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

In the Matter of the Accusation Against: **FUSION IV PHARMACEUTICALS, INC. dba AXIA PHARMACEUTICAL,** Pharmacy Permit No. PHY 53726 Sterile Compounding Permit No. LSC 100855, **NAVID VAHEDI** Pharmacist License No. RPH 59537, **CHRISTINA CHALIKIAS** Pharmacist License No. RPH 68840, Respondents.	Case No. 6371 OAH No. 2018101123

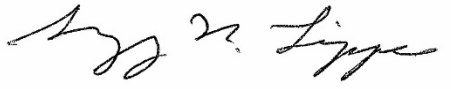
DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as the decision in the above-entitled matter, except that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), the following technical change is made to page 1 (caption page), and page 35 (paragraphs 1 and 4) wherein the pharmacy permit number should read as "PHY 53726" :

The technical change made above does not affect the factual or legal basis of the Proposed Decision, which shall become effective at 5:00 p.m. on October 25, 2019.

It is so ORDERED on September 25, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Greg Lippe
Board Vice President (Acting President)

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

In the Matter of the Accusation against:

FUSION IV PHARMACEUTICALS, INC. dba AXIA PHARMACEUTICAL,

Pharmacy Permit No. PHY 57326

Licensed Sterile Compounding No. LSC 100855

NAVID VAHEDI (PIC),

Pharmacist License No. RPH 59537

CHRISTINA CHALIKIAS (PIC),

Pharmacist License No. RPH 68840

Respondents.

Agency Case No. 6371

OAH No. 2018101123

PROPOSED DECISION

Deena R. Ghaly, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, heard this matter on March 11 through 14, 2019 and May 28, 2019, in Los Angeles, California.

Gillian E. Friedman, Deputy Attorney General, represented complainant Virginia Herrold, Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs (Department).[1] Al Mohajerian and Ann Anooshian, Mohajerian P.LC., Attorneys represented respondents Fusion IV Pharmaceuticals, Inc. doing business as Axia Pharmaceutical (Fusion IV) and Navid Vahedi (Vahedi) (collectively, respondents).[2] Vahedi was present at each day of hearing.

Oral and documentary evidence was received at the hearing. On May 28, 2019, the matter was submitted and the record was closed. For the reasons set out in the June 26, 2019 Order (Order), this ALJ reopened the record for additional briefing. In response, both parties filed timely briefs and responses. Complainant's submissions were marked as Exhibits 41 and 42 for identification. Respondents' submissions were

---

[1] Ms. Herrold was the Board's executive director at the time the Accusation was issued. She has since retired. Ann Sodergren is currently interim executive director and, for this matter, complainant.

[2] Prior to hearing, respondent Christina Chalikias entered into a stipulation with the Board, which resolved the disciplinary action against her. Therefore, charges in the Accusation against Ms. Chalikias, are not addressed in the Proposed Decision.

marked as Exhibits V and W for identification. All submissions were lodged into the record, which was closed on July 18, 2019.[3]

SUMMARY

Navid Vahedi is a pharmacist licensed by the Board and the sole owner and operator of Fusion IV. Fusion IV also holds a registration under federal law as an outsourcer (commercial drug manufacturer).

The Board issued an Accusation alleging that Vahedi and Fusion IV violated multiple provisions of pharmacy laws and regulations and seeking the suspension or revocation of their permit and licenses. Vahedi argued that the federal law under which Fusion IV operated as an outsourcer preempted state pharmacy law and therefore, Vahedi and Fusion IV could not be found liable for the Board's allegations. Vahedi also substantially denied the Board's factual allegations.

Preemption is not a viable defense in an administrative adjudication. Clear and convincing evidence established the allegations set out in the Accusation, many of which are safety-related. Vahedi's disciplinary history as well as the serious nature of the violations established that revocation of the permit and licenses held by Vahedi and Fusion IV is the only disposition consistent with the public safety.

[3] The parties' respective arguments are discussed at Legal Conclusion 10.

FACTUAL FINDINGS

Jurisdictional Matter

1. Complainant brought the Accusation solely in her official capacity. (Ex. 1.) Respondents timely requested a hearing to challenge the allegations in the Accusation and this matter ensued. (*Ibid.*)

Respondents' Licenses and Permits

2. On May 3, 2007, the Board issued Original Pharmacist License Number RPH 59537 to Vahedi. The Original Pharmacist License expired on May 31, 2019, unless it has been renewed.

3. On October 15, 2015, the Board issued Pharmacy Permit Number PHY 53726 to Fusion IV. On February 4, 2016, the Board issued Sterile Compounding License Number LSC 100855 to Fusion IV. Vahedi is Fusion IV's Chief Executive Officer, sole shareholder, Director, President, Secretary, and Treasurer/Chief Financial Officer. Pursuant to a Discontinuance of Business notice filed by respondents, the permit and the license were both cancelled effective April 1, 2018.

4. a. In January 2017, Fusion IV registered as an outsourcing facility under section 503(b) of the Food, Drug, and Cosmetic Act (21 U.S.C. § 353). Outsourcing facilities may compound both patient-specific and non-patient-specific drugs, and in larger quantities than facilities may under a Board-issued sterile compounding license.

b. Until 2017, outsourcing facilities were solely regulated under federal law. On January 1, 2017, Senate Bill 1193 (SB 1193), took effect and established a regulatory scheme for outsourcing facilities under state law. Codified at Code section

4129 et seq.,[4] SB 1193 required outsourcing facilities to be concurrently registered under both federal and state laws, prohibited facilities from simultaneously operating as a compounding pharmacy and an outsourcing facility at the same location, and prohibited outsourcing facilities from operating as a retail pharmacy. (See Code § 4129, subds. (b) and (e).)

5. a. In August 2017, Vahedi submitted an amended application for state registration as an outsourcing facility. On September 12, 2017, the Board denied the application. Respondent appealed the determination and the matter was brought before OAH under Board case number 6270. The ALJ upheld the license denial in a proposed decision. The Board adopted the proposed decision in a Board Decision and Order dated January 15, 2019. The January 2019 order is the subject of respondents' pending Petition for Reconsideration before the Board. The record is indeterminate regarding whether the Petition has been ruled upon.

b. In upholding the denial of Vahedi's outsourcing license, the ALJ cited, among other grounds, findings and determinations from an earlier Board disciplinary action in which Vahedi was a party, which was also adjudicated before OAH. In Board case number 5899, the ALJ made several factual findings including that Vahedi operated Fusion IV as a compounding pharmacy before receiving the compounding license in February 2016, and that he failed to cooperate with a Board investigation.

c. Relevant portions of the proposed decision in case number 6270 discuss the effects of the factual findings in case number 5899 under the doctrine of collateral estoppel:

[4] Undesignated statutory cites are to the Business and Professions code.

9. Complainant persuasively argued in its trial brief that the doctrine of collateral estoppel should be applied to the Decision and Order in case number 5899. (Ex. 14, p. 7-8.) The doctrine of collateral estoppel generally applies to administrative hearings. The California Supreme Court has held that an administrative decision can have preclusive effect in subsequent litigation when the tribunal that issued the decision was acting in its judicial capacity to resolve a disputed issue properly before it. (*People v. Sims* (1982) 32 Cal.3d 468, 479.) In this case, there is no doubt that the Board was acting in its judicial capacity in resolving the dispute regarding licensing discipline against Vahedi's individual pharmacist license and Fusion RX's pharmacy permit in case number 5899.

10. Five threshold requirements must be met for collateral estoppel to apply. These elements are as follows: 1) the issue to be precluded must be identical to that decided in the prior proceeding; 2) the issue must have been actually litigated at that time; 3) the issue must have been necessarily decided; 4) the decision in the prior proceeding must be final and on the merits; and 5) the party against whom preclusion is sought must be in privity with the party to the former proceeding. (*People v. Garcia* (2006) 39 Cal.4th 1070, 1077.)

11. In this case, the issues to be precluded, namely, Vahedi's pre-licensure conduct and discipline by the Board, are identical to that decided in case number 5899. Vahedi was represented and present during the two-day administrative hearing in case number 5899. He was afforded a full and fair opportunity to present his defenses during the hearing. . . . the issues were decided in the prior proceeding, and the Decision and Order in case number 5899 is final and on the merits, with the exception of the order pertaining to the suspension of Fusion Rx for 30 days.

