

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

In the Matter of the Accusation Against:

**CREATIVE COMPOUNDS INC.,
DBA HARBOR COMPOUNDING AND
HOME HEALTH CARE PHARMACY**

Pharmacy Permit No. PHY 50397

**CREATIVE COMPOUNDS INC.,
DBA HARBOR COMPOUNDING PHARMACY**

**Licensed Sterile Compounding Permit No.
99688**

MAYANK PARIMAL SHAH

Pharmacist License No. RPH 57834

MICHAEL CAN HUA

Pharmacist License No. RPH 61291

Case No. 5041

OAH No. 2014070068

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER AS TO
CREATIVE COMPOUNDS INC.,
DOING BUSINESS AS HARBOR
COMPOUNDING AND HOME
HEALTH CARE PHARMACY AND
HARBOR COMPOUNDING
PHARMACY ONLY**

DECISION AND ORDER

Pursuant to the Board of Pharmacy's action on September 30, 2015, the attached Stipulated Settlement and Disciplinary Order was adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on November 9, 2015.

It is so ORDERED on October 9, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 DESIREE I. KELLOGG
Deputy Attorney General
4 State Bar No. 126461
600 West Broadway, Suite 1800
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2996
7 Facsimile: (619) 645-2061
Attorneys for Complainant

8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 5041

12 **CREATIVE COMPOUNDS INC.,**
13 **DBA HARBOR COMPOUNDING AND**
14 **HOME HEALTH CARE PHARMACY**
2000 Harbor Blvd., Ste. C-100
Costa Mesa, CA 92627

OAH No. 2014070068

15 Pharmacy Permit No. PHY 50397

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER (CREATIVE
COMPOUNDS INC., DOING BUSINESS
AS HARBOR COMPOUNDING AND
HOME HEALTH CARE PHARMACY
AND HARBOR COMPOUNDING
PHARMACY)

16 **CREATIVE COMPOUNDS INC.,**
17 **DBA HARBOR COMPOUNDING**
18 **PHARMACY 2000 Harbor Blvd., Ste. C-100**
Costa Mesa, CA 92627

19 Licensed Sterile Compounding Permit No.
99688

20 **MAYANK PARIMAL SHAH**
21 P.O. Box 65
Downey, CA 90241

22 Pharmacist License No. RPH 57834

23 **MICHAEL CAN HUA**
24 37255 Tomasek Terrace
Fremont, CA 94536

25 Pharmacist License No. RPH 61291

26 Respondents.
27
28

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

3 PARTIES

4 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.
5 She brought this action solely in her official capacity and is represented in this matter by Kamala
6 D. Harris, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney
7 General.

8 2. Respondents Creative Compounds Inc. dba Harbor Compounding and Home Health
9 Care Pharmacy and Creative Compounds Inc., dba Harbor Compounding Pharmacy
10 (Respondents) are represented in this proceeding by attorney Herbert L. Weinberg of Fenton Law
11 Group, LLP whose address is: 1990 S. Bundy Drive, Suite 777, Los Angeles, CA 90025.

12 3. On or about August 25, 2010, the Board of Pharmacy issued Pharmacy Permit No.
13 PHY 50397 to Creative Compounds Inc. dba Harbor Compounding and Home Health Care
14 Pharmacy. The Pharmacy Permit was in full force and effect at all times relevant to the charges
15 brought in First Amended Accusation No. 5041 and will expire on August 1, 2015, unless
16 renewed.

17 4. On or about July 15, 2011, the Board of Pharmacy issued Licensed Sterile
18 Compounding Permit No. 99688 to Creative Compounds Inc. dba Harbor Compounding and
19 Home Health Care Pharmacy. The Licensed Sterile Compounding Permit was in full force and
20 effect at all times relevant to the charges brought in First Amended Accusation No. 5041 and will
21 expire on August 1, 2015, unless renewed.

22 JURISDICTION

23 5. First Amended Accusation No. 5041 was filed before the Board of Pharmacy (Board),
24 Department of Consumer Affairs, and is currently pending against Respondents. The First
25 Amended Accusation and all other statutorily required documents were properly served on
26 Respondent on April 28, 2015. Respondents timely filed their Notice of Defense contesting the
27 First Amended Accusation.

1 However, the revocation is stayed and Respondents are placed on probation for five (5) years on
2 the following terms and conditions.

3 **1. Suspension**

4 License number PHY 50397 issued to respondent Creative Compounds Inc., dba Harbor
5 Compounding and Home Health Care Pharmacy and Licensed Sterile Compounding Permit
6 number 99688 issued to Creative Compounds Inc., dba Harbor Compounding Pharmacy are
7 suspended beginning the effective of this decision, until one employee who prepares compounded
8 drug preparations and the pharmacist-in-charge complete ten (10) hours of remedial education in
9 the subject matter area of preparing compounded drug preparations in a course preapproved by
10 the board and provides satisfactory proof of completion of that remedial education to the board.

