

WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF THE LICENSE(S) OF

UW HEALTH PHARMACY SERVICES,
UNIVERSITY HOSPITAL AND CLINIC,
NICHOLAS F. ZETES, R.PH.,
STEVEN S. ROUGH, R.PH.,
LICENSEE(S).

:
: FINAL DECISION AND ORDER
: FOR REMEDIAL EDUCATION
:
:
:
:

0006087

Division of Legal Services and Compliance Case No. 16 PHM 019

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

UW Health Pharmacy Services
600 Highland Avenue
Room 1338
Mail Code C-150
Madison, WI 53792

University Hospital and Clinic
600 Highland Avenue
F6/133
Madison, WI 53792

Nicholas F. Zetes, R.Ph.
1706 Heim Avenue
Madison, WI 53705

Steven S. Rough, R.Ph.
6 Hawk Feather Circle
Madison, WI 53717

Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

1. Licensee UW Health Pharmacy Services, is licensed in the state of Wisconsin as a pharmacy, having license number 8740-42, first issued on April 26, 2007, and current through May 31, 2020. Licensee's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 600 Highland Avenue, Room 1338, Mail Code C-150, Madison, Wisconsin 53792.

2. Licensee University Hospital and Clinic, is licensed in the state of Wisconsin as a pharmacy, having license number 5940-42, first issued on June 8, 1978, and current through May 31, 2020. Licensee's most recent address on file with the Department is 600 Highland Avenue, F6/133, Madison, Wisconsin 53792.

3. Licensee Nicholas F. Zetes, R.Ph., (DOB November 19, 1978) is licensed in the state of Wisconsin to practice pharmacy, having license number 15975-40, first issued on July 6, 2010, and current through May 31, 2020. Licensee's most recent address on file with the Department is 1706 Heim Avenue, Madison, Wisconsin 53705.

4. Licensee Steven S. Rough, R.Ph., (DOB December 13, 1967) is licensed in the state of Wisconsin to practice pharmacy, having license number 11907-40, first issued on January 12, 1993, and current through May 31, 2020. Licensee's most recent address on file with the Department is 6 Hawk Feather Circle, Madison, Wisconsin 53717.

5. At all times relevant to this proceeding, Licensees Zetes and Rough were engaged in the practice of pharmacy in Madison, Wisconsin.

6. Mercaptopurine is a chemotherapy drug, used to treat acute lymphoblastic leukemia as part of a combination regimen.

7. Between 1953 and April 28, 2014, mercaptopurine was commercially available only as a 50 mg tablet. Hospital pharmacies commonly compounded the tablet into a suspension, in order to provide the dose adjustments necessary to treat children, since splitting tablets could not achieve the necessary dosage accuracy.

8. On April 28, 2014, the United States Food and Drug Administration approved a 20 mg/mL oral suspension of mercaptopurine called PurixanTM.

9. A suspension of mercaptopurine allows more flexibility in adjusting doses than was true of tablets. Further, the commercially produced suspension is more likely to provide consistent doses of mercaptopurine than ad hoc compounded formulations.

10. Despite the commercial availability of a suspension of mercaptopurine, Licensee(s) continued to compound mercaptopurine at a concentration of 5 mg/mL until the later part of 2016.

11. Upon being notified of this action by the Department, Licensee(s) discontinued the compounding of mercaptopurine.

12. Compounding mercaptopurine in a different concentration than the commercially available mercaptopurine suspension is not clinically necessary as PurixanTM is readily reduced to one-quarter dose, i.e., a 5 mg/mL suspension. Avoiding simple dosing volume changes does not constitute a medical or clinical necessity.

13. Mercaptopurine in a 5 mg/mL suspension is essentially a copy of PurixanTM, a commercially available medication.

14. This Order does not constitute the imposition of discipline by the Board.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10 and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

ORDER

1. The attached Stipulation is accepted.

2. Within one hundred twenty (120) days of the date of this Order, all staff pharmacists practicing in the pharmacy Licensees' compounding facilities shall, at pharmacy Licensees' own expense, take and successfully complete the one (1) hour education course provided by the American College of Apothecaries entitled, "503A/503B, USP/CGMP, BOP/FDA... Examples of Government Enforcement and What Not to Do."

a. Pharmacy Licensees shall submit proof of successful completion of the education in the form of verification from the institution providing the education to the Department Monitor at the address stated below.

b. None of the education completed pursuant to this requirement may be used to satisfy any continuing education requirements that have been or may be instituted by the Board or Department.

3. Proof of successful course completion by the staff pharmacists shall be sent by the Licensees to the Department Monitor at the address below:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190

Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

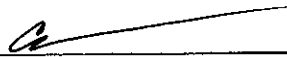
You may also submit this information online via DSPS' Monitoring Case Management System,
here:

<https://app.wi.gov/DSPSMonitoring>

4. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by:


A Member of the Board

2-27-2019
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF LICENSE(S) OF

UW HEALTH PHARMACY SERVICES,
UNIVERSITY HOSPITAL AND CLINIC,
NICHOLAS F. ZETES, R.PH.,
STEVEN S. ROUGH, R.PH.,
LICENSEE(S).

STIPULATION

0006087

Division of Legal Services and Compliance Case No. 16 PHM 019

Licensee UW Health Pharmacy Services, license number 8740-42, and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Licensee consents to the resolution of this investigation by Stipulation.

2. Licensee understands that by signing this Stipulation, Licensee voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Licensee, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Licensee;
- the right to call witnesses on Licensee's behalf and to compel their attendance by subpoena;
- the right to testify on Licensee's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Licensee under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Licensee is aware of Licensee's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation. Licensee is represented by Joe Hanes.

4. Licensee agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or


consent of the parties. Licensee waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Licensee or Licensee's attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Licensee is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.


8. The Division of Legal Services and Compliance joins Licensee in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.



UW Health Pharmacy Services, Licensee
Representative
600 Highland Avenue
Room 1338, Mailcode C-150
Madison, WI 53792
License no. 8740-42

2/21/19

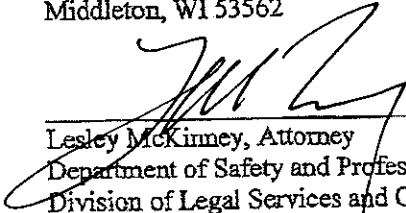
Date



Joe Hanes, Attorney for Licensee
UW Health
7974 UW Health Court
Middleton, WI 53562

2/22/19

Date



Lesley McKinney, Attorney
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

2/25/19

Date