

RICK SNYDER GOVERNOR

# STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

SHELLY EDGERTON DIRECTOR

## MICHIGAN BOARD OF PHARMACY JUNE 13, 2018 MEETING

### **APPROVED MINUTES**

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on June 13, 2018, at the Ottawa Building, Conference Room 3, 611 West Ottawa Street, Lansing, Michigan 48933.

#### **CALL TO ORDER**

Patricia Keim, R.Ph., Acting Chairperson, called the meeting to order at 10:03 a.m.

#### **ROLL CALL**

Members Present: Patricia Keim, R.Ph., Acting Chairperson

Cynthia Boston, BHS, R.PhT. Kathleen Burgess, Public Member

David Hills, Public Member Suit Hing Moy-Sandusky, R.Ph. Charles Mollien, PharmD, JD Kathleen Pawlicki, MS, FASHP Jonathan Pignataro, Public Member

James Stevenson, PharmD

Mary Ann Victor, JD, Public Member

**Members Absent:** Suit Hing Moy-Sandusky, R.Ph.

Nichole Cover, R.Ph., Chairperson

**Staff Present:** Andria Ditschman, Analyst, Boards and Committees Section

Kiran Parag, Analyst, Compliance Section

Michele Wagner-Gutkowski, Assistant Attorney General

Stephanie Wysack, Board Support, Boards and Committees Section

#### APPROVAL OF AGENDA

MOTION by Pignataro, seconded by Victor, to approve the agenda as presented.

A voice vote followed.

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#### MOTION PREVAILED

#### APPROVAL OF MINUTES

MOTION by Hills, seconded by Victor, to approve the April 11, 2018 meeting minutes as written.

A voice vote followed.

MOTION PREVAILED

## **Presentation – RWC Advocacy**

Elizabeth Weihl with RWC Advocacy introduced David W. Dryden of Greenwich Biosciences, A GW Pharmaceuticals PLC Company, who presented a handout entitled Update on Epidiolex (CBD) (Addendum #1).

#### REGULATORY CONSIDERATIONS

## **Cory Watson – Proposal for Decision**

MOTION by Stevenson, seconded by Pignataro, to accept the Proposal for Decision and grant licensure as a pharmacy technician.

A roll call was taken: Yeas: Boston, Hills, Pawlicki, Pignataro, Stevenson,

Victor, Keim

Nays: Burgess Recuse: Mollien

MOTION PREVAILED

#### **OLD BUSINESS**

## **Compounding Applications**

Joint Commission/Home Care Program – Sterile Compounding Accreditation Organization (Tabled August 9, 2017 and April 11, 2018)

MOTION by Hills, seconded by Victor, to untable from April 11, 2018.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

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MOTION by Hills, seconded by Burgess, to accept the application for compounding.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

#### MOTION PREVAILED

## TDS Inc – Sterile Compounding Accreditation by Compliance Team.org (Reconsideration Tabled April 11, 2018)

MOTION by Hills, seconded by Boston, to untable from April 11, 2018.

A voice vote followed.

MOTION PREVAILED

MOTION by Pignataro, seconded by Hills, to discuss.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

MOTION by Stevenson, seconded by Hills, to table the request so that the applicant may provide detailed information on the content of the surveys as well as proof that surveyors have taken training as discussed during the meeting.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

#### MOTION PREVAILED

#### **Controlled Substance Rules Discussion**

Ditschman provided an overview of public comments regarding R 338.3125, R 338.3135 and R 338.3161a and the changes recommended by the Rules Committee (Addendum #2, #3, and #4).

MOTION by Burgess, seconded by Victor, to accept R 338.3125 as presented.

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A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

#### MOTION PREVAILED

MOTION by Hills, seconded by Burgess, to accept R 338.3135 with modifications as presented.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

#### MOTION PREVAILED

MOTION by Burgess, seconded by Victor, to accept R 338.3161a with modifications as presented.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

#### MOTION PREVAILED

#### **NEW BUSINESS**

## **Resolution Honoring Jonathan Pignataro**

Keim presented the Resolution to Jonathan Pignataro honoring his time served as a member of the Board of Pharmacy.

Parag and Wagner-Gutkowski thanked Pignataro for his time on the Board.

## **Sterile Compounding Accrediting Applications**

## **Gates Consulting – Sterile Compounding Accreditation Organization**

Ditschman provided an overview of the application.

MOTION by Pawlicki, seconded by Hills, to discuss.

A voice vote followed.

#### **MOTION PREVAILED**

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Discussion held.

MOTION by Burgess, seconded by Victor, to approve the amended application as an accrediting organization for sterile compounding pharmacies which limits accreditations to two years.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Navs: None

#### **MOTION PREVAILED**

## **Internship Applications**

Nevine Mohamed Salah Koraiem, R.Ph., Ed. Lmt.

MOTION by Stevenson, seconded by Boston, to table for additional information.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

MOTION PREVAILED

Mai Y. I. Safi, R.Ph., Ed. Lmt.

MOTION by Stevenson, seconded by Pawlicki, to deny the request for internship hours.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

#### MOTION PREVAILED

#### **Continuing Education Review**

Keim directed the Board to the list of continuing education programs for consideration (Addendum #5).

MOTION by Burgess, seconded by Victor, to approve the continuing education programs.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Mollien, Pawlicki,

Pignataro, Stevenson, Victor, Keim

Nays: None

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#### MOTION PREVAILED

## **Chair Report**

None.

## **Department Update**

Ditschman announced that Cheryl Pezon has been named the Director of the Bureau of Professional Licensing.

Ditschman announced that Kim Gaedeke has been named the Deputy Director of Licensing and Regulatory Affairs (LARA).

#### **PUBLIC COMMENT**

None.

#### **ANNOUNCEMENTS**

The next regularly scheduled meeting will be held August 8, 2018, at 10:00 a.m. at the Ottawa Building, 611 West Ottawa Street, Upper Level Conference Center, Conference Room 3, Lansing, Michigan.

#### **ADJOURNMENT**

MOTION by Pignataro, seconded by Hills, to adjourn the meeting at 11:30 a.m.

A voice vote followed.

MOTION PREVAILED

Minutes approved by the Board on August 8, 2018.

Prepared by: Stephanie Wysack, Board Support Bureau of Professional Licensing

June 15, 2018