11 Respondents shall cease all pharmacy operations during the period of suspension. Failure
12 to comply with this suspension shall be considered a violation of probation.

13 **2. Obey All Laws**

14 Respondents owners shall obey all state and federal laws and regulations.

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

- 17 an arrest or issuance of a criminal complaint for violation of any provision of the
18 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
19 substances laws
- 20 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
21 criminal complaint, information or indictment
- 22 a conviction of any crime
- 23 discipline, citation, or other administrative action filed by any state or federal agency
24 which involves respondents' pharmacy permit and licensed sterile compounding
25 permit or which is related to the practice of pharmacy or the manufacturing,
26 obtaining, handling or distributing, billing, or charging for any drug, device or
27 controlled substance.

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

1 **3. Report to the Board**

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

10 **4. Interview with the Board**

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

16 **5. Cooperate with Board Staff**

17 Respondents owners shall cooperate with the board's inspection program and with the
18 board's monitoring and investigation of respondent's compliance with the terms and conditions of
19 their probation. Failure to cooperate shall be considered a violation of probation.

20 **6. Reimbursement of Board Costs**

21 As a condition precedent to successful completion of probation, respondents owners shall
22 be jointly and severally liable with Michael Can Hua and shall pay to the board its costs of
23 investigation and prosecution in the amount of \$12,262.00. Respondents owners shall make said
24 payments in a payment plan to be approved by the board. There shall be no deviation from this
25 schedule absent prior written approval by the board or its designee. Failure to pay costs by the
26 deadline(s) as directed shall be considered a violation of probation.

27 The filing of bankruptcy by respondents owners shall not relieve respondents of their
28 responsibility to reimburse the board its costs of investigation and prosecution.

1 **7. Probation Monitoring Costs**

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

6 **8. Status of License**

7 Respondents owners shall, at all times while on probation, maintain current licensure with
8 the board. If respondents owners submit an application to the board, and the application is
9 approved, for a change of location, change of permit or change of ownership, the board shall
10 retain continuing jurisdiction over the license, and the respondents shall remain on probation as
11 determined by the board. Failure to maintain current licensure shall be considered a violation of
12 probation.

13 If respondents owners' licenses expire or are cancelled by operation of law or otherwise at
14 any time during the period of probation, including any extensions thereof or otherwise, upon
15 renewal or reapplication respondents owners' licenses shall be subject to all terms and conditions
16 of this probation not previously satisfied.

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

18 Following the effective date of this decision, should respondents owners discontinue
19 business, respondents owners may tender the premises and sterile compounding license to the
20 board for surrender. The board or its designee shall have the discretion whether to grant the
21 request for surrender or take any other action it deems appropriate and reasonable. Upon formal
22 acceptance of the surrender of the license, respondents will no longer be subject to the terms and
23 conditions of probation.

24 Upon acceptance of the surrender, respondents owners shall relinquish the premises wall
25 and renewal license to the board within ten (10) days of notification by the board that the
26 surrender is accepted. Respondents owners shall further submit a completed Discontinuance of
27 Business form according to board guidelines and shall notify the board of the records inventory
28 transfer.

1 Respondents owners shall also, by the effective date of this decision, arrange for the
2 continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written
3 notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that
4 identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating
5 as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five
6 days of its provision to the pharmacy's ongoing patients, Respondents owners shall provide a
7 copy of the written notice to the board. For the purposes of this provision, "ongoing patients"
8 means those patients for whom the pharmacy has on file a prescription with one or more refills
9 outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)
10 days.

11 Respondents owners may not apply for any new licensure from the board for three (3) years
12 from the effective date of the surrender. Respondents owners shall meet all requirements
13 applicable to the license sought as of the date the application for that license is submitted to the
14 board.

15 Respondents owners further stipulates that he or she shall reimburse the board for its costs
16 of investigation and prosecution prior to the acceptance of the surrender.

17 **10. Notice to Employees**

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

28 "Employees" as used in this provision includes all full-time, part-time,

1 volunteer, temporary and relief employees and independent contractors employed or
2 hired at any time during probation.

3 **11. Owners and Officers: Knowledge of the Law**

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

10 **12. Posted Notice of Probation**

11 Respondents owners shall prominently post a probation notice provided by the board in a
12 place conspicuous and readable to the public. The probation notice shall remain posted during
13 the entire period of probation.

