STATE OF NEW JERSEY

DEPARTMENT OF HEALTH AND SENIOR SERVICES

IN RE: PUBLIC MEETING

MEDICINAL MARIJUANA
REVIEW PANEL

LOCATION: War Memorial
One Memorial Drive
Trenton, New Jersey 08608

DATE: October 25, 2017

TIME: 9:30 a.m.

J. H. BUEHRER & ASSOCIATES
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Page 2

BEFORE:
ALEX BEKKER, M.D., Ph.D., Panel Chairman
CHERYL KENNEDY, M.D., Panel Member
MARY L. JOHANSEN, Ph.D., NE-BC, RN, Panel Member
MARY M. BRIDGEMAN, Pharm.D, Panel Member
STEPHANIE ZARUS, M.D., Panel Member
PETROS LEVOUNIS, M.D., M.A., Panel Member (via telephone)

ALSO PRESENT:
Michele Stark, Executive Secretarial Assistant
Melissa Bayly, DAG
Susan Carson

Page 3

MS. STARK: This is a formal meeting of the Medicinal Marijuana Review Panel. Adequate notice of this meeting has been published in accordance with the provisions of Chapter 231, Public Law 1975-C10 -- I mean, sorry, C-10:4.10 of the State of New Jersey entitled Open Public Meetings Act. Notice was sent to the Secretary of State who posted the notice in a public place. Notices were published in two newspapers, the Star Ledger and the Courier Post and forwarded to the press covering the State House.

Now, do roll. Dr. Berkowitz is not here. Dr. Bridgeman?

DR. BRIDGEMAN: Here.

MS. STARK: Dr. Bekker?

DR. BEKKER: Here.

MS. STARK: Dr. Johansen?

DR. JOHANSEN: Here.

MS. STARK: Dr. Kennedy?

DR. KENNEDY: Right here.

MS. STARK: Dr. Levounis will be participating by phone later on. Dr. Scerbo is absent, and Dr. Zarus?

DR. ZARUS: Here.

Page 4

MS. STARK: We have five members of the board present, which is a quorum.

DR. BEKKER: So we are going to review and approve the minutes from our last meeting. The minutes of 5/11/17 have been distributed to the panel for review. Does anybody have any questions or comments from the panel?

(No response).

DR. BEKKER: Motion for approval?

DR. BRIDGEMAN: Motion to approve.

DR. KENNEDY: Second.

DR. BEKKER: Okay.

MS. STARK: Dr. Bridgeman?

DR. BRIDGEMAN: Yes.

MS. STARK: Dr. Bekker?

DR. BEKKER: Yes.

MS. STARK: Dr. Johansen?

DR. JOHANSEN: Yes.

MS. STARK: Dr. Kennedy?

DR. KENNEDY: Yes.

MS. STARK: And Dr. Zarus?

DR. ZARUS: Yes.

MS. STARK: Five yes. Motion carried.

Page 5

DR. BEKKER: So let me explain what's going to happen today. The members of the panel received 45 petitions and 45 petitions have been under consideration. So it will be -- so all of us, 45 petitions in the group with eight conditions and each condition was considered separately and the conditions are chronic pain related to musculoskeletal disorder, migraine, anxiety, chronic pain of visceral origin, Tourette's syndrome, asthma and chronic fatigue.

And a couple of groupings took place. Under the umbrella of anxiety, for example, we included anxiety associated with autism, anxiety associated with Alzheimer's disease and so on. Medicinal marijuana is not a cure for this disease but it alleviates symptoms. So this how the grouping was -- how we proceed.

So I will ask vice chair of this panel, Dr. Kennedy, to explain the factors which were considered in making our determination. After she will do that, we will separately look at every condition and see what additional comments, public comments, etcetera, and at that point we will be ready to go over each condition separately.

Page 6

(Susan Carson confers with Dr. Bekker.)
DR. BEKKER: Apparently before Dr. Kennedy will do it, each member has to reintroduce him or herself.
DR. KENNEDY: Go ahead.
DR. JOHANSEN: I'm Dr. Mary Johansen. I'm a clinical associate professor at Rutgers University and the Associate Director for the New Jersey Collaborating Center for Nursing.
DR. BEKKER: I'm Alex Bekker. I'm a professor and chair of the department of anesthesiology at Rutgers New Jersey Medical School.
DR. KENNEDY: Cheryl Kennedy. I'm an associate professor at New Jersey Medical School of Rutgers in Newark. I'm board certified in psychiatry and in addiction medicine.
DR. ZARUS: Stephanie Zarus. I'm the managing director of Avancer Group and my background is in care and hospice.
DR. BRIDGEMAN: I'm Mary Bridgeman. I'm a clinical associate professor in the Department of Pharmacy at Rutgers University and

Page 7

an internal medicine clinical pharmacist at Robert Wood Johnson University Hospital. I'm board certified in pharmacotherapy and geriatric pharmacotherapy.
DR. KENNEDY: Should I carry on now?
DR. BEKKER: Yes, please.
DR. KENNEDY: Okay. Thank you.
My name is Cheryl Kennedy and I'm going to tell you the factors that were considered by the panel according to our rules set forth in New Jersey A.C. 8:64-5.3 Section A.
Number one; the extent to which -- this is our consideration. The extent to which the condition is generally accepted by the medical community and other experts as a valid existing medical condition.
Number two; if one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition.
Number three; the extent to which the condition itself and/or the treatments thereof

Page 8

cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on the activities of daily living.
Number four; the availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof.
Number five; the extent to which the evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof, and, number six; letters of support from physicians or other licensed healthcare professionals knowledgeable about the condition.
I'll carry on here. Pursuant to N.J.A.C. 8:64-5.3 Section D, the panel is charged with and did make a recommendation to the Commissioner on the petitions as follows:
One; whether the medical condition and/or the treatment thereof are -- is or are debilitating, whether marijuana is more likely

Page 9

than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition and/or the treatment thereof, and, number three, other matters that the panel recommends that the Commissioner consider that are relevant to the approval or denial of the petition.
DR. BEKKER: Thank you, Dr. Kennedy.
So the next step is our panel -- May 25th of '16 was first meeting of this panel, then February 22nd, '17 and 5/11/17 and public hearing was held on 9/18/17.
Based on documents from this meeting and our reading extensive reading of the literature, we came up with our initial preliminary recommendation to Commissioner. The panel approved the additional chronic pain related to musculoskeletal disorder, migraine, anxiety, chronic pain of visceral origin and Tourette's syndrome and the panel did not approve the condition of asthma and chronic fatigue.
I just would like to kind of clarify how the panel came to this conclusion. Each member of the panel reviewed all evidentiary

Page 10

literature. I would like to emphasize that the decision of the panel are not based -- are not based on opinion, are not based on recommendation of some particular society. All our job is -- was, is and would be to objectively evaluate everything based on science. It's all what it should be.

Again, the opinion of different organization, medical organization, legal, clergy and whatever, this is not part of this -- part of our decision and each member of this panel will justify his or her position in very short statement. Again, I think at some point our evaluation will be posted on our website, but today we will have very short kind of explanation why, why member came to conclusion.

