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

12 In the Matter of the Accusation Against:

Case No. 5856

13 **WICKLIFFE PHARMACEUTICALS INC.**
14 **JACQUELINE S. BERNARD, PRESIDENT**
15 **4340 Georgetown Rd.**
16 **Lexington, KY 40511**

A C C U S A T I O N

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

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

21 Respondent.

22 Complainant alleges:

23 **PARTIES**

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

26 2. On or about January 27, 2012, the Board of Pharmacy issued Non-Resident Pharmacy
27 Permit Number NRP 1145 to Wickliffe Pharmaceuticals Inc., with Jacqueline S. Bernard
28 ("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
guilty, by any of the following methods:

13 (1) Suspending judgment.

14 (2) Placing him or her upon probation.

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

16 (4) Revoking his or her license.

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

19 6. Section 4300.1 of the Code states:

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

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

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

28 (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 4156 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 licentiate 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 our 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 b. On or about November 5, 2011, the Kentucky Board of Pharmacy issued an Agreed
2 order in Case No. 11-0196A against Respondent for violating sections 201 KAR 2:045, Section 2
3 and KRS 217.065(a). On or about August 23, 2011, a pharmacy technician at Respondent's
4 pharmacy initiated or received a telephonic communication regarding a new prescription that
5 violated the requirements of 201 KAR 2:045, Section 2. On or about August 23, 2011,
6 Respondent's pharmacy had a prescription incorrectly labeled in violation of KRS 217.065(1).
7 The Kentucky Board of Pharmacy ordered Respondent to pay a fine of \$1,000 (\$500 fine for
8 technician call violation and \$500 fine for misbranded prescription) by October 30, 2011.

9 **OTHER MATTERS**

10 22. Pursuant to Code section 4307, if discipline is imposed on Non-Resident Pharmacy
11 Permit Number NRP 1145 issued to Wickliffe Pharmaceuticals Inc., Wickliffe Pharmaceuticals Inc.
12 shall be prohibited from serving as a manager, administrator, owner, member, officer, director,
13 associate, or partner of a licensee for five years if Non-Resident Pharmacy Permit Number NRP
14 1145 is placed on probation or until Non-Resident Pharmacy Permit Number NRP 1145 is
15 reinstated if it is revoked.

16 23. Pursuant to Code section 4307, if discipline is imposed on Non-Resident Pharmacy
17 Permit Number NRP 1145 issued to Wickliffe Pharmaceuticals Inc., while Jacqueline S. Bernard
18 has been an officer and had knowledge of or knowingly participated in any conduct for which the
19 licensee was disciplined, Jacqueline S. Bernard shall be prohibited from serving as a manager,
20 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
21 Non-Resident Pharmacy Permit Number NRP 1145 is placed on probation or until Non-Resident
22 Pharmacy Permit Number NRP 1145 is reinstated if it is revoked.

23 **PRAYER**

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

26 1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1145, issued to
27 Wickliffe Pharmaceuticals Inc.;

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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;

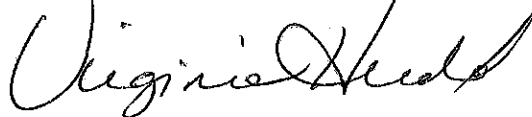
8 4. Prohibiting Jacqueline S. Bernard from serving as a manager, administrator, owner,
9 member, officer, director, associate, or partner of a licensee for five years if Non-Resident
10 Pharmacy Permit Number NRP 1145 is placed on probation or until Non-Resident Pharmacy
11 Permit Number NRP 1145 is 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.

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18 DATED: _____

8/15/16



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

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