1	STATE OF NEW JERSEY
2	DEPARTMENT OF HEALTH AND SENIOR SERVICES
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4	
5	IN RE: PUBLIC MEETING
6	MEDICINAL MARIJUANA REVIEW PANEL
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9	LOCATION: War Memorial One Memorial Drive
10	Trenton, New Jersey 08608
11	
12	DATE: October 25, 2017
13	TIME: 9:30 a.m.
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18 19	
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21	J. H. BUEHRER & ASSOCIATES
22	884 BREEZY OAKS DRIVE
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25	

	Page 2			Page 4
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	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	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	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?	
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1				
23		23	DR. ZARUS: Yes.	
24		24	MS. STARK: Five yes. Motion	
25		25	carried.	
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MS. STARK: This is a formal meeting 2 of the Medicinal Marijuana Review Panel. 3 Adequate notice of this meeting has been published in accordance with the provisions of Chapter 231, Public Law 1975-C10 -- I mean, 6 sorry, C-10:4.10 of the State of New Jersey 7 entitled Open Public Meetings Act. Notice was 8 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. 12 Now, do roll. Dr. Berkowitz is not 13 here. Dr. Bridgeman? 14 DR. BRIDGEMAN: Here. 15 MS, STARK: Dr. Bekker? 16 17 DR. BEKKER: Here. 18 MS. STARK: Dr. Johansen? DR. JOHANSEN: Here. 19 20 MS. STARK: Dr. Kennedy? DR, KENNEDY: Right here. 21 MS. STARK: Dr. Levounis will be 22 participating by phone later on. Dr. Scerbo is absent, and Dr. Zarus? 24

DR. BEKKER: So let me explain what's 2 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. 10 And a couple of groupings took place. 11 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 16 the grouping was -- how we proceed. 17 18 So I will ask vice chair of this 19 panel, Dr. Kennedy, to explain the factors which were considered in making our determination. After she will do that, we will separately look 21 at every condition and see what additional 22 comments, public comments, etcetera, and at that 23 point we will be ready to go over each condition

separately.

DR. ZARUS: Here.

	Page 6			Page 8
1	(Susan Carson confers with	1	cause severe suffering, such as severe and/or	
2	Dr. Bekker.)	2	chronic pain, severe nausea and/or vomiting or	
3	DR. BEKKER: Apparently before	3	otherwise severely impair the patient's ability	
4	Dr. Kennedy will do it, each member has to	4	to carry on the activities of daily living.	
5	reintroduce him or herself.	5	Number four; the availability of	
6	DR. KENNEDY: Go ahead.	6	conventional medical therapies other than those	
7	DR. JOHANSEN: I'm Dr. Mary Johansen.	7	that cause suffering to alleviate suffering	
8	I'm a clinical associate professor at	8	caused by the condition and/or the treatment	
9	Rutgers University and the Associate Director	9	thereof.	
10	for the New Jersey Collaborating Center for	10	Number five; the extent to which the	
11	Nursing.	11	evidence that is generally accepted among the	
12	DR. BEKKER: I'm Alex Bekker. I'm a	12	medical community and other experts supports a	
13	professor and chair of the department of	13	finding that the use of marijuana alleviates	
14	anesthesiology at Rutgers New Jersey Medical	14	suffering caused by the condition and/or the	
15	School.	15	treatment thereof, and, number six; letters of	
16	DR. KENNEDY: Cheryl Kennedy. I'm an	16	support from physicians or other licensed	
17	associate professor at New Jersey Medical School	17	healthcare professionals knowledgeable about the	
18	of Rutgers in Newark. I'm board certified in	18	condition.	
19	psychiatry and in addiction medicine.	19	I'll carry on here. Pursuant to	
20	DR. ZARUS: Stephanie Zarus. I'm the	20	N.J.A.C. 8:64-5.3 Section D, the panel is	
21	managing director of Avancer Group and my	21	charged with and did make a recommendation to	
22	background is in care and hospice.	22	the Commissioner on the petitions as follows:	
23	DR. BRIDGEMAN: I'm Mary Bridgeman.	23	One; whether the medical condition	
24	I'm a clinical associate professor in the	24	and/or the treatment thereof are is or are	
25	Department of Pharmacy at Rutgers University and	25	debilitating, whether marijuana is more likely	
	Page 7	-		Page 9

