MEMORANDUM

DATE	June 14, 2023
TO	Members California State Board of Pharmacy
FROM	Jane Zack Simon, Attorney III Legal Affairs
SUBJECT	**Proposed Precedent Decision** **In the Matter of the Second Amended Accusation Against: La Vita Compounding pharmacy LLC dba La Vita Compounding Pharmacy, and Christine Ann Givant** **Case No 6851**

The Board issued its Decision After Rejection in the matter of the Second Amended Accusation Against La Vita Compounding pharmacy LLC DBA La Vita Compounding pharmacy; Christine Ann Givant, effective April 29, 2023. Because the Decision contains a detailed and comprehensive discussion of issues relating to compounding, we recommend it be adopted as a precedent decision pursuant to Government Code section 11425.60. The executive director and senior staff counsel agree with this recommendation.

PROCEDURAL BACKGROUND

The Board of Pharmacy filed a Second Amended Accusation against respondents La Vita Compounding Pharmacy and its pharmacist-in-charge, Christina Ann Givant alleging numerous causes of discipline based on various compounding violations, most significantly that certain substances used by the respondents as ingredients to compound sterile injectable final drug products were dietary grade and/or ungraded and lacked the quality necessary for use in compounding non-sterile-to-sterile injectable drug preparations. The use of those inappropriate ingredients caused the final preparations to be adulterated.

The ALJ's Proposed Decision was rejected by the Board on December 22, 2022. On March 30, 2023, the Board issued its Decision After Rejection. Thereafter, the Board issued an Order correcting several mistakes or clerical errors in the Decision After Rejection. The Decision After Rejection became effective on April 29, 2023.

SIGNIFICANCE OF THE DECISION

The Decision in this case provides a comprehensive discussion of the state and federal laws regarding compounding. In particular, the following points are addressed in the Decision:

(1) The Decision provides an explanation and interpretation of certain United States Pharmacopeia (USP) standards for sterile compounding and how USP standards and U.S. Food and Drug Administration (FDA) interpretations interrelate with the definitions of "adulterated" and "quality" under federal and state law. Under California law, federal law, federal guidance, and USP Chapter 797-high risk sterile compounding standards, the quality of the starting ingredient must be appropriate for the mode of administration of the end preparation. (Decision, pg. 12, para 21; Decision, pg. 13, para 22.) Nonsterile ingredients, including manufactured products not created or intended for sterile routes of administration can contain potentially harmful impurities. (Decision, pg. 12, para 21; pg. 10, para 20.) The use of ingredients that are not appropriate for the mode of administration means that the final product is either contaminated or at a high risk of being contaminated, and is therefore adulterated under both federal and state law. (Decision, pg. 10, para 20, Decision, pg. 41, para 15; pg. 52-52, para 32-33; pg. 60, para 39.) The Decision found that Respondents' use of the dietary grade and/or ungraded glutathione and methylcobalamin for sterile injectable compounding resulted in the final products being adulterated under federal and state law.

In addition to the general overlay of the USP compounding standards and compliance with the Section 503A[1] exemption, both federal and state law have additional specific prohibitions against the distribution of adulterated drugs that apply to all drugs, including compounded drugs prepared by pharmacies operating under the Federal Food, Drug, and Cosmetic Act (FDCA) section 503A exemption. (Decision, pg. 11, para 15.)

(2) The Decision explains that the mere placement of glutathione and methylcobalamin on the 503A Category 1 list does not equate to being "authorized under federal law" without any restriction as to the appropriate grading of the bulk drug substances or the route of administration. (Decision, pg. 8, para 13.) Placement on the Category 1 list does not exempt compliance with all the other conditions under Section 503A, compliance with other provisions of the FDCA (including compliance with USP chapter 797), or the prohibition against the distribution of adulterated drugs. (Decision, pg. 37, para 7; pg. 38, para 8; pg. 38-39, para 9.)

An important condition of the Section 503A exemption is that compounding must comply with the applicable USP or NF drug monograph if one exists *and* with the USP chapters on pharmacy compounding. (Decision, pg. 37, para 7.) Thus, compliance with the USP chapters on compounding are incorporated into both federal and state law.[2] (Decision, pg. 51, para 7; pg. 50,

para 28.) USP Chapter 797 clarifies that compounded sterile preparations are either contaminated

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[1] *See* (21 U.S.C. § 353a.)
[2] Bus. & Prof. Code § 4126.8

or at a high risk to become contaminated if "nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g. oral) are incorporated ..." (Decision, pg. 10, para 20.) Therefore, placement of these two bulk drug substances on the Category 1 list does not allow for the compounding of a final drug product, but even if it did, it would only permit compounding of a final product for the same route of administration as the bulk drug substance; i.e., if the bulk drug substance is dietary grade, then only drugs administered orally may be compounded if all other requirements are met.

(3) The Decision concludes that the Board has the authority to take action against licensees for unprofessional conduct "for violation of applicable state or federal law." Business and Professions Code section 4301, subdivision (o), defines the violation of federal laws and regulations as unprofessional conduct. (Decision, pg. 50, para 28.) Additionally, the Decision explains that only the Board has authority over the license itself and "is enforcing its own licensing laws that effectively establish compliance with relevant federal law as a minimum requirement to maintain licensure." The FDA does not license 503A pharmacies, and therefore cannot discipline or revoke any license. (Decision, pgs. 50-51, para 28.)

(4) The Decision states that the Board interprets existing state and federal statutes and regulations in the course of case-specific adjudications, rather than enforcing any "underground regulation." The Board is interpreting the specific statutes applicable to the definition of quality and adulterated drugs under California and federal law in the context of this case, the specific sterile products compounded by these respondents, and the Certificates of Analysis (COAs) applicable to the bulk products used in this matter. The determination of whether a particular grade of product was appropriate to compound into a specific mode of administration will be dependent on the type of compounding performed (sterile or nonsterile) and whether the COAs for those bulk products contain residual contaminants that could cause patient harm depending on the mode of administration. The Board also is interpreting USP standards that

are incorporated into both California and federal law. (Decision, pgs. 54-56, para 35.) The Decision determined that interpretation of these broad provisions regarding adulterated drug products with similar potential impacts to public health are best done, at this time, in case-by-case adjudications where all of the relevant facts are presented. (Decision, pg. 56, para 35.)

PORTIONS OF DECISION TO BE DESIGNATED AS PRECEDENT

We recommend the bulk of the Decision After Rejection be designated as precedent, with the exception of the portions of the Decision that deal with costs and the specific discipline imposed, as follows:

1. The discussion of costs at page 34, paragraphs 78-79, and at page 76-77, paragraphs 78-79.
2. The discussion of the appropriate discipline to be imposed, at pgs. 71-76, paragraphs 70-79.
3. The Order, pages 77-90.

RATIONALE

Government Code section 11425.60 authorizes the Board to designate as a precedent decision a decision or part of a decision that contains a significant legal or policy determination of general application that is likely to recur.

The purpose of designating a decision as a precedent is to provide guidance about the Board's decisions, requirements and restrictions. A precedent decision sets forth the law and analysis the Board will use in similar cases.

The Decision After Rejection in this case contains significant policy determinations in that it provides a comprehensive analysis of the interplay between California law, federal law, general guidance and USP standards. It also clarifies and confirms how ingredients are categorized, and explains how a violation will be established and who is subject to discipline for violation of sterile compounding laws. The Decision will serve to educate licensees on the standards expected of them by the Board, and will provide guidance on the prosecution of future cases.

Issues relating to sterile compounding are recurring issues, and by designating this Decision as precedent, the Board will provide notice and guidance to its

licensees who engage in sterile compounding. The Board will also provide guidance to attorneys and administrative law judges in future cases. This step will help to ensure consistency in decision making in this complicated area of pharmacy law.

PROCEDURE GOING FORWARD

Government Code section 11425.60 does not specify any procedure for designating a Decision as precedent, and the Board has not promulgated a regulation in this area. The published Agenda for the Board's June 21, 2023 meeting provided public notice of the Board's intent to discuss, consider and possibly take action to adopt this matter as a Board Precedent Decision, thereby providing the opportunity for public input and comment.

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

In the Matter of the Second Amended Accusation Against:

LA VITA COMPOUNDING PHARMACY LLC dba LA VITA COMPOUNDING PHARMACY, and CHRISTINE ANN GIVANT

Respondents

Agency Case No. 6851

OAH No. 2020080624

ORDER CORRECTING DECISION AFTER REJECTION

The California State Board of Pharmacy (Board) issued a Decision after Rejection on March 30, 2023. On April 3, 2023, the Board received an email from respondent's counsel asking that both Respondents be "jointly and severally" responsible for the payment of the costs awarded to the Board without providing notice to the Complainant. The Board also has the authority to correct a mistake or clerical error on its motion, (Gov't Code section 11518.5, subd. (d).) and began evaluating whether there were clerical or mistakes in its Decision after Rejection related to the liability of each Respondent for the costs awarded and other errors in the decision. On April 12, 2023, the Board received via email a request for reconsideration from Respondent's counsel solely on the issue of the Respondents' responsibility for the costs awarded and Board staff provided that filing to the complainant's counsel (Petition for Reconsideration).

The Board notes that the Decision after Rejection contains three mistakes or clerical errors that warrant correction (Gov't Code section 11518.5, subd. (d).) Specifically, the Decision after Rejection erroneously omitted two footnotes contained in the Proposed Decision related to both respondents' responsibility to be jointly and severally liable to pay the costs of $50,000 awarded by the AJJ in the Proposed Decision. Under Section 125.3 of the Business and Professions Code, only an ALJ may award costs and although the Board may reduce or eliminate the cost award, the Board generally defers to the ALJ the on the assignment of respondents' responsibility to pay any cost award granted. The Proposed Decision contained footnotes in the probationary conditions for Christine Ann Givant (Givant) and the La Vita Compounding Pharmacy LLC (La Vita) governing their responsibility to pay the costs awarded.

Accordingly, the first sentence in Section 9 of the Probationary Conditions imposed on Givant on page 81 of the Decision after Rejection is amended to read as follows: "As a condition precedent to successful completion of probation, Givant shall pay to the board its cost of investigation and prosecution in the amount of $50,000.[106]" Footnote 106 is added and reads as follows: "This cost recovery is imposed jointly and severally with respect to La Vita's cost recovery, identified below. In other words, Givant and La Vita are jointly and severally liable for a total cost recovery amount of $50,000." This exact footnote was contained in the Proposed Decision at page 65.

Also, the first sentence in Section 6 of the Probationary Conditions imposed on La Vita on page 86 of the Decision after Rejection is amended to read as follows: "As a condition precedent to successful completion of probation, La Vita shall pay to the board its cost of investigation and prosecution in the amount of $50,000.[107]" Footnote 107 is added and reads as follows: "This cost recovery is imposed jointly and severally with respect to Givant's cost recovery, identified above. In other words, Givant and La Vita are jointly and severally liable for a total cost recovery amount of $50,000." This exact footnote was contained in the Proposed Decision at page 72.

Finally, there is a clerical error in Probationary Condition 13 on Page 82 of the Decision after Rejection imposed on Givant regarding the minimum number of practice hours that she must work per month to avoid tolling of her probationary period. Specifically, there is an

inconsistency in the number of hours spelled out in the text (thirty) versus the number in the parenthesis (40) in the first sentence of Condition 13 on page 82. The minimum hours that the Board imposes in this standard condition is generally tied to work week hours and 40 hours is one of the shortest periods that the Board imposes that effectively requires a pharmacist to work one week a month to avoid tolling. When replacing the minimum number of hours to 40 in the parenthetical, the text immediately before the parenthetical was not changed. Accordingly, the first sentence of Probationary Condition 13 on page 82 is removed and replaced with the following: "Except during periods of suspension, Givant shall, at all times while on probation, be employed as a Registered Pharmacist in California for a minimum of forty (40) hours per calendar month." The only change made was to align the word spelling of the minimum number of hours with the number recited in the parenthetical.

Because the changes are warranted as corrections of mistakes or clerical errors, Respondents' Petition for Reconsideration is denied but the changes requested in Respondents' Petition for Reconsideration were effectuated by the Board pursuant to its authority to correct mistakes or errors within fifteen days of the issuance of a decision. (Gov't Code section 11518.5(d).)

The Corrected Decision after Rejection is still effective at 5:00 p.m. on April 29, 2023.

It is so ORDERED on April 14, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

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

In the Matter of the Second Amended Accusation Against:

LA VITA COMPOUNDING PHARMACY LLC dba LA VITA COMPOUNDING PHARMACY, and CHRISTINE ANN GIVANT,

Respondents Agency Case No. 6851

OAH Case No. 2020080624

DECISION AFTER REJECTION

Wim van Rooyen, Administrative Law Judge (ALJ), Office of Administrative Hearings (OAH), State of California, heard this matter on May 23 through 26, June 8, and June 24, 2022, by videoconference from Sacramento, California.

Stephanie Alamo-Latif and Kristina T. Jarvis, Deputies Attorney General, represented Anne Sodergren (complainant), Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs, State of California.

Tony J. Park, Attorney at Law, California Pharmacy Lawyers, represented La Vita Compounding Pharmacy LLC, doing business as (dba) La Vita Compounding Pharmacy (La Vita), and Christine Ann Givant (Givant) (collectively, respondents).

Evidence was received and the record left open until October 7, 2022, to allow for submission of closing briefs.[1] On August 24, 2022, complainant filed her closing brief,

[1] At hearing, La Vita Grievance Reports for 2020 and the amicus curiae brief filed by the Alliance for Pharmacy Compounding (APC) were both inadvertently marked as Exhibit SS. Following hearing, the La Vita Grievance Reports for 2020 were marked and admitted as Exhibit SS, and APC's amicus curiae brief was re-marked as Exhibit XX and admitted as argument.

marked as Exhibit 127. On September 23, 2022, respondents filed their closing brief, marked as Exhibit AAA. On October 7, 2022, complainant filed her reply brief, marked as Exhibit 128. On October 7, 2022, Exhibits 127, 128, and AAA were admitted as argument, the record was closed, and the matter was submitted for decision.

On October 7, 2022, complainant also filed a motion to correct transcript errors, marked as Exhibit 129. Consequently, the record was reopened effective October 7, 2022, to allow respondents an opportunity to respond by October 14, 2022. No opposition was filed by the required deadline.

On October 14, 2022, Exhibit 129 was admitted as argument, complainant's motion to correct transcript errors was granted, the record was closed, and the matter was resubmitted for decision.

On October 22, 2022, the ALJ issued a Proposed Decision (Proposed Decision). On December 22, 2022, pursuant to section 11517 of the Government Code, the California State Board of Pharmacy (Board) issued an Order Rejecting the Proposed Decision and notified the parties that the deadline for submitting written argument was set for January 23, 2023. Written argument was timely received from both parties.

The Board, having reviewed and considered the entire record, including the transcript, exhibits and written argument from both parties, now issues this decision after rejection.

FACTUAL FINDINGS

Jurisdiction

1. On August 17, 1987, the Board issued Givant Registered Pharmacist License No. RPH 41076 (Registered Pharmacist License). The Registered Pharmacist License will expire on October 31, 2024, unless renewed.

2. On September 19, 2007, the Board issued La Vita Pharmacy Permit No. PHY 48731 (Pharmacy Permit), with Givant and Debra Hubers as Members and Givant as the Pharmacist In Charge (PIC). The Pharmacy Permit will expire on September 1, 2023, unless renewed. On or about April 23, 2022, La Vita Compounding Pharmacy (La Vita) applied to change the address of the Pharmacy Permit and applied for a temporary license with the new location. In order to issue the temporary permit while this disciplinary action was pending, the parties entered into a Stipulation for Continuing Jurisdiction that was effective on September 6, 2022. In this Stipulation, the parties agreed that any discipline

imposed in this matter would immediately accrue to La Vita's temporary license and any subsequent permanent license issued to La Vita for the new location.

3. On August 20, 2013, the Board issued La Vita Sterile Compounding Permit No. LSC 99842 (Sterile Compounding Permit). The Sterile Compounding Permit expired on March 23, 2022.[2]

4. On April 28, 2022, complainant signed and thereafter filed a Second Amended Accusation asserting 23 causes for discipline for unprofessional conduct against respondents based on their alleged nonsterile-to-sterile compounding of glutathione and methylcobalamin injectable drug preparations using dietary grade and/or ungraded ingredients.[3]

As to glutathione specifically, complainant alleges that respondents' sterile injectable drug preparations: lacked quality (First Cause for Discipline [CFD] against La Vita and Fifth CFD against Givant); were adulterated (Second CFD against La Vita and Sixth CFD against Givant); had unsupported beyond use dates (Third CFD against La Vita and Seventh CFD against Givant); and lacked complete compounding records (Fourth CFD against La Vita and Eighth CFD against Givant).

As to methylcobalamin specifically, complainant alleges that respondents' sterile injectable drug preparations: lacked quality (Ninth CFD against La Vita and Sixteenth CFD against Givant); were adulterated (Tenth CFD against La Vita and Seventeenth CFD against Givant); had unsupported beyond use dates (Eleventh CFD against La Vita and Eighteenth CFD against Givant); lacked complete compounding records (Twelfth CFD against La Vita and Nineteenth CFD against Givant); were improperly quarantined (Thirteenth CFD against La Vita and Twentieth CFD against Givant); and were prepared by a pharmacy technician without sufficient training and validation (Fourteenth CFD against La Vita and Twenty-First CFD against Givant). Complainant further alleged that respondents furnished some sterile injectable drug preparations to an unlicensed entity (Fifteenth CFD against La Vita and Twenty-Second CFD against Givant).

Additionally, based on the foregoing allegations concerning both glutathione and

[2] "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." (Bus. & Prof. Code, § 4300.1.)

[3] The original Accusation was signed on April 14, 2020.

methylcobalamin, complainant alleges that Givant engaged in unprofessional conduct as a pharmacist (Twenty-Third CFD against Givant only).

As additional disciplinary considerations, complainant alleges the prior issuance of warnings by the federal Food and Drug Administration (FDA) and Board citations to respondents.

Complainant requested revocation of the Registered Pharmacist License, Pharmacy Permit, and Sterile Compounding Permit; an order prohibiting La Vita and Givant from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until such licenses/permits are reinstated; and recovery of the Board's reasonable investigation and enforcement costs from La Vita and Givant.

5. Respondents timely filed a Notice of Defense. The matter was set for an evidentiary hearing before an ALJ of the OAH, an independent adjudicative agency of the State of California, pursuant to Government Code section 11500 et seq.

Background

COMPOUNDING

6. Compounding is the long-standing pharmacy practice of mixing, combining, or altering ingredients. Compounding may involve merely altering an existing drug product or creating an entirely new drug product. Compounded human drugs can serve an important role for patients "whose clinical needs" cannot be met by an FDA-approved drug.[4] A common example when compounding is used is when a patient is allergic to an ingredient in an FDA-approved drug or children who need a lower strength drug than what is commercially available.[5] However, compounded drugs can also pose a higher risk to patients than FDA-approved drugs because they are not FDA approved and because compounding pharmacies, unlike manufacturers and outsourcing facilities, are exempt from the requirements of current good manufacturing practices if they qualify for the

[4] *See* (Food & Drug Adm., Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug and Cosmetic Act, Guidance for Industry, at pp. 2-3 (Jan. 2018), 83 Fed.Reg. 2790 (Jan. 19, 2018).) (located at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-commercially-available-drug-product-under-section.)

[5] (*Id.*); *See also* (Food & Drug Adm., Bulk Drug Substances Used in Compounding, Bulk Drug Substances Used in Compounding | FDA (located at www. fda.gov/drugs/human-drug-compounding/bulk-drug-substances used-compounding).)

Section 503A exemption.[6]

7. Compounded drugs can be made for topical use, including topical creams, eye drops, oral use, such as capsules or tablets intended for oral ingestion, or injectable preparations. Drugs administered orally present less dangers to patients from residual contaminants than drugs injected into the human body. Drugs that are ingested orally go through the body's digestive tract and the human body has the ability to filter out and excrete residual impurities. In contrast, drugs injected into a patient's body bypasses the human body's main defense mechanisms to filter out residual impurities. For example, most vitamins and supplements are intended for oral use and are regulated as a food, and not a drug, for this reason. The acceptable levels of contaminants in sterile injectable drug preparations are lower than for topical or oral drugs. All injectable preparations must be sterile for this reason. A sterile injectable drug preparation compounded from non-sterile ingredients[7] is considered a high risk preparation due to its route of administration.

GENERAL REGULATION OF PHARMACY COMPOUNDING

8. Compounded drugs are not approved by the FDA. Thus, the FDA does not review such drugs to evaluate their safety, effectiveness, and quality before they are administered to patients. The FDA, however, has a role in approving the ingredients that may be used in compounding human drugs. States are the primary regulators of pharmacists and pharmacies engaged in compounding human drugs. Thus, pharmacists engaged in compounding (sterile or nonsterile) are subject to both federal and state law.

9. In 2012, fungal-contaminated compounded drug products from a compounding pharmacy in New England caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection in patients across the United States. This incident was a major impetus for the passage of the Drug Quality and Security Act (DQSA)

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[6] Outsourcing facilities are a new entity created in the 2012 amendments to the federal Food, Drug and Cosmetic Act (FDCA) that voluntarily register with the FDA and are required to be licensed in California**.** Outsourcing facilities perform the same functions as a compounding pharmacy but qualify for an exemption from certain federal requirements under Section 503B of the FDCA. The 503B exemption does not exempt these entities from the requirements of compliance with current good manufacturing practices. In contrast, compounding pharmacies do not have to meet the requirements of current good manufacturing practices that drug manufacturers and outsourcing facilities must meet and instead must meet USP standards for compounding.

[7] A non-sterile-to-sterile compounded drug preparation contains "two or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient." (Cal. Code Regs., tit. 16, § 1735.1, subd. (v).)

that was enacted on November 27, 2013. Part I of the DQSA was called the Compounding Quality Act and made many changes to the FDCA in the area of compounding, drug tracing and requirements for wholesalers and third party logistic providers.

Federal Law

10. Under the laws of the United States, the federal Food and Drug Administration (FDA) has the sole authority to approve drugs for use in the United States. It is violation of federal law for anyone to introduce or deliver for introduction into interstate commerce any new drug unless the FDA has approved an application filed.[8] Generally each time a drug is compounded, it would be a new drug requiring compliance with all FDCA requirements, including required approval of an application by the FDA which is not practical and would effectively prohibit all compounding of human drugs without an exemption from the new drug approval and certain other requirements in the FDCA.

Section 503A Exemption[9]

11. To ensure that compounding by state-licensed pharmacies is not effectively prohibited by the new drug approval process and other restrictions in the FDCA, Congress passed an exemption, Section 503A[10] of the FDCA, that provides an exemption for products compounded by a licensed pharmacist in a State-licensed pharmacy from FDCA requirements related solely to the new drug approval process (section 505), the labeling of drugs with adequate directions for use (section 502(f)(1)) and concerning compliance with current good manufacturing practice (section 501(a)(2)(B)).[11] This section , by its express terms, does not provide an exemption from other unenumerated provisions of the FDCA, including, but not limited to, the prohibition against distribution of adulterated drugs.[12]

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[8] *See* (Section 505 (21 U.S.C. § 355).) Generally, when the FDA evaluates a new drug for approval it considers clinical trials to evaluate both efficacy of a drug for a particular condition and the safety of the drug. The FDA's actions in this area must comply with notice and comment requirements giving all interested parties a chance to comment on proposed actions and the FDA's actions approving new drugs are traceable and discoverable through the proposing and adopting releases included in the Federal Register.

[9] This exemption applies to State-licensed pharmacists that are primarily regulated by the States who issue pharmacist licenses and sterile compounding permits.

[10] *See* (21 U.S.C. § 353a.)

[11] *See* (21 U.S.C. §§ 355 (requiring new product approval), 352(f) (regarding directions for use) & 351(a)(2)(B) (compliance with current good manufacturing practices.))

[12] *See* Section 301 (codified at 21 U.S.C. § 331(a) (prohibiting the introduction of adulterated drugs into interstate commerce)) and Section 501 (codified at 21 U.S.C. § 351(a) (defining adulterated).)

12. Section 503A(b)(1)(A)(i)[13] of the FDCA provides, that a drug product may be compounded if the licensed pharmacist or licensed physician compounds the drug using bulk substances that: 1) comply with the standards of (1) an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph; [14] 2) if such a monograph does not exist, are drug substances that are components of drugs approved by the FDA; or 3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, the substance appears on a list developed by the FDA.[15] The FDA also has interpreted the phrase an "applicable" USP or NF monograph for purposes of Section 503A to mean "an official USP or NF drug substance monograph and does not include dietary supplement monographs."[16] In response to a comment on the proposed rulemaking, the FDA explained its reasoning why it interprets an applicable USP or NF monograph to mean a USP or NF drug formulation for bulk substances rather than a supplemental or dietary formulation. The FDA stated:

> Accordingly, it is reasonable to interpret the phrase 'applicable United States Pharmacopoeia monograph in [Section 503A] as a reference to a USP drug monographs, not USP dietary supplement monographs. Moreover, adopting the alternative interpretation urged by the comment – *i.e.,* that "applicable USP monographs" include USP dietary supplement monographs – would not be in the best interest of the public health. USP monographs for dietary supplements can differ in significant ways from USP monographs for drugs because of the differences between dietary supplements and drug products. For example, dietary supplements are intended for ingestion only, and the standards contained in the USP dietary supplements are intended for ingestion only, and the standards

[13] (21 U.S.C. § 353a(b)(1)(A)(i).)

[14] Monographs provide standards for identity, quality, purity, strength, packaging, and labeling for bulk substances and other ingredients that may be used in compounded preparations. A substance may have multiple monographs with different standards depending on the intended use, such as a dietary monograph compared to a drug or pharmaceutical monograph.

[15] (21 U.S.C. § 353a(b)(1)(A)(i).) The statutory design sets out a hierarchy and if a drug monograph exists, it must be used.

[16] *See* (Food & Drug. Adm, List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act*,* 81 Fed.Reg. 91071, 91072 n.1 (Dec. 16, 2016) (proposing release issued by the FDA to describe the criteria it would use to evaluate bulk substances to be added to the list of compounding eligible substances) (2016 Bulk Substances Proposing Release); *See also* (Food & Drug Adm., List of Bulk Drug Substances That Can Be Used to Compound Drug Products In Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act*,* 84 Fed.Reg. 4696, 4704-4705 (Feb. 19, 2019).) (hereafter, the 2019 Bulk Substances Adopting Release).

> contained in the USP dietary supplement monographs are likewise intended for dietary supplements that will be ingested; the standards are not appropriate for use in compounding drug products that may have different routes of administration (*e.g.*, intravenous, intramuscular, topical). In addition, the USP limits for elemental impurities are different for drugs and dietary supplements. There are limits specified in USP General Chapters for many more elemental contaminants for drugs than there are for dietary supplements. Furthermore, the bioburden allowable for dietary supplements is considerably higher than that allowed for drug substances. Relying on the standards of a dietary supplement monograph for a substance that will be used in compounding drug products could therefore put patients at risk.[17]

13. Because there was no drug monograph for either of the substances at issue, compounding drug products using those substances could only be done in reliance on Section 503A(b)(1)(A)(i)(III). This prong requires that the substance be included on a list developed by the FDA. The rule establishing the list of approved bulk substances that can be used in compounding by state-licensed compounding pharmacists or physicians operating under the exemption in Section 503A is codified at 21 C.F.R. Section 216.23. To date, the FDA has not approved any bulk substance for administration via injection (all approved substances have been approved for topical use or as a dye for eye surgery). The Board will refer to these ingredients as "statutorily authorized drug ingredients". Neither methylcobalamin nor glutathione are on the current list of statutorily authorized drug ingredients.

14. The FDA, pursuant to its Bulk Drug Substances Interim Policy, while it is evaluating the bulk substances nominated with adequate information for it to evaluate the substance for inclusion or exclusion, has stated that it generally does not intend to take enforcement action if a bulk drug substance is listed in Category 1 of the FDA's website

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[17] *See* (2019 Bulk Substances Adopting Release, 84 Fed.Reg. at 4704-4705, *supra* n.16.) The FDA also has stated this interpretation is other guidance. *See* (Food & Drug Adm., Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act, Draft Guidance for Industry (Oct. 2015) at page 2, 80 Fed.Reg. 65781 (Oct. 27, 2015). This same position is also stated in the revised guidance dated (June 2016) at p. 2, 81 Fed.Reg. 37502 (Jun. 10, 2016), and the revised guidance dated January 2017 at pp. 2-3, *See* (Food & Drug Adm., Interim Policy on Compounding Using Bulk Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act, Guidance for Industry Revision 1 (Jan. 2017), at pp. 2-3.) (hereafter, FDA's Bulk Drug Substances Interim Policy) (located at https://www.fda.gov/media/94398/download).)

provided that, among other conditions, the drug product is compounded in compliance with all other conditions of Section 503A and the FDCA.[18] Both methylcobalamin and glutathione are both listed as Category 1 substances under the FDA's Bulk Drug Substances Interim Policy. If a bulk substance does not qualify as a statutory eligible ingredient under Section 503A or on Category 1 of the bulk list, then a drug compounded using such an ingredient is considered a new drug that is not exempt from the new drug approval process or other requirements of the FDCA. In this decision, the Board will refer to substances that do not meet one of the requirements in Section 503A(b)(1)(A)(i) or appear on the Category 1 list as "ineligible drug ingredients."[19] The Board will refer to substances that meet one of these requirements as "eligible drug ingredients."

15. In addition to satisfying the requirements of Section 503A(b)(1)(A)(i) of being an eligible drug ingredient, the substances must also comply with the other conditions in Section 503A(b)(1).[20] The most important additional condition at issue in this case is that compounding must comply with an applicable (*i.e.,* drug) USP or NF monograph if one exists and the USP chapter on pharmacy compounding.[21] Thus, under federal law, compounding by pharmacists must be done in compliance with the USP chapter on pharmacy compounding.

California Law

16. California also has an extensive statutory and regulatory scheme governing compounding by pharmacies. Similar to federal law, Section 111550(a) of the California Health and Safety Code prohibits the sale, delivery or giving away of a new drug that has not had a new drug application approved under Section 505 of the FDCA. Thus, the delivery of a new drug that does not comply with the exemption from Section 505 in Section 503A of the FDCA would violate both federal and state law.[22]

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[18] *See* (FDA's Bulk Drug Substances Interim Policy, *supra* n.17.)

[19] *See* (Food & Drug Adm., Tailor Made Warning Letter, (Apr. 1, 2020) (located at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tailor-made-compounding-llc-594743-04012020.) In this warning letter, the FDA referred to drug products that do not meet the requirements of Section 503A(b)(1)(A)(i) as "ineligible drug products.")

[20] The other conditions of Section 503A are not discussed herein as they are not dispositive of the compounding practices at issue by Givant and La Vita.

[21] *See* (Section 503A(b)(1)(B) (codified at 21 U.S.C. § 353a(b)(1)(B).)

[22] It is important to note that the State of California has not issued similar enforcement discretion guidance expanding out the list of statutorily eligible drug ingredients. Because this was not pleaded in the Second Amended Accusation, the Board does not reach or analyze whether California law would prohibit the compounding of these substances.

17. Business and Professions Code section 4126.8 expressly provides that the compounding of drug preparations by a pharmacy for furnishing in this state shall be consistent with "standards established in the pharmacy compounding chapters of the current version of the **United States Pharmacopeia-National Formulary** . . . ." This section also expressly authorizes the Board to adopt "regulations to impose additional standards for compounding drug preparations."[23] Thus, both state and federal law require compounding pharmacies to comply with the USP chapters on compounding.

Relevant USP Standards

18. Drug manufacturers and outsourcing facilities must comply with current good manufacturing practices. Both federal and state law specifically requires pharmacists and pharmacies to comply with the applicable USP chapter governing compounding practices in lieu of compliance with current good manufacturing practices. USP has general standards and specific Chapters dedicated to sterile compounding (intended for injection) and nonsterile compounding (intended for oral or topical use). USP's division of compounding practices by sterile or nonsterile compounding is due to the different risks to patients inherent in the mode of administration of a drug.

19. USP chapter 797 governs the compounding of sterile drug products (*i.e.,* those for injection) and in the section entitled Responsibility of Compounding Personnel provides that compounding personnel are responsible for, and written assurance procedure must include, checks that ensure "[i]ngredients have their correct identity, quality, and purity."[24] Compounding personnel also are required to "ascertain that the ingredients for CSPs are of the correct identity and appropriate quality . . . ."[25]

20. Further, USP Chapter 797 states that:

> "compounded sterile preparations compounded under any of the following conditions are either contaminated or at a high risk to become contaminated:
>
> (1) Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (*e.g.,* oral) are incorporated . . . .

[23] This section became operative on January 1, 2020 before respondents stopped compounding both substances using ungraded or dietary grade bulk products.
[24] *See* (Respondent's Ex. OO, p. Z88.)
[25] *See* (*Id.* at p. Z188.)

(5) **It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct examination**, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened packages of bulk ingredients (see Ingredient Selection under Pharmaceutical Compounding – Non Sterile Preparations (795) (emphasis added); Respondent's Exhibit Cx. OO, pp. Z-92-Z93).)[26]

PROHIBITION AGAINST DISTRIBUTION OF ADULTERATED DRUGS

15. In addition to the general overlay of the USP compounding standards and compliance with the Section 503A Exemption, both federal and state law have additional specific prohibitions against the distribution of adulterated drugs that applies to all drugs, including compounded drugs prepared by pharmacies operating under the Section 503A Exception.

Federal Law

16. Section 301(a) of the FDCA prohibits, among other things, "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."[27] Section 501(a)(1) and (2)[28] of the FDCA define adulterated and states, in pertinent part, that:

A drug or device shall be deemed to be adulterated –

(a) Poisonous, insanitary, etc., **ingredients,** adequate controls in manufacture
(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2) (A) if it has been prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have

[26] In the section entitled Component Selection, Handling and Storage in USP Chapter 795, number 3 states that "official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided." Paragraph 4 further states that "[w]hen components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society-certified may be used. However, these components should be used cautiously because the standards for analytical reagents or American Chemical Society-grade materials do not consider whether any impurity present raises human or animal safety concerns." USP Chapter 795 governs nonsterile compounding standards and hence ingredient selection and the quality of ingredients used also is important in nonsterile compounding.

[27] *See* (21 U.S.C. § 331(a).)

[28] *See* (21 U.S.C. § 351(a)(1) & (2).)

> been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . ..

21. The Section 503A Exemption, by its own terms does not exempt compounders from compliance with the prohibition against distributing adulterated drugs. Drugs held or produced under insanitary conditions are deemed to be adulterated under federal law[29] even if the drugs qualify for the exemptions set forth in Section 503A under the statutory definitions in the FDCA.[30] The FDA has reiterated this conclusion flowing from Section 503A in other guidance documents, including in a 2018 revision to the Insanitary Conditions Guidance and final guidance issued in 2020.[31] In the Insanitary Conditions Guidance, the FDA has interpreted Section 501(a)(2) of the FDCA and identified examples of insanitary conditions. In the Revised 2018 Insanitary Conditions Guidance and the Final 2020 Insanitary Conditions Guidance, the FDA identified one insanitary condition as "[u]sing active ingredients, inactive ingredients, or processing aides, that **have or may have** higher levels of impurities compared to a compendial or pharmaceutical grade equivalents (*e.g.,* ingredients with **potentially** harmful impurities, ingredients labeled with 'not for pharmaceutical use' **or an equivalent statement**)." (emphasis supplied).[32] This example of an insanitary condition included by the FDA is similar to the identification in USP Chapter 797 of a high risk sterile compounding practice that is either contaminated or at a high risk to be contaminated that includes using nonsterile ingredients, including incorporating "manufactured products not intended for sterile routes of administration (e.g., oral) . . .." (Relevant USP Standards, ¶20, at p. 10). Both of these statements are saying the same thing that the quality of the starting ingredient must be appropriate for the mode of administration.

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[29] *See* (Section 301(a)(2) of the FDCA, (codified at 21 U.S.C. § 331(a).)

[30] *See* (Food & Drug Adm., Insanitary Conditions at Compounding Facilities, Draft Guidance for Industry at p. 1 (Aug. 2016), 81 Fed.Reg. 51449 (Aug. 4, 2016) (2016 Insanitary Conditions Guidance.)

[31] *See* (Food & Drug Adm., Insanitary Conditions at Compounding Facilities, Draft Guidance for Industry at p. 1 (Sept. 2018), 83 Fed.Reg. 48631 (Sept. 26, 2018) (Revised 2018 Insanitary Conditions Guidance); *See* (Food & Drug Adm., Insanitary Conditions at Compounding Facilities, Guidance for Industry (Nov. 2020), 85 Fed.Reg. 71348 (Nov. 9, 2020) (Final 2020 Insanitary Conditions Guidance.)