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

18 Failure to post such notice shall be considered a violation of probation.

19 **13. Violation of Probation**

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

25 If respondents owners violate probation in any respect, the board, after giving respondents
26 owners notice and an opportunity to be heard, may revoke probation and carry out the
27 disciplinary order that was stayed. Notice and opportunity to be heard are not required for those
28 provisions stating that a violation thereof may lead to automatic termination of the stay and/or

1 revocation of the license. If a petition to revoke probation or an accusation is filed against
2 respondents during probation, the board shall have continuing jurisdiction and the period of
3 probation shall be automatically extended until the petition to revoke probation or accusation is
4 heard and decided.

5 **14. Completion of Probation**

6 Upon written notice by the board or its designee indicating successful completion of
7 probation, respondent licenses will be fully restored.

8 **15. Posted Notice of Suspension**

9 Respondents owners shall prominently post a suspension notice provided by the board in a
10 place conspicuous and readable to the public. The suspension notice shall remain posted during
11 the entire period of suspension ordered by this decision.

12 Respondents owners shall not, directly or indirectly, engage in any conduct or make any
13 statement, orally, electronically or in writing, which is intended to mislead or is likely to have the
14 effect of misleading any patient, customer, member of the public, or other person(s) as to the
15 nature of and reason for the closure of the licensed entity.

16 **16. Remedial Education**

17 Respondents shall submit to the board or its designee, for prior approval, an appropriate
18 program of remedial education in the subject matter area of preparing compounded drug
19 preparations for all employees involved in preparing compounded drug preparations. The
20 program of remedial education shall consist of at least ten (10) hours for each such employee at
21 respondents' own expense and shall be a course preapproved by the board. Satisfactory proof of
22 completion of such a course for all employees involved in preparing compounded drug
23 preparations shall be submitted to the board within sixty (60) days of the effective date of the
24 decision. Respondents' licenses shall be suspended until the remedial education program for one
25 employee involved in preparing compounded drug preparations and the pharmacist-in-charge
26 have been successfully completed and the satisfactory proof of compliance submitted to the
27 Board.
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1 **17. Pharmacy Consultant**

2 Within thirty (30) days of the effective date of this decision, respondents shall submit to the
3 board or its designee, for prior approval, the name and license number of an expert in preparing
4 compounded drug preparations that shall then be retained by the pharmacies at their own expense
5 as an independent consultant responsible for reviewing pharmacy operations on a monthly basis
6 during the period of probation for compliance by respondents with state and federal laws and
7 regulations governing the practice of pharmacy. The consultant shall not on probation with the
8 board. Respondents shall be responsible for ensuring that the consultant submits timely reports.
9 After twelve monthly reports have been submitted timely, respondents may request that the board
10 or its designee approve transition to quarterly review and reporting by the consultant. Approval
11 or denial of such transition shall be within the discretion of the board or its designee.

12 If an approved consultant is no longer able or willing to serve as a consultant for
13 respondents, respondents shall seek approval of a new consultant within thirty (30) days, and to
14 ensure timely reporting by the newly-approved consultant. Respondents may not operate as a
15 pharmacy without a consultant approved by the board or its designee, and failure to secure
16 approval of a consultant shall result in a further suspension of the pharmacy's operations until
17 such time as a consultant is approved and respondent is informed by the board or its designee that
18 it may resume pharmacy operations.

19 Failure to timely seek approval of, retain, or ensure timely reporting by the consultant shall
20 be considered a violation of probation.


21 **18. No Ownership of Licensed Premises**

22 Respondents shall not acquire any new ownership, legal or beneficial interest nor serve as a
23 manager, administrator, member, officer, director, trustee, associate, or partner of any additional
24 business, firm, partnership, or corporation licensed by the board. If respondents currently own or
25 have any legal or beneficial interest in, or serves as a manager, administrator, member, officer,
26 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently
27 or hereinafter licensed by the board, respondents may continue to serve in such capacity or hold
28 that interest, but only to the extent of that position or interest as of the effective date of this

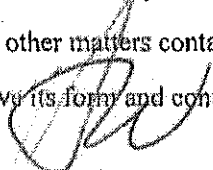
1 decision. Violation of this restriction shall be considered a violation of probation.

2 ACCEPTANCE

3 I am authorized to sign on behalf of Respondents. I have carefully read the above
4 Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney,
5 Herbert L. Weinberg. I understand the stipulation and the effect it will have on Respondents'
6 Pharmacy Permit, and Licensed Sterile Compounding Permit. I enter into this Stipulated
7 Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be
8 bound by the Decision and Order of the Board of Pharmacy.

9 DATED: 7/15/15 
10 MICHAEL CAN HUA, AUTHORIZED AGENT FOR
11 AND ON BEHALF OF CREATIVE COMPOUNDS
12 INC. DBA HARBOR COMPOUNDING AND HOME
13 HEALTH CARE PHARMACY AND CREATIVE
14 COMPOUNDS INC., DBA HARBOR
15 COMPOUNDING PHARMACY
16 Respondents

15 I have read and fully discussed with Respondent Creative Compounds Inc. dba Harbor
16 Compounding and Home Health Care Pharmacy and Creative Compounds Inc., dba Harbor
17 Compounding Pharmacy the terms and conditions and other matters contained in the above
18 Stipulated Settlement and Disciplinary Order. I approve its form and content.

