

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

In the Matter of the Accusation Against:

Case No. 5856

**WICKLIFFE PHARMACEUTICALS INC.
JACQUELINE S. BERNARD, PRESIDENT
4340 Georgetown Rd.
Lexington, KY 40511**

Non-Resident Pharmacy Permit No. NRP 1145

**Non-Resident Pharmacy Sterile Compounding
Permit No. NSC 99710**

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order 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 April 20, 2017.

It is so ORDERED on March 21, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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8 **BEFORE THE**
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9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

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12 **JACQUELINE S. BERNARD, PRESIDENT**
13 **4340 Georgetown Rd.**
Lexington, KY 40511

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

14 **Non-Resident Pharmacy Permit No.**
NRP 1145

15 **Non-Resident Pharmacy Sterile**
16 **Compounding Permit No. NSC 99710**

17 Respondent.

18
19 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
20 entitled proceedings that the following matters are true:

21 **PARTIES**

22 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy
23 ("Board"). She brought this action solely in her official capacity and is represented in this matter
24 by Kathleen A. Kencaly, Acting Attorney General of the State of California, by Malissa N.
25 Siemantel, Deputy Attorney General.

26 2. Respondent Wickliffe Pharmaceuticals Inc. ("Respondent") is representing itself in
27 this proceeding and has chosen not to exercise its right to be represented by counsel.

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1 CULPABILITY

2 10. Respondent admits the truth of each and every charge and allegation in Accusation
3 No. 5856.

4 11. Respondent agrees that its Non-Resident Pharmacy Permit and Non-Resident
5 Pharmacy Sterile Compounding Permit are subject to discipline and Respondent agrees to be
6 bound by the Board's probationary terms as set forth in the Disciplinary Order below.

7 CONTINGENCY

8 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
9 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
10 communicate directly with the Board regarding this stipulation and settlement, without notice to
11 or participation by Respondent. By signing the stipulation, Respondent understands and agrees
12 that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the
13 Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and
14 Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for
15 this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall
16 not be disqualified from further action by having considered this matter.

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

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

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

1 **DISCIPLINARY ORDER**

2 IT IS HEREBY ORDERED that Non-Resident Pharmacy Permit Number NRP 1145 and
3 Non-Resident Pharmacy Sterile Compounding Permit Number NSC 99710 issued to Respondent
4 are revoked. However, the revocation is stayed and Respondent is placed on probation for
5 three (3) years on the following terms and conditions.

6 **1. Obey All Laws**

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

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

- 10 an arrest or issuance of a criminal complaint for violation of any provision of the
11 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
12 substances laws
- 13 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
14 criminal complaint, information or indictment
- 15 a conviction of any crime
- 16 discipline, citation, or other administrative action filed by any state or federal agency
17 which involves Respondent's Non-Resident Pharmacy Permit or Non-Resident
18 Pharmacy Sterile Compounding Permit license or which is related to the practice of
19 pharmacy or the manufacturing, obtaining, handling or distributing, billing, or
20 charging for any drug, device or controlled substance.

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

22 **2. Report to the Board**

23 Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its
24 designee. The report shall be made either in person or in writing, as directed. Among other
25 requirements, Respondent shall state in each report under penalty of perjury whether there has
26 been compliance with all the terms and conditions of probation. Failure to submit timely reports
27 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
28 in submission of reports as directed may be added to the total period of probation. Moreover, if

1 the final probation report is not made as directed, probation shall be automatically extended until
2 such time as the final report is made and accepted by the Board.

3 **3. Interview with the Board**

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

9 **4. Cooperate with Board Staff**

10 Respondent shall cooperate with the Board's inspection program and with the Board's
11 monitoring and investigation of Respondent's compliance with the terms and conditions of its
12 probation. Failure to cooperate shall be considered a violation of probation.

13 **5. Reimbursement of Board Costs**

14 As a condition precedent to successful completion of probation, Respondent shall pay to the
15 Board its costs of investigation and prosecution in the amount of \$5,627.50. Respondent shall be
16 permitted to pay costs in a payment plan approved by the Board or its designee. There shall be no
17 deviation from this schedule absent prior written approval by the Board or its designee. Failure to
18 pay costs by the deadline(s) as directed shall be considered a violation of probation.

