INDIANA BOARD OF PHARMACY Indiana Government Center South Conference Center Room B 302 West Washington Street Indianapolis, Indiana 46204

Minutes of November 13, 2023

Mark Bunton, R.Ph., President, called the meeting to order at 8:52 a.m. and declared a quorum in accordance with IC 25-26-13-3(d), pursuant to public notice posted at the principal office for the Board, online at the board's website and on the state calendar at least forty-eight (48) hours before the time of the meeting.

Members Present:

Mark Bunton, R.Ph., President Jason Jablonski, R.Ph., Vice President Mark Smosna, R.Ph., Member Steve Anderson, R.Ph., Member Matt Balla, R.Ph., Member Andrew Meador, C,Ph.T., Member Kate Snedeker, Consumer Member

PLA Staff Present:

Evan Bartel, General Counsel (stepped out from 9a-9:30a) Christine Cowdin

Advisory Counsel:

Leif Johnson, J.D.

Court Reporter:

Accurate Reporting – Lindy Meyer

The Board moved to adopt the amended agenda. Smosna/Balla, 7-0-0 Motion carries

The Board moved to approve the minutes from the September 11, 2023 board meeting. Balla/Smosna, 5-0-2 Motion carries Meador and Snedeker abstained

The Board moved to approve the minutes from the October 16, 2023 board meeting. Balla/Jablonski, 4-0-3

Motion carries Smosna, Meador and Snedeker abstained

Personal Appearances

Isaac Alvis, R.Ph. - MPJE Repeat Exam App:

Isaac Alvis appeared before the Board and discussed his/her studying habits with the Board.

After discussion, the Board moved to APPROVE applicant's repeat exam application.

Smosna/Jablonski 7-0-0 Motion carries

Nathaniel Johnson, R.Ph. – NAPLEX and MPJE Repeat Exam App:

Nathaniel Johnson appeared before the Board and discussed his/her studying habits with the Board.

After discussion, the Board moved to APPROVE applicant's repeat exam application.

Balla/Jablonski, 7-0-0 Motion carries

Zoe Saulman, R.Ph. - NAPLEX Repeat Exam App:

Zoe Saulman appeared before the Board and discussed his/her studying habits with the Board.

After discussion, the Board moved to APPROVE applicant's repeat exam application.

Smosna/Jablonski, 7-0-0 Motion carries

Rehman Mustafa, R.Ph. - NAPLEX Repeat Exam App:

Rehman Mustafa appeared before the Board and discussed his/her studying habits with the Board.

After discussion, the Board moved to APPROVE applicant's repeat exam application.

Balla/Smosna, 7-0-0

Motion carries

Irwin Obispo, R.Ph. - MPJE Repeat Exam App:

Irwin Obispo appeared before the Board and discussed his/her studying habits with the Board.

After discussion, the Board moved to APPROVE applicant's repeat exam application.

Smosna/Jablonski, 7-0-0 Motion carries

Renee Majeski, R.Ph. - NAPLEX Repeat Exam App:

Renee Majeski appeared before the Board and discussed his/her studying habits with the Board.

After discussion, the Board moved to APPROVE applicant's repeat exam application.

Smosna/Jablonski, 7-0-0 Motion carries

Carrie Sargent - Pharm Tech/Tech in Training Initial Application – Positive Response:

Carrie Sargent appeared in person and was not represented by counsel regarding a positive response on a pharmacy technician/tech in training application. Open case, diversion has been accepted by but no paperwork yet. Set for pretrial conference, nothing in writing yet. Not currently employed as a pharmacy technician, trying to get a better job in a pharmacy.

After discussion, the Board moved to APPROVE applicant's pharmacy technician application.

Balla/Jablonski, 6-0-1 Motion carries Snedeker abstained

<u>Aaron Anthony - Pharm Tech/Tech in Training Initial App – Positive Response:</u> Failed to appear.