[32] *See* (Revised 2018 Insanitary Conditions Guidance, *id.* at p. 4.); *see also* (Final 2020 Insanitary Conditions Guidance, *id.* at p. 5.)

22. The FDA's identification that the grade of bulk substance used in both sterile and nonsterile compounding is critical for public health has been stressed in numerous materials published in the Federal Register for notice and comment beginning at least in 2016. A similar standard is included in USP Chapter 797 governing sterile compounding.

California Law

23. Also, similar to federal law, California law makes it unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug that is adulterated. (Health & Safety Code section 111295.) California law also provides that "[a]ny drug . . . . is adulterated if it consists, in whole or part, of any filthy, putrid, or decomposed substance." (Health & Safety Code section 111250.) California law also provides that that "[a]ny drug or device is adulterated if it has been produced, prepared, packed, or held under conditions where it **may** have been contaminated with filth, or where it **may** have been rendered injurious to health."[33] Finally, Section 111260 of the Health & Safety Code also provides that:

> Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

The Board has not further defined the term adulterated except to reference the relevant Health and Safety Code sections defined above.[34]

24. Board regulations also address issues such as quality, beyond use dates (BUDs),[35] recordkeeping, training and validation processes, end product testing for sterility

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[33] *See* (Health & Saf. Code § 111255 (emphasis added).)

[34] For example, Section 4169(a)(2) of the Business and Professions Code prohibits a person from purchasing, trading, selling or transferring dangerous drugs that the person knew or should have known were adulterated "as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code."); *see also* Bus. & Prof. Code § 4084(e) (defining adulterated by reference to Article III of the Health & Safety Code commencing with § 111250.)

[35] The term "beyond use date" means "the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes)." (Cal. Code Regs., tit. 16, § 1735.1, subd. (b).)

and pyrogens,[36] quarantine, and furnishing of compounded drugs. Under California law, the designated PIC "shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy," including compounding. (Bus. & Prof. Code, § 4113, subd. (c).) The Board's sterile compounding regulations define "quality" as "the absence of harmful levels of contaminants, including filth, putrid or decomposed substances, the absence of inactive ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula label."[37]

25. In 2019, the Board proposed promulgating a new regulation regarding compounding sterile drug preparations. Specifically, proposed California Code of Regulations, title 16, section 1751.9, subdivision (e), would have provided that:

> No component shall be used to compound a [sterile drug preparation] that meets only the European Pharmacopoeia standards, Japanese Pharmacopoeia standards, dietary supplement standards (such as USP-NF dietary monographs), food ingredient standards (such as Food- Chemical Codex (FCC)), food additive standards (such as General Standard for Food Additive (GSFA)), reagent standard (such as American Chemical Society (ACS)) or is of unspecified quality.[38]

[36] Pyrogens are fever-producing agents of bacterial origin, such as endotoxins. Endotoxins are part of the outer membrane of the cell wall of Gram-negative bacteria released upon disruption of intact bacteria. They are the most significant pyrogen found in injectable drugs and medical devices. Their presence in the blood stream may cause septic reactions with symptoms such as fever, hypotension, nausea, shivering, and shock. High concentrations can lead to serious complications including death.

[37] (Cal. Code Regs., tit. 16, § 1735.1, subdivision (ae).)

[38] This proposed rulemaking was initiated in response to proposed changes to the USP chapters on compounding in 2019. The 2019 USP amendments were withdrawn in response to extensive public comments and the Board did not finalize its rulemaking due to the fact that the proposed USP changes that prompted them were withdrawn. USP has now adopted significant changes to three of its chapters governing nonsterile and sterile compounding and radiopharmaceuticals with an effective date of November 1, 2023. The Enforcement and Compounding Committee is currently considering whether to adopt additional requirements to the revised USP chapters, as specifically authorized to do in Section 4126.8 of the Business and Professions Code, is appropriate.

BULK DRUG SUBSTANCES AT ISSUE

Glutathione

1. Glutathione is a substance made from amino acids and produced by the liver. It is involved in many bodily processes including tissue building and repair, making chemicals and proteins needed in the body, and in the functioning of the immune system. It is a dietary supplement also frequently prescribed as an injectable drug preparation by integrative medical practitioners for a range of claimed, but unproven, benefits such as combatting aging, improving skin, and treating liver disease, atherosclerosis, and Parkinson's disease. Prescribed glutathione injections are deemed dangerous drugs under Business and Professions Code section 4022.

2. Glutathione has a USP-NF dietary monograph, but not a USP-NF drug monograph. It is not disputed that the FDA has placed glutathione on the Category 1 list and eligible for compounding in compliance with the FDA's Bulk Drug Substances Interim Policy and other provisions of the FDCA.[39]

Methylcobalamin

3. Methylcobalamin is a synthetic form of Vitamin B-12 taken as a dietary supplement to treat Vitamin B-12 deficiency and anemia. It is also frequently prescribed as an injectable drug preparation by integrative medical practitioners for a range of claimed, but unproven, benefits, such as combatting fatigue and dementia, promoting weight loss, and treating various diseases including Autism Spectrum Disorder. Prescribed methylcobalamin injections are deemed dangerous drugs under Business and Professions Code section 4022.

4. Methylcobalamin has a USP-NF dietary monograph, but not a USP-NF drug monograph. It is not disputed that the FDA has placed methylcobalamin on the Category 1 list and eligible for compounding in compliance with the FDA's Bulk Drug Substances Interim Policy and other provisions of the FDCA.[40] Also, the FDA has approved B-12 drugs for injection for certain medical conditions, such as severe anemia.[41]

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[39] *See* (FDA's Bulk Drug Substances Interim Policy, n.17, *supra*.)

[40] *See (Id.*)

[41] Vitamin B12 - Health Professional Fact Sheet (nih.gov).

La Vita's Undisputed Sterile Compounding With Glutathione and Methylcobalamin

5. La Vita is a licensed sterile compounding pharmacy located in San Diego, California. Givant has been its PIC at all times relevant to this matter.

6. From approximately January 2018 through December 2018, La Vita compounded at least 44,900 ml of sterile injectable glutathione 200 mg/ml. Additionally, from approximately January 2018 through January 2019, La Vita sold at least 331 prescriptions for at least 38,370 ml of sterile injectable glutathione 200 mg/ml. Those drug preparations were compounded with bulk glutathione purchased from suppliers Fagron and Medisca.[42] It also is undisputed that the bulk substances from both entities were either ungraded or dietary graded.

7. From approximately September 2019 through March 2020, La Vita compounded at least 23,800 ml of methylcobalamin 1000 mcg/ml. Additionally, from approximately September 2019 through January 2020, La Vita sold at least 346 prescriptions for at least 6,330 ml of sterile injectable methylcobalamin 1000 mcg/ml. Those drug preparations were compounded with bulk methylcobalamin purchased from supplier Medisca. It also is undisputed that the bulk methylcobalamin used to prepare these sterile injectable drugs was ungraded.

Complainant's Evidence

TESTIMONY OF CHRISTINE ACOSTA, PHARM.D.

8. Christine Acosta (Acosta) received her doctor of pharmacy[43] degree from Western University of Health Sciences in May 2006. She has been a Supervising Inspector for the Board's Sterile Compounding Team since July 2014. Her duties are to serve as the Board's expert in compounding law, as well as to conduct complex inspections and investigations. Acosta was previously a Board Inspector on the Diversion Team from December 2011 to July 2014. From June 2006 to December 2011, Acosta worked as a licensed pharmacist for various employers.

9. On January 10, 2019, the Board received a report from another sterile compounding pharmacy of adverse drug reactions (ADRs) suffered by patients after being

[42] Fagron and Medisca are suppliers that purchase bulk drug substances from manufacturers, and then repackage and resell them to compounding pharmacies.

[43] This degree is referred to a Pharm.D degree and entitles the holder to the designation of Dr.

administered a compounded sterile injectable glutathione preparation made with bulk glutathione purchased from supplier Letco. The ADRs included facial reddening, sneezing, nausea, vomiting, shaking, and breathing difficulties.

10. Acosta then started an investigation of several California pharmacies that compounded glutathione, including La Vita. She was surprised to discover that these compounding pharmacies were using dietary grade or ungraded bulk glutathione in their compounding of sterile injectable drug preparations. She had not previously been aware of that practice.

11. As part of her investigation of La Vita, Dr. Acosta communicated with Givant and requested records pertaining to La Vita's compounding with glutathione. Givant responded and provided the requested records.

12. On July 3, 2019, Dr. Acosta issued a notice of violation to respondents with respect to their compounding with glutathione. She also prepared an associated investigation report dated July 18, 2019.

13. On March 4, 2020, Dr. Acosta inspected La Vita along with FDA investigators. During that inspection, Dr. Acosta discovered that La Vita had also used ungraded bulk methylcobalamin in its compounding of sterile injectable drug preparations.

14. During and following the inspection, Acosta communicated with Givant and requested records pertaining to La Vita's compounding with methylcobalamin. Givant responded and provided the requested records.

15. On June 2, 2020, Acosta issued notices of violation to respondents with respect to their compounding with methylcobalamin. She also prepared an associated investigation report dated June 17, 2020.

16. At hearing, Acosta testified consistently with her investigation reports concerning the issues raised by the Second Amended Accusation. Her relevant testimony as to each issue follows.

Lack of Quality/Adulteration

17. Acosta opined that quality should be built into every step of the compounding process. Thus, compounding pharmacies must ensure that all ingredients and bulk drug substances used to compound sterile injectable drug preparations are

manufactured under conditions and specifications appropriate for the intended route of administration. Compounders should not rely solely on end product testing, such as testing for sterility or endotoxins, to ensure drug quality. Acosta explained that filters used in compounding do not remove all contaminants present in the starting ingredients, nor is the end product tested for all such contaminants. Thus, a compounding pharmacist cannot start with "turtle pond water" to compound a sterile injectable drug preparation.

18. Acosta reviewed the Certificates of Analysis (COAs) for the bulk glutathione and methylcobalamin La Vita purchased from Fagron and Medisca.

The glutathione from Fagron was dietary grade and tested as compliant with the USP dietary monograph for glutathione. It contained up to 200 parts per million (ppm) of ammonium, 1 ppm of arsenic, 300 ppm of sulfate, 200 ppm of chloride, 10 ppm of iron, and 10 ppm of heavy metals.

The glutathione from Medisca was ungraded and tested as compliant with unspecified manufacturer's standards only. It contained up to 0.020 percent of ammonium, up to 1 ppm of arsenic, up to 0.030 percent of sulfate, up to 10 ppm of iron, less than 10 ppm of heavy metals, a total plate count (aerobic bacteria, yeast, mold, and fungi) of up to 1000 colony forming units per gram (cfu/g), and a fungi count of up to 100 cfu/g.

The methylcobalamin purchased from Medisca was ungraded and tested as compliant with unspecified manufacturer's standards only. It contained a total aerobic microbial count of up to 50 cfu/g, and a total yeasts and molds count of less than 10 cfu/g.

19. Acosta testified that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality and were adulterated. They were unsuitable for that route of administration for two reasons.

20. First, they were compounded with dietary grade or ungraded, as opposed to drug or pharmaceutical grade, bulk ingredients. Dietary supplements such as glutathione and methylcobalamin are generally defined and regulated as foods intended for oral ingestion. They are not of sufficient quality to be used in compounding sterile injectable drug preparations, which bypass the digestive system's biological filters. There is no USP drug monograph for either glutathione or methylcobalamin, and thus they were not tested for compliance with an appropriate USP drug monograph.

In further support of her opinion, Acosta explained that the FDA has issued industry guidance regarding "Insanitary Conditions at Compounding Facilities." Pursuant to that guidance, insanitary conditions that may give rise to drug adulteration include using ingredients that "have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (*e.g.,* ingredients with potentially harmful impurities, ingredients labeled with 'not for pharmaceutical use' or an equivalent statement)." The FDA industry guidance referenced by Acosta also states:

> In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

Acosta also noted that both the Board and the FDA had previously cautioned compounders about using dietary grade bulk drug substances to compound sterile injectable drug preparations. On January 11, 2019, the Board issued a Compounding Safety Alert, which noted that "[d]ietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as 10 times more impurities when compared to pharmaceutical grade standards appropriate for compounding. These impurities can cause patient harm." Additionally, on June 7, 2019, the FDA issued a Compounding Risk Alert titled "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." On June 10, 2019, the Board forwarded that FDA Compounding Risk Alert to its licensees.

21. Second, the COAs for the bulk glutathione and methylcobalamin purchased from Fagron and Medisca show that the bulk drug substances contained the above-mentioned contaminants and impurities, which included filthy, putrid, or decomposed substances. Because the final glutathione and methylcobalamin preparations were never tested for the presence of those specific contaminants or impurities, Acosta has no idea whether they were still present in the final preparations, and if so, at what specific levels. Thus, they caused the final drug preparations to lack quality and be adulterated.

BUDs

22. Generally, a high risk preparation is allowed to have BUDs of 24 hours at room temperature, three days with refrigeration, and 45 days in a frozen solid state. To extend a BUD, the compounding pharmacy must have appropriate supporting documentation of a method suitability test, a container closure integrity test, and stability studies.

Method suitability testing is performed to determine whether any inhibitory or antimicrobial properties in a drug product will prevent the sterility test from detecting the presence of viable microorganisms. It shows that the sterility test method is valid for a specific formulation of a drug product and reduces the possibility of a sterile result on a product that is not actually sterile.

A container closure integrity test verifies that a particular type of vial and its closure at the top are adequate to maintain a sterile barrier against potential contaminants.

Stability studies provide evidence of how the quality of a drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity, and light.

23. La Vita assigned BUDs of 90 days to its sterile injectable glutathione preparations. Acosta reviewed La Vita's supporting documentation concerning the BUDs for the following 11 lots of glutathione preparations: 158717@2, 158119@2, 156272@1, 153964@2, 152608@11, 145953@2, 144326@3, 142800@3, 140409@7, 138674@13, and 137779@18. She found the documentation inadequate for the following three reasons:

First, La Vita provided documentation of a November 17, 2016 method suitability test, which did not identify the tested lot. Thus, Acosta could not determine if the glutathione injection prepared and tested in November 2016 was the same formulation of glutathione injection prepared in 2018, and whether the preparation method was the same.

Second, La Vita provided documentation of a November 4, 2016 container closure integrity test that did not identify the lot number and also did not identify the specific type of 30 ml amber vial used during the testing. Acosta explained that there are "hundreds, probably more, manufacturers that make a 30 ml amber vial." Thus, she could not determine if La Vita used the same type of vial that had been tested in 2016 for the 2018 preparations at issue.

Third, La Vita provided only a small, incomplete portion of a 2010 stability study. Additionally, that study used ingredients from Professional Compounding Centers of America (PCCA). La Vita did not purchase its bulk glutathione from PCAA, and thus the information told Acosta "pretty much nothing" about the stability of La Vita's sterile injectable glutathione preparations.

24. La Vita assigned BUDs of 180 days to its sterile injectable methylcobalamin preparations. Acosta reviewed La Vita's supporting documentation concerning the BUDs for the following eight lots of methylcobalamin preparations: 174893@2, 176388@1, 176531@2, 178751@3, 180169@2, 1181213@1, 182972@1, and 183570@8. She found the documentation inadequate for the following three reasons:

First, La Vita provided documentation of a January 3, 2017 method suitability test, which does not identify the tested lot. Thus, Acosta could not determine if the methylcobalamin injection prepared and tested in January 2017 was the same formulation of methylcobalamin injection prepared in 2019 and 2020, and whether the preparation method was the same. Additionally, the test report indicated that "[m]ethod suitability for the sterility testing of this formulation is valid for up to 420 mL of sample. Method suitability will be required if a larger volume of sample is sent for USP<71> sterility testing." Acosta noted that La Vita compounded much larger amounts of up to 4,000 ml per lot, for which there was no valid method suitability test.

Second, La Vita provided documentation of November 4, 2016, and November 17, 2016, container closure integrity tests for 30 ml and 10 ml amber vials, respectively. The tests did not identify the lot numbers and also did not identify the specific types of amber vials used during the testing. Given the numerous types and manufacturers of amber vials, Acosta could not determine if La Vita used the same type of vials that had been tested in 2016 for the 2019/2020 preparations at issue.

Third, although La Vita provided a valid and complete 2016 stability study for methylcobalamin, the study used PCCA ingredients and included the following warning:

> This formula has been tested in the PCCA lab using only PCCA chemicals and proprietary bases (except when noted). Any variations to this formulation, including substitution with a non-PCCA chemical or non-PCCA base, may affect physical integrity, solubility, organoleptic properties or result in potency or content uniformity issues. This type of substitution will cause the assigned BUD to be invalid.

Because La Vita did not purchase its bulk methylcobalamin from PCCA, it could not rely on this stability study to establish its BUDs.

25. Consequently, Acosta concluded that La Vita's assigned BUDs for its sterile injectable glutathione and methylcobalamin preparations were unsupported. They lacked

appropriate supporting documentation of method suitability tests, container closure integrity tests, and stability studies.

Incomplete Compounding Records

26. Acosta explained that a compounding pharmacy is required to keep a single-document compounding log for each specific lot of drug preparation compounded, so that a reviewer "can always tell what happened during that one particular compound." The PIC is responsible for developing and maintaining compounding logs. California law requires certain information to be included in the compounding logs, including:

- The final quantity or amount of drug preparation compounded for dispensing. Acosta explained that the law requires documentation of the total number of vials made in a particular lot because that number determines the number of vials that must be sent for sterility testing.
- Documentation of quality reviews and required post-compounding process and procedures. This includes bubble point testing[44] of the specific filter used for sterilization to verify its integrity, and the results from end-product testing for sterility and endotoxins.
- The identity of the pharmacist reviewing and verifying the final drug preparation. The pharmacist must verify that all compounding steps and end-product testing were properly performed, and take responsibility for the final product.

27. Acosta reviewed La Vita's compounding logs for its glutathione preparations. She discovered several items of missing information on the logs.

For lot nos. 137779@18, 138674@13, 140409@7, 142800@3, 144326@3, 145953@2, and 152608@11, La Vita on each log failed to identify the total number of vials made in that lot and failed to document the identity of the pharmacist reviewing the final drug preparation. Regarding the latter, Givant and other La Vita pharmacists specifically failed to complete the designated fields on the logs for the name/signature/date of the reviewing pharmacist.

For lot nos. 153964@2, 156272@1, 158119@2, and 158717@2, La Vita on each log failed to identify the total number of vials made in that lot, failed to document the identity of the pharmacist reviewing the final drug preparation as explained above, and failed to document the filter lot number or type of filter used for that lot and that bubble point

[44] A bubble point test is a non-destructive method of filter integrity testing that allows the user to correlate their results with manufacturer-determined values that indicate proper function.

testing was performed on the filter.

28. Acosta also reviewed La Vita's compounding logs for its methylcobalamin preparations. She again discovered items of missing information on the logs. Specifically, for lot nos. 174893@2, 176388@1, 176531@2, 178751@3, 180169@2, and 1181213@1, La Vita for each log failed to document the filter lot number or type of filter used for that lot and that bubble point testing was performed on the filter.

Improper Quarantine

29. As part of her investigation, Acosta compared the methylcobalamin dispensing report La Vita originally provided her during the investigation (Original Dispensing Report) to the dates on which each lot of sterile injectable methylcobalamin preparation passed end product testing for sterility and endotoxins. Based on that comparison, Acosta determined that La Vita had dispensed prescriptions of sterile injectable methylcobalamin from the following lots before end product testing confirmed sterility and acceptable levels of endotoxins: 174893@2, 176388@1, 176531@2, 178751@3, 180169@2, and 1181213@1. Thus, La Vita failed to properly quarantine those lots.

30. For the first time at hearing, Acosta was given an opportunity to review La Vita's Revised Dispensing Report, discussed in greater detail below. Acosta expressed several concerns about the accuracy of the Revised Dispensing Report. First, she noted that she was not provided with any raw data to support the revised dates in the Revised Dispensing Report. Second, she noticed some obvious inaccuracies. For lot no. 176531@2, the Original Dispensing Report lists numerous dispenses, whereas the Revised Dispensing Report only lists a single dispense. Additionally, for lot no. 178751@3, the Revised Dispensing Report lists that end product testing results returned on November 8, 2019, which is impossible given that lot no. 178751@3 was only compounded on December 10, 2019.

31. Based on the foregoing, Acosta questions the authenticity and/or accuracy of the Revised Dispensing Report. She believes that its data is either flawed, inaccurately transposed, or potentially manipulated. She observed that the data from the Original Dispensing Report was "sent to me directly from respondent so I feel like I can authenticate that data better."

Insufficient Training and Validation

32. Acosta explained that pharmacy technicians must successfully demonstrate competency on aseptic technique before being allowed to prepare sterile drug preparations. Aseptic technique involves processing or manipulating a sterile substance without contaminating it.

33. California law requires that the training and validation process must be representative of the types of manipulations, products, and batch sizes the pharmacy technician is expected to prepare. The validation process must also be as complicated as the most complex manipulations performed by staff and contain the same or greater amount of volume transferred during the compounding process. Additionally, the same procedures and equipment must be used in the testing.

34. As part of her investigation, Acosta reviewed the training and testing records of CB, the only pharmacy technician who performed sterile compounding at La Vita. Acosta identified two deficiencies with respect to CB's training and validation testing:

First, although CB compounded both 10 ml and 30 ml vials of sterile injectable methylcobalamin preparation, she underwent no validation testing with the 10 ml vials. Thus, the testing did not involve all the same equipment and products as her compounding practice.

Second, the validation testing only involved 26 of the 30 ml vials, whereas CB on multiple occasions compounded well over 100 of the 30 ml vials per lot. Thus, the testing was not representative of the batch sizes CB was expected to prepare, nor did it involve the same or greater volume as is transferred during the compounding process. Acosta explained that this deficiency is significant, because fatigue is a factor that can substantially affect a pharmacy technician's performance.

35. Thus, Acosta concluded that CB compounded the following lots of sterile injectable methylcobalamin preparation before properly demonstrating competency on aseptic technique: 174893@2, 176388@1, 176531@2, 178751@3, 180169@2, 1181213@1, 182972@1, and 183570@8.

Furnishing to Unlicensed Entity

36. In the course of her investigation, Acosta discovered that on April 1, 2020, La Vita provided compounded lot no. 183570@8 of sterile injectable methylcobalamin

preparation to Allianz Transportation, Inc. (ATI) for destruction. Acosta verified that ATI was not licensed by the Board. Thus, she concluded that La Vita had furnished a dangerous drug to an unlicensed entity.

Unprofessional Conduct (Givant Only)

37. Based on Acosta's foregoing findings, Acosta opined that Givant, as the PIC at La Vita, engaged in acts or omissions that involved: (a) the inappropriate exercise of her education, training, or experience as a pharmacist; and (b) the failure to exercise or implement her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs. She opined such acts or omissions constituted unprofessional conduct.

PRIOR FDA WARNING LETTER AND CITATIONS

38. Complainant offered evidence that respondents had previously been issued an FDA warning letter as well as multiple Board citations. Each is addressed below.

FDA Warning Letter

39. On February 28, 2019, the FDA issued respondents a warning letter following an FDA inspection of La Vita conducted from June 4 through 8, 2018. During the inspection, the investigator noted that certain drug products failed to meet conditions of section 503A of the FD&C Act. Additionally, the investigator noted serious deficiencies in La Vita's practices for producing sterile drug products, which put patients at risk. The FDA strongly recommended a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems.

Board Citations to La Vita

40. On August 19, 2015, the Board issued La Vita Citation No. CI 2014 62003 for violation of Business and Professions Code section 4342 (sale of preparations or drugs lacking quality or strength) and California Code of Regulations, title 16, section 1735.2, subdivision (h) (expiration date violations). La Vita was ordered to pay a $2,500 fine, which it paid in full.

41. On December 13, 2018, the Board issued La Vita Citation No. CI 2018 80737 for violation of California Code of Regulations, title 16, sections 1714, subdivisions (b) and (d) (pharmacy security violations) and 1735.2, subdivisions (i)(2)(A) and (i)(3) (BUD violations). La Vita was ordered to pay a $1,500 fine, which it paid in full.

42. On December 20, 2018, the Board issued La Vita Citation No. CI 2017 80529 for violation of Business and Professions Code section 4115, subdivision (f)(1) (violation of pharmacist/pharmacy technician ratios) and Health and Safety Code section 11164, subdivision (b)(1) (failure to verify electronically-transmitted prescriptions). La Vita was ordered to pay a $500 fine, which it paid in full.

Board Citations to Givant

43. On February 23, 2012, the Board issued Givant Citation No. CI 2011 51366 for violation of Business and Professions Code section 4126.5, subdivision (a)(4) (improper furnishing of dangerous drugs). Givant was ordered to pay a $5,000 fine and complete an ethics course. Givant fully complied.

44. On August 19, 2015, the Board issued Givant Citation No. CI 2015 6665 for violation of Business and Professions Code section 4342 (sale of preparations or drugs lacking quality or strength) and California Code of Regulations, title 16, section 1735.2, subdivision (h) (expiration date violations). Givant was ordered to pay a $2,500 fine, which she paid in full.

45. On December 13, 2018, the Board issued Givant Citation No. CI 2018 82311 for violation of California Code of Regulations, title 16, sections 1714, subdivisions (b) and (d) (pharmacy security violations) and 1735.2, subdivisions (i)(2)(A) and (i)(3) (BUD violations). Givant was ordered to pay a $2,250 fine, which she paid in full.

46. On December 20, 2018, the Board issued Givant Citation No. CI 2018 82365 for violation of Business and Professions Code section 4115, subdivision (f)(1) (violation of pharmacist/pharmacy technician ratios) and Health and Safety Code section 11164, subdivision (b)(1) (failure to verify electronically-transmitted prescriptions). Givant was ordered to pay a $250 fine, which she paid in full.

Respondents' Evidence

47. Givant testified at hearing. Additionally, respondents offered the testimony of their expert consultant, Amy Summers, Pharm.D. (Summers).

TESTIMONY OF GIVANT

48. Givant received her bachelor of science in pharmacy degree from Drake

University in Des Moines, Iowa in 1987. That same year, she became licensed as a pharmacist in California. After several years as a staff pharmacist and pharmacy manager at a retail pharmacy, she worked as a lead formulation pharmacist at University Compounding Pharmacy from 2000 through 2007, performing both sterile and non-sterile compounding.

49. In October 2007, Givant co-founded La Vita, which she has operated through the present. Historically, La Vita has compounded a variety of drugs, including sterile injectable preparations, transdermal pain creams, and hormone medications. As La Vita's PIC, Givant oversees pharmacy operations, clinical activities, and regulatory compliance; trains pharmacists and technicians in sterile and non-sterile compounding; and interacts with prescribing doctors and patients.

50. Since 2015, La Vita has been accredited in both sterile and non-sterile compounding with the Pharmacy Compounding Accreditation Board (PCAB). Between 2015 and 2021, La Vita was also voted "Best Pharmacy" by the North Coast Readers Poll. In 2017, Givant was the recipient of the California Pharmacists Association's "Innovative Pharmacist of the Year" award. She considers herself a leader in the compounding industry.

51. La Vita had compounded sterile injectable glutathione and methylcobalamin preparations for many years. Although the Board inspected La Vita numerous times over those years, the Board never informed Givant or La Vita that they could not compound with glutathione or methylcobalamin. Despite being administered to over hundreds of patients, La Vita's sterile injectable glutathione and methylcobalamin preparations have also never been associated with any ADR reports.

52. Nevertheless, La Vita stopped compounding sterile injectable glutathione preparations in July 2019 after it received the related notice of violation from Acosta. However, La Vita and Givant continued to compound sterile injectable methylcobalamin using ungraded bulk products after receiving the 2019 notice of violation regarding its use of inappropriate grade ingredients to compound sterile injectable glutathione. La Vita and Givant only stopped compounding sterile injectable methylcobalamin preparations using ungraded bulk materials after the joint inspection in 2020 by the FDA and Board inspectors. Finally, La Vita ceased compounding sterile compounding altogether and has not renewed its Sterile Compounding Permit.

53. Givant does not believe that La Vita improperly compounded with glutathione and methylcobalamin; she believes such compounding is authorized because

the FDA has classified them as 503A Category 1 substances. Additionally, La Vita always sourced bulk drug substances from reputable suppliers with whom it had established relationships. La Vita never bought bulk glutathione from Letco, the supplier associated with the reported ADRs that led to the Board's investigation. Finally, La Vita's preparations at issue all passed end product testing for sterility and endotoxins. Thus, Givant strongly disagrees that La Vita's sterile injectable drug preparations lacked quality or were adulterated. Nonetheless, she made a business decision to be cautious and avoid further liability exposure by stopping all sterile compounding.

54. Since that decision, Givant has received many inquiries from former patients and prescribers about if and when La Vita would resume compounding with glutathione and methylcobalamin. They are reportedly concerned about patient access to such compounded drugs in California given complainant's position in this matter. Numerous prescribers and pharmacist colleagues submitted letters in support of continued compounding with glutathione and methylcobalamin, and/or attesting to Givant's competence, professionalism, dedication, trustworthiness, and focus on quality and safety.

55. Givant acknowledges that her recordkeeping practices had room for improvement. To that end, she worked with Summers to improve La Vita's standard operating procedures and forms. Givant denies ever dispensing methylcobalamin prescriptions before end product testing confirmed sterility and acceptable levels of endotoxins. She understands why Acosta came to that conclusion because the Original Dispensing Report provided erroneous dispensing dates. Instead of listing the actual dispensing dates, it listed the dates on which the prescriptions were typed into the dispensing software and the associated prescription labels were printed.

The error resulted from a software limitation that allowed only the prescription entry/label dates to be extracted into a report format. In reality, after prescriptions were typed into the system and the prescription labels printed, the prescriptions were always held until end product testing results returned. Only then were the individual prescriptions scanned with a bar code scanner to signal final pharmacist approval and subsequently dispensed. After Givant was made aware of complainant's allegation of failure to quarantine, Givant contacted the software provider to make modifications allowing for the actual pharmacist approval and shipment dates to be extracted from the system into a report format.

At hearing, respondents offered a revised methylcobalamin dispensing report generated after the software modifications (Revised Dispensing Report). For each

prescription, the Revised Dispensing Report shows the date the prescription was typed into the system, the date all end product testing results for the associated lot returned, the pharmacist's final approval date, and the date the prescription was shipped or picked up. Givant testified that the Revised Dispensing Report confirms that La Vita never dispensed any methylcobalamin prescriptions before end product testing results returned.

56. Givant denies furnishing a dangerous drug to an unlicensed entity. La Vita uses a Board-licensed entity for disposal of any controlled substances or commercial drugs. However, the compounded sterile injectable methylcobalamin preparations were not controlled substances. She provided the specified lot of sterile injectable methylcobalamin preparations to ATI for destruction, and the ATI disposal record shows that it was "treated," i.e., destroyed on April 3, 2020. ATI is licensed by the California Department of Public Health (CDPH) as a medical waste transporter/transport station to pick up, transport, and dispose of all medical waste, including non-controlled pharmaceutical drugs. ATI is also a registered hazardous waste hauler with the California Department of Toxic Substances Control (CDTSC). Givant's testimony is supported by an August 18, 2021 letter from ATI as well as CDPH and CDTSC permits/registrations.

TESTIMONY OF AMY SUMMERS, PHARM.D.

57. Summers received her doctor of pharmacy degree from the University of California, San Francisco in 2007. She became a licensed pharmacist in California that same year. For most of her pharmacist career, she has worked for various compounding pharmacies, sometimes as the PIC. Additionally, since October 2019, Summers has served as a consultant to state-licensed compounding pharmacies on business, operations, quality, and compliance issues. That work includes assisting pharmacies with responding to enforcement actions, implementing remediation plans, and providing expert witness testimony. Summers holds a Board Certified Sterile Compounding Pharmacist credential from the Board of Pharmacy Specialties.

58. Respondents retained Summers to conduct an assessment of complainant's allegations against respondents and offer an expert opinion as to whether respondents violated applicable pharmacy statutes and regulations. As part of her assessment, Summers inspected La Vita and reviewed records concerning respondents' compounding with glutathione and methylcobalamin. She authored an assessment report dated October 28, 2021.

59. At hearing, Summers testified consistently with her report concerning the issues raised by the Second Amended Accusation. Her relevant testimony as to each issue

follows.

Lack of Quality/Adulteration

60. Summers noted that although glutathione and methylcobalamin are dietary supplements, both substances have been compounded into sterile injectable preparations for years. The FDA has classified glutathione and methylcobalamin as 503A Category 1 substances, which allows them to be used for compounding drugs. California also has no regulation specifically prohibiting compounding with either bulk drug substance.

61. **Glutathione:** Summers explained that glutathione does not have a USP drug monograph, likely because the FDA has not yet approved a commercial glutathione drug in the United States. However, the bulk glutathione La Vita purchased from Fagron tested as compliant with the USP dietary monograph for glutathione. Additionally, although the COAs for the bulk glutathione La Vita purchased from Medisca showed it was ungraded, Summers analyzed their specifications and concluded that they were nonetheless compliant with the USP dietary monograph. She also noted that both Fagron and Medisca sourced their bulk glutathione from the same FDA-registered manufacturer and that packaging for both suppliers had stated that the substance was for "prescription compounding." Moreover, based on a comparative analysis using the COAs, Summers opined that the bulk glutathione from Fagron and Medisca both complied with the European Pharmacopoeia (EP) drug monograph for glutathione.

With respect to the specific contaminants or impurities identified in the bulk glutathione COAs, Summers observed that every substance contains some levels of contaminants or impurities. The pertinent question is whether the levels are harmful based on the dosage and method of administration. After an analysis of the COAs by reference to her computation of a maximum daily dose of sterile injectable glutathione preparation delivered to a patient, Summers opined that the levels of contaminants or impurities: (a) complied with the International Council for Harmonization Guidelines for Elemental Impurities and Impurities in New Drug Substances (ICH Guidelines); and (b) were less than levels in other injectable drug products such as acetylcysteine[45] and magnesium sulfate.[46]

[45] 11 Acetylcysteine (with the brand name Acetadote) is an intravenous antidote for the treatment of acetaminophen overdose.

[46] Magnesium sulfate is commonly administered intravenously for low levels of magnesium and to control seizures in eclampsia or pre-eclampsia (new onset high blood pressure and associated symptoms during pregnancy or after delivery).

Additionally, Summers explained that the presence of some levels of bacteria, yeast, mold, and fungi does not render the bulk drug substance putrid or harmful if the final preparation is properly sterilized through the aseptic processing or terminal sterilization methods La Vita performed. Although it is very difficult to remove endotoxins, La Vita's end product testing for all glutathione preparations met the specifications for sterility and endotoxins.

62. **Methylcobalamin:** Methylcobalamin also does not have a USP drug monograph, likely because the FDA has not yet approved a commercial methylcobalamin drug in the United States. Although the COAs for the bulk methylcobalamin La Vita purchased from Medisca showed it was ungraded, Summers analyzed their specifications and concluded that they were nonetheless compliant with the USP dietary monograph for methylcobalamin. Moreover, they complied with the Japanese Pharmacopoeia (JP) drug monograph for methylcobalamin, which is available as a commercial injectable drug in Japan.

Finally, as with glutathione, Summers noted that the presence of some levels of bacteria, yeast, mold, and fungi in the bulk methylcobalamin does not render the bulk drug substance putrid or harmful if the final preparation is properly sterilized through the aseptic processing or terminal sterilization methods La Vita performed. Although it is very difficult to remove endotoxins, La Vita's end product testing for all methylcobalamin preparations met the specifications for sterility and endotoxins.

63. **Conclusion:** Based on the foregoing, Summers opined that La Vita's sterile injectable glutathione and methylcobalamin preparations did not lack quality. Additionally, they were not adulterated.

BUDs

64. Summers opined that the sterility test methods used in the relied-upon method suitability tests were also compatible with La Vita's glutathione and methylcobalamin preparations at issue. She did not "think" La Vita made "a lot of different types of versions" of glutathione or methylcobalamin preparations over the years. However, she conceded that the absence of lot numbers tested was a "good question" and "documentation could have been improved here."

65. Additionally, Summers noted that La Vita used the same sizes of amber vials for the preparations at issue as the relied-upon container closure integrity tests. However, Summers would recommend "a more robust study design."

66. Finally, Summers disagreed that La Vita was required to use the same ingredients from the same supplier or manufacturer for a relied-upon stability study to be valid. She opined that it was sufficient to use the same ingredient of the same or better grade because no California regulation specifies that the same supplier or manufacturer is required. She characterized PCCA's warning as a competitive "company driven warning" rather than a "regulatory enforcement warning."

