California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

CEASE AND DESIST ORDER

Date: 07/25/2019
Permit No: Unlicensed
Names: Fusion IV Pharmaceuticals, Inc., dba Axia Pharmaceutical
Address: 1990 Westwood Blvd, Suite 135, Los Angeles, California 90025-4560

Authority for this Action

The California State Board of Pharmacy ("Board") through its Interim Executive Officer, acts pursuant to Business and Professions Code Section 4316, subdivision (a), which states that the Board "is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure without obtaining that licensure." Subdivision (b) of that section provides that, whenever the Board issues a cease and desist order, the Board must immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

Pertinent Laws and/or Regulations:

Business and Professions Code Sections 4129 and 4129.1 require that an outsourcing facility that is registered with the federal Food and Drug Administration (FDA), must also be licensed by the Board as an outsourcing facility before doing business within this state, if it compounds sterile or nonsterile medication for non-patient-specific distribution within or into California.

Acts or Omissions Upon Which this Action is Based

Fusion IV Pharmaceuticals, Inc., dba Axia Pharmaceutical ("Fusion IV"), located at 1990 Westwood Blvd, Suite 135, Los Angeles, California 90025-4560, is not licensed as an outsourcing facility by the Board or in any other capacity. Fusion IV has been federally registered as an outsourcing facility since 1/06/2017.

On or about 9/12/17, the Board denied Fusion IV's application for an outsourcing facility license. Fusion IV filed an administrative appeal. The Board issued a decision affirming the denial on or about 2/14/2019. Fusion IV subsequently brought a federal lawsuit challenging

the Board's authority to require federally registered outsourcing facilities to be concurrently licensed as outsourcing facilities by the Board. On or about June 21, 2019, Fusion IV's claims were dismissed without leave to amend. *See* Fusion IV Pharmaceuticals, Inc., et al. v. Executive Director Virginia Herold, et al. Case No. CV 19-1127 PA (FFMx).

An inspection of Fusion IV activities revealed that, between at least 7/1/2019 and 7/22/2019, Fusion IV compounded and furnished at least the following non-patient-specific sterile medications for distribution into or within California.

1. 280 orders for Glutathione 200mg/ml injectable,
2. 337 orders for Methylcobalamin injectables
3. 176 orders for AscorBIX 500mg/ml injectable (30ml)
4. 152 orders of MIC -B12 injectable
5. 128 orders for Testosterone Cyp in grapeseed oil 200mg/ml (10ml) injectable
6. 106 orders for MIC-Combo injectable
7. 85 orders for Zinc Chloride 10mg/ml injectable
8. 103 orders for Pyridoxine 100mg/ml injectable

Business and Professions Code Sections 4129 and 4129.1 requires Fusion IV to be licensed by the Board as an outsourcing facility before engaging in such activities.

ORDER

Based on the foregoing, the Board, through its Interim Executive Officer, ORDERS:

Effective immediately, Fusion IV Pharmaceuticals, Inc., dba Axia Pharmaceutical, an entity not licensed by the Board in any capacity, shall cease and desist all activities as an outsourcing facility within California. Fusion IV shall not compound or furnish any sterile or non-sterile non-patient-specific medication for distribution into or within California.

Unlicensed Entity's Right to be Heard and Procedure

Pursuant to Business and Professions Code Section 4316, subdivision (c), within 15 days of receipt of this notice, Fusion IV Pharmaceuticals, Inc., dba Axia Pharmaceutical, may request a hearing before the president of the Board to contest this cease and desist order. Any contest of the cease and desist order will comply with the requirements of Section 11425.10 of the Government Code, a copy of which is enclosed. Chapter 5 of the Administrative Procedure Act (commencing at Government Code Section 11500) does not apply to this proceeding. The hearing will be held no later than five (5) days from the date that the owner's request for a hearing is received by the Board. The president will render a written decision within five (5) days of the hearing. In the absence of the president of the Board, the vice president of the Board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the Board may be sought by the owner or person in possession or control of the

unlicensed entity pursuant to Section 1094.5 of the Code of Civil Procedure.

California State Board of Pharmacy
By: Anne Sodergren, Interim Executive Officer

Signed: Anne Sodergren
Date: 7/25/19

Acknowledgement
I hereby acknowledge receipt of the above cease and desist order and notice.

By:

Date:
Please return a copy of this signed and acknowledged document to the Board by fax to 916-518-3100.

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

In the Matter of the Statement of Issues Against:	Case No. 6270
FUSION IV PHARMACEUTICALS INC. **DBA AXIA PHARMACEUTICALS,** **NAVID VAHEDI, OWNER**	OAH No. 2018060309
Respondent.	

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on February 14, 2019.

It is so ORDERED on January 15, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Victor Law, R.Ph.
Board President

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

In the Matter of the Statement of Issues Against:	No. 6270
FUSION IV PHARMACEUTICALS INC. DBA AXIA PHARMACEUTICALS, NAVID VAHEDI, OWNER	OAH No. 2018060309
Respondent.	

PROPOSED DECISION

Ji-Lan Zang, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on October 29 and 30, 2018, in Los Angeles, California.

Gillian E. Friedman, Deputy Attorney General, represented Virginia Herold (complainant), Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.

Al Mohajerian, Attorney at Law, represented respondent Fusion IV Pharmaceuticals, Inc., doing business as Axia Pharmaceuticals (Fusion IV), and Navid Vahedi (Vahedi), owner, who was present.

Oral and documentary evidence was received. The record was closed and the matter was submitted for decision on October 30, 2018.

FACTUAL FINDINGS

Parties and Jurisdiction

1. On August 9, 2017, the Board received an amended application (application) for an instate outsourcing facility license from Fusion IV, listing Vahedi as its president, director, and 100 percent owner. (Ex. 3.) Vahedi signed the application on August 7, 2017, and certified under penalty of perjury to the truthfulness of all statements, answers, and representations contained therein. On September 12, 2017, the Board denied the application.

2. On April 30, 2018, complainant filed the Statement of Issues in her official capacity. Vahedi, on behalf of Fusion IV, timely filed a Notice of Defense and a Request for Hearing. This hearing ensued.

Instate Outsourcing Facilities

3. An outsourcing facility is an entity that compounds non-patient-specific drugs in large quantities for use by hospitals, doctors, and other healthcare practitioners. Outsourcing facilities are regulated under federal and California law.

4. Federal legislation enacted in 2013 requires an outsourcing facility to be registered with the Food and Drug Administration (FDA) under section 503B of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 353b).[1] By registering a facility under section 503B of the FDCA, an outsourcing facility is exempt from some of the requirements of the FDCA that would otherwise apply to manufacturers, such as misbranding (21 U.S.C. § 352(f)(1)), new drug application (21 U.S.C.§ 355), and transaction information (21 U.S.C. § 360eee-1). However, all compounding performed in a 503B outsourcing facility must meet Current Good Manufacturing Practice requirements (21 U.S.C. § 353b(a)(11)) pursuant to 21 Code of Federal Regulations, parts 210 and 211. Under federal law, a 503B outsourcing facility may compound both patient-specific and non-patient-specific drugs. (21 U.S.C. § 353b(d)(4)(C).)

5. Prior to January 1, 2017, California required any pharmacy that compounded sterile drug products, whether patient-specific or non-patient-specific, to obtain only a sterile compounding license issued by the Board. (Bus. & Prof. Code, § 4127.) At that time, California law did not recognize a separate licensing category for outsourcing facilities that compound non-patient-specific drugs.

6. Effective January 1, 2017, Senate Bill 1193 established a framework for the regulation of outsourcing facilities in California, which was more closely aligned with federal legislation. The bill added Article 7.7 to Chapter 9 of Division 2 of the Business and Professions Code (Bus. & Prof. Code, §§ 4129 et. seq.) Specifically, pursuant to Business and Professions Code section 4129, subdivision (a), a 503B outsourcing facility registered with the FDA now must be concurrently licensed with the Board as an outsourcing facility if "it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California." Business and Professions Code section 4129 makes other changes as well: it prohibits a sterile compounding pharmacy to be concurrently licensed as an outsourcing facility at the same location and an outsourcing facility from performing any pharmacy functions, including filling individual patient-specific prescriptions. (Bus. & Prof. Code, § 4129, subds. (b) and (e).) Therefore, under California law, an outsourcing facility cannot be concurrently licensed either as a retail pharmacy or as a pharmacy with a sterile compounding license.

---

[1] Section 503B was added to the FDCA by the Drug Quality and Security Act. (Pub. L. (2013) No.113-54, § 102(a), 127 Stat. 587, 587-588.)

7. Pursuant to Business and Professions Code section 4129, subdivision (c), the Legislature has provided that the Board may adopt regulations to establish policies, guidelines, and procedures to implement the new law regarding the licensure of outsourcing facilities. However, the Board has not promulgated any regulations, and it is currently using the Code of Federal Regulations to regulate the operations of outsourcing facilities in California.

Vahedi's Licenses with the Board

8. Vahedi is the president, director, and 100 percent shareholder of Fusion IV, located at 1990 Westwood Boulevard, Suite 135, in the City of Los Angeles. Fusion IV was formerly licensed both as a retail pharmacy (Permit number PHY 53726, issued on October 15, 2015) and as a sterile compounding pharmacy (Sterile Compounding License number LSC 100855, issued on February 4, 2016). As discussed more fully below, Fusion IV's retail pharmacy and sterile compounding licenses were cancelled on June 4, 2018, due to discontinuance of business, effective April 1, 2018. Fusion IV is a 503B outsourcing facility registered with the FDA, but it currently does not have any license issued by the Board.

9. Vahedi is a licensed pharmacist and holds Pharmacist License number RPH 59537 (issued on May 3, 2007). He is also the sole owner of the retail pharmacy Dr. N. Vahedi Pharmacy Inc., doing business as Fusion RX pharmacy (Fusion RX) (Permit number PHY 49937, issued on June 9, 2009), located at 2001 Westwood Blvd. #A in the City of Los Angeles. Vahedi became the Pharmacist-in-Charge (PIC) of Fusion RX on June, 9, 2009, until a date not established by the record when he turned over his PIC responsibilities to someone else. As discussed more fully below, Vahedi's pharmacist license and Fusion RX's pharmacy permit have been disciplined by the Board, and both licenses are currently under Board probation.

Board Discipline against Vahedi's Pharmacist License (RPH59537) and Fusion RX's Pharmacy Permit (PHY 49973) and Denial of Fusion IV's Application for an Instate Outsourcing Facility License

10. On January 30, 2017, the Board filed an Accusation in case number 5899 (OAH case number 2017040451) against Fusion RX's pharmacy permit (PHY 49973) and against Vahedi's pharmacist license (RPH 59537). The Accusation alleged 10 causes for discipline and separately alleged disciplinary considerations consisting of three prior citations.

11. While the disciplinary matter in case number 5899 was pending, Vahedi filed the application that is the subject matter of this proceeding. On September 12, 2017, the Board denied the application. In the denial letter, Jenna Weddle, the Board's Enforcement Analyst wrote, "This denial is based upon the board's pending discipline case (No. 5899) against Fusion Rx Compounding Pharmacy (PHY 49937)." (Ex. 6, p. 101.)

12. In a letter to the Board dated September 27, 2017, Vahedi wrote, "I've received the CA State Board of Pharmacy's response to my 503B Outsourcing Facility

License for Fusion IV Pharmaceuticals, Inc., dba Axia Pharmaceuticals and formally appeal the decision. I ask that the appeal be expedited as the matter is urgent." (Ex. 1, p. 45.)

13. On October 23, 2017, the Board's Supervising Inspector, Christine Acosta, wrote a letter to Vahedi to inform him of the expiration of Fusion IV's sterile compounding license (LSC 100855). In the same letter, Inspector Acosta, in an apparent mistake, stated that Fusion IV's application for an outsourcing facility license was "still under review." (Ex. A.)

14. On September 25 and 26, 2017, an administrative hearing was held in case number 5899. Vahedi was present and represented by counsel for both days of the hearing.

15. On October 26, 2017, a Proposed Decision was issued in case number 5899. The Proposed Decision ordered Fusion RX's pharmacy permit (PHY 49973) and Vahedi's pharmacist's license (RPH 59537) to be each placed on four years of probation with terms and conditions, including thirty days of suspension as to both the pharmacy permit (PHY 49973) and pharmacist license (RPH 59537). On January 2, 2018, the Board issued a Decision and Order (Decision and Order) adopting the Proposed Decision, effective February 1, 2018.