19 DATED: 7/15/2015 
20 Herbert L. Weinberg
21 ATTORNEY FOR RESPONDENTS CREATIVE
22 COMPOUNDS INC. DBA HARBOR
23 COMPOUNDING AND HOME HEALTH CARE
24 PHARMACY AND CREATIVE COMPOUNDS INC.,
25 DBA HARBOR COMPOUNDING PHARMACY

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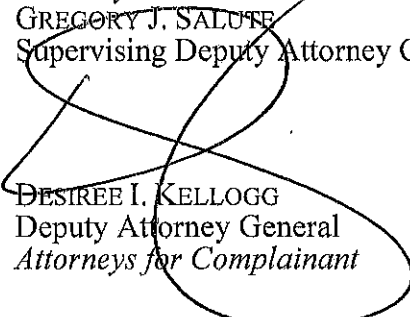
ENDORSEMENT

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

DATED: 7/16/15

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
~~GREGORY J. SALUTE~~
Supervising Deputy Attorney General


DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 5041

1 KAMALA D. HARRIS
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 DESIREE I. KELLOGG
Deputy Attorney General
4 State Bar No. 126461
110 West "A" Street, Suite 1100
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2996
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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9 **BEFORE THE**
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10 **DEPARTMENT OF CONSUMER AFFAIRS**
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11 In the Matter of the Accusation Against:

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13 **DBA HARBOR COMPOUNDING AND HOME**
14 **HEALTH CARE PHARMACY**
2000 Harbor Blvd., Ste. C-100
15 Costa Mesa, CA 92627

FIRST AMENDED ACCUSATION

16 Pharmacy Permit No. PHY 50397

17 **CREATIVE COMPOUNDS INC.,**
18 **DBA HARBOR COMPOUNDING PHARMACY**
2000 Harbor Blvd., Ste. C-100
Costa Mesa, CA 92627

19 Licensed Sterile Compounding Permit No. 99688

20 **MAYANK PARIMAL SHAH**
P.O. Box 65
21 Downey, CA 90241

22 Pharmacist License No. RPH 57834

23 **MICHAEL CAN HUA**
37255 Tomasek Terrace
24 Fremont, CA 94536

25 Pharmacist License No. RPH 61291

26 Respondents.

1 Complainant alleges:

2 **PARTIES**

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

6 2. On or about August 25, 2010, the Board of Pharmacy issued Pharmacy Permit
7 Number PHY 50397 to a corporate entity, Creative Compounds Inc., dba Harbor Compounding
8 and Home Health Care Pharmacy (Respondent Harbor Compounding and Home Health Care
9 Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges
10 brought herein and will expire on August 1, 2015, unless renewed.

11 3. On or about July 15, 2011, the Board of Pharmacy issued Licensed Sterile
12 Compounding Permit Number 99688 to a corporate entity, Creative Compounds Inc., doing
13 business as Harbor Compounding Pharmacy (Respondent Harbor Compounding Pharmacy). The
14 Licensed Sterile Compounding Permit was in full force and effect at all times relevant to the
15 charges brought herein and will expire on August 1, 2015, unless renewed.

16 4. On or about November 10, 2005, the Board of Pharmacy issued Pharmacist License
17 Number RPH 57834 to Mayank Parimal Shah (Respondent Mike Shah). The Pharmacist License
18 was in full force and effect at all times relevant to the charges brought herein and will expire on
19 August 31, 2015, unless renewed.

20 5. On or about August 6, 2008, the Board of Pharmacy issued Pharmacist License
21 Number RPH 61291 to Michael Can Hua (Respondent Michael Hua). The Pharmacist License
22 was in full force and effect at all times relevant to the charges brought herein and will expire on
23 June 30, 2016, unless renewed.

24 **JURISDICTION**

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

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13. Section 4127.7 of the Code states:

On or after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:

(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

14. Sections 4201(a) and (b)(2) of the Code states:

Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

As used in this section, and subject to subdivision (c), the term "beneficially interested" means and includes:

...

If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

15. 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

....

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

....

(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.

....