67. In sum, Summers opined that La Vita's BUDs for its sterile injectable glutathione and methylcobalamin preparations were adequately supported by appropriate method suitability tests, container closure integrity tests, and stability studies.

Incomplete Compounding Records

68. Summers reviewed La Vita's compounding logs for its sterile injectable glutathione and methylcobalamin preparations. She opined that Givant documented her review and approval of the final drug preparations by placing her mark, a "C" or "CG" in various places throughout the logs. Based on her discussions with Givant and review of La Vita's processes, Summers is confident that Givant actually performed the verifications, but conceded that it could have been documented more clearly and consistently.

69. Summers also reviewed La Vita's separate unit tracking logs from which she was able to ascertain the total number of vials made in each lot of glutathione and methylcobalamin, and the number of vials of each lot that were sent for sterility and endotoxin testing. Additionally, Summers reviewed separate documentation provided by La Vita from which she was able to ascertain the applicable filter lot numbers and confirm that bubble point testing was performed on each of those filters.

70. Summers opined that La Vita was "mostly compliant" with recordkeeping requirements in that it did everything the spirit of the law requires. However, there was room for improvement in the clarity of its documentation. To that end, Summers made specific recommendations to create and/or update certain standard operating procedures (SOPs) and forms. Givant was enthusiastic about those recommendations and "immediately got on it."

Improper Quarantine

71. Summers opined that La Vita never dispensed any methylcobalamin prescriptions before end product testing results for sterility and endotoxins returned. She

based her opinion on a review of the respective dates on the Revised Dispensing Report. She also performed "spot checks" in La Vita's dispensing software of at least one prescription per methylcobalamin lot to verify the Revised Dispensing Report's accuracy.

Insufficient Training and Validation

72. Summers opined that La Vita was mostly, but not fully, compliant with respect to training and validation of CB's aseptic technique.

Summers found that La Vita's decision to only use 30 ml vials in the validation testing was supported by scientific justifications. She explained that a 30 ml vial has a larger opening, has a larger volume, and takes longer to fill. Consequently, it is more prone to the exposure to and culture of airborne particles or microbes than a smaller vial when proper aseptic technique is not used. Thus, the 30 ml vial constitutes a "worst case vial size"; if CB demonstrated competency with the 30 ml vial, she is also competent to compound with the 10 ml vial.

Summers also noted that maximum batch size or volume is not a definitive factor in creating a worst case scenario for purposes of validation testing. Other factors could be adding complex manipulations or having testing performed near the end of the work day to test the technician's limits. Nevertheless, she acknowledged that California law requires the validation testing to involve the same or greater amount of volume transferred during the compounding process.

73. Despite any minor testing non-compliance, Summers expressed confidence in CB's competence with respect to aseptic technique. She noted that CB successfully passed all testing.

Furnishing to Unlicensed Entity

74. Summers reviewed ATI's letter and its permits/registrations. She opined that ATI was properly licensed by the CDPH to transport medical waste for destruction, including non-controlled pharmaceutical waste such as the sterile injectable methylcobalamin preparations at issue.

75. Summers further noted that ATI was not acting as a reverse distributor that requires a license from the Board. She explained that a reverse distributor is "a type of company often utilized to obtain a refund from commercial wholesalers on unused expired drugs and/or for controlled drug returns." Instead, ATI here acted merely as a

medical waste transporter transporting non-controlled pharmaceutical waste for destruction.

76. Unprofessional Conduct (Givant Only). Based on Summers's foregoing findings, she opined that Givant did not engage in unprofessional conduct. Although there was room for improvement with respect to some of La Vita's documentation, Givant appropriately used her education, training, and experience as a pharmacist. Givant also exercised her best professional judgment with respect to compounding the sterile injectable glutathione and methylcobalamin preparations at issue.

Brief Overview of Analysis

77. As discussed in greater detail in the Legal Conclusions below, complainant established that La Vita's sterile injectable glutathione and methylcobalamin preparations were adulterated under federal and state law and also lacked quality. Complainant also established most of the remaining pled causes for discipline. When the record as a whole is considered, a four-year probation period for the pharmacy license and revocation of the sterile compounding permit is the appropriate discipline and is necessary to protect public health, safety, and welfare. Also, a four-year probationary period for the pharmacist license issued to Givant is also appropriate for the legal violations of the pharmacy and violations of her duty as pharmacist and the PIC of La Vita. Additionally, reasonable investigation and enforcement costs are awarded, as discussed below.

Costs

78. The Board may recover its reasonable investigation and enforcement costs of a case. (Bus. & Prof. Code, § 125.3, subd. (a).) Here, complainant incurred a total of $11,207.75 in investigation costs and $91,230 in enforcement costs, for a total of $102,437.75. The requested costs are supported by Certifications of Costs with attachments, setting forth the general tasks performed, the time spent on each task, and the method of calculating the costs. The requested costs constitute a very large sum. Nevertheless, they are reasonable given the numerous issues and extensive evidentiary record in this case, which required six days of hearing to present.

79. The ALJ determined that the total requested costs of $102,437.75 were reasonable. However, the ALJ also noted that it was necessary to consider whether reduction of costs would be appropriate under the factors articulated in *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32 (*Zuckerman*). The ALJ's weighing of the *Zuckerman* factors, and assessment of costs are addressed in the Legal

Conclusions below.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. Complainant bears the burden of proving by a preponderance of the evidence that cause exists to discipline La Vita's Pharmacy Permit and Sterile Compounding Permit. (*In the Matter of the Third Amended Accusation Against IV Solutions, Inc.*, Case No. 3606, OAH Case No. 2011050988 [designated as precedential pursuant to Government Code section 11425.60 on October 20, 2020].) The term preponderance of the evidence means "more likely than not" (*Sandoval v. Bank of Am.* (2002) 94 Cal.App.4th 1378, 1387) or "evidence that has more convincing force than that opposed to it" (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567).

2. Complainant bears the burden of proving by clear and convincing evidence that cause exists to discipline Givant's Registered Pharmacist License. (*Ettinger v. Bd. of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) "Clear and convincing evidence requires a finding of high probability. The evidence must be so clear as to leave no substantial doubt. It must be sufficiently strong to command the unhesitating assent of every reasonable mind." (*In re David C.* (1984) 152 Cal.App.3d 1189, 1208.)

Weighing of Expert Witnesses

3. The testimony provided consisted of opposing pharmacists as to the appropriate sterile compounding standards. The Board has weighed the testimony of Dr. Acosta more heavily than the testimony of Givant for the following reasons. First, Dr. Acosta is a Pharm.D with a higher level of education than Givant. Also, Givant as the owner and PIC of La Vita had both a bias and financial incentive to testify as she did and to protect her reputation. The Board also weighed the testimony of Dr. Acosta more heavily than Dr. Summers for the following reasons. Dr. Summers, as a hired expert witness for Givant and La Vita, had a financial incentive to testify as she did. Also, portions of Dr. Summers report and testimony to justify the compounding practices at issue in this case does not weigh in favor of viewing her as an expert on USP standards, federal or California law in sterile compounding, as discussed in greater detail in this decision

Causes for Discipline

4. Business and Professions Code section 4301 provides, in relevant part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct includes, but is not limited to, any of the following:
> […]
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
> […]
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
> […]

5. Complainant asserts 23 causes for discipline based on unprofessional conduct pursuant to Business and Professions Code section 4301, subdivisions (j) and (o). Those causes for discipline are based on several distinct issues concerning La Vita's sterile injectable glutathione and methylcobalamin preparations. Each issue, including the associated alleged violations and causes for discipline, is addressed separately below.

Issues Presented

6. The operative issues in this case concern USP standards for sterile compounding and how certain USP standards and FDA interpretations interrelate with the definitions of "adulterated" and "quality" under federal and state law. There was a lot of confusion in the proposed decision and asserted justifications by respondents in this case trying to justify the compounding standards at issue in this case based on the fact that glutathione and methylcobalamin were included as Category 1 substances by the FDA and hence "eligible drug ingredients" under the FDA's Bulk Drug Substances Interim Policy.[47] In a recent disciplinary case entitled *In the Matter of the Accusation Against Absolute Pharmacy dba Absolute Pharmacy LLC and Andreas Dieter Dettlaff, President*, Case No. 3606, OAH Case No. 2011050988 (*Absolute Pharmacy*), the Board considered a case in which the respondent compounded with substances that did not meet the definition of an

[47] *See* (n.17, *supra*.)

eligible drug ingredient. In *Absolute Pharmacy*, the respondents tried to justify their practices because they complied with some, but not all of the operative conditions in the Section 503A exemption, particularly the requirement to use eligible drug ingredients. In this case, the respondents are arguing the converse approach and trying to justify their compounding of these substances because the FDA listed both substances on the Category 1 list and therefore respondents' compounding complied with both federal and state law. Because there was significant confusion in the proposed decision regarding issues under the Section 503A Exemption, this decision deals with the Section 503A Exemption first.

Section 503A Exemption under the FDCA

7. The Section 503A Exemption provides an exemption from the new drug approval process (Section 505) the labeling of drugs with adequate directions for use (section 502(f)(1) and the requirement to comply with current good manufacturing practices for drugs compounded by state licensed pharmacists if all of the conditions in Section 503A are met.[48] As specified in Paragraphs 11-15 in the Background Section of this decision, one of the conditions is that the substance must be an eligible drug ingredient as defined under Section 503A(b)(1)(A)(i)) or on Category 1 in the FDA's Bulk Drug Substances Interim Policy. It is undisputed that both substances appear on the Category 1 list and hence although not "statutorily authorized drug ingredients" they are "eligible drug ingredients" under the FDA's Bulk Drug Substances Interim Policy.[49] Therefore, the Board assumes that they are eligible drug ingredients under Section 503A(b)(1)(A)(i).

However, another important condition of the Section 503A Exemption is that the compounding must comply with an applicable USP or NF drug monograph if one exists and the USP chapter on pharmacy compounding.[50] USP Chapter 797 imposes obligations on compounding personnel to ensure that ingredients have the proper purity. It also identifies that compounded sterile preparations are either contaminated or at a high risk to become contaminated if "nonsterile ingredients, including manufactured products not intended for sterile routes of administration (*e.g.* oral) are incorporated . . .."[51] In this case, at best respondents used dietary or ungraded ingredients without reference to an applicable drug monograph for sterile injectable products which means that the products

[48] *See* (Background Section, ¶¶ 11-15, *supra,* pp. 6-9.)
[49] *See* (Bulk Drug Substances Interim Policy, *supra*, n.17.)
[50] *See* (Section 503A(b)(1)(B).)
[51] *See* (Relevant USP Standards, *supra* ¶ 20, at pp. 10-11.)

were contaminated or at a high risk to become contaminated under USP Standards contained in Chapter 797. [52] Compliance with the USP chapters on compounding are incorporated into both federal and state law.

8. Respondents argued, and the proposed decision was based in part, on the fact that glutathione and methylcobalamin is presently authorized under "federal law." However, neither federal statute nor regulation authorizes the compounding of either substance under the Section 503A exemption as statutorily authorized drug ingredients.[53] Rather, the FDA, pursuant to the Bulk Drug Substances Interim Policy announced that, while it is evaluating the bulk substances nominated with adequate information for it to evaluate the substance it generally does not intend to take enforcement action if a bulk drug substance is listed in Category 1 of the FDA's website, provided that, among other conditions, the drug product is compounded in compliance with other conditions of Section 503A and the FDCA.[54] Generally, when an agency announces that it will exercise "enforcement discretion" that is a clear signal that the practice would be a violation of existing law or there would be no reason to issue guidance stating that the agency will generally exercise enforcement discretion. The only implied interpretation in an enforcement discretion policy statement is that in the absence of the statement, the practice would violate existing law. For this reason, it is unjustifiable to elevate an enforcement discretion guidance document to the status of an interpretation of governing federal law much less to the status of a "federal law."

9. Respondents have argued, and the proposed decision also based its decision on the fact that the FDA clearly understood that no drug monograph existed and placed both substances on Category 1 without any specific restriction as to the appropriate grading of starting bulk substances depending on the route of administration. Compliance with the condition to use only eligible drug ingredients, however, does not exempt compliance with all the other conditions under Section 503A, or the prohibition against the

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[52] *See* (Section 503A(b)(1)(B), codified at 21 U.S.C. § 353a(b)(1)(B).). The Board questions whether the respondents in this case breached the conditions for reliance on the Section 503A Exemption. Generally, if a compounder fails to qualify for the Section 503A Exemption, it loses the exemption from the new drug approval process, the requirement to comply with good manufacturing practices and the exemption from the labeling requirements under the FDCA as delineated in the Section 503A exemption. Because these additional charges were not pled in the Accusation or Second Amended Accusation, the Board does not reach a decision on whether additional counts would have been proven if pled in the Second Amended Accusation.

[53] The rule establishing the list of bulk substances that are eligible for compounding under the 503A exemption is codified at 21 C.F.R. § 216.23. Neither glutathione and methylcobalamin are listed in this regulation and therefore are not statutorily authorized drug ingredients.

[54] *See* (FDA's Bulk Drug Substances Interim Policy at pp.2-3, *supra* n.17.)

distribution of adulterated drugs.

Second, both respondents and the proposed decision seem to imply that the FDA's placement of these two substances on Category 1 had to mean something, and therefore the FDA must have intended compounders to be able to use any grade in compounding injectable drug products in the absence of any specific restriction in the enforcement discretion policy statement. The FDA, when approving bulk substances, can approve them for only certain uses or modes of administration. To date, the FDA has not approved any bulk drug substance for injection (all approved substances have been approved for topical use or as a dye for eye surgery). Acceptance of the respondents' position would mean that placement on the Category 1 list would bestow the widest allowance of sterile compounding practices that the FDA has not, to date, authorized for any of the substances it has specifically reviewed and approved for inclusion on the list of statutorily eligible drug ingredients. The FDA would undoubtedly find such a proposition alarming. Also, the bulks list applies to both nonsterile and sterile compounding, and placement on the lists would permit pharmacists to compound nonsterile oral drugs using dietary grade ingredients at issue in this case, if all the other conditions of federal law and USP standards were met, including that the pharmacist verify by examination, and not assume, that the labelling and documentation received aligned with the standards of the appropriate USP dietary monograph.[55] Therefore, the FDA's placement of both substances on the Category 1 list did have effect – just not the effect respondents wished that it did.

10. The proposed decision also seemed to rely upon the fact that the FDA did not specifically limit compounding with Category 1 substances to an appropriate grade substance depending on its route of administration. However, the requirements to use appropriately graded ingredients are included in USP standards that Congress specifically incorporated into federal law as a requirement for the Section 503A Exemption. The FDA's interpretations of insanitary conditions that could render a drug adulterated flow, in large part, from the USP standards and how that interacts with the statutory definition of adulterated that the FDA is entrusted to administer. There is no requirement that the FDA reiterate prohibitions under other provisions of the FDCA that are not impacted by whether the FDA expanded the list of eligible drug ingredients in an enforcement discretion policy statement solely applicable to that prong of the Section 503A Exemption.

[55] *See* (Relevant USP Standards, ¶ 20, p. 10-11, *supra*.)

ADULTERATION (SECOND, SIXTH, TENTH, AND SEVENTEENTH CFDS)

11. Complainant asserted two distinct reasons why La Vita's sterile injectable glutathione and methylcobalamin preparations were adulterated and lacked quality: (a) La Vita used dietary grade or ungraded bulk drug substances; and (b) regardless of the grade, the bulk drug substances used contained specified contaminants and impurities.

(a) Use of Dietary Grade/Ungraded Bulk Drug Substances

12. Complainant argued that La Vita's sterile injectable glutathione and methylcobalamin preparations were adulterated because they were compounded with dietary grade or ungraded, as opposed to drug or pharmaceutical grade, bulk drug substances. In fact, it is uncontroverted that the glutathione and methylcobalamin injectable preparations were compounded using either "ungraded" or dietary grade bulk substances from 2018 until 2020. Dr. Acosta testified persuasively that there are different grades for substances dependent on their use. Dr. Acosta testified persuasively that dietary grade bulk substances mean that they may meet USP dietary monographs[56] which are suitable only for oral administration. The term "ungraded" substance means that the substance was not graded and therefore it is unknown, what if any specific standards they meet. Therefore, in the compounding industry, pharmacists generally use only pharmaceutical grade bulk product. However, under USP standards, pharmacists cannot merely rely on the grade listed on the bulk substances and must directly examine the labeling and ensure that the standards on the label meet the applicable USP drug monograph.

13. The ALJ determined that the complainant failed to prove this point because of the failure to point out any specific federal or state statute that specifically prohibited such compounding. The Board disagrees with the reasoning in the proposed decision as expressed in this decision.

(1) Federal Law

14. Under federal law, Section 301(a) of the FDCA prohibits among other things, "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded."[57] Section 501(a)(1) and (2) of the

[56] USP standards also require that the compounder not assume and must verify by examination of labeling and documentation that the chemical purity meet their compendial specifications and compare against the applicable USP monograph.

[57] (codified at 21 U.S.C. § 331(a).)

FDCA defines adulterated and states, in pertinent part, that:

> A drug or device shall be deemed to be adulterated –
>
> (a) Poisonous, insanitary, etc., **ingredients,** adequate controls in manufacture
> (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or
>
> (2) (A) if it has been prepared, packed or held under insanitary conditions whereby it **may** have been contaminated with filth, or whereby it **may** have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . .. (emphasis added).[58]

15. As stated earlier, USP Chapter 797 imposes obligations on compounding personnel to ensure that ingredients have the proper purity. It also identifies that compounded sterile preparations are either contaminated or at a high risk to become contaminated if "nonsterile ingredients, including manufactured products not intended for sterile routes of administration (*e.g.* oral) are incorporated . . .." USP is aware of the operative standards in federal drug law. Thus, if a compounded sterile product is either contaminated or at a high risk to become contaminated if nonsterile ingredients not intended for sterile routes of administration are incorporated, it would meet the statutory definition of adulterated in Section 301(a)(2) that the preparation may have been contaminated with filth or may have been rendered injurious to health. This condition identified in the USP standards is due to the scientific and medical reasoning provided by the FDA in the 2019 Bulk Substances Adopting Release and related to the FDA's interpretation that Section 503A requires an applicable drug monograph. The Board interprets this USP standard in relation to the statutory definition of "adulterated" and that the use of ingredients not appropriate for the mode of administration means that they are adulterated under federal law.

[58] (codified at 21 U.S.C. § 351(a) & (2).)

16. The FDA has also issued guidance interpreting these sections of the FDCA in its Insanitary Conditions Guidance.[59] In the 2018 Revised Guidance and the 2020 Final Insanitary Conditions Guidance, the FDA identified one insanitary condition as "[u]sing active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendia or pharmaceutical grade equivalents (*e.g.,* ingredients with potentially harmful impurities, ingredients labeled with 'not for pharmaceutical use" or with an equivalent statement)."[60] Drugs prepared under insanitary conditions "are deemed to be adulterated under federal law, regardless of whether the drugs qualify" for the 503A exemption.[61] This example of an insanitary condition is stating in slightly different words the same USP standard that incorporating ingredients not intended for sterile mode of administration is either contaminated or at a high risk to be contaminated.

The scientific and medical reasons why using inappropriate grade starting bulk materials was discussed at length by the FDA in the 2019 Bulk Substances Adopting Release and the 2016 Proposing Release for this rule and emanates from the different regulatory schemes governing foods (consumed orally) and sterile drug products.[62] It also is reflected in the USP standards applicable to sterile compounding.

17. The ALJ correctly noted that the FDA's Insanitary Conditions Guidance is not federal law, and therefore apparently gave it no weight in the decision. However, the FDA's Insanitary Conditions Guidance represents an interpretation of a statutory provision in the FDCA that the FDA is entrusted by Congress with administering, enforcing and interpreting. The FDA was interpreting Section 301(a)(2) of the FDCA and the header of subparagraph (a) includes the word "ingredients." Therefore, the FDA was interpreting what Section 301(a)(2) meant in relation to the use of ingredients in the compounding process and notifying industry participants, like Givant, that the FDA was interpreting this section in this manner using such ingredients would put compounders at risk for violating the prohibition against the distribution of adulterated drugs.

18. Under established federal judicial doctrines, an interpretation of the agency of the statute it is entrusted to administer is entitled to different forms of judicial

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[59] *See* (Insanitary Conditions Guidance, n.30 and n.31, *supra*.)
[60] (*Id.* at p. 5.)
[61] *See* (2016 Insanitary Conditions Guidance at p.2, n.30, *supra*; 2018 Insanitary Conditions Guidance at p. 1, n.31, *supra*; 2020 Insanitary Conditions Guidance at p. 1, n.31, *supra*.)
[62] *See* (n.31, *supra*.)

deference under either the Chevron deference standard[63] or the Skidmore[64] deference standard established in U.S. Supreme Court precedents.

19. Under the Chevron deference doctrine, the U.S. Supreme Court established a test for determining whether to grant deference to a government agency's interpretation of a statute which it administers. Whether to grant Chevron deference to a federal agency's interpretation is determined by reference to a two part analysis. If the statute is clear then no deference is given as courts must give effect to the unambiguous intent of Congress. However, if the court determines that Congress has not directly addressed the precise question and the statute is silent or ambiguous with respect to the specific issue, the court then determines if the agency's interpretation is reasonable and a permissible construction of the statute. If the agency's interpretation is reasonable and a permissible construction of the statute then the court does not impose its own construction of the statute but will give deference to the agency's interpretation.

At issue in this case are two FDA interpretations: 1) whether the Section 503A exemption requires a USP drug monograph in its various conditions; and 2) the FDA's identification of using inappropriate grade bulk substances for the mode of administration is an insanitary condition rendering the product adulterated under the FDCA. Section 503A refers to an "applicable" USP monograph. Because of the different types of USP monographs available, the statute is silent or ambiguous on the first point and the FDA was within its power to interpret the statute it is entrusted to administer. Also, the FDA's announcement of its interpretation that Section 503A conditions require compliance with a USP drug monograph was announced in connection with rulemaking under the FDCA establishing the criteria it would use in evaluating such bulk substances and identifying certain substances for inclusion or inclusion. Under federal law, rulemaking must be conducted with notice and comment, and the FDA's explanation for why it interpreted "applicable" monograph the way that it did was in response to a comment to the proposed rule and the FDA must respond to comments submitted. Generally, agency rulemaking determinations, subject to notice and comment, is virtually assured eligibility for Chevron deference.[65] Therefore, the Board finds that the FDA's interpretations in the 2016 and 2019 Bulk Substances, are entitled to Chevron deference and the references to an applicable USP or NF monograph in the sterile compounding area (intended for injection) means a USP or NF drug monograph.

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[63] *See* (*Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 104 S.Ct. 2778 (1984).

[64] (*Skidmore v. Swift Co.*, 323 U.S. 134 (1944).)

[65] *See e.g.*, (*Tibble v. Edison Intern.*, 729 F.3d 1110 (9th Cir. 2013).)

In the Insanitary Conditions Guidance, based on its observations during numerous inspections, the FDA announced an inexhaustive list of examples of things that would be considered examples of insanitary conditions and therefore render a product adulterated under Section 301(a)(2) of the FDCA. The FDA has the power to interpret and administer the FDCA. Section 301(a)(2) is silent as to examples of what constitutes insanitary conditions with respect to the use of ingredients and therefore the FDA has the authority to interpret this statute. The FDA also has published Insanitary Conditions Guidance for public comment in 2016, 2018 and again in 2020 and has amended the Guidance in response to those comments. Although the FDA did not issue this interpretive guidance in the context of rules destined for the Code of Federal Regulations, federal courts have given Chevron deference to agency interpretations outside of specific rulemaking.[66]

Other factors that weigh into whether to accord Chevron deference to an agency position include the consistency of the agency's position, the complexity of the statute and the special expertise of the agency entrusted to administer it and whether the question is of central importance to the administration of the statute.[67] Another reason to afford this interpretation by the FDA Chevron deference is that it is also contained in the USP standards, and compliance with USP standards are incorporated into various statutory provisions of the FDCA, including the Section 503A Exemption demonstrating consistency of the interpretation with other provisions of law. Also, this interpretive position also flows out of, and is consistent with, the scientific reasons underlying the FDA's interpretation of why a drug monograph is required under provisions in the Section 503A. Thus, the interpretation is intertwined with the FDA's other interpretations that would be afforded Chevron deference. Finally, the FDA's interpretation that the appropriate grade of ingredient must be used for the mode of administration is central to the regulatory construct to prevent patients from being exposed through injection to levels of residual contaminants that could cause patient harm.

20. Skidmore deference is a less deferential standard than Chevron deference. However, under Skidmore deference, a court may give deference to an administrative agency's interpretations as "a body of experience and informed judgment" that the courts may use for guidance. Courts can give deference to agency interpretations due to an agency's expertise and technical knowledge. Because identification of insanitary conditions is dependent on highly technical medical and scientific knowledge of the risks associated with different modes of drug administration and based on extensive

[66] (*Tibble v. Edison Intern.*, 729 F.3d at 1122-1123 (noting that there is no authority for "cabining" [the Chevron deference doctrine] to materials destined for the pages of the Code of Federal Regulations.")
[67] (*Id.*)

observations of the FDA during inspections, the Board also finds that courts would give, at a minimum, Skidmore deference to the FDA's Insanitary Conditions Guidance because it is highly technical, consistent with other FDA interpretations regarding the difference between drug and dietary monographs to assess the purity of sterile compounded products and also is required under USP standards that Congress incorporated into various provisions of the FDCA.[68]

21. Finally, the FDA issues its guidance documents pursuant to a regulation governing good guidance practices. (Good Guidance Practices, 21 C.F.R. §10.115.). This regulation specifies that you may use an alternative approach other than one set forth in a guidance document provided that, it complies with all relevant statutes and regulations. Because using inappropriate grade ingredients for the mode of administration cannot comply with statutory provisions of the FDCA incorporating USP standards, there is no alternative approach that will comply with statutory provisions. Finally, this regulation also states that the "FDA is willing to discuss an alternative approach with you to ensure that it complies with relevant statutes and regulations." (21 C.F.R. § 10.115(d)(2).) Because Givant seemed to be unaware of the USP standards and FDA interpretations, it is unlikely she could have exercised this option. If she had consulted the FDA or its website with extensive guidance in these areas prior to compounding sterile drug products with non-pharmaceutical grade drug ingredients, she would have received the general education in this area before respondents ended up with notices of violations and warning letters and observations from the FDA.

22. Also, the Board agrees with the FDA on its reasoning why non-pharmaceutical grade product is not appropriate for use in sterile compounding. For all these reasons, the Board finds that the FDA's identification of an insanitary condition as including "[u]sing active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendia or pharmaceutical grade equivalents (*e.g.,* ingredients with potentially harmful impurities, ingredients labeled with 'not for pharmaceutical use" or with an equivalent statement)" would be given deference by the federal courts.

23. The FDA's interpretation governing the importance of using the appropriate grade products for the mode of administration has been in existence since at least 2016.

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[68] California courts have utilized both Chevron and Skidmore deference doctrines in determining cases in California. *See* (*Yamaha Corp. v. State Bd. of Equalization,* (1998) 19 Cal.4th 1 (1998) (discussing Skidmore deference doctrine in relation to interpretation of agency annotation under California law); *see also* (*Wisner v. Dignity Health*, (2022) 85 Cal.App.5th 35, 47.)

Further the FDA's specific interpretation identifying using an inappropriate grade bulk ingredient as an insanitary condition, rendering the product adulterated, was published initially in 2018. Also, because these FDA interpretations were put out for notice and comment in the Federal Register, the respondents were on constructive notice of the FDA's interpretations in these areas before and during the time that respondents compounded the injectable drugs at issue in this case.

24. Because the proposed decision did not break out the analysis under federal law and California law separately, this decision will address the issues raised in the proposed decision or by the respondents by whether the Board believes that it applies to the federal or state law analysis.

25. Respondents' justifications for compounding using dietary grade and ungraded bulk materials have changed over time. Givant, in her first response to the notice of violation dated July 3, 2019 from Dr. Acosta regarding using dietary grade bulk substances to compound glutathione sterile preparations, indicated that she had received the Board subscriber alerts about compounding with dietary grade bulk sources and stated, "[i]n this Compounding Safety Alert sent on January 11, 2019 that "there was no mention of a USP Drug Monograph vs. a USP Dietary Monograph." (Ex. 31 at p. A325.) Later in the response, Givant also mentioned that the Drug Quality and Security Act does not state USP Drug Monograph but simply USP monograph." (*Id.* at p A326.) Givant's initial response to the 2019 notice of violation demonstrates that she was completely unaware of the FDA's interpretations in this area, and the operative standards in USP Chapter 797 that also identifies using inappropriate starting ingredients in a sterile compounded drug product as either contaminated or at a high risk of being contaminated.[69]

The Board finds that Givant's ignorance of the FDA interpretations in this area dating back, at least to 2015, both appalling and alarming particularly since the importance of the grade of the starting ingredients in a sterile product also are echoed in USP Chapter 797 governing sterile compounding that are minimum standards in California and under the Section 503A Exemption. These materials and other guidance in this area also are available on the FDA's website.[70] The industry also has been on notice since the 2012 fungal meningitis outbreak, that practices and standards in this industry were changing rapidly, and needed to change, as exemplified by the passage of the DQSA.

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[69] *See* (¶¶ 20 and 21, Background, Relevant USP Standards, at pp. 10-11, *supra*.)

[70] *See* (Human Drug Compounding | FDA, located at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.)

Givant's ignorance of developing FDA interpretations of the FDCA since 2012 and the USP standards is inexcusable.

Perhaps to soften the impact of Givant's blatant failure to keep abreast of federal law in this area, Dr. Summers in her testimony stated that as far as she knew "there was no standard of practice or requirements for pharmacists to keep up" with the notices in the Federal Register. (RT IV at p. 31.) Under California law, however, the PIC is responsible for ensuring a pharmacy's compliance with all applicable law, including operative federal law.[71] Operating in a highly regulated industry means that the costs of operations frequently include legal and compliance costs. Another cost of business of operating a nonsterile or sterile compounding business in California is a subscription to the USP service or obtaining access to the USP services through a knowledgeable consultant, and the ability to use and understand those services. Finally, as a co-owner of La Vita, Givant had the power to retain the necessary legal and compliance assistance and did not do that until after the Accusation was filed. Under California law, Givant, as the PIC, was responsible for ensuring compliance with operative federal law and she failed in that responsibility.

Givant also tried to justify the compounding of these substances based on the failure of Board inspectors to tell her that compounding with glutathione and methylcobalamin were not allowed. However, compounding with both substances is allowed under federal law if the proper grade ingredients for the mode of administration is used. Thus, respondents could have used the dietary grade in nonsterile compounding to create oral drugs if they complied with all USP standards and federal and state law. The FDA's issuance of Insanitary Conditions Guidance in 2016, 2018 and 2020 also were general education in this area. Finally, the evidence showed that the Board sent out compounding safety alerts to licensees two times in 2019 while respondents were compounding using dietary and ungraded bulk substances. Although communications to licensees are not law, they did represent education on the subject that Givant should have reviewed and then used her professional knowledge to apply to respondents' own compounding operations.

Also, neither the Board nor the FDA are responsible for providing free legal advice to licensees engaged in sterile human drug compounding to their specific business

[71] *See* (Bus. & Prof. Code § 4036.5 (defining pharmacist-in-charge as the person "person responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."); *see also* (Bus & Prof. Code § 4113(c) (the PIC "shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.")

operations. The PIC is responsible for ensuring compliance with all applicable law, including federal law. Licensees waiting for regulators to educate them on operative law applicable to their specific operations will frequently find that education comes in the form of disciplinary actions, fines and citations or warning letters or other actions by the FDA. The Board finds equally troubling that Givant failed to apply both the safety alerts sent by the Board and the education and the 2019 notice of violation received from Dr. Acosta regarding using inappropriate dietary grade bulk substances in compounding an injectable glutathione preparation to the compounding La Vita continued to do with respect to the use of ungraded methylcobalamin until the joint inspection in 2020 by the FDA and the Board. All of these lapses were inexcusable.[72] Finally, pharmacists are highly educated health care providers with specialized knowledge with respect to interactions of drugs and also the impact that contamination in drugs can have on patient's health.

26. The Proposed Decision was also based on the premise that there was no federal rule or statute that specifically prohibits compounding with dietary grade or ungraded ingredients. For the reasons reiterated previously, this requirement is established in USP standards which are incorporated both into federal and state law. Therefore, the Board believes that the requirement is spelled out in federal statute. Moreover, the FDA also has consistently interpreted statutory provisions under the FDCA to prohibit compounding using ingredients that are not appropriate for the mode of administration and the scientific and medical reasons were spelled out by the FDA in the 2019 Bulk Substances Adopting Release. Because the FDA's interpretations are entitled to Chevron and/or Skidmore deference, the Board finds this attempted justification unpersuasive under federal law. Also, the Board disagrees with the premise that every specific prohibition must be spelled out in a statute or a rule. Our judicial system is rooted in common law, and many important propositions, including prohibitions, are established by judicial interpretation of the governing statutes or regulations in the context of specific cases, including enforcement cases. Judicial interpretation also is particularly appropriate when Congress has enacted broad prohibitions. This decision will address the underground regulation issue under its analysis of the relevant California law.

27. Although not specifically raised by the respondents in the argument to the Board, the amicus curiae brief filed as argument before the ALJ raised an argument that the Board's failure to adopt a rule could have a chilling impact by causing compounders to

[72] It is important to note that pharmacists are highly trained health care professionals with specialized knowledge in the use of drugs to treat health conditions and also the impact that contamination can have on both a drug's efficacy and safety. The Board is not expecting consumers to understand these points which is why it is imperative that pharmacists exercise their specialized knowledge and experience to compound sterile drug products in full compliance with USP standards, and applicable federal and state law.

stop filling "valid prescriptions." (Ex. XX, p. B1271.) The Board is unsure but believes this argument is intended to raise as a defense that a doctor's decision to prescribe these substances for injections justifies compounding injectable drugs using inappropriate graded materials in violation of USP standards and federal and state law. However, as the Board covered in the recent decision in *Absolute Pharmacy*, the authority to approve a new drug or the bulk substances eligible for compounding resides solely and exclusively with the FDA. The FDA squarely addressed this issue in the 2019 Bulk Substances Adopting Release when it finalized the criteria it would use in evaluating bulk substances for inclusion on the 503A bulks list. One commenter objected that the proposed rule infringed on the practice of medicine and overregulated physicians' choices of ingredients that can be used in compounded drug products. In response to this comment, the FDA stated that:

> The [FDCA] established the framework for regulating the drugs that physicians may prescribe. Within this framework, once a drug becomes legally available, with certain limited exceptions, FDA does not interfere with physicians' decisions to use it when they determine that in their judgement it is medically appropriate for their patients. This Agency believes that this rule is consistent with this framework and does not overregulate.[73]

Thus, the FDA has the sole power to determine whether methylcobalamin and/or glutathione will be approved for injection and can establish other conditions, if warranted, such as dosage or duration of treatment limits. If the FDA approves either substance for injection, it will then be up to USP to establish the appropriate drug monograph for the substance that will undoubtedly take into account the duration of treatment approved by the FDA in the approved uses. Thus, physicians and pharmacists do not have the right to substitute their personal opinion as to the safety, effectiveness or legal availability of bulk drug substances to be used as drugs or lawful ingredients in compounded sterile drugs sold or distributed in the United States. That determination resides solely with the FDA. Also, when the FDA reviews or evaluates new substances, and when USP establishes new monographs, both processes are open for notice and comment from the entire scientific and medical community, as well as other interested stakeholders, and comments received from the entire community can be evaluated and taken into consideration in the final determinations reached.

[73] (2019 Bulk Substances Adopting Release, 84 Fed.Reg. at p. 4707, *supra* n.17.)

28. Finally, arguments have been made that the Board has no ability to enforce the FDCA as the enforcement of the FDCA resides solely with the FDA. Section 337 of the FDCA requires that to enforce or to restrain violations of the FDCA shall be by and in the name of the United States, except for certain state actions[74] Subdivision (o) of Section 4301 of the Business and Professions Code[75] authorizes the Board to take disciplinary actions against licensees for violation of applicable state or federal law. California courts have long upheld the Board of Pharmacy's ability to predicate discipline under this statutory section.[76] In this case, the Board is not seeking to enforce or restrain violations of the FDCA. Rather the Board is enforcing its own licensing laws that effectively establish compliance with relevant federal law as a minimum requirement to maintain licensure.