12. The final remaining issue is whether Fusion IV, which was not a party to case number 5899, is in privity with Vahedi, who was party to the prior adjudication. The question of privity has been restated in terms of whether a nonparty was "sufficiently close" to an unsuccessful party in a prior action as to justify the application of collateral estoppel against the nonparty." (*Lynch v. Glass* (1975) 44 Cal.App.3d 943, 948.) . . . Here, Fusion IV is in privity with Vahedi. Although Fusion IV is a corporate entity, Vahedi is the director, president, and 100 percent owner of Fusion IV. Their interests are identical. Moreover, Fusion IV had a strong interest in defending Vahedi's pharmacist's license and Fusion Rx's pharmacy permit against Board discipline, given that Fusion IV's license application denial was based on the pending disciplinary charges alleged in case number 5899.

> 13. Under these circumstances, Fusion IV is bound by the Decision and Order in case number 5899, and it is precluded from re-litigating the issues that were decided in that case.

(Exh. 37 at pp. 20-21.)

d. The ALJ hearing case number 6270 further found that the acts underlying the earlier disciplinary matter evinced Vahedi's present or potential unfitness to operate an outsourcing facility thus establishing a cause for denying his application. (*Ibid.*)

e. As another basis for denying Vahedi's application for instate outsourcing registration, the ALJ found that Vahedi had operated Fusion IV as a compounding facility without a license:

> 29. . . . Vahedi operated Fusion IV without a sterile compounding license from October 1, 2017, to October 23, 2017, and he has continued to compound drugs at Fusion IV without any license from April 1, 2018, until the present day. . . . By continuing to engage in sterile compounding at Fusion IV without any license, Vahedi is not complying with state law and is in violation of Condition 1 of his Board probation. Furthermore, Vahedi has assumed supervising authority at Fusion IV, in violation of Condition 7 of his Board probation.

(*Id.* at p. 25 [internal citations to Factual Findings omitted].)

Communications Between Vahedi and the Board's Supervising Inspector

6. Christine Acosta (Acosta) has been an inspector for the Board since December 2011. She received a Bachelor of Science degree in biological sciences from Holy Name College in 2000 and a Doctor of Pharmacy from Western University of Health Sciences in 2006. She also obtained her California pharmacist license in 2006. From 2011 to 2014, Acosta worked in the Board's diversion team, inspecting wholesale drug producers, pharmacies, and clinics. Since 2014, she has served as the supervising inspector for the Board's compounding team. Acosta has received specialized training in compounding and is familiar with the laws, regulations, and standards of practice in pharmacy.

7. a. On September 14, 2017, an inspector from Acosta's team, Ann Kalantar, arrived at Fusion IV for an annual inspection, as required in order to renew a compounding license. Fusion IV personnel did not allow her to enter the facility. The next day, Vahedi sent an e-mail communication to Acosta, stating in part:

> As the owner and president of a 503B Outsourcing Manufacturing facility in California, the multiple sets of rules by which we are regulated leave me in a very difficult position. Not only do we maintain federal registration of our facility as a 503B outsources, we are now required to register with the State, which presents multiple avenues to do so (either through a state Outsourcing License, a state-issued retail pharmacy license (PHY) and/or a sterile compounding license (LSC), As they have often done in the

past, California State license requirements put my business on a collision course with federal requirements, obstruct me from doing business, or both.

This issue arose again this week when, much to my surprise, Board of Pharmacy Inspector Kalantar arrived to perform an inspection of our facility, but for an LSC and/or PHY license renewal, not as an outsourcing facility. As you may be aware, we have decided to surrender our current LSC and PHY in order to obtain an Outsourcing License from California. Discussing the matter at length with the inspector, she suggested that I complete and submit a Discontinuation of Business form to the Board to explicitly terminate our LSC and/or PHY. Upon further examination, either termination or renewal of our LSC and/or PHY will trigger negative outcome for us, and I require clarification from the Board on exactly how to proceed.

(Exh. 9, p. AGO-146-147.)

b. Later the same day, Acosta responded to Vahedi, stating that the Board cannot assist with interpretations of state and federal law. Her communication continued as follows:

I can provide you with the following information. One premises may not be co-licensed as a pharmacy and an outsourcer with the California Board of Pharmacy. Additionally, as you stated in the email, you are currently

registered with the FDA as a 503B therefore you need to be licensed with the California Board as an outsourcer not a pharmacy, as required by 4129.

Given your need to transition into this new form of licensure we attempted to conduct the required annual inspection for your LSC, which you refused on 9/14/17. As you know, the renewal of a LSC requires the state to conduct and find a pharmacy in compliance with all applicable laws. I feel the need to formally notify you that as of 10/1/17, LSC100855 will be expired and all sterile compounding must cease at this location.

(Exh. 9, p. AGO -147.)

c. In response to Acosta's communication, Vahedi wrote that he had submitted the renewal fee to the Board for the compounding license and requested an inspection. (*Ibid.*)

Board Investigations

8. Applicable regulations prohibits pharmacies from compounding a drug preparation that is a copy or essentially a copy of a "commercially available" drug compound unless that drug appears on a government-issued list of drugs in short supply at the time the compounded drug is prepared and dispensed. On October 5, 2017, the Board received a complaint from the Jazz Pharmaceutical company (Jazz), alleging that Fusion IV was improperly manufacturing ziconotide, a pain management medication and a "dangerous drug" pursuant to Business and Professions code section

4022. According to Jazz's counsel, Fusion IV was manufacturing the drug even though there was no shortage of it and labeling it Prialt, Jazz's trade name for the drug. Jazz's counsel provided Acosta with a Fusion IV invoice for Prialt dated August 8, 2017 and a photograph depicting two vials of Fusion IV-compounded ziconotide 100mcg/ml. (Exh. 11.)

9. a. On October 12, 2017, Board Inspector Joshua Lee (Lee) performed Fusion IV's annual renewal sterile compounding inspection. As part of the inspection process, Lee requested documents to be produced as he waited. Vahedi produced documents identified as: a log of scripts for "Zicon;" the master formula for ziconotide; and the compound logs for biotin, atropine sulfate, two versions of CA-008, an experimental chemotherapy, and injectable B-Complex vitamins. Lee gave Vahedi a receipt for the documents Lee collected during the inspection. (Exh. 13, p. AGO-169.)

b. After the inspection, Lee prepared a report noting one violation, compounding drugs without a valid license. Specifically, according to the investigation report, drug compounding occurred at Fusion IV during this period as follows:

> October 4, 2017: one batch of Biotin 10mg/ml susp. (Lot #10042017+47781)
>
> October 6, 2017: one batch atropine sulfate monohydrate 0.1% (Lot #10062017+47814)
>
> October 10, 2017: one batch CA-008 HCL (PF) 0.5mg/ml injectable, an investigational (i.e., experimental) chemotherapy drug. (Lot # 10102017+47838)

October 10, 2017: one batch CA-008 HCL (PF) 1 mg/ml injectable (Lot # 10102017+47840)

October 11, 2017: one batch B-Complex 110 injectable (Lot # 10112017+47844)

(Exh. 13.)

c. The report also listed five corrections for Vahedi to resolve: Submit Fusion IV's biennial inventory; submit proof of safety and sterility training for staff and proof of compliance with sterility and cleanliness standards for certain rooms within the facility; and correct pressure differentials for air flow between the facility's fill and prep room and its ante room and between its chemo room and chemo ante room.

d. On October 17, 2017, Vahedi wrote to Lee, "I am writing this letter to inform you that we will not be able to make corrections 4 and 5 as listed in your inspection report." (Exh. 16, p. AGO-187.) Corrections 4 and 5 called for changes in the differential pressures between rooms at Fusion IV's facility. According to Vahedi, Inspector Lee's directives would have put Fusion IV in violation of federal regulations. He went on to state that the other three corrections had been made.

e. In a letter dated October 19, 2017, Vahedi wrote to the Board:

We wish to provide clarity regarding Violation 1 (regarding BPC 4121.1(a)) of the Inspection Report from 12OCT2017 as filed by Inspector Joshua Lee.