Okay. Now, we would like to -- initial recommendation. The initial recommendation you probably had a chance to read on web. It's there. So today what we're going to do, the purpose of this meeting is for the panel to discuss, deliberate its recommendation on the petitions. The panel may take into consideration the petitions themselves, information received with petition, public

Page 11

comments, their own research or that done by others, as well as any education, training, experience or other sources which helped the member to arrive at their recommendation. More specifically, the panel will determine whether, after having the benefit of reviewing input from the public hearing and comment period, there are any changes to be made to its initial recommendations.

At this point all members of the panel will participant. The panel submitted -- okay. Okay. Just to follow proceeding, I have to read a certain portion of this document.

Okay. So panel submitted its written initial recommendation to the Department of Health on 7 -- on July 21st, '17. The initial recommendation was posted for 60-day public comments on July 25th, '17. A public hearing was held on September 18, '17. Approximately 65 written comments were reviewed by the department. Copies of the comments and transcript of the public hearing were forwarded to the panel members for their consideration.

(Ms. Carson has contacted Dr. Petros Levounis via telephone and he is now

Page 12

present via telephone.)

DR. BEKKER: So, Dr. Levounis, at this point we are going to discuss and deliberate on each condition and vote on each particular condition. So this is where we stand right now.

Again, as I mentioned before, our recommendation, our role should be based scientifically on peer-reviewed publication, evidence base only. It's not opinion of particular organization. It's not opinion of clergy or anybody else. Our job is to evaluate valid scientific evidence for this condition. I just wanted to repeat that.

So having said that, we will start -- we will consider condition by condition and we'll start with chronic pain related to musculoskeletal disorder.

At this point -- and let me start and then each member will state his or her -- actually in this case, her position.

So my recommendation is based on extensive review of literature which clearly indicates that medicinal marijuana helps alleviate chronic pain, chronic pain syndrome

Page 13

associated with musculoskeletal disorders. This includes conditions like fibromyalgia, failed back syndrome and similar conditions.

In addition, there are systematic reviews and many analysis which confirm my conclusion. Academies of Sciences, Engineering and Medicine also recommend medicinal marijuana as a treatment for chronic pain, chronic back pain or pain secondary to musculoskeletal disorder.

So that's about all that I have to say on this. Questions -- actually I will ask you to -- if you don't mind as public, wait with your questions. Write it down. When deliberation for each particular condition would be over, you will have chance to ask -- comment or whatever, offer your opinion.

So Dr. Johansen.

DR. JOHANSEN: Thank you.

I also reviewed not only -- for each one of these I reviewed not only the petitions but the evidence that was provided by each of the petitioners as well as evidence that's out there in the literature.

The evidence that I looked at was

Page 14

peer-reviewed journals, which is very important because it does provide evidence of rigor in terms of research and science, and I am in agreement with Dr. Bekker. I found that there were clear evidence -- there was clear evidence to establish clear relationships between the use of medicinal marijuana to alleviate chronic pain related to musculoskeletal disorders.

DR. BEKKER: Dr. Kennedy.

DR. KENNEDY: Thank you.

I reviewed the literature extensively about the condition itself and about the treatments for it and I discovered although there are a multitude of therapies for gastrointestinal disorders or other sources of visceral pain, the only actually accepted treatment of these associated pains was opioid analgesic medication, some anticholinergic and anti-spasmatic medication can help relieve some painful bowel spasms but can worsen constipation and lead to difficulty in urination.

Some people may benefit from bile acid binders, bicholestyramine, but these can lead to painful bloating. Anti-depressants are commonly prescribed for pain relief, but these

Page 15

are associated with complications and do not actually address pain specifically but rather the other emotional states that may make pain worse.

Opioids are used in patients with more severe visceral pain, but may induce constipation, nausea, vomiting, duritis, which is itchiness on the skin, and respiratory distress and carries the risk of many adverse effects including death.

As is well known, these conditions -- these medications, the opioid analgesics are highly addictive. The opioid epidemic and its attendant sequela of overdoses including fatal ones is considered to be a major public health emergency at this time in the United States.

So the chronic pain related to pathophysiology and its treatment can lead to a lot of other additional problems and these conditions may dramatically reduce the quality of life and the ability of patients to work and obtain gainful employment.

The extent to which this evidence is accepted is -- there are more than 400 peer-reviewed publications on the subject. The

Page 16

petitions that I reviewed included a number of supportive articles and there are letters of support from physicians and other licensed healthcare professionals knowledge about -- knowledgeable about the condition.

It is -- so that this chronic visceral pain is often physically and psychologically incapacitating and these petitions present heartbreaking stories of dramatically diminished quality of life and it is therefore my opinion that there is sufficient medical evidence to support the recommendation for medicinal marijuana for the treatment of pain of visceral origin.

DR. BEKKER: Superb, Dr. Kennedy.

Dr. Zarus.

DR. ZARUS: Okay. But we are talking about pain related to musculoskeletal?

DR. BEKKER: Musculoskeletal, right.

DR. KENNEDY: I'm sorry. I went on a tangent. It's actually quite --

DR. BEKKER: Here we have two separate conditions. There are some differences physiologically and how these conditions are treated. That's why original grouping put this

Page 17

in two different categories.

DR. ZARUS: Right.

DR. BEKKER: They're treated by doctors different, different medication. So that's how they grouped that.

Dr. Zarus.

DR. ZARUS: So we'll come back to visceral pain, but I'm going to go back to musculoskeletal.

DR. BEKKER: Exactly.

DR. ZARUS: With regard to the petitions that I reviewed related to musculoskeletal disorder, there were 32 of them in which we found -- in which I found the value or benefit of medicinal marijuana, particularly in subgroups of individuals who are unresponsive to conventional therapy. So conventional therapy does exist for managing musculoskeletal disorders and the pain related to that disorder in the majority of patients, but there are subgroups of patients whose condition is not palated (ph) or improved with conventional medication and/or the adverse effects of that conventional treatment may outweigh the use of it and in these particular patients the value

Page 18

and ability to use medicinal marijuana has been demonstrated through medical evidence, and so I continue to support first the individual petitions to approve or enable medicinal marijuana to be available for individuals who are unresponsive to conventional therapy in the management of chronic pain related to musculoskeletal disorders.

DR. BEKKER: Thank you, Dr. Zarus.

Dr. Bridgeman.

DR. BRIDGEMAN: Thank you.

So I just want to preface sort of my comments with sharing the fact that there was a report that was published in January of 2017, The Health Effects of Cannabis and Cannabinoids, The Current State of Evidence and Recommendations for Research, and this was a document made available by the National Academies of Sciences, Engineering and Medicine and this was a document that I found in my research with all of these petitions that was particularly helpful in summarizing the state of the evidence and the state of the science and pointing to some of the primary literature that I used in developing my opinion.

Page 19

With regards to the chronic pain question and particularly chronic pain related to musculoskeletal disorders, it's been pointed out by my colleagues that while there are conventional therapies that exist for managing these types of pain, the petitions that were largely reviewed were in situations where either traditional therapy had failed or symptoms were refractory to traditional therapy.

We also read in the petitions about severe debilitating symptoms or debilitations related to adverse effects of certain medications.

In that regard and in considering the systematic reviews -- there are two systematic reviews, a meta-analysis that suggests moderate to high quality evidence that medicinal cannabis was used to improve pain scores in patients with chronic pain and based on the evidence from the National Academies of Sciences there is conclusive or substantial evidence that cannabis or cannabinoids are effective in chronic pain in adult patients, I came to the conclusion that this would be an appropriate indication and use of this therapy.