16. On January 29, 2018, Vahedi and Fusion RX filed an ex parte application for Petition for Writ of Administrative Mandamus in the Superior Court of California, County of Los Angeles, challenging only the Board's 30-day suspension of Fusion RX's pharmacy permit (PHY 49973) pursuant to the Decision and Order. On January 31, 2018, the Superior Court issued an order, effective February 1, 2018, staying the Decision and Order only as to the 30-day suspension of Fusion RX's pharmacy permit (PHY 49973) pending the outcome of the Writ of Administrative Mandamus. All other provisions of the Decision and Order remained in effect.

17. On January 19, 2018, Vahedi and Fusion RX timely petitioned the Board to reconsider of a specific portion of the Decision and Order pertaining to Fusion RX's pharmacy permit (PHY 49973) only. On February 9, 2018, the Board granted the petition for reconsideration and temporarily stayed that portion of the decision regarding Fusion RX's pharmacy permit (PHY 49973) only. In its Order Granting Reconsideration in Part, the Board specified that the portion of the Decision and Order relating to Vahedi's pharmacist license (RPH 59537) was effective at 5 p.m. on February 11, 2018. (Ex. 7, p. 111.)

18. On May 31, 2018, the Board issued its Decision After Reconsideration (as to Fusion RX only), which upheld the Decision and Order, except that it modified certain language in the discussion regarding discipline in the Legal Conclusions portion of the Decision and Order. The Board's Decision After Reconsideration, effective July 2, 2018, placed Fusion RX's pharmacy permit (PHY 49973) on probation for four years, from July 2, 2018, though July 1, 2022, inclusive. (Ex. 7, p. 109.)

19. Thus, as of the date of the hearing for the present matter, the only issue that remained on appeal of the Decision and Order is the 30-day suspension of Fusion RX's

pharmacy permit (PHY 49973). Both Vahedi's pharmacist license (RPH 59537) and Fusion RX's pharmacy permit (PHY 49973) are currently on Board probation. Vahedi has already served his 30-day suspension.

The Decision and Order in Case Number 5899

20. The Decision and Order in case number 5899 was based on findings that nine causes for discipline were established against Vahedi's pharmacist license (RPH 59537) and Fusion RX's pharmacy permit (PHY 49973). These nine causes for discipline were as follows:

(1) failure to provide to Board inspectors a copy of written policies and procedures to help patients with limited or no English proficiency (in violation of California Code of Regulations, title 16,[2] section 1707.5, subdivision (d));
(2) sale of expired drugs lacking in quality and strength (in violation of Business and Professions Code section 4342, subdivision (a));
(3) erroneous or uncertain prescriptions (in violation of CCR section 1761, subdivisions (a) and (b));
(4) failure to comply with certain prescription requirements (in violation of Business and Professions Code section 4040, subdivision (a)(1)(F), in conjunction with Health and Safety Code section 11164, subdivision (a)(1)(b));
(5) failure to provide to Board inspectors a copy of written policy for theft or impairment of an employee (in violation of Business and Professions Code section 4104, subdivision (a));
(6) operating a pharmacy, Fusion IV, before it was licensed (in violation of Business and Professions Code section 4110, subdivision (a));
(7) engaging in unprofessional conduct (commission of acts involving dishonesty and deceit) by representing that Fusion IV was capable of performing acts requiring a license before Fusion IV was licensed (in violation of Business and Professions Code section 4301, subdivision (f));
(8) engaging in unprofessional conduct by making documents that falsely represented Fusion IV as a pharmacy in full operation before it was licensed (in violation of Business and Professions Code section 4301, subdivision (g)); and
(9) engaging in unprofessional conduct by subverting a Board investigation (in violation of Business and Professions Code section 4301, subdivision (q)).

//

//

//

---

[2] All references to the California Code of Regulations are to title 16, and are designated "CCR."

21. The factual findings supporting the nine causes for discipline were detailed in the Decision and Order, in pertinent part, as follows:[3]

> *Inspection of Pharmacy*
>
> 4. In early 2015, the Board received a complaint concerning [Fusion RX]. The investigation of the complaint was assigned to Jennifer Hall, Pharm. D., an inspector for the Board who holds a pharmacist license issued by the Board. On August 26, 2015, Inspector Hall and her colleague, Inspector Anna Kalantar, performed an unannounced inspection of [Fusion RX] at its facility at 2001 Westwood Boulevard, Los Angeles, California.
>
> 5. The inspectors spoke to pharmacist Rod Delijani and several other employees. [Vahedi] arrived later, during the inspection. During the inspection, Inspector Hall also spoke by telephone to [Vahedi and Fusion RX's] attorney, Mr. Weinberg. The inspectors did not find sufficient information to substantiate the complaint. However, they found circumstances that resulted in the allegations set forth in the Accusation.
>
> *Operating Policies; Cooperation with Investigation*
>
> 6. Licensed pharmacies are required to have written policies and procedures covering various subjects, including policies (a) to help patients with limited or no English proficiency understand the information on the label of a medication, and (b) for theft of a dangerous drug by an employee, or chemical, mental or physical impairment of an employee.
>
> 7. The inspectors requested copies of these policies. Neither [Fusion RX] nor [Vahedi] provided copies of these written policies to the inspectors at the inspection on August 26, 2015. On that date, Inspector Hall wrote a notice that these policies were required and requested that [Vahedi] send to her a statement relating to the policies. Inspector Hall did not receive any response to that request.

---

[3] Collateral estoppel applies in this case, and Fusion IV and Vahedi are estopped from re-litigating the issues that were decided in case number 5899. (See Legal Conclusions 10 through 15.)

8. At the hearing, [Vahedi] testified credibly that these two policies could be found in notebooks maintained at the facility. He submitted copies of the policies, received in evidence as exhibit H. The policies had been implemented when [Vahedi] sought accreditation in 2012 from the Pharmacy Compounding Accreditation Board (PCAB), a voluntary, national organization that sets standards for compounding pharmacies.

9. [Vahedi] testified credibly that, after the inspection, he purchased a set of operating policies in a manual compiled and sold by an attorney with expertise in pharmacy law. This manual has policies on both subjects (see ex. A, pp. 10 and 12). The new policies were attached to a letter from [Vahedi and Fusion RX's] attorney, Mr. Weinberg, addressed to Inspector Hall and dated September 8, 2015 (ex. A, pp. 1 and 2). Mr. Weinberg's letter also addressed several of the inspector's findings of violations, and included other attachments (ex. A, pp. 3 through 14) relating to those findings, including a statement from pharmacist Delijani.

10. a. Inspector Hall did not receive the letter and attachments. In her report (ex. 4), she noted all of her contacts with [Vahedi and Fusion RX] and Mr. Weinberg. Mr. Weinberg's September 8, 2015 letter is not noted. Inspector Hall noted in her report that she received a declaration sent directly from pharmacist Delijani. Inspector Hall also noted that, when she had not received any response to the notices in her inspection report from [Vahedi] by October 1, 2015, she notified him that a response was necessary or she would cite him for subverting an investigation (ex. 4, p. 10). [Vahedi] sent an email that same day with an apology, indicating that his attorney was supposed to send the information earlier.

b. [Vahedi] sent a statement to Inspector Hall, received October 5, 2015. This statement addressed questions posed by Inspector Hall relating to the initial complaint. Although there was further correspondence between Mr. Weinberg or [Vahedi], on the one hand, and Inspector Hall, there was no other reference made to Mr. Weinberg's September 8, 2015 letter or its attachments. Inspector Hall first saw the letter and attachments during the administrative hearing.

11. Under these circumstances, it is found that [Vahedi and Fusion RX] did not produce policies on both subjects to

Inspector Hall from the time of the inspection to the time of the hearing.

Sale of Drugs Lacking Quality and Strength

12. Under Business and Profession Code section 4342, subdivision (a), the Board may take action to prevent the sale of drugs "that do not conform to the standard and tests as to quality and strength" by reference to named, standard texts.

13. a. During the inspection, Inspector Hall found 14 jars of an expired compounded medication, several other expired medications, and a compounded medication that contained an expired ingredient. Inspector Hall's testimony established that a medication with an expired ingredient does not meet the standards for quality and strength.

b. More specifically, the 14 jars were of a drug (fluticasone/ evocetirizine/ pentoxyfylline/ prilocaine/ caffeine) that was compounded on May 7, 2015. The expiration date was August 5, 2015, approximately three weeks before the inspection. [Vahedi] explained that the pharmacy would periodically gather expired medications and later dispose of them in authorized manners. However, [Vahedi] did not establish that these 14 jars were identified for disposal. Rather, Inspector Hall was told that pharmacy employees made enough medication to last several months for the patient.

c. The inspection report notes "several expired drugs in the drug locker and two expired drugs in the refrigerator." (Ex. 4, p. 5.) Inspector Hall explained at the hearing that she found tablets and capsules that were expired, and that employees told her the medications were in an area of medications to be dispensed to patients. [Vahedi] noted that these medications had not been dispensed to patients.

d. Clear and convincing evidence established that [Vahedi and Fusion RX] were prepared to dispense the 14 jars and the tablets and capsules that had expired, and therefore did not conform to the standard and tests as to quality and strength.

[¶] . . . . [¶]

//

Erroneous or Uncertain Prescriptions; Prescription Requirements

15. The third and sixth causes for discipline in the Accusation relate to prescriptions for human chorionic gonadotropin (HCG), a controlled substance. It is alleged that [Vahedi and Fusion RX] filled prescriptions from an order form completed by a sales representative, that the drug and strength were preprinted on the order form, that physicians did not sign the form, and that the orders were transferred to a hard copy prescription by a technician and not completed or verified by the pharmacist. It is further alleged that these practices amount to violations of statutes and regulations relating to erroneous or uncertain prescriptions, and prescription requirements. [Footnote omitted.]

16. During the inspection, Inspector Hall found various prescription order forms that were "authorized" by a sales representative of MWC Medical Sales (MWC), a drug distributer. One such form, admitted in evidence as exhibit 8, has the name of a weight loss clinic and doctor (Curlee Ross, M.D.) filled in, but was not signed by the doctor. Under [Vahedi and Fusion RX's] regular practices in such instances, the orders on the form were transferred to hardcopy prescriptions by a technician and not completed by the pharmacist. Mr. Delijani told Inspector Hall that he did not always check the prescriptions after the technician rewrote them, nor did he verify the prescriptions with the doctor. However, in his written statement, Mr. Delijani wrote (1) that he believed MWC was an authorized agent of the doctors, (2) that technicians would either phone the prescriber to verify the prescriptions or might choose not to call if the order was a repeat of, or similar to, prior orders, (3) that he examined and initialed the prescriptions written by the technicians, and (4) that the medications were prepared and verified by a second pharmacist before being sent to the doctor's offices. The rewritten prescription forms in exhibits 9 and 10 all have a pharmacist's initials, often of Mr. Delijani.

17. a. According to [Vahedi], MWC was employed by doctors to set up weight loss procedures for patients, including in-office drug dispensaries, and assure compliance with best practices. [Vahedi] also believed that MWC and the sales representative had been authorized by various doctors to submit the order forms when the doctor requested any of the

medications already listed on the form. One of the attachments to Mr. Weinberg's letter is a letter from Dr. Lester Lee, indicating that MWC is an authorized agent of his practice and may relay orders to [Vahedi and Fusion RX]. (Ex. A, p. 4.) Dr. Lee signed an MWC order form in evidence as exhibit 10.

b. With respect to the medication "MIC-Den" listed in the order form listing Dr. Ross in exhibit 8, [Vahedi] believed this was for use in the doctor's office, not a prescription for a particular patient. The same order form indicated two bottles of HCG were ordered. [Vahedi] believed this was also for office use. However, as HCG is a controlled substance, [Vahedi] believed it was a better practice to have specific references to the patient names on the order form. At his request, the HCG order forms included names of patients who would receive the HCG at the doctors' offices. [Vahedi] believed that, in this way, the controlled substance could be tracked to a particular patient by use of the CURES database, discussed in more detail below. [Vahedi] testified that he later learned that orders of HCG for a doctor's office use did not require reference to the patient names. However, [Vahedi] admitted that, in the period of time that individual patient's names were associated with the orders, the orders were no longer considered to be for the doctors' office use and in each instance the requirements for individual prescriptions would apply.

c. Several other MWC order forms are in evidence as exhibit 10. One, several pages long listing numerous patients' names, is signed by Dr. Lee. Exhibit 10 also includes unsigned order forms related to other doctors. As noted above, Dr. Lee's letter includes that he authorized MWC to submit orders for his office.

d. In most instances of the rewritten prescription forms in evidence, a blank for "Phone by" is filled in with typed "MD." However, in exhibit 9 are two rewritten prescription forms for Dr. Ross, with the blank filled in as "Victoria." [Vahedi] believes this was an employee of Dr. Ross who confirmed the HCG prescriptions for the two patients written on the MWC order form in exhibit 8. Exhibit 10 contains numerous other order forms and rewritten prescription forms. The prescription forms for Dr. Chao and Dr. McKnight include a name in the "Phone by" blank. The forms for Dr. Fatemeh are filled in with "MD."

