yes/N	0		Yes	s/No	
	Retail			-	Off-site Cognitive Services
	Hospital (# beds)	\checkmark		Parenteral **
	Internet				Parenteral (outpatient)
	Nuclear				Outpatient/Discharge
	Ambulatory Surgery C	enter			Mail Service
	Community				Long Term Care
	Other: Mail Order/Close	ed Door			Sterile Compounding **
					Non Sterile Compounding
All bo	xes must be checked		\checkmark		Mail Service Sterile Compounding **
For th	e application to be comp	olete		26 Yes	Other Services:

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

67002

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes 🗆 No 🗹
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes 🗆 No 🗹
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?	Yes 🗆 No 🗹
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	Yes 🗆 No 🗹
5)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	Yes 🗆 No 🗹

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

wrch

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mary Lisa Sackuvich, RN, BSN, CRNI

Print Name of Authorized Person

Amount: 500

Board	Use	Only	

Date Processed:

		1	a	У	C

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Kansas
Parent Company if any: N/A
Mailing Address: 10049 Lakeview Avenue
City: Lenexa State: KS Zip: 66219
Telephone: (866) 451-8804 Fax: (877) 451-8955
Contact Person: William E. Cary, RPh
For any corporation non publicly traded, disclose the following:
1) List top 4 persons to whom the shares were issued by the corporation?
a) Mary Lisa Sackuvich, 17713 Emerald View Dr., Raymore, MO 64083 Name Address
b) Douglas P. Martin, 8315 Jacomo Ridge, Lee's Summit, MO 64064
Name Address
C)
Name Address
d)
Name Address
2) Provide the number of shares issued by the corporation. 5000
3) What was the price paid per share? <u>\$0.01</u>
4) What date did the corporation actually receive the cash assets? <u>6/1/2000</u>
5) Provide a copy of the corporation's stock register evidencing the above information See Exh.
List any physician shareholders and percentage of ownership.
Name: <u>N/A</u> %: <u>N/A</u>
Name:%:%
Hours of Operation for the pharmacy:
Monday thru Friday <u>8:30</u> am <u>5:00</u> pm * Saturday *ampm
Sunday *ampm 24 Hours X*
*24hr on-call 7 days/week A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: <u>N/A</u>

Page 4

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

L Mary Lisa Sackuvich, RN, BSN, CRNI

Responsible Person of ARJ Infusion Services, Inc.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Da AacRuurch Person Authorized to Submit Application, no copies or stamps

Mary Lisa Sackuvich, RN, BSN, CRNI Print Name of Authorized Person

5/22/2014

800 SW Jackson St., Suite 1414 Topeka, KS 66612



Phone: (785) 296-4056 Fax: (785) 296-8420 pharmacy@pharmacy.ks.gov www.kansas.gov/pharmacy

Debra L. Billingsley, Executive Secretary

Sam Brownback, Governor

April 8, 2014

Nevada State Board of Pharmacy Larry L Pinson, Executive Secretary 431 W Plumb Lane Reno NV 89509

Dear Sir/Madam:

ARJ Infusion Services Inc, 10049 Lakeview Avenue, Lenexa, Kansas 66219 was issued a pharmacy license 7-21-04 and the license expires 6-30-14. The license number 2-09948 is active, in good standing, and has no disciplinary actions.

If you have any questions, contact me at 785-296-4056 or by email Jamie.Fitzhugh@pharmacy.ks.gov

Sincerely,

Jame

Jamie Fitzhugh Senior Administrative Assistant Kansas Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

Check box below for type of ownership and complete all r	equired forms. ☐ Partnership - Pages 1.2.5.7
Publicly Traded Corporation – Pages 1,2,3,7 Non Publicly Traded Corporation – Pages 1,2,4,7	☐ Sole Owner – Pages 1,2,6,7
GENERAL INFORMATION to be completed by all t	types of ownership
Pharmacy Name: <u>Aureus Pharmacy</u>	
Physical Address: 305 Merchant Lan	e, Pittsburgh PA 15205
Mailing Address: 305 Merchant Lane	
City: <u>Pitts burgh</u> State: <u>PA</u>	Zip Code: 15205
Telephone: 412-788-2800 Fax: 412	
Toll Free Number: 844-428-7387 (Req	uired per NAC 639.708)
E-mail: info Baureushealth services comWebs	site: WWW. au/eushealthservices.com
Managing Pharmacist: Edward P. Finn	License Number: RP034684L
TYPE OF PHARMACY AND	SERVICES PROVIDED
Yes/No	Yes/No
🐱 🗆 Retail	D D Off-site Cognitive Services
🗆 🖙 Hospital (# beds)	Parenteral * per phone call 4/17 Ch
🗆 🖼 Internet	Approximation (outpatient)
ED Nuclear	Outpatient/Discharge
Ambulatory Surgery Center	🔂 🗆 Mail Service
🔂 🗆 Community	□ 🔂 Long Term Care
□	□ 🔁 Sterile Compounding **
	🗆 🕤 Non Sterile Compounding
All boxes must be checked	Mail Service Sterile Compounding **
For the application to be complete	Arr Other Services:

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes 🗆 No 🔯
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes 🗆 No 🔯
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?	Yes 🗆 No 🐙
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	Yes 🗆 No 🕅
5)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	Yes 🗆 No 🔯

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Valenti, CFO

Print Name of Authorized Person

Board Use Only

Amount:	500-	

Page 2

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware
Parent Company if any: Town Total Health, LLC
Mailing Address: 532 Broadhollow Rd. Ste. 137
City: Melville State: NY Zip: 11747
Telephone: 516.249.7400 Fax: 631.532.3437
Contact Person: Paul A. Valenti
For any corporation non publicly traded, disclose the following:
1) List top 4 persons to whom the shares were issued by the corporation?
a) TOWN TOTAL Holdings, Inc., Sole Member Melville My 11747 Name Address
b)
Name Address
c)
Name Address
d)
Name Address
2) Provide the number of shares issued by the corporation. <u>N/A</u>
3) What was the price paid per share? <u>N/A</u>
4) What date did the corporation actually receive the cash assets? N/A
5) Provide a copy of the corporation's stock register evidencing the above information N/A
List any physician shareholders and percentage of ownership.
Name: N/A %:%
Name:%:
Hours of Operation for the pharmacy:
Monday thru Friday 9 am 9 pm Saturday closed am pm
Sunday closed am pm 24 Hours on <u>call</u> pharmacist via
A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

1, Paul A-Valenti

Responsible Person of Avreus Pharmacy hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Paul A. Valenti

Print Name of Authorized Person

4/11/14 Date

April 15, 2014

CERTIFICATION OF LICENSE

This is to certify that the individual or business named below is licensed by the Department of State, Bureau of Professional and Occupational Affairs:

NAME:	AUREUS PHARMACY
LICENSE TYPE:	Pharmacy
LICENSE NUMBER:	PP482443
ORIGINAL LICENSURE DATE:	01/27/2014
EXPIRATION DATE:	08/31/2015
STATUS:	Active

The license is in good standing and the records indicate no derogatory information.

Seal

Travis N. Ley

Commissioner Bureau of Professional and Occupational Affairs

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

irrent license number if making changes: PH_D2329 required forms.
Partnership - Pages 1,2,5,7
types of ownership
armacies LLC DBA Band HPharmacy
F
Zip Code: 84601
-373-0673
quired per NAC 639.708)
site:
License Number:6 <u>046694-1</u> 70
SERVICES PROVIDED
Yes/No
A Off-site Cognitive Services
□ 🕱 Parenteral **
🗷 🛛 Parenteral (outpatient)
⁻j⊀ □ Outpatient/Discharge
□ 🕱 Mail Service
🜾 🗆 Long Term Care
Sterile Compounding **
□ Sterile Compounding ** ズ □ Non Sterile Compounding

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

44154

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes I No X 	1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes 🗆 No 🛧
 interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes INO X 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes INO X 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration 	2)	any interest, ever been denied a license, permit or certificate of	Yes 🗆 No 🕱
 interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration 	3)	interest, ever been the subject of an administrative action, board citation,	Yes 🗆 No 🎸
interest, ever surrendered a license, permit or certificate of registration	4)	interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled	Yes 🗆 No 🕅
	5)	interest, ever surrendered a license, permit or certificate of registration	Yes 🗆 No 🐙

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

lean-	and Authorize	d to Submit Applicati	on, no copies or stamps	
Kent	(ay loc		5(20/14	
Print Name of Aut	horized Person		Date	Page 2
Board Use Only	Date Processed: _	6/17/14	Amount: 500-	

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP	General	Limited
Partnership Name: Hobble Creek Fam	ily Pharmacies	LLC
Mailing Address: <u>367 ご 1400 ル</u>		
City: <u>Mapleton</u> State: _	UT Zip Code:	84664
Telephone Number: <u>80(-}19-2345</u> F Contact Person: <u>Kent Taylor</u>	ax Number: <u>NA</u>	
Contact Person: Kent Taylor		
List each partner and identify whether (G)eneral of Use separate sheet if necessary	or (L)imited partner and	percentage of ownership
Name	<u>G</u> or	<u>Percentage</u>
	·	
List names of 4 largest partners and percentage of Name: $Keut$		%: /.5
Name: Shelley Cupler		%. 35
Name: <u>Kent (aylor</u> Name: <u>Shelley (aylor</u> Name: <u>Niccole Webster</u>		%: 50
Name:		
List any physician shareholders and percentage o	f ownership.	
Name:		%:
Name:		%:
Name:		%:
Hours of Operation for the pharmacy:		
Monday thru Fridayampm	Saturdav	<u> </u>
Sunday ampm	24 Hours	
A Nevada business license is not required, howev		·

Page 6

license please provide the number:

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

1. Kent Taylor Responsible Person of Hobble Creek Family Pharmacies LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Kent Taylor 5/20/14 Print Name of Authorized Person Date



State of Utah Department of Commerce

Division of Occupational and Professional Licensing

GARY R. HERBERT Governor FRANCINE A. GIANI Executive Director MARK B. STEINAGEL Division Director

VERIFICATION OF UTAH LICENSURE

DOPL-FM-001 REV 06/08/2009 Created On: 5/27/2014 Created By: Ben Jones

Name of Licensee (as it appears in our records): Hobble Creek Family Pharmacies LLC DBA B & H Pharmacy

286 W Center St Provo UT 84601

Classification of License Issued: Pharmacy - Class A

License Number: 8890134-1703

Obtained by: Application

Current Status: Active

Original Date of Licensure: 12/23/2013

Expiration Date: 09/30/2015

Disciplinary Action:

____x___No

Title:_ LEC. Spec Signature: Date: May

The information provided on this form is accurate and correct as of the verification creation date listed on the top of this form. Original issue dates listed, as 01/01/1910 and 01/01/1911 were unknown when the division implemented its first licensing database. If you have any questions, please contact the Division.





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NEVADA STATE BOARD OF PHARMACY 431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440 APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

1

· ·] Ownership Change
(Please provide current license number if r	making changes: PH)
□ Publicly Traded Corporation – Pages 1,2,3,7	Partnership - Pages 1,2,5,7
Non Publicly Traded Corporation – Pages 1,2,4,7	
GENERAL INFORMATION to be completed by all typ	es of ownership
Pharmacy Name: FOCUS RV	
Physical Address: 1361 Lincoln AVE.	LINIT 9
Mailing Address: 13/01 Lincoln AVE.	Unit9
City: HONDROCK State: NEW) <u>イバイ</u> Zip Code: <u>1174</u>
Telephone: (231) 319-1920 Fax: (103)	
Toll Free Number: $(889) 464 - 8987$ (Require	ed per NAC 639.708)
E-mail: <u>Bicharolem pacusa.com</u> Website	: myforusrx.com
Managing Pharmacist: Richard F, Colling	License Number: 046263

	Yes/No	Yes/No
R- 4	🗆 🖄 Retail	I Ø Off-site Cognitive Services
	□ 🛛 Hospital (# beds)	D Parenteral **
	Ki Internet	고 고 Parenteral (outpatient)
	D X Nuclear	D G Outpatient/Discharge
	Ambulatory Surgery Center	🔯 🛛 Mail Service
	D Other: Specialty /	🛛 🖾 Long Term Care
	Infusion	□ Ø Sterile Compounding **
		口 的 Non Sterile Compounding
		🗡 🗆 Mail Service Sterile
		Compounding **
		Other Services:

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

APPLICATION FOR OUT-OFSTATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes 🗆 No 🛛
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes 🗆 No 🗹
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry?	Yes 🗆 No 🗹
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	Yes 🗆 No 🖌
5)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	Yes 🗆 No 🗹

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Richard E. Collins	1 30 14
Print Name of Authorized Person	Date
1	

Board Use Only	Received:	2/24/14-	Amount: \$500.00
		D 0	

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: New York
Parent Company if any:
Corporation Name: FOCUS RX Pharmany Services Inc.
Mailing Address: 1361 Lincoln AVE. UNIT 9
City: HOIbroak State: NewYorkzip: 1174
Telephone: (031)319-10120 Fax:(1031) 319-1921
Contact Person: Richard E. Collins

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

	a) R(Hand E. COllins TANDECA: Blue Point NY 11715 Name Address
	b) Chris Var Varo 333 canada Ave, Sayville NY 11792 Name Address
	c) ELDANE BASIN'I 171 CPOLAR KINE BABYION NY 11'702 Name Address
	d) Laure Rame Address
2)	Provide the number of shares issued by the corporation. 200
3)	What was the price paid per share? No par value
4)	What date did the corporation actually receive the cash assets?
5)	Provide a copy of the corporation's stock register evidencing the above information
List an	y physician shareholders and percentage of ownership.
Name:	%:
Name:	%:%

Include with the application for a non publicly traded corporation

<u>Certificate of Corporate Status</u> (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

CORPORATE STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

1. Richard E. Collins Responsible Person of Focus Ax Pharmacy Services Inc. hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

INE

Original Signature of Person Authorized to Submit Application, no copies or stamps

Richard E. Collin 1/30/14 Print Name of Authorized Person Date

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

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(non-refundable and not transferable money order or cashier's check only) Application must be printed legibly or typed