Page 20

DR. BEKKER: Thank you, Dr. Bridgeman.

Dr. Levounis.

DR. LEVOUNIS: Yes, I also reviewed the literature extensively as well as the testimony presented in front of this panel.

The first question of whether the medical condition or treatment is debilitating, I agree and I vote yes for that. The heartbreaking stories that we all heard I think substantiate this vote.

The second question of is marijuana more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition or the treatment thereof, I vote no.

I have found that smoking as a means of (indiscernible) and of course the components of marijuana (indiscernible) in the U.S.

At this point I find that there's insufficient evidence for (indiscernible) of smoking cannabinoids such as marijuana (indiscernible).

I just want to add that this was supported also by a number of the

Page 21

(indiscernible) from the American Cancer Association and the American Society of (indiscernible).

DR. BEKKER: Okay. Should we deliberate or just vote? What's the process? Or maybe public has a comment or question.

(Dr. Bekker confers with colleagues.)

DR. BEKKER: So right now members of public you have a chance to comment. Please be short. It's a lot of -- it's very long. So if you have any comments, on this condition only, so please do.

And if there's no public comments, and it doesn't look to me, so we'll just continue with the next condition.

MR. LIVINGSTON: Hi, Doctors. I'm Edward Livingston.

As far as chronic pain goes, what were some of the subcategories of chronic pain? I'm very interested in being hopefully a patient. I'm a little skeptical as well as I heard from the other doctor, but I would rather -- I'm agreeing with Dr. Kennedy, I would rather -- I would rather try something else other than opioid medicine since there's a big

Page 22

epidemic of opioid medicine of which we all are aware of in the nation. So I would like to know some of the subcategories and how many patients. I heard numbers thrown around, but how many patients were -- had a positive affect from your studies?

DR. BEKKER: It's not our studies, but I can review conditions which would fall under the umbrella of chronic pain --

MR. LIVINGSTON: Yes.

DR. BEKKER: -- of musculoskeletal origin. This will include spinal stenosis, herniated disk, failed back syndrome, fibromyalgia, complex regional pain syndrome, disk herniation, degenerative disk disease.

A lot of these conditions are not clear -- they don't have clear-defined etiology, but patient suffers and from what we know marijuana alleviates this pain and in large study, it's kind of an epidemiological study in states where marijuana was approved for medicinal purposes, patients started using marijuana, the opioid requirement went down by about 30 percent, which is obviously a positive thing to consider.

Page 23

Again, I want to emphasize this point. Opinion of medical organizations are available at this point. All opinions provide evidence-based medicine and this is what panel did.

MR. LIVINGSTON: I appreciate it. Thank you, Doctor.

DR. BEKKER: Unless there are any other comments, we'll go for the next condition.

To the members, before we go, do we have any -- any of you change your position in view of this last comment? I guess not, but I supposed to ask you this question. Nobody?

(No response.)

DR. BEKKER: So next condition which we'll consider is migraine, and under migraine it's kind of a little bit broader definition than actual technical definition of migraine. It will include cluster headache, headache of unknown origin, but we all -- all these conditions group under umbrella of migraine.

So my review of the literature suggests that -- I mean migraine it's very difficult -- let me preface by saying that migraine is extremely difficult condition to

Page 24

treat. Currently we'll use NSAIDS, Ergots, treatments and things like that. However, this treatment do not alleviate pain in some patients and are associated with many side effects. We all know NSAIDs cause intestinal bleeding, heartburn. This may adversely affect kidneys and things like this.

So current treatment is not effectively -- it's not effective in some patients. A number of studies suggest favorable effects of cannabis for treatment of migraines. This has been summarized in at least two reviews and my evaluation includes these references.

So based on this literature and petitions which kind of heartbreaking, some of these stories, debilitating conditions, my recommendation is to approve medicinal marijuana for treatment of migraines which includes -- again, it's kind of broader definition of migraine than actually medical definition of it.

Okay. We go the other way right now. We start with Dr. Bridgeman.

DR. BRIDGEMAN: Sure. I absolutely agree with your comments, Dr. Bekker, with regards to the adverse effects associated with

Page 25

medications that are used in the management of migraines both in the treatment as well as the prophylactic and prevention of migraine headaches.

Again, in addition to reviewing these petitions, I found a small -- there were a number of -- 121 patients included in a clinical evaluation on medicinal marijuana on migraine headache frequency in adults that was published in the Journal of Pharmacotherapy in 2016. Based on this retrospective chart review of adult patients who had been using medicinal cannabis for migraine treatment or prophylactics, the investigators concluded that medicinal cannabis was associated with significant, significantly significant reduction in migraine frequency attributed to medicinal cannabis use and I found that compelling evidence to support my recommendation for permitting migraines as an indication for medicinal cannabis use in New Jersey.

DR. BEKKER: Thank you, Dr. Bridgeman.

Dr. Zarus.

DR. ZARUS: Yes, and I also concur in

Page 26

expanding the use to include medicinal marijuana for those individuals suffering from migraines and, again, it can be very debilitating to individuals who are not able to manage it with conventional therapy or have incidents that's not allowing them to have their migraine managed by conventional therapy.

Again, I think of the articles referenced, there were a number that do support either eliminating or mitigating the effects of migraines through the use of the medicinal marijuana. So I also support that. Thank you.

DR. BEKKER: Thank you, Dr. Zarus.

DR. BRIDGEMAN: I just want to point out also from a pharmacologic perspective it may make sense to use medicinal cannabis for this particular condition because it has been hypothesized that cannabis may modulate the synergistic neural pathways. So it sort of makes sense when you think of the pharmacologic use for migraine management, that medicinal cannabis may have a role here.

DR. BEKKER: Okay. Dr. Kennedy.

DR. KENNEDY: Thank you.

As stated, the condition of migraine

Page 27

or cluster headaches, retractible headaches are a well-known medical condition as well as described in medical literature as are some of the treatments and their various side effects and in many cases failure to actually treat the condition effectively.

Many of the medications that are in current use, as stated and I agree, can cause very adverse effects in several organs. The NSAIDs, which are commonly known as ibuprofen, naproxen and medications of that order can cause severe GI tract problems, kidney failure in the elderly and can have cardiac effects and people that take anticoagulant therapy, which is very much in use these days, cannot -- should not also use these medications.

There's also the Triptans, which are the most recent entrants into the pharmacopeia for headaches of this type can cause nausea, vomiting, dizziness on their own and they -- these drugs can lead to what is known as a medication overuse headache and it's defined in our canon as occurring in 15 or more days per month in a patient with a pre-existing headache that uses these Triptans and they cannot be used

Page 28

in some variants of this disorder, the Triptan cannot in migraines because these drugs are also associated with an increased incidence of stroke.

So the conventional therapies are ineffective for some patients and although medication may help many patients, there are individuals who are unresponsive and the condition leaves them quite disabled and debilitated with a very decreased quality of life and ability to function.

Four of the five petitions were supported by licensed healthcare professionals. So I also considered that along with the literature that was already cited by my colleagues here. So I continue to come to the conclusion that this is a likely effective treatment for some people who have this debilitating type of headache.

DR. BEKKER: Thank you, Dr. Kennedy.

Dr. Johansen.