18. With respect to all of the MWC order forms in evidence that were submitted on behalf of doctors other than Dr. Lee, it was established by clear and convincing evidence that the forms were not signed by the doctors and that [Vahedi and Fusion RX] filled the prescriptions. With respect to the two patients of Dr. Ross identified in exhibits 8 and 9, and the patients of Drs. Chao, McKnight and Fatemeh, it was established that the doctor authorized the prescriptions. With respect to all of the MWC order forms admitted in evidence, it was not established by clear and convincing evidence that once the orders were transferred to hard copy prescriptions by a technician, the orders were not reviewed or verified by the pharmacist.

Unlicensed Activity of Fusion IV Specialty Pharmacy

19. [Vahedi] developed, sought and obtained licensure for another pharmacy. The Board issued a permit on October 15, 2015, for Fusion IV Pharmaceuticals, Inc., doing business as Fusion IV Specialty Pharmacy (Fusion IV), with [Vahedi] as its chief executive officer, only shareholder, and PIC. The address of record is 1990 Westwood Boulevard, Los Angeles. (Fusion IV subsequently changed its name and PIC.)

20. During the inspection, Inspector Hall gathered documents indicating that [Vahedi and Fusion RX] received prescriptions, and compounded and delivered a medication for patient MP on August 24, 2015, with all of the paperwork indicating the work was done by Fusion IV. (Ex. 12.) Inspector Hall also found a brochure for Fusion IV containing its address of record, and a phone number for Fusion RX. The brochure described Fusion IV as specializing in intravenous and other medications and infusion and other special services. The work to fill MP's prescription, including compounding the medication, was done by [Vahedi and Fusion RX's] employees at the premises of Fusion RX.

21. [Vahedi] told Inspector Hall he had submitted an application for licensure for Fusion IV, but the license had not yet been issued. He testified he was preparing to open Fusion IV across the street and was training employees who would transfer to Fusion IV once it opened. He transferred some employees once Fusion IV was licensed and the new office was opened. The brochure was to market Fusion IV's services once it opened.

[¶] . . . . [¶]

26. As discussed in more detail below, on January 8, 2016, and numerous times thereafter, Inspector Hall requested that [Vahedi and Fusion RX] provide a record of all medications dispensed from January 1, 2013, to January 1, 2016. [Vahedi and Fusion RX] acknowledged the request but claimed it was overly broad, not necessary, and would take too long to produce. The records requested were not produced. Presumably, those records would answer the question whether [Vahedi and Fusion RX] dispensed controlled substances during the period of the gap.

Failure to Cooperate with Investigation

27. In the ninth cause for discipline in the Accusation, complainant alleges that, between August 26, 2015, and February 29, 2016, [Vahedi and Fusion RX] subverted the investigation. More specifically, [Vahedi and Fusion RX] allegedly failed to respond to multiple requests for documents, including a dispensing report of all products dispensed from January 1, 2013, to January 1, 2016, order forms for HCG, policies and procedures requested at the time of the inspection, and statements from the PIC.

28. As noted in Factual Finding 26, Inspector Hall requested a dispensing report and [Vahedi and Fusion RX] replied that there were reasons why they would not provide it, including the time it would take and questions by Mr. Weinberg about why it was needed. The reasons given by [Vahedi and Fusion RX] do not excuse [Vahedi and Fusion RX's] duty to maintain and provide records for inspection. [Footnote omitted.] Inspector Hall testified credibly that other pharmacies provided dispensing reports in other investigations she conducted, and that, to her knowledge, [Vahedi and Fusion RX's] computer software could compile and print the requested information. By failing to provide the dispensing report, [Vahedi and Fusion RX] subverted the investigation.

29. During the inspection, Inspector Hall requested that [Vahedi] provide the hardcopy order forms that corresponded to rewritten prescriptions for HCG for which she did not find the order forms during the inspection. Inspector Hall had requested information from Mr. Delijani about the MWC forms, and received his written statement including that information. (See

Inspector Hall's report, ex. 4, pp. 9 and 10.) Mr. Weinberg supplied one hardcopy order form (see ex. 10, pp. 38 and 39) that related to some, but not all, of the prescriptions she had gathered. Inspector Hall requested more hardcopy order forms. Neither [Vahedi] nor Mr. Weinberg provided them.

30. As noted in Factual Findings 7 through 11, [Vahedi and Fusion RX] did not provide the written policies and procedures relating to helping patients with limited or no English proficiency understand the information on the label of a medication, and theft of a dangerous drug by an employee, or chemical, mental or physical impairment of an employee. This is another instance of subverting the investigation.

(Ex. 7, pp. 115-122.)

22. The terms and conditions of Vahedi's and Fusion RX's four years of Board probation, as set forth in the Decision and Order, include the following:

1. Obey All Laws

[Vahedi] shall obey all state and federal laws and regulations.

[¶] . . . . [¶]

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, [Vahedi] shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

(Ex. 7, p. 133, 135.)

Subsequent Acts by Vahedi and Fusion IV

CONTINUED UNLICENSED ACTIVITY OF FUSION IV

23. As set forth in Factual Finding 8, Vahedi originally operated Fusion IV as a licensed retail pharmacy and a licensed sterile compounding pharmacy. After Senate Bill 1193 was enacted on January 1, 2017, however, Fusion IV, which is registered as a 503B outsourcing facility with the FDA, was also required to be licensed as an outsourcing facility by the Board. (Bus. & Prof. Code, § 4129.1, subd.(a).) Once licensed as an outsourcing

facility, however, Fusion IV could no longer be concurrently licensed either as a retail pharmacy or as a sterile compounding pharmacy. (Bus. & Prof. Code, § 4129, subds. (b) and (e); see Factual Finding 6.)

24. Although Vahedi had submitted the application for Fusion IV to be licensed as an outsourcing facility on or about August 9, 2017, the Board denied the application on September 12, 2017. In an email to the Board dated September 15, 2017, Vahedi expressed his frustration with the new regulatory structure for outsourcing facilities and requested clarification from the Board. He wrote:

> As if this apparent "Catch-22" scenario isn't bad enough, we are about to end up with *no* licenses whatsoever. Currently, our Outsourcing Facility application has been in the possession of the Board since late May of this year; we had hoped that we would have been in receipt of the license by now but are still without. Furthermore, both the LSC and PHY [Fusion IV's sterile compounding and retail pharmacy licenses], which we did not intend to renew, expire October 1 of this year (less than three weeks from today). Therefore, we need your advice how to proceed, urgently.

(Ex. 13, p. 4.)

25. In response, on September 27, 2017, Supervising Inspector Christine Acosta of the Board's sterile compounding team advised Vahedi in an email to seek legal counsel regarding how to proceed. Moreover, Inspector Acosta wrote:

> 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 4129.1(a).
>
> . . . . I feel the need to formally notify you that as of 10/1/17, LSC 100855 will be expired and all sterile compounding must cease at this location. . . .

(Ex. 13, p. 2.)

26. Based on this correspondence, Vahedi was aware of the expiration of Fusion IV's sterile compounding license on October 1, 2017. Vahedi was also put on notice that as soon as this license expired, he was required to cease sterile compounding at Fusion IV. However, between October 1, 2017, and October 23, 2017, after the expiration of this license, Fusion IV continued to engage in sterile compounding activities.

27. In a letter dated October 23, 2018, Inspector Acosta again informed Vahedi that Fusion IV's sterile compounding license expired as of October 1, 2017. The letter further stated:

> 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 license 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 [sterile compounding] 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 eight (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.

(Ex. A.)

28. Although Fusion IV was granted a temporary renewal of its sterile compounding license (LSC 100855) from October 23, 2017, until April 30, 2018, this license was cancelled on June 4, 2018, due to a filing of discontinuance of business, effective April 1, 2018. Fusion IV's retail pharmacy license (PHY 53726) was also cancelled due to the same filing of discontinuance of business, effective April 1, 2018. Thus, currently, Fusion IV does not possess any license issued by the Board. However, Fusion IV has not ceased its operations, and it has compounded drugs without any license from April 1, 2018, until the present day.

29. Vahedi's September 15, 2017 email clearly indicated his intent not to renew Fusion IV's retail pharmacy and sterile compounding license. Furthermore, Inspector Acosta's September 27, 2017 email and October 23, 2017 letter notified Vahedi of the requirement for Fusion IV to be licensed as an outsourcing facility with the Board. Thus, the continuation of unlicensed compounding activities at Fusion IV has occurred with Vahedi's full knowledge that under California law, conducting such activities requires licensure from the Board.

//

//

VAHEDI'S ASSUMPTION OF SUPERVISING AUTHORITY AT FUSION IV

30. In a Certification of Personnel dated May 18, 2017, attached to Fusion IV's application for an instate outsource facility license, Christina Chalikias (Chalikais) indicated that she will serve as "PIC" of Fusion IV. (Ex. 3, p.60.)

31. Although Chalikias held the title of Operations Manager at Fusion IV, her duties were that of a supervising pharmacist. Chalikias resigned from her position two weeks prior to the date of the hearing. Since Chalikias's resignation, Vahedi has assumed supervising authority at Fusion IV and served as its supervising pharmacist.

Testimony of Vahedi

32. Vahedi graduated from the University of California, Los Angeles, in 2003. He received his doctorate in pharmacy from Roseman University in 2006. After his graduation, Vahedi became an intern and later a pharmacist at Long's Drugs. Subsequently, he worked for Rite-Aide as a PIC. In 2009, Vahedi opened Fusion RX and served as its PIC. In 2015, he established Fusion IV, which began operating in 2016.

33. At the hearing, Vahedi admitted that Fusion IV has compounded drugs without a sterile compounding license from October 1, 2017, to October 23, 2017, and without any license from April 1, 2018, until the present. Vahedi also admitted that he has been serving as Fusion IV's supervising pharmacist since Chalikias resigned from Fusion IV.

34. However, Vahedi insisted that it was not his intention or desire to violate any laws, but he was, in his words, "put in a position where [he] had no options." Vahedi has invested his life savings in Fusion IV. His investment consists of an outstanding bank loan of $1 million and a line of credit of approximately $700,000. If he were to cease operating Fusion IV, Vahedi reported that it would force him into bankruptcy. Vahedi also understands that the terms of Condition 7 of his Board Probation prohibit his assumption of supervising authority at Fusion IV. Regardless, Vahedi claimed that the Board "scared away" (his term) Chalikias, and that he is acting as Fusion IV's supervising pharmacist against his will.

35. Vahedi believes that Fusion IV's application for an instate outsourcing facility license was wrongfully denied because at the time of the denial, on September 12, 2017, the disciplinary matter against his pharmacist license and Fusion RX's pharmacy permit in case number 5899 was still pending and none of the charges had been adjudicated. Vahedi also believes that he was denied due process because the Board failed to provide him with a hearing within 90 days of September 27, 2017, when he initially requested a hearing. Vahedi further believes that the findings against his pharmacist license and Fusion RX, contained in the Decision and Order, cannot be the grounds for denial of Fusion IV's application for an instate outsourcing facility license because Fusion IV is not an entity of Fusion RX and was not a party to case number 5899.

36. Vahedi believes that findings contained in the Decision and Order in case number 5899 do not reflect who he truly is. Specifically, Vahedi disagreed with findings that Fusion IV conducted unlicensed activities on Fusion RX's premises. Vahedi testified that under his own interpretation of the law, "unlicensed activity has to occur at an unlicensed location" and Fusion RX is properly licensed as a retail pharmacy. Vahedi also disagreed with the findings in the Decision and Order that he subverted the Board's investigation. Although Vahedi claimed that he took responsibility for failing to submit certain documents, including dispensing reports and hardcopy order forms, to the Board for inspection, he placed the blame mostly on his former attorney, Herbert Weinberg. Vahedi stated that he had relied on Mr. Weinberg to produce the documents to the Board but that Mr. Weinberg had, in Vahedi's words, "dropped the ball."

