

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

In the Matter of the Accusation Against:

**ASD SPECIALTY HEALTHCARE, LLC, DBA ONCOLOGY SUPPLY,
STEVEN H. COLLIS, JOHN CHOU, J.F. QUINN, JAMES F. CLEARY, JR.,
HYUNG J. BAK, JOSEPH VARNER**

Out of State Distributor License No. OSD 3321,

Respondent.

Agency Case No. 7213 OAH

Case No. 2022050360

DECISION AND ORDER AFTER REMAND


The attached Stipulated Settlement and Disciplinary Order After Remand is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 29, 2024.

It is so ORDERED on October 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is fluid and cursive, with the first name "Seung" and last name "Oh" being clearly legible, and "W." in the middle.

Seung W. Oh, Pharm.D.
Board President

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Attorney General of California
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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

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13 In the Matter of the Accusation Against:

Case No. 7213

14 **ASD SPECIALTY HEALTHCARE LLC;**
DBA ONCOLOGY SUPPLY, STEVEN H.
15 **COLLIS, JOHN CHOU, J.F. QUINN,**
JAMES F. CLEARY, JR., HYUNG J. BAK,
16 **JOSEPH VARNER**
2811 Horace Shepard Drive
17 Dothan, AL 36303

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER AFTER
REMAND

18 **Out of State Distributor License No. OSD**
19 **3321**

20 Respondent.

21 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
22 entitled proceedings that the following matters are true:

23 **PARTIES**

24 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
25 (Board). She brought this action solely in her official capacity and is represented in this matter by
26 Rob Bonta, Attorney General of the State of California, by Steve Pyun, Deputy Attorney General.
27
28

2. Respondent ASD Specialty Healthcare LLC dba Oncology Supply (Respondent) is represented in this proceeding by attorney Sweta Patel, whose address is: 1255 Treat Blvd Ste 300, Walnut Creek, CA 94597-7965.

3. On or about September 20, 1999, the Board of Pharmacy issued Out of State Distributor License Number OSD 3321 to ASD Specialty Healthcare LLC dba Oncology Supply (Respondent), with Steve H. Collis designated as President since September 20, 1999; John Chou designated as Vice President and Treasurer/Chief Financial Officer since August 2, 2007; J.F. Quinn designated as Vice President since June 25, 2015; James F. Cleary, Jr. designated as Vice President/Chief Financial Officer since November 9, 2018; Hyung J. Bak designated as Secretary since May 31, 2019; and Joseph Varner designated as Designated Representative-in-Charge since October 28, 2013. The Out of State Distributor License was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2025, unless renewed.

JURISDICTION

4. Accusation No. 7213 proceeded to an administrative hearing, after which the Administrative Law Judge (ALJ) assigned to hear the case issued a Proposed Decision and Order. The Board rejected this Proposed Decision and Order, requested written argument from the parties, and issued a Decision and Order after Rejection with an effective date of March 29, 2024. The Decision and Order after Rejection revoked Respondent's license; however the revocation was stayed, and Respondent was placed on probation for three years under certain terms and conditions.

5. Respondent filed a Petition for Writ of Mandate in the Los Angeles County Superior Court, Case no. 24STCP00935.

6. On or about September 30, 2024, the parties entered into a confidential settlement agreement, subsequent to which Respondent and Complainant filed a joint stipulation and order for remand returning jurisdiction to the Board.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7213. Respondent has also carefully read, fully

1 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
2 Order.

3 8. Respondent is fully aware of its legal rights in this matter, including the right to a
4 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine
5 the witnesses against them; the right to present evidence and to testify on its own behalf; the right
6 to the issuance of subpoenas to compel the attendance of witnesses and the production of
7 documents; the right to reconsideration and court review of an adverse decision; and all other
8 rights accorded by the California Administrative Procedure Act and other applicable laws.

9 9. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
10 every right set forth above.

11 **CULPABILITY**

12 10. Respondent understands and agrees that the charges and allegations in Accusation
13 No. 7213, if proven at a hearing, constitute cause for imposing discipline upon its Out of State
14 Distributor License.

15 11. For the purpose of resolving the Accusation without the expense and uncertainty of
16 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual
17 basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest
18 those charges.

19 12. Respondent agrees that its Out of State Distributor License is subject to discipline and
20 it agrees to be bound by the Board's disciplinary and probationary terms as set forth in the
21 Disciplinary Order below.

22 **CONTINGENCY**

23 13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
24 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
25 communicate directly with the Board regarding this stipulation and settlement, without notice to
26 or participation by Respondent or its counsel. By signing the stipulation, Respondent understands
27 and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the
28 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its

Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Out of State Distributor License No. OSD 3321 issued to Respondent ASD Specialty Healthcare LLC dba Oncology Supply, is revoked. However, the revocation is stayed and Respondent is placed on probation for one (1) year, beginning on the effective date of March 29, 2024, on the following terms and conditions:

1. Definition: Respondent

For the purposes of these terms and conditions, “respondent” shall refer to ASD Specialty Healthcare LLC dba Oncology Supply. 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 respondent 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.

1 **2. Obey All Laws**

2 Respondent shall obey all state and federal laws and regulations.

3 Respondent shall report any of the following occurrences to the Board, in writing, within
4 seventy-two (72) hours of such occurrence:

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

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

16 **3. Report to the Board**

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

25 **4. Interview with the Board**

26 Upon receipt of reasonable prior notice, respondent shall appear in person for interviews
27 with the Board or its designee, at such intervals and locations as are determined by the Board or
28 its designee. Failure to appear for any scheduled interview without prior notification to Board

1 staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee
2 during the period of probation, shall be considered a violation of probation.

3 **5. Cooperate with Board Staff**

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

10 **6. Reimbursement of Board Costs**

11 As a condition precedent to successful completion of probation, respondent shall pay to the
12 Board its costs of investigation and prosecution in the amount of \$22,375.00.

13 Failure to pay costs by the deadline as directed shall be considered a violation of probation.

14 **7. Probation Monitoring Costs**

15 Respondent shall pay any costs associated with probation monitoring as determined by the
16 Board. Such costs shall be payable to the Board on a schedule as directed by the Board or its
17 designee. Failure to pay such costs by the deadline as directed shall be considered a violation of
18 probation.

19 **8. Status of License**

20 Respondent shall, at all times while on probation, maintain current Out of State Distributor
21 License with the Board. Failure to maintain current licensure shall be considered a violation of
22 probation.

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

27 **9. License Surrender While on Probation/Suspension**

28 Following the effective date of this decision, should respondent wish to discontinue

1 business, respondent may tender the premises license to the Board for surrender. The Board or its
2 designee shall have the discretion whether to grant the request for surrender or take any other
3 action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the
4 license, respondent will no longer be subject to the terms and conditions of probation.

5 Respondent may not apply for any new license from the Board for three (3) years from the
6 effective date of the surrender. Respondent shall meet all requirements applicable to the license
7 sought as of the date the application for that license is submitted to the Board.

8 Respondent further stipulates that it shall reimburse the Board for its costs of investigation
9 and prosecution prior to the acceptance of the surrender.

10 **10. Sale or Discontinuance of Business**

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

19 **11. Notice to Employees**

20 Respondent shall, upon or before the effective date of this decision, ensure that all
21 employees involved in permit operations are made aware of all the terms and conditions of
22 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
23 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
24 remain posted throughout the probation period. Respondent shall ensure that any employees hired
25 or used after the effective date of this decision are made aware of the terms and conditions of
26 probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit
27 written notification to the Board, within fifteen (15) days of the effective date of this decision,
28 that this term has been satisfied. Failure to timely provide such notification to employees, or to

1 timely submit such notification to the Board shall be considered a violation of probation.

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

5 **12. Owners and Officers: Knowledge of the Law**

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

12 **13. Premises Open for Business**

13 Respondent shall remain open and engaged in its ordinary business as an out-of-state
14 distributor for a minimum of 80 hours per calendar month. Any month during which this
15 minimum is not met shall toll the period of probation, i.e., the period of probation shall be
16 extended by one month for each month during with this minimum is not met. During any such
17 period of tolling of probation, respondent must nonetheless comply with all terms and conditions
18 of probation, unless respondent is informed otherwise in writing by the Board or its designee. If
19 respondent is not open and engaged in its ordinary business as an out-of-state distributor for a
20 minimum of 80 hours in any calendar month, for any reason (including vacation), respondent
21 shall notify the Board in writing within ten (10) days of the conclusion of that calendar month.
22 This notification shall include at minimum all of the following: the date(s) and hours respondent
23 was open; the reason(s) for the interruption or why business was not conducted; and the
24 anticipated date(s) on which respondent will resume business as required. Respondent shall
25 further notify the Board in writing with ten (10) days following the next calendar month during
26 which respondent is open and engaged in its ordinary business as an out-of-state distributor for a
27 minimum of 80 hours. Any failure to timely provide such notification(s) shall be considered a
28 violation of probation.

1 **14. Posted Notice of Probation**

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

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

10 **15. Violation of Probation**

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

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

21 **16. Completion of Probation**

22 Upon written notice by the Board or its designee indicating successful completion of
23 probation, respondent's license will be fully restored.

24 **17. Administrative Fine**

25 Respondent shall pay to the Board an administrative fine in the amount of \$150,000.00.
26 Payment shall be made prior to the end date of probation.

27 //

28 //

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Sweta Patel. I understand the stipulation and the effect it will have on my out of state distributor license. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: September 21, 2024



ASD SPECIALTY HEALTHCARE LLC dba
ONCOLOGY SUPPLY
By: CHRISTOPHER CASALENUOVO
Vice President and Associate General Counsel
Respondent

APPROVAL OF FORM AND CONTENT

I have read and fully discussed with Respondent ASD Specialty Healthcare LLC dba Oncology Supply the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 9/23/24



SWETA PATEL
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: October 9, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
DAVID E. BRICE
~~Supervising~~ Deputy Attorney General

Steve Pyun

STEVE PYUN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7213

1 ROB BONTA
Attorney General of California
2 DAVID E. BRICE
Supervising Deputy Attorney General
3 STEVE J. PYUN
Deputy Attorney General
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7 *Attorneys for Complainant*

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15 **COLLIS, JOHN CHOU, J.F. QUINN,**
16 **JAMES F. CLEARY, JR., HYUNG J. BAK,**
17 **JOSEPH VARNER**
2811 Horace Shepard Drive
Dothan, AL 36303

ACCUSATION

18 **Out of State Distributor License No. OSD**
19 **3321**

Respondent.

20
21
22 **PARTIES**

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

25 2. On or about September 20, 1999, the Board of Pharmacy issued Out of State
26 Distributor License Number OSD 3321 to ASD Specialty Healthcare LLC dba Oncology Supply
27 (Respondent), with Steve H. Collis designated as President since September 20, 1999; John Chou
28 designated as Vice President and Treasurer/Chief Financial Officer since August 2, 2007; J.F.

1 Quinn designated as Vice President since June 25, 2015; James F. Cleary, Jr. designated as Vice
2 President/Chief Financial Officer since November 9, 2018; Hyung J. Bak designated as Secretary
3 since May 31, 2019; and Joseph Varner designated as Designated Representative-in-Charge since
4 October 28, 2013. The Out of State Distributor License was in full force and effect at all times
5 relevant to the charges brought herein and will expire on September 1, 2022, unless renewed.

6 **JURISDICTION**

7 3. This Accusation is brought before the Board, under the authority of the following
8 laws. All section references are to the Business and Professions Code (Code) unless otherwise
9 indicated.