None of the several batches of material prepared after our sterile compounding license (LSC) expired on 01OCT2017

have been for sale as injectable sterile drug products. Instead, these materials were made with the sole intent of providing experimental samples for use by our Quality department. In order to comply with the state regulations concerning BUD issuance, we have made a concerted effort to establish our Stability program and generate data. Accordingly, while awaiting the Board's inspection, we only generated samples to meet this goal. Attached is the commercial dispensing history for the month of October as evidence of this.

(Exh. 16, p. AGO-202.)

f. Two documents were attached to Vahedi's October 19, 2017 letter, a single page document entitled Prescriptions Filled between 10/1/17 and 10/13/17 with a notation, "0 prescriptions in report" (Exh. 16, p. AGO-171) and "Formula Worksheet" for ziconotide acetate (PF) 100 mcg/ml injectable. The Formula Worksheet is a form with a number of spaces for information to be input. The one submitted by Vahedi is entirely blank. (Exh. 16, p. AGO-172.)

10. On October 23, 2017, Acosta sent a letter to Vahedi via an e-mailed attachment. The e-mail included the following notation: "Attached is important information regarding the renewal of [the compounding pharmacy license]." Acosta's letter began by stating that Vahedi's instate outsourcing application was still under review. Acosta's letter went on to state:

As you may be aware, with certain exceptions not applicable here, each facility may only hold one premises license from the board. So, you will need to select between your outsourcing facility application and your existing pharmacy/sterile compounding pharmacy licensure for your future operations. We understand that you have selected the outsourcing facility licensure as the method under which you intend to operate in the future. We also believe that this is the more appropriate structure to your practice model.

However, because it will not be possible to process your outsourcing facility application and complete the necessary pre-licensure inspection(s) before your LSC license expires, and in order to avoid an interruption in service to your patients, pursuant to Business and Professions Code section 4127.8 we are issuing a temporary renewal of your LSC licensure for one hundred eighty (180) days beyond its present October 1, 2017 expiration, to allow sufficient time to review and process your outsourcing facility application. Once renewed, it will be current and active until April 30, 2018. As of that date, the temporary renewal will expire of its own accord, and there will be no further opportunity for renewal of the pharmacy and sterile compounding licenses.

(Exh. 17, p. AGO-205.)

11. a. In November 2017, Acosta became more directly involved with respondents both in connection with Fusion IV's annual inspection and the complaint from Jazz. On November 3, 2017, Acosta wrote to Vahedi, requesting documentation and additional information regarding 11 issues, including records of compounding, purchasing or dispensing ziconotide or Prialt, and records of any dispensing any of the five drugs compounded during the period of October 1 through October 12, 2017, and which Vahedi had claimed were prepared for quality control purposes only.

b. In a letter dated November 20, 2017, Vahedi's counsel, Al Mohajerian, wrote that Fusion IV was in compliance with federal law in producing ziconotide and disputing that Fusion IV had produced the drug when it was commercially available. Regarding its commercial availability, Mohajerian pointed to two communications from Jazz. The first, dated October 27, 2016 was a bulletin from Jazz reporting the "temporary interruption" in the supply of 25 mcg/ml 20 ml vials of the drug. The second, dated January 9, 2017, reported a temporary shortage of the 100 mcg/ml 1 ml vials. Finally, Mohojerian noted that Fusion IV did not "mass produce" ziconotide but only prepared discrete batches for doctors' use in their offices. (Exh. 21, pp. AGO-216-228.)

12. a. On November 20, 2017, Acosta wrote to Vahedi and Mohajerian, requesting additional information. In response to Acosta's letter, Vahedi affirmed that he had just one communication from Jazz, an October 5, 2017 letter. Regarding other documents for which Acosta had requested production from a date range beginning in October 16, 2015 but had not received anything from that year, Vahedi replied that since he did not commence business until February 2016, he assumed Acosta meant a date range commencing October 16, 2016, not 2015 and therefore produced documents from that date forward. Finally, in her initial inquiry, Acosta had requested

the investigation protocol for the two investigative drugs (see Factual Finding 9b) compounded in early October 2017. Vahedi replied that he did not have the protocol and would not have been able to share it with the Board if he did as he had signed a nondisclosure agreement his customer, a clinical trial group.

b. The second group of inquiries requested contact information for doctors from which Vahedi had obtained statements regarding ziconotide shortages. Vahedi provided this information. (See Exh. H.)

13. a. Acosta testified at the hearing. She stated that she found Vahedi to be uncooperative and dishonest in his dealings with the Board. Specifically, she found Vahedi's documentation of the ziconotide shortage suspicious for several reasons. The bulletins from Jazz regarding temporary interruptions were not from the same time period when Fusion IV was compounding and distributing ziconotide. A third bulletin from Jazz, dated March 22, 2017, expressly stated that Jazz had resolved the temporary shortages and that all dosages were available, yet Vahedi did not address or acknowledge this during the investigation. Moreover, Vahedi had provided doctors' notes ostensibly to further support his assertion of a ziconotide shortage. However, because these notes, prepared on pre-written forms, devoid of any contact information for the doctors who signed them, containing identical information, and prepared after the fact, not contemporaneously with Fusion IV's manufacturing of the drug, Acosta found them suspect and unconvincing.

b. Acosta also stated that documents produced pursuant to her November 20, 2017 request appeared inconsistent with information Vahedi had provided to the Board in October 2017. As noted in Factual Finding 9, Vahedi had written to the Board

affirmatively stating that compounds prepared between October 1 and October 12, 2017 had not been dispensed. Records provided to the Board in November included a multi-page document showing that Fusion IV had compounded and dispensed hundreds of drugs during that period, including the ones noted in Lee's report and at least 65 orders of ziconotide. (See Exh. B, pp. 126-152.) In some five instances, drugs were dispensed to Fusion Rx, Vahedi's retail pharmacy and a separate entity from Fusion IV. During the hearing, Vahedi maintained that the initial communication about the drugs was the result of his reliance on a mistake made by one of his employees. In light of the serious nature of a regulatory inspection, Vahedi's central and unique role in Fusion IV's management, and the vast difference between the document produced in October showing zero medications dispensed and the log produced in November showing hundreds of medications dispensed, Vahedi's testimony is not found credible.

14. a. Under applicable pharmacy laws and regulations, a commercially available drug may not be "imitated" and the manufacturing and dispensing of such drugs violate laws against misbranding and the selling or transfer of misbranded drugs.

b. Comparing Fusion IV's Formula Worksheet and batch records for ziconotide to the manufacturing information provided by Jazz, Acosta determined that the formulas used were virtually identical and that therefore Fusion IV's version was an impermissible imitation drug. As an imitation drug, Fusion IV's use of the drug's trade name, Prialt constituted to impermissible misbranding and dispensing the drug with those names constituted impermissible selling or transferring of misbranded drugs. (Exh. 25.)

15. Acosta compared the master formula used by respondents for ziconotide and noted that the beyond-use date (BUD) was just three days, consistent with the information provided by Jazz. (Exh. 18.) However, Fusion IV's Formula Worksheets, reflecting when batches of ziconotide were made and what the BUD was, show a 90-day BUD. (See, e.g. Exh. 31, p. AGO-419 [date made: 1/16/2017; BUD: 4/16/17].) Acosta further determined that respondents had not performed the required tests and studies to support an extended BUD.

16. Acosta also examined respondents' records for completeness and accuracy. For the five drugs compounded between October 1 and October 12, 2012, as set out in Factual Finding 9b, all five were missing the names of the manufacturers of the compounded ingredients. The batch record for the Biotin did not include a final check, yet it had been dispensed on October 16, 2017. For the experimental chemotherapy drug CA-008, the lots were each identified only as ABCD 1234. For the B-Complex injectable, there was no clear beyond use date (BUD).

17. a. Acosta stated that applicable laws and regulations require compounded drugs to be tested and monitored for acceptable levels of pyrogens (toxins), a 14-day process. By comparing the "made by" date on certain lots of drugs produced by respondents to their release date, Acosta determined that they had not been held for the required period.

b. In the Accusation, three instances of this are alleged as follows: Lot Number 05042017+4586 shows a "made-by" date of May 4, 2017 and dispense dates of May 3 and May 8, 2017; Lot Number 07052017+46774 shows a made-by date of July 5,

2017 and a release date of July 7, 2017; Lot Number 08012017+47101 shows a made-by date of August 1, 2017 and a dispense date of August 11, 2017. (Exh. 1, p. AGO -032.)

c. The formula work sheets at Exhibit 31, pages AGO-486, 530, and 533, show that the lots identified in the Accusation were made on the dates alleged. The Prescription Filled logs at Exhibit B, pages 49, 75, and 97 confirm the dispense dates May 8, July 7, and August 11, 2017 respectively. There is no documentation supporting complainant's contention that medication showing a "made-by" date on May 4, 2017 was dispensed on May 3, 2017, which, as respondents have pointed out, would have been impossible.