Page 7 1 than not to have the potential to be beneficial 1 an internal medicine clinical pharmacist at to treat or alleviate the debilitation 2 Robert Wood Johnson University Hospital. I'm associated with the medical condition and/or the board certified in pharmacotherapy and geriatric treatment thereof, and, number three, other pharmacotherapy. matters that the panel recommends that the DR. KENNEDY: Should I carry on now? 5 Commissioner consider that are relevant to the DR. BEKKER: Yes, please. 6 approval or denial of the petition. DR. KENNEDY: Okay. Thank you. 7 DR. BEKKER: Thank you, Dr. Kennedy. 8 My name is Cheryl Kennedy and I'm So the next step is our panel -going to tell you the factors that were May 25th of '16 was first meeting of this panel, considered by the panel according to our rules then February 22nd, '17 and 5/11/17 and public set forth in New Jersey A.C. 8:64-5.3 Section A. 11 hearing was held on 9/18/17. 12 Number one; the extent to which --12 13 Based on documents from this meeting 13 this is our consideration. The extent to which and our reading extensive reading of the the condition is generally accepted by the 14 literature, we came up with our initial medical community and other experts as a valid preliminary recommendation to Commissioner. The existing medical condition. 16 panel approved the additional chronic pain Number two; if one or more treatments 17 related to musculoskeletal disorder, migraine, of the condition, rather than the condition 18 anxiety, chronic pain of visceral origin and itself, are alleged to be the cause of the Tourette's syndrome and the panel did not patient's suffering, the extent to which the approve the condition of asthma and chronic 21 treatments causing suffering are generally 21 22 fatigue. accepted by the medical community and other 23 I just would like to kind of clarify experts as valid treatments for the condition. 23 how the panel came to this conclusion. Each Number three; the extent to which the 24

member of the panel reviewed all evidentiary

condition itself and/or the treatments thereof

	,		Octob	er 25, 2017
	Page 10			Page 12
1	literature. I would like to emphasize that the	1	present via telephone.)	
2	decision of the panel are not based are not	2	DR. BEKKER: So, Dr. Levounis, at	
3	based on opinion, are not based on	3	this point we are going to discuss and	
4	recommendation of some particular society. All	4	deliberate on each condition and vote on each	
5	our job is was, is and would be to	5	particular condition. So this is where we stand	
6	objectively evaluate everything based on	6	right now.	
7	science. It's all what it should be.	7	Again, as I mentioned before, our	
8	Again, the opinion of different	8	recommendation, our role should be based	
9	organization, medical organization, legal,	9	scientifically on peer-reviewed publication,	
10	clergy and whatever, this is not part of this	10	evidence base only. It's not opinion of	
11	part of our decision and each member of this	11	particular organization. It's not opinion of	
12	panel will justify his or her position in very	12	clergy or anybody else. Our job is to evaluate	
13	short statement. Again, I think at some point	13	valid scientific evidence for this condition. I	
14	our evaluation will be posted on our website,	14	just wanted to repeat that.	
15	but today we will have very short kind of	15	So having said that, we will start	
16	explanation why, why member came to conclusion.	16	we will consider condition by condition and	
17	Okay. Now, we would like to	17	we'll start with chronic pain related to	
18	initial recommendation. The initial	18	musculoskeletal disorder.	
19	recommendation you probably had a chance to read	19	At this point and let me start and	
20	on web. It's there. So today what we're going	20	then each member will state his or her	
21	to do, the purpose of this meeting is for the	21	actually in this case, her position.	
22	panel to discuss, deliberate its recommendation	22	So my recommendation is based on	
23	on the petitions. The panel may take into	23	extensive review of literature which clearly	
24	consideration the petitions themselves,	24	indicates that medicinal marijuana helps	

