# Theresa Daniello Ohio Senate General Government Committee Senate Bill 326, Interested Party December 3, 2024

Chairman Wilkin, Ranking Member DeMora, and members of the Ohio Senate General Government Committee. Thank you for the opportunity to submit testimony as an Interested Party of Senate Bill 326. I would also like to thank Senator Huffman for swiftly addressing the dangerous, new synthesized cannabinoids that are now being sold over the counter, nationally.

As a University of Dayton graduate, I have been involved with cannabis reform since 2011 on a statewide and national level. My focus has been public health and safety, while publicly speaking for patients' need for safe, affordable, accessible and accountability in their use of medical cannabis. I have provided critical information to the Ohio Executive Branch in the formation of the Medical Cannabis HB523, and the Ohio Hemp bill, SB 57. In addition, I have attended over 10 Clinical Conferences focused on the Endocannabinoid System, while nationally attending legislative and business events. I advised multiple states in their formation of cannabis law, in the best interest of public health and safety. In addition to many projects, I have documented factual history and predatory behavior for the private collection associated with The Cannabis Museum. Due to my travels since 2011, I have interacted with attorneys, business persons and the general public with many seeking to "hit the cannabis jackpot".

#### History

In 2018, after the passage of the Federal Farm bill, many of us witnessed the emergence of newly formed hemp trade groups, after hemp trade groups. These trade groups, many with the same players in leadership, claimed hemp "expertise" while targeting farmers nationally with the promise of \$60,000 an acre for CBD. Many of these trade groups sold seeds to farmers at outrageous prices. Due to the false promise of riches, an overabundance of CBD flooded the market - and farmers were unable to sell their product. As a result, many farmers "lost the farm".

Wisely, the Ohio Agriculture Dept, after the passage of SB57, listened to the predatory history, and vocally warned our farmers in agricultural meetings, statewide. As a result, many Ohio farmers were protected and did not fall victim to this predatory behavior.

Many other state farmers were not so lucky. They were sitting on mountains of CBD. Inorder to attempt recoup some of their money - a "brilliant" mind decided to become a chemist, and acid wash the CBD molecule - synthesizing - the naturally forming CBD molecule into the Delta-8 molecule. The natural **phyto**-cannabinoid - Delta-8 - in the plant in *extremely* small amounts. (A **phyto**-cannabinoid is a cannabinoid in the plant. CBD, CBG, CBN, THCa)

The Delta-8 molecule has **NEVER** - in the history of humanity - been used at the rate it is with these products. We have no idea of the long term effects on the body and brain - specifically The Endocannabinoid System.

#### The Endocannabinoid System - ECS

Inorder to understand the true danger these synthesized molecules in the body, we must discuss the Endocannabinoid System. If we are asking our young people not to use Delta-8 and other synthetic cannabinoids for safety reasons, providing them with the science behind the ECS is critical to their knowledgebase. It is also critical for healthcare professionals to obtain this information.

The Endocannabinoid System is a biological system discovered in the 1990's. Researchers around the world are quickly understanding the importance of this biological system. The National Institute of Health, during the Marijuana and Cannabinoids: A Neuroscience Research Summit, the Director of the National Institute on Drug Abuse, Dr Nora Volkow, clearly discussed this biological system and stated they have much funds available for researchers. NIH is learning the ECS plays a critical role in addiction.

The biological system is made up of multiple parts.

- 1- Natural **cannabinoid receptors** are throughout the body, and the brain.
- 2 The body naturally produces **endo**-cannabinoids Anandamide and 2-AG that act as agonists at cannabinoid receptors. These naturally, produced in the body, **endo**-cannabinoids, bind to and activate receptors for a signaling effect. For example, the "runners high" has now been proven to be the ECS, not endorphins. Anandamide, the endocannabinoid bliss molecule, is released during exercise. There are multiple other easy ways to release the bliss molecules, naturally.
- 3 Enzymes break down the endo-cannabinoids.

According to the attached Harvard Medical School document: "The ECS regulates and controls many of our most critical bodily functions such as learning and memory, emotional processing, sleep, temperature control, pain control, inflammatory and immune responses, and eating."

