GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree St., NW, 6th Floor
Atlanta, GA 30303
October 31, 2018
4:00 p.m.

The following Board members were present:
Bill Prather, President *(arrived @ 4:15 p.m.)*
Vicki Arnold, Vice-President
Carrie Ashbee *(departed @ 4:44 p.m.)*
Michael Brinson
Lisa Harris
Hal Henderson
Bob Warnock

Staff present:
Tanja Battle, Executive Director
Eric Lacefield, Deputy Executive Director
Dennis Troughton, Director, GDNA
Ronnie Higgins, Deputy Director, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Open Session

Vice-President Arnold established that a quorum was present and called the meeting to order at 4:03 p.m.

Mike Brinson made a motion to post Rule 480-34-.15 Additional Compounds under Schedule V. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Rule 480-34-.15 Additional Compounds under Schedule V
(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places an additional compound as specifically identified here under Schedule V of the Georgia Controlled Substances Act, Section 16-13-29 as follows:
(1.5) Epidiolex: A drug product in finished dosage formulation in its original container that has been approved by and labelled in compliance with the U.S. Food and Drug Administration (FDA) that contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.
(2) This rule is based on the following findings of the Board:
(a) that the FDA approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is an oral solution that contains CBD extracted from the cannabis plant.
(b) that the U.S. Drug Enforcement Administration (DEA) did seek a medical and scientific evaluation or scheduling recommendation from the U.S. Department of Health and Human Services (HHS) with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and therefore, recommended that if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in Schedule V of the Federal Controlled Substance Act (CSA).
(c) that the Board has considered, based on available information, the potential for abuse; scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; and the potential of the drug to produce psychic or physiological dependence liability.

A motion was made by Michael Brinson, seconded by Lisa Harris, and the Board voted that the formulation and adoption of this proposed rule does not impose excessive regulatory cost on any licensee

and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board also voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this proposed rule will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Michael Brinson made a motion and Hal Henderson seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and § 43-1-2(k) to consider the release of information. Voting in favor of the motion were those present who included Vicki Arnold, Carrie Ashbee, Michael Brinson, Lisa Harris, Hal Henderson, and Bob Warnock.

Executive Session

- GDNA Case #A-32639
- GDNA Case #A-32481

No voted were taken in Executive Session. President Prather declared the meeting back in Open Session.

Open Session

In regards to GDNA Case #A-32481, Hal Henderson made a motion for the Board to refer this case to the Department of Law for a Summary Suspension in the event the individual does not voluntarily surrender his license within twenty-four (24) hours. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

In regards to GDNA Case #A-32639, Michael Brinson made a motion for the Board to accept the Voluntary Surrender signed with express permission upon receipt of the original. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 4:51 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, November 14, 2018 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I
Minutes edited by Tanja D. Battle, Executive Director