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1 comments, their own research or that done by others, as well as any education, training, experience or other sources which helped the 4 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 10 panel will participant. The panel submitted -okay. Okay. Just to follow proceeding, I have 12 13 to read a certain portion of this document. 14 Okay. So panel submitted its written initial recommendation to the Department of 15 Health on 7 -- on July 21st, '17. The initial 16 17 recommendation was posted for 60-day public comments on July 25th, '17. A public hearing was held on September 18, '17. Approximately 65 19 written comments were reviewed by the 20 department. Copies of the comments and 21 transcript of the public hearing were forwarded to the panel members for their consideration. 23 (Ms. Carson has contacted Dr. Petros 24

Levounis via telephone and he is now

25 information received with petition, public

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. 10 So that's about all that I have to 11 say on this. Questions -- actually I will ask you to -- if you don't mind as public, wait with 13 your questions. Write it down. When 14 15 deliberation for each particular condition would be over, you will have chance to ask -- comment 16 or whatever, offer your opinion. 17 So Dr. Johansen. 18 19 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 22 the petitioners as well as evidence that's out 23 24 there in the literature. The evidence that I looked at was 25

alleviate chronic pain, chronic pain syndrome

associated with musculoskeletal disorders. This

includes conditions like fibromyalgia, failed

In addition, there are systematic

back syndrome and similar conditions.

Page 16 Page 14 petitions that I reviewed included a number of 1 peer-reviewed journals, which is very important 2 because it does provide evidence of rigor in supportive articles and there are letters of support from physicians and other licensed 3 terms of research and science, and I am in healthcare professionals knowledge about -agreement with Dr. Bekker. I found that there 5 were clear evidence -- there was clear evidence knowledgeable about the condition. to establish clear relationships between the use 6 It is -- so that this chronic visceral pain is often physically and of medicinal marijuana to alleviate chronic pain related to musculoskeletal disorders. psychologically incapacitating and these petitions present heartbreaking stories of 9 DR. BEKKER: Dr. Kennedy. dramatically diminished quality of life and it 10 DR. KENNEDY: Thank you. 10 is therefore my opinion that there is sufficient I reviewed the literature extensively 11 medical evidence to support the recommendation about the condition itself and about the 12 12 for medicinal marijuana for the treatment of 13 treatments for it and I discovered although 13 pain of visceral origin. there are a multitude of therapies for 14 14 gastrointestinal disorders or other sources of DR. BEKKER: Superb, Dr. Kennedy. 15 15 Dr. Zarus. visceral pain, the only actually accepted 16 DR. ZARUS: Okay. But we are talking treatment of these associated pains was opioid 17 17 about pain related to musculoskeletal? 18 analgesic medication, some anticholinergic and 18 DR. BEKKER: Musculoskeletal, right. anti-spasmatic medication can help relieve some 19 DR. KENNEDY: I'm sorry. I went on a painful bowel spasms but can worsen constipation 20 20 21 tangent. It's actually quite -and lead to difficulty in urination. 21 DR. BEKKER: Here we have two 22 Some people may benefit from bile 22 separate conditions. There are some differences acid binders, bicholestyramine, but these can 23 23 physiologically and how these conditions are lead to painful bloating. Anti-depressants are treated. That's why original grouping put this commonly prescribed for pain relief, but these

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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

6 more severe visceral pain, but may induce
7 constipation, nausea, vomiting, duritis, which
8 is itchiness on the skin, and respiratory
9 distress and carries the risk of many adverse
10 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

1 in two different categories.

2 DR. ZARUS: Right.

3 DR. BEKKER: They're treated by

4 doctors different, different medication. So

5 that's how they grouped that.

Dr. Zarus.

6

7

DR. ZARUS: So we'll come back to

8 visceral pain, but I'm going to go back to

9 musculoskeletal.