Research has proven the ECS is responsible for homeostasis - balance - in the body. Just as we cannot ignore the digestive system and the immune system, we cannot ignore the Endocannabinoid System. Ignoring this biological system would be to the detriment of future generations.

Based on work done nationally, I was able to advise that healthcare ECS education is necessary when changing medical cannabis laws. It is now commonplace that physicians, who make medical cannabis recommendations, require ECS education approved by medical boards. However, physicians and nurses who see patients on a daily basis, do not know this biological system exists. This is illogical.

Unfortunately, due to my health issues, I have not focused on public health and safety issues involving the lack of ECS education as states legalized cannabis. This is a major hole in the recreational cannabis and ingestion hemp laws, nationally. Currently, New York has a proposed bill, and multiple states do discuss the importance of this education for our healthcare professionals. Also unfortunately, monied interests do not discuss the ECS, and are solely focused on their bottom line instead of the science behind the ECS.

## Importantly, Ohio does allow Physician education requirements in legislation:

Ohio HB 523 4731.03, Page 75

(F) Each physician who holds a certificate to recommend shall complete annually at least two hours of continuing medical education in medical marijuana approved by the state medical board.

### Synthetic Cannabinoid vs Natural Cannabinoids

I believe it is very important to define these molecules separately in any bill passed. These terms should not be mixed. They are not interchangeable.

## <u>Patients</u>

I would be remiss for not mentioning Ohio's patients in my testimony today. I would like to bring to the attention of the General Governance Committee:

- 1- Patients are paying taxes on their medical cannabis. Our families and neighbors who qualify for medical cannabis are very ill in Ohio. Taxes are a burden.
- 2 Many Ohio medical cannabis patients are in hospice or other facilities. Enabling patients to acquire and use what is needed to alleviate their suffering while in the facilities, would be most welcome. It is not right that patients in the facilities cannot access their medicine the same as those who are not in a facility. I am hoping this becomes a priority and addressed in the near future.
- 3 Illogically, patients in Ohio are <u>only allowed</u> to vape cannabis as an inhalation method. This is very concerning as vaping is not a proven safe method of ingestion. Vaping was a harm reduction tool for nicotine, not an ingestion method for medicine. Many states, including Ohio, have debated removing all vapes from the market. Ohio patients should have a choice in their ingestion/inhalation use of cannabis instead of requiring an unproven potentially unsafe method. The oils added and used for vaping have never been researched for lung inhalation. Only allowing patients to vape as an inhalation method, is unreasonable and not based in science.
- 4 On a national level, Ohio has made some errors in their regulations specifically what is known across the country as the "Ohio Tenth". Ohio laws illogically mix the old English form of measurement, with the metric form of measurement. For example, Ohio specifies that an ounce is to be broken down to tenths for sales. 2.83 grams. Ohio is the only state that does this. Instead, other states of the usual ½,¼,½ oz measurements.. Changing this requirement would bring Ohio in line with every other state and their medical program.

In conclusion, Delta-8 should be banned immediately.

- 1 Healthcare professional education requirements in the Endocannabinoid System should be included in any bill discussing ingestion of hemp or cannabis. Attached: NY proposed bill.
- 2 Ohio should specifically define natural cannabinoids vs. synthetic cannabinoids.
- 3 Patients in Ohio would benefit from updated rules and regulations for their health and financial needs.
- 4 There are self-serving trade groups acting as "experts" with many of the same players in multiple trade groups advising for their own financial interest instead of public health and safety. This potentially puts our farmers, small business persons, and communities in danger, as witnessed in the formation of the synthesized Delta-8 molecule.

Thank you again for your time, and I am able to answer any questions.