Respondents' Evidence

18. a. Respondents deny that they engaged in unlicensed compounding activity, as charged in the first cause of discipline in the Accusation. During his testimony and throughout communications with the Board while they were under investigation, Vahedi maintained that he was not engaged in compounding as defined by state laws and regulation or in the practice of pharmacy, which he contends is limited to filling patient-specific prescriptions. Vahedi also denied engaging in unlicensed outsourcing by dispensing Fusion IV-manufactured drugs to Fusion Rx, a retail pharmacy. According to Vahedi, because he is the sole owner of both facilities, any dispensing from one to another amount only to a transfer of property.

b. Additionally, as more fully set out in Legal Conclusion 10 below, Vahedi argued that Acosta's letter of October 23, 2017, had the legal effect of reviving Fusion IV's expired compounding license and, therefore, to the extent it engaged in compounding practice, it cannot be found to have done so during an unlicensed status.

c. Vahedi denied engaging in unprofessional conduct, including committing acts of dishonesty and fraud, and providing false documents, alleged in the third, fourth, and fifth cause for discipline of the Accusation. Vahedi maintained that any failure to provide correct information or records to the Board were the result of mistake, confusion, and miscommunications. In particular, he noted that the Board's use of the term "prescription" confused him. Although his own software-generated records use the term, Vahedi stated that when Board investigators requested records relating to certain prescription numbers or otherwise used the term prescription, he did not understand what they meant or did not believe he had any responsive documents because, as an outsourcing facility, Fusion IV did not fill prescriptions.

d. Vahedi denied all allegations of misconduct related to Fusion IV's manufacturing of ziconotide as alleged in causes for discipline 6 through 10 in the Accusation and allegations of failing to maintain compounding records as alleged in causes for discipline 11 and 12 in the Accusation. As with other the allegations, Vahedi maintained that the laws and regulations alleged to have been violated were preempted by federal law.

d. Vahedi's assertions of good faith efforts and honest attempts to cooperate with the Board are belied by the overwhelming documentary evidence produced by Fusion IV which contradicting his initial statement to Board inspectors. As the sole owner and operator of Fusion IV, his assertions about mistakes and misunderstanding are not credible.

Prior Discipline

19. Vahedi has an extensive prior disciplinary history. In addition to the disciplinary matter discussed in Factual Finding 5, between September 2015 and October 2016, Vahedi incurred three citations for safety-related violations. Vahedi was fined a total of $6500 for the citations and was placed on probation for a four -year period for the disciplinary action.

Investigation and Prosecution Costs

18. a. Complainant submitted two declarations of costs: (i) the declaration of Anne Sodergren, Acting Executive Director, in which she certified that the Board incurred $10,559 in investigatory costs for the matter; and (ii) the declaration of Gillian Friedman, Deputy Attorney General, in which she certified that the Justice Department incurred $18,072.50 in costs related to the prosecution of this matter. The costs total $28,631.50

b. Counsel for respondents submitted a Response and Objection to Certification of Prosecution Costs (Costs Response).[5] Respondents argued that they should not be liable for costs because the allegations underlying this matter are "directed towards 'pharmacy' violations where Fusion IV is not a pharmacy and has not been a pharmacy since registering as a federal outsourcing facility on or about January 6, 2017." (Costs Response, p. 2.) Moreover, they argue that the Board's investigation and prosecution were unreasonable and unwarranted because Board officials were aware that respondents had filed a federal preemption suit in 2018 and they should not have

[5] The Costs Response was filed with OAH and served on complainant prior to the hearing.

pursued this disciplinary action within days of the federal preemption suit's dismissal on technical grounds and without prejudice. As discussed further in Legal Conclusion 22, these arguments are deemed irrelevant for determining cost awards.

LEGAL CONCLUSIONS

Board Mandate

1. The Board is vested with the administration and enforcement of pharmacy law. (Code, § 4001.) In exercising its licensing, regulatory, and disciplinary functions, protection of the public is its highest priority. (Code, § 4001.1)

Burden and Standard of Proof; Evidentiary Requirements

2. The Board, as the party making the charges, bears the burden of proof and has the obligation to produce evidence in support of the charges it is alleging. (*Brown v. City of Los Angeles* (2002) 102 Cal. App. 4th 155, 175.) Such burden applies to "each fact the existence or nonexistence of which is essential to the claim for relief or defense that he is asserting." (Evid. Code, § 500.)

3. As the charging party, the burden of proof is on complainant to establish alleged violations by "clear and convincing proof to a reasonable certainty." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.)

4. Evidence does not have to be direct in order to effectively carry the burden of establishing a claim; circumstantial evidence may be as persuasive and convincing as direct evidence. (See *People v. Overstock.com, Inc.* (2017) 12 Cal.App.5th 1064, 1086.) "Inferences may constitute substantial evidence but they must be the

product of logic and reason. Speculation or conjecture alone is not substantial evidence." (*Feduniak v. California Coastal Commission* (2007) 148 Cal.App.4th 1346, 1360.)

General Provisions of Pharmacy Law

5. The State of California has the power to regulate, through the exercise of its police power, the practice of medicine, dentistry and pharmacy within the state (see e.g., *Rosenblatt v. Cal. St. Bd. of Pharmacy* (1945) 69 Cal.App.2d 69) and the state may regulate the administration of drugs (*Blinder v. Division of Narcotic Enforcement* (1972) 25 Cal.App.3d 174), including outright banning of such distribution (see *California Optometric Assn. v. Lackner* (1976) 60 Cal.App.3d 500).

6. "Pharmacy" is defined as a specific location, that is, "an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. 'Pharmacy' includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." (§ 4037, subd. (a).) "Pharmacist" means a natural person licensed by the Board. (§ 4036.) Permitted pharmacist functions include "[f]urnish[ing] a reasonable quantity of compounded product to a prescriber for office use by the prescriber." (§ 4052.)

7. Pharmacists and pharmacies are separately licensed (see §§ 4036, 4037, subd. (a)), and a pharmacy acts through its pharmacist. A pharmacist's misconduct can support administrative penalties against both the pharmacist and the pharmacy. (See

Arenstein v. California State Bd. of Pharmacy (1968) 265 Cal.App.2d 179 [overruled on other grounds in *Barber v. Long Beach Civil Service Com.* (1996) 45 Cal.App.4th 652, 658.)

8. Drug compounding refers to combining, mixing, or altering ingredients to create a medication and has been recognized as a traditional component within the practice of a pharmacy. (See *Thompson v. W. States Med. Ctr.* (2002) 535 U.S. 357, 360-361.) The Board regulates compounding practices as part of its regulation of pharmacies. Under California Code of Regulations, title 16 (Regulation) section 1735 et seq., a compound drug may only be produced by a licensed pharmacist upon the prescription of a licensed physician with the compound drug formulated for an individual patient or, at the direction of a physician, for office use. A pharmacist may not mass produce and pre-compound drugs for commercial distribution. (Reg. § 1735.)

Preemption and Collateral Estoppel

9. a. Respondents argue that, as of January 2017 when Fusion IV became a federally registered outsourcing facility, they were no longer subject to the state's licensing requirements for compounding drugs and thereof cannot be held liable for compounding without a license under state law. Additionally, because the federal laws under which they operated preempt all state law, respondents argue they cannot be liable for any violations under state pharmacy law.

b. Pursuant to the California Constitution, this forum is not authorized to decide a preemption defense. Under Article 3, section 3.5 of the California Constitution, "An administrative agency . . . has no power: . . . (c) to declare a statute unenforceable or to refuse to enforce a statute on the basis that federal law or federal regulations prohibit the enforcement of such statutes unless an appellate court has

made a determination that the enforcement of such statue is prohibited by federal law or federal regulation."

c. Respondents have communicated their intention to pursue a federal preemption suit once they have exhausted their administrative remedies. As it stands, however, there is no appellate court guidance providing the necessary authority to declare the laws and regulations at issue preempted by federal law. As such, respondents' defense must fail.