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New Pharmacy or Ownership Change (Provide current license number if making changes: PH Check box below for type of ownership and complete all required forms. Publicly Traded Corporation – Pages 1,2,3,7 Non Publicly Traded Corporation – Pages 1,2,4,7 Sole Owner – Pages 1,2,6,7			
GENERAL INFORMATION to be completed by all types of ownership			
Pharmacy Name: Inventive Linfulon Solutions, LP			
Physical Address: 18866 Store Or	ale Parkway Ste 101 a		
Mailing Address: 18866 STONE C			
City: San Antonio State:			
Telephone: 210 - 494 - 4272 Fax: 210	-494-0200		
Toll Free Number: 1877-234-3682 (Required per NAC 639.708)			
E-mail: Jeremy@invontiverx.com Webs	ite: inventile ix. com		
Managing Pharmacist: Jeremy Drivila License Number: 41669			
1	SERVICES PROVIDED		
Yes/No	Yes/No		
□ 🗹 Retail	Off-site Cognitive Services		
□ 🗹 Hospital (# beds)	□ 😰 Parenteral **		
□ ū⁄ Internet	₽ □ Parenteral (outpatient)		
D 🗹 Nuclear	□ ☑ Outpatient/Discharge		
Ambulatory Surgery Center	₪ / □ Mail Service		
🕅 🗆 Community	Long Term Care		
Other:	🕼 🛛 Sterile Compounding **		
	Non Sterile Compounding		
All boxes must be checked	Mail Service Sterile Compounding **		
For the application to be complete	Other Services:		

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,



APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes 🗆 No 🖌
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes 🗆 No 🗹
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?	Yes 🗆 No 🛛
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	Yes 🗆 No 🗹
5)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	Yes 🗆 No 🗹

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

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Original Signature of Person Authorized to Submit Application, no copies or stamps 1274 Name of Authorized Person Date

6 25/14

Date Processed:

Board Use Only

Page 2 Amount: \$500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General Limited
Partnership Name:Interntive Infusion Solutions, LP
Mailing Address: 18866 Stone Oak Parkway Stel0/a
City: <u>San Antonia</u> State: <u>TX</u> Zip Code: <u>7F258</u>
Telephone Number: 210-494-4272 Fax Number: 216-494-0200
Contact Person: Teremy R Davils
List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership Use separate sheet if necessary
Name <u>Gor L</u> Percentage
Store Oak Pharmany Manasament Com LLC G
List names of 4 largest partners and percentage of ownership: Name: <u>Ernesite Carta Bongera II</u> %: <u>49.5</u>
Name: Jerenny R. Davili %: 49.5
Name:%:%
Name:%:%
List any physician shareholders and percentage of ownership.
Name:%:%
Name:%:%
Name:%:%
Hours of Operation for the pharmacy:
θ β
Sundayampm 24 Hours

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number:

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

R Dovil Ι. JUHUNS Responsible Person of

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Print Name of Authorized Person

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

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□ New Pharmacy or **ACONNERShip Change** (Provide current license number if making changes: PHC [3 4 0 Check box below for type of ownership and complete all required forms. □ Publicly Traded Corporation – Pages 1,2,3,7 □ Partnership - Pages 1,2,5,7 □ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership				
Pharmacy Name: JCB Laboratories				
Physical Address: 7335 W 33th Street North				
weet North				
Zip Code: 67705				
- 773-0406				
uired per NAC 639.708)				
ite: ; cblabs, com				
E-mail: <u>brian@jcblabs.com</u> Website: <u>jcblabs.com</u> Managing Pharmacist: <u>Jason Syring</u> License Number: <u>1-12347</u>				
SERVICES PROVIDED				
Yes/No				
Off-site Cognitive Services				
Parenteral **				
Parenteral (outpatient)				
Outpatient/Discharge				
Mail Service				
Long Term Care				
௴ □ Sterile Compounding **				
In Non Sterile Compounding				
☑ Mail Service Sterile Compounding **				
□ Ø Other Services:				

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes 🗆 No 🖄
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes 🗆 No 🖆
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?	Yes 🗆 No 🖆
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	Yes 🗆 No 🖆
5)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	Yes 🗆 No 🖾

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Brian Williamson

06-03-2014 Date

Print Name of Authorized Person

Page 2

Board	Use	Only	

Date Processed:	6	4	14-

Amount: <u>\$500,00</u>

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: <u>NE</u>	
Parent Company if any: Fagron Holding USA, LLC	
Mailing Address: 1111 Brickell AVENUE, Suite 1550	_
City: M_{MM} State: FL Zip: 33/3	
Telephone: 855-846-3811 Fax: 305-575-1083	
Contact Person: Jake Jackson	

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

-	ALLA				
	a)NAme	Addres	S		
	b)NA_NA	Addres	S	·	
	c)N	Addres	S		
	d)N()۸ Name	Addres	S		
2)	Provide the number of shares is	ssued by the co	rporation.	** <u></u>	
3)	What was the price paid per sha	are?			
4)	What date did the corporation a	ctually receive	the cash assets? _		
5)	Provide a copy of the corporation	on's stock regis	er evidencing the a	bove informati	on
List a	ny physician shareholders and p	ercentage of ov	vnership.		
Name	:None			%:	
Name	:			%:	
<u>Hour</u>	s of Operation for the pharmac	<u>V:</u>			
Mond	ay thru Friday <u>8</u> am <u>5</u> Sunday 24WS am		Saturday 24 Hours	<u>Alks</u> am	pm
	· · · ·				

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number:

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

1, Brian Williamson Responsible Person of JCB Caborateries hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Print Name of Authorized Person

Brian Williamson 06-03-2014 Date

800 SW Jackson St., Suite 1414 Topeka, KS 66612

Debra L. Billingsley, Executive Secretary

Phone: (785) 296-4056 Fax: (785) 296-8420 pharmacy@pharmacy.ks.gov www.kansas.gov/pharmacy

Sam Brownback, Governor

January 21, 2014

Dear Sir/Madam:

JCB Laboratories, 7335 W 33rd Street North, Wichita, Kansas 67205 has a Kansas pharmacy license number 2-13016. The license was issued on 12-30-13 and expires 6-30-2015. There are no disciplinary actions. The license is in good standing.

In addition, Jason P. Syring has a Kansas pharmacist license number 1-12347. The license was issued 7-26-1995 and expires 6-30-15. There are no disciplinary actions. This license is in good standing.

Sincerely,

Jamie J itghugh

Jamie Fitzhugh Senior Administrative Assistant Kansas Board of Pharmacy Jamie.Fitzhugh@pharmacy.ks.gov



Blank

NEVADA STATE BOARD OF PHARMACY 431 W Plumb Lane – Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

New Pharmacy or <i>Downership Change</i> (Provide cull Check box below for type of ownership and complete all r	
Publicly Traded Corporation – Pages 1,2,3,7	□ Partnership - Pages 1,2,5,7
Publicly Traded Corporation – Pages 1,2,3,7 Non Publicly Traded Corporation – Pages 1,2,4,7	☐ Sole Owner – Pages 1,2,6,7
GENERAL INFORMATION to be completed by all	
Pharmacy Name: <u>RSF Pharmacy, Inc.</u> Physical Address: <u>6056 EL TORDO</u>	dba Rancho Sunta E Phonmace
Physical Address: 6056 EL TORDO	Rancho Santa Fe CA 92067
Mailing Address: P.O. BOX 1188	
City: Rancho Sanha Fe State: 0	Zip Code: <u>9206</u> 7
Telephone: 858-756-3096 Fax: 855	5-329-2773
Toll Free Number: <u>855-773-2229</u> (Req	
E-mail: rsfprx @ gmail.com Webs	site: <u>N/A</u>
Managing Pharmacist: Gholam Reza Rouzita	License Number: 11626
TYPE OF PHARMACY AND	SERVICES PROVIDED
Yes/No	Yes/No
🕱 🗆 Retail	Off-site Cognitive Services
□ 📜 Hospital (# beds)	D X Parenteral **
D 🎽 Internet	Parenteral (outpatient)
🗆 💢 Nuclear	Outpatient/Discharge
Ambulatory Surgery Center	🕱 🗆 Mail Service
🗆 💢 Community	Long Term Care
□ 🕅 Other:	□ X Sterile Compounding **
	🕅 🗆 Non Sterile Compounding
All boxes must be checked	Mail Service Sterile Compounding **
For the application to be complete	Other Services:

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

67338

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, estimated background, qualification and reputation.

Original Signature	of Person Authorized	to Submit Application	n, no copi	es or stamps	_
Hamidreza Print Name of Auth			 Date	1/2014	-
					Page 2
Board Use Only	Date Processed:	6414	Amount:	\$ 500.00	

Yes 🗆 No 🗙 Yes 🗆 No 🖌

Yes 🗆 No 🗙

Yes 🗆 No 🎾

Yes 🗆 No 🕅

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION
State of Incorporation: California
Parent Company if any:
Mailing Address: P.O BOX 1188
City: Raycho Santa Fe_ State: CA Zip: 2067
Telephone: 858-756-3096 Fax: 855-329-2773
Contact Person: Jason Sabouri
For any corporation non publicly traded, disclose the following:
1) List top 4 persons to whom the shares were issued by the corporation?
a) Humidreza Jasan Saboreri P.O. Box 2102 Rancho Santa FE, Ct Name Address 92067
b)
Name Address
c)
Name Address
d) Name Address
\bigcirc
2) Provide the number of shares issued by the corporation.
3) What was the price paid per share? $\#0.01$ par value
4) What date did the corporation actually receive the cash assets? \$20.
5) Provide a copy of the corporation's stock register evidencing the above information
List any physician shareholders and percentage of ownership.
Name:%:%
Name:%:
Hours of Operation for the pharmacy:
Monday thru Friday <u>9:00</u> am <u>6:00</u> pm Saturday <u>[0:00</u> am <u>9:00</u> pm
Sundayampm 24 Hours

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number:

Page 4

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

Responsible Person of narma

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

thorized Person

Hi Larry,

I hope you are doing well. We certainly appreciated the time that you and your staff gave us when we met with you in Las Vegas in April. We are looking forward to meeting with you in regard to the nasal compounded preparations. Having said that, I do have a huge favor to ask. Eric Kastango who I believe you probably know and is someone that I have known for over 20 years going back to his Compass Compounding days at Baxter is someone the company has engaged to help in this matter. Eric as you also probably know is someone who was on the USP <797> Sterile Compounding committee for a number of years and is now a recognized USP <797> expert.

Since we all want to do the right thing, the company has engaged Eric to work with me on this Board presentation. I have supplied Eric with all the background information such that he can make his own independent assessment, and we will

probably have him visit the operations to more fully understand the compounded products. He has agreed to accompany me to the Board meeting.

The one problem that we have is that Eric will be overseas on a long planned vacation the first two weeks in June. My favor is to ask if we could postpone our presentation and postpone any decisions until the July meeting. Eric has indicated that he would be available for the Board meeting in July.

While I could probably articulate the position, I think it would be useful for you and the Board to have an expert such as Eric give his thoughts on this as well. We can certainly discuss this, but I would hope that postponing this would be acceptable to you and your staff as well as to the other Board members.

I look forward to hearing back from you. If you would like to discuss this live, I can certainly give you a call.

Regards,

John Quick



Drug Deliv Transl Res. Feb 2013; 3(1): 42–62. Published online Oct 18, 2012. doi: <u>10.1007/s13346-012-0108-9</u> PMCID: PMC3539067

Nasal drug delivery devices: characteristics and performance in a clinical perspective—a review

Per Gisle Diupesland

OptiNose, Oslo, Norway Per Gisle Djupesland, Email: <u>pgd@optinose.no</u> ^{IX}Corresponding author.

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Abstract

Go to:

Nasal delivery is the logical choice for topical treatment of local diseases in the nose and paranasal sinuses such as allergic and non-allergic rhinitis and sinusitis. The nose is also considered an attractive route for needle-free vaccination and for systemic drug delivery, especially when rapid absorption and effect are desired. In addition, nasal delivery may help address issues related to poor bioavailability, slow absorption, drug degradation, and adverse events in the gastrointestinal tract and avoids the first-pass metabolism in the liver. However, when considering nasal delivery devices and mechanisms, it is important to keep in mind that the prime purpose of the nasal airway is to protect the delicate lungs from hazardous exposures, not to serve as a delivery route for drugs and vaccines. The narrow nasal valve and the complex convoluted nasal geometry with its dynamic cyclic physiological changes provide efficient filtration and conditioning of the inspired air, enhance olfaction, and optimize gas exchange and fluid retention during exhalation. However, the potential hurdles these functional features impose on efficient nasal drug delivery are often ignored. With this background, the advantages and limitations of existing and emerging nasal delivery devices and dispersion technologies are reviewed with focus on their clinical performance. The role and limitations of the in vitro testing in the FDA guidance for nasal spray pumps and pressurized aerosols (pressurized metered-dose inhalers) with local action are discussed. Moreover, the predictive value and clinical utility of nasal cast studies and computer simulations of nasal airflow and deposition with computer fluid dynamics software are briefly discussed. New and emerging delivery technologies and devices with emphasis on Bi-Directional™ delivery, a novel concept for nasal delivery that can be adapted to a variety of dispersion technologies, are described in more depth.

Keywords: Drug delivery, Nasal, Device, Paranasal sinuses, Topical, Systemic, Vaccine, Nasal valve, Particle deposition, Clearance

Introduction

Go to:

Intuitively, the nose offers easy access to a large mucosal surface well suited for drug- and vaccine delivery. However, factors related to the nasal anatomy, physiology and aerodynamics that can severely limit this potential, have historically been challenging to address. The most recent FDA guidance for nasal devices provides detailed guidelines for in vitro testing of the physical properties such as in vitro reproducibility and accuracy of plume characteristics and dose uniformity of mechanical liquid spray pumps and pressurized metered-dose inhalers (pMDIs) for nasal use [1]. The guidance primarily addresses in vitro testing of nasal sprays and pressurized aerosols for local action. The reference to in vivo performance is limited to the recommendation of minimizing the fraction of respirable particles below 9 µm in order to avoid lung inhalation of drugs intended for nasal delivery. Thus, although important as measures of the quality and reliability of the spray pump and pMDI mechanics, these in vitro tests do not necessarily predict the in vivo particle deposition, absorption, and clinical response [2]. Furthermore, the guidance offers no or limited guidance on nasal products for systemic absorption and for alternative dispensing methods like drops, liquid jets, nebulized aerosol, vapors, and powder formulations. Finally, it does not address aspects and challenges related to the nasal anatomy and physiology that are highly relevant for the device performance in the clinical setting like body position, need for coordination, and impact of airflow and breathing patterns at delivery.