In California, pharmacies and pharmacists operate in a regulatory landscape that includes compliance with both applicable federal[77] and state laws. The prohibition against the distribution of adulterated drugs is prohibited under both state and federal law. The California Legislature had determined that disciplinary actions could be undertaken under Subsection (o) of Section 4301 of the Business and Professions Code for "violating or attempting to violate . . . applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency." The Board is not aware of any federal or state appellate decision invoking Section 337 to deny a State licensing Board the ability to discipline a license or permit issued to a pharmacist or a pharmacy.[78]

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[74] (21 U.S.C. § 337(a).)

[75] Section 4301(j) and (o) of the Business and Professions Code authorizes the Board to institute disciplinary action for violations of applicable state or federal law.

[76] *See, e.g.,* (*Banks v. Board of Pharmacy,* (1984) 161 Cal.App.3d 708, 715.)

[77] For example, pharmacies and pharmacists must comply with rules of the Drug Enforcement Agency in the handling of controlled substances and other requirements established in the FDCA and the Board has disciplined licensees for violations of those laws as well as specific California laws.

[78] The Board is aware of two 9th Circuit decisions interpreting this section in the context of a private party seeking to use a violation of the FDCA in a tort action against another private third party. *See, e.g.*, (*Perez v. Nidek Co., LTD* (9th Cir. 2012) 711 F.3d 1109) (involving private party claims in medical devices area and fraud on the FDA in a failure to warn case); *see also* (*Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.* (9th Cir 2022), 48 F.4th 1040) (owner of approved drug sued outsourcing facilities for damages for compounding essentially copies of its approved drug allegedly in violation of the FDCA). Both of these cases involved private parties trying to assert claims against other private parties based on alleged violations of the FDCA. In *Nexus Pharmaceuticals*, the 9th Circuit also noted that the FDA has indicated that it intends to issue "clarifying regulations on what 'essentially a copy' means that was a central issue to the private right seeking to be enforced. (*Id.,* 48 F.4th at p.1050). The Board does not believe that those cases are controlling as they do not address the ability of a state to predicate discipline on licensure on violations of the FDCA if disciplinary action is authorized under applicable state licensing laws. Article 3, Section 3.5 of the California Constitution generally prohibits an administrative agency from declaring that state statutes are

Although the FDA has significant enforcement tools, including the right to seek injunctions, recalls and have the federal government institute criminal proceedings in appropriate cases, the FDA does not have the ability to either issue, discipline or revoke pharmacist's licenses to practice pharmacy or pharmacy licenses or sterile compounding permits issued by a state. The power to issue and discipline such licenses and permits resides solely with the States that issue them. Also, although the FDA has jurisdiction to inspect or take action against any person violating the FDCA, including compounding pharmacies or individuals who violate the FDCA, the FDA has limited resources to comprehensively inspect and oversee the activities of all compounding pharmacies.[79] The FDA has stated that "States are primarily responsible for day-to-day oversight over the vast majority of the thousands of compounders in the United States, most of which do not register with FDA. State officials are often the first to identify compounders that are operating like conventional manufacturers or that engage in poor drug production practices that could lead to patient harm. It is critical that FDA and the states continue to work together to identify and take appropriate action against compounders whose practices present the greatest risk to public health."[80] The FDA also has recognized that state regulatory actions, as the primary regulators of compounding pharmacies, can take complementary state regulatory action. For example, in its Insanitary Conditions Guidance the FDA stated:

> However, compounding facilities that are not registered with FDA as outsourcing facilities are primarily overseen by the states and, as explained above, generally are not routinely inspected by the FDA. FDA strongly encourages state regulatory agencies to assess during inspections whether compounding facilities that they oversee engage in poor practices, including those described below. Where insanitary conditions are identified, FDA encourages states to take appropriate action, consistent with state laws and regulations, and to contact FDA.[81]

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unconstitutional (including based on preemption) unless an appellate court has declared the statute unconstitutional. Thus, in the absence of an appellate court opinion directly on point, the Board will enforce the statutes enacted by the State of California.

[79] *See* (*Wyeth v. Levine, (*2009) 555 U.S. 555, 578-579 (noting in preemption analysis "the FDA has limited resources to monitor the 11,000 drugs on the market as justification for traditionally regarding tort law as complementary to FDA regulation).) *See also* (Insanitary Conditions Guidance, *supra* n.30 at p. 3.)

[80] (Food & Drug Adm., Compounding Information for States (Compounding Information for States | FDA,located at https://www.fda.gov/drugs/human-drug-compounding/compounding-information-states).)

[81] (Insanitary Conditions Guidance at p. 3., *supra* n.30.)

29. For all of these reasons, the Board finds that complainant established that La Vita's sterile injectable glutathione and methylcobalamin preparations were adulterated under federal law.

(2) California Law and Analysis

30. Unlike the FDA, the Board of Pharmacy has not issued interpretive guidance in this area in the form of regulations. In the absence of regulations or guidance in the form of Frequently Asked Questions, the Board generally announces its interpretations of relevant pharmacy law in the context of disciplinary actions raising specific facts to interpret the California pharmacy law it is entrusted to administer and enforce by California statute.[82] Consistent with Dr. Acosta's testimony, in the U.S., there are different grades of products, including, among others, dietary grade, feed grade, animal food grade and pharmaceutical grade. Although these terms are not defined in specific regulations or statute, they are common industry terms that arise from the different regulatory constructs and requirements, and the risks associated with how those substances are administered or consumed. Sterile compounding pharmacists generally compound sterile products using only pharmaceutical grade product. The term ungraded also is a common pharmaceutical term and it means that the product has not met any specific standards of any type of USP monograph.[83]

31. Similar to federal law, under California law, "[a]ny drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance." (Health & Saf. Code, § 111250.) "Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it **may** have been contaminated with filth, or whereby it **may** have been rendered injurious to health." (Heath & Saf. Code, § 111255) (emphasis added.) There are no further regulations defining adulterated drugs.

32. California law also establishes compliance with USP compounding standards as minimum operating procedures for compounded human drug products in California. USP standards state that compounded sterile preparations compounded under certain

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[82] See (Bus. & Prof. Code § 4001(a) establishing the Board to administer and enforce pharmacy law.)

[83] The Board also notes that the FDA has issued warning letters to other compounding pharmacies, including La Vita for the use of "ungraded" bulk substances. *See* (Food & Drug Adm.. Warning Letter to ImprimisRX CA, Inc., dba ImprimisRX at p.3 (Mar. 26, 2019) (located at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/imprimisrx-ca-inc-dba-imprimisrx-541375-03262019.); *see also* (Food & Drug Adm., Inspection Observation Letter to DA La Vita Compounding Pharmacy (May 11, 2020) (located at https://www.fda.gov/media/137497/download, La Vita Compounding Pharmacy, LLC, San Diego, CA. 483 issued 03/11/2020 (fda.gov).)

conditions are either contaminated or at a high risk to be contaminated, including use of nonsterile ingredients, including incorporating manufactured products not intended for sterile routes of administration (*e.g.,* oral).[84] If a product is either contaminated or at a high risk to be contaminated under USP standards, it necessarily follows that the drug product has been "produced or prepared" whereby it **may** have been contaminated with filth or **may** have been rendered injurious to health within the meaning of Section 111255(a) of the Health and Safety Code. Generally, the word "may" indicates a possibility as compared to using the words "shall or must" which would indicate a requirement.[85] Therefore if there is a possibility that a drug product produced may have filth or may have been rendered injurious to health then it would be "adulterated" under California's definition. In the instant case, because the COAs for both substances clearly stated that they were dietary grade or "ungraded" [86] and because there was no drug monograph for the pharmacist to assess whether the residual contaminants listed on the COAs was appropriate for injection, neither dietary grade bulk products nor ungraded bulk substances should have been used to prepare sterile compounded drug products.

33. The Board's interpretation is reasonable due to the statutory definition of adulterated and USP standards for sterile compounding in Chapter 797 that are minimum operating standards in California. The Board also notes that it is reasonable to interpret these California statutory requirements, at a minimum, consistently with the FDA's interpretation based on the similarity in the statutory language and because interpreting California requirements more leniently could give licensees the false impression that compliance with California law would mean compliance with all applicable law, including federal law. Such an interpretation also would not give effect to the statutory provision authorizing the Board to institute disciplinary action against licensees for violations of federal law, which in essence establishes compliance with applicable federal law as a minimum requirement to avoid discipline against licenses and permits issued by the State of California.

34. USP standards also states that if compounded sterile drug products are compounded under conditions "where it is assumed, and not verified by examination of the labeling and documentation from suppliers or by direct examination that the chemical purity and content strength of ingredients meet their original or compendial

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[84] *See* (¶¶ 20 and 21 of Background Section, USP Standards, at pp.10-11.)

[85] See (May Definition & Meaning - Merriam-Webster, (located at https://www.merriam-webster.com/dictionary/may.)

[86] As stated in the *Absolute Pharmacy* decision, the Board interprets grading or wording on bulk substance COAs that refer to a non-pharmaceutical grade or that contains no grade description as the functional equivalent of stating that they are not appropriate for sterile compounding.

specifications" that the resulting compounded drugs are either contaminated or at a high risk to become contaminated.[87] In this case, the evidence established that Givant was completely unaware that the COAs from Medisca for the methylcobalamin bulk substances used were ungraded.[88] Therefore, Givant's admission that the COAs for the methylcobalamin received from Medisca were not reviewed establish that the methylcobalamin compounded from at least October 3, 2019 until January 27, 2020 was compounded under a condition where Givant assumed, but did not verify by direct examination or comparison to an appropriate USP monograph was appropriate for sterile compounding demonstrates an independent ground under USP standards and California law that those specific lots were adulterated. In fact, the Board questions, given Givant's ignorance of the importance of the grade of the starting ingredients whether Givant ever exercised her professional judgment to evaluate the COAs upon receipt and instead viewed receipt of those COAs as a mere formality on a bureaucratic checklist. For both of these reasons, the complainant established that the glutathione and methylcobalamin drug products also were adulterated under California law.

35. The ALJ determined that the complainant failed to prove this point because of the failure to point out any state statute or regulation that specifically prohibited compounding with dietary grade or ungraded bulk products. However, as stated earlier, this requirement is incorporated in the USP standards and compliance with those standards are minimum requirements under California law. Therefore, the Board believes that this requirement is incorporated into California statutory requirement under Business and Professions Code section 4126.8.

However, the proposed decision was based largely on the premise that requiring that licensees compound with an appropriate grade starting ingredient must be done via a very specific statutory provision, regulation or rule, and therefore the complainant's attempt to impose such a general rule amounted to an underground regulation in violation of California law. The Board disagrees. The Board understands that rules and regulations must be adopted in compliance with California's Administrative Procedures Act. However, under California case law, an agency's interpretation of a statute in the course of case-specific adjudication is not a regulation.[89] As detailed in the preceding paragraphs, the Board is interpreting the specific statutes applicable to the definition of an

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[87] *See* (Relevant USP Standards, ¶¶ 20-21, p. 10-11, *supra*.)

[88] In response to the FDA inspection conducted, the Establishment Inspection Report prepared by the FDA stated that "[t]he use of these materials was primarily due to a lack of review of incoming COA details at the time of receipt." (Ex. PP at p. Z162; *see also* (RT II at p. 198) (FDA inspector testified to the statement in Exhibit PP and confirmed it was made by Givant.)

[89] *See* (*Tidewater Marine Western, Inc. v. Bradshaw*, (1996), 14 Cal.4th 557, 571.)

adulterated drug under California law in the context of this case and the sterile products compounded by these respondents and the COAs applicable to the bulk products used. The application of whether a particular grade of product was appropriate for the mode of administration will be dependent on the type of compounding performed (sterile or nonsterile) and whether the COAs for those bulk products contained residual contaminants that could cause patient harm depending on the mode of administration.[90] The Board also is interpreting USP standards that are incorporated into both California and federal law.

The Board believes that what the respondents and some other industry participants are really advocating is that the Board must identify in a rule every possible way in which a drug product could be adulterated before the Board can discipline a licensee for a violation of these California law prohibitions. In short, some industry participants want a determination that pharmacists can do anything not expressly and specifically identified and prohibited in a rule or statute without having to use their professional judgment. This is similar to one of the arguments made in *Absolute Pharmacy* that each prohibition must be spelled out in a rule. However, requiring the Board to try to anticipate every potential condition that could render a drug adulterated and put it into a rule before enforcement was possible would leave regulatory gaps that would be inconsistent with the broad prohibitions contained in the Health and Safety Code adopted by our elected officials. This argument also ignores the fact that our judicial system is rooted in common law and courts have established specific requirements and legal propositions by their interpretation of statutory language by reference to specific conduct in a given case.[91] Similar to the area

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[90] For example, if COAs accurately reflected all ingredients in the substances and showed no residual contaminants that could be harmful to patients depending on the mode of administration, the Board is generally not going to institute disciplinary action even if the bulk substance lacked a specific grade to it unless the governing law changes. In contrast, a general rule of application such as requiring a specific label including the grade on each bulk substance prior to use would be a general rule of application that would need to be adopted by regulation.

[91] For example, pharmacists have a duty of corresponding responsibility under Health & Safety Code § 11153(d) that a prescription for controlled substances is issued for a legitimate medical purpose. The duty of corresponding responsibility has not been further defined by regulation. Rather, the contours of a pharmacist's duty of corresponding responsibility have been developed judicially in case law dating back decades when reviewing specific Board of Pharmacy decisions. *See*, *e.g.* (*Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App 3d 19.) Currently, under a precedential decision, certain red flags have been identified that could show that a prescription may not be for a legitimate purpose. (*In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran, Case No. 3802; OAH No. 2011010644, Precedential Decision No. 2013-01*). These red flags are not an exhaustive list of items that could give rise to a violation of a pharmacist's duty of corresponding responsibility. The Board believes that certain members in the industry are trying to effectively state that judicial decisions cannot establish interpretations of relevant statutes and thereby create precedential decisions. Under this theory, if accepted, the Board could not look at "red flags" unless they were specifically identified in a rule or regulation and a new "red flag"

of corresponding responsibility that has never been developed via specific rulemaking or more specific statutory definition, the Board believes that interpretations of these broad Health and Safety Code provisions regarding adulterated drug products with similar potential impacts to public health are best, at this time, to be done in case-by-case adjudications where all the relevant facts are presented. It does not mean that the Board will never address some issues in regulations but it is premature to require the Board to anticipate or predict every practice in a rapidly changing industry that could render a drug product adulterated and enshrine it in a rule before a pharmacist could be disciplined. The Board's disciplinary actions are always reviewable by California courts on writ proceedings.

The proposed decision also gave disproportionate weight to the fact that the Board did not adopt changes to a rule in 2019 that would have set out in regulation the inapplicability of Japanese and other non-US governmental standards and required use of an appropriate grade of starting materials for the mode of administration. The California Supreme Court has questioned the validity of relying on the failure of the Legislature to enact a proposed revision to law as there are numerous reasons why it may have failed to act. (*Arnett v. Dal Cielo* (1996) 14 Cal.4th 4, 28.) A recent Court of Appeals decision involving another licensing Board has applied this reasoning to an agency's failure to adopt a change to an existing regulation. (*West Coast Univ., Inc. v. Board of Registered Nursing*, (2022) 82 Cal.App.5th 624, 640-641.) In this case, the proposed rule was withdrawn because the rulemaking was in response to the USP 2019 proposed changes that were withdrawn. The requirement to use USP standards is established under both federal and state law. Although the Board sometimes may consolidate requirements into rules, the Board is not required to restate USP standards[92], federal or state law into its rules to make it easier for PICs to fulfill their responsibility that the pharmacy is in compliance with all operative federal and state law.

(b) Specified Contaminants and Impurities

36. Complainant also argued, based on Dr. Acosta's testimony, that the COAs for La Vita's bulk glutathione and methylcobalamin show that the bulk drug substances contained specific contaminants and impurities, which included filthy, putrid, or decomposed substances. Specifically, the COAs for the substances at issue showed filth, contaminants and decomposed contaminants such as heavy metals, arsenic, sulfate, ammonium, yeast/mold, aerobic bacteria and fungi. (Ex. 18 RT I at pp. 160-161). All of these substances have purity levels in drug and dietary supplements. The 2012 fungal

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could not be utilized in enforcement cases until specifically enumerated in a rule.

[92] There are also copyright issues with the Board reiterating USP standards which is why access to the USP standards is a cost of doing business in the human drug compounding industry.

meningitis outbreak was caused by compounded drug products contaminated with fungi which was one of the contaminants identified in the COAs at issue in this case. Some of these residual contaminants, such as heavy metals and arsenic can build up in a patient's tissue when injected and not excreted.

37. USP drug monographs sets forth quality expectations and testing standards for substances for which a drug monograph has been established. USP standards are put out for notice and comment and gives the entire scientific (medical and research) community and other interested stakeholders a chance to weigh in the components of different USP chapters and purity levels for specific monographs thereby ensuring that the full range of medical and scientific opinion on a standard or monograph are weighed. There was no USP drug monograph for any of these substances. Because there was no drug monograph for either substance, there was no way for a pharmacist to compare the purity levels in both substances to a safe level for injection into the human body. Therefore, those substances should not have been used to compound injectable human drugs.

Respondents argued that a drug monograph has not been established yet because the FDA has not approved either substance in an FDA approved drug. The failure to develop a drug monograph by USP is undoubtedly related to uncertainty whether the FDA will approve either substance for injection. To date, the FDA has not approved a bulk substance for injection. Also, USP cannot adequately consider the safety risks of substances to establish an appropriate drug monograph until the FDA approves the drug for particular uses that could impact the compendial purity level USP will establish for the drug monograph. The issue squarely before the FDA now is whether to approve methylcobalamin for injection for, among other things, to treat autism disorder that is generally used in daily shots. If the FDA approves either of these substances for daily injections, USP, in developing an appropriate drug monograph, would or could take into account the duration of the treatment (*i.e.,* unlimited) and could set purity levels of contaminants lower than a limited duration drug to control a patient's cumulative exposure to residual contaminants present in the bulk substance. At any rate, USP's failure to create a drug monograph for either substance does not relieve a pharmacist from their responsibility to use appropriate quality starting ingredients as required under USP standards. As stated earlier, the placement of these two substances on the Category 1 list would allow compounding oral drugs if dietary grade bulk substances were available and therefore the placement on the Category 1 list was operative to permit some human drug compounding, if not the sterile compounding done by respondents.

Respondents and the ALJ relied on the fact that every substance has residual

impurities and therefore complainant had to prove that harmful impurities were present in harmful levels in the final product. The Board finds this argument unpersuasive because it ignores Congress' and the Legislature's determination that a drug is adulterated if it **may** be contaminated or **may** be injurious to public health. Also, because drug products are usually dispensed before Board inspectors arrive for inspection, the proposed decision would create an impossible burden of proof unjustified by the statutory definition that requires only a possibility of contamination. Under this proposed burden of proof, licensees could dispense or destroy all sterile drug products before inspectors arrive and insulate themselves from discipline or liability for harm caused. This would be inconsistent with the statutory language and fundamentally incompatible with the protection of public health as reflected in the provisions under the Health and Safety Code.

38. The ALJ gave considerable weight to Dr. Summers' opinion that the levels of contaminants and impurities at issue complied with ICH Guidelines and may or may not have complied with Japanese and/or European Union standards. Summers opined that the level of contaminants and impurities at issue complied with the ICH Guidelines and were less than levels in other injectable drug products such as acetylcysteine and magnesium sulfate.[93] Dr. Acosta testified in rebuttal and faulted Dr. Summers' analysis on several grounds, including that: (1) Summers inappropriately relied on the IHC Guidelines that only apply to new drug substances produced by manufacturers subject to current good manufacturing practices; (2) Summers calculations were based on erroneous maximum daily dosing levels when dispensing records showed that some patients were receiving significantly more than the maximum daily dose used in her report; and (3) Summers' comparison to acetylcysteine and magnesium sulfate were inappropriate because she used outdated monographs and/or those of life saving drugs for specific medical conditions that are limited in treatment duration and not routinely taken like glutathione and methylcobalamin. The Board finds Dr. Acosta's rebuttal testimony and the flaws she identified in Dr. Summers report and testimony persuasive for the following reasons.

Firstly, Dr. Summers tried to compare the impurity levels to both Japanese and European Union purity levels. Dr. Acosta pointed out that Dr. Summers was also confused about the whether these foreign standards referred to dietary or injectable grade sterile products. More importantly, the United States is a sovereign nation and has not delegated its police power to protect U.S. citizens to any foreign government. Rather, federal law as

[93] Acetylcysteine is an FDA-approved drug used to treat patients who have overdosed on Tylenol and ingested an amount that could cause liver damage and/or death. (RT V, p. 154.) Magnesium sulfate is given in another life saving situation to control seizures in eclampsia and pre-eclampsia in pregnant women and is given when necessary to protect a mother and/or baby's life. (RT V, p. 155.)

discussed throughout this opinion requires compliance with the USP standards. Moreover, the State of California, as a co-sovereign in our federal structure, also has not delegated its police powers to protect California citizens to standards developed in another nation. Rather, the State of California established, in statute, that USP standards are the minimum operating standards for human drug compounding in California. In fact, the Board has disciplined licensees for selling dangerous drugs in the State of California that have been approved in another country but either not approved in the United States or been withdrawn from the U.S. market for safety reasons that arise after approval.[94] Therefore, the comparison to Japanese or other non-US dietary or drug monographs is legally irrelevant.

Second, Dr. Summers and the ALJ erroneously concluded that because residual impurities exist in every substance that comparison to certain drugs that have a limited duration for treatment demonstrated that the specific impurities in the bulk substances used by La Vita and Givant were not harmful. However, health dangers from residual impurities can arise from a single dose and/or the cumulative exposure and accumulation of residual impurities based on the duration of the treatment. For example, the FDA has approved certain drugs that have dosage and/or duration treatments with residual contaminants because the dosage and duration limitations can effectively limit the cumulative amount of a patient's exposure to harmful impurities. Dr. Acosta testified credibly that Dr. Summers attempt to justify the impurity levels in respondents bulk substances by references to two drugs that are used to treat a discernible high risk medical conditions that are limited in duration was somehow justification for the impurity levels in the grade of the starting bulk products used by La Vita for the dosages and daily injections used by patients was fundamentally incorrect and failed to take into account the potential cumulative impact of those treatments.

Finally, both respondents and Dr. Summer contend that end product sterility testing showed that the products produced were sterile and not adulterated. The Board finds this argument unpersuasive under both federal and state law. Quality must be built into the whole process and must start with the appropriate grade or quality of bulk ingredients for the intended mode of administration.[95] Compounding standards and practices are

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[94] *See* (*In the Matter of the Accusation Against Agapi Pharmacy, Inc. dba Agapi Pharmacy, Asmik Ayrapetyan, President and Pharmacist-in-Charge*, Case No. 6924, OAH No. 2021020709 (Nov. 8, 2021)(pharmacy and pharmacist license revoked, in part, for offering foreign medications for sale that were not approved for use in the U.S. and some had been withdrawn due to safety risks.)

[95] The FDA in its 2019 Alert about dietary grade glutathione also stressed that "[i]t is critical that compounders understand that quality should be built into the drug production, and that testing alone should not be relied on to ensure drug quality. Therefore, compounders should ensure that all ingredients

designed to reduce the risk of additional contaminants (airborne or surface) being introduced while the product is being compounded but does not remove impurities present at the start of the process. Therefore, end product sterility testing does not ensure that contaminants introduced at the start of the process in the ingredients used are removed by processes that generally are designed to reduce the likelihood of additional contaminants being introduced during compounding and do not test the end product for the starting contaminants. Finally, end product sterility testing is done on a sample of the products and does not ensure that all lots are sterile and does not determine whether contaminants in the starting ingredients used are still present in the final product.

For all of these reasons, the Board credited Dr. Acosta's testimony over that of Dr. Summers. Dr. Summers' report, in the Board's view, used misleading old monographs and legally irrelevant non-US standards to try to justify, after the fact, a high risk compounding event that was unjustifiable under existing USP standards, and existing federal and California law. For these reasons, the Board also seriously questions whether Dr. Summers is an expert in compounding either under USP standards or federal or California law, and discounts Dr. Summers' report as one motivated by the financial fee she received for producing and testifying about it.

39. Thus, complainant established that La Vita's sterile injectable glutathione and methylcobalamin preparations were adulterated under both federal and California law (including under Health and Safety Code sections 111250 and 111255) and under the USP standards for sterile compounding. Thus, there is cause to discipline La Vita and Givant as the PIC pursuant to Business and Professions Code section 4301, subdivisions (j) or (o), as pled in the Second, Sixth, Tenth, and Seventeenth causes for discipline.

LACK OF QUALITY (FIRST, FIFTH, NINTH, AND SIXTEENTH CFDS)

40. Complainant alleges that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality. California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), provide that:

> (g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength

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they use to produce sterile injectable drugs are manufactured under conditions and specifications appropriate for the intended route of administration." *See* (FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables | FDA, located at https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-using-dietary-ingredient-glutathione-compound-sterile-injectables.)

> of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.
>
> (h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

41. California Code of Regulations, title 16, section 1735.2, subdivision (ae), provides:

> 'Quality' means the absence of harmful level of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

42. USP standards, which are minimum requirements for compounding drug preparations in California,[96] also requires compounding personnel to ensure that ingredients have the correct quality and purity. USP standards also state that compounded sterile preparations compounded under certain conditions are contaminated or at a high risk to be contaminated, including incorporating nonsterile ingredients not intended for sterile routes of administration (*e.g.*, oral) or if it is assumed and not verified by examination of labeling and documentation from suppliers or by direct examination that the chemical purity and content strength meet their original or compendial specifications.[97]

43. Quality is defined as the absence of harmful levels of contaminants of three prongs joined together with the word "and." [98] Because quality is defined as the absence of all of the three prongs, it follows that a drug preparation to meet the definition of "quality" must satisfy each prong in the definition. Failure of any prong in this definition would mean that the preparation lacks quality for one or more of those reasons. The first prong of the definition of quality includes any preparation with harmful level of contaminants, including filth, putrid or decomposed substances. This prong incorporates

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[96] *See* (Bus. & Prof. Code § 4126.8.)

[97] *See* (Relevant USP Standards ¶¶ 20-21, pp. 10-11.)

[98] *See* (*Id.*)

the definition of an adulterated product under California law.[99] Because the wording of this regulation mirrors the definition in California's Health and Safety Code, it is reasonable to interpret the regulation by reference to the statutory definition enacted by the Legislature particularly since the Board has not adopted regulations designating a different definition. This interpretation also is reasonable because if a drug is adulterated under California or federal law it stands to reason that it also lacks quality. Also, under the facts of this case, the COAs at issue demonstrate that the substances had impurities that can be harmful to human health. Because there was no drug monograph there was nothing to compare the impurities listed on the COAs with a safe level established by the USP, particularly given the dosing and duration of the treatments received by patients as described in Dr. Acosta's rebuttal testimony to the expert report submitted by Dr. Summers.

44. Because complainant established that La Vita's sterile injectable glutathione and methylcobalamin were adulterated, complainant also proved that La Vita's sterile injectable glutathione and methylcobalamin lacked quality under the facts of this case. As such, both La Vita and Givant as the PIC violated California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), as they interact with California Code of Regulations, title 16, section 1735.1, subdivision (ae). Thus, there is cause to discipline both La Vita and Givant as the PIC for unprofessional pursuant to Business and Professions Code section 4301, subdivisions (j) or (o), as pled in the First, Fifth, Ninth, and Sixteenth CFDs.

BUDs (THIRD, SEVENTH, ELEVENTH, AND EIGHTEENTH CFDs)

45. Complainant alleges that La Vita's sterile injectable glutathione and methylcobalamin preparations had unsupported BUDs. California Code of Regulations, title 16, section 1735.2, subdivision (i), provides, in pertinent part:

> Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.
> […]
> (3) For sterile compounded drug preparations, extension of a beyond

[99] A drug is adulterated if it consists, in whole or part, of any filthy, putrid or decomposed substance. *See* (Health & Saf. Code §111250.) Any drug is adulterated "if it has been produced, prepared or packed, or held under conditions where it **may** have been contaminated with filth, or where it **may** have been rendered injurious to health." *See* (Health & Saf. Code § 111255 (emphasis added).)

use date is only allowable when supported by the following: (A) Method Suitability Test; (B) Container Closure Integrity Test; and (C) Stability Studies.

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.
[…]

46. Acosta persuasively testified that La Vita's relied-upon method suitability tests and container closure integrity tests were inadequate to support the assigned BUDs. Summers failed to address the information deficiencies identified by Acosta and even conceded that the documentation could be improved.

47. The adequacy of the stability studies is a closer question because the regulation states that the studied drug preparation and the drug preparation at issue shall be "identical in ingredients." It is unclear whether that requires ingredients from the same manufacturer or supplier, or merely ingredients of the same or better grade. But if it is the latter, there was insufficient information to determine that the ingredients from the studied drug preparations and the drug preparations at issue were of the same grade.

48. Even assuming, without deciding, the correctness of Summers's analysis concerning the stability studies, the method suitability tests and container closure integrity tests were inadequate, as discussed above. As such, the BUDs for La Vita's sterile injectable glutathione and methylcobalamin preparations were unsupported and violated California Code of Regulations, title 16, section 1735.2, subdivision (i). Thus, cause exists to discipline La Vita as pled in the Third and Eleventh CFDs, and Givant as the PIC as pled in the Seventh and Eighteenth CFDs, pursuant to Business and Professions Code section 4301, subdivision (o).

INCOMPLETE COMPOUNDING RECORDS (FOURTH, EIGHTH, TWELFTH, AND NINETEENTH CFDS)

49. Complainant alleges that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked complete compounding records. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2), provides, in pertinent part:

> For each compounded drug preparation, pharmacy records shall include:
> […]
> (2) A compounding log consisting of a single document containing all of the following:
> […]
> (D) The identity of the pharmacist reviewing the final drug preparation.
> […]
> (I) The final quantity or amount of drug preparation compounded for dispensing.
> (J) Documentation of quality reviews and required post-compounding process and procedures.

(Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D), (I), & (J).)

50. Acosta persuasively testified that La Vita's compounding logs were incomplete and non-compliant.

As to the identity of the reviewing pharmacist, Givant placed her initials in various places throughout the logs, resulting in erratic and inconsistent verification documentation. Even though the law may not require a specific format for a compounding log, Givant chose the particular form at issue and was required to properly complete it. Moreover, it is impossible to positively identify the reviewing pharmacist without resorting to some external key matching initials with particular individuals. The logs themselves do not provide such a key.

Additionally, although Summers was ultimately able to confirm the total number of vials made in each lot of glutathione and methylcobalamin, the number of vials of each lot that were sent for sterility and endotoxin testing, the applicable filter lot numbers, and the fact that bubble point testing was performed on each of those filters, she could only do so after consulting documentation external to the compounding logs. The regulation requires all that information to be provided in a single-document compounding log. That requirement facilitates easy and timely access to the information, such as during a recall.

51. In sum, the compounding logs for La Vita's sterile injectable glutathione and methylcobalamin preparations were incomplete and non-compliant with California Code of Regulations, title 16, section 1735.3, subdivisions (a)(2)(D), (I), & (J).) Thus, cause exists to discipline La Vita as pled in the Fourth and Twelfth CFDs, and Givant as the PIC as pled in

the Eighth and Nineteenth CFDs, pursuant to Business and Professions Code section 4301, subdivision (o).

IMPROPER QUARANTINE (THIRTEENTH AND TWENTIETH CFDS)

52. Complainant alleges that La Vita failed to properly quarantine specified lots of sterile injectable methylcobalamin preparations until end product testing confirmed sterility and acceptable levels of endotoxins. With exceptions not relevant here, California Code of Regulations, title 16, section 1751.7, subdivision (e)(1), provides that:

> Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients . . . shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

53. The Original Dispensing Report on its face indicates that La Vita dispensed prescriptions of methylcobalamin from several lots before end product testing confirmed sterility and acceptable levels of endotoxins. Respondents provided the Original Dispensing Report to Acosta as part of her investigation, and she was entitled to rely on it.

54. Admittedly, the Revised Dispensing Report suggests otherwise. However, respondents failed to explain why the Revised Dispensing Report was only provided to Acosta for the first time at hearing, leaving little time to verify its authenticity and accuracy. Moreover, even based on her limited review of the Revised Dispensing Report at hearing, Acosta articulated several legitimate reasons to question its accuracy. Although there is insufficient evidence to conclude that La Vita intentionally manipulated the data in the Revised Dispensing Report, Acosta persuasively testified that it is not reliable. Because Summers based her testimony solely on the Revised Dispensing Report and a few "spot checks," her testimony on this issue is given little weight.

55. In sum, based on the only reliable evidence in the record—the Original Dispensing Report—La Vita failed to properly quarantine several lots of sterile injectable methylcobalamin preparations until end product testing confirmed sterility and acceptable levels of endotoxins. As such, it violated California Code of Regulations, title 16, section 1751.7, subdivision (e)(1). Thus, cause exists to discipline La Vita as pled in the Thirteenth CFD and Givant as the PIC as pled in the Twentieth CFD, pursuant to Business and Professions Code section 4301, subdivision (o).

INSUFFICIENT TRAINING AND VALIDATION (FOURTEENTH AND TWENTY- FIRST CFDS)

56. Complainant alleges that several lots of sterile injectable methylcobalamin preparations were prepared by a La Vita pharmacy technician without sufficient training and process validation. California Code of Regulations, title 16, section 1751.7, subdivision (b)(1), provides, in relevant part:

> The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing.

57. Acosta persuasively testified that La Vita's training and validation testing did not involve all the same equipment, products, batch sizes, and volumes as La Vita's compounding practice. Even if, as Summers opined, La Vita's testing regimen can be justified scientifically, it nonetheless failed to comply with the specific requirements of California law, which Summers also concedes.

58. Consequently, complainant established that La Vita violated California Code of Regulations, title 16, section 1751.7, subdivision (b)(1). Thus, cause exists to discipline La Vita as pled in the Fourteenth CFD and Givant as the PIC as pled in the Twenty-First CFD, pursuant to Business and Professions Code section 4301, subdivision (o).

FURNISHING TO UNLICENSED ENTITY (FIFTEENTH AND TWENTY-SECOND CFDS)

59. Complainant alleges that La Vita furnished a specified lot of sterile injectable methylcobalamin preparations, a dangerous drug, to an unlicensed entity. Business and

Professions Code section 4126.5, subdivision (a), generally provides:

> A pharmacy may furnish dangerous drugs only to the following:
> (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
> (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
> (3) A licensed wholesaler acting as a reverse distributor.
> (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
> (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
> (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
> (7) To another pharmacy under common control. During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.

"'Furnish' means to supply by any means, by sale or otherwise." (Bus. & Prof. Code, § 4026.)

60. It is undisputed that La Vita provided the specified lot of sterile injectable methylcobalamin preparations, a dangerous drug, to ATI. It is also undisputed that ATI was not licensed by the Board but was licensed by the California Department of Public Health as waste management company.

61. Dr. Summers testified that the requirement to use a wholesaler licensed as a reverse distributor was to facilitate refunds to pharmacies. That is incorrect. The requirement to only furnish dangerous drugs to Board licensees, such as wholesalers licensed as reverse distributors, is to ensure suspect, quarantined or expired drug products are removed from the legitimate drug supply chain. Board licensees such as wholesalers and reverse distributors are under regulatory obligations under federal and state law to establish and follow procedures to ensure that suspect products are identified and permanently removed from the legitimate drug supply and are subject to disciplinary action for failure to exercise those responsibilities. The ALJ interpreted the word "furnish"

narrowly. The ALJ also cited Optional Condition 24 in the Board's Disciplinary Guidelines as authority for the proposition that destruction of product may be done by a waste management company. The Board does not find that rationale persuasive as conditions can be modified when appropriate and cannot be used to override statutory requirements.

62. However, La Vita produced documentation that it contracted with a waste management company licensed by the California Department of Public Health (CDPH) to destroy that lot and produced the contract and destruction documents provided by the CDPH licensee. CDPH has strict requirements for the handling and destruction of a wide range of medical waste generated by hospitals. For these reasons alone, the Board does not believe public interest or public safety weighs in favor of disciplining Givant's or La Vita's license for unprofessional conduct pursuant to Business and Professions Code section 4301, subdivisions (j) or (o), as pled in the Fifteenth and Twenty-Second CFDs based on the unique circumstances of this case. The Board expresses no opinion whether, under the facts of this case, an administrative action such as a fine or citation or letter of correction might have been a more appropriate action. The Board is not stating that disciplinary action of a license would never be appropriate but not under the facts of this case.