19 The filing of bankruptcy by Respondent shall not relieve Respondent of its responsibility to
20 reimburse the Board its costs of investigation and prosecution.

21 **6. Probation Monitoring and Inspection Fees**

22 Respondent shall pay any costs associated with probation monitoring as determined by the
23 Board each and every year of probation. Respondent shall reimburse the Board for all actual and
24 necessary costs incurred by the Board in conducting an inspection of the non-resident pharmacy.
25 Failure to pay such costs by the deadline(s) as directed shall be considered a violation of
26 probation.

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1 **7. Status of License**

2 Respondent shall, at all times while on probation, maintain current licensure with the
3 Board. If Respondent submits an application to the Board, and the application is approved, for a
4 change of location, change of permit or change of ownership, the Board shall retain continuing
5 jurisdiction over the license, and the Respondent shall remain on probation as determined by the
6 Board. Failure to maintain current licensure shall be considered a violation of probation.

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

11 **8. License Surrender While on Probation**

12 Following the effective date of this decision, should Respondent discontinue business,
13 Respondent may tender the premises license to the Board for surrender. The Board or its
14 designee shall have the discretion whether to grant the request for surrender or take any other
15 action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the
16 license, Respondent will no longer be subject to the terms and conditions of probation.

17 Upon acceptance of the surrender, Respondent shall relinquish the premises wall and
18 renewal license to the Board within ten (10) days of notification by the Board that the surrender is
19 accepted. Respondent shall further submit a completed Discontinuance of Business form
20 according to Board guidelines and shall notify the Board of the records inventory transfer.

21 Respondent shall also, by the effective date of the decision accepting the surrender, arrange
22 for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a
23 written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and
24 that identifies one or more area pharmacies capable of taking up the patients' care, and by
25 cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients.
26 Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide
27 a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients"
28 means those patients for whom the pharmacy has on file a prescription with one or more refills

1 outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)
2 days.

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

6 Respondent further stipulates that he or she shall reimburse the Board for its costs of
7 investigation and prosecution prior to the acceptance of the surrender.

8 **9. Notice to Employees**

9 Respondent shall, upon or before the effective date of this decision, ensure that all
10 employees involved in permit operations are made aware of all the terms and conditions of
11 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
12 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
13 remain posted throughout the probation period. Respondent shall ensure that any employees
14 hired or used after the effective date of this decision are made aware of the terms and conditions
15 of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall
16 submit written notification to the Board, within fifteen (15) days of the effective date of this
17 decision, that this term has been satisfied. Failure to submit such notification to the Board shall
18 be considered a violation of probation.

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

22 **10. Owners and Officers: Knowledge of the Law**

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

1 **11. Posted Notice of Probation**

2 Respondent shall prominently post a probation notice provided by the Board in a place
3 conspicuous and readable to the public. The probation notice shall remain posted during the
4 entire period of probation.

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

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

10 **12. 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's license, and probation shall be automatically
13 extended until all terms and conditions have been satisfied or the Board has taken other action as
14 deemed appropriate to treat the failure to comply as a violation of probation, to terminate
15 probation, and 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. Notice and opportunity to be heard are not required for those provisions stating that a
19 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
20 a petition to revoke probation or an accusation is filed against Respondent during probation, the
21 Board shall have continuing jurisdiction and the period of probation shall be automatically
22 extended until the petition to revoke probation or accusation is heard and decided.

23 **13. Completion of Probation**

24 Upon written notice by the Board or its designee indicating successful completion of
25 probation, Respondent's license will be fully restored.

26 **14. Inspection Reports**

27 Within sixty (60) days of the effective date of this Decision, Respondent shall provide to
28 the Board copies of all inspection reports conducted of the pharmacy's premises and any reports

1 from a private accrediting agency documenting the pharmacy's operations that were conducted in
2 the prior twelve (12) months of the effective date of this Decision.

3 During the period of probation, Respondent shall provide to the Board copies of all
4 inspection reports conducted of the pharmacy's premises and any reports from a private
5 accrediting agency documenting the pharmacy's operations within seventy-two (72) hours of
6 Respondent's receipt of the reports. If Respondent has not received a report(s) within seven (7)
7 days after the occurrence of an inspection conducted of the pharmacy's premises and/or a private
8 accrediting agency documenting the pharmacy's operations, Respondent shall immediately notify
9 the Board in writing of the inspection and/or review of the pharmacy's operations and the absence
10 of a report.