37. Vahedi also contended that the acts which warranted Board discipline in case number 5899 are not related to the operations of Fusion IV as an outsourcing facility. He emphasized that unlike a pharmacy, Fusion IV does not consult with any patients. However, on cross-examination, Vahedi admitted that for both pharmacies and outsourcing facilities, the ultimate end users of the drug products are patients.

Testimony of Inspector Margaret Panella-Spangler

38. Margaret Panella-Spangler, the Board's Supervising Investigator, has been a licensed pharmacist since 1979. She has been employed with the Board for four years and has been a member of the Board's outsourcing facilities team for one and half years. In that capacity, Inspector Panella-Spangler assisted the Board in developing its program to regulate outsourcing facilities. She has received training from the FDA on federal regulation and inspections of outsourcing facilities.

39. At the hearing, Inspector Panella-Spangler explained that while registration with the FDA as a 503B outsourcing facility is voluntary, California requires licensure of outsourcing facilities under Business and Professions Code section 4129. Although the FDA inspects federally registered 503B outsourcing facilities, the Board conducts its own inspections of outsourcing facilities in California before granting a license. The Board inspection of applicant outsourcing facilities is vigorous and requires two inspectors to complete the process over three days. Voluminous amounts of documents are requested from the applicant facilities because, in Inspector Panella-Spangler's words, "raw data and documents are the hallmark of an inspection."

40. Inspector Panella-Spangler admitted that outsourcing facilities are not pharmacies, in that outsourcing facilities do not consult with individual patients and do not have a designated PIC. However, she observed that many similarities exist between the operations of an outsourcing facility and that of a pharmacy. The foremost goal for both types of facilities is to protect the consumer because the facilities' end product in both instances is given to patients. To achieve this goal, both pharmacies and outsourcing facilities must maintain good sterile practice, excellent record keeping, and vigilant oversight. Whereas the PIC has oversight in a pharmacy, the owner bears the responsibility

of oversight at an outsourcing facility. And, as the overseer of an outsourcing facility, the owner must ensure the authenticity and potency of the compounded drugs. The owner also must ensure that the process and techniques used at the facility, such as incubation and sterilization, are valid. Additionally, the owner must ensure that the personnel at the facility are performing their duties according to set policies and procedures.

41. Inspector Panella-Spangler opined that honesty, integrity, and a willingness to make a quality product are important characteristics for the owner of an outsourcing facility. She indicated that a willingness to cooperate with the Board and to produce documents as requested is also an important attribute for the owner of an outsourcing facility to possess, in light of the fact that intensive document review is necessary to substantiate the qualifications of an outsourcing facility.

Testimony of Inspector Christine Acosta

42. Inspector Acosta is the Supervising Inspector of Board's sterile compounding team. She has been a licensed pharmacist since 2006. Inspector Acosta also works with Inspector Panella-Spangler on the outsourcing facility team. Whereas Inspector Panella-Spangler focuses on inspections of outsourcing facilities, Inspector Acosta works on the administrative aspects of the Board's efforts to regulate outsourcing facilities.

43. At the hearing, Inspector Acosta testified regarding her correspondences with Vahedi and the continued unlicensed activity of Fusion IV, as set forth above in Factual Findings 25 to 31. Additionally, Inspector Acosta stated that many of the Board's laws and regulations apply to pharmacies as well as outsourcing facilities. For example, Business Professions Code section 4342, subdivision (a)(failure to prevent the sale of expired drugs), which Fusion RX and Vahedi were found to have violated in case number 5899, is applicable to outsourcing facilities. The prohibition against unlicensed activities also applies to pharmacies as well as outsourcing facilities. Inspector Acosta emphasized that the continuation of Fusion IV's unlicensed activity is of great concern to the Board, as licensure forms the basis for the Board's ability to provide consumer protection. Any unlicensed activity fundamentally negates the Board's ability to protect the public from drugs that may be harmful.

44. Inspectors Acosta and Panella-Spangler's opinions regarding the similarities between pharmacies and outsourcing facilities and the functions, duties, and qualifications of an outsourcing facility owner are credible and unrefuted. Thus, they are afforded significant weight.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. The respondent generally bears the burden of proof at the hearing regarding a statement of issues. (*Coffin v. Department of Alcoholic Beverage Control* (2006) 139

Cal.App.4th 471, 476.) The standard of proof is preponderance of evidence. (Evid. Code § 115; *Mann v. Department of Motor Vehicles* (1999) 76 Cal.App.4th 312, 322-323.) "'Preponderance of the evidence means evidence that has more convincing force than that opposed to it.' (Citations omitted) . . . . The sole focus of the legal definition of 'preponderance' in the phrase 'preponderance of the evidence' is on the *quality* of the evidence. The *quantity* of evidence presented by each side is irrelevant." (*Glage v. Hawes Firearms Company* (1990) 226 Cal.App.3d 314, 324-325.) (Emphasis in original.)

The Effect of the Decision and Order in Case Number 5899

FAILURE TO COMPLY WITH BUSINESS AND PROFESSIONS CODE SECTION 487

2. At the hearing, Vahedi contended that the Board's failure to comply with Business and Professions Code section 487 necessitates the exclusion of the Decision and Order in case number 5899 for consideration in this proceeding. This argument was not convincing.

3. Business and Professions Code section 487 states, in pertinent part, "If a hearing is requested by the applicant, the board shall conduct such hearing within 90 days from the date the hearing is requested unless the applicant shall request or agree in writing to a postponement or continuance of the hearing."

4. Vahedi requested a hearing on the denial of Fusion IV's application for an instate outsourcing license on September 27, 2017, but a hearing was not provided until October 2018, more than 90 days after Vahedi's request. Thus, the Board did not comply with Business and Professions Code section 487. Nevertheless, the issue that remains is whether the language of the statute is mandatory or directory. If the language is mandatory, the Board would necessarily lose its jurisdiction over this matter, rendering any decision void. If the language is directory, the Board may still hold a hearing in this matter beyond the 90-day limit and render a valid decision.

5. Vahedi argued that the "shall" language of Business and Professions Code section 487 is mandatory, not directory. In support of this argument, Vahedi cited to Government Code section 14, which states, "'Shall' is mandatory and 'may' is permissive." However, rather than following the logical consequence of this argument that the Board would lose jurisdiction over this matter, Vahedi further contended that the remedy for the Board's failure to comply with Business and Professions Code section 487 is evidence preclusion. Under this theory, the Decision and Order in case number 5899 should not be considered in this matter because the charges against Vahedi and Fusion RX were not adjudicated until January 2, 2018, more than 90 days after Vahedi filed his request for hearing. Had the Board complied with Business and Professions Code section 487 and provided Vahedi with a timely hearing on the application denial, the Board's only basis for denial of Fusion IV's application would have been the pending charges in Accusation number 5899. Vahedi did not cite to any authority in support of this theory. Indeed, as discussed more fully below, case law indicates that if the language of statute setting time

limits for holding a hearing is construed as mandatory, the remedy for noncompliance is jurisdictional, not evidentiary, in nature.

6. Under ordinary rule of statutory interpretation, when the Legislature has defined the term "shall," the court should give it its legislatively defined meaning. The plain language rule of statutory interpretation also requires reading the use of the word "shall" in Business and Professions Code section 487 as mandatory rather than directory. However, several California court have held that where no purpose is served by treating the word "shall" as mandatory, then regardless of statutory language defining "shall" in mandatory terms, it is treated as directory. (*Garrison v. Rourke*, (1948) 32 Cal.2d 430, 435-436 , overruled on other grounds in *Keane v. Smith*, (1971) 4 Cal.3d 932, 939.)

7. In *Edwards v. Steele* (1979) 25 Cal.3d. 406, the California Supreme Court set forth two general tests as to whether the word "shall" should be construed as mandatory or directory in a statute. The California Supreme Court stated:

> In ascertaining probable intent, California courts have expressed a variety of tests. In some cases focus has been directed at the likely consequences of holding a particular time limitation mandatory, in an attempt to ascertain whether those consequences would defeat or promote the purpose of the enactment. [Citations.] Other cases have suggested that a time limitation is deemed merely directory "unless a consequence or penalty is provided for failure to do the act within the time commanded." [Citations.]

(*Id.* at p. 410.)

8. Applying either test to the present statute, it is clear that the 90-day limit for the Board to conduct a hearing under Business and Professions Code section 487 is directory rather than mandatory. The probable intent underlying the statute is to provide a respondent with a reasonably timely hearing of, and decision on, his administrative appeal. It would only further aggrieve a respondent to hold that the provisions are mandatory and jurisdictional because the respondent would be denied a hearing altogether. Moreover, no "consequence or penalty" for noncompliance with the time limitations is contained in the statute, and nothing in the language suggests an intent to nullify a timely filed appeal solely because the board has delayed in setting a hearing. Given that Business and Professions Code section 487 is directory rather than mandatory, the proper remedy for a respondent who has not been provided with a timely hearing under the statute is to petition the Superior Court for an order directing the Board to set a hearing.

APPLICATION OF COLLATERAL ESTOPPEL

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. As set forth in Factual Findings 10 through 19, 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.) More precisely, the Appellate Court in *Citizens for Open Access to Sand and Tide, Inc. v. Seadrift Assn.* (1998) 60 Cal.App.4th 1053, stated:

> A party is adequately represented for purposes of the privity rule "if his or her interests are so similar to a party's interest that the latter was the former's virtual representative in the earlier action. We measure the adequacy of 'representation by inference,' examining whether the party in the suit which is asserted to have a preclusive effect had the same interest as the party to be precluded, and whether that party had a strong motive to assert that interest. If the interests of the parties in question are likely to have been divergent, one does not infer adequate representation and there is no privity. If the party's motive for asserting a common interest is relatively weak, one does not infer adequate representation and there is no privity."

(*Id.* at pp. 1070-1071, citations omitted.)

13. 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.

14. 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.

First Cause for Denial of Application (Acts Warranting Revocation of Licensure)

15. Cause exists to deny Fusion IV's application for an instate outsourcing facility license, pursuant to Business and Professions Code section 480, subdivision (a)(3)(A), in that Vahedi had committed acts that, if done by a licentiate of the Board, would be grounds for suspension or revocation of license. As adjudicated in case number 5899, Vahedi committed acts as the owner of Fusion RX and as an individual pharmacist that warranted discipline against his pharmacist license (RPH 59537) and Fusion RX's pharmacy permit (PHY 49973). (Factual Findings 10 through 22.)

16. Pursuant to Business and Professions Code section 480, subdivision (a)(3)(B), the Board may deny a license based on Business and Professions Code section 480, subdivision (a)(3)(A), if the act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

17. CCR section 1770 states:

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

19. The question of whether a substantial relationship exists is ultimately an issue of law. (*Morrison v. State Board of Education* (1969) 1 Cal.3d, 214, 238.) However, that legal determination may be based on a factual showing to establish the type of conduct that is related to the fitness to practice a particular profession. (*Grannis v. Board of Medical Examiners* (1971) 19 Cal.App.3d, 551, 563.)

20. In this case, the testimonies of Inspectors Panella-Spangler and Acosta established that Vahedi's acts as a pharmacist and as the owner of Fusion RX are

substantially related to the qualifications, functions, or duties of an outsourcing facility owner. The owner of an outsourcing facility, like a pharmacist or the owner of a pharmacy, must be honest and must ensure the safety and potency of drugs for consumption by patients. The owner of an outsourcing facility, like a pharmacist or the owner of a pharmacy, must also be willing to comply with the Board's laws and regulations and cooperate with the Board's inspections. As a pharmacist and the owner of Fusion RX, Vahedi failed to prevent sale of expired drugs, conducted pharmacy business as Fusion IV before it was licensed, engaged in acts involving dishonesty and deceit, and subverted Board inspections by refusing to submit requested documentation. These acts evidence Vahedi's present or potential unfitness to perform the functions authorized by an instate outsourcing facility license in a manner consistent with the public health, safety, or welfare.

Second Cause for Discipline (Unprofessional Conduct)

21. Cause exists to deny Fusion IV's application for an instate outsourcing facility license, pursuant to Business and Professions Code section 4300, subdivisions (a), (b), and (c), in that Vahedi engaged in unprofessional conduct. As adjudicated in case number 5899, Vahedi, as the owner of Fusion RX and as an individual pharmacist, engaged in unprofessional conduct by committing acts involving dishonesty and deceit, making documents with false representations, and subverting a Board investigation. (Factual Findings 10 through 22.)