63. The Board cautions other licensees that the expectation and law require supplying dangerous drugs only to statutorily authorized Board licensees to ensure that dangerous drugs are handled by Board licensees that have statutory and regulatory obligations under federal and state law to identify, quarantine and remove or destroy suspect drugs from the legitimate drug supply.

UNPROFESSIONAL CONDUCT (TWENTY-THIRD CFD AGAINST GIVANT ONLY)

64. Complainant alleges that Givant engaged in unprofessional conduct based on her acts and omissions in this matter. Business and Professions Code section 4306.5 provides, in pertinent part:

> Unprofessional conduct for a pharmacist may include any of the following:
> (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
[…]

65. Based on the foregoing factual findings, Givant engaged in acts or omissions that involved the inappropriate exercise of her education, training, or experience as a pharmacist; and the failure to exercise or implement her best professional judgment regarding the dispensing or furnishing of dangerous drugs. Specifically, the pharmacy for which she served as the PIC compounded sterile injectable drug preparations that were adulterated, lacked quality, had unsupported beyond use dates, lacked complete compounding records, were improperly quarantined, and were prepared by a pharmacy technician without sufficient training and validation process. All of these violations presented health risks to recipients of these injectable products.

66. The Board is also concerned that a large proportion of these adulterated injectable products appeared to be used for general wellness as opposed to treatment of discernible medical conditions. There are substantial differences between supplemental formulations intended for oral administration and sterile compounded drug preparations. When adopting the rule governing its consideration of substances for the 503A bulks list, the FDA rejected comments that the availability of an FDA-approved drugs or OTC drugs to treat the same condition should not factor into the FDA's determination whether to include the substance on the bulks list. The FDA stated that the availability of FDA approved drugs could be relevant when considering the safety of a bulk substance and could weigh against inclusion of the bulk substance during the FDA's consideration of the safety of the bulk substance.[100] Similarly, the FDA rejected comments that the severity of the underlying medical condition should not impact inclusion or exclusion of a bulk drug substance. The FDA stated that "[w]hen evaluating a bulk drug substance that is proposed for the treatment of a less serious disease, FDA will generally be more concerned about the safety of the substance than about its effectiveness."[101]

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[100] (2019 Bulk Substances Adopting Release, 84 Fed.Reg. at p. 4699, *supra* n.17.) The FDA noted that in many cases there is minimal data regarding the safety or effectiveness of compounded drugs and the absence of information does not mean there is no risk. Therefore, the availability of FDA-approved drugs that have been proven to be safe under the conditions of use approved in the label could weigh in favor of exclusion of the substance in the bulks list.

[101] (2019 Bulk Substances Adopting Release, 84 Fed.Reg. at p. 4700, *supra* n.17.)

67. The Board is very concerned that a licensed compounding pharmacy in California compounded adulterated sterile drug products for general wellness when there were other FDA-approved injectable drugs that have been through safety and efficacy reviews. For example, the FDA has approved injectable B-12 drugs and methylcobalamin, as a synthetic B-12, would only be necessary if the patient had certain medical conditions that prevented absorption and processing of an approved sterile B-12. Generally, FDA-approved drugs are more expensive than compounded drugs because they have embedded research and development costs associated with the necessary clinical trials to obtain FDA approval and the manufacturers of these drugs are subject to current good manufacturing practice. Drugs cannot be compounded if they are essentially a copy of an FDA-approved drug and the FDA has issued guidance on its interpretation of what essentially a copy means.[102] Currently the Enforcement and Compounding Committee and eventually the Board will be addressing regulation changes in response to the USP changes effective November 1, 2023. The Committee and the Board will be considering whether to impose additional standards above the revised USP standards in all areas, and that could include imposing additional requirements for defining what is "essentially a copy" under California law for compounding pharmacies given that those pharmacies are not subject to current good manufacturing practices.

68. Givant's last justification for these practices was that these substances have been compounded for years and have been commercially available for a long time. The Board has no way of knowing if there is a pharmaceutical grade for either substance. If pharmacies were compounding using inappropriate grade product for sterile administration containing contaminants present on these COAs, and therefore these products were commercially available, it does not mean it was done in compliance with law. Compounding pharmacies, outsourcing facilities and drug manufacturers are the entities that have the ability to produce large amounts of a drug product and cause the widest arc of harm if the products are contaminated. When a consumer receives a prescription from a licensed pharmacy in California, there is an implicit assumption, that at a minimum, the drugs received are appropriate and safe for the intended use. Compounding sterile products in violation of law also could mean that other practitioners hear of these products and prescribe for a wider variety of reasons, including general wellness, without knowing the efficacy of the treatment or the contaminants contained in compounded drugs using inappropriate starting grade

[102] *See* (n.4, *supra*.)

ingredients for the mode of administration.

69. Consequently, Givant violated Business and Professions Code section 4306.5, subdivisions (a) and (b). As such, cause exists to discipline Givant as pled in the Twenty-Third CFD, pursuant to Business and Professions Code section 4301, subdivisions (j) and (o).

Appropriate Discipline

70. Protection of the public is the Board's highest priority in exercising its licensing, regulatory and disciplinary functions. (Bus. & Prof. Code § 4001.1.) "[W]hen that goal is inconsistent with other interests, the public's protection is paramount." (*Oduyale v. California State Bd. of Pharmacy*, (2019) 41CalApp.5th 101, 118.)

71. The Board's Disciplinary Guidelines, incorporated by reference in its regulations (Cal. Code Regs., tit. 16 § 1760) divide violations into four categories for purposes of determining the appropriate disciplinary action.

72. The Board classifies as Category III violations "repeat or serious violation(s) involving the improper compounding of drug products." (Disciplinary Guidelines at p.7.) Givant and La Vita's proven causes of discipline were Category III violations based on the repeat nature of them and the seriousness of the violations. The Disciplinary Guidelines establish a range of permissible discipline for Category III violations from a minimum discipline of revocation with revocation stayed, 90 days actual suspension, and three to five years probation up to a maximum discipline of revocation of the license or permit. (Disciplinary Guidelines at pp. 6-7.)

73. The Board's Disciplinary Guidelines also list 17 factors to be considered in determining whether a minimum, maximum or intermediate penalty should be imposed in a given case. "No single one or combination of the . . . factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one." (Id. at p. 3.) The relevant factors and evidence for each factor are discussed below:

a) Actual or potential harm to the public

Respondent's violations posed severe potential harm to the public because the respondents sold and transferred sterile compounded drug products that were adulterated and lacked quality, and had insupportable BUD dates and improper quarantine. Respondents testified that no patient was actually harmed, and they received

no adverse serious reactions notifications from California consumers. However, by selling and transferring sterile drug products for, in many cases, the general wellness of consumers that were adulterated and lacked quality and have not been reviewed by the FDA or scientific and medical community for safety and efficacy, ignores the fact patients were exposed to severe potential harm. Because these adulterated substances were used for general wellness, the Board is even more concerned that the safety of the recipients of the products was never adequately considered.

b) Actual or potential harm to any consumer

The violations posed significant potential harm to receiving consumers as described in (a) above.

c) Prior disciplinary record, including level of compliance with disciplinary order(s)

Respondent has not prior disciplinary action with the Board.

d) Prior warnings(s), including but not limited to citation(s) and fine(s), letters of admonishment, and/or correction notice(s)

Complainant offered evidence that respondents had previously been issued an FDA warning letter as well as multiple Board citations as detailed on pages 25-26 of this decision. The FDA warning letter issued in 2019 involved compounding and the investigator noted serious deficiencies in La Vita's practices for producing sterile drug products and strongly recommended a comprehensive assessment of operations. Two of the previous Board citations also involved violations of compounding standards.

e) Number and variety of current violations

Respondents were charged with 23 separate violations of pharmacy law and the Board found cause to discipline the licenses of the respondents for 21 of the causes of discipline alleged. The Board is particularly concerned regarding the repeat nature of these offenses. The number of violations, the repeat nature of them and particularly Givant's apparent total ignorance of USP standards, federal and state law demonstrate that, at a minimum a significant period of probation and significant remedial education is necessary. The Board is also concerned that Givant, even after receiving education and the 2019 notice of violation from Dr. Acosta regarding using inappropriate grade materials for injectable glutathione, did not apply that education using her professional

knowledge and judgement to La Vita's compounding of methylcobalamin using ungraded materials. She also, by admission to the FDA, was not even aware that the Medisca product that she used was ungraded. La Vita only stopped all sterile compounding after the 2020 joint inspection by the FDA and Board inspectors.

f) Nature and severity of the act(s), offense(s) or crime(s) under consideration

The violations were severe and repeated and classified as multiple Category III violations.

g) Aggravating Evidence

The repeat nature of Respondents violations is a matter in aggravation. Givant's ignorance of relevant law, including USP standards, as the PIC and failure to understand or apply the education available from the FDA, USP, Board alerts and the 2019 Notice of Violation received from Dr. Acosta to influence her actions and respondents continued compounding injectable methylcobalamin until 2020 are also aggravating factors.

h) Rehabilitation Evidence

The main rehabilitation evidence presented was that La Vita stopped all sterile compounding after the 2020 joint FDA/Board inspection and so those violations are not likely to be repeated as La Vita allowed its sterile compounding permit to expire. However, the Board finds that finally stopping sterile compounding that produced adulterated products only after notice of violations issued in 2019, and the joint FDA/Board inspection in 2020 is not sufficient because the sterile preparations at issue should never have been compounded using dietary and ungraded materials under existing law. Also, La Vita can still do nonsterile compounding under its pharmacy license and the selection of the appropriate grade is still a consideration in nonsterile compounding under USP Chapter 795.[103] In short, the Board is not convinced that Givant, given her ignorance of the relevant federal, state and USP standards, would not run afoul of similar standards governing nonsterile compounding without Board supervision.

Respondent also introduced evidence of recordkeeping and other changes for the other charges alleged. Finally, Givant's failure to acknowledge the wrongfulness of the respondent's conduct and her failure to acknowledge an understanding of the safety issues implicated by La Vita's compounding practices weighs against use of this as

[103] *See* (Relevant USP Standards, ¶ 20, at pp 10-11, *supra*.)

mitigating evidence.

The Board remains concerned that respondent's future compliance with applicable USP changes, including the amendments to the USP chapters effective November 1, 2023, and applicable federal and state law is not ensured.

i) Time passed since the act(s) or offense(s).

Respondents' violations were recent and involved compounding and distribution of adulterated drugs and drugs lacking quality among the other violations even after receipt of an FDA warning letter in 2019, and other Board citations in the past. Respondents only stopped sterile compounding after the 2020 joint inspection.

j) Whether the conduct was intentional or negligent, demonstrated incompetence, or if the respondent is being held to account for conduct committed by another

Non-compliance with law can be the result of being uninformed, misinformed or unscrupulous. The Board finds that the conduct, if not intentional, demonstrated gross negligence in Givant's understanding of federal law, state law and USP standards, and the potential risk to patients from the adulterated sterile products distributed to them. Her initial responses to the 2019 notice of violation demonstrated that she clearly was not aware of any FDA interpretations in this area and, as PIC, she was responsible for La Vita's compliance with all applicable law. Given the 2012 fungal meningitis outbreak and the substantial changes to federal and state law since that time, the Board finds that her lack of knowledge fell short of the skills necessary to act as a PIC in high risk sterile compounding. These injectable products should never have been compounded with the grade and contaminants shown in the COAs and it is unclear to the Board whether Givant ever reviewed those COAs to see if they matched up with an appropriate USP monograph as required under USP standards. For those reasons, the Board finds that respondent's conduct, if not intentional to generate a profit, demonstrated, at least incompetence or gross negligence, and showed a reckless disregard for the health of the recipients. The changing justifications for the compounding practices at issue also demonstrates that respondents have not accepted full responsibility for the wrongfulness of their prior conduct.

k) Financial benefit to the respondent from the misconduct

Respondents received some financial benefit from the misconduct. Although sterile compounding represented a small amount of La Vita's business according to statements

made by Givant to the FDA, it is reasonable to assume that the activities generated profit. Givant as a co-owner also shared in any profit made from these activities.

74. Complainant established the most serious causes for discipline alleged against respondents—that the sterile injectable glutathione and methylcobalamin preparations were adulterated and lacked quality. The other proven causes of discipline also involved serious violations, including Givant and La Vita's failure to use properly-supported BUDs and the failure to properly quarantine certain preparations had the potential to result in serious harm to patients and the public. Additionally, this matter involved a significant number and variety of violations, much more than would be expected of a long-established pharmacy, an experienced compounding pharmacist and a self-professed leader in the field.

75. Considering these factors and the entire record in this case, the Board finds that the maximum penalty against La Vita's sterile compounding permit is appropriate and necessary to guarantee respondents' full compliance with applicable state and federal law and guarantee the protection of the public consistent with the Board's obligations set out in Section 4001. The Board believes that respondents' failure to fully acknowledge the wrongfulness of their past conduct with the changing excuses for their failures combined with Givant's failure to understand or choose to comply fully with applicable federal and state law, including USP standards, justify revocation of the sterile compounding permit. The Board does not believe that an intermediate penalty would guarantee public protection and would prefer that if La Vita chooses to engage in sterile compounding again it be forced to petition the Board for reinstatement whereby the Board can determine the extent of respondents' rehabilitation and set any appropriate conditions on reinstating this permit consistent with its duty to protect the public.

76. The Board is concerned that respondents' failures in the sterile compounding area could also be carried over to its nonsterile compounding and other activities. The Board only inspected La Vita's sterile compounding operations. For these reasons, the Board also believes that discipline against La Vita's pharmacy license and Givant's pharmacist license is both appropriate and necessary to protect public health.

When exercising its responsibility to protect the public, the Board generally considers disruption in services to patients when patients have to find a new pharmacy. In *Absolute Pharmacy*, the Board recently revoked a non-resident pharmacy license because it did not have the appropriate resources to effectively ensure that the respondent, located 3,000 miles away, would comply with all applicable federal and state law. However, in this case Givant is a licensed California pharmacist working in a pharmacy located in California,

and the Board does have the appropriate resources to effectively supervise La Vita's pharmacy license and Givant's pharmacist license. For these reasons, the Board believes that an intermediate penalty, without suspension, is justified against the pharmacy license and Givant's pharmacist license with a significant period of probation to ensure that respondents understand and fully comply with the applicable USP standards governing nonsterile compounding and applicable federal and state law. Under supervision, the Board believes that Givant can be rehabilitated and could gain significant knowledge of nonsterile compounding standards throughout the probationary period.[104] Finally, the Board also believes that significant remedial and continuing education is necessary for Givant over the course of her probationary period to ensure that she maintains current in her understanding of the USP standards governing nonsterile compounding, including the new amendments effective in November 2023 and any new Board regulations adopted in response to these changes to specify additional requirements beyond USP standard, as well as other operative federal and state law. The Board also believes imposition of certain special and optional conditions are warranted as detailed in the order and conditions of probation for both respondents.

77. In sum, when the record, as a whole is, considered, it is appropriate to place Givant's Registered Pharmacist License as well as La Vita's Pharmacy Permit on probation for a period of four years on the terms described above and outlined in greater detail below. Such terms are sufficient to protect public health, safety, and welfare. However, revocation of La Vita's sterile compounding permit is required to protect public health and safety.[105]

Costs

78. In *Zuckerman*, the California Supreme Court set forth guidelines to determine whether the costs should be assessed in the particular circumstances of each case. These factors include whether the licensee has been successful at hearing in getting charges dismissed or reduced, the licensee's subjective good faith belief in the merits of her position, whether the licensee has raised a colorable challenge to the proposed discipline, the licensee's financial ability to pay, and whether the scope of the investigation was appropriate to the alleged misconduct.

[104] Exhibits were introduced that Givant was contacting USP with questions using her specialized skill and knowledge as a petitioner. (Ex. FF at p. B1261.)

[105] La Vita may petition for reinstatement of the sterile compounding permit in accordance with Section 4309 of the Business and Professions Code.

79. The ALJ found that the scope of the investigation was appropriate. However, the ALJ found that cost mitigation was appropriate because in the rejected proposed decision, the ALJ concluded that complainant failed to prove the most serious charges and reduced the cost recovery to $50,000. Under Section 125.3 of Business and Professions Code, only an ALJ can order costs to be paid. Accordingly, the costs of $50,000 ordered by the ALJ are imposed.

ORDER

1. Sterile Compounding Permit No. LSC 99842 issued to La Vita Compounding Pharmacy LLC, dba as La Vita Compounding Pharmacy is revoked.

2. Registered Pharmacist License No. RPH 41076 issued to Christine Ann Givant; Pharmacy Permit No. PHY 48731 issued to La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy (and any subsequent temporary or permanent license issued to La Vita after the date of the Stipulation for Continuing Jurisdiction referenced in ¶ 2 of the Factual Findings) are REVOKED. However, the revocation of Givant's pharmacist license and La Vita's pharmacy permit(s) is STAYED and the pharmacist license and pharmacy permit are placed ON PROBATION for a period of FOUR YEARS on the following terms and conditions:

REGISTERED PHARMACIST LICENSE (Givant)

1. Obey all Laws

Givant shall obey all state and federal laws and regulations.

Givant shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Givant's license or which is related to the practice of pharmacy or the

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

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Givant shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Givant shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, Givant shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Givant shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of Givant's compliance with the terms and conditions of her probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education

Givant shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Reporting of Employment and Notice to Employers

During the period of probation, Givant shall notify all present and prospective employers of the decision in case no. 6851 and the terms, conditions and restrictions imposed on Givant by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Givant shall report to the board in writing the name, physical address, and mailing address of each of her employer(s), and the name(s) and telephone number(s) of all of her direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Givant shall also include the reason(s) for leaving the prior employment. Givant shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of Givant's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning Givant's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Givant undertaking any new employment, Givant shall cause (a) her direct supervisor, (b) her pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of her employer, to report to the board in writing acknowledging that the listed individual(s) has or have read the decision in case no. 6851, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Givant's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Givant shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case no. 6851, and the terms and conditions imposed thereby.

If Givant works for or is employed by or through an employment service, Givant

must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case no. 6851, and the terms and conditions imposed thereby in advance of Givant commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Givant undertaking any new employment by or through an employment service, Givant shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case no. 6851, and the terms and conditions imposed thereby. It shall be Givant's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a Registered Pharmacist, or any position for which a Registered Pharmacist license is a requirement or criterion for employment, whether Givant is an employee, independent contractor, or volunteer.

7. Notification of Change(s) in Name, Address(es), or Phone Number(s)

Givant shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address, or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. Restrictions on Supervision and Oversight of Licensed Facilities

During the period of probation, Givant shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Givant may be a pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor of only La Vita, but only if Givant or La Vita retains, at her expense, an independent consultant who shall be responsible for reviewing the operations of the

entity on a quarterly basis for compliance by Givant and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by Givant with the obligations of her supervisory position. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Givant shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Givant shall pay to the board its costs of investigation and prosecution in the amount of $50,000.

Givant shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

There shall be no deviation from the payment schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

10. Probation Monitoring Costs

Givant shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. Status of License

Givant shall, at all times while on probation, maintain an active, current Registered Pharmacist license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Registered Pharmacist license shall be considered a violation of probation.

If Givant's Registered Pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof

due to tolling or otherwise, upon renewal or reapplication Givant's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Givant cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Givant may relinquish her license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Givant will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of Givant's license history with the board.

Upon acceptance of the surrender, Givant shall relinquish her pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Givant may not reapply for any license from the board for three (3) years from the effective date of the surrender. Givant shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. Practice Requirement – Extension of Probation

Except during periods of suspension, Givant shall, at all times while on probation, be employed as a Registered Pharmacist in California for a minimum of thirty (40) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Givant must nonetheless comply with all terms and conditions of probation, unless Givant receives a waiver in writing from the board or its designee.

If Givant does not practice as a Registered Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Givant shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Givant will resume practice at the required level. Givant shall further notify the board in writing within ten (10) days following the next calendar month

during which Givant practices as a Registered Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Givant's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non- consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. Violation of Probation

If Givant has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Givant, and the board shall provide notice to Givant that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Givant violates probation in any respect, the board, after giving Givant notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Givant during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, Givant's license will be fully restored.

16. Remedial Education

Within thirty (30) days of the effective date of this decision, Givant shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to the laws and standards governing nonsterile compounding. The program of remedial education shall consist of at least 30 hours, which shall be completed within and over the course of the forty eight (48) months of her probation to ensure that she maintains current in her understanding of USP standards, and applicable

federal and state law at Givant's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require Givant, at her own expense, to take an approved examination to test Givant's knowledge of the course. If Givant does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Givant shall take another course approved by the board in the same subject area.

17. No Ownership or Management of Licensed Premises

Givant shall not acquire any new ownership, legal, or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Givant currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Givant may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

PHARMACY PERMIT (La Vita)

1. Definition: La Vita

For the purposes of these terms and conditions, "La Vita" shall refer to La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy (PHY 48731) and, pursuant to the Stipulation for Continuing Jurisdiction signed by both parties effective September 6, 2022, to any temporary pharmacy permit issued to La Vita Compounding Pharmacy at a new location and any subsequent permanent permit for the new location of La Vita. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be

made by La Vita to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. Obey All Laws

La Vita shall obey all state and federal laws and regulations.

La Vita shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information, or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves La Vita's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

3. Report to the Board

La Vita shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, La Vita shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, La Vita shall appear in person for

interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

La Vita shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of La Vita's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, La Vita shall pay to the board its costs of investigation and prosecution in the amount of $50,000.

La Vita shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

There shall be no deviation from the payment plan's schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

7. Probation Monitoring Costs

La Vita shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. Status of License

La Vita shall, at all times while on probation, maintain a current Pharmacy Permit (and if La Vita elects to renew it, a Sterile Compounding Permit) with the board. Failure to

maintain current licensure shall be considered a violation of probation.

If La Vita's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication La Vita's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should La Vita wish to discontinue business, La Vita may tender the premises license(s) to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license(s), La Vita will no longer be subject to the terms and conditions of probation.

La Vita may not apply for any new license from the board for three (3) years from the effective date of the surrender. La Vita shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

La Vita further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should La Vita sell, trade, or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to La Vita, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. Notice to Employees

La Vita shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such

notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. La Vita shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, La Vita shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary, and relief employees and independent contractors employed or hired at any time during probation.

12. Owners and Officers: Knowledge of the Law

La Vita shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in La Vita or La Vita's stock, and all of its officers, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

La Vita shall remain open and engaged in its ordinary business as a pharmacy (and sterile compounding pharmacy, if applicable) in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, La Vita must nonetheless comply with all terms and conditions of probation, unless La Vita is informed otherwise in writing by the board or its designee. If La Vita is not open and engaged in its ordinary business as a pharmacy (and sterile compounding pharmacy, if applicable) for a minimum of 120 hours in any calendar month, for any reason (including vacation), La Vita shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours La Vita was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which La Vita will resume business as required. La Vita shall further notify the board in writing within ten (10) days following the

next calendar month during which La Vita is open and engaged in its ordinary business as a pharmacy (and sterile compounding pharmacy, if applicable) in California for a minimum of 120 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. Posted Notice of Probation

La Vita shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

La Vita shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. Violation of Probation

If La Vita has not complied with any term or condition of probation, the board shall have continuing jurisdiction over La Vita, and probation shall be automatically extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If La Vita violates probation in any respect, the board, after giving La Vita notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against La Vita during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, La Vita's license(s) will be fully restored.

17. Destruction of Dangerous Drugs and/or Dangerous Devices

La Vita shall, by the effective date of this decision, arrange for the destruction of all compounded drug products at issue in Case No. 6851, and the ungraded bulk products at issue in Case No. 6851, by a waste management company licensed by the California Department of Public Health to destroy medical waste or by a licensed wholesaler and reverse distributor. La Vita shall provide written proof of such destruction within five days of disposition. The Board or its designee shall have the right to retain a sample(s) of any and all compounded drug products at issue in Case No. 6851, or components used to compound drug products at issue in Case No. 6851. Any dietary grade bulk substance at issue in this Case may be retained for nonsterile compounding, provided that the PIC reviews the COAs associated for those products and verifies that they meet the requirements of the applicable USP monograph, and documentation of that review is maintained for review by the required consultant if Givant prepares the review, and available to Board staff for review for compliance with this condition.

18. No Additional Ownership or Management of Licensed Premises

La Vita shall not acquire any additional ownership, legal, or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board except as approved by the board or its designee. Violations of this restriction shall be considered a violation of probation.

This Decision shall become effective at 5:00 p.m. on April 29, 2023.

It is so ORDERED on March 30, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

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

In the Matter of the Second Amended Accusation Against:

LA VITA COMPOUNDING PHARMACY LLC dba LA VITA COMPOUNDING PHARMACY, and CHRISTINE ANN GIVANT

Respondents

Agency Case No. 6851

OAH No. 2020080624

ORDER REJECTING PROPOSED DECISION and ORDER SETTING DATE FOR SUBMISSION OF WRITTEN ARGUMENT

Pursuant to section 11517 of the Government Code, the Proposed Decision of the Administrative Law Judge in the above-entitled matter is rejected. The California State Board of Pharmacy (hereinafter "board") will decide the case upon the record, including the transcript(s) and exhibits, of the hearing (Administrative Record), and upon such written argument as the parties may wish to submit. No new evidence may be submitted.

The Administrative Record of the hearing in the above-entitled matter having now become available, the parties are hereby notified of the opportunity to submit written argument. Written argument shall be filed with the Board of Pharmacy, Attn. Susan Cappello, 2720 Gateway Oaks Drive, Suite 100, Sacramento, California, 95833, or susan.cappello@dca.ca.gov on or before **January 23, 2023**.

It is so ORDERED on December 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

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

In the Matter of the Second Amended Accusation Against:

LA VITA COMPOUNDING PHARMACY LLC dba LA VITA COMPOUNDING PHARMACY, and CHRISTINE ANN GIVANT, Respondents

Agency Case No. 6851

OAH Case No. 2020080624

PROPOSED DECISION

Wim van Rooyen, Administrative Law Judge (ALJ), Office of Administrative Hearings (OAH), State of California, heard this matter on May 23 through 26, June 8, and June 24, 2022, by videoconference from Sacramento, California.

Stephanie Alamo-Latif and Kristina T. Jarvis, Deputies Attorney General, represented Anne Sodergren (complainant), Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs, State of California.

Tony J. Park, Attorney at Law, California Pharmacy Lawyers, represented La Vita Compounding Pharmacy LLC, doing business as (dba) La Vita Compounding Pharmacy (La Vita), and Christine Ann Givant (Givant) (collectively, respondents).

Evidence was received and the record left open until October 7, 2022, to allow for submission of closing briefs.[1] On August 24, 2022, complainant filed her closing brief, marked as Exhibit 127. On September 23, 2022, respondents filed their closing brief, marked as Exhibit AAA. On October 7, 2022, complainant filed her reply brief, marked as Exhibit 128. On October 7, 2022, Exhibits 127, 128, and AAA were admitted as argument, the record was closed, and the matter was submitted for decision.

On October 7, 2022, complainant also filed a motion to correct transcript errors, marked as Exhibit 129. Consequently, the record was reopened effective October 7, 2022, to allow respondents an opportunity to respond by October 14, 2022. No opposition was filed by the required deadline.

On October 14, 2022, Exhibit 129 was admitted as argument, complainant's motion to correct transcript errors was granted, the record was closed, and the matter was resubmitted for decision.

[1] At hearing, La Vita Grievance Reports for 2020 and the amicus curiae brief filed by the Alliance for Pharmacy Compounding (APC) were both inadvertently marked as Exhibit SS. Following hearing, the La Vita Grievance Reports for 2020 were marked and admitted as Exhibit SS, and APC's amicus curiae brief was re-marked as Exhibit XX and admitted as argument.

FACTUAL FINDINGS

Jurisdiction

1. On August 17, 1987, the Board issued Givant Registered Pharmacist License No. RPH 41076 (Registered Pharmacist License). The Registered Pharmacist License will expire on October 31, 2024, unless renewed.

2. On September 19, 2007, the Board issued La Vita Pharmacy Permit No. PHY 48731 (Pharmacy Permit), with Givant and Debra Hubers as Members and Givant as the Pharmacist In Charge (PIC). The Pharmacy Permit will expire on September 1, 2023, unless renewed.

3. On August 20, 2013, the Board issued La Vita Sterile Compounding Permit No. LSC 99842 (Sterile Compounding Permit). The Sterile Compounding Permit expired on March 23, 2022.[2]

4. On April 28, 2022, complainant signed and thereafter filed a Second Amended Accusation asserting 23 causes for discipline for unprofessional conduct against respondents based on their alleged nonsterile-to-sterile compounding of

[2] "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." (Bus. & Prof. Code, § 4300.1.)

glutathione and methylcobalamin injectable drug preparations using dietary grade and/or ungraded ingredients.[3]

As to glutathione specifically, complainant alleges that respondents' sterile injectable drug preparations: lacked quality (First Cause for Discipline [CFD] against La Vita and Fifth CFD against Givant); were adulterated (Second CFD against La Vita and Sixth CFD against Givant); had unsupported beyond use dates (Third CFD against La Vita and Seventh CFD against Givant); and lacked complete compounding records (Fourth CFD against La Vita and Eighth CFD against Givant).

As to methylcobalamin specifically, complainant alleges that respondents' sterile injectable drug preparations: lacked quality (Ninth CFD against La Vita and Sixteenth CFD against Givant); were adulterated (Tenth CFD against La Vita and Seventeenth CFD against Givant); had unsupported beyond use dates (Eleventh CFD against La Vita and Eighteenth CFD against Givant); lacked complete compounding records (Twelfth CFD against La Vita and Nineteenth CFD against Givant); were improperly quarantined (Thirteenth CFD against La Vita and Twentieth CFD against Givant); and were prepared by a pharmacy technician without sufficient training and validation (Fourteenth CFD against La Vita and Twenty-First CFD against Givant). Complainant further alleged that respondents furnished some sterile injectable drug preparations to an unlicensed entity (Fifteenth CFD against La Vita and Twenty-Second CFD against Givant).

[3] The original Accusation was signed on April 14, 2020.

Additionally, based on the foregoing allegations concerning both glutathione and methylcobalamin, complainant alleges that Givant engaged in unprofessional conduct as a pharmacist (Twenty-Third CFD against Givant only).

As additional disciplinary considerations, complainant alleges the prior issuance of warnings by the federal Food and Drug Administration (FDA) and Board citations to respondents.

Complainant requests revocation of the Registered Pharmacist License, Pharmacy Permit, and Sterile Compounding Permit; an order prohibiting La Vita and Givant from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until such licenses/permits are reinstated; and recovery of the Board's reasonable investigation and enforcement costs from La Vita and Givant.

5. Respondents timely filed a Notice of Defense. The matter was set for an evidentiary hearing before an ALJ of the OAH, an independent adjudicative agency of the State of California, pursuant to Government Code section 11500 et seq.

Background

COMPOUNDING

6. Compounding is the long-standing pharmacy practice of mixing, combining, or altering ingredients. Compounding may involve merely altering an existing drug product or creating an entirely new drug product. Typically, pharmacies compound to meet the unique needs of an individual patient when a commercially available drug approved by the FDA does not meet those needs.

7. Compounded drugs may include topical creams, eye drops, capsules or tablets intended for oral ingestion, or injectable preparations. Injectable preparations must be sterile. A sterile injectable drug preparation compounded from non-sterile ingredients[4] is considered a high risk preparation due to its route of administration. Specifically, it enters the bloodstream without the natural biological filters of the skin or digestive system. Thus, the acceptable levels of contaminants in sterile injectable drug preparations are generally lower than for topical or oral drugs. California pharmacies require a sterile compounding permit to engage in sterile compounding.

8. Compounded drugs are not approved by the FDA. Thus, the FDA does not review such drugs to evaluate their safety, effectiveness, and quality before they are administered to patients.

REGULATION OF PHARMACY COMPOUNDING

9. Although compounded drugs are not subject to FDA approval, compounding pharmacies are subject to both federal and state statutes and regulations.

Federal Law

10. Subject to various conditions, section 503A of the federal Food Drug and Cosmetic Act (FD&C Act) exempts drug products compounded by state-licensed pharmacies from some of the FD&C Act's requirements, including FDA approval prior

[4] A non-sterile-to-sterile compounded drug preparation contains "two or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient." (Cal. Code Regs., tit. 16, § 1735.1, subd. (v).)

to marketing, compliance with Current Good Manufacturing Practices (CGMP), and certain labeling provisions. However, the FD&C Act requires a state-licensed pharmacy to compound drug products using bulk drug substances that comply with the following:

(1) The standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF)[5] monograph,[6] if a monograph exists, and the USP chapter on pharmacy compounding; or

(2) If such a monograph does not exist, the bulk drug substance is a component of a drug already approved by the FDA; or

[5] USP is a non-profit scientific organization that develops and disseminates public compendial quality standards for medicines and other articles. NF was established by the American Pharmaceutical Association to publish compendial quality standards for excipients (inactive ingredients), botanicals, and other similar products. USP purchased NF in 1975, and the two publications are now combined creating the USP-NF. The USP-NF is the officially recognized compendium in the United States at a federal level and in California at a state level.

[6] Monographs provide standards for identity, quality, purity, strength, packaging, and labeling for bulk substances and other ingredients that may be used in compounded preparations. A substance may have multiple monographs with different standards depending on the intended use, such as a dietary monograph compared to a drug or pharmaceutical monograph.

(3) If such a monograph does not exist and the bulk drug substance is not a component of a drug approved by the FDA, the bulk drug substance must appear on a list developed by the FDA (the 503A Bulks List).

(See 21 U.S.C. § 353a, subd. (b)(1)(A)(i).)

11. Certain bulk drug substances have been nominated for placement on the 503A Bulks List and are currently being evaluated by the FDA. The FDA classifies such substances as part of "503A Category 1 – Substances Nominated for the Bulks List Currently Under Evaluation" (503A Category 1). The FDA has indicated that until a final decision is reached as to a particular 503A Category 1 substance, it does not intend to take action against state-licensed pharmacies for compounding with that substance on the basis that it has not been finally approved for placement on the 503A Bulks List.

California Law

12. California also has an extensive statutory and regulatory scheme governing compounding pharmacies and sterile compounding. Those laws address issues such as quality, adulteration, beyond use dates (BUDs),[7] recordkeeping, training and validation processes, end product testing for sterility and pyrogens,[8] quarantine,

[7] The term "beyond use date" means "the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes)." (Cal. Code Regs., tit. 16, § 1735.1, subd. (b).)

[8] Pyrogens are fever-producing agents of bacterial origin, such as endotoxins. Endotoxins are part of the outer membrane of the cell wall of Gram-negative bacteria released upon disruption of intact bacteria. They are the most significant pyrogen

and furnishing of compounded drugs. Under California law, the designated PIC "shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy," including compounding. (Bus. & Prof. Code, § 4113, subd. (c).)

13. In 2019, the Board proposed promulgating a new regulation regarding compounding sterile drug preparations. Specifically, proposed California Code of Regulations, title 16, section 1751.9, subdivision (e), would have provided that:

> No component shall be used to compound a [sterile drug preparation] that meets only the European Pharmacopoeia standards, Japanese Pharmacopoeia standards, dietary supplement standards (such as USP-NF dietary monographs), food ingredient standards (such as Food-Chemical Codex (FCC)), food additive standards (such as General Standard for Food Additive (GSFA)), reagent standard (such as American Chemical Society (ACS)) or is of unspecified quality.

However, the Board suspended the rulemaking process and that proposed regulation has not been promulgated to date.

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found in injectable drugs and medical devices. Their presence in the blood stream may cause septic reactions with symptoms such as fever, hypotension, nausea, shivering, and shock. High concentrations can lead to serious complications including death.

BULK DRUG SUBSTANCES AT ISSUE

Glutathione

14. Glutathione is a substance made from amino acids and produced by the liver. It is involved in many bodily processes including tissue building and repair, making chemicals and proteins needed in the body, and in the functioning of the immune system. It is a dietary supplement also frequently prescribed as an injectable drug preparation by integrative medical practitioners for a range of claimed benefits such as combatting aging, improving skin, and treating liver disease, atherosclerosis, and Parkinson's disease. Prescribed glutathione injections are deemed dangerous drugs under Business and Professions Code section 4022.

15. Glutathione has a USP-NF dietary monograph, but not a USP-NF drug monograph. It is not a component of a drug already approved by the FDA. It has not been finally approved for placement on the 503A Bulks List, but is a 503A Category 1 substance under evaluation by the FDA.