The mechanical properties of different modes of aerosol generation are already well described in depth in a previous publication [3]. The anatomy and physiology of the nasal airway has also recently been summarized in an excellent recent review [4]. The aim of this paper is to take a step further by reviewing the characteristics of existing and emerging nasal delivery devices and concepts of aerosol generation from the perspective of achieving the clinical promise of nasal drug and vaccine delivery. Focus is put on describing how the nasal anatomy and physiology present substantial obstacles to efficient delivery, but also on how it may be possible to overcome these hurdles by innovative approaches that permit realization of the therapeutic potential of nasal drug delivery. Specific attention is given to the particular challenge of targeted delivery of drugs to the upper narrow parts of the complex nasal passages housing the middle meatus where the sinuses openings are located, as well as the regions innervated by the olfactory nerve and branches of the trigeminal nerve considered essential for efficient "nose-to-brain" (N2B) transport.

Nasal anatomy and physiology influencing drug delivery

Go to:

Regulation of nasal airflow

Nasal breathing is vital for most animals and also for human neonates in the first weeks of life. The nose is the normal and preferred airway during sleep, rest, and mild exercise up to an air volume of 20–30 l/min [5]. It is only when exercise becomes more intense and air exchange demands increase that oral breathing supplements nasal breathing. The switch from nasal to oronasal breathing in young adults appears when ventilation is increased to about 35 l/min, about four times resting ventilation [6]. More than 12,000 l of air pass through the nose every day [5]. The functionality of the nose is achieved by its complex structure and aerodynamics. Amazingly, the relatively short air-path in the nose accounts for as much as 50–75 % of the total airway resistance during inhalation [7, 8].

The nasal valve and aerodynamics

The narrow anterior triangular dynamic segment of the nasal anatomy called the nasal valve is the primary flow-limiting segment, and extends anterior and posterior to the head of the inferior turbinate approximately 2 - 3 cm from the nostril opening [**q**]. This narrow triangular-shaped slit acts as a dynamic valve to modify the rate and direction of the airflow during respiration [**10**, **11**]. Anatomical studies describe the static valve dimensions as 0.3-0.4 cm² on each side, whereas acoustic rhinometry studies report the functional crosssectional area perpendicular to the acoustic pathway to be between 0.5 and 0.6 cm² on each side, in healthy adults, with no, or minimal gender differences [**11**-**14**]. The flow rate during tidal breathing creates air velocities at gale force (18 m/s) and can approach the speed of a hurricane (32 m/s) at sniffing [**11**, **15**]. At nasal flow rates found during rest (up to 15 l/min), the flow regimen is predominantly laminar throughout the nasal passages. When the rate increases to 25 l/min, local turbulence occurs downstream of the nasal valve [**10**, **11**]. The dimensions can expand to increase airflow by dilator muscular action known as flaring, or artificially by mechanical expansion by internal or external dilators [**16**, **17**]. During inhalation, Bernoulli forces narrow the valve progressively with increasing inspiratory flow rate and may even cause complete collapse with

vigorous sniffing in some subjects [5]. During exhalation, the valve acts as a "brake" to maintain a positive expiratory airway pressure that helps keep the pharyngeal and lower airways open and increase the duration of

the expiratory phase. This "braking" allows more time for gas exchange in the alveoli and for retention of fluid and heat from the warm saturated expiratory air [4, 17, 18]. In fact, external dilation of narrow noses in obstructive sleep apnea patients had beneficial effects, whereas dilation of normal noses to "supernormal" dimensions had deleterious effects on sleep parameters [17]. However, in the context of nasal drug delivery, the small dimensions of the nasal valve, and its triangular shape that narrows further during nasal inhalation, represent important obstacles for efficient nasal drug delivery.

The nasal mucosa-filtration and clearance

The region anterior to the valve called the vestibule is lined by non-ciliated squamous epithelium that in the valve region gradually transitions into ciliated epithelium typical of the ciliated respiratory epithelium posterior to the valve region [4, 19]. Beyond the nasal valve, the nasal turbinates divide the nasal cavity into slit-like passages with much larger cross-sectional area and surface area (Figs. 1, 2 and 3). Here, the predominantly laminar airflow is slowed down to speeds of 2-3 m/s and disrupted with eddies promoting deposition of particles carried with the air at and just beyond the valve region [11]. The ciliated respiratory mucosa posterior to the nasal valve is covered by a protective mucous blanket designed to trap particles and microorganisms [4, 19]. The beating action of cilia moves the mucous blanket towards the nasopharynx at an average speed of 6 mm/min (3-25 mm/min) [20, 21]. The large surface area and close contact enables effective filtering and conditioning of the inspired air and retention of water during exhalation (Figs. 1, 2 and 3). Oral breathing increases the net loss of water by as much as 42 % compared to nasal breathing [22]. The nasal passages were optimized during evolution to protect the lower airways from the constant exposure to airborne pathogens and particles. Specifically, particles larger than 3–10 µm are efficiently filtered out and trapped by the mucus blanket [19]. The nose also acts as an efficient "gas mask" removing more that 99 % of water-soluble, tissue-damaging gas like sulfur dioxide [23]. Infective agents are presented to the abundant nasal immune system both in the mucous blanket, in the mucosa, and in the adjacent organized lymphatic structures making the nose attractive for vaccine delivery with potential for a longstanding combination of systemic and mucosal immune responses [24]. The highly vascularized respiratory mucosa found beyond the valve allows exchange of heat and moisture with the inspired air within fractions of a second, to transform cold winter air into conditions more reminiscent of a tropical summer [19].



The complex anatomy of the nasal airways and paranasal sinuses



Fig. 2

Fig. 1

Illustration of the breath-powered Bi-Directional™ technology. See text for detailed description



Fig. 3

Cross-sections of a human nose with normal dimensions during soft palate closure with Bi-Directional[™] flow assessment using CFD. The airflow is entering the right nostril and exiting the left nostril. The figure illustrates the narrow triangular ...

The nasal cycle

The physiological alternating congestion and decongestion observed in at least 80 % of healthy humans is called the nasal cycle [5, 25]. The nasal cycle was first described in the rhinological literature by a German physician in 1895, but was recognized in Yoga literature centuries before [5]. Healthy individuals are normally unaware of the spontaneous and irregular reciprocal 1–4-h cycling of the nasal caliber of the two individual passages, as the total nasal resistance remains fairly constant [26]. The autonomic cyclic change in airflow resistance is mainly dependent on the blood content of the submucosal capacitance vessels that constitute the erectile component at critical sites, notably the nasal valve region. Furthermore, the erectile tissues of the septal and lateral walls and the turbinates respond to a variety of stimuli including physical and sexual activity and emotional states that can modify and override the basic cyclic rhythm [4]. The cycle is present during sleep, but overridden by pressures applied to the lateral body surface during recumbency to decongest the uppermost/contralateral nasal passage. It has been suggested that this phenomenon causes a person to turn from one side to the other while sleeping [5, 27]. The cycle is suppressed in intubated subjects, but restored by resumption of normal nasal breathing [28]. The cycle may also cause accumulation of nitric oxide (NO) in the congested passage and adjacent sinuses and contribute to defense against microbes through direct antimicrobial action and enhanced mucociliary clearance [29]. Measurements have shown that the concentration of NO in the inspired air is relatively constant due to the increase in NO concentration within the more congested cavity, which nearly exactly counterbalances the decrease in nasal airflow [30]. In some patients, as a result of structural deviations and inflammatory mucosal swelling, the nasal cycle may become clinically evident and cause symptomatic obstruction [19]. Due to the cycle, one of the nostrils is considerably more congested than the other most of the time, and the vast majority of the airflow passes through one nostril while the other remains quite narrow especially at the valve region [5]. Consequently, the nasal cycle contributes significantly to the dynamics and resistance in the nasal valve region and must be taken into consideration when the efficiency of nasal drug delivery devices is considered.

Nasal and sinus vasculature and lymphatic system

For nasally delivered substances, the site of deposition may influence the extent and route of absorption along with the target organ distribution. Branches of the ophthalmic and maxillary arteries supply the mucous membranes covering the sinuses, turbinates, meatuses, and septum, whereas the superior labial branch of the facial artery supplies the part of the septum in the region of the vestibule. The turbinates located at the lateral nasal wall are highly vascularized with a very high blood flow and act as a radiator to the airway. They contain erectile tissues and arteriovenous anastomoses that allow shunting and pooling related to temperature and water control and are largely responsible for the mucosal congestion and decongestion in health and disease [19, 31].

Substances absorbed from the anterior regions are more likely to drain via the jugular veins, whereas drugs absorbed from the mucosa beyond the nasal valve are more likely to drain via veins that travel to the sinus cavernous, where the venous blood comes in direct contact with the walls of the carotid artery. A substance absorbed from the nasal cavity to these veins/venous sinuses will be outside the blood-brain barrier (BBB), but for substances such as midazolam, which easily bypass the BBB, this route of local "counter-current transfer" from venous blood may provide a faster and more direct route to the brain. Studies in rats support that a preferential, first-pass distribution to the brain through this mechanism after nasal administration may exist for some, but not all small molecules [32, 33]. The authors suggested that this counter-current transport takes place in the area of the cavernous sinus-carotid artery complex, which has a similar structure in rat and man, but the significance of this mechanism for nasally delivered drugs has not been demonstrated in man [32, 33].

The lymphatic drainage follows a similar pattern as the venous drainage where lymphatic vessels from the vestibule drain to the external nose to submandibular lymph nodes, whereas the more posterior parts of the nose and paranasal sinuses drain towards the nasopharynx and internal deep lymph nodes [4]. In the context

of nasal drug delivery, perivascular spaces along the olfactory and trigeminal nerves acting as lymphatic pathways between the CNS and the nose have been implicated in the transport of molecules from the nasal cavity to the CNS [34].

Innervation of the nasal mucosa

The nose is also a delicate and advanced sensory organ designed to provide us with the greatest pleasures, but also to warn and protect us against dangers. An intact sense of smell plays an important role in both social and sexual interactions and is essential for quality of life. The sense of smell also greatly contributes to taste sensations [35]. Taste qualities are greatly refined by odor sensations, and without the rich spectrum of scents, dining and wining and life in general would become dull [36]. The olfactory nerves enter the nose through the cribriform plate and extend downwards on the lateral and medial side of the olfactory cleft. Recent biopsy studies in healthy adults suggest that the olfactory nerves extend at least 1–2 cm further anterior and downwards than the 8–10 mm described in most textbooks (see Figs. 1 and 2) [37, 38]. The density decreases, but olfactory filaments and islets with olfactory epithelium are found in both the anterior and posterior parts at the middle turbinate. In addition, sensory fibers of both the ophthalmic and maxillary branches of the trigeminal nerve provide sensory innervation to the anterior part of the nose including the vestibule, whereas maxillary branches innervate the posterior part of the nose as well as the regions with olfactory epithelium.

The olfactory and trigeminal nerves mutually interact in a complex manner. The trigeminal system can modulate the olfactory receptor activity through local peptide release or via reflex mechanisms designed to minimize the exposure to and effects of potentially noxious substances [39]. This can occur by alteration of the nasal patency and airflow and through changes in the properties of the mucous blanket covering the epithelium. Trigeminal input may amplify odorous sensation through perception of nasal airflow and at the chemosensory level. Interestingly, an area of increased trigeminal chemosensitivity is found in the anterior part of the nose, mediating touch, pressure, temperature, and pain [39]. Pain receptors in the nose are not covered by squamous epithelium, which gives chemical stimuli almost direct access to the free nerve endings. In fact, loss of trigeminal sensitivity and function, and not just olfactory nerve function, may severely reduce the sense of smell [40]. This should not be forgotten when addressing potential causes of reduced or altered olfaction.

The sensitivity of the nasal mucosa as a limiting factor

In addition to the limited access, obstacles imposed by its small dimensions and dynamics, the high sensitivity of the mucosa in the vestibule and in the valve area is very relevant to nasal drug delivery. Direct contact of the tip of the spray nozzle during actuation, in combination with localized concentrated anterior drug deposition on the septum, may create mechanical irritation and injury to the mucosa resulting in nosebleeds and crusting, and potentially erosions or perforation [41]. Furthermore, the high-speed impaction and low temperature of some pressurized devices may cause unpleasant sensations reducing patient acceptance and compliance.

The role of the high sensitivity of the nasal mucosa as a natural nasal defense is too often neglected when the potential of nasal drug delivery is discussed, in particular when results from animal studies, cast studies, and computer fluid dynamics (CFD) are evaluated. Exposure to chemicals, gases, particles, temperature and pressure changes, as well as direct tactile stimuli, may cause irritation, secretion, tearing, itching, sneezing, and severe pain [30]. Sensory, motor, and parasympathetic nerves are involved in a number of nasal reflexes with relevance to nasal drug delivery [4]. Such sensory inputs and related reflexes are suppressed by the anesthesia and/or sedation often applied to laboratory animals, potentially limiting the clinical predictive value of such studies. Further, the lack of sensory feedback and absence of interaction between the device and human subjects/patients are important limitations of in vitro testing of airflow and deposition patterns in nasal casts and in CFD simulation of deposition. Consequently, deposition studies in nasal casts and CFD simulation of

airflow and deposition are of value, but their predictive value for the clinical setting are all too often overestimated.

Targeted nasal delivery

For most purposes, a broad distribution of the drug on the mucosal surfaces appears desirable for drugs intended for local action or systemic absorption and for vaccines [3]. However, in chronic sinusitis and nasal polyposis, targeted delivery to the middle and superior meatuses where the sinus openings are, and where the polyps originate, appears desirable [42, 43]. Another exception may be drugs intended for "nose-to-brain" delivery, where more targeted delivery to the upper parts of the nose housing the olfactory nerves has been believed to be essential. However, recent animal data suggest that some degree of transport can also occur along the branches of the first and second divisions of the trigeminal nerve innervating most of the mucosa at and beyond the nasal valve [44]. This suggests that, in contrast to the prevailing opinion, a combination of targeted delivery to the olfactory region and a broad distribution to the mucosa innervated by the trigeminal nerve may be optimal for N2B delivery. Targeted delivery will be discussed in more detail below.