10. a. In the alternative, respondents argued that, even if the laws and regulations relating to licensing in California apply, Acosta's October 23, 2017 letter, as an official document from a senior Board official, should be binding on the Board and, as it plainly states that respondents' compounding license was temporarily renewed 180 days "beyond its present October 1, 2017 expiration," (Factual Finding 10), that means the license was in effect at all relevant times. Complainant counters that, as with the binding effect of case number 5899 on case number 6270, the doctrine of collateral estoppel requires that case number 6270's finding that respondents had compounded drugs while the compounding license was expired is binding here. Moreover, complainant argued that, as a factual matter, respondents were clearly in violation of licensing requirements because they could not have known about the coming temporary renewal when they engaged in compounding activity before receiving Acosta's letter and before completing the necessary annual inspection.

b. *People v. Sims, supra*, 32 Cal.3d at p. 479, the case relied upon in case number 6270 and by the complainant to establish the applicability of collateral estoppel, casts some doubt on its application when the standard of proof for the prevailing party – here, the Board – was lower in the first matter than the second. In case number 6270, a statement of issues, the standard of proof was preponderance of

the evidence and the burden was on respondents. In the instant case, the standard is clear and convincing evidence and the burden is on the Board. Additionally, the record is not clear regarding whether respondents' petition for reconsideration has been decided, raising a question about whether the finality element is met. The weight of the evidence presented in the instant matter, however, strongly supports a finding that respondents operated Fusion IV under an expired license from the period of October 1, 2017 through at least October 23, 2017 when they received Acosta's letter. Vahedi's earlier communications and efforts to pay the fee at the final hour in late September 2017, as well as his request for an expedited inspection, clearly demonstrate he knew his license would expire on October 1, 2017, yet allowed Fusion IV to continue to compound and dispense drugs.[6]

Causes for Discipline

UNLICENSED ACTIVITY

11. a. Code section 4127.1, subdivision (a), provides that a pharmacy "shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding license from the [B]oard pursuant to this section." Code section 4129.1, subdivision (a), provides that a federally-registered outsourcing facility located in California, "shall also be licensed by the [B]oard as an outsourcing facility before doing business within this state."

[6] In Complainant's post-hearing submissions, she requests that the Accusation be amended to conform to proof by changing the dates of operations under an expired license to October 1, 2017 through October 23, 2017. The motion is granted.

b. Clear and convincing evidence established that respondents prepared and sold sterile drug preparations between October 1, 2017 and October 23, 2017, a period when respondents' sterile compounding license, was expired, as alleged in count 1 of the Accusation. (Factual Finding 9 and Legal Conclusion 11a.)

c. Clear and convincing evidence established that respondents, while located in this state, engaged in outsourcing activity as alleged in the second cause for discipline in the Accusation. Fusion IV dispensed drugs to Fusion Rx. Fusion Rx is a retail pharmacy, which in turn could hold out drugs in its possession, including those manufactured by Fusion IV, for sale to the public. This is the very activity regulated by the instate outsourcing regulations. That Vahedi is the owner of the two facilities is not a defense. On the contrary, such an arrangement appears to be an attempt to circumvent state regulatory limitation on outsourcing. (Factual Finding 18a and Legal Conclusion 11a.)

UNPROFESSIONAL CONDUCT

12. a. Code section 4301 provides that the Board "shall take action against any holder of a license who is guilty of unprofessional conduct." Unprofessional conduct" includes "[t]he commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not." (Code, § 4301, subd. (f)), knowingly making or signing false documents (Code, § 4301, subd. (g)), or subverting a Board investigation (Code, § 4301, subd. (q)).

b. Clear and convincing evidence established that respondent Vahedi engaged in unprofessional conduct by fraudulently representing to the Board, and

presenting signed records indicating that Fusion IV had not dispensed any product with "zicon" in the name when in fact respondents sold ziconotide some 65 times during the period of January 1 to October 12, 2017 establish that they engaged in unprofessional conduct as charged in counts 4 and 5 in the Accusation. (Factual Findings 13 and Legal Conclusion 12a.)

c. Clear and convincing evidence established that respondent Vahedi engaged in unprofessional conduct by subverting the Board's investigation in that he failed to timely provide requested records and to sufficiently explain records produced at the request of Board personnel as charged in count 5 of the Accusation. (Factual Finding 11 and Legal Conclusion 12a.)

VIOLATIONS RELATED TO COMPOUNDING COMMERCIALLY AVAILABLE DRUGS AND MISBRANDING DRUGS

13. a. Health and Safety Code section 111395, subdivision (a) provides that a drug is misbranded if it is an imitation of another drug. Health and Safety Code section 111445 provides that it is unlawful to misbrand drugs.

b. Clear and convincing evidence established that respondents manufactured an imitation drug and therefore, misbranded drug as alleged in the sixth cause of discipline in the Accusation. (Factual Finding 13 and Legal Conclusion 11a.)

14. a. Code section 4169, subdivision (a)(3) in conjunction with Health and Safety Code section 111335 prohibit dispensing misbranded drugs.

b. Clear and convincing evidence established that from at least January 1, 2017 until September 25, 2017, respondent dispensed ziconotide acetate some 65 times. (Factual Finding 13 and Legal Conclusion 14a.)

FAILURE TO HAVE A MASTER FORMULA PRIOR TO COMPOUNDING

15. a. Regulation section 1735.2, subdivision (e)(4) provides that a drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes "[t]he maximum allowable beyond use date for the preparation and the rational or reference source justifying its determination."

b. Clear and convincing evidence established that respondents violated regulation section 1735.2, subdivision (e)(4) as alleged in the eight cause of discipline in the Accusation. Although respondents maintained a master formula for ziconotide on the premises that they submitted to Lee during the October 12, 2017 inspection (Fact Finding 9), batch records showed that Fusion IV's actual production of ziconotide had a much longer BUD than what is called for on the master formula. As there was no other master formula discovered or produced, the evidence supports the inference that the ziconotide was produced without first preparing a master formula. (Factual Findings 15 and Legal Conclusion 15a.)

COMPOUNDING OF A COMMERCIALLY AVAILABLE PRODUCT

16. a. Code section 4301, in conjunction with Regulation 1735.2, subdivision (d)(3) prohibits licensed compounding pharmacies from compounded commercially available drugs.

b. Clear and convincing evidence established that from January 1 to September 25, 2017, respondents compounded ziconotide acetate seven times and dispensed it at least 65 times as alleged in the ninth cause for discipline of the Accusation. (Facual Finding 15 and Legal Conclusion 16a.)

FAILURE TO SUPPORT THE BEYOND USE DATE ASSIGNED

17. a. Code section 4301, subdivision (o), in conjunction with Regulation section 1735.3, subdivision (a)(2) require that compounding pharmacies maintain a master formula for compounded drugs as part of the records required.

b. Although respondents maintained a master formula for ziconotide on the premises that they submitted to Lee during the October 12, 2017 inspection (Fact Finding 9), batch records showed that Fusion IV's actual production of ziconotide had a much longer BUD than what is called for on the master formula provided. As there was no other master formula discovered or produced, the evidence supports the inference that there was no master formula for ziconotide produced by respondents as alleged in the tenth cause of discipline in the Accusation. (Factual Findings 15 and Legal Conclusion 17a.)

FAILURE TO HAVE COMPLETE COMPOUNDING RECORDS

18. a. In addition to the BUD and the master formula, Code section 4301, subdivision (o), in conjunction with Regulation section 1735.3, subdivision (a)(2), requires that compounding pharmacies maintain records of the manufacturer of the compounded ingredients, the pharmacist who performed the final check on the drug before it was dispensed, among other recordkeeping requirements.

b. Clear and convincing evidence established that respondents did not maintain all required recordkeeping in the process of compounding drugs as alleged in the eleventh count of the Accusation. (Factual Finding 16 and Legal Conclusion 18a.)

FAILURE TO MAINTAIN STERILITY STANDARDS

19. a. Code section 4301, subdivision (o) in conjunction with Regulation 1751.7, subdivision (e)(1) require compounding pharmacies to perform sterility testing prior to dispensing the drugs they produce.

b. Clear and convincing evidence established that respondents failed to complete required sterility testing as alleged in the twelfth count of the Accusation. (Factual Finding 17 and Legal Conclusion 19a.)