Methylcobalamin

16. Methylcobalamin is a form of Vitamin B-12 taken as a dietary supplement to treat Vitamin B-12 deficiency and anemia. It is also frequently prescribed as an injectable drug preparation by integrative medical practitioners for a range of claimed benefits such as combatting fatigue and dementia, promoting weight loss, and treating various diseases including Autism Spectrum Disorder. Prescribed methylcobalamin injections are deemed dangerous drugs under Business and Professions Code section 4022.

17. Methylcobalamin has a USP-NF dietary monograph, but not a USP-NF drug monograph. It is not a component of a drug already approved by the FDA. It has not been finally approved for placement on the 503A Bulks List, but is a 503A Category 1 substance under evaluation by the FDA.

La Vita's Undisputed Compounding With Glutathione and Methylcobalamin

18. La Vita is a licensed sterile compounding pharmacy located in San Diego, California. Givant has been its PIC at all times relevant to this matter.

19. From approximately January 2018 through December 2018, La Vita compounded at least 44,900 ml of sterile injectable glutathione 200 mg/ml. Additionally, from approximately January 2018 through January 2019, La Vita sold at least 331 prescriptions for at least 38,370 ml of sterile injectable glutathione 200 mg/ml. Those drug preparations were compounded with bulk glutathione purchased from suppliers Fagron and Medisca.[9]

20. From approximately September 2019 through March 2020, La Vita compounded at least 23,800 ml of methylcobalamin 1000 mcg/ml. Additionally, from approximately September 2019 through January 2020, La Vita sold at least 346 prescriptions for at least 6,330 ml of sterile injectable methylcobalamin 1000 mcg/ml. Those drug preparations were compounded with bulk methylcobalamin purchased from supplier Medisca.

[9] Fagron and Medisca are suppliers that purchase bulk drug substances from manufacturers, and then repackage and resell them to compounding pharmacies.

Complainant's Evidence

TESTIMONY OF CHRISTINE ACOSTA, PHARM.D.

21. Christine Acosta (Acosta) received her doctor of pharmacy degree from Western University of Health Sciences in May 2006. She has been a Supervising Inspector for the Board's Sterile Compounding Team since July 2014. Her duties are to serve as the Board's expert in compounding law, as well as to conduct complex inspections and investigations. Acosta was previously a Board Inspector on the Diversion Team from December 2011 to July 2014. From June 2006 to December 2011, Acosta worked as a licensed pharmacist for various employers.

22. On January 10, 2019, the Board received a report from another sterile compounding pharmacy of adverse drug reactions (ADRs) suffered by patients after being administered a compounded sterile injectable glutathione preparation made with bulk glutathione purchased from supplier Letco. The ADRs included facial reddening, sneezing, nausea, vomiting, shaking, and breathing difficulties.

23. Acosta then started an investigation of several California pharmacies that compounded glutathione, including La Vita. She was surprised to discover that these compounding pharmacies were using dietary grade or ungraded bulk glutathione in their compounding of sterile injectable drug preparations. She had not previously been aware of that practice.

24. As part of her investigation of La Vita, Acosta communicated with Givant and requested records pertaining to La Vita's compounding with glutathione. Givant responded and provided the requested records.

25. On July 3, 2019, Acosta issued a notice of violation to respondents with respect to their compounding with glutathione. She also prepared an associated investigation report dated July 18, 2019.

26. On March 4, 2020, Acosta inspected La Vita along with FDA investigators. During that inspection, Acosta discovered that La Vita had also used ungraded bulk methylcobalamin in its compounding of sterile injectable drug preparations.

27. During and following the inspection, Acosta communicated with Givant and requested records pertaining to La Vita's compounding with methylcobalamin. Givant responded and provided the requested records.

28. On June 2, 2020, Acosta issued notices of violation to respondents with respect to their compounding with methylcobalamin. She also prepared an associated investigation report dated June 17, 2020.

29. At hearing, Acosta testified consistently with her investigation reports concerning the issues raised by the Second Amended Accusation. Her relevant testimony as to each issue follows.

Lack of Quality/Adulteration

30. Acosta opined that quality should be built into every step of the compounding process. Thus, compounding pharmacies must ensure that all ingredients and bulk drug substances used to compound sterile injectable drug preparations are manufactured under conditions and specifications appropriate for the intended route of administration. Compounders should not rely solely on end product testing, such as testing for sterility or endotoxins, to ensure drug quality. Acosta explained that filters used in compounding do not remove all contaminants present in

the starting ingredients, nor is the end product tested for all such contaminants. Thus, a compounding pharmacist cannot start with "turtle pond water" to compound a sterile injectable drug preparation.

31. Acosta reviewed the Certificates of Analysis (COAs) for the bulk glutathione and methylcobalamin La Vita purchased from Fagron and Medisca.

The glutathione from Fagron was dietary grade and tested as compliant with the USP dietary monograph for glutathione. It contained up to 200 parts per million (ppm) of ammonium, 1 ppm of arsenic, 300 ppm of sulfate, 200 ppm of chloride, 10 ppm of iron, and 10 ppm of heavy metals.

The glutathione from Medisca was ungraded and tested as compliant with unspecified manufacturer's standards only. It contained up to 0.020 percent of ammonium, up to 1 ppm of arsenic, up to 0.030 percent of sulfate, up to 10 ppm of iron, less than 10 ppm of heavy metals, a total plate count (aerobic bacteria, yeast, mold, and fungi) of up to 1000 colony forming units per gram (cfu/g), and a fungi count of up to 100 cfu/g.

The methylcobalamin purchased from Medisca was ungraded and tested as compliant with unspecified manufacturer's standards only. It contained a total aerobic microbial count of up to 50 cfu/g, and a total yeasts and molds count of less than 10 cfu/g.

32. Acosta testified that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality and were adulterated. They were unsuitable for that route of administration for two reasons.

33. First, they were compounded with dietary grade or ungraded, as opposed to drug or pharmaceutical grade, bulk ingredients. Dietary supplements such as glutathione and methylcobalamin are generally defined and regulated as foods intended for oral ingestion. They are not of sufficient quality to be used in compounding sterile injectable drug preparations, which bypass the digestive system's biological filters. There is no USP drug monograph for either glutathione or methylcobalamin, and thus they were not tested for compliance with an appropriate USP drug monograph.

In further support of her opinion, Acosta explained that the FDA has issued industry guidance regarding "Insanitary Conditions at Compounding Facilities." Pursuant to that guidance, insanitary conditions that may give rise to drug adulteration include using ingredients that "have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with 'not for pharmaceutical use' or an equivalent statement)." The FDA industry guidance referenced by Acosta also states:

> In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

Acosta also noted that both the Board and the FDA had previously cautioned compounders about using dietary grade bulk drug substances to compound sterile injectable drug preparations. On January 11, 2019, the Board issued a Compounding Safety Alert, which noted that "[d]ietary supplements, food grade chemicals, and

cosmetic grade ingredients may have as much as 10 times more impurities when compared to pharmaceutical grade standards appropriate for compounding. These impurities can cause patient harm." Additionally, on June 7, 2019, the FDA issued a Compounding Risk Alert titled "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." On June 10, 2019, the Board forwarded that FDA Compounding Risk Alert to its licensees.

34. Second, the COAs for the bulk glutathione and methylcobalamin purchased from Fagron and Medisca show that the bulk drug substances contained the above-mentioned contaminants and impurities, which included filthy, putrid, or decomposed substances. Because the final glutathione and methylcobalamin preparations were never tested for the presence of those specific contaminants or impurities, Acosta has no idea whether they were still present in the final preparations, and if so, at what specific levels. Thus, they caused the final drug preparations to lack quality and be adulterated.

BUDs

35. Generally, a high risk preparation is allowed to have BUDs of 24 hours at room temperature, three days with refrigeration, and 45 days in a frozen solid state. To extend a BUD, the compounding pharmacy must have appropriate supporting documentation of a method suitability test, a container closure integrity test, and stability studies.

Method suitability testing is performed to determine whether any inhibitory or antimicrobial properties in a drug product will prevent the sterility test from detecting the presence of viable microorganisms. It shows that the sterility test method is valid

for a specific formulation of a drug product and reduces the possibility of a sterile result on a product that is not actually sterile.

A container closure integrity test verifies that a particular type of vial and its closure at the top are adequate to maintain a sterile barrier against potential contaminants.

Stability studies provide evidence of how the quality of a drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity, and light.

36. La Vita assigned BUDs of 90 days to its sterile injectable glutathione preparations. Acosta reviewed La Vita's supporting documentation concerning the BUDs for the following 11 lots of glutathione preparations: 158717@2, 158119@2, 156272@1, 153964@2, 152608@11, 145953@2, 144326@3, 142800@3, 140409@7, 138674@13, and 137779@18. She found the documentation inadequate for the following three reasons:

First, La Vita provided documentation of a November 17, 2016 method suitability test, which did not identify the tested lot. Thus, Acosta could not determine if the glutathione injection prepared and tested in November 2016 was the same formulation of glutathione injection prepared in 2018, and whether the preparation method was the same.

Second, La Vita provided documentation of a November 4, 2016 container closure integrity test that did not identify the lot number and also did not identify the specific type of 30 ml amber vial used during the testing. Acosta explained that there are "hundreds, probably more, manufacturers that make a 30 ml amber vial." Thus, she

could not determine if La Vita used the same type of vial that had been tested in 2016 for the 2018 preparations at issue.

Third, La Vita provided only a small, incomplete portion of a 2010 stability study. Additionally, that study used ingredients from Professional Compounding Centers of America (PCCA). La Vita did not purchase its bulk glutathione from PCAA, and thus the information told Acosta "pretty much nothing" about the stability of La Vita's sterile injectable glutathione preparations.

37. La Vita assigned BUDs of 180 days to its sterile injectable methylcobalamin preparations. Acosta reviewed La Vita's supporting documentation concerning the BUDs for the following eight lots of methylcobalamin preparations: 174893@2, 176388@1, 176531@2, 178751@3, 180169@2, 1181213@1, 182972@1, and 183570@8. She found the documentation inadequate for the following three reasons:

First, La Vita provided documentation of a January 3, 2017 method suitability test, which does not identify the tested lot. Thus, Acosta could not determine if the methylcobalamin injection prepared and tested in January 2017 was the same formulation of methylcobalamin injection prepared in 2019 and 2020, and whether the preparation method was the same. Additionally, the test report indicated that "[m]ethod suitability for the sterility testing of this formulation is valid for up to 420 mL of sample. Method suitability will be required if a larger volume of sample is sent for USP<71> sterility testing." Acosta noted that La Vita compounded much larger amounts of up to 4,000 ml per lot, for which there was no valid method suitability test.

Second, La Vita provided documentation of November 4, 2016, and November 17, 2016, container closure integrity tests for 30 ml and 10 ml amber vials, respectively.

The tests did not identify the lot numbers and also did not identify the specific types of amber vials used during the testing. Given the numerous types and manufacturers of amber vials, Acosta could not determine if La Vita used the same type of vials that had been tested in 2016 for the 2019/2020 preparations at issue.

Third, although La Vita provided a valid and complete 2016 stability study for methylcobalamin, the study used PCCA ingredients and included the following warning:

> This formula has been tested in the PCCA lab using only PCCA chemicals and proprietary bases (except when noted). Any variations to this formulation, including substitution with a non-PCCA chemical or non-PCCA base, may affect physical integrity, solubility, organoleptic properties or result in potency or content uniformity issues. This type of substitution will cause the assigned BUD to be invalid.

Because La Vita did not purchase its bulk methylcobalamin from PCCA, it could not rely on this stability study to establish its BUDs.

38. Consequently, Acosta concluded that La Vita's assigned BUDs for its sterile injectable glutathione and methylcobalamin preparations were unsupported. They lacked appropriate supporting documentation of method suitability tests, container closure integrity tests, and stability studies.

Incomplete Compounding Records

39. Acosta explained that a compounding pharmacy is required to keep a single-document compounding log for each specific lot of drug preparation

compounded, so that a reviewer "can always tell what happened during that one particular compound." The PIC is responsible for developing and maintaining compounding logs. California law requires certain information to be included in the compounding logs, including:

- The final quantity or amount of drug preparation compounded for dispensing. Acosta explained that the law requires documentation of the total number of vials made in a particular lot because that number determines the number of vials that must be sent for sterility testing.

- Documentation of quality reviews and required post-compounding process and procedures. This includes bubble point testing[10] of the specific filter used for sterilization to verify its integrity, and the results from end-product testing for sterility and endotoxins.

- The identity of the pharmacist reviewing and verifying the final drug preparation. The pharmacist must verify that all compounding steps and end-product testing were properly performed, and take responsibility for the final product.

40. Acosta reviewed La Vita's compounding logs for its glutathione preparations. She discovered several items of missing information on the logs.

[10] A bubble point test is a non-destructive method of filter integrity testing that allows the user to correlate their results with manufacturer-determined values that indicate proper function.

For lot nos. 137779@18, 138674@13, 140409@7, 142800@3, 144326@3, 145953@2, and 152608@11, La Vita on each log failed to identify the total number of vials made in that lot and failed to document the identity of the pharmacist reviewing the final drug preparation. Regarding the latter, Givant and other La Vita pharmacists specifically failed to complete the designated fields on the logs for the name/signature/date of the reviewing pharmacist.

For lot nos. 153964@2, 156272@1, 158119@2, and 158717@2, La Vita on each log failed to identify the total number of vials made in that lot, failed to document the identity of the pharmacist reviewing the final drug preparation as explained above, and failed to document the filter lot number or type of filter used for that lot and that bubble point testing was performed on the filter.

41. Acosta also reviewed La Vita's compounding logs for its methylcobalamin preparations. She again discovered items of missing information on the logs. Specifically, for lot nos. 174893@2, 176388@1, 176531@2, 178751@3, 180169@2, and 1181213@1, La Vita for each log failed to document the filter lot number or type of filter used for that lot and that bubble point testing was performed on the filter.

Improper Quarantine

42. As part of her investigation, Acosta compared the methylcobalamin dispensing report La Vita originally provided her during the investigation (Original Dispensing Report) to the dates on which each lot of sterile injectable methylcobalamin preparation passed end product testing for sterility and endotoxins. Based on that comparison, Acosta determined that La Vita had dispensed prescriptions of sterile injectable methylcobalamin from the following lots before end product testing confirmed sterility and acceptable levels of endotoxins: 174893@2, 176388@1,

176531@2, 178751@3, 180169@2, and 1181213@1. Thus, La Vita failed to properly quarantine those lots.

43. For the first time at hearing, Acosta was given an opportunity to review La Vita's Revised Dispensing Report, discussed in greater detail below. Acosta expressed several concerns about the accuracy of the Revised Dispensing Report. First, she noted that she was not provided with any raw data to support the revised dates in the Revised Dispensing Report. Second, she noticed some obvious inaccuracies. For lot no. 176531@2, the Original Dispensing Report lists numerous dispenses, whereas the Revised Dispensing Report only lists a single dispense. Additionally, for lot no. 178751@3, the Revised Dispensing Report lists that end product testing results returned on November 8, 2019, which is impossible given that lot no. 178751@3 was only compounded on December 10, 2019.

44. Based on the foregoing, Acosta questions the authenticity and/or accuracy of the Revised Dispensing Report. She believes that its data is either flawed, inaccurately transposed, or potentially manipulated. She observed that the data from the Original Dispensing Report was "sent to me directly from respondent so I feel like I can authenticate that data better."

Insufficient Training and Validation

45. Acosta explained that pharmacy technicians must successfully demonstrate competency on aseptic technique before being allowed to prepare sterile drug preparations. Aseptic technique involves processing or manipulating a sterile substance without contaminating it.

46. California law requires that the training and validation process must be representative of the types of manipulations, products, and batch sizes the pharmacy

technician is expected to prepare. The validation process must also be as complicated as the most complex manipulations performed by staff and contain the same or greater amount of volume transferred during the compounding process. Additionally, the same procedures and equipment must be used in the testing.

47. As part of her investigation, Acosta reviewed the training and testing records of CB, the only pharmacy technician who performed sterile compounding at La Vita. Acosta identified two deficiencies with respect to CB's training and validation testing:

First, although CB compounded both 10 ml and 30 ml vials of sterile injectable methylcobalamin preparation, she underwent no validation testing with the 10 ml vials. Thus, the testing did not involve all the same equipment and products as her compounding practice.

Second, the validation testing only involved 26 of the 30 ml vials, whereas CB on multiple occasions compounded well over 100 of the 30 ml vials per lot. Thus, the testing was not representative of the batch sizes CB was expected to prepare, nor did it involve the same or greater volume as is transferred during the compounding process. Acosta explained that this deficiency is significant, because fatigue is a factor that can substantially affect a pharmacy technician's performance.

48. Thus, Acosta concluded that CB compounded the following lots of sterile injectable methylcobalamin preparation before properly demonstrating competency on aseptic technique: 174893@2, 176388@1, 176531@2, 178751@3, 180169@2, 1181213@1, 182972@1, and 183570@8.

Furnishing to Unlicensed Entity

49. In the course of her investigation, Acosta discovered that on April 1, 2020, La Vita provided compounded lot no. 183570@8 of sterile injectable methylcobalamin preparation to Allianz Transportation, Inc. (ATI) for destruction. Acosta verified that ATI was not licensed by the Board. Thus, she concluded that La Vita had furnished a dangerous drug to an unlicensed entity.

Unprofessional Conduct (Givant Only)

50. Based on Acosta's foregoing findings, Acosta opined that Givant, as the PIC at La Vita, engaged in acts or omissions that involved: (a) the inappropriate exercise of her education, training, or experience as a pharmacist; and (b) the failure to exercise or implement her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs. She opined such acts or omissions constituted unprofessional conduct.

PRIOR FDA WARNING LETTER AND CITATIONS

51. Complainant offered evidence that respondents had previously been issued an FDA warning letter as well as multiple Board citations. Each is addressed below.

FDA Warning Letter

52. On February 28, 2019, the FDA issued respondents a warning letter following an FDA inspection of La Vita conducted from June 4 through 8, 2018. During the inspection, the investigator noted that certain drug products failed to meet conditions of section 503A of the FD&C Act. Additionally, the investigator noted serious deficiencies in La Vita's practices for producing sterile drug products, which put

patients at risk. The FDA strongly recommended a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems.

Board Citations to La Vita

53. On August 19, 2015, the Board issued La Vita Citation No. CI 2014 62003 for violation of Business and Professions Code section 4342 (sale of preparations or drugs lacking quality or strength) and California Code of Regulations, title 16, section 1735.2, subdivision (h) (expiration date violations). La Vita was ordered to pay a $2,500 fine, which it paid in full.

54. On December 13, 2018, the Board issued La Vita Citation No. CI 2018 80737 for violation of California Code of Regulations, title 16, sections 1714, subdivisions (b) and (d) (pharmacy security violations) and 1735.2, subdivisions (i)(2)(A) and (i)(3) (BUD violations). La Vita was ordered to pay a $1,500 fine, which it paid in full.

55. On December 20, 2018, the Board issued La Vita Citation No. CI 2017 80529 for violation of Business and Professions Code section 4115, subdivision (f)(1) (violation of pharmacist/pharmacy technician ratios) and Health and Safety Code section 11164, subdivision (b)(1) (failure to verify electronically-transmitted prescriptions). La Vita was ordered to pay a $500 fine, which it paid in full.

Board Citations to Givant

56. On February 23, 2012, the Board issued Givant Citation No. CI 2011 51366 for violation of Business and Professions Code section 4126.5, subdivision (a)(4)

(improper furnishing of dangerous drugs). Givant was ordered to pay a $5,000 fine and complete an ethics course. Givant fully complied.

57. On August 19, 2015, the Board issued Givant Citation No. CI 2015 6665 for violation of Business and Professions Code section 4342 (sale of preparations or drugs lacking quality or strength) and California Code of Regulations, title 16, section 1735.2, subdivision (h) (expiration date violations). Givant was ordered to pay a $2,500 fine, which she paid in full.

58. On December 13, 2018, the Board issued Givant Citation No. CI 2018 82311 for violation of California Code of Regulations, title 16, sections 1714, subdivisions (b) and (d) (pharmacy security violations) and 1735.2, subdivisions (i)(2)(A) and (i)(3) (BUD violations). Givant was ordered to pay a $2,250 fine, which she paid in full.

59. On December 20, 2018, the Board issued Givant Citation No. CI 2018 82365 for violation of Business and Professions Code section 4115, subdivision (f)(1) (violation of pharmacist/pharmacy technician ratios) and Health and Safety Code section 11164, subdivision (b)(1) (failure to verify electronically-transmitted prescriptions). Givant was ordered to pay a $250 fine, which she paid in full.

Respondents' Evidence

60. Givant testified at hearing. Additionally, respondents offered the testimony of their expert consultant, Amy Summers, Pharm.D. (Summers).

TESTIMONY OF GIVANT

61. Givant received her bachelor of science in pharmacy degree from Drake University in Des Moines, Iowa in 1987. That same year, she became licensed as a

pharmacist in California. After several years as a staff pharmacist and pharmacy manager at a retail pharmacy, she worked as a lead formulation pharmacist at University Compounding Pharmacy from 2000 through 2007, performing both sterile and non-sterile compounding.

62. In October 2007, Givant co-founded La Vita, which she has operated through the present. Historically, La Vita has compounded a variety of drugs, including sterile injectable preparations, transdermal pain creams, and hormone medications. As La Vita's PIC, Givant oversees pharmacy operations, clinical activities, and regulatory compliance; trains pharmacists and technicians in sterile and non-sterile compounding; and interacts with prescribing doctors and patients.

63. Since 2015, La Vita has been accredited in both sterile and non-sterile compounding with the Pharmacy Compounding Accreditation Board (PCAB). Between 2015 and 2021, La Vita was also voted "Best Pharmacy" by the North Coast Readers Poll. In 2017, Givant was the recipient of the California Pharmacists Association's "Innovative Pharmacist of the Year" award. She considers herself a leader in the compounding industry.

64. La Vita had compounded sterile injectable glutathione and methylcobalamin preparations for many years. Although the Board inspected La Vita numerous times over those years, the Board never informed Givant or La Vita that they could not compound with glutathione or methylcobalamin. Despite being administered to over hundreds of patients, La Vita's sterile injectable glutathione and methylcobalamin preparations have also never been associated with any ADR reports.

65. Nevertheless, La Vita stopped compounding sterile injectable glutathione preparations in July 2019 after it received the related notice of violation from Acosta. It

also stopped compounding sterile injectable methylcobalamin preparations upon the original Accusation's filing in April 2020. Moreover, La Vita has stopped performing sterile compounding altogether and has not renewed its Sterile Compounding Permit.

66. Givant does not believe that La Vita improperly compounded with glutathione and methylcobalamin; she believes such compounding is authorized because the FDA has classified them as 503A Category 1 substances. Additionally, La Vita always sourced bulk drug substances from reputable suppliers with whom it had established relationships. La Vita never bought bulk glutathione from Letco, the supplier associated with the reported ADRs that led to the Board's investigation. Finally, La Vita's preparations at issue all passed end product testing for sterility and endotoxins. Thus, Givant strongly disagrees that La Vita's sterile injectable drug preparations lacked quality or were adulterated. Nonetheless, she made a business decision to be cautious and avoid further liability exposure by stopping all sterile compounding.

67. Since that decision, Givant has received many inquiries from former patients and prescribers about if and when La Vita would resume compounding with glutathione and methylcobalamin. They are reportedly concerned about patient access to such compounded drugs in California given complainant's position in this matter. Numerous prescribers and pharmacist colleagues submitted letters in support of continued compounding with glutathione and methylcobalamin, and/or attesting to Givant's competence, professionalism, dedication, trustworthiness, and focus on quality and safety.

68. Givant acknowledges that her recordkeeping practices had room for improvement. To that end, she worked with Summers to improve La Vita's standard operating procedures and forms.

69. Givant denies ever dispensing methylcobalamin prescriptions before end product testing confirmed sterility and acceptable levels of endotoxins. She understands why Acosta came to that conclusion because the Original Dispensing Report provided erroneous dispensing dates. Instead of listing the actual dispensing dates, it listed the dates on which the prescriptions were typed into the dispensing software and the associated prescription labels were printed.

The error resulted from a software limitation that allowed only the prescription entry/label dates to be extracted into a report format. In reality, after prescriptions were typed into the system and the prescription labels printed, the prescriptions were always held until end product testing results returned. Only then were the individual prescriptions scanned with a bar code scanner to signal final pharmacist approval and subsequently dispensed. After Givant was made aware of complainant's allegation of failure to quarantine, Givant contacted the software provider to make modifications allowing for the actual pharmacist approval and shipment dates to be extracted from the system into a report format.

At hearing, respondents offered a revised methylcobalamin dispensing report generated after the software modifications (Revised Dispensing Report). For each prescription, the Revised Dispensing Report shows the date the prescription was typed into the system, the date all end product testing results for the associated lot returned, the pharmacist's final approval date, and the date the prescription was shipped or picked up. Givant testified that the Revised Dispensing Report confirms that La Vita never dispensed any methylcobalamin prescriptions before end product testing results returned.

70. Givant denies furnishing a dangerous drug to an unlicensed entity. La Vita uses a Board-licensed entity for disposal of any controlled substances or

commercial drugs. However, the compounded sterile injectable methylcobalamin preparations were not controlled substances. She provided the specified lot of sterile injectable methylcobalamin preparations to ATI for destruction, and the ATI disposal record shows that it was "treated," i.e., destroyed on April 3, 2020. ATI is licensed by the California Department of Public Health (CDPH) as a medical waste transporter/transport station to pick up, transport, and dispose of all medical waste, including non-controlled pharmaceutical drugs. ATI is also a registered hazardous waste hauler with the California Department of Toxic Substances Control (CDTSC). Givant's testimony is supported by an August 18, 2021 letter from ATI as well as CDPH and CDTSC permits/registrations.

TESTIMONY OF AMY SUMMERS, PHARM.D.

71. Summers received her doctor of pharmacy degree from the University of California, San Francisco in 2007. She became a licensed pharmacist in California that same year. For most of her pharmacist career, she has worked for various compounding pharmacies, sometimes as the PIC. Additionally, since October 2019, Summers has served as a consultant to state-licensed compounding pharmacies on business, operations, quality, and compliance issues. That work includes assisting pharmacies with responding to enforcement actions, implementing remediation plans, and providing expert witness testimony. Summers holds a Board Certified Sterile Compounding Pharmacist credential from the Board of Pharmacy Specialties.

72. Respondents retained Summers to conduct an assessment of complainant's allegations against respondents and offer an expert opinion as to whether respondents violated applicable pharmacy statutes and regulations. As part of her assessment, Summers inspected La Vita and reviewed records concerning

respondents' compounding with glutathione and methylcobalamin. She authored an assessment report dated October 28, 2021.

73. At hearing, Summers testified consistently with her report concerning the issues raised by the Second Amended Accusation. Her relevant testimony as to each issue follows.

Lack of Quality/Adulteration

74. Summers noted that although glutathione and methylcobalamin are dietary supplements, both substances have been compounded into sterile injectable preparations for years. The FDA has classified glutathione and methylcobalamin as 503A Category 1 substances, which allows them to be used for compounding drugs. California also has no regulation specifically prohibiting compounding with either bulk drug substance.

75. **Glutathione:** Summers explained that glutathione does not have a USP drug monograph, likely because the FDA has not yet approved a commercial glutathione drug in the United States. However, the bulk glutathione La Vita purchased from Fagron tested as compliant with the USP dietary monograph for glutathione. Additionally, although the COAs for the bulk glutathione La Vita purchased from Medisca showed it was ungraded, Summers analyzed their specifications and concluded that they were nonetheless compliant with the USP dietary monograph. She also noted that both Fagron and Medisca sourced their bulk glutathione from the same FDA-registered manufacturer and that packaging for both suppliers had stated that the substance was for "prescription compounding." Moreover, based on a comparative analysis using the COAs, Summers opined that the bulk glutathione from

Fagron and Medisca both complied with the European Pharmacopoeia (EP) drug monograph for glutathione.

With respect to the specific contaminants or impurities identified in the bulk glutathione COAs, Summers observed that every substance contains some levels of contaminants or impurities. The pertinent question is whether the levels are harmful based on the dosage and method of administration. After an analysis of the COAs by reference to her computation of a maximum daily dose of sterile injectable glutathione preparation delivered to a patient, Summers opined that the levels of contaminants or impurities: (a) complied with the International Council for Harmonization Guidelines for Elemental Impurities and Impurities in New Drug Substances (ICH Guidelines); and (b) were less than levels in other injectable drug products such as acetylcysteine[11] and magnesium sulfate.[12]

Additionally, Summers explained that the presence of some levels of bacteria, yeast, mold, and fungi does not render the bulk drug substance putrid or harmful if the final preparation is properly sterilized through the aseptic processing or terminal sterilization methods La Vita performed. Although it is very difficult to remove endotoxins, La Vita's end product testing for all glutathione preparations met the specifications for sterility and endotoxins.

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[11] Acetylcysteine (with the brand name Acetadote) is an intravenous antidote for the treatment of acetaminophen overdose.

[12] Magnesium sulfate is commonly administered intravenously for low levels of magnesium and to control seizures in eclampsia or pre-eclampsia (new onset high blood pressure and associated symptoms during pregnancy or after delivery).

76. **Methylcobalamin:** Methylcobalamin also does not have a USP drug monograph, likely because the FDA has not yet approved a commercial methylcobalamin drug in the United States. Although the COAs for the bulk methylcobalamin La Vita purchased from Medisca showed it was ungraded, Summers analyzed their specifications and concluded that they were nonetheless compliant with the USP dietary monograph for methylcobalamin. Moreover, they complied with the Japanese Pharmacopoeia (JP) drug monograph for methylcobalamin, which is available as a commercial injectable drug in Japan.

Finally, as with glutathione, Summers noted that the presence of some levels of bacteria, yeast, mold, and fungi in the bulk methylcobalamin does not render the bulk drug substance putrid or harmful if the final preparation is properly sterilized through the aseptic processing or terminal sterilization methods La Vita performed. Although it is very difficult to remove endotoxins, La Vita's end product testing for all methylcobalamin preparations met the specifications for sterility and endotoxins.

77. **Conclusion:** Based on the foregoing, Summers opined that La Vita's sterile injectable glutathione and methylcobalamin preparations did not lack quality. Additionally, they were not adulterated.

BUDs

78. Summers opined that the sterility test methods used in the relied-upon method suitability tests were also compatible with La Vita's glutathione and methylcobalamin preparations at issue. She did not "think" La Vita made "a lot of different types of versions" of glutathione or methylcobalamin preparations over the years. However, she conceded that the absence of lot numbers tested was a "good question" and "documentation could have been improved here."

79. Additionally, Summers noted that La Vita used the same sizes of amber vials for the preparations at issue as the relied-upon container closure integrity tests. However, Summers would recommend "a more robust study design."

80. Finally, Summers disagreed that La Vita was required to use the same ingredients from the same supplier or manufacturer for a relied-upon stability study to be valid. She opined that it was sufficient to use the same ingredient of the same or better grade because no California regulation specifies that the same supplier or manufacturer is required. She characterized PCCA's warning as a competitive "company driven warning" rather than a "regulatory enforcement warning."

81. In sum, Summers opined that La Vita's BUDs for its sterile injectable glutathione and methylcobalamin preparations were adequately supported by appropriate method suitability tests, container closure integrity tests, and stability studies.

Incomplete Compounding Records

82. Summers reviewed La Vita's compounding logs for its sterile injectable glutathione and methylcobalamin preparations. She opined that Givant documented her review and approval of the final drug preparations by placing her mark, a "C" or "CG" in various places throughout the logs. Based on her discussions with Givant and review of La Vita's processes, Summers is confident that Givant actually performed the verifications, but conceded that it could have been documented more clearly and consistently.

83. Summers also reviewed La Vita's separate unit tracking logs from which she was able to ascertain the total number of vials made in each lot of glutathione and methylcobalamin, and the number of vials of each lot that were sent for sterility and

endotoxin testing. Additionally, Summers reviewed separate documentation provided by La Vita from which she was able to ascertain the applicable filter lot numbers and confirm that bubble point testing was performed on each of those filters.

84. Summers opined that La Vita was "mostly compliant" with recordkeeping requirements in that it did everything the spirit of the law requires. However, there was room for improvement in the clarity of its documentation. To that end, Summers made specific recommendations to create and/or update certain standard operating procedures (SOPs) and forms. Givant was enthusiastic about those recommendations and "immediately got on it."

Improper Quarantine

85. Summers opined that La Vita never dispensed any methylcobalamin prescriptions before end product testing results for sterility and endotoxins returned. She based her opinion on a review of the respective dates on the Revised Dispensing Report. She also performed "spot checks" in La Vita's dispensing software of at least one prescription per methylcobalamin lot to verify the Revised Dispensing Report's accuracy.

Insufficient Training and Validation

86. Summers opined that La Vita was mostly, but not fully, compliant with respect to training and validation of CB's aseptic technique.

Summers found that La Vita's decision to only use 30 ml vials in the validation testing was supported by scientific justifications. She explained that a 30 ml vial has a larger opening, has a larger volume, and takes longer to fill. Consequently, it is more prone to the exposure to and culture of airborne particles or microbes than a smaller

vial when proper aseptic technique is not used. Thus, the 30 ml vial constitutes a "worst case vial size"; if CB demonstrated competency with the 30 ml vial, she is also competent to compound with the 10 ml vial.

Summers also noted that maximum batch size or volume is not a definitive factor in creating a worst case scenario for purposes of validation testing. Other factors could be adding complex manipulations or having testing performed near the end of the work day to test the technician's limits. Nevertheless, she acknowledged that California law requires the validation testing to involve the same or greater amount of volume transferred during the compounding process.

87. Despite any minor testing non-compliance, Summers expressed confidence in CB's competence with respect to aseptic technique. She noted that CB successfully passed all testing.

Furnishing to Unlicensed Entity

88. Summers reviewed ATI's letter and its permits/registrations. She opined that ATI was properly licensed by the CDPH to transport medical waste for destruction, including non-controlled pharmaceutical waste such as the sterile injectable methylcobalamin preparations at issue.

89. Summers further noted that ATI was not acting as a reverse distributor that requires a license from the Board. She explained that a reverse distributor is "a type of company often utilized to obtain a refund from commercial wholesalers on unused expired drugs and/or for controlled drug returns." Instead, ATI here acted merely as a medical waste transporter transporting non-controlled pharmaceutical waste for destruction.

Unprofessional Conduct (Givant Only)

90. Based on Summers's foregoing findings, she opined that Givant did not engage in unprofessional conduct. Although there was room for improvement with respect to some of La Vita's documentation, Givant appropriately used her education, training, and experience as a pharmacist. Givant also exercised her best professional judgment with respect to compounding the sterile injectable glutathione and methylcobalamin preparations at issue.

Brief Overview of Analysis

91. As discussed in greater detail in the Legal Conclusions below, complainant did not establish that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality or were adulterated. However, complainant established most of the remaining pled causes for discipline. When the record as a whole is considered, a four-year probation period for the license and permits at issue is the appropriate discipline and is sufficient to protect public health, safety, and welfare. Additionally, reasonable investigation and enforcement costs are awarded, as discussed below.

Costs

92. The Board may recover its reasonable investigation and enforcement costs of a case. (Bus. & Prof. Code, § 125.3, subd. (a).) Here, complainant incurred a total of $11,207.75 in investigation costs and $91,230 in enforcement costs, for a total of $102,437.75. The requested costs are supported by Certifications of Costs with attachments, setting forth the general tasks performed, the time spent on each task, and the method of calculating the costs. The requested costs constitute a very large

sum. Nevertheless, they are reasonable given the numerous issues and extensive evidentiary record in this case, which required six days of hearing to present.

93. In sum, the total requested costs of $102,437.75 are reasonable. However, it also necessary to consider whether reduction of costs may be appropriate under the factors articulated in *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32 (*Zuckerman*). The *Zuckerman* factors are addressed in the Legal Conclusions below.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. Complainant bears the burden of proving by a preponderance of the evidence that cause exists to discipline La Vita's Pharmacy Permit and Sterile Compounding Permit. (*In the Matter of the Third Amended Accusation Against IV Solutions, Inc.*, Case No. 3606, OAH Case No. 2011050988 [designated as precedential pursuant to Government Code section 11425.60 on October 20, 2020].) The term preponderance of the evidence means "more likely than not" (*Sandoval v. Bank of Am.* (2002) 94 Cal.App.4th 1378, 1387) or "evidence that has more convincing force than that opposed to it" (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567).