1 16. Section 4302 of the Code states:

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

7 17. Section 4307(a) of the Code states that:

8 Any person who has been denied a license or whose license has been revoked
9 or is under suspension, or who has failed to renew his or her license while it was
10 under suspension, or who has been a manager, administrator, owner member, officer,
11 director, associate, or partner of any partnership, corporation, firm, or association
12 whose application for a license has been denied or revoked, is under suspension or
13 has been placed on probation, and while acting as the manger, administrator, owner,
14 member, officer, director, associate, or partner had knowledge or knowingly
15 participated in any conduct for which the license was denied, revoked, suspended, or
16 placed on probation, shall be prohibited from serving as a manger, administrator,
17 owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

23 **REGULATORY PROVISIONS**

24 18. Title 16, California Code of Regulations, section 1735(a) states in pertinent part:

25 "Compounding" means any of the following activities occurring in a licensed
26 pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a
27 prescription:

28 (1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

...

19. Title 16, California Code of Regulations, section 1735.2(h) states:

Every compounded drug product shall be given an expiration date representing
the date beyond which, in the professional judgment of the pharmacist performing or
supervising the compounding, it should not be used. This "beyond use date" of the
compounded drug product shall not exceed 180 days from preparation or the shortest
expiration date of any component in the compounded drug product, unless a longer
date is supported by stability studies of finished drugs or compounded drug products
using the same components and packaging. Shorter dating than set forth in this

1 subsection may be sued if it is deemed appropriate in the professional judgment of the
2 responsible pharmacist.

3 20. Title 16, California Code of Regulations, section 1735.5(c) states:

4 (c) The policy and procedure manual shall include the following:

5 (1) Procedures for notifying staff assigned to compounding duties of any
6 changes in processes or to the policy and procedures manual

7 (2) Documentation of a plan for recall of a dispensed compounded drug product
8 where subsequent verification demonstrates the potential for adverse effects with
9 continued use of a compounded drug product;

10 (3) The procedures for maintaining, storing, calibrating, cleaning, and
11 disinfecting equipment used in compounding, and for training on those procedures as
12 part of the staff training and competency evaluation process.

13 (4) Documentation of the methodology used to test integrity, potency, quality,
14 and labeled strength of compounded drug products.

15 (5) Documentation of the methodology used to determine appropriate
16 expiration dates for compounded drug products.

17 21. Title 16, California Code of Regulations, section 1735.7(a) states:

18 Any pharmacy engaged in compounding shall maintain written documentation
19 sufficient to demonstrate that the pharmacy personnel have the skills and training
20 required to properly and accurately perform their assigned responsibilities relating to
21 compounding.

22 22. Title 16, California Code of Regulations, section 1751.7(c) states:

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

27 23. Title 16, California Code of Regulations, section 1793.7(b) states:

28 Pharmacy technicians must work under the direct supervision of a pharmacist
and in such a relationship that the supervising pharmacist is fully aware of all
activities involved in the preparation and dispensing of medications, including the
maintenance of appropriate records.

COST RECOVERY

24 24. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
25 administrative law judge to direct a licentiate found to have committed a violation or violations of
26 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
27 enforcement of the case.
28

1 **DRUGS**

2 25. Testosterone Pellets are Schedule III controlled substances pursuant to Health and
3 Safety Code section 11056(f)(30) and dangerous drugs pursuant to Business and Professions
4 Code section 4022.

5 26. Estradiol Pellets are dangerous drugs pursuant to Business and Professions Code
6 section 4022.

7 **FACTUAL ALLEGATIONS**

8 27. On or about July 19, 2010, on behalf of Respondent Harbor Compounding and Home
9 Health Care Pharmacy, Rebecca Rodriguez-Torres, Respondent Mike Shah and Respondent
10 Michael Hua submitted an application for a pharmacy permit. The application stated that “any
11 material misrepresentation in the answer of any question is grounds for refusal or subsequent
12 revocation of a license, and is a violation of the Penal Code of California.” Respondent Michael
13 Hua and Rebecca Rodriguez-Torres certified under penalty of perjury under the laws of the State
14 of California that each and all statements made in the application and supplemental statements
15 were true and that no person other than the applicants had any direct or indirect interest in the
16 applicants’ business. In the application, Respondent Mike Shah, Respondent Michael Hua and
17 Rebecca Rodriguez-Torres identified Rebecca Rodriguez-Torres as a seventy-nine percent owner
18 and Respondent Michael Hua as a twenty-one percent owner of Respondent Harbor
19 Compounding and Health Care Pharmacy. Respondent Mike Shah was not identified as an owner
20 when in fact, Mike Shah was an owner of Harbor Compounding and Home Health Care
21 Pharmacy and has been operating that pharmacy in his capacity as an owner.

22 28. On or about April 11, 2011, Rebecca Rodriguez-Torres, Respondent Mike Shah and
23 Respondent Michael Hua submitted an application for a sterile compounding license in
24 connection with their pharmacy permit. The application stated that “any material
25 misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of
26 a license, and is a violation of the Penal Code of California.” Respondent Michael Hua certified
27 under penalty of perjury under the laws of the State of California that each and all statements
28 made in the application and supplemental statements were true and that no person other than the

1 applicant has any direct or indirect interest in the applicant's business. He also acknowledged
2 that any falsification of any information in this application may constitute grounds for denial or
3 subsequent revocation of license. Respondent Mike Shah was not identified as an owner of
4 Respondent Harbor Compounding Pharmacy.