10 4. Section 4011 of the Code provides that the Board shall administer and enforce both
11 the Pharmacy Law [Code sections 4000 *et seq.*] and the Uniform Controlled Substances Act
12 [Health & Safety Code sections 11000 *et seq.*].

13 5. Section 4300 of the Code states, in pertinent part, that “[e]very license issued may be
14 suspended or revoked.”

15 6. Section 4300.1 of the Code states:

16 The expiration, cancellation, forfeiture, or suspension of a board-issued license by
17 operation of law or by order or decision of the board or a court of law, the placement of a
18 license on a retired status, or the voluntary surrender of a license by a licensee shall not
19 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.

20 **STATUTORY PROVISIONS**

21 7. Section 4301 of the Code states:

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

24 . . .

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

27 . . .

28 (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.

...

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

...

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

8. Section 4302 of the Code states:

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

9. Section 4307 of the Code states:

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

denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

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

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

REGULATORY PROVISIONS

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

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

COST RECOVERY

11. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licensee 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.

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FACTUAL ALLEGATIONS

Federal Conviction/Settlement

12. Amerisourcebergen Specialty Group, LLC (ABSG) is the 100% owner of Respondent. On or about September 27, 2017, ABSG, after pleading guilty, was convicted of one count of violating 21 U.S.C. §§ 331, subdivision (a), and 333, subdivision (a)(1) [illegal distribution of misbranded drugs] in the criminal proceeding entitled *U.S. v. Amerisourcebergen Specialty Group, LLC* (U.S. District Court, Eastern District of New York, Case No. 17-507(NG)). ABSG entered into a three-year compliance agreement, and was ordered to pay a \$208 million criminal fine and \$52 million in criminal forfeiture. The circumstances underlying the conviction are that between at least 2001 through 2014, two of ABSG's wholly-owned subsidiaries, Respondent and Medical Initiative, Inc. (MII), dispensed millions of pre-filled syringes of adulterated oncology supportive care drugs to healthcare providers in all 50 states. Respondent first obtained FDA-approved drugs that were originally packaged into glass vials. The vials included the FDA-approved dosage and "overfill," which was an extra amount of the drug to account for possible injection issues/errors. Respondent transferred the drugs to MII, where employees removed the FDA-approved drug products from the original glass vials and repackaged them into plastic syringes. This allowed ABSG to profit by utilizing the "overfill" to create more product. However, the extraction and transfer processes performed by MII were conducted in unclean, non-sterile environments, which resulted in contamination of some pre-filled syringes. ABSG did not disclose its process and the increased risk of contamination it created to healthcare providers.

13. On or about October 1, 2018, ABSG and its subsidiaries, including Respondent, agreed to pay \$625 million to resolve a civil suit filed by the U.S. government arising out of the same underlying conduct that led to the 2017 criminal conviction for illegal distribution of misbranded drugs.

Florida Discipline

14. On or about June 21, 2018, Respondent entered into a Settlement Agreement with the Florida Department of Business and Professional Regulation. Respondent agreed to pay a

1 \$15,000 fine based on allegations that Respondent violated the Florida Drug and Cosmetic Act.
2 The terms of the Settlement Agreement state that it constitutes disciplinary action against
3 Respondent.

4 Alabama Discipline

5 15. On or about July 17, 2020, the Alabama State Board of Pharmacy issued a Consent
6 Order against Respondent based on the September 27, 2017, criminal conviction for illegal
7 distribution of misbranded drugs and the June 21, 2018, Settlement Agreement with the Florida
8 Department of Business and Professional Regulation. Respondent was ordered to pay a
9 \$25,000.00 administrative fine.

10 **FIRST CAUSE FOR DISCIPLINE**

11 **(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)**

12 16. Respondent is subject to disciplinary action under Code section 4301, subdivision (f),
13 in that Respondent committed acts involving moral turpitude, dishonesty, fraud, deceit, or
14 corruption. Complainant refers to, and by this reference incorporates, the allegations set forth
15 above in paragraphs 11 through 14 as though set forth fully herein.