Akram Musleh - Pharm Tech/Tech in Training Initial App – Positive Response:

Failed to appear.

Malihaya Teague - Pharm Tech/Tech in Training Initial App – Positive Response:

Malihaya Teague appeared in person and was not represented by counsel regarding a positive response on a pharmacy technician/tech in training application. Rented U-Haul, had medical emergency, ended up in the hospital could not return truck. Drove the vehicle later to try and make money, was homeless, got pulled over and was arrested for theft of the vehicle. Pending charges, currently in diversion agreement. Currently working for Walgreens pharmacy warehouse, currently just packing shipments.

After discussion, the Board moved to APPROVE applicant's pharmacy technician application with condition that all fees associates with pending criminal case be paid before permit/license is issued.

Jablonski/Balla, 6-0-1 Motion carries Snedeker abstained

<u>Stacia Brown - Pharm Tech/Tech in Training Initial App – Positive Response:</u> Matter continued to December meeting.

<u>Cortlyn Taylor - Pharm Tech/Tech in Training Initial App – Positive Response:</u> Failed to appear.

Autumn Caine - Pharm Tech/Tech in Training Initial App – Positive Response: Failed to appear.

Jasmine Branham - Pharm Tech/Tech in Training Initial App – Positive Response: Failed to appear.

Meagan Petersen, Nursing CSR Initial App – Positive Response:

Meagan Petersen appeared in person and was not represented by counsel regarding a positive response on a Nursing CSR application.

First nursing job was 21 years old employed at Morton hospital about a year into

employment received notice that she was not documenting narcotics correctly. She was let go from employer, Aug 2019. Reported to KY board, had substance abuse eval, Oct 2021 was seen by KY board, consent decree with KY has been completed. Was not disciplined in KY, IN licenses are all active and unencumbered.

After discussion, the Board moved to APPROVE the applicant's Nursing CSR application.

Smosna/Jablonski, 6-0-1 Motion carries Snedeker abstained

DISCUSSION

Monthly Reports

Board Director's Report – Presented by Christine Cowdin Currently in renewals for in-state pharmacies, non-resident pharmacies, HMEs, and facility CSRs.

OAG Report - Presented by DAG, Ryan Eldridge

Compliance Director's Report – Presented by Zaneta Nunnally and Tim Thomas

ADMINISTRATIVE HEARINGS

Leonard Dale Guyer, M.D., License No: 01040481B - Cause No. 2021 IBP 0045 Petition for Summary Suspension

Agreement

| DAG: Respondent: Exhibit(s): | Petitioner Exhibit 1 – Consumer Complaint Petitioner Exhibit 2 – Response Petitioner Exhibit 3 – Secretary of State Information Petitioner Exhibit 4 – Secretary of State Information Petitioner Exhibit 5 – 2020 Facebook Posts Petitioner Exhibit 6 – 2023 Facebook Posts Petitioner Exhibit 6 – 2023 Facebook Posts Petitioner Exhibit 7 – Feb 6, 2020 SDT to Guyer Petitioner Exhibit 8 – March 2, 2020 SDT Response Petitioner Exhibit 9 – March 2. 2020 SDT Response Attachments Petitioner Exhibit 10 – Petition to Enforce SDT Petitioner Exhibit 11 – Court Order Petitioner Exhibit 12 – March 18, 2021 Supplemental SDT Response |
|------------------------------------|---|
| | Petitioner Exhibit 13 – Responsive Documents Demonstrative Exhibit |