Appropriate Level of Discipline

20. a. The Board has developed the Model of Disciplinary Guidelines and Model Disciplinary Orders (Guidelines), codified at Regulation 1760. The Guidelines recommend ranges of discipline for violations, which are each categorized under one of four categories, category I as the least serious and category IV as the most serious. In matters involving multiple violations, the minimum and maximum penalty parameters should be those for the violation or violations in the highest category. (Guidelines, p. 8.)

b. The violations in this matter span three categories: Category I – recordkeeping violations; Category II – violations of self-assessment obligations; violations involving moral turpitude, dishonesty or fraud; Category III – violations

involving fraudulent acts, trading, selling or transferring misbranded or expired dangerous drugs. The range of penalties for the highest of these categories, category III, is a minimum of stayed revocation with three to five years' probation and the maximum penalty is revocation. (Guidelines, pp. 2-4.)

21. a. Under the Guidelines, relevant factors to consider when determining the specific discipline within a given range are: whether the violations caused actual or potential harm to the public or any individual consumer, prior disciplinary record or warnings, number and/or variety of current violations, nature and severity of the offenses, any aggravating or mitigating circumstances, whether the violations were committed with intent or were the result of negligence, and whether there was financial benefit to the respondent from the misconduct.

b. Applying the Guidelines criteria for determining penalty: (i) the record did not establish actual harm to anyone; however, respondents' failure maintain licensure status, extending the beyond use dates of certain drugs without sufficient studies or documentation to support the extension, and even their failure to properly maintain compounding records properly, all raised the specter of harm to their patients and evince a general attitude inconsistent with the public welfare; (ii) Respondent Vahedi has an extensive disciplinary history with the Board, including for discipline related to safety related matters; (iii) the offenses, as a whole and considered individually, are serious considering the potential harm to patients from improperly manufactured medication; and (iv) It can be reasonably inferred that Vahedi, as the sole owner of Fusion IV, stood to gain financially from operating without the constraints and burdens of applicable laws and regulations.

22. Respondents' practice implicates serious issues of health and public safety. The violations established, the history of lesser penalties Vahedi has incurred in the past, and the application of the Guidelines criteria, considered together, support issuing the most serious level of discipline, revocation of respondents' permit and licenses.

Cost Recovery

21. a. Under Business and Professions Code section 125.3, a licensee may be ordered to pay the reasonable costs of the investigation and enforcement of the case. In *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, the California Supreme Court considered whether a similar cost recovery provision impermissibly discouraged licensees from exercising their due process rights to a hearing before their licenses could be revoked or suspended. The Court determined that cost recovery for investigation and prosecution is permissible as long as certain conditions are met: assessment of the costs will not unfairly penalize a licensee who is found to have committed some wrongdoing but has used the hearing process to reduce the charges or the severity of the discipline; the licensee has a subjective belief in the merits of her position; the licensee has the means to pay the costs; and the costs are not disproportionally large when considered in the context of the innocuousness of the charge at issue. (*Zuckerman*, 29 Cal.4th at p. 45.)

b. Here, respondents may have had a subjective belief in the merits of their position but they did not succeed in reducing the charges or lessening the severity of the discipline imposed. The costs submitted were reasonable for the breadth and complexity of the matter. Nothing in the record indicates respondents do not have the means to pay them. Under these circumstances, the full amount of the costs requested, $28,631.50, are awarded pursuant to the Order below.

OTHER MATTERS

22. a. Code section 4307 prohibits Board licensees who have had their licenses or permits revoked from serving as a manager, administrator, owner, member, officer, director, associate, or partner, or in any other position with management or control of a licensee until their license is reinstated.

b. As set out in the Order below, respondents' permit and licenses are revoked and so they are subject to the prohibitions of Code section 4307.

ORDER

1. Pharmacy Permit Number PHY 57326 issued to respondent Fusion IV pharmaceuticals Inc., doing business as Axia Pharmaceutical is revoked.

2. Licensed Sterile Compounding Number LSC 100855 issued to respondent Fusion IV pharmaceuticals Inc., doing business as Axia Pharmaceutical is revoked.

3. Pharmacist License Number RPH 59537 issued to respondent Navid Vahedi is revoked.

4. Pursuant to Code section 4307, respondent Navid Vahedi is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position of management or control of a licensee Pharmacy Permit Number PHY 57326, Licensed Sterile Compounding Number LCS 100855, and Pharmacist License No. RPH 68840 are reinstated.

5. Navid Vahedi shall pay to the Board its costs of investigation and prosecution in the amount of $28,631.50 under terms and conditions established by the Board.

DATE: August 27, 2019

DocuSigned by:
Deena R. Ghaly
[illegible]
DEENA R. GHALY

Administrative Law Judge

Office of Administrative Hearings

XAVIER BECERRA
Attorney General of California
MARC D. GREENBAUM
Supervising Deputy Attorney General
GILLIAN E. FRIEDMAN
Deputy Attorney General
State Bar No. 169207
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6294
Facsimile: (213) 897-2804
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **FUSION IV PHARMACEUTICALS INC.** **DBA AXIA PHARMACEUTICAL** 1990 Westwood Blvd., #135 Los Angeles, CA 90025 **Pharmacy Permit No. PHY 53726** **License Sterile Compounding No. LSC 100855** **NAVID VAHEDI (PIC)** 12001 Westwood Blvd Ste A. Los Angeles, CA 90025 **Pharmacist License No. RPH 59537** **CHRISTINA CHALIKIAS (PIC)** 3626 Veteran Avenue, Los Angeles, CA 90034 **Pharmacist License No. RPH 68840** Respondents.	Case No. 6371 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

Fusion IV Pharmaceuticals - PHY 53726

2. On or about October 15, 2015, the Board of Pharmacy issued Pharmacy Permit Number PHY 53726 to Fusion IV Home Infusion Inc DBA Axia Pharmaceutical with Navid Vahedi as the CEO, 100% shareholder, Director, President, Secretary, and Treasurer/Chief Financial Officer. On April 27, 2016, Fusion IV Home Infusion Inc. changed its corporate name to Fusion IV Pharmaceuticals DBA Axia Pharmaceutical (Respondent Fusion IV Pharmacy). Navid Vahedi was also the Pharmacist in Charge from October 15, 2015 to June 6, 2016 and from September 19, 2017 to April 1, 2018. Christina Chalikias was the Pharmacist in Charge from June 6, 2016 to September 18, 2017. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein. The license was canceled on April 1, 2018.

Fusion IV Pharmaceuticals - LSC 100855

3. On or about February 4, 2016, the Board of Pharmacy issued Sterile Compounding License Number LSC 100855 to Fusion IV Home Infusion Inc DBA Fusion IV Specialty Pharmacy. On December 8, 2017, Fusion IV Pharmaceuticals Inc. changed its corporate name to Fusion IV Pharmaceuticals Inc. DBA AXIA Pharmaceutical (Respondent Fusion IV LSC). Navid Vahedi was also the Pharmacist in Charge from October 15, 2015 to June 6, 2016 and from September 19, 2017 to April 1, 2018. Christina Chalikias was the Pharmacist in Charge from June 6, 2016 to September 18, 2017. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein, except during the period October 1, 2017 to November 8, 2017 when it was in expired status. The license was canceled on April 1, 2018.

Navid Vahedi - RPH 59537

4. On or about May 3, 2007, the Board of Pharmacy issued Original Pharmacist License Number RPH 59537 to Navid Vahedi (Respondent Vahedi). From February 4, 2016 to June 6, 2016, and from September 18, 2017 until August 1, 2018, Respondent Vahedi was PIC for Respondent Fusion IV Pharmacy and Fusion IV LSC. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2019, unless renewed.

///

Christina Chalikias - RPH 68840

5. On or about July 1, 2013, the Board of Pharmacy issued Original Pharmacist License Number RPH 68840 to Christina Chalikias (Respondent Chalikias). On June 6, 2016 and continuing through September 18, 2017, Respondent Chalikias was the PIC for Respondent Fusion IV Pharmacy and Fusion IV LSC. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2019, unless renewed.

JURISDICTION

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

7. Section 4110 of the Code states in pertinent part:

"(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred."

8. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

9. Section 4301 of the Code states:

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

. . . .

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . . . .

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

. . . .

"(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board."

10. Section 4307 of the Code states in pertinent part:

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee."

11. Section 4127.1 of the Code states in pertinent part:

"(a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable."

12. Section 4127.1 of the Code states in pertinent part:

"(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.'

13. Section 4169 of the Code states in pertinent part:

"(a) A person or entity shall not do any of the following:

"(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

"(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

"(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

"(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years."

. . . . .

14. Section 4342 of the Code states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

15. Section 111335 of the Health and Safety Code states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

16. Section 111395 of the Health and Safety Code states:

"Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug.

(b) It is offered for sale under the name of another drug.

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package."

REGULATIONS

17. 16 California Code of Regulations Section 1735.2 states in pertinent part:

. . . .

"(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists)

or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

"(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation."

. . . . .

"(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

. . . .

"(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies"

. . . .

16. 16 California Code of Regulations Section 1635.3 states in pertinent part:

"(a) For each compounded drug preparation, pharmacy records shall include:

. . . . .

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. "

16. 16 California Code of Regulations Section 1751.7 states in pertinent part:

(e) (1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

COSTS

18. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of

the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case

FIRST CAUSE FOR DISCIPLINE

(Unlicensed Activity)

19. Respondents Fusion IV LSC, Fusion IV Pharmacy and Vahedi are subject to disciplinary action under section 4127.1 subdivision (a) in that between October 2, 2017 and November 8, 2017, Respondents engaged in sterile compounding while the sterile compounding pharmacy license was in expired status. The circumstances are as follows:

20. Between October 2, 2017 and November 8, 2017, Respondents compounded at least five (5) batches of sterile drug preparations and sold at least 426 prescriptions for sterile drug preparations while its sterile compounding pharmacy license was expired.

SECOND CAUSE FOR DISCIPLINE

(Unlicensed Activity)

21. Respondents Fusion IV LSC, Fusion IV Pharmacy and Vahedi are subject to disciplinary action under section 4129.1 subdivision (a) in that between October 2, 2017 and November 8, 2017, Respondent Fusion IV Pharmacy sold compounded preparations to Fusion Rx Compounding Pharmacy, a licensed pharmacy, owned by Respondent Vahedi, without first obtaining a license from the Board of Pharmacy as an outsourcing facility. The circumstances are as follows:

22. On the following dates, Fusion IV Pharmacy, sold compounded preparations to Fusion Rx Compounding Pharmacy, a licensed pharmacy, without a license therefore: 10/23/17, 10/24/17, 10/25/17, 10/26/17, 10/27/17, 10/30/17, 11/1/17, 11/2/17, 11/3/17, 11/6/17, 11/7/17, and 11/8/17.

///

///

///

///

///

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, Or Corruption)

23. Respondents Fusion IV LSC, Fusion IV Pharmacy and Vahedi are subject to disciplinary action under section 4301 subdivision (f) in that Respondents produced fraudulent documents to the Board. The circumstances are as follows:

24. On or about October 12, 2017, Respondent Vahedi provided the Board with records that fraudulently reported that no product with "zicon" in the name was dispensed from the period of January 1, 2017 to October 12, 2017.

25. On or about October 13, 2017, Respondent Vahedi provided the Board with records that fraudulently reported the batches made from October 1, 2017 through October 10, 2017 were "made with the sole intent of providing experimental samples for use by our Quality department" when in fact they were not.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Providing False Documents)

26. Respondents Fusion IV LSC, Fusion IV Pharmacy and Vahedi are subject to disciplinary action under section 4301 subdivision (g) in that Respondents knowingly made or signed false documents. The circumstances are as follows:

27. On or about October 12, 2017, Respondent Vahedi knowingly signed and provided records to Board representatives that falsely reported that no product with "zicon" in the name had been dispensed during the period January 1, 2017 to October 12, 2017, when in fact records were received from Respondents on or about November 20, 2017, demonstrating that a product was sold with ziconotide in it on at least sixty-seven (67) occassions.

28. On or about October 13, 2017, Respondent Vahedi knowingly signed and provided records to Board representatives that falsely reported that batches made from the period October 1, 2017 through October 10, 2017 were "made with the sole intent of providing experimental samples for use by our Quality department." However, records were received from Respondents

on or about November 20, 2017 that demonstrated the dispensing of several of the lots that were represented to be used as samples only.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Providing False Documents)

29. Respondents Fusion IV LSC, Fusion IV Pharmacy and Vahedi are subject to disciplinary action under section 4301 subdivision (q) in that Respondents engaged in conduct that subverts or attempts to subvert an investigation of the Board. Specifically, on or about November 3, 2017 and again on or about November 21, 2017, Respondents failed to respond to requests from the Board to produce certain records described below:

a. All records showing purchasing, compounding, and dispensing for PRIALT, ziconotide, PRIALT 1NJ 100mcg/ml, and ziconotide acetate 100mcg/ml injectable or any variation of from the period October 16, 2015 to November 3, 2017.

b. A complete list of products compounded or sold from October 16, 2015 to November 3, 2017.

c. Provide the fully executed investigational protocol for at least CA-008 HCL (PF) 0.5mg/ml injectable (investigational drug) Lot 10102017+47838 and CA-008 HCL (PF) l mg/ml injectable (investigational drug) Lot 10102017+47840.

30. Respondents Fusion IV LSC, Fusion IV Pharmacy and Vahedi failed to produce records requested by the Board's representatives on November 21, 2017 or at any time thereafter. Specifically, Respondents failed to comply with the following requests:

a. A copy of at least 7 prescriptions: RX 90015156, RX 90015174, RX 90015175, RX 90015178, RX 90015179, RX 90015180, RX 90015181.

b. A profile for all compounded preparations sold to Fusion Rx DEA FF1542617 from October 16, 2015 to November 21, 2017.

c. The authority in which Fusion IV, a California licensed pharmacy, is providing non-patient specific compounding drug preparations to Fusion Rx, a California licensed pharmacy.

d. The certificate of analysis for ziconotide acetate purchased from Attix: Lot A3269A

e. Method Suitability Test, Container Closure Integrity Test, and Stability Studies to support the BUD assigned to ziconotide acetate 100mcg/ml

31. On or about November 21, 2017, Respondents produced documents that had no meaning to the above-described investigation and Respondents failed to clarify the meaning of the documents despite a request to do so.

SIXTH CAUSE FOR DISCIPLINE

(Misbranding Of Compounded Preparations: Imitation Of Another Drug)

32. Respondents Fusion IV LSC, Fusion IV Pharmacy, Vahedi and Chalikias are subject to disciplinary action under California Health and Safety Code sections 111395 subdivision (a) and 111445 in that from at least January 1, 2017 to September 25, 2017, Respondents compounded ziconotide acetate 100 mcg/ml at least seven (7) times and dispensed at least sixty-five (65) prescriptions (approximately 250 vials). Ziconotide acetate 100 mcg/ml is an imitation of PRIALT, a commercially available drug product.

SEVENTH CAUSE FOR DISCIPLINE

(Prohibited Acts: Purchase, Trade, Sell, Or Transfer Of Misbranded Drugs)

33. Respondents Fusion IV LSC, Fusion IV Pharmacy, Vahedi and Chalikias are subject to disciplinary action under Code section 4169 subdivision (a)(3) and Health and Safety Code section 111335 in that from at least January 1, 2017 to September 25, 2017, Respondents dispensed ziconotide acetate 100 mcg/ml, a misbranded drug, sixty-five (65) times (approximately 250 vials).

EIGHTH CAUSE FOR DISCIPLINE

(Failure To Have A Master Formula Prior To Compounding A Drug Preparation)

34. Respondents Fusion IV LSC, Fusion IV Pharmacy, Vahedi and Chalikias are subject to disciplinary action under California Code of Regulations section 1735.2 subdivision (e) in that on or about October 12, 2017, Respondents provided a master formula for ziconotide acetate 100 mcg/ml showing the maximum allowable beyond use date (BUD) of three (3) days and the use of a Millex GV Durapore PVF filler for sterilization. However, the compounding logs for ziconotide acetate 100 mcg/ml varied from the master formula in that they included an

assignment of a BUD of approximately ninety (90) days and the use of Whatman Puradisc 25 filter and MDI Asepticap WA-y inline filters for sterilization rather than the products included in the master formula.