DR. BEKKER: Exactly.

DR. ZARUS: With regard to the

12 petitions that I reviewed related to

13 musculoskeletal disorder, there were 32 of them

14 in which we found -- in which I found the value

15 or benefit of medicinal marijuana, particularly

16 in subgroups of individuals who are unresponsive

16 Ill subgroups of murviduals who are unresponsiv

17 to conventional therapy. So conventional

18 therapy does exist for managing musculoskeletal

19 disorders and the pain related to that disorder

20 in the majority of patients, but there are

21 subgroups of patients whose condition is not

22 palated (ph) or improved with conventional

23 medication and/or the adverse effects of that

24 conventional treatment may outweigh the use of

25 it and in these particular patients the value

			Octobe	1 23, 2017
	Page 18			Page 20
1	and ability to use medicinal marijuana has been	1	DR. BEKKER: Thank you,	
2	demonstrated through medical evidence, and so I	2	Dr. Bridgeman.	
3	continue to support first the individual	3	Dr. Levounis.	
4	petitions to approve or enable medicinal	4	DR. LEVOUNIS: Yes, I also reviewed	
5	marijuana to be available for individuals who	5	the literature extensively as well as the	
6	are unresponsive to conventional therapy in the	6	testimony presented in front of this panel.	
7	management of chronic pain related to	7	The first question of whether the	
8	musculoskeletal disorders.	8	medical condition or treatment is debilitating,	
9	DR. BEKKER: Thank you, Dr. Zarus.	9	I agree and I vote yes for that. The	
10	Dr. Bridgeman.	10	heartbreaking stories that we all heard I think	
11	DR. BRIDGEMAN: Thank you.	11	substantiate this vote.	
12	So I just want to preface sort of my	12	The second question of is marijuana	
13	comments with sharing the fact that there was a	13	more likely than not to have the potential to be	
14	report that was published in January of 2017,	14	beneficial to treat or alleviate the	
15	The Health Effects of Cannabis and Cannabinoids,	15	debilitation associated with the medical	
16	The Current State of Evidence and	16	condition or the treatment thereof, I vote no.	
17	Recommendations for Research, and this was a	17	I have found that smoking as a means	
18	document made available by the National	18	of (indiscernible) and of course the components	
19	Academies of Sciences, Engineering and Medicine	19	of marijuana (indiscernible) in the U.S.	
20	and this was a document that I found in my	20	At this point I find that there's	
21	research with all of these petitions that was	21	insufficient evidence for (indiscernible) of	
22	particularly helpful in summarizing the state of	22	smoking cannabinoids such as marijuana	
23	the evidence and the state of the science and	23	(indiscernible).	
24	pointing to some of the primary literature that	24	I just want to add that this was	
25		25	supported also by a number of the	
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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. 9 We also read in the petitions about 10 severe debilitating symptoms or debilitations 11 related to adverse effects of certain 13 medications. 14 In that regard and in considering the systematic reviews -- there are two systematic 15

to high quality evidence that medicinal cannabis 17 was used to improve pain scores in patients with chronic pain and based on the evidence from the 20 National Academies of Sciences there is 21 conclusive or substantial evidence that cannabis 22 or cannabinoids are effective in chronic pain in 23 adult patients, I came to the conclusion that

reviews, a meta-analysis that suggests moderate

this would be an appropriate indication and use of this therapy.

(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. 7

(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, 11

12 so please do.