DR. JOHANSEN: Yeah, so my colleagues have been very eloquent in stating all of the evidence from the literature and they spoke to

Page 29

conventional treatments, which are the NSAIDs we're talking about, the Advil, ibuprofen, naproxen. For patients that have other comorbidities that require them to take blood thinners, if you will, some of those modalities are not available to them. So many patients actually go to alternative therapies like biofeedback, aromatherapy. They stop smoking. They may not eat different foods as triggers, environmental triggers.

So when I reviewed not only the petitions but the literature and actually did take a look back at the alternative therapies, I came to the conclusion that the potential effects of cannabis or cannabinoids I should say on the central nervous system indicates that marijuana may be a therapeutic alternative.

I looked at several pieces of literature that did support that. One was by Russo who most certainly made that relationship established. So my conclusion was most certainly that this was definitely a modality that could be used for patients in an effective and therapeutic manner. So I vote yes.

DR. BEKKER: Thank you, Dr. Johansen.

Page 30

I just would like to add that most of therapy recommendations in our purview and in our making this type of decision smoking is not the only way to deliver cannabis as a route. So, again, it's not our goal to figure out how to deliver. There are other methods of delivery. So I just want to make clear we are not advocating smoking or not smoking. This is not our job.

Dr. Levounis.

DR. LEVOUNIS: Yeah, I opine that the medical condition of migraine, cluster headache, headaches of unknown origin are certainly debilitating and they are heartbreaking stories. We heard that they truly are (indiscernible).

So on the issue -- the second question of the potential being beneficial will be the same as before, I vote no on that because some of the components (indiscernible) migraine and other headache, then we should (indiscernible). There are many other medicine in the United States.

DR. BEKKER: Thank you, Dr. Levounis.

Any member from the audience would like to comment, let's do it now.

Page 31

(No response.)

DR. BEKKER: No comments.

Okay. We'll go to next condition. Next condition on my list is primary and secondary anxiety, and we'll collaborate a little bit what it means, secondary anxiety. We had three petition on this issue. Some of them related to primary disorder, being like autism or Alzheimer's and we don't -- we do not recommend -- we just cannot (indiscernible) for treating of autism -- either autism or Alzheimer. However, anxiety, and it's very critical, just bear with me, anxiety associated with autism, either autism or Alzheimer's can be treated with marijuana. We treat the disease, but we addressing the symptom.

Okay. Now, anxiety is a debilitating disorder. Usually medication -- medication generally may not alleviate symptom and pharmacotherapy usually include anti-depressant. This adversely affect such like nausea, vomiting, insomnia, some lead to suicidal ideation, weight gain.

Benzodiazepine is another class of drug. Common side effect include headache,

Page 32

confusion, tiredness. In some people it causes nightmares, difficulty thinking and remembering stuff. It affects memory and actually use this drug to -- for amnesia. So it definitely will affect memory.

So my review of literature suggests that it might alleviate some of the symptoms with less side effects than commonly accepted medical treatment. So based on this fact, I approve -- I will recommend to approve marijuana for treatment of anxiety primary and secondary.

I guess we'll start from here. Dr. Johansen.

DR. JOHANSEN: So again, Dr. Bekker mostly gave a broad overview of anxiety. I would like to add that anxiety in a mild form is generally treated with like a type of therapy or a counseling. It's not always a primary measure to go to pharmacotherapy to treat patients. So patients that do have these kind of issues actually wind up having to go through a progression before anything is prescribed to them and then when they are prescribed, it's usually some type of an anti-depressant possibly or Benzodiazepine and many of these can be

Page 33

actually treated via -- they're poorly tolerated by many patients depending upon what other comorbidities or things are going on with them.

I went back to the literature -- again, there was many pieces of literature that were submitted by the petitioners, but I went back to the literature and found in excess of 425 research articles that established the relationship for symptom management for those individuals with anxiety and based upon that I came to the conclusion that it would be best served for the citizens of New Jersey that marijuana be approved for symptoms treated for anxiety.

DR. BEKKER: Thank you, Dr. Johansen.

Dr. Kennedy.

DR. KENNEDY: Thank you.

Yes, anxiety is a debilitating and disabling condition in many cases and yes, there are mild forms that can be treated with non-pharmacologic intervention.

However, when the anxiety does require a pharmacologic intervention, whether it's primary or secondary in nature depending on the origin of the anxiety, my review of the

Page 34

literature and of the available information about these conditions tells me that the conventional therapies are unacceptable in many cases because of the side effects and I'd like to point out that the Benzodiazepines, which are the primary go-to gold standard for treating anxiety disorders, are known to be controlled substances. They are widely abused in the community. This is well known and follows the opioid crisis in some ways. Although it is difficult to overdose purely from Benzodiazepine, the actual withdrawal from these medications can be life threatening and requires medical supervision if people become dependent or addicted upon them.

So there are some serious adverse effects related to the primary treatment modality and many patients are unwilling or unable to tolerate these medications because of these problems, and it is apparent through the review of literature already cited by some of my colleagues that these conditions, these types of anxiety conditions can be possibly effectively treated with the medicinal marijuana and, as we know, there are a variety of delivery forms

Page 35

including non-smoking forms that are available in New Jersey, and so I continue to come to the conclusion that this -- these conditions, that is primary and secondary anxiety should be approved for use by the Commissioner.

Thank you.

DR. BEKKER: Thank you, Dr. Kennedy.

Dr. Zarus.

DR. ZARUS: Thank you.

I too support the conclusion of my colleagues that medicinal marijuana can be a benefit in anxiety, particularly in those patients that suffer anxiety at its worst, which can even conclude in suicide or lead people towards suicide.

I think there are a number of things we already heard and again the risks can be intolerable in some people and there is significant evidence to demonstrate that there is a place for medicinal marijuana in the primary care of fighting anxiety in those who have it in the worst possible condition.

DR. BEKKER: Thank you, Dr. Zarus.

And Dr. Bridgeman.

DR. BRIDGEMAN: I think I'm a little

Page 36

more ambivalent than half of my colleagues with regard to my evaluation of anxiety as an indication. I absolutely appreciate the attention and the evidence that was supported with regards to these claims and my assessment was really based on sort of a risk benefit analysis here.

I think the evidence for anxiety as an indication is a little bit more limited than the clinical evidence, which is very robust for chronic pain and the indication we spoke of.

There is limited clinical evidence that cannabis and cannabinoids, and especially cannabidiol is effective in managing anxiety symptoms and in my evaluation of the literature it was in particular social anxiety disorder which seemed to have the most robust evidence at this time.

I do want to just express the fact that there are some concerns and there is some evidence in the literature that cannabis may also exacerbate anxiety symptoms or an adverse effect related to cannabis may be associated with anxiety.

So sort of weighing out exacerbating

Page 37

anxiety versus the limited evidence, I did come to the conclusion that there wasn't enough evidence to support a recommendation for use in those patients refractory to traditional pharmacotherapy.

I also just want to point out that we've never had an FDA-approved medication that was administered via smoking and I'm not an advocate of smoking as drug administration here as well, but there are alternative dosage forms available and as a pharmacist I'm remiss if I don't mention that.

DR. BEKKER: Dr. Kennedy would like to add a comment.

DR. KENNEDY: Yes. I would agree with Dr. Bridgeman's statements about you can have anxiety produced from the use of medicinal marijuana and one would certainly hope that if the condition one is trying to treat is exacerbated, you would no longer seek that treatment.