11 Failure to submit any report(s) and/or notification(s) to the Board shall be considered a
12 violation of probation.

13 ACCEPTANCE

14 I, Jacqueline S. Bernard, as president of Wickliffe Pharmaceuticals Inc., have carefully read
15 the Stipulated Settlement and Disciplinary Order. I, on behalf of Wickliffe Pharmaceuticals Inc.,
16 understand the stipulation and the effect it will have on the Non-Resident Pharmacy Permit and
17 Non-Resident Pharmacy Sterile Compounding Permit. I am authorized to enter into this
18 Stipulated Settlement and Disciplinary Order on behalf of Wickliffe Pharmaceuticals Inc.
19 Wickliffe Pharmaceuticals Inc. enters into this Stipulated Settlement and Disciplinary Order
20 voluntarily, knowingly, and intelligently, and agrees to be bound by the Decision and Order of the
21 Board of Pharmacy.

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23 DATED: 2/13/17


24 WICKLIFFE PHARMACEUTICALS INC.
25 JACQUELINE S. BERNARD, PRESIDENT
26 Respondent

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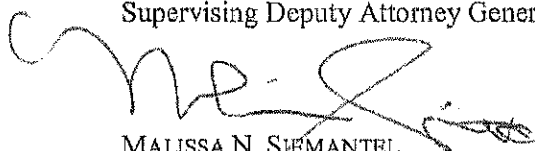
ENDORSEMENT

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

Dated: 2/22/17

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General



MALISSA N. SIEMANTEL
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5856

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**WICKLIFFE PHARMACEUTICALS INC.
JACQUELINE S. BERNARD, PRESIDENT
4340 Georgetown Rd.
Lexington, KY 40511**
**Non-Resident Pharmacy Permit No.
NRP 1145**
**Non-Resident Pharmacy Sterile
Compounding Permit No. NSC 99710**

Respondent.

Case No. 5856

ACCUSATION

Complainant alleges:

PARTIES

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
2. On or about January 27, 2012, the Board of Pharmacy issued Non-Resident Pharmacy Permit Number NRP 1145 to Wickliffe Pharmaceuticals Inc., with Jacqueline S. Bernard ("Bernard") as president ("Respondent"). The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2017, unless renewed.

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1 3. On or about March 27, 2012, the Board of Pharmacy issued Non-Resident Pharmacy
2 Sterile Compounding Permit Number NSC 99710 to Respondent. The sterile compounding
3 license was in full force and effect at all times relevant to the charges brought herein and will
4 expire on January 1, 2017, unless renewed.

5 **JURISDICTION / STATUTORY AND REGULATORY PROVISIONS**

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

9 5. Code Section 4300 states, in pertinent part:

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

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

14 (1) Suspending judgment.

15 (2) Placing him or her upon probation.

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

17 (4) Revoking his or her license.

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

20 6. Section 4300.1 of the Code states:

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

27 7. Section 4301 of the Code states, in pertinent part:

28 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:

(j) The violation of any of the statutes of this state, or any other state, or of the
United States regulating controlled substances and dangerous drugs.

1 (n) The revocation, suspension, or other discipline by another state of a license to
2 practice pharmacy, operate a pharmacy, or do any other act for which a license is
3 required by this chapter.

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

9 8. Section 4307(a) of the Code states:

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

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

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

26 9. Code section 4.156 states that "[a] pharmacy corporation shall not do, or fail to do,
27 any act where doing or failing to do the act would constitute unprofessional conduct under any
28 statute or regulation. In conduct of its practice, a pharmacy corporation shall observe and be
bound by the laws and regulations that apply to a person licensed under this chapter."

COST RECOVERY

10 10. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
11 administrative law judge to direct a licensee found to have committed a violation or violations of
12 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
13 enforcement of the case.

DRUG CLASSIFICATIONS

14 11. Pyrimethamine is an anti-infective used for protozoal infections that requires a
15 prescription.

1 12. Toltrazuril is an anti-infective veterinary drug that requires a prescription.

2 13. The above substances are dangerous drugs pursuant to Code section 4022.