5 29. Since August 25, 2010, Respondent Michael Hua has been the Pharmacist-in-Charge
6 of Respondent Harbor Compounding and Home Health Care Pharmacy. Since July 15, 2011,
7 Respondent Michael Hua has been the Pharmacist-in-Charge of Respondent Harbor
8 Compounding Pharmacy.

9 30. In 2012 and 2013, Respondents compounded and sold testosterone pellets and
10 estradiol pellets, among other sterile and non-sterile injectable drug products.

11 31. In August 2012, Respondents tested compounded sample numbers W-1-136, W-1-
12 150 and W-1-151 of testosterone pellets for potency, but not for sterility and endotoxins. In
13 November 2012, Respondents tested compounded sample W-1-193 of estradiol pellets for
14 potency and sterility but not for endotoxins.

15 32. In or about June 2013, Respondents' pharmacists dispensed prescriptions in the retail
16 section of the premises while Respondents' multiple pharmacy technicians and one intern
17 pharmacist compound sterile injectable drug products in the rear of the premises without any
18 pharmacists being present and supervising the compounding being done, including the weighing,
19 mixing, pouring, compounding, and labeling of finished drug products. Respondents also did not
20 provide training to the newly hired pharmacy technician and pharmacist intern or ascertain if they
21 possessed the skills necessary to compound.

22 33. Respondents did not maintain written policies and procedures for maintaining,
23 storing, calibrating, cleaning and disinfecting their compounding equipment, including the new
24 capsule machine, the ungunators, the Mills for creams/ointments, the V-blender or the pellet
25 presses. Respondents did not possess the records to show that they had cleaned them.

26 34. Respondents refilled stock bottle containers of cream from the barrels of over stock
27 cream bases without cleaning the stock bottle containers, thereby increasing the possibility of
28 contamination.

1 35. Respondents compounded drug products with expired chemical ingredients in June
2 2013 and assigned beyond use dates which exceeded the shortest expiration date of components
3 used to compound drugs.

4 36. Respondents compounded sterile injectable products, namely testosterone and
5 estradiol pellets, but failed to perform the compounding in either: (a) an ISO class 5 laminar
6 airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to
7 the adjacent areas; (b) an ISO class 5 cleanroom or (c) a barrier isolator that provides an ISO class
8 5 environment for compounding.

9 **FIRST CAUSE FOR DISCIPLINE**

10 **(Allowing Pharmacy Technicians to Compound Without Direct Supervision of Pharmacist**
11 **against Respondents Harbor Compounding and Home Health Care Compounding**
12 **Pharmacy, Harbor Compounding Pharmacy and Michael Hua)**

13 37. Respondents are subject to disciplinary action under Code section 4301(o), for
14 violating title 16, California Code of Regulations, section 1793.7(b), in that they allowed
15 pharmacy technicians to compound drug products when they were not under the direct
16 supervision of a pharmacist, as set forth in paragraphs 26 through 36, which are incorporated
17 herein by reference.

18 **SECOND CAUSE FOR DISCIPLINE**

19 **(Allowing Untrained Staff to Perform Compounding against Respondents Harbor**
20 **Compounding and Home Health Care Compounding Pharmacy, Harbor Compounding**
21 **Pharmacy and Michael Hua)**

22 38. Respondents are subject to disciplinary action under Code section 4301(o), for
23 violating title 16, California Code of Regulations, section 1735.7(a), in that they allowed an
24 untrained pharmacy technician and an intern pharmacist to compound drug products and did not
25 possess the records necessary to demonstrate that this untrained staff had the skills and training
26 necessary to compound drug products, as set forth in paragraphs 26 through 36, which are
27 incorporated herein by reference.
28

1 **THIRD CAUSE FOR DISCIPLINE**

2 **(Failure to Clean Compounding Equipment and Maintain Cleaning Records against**
3 **Respondents Harbor Compounding and Home Health Care Compounding Pharmacy,**
4 **Harbor Compounding Pharmacy and Michael Hua)**

5 39. Respondents are subject to disciplinary action under Code section 4301(o), for
6 violating title 16, California Code of Regulations, section 1735.5(c), in that they did not
7 document the cleaning, maintenance, storing, calibrating and disinfecting of the compounding
8 equipment and maintain the records necessary to show that they cleaned such equipment, as set
9 forth in paragraphs 26 through 36, which are incorporated herein by reference.