Additionally I would like to say that all the petitions were supported by licensed healthcare professionals.

DR. BEKKER: Dr. Levounis.

Page 38

DR. LEVOUNIS: Yes, I agree with my colleagues that the medical condition is debilitating for both primary and secondary anxiety. In terms of being beneficial, exactly as I mentioned before, I vote no.

There is benefit profile in favor of marijuana at this point at least and I wish to reserve the ability to analyze the components of marijuana in the future (indiscernible).

I just want to make one more clarification. It was mentioned before the gold standard treatment for anxiety was in 2017 Benzodiazepine. (Indiscernible).

DR. BEKKER: Thank you, Dr. Levounis.

Yes, Dr. Kennedy would like to respond, please.

DR. KENNEDY: Right. Thank you, Dr. Levounis, and I do appreciate that current recommendation for anxiety. However, in cases of acute anxiety anti-depressants, which may be effective in some patients with anxiety, anti-depressants are not effective initially in an acute condition; panic, etcetera. They take anywhere from two to six weeks at the right dose to provide an effective dose, if they're going

Page 39

to be effective.

Thank you.

DR. BEKKER: I also would like to comment and say that also conceptually I absolutely agree with Dr. Levounis that in the future if we can determine what component of marijuana are useful, we should definitely pursue this venue.

However, currently we don't know what exactly -- how marijuana works. You know, kind of it's always better to be wealthy and healthy than poor and sick, yes, I agree with you, but right now we don't have this medication. So we kind of -- at least at this current state of science. My approval may change in future, but right now we don't have this medication.

So I just want to put it for the record. We don't have this piece, which extract, particular component, chemical which deal with this anxiety or this chronic pain.

Okay. So I think we done with comments on anxiety and our next condition is --

MS. STARK: Wait.

MR. MILLER: Excuse me, Doctor.

DR. BEKKER: Oh, yeah.

Page 40

MR. MILLER: Are you taking comments?

DR. BEKKER: I'm sorry. Please. I apologize. It's time for public to comment on this condition. Again, my apologies.

MR. MILLER: Thank you. James Miller, co-founder of Coalition for Medical Marijuana in New Jersey. I want to point out two things to what you were just talking about.

Dr. Johansen, you mentioned Dr. Russo's studies for migraines. The interesting point about one of his studies is he could not get FDA approval for the -- he couldn't get the cannabis with National Institute on Drug Abuse approval because they released the marijuana for efficacy citings. He had to wait a period of time and submit the exact same protocol saying he was worried it might harm them in some way and then he did get to proceed with that.

So my point is is when there are not efficacy studies done, unless you can say that you know how many were turned down and not allowed, you know, it's very important.

Page 41

The second thing is as to yes, marijuana will cause anxiety in some people. So it's counterintuitive to let somebody with anxiety have it. Sometimes weirdly enough it's like minus two times minus two isn't minus four, you know.

Another thing though the FDA-approved drugs for anxiety also have anxiety as a potential side effect, yet they have other FDA-approved drugs to counteract. You know, it's bizarre.

So I appreciate Dr. Bekker taking -- especially making a point to take the side effects into account because from a patient point of view, FDA-approved side effects are no better than unapproved side effects. They hurt just the same.

So that's it.

DR. BEKKER: Thank you, Mr. Miller.

If there are no other comments, we will move on.

Our next condition is Tourette syndrome. Give me one second. Give me one second to find my recommendation.

(Dr. Bekker confers with colleagues.)

Page 42

DR. BEKKER: Oh, okay. I'm sorry. I apologize. Next condition we will consider will be chronic pain of visceral origin.

There are three petitions related to this condition, which include chronic acute pancreatitis, pain related to neurogenic bladder and bowel disfunction, and irritable bowel syndrome.

This is rare condition, but extremely painful and extremely difficult to treat. Any pain of visceral origin well documented is extremely difficult condition to treat and my recommendation based partially on -- partially on available literature but partially simply on compassionate kind of use of this drug.

It appears that it relieves pain and even if evidence here is not as clear or as clean as what chronic back pain or chronic pain of muscle origin, it's not -- I admit it's not as clear-cut evidence. However, I believe that part of being a doctor is to appreciate the suffering of people. So partially my decision is based just on that. So based on that I will recommend to approve marijuana for pain secondary to visceral origin.

Page 43

Let's go the other way around. Dr. Bridgeman.

DR. BRIDGEMAN: So, you know, undoubtedly chronic pain of visceral origin is a condition that's accepted by the medical community as being potentially severe and debilitating and we realize that there are both non-pharmacologic interventions in the case of irritable bowel syndrome or some of these conditions as well as drug therapies that may have a role in alleviating symptoms of chronic pain associated with either irritable bowel or chronic pancreatitis.

You know, when we think about the adverse effects associated with the medications including the opioids which can be used for these conditions, they can be severe and debilitating. We've already discussed that.

There is evidence to suggest that medicinal use of cannabis may have efficacies of treatment of chronic pain syndrome and we do have some limited clinical evidence to suggest that cannabinoids in the treatment of pancreatitis or irritable bowel may have efficacy and that was largely where I came to my

Page 44

conclusion on indicating or expanding use for these conditions in New Jersey.

There is evidence that suggests that the endo-pathway system plays a role in modulating these disorders and in my mind from a pharmacological perspective, use of cannabis sort of intuitively would make sense based on some sort of pathophysiology that's been described.

DR. BEKKER: Thank you, Dr. Bridgeman.

Dr. Zarus.

DR. ZARUS: Yes, thank you.

Well, I concur. I mean we -- this is a condition in which internal organs are distended in some way. The pain related to that, while there is some pharmacological benefit available today, in many cases people are refractory to that and the condition can be, you know, retractable and debilitating and there is evidence, as you heard, of the benefit that medicinal marijuana can play from a pharmacological perspective on the ability for -- or quality of life for an individual.

So I do concur that including pain of

Page 45

visceral origin should be added to the list of acceptable conditions for medicinal marijuana.

DR. BEKKER: Thank you, Dr. Zarus.

Dr. Kennedy.

DR. KENNEDY: Thank you.

I'd like to do a partial correction to the record regarding my previous remark about visceral pain which I addressed earlier when we were addressing musculoskeletal pain.

So regarding musculoskeletal pain, just to make sure the record is clear, I agree with my colleagues who spoke on that, that yes, it is actually known as the top five medical conditions that disables people, this chronic pain syndrome of musculoskeletal origin.

Now, to address the pain of visceral origin, many of the pains that come from visceral origin are actually related to muscles and other tissue within the internal organs or surrounding the internal organs which sometimes expands due to congestion and inflammation and these can cause severe and debilitating pain and, as already noted, the current pharmacotherapy cannot only exacerbate the problem, especially in the GI tract if people

Page 46

are suffering with constipation, opioid analgesics continue to worsen that kind of effect.

So these kinds of pains are extremely debilitating and very, very difficult to treat even with the opioid analgesics and any other kinds of pharmacological intervention.

So I have found that there are several peer-reviewed publications that speak to the beneficial effects of cannabis for the treatment of pain resulting from inflammation or malfunction of the internal organs. They were published in respected peer-reviewed journals in 2007, 2011 and 2013, to mention three of them.

So in my opinion there is more than sufficient evidence to recommend medicinal cannabinoids for visceral pain.

DR. BEKKER: Thank you, Dr. Kennedy.