3 KENTUCKY CASE NO. 14-0250A

4 14. On or about March 24, 2014, Respondent dispensed toltrazuril 227mg/pyrimethamine
5 340mg/ml paste. Two horses in Kentucky died after being administered a paste compounded by
6 Respondent. The Food and Drug Administration ("FDA") determined that the dose of paste
7 administered to the horses resulted in an overdose of pyrimethamine. Samples of the active
8 pharmaceutical ingredients ("APIs") were tested for potency as well as two tubes of the paste,
9 with the results being for Tube 1 was pyrimethamine was 82% of declared potency and toltrazuril
10 was 83% of declared potency, and Tube 2 was pyrimethamine was 80% of declared potency and
11 toltrazuril was 82% of declared potency. The potency testing indicated that the compounded
12 preparation was adulterated, in violation of Kentucky Revised Statutes ("KRS") 217.055 and KRS
13 315.121(1)(h).

14 15. On or about May 8, 2014, Bernard advised the FDA and an inspector for the
15 Kentucky Board of Pharmacy that a horse in Florida died after being administered toltrazuril
16 416mg/pyrimethamine 17 mg/ml suspension compounded by Respondent. The suspension was
17 compounded by Respondent on or about March 28, 2014. A total of two horses died and six
18 additional horses were hospitalized after they received this compounded suspension. The FDA lab
19 testing indicated the pyrimethamine was 2380% of the declared potency and the toltrazuril was
20 3.74% of the declared potency. The potency testing indicated that the compounded preparation
21 was adulterated, in violation of KRS 217.055 and KRS 315.121(1)(h).

22 16. On or about November 5, 2014, an inspection by the Kentucky Board of Pharmacy
23 discovered the following:

24 a. Technicians performed functions without the immediate supervision of a pharmacist, in
25 violation of 201 Kentucky Administrative Regulations ("KAR") 2:045, Section 3 and KRS
26 315.020(1).

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- 1 b. There was no documented stability data to substantiate the extended beyond use date
2 of various compounded sterile preparations and compounded nonsterile preparations, in violation
3 of KRS 315.121(1)(a).
- 4 c. Hazardous drugs were improperly stored and handled, in violation of KRS
5 315.121(1)(a).
- 6 d. A container of Phenylbutazone alfalfa flavor did not have a tight fitting lid in violations
7 of KRS 315.121(1)(a).
- 8 e. APIs were transferred into smaller containers that are not identified with the
9 component name, original supplier, lot or control number, transfer date and expiration date, in
10 violation of KRS 315.121(1)(a).
- 11 f. Hazardous drugs were not prepared in a Biological Safety Cabinet or Compounding
12 Aseptic Containment Isolator, in violation of KRS 315.121(1)(a).
- 13 g. Prescription labels did not always correctly identify the identity of the dispensing
14 pharmacist as required by 201 KAR 2:076, Section 4, and KRS 315.121(1)(a) and (h).
- 15 h. Prescription labels did not contain adequate directions for use as required by 201 KAR
16 2:076, Section 4, and KRS 315.121(1)(a) and (h).
- 17 i. A person not registered as a technician nor licensed as a pharmacist or pharmacist
18 intern, made an over-the-counter product for another company in a nonsterile compounding room
19 in the pharmacy, in violation of 201 KAR 2:100, Section 1; and KRS 315.121(1)(h).
- 20 j. Drug Utilization Review was not performed by a pharmacist on all prescriptions as
21 required by 201 KAR 2:210, Section 4, and KRS 315.121(1)(h).
- 22 k. Compounded Sterile Preparations were dispensed utilizing a prescriber whose license
23 and/or DEA number was/were not current, in violation of 201 KAR 2:100, Section 4, and KRS
24 315.121(1)(a) and (h).
- 25 l. Respondent permitted prepared prescription medications to be left outside the
26 pharmacy for pickup, in violation of 201 KAR 2:100, Section 4, and KRS 315.121(1)(a) and (h).
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1 KENTUCKY CASE NO. 15-0279A

2 17. On or about and between March 31, 2103, and May 27, 2015, Respondent employed
3 a person not appropriately registered with the Kentucky Board of Pharmacy, in violation of KRS
4 315.121(1)(g).