And if there's no public comments, 13

and it doesn't look to me, so we'll just

continue with the next condition. 15

MR. LIVINGSTON: Hi, Doctors. I'm 16

17 Edward Livingston.

As far as chronic pain goes, what 18

were some of the subcategories of chronic pain? 19

I'm very interested in being hopefully a 20

patient. I'm a little skeptical as well as I 21

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

(5) Pages 18 - 21

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

10

- 7 DR. BEKKER: It's not our studies,
- 8 but I can review conditions which would fall
- 9 under the umbrella of chronic pain --
 - MR. LIVINGSTON: Yes.
- DR. BEKKER: -- of musculoskeletal
- 12 origin. This will include spinal stenosis,
- 13 herniated disk, failed back syndrome,
- 14 fibromyalgia, complex regional pain syndrome,
- 15 disk herniation, degenerative disk disease.
- A lot of these conditions are not
- 17 clear -- they don't have clear-defined etiology,
- 18 but patient suffers and from what we know
- 19 marijuana alleviates this pain and in large
- 20 study, it's kind of an epidemiological study in
- 21 states where marijuana was approved for
- 22 medicinal purposes, patients started using
- 23 marijuana, the opioid requirement went down by
- 24 about 30 percent, which is obviously a positive
- 25 thing to consider.

- 1 treat. Currently we'll use NSAIDS, Ergots,
- 2 treatments and things like that. However, this
- 3 treatment do not alleviate pain in some patients
- 4 and are associated with many side effects. We
- 5 all know NSAIDs cause intestinal bleeding,
- 6 heartburn. This may adversely affect kidneys
- 7 and things like this.
- 8 So current treatment is not
- 9 effectively -- it's not effective in some
- 10 patients. A number of studies suggest favorable
- 11 effects of cannabis for treatment of migraines.
- 12 This has been summarized in at least two reviews
- 13 and my evaluation includes these references.
- 14 So based on this literature and
- 15 petitions which kind of heartbreaking, some of
- 16 these stories, debilitating conditions, my
- 17 recommendation is to approve medicinal marijuana
- 18 for treatment of migraines which includes --
- 19 again, it's kind of broader definition of
- 20 migraine than actually medical definition of it.
- Okay. We go the other way right now.
- 22 We start with Dr. Bridgeman.
 - DR. BRIDGEMAN: Sure. I absolutely
- 24 agree with your comments, Dr. Bekker, with
 - 5 regards to the adverse effects associated with

Page 23

23

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- Again, I want to emphasize this
 point. Opinion of medical organizations are
- 3 available at this point. All opinions provide
- 4 evidence-based medicine and this is what panel5 did.
- 6 MR. LIVINGSTON: I appreciate it.
- 7 Thank you, Doctor.
- 8 DR. BEKKER: Unless there are any
- 9 other comments, we'll go for the next condition.
- To the members, before we go, do we
- 11 have any -- any of you change your position in
- 12 view of this last comment? I guess not, but I
- 13 supposed to ask you this question. Nobody?
 - (No response.)
- DR. BEKKER: So next condition which
- 16 we'll consider is migraine, and under migraine
- 17 it's kind of a little bit broader definition
- 18 than actual technical definition of migraine.
- 19 It will include cluster headache, headache of
- 20 unknown origin, but we all -- all these
- 21 conditions group under umbrella of migraine.
- 22 So my review of the literature
- 23 suggests that -- I mean migraine it's very
- 24 difficult -- let me preface by saying that
- 5 migraine is extremely difficult condition to

- 1 medications that are used in the management of
- 2 migraines both in the treatment as well as the
- 3 prophylactic and prevention of migraine
- 4 headaches.
- 5 Again, in addition to reviewing these
- 6 petitions, I found a small -- there were a
- 7 number of -- 121 patients included in a clinical
- 8 evaluation on medicinal marijuana on migraine
- 9 headache frequency in adults that was published
- 10 in the Journal of Pharmacotherapy in 2016.
- 11 Based on this retrospective chart review of
- 12 adult patients who had been using medicinal
- 13 cannabis for migraine treatment or
- 14 prophylactics, the investigators concluded that
- 15 medicinal cannabis was associated with
- 16 significant, significantly significant reduction
- 17 in migraine frequency attributed to medicinal
- 18 cannabis use and I found that compelling
- 19 evidence to support my recommendation for
- 20 permitting migraines as an indication for
- 21 medicinal cannabis use in New Jersey.
- 22 DR. BEKKER: Thank you,
- 23 Dr. Bridgeman.
- 24 Dr. Zarus.
- DR. ZARUS: Yes, and I also concur in