10 **FOURTH CAUSE FOR DISCIPLINE**

11 **(Using Expired Chemical Ingredients to Compound Drug Products and Assigning**
12 **Improper Beyond Use Dates against Respondents Harbor Compounding and Home Health**
13 **Care Compounding Pharmacy, Harbor Compounding Pharmacy and Michael Hua)**

14 40. Respondents are subject to disciplinary action under Code section 4301(o), for
15 violating title 16, California Code of Regulations, section 1735.2(h), in that they used expired
16 chemical ingredients to compound drug products and assigned beyond use dates which exceeded
17 the shortest expiration date of components in the compounded drugs, as set forth in paragraphs 26
18 through 36, which are incorporated herein by reference.

19 **FIFTH CAUSE FOR DISCIPLINE**

20 **(Failure to Compound Sterile Injectable Drugs in Authorized Environment against**
21 **Respondents Harbor Compounding and Home Health Care Compounding Pharmacy,**
22 **Harbor Compounding Pharmacy and Michael Hua)**

23 41. Respondents are subject to disciplinary action under Code section 4301(o), for
24 violating Business and Professions Code section 4127.7, in that on or about June 2013, they
25 compounded sterile injectable drugs from non-sterile ingredients, in an environment which was
26 not authorized by law, as set forth in paragraphs 26 through 36, which are incorporated herein by
27 reference.

1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Failure to Properly Test Sterile Injectable Drug Products against Respondents Harbor**
3 **Compounding and Home Health Care Compounding Pharmacy, Harbor Compounding**
4 **Pharmacy and Michael Hua)**

5 42. Respondents are subject to disciplinary action under Code section 4301(o), for
6 violating title 16, California Code of Regulations, section 1751.7(c), in that they failed to properly
7 test certain samples of testosterone and estradiol pellets, as set forth in paragraphs 26 through 36,
8 which are incorporated herein by reference.

9 **SEVENTH CAUSE FOR DISCIPLINE**

10 **(Commission of Act Involving Dishonesty, Fraud, Deceit or Corruption against**
11 **Respondents Mike Shah and Michael Hua)**

12 43. Respondents Mike Shah and Michael Hua are subject to disciplinary action under
13 Code section 4301(f), for committing acts involving dishonesty, fraud, deceit or corruption, as set
14 forth in paragraphs 26 through 36, which are incorporated herein by reference.

15 **EIGHTH CAUSE FOR DISCIPLINE**

16 **(Operating a Pharmacy Without a License Against Respondent Mike Shah)**

17 44. Respondent Mike Shah is subject to disciplinary action under Code section 4301(o),
18 for violating Business and Professions Code section 4110(a), in that he operated a pharmacy
19 without a permit, as set forth in paragraphs 26 through 36, which are incorporated herein by
20 reference.

21 **NINTH CAUSE FOR DISCIPLINE**

22 **(Failure to Disclose All Owners on Applications Against Respondents)**

23 45. Respondents are subject to disciplinary action under Code section 4301(o), for
24 violating Business and Professions Code section 4201(b)(2), in that they hid the true ownership of
25 Respondents Harbor Compounding and Home Health Care Pharmacy and Harbor Compounding
26 Pharmacy by failing to disclose that Respondent Mike Shah was an owner and by representing
27 that Rebecca Rodriguez-Torres was the majority owner, as set forth in paragraphs 26 through 36,
28 which are incorporated herein by reference.

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TENTH CAUSE FOR DISCIPLINE

(Misconduct by Owners and/or Corporate Officers Against Respondents Harbor Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy)

46. Respondents Harbor Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are subject to disciplinary action under Code sections 4301(o) and 4302, in that a person holding more than ten percent of the stock of those corporations and corporate officers and directors engaged in conduct that constitutes grounds for disciplinary action, as set forth in paragraphs 26 through 36, which are incorporated herein by reference.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

47. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 26 through 36 above, which are incorporated herein by reference.

OTHER MATTERS

48. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50397 and Sterile Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy, they 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 50397 and Sterile Compounding License Number LSC 99688 are placed on probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding License Number LSC 99688 are reinstated if they are revoked.

49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50397 and Sterile Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy, while Mayank Parimal Shah has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Mayank Parimal Shah shall be prohibited from serving as a manager, administrator, owner,

1 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
2 Number PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on
3 probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding License
4 Number LSC 99688 are reinstated if they are revoked.

5 50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
6 Number PHY 50397 and Sterile Compounding License Number LSC 99688 issued to Creative
7 Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy and Harbor
8 Compounding Pharmacy, while Michael Can Hua has been an officer and owner and had
9 knowledge of or knowingly participated in any conduct for which the licensee was disciplined,
10 Michael Can Hua shall be prohibited from serving as a manager, administrator, owner, member,
11 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
12 PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on probation or
13 until Pharmacy Permit Number PHY 50397 and Sterile Compounding License Number LSC
14 99688 are reinstated if they are revoked.