22. At the hearing, Vahedi contended that Business and Professions Code section 480 is the only legal authority upon which the Board may rely to form the grounds for license denial. In support of this argument, Vahedi cited to *Brandt v. Fox* (1979) 90 Cal.App.3d 737. This is a misreading of the case.

23. *Brandt v. Fox* does not stand for the proposition that Business and Professions Code section 480 is the sole controlling authority for license denial, and it does not invalidate agency-specific statutes on license denial. In *Brandt v. Fox*, the Appellate Court found that the substantial relationship test, imposed by Business and Professions Code section 480, subdivision (a), was intended to limit the scope of a licensing statute such as Business and Professions Code section 10177, subdivision (b), which allows the Department of Real Estate to deny a license based on a prior conviction but does not contain a substantial relationship test. (*Id.* at p. 748.) Thus, *Brandt v. Fox* held that the *limitations* imposed by Business and Professions Code section 480 prevail over agency-specific statues on license denial pertaining to specific bad acts and criminal convictions because the legislature intended to insure that licensing for a business or profession could not be barred for arbitrary reasons. (Bus & Prof., § 475; *Brandt v. Fox*, *supra,* 90 Cal.App.3d at p. 749; *Pieri v Fox* (1979) 96 Cal.App.3d 802, 808.)

24. Indeed, many agencies have their own laws that add grounds for license denial in addition to those specified under Business and Professions Code section 480. For example, aiding or abetting another individual with examination subversion is a ground for license denial under the laws of the Board of Accountancy. (Bus & Prof., § 5110.) False

advertising is a ground for license denial under the laws of the Board of Behavioral Sciences. (Bus & Prof., § 4982, subd. (p).) Moreover, impersonating a licensed practitioner is grounds for license denial under the laws of the Board of Registered Nursing and the Board of Occupational Therapy. (Bus & Prof., §§2570.28, subd. (g); 2761, subd. (h)). Vahedi has not cited to any legal authority to demonstrate that these agency-specific grounds, which are additional to those under Business and Professions Code section 480, are invalid.

Third Cause for Denial of Application (Existing Conditions in Relation to Officer or Director that Constitute Grounds for Disciplinary Action)

25. Cause exists to deny Fusion IV's application for an instate outsourcing facility license, pursuant to Business and Professions Code section 4302, in that conditions exist in relation to Vahedi, who is president, director, and 100 percent shareholder of Fusion IV, that would constitute grounds for disciplinary action against him. As adjudicated in case number 5899, Vahedi committed acts as the owner of Fusion RX and as an individual pharmacist that warranted discipline against his pharmacist license (RPH 59537) and Fusion RX's pharmacy permit (PHY 49973). (Factual Findings 10 through 22.)

Fourth Cause for Denial of Application (Participation in Conduct by Officer, Director or Person with Management or Control that Constitute Grounds for Disciplinary Action)

26. Cause exists to deny Fusion IV's application for an instate outsourcing facility license, pursuant to Business and Professions Code section 4307, subdivisions (a) and (b), in that Vahedi is 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. Vahedi's pharmacist license (RPH 59537) and Fusion RX's pharmacy permit (PHY 49973) are currently on probation, and Vahedi had knowledge or knowingly participated in the conduct for which his pharmacist license and Fusion RX's pharmacy permit was placed on probation. (Factual Findings 10 through 22.)

Rehabilitation

27. CCR section 1769 states:

> (a) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:
>
> (1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.
>
> (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

28. In the case at hand, Vahedi's violations as a pharmacist and as Fusion RX's owner in case number 5899 ranged in their nature and severity. Among the nine violations that were found against Vahedi and Fusion RX, of particular concern are the failure to prevent the sale of expired drugs, conducting business without a pharmacy license, and subverting a Board investigation, because the laws and regulations that govern these violations also directly apply to outsourcing facilities.

29. It is even more troubling that Vahedi continues to engage in the deliberate violation of the Board's laws and regulations by his subsequent acts. 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. (Factual Findings 24 through 31.) 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. (Factual Findings 24, 32, and 31.)

30. Vahedi's violations in case number 5899 and his subsequent acts form a pattern of conduct demonstrating an unwillingness to comply with the Board's laws and regulations and the terms of his Board probation. This pattern of conduct is intentional. As set forth in the Decision and Order in case number 5899, as the owner of Fusion RX, Vahedi knew of requests from the Board to submit certain documents for inspection, but he did not do so. Prior to October 15, 2015, Vahedi also knew that Fusion IV was not yet licensed as a retail pharmacy, but he nevertheless began to operate Fusion IV on Fusion RX's premises. Subsequently, in 2017, Vahedi was placed on notice several times that Fusion IV did not have the proper licensure to continue compounding drugs, but Fusion IV has continued its compounding activities. Vahedi also continues to violate the terms of his Board probation despite his awareness of what those terms entail. Although there was no evidence of direct patient harm, this pattern of conduct potentially harms the public. Proper licensure and compliance with Board probation are the means through which the Board regulates its licensees and protects the public from unsafe drugs.

31. Because Vahedi has continued his pattern of flouting the Board's laws and regulations, no time has elapsed since his last violation. At the hearing, Vahedi did not take responsibility for the violations he committed in case number 5899. Vahedi also claimed at that he was forced to operate Fusion IV unlicensed and to assume a supervising role at the

company. In fact, Vahedi continues to engage in this misconduct not because he does not have a choice, but because he benefits financially from Fusion IV's unlicensed activities.

32. Given Vahedi's disregard for Board oversight, he cannot be relied upon to comply with reasonable terms or conditions that would be imposed if Fusion IV were allowed to operate under a probationary license. Therefore, the protection of public interest, health, and welfare requires the denial of Fusion IV's application for an instate outsourcing facility license.

ORDER

The application of Fusion IV Pharmaceuticals, Inc., doing business as Axia Pharmaceuticals, Navid Vahedi, owner, for an instate outsourcing facility license is denied.

DATED: November 26, 2018

DocuSigned by:
Ji-Lan Zang
JI-LAN ZANG
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 Statement of Issues Against: **FUSION IV PHARMACEUTICALS INC. DBA AXIA PHARMACEUTICALS, NAVID VAHEDI, OWNER** **Instate Outsourcing Facility License Applicant** Respondents.	Case No. 6270 **STATEMENT OF ISSUES**

Complainant alleges:

PARTIES

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

2. On or about August 9, 2017, the Board of Pharmacy, Department of Consumer Affairs received an amended application for Instate Outsourcing Facility License from Fusion IV Pharmaceuticals Inc. dba Axia Pharmaceuticals with Navid Vahedi as Owner (Applicant). On or about August 7, 2017, Navid Vahedi certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the amended application on September 12, 2017.

JURISDICTION

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

STATUTORY PROVISIONS

4. Business and Professions Code section 4300 states:

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

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

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

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

. . . .

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

5. Section 4300.1 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.

6. Section 4402, subdivision (a), provides that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

7. Section 4302 states:

> The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

8. Section 4307 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.

9. Section 480 states, in pertinent part:

> (a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:
>
> . . .
>
> (3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.
>
> (B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

REGULATIONS

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

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

FACTS

11. On January 30, 2017, the Board filed Accusation number 5899 against Dr. N. Vahedi Pharmacy Inc. dba Fusion Rx Compounding Pharmacy with Navid Vahedi, president and Pharmacist in Charge (Pharmacy Permit No. PHY 49937) and individually against Navid Vahedi (Pharmacist License No. RPH 59537). The Accusation alleged ten (10) Causes for Discipline and separately alleged disciplinary considerations, consisting of six (6) prior citations, for acts warranting discipline on the licenses of both Fusion Rx Compounding Pharmacy and pharmacist Navid Vahedi. A proposed decision was issued on October 26, 2017. The proposed decision, following the hearing on September 25-26, 2017, recommending separate disciplinary orders against both Pharmacy Permit No. PHY 49937 and Pharmacist License No. RPH 59537.

12. The proposed decision found that cause existed to suspend or revoke the pharmacy permit (Pharmacy Permit No. PHY 49937) and pharmacist's licenses (Pharmacist License No. RPH 59537) due to various violations of pharmacy laws and regulations and ordered the pharmacy permit and pharmacist's license to each be placed on four (4) years probation with terms and conditions including thirty (30) days suspension as to both the pharmacy permit and pharmacist's license with additional terms and conditions.

13. On or about January 2, 2018, the California State Board of Pharmacy (Board) issued a Decision and Order adopting the Proposed Decision of the administrative law judge dated October 26, 2017 as its decision in this matter. A true and correct copy of Accusation number 5899 and the Proposed Decision after hearing is attached as exhibit A and is incorporated by reference herein.

14. On January 19, 2018, respondent Dr. N. Vahedi Pharmacy Inc., dba Fusion Rx Compounding Pharmacy and its president, Navid Vahedi, timely requested reconsideration of a specific portion of the January 2, 2018, Decision and Order pertaining to pharmacy permit number PHY 49937. On February 9, 2018, the Board granted the reconsideration of the January 2, 2018, Decision and Order as to respondent Fusion Rx Compounding Pharmacy (PHY 49937), only and stayed that portion of the decision.

15. On January 29, 2017, respondent Dr. N. Vahedi Pharmacy Inc., dba Fusion Rx Compounding Pharmacy and its president, Navid Vahedi filed an ex parte application for stay of administrative decision and order in the Superior Court in the matter captioned as *Dr. N. Vahedi Pharmacy Inc., dba Fusion Rx Compounding Pharmacy; Navid Vahedi vs. California Board of Pharmacy*, Superior Court Case number BS172303. On January 31, 2018, the Superior Court issued an order, effective February 1, 2018 staying the Decision and Order dated January 2, 2018 as to the thirty (30) day suspension of the pharmacy only pending the outcome of petitioner's writ of mandate.

16. On February 9, 2018, the Board issued an Order granting reconsideration of the January 2, 2018, Decision and Order as to respondent Fusion Rx Compounding Pharmacy (PHY 49937), only in the administrative case.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Acts Warranting Revocation of Licensure: Accusation No. 5899)

17. The application for Instate Outsourcing Facility License is subject to denial under section 480, subdivision (a)(3), in that while holding Pharmacy Permit Number PHY 49937 and Pharmacist License Number RPH 59537, Applicant committed acts that warrant revocation of licensure. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraph 11-16, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 5899.

///

///

///

SECOND CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct)

18. The application for Instate Outsourcing Facility License is subject to denial under section 4300, subdivisions (a),(b) and (c), in that Applicant Vahedi engaged in unprofessional conduct in connection with his duties as president and pharmacist in charge of Dr. N. Vahedi Pharmacy Inc. dba Fusion Rx Compounding Pharmacy. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraph 11-16, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 5899.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Existing Conditions in Relation to Officer or Director that Constitute Grounds for Disciplinary Action)

19. The application for Instate Outsourcing Facility License is subject to denial under section 4302, in that Applicant Vahedi engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraph 11-16, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 5899.

FORTH CAUSE FOR DENIAL OF APPLICATION

(Participation in Conduct by Officer, Director or Person with Management and Control that Constitute Grounds for Disciplinary Action)

20. The application for Instate Outsourcing Facility License is subject to denial under section 4307 subdivisions (a) and (b), in that Applicant Vahedi is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years where Pharmacy Permit Number PHY 49937 is placed on probation and Applicant Vahedi was an officer, owner, or person with management or control of Pharmacy Permit PHY 49937 and had knowledge of or knowingly participated in any conduct for which discipline was issued. Complainant refers to, and by this reference incorporates, the allegations set forth in

paragraph 11-16, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 5899.

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. Denying the application of Fusion IV Pharmaceuticals Inc. dba Axia Pharmaceuticals, with Navid Vahedi as Owner for an Instate Outsourcing Facility License; and

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

DATED: 4/30/18

Virginia Herold

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

LA2017507212
52830148.doc

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 19-1127 PA (FFMx)	Date	June 21, 2019
Title	Fusion IV Pharmaceuticals, Inc., et al. v. Executive Director Virginia Herold, et al.		

Present: The Honorable	PERCY ANDERSON, UNITED STATES DISTRICT JUDGE	
Kamilla Sali-Suleyman	Not Reported	N/A
Deputy Clerk	Court Reporter	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
None	None

Proceedings: IN CHAMBERS - COURT ORDER

Before the Court are a Motion for Judgment on the Pleadings Pursuant to FRCP 12(c) (Docket Nos. 47, 49)[1/] filed by plaintiffs Fusion IV Pharmaceuticals, Inc. d/b/a Axia Pharmaceutical ("Fusion IV") and Navid Vahedi ("Vahedi") (collectively, "Plaintiffs") and a Motion for Judgment on the Pleadings (Docket No. 52) filed by defendant Anne Sodergren, Interim Executive Officer of the California State Board of Pharmacy ("Defendant"). Pursuant to Rule 78 of the Federal Rules of Civil Procedure and Local Rule 7-15, the Court finds these matters appropriate for decision without oral argument. The hearing calendared for June 24, 2019 is vacated, and the matters taken off calendar.

I. Background

"Generally, the [Food, Drug, and Cosmetic Act ('FDCA')] and parallel state statutes require approval by the FDA and other state agencies before drugs can be sold. Compounded drugs are exempted from these requirements, inter alia, under both federal and state laws when certain conditions are met." Allergan USA, Inc. v. Prescribers Choice, Inc., 364 F. Supp. 3d 1089, 1103-04 (C.D. Cal. 2019) (citations omitted). With this action, Plaintiffs challenge the validity of certain state laws concerning compounded drugs.

"In 2013, Congress passed the Drug Quality and Security Act ('DQSA'), amending FDCA Section 503A and adding Section 503B." Allergan USA, Inc. v. Prescribers Choice, Inc., 364 F. Supp. 3d 1089, 1103-04 (C.D. Cal. 2019) (citing DQSA, 113 Pub. L. No. 54, 127 Stat. 587 (2013)). Section 503B of the FDCA allows a drug-compounding facility to avoid certain regulatory requirements for a drug, such as the new drug approval process, if the drug is compounded in a facility that has registered as an "outsourcing facility" with the Food and Drug Administration ("FDA") and other conditions are satisfied. Id. § 353b(a), (b). California law requires that an outsourcing facility registered with the FDA "be concurrently licensed with the [California Board of Pharmacy (the 'Board')] . . . if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California." Cal. Bus. & Prof. Code § 4129; see id. §§ 4129.1, .2. The state license must be renewed

[1/] Plaintiffs have filed two identical versions of their motion.

annually, and the facility must undergo an inspection by and provide certain information to the Board in order to obtain or renew a license. Id. §§ 4129.1, .2.

According to the operative Third Amended Complaint ("TAC"), Fusion IV is a federally registered outsourcing facility. (Docket No. 40 at 1, 11-12, 25.) After Fusion IV received its federal registration, Plaintiffs applied for a California outsourcing facility license, but the Board (improperly, in Plaintiffs' view) denied their application. (Id. at 1, 3, 26.) Plaintiffs contend that Congress intended for outsourcing facilities to be subject only to federal regulation; the California laws governing outsourcing facilities conflict with federal law in various ways; and the California laws impermissibly interfere with intersta10
te commerce. (See generally TAC.) Plaintiffs thus argue that the state laws are preempted and also invalid under the United States Constitution's Commerce Clause. (Id. at 2.) Plaintiffs seek declaratory relief including, among other things, an order ruling the state outsourcing facility laws invalid and holding that Plaintiffs are subject only to federal regulation in their outsourcing-facility activities. (Id. at 38-39.)

Plaintiffs and Defendant have filed motions for judgment on the pleadings. As in their TAC, Plaintiffs argue that California's outsourcing facility laws are preempted by federal law under theories of express, field, and implied preemption and also invalid under the Commerce Clause. (See Pls.' Mot.; Pls.' Opp'n to Def.'s Mot., Docket No. 58.[2/]) Defendant argues that the state laws are valid. (See Def.'s Mot.; Def.'s Opp'n to Pls.' Mot., Docket No. 55.)

II. Legal Standard

Under Federal Rule of Civil Procedure ("Rule") 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." In ruling on a motion for judgment on the pleadings brought pursuant to Rule 12(c), "the allegations of the non-moving party must be accepted as true, while the allegations of the moving party which have been denied are assumed to be false." Hal Roach Studios, Inc. v. Richard Feiner & Co., 896 F.2d 1542, 1550 (9th Cir. 1990) (citing Doleman v. Meiji Mutual Life Ins. Co., 727 F.2d 1480, 1482 (9th Cir. 1984); Austad v. United States, 386 F.2d 147, 149 (9th Cir. 1967)). Rule 12(c) is "functionally identical" to Rule 12(b)(6), and the same standard "applies to motions brought under either rule." Cafasso ex rel.

[2/] Plaintiffs' opposition to Defendant's motion exceeds the applicable page limit and was untimely. See L.R. 7-9; L.R. 11-6. (See also Docket No. 22 at 5.) Defendant argues that the opposition should be disregarded, Defendant's motion should be granted or the case dismissed, and Plaintiffs should be sanctioned for these and other violations of the Local Rules. (Def.'s Reply at 1-3, Docket No. 59.) Plaintiffs have filed motions to exceed the page limitation and to have their opposition considered despite its untimeliness. (Docket Nos. 60, 62, 63.) Plaintiffs' arguments in their opposition are essentially the same as those in their own motion, and the Court ultimately concludes that Defendant is entitled to Judgment in its favor even if Plaintiffs' opposition is considered. Accordingly, the Court considers Plaintiff's opposition despite these procedural deficiencies.

United States v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1054 n.4 (9th Cir. 2011). Therefore, whether a motion is brought under Rule 12(b)(6) or Rule 12(c), the pleadings must satisfy the "plausibility standard," in which the complaint must "raise a reasonable expectation that discovery will reveal evidence of [the alleged infraction]." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). For a complaint to meet this standard, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Id. at 555 (citing 5 C. Wright & A. Miller, Federal Practice and Procedure §1216, pp. 235-36 (3d ed. 2004) ("[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action")); see also Daniel v. County of Santa Barbara, 288 F.3d 375, 380 (9th Cir. 2002) ("All allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party." (quoting Burgert v. Lokelani Bernice Pauahi Bishop Tr., 200 F.3d 661, 663 (9th Cir. 2000))). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555 (internal quotation marks omitted). In construing the Twombly standard, the Supreme Court has advised that "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009).

"Judgment on the pleadings is proper when the moving party clearly establishes on the face of the pleadings that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law." Hal Roach Studios, 896 F.2d at 1550 (citing Doleman, 727 F.2d at 1482). Alternatively, the Court has discretion to grant leave to amend or to dismiss causes of action rather than grant judgment on a Rule 12(c) motion. See Lonberg v. City of Riverside, 300 F. Supp. 2d 942, 945 (C.D. Cal. 2004); Carmen v. S.F. Unified Sch. Dist., 982 F. Supp. 1396, 1401 (N.D. Cal. 1997).

III. The Parties' Requests for Judicial Notice

"In a motion for judgment on the pleadings, the Court may consider information 'contained in materials of which the court may take judicial notice' and documents attached to the complaint." Mays v. Wal-Mart Stores, Inc., 354 F. Supp. 3d 1136, 1141 (C.D. Cal. 2019) (quoting Heliotrope Gen., Inc. v. Ford Motor Co., 189 F.3d 971, 981 n.18 (9th Cir. 1999); and citing United States v. Ritchie, 342 F.3d 903, 908 (9th Cir. 2003))). Both sides have filed requests for judicial notice (Docket Nos. 44, 53, 56), and neither side has opposed to the others' requests.

Among other things, Plaintiffs request that the Court take judicial notice of the "fact" that Section 503B of the FDCA "establishes a registration 'authorization' in order for outsourcing facilities to begin to conduct business in compounding drugs to be placed into interstate commerce." (Docket No. 44 at 1.) The Court denies this request because the purported fact is a legal conclusion about the effect of a statute at issue in this case. See, e.g., United States v. Molen, No. 2:10-cv-02591 MCE KJN PS, 2011 WL 1810449, at *6 (E.D. Cal. May 9, 2011) ("[T]here is typically no need to request judicial

notice of statutes and regulations pursuant to Federal Rule of Evidence 201 . . . . Instead of requesting 'judicial notice' of statutes and regulations they believe support their arguments, [parties] should simply include citations to the statutes and regulations within the legal argument portion of their motions.").

Plaintiffs also request that the Court take judicial notice of the fact that in 2012, there was an "incident involving adulterated compounded drugs which occurred in Massachusetts, leading to the deaths of sixty-four individuals and the illness of over 700 others, who contracted fungal meningitis, as reflected in [material on a webpage maintained by the United States Senate] (and Congressional Record excerpts within Plaintiffs' Complaint)." (Docket No. 44 at 2.) The Court grants this request. See, e.g., Anderson v. Holder, 673 F.3d 1089, 1094 n.1 (9th Cir. 2012); Hadley v. Kellogg Sales Co., 243 F. Supp. 3d 1074, 1087 (N.D. Cal. 2017).

The remainder of the materials provided by the parties are not relevant to the disposition of their motions. The Court denies the parties' requests as moot with respect to those materials. See, e.g., Bryant v. Mickelsen, 551 F. App'x 348, 349 (9th Cir. 2014).

IV. Discussion

A. Preemption

As a preliminary matter, a "presumption against preemption applies generally, but is especially strong when . . . 'Congress has legislated in a field which the states have traditionally occupied.'" Chinatown Neighborhood Ass'n v. Harris, 794 F.3d 1136, 1141 (9th Cir. 2015) (quoting McDaniel v. Wells Fargo Invs., LLC, 717 F.3d 668, 674 (9th Cir. 2013); and citing Bayside Fish Flour Co. v. Gentry, 297 U.S. 422, 426, 56 S. Ct. 513, 80 L. Ed. 772 (1936)). Plaintiffs suggest at various points in the TAC and their briefing that "there is no 'traditional state regulation' which would create a presumption that a federal statute does not supplant state law." (TAC at 6-7, 37; see Pls.' Mot. at 12; Pls.' Opp'n to Def.'s Mot. at 11-12.) However, as Defendant argues, drug compounding predates the federal outsourcing facility laws and was regulated by the states. (Def.'s Opp'n to Pls.' Mot. at 2-3; Def.'s Reply at 3.) See Stacey L. Worthy et al., The Compounding Conundrum: How Insufficient Delineation of Regulatory Responsibility Has Created a Need for State and Federal Drug Law Reform, 72 Food & Drug L.J. 506, 508 (2017) ("While the regulation of new drugs falls under FDA's federal authority, the practice of pharmacy and medicine has traditionally been under the states' purview. Therefore, given that compounded drugs are produced by pharmacies or physicians, they have long fallen under state oversight." (footnotes omitted)); Nathan A. Brown & Eli Tomar, Could State Regulations Be the Next Frontier for Preemption Jurisprudence?: Drug Compounding as a Case Study, 71 Food & Drug L.J. 271, 272, 288, 295 (2016) (noting that "states have long been actively engaged in compounding oversight"). Additionally, regulation of drug compounding is more broadly an issue of public health or safety, and the Supreme Court has specifically noted a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 715, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985). Accordingly, the "California [outsourcing facility] statute[s] cannot be set aside absent 'clear evidence' of a conflict" with federal law. See Chinatown Neighborhood Ass'n, 794 F.3d at 1141-42 (quoting Geier v. Am.

Honda Motor Co., 529 U.S. 861, 885, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000); and citing McClellan v. I-Flow Corp., 776 F.3d 1035, 1039 (9th Cir. 2015)).

Plaintiffs also contend that California law explicitly acknowledges federal preemption by providing that an outsourcing facility's state license is immediately canceled, revoked, or suspended upon the FDA's cancellation, revocation, or suspension of its federal registration. (TAC at 21-22; Pls.' Mot. at 35-36; Pls.' Opp'n to Def.'s Mot. at 33-34.) Under California law, "[i]f the [FDA] cancels, revokes, or suspends an outsourcing facility's registration for any reason, any license issued pursuant to Section 4129.2 shall be immediately canceled, revoked, or suspended by operation of law." Cal. Bus. & Prof. Code § 4303.1. As Defendant points out, "this section simply states that FDA registration is a prerequisite to holding a state outsourcing facility license." (Def.'s Opp'n to Pls.' Mot. at 15 n.2; see Def.'s Reply at 7.) See also Cal. Bus. & Prof. Code § 4129.2(a). Contrary to Plaintiffs' suggestion, the California legislature's decision to automatically revoke a state license upon loss of a federal registration does not mean that the state must grant a license if a federal registration is issued.

1. Express Preemption

"The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.' Under this principle, Congress has the power to preempt state law. There is no doubt that Congress may withdraw specified powers from the States by enacting a statute containing an express preemption provision." Arizona v. United States, 567 U.S. 387, 398, 132 S. Ct. 2492, 183 L. Ed. 2d 351 (2012) (citations omitted).