Petitioner Exhibit 14 – Responsive Documents Petitioner Exhibit 16 – June 3, 2021 Inspection Report Petitioner Exhibit 17 – FDA Authorization Petitioner Exhibit 18 – Bei He CV Petitioner Exhibit 19 – FDA 482 Petitioner Exhibit 20 – Guyer Brochure Petitioner Exhibit 21 – Redacted FDA 483 Petitioner Exhibit 22 – Response to FDA 483 Petitioner Exhibit 23 – Facility Diagram Petitioner Exhibit 24 – FDA Photos of Facility Petitioner Exhibit 25 – FDA Photos of Syringe Fills Petitioner Exhibit 26 – IV Walk-in Menu Petitioner Exhibit 27 – Guyer Billboard Petitioner Exhibit 29 – IV Questionnaire Petitioner Exhibit 30 – FDA Photos of IV Bag Production Petitioner Exhibit 31 – Sterile Compounding Logs Petitioner Exhibit 32 – Cleaning Log Petitioner Exhibit 33 – FDA Photos of Facility and Equipment Petitioner Exhibit 34 – FDA Photos of IV Bag Production Petitioner Exhibit 35 – FDA Photos of Nonsterile Operations Petitioner Exhibit 36 – Stock IV Request Form from IV Area Petitioner Exhibit 37 – Medisca CF Petitioner Exhibit 38 – CF Peptides Petitioner Exhibit 39 – FDA Authorization Letter for Dominic Markwordt Petitioner Exhibit 40 – CV of Dominic Markwordt Petitioner Exhibit 42 – Prescription Requirement under 503 A of the FD&C Petitioner Exhibit 43 – FDA Authorization Letter for Stacev DeGarmo Petitioner Exhibit 44 – CV of Stacey DeGarmo Respondent's Exhibit A – INSPECT Records Respondent's Exhibit B – Controlled Substance Inventories Respondent's Exhibit C – SOPs for Syringe and Needle Use Respondent's Exhibit E – Hood SOPs Certifications, Cleaning Logs Respondent's Exhibit F – SOPs for Gloves Respondent's Exhibit G – Alternate- SOPs for BUDs, Labels (further redacted) Respondent's Exhibit H – SOPs for Cleaning Respondent's Exhibit I – Master Formula Records and Compounding Formula Logs Respondent's Exhibit J – Collin Baker CV Respondent's Exhibit K – Dr. Guyer Certificate of Completion Respondent's Exhibit L – Dr. Speidel CV Respondent's Exhibit N – Map of New Facility Respondent's Exhibit R – 503A (21 USC 353A) Respondent's Exhibit S – Patient Rx Label Exemplar Respondent's Exhibit T – Unclassified Segregated Compounding Area Respondent's Exhibit U – Sterile SOPs

Witness(es): Brittany Snow Investigator OAG Investigator, Zaneta Nunnally IPLA Compliance Director, Lt. Bei He FDA consumer safety officer, Dominic Markwordt Regulatory Counsel FDA, Stacey DeGarmo Team Lead Div of Compounding I with FDA, Collin Baker, RPh employed by Advanced Neutriceuticles LLC, Guyer Institute, Leonard Dale Guyer, MD, Ken Speidel, RPh

A motion was made and seconded to find in violation of Count 1: Balla/Smosna 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 2: Smosna/Jablonski 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 3: Smosna/Balla 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 4: Balla/Jablonski 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 5: Jablonski/Smosna 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 6: Smosna/Jablonski 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 7: Smosna/Jablonski 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 8: Jablonski/Balla 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 9: Smosna/Jablonski 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 10: Smosna/Balla 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 11: Smosna/Balla 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 12: Jablonski/Balla 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 13: Jablonski/Smosna 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 14: Smosna/Jablonski 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Count 15: Anderson/Balla 6-0-1 – Snedeker abstained

A motion was made and seconded to find in violation of Counts 16 - 24: Smosna/Jablonski – Snedeker abstained A motion was made and seconded to place Dr. Guyer's CSR license on indefinite PROBATION for a minimum of twelve (12) months with terms and conditions, impose a fine of \$19,500, and pay health records fee of \$5.00.

Anderson/Jablonski, 6-0-1 Motion carries Snedeker abstained

There being no further business the Board ADJOURNED at 8:53 p.m.