15 51. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License
16 No. RPH 57834 issued to Mayank Parimal Shah, Mayank Parimal Shah shall be prohibited from
17 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
18 licensee for five years if Pharmacist License Number RPH 57834 is placed on probation or until
19 Pharmacist License Number RPH 57834 is reinstated if it is revoked.

20 52. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License
21 No. RPH 61291 issued to Michael Can Hua, Michael Can Hua shall be prohibited from serving
22 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
23 for five years if Pharmacist License Number RPH 61291 is placed on probation or until
24 Pharmacist License Number RPH 61291 is reinstated if it is revoked.

25 **DISCIPLINARY CONSIDERATIONS**

26 53. To determine the degree of discipline, if any, to be imposed on Respondents,
27 Complainant alleges:
28

1 a. On July 5, 2013, the Board issued Citation number CI 2012 54273 against
2 Respondent Harbor Compounding and Home Health Care for violating title 16, California Code
3 of Regulations, sections 1735.4(d), 1751.7(c) and 1735.3(a) for improper compounding. The
4 Board issued a fine which Respondent has paid.

5 b. On July 5, 2013, the Board issued Citation number CI 2012 57447 against
6 Respondent Michael Hua for violating title 16, California Code of Regulations, sections
7 1735.4(d), 1751.7(c) and 1735.3(a) for improper compounding. The Board issued a fine which
8 Respondent has paid.

9 **PRAYER**

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

- 12 1. Revoking or suspending Pharmacy Permit Number PHY 50397, issued to Creative
13 Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy;
- 14 2. Revoking or suspending Licensed Sterile Compounding Permit Number 99688,
15 issued to Creative Compounds Inc., doing business as Harbor Compounding Pharmacy;
- 16 3. Revoking or suspending Pharmacist License Number RPH 57834, issued to Mayank
17 Parimal Shah;
- 18 4. Revoking or suspending Pharmacist License Number RPH 61291, issued to Michael
19 Can Hua;
- 20 5. Prohibiting Creative Compounds Inc., dba as Harbor Compounding and Home
21 Health Care Pharmacy and Harbor Compounding Pharmacy from serving as a manager,
22 administrator, owner, member, officer, director, associate, or partner of a licensee for five years
23 if Pharmacy Permit Number PHY 50397 and Sterile Compounding License Number LSC 99688
24 are placed on probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding
25 License Number LSC 99688 are reinstated if Pharmacy Permit Number PHY 50397 and Sterile
26 Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba as Harbor
27 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are
28 revoked;

1 6. Prohibiting Mayank Parimal Shah from serving as a manager, administrator, owner,
2 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
3 Number PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on
4 probation or until Pharmacy Permit Numbers PHY 50397 and Sterile Compounding License
5 Number LSC 99688 are reinstated if Pharmacy Permit Number PHY 50397 and Sterile
6 Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba as Harbor
7 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are
8 revoked;

9 7. Prohibiting Michael Can Hua from serving as a manager, administrator, owner,
10 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
11 Number PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on
12 probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding License
13 Number LSC 99688 are reinstated if Pharmacy Permit Number PHY 50397 and Sterile
14 Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba as Harbor
15 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are
16 revoked;

17 8. Prohibiting Mayank Parimal Shah from serving as a manager, administrator, owner,
18 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
19 Number RPH 57834 is placed on probation or until Pharmacist License Number RPH 44796 is
20 reinstated if Pharmacist License Number RPH 57834 issued to Mayank Parmil Shah is revoked;

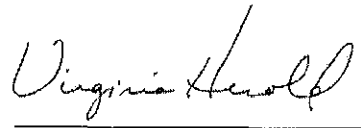
21 9. Prohibiting Michael Can Hua from serving as a manager, administrator, owner,
22 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
23 Number RPH 61291 is placed on probation or until Pharmacist License Number RPH 44796 is
24 reinstated if Pharmacist License Number RPH 61291 issued to Michael Can Hua Shah is
25 revoked;

26 10. Ordering Creative Compounds Inc., dba Harbor Compounding and Home Health
27 Care Pharmacy, Creative Compounds Inc., doing business as Harbor Compounding Pharmacy,
28 Mayank Parimal Shah and Michael Can Hua to pay the Board of Pharmacy the reasonable costs

1 of the investigation and enforcement of this case, pursuant to Business and Professions Code
2 section 125.3;

3 11. Taking such other and further action as deemed necessary and proper.

4 DATED: April 28, 2015

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7
8 VIRGINIA HEROLD
9 Executive Officer
10 Board of Pharmacy
11 Department of Consumer Affairs
12 State of California
13 *Complainant*

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