NINTH CAUSE FOR DISCIPLINE

(Compounding Of A Commercially Available Product)

35. Respondents Fusion IV LSC, Fusion IV Pharmacy, Vahedi and Chalikias are subject to disciplinary action under Code section 4301 subdivision (o) and California Code of Regulations section 1735.2 subdivision (d)(3) in that Respondents unlawfully compounded a commercially available product. The circumstances are that from at least January 1, 2017 to September 25, 2017, Respondents compounded ziconotide acetate 100 mcg/ml at least seven (7) times and dispensed at least sixty-five (65) prescriptions (approximately 250 vials). Ziconotide acetate 100mcg/ml is a copy of PRIALT, a commercially available drug product.

TENTH CAUSE FOR DISCIPLINE

(Failure To Support The Beyond Use Date Assigned)

36. Respondents Fusion IV LSC, Fusion IV Pharmacy and Chalikias are subject to disciplinary action under Code section 4301 subdivision (o) and California Code of Regulations section 1735.2 subdivision (i)(3) in that from at least January 1, 2017 to October 1, 2017, Respondents did not have suitable tests, container closure integrity studies or stability studies for ziconotide acetate 100 mcg/ml, non-sterile to sterile preparations, which preparations were assigned a BUD of ninety (90) days. Specifically, Respondents failed to support the BUD assigned for the lots described as follows: 01162017+44322, 02222017+44799, 03242017+45254, 05042017+45886, 05252017+46202, 07052017+46774, 08012017+47101.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure To Have Complete Compounding Records)

37. Respondents Fusion IV LSC, Fusion IV Pharmacy and Chalikias are subject to disciplinary action under Code section 4301 subdivision (o) and California Code of Regulations section 1735.2 subdivision (a)(2) in that for certain lots compounded between October 4, 2017 and October 11, 2017, Respondents failed to maintain complete compounding records.

38. The circumstances are that on the following lots complete compounding records were not maintained:

Date	Lot number	Drug	Missing from compounding record
10/4/17	10042017+47781	Biotin 10mg/ml	No manufacturer noted on biotin No final check noted on batch record or worksheet but dispensed on 10/26/17
10/6/17	10062017+47814	Atropine sulfate monohydrate 0.1% stock solution	No manufacturer noted on sterile water for injection No final check noted on batch record or worksheet.
10/10117	10102017+47838	CA-008 HCL (PF) 0.5mg/ml injectable	No manufacturer noted on CA-008 HCL powder and lot was listed only as ABCD1234
10/10/17	10102017 + 47840	CA-008 HCL (PF) 1mg/ml injectable	No manufacturer noted on CA-008 HCL powder and lot was listed only as ABCD1234
10/11/17	10112017+47844	B-Complex 110 injectable	No manufacturer noted on Thiamine or niacinamide Assigned BUD on the worksheet is edited 3 times unsure of assigned BUD

TWELFTH CAUSE FOR DISCIPLINE

(Failure To Have Complete Compounding Records)

39. Respondents Fusion IV LSC, Fusion IV Pharmacy and Chalikias are subject to disciplinary action under Code section 4301 subdivision (o) and California Code of Regulations section 1751.7 subdivision (e)(1) in that Respondents failed to perform to product testing for sterility and monitoring of acceptable levels of pryogens prior to dispensing in compliance with testing and monitoring requirements. The circumstances are as follows:

40. On the following lots the nonsterile batched preparations were released before the fourteen (14) day compliant sterility testing confirmed sterility:

a. Respondents released lot number 05042017+45886, made on May 4, 2017, which contained 50 ml on May 3, 2017 and May 8, 2017.

b. Respondents released lot number 07052017+46774, made on July 5, 2017, which contained 50 ml on July 7, 2017.

c. Respondents released lot number 08012017+47101, made on August 1, 2017, which contained 90 ml on August 11, 2017.

DISCIPLINE CONSIDERATIONS

27. To determine the degree of discipline, if any, to be imposed on Respondent Vahedi, Complainant alleges as follows:

a. On or about January 2, 2018, in the Matter of the Accusation against Dr. N. Vahedi Pharmacy Inc. dba Fusion Rx Compounding Pharmacy and Navid Vahdi, Case No. 5899 and OAH No. 2017040451, Board of Pharmacy issued a Decision and Order adopting the Proposed Decision by the Administrative Law Judge where in Respondent Vahedi, among other things, was placed on a four (4) year probation, which included a thirty (30) day suspension. While on probation, Respondent Vahedi was required to complete remedial education, and comply with other reporting, monitoring, and supervision requirements.

b. On or about October 27, 2016, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 67663 based on violations of CCR, Title 16, § 1751.4 subdivision (a) [Respondent served as PIC where Fusion RX Pharmacy, owned by Respondent, did not maintain the compounding environment in accordance to criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug product] Respondent was required to pay $1,500.00. That Citation is now final and is incorporated by reference as if fully set forth.

c. On or about October 27, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 67653 based on violations of CCR, Title 16, § 1713 [Participating In An Arrangement Where Prescriptions Or Prescription Medications Is Left At, Picked Up From, Accepted By, Or Delivered To Any Place Not Licensed As A Retail Pharmacy] and Bus. & Prof. Code § 4052(a) and CCR, Title 16, § 1735.2 [Compounded medications not for office use and in quantity for advanced male medical in excess of 72-hour supply of compounded medications.] Respondent to pay $2,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

d. On or about September 10, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 66976 based on violations of Health & Safety Code § 111397 (a) [Compounding with an Unapproved Foreign Drug], Bus. & Prof. Code § 4169(a) and CCR, Title 16, § 1735.3(c) [Prohibited Act/Obtaining Compounding Chemicals from Unreliable Source] , 1735(d) [Compounding Commercially Available Drugs/Patent Infringement] and ordered

Respondent to pay $3,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

e. On or about September 27, 2012, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 53992 based on violations of Bus. & Prof. Code § 4076(a)(9) [Prescription label date beyond manufacturing date], Health & Safety Code § 11165(d) [Failure to Report to Cures], and Title 21 CFR § 1304.11 [Failure to take DEA Inventory] and ordered Respondent to pay $1250.00. That Citation is now final and is incorporated by reference as if fully set forth.

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 53726 or Licensed Sterile Compounding No. 100855 issued to Fusion IV Pharmaceuticals DBA Axia Pharmaceutical, Respondent Navid Vahedi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53726 or Licensed Sterile Compounding No. 100855 is placed on probation or until Pharmacy Permit Number PHY 53726 or Licensed Sterile Compounding No. 100855 is reinstated if it is revoked.

42. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 53726 or Licensed Sterile Compounding No. 100855 issued to Fusion IV Pharmaceuticals DBA Axia Pharmaceutical, while Navid Vahedi had been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Respondents Navid Vahedi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53726 or Licensed Sterile Compounding No. 100855 is placed on probation or until Pharmacy Permit Number PHY 53726 or Licensed Sterile Compounding No. 100855 is reinstated if it is revoked.

///

///

///

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 53726, issued to Fusion IV Pharmaceuticals Inc. DBA AXIA Pharmaceutical with Navid Vahedi as the CEO, 100% shareholder, Director, President, Secretary, and Treasurer/Chief Financial Officer;

2. Revoking or suspending Licensed Sterile Compounding Number LSC 100855 issued Fusion IV Pharmaceuticals Inc. DBA AXIA Pharmaceutical, with Navid Vahedi as the CEO, 100% shareholder, Director, President, Secretary, and Treasurer/Chief Financial Officer;

3. Revoking or suspending Pharmacist License Number RPH 59537, issued to Navid Vahedi;

4. Revoking or suspending Pharmacist License Number RPH 68840, issued to Christina Chalikias;

5. Prohibiting Navid Vahedi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53726 is placed on probation or until Pharmacy Permit Number PHY 53726 is reinstated if Pharmacy Permit Number 53726 is revoked;

6. Prohibiting Navid Vahedi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding Number LCS 100855 is placed on probation or until Licensed Sterile Compounding Number LCS 100855 is reinstated if Licensed Sterile Compounding Number LCS 100855 is revoked;

7. Ordering Fusion IV Pharmaceuticals Inc. DBA AXIA Pharmaceutical, Navid Vahedi and Christina Chalikias jointly and severally to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

///

///

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

DATED: 9/2/18

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

LA2018500802
13067511