Nasal drug delivery devices

The details and principles of the mechanics of particle generation for the different types of nasal aerosols have been described in detail by Vidgren and Kublik [3] in their comprehensive review from 1998 and will only be briefly described here, with focus instead on technological features directly impacting particle deposition and on new and emerging technologies and devices. Liquid formulations currently completely dominate the nasal drug market, but nasal powder formulations and devices do exist, and more are in development. Table 1 provides an overview of the main types of liquid and powder delivery devices, their key characteristics, and examples of some key marketed nasal products and emerging devices and drug-device combination products in clinical development (Table 1).



Table 1

Overview of the main types of liquid and powder delivery devices, their key characteristics, and examples of some key marketed nasal products and emerging devices and drug-device combination products in clinical development

Devices for liquid formulations

The liquid nasal formulations are mainly aqueous solutions, but suspensions and emulsions can also be delivered. Liquid formulations are considered convenient particularly for topical indications where humidification counteracts the dryness and crusting often accompanying chronic nasal diseases [3]. In traditional spray pump systems, preservatives are typically required to maintain microbiological stability in liquid formulations. Studies in tissue cultures and animals have suggested that preservatives, like benzalkonium chloride in particular, could cause irritation and reduced ciliary movement. However, more recent human studies based on long-term and extensive clinical use have concluded that the use of benzalkonium chloride is safe and well tolerated for chronic use [45]. For some liquid formulations, in particular peptides and proteins, limited stability of dissolved drug may represent a challenge [46].

Drops delivered with pipette Drops and vapor delivery are probably the oldest forms of nasal delivery. Dripping breast milk has been used to treat nasal congestion in infants, vapors of menthol or similar substances were used to wake people that have fainted, and both drops and vapors still exist on the market (e.g., **www.vicks.com**). Drops were originally administered by sucking liquid into a glass dropper, inserting the dropper into the nostril with an extended neck before squeezing the rubber top to emit the drops. For multi-use purposes, drops have to a large extent been replaced by metered-dose spray pumps, but inexpensive single-dose pipettes produced by "blow-fill-seal" technique are still common for OTC products like decongestants and

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saline. An advantage is that preservatives are not required. In addition, due to inadequate clinical efficacy of spray pumps in patients with nasal polyps, a nasal drop formulation of fluticasone in single-dose pipettes was introduced in the EU for the treatment of nasal polyps. The rationale for this form of delivery is to improve drug deposition to the middle meatus where the polyps emerge [47, 48]. However, although drops work well for some, their popularity is limited by the need for head-down body positions and/or extreme neck extension required for the desired gravity-driven deposition of drops [43, 49]. Compliance is often poor as patients with rhinosinusitis often experience increased headache and discomfort in head-down positions.

Delivery of liquid with rhinyle catheter and squirt tube A simple way for a physician or trained assistant to deposit drug in the nose is to insert the tip of a fine catheter or micropipette to the desired area under visual control and squirt the liquid into the desired location. This is often used in animal studies where the animals are anesthetized or sedated, but can also be done in humans even without local anesthetics if care is taken to minimize contact with the sensitive mucosal membranes [50]. This method is, however, not suitable for self-administration. Harris et al. [51] described a variant of catheter delivery where 0.2 ml of a liquid desmopressin formulation is filled into a thin plastic tube with a dropper. One end of the tube is positioned in the nostril, and the drug is administered into the nose as drops or as a "liquid jet" by blowing through the other end of the thin tube by the mouth [51]. Despite a rather cumbersome procedure with considerable risk of variability in the dosing, desmopressin is still marketed in some countries with this rhinyle catheter alongside a nasal spray and a tablet for treatment of primary nocturnal enuresis, Von Willebrand disease, and diabetes insipidus.

Squeeze bottles Squeeze bottles are mainly used to deliver some over-the-counter (OTC) products like topical decongestants. By squeezing a partly air-filled plastic bottle, the drug is atomized when delivered from a jet outlet. The dose and particle size vary with the force applied, and when the pressure is released, nasal secretion and microorganisms may be sucked into the bottle. Squeeze bottles are not recommended for children [3].

Metered-dose spray pumps Metered spray pumps have, since they were introduced some four decades ago, dominated the nasal drug delivery market (Table 1). The pumps typically deliver 100 µl (25-200 µl) per spray, and they offer high reproducibility of the emitted dose and plume geometry in in vitro tests. The particle size and plume geometry can vary within certain limits and depend on the properties of the pump, the formulation, the orifice of the actuator, and the force applied [3]. Traditional spray pumps replace the emitted liquid with air, and preservatives are therefore required to prevent contamination. However, driven by the studies suggesting possible negative effects of preservatives, pump manufacturers have developed different spray systems that avoid the need for preservatives. These systems use a collapsible bag, a movable piston, or a compressed gas to compensate for the emitted liquid volume [3] (www.aptar.com and www.rexam.com). The solutions with a collapsible bag and a movable piston compensating for the emitted liquid volume offer the additional advantage that they can be emitted upside down, without the risk of sucking air into the dip tube and compromising the subsequent spray. This may be useful for some products where the patients are bedridden and where a head-down application is recommended. Another method used for avoiding preservatives is that the air that replaces the emitted liquid is filtered through an aseptic air filter. In addition, some systems have a ball valve at the tip to prevent contamination of the liquid inside the applicator tip (www.aptar.com). These preservative-free pump systems become more complex and expensive, and since human studies suggest that preservatives are safe and well tolerated, the need for preservative-free systems seems lower than previously anticipated [45]. More recently, pumps have been designed with side-actuation and introduced for delivery of fluticasone furoate for the indication of seasonal and perennial allergic rhinitis [52]. The pump was designed with a shorter tip to avoid contact with the sensitive mucosal surfaces. New designs to reduce the need for priming and re-priming, and pumps incorporating pressure point features to improve the dose reproducibility and dose counters and lock-out mechanisms for enhanced dose control and safety are available (www.rexam.com and www.aptar.com). Importantly, the in vivo deposition and clinical performance of metered-dose spray pumps can be enhanced for some applications by adapting the pumps to a novel breath-powered "Bi-Directional™" delivery technology described in more detail below [13].

Single- and duo-dose spray devices Metered-dose spray pumps require priming and some degree of overfill to maintain dose conformity for the labeled number of doses. They are well suited for drugs to be administered daily over a prolonged duration, but due to the priming procedure and limited control of dosing, they are less suited for drugs with a narrow therapeutic window. For expensive drugs and vaccines intended for single administration or sporadic use and where tight control of the dose and formulation is of particular importance, single-dose or duo-dose spray devices are preferred (www.aptar.com).

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A simple variant of a single-dose spray device (MAD) is offered by LMA (LMA, Salt Lake City, UT, USA; www.lmana.com). A nosepiece with a spray tip is fitted to a standard syringe. The liquid drug to be delivered is first drawn into the syringe and then the spray tip is fitted onto the syringe. This device has been used in academic studies to deliver, for example, a topical steroid in patients with chronic rhinosinusitis and in a vaccine study [53, 54]. A pre-filled device based on the same principle for one or two doses (AccusprayTM, Becton Dickinson Technologies, Research Triangle Park, NC, USA; www.bdpharma.com) is used to deliver the influenza vaccine FluMist (www.flumist.com), approved for both adults and children in the US market [55, 56]. A similar device for two doses was marketed by a Swiss company for delivery of another influenza vaccine a decade ago. This vaccine was withdrawn due to occurrence of adverse events (Bell's palsy) potentially related to the cholera toxin adjuvant used [57]. The device technology is now owned by a Dutch vaccine company (Crucell N.V. Leiden, the Netherlands; www.crucell.com), but to our knowledge is not currently used in any marketed products.

The single- and duo-dose devices mentioned above consist of a vial, a piston, and a swirl chamber. The spray is formed when the liquid is forced out through the swirl chamber. These devices are held between the second and the third fingers with the thumb on the actuator. A pressure point mechanism incorporated in some devices secures reproducibility of the actuation force and emitted plume characteristics **[58]**. Currently, marketed nasal migraine drugs like Imitrex (www.gsk.com) and Zomig (www.az.com; Pfeiffer/Aptar single-dose device) and the marketed influenza vaccine FluMist (www.flumist.com; Becton Dickinson single-dose spray device) are delivered with this type of device **[59]** (Table **1**). With sterile filling, the use of preservatives is not required, but overfill is required resulting in a waste fraction similar to the metered-dose, multi-dose sprays. To emit 100 μ l, a volume of 125 μ l is filled in the device (Pfeiffer/Aptar single-dose device) used for the intranasal migraine medications Imitrex (sumatriptan) and Zomig (zolmitriptan) and about half of that for a duo-dose design **[58]**.

Nasal pressurized metered-dose inhalers (pMDIs) Most drugs intended for local nasal action are delivered by spray pumps, but some have also been delivered as nasal acrosols produced by pMDIs. Following the ban on ozone-depleting chlorofluorocarbon (CFC) propellants, the number of pMDI products for both pulmonary and nasal delivery diminished rapidly, and they were removed from the US market in 2003 [60]. The use of the old CFC pMDIs for nasal products was limited due to complaints of nasal irritation and dryness. The particles from a pMDI are released at a high speed and the expansion of a compressed gas, which causes an uncomfortable "cold Freon effect" [61]. The particles emitted from the traditional pMDIs had a particle velocity much higher than a spray pump (5,200 vs. 1,500 cm/s at a distance 1–2 cm from the actuator tip) [3]. The issues related to the high particle speed and "cold Freon effect" have been reduced with the recently introduced hydrofluoroalkane (HFA)-based pMDI for nasal use offering lower particle speeds [60]. Recently, the first nasal pMDI using HFA as propellant to deliver the first generation topical steroid beclomethasone dipropionate (BDP) was approved for allergic rhinitis in the USA [62]. Like spray pumps, nasal pMDIs produce a localized deposition on the anterior non-ciliated epithelium of the nasal vestibule and in the anterior parts of the narrow nasal valve, but due to quick evaporation of the spray delivered with a pMDI, noticeable "drip-out" may be less of an issue [62].

Mismatch between geometry of anterior nose and the spray plume The pressure created by the force actuating a spray pump drives the liquid through the swirl chamber at the tip of the applicator and out through the circular nozzle orifice [64]. The combination of radial and axial forces creates a swirling thin sheet of liquid that, after

some millimeters, becomes unstable and breaks up into "ligaments" before forming the particles (break-up length). Importantly, a hollow spray cone is formed with particles mainly at the periphery. The key parameters influencing the properties of the plume and subsequently the deposition pattern of the particles are the swirl effect, nozzle orifice dimensions, the spray cone angle, and the break-up length. Inthavong ct al. [64] reported for a spray with a nozzle diameter of 0.5 mm, a spray cone angle of 30°, and a break-up length of about 3.5 mm, and the diameter at the break-up point is already 4 mm. One study reported the smallest spray cone diameters $(D_{\text{max}}/D_{\text{min}})$ for a spray angle with 54.6° to be 2.34/1.92 and 3.30/3.08 cm at distances of 1.0 and 2.5 cm from the nozzle [2]. Another study reported a spray cone diameter of 2.52/1.58 at 3 cm from the nozzle for a spray angle of 39° [65]. Even if the spray pump is inserted as deep as 10–15 mm into the nostril, there is an obvious mismatch between the dimensions and shape of the circular plume (diameter=2 cm) and the narrow triangular valve opening. With most of the particles in the periphery of the plume, it becomes quite evident that the majority of the particles will impinge in the non-ciliated mucosal walls of the vestibule anterior to the valve. Particles actually penetrating the valve will do so primarily through the lower and wider part of the triangle, a delivery pattern that is accentuated if delivery is performed during sniffing. Although the aerosol-generating mechanisms are different, a similar mismatch would exist between constricting geometry of the nasal vestibule and the conical-shaped plumes produced by other powered devices like pMDIs, nebulizers/atomizers, and many powder devices (see below).

Powered nebulizers and atomizers Nebulizers use compressed gasses (air, oxygen, and nitrogen) or ultrasonic or mechanical power to break up medical solutions and suspensions into small acrosol droplets that can be directly inhaled into the mouth or nose. The smaller particles and slow speed of the nebulized aerosol are advocated to increase penetration to the target sites in the middle and superior meatuses and the paranasal sinuses [42]. Indeed, nasal inhalation from a nebulizer has been shown to improve deposition to the upper narrow part of the nose when compared to a metered-dose spray pump, but with 33 % and 56 % of the delivered dose deposited in the lungs in the subjects assessed [66]. In light of this problem of lung delivery, it is unsurprising that nasal inhalation of nebulized antibiotics intended for topical action in patients with chronic rhinosinusitis resulted in coughing and increased need for inhaled medications following nasal inhalation [67].

VibrENT pulsation membrane nebulizer A new nebulizer intended for delivery to the nose and sinuses in patients with chronic rhinosinusitis utilizing a pulsating aerosol generated via a perforated vibrating membrane has recently been introduced (VibrENT PARI Pharma GmbH). The pulsation in combination with small particles is assumed to offer better penetration to the sinuses, and instruction on specific breathing technique during delivery is advocated to minimize inhalation [68]. Delivery of an aerosol with small particles with a mass mcdian aerodynamic diameter (MMAD) of 3.0 µm was performed with two different techniques and compared to a spray pump. Aerosol administration into one nostril for 20 s at a rate of mass output of 0.3 ml/min, with an exit filter attached to the other nostril during nasal breathing, resulted in 4.5% of the fraction deposited in the nose (63 %) reaching the sinuses (i.e., 2.8 % of the delivered dose), 27 % in the exit filter, and significant lung deposition (10 %). Nasal aerosol delivery was also performed when the subjects were instructed to maintain the soft palate closed while a flow resistor was connected to the left nostril. Following this procedure, 70 % of the radioactivity was deposited in the nose, 30 % in the exit filter, a negligible fraction in the lungs, and 7 % of the fraction in the nose (i.e., 4.9 % of the delivered dose) was found in the sinuses [68]. Following delivery of 100 µl with a traditional spray pump, 100 % of the dose was found in the nose with no deposition in the lungs and non-significant deposition in the sinuses [68]. Correction for background radiation and decay was performed, but correction for tissue attenuation was not performed, which is likely to change the relative distribution and potentially increase the fraction actually deposited in the lungs [68-71]. Nevertheless, the results suggest that the use of a pulsating aerosol in combination with the breathing technique and an exit resistor may enhance deposition in the sinuses in healthy volunteers. However, the clinical relevance of these results from healthy volunteers for rhinosinusitis patients with blocked sinus openings remains to be determined. The proposed breathing technique used to prevent lung deposition may also prove challenging as compared to the automatic integration of velum closure and the drug delivery process, as achieved when using

Aeroneb Solo vibrating mesh nebulizer Distinct anterior deposition in the valve area with nebulizers is confirmed in another very recent publication comparing nasal inhalation from a nasal sonic/pulsating jet nebulizer (Atomisor NL11S[®] sonic, DTF-Medical, France) and a new nasal mesh nebulizer system designed to minimize lung inhalation (Aeroneb Solo[®], Aerogen, Galway, Ireland; DTF-Aerodrug, Tours, France) with the same mean particle size $(5.6 \pm 0.5 \ \mu\text{m})$ [72]. The new system consists of two integrated components: the nebulizer compressor administering a constant airflow rate transporting the aerosol into one nostril via a nozzle and a pump simultaneously aspirating from a second nozzle in the other nostril at the same airflow rate while the subject is instructed to avoid nasal breathing [72]. The new nasal mesh nebulizer produced more deposition in terms of volume of liquid (27 % vs. 9 %, i.e., 0.81 vs. 0.27 ml) in the nasal cavity. The much higher fraction found in the nasal cavity in this study is probably a result of the shorter nebulizing time and smaller delivered volume in the study testing the PARI pulsating nebulizer (20 s at a rate of 0.3 ml/min to each nostril versus delivery of 3 ml for up to 10 min) before assessment of deposition was performed [68, 72]. With much longer delivery time, a substantial fraction of the dose delivered beyond the nasal valve will be cleared to the gastrointestinal (GI) tract.

Acrosol distribution deposition showed a distinct maximum value at 2 cm from the nostril for both nebulizers corresponding to deposition in the nasal valve region [72]. Furthermore, acrosol distribution deposition in the vertical plane showed a similar profile for both nebulizers with a distinct maximum close to the floor of the nose (0.75 cm for the mesh nebulizer and 1.2 cm for the sonic jet nebulizer) [72]. Importantly, the delivery efficiencies for both nebulizers and delivery techniques appear very low with only 27 % vs. 9 %, i.e., 0.81 vs. 0.27 ml, possibly due to the long delivery time and resulting differences in mucociliary and other mechanisms of clearance [72]. In other words, a study assessing deposition after several minutes of delivery is likely to underestimate the actual exposure to the posterior ciliated part of the nose compared to the study assessing deposition after a short period of delivery of less than 1 min (20 s \times 2) [68, 72].

Clinical relevance of deposition results with nebulizers Lung deposition and relatively low nasal delivery fractions are issues with nasal nebulizers. Although lung deposition appears to be reduced with simultaneous aspiration from the contralateral nostril and with specific breathing instructions, this complex mechanism for use, coupled with the need for careful patient compliance with breathing, may be challenging, especially in children or other special populations [<u>66</u>, <u>68</u>, <u>72</u>]. The study design, comparing not only two different nebulization techniques but also very different breathing techniques, makes interpretation of the results comparing the nasal nebulizers in terms of deposition efficacy and clinical significance very difficult.

The rationale for using small particles and sonic/pulsation techniques is to increase the delivery into the sinuses, but at the expense of low delivery efficacy and significant potential for lung deposition. Moreover, despite the intended advantages of the vibrating mesh nebulizer that employs aspiration from the contralateral nostril, the quantification of deposition in the different planes (cartography) demonstrates the typical highly preferential deposition in the anterior (anterior 2–3 cm) and lower (lower 1–2 cm) parts of the nasal cavity. This pattern of deposition suggests the nebulizer is not effectively delivering to the prime target sites for chronic rhinosinusitis and nasal polyposis (i.e., the middle and superior meatuses or sinuses) [42, 72]. To date, no clinical data has been published with the new nebulizer systems [68, 72].

One approach to avoiding lung deposition is the Bi-DirectionalTM technology employed in OptiNose devices; this technology ensuring operation of the nebulizer only on generation of a pressure sufficient to close the palate, avoiding the problems associated with suction pumps and special breathing instructions. However, clinical data using this approach with a nebulizer has also not been published.

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ViaNase atomizer A handheld battery-driven atomizer intended for nasal drug delivery has been introduced (ViaNase by Kurve Technology Inc., Lynnwood, WA, USA). This device atomizes liquids by producing a vortical flow on the droplets as they exit the device (www.kurvetech.com). The induced vortical flow characteristics can be altered in circular velocity and direction to achieve different droplet trajectories [42, 73]. As discussed above, it is not clear that vortex flow is desirable for penetration past the nasal valve; however, it has been suggested that this technology is capable of targeting the sinuses, and some gamma-deposition images suggesting delivery to the sinuses have been published. However, no information related to impact of prior surgery or numerical quantification of nasal or sinus deposition verifying the claimed improved deposition to the upper parts of the nose has been published [42, 73]. The ViaNase device has been used to deliver nasal insulin in patients with early Alzheimer's disease (AD), and clinical benefit has been demonstrated [74, 75]. In these studies, delivery of insulin was performed over a 2-min period by nasal inhalation. However, when insulin is delivered with this device, lung deposition is likely to occur, and some concerns related to airway irritation and reduction in pulmonary function have been raised in relation to long-term exposure to inhaled insulin when Exubera was marketed for a short period as a treatment for diabetes [71, 76]. This example highlights the issue of unintended lung delivery, one important potential clinical problem associated with using nebulizers and atomizers producing respirable particles for nasal drug delivery.

Impel nitrogen-driven atomizer A nasal atomizer driven by highly pressurized nitrogen gas is under development by Impel Inc. (<u>www.impel.com</u>). The device is intended to enable drug delivery to the upper parts of the nose in order to achieve N2B delivery [77]. To date, only animal data has been presented, making it difficult to evaluate its potential in human use, as nasal deposition and the assessment of nasal deposition in animal models vary significantly from humans. As previously noted, however, pMDIs are associated with a number of limitations. It therefore remains to be seen if a pressurized "open-palate" nebulizer will be capable of creating the desired delivery pattern.

Powder devices

Powder medication formulations can offer advantages, including greater stability than liquid formulations and potential that preservatives may not be required. Powders tend to stick to the moist surface of the nasal mucosa before being dissolved and cleared. The use of bioadhesive excipients or agents that slow ciliary action may decrease clearance rates and improve absorption [46, 78]. A number of factors like moisture sensitivity, solubility, particle size, particle shape, and flow characteristics will impact deposition and absorption [3].

The function of nasal powder devices is usually based on one of three principles (Table 1):

- 1. Powder sprayers with a compressible compartment to provide a pressure that when released creates a plume of powder particles fairly similar to that of a liquid spray;
- 2. Breath-actuated inhalers where the subject uses his own breath to inhale the powder into the nostril from a blister or capsule; and
- 3. Nasal insufflators describe devices consisting of a mouthpiece and a nosepiece that are fluidly connected. Delivery occurs when the subject exhales into the mouthpiece to close the velum, and the airflow carries the powder particles into the nose through the device nosepiece similar to the rhinyle catheter described above. The principle can be applied to different dispersion technologies and has been further developed and extended into the breath-powered Bi-Directional[™] delivery technology (see below).

Nasal powder inhalers

- Astra Zenaca markets budesonide powder delivered with the Turbuhaler multi-dose inhaler device modified for nasal inhalation (Rhinocort Turbuhaler[®]; <u>www.az.com</u>) [79]. It is marketed for allergic rhinitis and nasal polyps in some markets as an alternative to the liquid spray, but it does not seem to offer any particular advantage [80]. In a study comparing twice daily treatment with aqueous
- budesonide spray (128 μ g × 2) and the Rhinocort Turbuhaler[®] (140 μ g × 2) in nasal polyp patients, both treatments significantly reduced polyp size compared to placebo, but with no difference between the

active treatments. However, nasal symptom scores were significantly more reduced in the liquid spray compared to the powder [80]. A gamma-deposition study with Rhinocort Turbuhaler) has shown predominantly anterior deposition with a "hot spot" at the nasal valve area and about 5 % lung deposition [79]. If corrected for tissue attenuation in the lungs, it is likely that the fraction would be substantially higher [69, 79].

- Aptar group (www.aptar.com) offers a simple blister-based powder inhaler. The blister is pierced before use and the device nosepiece placed into one nostril. The subject closes the other nostril with the finger and inhales the powder into the nose. A powder formulation of apomorphine for Parkinson's using this blister-based powder inhaler (BiDose™/Prohaler™) from Pfeiffer/Aptar was in clinical development by Britannia, a UK company recently acquired by Stada Pharmaceutical (www.stada.de). Apparently, further development has been discontinued.
- Nippon Shinyaku Co., Ltd. (www.nippon-shinyaku.co.jp) markets in Japan a topical steroid (dexamethasone cipecilate) delivered with a powder-based inhalation device for allergic rhinitis. The device (Twin-lizer™) has two chambers with capsules inside. The capsule is pierced, and when the subject inhales from the nosepiece, the powder is deagglomerated and delivered into the nose with the airflow.

Nasal powder sprayers

- SBNL Pharma (www.snbl.com) recently reported data on a Phase 1 study described in a press release (www.snbl.com) with a zolmitriptan powder cyclodextrin formulation (µco[™] System) for enhanced absorption, described previously in an in vitro study [81]. The zolmitriptan absorption was rapid, and the relative bioavailability was higher than the marketed tablet and nasal spray (www.snbl.com). The company has their own capsule-based, single-dose powder devices (Fit-lizer) [82]. When inserted into a chamber, the top and bottom of the capsule is cut off by sharp blades. A plastic chamber is compressed by hand, compressed air passes through a one-way valve and the capsule during actuation, and the powder is emitted. In vitro testing shows high-dose reproducibly and minimal residuals, but no data on particle size distribution or in vivo deposition and clearance patterns appear to be available. The company has also completed a Phase 2 study with the drug granisetron for the indication of delayed chemotherapy-induced nausea and vomiting based on the same formulation technology and delivered with the Fit-lizer[™] device [81]. They have also announced plans to develop a powder-based influenza vaccine (www.snbl.com).
- Bespak (<u>www.bespak.com</u>), the principle for Unidose-DP[™], is similar to the Fit-lizer device. An air-filled compartment is compressed until a pin ruptures a membrane to release the pressure to emit the plume of powder. Delivery of powder formulations of a model antibody (human IgG) has been tested in a nasal cast model based on human MRI images. Approximately 95 % of the dose was delivered to the nasal cavity, but the majority of it was deposited no further than the nasal vestibule with only about 30 % deposited into deeper compartments of the nasal cavity [83]. The company report in their website that they have entered into a collaboration to develop an undisclosed nasal powder product with this device (www.bespak.com).
- Aptar group (Pfeiffer/Valois) (<u>www.aptar.com</u>) offers a powder device (Monopowder) based on the same principle as the devices above but with a plunger that when pressed creates a positive pressure that ruptures a membrane to expel the powder. The device has been used in studies in rabbits, but no data from human deposition or clinical studies have been published [84].
- BD (www.bdpharma.com) also has a powder device (SoluVent[™]) where a positive pressure is created with a plunger that pierces a membrane to expel the powder. A device based on this technology is being tested with powder vaccines [85].

Nasal powder insufflators

• Trimel (<u>www.trimel.com</u>) has acquired a device originally developed by a Danish company (Direct Haler). There are two versions of this device that looks like a small drinking straw. One version is

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intended for pulmonary drug delivery where subjects inhale through the small tubular device and one for nasal drug delivery where subjects blow into one end of the tube while the other end is inserted into the vestibule of the nostril. The device can in principle be viewed as a powder version of the rhinyle catheter for liquid delivery. This tubular device includes a middle section with corrugations. The corrugations allow flexion of the device and create turbulence that deagglomerates the powder. One end of the small tubular device is inserted between the lips and the other into the nasal vestibule. The subject then exhales through the device to expel the powder from the tube and into the nostril. As when using the rhinyle catheter, exhalation into the device causes the soft palate to automatically elevate to separate the oral cavity and the nasal passages, preventing lung inhalation during delivery. No clinical data with the device is available apart from a small gamma study in a patent stating that the device produced clearance and areas of deposition that were not significantly different from a "state-of-the-art" powder inhalation device (device details not identified) [<u>86</u>].

• OptiNose (<u>www.optinose.com</u>) has developed a breath-powered Bi-Directional[™] nasal delivery technology for liquid and powder medications which utilizes the exhaled breath to deliver the drug into the nose, but with additional key distinguishing features that importantly impact drug deposition and clearance patterns and clinical device performance.

Breath-powered Bi-Directional™ technology—a new nasal drug delivery concept This novel concept exploits natural functional aspects of the upper airways to offer a delivery method that may overcome many of the inherent limitations of traditional nasal devices. Importantly, the breath-powered Bi-Directional[™] technology can be adapted to any type of dispersion technology for both liquids and powders. Breath-powered Bi-Directional™ devices consist of a mouthpiece and a scaling nosepiece with an optimized frusto-conical shape and comfortable surface that mechanically expands the first part of the nasal valve (Figs. 1, 2, and 3). The user slides a sealing nosepiece into one nostril until it forms a seal with the flexible soft tissue of the nostril opening, at which point, it mechanically expands the narrow slit-shaped part of the nasal triangular valve. The user then exhales through an attached mouthpiece. When exhaling into the mouthpiece against the resistance of the device, the soft palate (or velum) is automatically elevated by the positive oropharyngeal pressure, isolating the nasal cavity from the rest of the respiratory system. Owing to the scaling nosepiece, the dynamic pressure that is transferred from the mouth through the device to the nose further expands the slit-like nasal passages. Importantly, the positive pressure in the entry nostril will, due to the sealing nosepiece, balance the oropharyngeal pressure across the closed velum to prevent the velum from being "over-elevated," thus securing an open flow path between the two nasal passages behind the nasal septum and in front of the elevated velum.