La Vita raises two unavailing arguments for applying a higher clear and convincing evidence standard of proof with respect to the Sterile Compounding Permit. First, it contends that a sterile compounding permit is more akin to a professional license, because it requires rigorous and comprehensive training and testing. Second, La Vita claims that the clear and convincing evidence standard has

been applied to such permits in prior cases. Regardless of the potential merit of those arguments, there is no discretion to depart from a precedential decision. Additionally, any failure to apply the correct standard of proof in other cases does not justify importing such error into this case. Finally, even if a clear and convincing evidence standard applied, complainant has met that standard with respect to all sustained causes for discipline discussed below.

2. Complainant bears the burden of proving by clear and convincing evidence that cause exists to discipline Givant's Registered Pharmacist License. (*Ettinger v. Bd. of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) "Clear and convincing evidence requires a finding of high probability. The evidence must be so clear as to leave no substantial doubt. It must be sufficiently strong to command the unhesitating assent of every reasonable mind." (*In re David C.* (1984) 152 Cal.App.3d 1189, 1208.)

Cause for Discipline

3. Business and Professions Code section 4301 provides, in relevant part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct includes, but is not limited to, any of the following:
>
> […]
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> […]

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

4. Complainant asserts 23 causes for discipline based on unprofessional conduct pursuant to Business and Professions Code section 4301, subdivisions (j) and (o). Those causes for discipline are based on several distinct issues concerning La Vita's sterile injectable glutathione and methylcobalamin preparations. Each issue, including the associated alleged violations and causes for discipline, is addressed separately below.

LACK OF QUALITY (FIRST, FIFTH, NINTH, AND SIXTEENTH CFDS)

5. Complainant alleges that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality. California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), provide:

> (g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

> (h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

6. Complainant asserts two distinct reasons why La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality: (a) La Vita used dietary grade or ungraded bulk drug substances; and (b) regardless of the grade, the bulk drug substances used contained specified contaminants and impurities.

(a) Use of Dietary Grade/Ungraded Bulk Drug Substances

7. Complainant argues that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality because they were compounded with dietary grade or ungraded, as opposed to drug or pharmaceutical grade, bulk drug substances. However, complainant fails to point to any federal or state statute or regulation that specifically prohibits such compounding.

8. Compounding with glutathione and methylcobalamin is presently authorized under federal law. The FDA has placed both substances on the 503A Category 1 list, without any specific restriction as to the bulk drug substances' grading or the route of administration. Although it is true that federal law generally classifies dietary supplements such as glutathione and methylcobalamin as foods and not drugs, the FDA was plainly aware that both substances lacked a USP drug monograph. Otherwise, there would have been no need to classify them as 503A Category 1 substances under evaluation for placement on the 503A Bulks List. If they had USP

drug monographs, they would instead have been authorized for compounding based on compliance with an existing USP drug monograph.

9. Nevertheless, as complainant correctly notes, glutathione and methylcobalamin's placement on the 503A Category 1 list is not dispositive. Compounding with such bulk drug substances must still comply with other applicable laws concerning sanitation and quality.

10. California defines quality as "the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document." (Cal. Code Regs., tit. 16, § 1735.1, subd. (ae).) Conspicuously absent from the regulatory definition is any requirement to use only bulk drug substances that are "pharmaceutical grade" or have a USP drug monograph.

11. Nevertheless, complainant advances a general rule that bulk drug substances that do not have a USP drug monograph, including dietary grade and ungraded substances, categorically lack quality under California law and are inappropriate for compounding sterile injectable drug preparations. Regardless of its potential wisdom or scientific merit, such a rule does not currently exist in California law. As noted in Factual Finding 13, proposed California Code of Regulations, title 16, section 1751.9, subdivision (e), was never promulgated. Thus, complainant's proposed rule, which would apply generally to all California-licensed compounding pharmacies when determining the quality of their sterile injectable drug preparations, amounts to an impermissible underground regulation. (*Tidewater Marine Western, Inc. v. Bradshaw* (1996) 14 Cal.4th 557, 571.) Discipline cannot be based on an underground regulation.

12. Complainant's reliance on the FDA's industry guidance regarding "Insanitary Conditions at Compounding Facilities" is misplaced because, by its own terms, it provides recommendations and does not establish legally enforceable responsibilities. Similarly, FDA and Board compounding alerts do not constitute federal or California statutes and regulations.

13. In sum, to establish that La Vita's sterile injectable preparations lacked quality, complainant cannot merely rely on the fact that the bulk glutathione and methylcobalamin were dietary grade or ungraded. Additionally, given the conclusion that no current federal or California statute or regulation categorically prohibits compounding sterile injectable drug preparations with dietary grade or ungraded bulk drug substances, it is unnecessary to reach respondents' arguments regarding the sufficiency of any compliance with EP or JP drug monographs.

(b) Specified Contaminants and Impurities

14. Complainant also argues, based on Acosta's testimony, that the COAs for La Vita's bulk glutathione and methylcobalamin show that the bulk drug substances contained specific contaminants and impurities, which included filthy, putrid, or decomposed substances. However, as Summers persuasively noted, all substances have some levels of contaminants and impurities. The pertinent question is whether they are present at harmful levels.

15. Summers opined that the levels of contaminants and impurities at issue complied with the ICH Guidelines and were less than levels in other injectable drug products such as acetylcysteine and magnesium sulfate. Complainant faults Summers's analysis on several grounds, including that: (1) Summers inappropriately relied on the IHC Guidelines that only apply to new drug substances; (2) Summers's calculations

were based on erroneous maximum daily dosing levels; and (3) Summers's comparison to acetylcysteine and magnesium sulfate was inappropriate because she used outdated monographs and/or those are life-saving drugs not taken routinely like glutathione and methylcobalamin.

Even if complainant's assertions are correct, it remains *complainant's* affirmative burden to establish that the above-mentioned contaminants and impurities were present at harmful levels. That requires testing of the final preparations for the specific contaminants and impurities. It also requires a detailed analysis of the purposes for which the drugs are taken, dosage, frequency of dosing, and route of administration, among other factors. Even assuming that Acosta has sufficient knowledge of pharmaceutical toxicology, she has not performed such testing and analysis with respect to the specific contaminants or impurities at issue. Merely professing a lack of knowledge regarding the levels of contaminants and impurities in the final preparations does not constitute preponderant evidence, let alone clear and convincing evidence. Nor do metaphoric assertions like "turtle pond water," however vivid, carry the day.

16. Nothing in this decision should be construed to dismiss complainant's concerns about compounding sterile injectable drug preparations using dietary grade or ungraded bulk drug substances. But complainant has a viable option to address such concerns—it can promulgate an appropriate regulation through the rulemaking process, allowing for comment and input by appropriate stakeholders. What complainant cannot do is invent an underground regulation and then use that underground regulation to discipline licensees.

17. Under current California law, complainant has not demonstrated that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked quality.

As such, neither La Vita nor Givant violated California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), as they interact with California Code of Regulations, title 16, section 1735.1, subdivision (ae). Thus, there is no cause to discipline La Vita or Givant as the PIC for unprofessional conduct pursuant to Business and Professions Code section 4301, subdivisions (j) or (o), as pled in the First, Fifth, Ninth, and Sixteenth CFDs.

ADULTERATION (SECOND, SIXTH, TENTH, AND SEVENTEENTH CFDS)

18. Complainant alleges that La Vita's sterile injectable glutathione and methylcobalamin preparations were adulterated. "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated." (Health & Saf. Code, § 111295.) "A person or entity shall not do any of the following: . . . Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated . . . ." (Bus. & Prof. Code, § 4169, subd. (a)(2).)

19. "Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance." (Health & Saf. Code, § 111250.) "Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." (Heath & Saf. Code, § 111255.) Additionally, a drug shall be deemed adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." (21 U.S.C. § 351, subd. (a)(2)(A).)

20. Complainant failed to establish that La Vita's sterile injectable glutathione and methylcobalamin preparations were adulterated for the same reasons articulated above with respect to quality. First, no current federal or California statute or

regulation deems a sterile injectable drug preparation adulterated merely because it was compounded with a dietary grade or ungraded bulk drug substance. Second, complainant has not established that the contaminants and impurities present in La Vita's bulk glutathione and methylcobalamin were present in the final preparations at harmful levels.

21. As such, neither La Vita nor Givant violated Health and Safety Code section 111295 or Business and Professions Code section 4169, subdivision (a)(2), as they interact with Health and Safety Code sections 111250 and 111255, and United States Code, title 21, section 351, subdivision (a)(2)(A). Thus, there is no cause to discipline La Vita or Givant as the PIC pursuant to Business and Professions Code section 4301, subdivisions (j) or (o), as pled in the Second, Sixth, Tenth, and Seventeenth CFDs.

BUDs (Third, Seventh, Eleventh, and Eighteenth CFDs)

22. Complainant alleges that La Vita's sterile injectable glutathione and methylcobalamin preparations had unsupported BUDs. California Code of Regulations, title 16, section 1735.2, subdivision (i), provides, in pertinent part:

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

> (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test; (B) Container Closure Integrity Test; and (C) Stability Studies.
>
> (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.
>
> […]

23. Acosta persuasively testified that La Vita's relied-upon method suitability tests and container closure integrity tests were inadequate to support the assigned BUDs. Summers failed to address the information deficiencies identified by Acosta and even conceded that the documentation could be improved.

24. The adequacy of the stability studies is a closer question because the regulation states that the studied drug preparation and the drug preparation at issue shall be "identical in ingredients." It is unclear whether that requires ingredients from the same manufacturer or supplier, or merely ingredients of the same or better grade. But if it is the latter, there was insufficient information to determine that the ingredients from the studied drug preparations and the drug preparations at issue were of the same grade.

25. Even assuming, without deciding, the correctness of Summers's analysis concerning the stability studies, the method suitability tests and container closure

integrity tests were inadequate, as discussed above. As such, the BUDs for La Vita's sterile injectable glutathione and methylcobalamin preparations were unsupported and violated California Code of Regulations, title 16, section 1735.2, subdivision (i). Thus, cause exists to discipline La Vita as pled in the Third and Eleventh CFDs, and Givant as the PIC as pled in the Seventh and Eighteenth CFDs, pursuant to Business and Professions Code section 4301, subdivision (o).

INCOMPLETE COMPOUNDING RECORDS (FOURTH, EIGHTH, TWELFTH, AND NINETEENTH CFDS)

26. Complainant alleges that La Vita's sterile injectable glutathione and methylcobalamin preparations lacked complete compounding records. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2), provides, in pertinent part:

> For each compounded drug preparation, pharmacy records shall include:
>
> [...]
>
> (2) A compounding log consisting of a single document containing all of the following:
>
> [...]
>
> (D) The identity of the pharmacist reviewing the final drug preparation.
>
> [...]
>
> (I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D), (I), & (J).)

27. Acosta persuasively testified that La Vita's compounding logs were incomplete and non-compliant.

As to the identity of the reviewing pharmacist, Givant placed her initials in various places throughout the logs, resulting in erratic and inconsistent verification documentation. Even though the law may not require a specific format for a compounding log, Givant chose the particular form at issue and was required to properly complete it. Moreover, it is impossible to positively identify the reviewing pharmacist without resorting to some external key matching initials with particular individuals. The logs themselves do not provide such a key.

Additionally, although Summers was ultimately able to confirm the total number of vials made in each lot of glutathione and methylcobalamin, the number of vials of each lot that were sent for sterility and endotoxin testing, the applicable filter lot numbers, and the fact that bubble point testing was performed on each of those filters, she could only do so after consulting documentation external to the compounding logs. The regulation requires all that information to be provided in a single-document compounding log. That requirement facilitates easy and timely access to the information, such as during a recall.

28. In sum, the compounding logs for La Vita's sterile injectable glutathione and methylcobalamin preparations were incomplete and non-compliant with California Code of Regulations, title 16, section 1735.3, subdivisions (a)(2)(D), (I), & (J).) Thus, cause exists to discipline La Vita as pled in the Fourth and Twelfth CFDs, and Givant as

the PIC as pled in the Eighth and Nineteenth CFDs, pursuant to Business and Professions Code section 4301, subdivision (o).

IMPROPER QUARANTINE (THIRTEENTH AND TWENTIETH CFDS)

29. Complainant alleges that La Vita failed to properly quarantine specified lots of sterile injectable methylcobalamin preparations until end product testing confirmed sterility and acceptable levels of endotoxins. With exceptions not relevant here, California Code of Regulations, title 16, section 1751.7, subdivision (e)(1), provides that:

> Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients . . . shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

30. The Original Dispensing Report on its face indicates that La Vita dispensed prescriptions of methylcobalamin from several lots before end product testing confirmed sterility and acceptable levels of endotoxins. Respondents provided the Original Dispensing Report to Acosta as part of her investigation, and she was entitled to rely on it.

31. Admittedly, the Revised Dispensing Report suggests otherwise. However, respondents failed to explain why the Revised Dispensing Report was only provided to Acosta for the first time at hearing, leaving little time to verify its authenticity and accuracy. Moreover, even based on her limited review of the Revised Dispensing Report at hearing, Acosta articulated several legitimate reasons to question its accuracy. Although there is insufficient evidence to conclude that La Vita intentionally

manipulated the data in the Revised Dispensing Report, Acosta persuasively testified that it is not reliable. Because Summers based her testimony solely on the Revised Dispensing Report and a few "spot checks," her testimony on this issue is given little weight.

32. In sum, based on the only reliable evidence in the record—the Original Dispensing Report—La Vita failed to properly quarantine several lots of sterile injectable methylcobalamin preparations until end product testing confirmed sterility and acceptable levels of endotoxins. As such, it violated California Code of Regulations, title 16, section 1751.7, subdivision (e)(1). Thus, cause exists to discipline La Vita as pled in the Thirteenth CFD and Givant as the PIC as pled in the Twentieth CFD, pursuant to Business and Professions Code section 4301, subdivision (o).

INSUFFICIENT TRAINING AND VALIDATION (FOURTEENTH AND TWENTY-FIRST CFDS)

33. Complainant alleges that several lots of sterile injectable methylcobalamin preparations were prepared by a La Vita pharmacy technician without sufficient training and process validation. California Code of Regulations, title 16, section 1751.7, subdivision (b)(1), provides, in relevant part:

> The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in

> place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing.

34. Acosta persuasively testified that La Vita's training and validation testing did not involve all the same equipment, products, batch sizes, and volumes as La Vita's compounding practice. Even if, as Summers opined, La Vita's testing regimen can be justified scientifically, it nonetheless failed to comply with the specific requirements of California law, which Summers also concedes.

35. Consequently, complainant established that La Vita violated California Code of Regulations, title 16, section 1751.7, subdivision (b)(1). Thus, cause exists to discipline La Vita as pled in the Fourteenth CFD and Givant as the PIC as pled in the Twenty-First CFD, pursuant to Business and Professions Code section 4301, subdivision (o).

FURNISHING TO UNLICENSED ENTITY (FIFTEENTH AND TWENTY-SECOND CFDs)

36. Complainant alleges that La Vita furnished a specified lot of sterile injectable methylcobalamin preparations, a dangerous drug, to an unlicensed entity. Business and Professions Code section 4126.5, subdivision (a), provides:

> A pharmacy may furnish dangerous drugs only to the following:
>
> (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
>
> (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
>
> (3) A licensed wholesaler acting as a reverse distributor.
>
> (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
>
> (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
>
> (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

> (7) To another pharmacy under common control. During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.

"'Furnish' means to supply by any means, by sale or otherwise." (Bus. & Prof. Code, § 4026.)

37. It is undisputed that La Vita provided the specified lot of sterile injectable methylcobalamin preparations, a dangerous drug, to ATI. It is also undisputed that ATI was not licensed by the Board.

38. However, complainant failed to establish that La Vita "furnished" the methylcobalamin to ATI, as that term is defined in Business and Professions Code section 4026, in violation of Business and Professions Code section 4126.5, subdivision (a). That statute permits selling or otherwise supplying dangerous drugs only to designated entities or persons. But La Vita did not "supply" ATI with methylcobalamin; it contracted with ATI to destroy it. ATI was properly licensed by the CDPH to transport medical waste for destruction, including non-controlled pharmaceutical waste. Notably, even the Board's model probation condition no. 24 for premises licensees references destruction of dangerous drugs by a "waste management company" or reverse distributor.

39. In sum, complainant failed to establish that La Vita furnished a dangerous drug to an unlicensed entity. Thus, cause does not exist to discipline La Vita or Givant as the PIC for unprofessional conduct pursuant to Business and Professions Code section 4301, subdivisions (j) or (o), as pled in the Fifteenth and Twenty-Second CFDs.

UNPROFESSIONAL CONDUCT (TWENTY-THIRD CFD AGAINST GIVANT ONLY)

40. Complainant alleges that Givant engaged in unprofessional conduct based on her acts and omissions in this matter. Business and Professions Code section 4306.5 provides, in pertinent part:

> Unprofessional conduct for a pharmacist may include any of the following:
>
> (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.
>
> (b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
>
> [...]

41. Based on the foregoing factual findings, Givant engaged in acts or omissions that involved the inappropriate exercise of her education, training, or experience as a pharmacist; and the failure to exercise or implement her best professional judgment or corresponding responsibility with regard to the dispensing

or furnishing of dangerous drugs. Specifically, the pharmacy for which she served as the PIC compounded sterile injectable drug preparations that had unsupported beyond use dates, lacked complete compounding records, were improperly quarantined, and were prepared by a pharmacy technician without sufficient training and validation process.

42. Consequently, Givant violated Business and Professions Code section 4306.5, subdivisions (a) and (b). As such, cause exists to discipline Givant as pled in the Twenty-Third CFD, pursuant to Business and Professions Code section 4301, subdivisions (j) and (o).

Appropriate Discipline

43. The Board has issued a "Manual of Disciplinary Guidelines and Model Disciplinary Orders" (Guidelines). The Guidelines direct consideration of several factors to determine the appropriate degree of discipline, including the following relevant to this matter: (1) actual or potential harm to the public; (2) actual or potential harm to any consumer; (3) prior disciplinary record; (4) prior warnings, including citations; (5) number and/or variety of current violations; (6) nature and severity of the acts under consideration; (7) whether the conduct was intentional or negligent, or demonstrated incompetence; (8) aggravating evidence; (9) mitigating evidence; and (10) rehabilitation evidence.

44. Here, complainant failed to establish the most serious causes for discipline alleged against respondents—that the sterile injectable glutathione and methylcobalamin preparations lacked quality and were adulterated. The remaining established causes for discipline involved negligence or deficient knowledge rather than intentional misconduct or fraud. Additionally, neither respondent has previously

been the subject of formal Board discipline. It is also encouraging that Givant expressed a willingness to make recommended changes to La Vita's policies and practices. Consequently, probation is a more appropriate degree of discipline than revocation. (*See Fahmy v. Medical Bd. of California* (1995) 38 Cal.App.4th 810, 817 [the purpose of a license discipline proceeding is not to punish, but to protect the public].)

45. That said, a more substantial probation term of four years is warranted here. Although complainant failed to establish the most serious causes for discipline, some of the established causes for discipline were nonetheless very concerning. For example, La Vita's failure to use properly-supported BUDs and failure to properly quarantine had the potential to result in serious harm to patients and the public. Additionally, this matter involved a significant number and variety of violations, more than would be expected of a long-established pharmacy and an experienced compounding pharmacist. Finally, respondents have previously received an FDA warning letter and multiple Board citations.

46. The Guidelines contain standard and optional probation conditions for individual and premises licensees that may be imposed in a given case as appropriate.

All standard conditions will be imposed. As to standard condition no. 8 for individual licensees (restrictions on supervision and oversight of licensed facilities) in particular, the Guidelines provide various options. Here, option 2 is most appropriate. That option allows Givant to remain as PIC of La Vita only, provided that Givant and La Vita retain a Board-approved independent consultant to monitor their compliance on a quarterly basis. Additionally, Givant will not be permitted to supervise any intern pharmacist or serve as a consultant to any Board-licensed entity.

Additionally, optional conditions for individual licensees nos. 33 (remedial education) and 36 (no ownership or management of licensed premises, with the option to continue existing ownership of a licensed entity) will be imposed. Also, optional conditions for premises licensees nos. 24 (destruction of dangerous drugs) and 25 (no additional ownership or management of licensed premises) will be imposed. Destruction of any remaining sterile injectable preparations at issue in this matter is necessary because they have unsupported BUDs.

47. In sum, when the record as a whole is considered, it is appropriate to place Givant's Registered Pharmacist License as well as La Vita's Pharmacy Permit and Sterile Compounding Permit on probation for a period of four years on the terms described above and outlined in greater detail below.[13] Such terms are sufficient to protect public health, safety, and welfare.

Costs

48. In *Zuckerman*, the California Supreme Court set forth guidelines to determine whether the costs should be assessed in the particular circumstances of each case. These factors include whether the licensee has been successful at hearing in getting charges dismissed or reduced, the licensee's subjective good faith belief in the merits of her position, whether the licensee has raised a colorable challenge to the

[13] As noted above, La Vita stopped performing sterile compounding altogether and has not renewed its Sterile Compounding Permit. However, if La Vita ever elects to renew its Sterile Compounding Permit, it shall be subject to the probation terms outlined below.

proposed discipline, the licensee's financial ability to pay, and whether the scope of the investigation was appropriate to the alleged misconduct.

49. Here, the scope of the investigation was appropriate. Additionally, respondents did not present any evidence of financial inability to pay costs. However, respondents were also successful in getting the most serious charges dismissed. They generally displayed a good faith belief in the merits of their position, although that belief was mistaken as to several of the issues. They raised a colorable challenge to complainant's proposed discipline of revocation.

50. When the appropriate factors and the record as a whole are considered, it is appropriate to reduce the cost recovery to $50,000. Such costs will be payable pursuant to a Board-approved payment plan as a condition of probation.

ORDER

Registered Pharmacist License No. RPH 41076 issued to Christine Ann Givant; Pharmacy Permit No. PHY 48731 issued to La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy; and Sterile Compounding Permit No. LSC 99842 issued to La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy, are REVOKED. However, the revocation is STAYED and the license and permits are placed ON PROBATION for a period of FOUR YEARS on the following terms and conditions:

REGISTERED PHARMACIST LICENSE (Givant)

1. Obey all Laws

Givant shall obey all state and federal laws and regulations.

Givant shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Givant's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Givant shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Givant shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, Givant shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Givant shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of Givant's compliance with the terms and conditions of her probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education

Givant shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Reporting of Employment and Notice to Employers

During the period of probation, Givant shall notify all present and prospective employers of the decision in case no. 6851 and the terms, conditions and restrictions imposed on Givant by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Givant shall report to the board in writing the name, physical address, and mailing address of each of her employer(s), and the name(s) and telephone number(s) of all of her direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Givant shall also include the reason(s) for leaving the prior employment. Givant shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of Givant's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning Givant's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Givant undertaking any new employment, Givant shall cause (a) her direct supervisor, (b) her pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of her employer, to report to the board in writing acknowledging that the listed individual(s) has or have read the decision in case no. 6851, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Givant's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the

event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Givant shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case no. 6851, and the terms and conditions imposed thereby.

If Givant works for or is employed by or through an employment service, Givant must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case no. 6851, and the terms and conditions imposed thereby in advance of Givant commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Givant undertaking any new employment by or through an employment service, Givant shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case no. 6851, and the terms and conditions imposed thereby. It shall be Givant's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a Registered Pharmacist, or any position for which a Registered Pharmacist license is a requirement

or criterion for employment, whether Givant is an employee, independent contractor, or volunteer.

7. Notification of Change(s) in Name, Address(es), or Phone Number(s)

Givant shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address, or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. Restrictions on Supervision and Oversight of Licensed Facilities

During the period of probation, Givant shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Givant may be a pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor of any single entity licensed by the board, but only if Givant or that entity retains, at her expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a quarterly basis for compliance by Givant and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by Givant with the obligations of her supervisory position. Givant may serve in such a position at only one entity licensed by the board, only upon approval by the board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Givant shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any

unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Givant shall pay to the board its costs of investigation and prosecution in the amount of $50,000.[14]

Givant shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

There shall be no deviation from the payment schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

10. Probation Monitoring Costs

Givant shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

[14] This cost recovery is imposed jointly and severally with respect to La Vita's cost recovery, identified below. In other words, Givant and La Vita are jointly and severally liable for a total cost recovery amount of $50,000.

11. Status of License

Givant shall, at all times while on probation, maintain an active, current Registered Pharmacist license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Registered Pharmacist license shall be considered a violation of probation.

If Givant's Registered Pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Givant's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Givant cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Givant may relinquish her license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Givant will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of Givant’s license history with the board.

Upon acceptance of the surrender, Givant shall relinquish her pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Givant may not reapply for any license from the board for three (3) years from the effective date of the surrender. Givant shall meet all requirements

applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. Practice Requirement – Extension of Probation

Except during periods of suspension, Givant shall, at all times while on probation, be employed as a Registered Pharmacist in California for a minimum of thirty (30) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Givant must nonetheless comply with all terms and conditions of probation, unless Givant receives a waiver in writing from the board or its designee.

If Givant does not practice as a Registered Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Givant shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Givant will resume practice at the required level. Givant shall further notify the board in writing within ten (10) days following the next calendar month during which Givant practices as a Registered Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Givant's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. Violation of Probation

If Givant has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Givant, and the board shall provide notice to Givant that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Givant violates probation in any respect, the board, after giving Givant notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Givant during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, Givant's license will be fully restored.

16. Remedial Education

Within thirty (30) days of the effective date of this decision, Givant shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding and recordkeeping. The program of remedial education shall consist of at least 12 hours, which shall be completed within twelve

(12) months at Givant's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require Givant, at her own expense, to take an approved examination to test Givant's knowledge of the course. If Givant does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Givant shall take another course approved by the board in the same subject area.

17. No Ownership or Management of Licensed Premises

Givant shall not acquire any new ownership, legal, or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Givant currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Givant may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

PHARMACY PERMIT AND STERILE COMPOUNDING PERMIT (La Vita)

1. Definition: La Vita

For the purposes of these terms and conditions, "La Vita" shall refer to La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by La Vita to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. Obey All Laws

La Vita shall obey all state and federal laws and regulations.

La Vita shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information, or indictment;
- a conviction of any crime; or

- discipline, citation, or other administrative action filed by any state or federal agency which involves La Vita's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

3. Report to the Board

La Vita shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, La Vita shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, La Vita shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

La Vita shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of La Vita's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, La Vita shall pay to the board its costs of investigation and prosecution in the amount of $50,000.[15]

La Vita shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

There shall be no deviation from the payment plan's schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

[15] This cost recovery is imposed jointly and severally with respect to Givant's cost recovery, identified above. In other words, Givant and La Vita are jointly and severally liable for a total cost recovery amount of $50,000.

7. Probation Monitoring Costs

La Vita shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. Status of License

La Vita shall, at all times while on probation, maintain a current Pharmacy Permit (and if La Vita elects to renew it, a Sterile Compounding Permit) with the board. Failure to maintain current licensure shall be considered a violation of probation.

If La Vita's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication La Vita's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should La Vita wish to discontinue business, La Vita may tender the premises license(s) to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license(s), La Vita will no longer be subject to the terms and conditions of probation.

La Vita may not apply for any new license from the board for three (3) years from the effective date of the surrender. La Vita shall meet all requirements applicable

to the license sought as of the date the application for that license is submitted to the board.

La Vita further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should La Vita sell, trade, or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to La Vita, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. Notice to Employees

La Vita shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. La Vita shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, La Vita shall submit written notification to the board, within fifteen (15) days of the effective date of

this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary, and relief employees and independent contractors employed or hired at any time during probation.

12. Owners and Officers: Knowledge of the Law

La Vita shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in La Vita or La Vita's stock, and all of its officers, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

La Vita shall remain open and engaged in its ordinary business as a pharmacy (and sterile compounding pharmacy, if applicable) in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, La Vita must nonetheless comply with all terms and conditions of probation, unless La Vita is informed otherwise in writing by the board or its designee. If La Vita is not open and engaged in its ordinary business as a pharmacy (and sterile compounding pharmacy, if applicable) for a minimum of 120 hours in any calendar

month, for any reason (including vacation), La Vita shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours La Vita was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which La Vita will resume business as required. La Vita shall further notify the board in writing within ten (10) days following the next calendar month during which La Vita is open and engaged in its ordinary business as a pharmacy (and sterile compounding pharmacy, if applicable) in California for a minimum of 120 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. Posted Notice of Probation

La Vita shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

La Vita shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. Violation of Probation

If La Vita has not complied with any term or condition of probation, the board shall have continuing jurisdiction over La Vita, and probation shall be automatically extended, until all terms and conditions have been satisfied or the board has taken

other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If La Vita violates probation in any respect, the board, after giving La Vita notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against La Vita during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, La Vita's license(s) will be fully restored.

17. Destruction of Dangerous Drugs and/or Dangerous Devices

La Vita shall, by the effective date of this decision, arrange for the destruction of all compounded drug products at issue in Case No. 6851, and the components used to compound drug products at issue in Case No. 6851, by a licensed waste management company or reverse distributor. La Vita shall provide written proof of such destruction within five days of disposition. The Board or its designee shall have the right to retain a sample(s) of any and all compounded drug products at issue in Case No. 6851, or components used to compound drug products at issue in Case No. 6851.

18. No Additional Ownership or Management of Licensed Premises

La Vita shall not acquire any additional ownership, legal, or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by

the board except as approved by the board or its designee. Violations of this restriction shall be considered a violation of probation.

DATE: October 27, 2022

Wim vanRooyen

WIM VAN ROOYEN

Administrative Law Judge

Office of Administrative Hearings

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

In the Matter of the Accusation Against: **LA VITA COMPOUNDING PHARMACY LLC DBA LA VITA COMPOUNDING PHARMACY;** **CHRISTINE ANN GIVANT, MEMBER** **DEBRA HUBERS, MEMBER** **3978 Sorrento Valley Blvd. #300** **San Diego, CA 92121** **Pharmacy Permit No. PHY 48731** **Sterile Compounding License No. LSC 99842** **and** **CHRISTINE ANN GIVANT** **3978 Sorrento Valley Blvd. #300** **San Diego, CA 92121** **Registered Pharmacist License No. RPH 41076** Respondents.	Case No. 6851 **SECOND AMENDED ACCUSATION**

PARTIES

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

2. On or about September 19, 2007, the Board issued Pharmacy Permit Number PHY 48731 to La Vita Compounding Pharmacy LLC (Respondent La Vita) dba La Vita Compounding Pharmacy. On or about September 19, 2007, Christine Ann Givant became a Member and the Pharmacist In Charge (PIC). On or about September 19, 2007, Debra Hubers became a Member. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2021, unless renewed.

3. On or about August 20, 2013, the Board issued Sterile Compounding License Number LSC 99842 to Respondent La Vita. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2021, unless renewed.

4. On or about August 17, 1987, the Board issued Registered Pharmacist License Number RPH 41076 to Christine Ann Givant (Respondent Givant). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2022, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Section 4011 of the Code provides that that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 et seq.).

7. Section 4300 of the Code states, in pertinent part:

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

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

8. Section 4300.1 of the Code states:

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

STATUTORY PROVISIONS

9. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____" "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

10. Section 4026 of the Code states:

"Furnish" means to supply by any means, by sale or otherwise.

11. Section 4113, subdivision (c) of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Section 4126, subdivision (a) of the Code states:

A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a

dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control. During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.

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

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

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

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

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

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

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

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

…

14. Section 4301 of the Code states, in pertinent part:

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

…

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

...

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

…

15. Section 4126.8 of the Code states:

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.

16. Section 4306.5 of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

17. Section 4307, subdivision (a) of the Code states, in pertinent part:

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.

18. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

19. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

20. Health and Safety Code section 111260 states:

Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

21. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

FEDERAL STATUTES

22. Section 321, subdivision (ff) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321) states, in pertinent part:

(ff) The term "dietary supplement" –

(1) Means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) Means a product that –

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does-

(A) Include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include-

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be unlawful under this chapter.

Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

23. Section 350, subdivision (c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 350(c)) states, in pertinent part:

(c) Definitions

(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use-

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which-

(i) is intended for ingestion in table, capsule, powder, softgel, gelcap, or liquid form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

24. Section 501, subdivisions (a)(1) and (2), of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351[1](a)(1) and (2)) states:

A drug or device shall be deemed to be adulterated--

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess …

REGULATORY PROVISIONS

25. California Code of Regulations (Cal. Code Regs.), title 16, section 1735.1, states, in pertinent part:

…

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

…

(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

…

(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

…

(ad) "Product" means a commercially manufactured drug or nutrient evaluated

[1] 21 U.S.C. 351 is referenced as Section 501 of the Federal Food, Drug, and Cosmetic Act.

for safety and efficacy by the FDA.

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

…

26. Cal. Code Regs. Cal. Code Regs., title 16, section 1735.2, subdivisions (g), (h) and (i) state:

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

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

…

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

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

…

27. Cal. Code Regs., title 16, section 1735.3 states, in pertinent part:

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

(1) The master formula document.

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

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

(B) The date the drug preparation was compounded.

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

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

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

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

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA).

28. Cal. Code Regs., title 16, section 1751.7, subdivisions (b)(1) and (e) state:

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the

individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

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

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

COST RECOVERY

29. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DEFINITIONS

30. Glutathione infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

31. Methylcobalamin (methyl vitamin B12) is the synthetic and active form of cobalamin (vitamin B12) that helps in synthesis of methionine and S-adenosylmethionine. Methylcobalamin is required for integrity of myelin, neuronal function, proper red blood cell formation and DNA synthesis. Cobalamin is an essential nutrient which is not synthesized in humans and therefore must be obtained by dietary intake or supplementation. Cobalamin is created by bacteria and can

only be found naturally in animal products; however, synthetic forms are widely available as dietary supplements and added to many foods such as packaged cereals.

Cobalamin can be converted by the liver to methylcobalamin, unless an individual has methenyltetrahydrofolate synthetase deficiency disorder. Methenyltetrahydrofolate synthetase deficiency is a rare neurodevelopmental disorder caused by mutations affecting the MTHFS gene and is generally diagnosed at birth or early infancy.

Cyanocobalamin is the only FDA approved commercially available injectable drug product indicated to treat deficiencies in inadequate absorption such as pernicious anemia.

Injectable Methylcobalamin is not an FDA approved product to treat any disease or disorder.

There are many nonprescription oral dietary supplements with either cyanocobalamin or methylcobalamin meant to alleviate insufficient dietary intake.

Methylcobalamin infusions are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

FACTUAL ALLEGATIONS - GLUTHATHIONE

32. La Vita Compounding Pharmacy is a licensed sterile compounding pharmacy located in San Diego, California. It compounds non-sterile to sterile compounded sterile preparations and furnishes sterile injectable drugs (i.e., infusion) to physicians and clinics for administration to patients. At all times relevant herein, Christine Ann Givant was the Pharmacist-in-Charge and member of the Limited Liability Company that owns Respondent La Vita. Board investigations revealed violations of Pharmacy Law.

33. On or about January 10, 2019, the Board received a report from sterile compounding pharmacy E.P. of adverse drug reactions (ADRs) (i.e., red face, sneezing, nausea, vomiting, shaking, and breathing difficulties) suffered by patients after being administered a compounded non-sterile to sterile injectable glutathione preparation.

34. The Board initiated an investigation, which found that Respondents were using L-glutathione ingredients (i.e., dietary grade and ungraded bulk substances) for compounding non-

sterile to sterile injectable preparations for California patients. The L-glutathione ingredients used in this case were not active pharmaceutical ingredients (API).

35. The Certifications of Analysis (CoA) show that the glutathione ingredients used by Respondents in compounding sterile injectable drug preparations contained filthy, putrid, and/or decomposed substances, including but not limited to, ammonium, arsenic, sulfate, iron, heavy metals, and/or fungi and other unidentified impurities. These ingredients were tested in accordance with compliance standards for human ingestion as a dietary supplement, or only to manufacturer's specifications.

36. In January 2019, the Board issued Compounding Safety Alerts about the use of inappropriate ingredients to compound sterile injectable drugs and strongly encouraged sterile compounding pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action was required. The Board noted that dietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as ten times more impurities when compared to pharmaceutical grade ingredients, increasing the risk of patient harm. On February 1, 2019, the United States Food and Drug Administration (FDA) warned compounders not to use a dietary grade bulk substance distributed by Letco to compound sterile injectable drugs for patients due to higher levels of endotoxins in that dietary grade bulk substance.

37. In June 2019, the FDA issued a warning highlighting concerns with using dietary ingredient glutathione to compound sterile injectables. The FDA collected and tested samples of the L-gluthathione from Letco and E.P., the pharmacy that compounded the drug associated with the adverse reactions. The FDA found that the adverse events were consistent with reactions patients experience with excessive levels of endotoxin, and FDA's testing confirmed higher levels of endotoxin than is appropriate based on the dose of L-glutathione received intravenously. The L-glutathione powder the pharmacies received was labeled with "Caution: Dietary Supplement" and should not have been used to compound sterile injectable drugs. The FDA warned that ingredients not intended for use in compounding sterile injectable drugs can be harmful when administered to patients because they may contain impurities and contaminants, including

endotoxins. It is critical that compounders understand that quality should be built into the drug production, and that testing alone should not be relied on to ensure drug quality. Therefore, compounders should ensure that all ingredients they use to produce sterile injectable drugs are manufactured under conditions and specifications appropriate for the intended route of administration. The FDA also urged manufacturers and repackagers to clearly label ingredients intended for use in dietary supplements. Additionally, repackagers should ask the manufacturer about the intended use of the ingredient. The FDA urged that clarifying information on ingredient labels and in the CoA could help prevent compounders from using ingredients not appropriate for sterile injectable drugs.

38. Respondents compounded and dispensed sterile injectable glutathione drug preparations using ingredients (i.e., dietary grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, impurities, and mold, than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

39. On or about July 3, 2019, the Board issued an updated Notice of Violation to Respondents for this unsafe practice of using ingredients intended for dietary use only, glutathione, to compound to sterile injectable preparations.

Respondent La Vita

FIRST CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drug Preparations Lacking in Quality)

40. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Cal. Code Regs., title 16, section 1735.2, subdivisions (g) and (h), in that from at least January 1, 2018 through January 15, 2019, Respondent La Vita compounded and sold at least 331 prescriptions for at least 38,370ml of injectable glutathione 200mg/ml, that lacked quality as defined by Cal. Code Regs., title 16, section 1735.1, subdivision (ae) and as set forth above in paragraphs 32 through 39.

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SECOND CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

41. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that from at least January 4, 2018 through December 8, 2018, they manufactured, held, sold, offered for sale and/or delivered (including under insanitary conditions) at least 44,900ml of glutathione 200mg/ml injectable drug preparations that were compounded using inappropriate ingredients (i.e., dietary grade and ungraded bulk substances); the glutathione injectable drug preparations were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as set forth above in paragraphs 32 through 39.

THIRD CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

42. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that Respondent La Vita violated Cal. Code Regs., title 16, as set forth more fully above in paragraphs 32 through 39, and as follows: From at least January 4, 2018 through December 8, 2018, Respondent La Vita compounded at least 44,900ml of glutathione 200mg/ml and assigned Beyond Use Dates (BUD) of 90 days without first having method stability tests, container closure integrity tests, and/or stability studies, in violation of Cal. Code Regs., title 16, section 1735.2, subdivision (i)(3). Respondent La Vita failed to support the assigned BUD for at least the following 11 lots of non-sterile to sterile compounded drug preparations:

Lot Number	Date Compounded	BUD Assigned
158717@2	12/6/18	3/6/19
158119@2	11/27/18	2/25/19
156272@1	10/25/18	1/23/19
153964@2	9/19/18	12/18/18

152608@11	8/29/18	11/27/18
145953@2	5/7/18	8/5/18
144326@3	4/11/18	7/10/18
142800@3	3/20/18	6/18/18
140409@7	2/12/18	5/13/18
138674@13	1/17/18	4/17/18
137779@18	1/4/18	4/4/18

FOURTH CAUSE FOR DISCIPLINE

(Failure to have Complete Compounding Records)

43. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that Respondent La Vita violated Cal. Code Regs., title 16, when it failed to have complete compounding records, as set forth above in paragraphs 32 through 39, and as follows:

a. Cal. Code Regs., title 16, section 1735.3(a)(2)(D) and 1735.3(a)(2)(I): On and between January 4, 2018, through August 29, 2018, Respondent La Vita compounded the following lots of glutathione and failed to document how many units were made and failed to document the identity of the pharmacist reviewing the final drug preparation, in violation of Cal. Code Regs., title 16, sections 1735.3(a)(2)(D) and 1735.3(a)(2)(I).

Lot Number	Date Compounded	Amount Compounded
137779@18	1/4/18	4,000ml
138674@13	1/17/18	5,000ml
140409@7	2/12/18	4,000ml
142800@3	3/20/18	5,000ml
144326@3	4/11/18	3,000ml
145953@2	5/7/18	4,000ml
152608@11	8/29/18	5,000ml

b. Cal. Code Regs., title 16, sections 1735.3(a)(2)(D), 1735.3(a)(2)(I), and 1735.3(a)(2)(J): On and between September 19, 2018, through December 6, 2018, Respondent La Vita compounded the following lots of glutathione and failed to document how many units were made, failed to document the identity of the pharmacist reviewing the final drug preparation, and failed to document quality reviews and required post-compounding process and procedures, in violation of Cal. Code Regs., title 16, sections 1735.3(a)(2)(D), 1735.3(a)(2)(I), and 1735.3(a)(2)(J).

Lot Number	Date Compounded	Amount Compounded
153964@2	9/19/18	5,000ml
156272@1	10/25/18	3,000ml
158119@2	11/27/18	4,000ml
158717@2	12/6/18	2,900ml

Respondent Givant

FIFTH CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drug Preparations Lacking in Quality)

44. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Cal. Code Regs., title 16, section 1735.2, subdivisions (g) and (h), in that from at least January 1, 2018 through January 15, 2019, Respondent La Vita compounded and sold at least 331 preparations for at least 38,370ml of injectable glutathione 200mg/ml, that lacked quality as defined by Cal. Code Regs., title 16, section 1735.1, subdivision (ae) and as set forth above in paragraphs 32 through 39.

SIXTH CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

45. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that from at least January 4, 2018 through December 8, 2018, with Respondent Givant as PIC, Respondent La Vita Pharmacy manufactured,

held, sold, offered for sale and/or delivered (including under insanitary conditions) at least 44,900ml of glutathione 200mg/ml injectable drug preparations that were compounded using inappropriate ingredients (i.e., dietary grade and ungraded bulk substances); the glutathione injectable drug preparations were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as set forth above in paragraphs 32 through 39.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

46. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Cal. Code Regs., title 16, as set forth more fully above in paragraphs 32 through 39, and as follows: From at least January 4, 2018 through December 8, 2018, with Respondent Givant as PIC, Respondent La Vita compounded at least 44,900ml of glutathione 200mg/ml and assigned BUDs of 90 days without first having method stability tests, container closure integrity tests, and/or stability studies, in violation of Cal. Code Regs., title 16, section 1735.2, subdivision (i)(3). Respondent La Vita, with Respondent Givant as PIC, failed to support the assigned BUDs for at least the following 11 lots of non-sterile to sterile compounded drug preparations:

Lot Number	Date Compounded	BUD Assigned
158717@2	12/6/18	3/6/19
158119@2	11/27/18	2/25/19
156272@1	10/25/18	1/23/19
153964@2	9/19/18	12/18/18
152608@11	8/29/18	11/27/18
145953@2	5/7/18	8/5/18
144326@3	4/11/18	7/10/18
142800@3	3/20/18	6/18/18
140409@7	2/12/18	5/13/18

138674@13	1/17/18	4/17/18
137779@18	1/4/18	4/4/18

EIGHTH CAUSE FOR DISCIPLINE

(Failure to have Complete Compounding Records)

47. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Cal. Code Regs., title 16, as set forth above in paragraphs 32 through 39, and as follows:

a. Cal. Code Regs., title 16, section 1735.3(a)(2)(D) and 1735.3(a)(2)(I): On and between January 4, 2018, through August 29, 2018, with Respondent Givant as PIC, Respondent La Vita compounded the following lots of glutathione and failed to document how many units were made and failed to document the identity of the pharmacist reviewing the final drug preparation, in violation of Cal. Code Regs., title 16, sections 1735.3(a)(2)(D) and 1735.3(a)(2)(I).

Lot Number	Date Compounded	Amount Compounded
137779@18	1/4/18	4,000ml
138674@13	1/17/18	5,000ml
140409@7	2/12/18	4,000ml
142800@3	3/20/18	5,000ml
144326@3	4/11/18	3,000ml
145953@2	5/7/18	4,000ml
152608@11	8/29/18	5,000ml

b. Cal. Code Regs., title 16, section 1735.3(a)(2)(D), 1735.3(a)(2)(I), and 1735.3(a)(2)(J): On and between September 19, 2018, through December 6, 2018, with Respondent Givant as PIC, Respondent La Vita compounded the following lots of glutathione and failed to document how many units were made, failed to document the identity of the pharmacist reviewing the final drug preparation, and failed to document quality reviews and

required post-compounding process and procedures, in violation of Cal. Code Regs., title 16, sections 1735.3(a)(2)(D), 1735.3(a)(2)(I), and 1735.3(a)(2)(J).

Lot Number	Date Compounded	Amount Compounded
153964@2	9/19/18	5,000ml
156272@1	10/25/18	3,000ml
158119@2	11/27/18	4,000ml
158717@2	12/6/18	2,900ml

FACTUAL ALLEGATIONS- MARCH 4, 2020 INSPECTION RE METHYLCOBALAMIN

48. Respondents continued to compound and dispense sterile injectable drug preparations from inappropriate ingredients, including methylcobalamin, after receiving the Notice of Violation, education by Supervising Inspector C.A., FDA warnings, and the Compounding Safety Alerts, as set forth more fully above in paragraphs 32 through 39 and incorporated by reference herein.

49. On or about March 4, 2020, Board Supervising Inspector C.A. conducted an inspection at Respondent's pharmacy located in San Diego, California. The Supervising Inspector was accompanied by Investigators from the FDA. PIC Givant was present during the inspection and assisted the Supervising Inspector and Investigators. The inspection revealed that Respondent La Vita and Respondent Givant were in violation of multiple pharmacy laws and regulations.

50. Respondent La Vita purchased methylcobalamin ingredients for use in the production of a sterile solution for injection; the methylcobalamin lacks a description of grade. Respondents used these ungraded methylcobalamin ingredients for compounding non-sterile to sterile injectable preparations for California patients.

51. The CoAs show that the methylcobalamin ingredients used by Respondents in compounding sterile injectable drug preparations contained filthy, putrid, and/or decomposed substances, including but not limited to unidentified impurities and gross contamination of yeasts/mold and aerobic bacteria. These ingredients were not tested in accordance with any

compliance standards for human use (oral or injectable) in the United Stated and are considered to be ungraded ingredients (having no known purity level).

52. Respondents compounded and dispensed sterile injectable methylcobalamin drug preparations using ingredients (i.e., ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, impurities, and mold, than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

53. On or about March 11, 2020, the FDA issued a Form FDA 483 to Respondent La Vita observing among other violations, that Respondent La Vita used a non-pharmaceutical grade component in the formulation of a drug product. Specifically, the FDA found that Respondents purchased methylcobalamin active ingredients from Medisca for use in the production of methylcobalamin solution for injection. Respondents purchased and used methylcobalamin ingredients that lacked a description grade. These ungraded ingredients were used in finished product batches.

54. During a telephonic meeting between the FDA, Board Inspector, and Respondent Givant, on March 11, 2020, the Board's Supervising Inspector informed Respondent Givant about the safety risks associated with La Vita's practice of compounding sterile injectable drugs with inappropriate ingredients containing higher levels of contaminants than pharmaceutical grade ingredients.

55. On or about June 2, 2020, the Board issued Notice of Violations to Respondents for this unsafe practice of using ungraded non-pharmaceutical ingredients, methylcobalamin, to compound to sterile injectable preparations.

Respondent La Vita

NINTH CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drug Preparations Lacking in Quality)

56. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Cal. Code Regs., title 16, section 1735.2, subdivisions (g) and (h), in that from at least September 24, 2019 to January 27, 2020, Respondent Pharmacy compounded and sold at least 346 prescriptions for at least 6,330mls of methylcobalamin

l000mcg/ml w/ pres, that lacked quality as defined by Cal. Code Regs., title 16, section 1735.1, subdivision (ae), as more fully set forth above in paragraphs 48 through 55, and as follows: Specifically, Respondent La Vita purchased methylcobalamin active ingredients from Medisca for use in the production of methylcobalamin solution for injection. Respondent La Vita purchased and used three lots of the active ingredient methylcobalamin which were ungraded. These ungraded active ingredients were used in the production of the following finished batches:

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log	Methylcobalamin used
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Medisca: lot 152056/G
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Medisca: lot 155828/A
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Medisca: lot 155828/A
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Medisca: lot 155828/A
1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Medisca: lot 155828/A
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Medisca: lot 155828/A
2/24/20	182972@1	4,000ml	45- 10ml 110- 30mls	Medisca: lot 155828/A
3/9/20	183570@8	900ml	27- 10ml 20- 30mls	Medisca: lot 158765/A
Totals		23,800ml	251- 10mls 636- 30mls	

TENTH CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

57. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that from at least September 24, 2019 through January 27, 2020, they manufactured, held, sold, offered for sale and/or delivered (including under insanitary conditions) at least 23,800ml of methylcobalamin l000mcg/ml w/ pres injectable drug preparations that were compounded using inappropriate ingredients (i.e., ungraded bulk substances); the methylcobalamin injectable drug preparations were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as more fully set forth more fully above in paragraphs 48 through 55, and as follows: Respondent La Vita purchased and used three lots of the methylcobalamin which was ungraded; These ungraded ingredients were used in compounding sterile injectable drug preparations of the following finished batches, which are adulterated:

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log	Methylcobalamin used
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Medisca: lot 152056/G
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Medisca: lot 155828/A
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Medisca: lot 155828/A
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Medisca: lot 155828/A

1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Medisca: lot 155828/A
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Medisca: lot 155828/A
2/24/20	182972@1	4,000ml	45- 10ml 110- 30mls	Medisca: lot 155828/A
3/9/20	183570@8	900ml	27- 10ml 20- 30mls	Medisca: lot 158765/A
Totals		23,800ml	251- 10mls 636- 30mls	

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

58. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that Respondent La Vita violated Cal. Code Regs., title 16, as set forth more fully above in paragraphs 48 through 55, and as follows: From at least September 24, 2019 to March 9, 2020, Respondent La Vita compounded at least 23,800ml of methylcobalamin 1000mcg/ml w/ pres and assigned BUDs of 180 days without first having method suitability tests, container closure integrity tests, and stability studies, in violation of Cal. Code Regs., title 16, section 1735.2, subdivision (i). Respondent La Vita failed to support the assigned BUDs for at least the following 8 lots of non-sterile to sterile compounded methylcobalamin 1000mcg/ml w/ pres:

Date Compounded	Lot Number	BUD assigned
9/24/19	174893@2	3/22/20 (180 days)
10/24/19	176388@1	3/31/20 (180 days)
10/28/19	176531@2	3/31/20 (180 days)
12/10/19	178751@3	6/7/20 (180 days)
1/7/20	180169@2	7/5/20 (180 days)

1/27/20	1181213@1	1/27/20 (180 days)
2/24/20	182972@1	8/22/20 (180 days)
3/9/20	183570@8	9/5/20 (180 days)

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Have Complete Compounding Records)

59. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that Respondent La Vita violated Cal. Code Regs., title 16, as set forth more fully above in paragraphs 48 through 55, and as follows:

a. Cal. Code Regs., title 16, sections 1735.3(a)(2)(D), 1735.3(a)(2)(I) and 1735.3(a)(2)(J): On and between September 24, 2019, through March 9, 2020, Respondent La Vita compounded the following lots of methylcobalamin 1000mcg/ml w/ pres and failed to document required items on the compounding log, including failing to document bubble point on the log, failing to document filler lot on the log, and failing to document final verification when the RPH signed off before final sterility was back, in violation of Cal. Code Regs., title 16, sections 1735.3(a)(2)(D), 1735.3(a)(2)(I) and 1735.3(a)(2)(J).

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log	Release Information	Verified by per PIC
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Endotoxin: 9/30/19 Sterility: 10/9/19	Unnati Desai 9/24/20
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Endotoxin: 10/30/19 Sterility: 11/8/19	Unnati Desai 10/24/20

10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Endotoxin: 11/1/19 Sterility: 11/12/19	Unnati Desai 10/28/20
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Endotoxin: 12/16/19 Sterility: 11/8/19	Chris Givant 12/10/19
1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Endotoxin: 1/13/20 Sterility: 1/22/20	Unnati Desai 1/7/20
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Endotoxin: 1/31/20 Sterility: 2/11/20	Chris Givant 1/27/20

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Until End Product Testing Confirms Sterility and Acceptability)

60. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that Respondent La Vita violated Cal. Code Regs., title 16, section 1751.7(e)(1), as set forth more fully above in paragraphs 48 through 55, and as follows: From at least October 4, 2019 to February 10, 2020, Respondent La Vita dispensed the following lots containing at least 73 prescriptions for 1,820ml of methylcobalamin 1000mcg/ml w/ pres before end product testing confirmed sterility and acceptable levels of pyrogens.

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Date compounded	Lot number	Amount compounded	Amount made per PIC not on log	Release Information	Dispensed Dates	Amount Sold	Verified by per PIC
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Endotoxin: 9/30/19 Sterility: 10/9/19	10/4/19 to 10/8/19	8 Scripts 120ml	Unnati Desai 9/24/20
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Endotoxin: 10/30/19 Sterility: 11/8/19	10/14/19 to 11/7/19	36 Scripts 660ml	Unnati Desai 10/24/20
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Endotoxin: 11/1/19 Sterility: 11/12/19	11/8/19	1 Script 30ml	Unnati Desai 10/28/20
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Endotoxin: 12/16/19 Sterility: 11/8/19	12/6/19 to 12/24/19	30 Scripts 420ml	Chris Givant 12/10/19
1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Endotoxin: 1/13/20 Sterility: 1/22/20	1/3/20 to 1/21/20	19 Scripts 380ml	Unnati Desai 1/7/20
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Endotoxin: 1/31/20	2/4/20 to 2/10/20	9 Scripts 210ml	Chris Givant 1/27/20

				Sterility: 2/11/20			

FOURTEENTH CAUSE FOR DISCIPLINE

(Sterile Compounding Process Validation and Training)

61. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that Respondent La Vita violated Cal. Code Regs., title 16, section 1751.7(b)(1), as set forth more fully above in paragraphs 48 through 55, and as follows: Pharmacy Technician CB failed to successfully demonstrate competency on aseptic technique before being allowed to prepare sterile drug preparations. Pharmacy Technician CB's validation process from 4/22/19, 10/10/19, and 3/17/20 was 26 30ml vials however on at least the following dates she compounded more than 26 30ml vials. Additionally, Pharmacy Technician CB had no process validation for compounding 10mls vials. Pharmacy Technician CB compounded at least the follow lots prior to successfully demonstrate competency on aseptic technique which was representative of the types of manipulations, products and batch sizes she was expected to prepare as required.

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls

1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls
2/24/20	182972@1	4,000ml	45- 10ml 110- 30mls
3/9/20	183570@8	900ml	27- 10ml 20- 30mls

FIFTEENTH CAUSE FOR DISCIPLINE

(Furnishing a Dangerous Drug to an Unlicensed Entity)

62. Respondent La Vita is subject to disciplinary action under Code section 4301, subdivision (o) and/or (j), in that Respondent La Vita violated Code section 4126.5, subdivision (a), when it furnished dangerous drugs to an unlicensed entity. Specifically, on or about April 1, 2020, Respondent La Vita provided dangerous drugs, namely methylcobalamin 1000mcg/ml inj w/ pres lot 183570@8, to Allianz Transportation, Inc. (ATI) located at 28358 Constellation RD unit 640 Valencia CA 91355, an unlicensed entity.

Respondent Givant

SIXTEENTH CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drug Preparations Lacking in Quality)

63. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Cal. Code Regs., title 16, section 1735.2, subdivisions (g) and (h), in that from at least September 24, 2019 to January 27, 2020, in that with Respondent Givant as PIC, Respondent La Vita compounded and sold at least 346 prescriptions for at least 6,330mls of methylcobalamin l000mcg/ml w/ pres, that lacked quality as defined by Cal. Code Regs., title 16, section 1735.1, subdivision (ae), as more fully set forth above in paragraphs 48 through 55, and as follows: Specifically, Respondent La Vita purchased methylcobalamin active ingredients from Medisca for use in the production of methylcobalamin solution for injection.

Respondent La Vita purchased and used three lots of the active ingredient methylcobalamin, which were ungraded. These ungraded active ingredients were used in the production of the following finished batches:

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log	Methylcobalamin used
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Medisca: lot 152056/G
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Medisca: lot 155828/A
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Medisca: lot 155828/A
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Medisca: lot 155828/A
1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Medisca: lot 155828/A
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Medisca: lot 155828/A
2/24/20	182972@1	4,000ml	45- 10ml 110- 30mls	Medisca: lot 155828/A
3/9/20	183570@8	900ml	27- 10ml 20- 30mls	Medisca: lot 158765/A
Totals		23,800ml	251- 10mls 636- 30mls	

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SEVENTEENTH CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

64. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that from at least September 24, 2019 through January 27, 2020, with Respondent Givant as PIC, Respondent La Vita manufactured, held, sold, offered for sale and/or delivered (including under insanitary conditions) at least 23,800ml of methylcobalamin l000mcg/ml w/ pres injectable drug preparations that were compounded using inappropriate ingredients (i.e., ungraded bulk substances); the methylcobalamin injectable drug preparations were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as more fully set forth more fully above in paragraphs 48 through 55, and as follows: Respondent La Vita purchased and used three lots of the methylcobalamin which were ungraded; These ungraded ingredients were used in compounding sterile injectable drug preparations of the following finished batches, which are adulterated:

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log	Methylcobalamin used
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Medisca: lot 152056/G
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Medisca: lot 155828/A
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Medisca: lot 155828/A
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Medisca: lot 155828/A

1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Medisca: lot 155828/A
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Medisca: lot 155828/A
2/24/20	182972@1	4,000ml	45- 10ml 110- 30mls	Medisca: lot 155828/A
3/9/20	183570@8	900ml	27- 10ml 20- 30mls	Medisca: lot 158765/A
Totals		23,800ml	251- 10mls 636- 30mls	

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

65. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that with Respondent Givant as PIC, Respondent La Vita violated Cal. Code Regs., title 16, as set forth more fully above in paragraphs 48 through 55, and as follows: From at least September 24, 2019 to March 9, 2020, Respondent La Vita compounded at least 23,800ml of methylcobalamin 1000mcg/ml w/ pres and assigned a BUD of 180 days without first having method suitability test, container closure integrity test, and stability studies, in violation of Cal. Code Regs., title 16, section 1735.2, subdivision (i). Respondent La Vita failed to support the assigned BUD for at least the following 8 lots of non-sterile to sterile compounded methylcobalamin 1000mcg/ml w/ pres:

Date Compounded	Lot Number	BUD assigned
9/24/19	174893@2	3/22/20 (180 days)
10/24/19	176388@1	3/31/20 (180 days)
10/28/19	176531@2	3/31/20 (180 days)
12/10/19	178751@3	6/7/20 (180 days)

1/7/20	180169@2	7/5/20 (180 days)
1/27/20	1181213@1	1/27/20 (180 days)
2/24/20	182972@1	8/22/20 (180 days)
3/9/20	183570@8	9/5/20 (180 days)

NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Have Complete Compounding Records)

66. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that with Respondent Givant as PIC, Respondent La Vita violated Cal. Code Regs., title 16, as set forth more fully above in paragraphs 48 through 55, and as follows:

a. Cal. Code Regs., title 16, sections 1735.3(a)(2)(D), 1735.3(a)(2)(I) and 1735.3(a)(2)(J): On and between September 24, 2019, through March 9, 2020, Respondent La Vita compounded the following lots of methylcobalamin 1000mcg/ml w/ pres and failed to document required items on the compounding log, including failing to document bubble point on the log, failing to document filler lot on the log, and failing to document final verification when the RPH signed off before final sterility was back, in violation of Cal. Code Regs., title 16, sections 1735.3(a)(2)(D), 1735.3(a)(2)(I) and 1735.3(a)(2)(J).

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log	Release Information	Verified by per PIC
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Endotoxin: 9/30/19 Sterility: 10/9/19	Unnati Desai 9/24/20
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Endotoxin: 10/30/19 Sterility: 11/8/19	Unnati Desai 10/24/20

10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Endotoxin: 11/1/19 Sterility: 11/12/19	Unnati Desai 10/28/20
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Endotoxin: 12/16/19 Sterility: 11/8/19	Chris Givant 12/10/19
1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Endotoxin: 1/13/20 Sterility: 1/22/20	Unnati Desai 1/7/20
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Endotoxin: 1/31/20 Sterility: 2/11/20	Chris Givant 1/27/20

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Quarantine Until End Product Testing Confirms Sterility and Acceptability)

67. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that with Respondent Givant as PIC, Respondent La Vita violated Cal. Code Regs., title 16, section 1751.7(e)(1), as set forth more fully above in paragraphs 48 through 55, and as follows: From at least October 4, 2019 to February 10, 2020, Respondent La Vita dispensed the following lots containing at least 73 prescriptions for 1,820ml of methylcobalamin 1000mcg/ml w/ pres. before end product testing confirmed sterility and acceptable levels of pyrogens.

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Date compounded	Lot number	Amount compounded	Amount made per PIC not on log	Release Information	Dispensed Dates	Amount Sold	Verified by per PIC
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls	Endotoxin: 9/30/19 Sterility: 10/9/19	10/4/19 to 10/8/19	8 Scripts 120ml	Unnati Desai 9/24/20
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls	Endotoxin: 10/30/19 Sterility: 11/8/19	10/14/19 to 11/7/19	36 Scripts 660ml	Unnati Desai 10/24/20
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls	Endotoxin: 11/1/19 Sterility: 11/12/19	11/8/19	1 Script 30ml	Unnati Desai 10/28/20
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls	Endotoxin: 12/16/19 Sterility: 11/8/19	12/6/19 to 12/24/19	30 Scripts 420ml	Chris Givant 12/10/19
1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls	Endotoxin: 1/13/20 Sterility: 1/22/20	1/3/20 to 1/21/20	19 Scripts 380ml	Unnati Desai 1/7/20
1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls	Endotoxin: 1/31/20	2/4/20 to 2/10/20	9 Scripts 210ml	Chris Givant 1/27/20

				Sterility: 2/11/20			

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Sterile Compounding Process Validation and Training)

68. Respondent Givant is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that with Respondent Givant as PIC, Respondent La Vita violated Cal. Code Regs., title 16, section 1751.7(b)(1), as set forth more fully above in paragraphs 48 through 55, and as follows: Pharmacy Technician CB failed to successfully demonstrate competency on aseptic technique before being allowed to prepare sterile drug preparations. Pharmacy Technician CB's validation process from 4/22/19, 10/10/19, and 3/17/20 was 26 30ml vials however on at least the following dates she compounded more than 26 30ml vials. Additionally, Pharmacy Technician CB had no process validation for compounding 10mls vials. Pharmacy Technician CB compounded at least the follow lots prior to successfully demonstrate competency on aseptic technique which was representative of the types of manipulations, products and batch sizes she was expected to prepare as required.

Date Compounded	Lot Number	Amount compounded	Amount made per PIC not on log
9/24/19	174893@2	2,000ml	26- 10ml 55- 30mls
10/24/19	176388@1	2,000ml	27- 10ml 52- 30mls
10/28/19	176531@2	4,000ml	10- 10ml 112- 30mls
12/10/19	178751@3	2,500ml	32- 10ml 65- 30mls
1/7/20	180169@2	4,000ml	49- 10ml 106- 30mls

1/27/20	1181213@1	4,000ml	35- 10ml 116- 30mls
2/24/20	182972@1	4,000ml	45- 10ml 110- 30mls
3/9/20	183570@8	900ml	27- 10ml 20- 30mls

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Furnishing a Dangerous Drug to an Unlicensed Entity)

69. Respondent Givant is subject to disciplinary action under Code section 4301, subdivision (o) and/or (j), in that with Respondent Givant as PIC, Respondent La Vita violated Code section 4126.5, subdivision (a), when it furnished dangerous drugs to an unlicensed entity. Specifically, on or about April 1, 2020, Respondent La Vita provided dangerous drugs, namely methylcobalamin 1000mcg/ml inj w/ pres lot 183570@8, to Allianz Transportation, Inc. (ATI) located at 28358 Constellation RD unit 640 Valencia CA 91355, an unlicensed entity.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

70. Respondent Givant is subject to disciplinary action under Code section 4301, subdivision (o) and/or (j), for unprofessional conduct, in that Respondent Givant violated Code section 4306.5, as follows:

i. 4306.5, subdivision (a): Respondent Givant, as PIC of Respondent La Vita, engaged in acts or omissions that involve, in whole or in part, the inappropriate exercise of her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board. The facts and circumstances are more fully set forth above in paragraphs 32 through 69.

ii. 4306.5, subdivision (b): Respondent Givant, as PIC of Respondent La Vita, engaged in acts or omissions that, in whole or in part, demonstrate the failure to exercise or implement her best professional judgment or corresponding responsibility with regard to the

dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services. The facts and circumstances are more fully set forth above in paragraphs 32 through 69.

DISCIPLINE CONSIDERATIONS

FDA Warnings and/or Notices

71. From on or about June 4, 2018, to June 8, 2018, a U.S. Food and Drug (FDA) investigator inspected Respondent's facility in San Diego, California. On or about February 28, 2019, the FDA issued a Warning Letter to Respondents based off the June 2018 inspection. The FDA noted that during the inspection, the investigator observed that, among other violations, drug products produced by Respondent La Vita failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. §353a] for exemption from certain provisions of the FDCA. Therefore, Respondents produced drug products that violate the FDCA. Additionally, the investigator noted serious deficiencies in Respondents' practices for producing sterile drug products, which put patients at risk. The FDA advised Respondents to please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products Respondents compound meet the conditions of section 503A, including the condition on compounding drug products using a bulk drug substance that complies with applicable USP or NF monograph, is a component of an FDA-approved human drug or appears on the 503A bulks list. Further, the FDA strongly recommended that Respondents' management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems.

72. In February 2019, and June 2019, the FDA issued warnings highlighting concerns with using dietary ingredient glutathione to compound sterile injectables, as more fully set forth above in paragraphs 36 and 37.

73. On or about March 11, 2020, the FDA issued a Form FDA 483 to Respondent La Vita observing among other violations, that Respondents purchased and used methylcobalamin that lacked a description grade, and the ungraded ingredient was used in finished product batches, as more fully set forth above in paragraphs 53 and 54.

Prior Citations

74. To determine the degree of discipline, if any, to be imposed on Respondent La Vita, Complainant alleges that on or about August 19, 2015, in a prior action, the Board issued Citation No. CI 2014 62003 to Respondent La Vita for violating Code section 4342 (sale of preparations or drugs lacking quality or strength) and Cal. Code Regs., title 16, section 1735.2, subdivision (h)(failed to provide expiration date for compounded drugs). Respondent was ordered to pay a fine in the amount of $2,500 and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

75. To determine the degree of discipline, if any, to be imposed on Respondent La Vita, Complainant alleges that on or about August 19, 2015, in a prior action, the Board issued Citation No. CI 2014 62003 to Respondent La Vita for violating Code section 4342 (sale of preparations or drugs lacking quality or strength) and Cal. Code Regs., title 16, section 1735.2, subdivision (h)(failed to provide expiration date for compounded drugs). Respondent was ordered to pay a fine in the amount of $2,500 and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

76. To determine the degree of discipline, if any, to be imposed on Respondent La Vita, Complainant alleges that on or about December 13, 2018, in a prior action, the Board issued Citation No. CI 2018 80737 to Respondent La Vita for violating Cal. Code Regs., title 16, sections 1714, subdivisions (b) and (d) (operational standards and security- pharmacy responsible for pharmacy security), and section 1735.2, subdivisions (i)(2)(A) and (i)(3) (compounding limitations and requirements- beyond use date). Respondent was ordered to pay a fine in the amount of $1,500 and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

77. To determine the degree of discipline, if any, to be imposed on Respondent La Vita, Complainant alleges that on or about December 20, 2018, in a prior action, the Board issued Citation No. CI 2017 80529 to Respondent La Vita for violating Code section 4115, subdivision (f)(1) (pharmacy with only one pharmacist shall have no more than one pharmacy technician and the ratios of pharmacy technicians performing the tasks to any additional pharmacist shall not

exceed 2:1) and Health and Safety Code, section 11164, subdivision (b) (1) (any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of prescriptions). Respondent was ordered to pay a fine in the amount of $500 and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

78. To determine the degree of discipline, if any, February 23, 2012, in a prior action, the Board issued Citation No. CI 2011 51366 to Respondent Givant for violating Code section 4126.5, subdivision (a)(4) (furnishing dangerous drugs by pharmacy; pharmacy or wholesale alleviate temporary shortage). Respondent was ordered to pay a fine in the amount of $5,000 and to complete an ethics course, and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

79. To determine the degree of discipline, if any, August 19, 2015, in a prior action, the Board issued Citation No. CI 2015 66665 to Respondent Givant for violating Code section 4342 (sale of preparations or drugs lacking quality or strength) and Cal. Code Regs., title 16, section 1735.2, subdivision (h)(failed to provide expiration date for compounded drugs). Respondent was ordered to pay a fine in the amount of $2,500, and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

80. To determine the degree of discipline, if any, December 13, 2018, in a prior action, the Board issued Citation No. CI 2018 82311 to Respondent Givant for violating Cal. Code Regs., title 16, section 1714, subdivisions (b) and (d) (operational standards and security-pharmacy responsible for pharmacy security), and section 1735.2, subdivisions (i)(2)(A) and (i)(3) (compounding limitations and requirements- beyond use date). Respondent was ordered to pay a fine in the amount of $2,250, and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

81. To determine the degree of discipline, if any, December 20, 2018, in a prior action, the Board issued Citation No. CI 2018 82365 to Respondent Givant for violating Code section 4115, subdivision (f)(1) (pharmacy with only one pharmacist shall have no more than one pharmacy technician and the ratios of pharmacy technicians performing the tasks to any

additional pharmacist shall not exceed 2:1) and Health and Safety Code, section 11164, subdivision (b) (1) (any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of prescriptions). Respondent was ordered to pay a fine in the amount of $250, and Respondent complied. That citation is now final and is incorporated by reference as if fully set forth.

OTHER MATTERS

82. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48731, issued to La Vita Compounding Pharmacy LLC dba La Vita Compounding Pharmacy, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48731 is placed on probation or until Pharmacy Permit Number PHY 48731 is reinstated, if it is revoked.

83. Pursuant to Code section 4307, if discipline is imposed on Sterile Compounding License Number LSC 99842, issued to La Vita Compounding Pharmacy LLC dba La Vita Compounding Pharmacy, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48731 is placed on probation or until Sterile Compounding License Number LSC 99842 is reinstated, if it is revoked.

84. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48731, issued to La Vita Compounding Pharmacy LLC dba La Vita Compounding Pharmacy, while Christine Ann Givant was an officer or owner and had knowledge of or knowingly participated in any conduct for which the license is disciplined, Christine Ann Givant shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48731 is placed on probation or until Pharmacy Permit Number PHY 48731 is reinstated, if it is revoked.

85. Pursuant to Code section 4307, if discipline is imposed on Sterile Compounding License Number LSC 99842, issued to La Vita Compounding Pharmacy LLC dba La Vita Compounding Pharmacy, while Christine Ann Givant was an officer or owner and had

knowledge of or knowingly participated in any conduct for which the license is disciplined, Christine Ann Givant shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Sterile Compounding License Number LSC 99842 is placed on probation or until Sterile Compounding License Number LSC 99842 is reinstated, if it is revoked.

86. Pursuant to Code section 4307, if discipline is imposed on Registered Pharmacist License Number RPH 41076, issued to Christine Ann Givant, she shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 48731, issued to La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 99842, issued to La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy;

3. Revoking or suspending Registered Pharmacist License Number RPH 41076, issued to Christine Ann Givant;

4. Prohibiting La Vita Compounding Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48731 and/or Sterile Compounding License Number LSC 99842 is placed on probation or until Pharmacy Permit Number PHY 48731 and/or Sterile Compounding License Number LSC 99842 is reinstated, if it is revoked.

5. Prohibiting Christine Anne Givant from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48731 and/or Sterile Compounding License Number LSC 99842 is placed on

probation or until Pharmacy Permit Number PHY 48731 and/or Sterile Compounding License Number LSC 99842 is reinstated, if it is revoked;

6. Prohibiting Christine Anne Givant from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Registered Pharmacist License Number RPH 41076 is placed on probation or until Registered Pharmacist License Number RPH 41076 is reinstated, if it is revoked;

7. Ordering La Vita Compounding Pharmacy LLC, dba La Vita Compounding Pharmacy and Christine Anne Givant, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 4/28/2022

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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