Plaintiffs assert that Congress expressly preempted state regulation of outsourcing facilities in Section 503B(a)(11) and (d)(4)(A) of the FDCA as well as the DQSA's prohibition of state product-tracing requirements. (TAC at 9, 17, 27; see Pls.' Mot. at 32, 36, 39; Pls.' Opp'n to Def.'s Mot. at 10-11, 20.) However, none of these, nor any other provisions in the FDCA, expressly preempt state regulation of outsourcing facilities.

Section 503B(a)(11) of the FDCA provides that a drug is exempt from certain regulatory requirements if, among other conditions, the "drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section." 21 U.S.C. § 353b(a)(11). This provision simply states that the exemption only applies if the drug is compounded in accordance with Section 503B's requirements; it does not state that other regulation is not possible.

Section 503B(d)(4)(A) defines "outsourcing facility" to mean "a facility at one geographic location or address that--(i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section." 21 U.S.C. § 353b(d)(4)(A). This provision merely establishes what the term "outsourcing facility" means in the context of the statute, and it reiterates that the federal regulatory exemption only applies if an entity complies with certain specific requirements.

Finally, the portion of the DQSA concerning product-tracing that Plaintiffs cite provides that "[b]eginning on November 27, 2013, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system" that are inconsistent with, stricter than, or in addition to certain specified federal laws and regulations. 21 U.S.C. § 360eee-4(a). However, the statute makes clear that "[n]othing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) . . . ." Id. § 360eee-4(c). The state laws that Plaintiffs are challenging are not "related to product tracing" and therefore are explicitly excluded from the provision's preemptive scope. Furthermore, this provision is located in the Drug Supply Chain Security Act, a separate title in the DQSA from the Compounding Quality Act, which created Section 503B of the FDCA. See DQSA. The existence of a provision explicitly preempting some state regulation "impl[ies] that Congress intentionally did not preempt state law generally, or in respects other than those it addressed." Keams v. Tempe Tech. Inst., Inc., 39 F.3d 222, 225 (9th Cir. 1994).

Plaintiffs also contend that the DQSA's legislative history demonstrates Congress's intent to preempt state regulation, including legislators' remarks prior to passage of the bill. (See TAC Ex. H, Docket No. 40-2 at 1-11.) For example, shortly before the bill's passage, one senator stated that under the new law, "[s]terile compounding facilities that do not want to comply with the patchwork of State laws and requirements can choose instead to have FDA regulate their compounding." (TAC Ex. H, Docket No. 40-2 at 3; see also id. at 10-11.) Another senator stated that the DQSA "aims to address [the] regulatory gray area [of mass compounding] by clarifying the responsibilities of the FDA with regard to the oversight of mass compounded pharmaceuticals. . . . Under this bill, mass compounding pharmacies can choose to register as outsourcing facilities that would be subject to new FDA regulatory oversight similar to that of other pharmaceutical manufacturers." (Id. at 5; see also id. at 10-11; TAC Ex. G., Docket No. 40-1 at 43-92 (Government Accountability Office report discussing lack of clarity concerning regulatory authority and this legislative history).) But the view of one or two legislators is not sufficient to establish Congress's intent. See Chinatown Neighborhood Ass'n, 794 F.3d at 1144 n.7 (stating that "a lone statement in the legislative history is not a 'clear and manifest' expression of Congress's intent to preempt"). Moreover, the legislative materials provided by Plaintiffs show that Congress's primary motivation in enacting the DQSA was public safety in light of a recent meningitis outbreak, not merely to establish a uniform system of regulation or to increase the availability of certain drug products as Plaintiffs contend. The senators' remarks in particular suggest that Congress was acting to fill a regulatory gap that had existed with respect to mass compounders, and to clarify that the FDA would be responsible for that regulation under the new law. On the whole, it does not clearly establish that Congress intended the FDA alone to have regulatory authority going forward.

Plaintiffs also allege that Congress's intent to preempt state law is confirmed by the FDA, which "has spoken and advised states against legislation which conflicts with 21 U.S.C. § 353b." (TAC at 8, 18-21; see Pls.' Mot. at 25, 32-35; Pls.' Opp'n to Def.'s Mot. at 10, 20-25.) The Supreme Court "has recognized that an agency regulation with the force of law can pre-empt conflicting state requirements." Wyeth v. Levine, 555 U.S. 555, 576, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009) (citing Geier, 529 U.S. 861; Hillsborough County, 471 U.S. at 713). But Plaintiffs have not identified any agency regulations and instead provide only unpublished documents apparently created for a meeting between FDA and

state officials. (TAC Ex. A, Docket No. 40-1 at 1-21; TAC Ex. B, Docket No. 40-1 at 22-27.) See Wyeth, 555 U.S. at 576-78 (stating that the "weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness," and declining to afford deference to a statement concerning preemption in the preamble to an FDA regulation). Moreover, the materials provided do not show that the FDA believed Congress to have preempted state law or that FDA regulations would preempt state law. To the contrary, the materials reflect the FDA's understanding that state licensure and regulation of outsourcing facilities was possible, and even recommended, although the FDA expressed general concerns about varying state regulatory approaches and the possibility of different state and federal standards. (See, e.g., TAC Ex. A, Docket No. 40-1 at 16 (stating that the FDA "recommend[s] that states create a licensure or registration category specific to outsourcing facilities" and that "[c]ompliance with federal law applicable to outsourcing facilities should be a condition of state licensure or registration under this category").

Accordingly, Plaintiffs fail to establish that Congress expressly preempted state regulation of outsourcing facilities.

2. Field Preemption

"Under the doctrine of 'field preemption,' state law is preempted if it regulates 'conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance.'" Chinatown Neighborhood Ass'n, 794 F.3d at 1141 n.5 (citation omitted) (quoting Arizona, 567 U.S. at 399). "The intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" Arizona, 567 U.S. at 399 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, 67 S. Ct. 1146, 91 L. Ed. 1447 (1947); and citing English v. Gen. Elec. Co., 496 U.S. 72, 79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990)).

Plaintiffs allege that Congress enacted the DQSA "in order to oversee and regulate the national distribution of compounded drugs" and to create the category of "outsourcing facilities," which "would be regulated by the FDA under very strict guidelines and oversight." (TAC at 5-7, 10, 16-17; see Pls.' Mot. at 36-40.) Plaintiffs also allege that "the federal scheme in enacting 21 U.S.C. § 353b is so pervasive as to leave no room for states to supplement with further regulations" and that "the dominance of the federal interest in compounding of sterile drugs to be distributed in interstate commerce, is shown by the enactment of the Drug Quality and Security Act after a fatal incident of tainted compounded drugs." (TAC at 10, 16-17, 31; see Pls.' Mot. at 13-15, 25-26.) However, "[t]he mere existence of a detailed regulatory scheme does not by itself imply preemption of state remedies." Keams, 39 F.3d at 225-26 (citing English, 496 U.S. at 87). Nor does the Court find that an intent to preempt the field must be inferred due to a strong federal interest in the field. See Hillsborough County, 471 U.S. at 719 ("Undoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law. . . . [A]s we have stated, the regulation of health and safety matters is primarily, and historically, a matter of local concern." (citing Rice, 331 U.S. at 230)). Indeed, that the DQSA included a limited express preemption

provision elsewhere but not in the Compounding Quality Act suggests that Congress did not intend to preempt state regulation of outsourcing facilities. See Keams, 39 F.3d at 225-26.

Moreover, the statute actually contemplates some concurrent state regulation. For example, Section 503B of the FDCA provides that payment of the federal registration fee "shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees." 21 U.S.C. § 353b(d). Additionally, it requires an outsourcing facility to be supervised by a licensed pharmacist in order for the regulatory exemptions to apply, id. § 353b(a), and pharmacist licensure is handled by state boards of pharmacy. See Cal. Bus. & Prof. Code §§ 4036, 4200(a); see also Ouellette v. Mills, 91 F. Supp. 3d 1, 9 (D. Me. 2015) ("Pharmacist licensure does indeed implicate the traditionally local sphere of public health and safety. The [FDCA] does not regulate the licensure of pharmacists; it instead leaves that area to individual states." (citing 21 U.S.C. §§ 360(g), 384(a)(2))). The DQSA also directed "the Comptroller General of the United States [to] submit to Congress a report on pharmacy compounding and the adequacy of State and Federal efforts to assure the safety of compounded drugs." DQSA § 107(a). The report was required to include, among other things, "a review of the State laws and policies governing pharmacy compounding, including enforcement of State laws and policies" and "an evaluation of the effectiveness of the communication among States and between States and the Food and Drug Administration regarding compounding." DQSA § 107(b)(2), (4). It thus does not appear that Congress intended the DQSA to supplant the states' role in regulating compounded drugs generally or outsourcing facilities specifically.

Plaintiffs again point to the DQSA's legislative history and the FDA's statements as supporting a finding of field preemption. (TAC at 28-32; see Pls.' Mot. at 26-27, 36-40; Pls.' Opp'n to Def.'s Mot. at 19, 24.) However, for the reasons already discussed, the legislative history does not establish Congress's intent to preempt state regulation, and Plaintiffs' submissions show that the FDA actually supports state licensure and regulation of outsourcing facilities.

The Court thus concludes that Congress did not intend to preempt the field of regulation with respect to compounding facilities.

3. Conflict Preemption

"[A] federal statute has preemptive effect if it conflicts with state law. This can occur when 'compliance with both federal and state regulations is a physical impossibility,' or when a state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Chinatown Neighborhood Ass'n, 794 F.3d at 1141 (citation omitted) (quoting Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43, 83 S. Ct. 1210, 10 L. Ed. 2d 248 (1963); and then Arizona, 567 U.S. at 399-400).

Plaintiffs allege that California's outsourcing facility laws and regulations conflict with federal law in a number of ways, including by preventing Plaintiffs from compounding bulk drug substances, and in particular ziconotide; by not allowing certain FDA-approved methods of sterility testing; by defining terms differently from federal law; by requiring different "engineering controls"; by imposing

different invoicing requirements; and by having differing training requirements for the Board's inspectors. (TAC at 2, 11-14, 16; Pls.' Mot. at 21-23, 28-32; Pls.' Opp'n to Def.'s Mot. at 27-32.) However, Plaintiffs fail to identify a state law or regulation actually conflicting with federal law as to any of these subjects. California's outsourcing facility statutes provide that outsourcing facilities "shall compound all sterile products and nonsterile products in compliance with regulations issued by the [Board] and with federal current good manufacturing practices applicable to outsourcing facilities." Cal. Bus. & Prof. Code § 4129.1(b); see id. § 4129.2(b). California law thus subjects outsourcing facilities to both federal and state standards, but it otherwise does not address any of the alleged areas of conflict that Plaintiffs cite, and the Board has not yet implemented any regulations concerning compounding at outsourcing facilities. See Cal. Bus. & Prof. Code §§ 4129 to 4129.9; Cal. Code Regs. tit. 16, arts. 4.5, 7. (See also Def.'s Opp'n to Pls.' Mot. at 9 n.2, 13.)

Plaintiffs also argue that state and federal laws conflict because federal law requires Fusion IV to have a licensed pharmacist overseeing its compounding activities, but "California will not license Fusion IV as an outsourcing facility" and "continues to discipline Fusion IV as a 'pharmacy.'" (TAC at 3, 11, 14; Pls.' Mot. at 21, 28-29; Pls.' Opp'n to Def.'s Mot. at 17-18.) For the regulatory exemptions under Section 503B of the FDCA to apply, a drug must be "compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility." 21 U.S.C. § 353b(a). California law prohibits an outsourcing facility from also being licensed as a sterile compounding pharmacy and from performing the duties of a pharmacy. Cal. Bus. & Prof. Code § 4129(b), (e). However, California law does not prohibit an individual who is a licensed pharmacist from supervising the compounding of a drug at an outsourcing facility. That Plaintiffs are not able to obtain a state outsourcing facility license is not evidence of a conflict between state and federal laws but rather is the result of circumstances particular to them. And although Plaintiffs contend that the state's denial of their license was improper, those issues are not before the Court in this action. (See, e.g., TAC at 1-2 (stating that the denial of Plaintiffs' application "*is not at issue herein – Plaintiffs appealed and a hearing was held, and ensuing writ of administrative mandamus filed – relating to the state proceedings. This complaint is entirely based upon the federal preemption issues/interstate commerce issues*."); see also Docket Nos. 41, 42.)

Plaintiffs also argue that "federal law **allows an outsourcing facility to also have a state licensed pharmacy** on its premises. California law prohibits this. While this does not make it impossible for an outsourcing facility to 'function', it makes it impossible for an outsourcing facility to choose to have a pharmacy on its premises as expressly provided for under federal law." (TAC at 16; see id. at 19; Pls.' Opp'n to Def.'s Mot. at 31.) Under Section 503B, "[a]n outsourcing facility is not required to be a licensed pharmacy," and it "may or may not obtain prescriptions for identified individual patients." 21 U.S.C. § 353a(c)(4)(B), (C). California law provides that "[a] facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location" and an "outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients." Cal. Bus. & Prof. Code § 4129(b), (e). However, "the possibility of proscription by [a state] of conduct that federal law might permit is not sufficient to warrant preemption." Chevron U.S.A., Inc. v. Hammond, 726 F.2d 483, 498 (9th Cir. 1984) (quoting William Inglis & Sons Baking Co. v. ITT

Cont'l Baking Co., 668 F.2d 1014, 1049 (9th Cir.1981); and citing Fla. Lime & Avocado Growers, 373 U.S. 132). As Plaintiffs acknowledge, it is not impossible to comply with both the state and federal laws. Cf. N. Star Int'l v. Ariz. Corp. Comm'n, 720 F.2d 578, 582-83 (9th Cir. 1983) ("While the state standards are more stringent than the federal standards, it is possible to comply with both. We hold that there is no actual conflict between [the state law] and the federal . . . laws." (citing Fla. Lime & Avocado Growers, 373 U.S. at 141-43)).

Plaintiffs also cite the possibility of varying requirements among states as supporting a finding of preemption. (TAC at 15.) But without further evidence of Congress's intent to preempt state law, whether and to what extent California's laws differ from other states' is not relevant. See Keams, 39 F.3d at 226 ("Congress could have avoided diversity by express preemption, had it wished to do so, yet it did not."). The Court also finds that Congress's primary motivation in enacting the DQSA appears to have been public safety and to ensure that mass compounding was subject to some regulation, not necessarily to establish a uniform, nationwide standard of regulation. See, e.g., Chamberlain v. Ford Motor Co., 314 F. Supp. 2d 953, 962-63 (N.D. Cal. 2004) (finding no preemption where primary congressional objective was safety rather than uniform administration).

Ultimately, most of Plaintiffs' arguments boil down to a dispute over whether they must obtain a state license at all. Plaintiffs contend that California's statutes and licensure requirement for outsourcing facilities are preempted because they interfere with the use of Plaintiffs' federal license. (TAC at 3, 4, 8-9, 11-14, 19, 21-22, 24, 26-28, 32-33; Pls.' Mot. at 15-21; Pls.' Opp'n to Def.'s Mot. at 9-10, 11-18.) It is true that a "State may not enforce licensing requirements which, though valid in the absence of federal regulation, give the State's licensing board a virtual power of review over the federal determination that a person or agency is qualified and entitled to perform certain functions, or which impose upon the performance of activity sanctioned by federal license additional conditions not contemplated by Congress. No State law can hinder or obstruct the free use of a license granted under an act of Congress." Sperry v. State of Florida, 373 U.S. 379, 385, 83 S. Ct. 1322, 10 L. Ed. 2d 428 (1963) (footnotes and internal quotation marks omitted). But the mere fact of concurrent licensure does not establish preemption. See, e.g., UFO Chuting of Haw., Inc. v. Smith, 508 F.3d 1189, 1192-93 (9th Cir. 2007) ("No State may completely exclude federally licensed commerce. However, a state may impose upon federal licensees reasonable, nondiscriminatory conservation and environmental protection measures otherwise within their police power." (alteration, citations, and internal quotation marks omitted)); see also Brown & Tomar, supra, at 295 ("It is unlikely that Congress specifically intended to prohibit states from licensing outsourcing facilities.").

Moreover, as Defendant argues, the wording of the DQSA suggests that "registration as an outsourcing facility with the FDA is voluntary." (Def.'s Opp'n to Pls.' Mot. at 2-3 (emphasis omitted) (citing 21 U.S.C. § 353b(a)).) See also 21 U.S.C. § 353b(d)(4)(A)(ii) (defining "outsourcing facility" as a facility that, among other things, "has elected to register as an outsourcing facility" (emphasis added)). Registration itself does not bestow any benefits but is one prerequisite for a facility's avoidance of certain regulatory requirements for a particular drug. See id. § 353b(a), (b); Worthy et al., supra, at 524 ("Under the FDCA, registering with FDA is voluntary. Only those compounders that wish to be classified as outsourcing facilities under section 503B [of the FDCA] must do so."); Brown & Tomar,

supra, at 296 ("[I]t is not clear that registration with FDA under section 503B constitutes a 'license' to engage in outsourcing beyond the scope of practice permitted under state law. The statutory language could be read to suggest only that compliance with section 503B provides a license, or exemption, from more onerous requirements of federal law, such as premarket approval for new drugs."); see also Wisc. Pub. Intervenor v. Mortier, 501 U.S. 597, 613-14, 111 S. Ct. 2476, 115 L. Ed. 2d 532 (1991) ("FIFRA nowhere seeks to establish an affirmative permit scheme for the actual use of pesticides. It certainly does not equate registration and labeling requirements with a general approval to apply pesticides throughout the Nation without regard to regional and local factors like climate, population, geography, and water supply. Whatever else FIFRA may supplant, it does not occupy the field of pesticide regulation in general or the area of local use permitting in particular."). A lack of a registration does not prevent a facility from compounding drugs; it simply subjects them to other regulations. (TAC Ex. B, Docket No. 40-1 at 23 ("Compounders in the United States that have not registered with FDA as outsourcing facilities may produce drugs that are eligible for the exemptions under section 503A of the [FDCA].").)

Plaintiffs thus fail to establish that California's outsourcing facility laws conflict with federal law or present an obstacle to federal objectives.

B. The Commerce Clause

"The Commerce Clause grants Congress the power '[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian tribes.' Despite its textual focus solely on congressional power, the Clause also has long been understood to have a negative aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce. This so-called 'dormant' Commerce Clause is driven by concern about economic protectionism – that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." Am. Fuel & Petrochemical Mfrs. v. O'Keeffe, 903 F.3d 903, 910 (9th Cir. 2018) (citations and some internal quotation marks omitted).

> "The Supreme Court has adopted a two-tiered approach to analyzing state economic regulation under the Commerce Clause. If a state statute directly regulates or discriminates against interstate commerce, or its effect is to favor in-state economic interests over out-of-state interests, it is struck down without further inquiry. When, however, a state statute has only indirect effects on interstate commerce and regulates evenhandedly, it violates the Commerce Clause only if the burdens of the statute so outweigh the putative benefits as to make the statute unreasonable or irrational." Chinatown Neighborhood Ass'n, 794 F.3d at 1145 (alterations, citations, and internal quotation marks omitted); see O'Keeffe, 903 F.3d at 910.

"[A] statute that treats all private companies exactly the same does not discriminate against interstate commerce." Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris, 729 F.3d 937, 947

(9th Cir. 2013) (alteration and internal quotation marks omitted) (quoting United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 342, 127 S. Ct. 1786, 167 L. Ed. 2d 655 (2007)). California's outsourcing facility laws subject both instate and out-of-state outsourcing facilities to state licensure and to other requirements that are virtually the same, an a facility must only obtain a license "if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California." Cal. Bus. & Prof. Code § 4129(a); see id. §§ 4129.1, .2. The laws are facially neutral and do not impermissibly seek to regulate interstate or out-of-state commerce. See, e.g., Pharm. Research & Mfrs. of Am. v. County of Alameida, 768 F.3d 1037, 1042 (9th Cir. 2014) ("The Ordinance, both on its face and in effect, applies to all manufacturers that make their drugs available in Alameda County—without respect to the geographic location of the manufacturer. . . . In other words, the Ordinance does not discriminate . . . ."); O'Keeffe, 903 F.3d at 916-17 (rejecting argument that state regulation impermissibly regulated conduct wholly outside of the state's borders because the regulation "expressly applies only to fuels sold in, imported to, or exported from Oregon").

Plaintiffs primarily contend that having to obtain a state license is an impediment to interstate commerce. (TAC at 33-34; see Pls.' Mot. at 40-42; Pls.' Opp'n to Def.'s Mot. at 25.) But the state's license requirement, without more, does not violate the dormant Commerce Clause. See, e.g., Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 447, 80 S. Ct. 813, 4 L. Ed. 2d 852 (1960) ("The mere possession of a federal license . . . does not immunize a ship from the operation of the normal incidents of local police power, not constituting a direct regulation of commerce."); Sixth Angel Shepherd Resue, Inc., No. CIV.A. 10-3101, 2011 WL 605697, at *6 (E.D. Pa. Feb. 15, 2011) ("[R]equiring requiring a license to do business in a state is generally not an undue burden on interstate commerce." (citing Quik Payday, Inc. v. Stork, 549 F.3d 1302, 1312-13 (10th Cir. 2008))). Nor does Plaintiffs' personal inability to obtain a state license establish an undue burden on interstate commerce. See Quik Payday, 549 F.3d at 1312 ("[W]e turn to Quik Payday's argument based on the specifics of the KUCCC. It contends that subjecting it to regulation by multiple states will in fact create inconsistency that would unduly burden interstate commerce. . . . Quik Payday is not being penalized by Kansas for the way it renews loans, or even for the interest rate it charges. Its misconduct was a simple failure to get a Kansas license."); see also O'Keeffe, 903 F.3d at 914 ("The Commerce Clause 'protects the interstate market, not particular interstate firms.'" (quoting Exxon Corp. v. Governor of Maryland, 437 U.S. 117, 127, 98 S. Ct. 2207, 57 L. Ed. 2d 91 (1978))).

Plaintiffs also refer to varying regulations among states. (TAC at 15, 34-36; Pls.' Mot. at 41-43; Pls.' Opp'n to Def.'s Mot. at 25-27, 33.) But such concerns are only relevant when one state attempts to regulate conduct in other states. See Healy v. Beer Inst., Inc., 491 U.S. 324, 336-37, 109 S. Ct. 2491, 105 L. Ed. 2d 275 (1989); Rocky Mountain Farmers Union v. Corey, 730 F.3d 1070, 1101 (9th Cir. 2013). California's outsourcing facility laws permissibly regulate only those facilities producing medications for distribution into or within California. See O'Keeffe, 903 F.3d at 917; see also Chinatown Neighborhood Ass'n, 794 F.3d at 1145-46.

Furthermore, Defendants contend, and Plaintiffs concede, that California's outsourcing facility laws are motivated by a desire to protect public safety. (See Def.'s Mot. at 16, 20; Def.'s Opp'n to Pls.' Mot. at 16-17; Pls.' Mot. at 3, 14; Pls.' Opp'n to Def.'s Mot. at 7.) Because this is a "legitimate matter[]

of local concern" and it implicates an area in which state and federal cooperation is contemplated, "[t]here is . . . no significant interference with interstate commerce." See Chinatown Neighborhood Ass'n, 794 F.3d at 1147; see also Pharm. Research & Mfrs., 768 F.3d at 1042 (noting that "regulations that touch upon safety . . . are those that the [Supreme] Court has been most reluctant to invalidate. Indeed, if safety justifications are not illusory, the Court will not second-guess legislative judgment about their importance in comparison with related burdens on interstate commerce" (quoting Kassel v. Consol. Freightways Corp. of Del., 450 U.S. 662, 670, 101 S. Ct. 1309, 67 L. Ed. 2d 580 (1981))).

Accordingly, Plaintiffs fail to establish that California's outsourcing facility laws are invalid under the Commerce Clause.

Conclusion

Plaintiffs fail to demonstrate that California's outsourcing facility laws are preempted by federal law or that they are invalid under the Commerce Clause. For the foregoing reasons, Plaintiffs' motions to exceed the page limitation for their opposition brief and to have that brief considered despite its untimeliness (Docket Nos. 60, 62, 63) are granted; Plaintiffs' Motion for Judgment on the Pleadings Pursuant to FRCP 12(c) (Docket Nos. 47, 49) is denied; and Defendant's Motion for Judgment on the Pleadings (Docket No. 52) is granted. The Court finds that amendment of Plaintiffs' claims would be futile and therefore dismisses the TAC without leave to amend. The Court will enter a Judgment consistent with this Order.

IT IS SO ORDERED.