This "breath-powered" mechanism enables release of liquid or powder particles into an air stream that enters one nostril, passes entirely around the nasal septum, and exits through the opposite nostril, following a "Bi-Directional[™]" flow path. Actuation of drug release in devices employing this approach has been described using manual triggering as well as mechanisms automatically triggered by flow and/or pressure [<u>13</u>, <u>69</u>, <u>70</u>, <u>87</u>, <u>88</u>]. By optimizing design parameters, such as the nosepiece shape, the flow rate, the particle size profile, and release angle, it is possible to optimize delivery to target sites beyond the nasal valve, avoid lung deposition, and to assure that particles are deeply deposited without exiting the contralateral nostril. The Bi-Directional[™] devices currently in phase 3 clinical trials are a multi-dose liquid device incorporating a standard spray pump and a capsule-based powder multi-use device with disposable drug chamber and nosepiece (Fig. <u>3</u>), but other configurations are possible. Importantly, the Bi-Directional[™] delivery concept can be adapted to a variety of dispersion technologies for both liquids and powders,

Human evidence for nasal deposition patterns with Bi-Directional[™] delivery Device variants using this mechanism of nasal drug delivery have been tested in gamma-deposition studies where assessments of the regional deposition and clearance patterns in human subjects were studied in detail [13, 14, 69]. Comparison of conventional nasal inhalation and Bi-Directional[™] delivery with the same nebulizer producing small particles showed that lung inhalation can be prevented with Bi-Directional[™] delivery even when small respirable

particle are delivered [<u>69</u>]. In one published study, a breath-actuated Bi-DirectionalTM device incorporating a standard spray pump was compared directly to the same nasal spray pump actuated by hand in the traditional way, and in a second published study, a Bi-DirectionalTM powder device was directly compared to a traditional spray device [<u>13</u>, <u>14</u>]. Both studies demonstrated less deposition in the non-ciliated nasal vestibule and significantly greater deposition to the upper posterior regions beyond the nasal valve with the Bi-DirectionalTM devices as compared to conventional delivery with a spray pump [<u>13</u>, <u>14</u>] (Fig. <u>4</u>). In the most recent gamma study with Bi-DirectionalTM powder device (Opt-Powder) seen in Fig. <u>2</u>, the initial deposition in the upper and middle posterior regions of the nose was significantly larger than a traditional spray (upper posterior region; Opt-Powder 18.3 ± -11.5 % vs. spray 2.4 ± 1.8 %, *p* < 0.02; sum of upper and middle posterior regions; Opt-Powder 53.5 ± 18.5 % vs. spray 15.7 ± 13.8 %, *p* < 0.02) [<u>14</u>]. In contrast, the summed initial deposition to the lower anterior and posterior regions for spray was three times higher compared to Opt-Powder (Opt-Powder 17.4 ± 24.5 % vs. spray 59.4 ± 18.2 %, *p* < 0.04; Fig. <u>4</u>) [<u>14</u>].

Fig. 4

Gamma camera image information (logarithmic "hot iron" intensity scale) from the nasal cavity is superimposed on the corresponding sagittal MRI section. The images are from the same subject and present deposition 2 min after delivery ...

Published clinical outcomes with breath-powered Bi-Directional[™] delivery devices In addition to human studies of deposition patterns, devices using the breath-powered Bi-Directional[™] technology have also been evaluated in a number of clinical trials. Results generally suggest that superior deep nasal deposition with clinically important potential can be achieved in the clinic, and two drug–device combinations are currently in Phase 3 development: sumatriptan powder for acute migraine and fluticasone propionate for chronic rhinosinusitis with nasal polyposis [87–90] (www.optinose.com).

- · Midazolam-sedation: Midazolam is a drug with high bioavailability (BA), reasonable ability to cross the BBB, and easily observed pharmacodynamic effects (sedation). In a three-way crossover study of 12 healthy volunteers, delivery of the same dose of midazolam (3.4 mg) with a breath-powered Bi-Directional[™] device prototype was assessed relative to a standard nasal spray and intravenous (IV) administration [91]. Drug pharmacokinetics (PK) with both nasal delivery approaches were similar, as is not unexpected for a small molecule easily absorbed to the blood with a high BA of ≈70 %. Interestingly, the pharmacodynamic effects (onset and level of sedation) reported with Bi-Directional™ delivery were very similar to IV administration despite substantially lower maximum serum levels (Bi-Directional™ with median $C_{\text{max}} = 3 \text{ Ng/ml vs.}$ IV with median $C_{\text{max}} = 5 \text{ ng/ml}$). In contrast, the onset was slower, and the degree of sedation was lower following traditional spray delivery despite similar PK values as Bi-Directional[™] delivery [01]. These findings suggest that the sedative effect following Bi-Directional[™] nasal delivery may not merely be a result of absorption to the blood and subsequent passage into the brain across the BBB as occurs with a standard nasal spray. Alternative transport routes to the brain by passing the BBB described in animal studies may contribute to the sedative effects [32-34, 44]. Absorption from the posterior part of the nose may offer a more direct route to brain arterial blood through the particular venous drainage pathway from the posterior parts of the nose called "countercurrent transfer" [32, 33]. Moreover, direct transport to the brain for both small and large molecules may occur along ensheathed cells forming channels around the olfactory and trigeminal nerves [34, 44]. Contribution from such alternative transport routes would be consistent with a clinically important improvement in the pattern of deep nasal drug deposition with breath-powered Bi-Directional™ delivery (Fig. 4) [13, 14].
- Sumatriptan—migraine: Unlike midazolam, the serotonin antagonist sumatriptan has poor BA when delivered orally (14 %) and is only marginally higher when delivered as a nasal spray (Pfeiffer single-dose device). It has been estimated that only about 10 % of the drug delivered by standard nasal spray

(Imitrex) is absorbed rapidly across the nasal mucosa within the first 20 min with much of a dose undergoing delayed absorption from the GI tract with a T_{max} of 90 min [92, 93]. Hypothesizing that breath-actuated Bi-Directional[™] powder delivery may produce clinically different results than previously reported for nasal spray delivery, investigators conducted a cross-over PK study in 12 migraineurs, comparing subcutaneous injection of 6 mg sumatriptan with 10 and 20 mg of intranasal sumatriptan powder. Bi-directionally delivered nasal sumatriptan powder was pharmacodynamically similar to injection, inducing a similar EEG profile and preventing migraine attacks in patients when delivered 15 min before glyceryl trinitrate challenge. The PK curves showed a similar bi-phasic absorption pattern as described for sumatriptan nasal spray delivery, but with a substantially higher initial predominantly nasal absorption peak at 20 min estimated to account for approximately 30 % of the total absorption which is about three times the estimated 10 % fraction absorbed nasally for the marketed Imitrex nasal spray [89, 92]. These PK results lend credence to the conclusion that clinically differentiated nasal deposition is produced by the breath-powered Bi-Directional™ device compared to what has been previously reported with standard nasal spray delivery. A more definitive study directly comparing sumatriptan delivery with a breath-powered Bi-Directional[™] device to delivery by standard nasal spray, oral delivery, and injection delivery is being conducted and should report results soon (www.clinicaltrials.gov). In a randomized, double-blind, parallel group, placebo-controlled study, a single migraine attack was treated in-clinic with two doses of sumatriptan powder (7.5 or 15 mg delivered doses or placebo) administered intranasally by a novel Bi-Directional™ powder delivery device; fast onset of pain relief was observed for both doses [90]. The pain relief rates were similar to historical data SC injection despite much lower systemic exposure [90, 92]. The results suggest that the enhanced deposition associated with the breath-powered Bi-Directional[™] delivery of sumatriptan powder may contribute to greater initial nasal absorption and offer clinical benefits [94]. However, based on comparisons with historical data on the PK and pharmacodynamics profiles of sumatriptan delivered through different routes, it has been speculated that the rate of systemic absorption of nasal sumatriptan may not alone explain differences in headache response suggesting the potential for an additional route to the site of action as discussed above [14]. A Phase 3 study is currently in progress (www.clinicaltrials.gov and www.optinose.com).

Fluticasone propionate—chronic rhinosinusitis with nasal polyps: Fluticasone is a topical steroid, available as a standard nasal spray for treatment of rhinitis but often used with limited benefit in the treatment of chronic rhinosinusitis (CRS) with and without nasal polyps. In a 3-month placebo controlled study in 109 patients with chronic rhinosinusitis (CRS) with nasal polyps, delivery of fluticasone (400 µg b.i.d.) with an OptiNose breath-powered Bi-Directional™ liquid drug delivery device was reported to be well tolerated and to produce a large magnitude of reduction in both symptoms and the overall polyp score. Particularly notable relative to expectations with standard nasal spray delivery, complete elimination of the polyps in close to 20 % of the subjects was reported after 3 months [87]. The proportion of subjects with improvement in summed polyp score was significantly higher with OptiNose fluticasone propionate (Opt-FP) compared with placebo at 4, 8, and 12 weeks (22 % vs. 7 %, p = 0.011, 43 % vs. 7 %, p < 0.001, 57 % vs. 9 %, p < 0.001). Despite relatively lower baseline polyp scores after 12 weeks, the summed polyp score was significantly reduced from 2.8 to 1.8 in the active treatment group, whereas a minor increase in polyp score was seen in the placebo group (-0.98 vs. + 0.23, p < 0.02)0.001). Peak nasal inspiratory flow (PNIF) increased progressively during Opt-FP treatment (*p* < 0.001). Combined symptom score, nasal blockage, discomfort, rhinitis symptoms, and sense of smell were all significantly improved [87]. The highly significant progressive treatment effect of Opt-FP was observed regardless of baseline polyps score. Previous sinus surgery had no impact on the efficacy. Coupled with the complete removal of polyps in many patients with small polyps, this suggests that improved deposition to target sites achieved with the Bi-Directional™ delivery device may translate into true clinical benefits and possibly reduced need for surgery [95]. A Phase 3 study is currently in progress (www.clinicaltrials.gov and www.optinose.com).

The same drug-device combination product was also evaluated in a small placebo controlled study (N = 20) in patients with post-surgical recalcitrant CRS without polyps, producing clinically significant improvements on both objective measures and subjective symptoms [88]. Endoscopy score for edema showed a significant and progressive improvement [12 weeks (median scores): Opt-FP -4.0, PBO -1.0, p = 0.015]. PNIF increased significantly during Opt-FP treatment compared to placebo (4 weeks: p = 0.006; 8 weeks: p = 0.03). After 12 weeks, MRI scores in the Opt-FP group improved against baseline (p = 0.039), and a non-significant trend was seen vs. placebo. The nasal RSOM-31 subscale was significantly improved with Opt-FP treatment (4 weeks: p = 0.009, 8 weeks: p = 0.016, 12 weeks: NS). Sense of smell, nasal discomfort, and combined score were all significantly improved (p < 0.05). Notably, this is a condition marked by many recent negative placebo-controlled trials [96, 97]. This context, in addition to comparison with historical data in similar patient populations, again suggests that breath-powered bi-directional delivery is capable of producing superior deep nasal deposition in clinical practice (improved targeting of the middle meatus in this case) which can translate into improved clinical response (Fig. 4) [13, 87, 88].

Influenza vaccine: In a four-armed parallel group study with a whole-virus influenza liquid vaccine without adjuvant, delivery with the breath-powered Bi-Directional[™] OptiNose device and nasal drops were found to provide better overall immune response than a traditional nasal spray and an oral spray [50]. In contrast to the self-administration with the OptiNose device, the nasal drops were delivered by an assistant inserting the pipette tip in a controlled manner beyond the nasal valve with the neck extended. These results suggest that Bi-Directional[™] devices are a practical delivery method capable of producing a clinically relevant broader and deeper distribution of vaccines to the nasal respiratory inucosa, areas rich in dendritic cells and aggregates of lymphoid tissue, offering potential for a range of vaccines to produce improved immune response in non-parenteral delivery forms [24, 50].

Assessment of nasal deposition and clearance-clinical aspects

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CFD simulations

With development of high-resolution CT and MRI technology, it has become possible to generate accurate 3D reconstructions of the complex nasal anatomy (Fig. 3). The field of computational fluid dynamics (CFD) is rapidly progressing in medicine and has enabled CFD simulations of nasal aerodynamics and deposition patterns [98–101]. The greatly improved density of the grids used and algorithms, along with much faster computers available for simulation, now allow implementation of more realistic conditions. For example, recent publications describe algorithms to simulate septal abnormalities, post-surgical changes, as well as heat and water exchange, and to more accurately simulate the true properties of aerosol generation and plume characteristics [99–101]. Undoubtedly, as the quality and capabilities increase, CFD simulations will play an increasingly important role and allow for realistic simulation of nasal physiology and drug delivery. A more detailed review of this exciting field is outside the scope of this review.

Deposition studies in casts

The progress in imaging and reconstruction software has also made it possible to make physical models in rigid materials by modern 3D printing techniques like stereolithography with correct nasal geometry and dimensions. Casts made in softer material like silicone may offer advantages in terms of more realistic device cast interface. However, caution is necessary because even the softer silicone casts do not realistically represent the nasal valve dynamics, the cyclic physiological changes of the mucosa, or reflect the in vivo surface properties of the nasal mucosa, including the impact on mucocliliary clearance **[102]**.

An in depth review of in vitro drug delivery simulation performed in nasal casts is also outside the scope of this review, but some comments related to recent work are included to highlight issues related to the interpretation and predictive value of results obtained with nasal delivery devices in cast studies. Three recent publications report in detail on the effect of breathing patterns, formulation, spray pump variables, and the site of

deposition in a particular commercially available silicone cast (Koken Co., Japan) [65, 103, 104]. An interesting gel coating method that changes color in contact with the liquid allowing quantification of deposition by photometric analysis of deposition images is described [103]. In the most recent work, different insertion depth, spray angle, and plume characteristics (cone angle and particle size distribution) were studied. Data on the dimensions of the cast are not presented in these reports; however, it is critical to note that the Koken cast is, according to the manufacturer, primarily an educational tool and that it therefore has a flat transparent septum to enable visualization of complicated nasal structures. Inspection of the nasal valve area and objective measurements of the dimensions reveals that the dimensions at the valve area are several-fold larger than the average human valve dimensions and outside the normal range [105]. It is suggested in these recent publications that casts studies have potential for establishing in vivo bioequivalence and as indicators of critical quality attributes [65]. While an admirable goal, the lack of validation of all cast dimensions coupled with the inability of the cast to reproduce important dynamic aspects of nasal anatomy and physiology discussed previously, certainly casts doubt on the ability to achieve this objective with the Koken cast, and potentially any rigid nasal cast. Nevertheless, the use of ever-improving casts coupled with innovative techniques such as photometrics may be very useful in development of new nasal delivery devices. Reliance on standards published by FDA for performance of spray pumps may seem appropriate for comparison of nasal delivery devices; however, published analysis also suggests that the in vitro measurements in the FDA guidance related to performance of spray pumps are not clinically relevant [2]. Thus, in light of current methodological and technological limitations, human in vivo deposition and clearance studies, and relevant human clinical trials, allowing regional deposition quantification and direct clinical comparisons, respectively, are still ultimately required. A recent review concludes that although both in vitro studies and in vivo imaging methods may be of value during the device development stages, ultimately, randomized placebo-controlled trials quantifying both symptoms and functional parameters are required to determine drug delivery efficiency of different devices [42].