For additional information about the Endocannabinoid System, please view the very entertaining and shocking documentary, The Scientist. This documentary follows Dr. Raphael Mechoulam from the 1960's until its release in 2015. Dr Macheilum and his team discovered THC, and the Endocannabinoid System. Dr Mecholum discusses his decades of NIH funding, and research in Israel. The Scientist

# STATE OF NEW YORK

10001

## IN ASSEMBLY

May 1, 2024

Introduced by M. of A. KELLES -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing the endocannabinoid system awareness program

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The public health law is amended by adding a new section 1 3309-c to read as follows:

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§ 3309-c. Endocannabinoid system awareness program. 1. There is hereby 4 established within the department the endocannabinoid system awareness 5 program which shall educate health care practitioners regarding the endocannabinoid system and how it interacts with other bodily systems.

- 2. The commissioner, in consultation with the department of education and the office of cannabis management, shall establish standards, review and approve course work or training on the endocannabinoid system, and publish information related to such standards, course work or training on the department's website. The commissioner, the department of education and the office of cannabis management may consider existing course work or training, including course work or training developed by a nationally recognized health care professional, specialty, provider association or nationally recognized pain management association, when establishing such standards and reviewing or approving such course work or training.
- 3. The commissioner shall set the following minimum hours of course work and training required to satisfactorily meet the criteria established pursuant to subdivision two of this section:
- (a) every person licensed under title eight of the education law shall 22 on or before July first, two thousand twenty-five and once every three 23 years thereafter, complete three hours of course work or training on the endocannabinoid system which has been approved by the department. 24
- (b) every person who shall receive a license on or after July first, 26 two thousand twenty-five under title eight of the education law, and 27 every medical resident, shall complete such course work or training

EXPLANATION -- Matter in italics (underscored) is new; matter in brackets [-] is old law to be omitted.

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within one year of gaining such status and once every three years there-

4. The commission shall consider the following course work or training topics as satisfactorily meeting the training standards established pursuant to subdivision two of this section and shall include the following topics and accompanying subtopics:

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- (a) the endocannabinoid system, including the following subtopics:
- (i) the history of tetrahydrocannabinol (THC) pharmacology;
- (ii) the clinical effects of the endocannabinoid system;
- (iii) limitations of available research on the endocannabinoid system;
- 11 (iv) understanding how the endocannabinoid system is dependent on 12 lipid-based pharmacokinetics and pharmacodynamics;
- 13 (v) the components of the endocannabinoid system;
- (vi) specific enzymes used by the endocannabinoid system;
- 15 (vii) ligands of the endocannabinoid system receptors;
- (viii) ligands of the CB1 and CB2 receptors;
- (ix) dynamics of the endocannabinoid system receptor expression;
- 18 (x) the location and function of CB1 receptors, and how such receptors
  19 express themselves in bodily systems:
  - (xi) specific immune system functions of the endocannabinoid system; and
- 22 (xii) specific physiologic functions related to the endocannabinoid 23 system:
  - (b) cannabinoids, chronic pain and opioids, including the following subtopics:
  - (i) comparisons between the efficiency of non-opioid and opioid drugs for chronic back pain;
    - (ii) the magnitude of the prescription opioid overdose epidemic;
  - (iii) how concomitant use of opioids and benzodiazepines have adverse impacts on health;
  - (iv) the mechanisms by which cannabinoids impact the nociception system and spasticity;
    - (v) receptors involved with cannabinoid effects on pain modulation;
  - (vi) general safety and adverse effects between opioids, non-steroidal anti-inflammatory drugs, and cannabinoids;
- 36 (vii) common conditions in which medical cannabis should be recom-37 mended;
  - (viii) negative side effects opioid sparing helps reduce;
  - (ix) the addition of cannabinoid medication to chronic opioid therapy; and
- 40 and
  41 (x) which form of cannabis a patient should use when tapering from a
  42 slow-release opioid;
  - (c) pharmacogenetics and cannabis, including the following subtopics:
- (i) how to identify patient access issues and strategies on how to explain pharmacogenetics are no longer as expensive;
  - (ii) description of the variation of alleles;
- 47 (iii) identifying the principal organ responsible for metabolizing 48 medications;
  - (iv) the importance of how THC is metabolized;
- 50 (v) how cannabinoids act as drug metabolizing enzymes;
- 51 (vi) how cytochrome P450 (CYP) monooxygenases enzymes interact with a comprehensive metabolic panel and the liver;
  - (vii) how to interpret genotype information for patient care;
- 54 (viii) the clinical application of cannabis with opioids;
- 55 (ix) which clinical conditions support the need for propoxyphene test-56 ing:

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- (x) the potential risk of cannabis dependency; and
- (xi) the history of psychosis induced by THC use; and
- (d) food and drug administration (FDA) approved cannabinoid medications, including the following subtopics:

- (i) identifying the currently approved FDA cannabinoid drugs;
- (ii) the history behind the first synthetic THC medications originally approved by the FDA to treat clinical conditions;
- (iii) the clinical conditions for which the FDA approved the plant extract isolate of CBD;
- (iv) the two thousand seventeen report by the national academies of sciences on the clinical use of cannabinoids;
  - (v) pharmacokinetics of nabilone and THC analogues such as dronabinol; (vi) conditions that dronabinol have been used for that are not FDA
- (vi) conditions that dronabinol have approved and common side effects; and
  - (vii) education on how nabiximols are administered.
    - 5. Every person licensed or in the process of being licensed pursuant to subdivision three of this section shall attest to the department that such licensed person or person in the process of being licensed shall have completed the necessary course work or training required by this section on a form prescribed by the commissioner.
    - 6. The department shall establish a procedure for allowing licensees an exemption from the requirements of this section if any licensed person establishes that:
    - (a) the licensed person or person in the process of being licensed clearly demonstrates to the department's satisfaction that there would be no need for such licensed person to complete such course work or training; or
  - (b) the licensed person or person in the process of being licensed completed course work or training deemed by the department to be equivalent to the course work or training approved by the department pursuant to subdivision two of this section.
    - 7. Nothing in this section shall preclude such course work or training about the endocannabinoid system from counting toward the continuing education requirements under title eight of the education law or the continuing requirements of a nationally accredited medical board to the extent acceptable to such board.
    - § 2. The public health law is amended by adding a new section 3309-d to read as follows:
    - § 3309-d. Endocannabinoid system work group for public awareness. 1. The commissioner of public health shall establish an endocannabinoid system work group (referred to in this section as the "work group"). Such work group shall be established no later than one year after the effective date of this section. Such work group shall be composed of experts with significant knowledge and expertise related to the endocannabinoid system, and shall include, but not be limited to, consumer advisory organizations, health care practitioners and providers, and pharmacists and pharmacies. Members of such work group shall receive no compensation for their services but shall be allowed the actual and necessary expenses in the performance of their duties pursuant to this section.
  - 2. The work group shall report to the commissioner regarding the development of recommendations and model courses for continuing medical education, refresher courses, and other training materials for licensed health care professionals related to the endocannabinoid system and continuing education requirements for pharmacists related to the endocannabinoid system. Such recommendations, model courses, and other

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training materials shall be submitted to the commissioner, who shall make such information available for use in medical education, residency programs, fellowship programs, and in continuing medication education programs no later than January first, two years after the effective date of this section.

3. No later than January first, two years after the effective date of this section, the work group shall provide outreach and assistance to health care professional organizations to encourage and facilitate continuing medical education training programs for their members related to the endocannabinoid system.

4. On or before September first, one year after the effective date of this section, the commissioner of health, in consultation with the office of cannabis management, the commissioner of the department of education, and the executive secretary of the state board of pharmacy, shall have the authority to add additional members to the work group as appropriate to provide guidance in furtherance of the implementation of the work group's efforts.

5. The work group shall be responsible for developing a public awareness campaign to be provided to the commissioner of health, such public awareness campaign shall include information and resources about the endocannabinoid system and be available on the department of health's website with active weblinks to materials for the public to access.

6. The commissioner shall have the power to direct the work group to consider and research any issue on the endocannabinoid system deemed 24 relevant under their discretion. 25

7. The commissioner shall report to the governor, the temporary president of the senate and the speaker of the assembly no later than two years after the effective date of this section and annually thereafter on the work group's findings in regard to its continuing education efforts, the status of the public awareness campaign, and any other issues deemed relevant by the commissioner on the endocannabinoid system.

§ 3. This act shall take effect immediately.