5 FIRST CAUSE FOR DISCIPLINE

6 (Discipline By the Board of Another State)

7 18. Respondent's pharmacy permit is subject to disciplinary action for unprofessional
8 conduct pursuant to Code section 4301, subdivision (n), for revocation, suspension, or other
9 discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other
10 act for which a license is required by Code sections 4000, et seq., as follows:

11 a. On or about February 13, 2013, the Michigan Board of Pharmacy, in Case Number
12 53-12-123396, imposed discipline on Respondent's Michigan pharmacy license when it ordered
13 Respondent, doing business as Wickliffe Veterinary Pharmacy, fined in the amount of \$250. The
14 circumstances are that Respondent violated section 17768(2)(d) of the Michigan Public Health
15 Code based upon Respondent's discipline by the Kentucky Board of Pharmacy in Kentucky Board
16 of Pharmacy Case Number 11-0196A, as set forth below in paragraph 21, subparagraph b.

17 b. On or about October 23, 2015, the Kentucky Board of Pharmacy, in an order for Case
18 Number 14-0250A and 15-0279A, imposed discipline on Respondent's Kentucky pharmacy
19 license when it ordered Respondent fined in the amount of \$100,000 and placed on probation for a
20 minimum of three years or until the last installment payment of the fine is made should Respondent
21 choose to make the fourth and final installment payment as late as December 1, 2018. The
22 circumstances are as set forth in paragraphs 14 through 17, above.

23 c. On or about February 10, 2016, the Oregon Board of Pharmacy, in Case Number
24 2015-0594, imposed discipline on Respondent's Oregon pharmacy license when it ordered
25 Respondent placed on probation for the duration of their probation with the Kentucky Board of
26 Pharmacy. The circumstances are that Respondent committed unprofessional conduct as defined
27 by Oregon Administrative Rules ("OAR") and Oregon Revised Statutes ("ORS") based upon the
28 Kentucky Board of Pharmacy Agreed Order Case No. 14-0250A and 15-0279A.

1 d. On or about March 8, 2016, the Iowa Board of Pharmacy, in Case Number 2014-181,
2 imposed discipline on Respondent's Iowa pharmacy license when it ordered Respondent, doing
3 business as Wickliffe Veterinary Pharmacy, placed on probation for the entirety of Respondent's
4 probationary period in Kentucky and to pay a civil penalty in the amount of \$1,000. The
5 circumstances are that Respondent violated Iowa Code section 155A.13A(3), 657 Iowa
6 Administrative Code ("IAC") 19.10 and 657 IAC 36.1(4)"ad" by violating the pharmacy or drug
7 laws or rules of another state while under the jurisdiction of that state based upon the Kentucky
8 Board of Pharmacy Agreed Order Case No. 14-0250A and 15-0279A.

9 e. On or about May 3, 2016, the Texas Board of Pharmacy, in Case Number L-14-055,
10 imposed discipline on Respondent's Texas pharmacy license when it ordered Respondent placed
11 on probation for a period of three years and to pay a probation fee of \$1,200 based upon the
12 Kentucky Board of Pharmacy Agreed Order Case No. 14-0250A and 15-0279A.

13 f. On or about July 1 2016, the Florida Board of Pharmacy, in Case Number 2014-
14 07670, imposed discipline on Respondent's Florida pharmacy license when it ordered Respondent
15 placed on probation for the entirety of Respondent's probationary period in Kentucky and to pay a
16 administrative fine in the amount of \$10,000 based upon the Kentucky Board of Pharmacy Agreed
17 Order Case No. 14-0250A and 15-0279A.

18 **SECOND CAUSE FOR DISCIPLINE**

19 **(Violation of Statutes Regulating Controlled Substances and Dangerous Drugs)**

20 19. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
21 Code section 4301, subdivision (j), for violating statutes regulating controlled substances and
22 dangerous drugs, as follows:

23 a. On or about February 10, 2016, Respondent was found in violation of Oregon Revised
24 Statutes and rules adopted pursuant to Oregon Revised Statutes when Respondent improperly
25 stored and handled hazardous drugs, did not perform drug utilization review by a pharmacist on all
26 prescriptions and dispensed CSPs (Controlled Substance Prescriptions) utilizing a prescriber
27 whose license and/or DEA number was/were not current in violation of ORS 689.405(e)(B), (i)
28 and OAR 855-041-1105(1) and 855-045-0260(5).