In vivo assessment of deposition and clearance

A number of gamma deposition studies, a study using radiopaque contrast, and studies using colored dyes confirm that administration with conventional spray pumps, pMDIs, nebulizers, and powder devices all result in deposition mainly in the anterior non-ciliated segments of the nose anterior to and at the narrow nasal valve, which is regarded suboptimal for clinical efficacy where deep and broad nasal deposition is required [13, 43, 63, 66, 72, 79, 106]. Colored dyes may offer a quick and inexpensive semi-quantitative assessment of deposition and clearance, and a number of studies have assessed deposition patterns with dyes with the goal of improving deposition and the clinical outcome of delivery with spray pumps and drops [43, 107, 108]. Although results vary, the effect of different body positions and administration techniques appears to have limited impact on initial deposition patterns. In fact, a recent single-blind, cross-over study comparing seven different administration techniques of colored dyes in healthy individuals using endoscopic video imaging concluded that there may not be a single "best" technique for topical nasal drug delivery with conventional nasal sprays [108]. Lack of patient compliance further reduces the clinical usefulness of these delivery techniques.

More detailed assessment of drug deposition using regional gamma-deposition patterns have added to the understanding of deposition and clearance patterns and how they may have an impact on the clinical outcomes [13, 14, 66, 70, 72]. Improved methods for positioning and re-positioning of the test subjects and the use of radiolabeled gases and MRI overlay allow regional quantification of nasal deposition and outcomes [66, 70]. Furthermore, in contrast to earlier studies, proper correction for regional differences in tissue attenuation in the different nasal segments and between the nose and lungs is now being performed [13, 14, 70]. This review only addresses in vivo gamma-deposition studies dealing with some key aspects related to the in vivo performance of nasal delivery devices that normally get limited attention.

Impact of delivery instructions, patient compliance, and body position

One factor too often neglected when comparing deposition studies is whether the delivery procedure was performed by the subjects themselves or by an assistant. Clearly, delivery by the subjects is much closer to the real-life situation, but inevitably introduces more variability. In most gamma-deposition studies, a trained assistant inserts the spray device and performs the actuation according to a strict protocol. This was the case in a study assessing deposition of radiolabeled cromoglycate substantial delivery beyond the nasal valve along the nasal floor was observed [109]. In contrast, in a study with radiolabeled insulin where the spray was actuated by the subjects themselves, it was noted that individual administration technique resulted in the majority of doses being deposited in the anterior rather than the posterior nasal cavity in five out of six subjects, with the dose then being cleared via the nares rather than the nasopharynx [110]. Contrary to expectations, no sign of systemic absorption of insulin was observed, and the authors commented that this effect of individual administration technique raises a separate question on the usefulness of nasal spray doses for delivery of insulin intended for systemic absorption [110].

Overall versus regional clearance patterns

Gamma studies must be performed in a controlled setting where subjects are more likely to adhere to instructions for use of the devices than in real life. It is very common to observe that subjects during, or immediately after, administration of drug using nasal devices intuitively sniff to avoid the concentrated anterior liquid deposition from dripping out and down on the upper lips. Sometimes, the anteriorly deposited surplus is wiped off, as has been observed in gamma-deposition studies [111]. In fact, considerable early dripout has been observed in a gamma study following self-administration with a 100-µl standard nasal spray pump, which causes concentrated anterior deposition. This phenomenon has also been observed after delivery with nebulizers [14, 72]. Recent studies offering regional clearance curves for four or six nasal segments highlight that the initial site of deposition has a major impact on the clearance rates and that determination of overall masal clearance is a very crude and potentially misleading measure that does not predict clinical performance [13, 14]. Interestingly, a recent review on pulmonary drug delivery states that total lung deposition appears to be a poor predictor of clinical outcome; rather, regional deposition needs to be assessed to predict therapeutic effectiveness [112]. In a study comparing nasal deposition and clearance after selfadministration of the same conventional spray pump (100 μ l) by hand in the traditional way and by breath actuation with a Bi-Directional™ delivery device (see below for details), the percentage left in the nose 30 min after hand actuation is twice that of breath actuation (46 % vs. 23 %). However, the regional deposition patterns (divided in four nasal segments) reveal that this difference is primarily a result of anterior retention in the predominantly non-ciliated anterior two nasal quadrants following hand-actuated spray delivery. The deposition pattern is reversed with the Bi-Directional™ device, which was reported to offer three times greater broader and more reproducible deposition to the ciliated respiratory mucosa beyond the nasal valve and, in particular, in the upper posterior segments, with removal at a speed corresponding to expected mucocliliary clearance rate [13]. Another study comparing self-administration of a spray pump and a Bi-Directional[™] breath-actuated powder device showed a similar significant difference in the regional deposition and clearance patterns, further reinforcing the importance of evaluating not only overall or "whole-nose" deposition and clearance but instead also evaluating regional patterns when developing or comparing nasal delivery devices [14] (Fig. 4).

Impact of site of delivery and volume on deposition and clearance

The results from the study described above comparing deposition and clearance after delivery from the same spray pump actuated in different manners show that the initial site of deposition has a profound impact on the clearance rates [3, 13, 14]. Interestingly, McLean et al. [113] described three different phases of nasal clearance.

1. The first phase occurs within the first minute after administration and is particularly evident following delivery of large concentrated volumes that rapidly pass along the floor of the nose to the pharynx to be swallowed. This applies in particular to delivery of drops and can contribute to explaining the much

lower absorption of desmopressin delivered as drops, but also applies to spray delivery with higher spray volumes [3, 14, 51, 113]. The initial and very rapid removal may not always be recognized, as the initial gamma image often includes averaging of registration of counts over a 2-min period due to the relatively small dose of radioactivity used (for ethical reasons) [14].

- 2. The second phase lasts for about 15 min and corresponds to mucociliary clearance of the fraction initially deposited on the ciliated respiratory mucosa found at and beyond the nasal valve [3, 13, 14, 51, 63, 70, 113, 114].
- 3. The third prolonged late phase represents the slow removal of residual drug deposited in the anterior non-ciliated parts of the nasal surface and can take hours, unless mechanically removed by nose blowing and/or wiping of the nose [63]. Consequently, depending on whether the substance in question has local action, is intended for systemic absorption, for N2B transport, or a combination, the primary goal is frequently to maximize exposure to the ciliated mucosa beyond the nasal valve. One strategy for enhanced exposure is to slow clearance by thixotropic or bloadhesive agents or agents which slow ciliary action in order to increase the residence time in this region or by adding absorption enhancer if systemic absorption is the objective [78, 115].

In principle, an alternative, complementary, and probably better way to enhance the exposure is to modify/improve the administration method or technique. The goal should be to reduce the amount of drug quickly passing through the nose to be swallowed in the first phase, to reduce the amount deposited outside the nose, and to increase the amount bypassing the nasal valve and the nasal respiratory mucosal surface covered. Delivery of smaller particles with a traditional spray offers advantages in terms of absorption and biological response compared to delivery of drops, and repeated delivery of a smaller volume, as 2×50 -µl spray has been reported to be better than 1×100 µl for systemic absorption [51, 114]. In contrast, another study found that spraying 1×100 µl resulted in larger deposition than 2×50 µl beyond the nasal valve with more rapid overall clearance, but the study did not assess absorption or biological response [63]. A narrow cone angle resulted in more posterior deposition and faster clearance than a cone of 60°, and drops deposited more posteriorly are cleared faster [116, 117].

For locally acting anti-inflammatory drugs like steroids and antihistamines, as well as for vaccines, the nonciliated surface of the vestibule is not the target [42]. However, recent publications continue to advocate concentrated anterior deposition and retention as desirable and a key advantage of the novel HFA-based nasal pMDI with topically acting drug [118]. Reference is made to a paper from 1987 with CFC-based pMDI showing that as much as 65 % of the initial radioactivity is retained in the anterior parts of the nose after 30 min and incorrectly stating that an almost total clearance was observed 30 min after delivery with aqueous spray [63]. A recent publication even claims that the anterior retention following pMDI delivery provides evidence for enhanced efficacy, which seems to be in conflict with the prevailing opinion [42, 118].

Conclusions

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The nose is attractive for delivery of many drugs and vaccines, but the potential has not been fully realized. Inherent challenges related to the nasal anatomy, physiology, and aerodynamics that may severely limit the potential and clinical efficiency are not widely understood. The small and dynamic dimensions of the nasal cavity and the anterior anatomy are among the most important hurdles for more efficient nasal drug delivery. Despite important improvements in the technical device attributes that can offer more reproducible and reliable in vitro performance, this has to a limited extent translated into improved clinical performance. While in vitro performance testing is undoubtedly of value for product quality assessment, predictive value for in vivo clinical performance is highly questionable [2]. CFD simulations of nasal aerodynamics and cast studies may be of value in the developmental stages of device design, and future advances may improve their predictive value. Human in vivo deposition and clearance studies can be very important, providing valuable information particularly if recent advances allowing regional quantification and tissue attenuation correction are employed [14, 70, 112]. Still, delivery by trained assistants in controlled environments may not adequately reflect the device performance in the clinical setting. Even the most advanced nebulizer technologies introduced have shown poor delivery efficiency, with undesirable localized delivery in the non-ciliated anterior nasal region and along the floor of the nose and problems with inhalation exposure of the lungs [72]. As stated in a recent review, well-controlled clinical studies are currently required to quantify changes in both symptoms and functional parameters, and ultimately to determine the efficacy of novel drug/device combinations [42]. The Bi-Directional[™] drug delivery concept introduces a novel approach that can overcome inherent limitations of conventional nasal delivery imposed by the dynamics of the nasal valve. Gamma-scintigraphy studies with both powder and liquid Bi-Directional[™] device variants confirm significant improvements in regional in vivo deposition and clearance patterns, and a number of clinical trials suggest that this deep nasal deposition translates into clinical benefits for the patients. This delivery technology can be combined with a variety of dispersion technologies for both liquids and powders, and promises to expand the possibilities of nasal drug delivery.

Conflict of interest

P.G. Djupesland is a founder, CSO and shareholder of OptiNose, a commercial company developing nasal delivery devices.

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Particle size and airflow: Implications for nasal and paranasal sinus delivery

Summary: Topical intranasal drug delivery presents several challenges to the drug delivery system. These challenges include delivering a high concentration of drug throughout the nasal and paranasal sinus cavities while at the same time preventing delivery of the drug to the pulmonary system. Delivery systems include high volume nasal lavage, small particle nebulizers adapted from pulmonary delivery systems, spray bottles and metered dose inhalers (MDI). Each presents with its own issues. An alternative method of delivery is a large particle nebulizer delivering a sufficient airflow that generates a deep penetrating plume. This system is the NasoNeb Nasal Nebulizer. The NasoNeb Nasal Nebulizer is specifically designed for intranasal delivery of drugs. The NasoNeb System generates a unique plume that is characterized by large liquid particles delivered with sufficient airflow, which results in a deep, penetrating aerosol. This aerosol delivers a high percentage of medication into the nasal and paranasal sinus cavities while preventing unwanted pulmonary deposition observed with small particle delivery systems.

Particle Size Measurement of the NasoNeb Nasal Nebulizer

MedInvent contracted Powerscope, Inc. of Eden Prairie, MN to measure the particle size and velocity of the NasoNeb Nasal Nebulizer. Using an Artium Technologies Inc. Phase Doppler Interferometer (PDI^{*} system), the team at Powerscope determined that the average particle size (mode) was 23.3 microns and that there were virtually no particles smaller than 15 microns. The nasal cavity filters particles that are 10 microns and larger; thus, the nasal and paranasal sinus cavities are able to capture virtually all of the particles delivered via the NasoNeb Nasal Nebulizer that pass through the nasal valve.



Table 1. Percentage of NasoNeb-generated particles
by size, in microns

Particle Size	NasoNeb System		
<5 µm	0.0083±0.0098%		
<10 µm	0.055±0.037%		
>10 µm	99.94%±0.0468%		

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These data demonstrate the NasoNeb Nasal Nebulizer's ability to meet the requirements in the guidance established by the FDA with respect to developing intranasal drug delivery systems. These guidelines include the following:

"When developing a drug product for nasal delivery, the aerodynamic characteristics of the formulation generated by the delivery system should be considered to ensure that the drug product will be retained in the nasal cavity and not inhaled into the lung. One important consideration is the aerodynamic-based sizing of the particles or droplets. Particles or droplets that are aerodynamically smaller than the standard 5 micron upper bound of the respirable fragment size can be inhaled. For nasal deposition, the optimal droplet or particle size should be, on the whole, substantially larger than the respirable fragment size."¹¹

Discussion

Unlike the NasoNeb Nasal Nebulizer, traditional jet and vibrating mesh nebulizers are specifically designed for delivery of medications to the lungs; as such, these devices generate respirable particles sized in the 3-5 micron range in order to reach the pulmonary mucosa. Therapy delivery to the lungs is typically offered with both oral (via mouthpiece attachment) and nasal (via mask attachment) routes.

When pulmonary devices are adapted for nasal delivery using nasal adapters, the particle size generated remains in the 3-5 micron range. In this size range, studies have demonstrated that 3% of the drug deposits in the nasal cavity, 18-22% deposits in the lungs, and the rest is lost to inhalation⁶.

When the NasoNeb's large particles are coupled with the airflow generated by the NasoNeb compressor, they are distributed throughout the whole nasal cavity, including the clinically important superior and posterior structures, as demonstrated in two clinical trials^{3,7}. Areas reached by the NasoNeb Nasal Nebulizer include the frontal recess/sinus, spheno-ethmoid recess, ethmoid cavity, sphenoid and maxillary sinuses, all turbinates, the middle meatus and olfactory cleft.

In the case of pulmonary drug delivery devices, airflow generated by the delivery system is considered counterproductive since particles driven at any velocity would be delivered to the back of the throat, adhere and not be available to the lungs. Therefore, excess air generated by the compressor is vented off and the respirable particles are held in a reservoir through which the patient inhales to deliver the medication. Small particle nebulizers adapted for nasal cavity therapy delivery also rely on patient inhalation for delivery; thus, particles from these systems are primarily delivered to the pulmonary system via the patient's breath. Those particles that do deposit in the nasal cavity are concentrated in the nasal antrum and are carried through the floor of the nose to the throat by mucociliary clearance. They have not been shown to reach the superior and posterior area of the nasal cavity with any appreciable level of concentration⁶.

Pulmonary delivery of drugs dramatically increases the potential for systemic absorption and unwanted side effects. Intranasal drugs are eventually cleared by mucociliary clearance to the gut where they may be destroyed by the digestive action of the gut or metabolized to inactive moieties during first past metabolism⁸. Drugs absorbed through the pulmonary mucosa bypass first pass metabolism and are thus systemically available⁸. For instance, fluticasone propionate has an oral bioavailability of <1% due to first pass metabolism yet has an absolute bioavailability (systemic+pulmonary) of 17% when delivered to the lungs via a DPI and 26 – 29% as a liquid delivered via an MDI¹².

Inadvertent delivery of topical drugs to the pulmonary system can lead to alteration of voice¹⁰, antimicrobial resistance⁹, eosinophilic pneumonia¹⁰, chronic cough¹⁰, toxic amyloid formation⁵, reduced lung function⁸, and cancer¹.

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Spray bottles and Metered Dose Inhalers (MDI's) exhibit similar patterns, reaching only the first third of the inferior and middle turbinate at best². These devices generate no airflow and as a result the particles lose significant momentum as soon as they are formed at the nozzle. The NasoNeb System, on the other hand, generates an air column that continues to propel the particles after they leave the device to help drive them deep into the nasal cavity.

Irrigation bottles are sometimes used off-label to deliver medication in a high volume of fluid (as much as

8 oz. are delivered in one dose). While irrigation bottles distribute liquid more broadly across the nasal mucosa, only 1.8% - 2.4% of the liquid is retained. The rest of the liquid washes out the contra-lateral nostril and down the sink, carrying virtually all of the medication into the environment^{4,6}. The NasoNeb System delivers between 0.2 and 15 ml total volume, ensuring that the medication stays in the nasal and paranasal sinus cavities and does not simply run down the sink.

Intranasal Drug Delivery Options	Particle size	Supporting air flow	Intranasal deposition	Intranasal drug retention	Pulmonary deposition
NasoNeb Nasal Nebulizer	23.3 jum	Yes	Broad ^{1,7}	High	No
Small particle Nebulizers	3-5 µm	No	Antrum ⁶	Low	Yes
Spray bottles	37-157 μm	No	Antrum ²	High	No
Irrigation bottles	Fluid	No	Broad ^{4,6}	Low	No

Table 2. Comparing Intranasal Drug Delivery Systems

Conclusion

Particle size is critical to ensure that the intranasal drug delivery deposits in the nasal and paranasal cavities. An appropriate level of airflow during delivery is critical to ensure that the particles are propelled past the nasal valve and to reach the posterior and superior regions of the nasal cavity. Small particle nebulizers generate respirable particles in the 3-5 micron range that can be inhaled into the lungs, regardless of whether the user chooses an oral or nasal method of introduction. For nasal deposition, the optimal droplet or particle size should be, on the whole, substantially larger than the respirable fragment size, or larger than 5 microns¹¹.

The NasoNeb Nasal Nebulizer delivers a large particle, deep-penetrating aerosol that is captured by and deposited throughout the nasal and paranasal sinus cavities^{3,7}. The NasoNeb System delivers a high concentration of drug to the target site while avoiding pulmonary deposition and the associated risk of unwanted side effects⁷. The NasoNeb System delivers a relatively small volume of liquid that stays in the nasal and paranasal sinus cavities and reduces waste associated with other therapy delivery options.



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a drug product the preparation and dispensing of which require compounding and which is required to be sterile by either the provisions of chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of <u>NAC 639.670</u>, or the provisions of <u>NAC 639.661</u> to <u>639.690</u>, inclusive.

Pasted from USP 797 (from page 797) Pharmaceutical Compounding - Sterile Preparations : Official June 1, 2008

pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following:

- (1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.
- Manufactured sterile products that are either prepared strictly ac-(2) cording to the instructions appearing in manufacturers' approved la-L beling (product package inserts) or prepared differently than published in such labeling. [NOTE—The FDA states that "Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling" [21 USC 321 (k) and (m)]. However, the FDA-approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times (see General Notices and Requirements and Pharmaceutical Compounding-Nonsterile Preparations (795)) for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological puritv or safety.]

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Paul Edwards

From:	Charity Gavin <cgavin@appriss.com></cgavin@appriss.com>
Sent:	Monday, May 19, 2014 8:37 AM
То:	Paul Edwards
Subject:	Nevada NPLEx - Implementation and Deployment

Hi Paul,

My name is Charity Gavin and I was recently given the turnover information for beginning the implementation of NPLEx within Nevada. If you have some time in the next day or two I'd like to chat with you about the NVNPLEx Implementation.

Normally, if it is okay with you, we like to hold a "stakeholder" meeting in your state so that I can meet you in person and go over some documentation regarding NPLEx and all the features that are available for Pharmacies and Law Enforcement. This is a great time for you to invite anyone from your group or members from the Law Enforcement and Pharmaceutical communities so that I can personally answer their questions and provide them with a presentation of all the features available to them. This is completely up to you, but we find that it does help to engage the stakeholders as we move into the Implementation process.

Also, I would like to work with you on getting a letter together that we send via email to pharmacies and law enforcement letting them know about NPLEx and how to register for the service. As we go through this implementation, I would also like to have weekly calls with you to discuss our progress and let you know how we are doing getting your state registered and utilizing the service.

When you have a few moments to talk, I'd like to speak with you and start some discussions around how we can proceed and together create a successful implementation.

Thanks for your time,

Charity L. Gavin

Delivery & Program Manager MethCheck/NPLEx/MoneyTrack Appriss Inc. 10401 Linn Station Rd. Louisville, KY 40223 Office: (502)815-3848 Cell: (812)207-9835 Toll Free: (866)Appriss ext.3848



Nevada State Board of Pharmacy

431 W. Plumb Lane • Reno, NV 89509 (775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444 E-mail: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

YOU'RE INVITED!

NPLEx Overview & Demonstration

Given your role as a stakeholder in the fight to curb the illegal use of pseudoephedrine products in the manufacture of methamphetamine and the important constituencies you represent, please join Appriss and representatives from the Nevada Steve Board of Pharmacy from 2:30 to 3:30 PM on July 24, 2014 at the Hilton Garden Inn on Las Vegas Boulevard in Las Vegas, Nevada to learn about the implementation plan for the National Precursor Log Exchange Program (NPLEx).

The information presented at this meeting will provide you and your organization with a basis of understanding of the timeline for implementation of the NPLEx program, how it will be introduced to retailers across the State and how law enforcement can utilize the program.

- WHAT: NPLEx Implementation Plan & Program Demonstration
- WHO: Nevada Pharmacists, Pharmacies and other Stakeholders
- WHERE: Hilton Garden Inn 7830 S. Las Vegas Blvd., Las Vegas, Nevada
- WHEN: July 24, 2014, 2:30 to 3:30 PM Pacific Time

Please let us know if you or a representative can attend this important meeting by emailing <u>cgavin@appriss.com</u>. For questions or additional information, please contact Charity Gavin at 502-815-3848.



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June 16, 2014

Dear Pharmacy Manager or Business Owner:

The Nevada State Board of Pharmacy is sending this letter to notify you of AB 39, which appears in the Nevada Revised Statutes at NRS 639.430 through 639.450. This bill requires all pharmacies in the State of Nevada that sell *over the counter* cold and allergy medications containing ephedrine and/or pseudoephedrine (PSE) to participate in a statewide, real-time electronic PSE monitoring program for the purpose of detecting and tracking illegal PSE purchases.

In compliance with AB 39, the State of Nevada has joined the National Precursor Log Exchange (NPLEx). To implement Nevada's participation in NPLEx, Appriss, the software provider of NPLEx, will provide a web-accessed database and access licenses at no charge to pharmacies in the State. The system will satisfy the Federal Combat Methamphetamine Act of 2005 (CMEA), which requires pharmacies to capture certain data regarding PSE sales, but it will enable pharmacies to easily enter the same PSE sales data into the NPLEx online system, rather than in the manual logs or in-store computer systems typically used. The data will be stored in a secure, central repository that treats the data collected as if it were HIPAA data. Furthermore, the collected data will be viewable by law enforcement in keeping with CMEA and AB 39.

To secure and protect your sales information, only your pharmacy will be able to inquire and view your store's sales data. Appriss will provide to pharmacies system licenses and system training at *no cost*. NPLEx will also assist pharmacies by speeding up the logging and maintenance of purchases/sales information. For law enforcement, NPLEx will provide real-time access to view PSE purchases and will computerize tracking and investigative reporting information. The Nevada State Board of Pharmacy encourages all pharmacies in the state to begin using this system by August 15th 2014 (or sooner) to ensure compliance with the new electronic reporting requirements by September 3rd 2014, at which time participation will be mandatory.

To use NPLEx, your business needs only an internet connected computer with a standard web browser. If your store does not sell any over the counter cold and allergy medicine that contain PSE as the active ingredient, please send an email to NVNPLEx@appriss.com. The email should contain your store name, DEA number, NCPDP number, name and brief verbiage that you do not sell such products. Once Appriss receives this information, it will be added to the NPLEx database. However, if your store or pharmacy sells PSE over the counter, you will need to register for an account.

Please have only one manager or pharmacist in charge follow the steps below to request a store account:

- Go to nplex.appriss.com,
- Click on the "Register for a Store Account" link in the bottom right,
- At the top of the next form choose Pharmacy or Non-Pharmacy from the drop down box,
- Fill out the required information for your store type and click Submit.

- Please confirm that the email address is valid.
- Please note that if you have more than one store, you must use a unique email address for
- each store. The email address cannot be associated with more than one store account.

Shortly after you register for your store account, you will receive an email message to the email address you provided during registration. This email will provide you with next steps to set up a user account. The registration needs to be completed by August 1st 2014, in order to comply with the new reporting requirements by September 3rd, 2014. Some email systems may send this email to your SPAM folder, so please check that folder if you do not see it in your email inbox. If you do not receive an email within a week of registering, please contact NPLEx Implementation Support at NVNPLEx@appriss.com or 1.855.675.3968 (1.855NPLEx.NV).

After you have registered for your store account, you may want to attend a web-based training, which Appriss will provide at no cost. During this training session, Appriss will perform a live demonstration of NPLEx, provide training on how to use the application and answer any questions you may have about the service. Trainings will be held every 3rd Tuesday from 11:00AM EST to 12:00PM EST, except for holidays. You can access the webinar at

https://appriss.adobeconnect.com/nplexretail/. For the audio portion of this training, dial **1(866) 879-2360** and enter Conference Code **5202682063**.

You may contact the Appriss Implementation Team at 1.855.675.3968 (1.855.NPLEx.NV) Mon-Fri, 9:00 AM – 5:00 PM EST or by email at NVNPLEx@appriss.com with questions related to account login issues and/or other general questions.

Additional Information:

Optional Scanner: The NPLEx retail web portal does not require any scanner hardware. However, pharmacies interested in further enhancing their workflow have the option of purchasing a scanner that will scan 2D Driver's Licenses, product UPCs, and capture a signature. The State of Nevada does **NOT** require a scanner to participate in NPLEx. If your pharmacy is interested in obtaining more information about a scanner, or has additional questions, please email NVNPLEx@appriss.com.

Point-of-Sale Integration: Appriss has also completed, or is in the process of developing, integrations with several point-of-sale (POS) vendors. By integrating with the POS software, transactions can be submitted directly to NPLEx from your POS system instead of using the NPLEx retail web portal. For additional information on whether your POS system can be integrated with NPLEx, please have your POS vendor contact Appriss at NVNPLEx@appriss.com.

This project is sponsored by the National Association of Drug Diversion Investigators. Again, there is no charge to your pharmacy for participating in the project or using the NPLEx retail web portal.

Thank you in advance for your prompt attention to this matter.

Sincerely,

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Larry L. Pinson, Pharm.D. Executive Secretary Nevada State Board of Pharmacy

TEMPORARY LICENSES (Issued since last board meeting)

Renown Regional Medical Center

Kyle Roberts

Blank



Neuada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

ACTIVITIES REPORT

JUNE 11-12, 2014 BOARD MEETING HELD IN RENO, NEVADA

This report is prepared and presented to keep interested legislators and others abreast of the activities of the Nevada State Board of Pharmacy. Following is a summary of the June, 2014 Board meeting.

Licensing Activity:

- 7 licenses were granted for Out-of-State MDEG (Medical Devices, Equipment and Gases) companies.
- 31 licenses were granted for Out-of-State pharmacies, pending receipt of a favorable inspection for all compounding pharmacies residing in another state.
- 16 licenses were granted for Out-of-State wholesalers.
- 6 applications were approved for Nevada pharmacies pending inspection.
- 3 licenses were granted for a Nevada MDEG license.
- 1 application for an intern pharmacist with a past DUI was approved after demonstrating a one-time occurrence and realizing the mistake.
- 2 applications for pharmaceutical technicians with past history of drug use were approved after satisfactorily demonstrating complete recovery and with continued monitoring.

Disciplinary Actions:

- Pharmacists AM and AP were fined \$1049; ordered CE on error prevention; Pharmacist AM was fined an additional \$750 and ordered CE on counseling patients; and Pharmacy WG was fined \$500 all for misfilling a fertility drug with an antipsychotic resulting in adverse symptoms in the patient.
- Pharmaceutical technician DB was revoked for diversion of over 18,000 doses of controlled substances.
- Pharmacist SB was revoked for diversion of controlled substances and dangerous drugs in the state of California.
- Pharmacist BV was fined \$250 and ordered 80.5 hours of CE prior to license renewal for failing to complete his required CE for the second licensing period in a row.

- Pharmacist MC was fined \$500 and ordered 119 hours of CE, and to take and pass the Nevada law exam for failed to complete any CE last renewal period.
- Pharmacist DJ was put on probation with many conditions to parallel action taken in California for diversion of controlled substances for personal use.

Other Activity:

- The usual Board business reports were given, including recent and future speaking engagements; reports on national meetings; and collaboration with other state agencies.
- A presentation was given by Caleb Cage, Director of Military and Veterans Policy, Office of the Governor regarding expedited licensure for veterans.
- Personnel evaluations were conducted.

Workshop:

None.

Public Hearing:

None.