And Dr. Johansen.

DR. JOHANSEN: I concur with my colleagues regarding the evidence in the literature and I would like to add the following; the individual who has chronic pain related to visceral origin more often than not it could be a bowel malfunction like irritable

Page 47

bowel syndrome, Crohn's is commonly -- you kind of hear that when you talk about visceral disfunction, but these individuals experience not only the physical pain, but they also experience problems that are psychosocial in nature, which includes suicidal ideation, depression, pain and anxiety, which actually impacts the individual's quality of life and these can be extraordinarily detrimental.

And in addition to the pharmacological treatment for chronic pain related to bowel malfunction and specifically related to viscera may actually lead to an exacerbation of the individual's symptoms.

I also noted that there was no one accepted treatment of pain of visceral origin which is a -- which is not necessarily a concern. The management by any provider most certainly needs to provide optimal situations for the patient in terms of quality of life and pain management, but some of the anticholinergic and antispasmodic medication that they use do indeed provide some painful relief of bowel spasms, but there are pretty significant side effects to that and that really can be almost

Page 48

more detrimental than the pain. Patients have to kind of weigh back and forth, what is the best modality for them to do.

And so based upon the evidence from the literature and my feelings and experience with the quality of life with these patients, certainly I support the use of marijuana, medicinal marijuana for the treatment.

DR. BEKKER: Thank you, Dr. Johansen.

And Dr. Levounis.

DR. LEVOUNIS: Yes, on the issue of whether the chronic pain of visceral origin is debilitating, I vote yes, and on the second issue of the benefit of (indiscernible) I vote no.

At this point we're hearing something that has come up in the testimony we heard before and as to opioid, some people put forward the idea that perhaps cannabis use can double as a means of curbing the issue of the opioid epidemic somehow in the future in that regard.

There was a very extensive article that was published in the American Journal of Psychiatry in September of 2017 and that's why it's not in my original testimony.

Page 49

(Indiscernible) and colleague concludes that cannabis use appears to increase rather than decrease the (indiscernible) opioid use and opioid use is shorter, and this I state on the data of over 34,500 patients.

DR. BEKKER: Thank you, Dr. Levounis.

DR. LEVOUNIS: Or rather 500 people, not patients. 34,500.

DR. BEKKER: Thank you, Dr. Levounis. I'm not familiar with this study. I guess it just came out. The study which was published in JAMA in 2015 assessed the results of legalization of medicinal marijuana in Colorado and they state in JAMA article that deaths association with opioid overdose went down by about 28 percent, something like this after legalization.

There was another study, which is in my evaluation, which shows that patients on chronic opioid -- again this is large study. Patient on chronic opioid who use marijuana, use of opioid went down by about 40 percent and about 10 -- another 10 percent of patient completely off opioid.

So, again, I would be interested to

Page 50

read this publication in American Journal of Psychiatry, but leaving this issue aside, from all other systematic review in meta-analysis suggest that use of opioid is reduced when -- in states with the medicinal marijuana or legalized marijuana, as a matter of fact.

DR. LEVOUNIS: You know, this is based on (indiscernible) and that's why (indiscernible) as to what's going on in the association between cannabis use and (indiscernible).

DR. BEKKER: Right. I'm sorry that I didn't read this article, so I cannot comment. They're probably very sure they're correct, but there are studies on both sides. So one study, you cannot say that this study absolutely denied all available evidence like (indiscernible) studies, stuff like that. Science is developing.

Maturity (indiscernible) studies shows that marijuana reduces opioid consumption and (indiscernible) shows something else. So until, you know, this should be -- public should know about this study and thank you for bringing this particular research to our attention. I

Page 51

presume that members of this panel will familiarize ourselves -- acquaint ourselves with this research and see how it will pan out in the future, but our recommendation also -- because they met with many more studies which suggest its effect is positive.

DR. KENNEDY: May I make a comment?

DR. BEKKER: Yes. Dr. Kennedy would like to comment as well.

DR. KENNEDY: Right. Regarding the article Dr. Levounis has referenced in the September 2017 American Psychiatric Association Journal, it is data -- the investigators analyzed data from the National Epidemiologic Surveys on alcohol and related conditions which interviewed more than 43,000 American adults in 2001 to 2002. Subsequently they were followed up, more than 34,000 of them, in 2004 and 2005.

I would point out that this data then was collected more than ten years ago and the opioid crisis has significantly changed since then and there are many, many, many more users of opioids now.

So although the study may have valid conclusions based on the data they reviewed,

Page 52

this type of study should be revalidated given the current situation we find ourselves in with the opioid crisis.

Thank you.

DR. BEKKER: Thank you.

Members of audience, any comments? Mr. Miller?

MR. MILLER: Briefly I would like to add that it was 2014 when the American Medical Association looked at the effects of the first 13 states with medical marijuana laws. They all included general pain provisions. Unlike New Jersey, we started very bad perhaps with -- as the 14th state, but in those 13 they found there was 24.8 percent reduction in the overdose death rate due to opioids.

In New Jersey we have a thousand overdose deaths of opioids both prescribed and illegal and that would translate statistically to 250 lives that could have been saved.

Now of course the American Medical Association, and rightly so, cannot attribute cause and effect to it. We cannot say this is what we will find, but when it happens in all 13 states and it combines for a 25 percent

Page 53

reduction, people need to be reminded that it is an additional medicine, adjunct medicine, not a replacement medicine and The Coalition for Medical Marijuana for over 12 years now has heard literally thousands of stories about the reduction in the opioid abuse of people combining cannabis with it.

So thank you for taking that into account. If we really are having the epidemic that we are, this could be the single most important thing going on and I regret to say, and you already know, you haven't heard this anywhere else in the state of New Jersey.

So this is my only -- it's not being used. It's not being talked about. New Jersey does not mention this. So I hope that eventually it will work that you folks will bear fruit in New Jersey and we will be better off for it.

So thank you very much.

DR. BEKKER: Thank you, Mr. Miller.

If there isn't any other comment, we will move on.

(No response.)

DR. BEKKER: No other comments.

Page 54

So next condition on our list is Tourette syndrome. Tourette syndrome is a neurological disorder which is characterized by repetitive involved in movement and occasionally verbal outbursts. There are no accepted pharmacological treatment for this condition. Also all kinds of medication been tried to treat Tourette syndrome. Only neuroleptic officially approved by FDA for treating Tourette syndrome but treatment is not very successful. It's very difficult to treat condition, very debilitating.

Underlying cause of Tourette syndrome is relatively unknown, uncertain. However, there are number of clinical reports. I found 12 peer-reviewed publications which suggests that marijuana is helpful and we had, like all of us probably remember, heartbreaking story about mother who has 17-year-old kid, very intelligent and smart, but depressed and lonely simply because he cannot be in a normal environment at school.

So based on this -- my review of the literature and compelling stories, I would recommend to approve cannabis for treatment of Tourette syndrome.

Page 55

Dr. Johansen.

DR. JOHANSEN: Thank you, Dr. Bekker.

So there is no -- there is no one primary medication or go-to drug that practitioners use to treat this. So there have not certainly been -- there's a varying approach to how it's addressed.

There are also non-neuroleptical approaches as well, therapeutic modalities which may or may not be effective, but just as a reminder, these patients with Tourette syndrome have experienced -- their quality of life is huge and depending upon most certainly where they are in their life span, whether they're adolescent, young adults or older adults or someone who's in their -- or an older adult, they can -- will certainly have social isolation, which is very, very common, which then puts them in compliance with depression, anxiety, you know, insomnia and so forth, and so even when they do seek pharmacological treatment, they indeed might have an exacerbation of these symptoms merely as a side effect.

So looking at the literature, there

Page 56

were I think 12 peer-reviewed publications that were provided. An additional search that I conducted as well actually proved that there were clinical trials that actually established that medical marijuana as a treatment for Tourette's is clearly effective and based upon that I recommend it to be used.

DR. BEKKER: Thank you, Dr. Johansen.

Dr. Kennedy.

DR. KENNEDY: Thank you.

Yes, Tourette's is a well-recognized debilitating disabling medical condition that frequently has its onset early in childhood. So when this condition does affect an individual, their entire life span can be affected including the ability to be in conventional educational settings and these -- some of these individuals are so disabled by their condition, they cannot be in standard schools, even in school settings that have additional help. Because of the particular nature of the condition, it often makes other people feel uncomfortable and shun them socially and so on.

The tics are involuntarily. They can include vocalization that can be unpleasant to

Page 57

hear by other people and make people feel uncomfortable. So these individuals are frequently excluded from a variety of situations that are necessary for them to grow and develop and reach their potential.

The approved medication for Tourette's syndrome falls into the category of anti-psychotic medication, also known as neuroleptics in some places. These medications are actually not being used for psychosis. Tourette's is not generally associated with psychotic symptoms, but are being used because of their effect on what we call the extraforaminal system in the brain which involves structures very deep in the brain, the basal ganglia, which we know are implicated in Tourette's syndrome although we haven't identified the full etiology of the condition, but sometimes these medications can suppress the tic.

However, their efficacy is questionable because they have much less than an 80 percent rate of tic suppression and given that, because they have tremendous side effects that are very adverse -- they can cause weight

Page 58

gain, metabolic syndrome, diabetes, stroke. They can cause other movement disorders. They can have serious cardiac affects that have to be monitored and they may cause drowsiness as do the SRRI, which are the anti-depressant class that is often used for these -- for this condition, but all of these medications, particularly the anti-psychotics can have very, very debilitating and sometimes dangerous medical adverse effects.

So given the review of the literature and the number of clinical reports that describes the successful treatment of this condition by using cannabinoids and I reviewed 12 peer-reviewed publications that were listed and there are letters of support from physicians and other licensed healthcare professionals knowledgeable about the condition, I concluded that medicinal cannabinoids, medicinal marijuana may be effective and should be considered for the use of this condition.

DR. BEKKER: Thank you, Dr. Kennedy.

Dr. Zarus.

DR. ZARUS: Thank you.

And all of my colleagues, I concur in

Page 59

the same direction. We heard that the condition itself, Tourette's is well-recognized, although we don't have clarity on how the neurologic system is causing Tourette syndrome. We're still unclear about the etiology of the condition itself, making it difficult for medication and the therapeutic toolboxes are relatively empty.

You heard there's not really a go-to regimen made up of multiple drugs. There's just a few things out there. Only one FDA-approved therapeutic category, and for those of you who follow along with all these meetings, we had an opportunity to meet a young woman who gave a testimonial of not only the difficulty she's having handling the condition itself, but the quality of life and even other issues that have been brought up as her own personal condition of Tourette's.

So it's really a quality of life issue. It's a condition for which there is some -- whether it's peer-reviewed data and literature, evidence to demonstrate the effectiveness and we should also look at the pharmacologic opportunity that the cannabinoid

Page 60

can present for us and we can deduct that this would be a reason why medicinal marijuana would be effective.

So yes, I'm all for it with the rest of the team.

DR. BEKKER: Thank you, Dr. Zarus.

And Dr. Bridgeman.

DR. BRIDGEMAN: So I just want to point out again my assessment was based on risk and benefit analysis and we do know that neurocognitive development continues up until age 25 years. So I am not a pediatric expert, but I did have some in looking at this therapy in regards to the developmental effects of cannabis on the developing brain. So that was one of the sort of risk aspects of my evaluation.

You know, again, according to the compassion use of medical marijuana, as in New Jersey our state permits use of therapy or use of cannabis if the condition is resistant to or the patient is intolerant to conventional therapy and Tourette's syndrome in my mind falls in that category where we've heard from -- you know, my colleague said this is a condition

Page 61

where traditional therapy -- the traditional drug therapies don't often respond.

When I look at the evidence, there is evidence that cannabis may be effective in the treatment of movement disorders including Tourette syndrome. The evidence dates back to the 1990s. There is individuals demonstrated that there's improvement in local functioning and tic varying scores when cannabis is utilized.

There was a review in the Journal of the American Medical Association in 2015 that concluded that there was local quality evidence, but evidence nonetheless to support cannabis in improving symptoms associated with Tourette's and I would also point out that Tourette's is one of the medical indications for compassionate use of cannabis in the State of Minnesota.

So in suggesting that this indication be considered by our Commissioner, the Department of Health, I think that there's enough evidence that I can comfortably conclude that this is an appropriate indication.

DR. BEKKER: Thank you, Dr. Bridgeman.

Page 62

And Dr. Levounis.
DR. LEVOUNIS: Yes, I agree with my colleagues about how debilitating is Tourette syndrome indeed and how the other treatments (indiscernible).
On the second issue of the balance of the benefits and evidence to support the cannabis, I vote no on the second question.
DR. BEKKER: Thank you, Dr. Levounis.
Members of the audience, any comments?
(No response).
DR. BEKKER: Okay. So the next condition is one petition for requesting use of cannabis to treat asthma.
Asthma is a respiratory condition which characterized by spasm in bronchi causing difficulty breathing and an extreme condition can lead to death. The onset of this disease actually is well understood and there are numerous available treatments that can alleviate these symptoms.
I read the literature on the use of cannabis to treat asthma. I found lot of clinical studies, but unfortunately or

Page 63

fortunately, I'm not sure, there's no clinical documentation of use of marijuana for asthma. It kind of doesn't make a whole lot of sense to me.
So based on my review of literature and other ability of medication to treat this condition, my recommendation would be no.
Dr. Johansen.
DR. JOHANSEN: So I did go back to the literature as well. The triggers for asthma across the life span for pediatric and for adults and older adults, they are different from person to person, but there is evidence based and medically accepted and effective treatment for long-term control and for quick relief, for short acting relief that are both effective and provide minimal side effects, if any, and so I did go back to the literature to see if there were any clinical based trials that would suggest that marijuana would be an alternative modality to effectively treat asthma and I could not find anything to support that relationship. So I recommend that it not be used for this condition.
DR. BEKKER: Thank you, Dr. Johansen.

Page 64

Dr. Kennedy.
DR. KENNEDY: Thank you.
Yes, while asthma can be debilitating and indeed life-threatening in an acute exacerbation without treatment, there are well known and very effective treatments available for this condition and there are no clinical trials that I could find documenting usefulness of cannabis in this condition.
So therefore I do not recommend it to the Commissioner for addition to the medicinal marijuana grouping.
Thank you.
DR. BEKKER: Thank you, Dr. Kennedy.
Dr. Zarus.
DR. ZARUS: Thank you.
In addition to the lack of peer-reviewed data, there are no supportive healthcare professionals that recommended that we consider this. It doesn't seem to have anyone supporting the use and there is certainly no data. So I also concur that we should hold on this one until there's more evidence.
DR. BEKKER: Thank you, Dr. Zarus.
And Dr. Bridgeman.

Page 65

DR. BRIDGEMAN: Asthma is an absolutely debilitating condition and as a clinician working in the intake acute care setting, we see many adult patients with asthma exacerbation and we know despite the availability of a number of pharmacologic compounds, a significant portion of our patients who have asthma remains uncontrolled.
That being said, there is also some evidence to suggest that there may be an anti-inflammatory effect of the cannabinoid. However, as was pointed out, this is pre-clinical evidence and by my assessment it's too soon to conclude that there's a role for cannabis in either reduction of exacerbation or in otherwise mitigating symptoms associated with asthma.
I also want to just point out that inhalation of the byproduct of the combustion is one of the known triggers for asthma exacerbation. So with that regard, my assessment was no to expanding use for this indication.
DR. BEKKER: Thank you, Dr. Bridgeman.

Page 66

And Dr. Levounis.
DR. LEVOUNIS: I fully 100 percent agree with my colleagues that asthma can be debilitating, but I vote no on the second question of whether it should (indiscernible).
DR. BEKKER: Thank you, Dr. Levounis.
And members of the audience, anybody would like to comment on our recommendation?
(No response).
DR. BEKKER: Okay. So our next and last condition, we had one petition for -- requesting medicinal marijuana to treat chronic fatigue syndrome.
Chronic fatigue syndrome is a debilitating condition which is characterized by extreme fatigue, tiredness. It does not go away with rest and cannot be explained by underlying medical conditions.
The cause of chronic fatigue syndrome is not clearly understood and there are no current treatment. People just try whatever is possible and each affected person has different symptoms. It's kind of difficult to develop general kind of recommendation.
So I reviewed the literature on use

Page 67

of medicinal marijuana for treating this syndrome. I could not find any clinical studies which address this disease, indicating conceptually it's very -- neurologically it's very difficult for me to imagine how or explain how cannabis can help alleviate this symptom. So based on this fact, my recommendation is no.
So let's go the other way around so we kind of equalize forces.
Dr. Bridgeman.
DR. BRIDGEMAN: Sure. And I'm really just going to echo Dr. Bekker's comments here. We know that chronic fatigue syndrome is -- the treatment approach is largely tailored to the patient's presenting symptoms and just with regard to the fact that the pathophysiology that explains this disorder hasn't been completely elucidated or current treatment options are largely palative and symptom triggered, I also found no evidence to support the use of cannabis for this particular condition at this time and, again, even from a pathophysiologic pharmacologic approach, kind of couldn't rationalize that as well.
So I concluded that it should not be

Page 68

expanded -- an indication in New Jersey.
DR. BEKKER: Thank you, Dr. Bridgeman.
Dr. Zarus.
DR. ZARUS: And I'm also concluding that we should hold on this. There's not enough evidence and while again conventional therapy doesn't really fix it, which would otherwise make me think this is valuable for patients, in this particular case we still don't have enough information to be able to say that. So...
DR. BEKKER: Thank you, Dr. Zarus.
Dr. Kennedy.
DR. KENNEDY: Yes, thank you.
I concur with my colleagues. I was unable to find any clinical evidence that medicinal marijuana or cannabinoids could be helpful in this condition and although this condition has been researched for nearly 30 years quite extensively by various groups, there is really not yet a good elucidation of the etiology of this condition and why people have it or what treatment would be helpful.
Many patients use other adjunctive complementary therapy; yoga, acupuncture,

Page 69

etcetera. However, I conclude that there is not any sufficient evidence to expand medicinal marijuana use in New Jersey to chronic fatigue syndrome.
DR. BEKKER: Thank you, Dr. Kennedy.
Dr. Johansen.
DR. JOHANSEN: I want to concur with my colleagues and yes, I could not find any evidence to support this and I guess on behalf of the panel I want to make sure that we recognize that this is a medical condition and there is an issue in that there are most certainly physical, psychological, debilitating associated symptoms that are related with this. However, in order to support the use of medicinal marijuana to treat this and be able to modify symptoms, there has to be some evidence to support that.
So I voted again with my colleagues that there was nothing there to support that at this time.
DR. BEKKER: Thank you, Dr. Johansen.
And Dr. Levounis.
DR. LEVOUNIS: I agree with my colleagues that chronic fatigue is a very

Page 70

debilitating medical condition, but I don't find the profile of medicinal cannabis to be in favor of sufficient -- sufficient evidence in favor of yes. So I vote no.

DR. BEKKER: Thank you, Dr. Levounis.

And members of the audience, if anybody would like to comment on chronic fatigue syndrome.

(No response).

DR. BEKKER: So no comments. So I just need to ask members of the panel if in your deliberation or public comment, you change your view on the petitions, and I guess you have to state for the record. Dr. Bridgeman?

DR. BRIDGEMAN: I have not changed my views.

DR. BEKKER: Dr. Zarus?

DR. ZARUS: I have not changed my views.

DR. BEKKER: Dr. Kennedy?

DR. KENNEDY: I have not changed my view.

DR. BEKKER: Dr. Johansen?

DR. JOHANSEN: I have not changed my view.

Page 71

DR. BEKKER: Dr. Levounis?

DR. LEVOUNIS: I have not changed my view.

DR. BEKKER: And I did not change my view.

So our deliberation did not change our recommendation, our initial recommendation. So initial recommendation stands as -- as presented and depicted on the web site. So our recommendation stands.

Any other procedural issues?

(Dr. Bekker confers with Ms. Carson.)

DR. BEKKER: Okay. Members of panel, next vote refers to -- I guess second vote to confirm our initial recommendation.

DR. BRIDGEMAN: Second.

DR. BEKKER: Yes.

DR. ZARUS: Second.

DR. BEKKER: Yes.

MS. JOHANSEN: Second.

DR. BEKKER: Yes.

DR. KENNEDY: Second.

DR. BEKKER: Yes.

Dr. Levounis.

DR. LEVOUNIS: Second.

Page 72

DR. BEKKER: Yes. Okay.

Any other procedural...

MS. CARSON: So he just went through the roll for you.

MS. STARK: Okay.

DR. BEKKER: So if nobody else --

MS. CARSON: Procedurally then -- she took Dr. Bekker's roll call as hers.

MS. STARK: Yeah.

MS. CARSON: That's fine.

DR. BEKKER: So if there are no other comments, is there motion to adjourn?

DR. KENNEDY: So move.

DR. ZARUS: Second.

DR. BEKKER: Okay. Thank you everybody for your participation. Members of the panel, thank you so much.

(The proceedings are adjourned at 11:37 a.m.)

Page 73

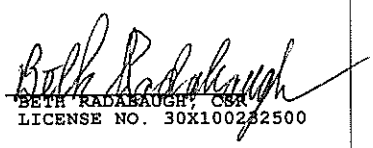
C E R T I F I C A T E

STATE OF NEW JERSEY)
: ss.
COUNTY OF HUNTERDON)

I, BETH RADABAUGH, a Certified Shorthand Reporter and Notary Public within and for the State of New Jersey, do hereby certify that the within is a true and accurate transcript, to the best of my ability, of the proceedings taken on October 25, 2017.

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 3rd day of December, 2017.



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