1 THIRD CAUSE FOR DISCIPLINE

2 (Violation of Laws and Regulations Governing Pharmacy)

3 20. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
4 Code section 4301, subdivision (o), for violating or attempting to violate, directly or indirectly,
5 assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy
6 Law (Code sections 4000, et seq.), and federal and state laws and regulations governing pharmacy,
7 as follows:

8 a. On or about February 13, 2013, Respondent violated the laws and regulations
9 governing pharmacy of the State of Michigan, as set forth above in paragraph 18, subparagraph a.

10 b. On our about October 23, 2014, violated the laws and regulations governing pharmacy
11 of the State of Kentucky, as set forth in paragraphs 14 through 17, above.

12 c. On or about February 10, 2016, Respondent violated the laws and regulations
13 governing pharmacy of the State of Oregon, as set forth above in paragraph 18, subparagraph c,
14 and paragraph 19, subparagraph a.

15 d. On or about March 8, 2016, Respondent violated the laws and regulations governing
16 pharmacy of the State of Iowa, as set forth above in paragraph 18, subparagraph d.

17 e. On or about July 1, 2016, Respondent violated the laws and regulations governing
18 pharmacy of the State of Florida, as set forth above in paragraph 18, subparagraph f.

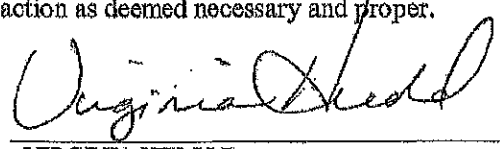
19 MATTERS IN AGGRAVATION

20 21. To determine the degree of discipline to be assessed against Respondent, if any,
21 Complainant alleges as follows:

22 a. On or about July 9, 2003, the Kentucky Board of Pharmacy issued an Agreed order in
23 Case No. 03-0036A against Respondent for violating section KRS 315.035. On or about and
24 between March 1, 2003, and March 12, 2003, Respondent's pharmacist-in-charge practiced the
25 profession of pharmacy in Kentucky without a current active license, and Respondent operated a
26 pharmacy without a licensed pharmacist-in-charge of the operation of the pharmacy. The
27 Kentucky Board of Pharmacy ordered Respondent to pay a fine of \$500 before the date the
28 Agreed Order was entered by the Kentucky Board of Pharmacy.

- 1 2. Revoking or suspending Non-Resident Pharmacy Sterile Compounding Permit
- 2 Number NSC 99710, issued to Wickliffe Pharmaceuticals Inc.;
- 3 3. Prohibiting Wickliffe Pharmaceuticals Inc. from serving as a manager, administrator,
- 4 owner, member, officer, director, associate, or partner of a licensee for five years if Non-Resident
- 5 Pharmacy Permit Number NRP 1145 is placed on probation or until Non-Resident Pharmacy
- 6 Permit Number NRP 1145 is reinstated if Non-Resident Pharmacy Permit Number NRP 1145,
- 7 issued to Wickliffe Pharmaceuticals Inc., is revoked;
- 8 4. Prohibiting Jacqueline S. Bernard from serving as a manager, administrator, owner,
- 9 member, officer, director, associate, or partner of a licensee for five years if Non-Resident
- 10 Pharmacy Permit Number NRP 1145 is placed on probation or until Non-Resident Pharmacy
- 11 Permit Number NRP 1145 is reinstated if Non-Resident Pharmacy Permit Number NRP 1145,
- 12 issued to Wickliffe Pharmaceuticals Inc., is revoked;
- 13 5. Ordering Wickliffe Pharmaceuticals Inc. to pay the Board of Pharmacy the reasonable
- 14 costs of the investigation and enforcement of this case, pursuant to Business and Professions Code
- 15 section 125.3;
- 16 6. Taking such other and further action as deemed necessary and proper.

17
18 DATED: 8/15/16



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

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

In the Matter of the Accusation Against:

Case No. 5856

**WICKLIFFE PHARMACEUTICALS INC.
JACQUELINE S. BERNARD, PRESIDENT
4340 Georgetown Rd.
Lexington, KY 40511**

**Non-Resident Pharmacy Permit No.
NRP 1145**

**Non-Resident Pharmacy Sterile
Compounding Permit No. NSC 99710**

Respondent.

DECISION AND ORDER

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

This Decision shall become effective on _____.

It is so ORDERED _____.

FOR THE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS