

GEORGIA BOARD OF PHARMACY
Conference Call
August 28, 2014
2 Peachtree St., N.W., 36th Floor
Atlanta, GA 30303
10:30 a.m.

The following Board members were present:

Al McConnell, Chairperson
Jim Bracewell
Mike Faulk
Chris Jones
Laird Miller
Tony Moye

Staff present:

Tanja Battle, Executive Director
Janet Wray, Senior Assistant Attorney General
Rick Allen, GDNA
Anil Foreman, Legal Officer
Brandi Howell, Business Operations Specialist

Open Session

Chairperson McConnell established that a quorum was present and called the meeting to order at 10:31 a.m.

Tony Moye made a motion to adopt emergency Rule 480-34-0.19-.04 Additional Synthetic Cannabinoids. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

480-34-0.19-.04. Additional Synthetic Cannabinoids.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains these substances or their derivatives, salts, isomers, or salts of isomers, halogen analogues, and/or homologues, collectively known as Synthetic Cannabinoids, under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(12) as follows:

(bb) (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (FUB-144)

(2) This rule is based on the following findings of the Board:

(a) that Synthetic Cannabinoids have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act;

(f) that these compounds have no known precursor already scheduled under the Act; and

(g) that the DEA encourages all states to add these compounds to their respective Controlled Substances Acts while DEA follows its procedures to add such compounds to the Federal Controlled Substances Act under Schedule I.

A motion was made by Chris Jones, seconded by Mike Faulk, and the Board voted that pursuant to O.C.G.A. Section 26-4-28(a)(9), the Board has the right to seize any drugs and devices found by the Board to constitute an imminent danger to the public health and welfare. Pursuant to O.C.G.A. Section 26-3-4(a), any duly authorized agent of the Board who finds or has probable cause to

believe any drug is adulterated or misbranded as to be dangerous or fraudulent may tag the article to detain or embargo the article. If the article is unsound or unsafe, O.C.G.A. Section 26-3-4(d) authorizes the Board or its authorized agents to condemn or destroy the article. The agents of the Georgia Drugs and Narcotics Agency (“GDNA”) are authorized agents of the Board. O.C.G.A. Section 26-4-29(b)(5) authorizes agents of GDNA to seize and take possession of all articles of contraband. O.C.G.A. Section 26-4-29(b)(7) provides that the GDNA shall perform such other duties as the Board may direct.

In consideration of these Code sections and the danger to the public health, safety and welfare, the Board is directing GDNA to take the lead in enforcement of Emergency Rule 480-34-0.19-.04, and is directing that GDNA designate, on behalf of the Board, POST certified officers who are members of state and local law enforcement agencies to act as Board agents to: (1) seize drugs, compounds and/or articles identified in Emergency Rule 480-34-0.19-.04 on behalf of the Board and to maintain such seized drugs, compounds and/or articles within their evidence rooms, or (2) tag adulterated or misbranded drugs identified in Emergency Rule 480-34-0.19-.04 to detain or embargo such drugs. Any law enforcement agencies operating on behalf in the Board in enforcing Emergency Rule 480-34-0.19-.04 shall provide GDNA with notification of any seizure, detention or embargo. Finally, GDNA is authorized to utilize in enforcing Emergency Rule 480-34-0.19-.04 any state agency identified in O.C.G.A. Section 26-3-18.

Mike Faulk made a motion to post Rule 480-34-.04 Synthetic Cannabinoids. Laird Miller seconded and the Board voted unanimously in favor of the motion.

480-34-.04 Synthetic Cannabinoids

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places newly identified compounds, including any material, compound, mixture, or preparation which contains these substances or their derivatives, salts, isomers, or salts of isomers, halogen analogues, and/or homologues, collectively known as Synthetic Cannabinoids, under Schedule I, of the Georgia Controlled Substances Act, Code Section 16-13-25 (12) as follows:

(M) (1-Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl) methanone (UR-144)

(N) [1-(5-fluoropentyl)indole-3yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (XLR11)

(O) [1,1'-biphenyl]-3-yl-carbamic acid, cyclohexyl ester (URB602)

(P) [1-(2-morpholin-4-ylethyl)-1H-indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (A-796,260)

(Q) [3-(3-carbamoylphenyl)phenyl] N-cyclohexylcarbamate (URB597).

(R) 6-methyl-2-[(4-methylphenyl)amino]-1-benzoxazin-4-one (URB754)

(S) 1-pentyl-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indazole-3-carboxamide (AKB48)

(T) 1-pentyl-3-(1-adamantylamido)indole (2NE1)

(U) 1-(5-fluoropentyl)-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3-carboxamide (STS-135)

(V) 1-naphthalenyl[4-(pentyl)-1-naphthalenyl]-methanone (CB-13)

(W) (1-(5-chloropentyl)indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (5-Chloro-UR-144)

(X) (1-(5-bromopentyl)indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (5-Bromo-UR-144)

(Y) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indole-3-carboxamide (ADBICA)

(Z) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5-Fluoro-ADBICA)

(aa) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5-fluoro-ABICA)

(bb) (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (FUB-144)

(2) This rule is based on the following findings of the Board:

(a) that Synthetic Cannabinoids have an extremely high potential for abuse;

- (b) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;
- (c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;
- (d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;
- (e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act;
- (f) that these compounds have no known precursor already scheduled under the Act; and
- (g) that the DEA encourages all states to add these compounds to their respective Controlled Substances Acts while DEA follows its procedures to add such compounds to the Federal Controlled Substances Act under Schedule I.

A motion was made by Mike Faulk, seconded by Chris Jones, and the Board voted that the formulation and adoption of this 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 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 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.

Rick Allen discussed a rule from the DEA which moves hydrocodone from Schedule III to Schedule II, effective October 6, 2014. He stated that the DEA is going to allow refills on any prescriptions for hydrocodone prior to October 6th. Mr. Allen would like for the Board to consider an emergency rule to mirror the DEA rule that would be effective October 6th. Chairperson McConnell stated that the computer system would not allow the refills and will most likely void or expire immediately. He further stated that if the Board considers an emergency rule pertaining to this matter, the rule will need to be more strict than the DEA's rule. Ms. Wray stated that if the Board is going to take the position of being more strict than the DEA, the Board will need to let doctors and pharmacists know. Mr. Allen stated he will reach out to his contacts in surrounding states to see how they are handling the matter and will report back to the Board.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, September 17, 2014, at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 10:46 a.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist
Minutes edited by Tanja D. Battle, Executive Director