16 **SECOND CAUSE FOR DISCIPLINE**

17 **(Violation of Statutes Regulating Controlled Substances or Dangerous Drugs)**

18 17. Respondent is subject to disciplinary action under Code section 4301, subdivision (j),
19 in that Respondent violated statutes of the United States regulating controlled substances and
20 dangerous drugs. Complainant refers to, and by this reference incorporates, the allegations set
21 forth above in paragraphs 11 through 14 as though set forth fully herein.

22 **THIRD CAUSE FOR DISCIPLINE**

23 **(Conviction of Substantially Related Crime)**

24 18. Respondent is subject to disciplinary action under Code section 4301, subdivision (l),
25 in that Respondent was convicted of a crime substantially related to the qualifications, functions,
26 and duties of a licensee. Complainant refers to, and by this reference incorporates, the allegations
27 set forth above in paragraphs 11 through 14 as though set forth fully herein.

28 //

1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Out-of-State Discipline)**

3 19. Respondent is subject to disciplinary action under Code section 4301, subdivision (n),
4 based on discipline by other states of Respondent's license to perform acts for which a license is
5 required under the Pharmacy Law. Complainant refers to, and by this reference incorporates, the
6 allegations set forth above in paragraphs 11 through 14 as though set forth fully herein.

7 **OTHER MATTERS**

8 20. Pursuant to Code section 4307, if discipline is imposed on Out of State Distributor
9 License Number OSD 3321, issued to ASD Specialty Healthcare LLC dba Oncology Supply,
10 Respondent shall be prohibited from serving as a manager, administrator, owner, member, officer,
11 director, associate, or partner of a licensee for five years if Out of State Distributor License
12 Number OSD 3321 is placed on probation or until Out of State Distributor License Number OSD
13 3321 is reinstated if it is revoked.

14 21. Pursuant to Code section 4307, if discipline is imposed on Out of State Distributor
15 License Number OSD 3321, issued to ASD Specialty Healthcare LLC dba Oncology Supply,
16 while Steven H. Collis, John Chou, J.F. Quinn, James F. Cleary, Jr., Hyung J. Bak, and/or Joseph
17 Varner have been an officer, director, and/or owner and had knowledge of or knowingly
18 participated in any conduct for which the licensee was disciplined, Steve. H. Collis, John Chou,
19 J.F. Quinn, James F. Cleary, Jr., Hyung J. Bak, and/or Joseph Varner shall be prohibited from
20 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
21 licensee for five years if Out of State Distributor License Number OSD 3321 is placed on
22 probation or until Out of State Distributor License Number OSD 3321 is reinstated if it is
23 revoked.

24 **PRAYER**

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

27 1. Revoking or suspending Out of State Distributor License Number OSD 3321, issued
28 to ASD Specialty Healthcare LLC dba Oncology Supply;

2. Prohibiting ASD Specialty Healthcare LLC dba Oncology Supply from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Out of State Distributor License Number OSD 3321 is placed on probation or until Out of State Distributor License Number OSD 3321 is reinstated if Out of State Distributor License Number OSD 3321 is revoked;

3. Prohibiting Steven H. Collis, John Chou, J.F. Quinn, James F. Cleary, Jr., Hyung J. Bak, and/or Joseph Varner from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Out of State Distributor License Number OSD 3321 is placed on probation or until Out of State Distributor License Number OSD 3321 is reinstated if Out of State Distributor License Number OSD 3321 is revoked;

4. Ordering ASD Specialty Healthcare, LLC dba Oncology Supply 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,

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

DATED: 2/21/2022

Sodergren,
Anne@DCA

Digitally signed by Sodergren,
Anne@DCA
Date: 2022.02.21 17:19:11 -08'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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