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- 1 expanding the use to include medicinal marijuana
- 2 for those individuals suffering from migraines
- 3 and, again, it can be very debilitating to
- 4 individuals who are not able to manage it with
- 5 conventional therapy or have incidents that's
- 6 not allowing them to have their migraine managed
- 7 by conventional therapy.
- 8 Again, I think of the articles
- referenced, there were a number that do support
- either eliminating or mitigating the effects of
- 11 migraines through the use of the medicinal
- 12 marijuana. So I also support that. Thank you.
- DR. BEKKER: Thank you, Dr. Zarus.
- DR. BRIDGEMAN: I just want to point
- 15 out also from a pharmacologic perspective it may
- 16 make sense to use medicinal cannabis for this
- 17 particular condition because it has been
- 18 hypothesized that cannabis may modulate the
- 19 synergistic neural pathways. So it sort of
- 20 makes sense when you think of the pharmacologic
- 21 use for migraine management, that medicinal
- 22 cannabis may have a role here.
- DR. BEKKER: Okay. Dr. Kennedy.
- DR. KENNEDY: Thank you.
- 25 As stated, the condition of migraine

- 1 in some variants of this disorder, the Triptan
- 2 cannot in migraines because these drugs are also
- 3 associated with an increased incidence of
- 4 stroke.
- 5 So the conventional therapies are
- 6 ineffective for some patients and although
- 7 medication may help many patients, there are
- 8 individuals who are unresponsive and the
- 9 condition leaves them quite disabled and
- 10 debilitated with a very decreased quality of
- 11 life and ability to function.
- Four of the five petitions were
- 13 supported by licensed healthcare professionals.
- 14 So I also considered that along with the
- 15 literature that was already cited by my
- 16 colleagues here. So I continue to come to the
- 17 conclusion that this is a likely effective
- 18 treatment for some people who have this
- 19 debilitating type of headache.
 - DR. BEKKER: Thank you,
- 21 Dr. Kennedy.

20

22

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

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- 1 or cluster headaches, retractible headaches are
- 2 a well-known medical condition as well as
- 3 described in medical literature as are some of
- 4 the treatments and their various side effects
- 5 and in many cases failure to actually treat the
- 6 condition effectively.
- 7 Many of the medications that are in
- 8 current use, as stated and I agree, can cause
- 9 very adverse effects in several organs. The
- 10 NSAIDs, which are commonly known as ibuprofen,
- 11 naproxen and medications of that order can cause
- 12 severe GI tract problems, kidney failure in the
- 13 elderly and can have cardiac effects and people
- 14 that take anticoagulant therapy, which is very
- 15 much in use these days, cannot -- should not
- 16 also use these medications.
 - There's also the Triptans, which are
- 18 the most recent entrants into the pharmacopeia
- 19 for headaches of this type can cause nausea,
- 20 vomiting, dizziness on their own and they --
- 21 these drugs can lead to what is known as a
- 22 medication overuse headache and it's defined in
- 23 our canon as occurring in 15 or more days per
- 24 month in a patient with a pre-existing headache
- that uses these Triptans and they cannot be used

- 1 conventional treatments, which are the NSAIDs
- 2 we're talking about, the Advil, ibuprofen,
- 3 naproxen. For patients that have other
- 4 comorbidities that require them to take blood
- 5 thinners, if you will, some of those modalities
- 6 are not available to them. So many patients
- 7 actually go to alternative therapies like
- 8 biofeedback, aromatherapy. They stop smoking.
- 9 They may not eat different foods as triggers,
- 10 environmental triggers.
- 11 So when I reviewed not only the
- 2 petitions but the literature and actually did
- 13 take a look back at the alternative therapies, I
- 14 came to the conclusion that the potential
- 15 effects of cannabis or cannabinoids I should say
- 16 on the central nervous system indicates that
- 17 marijuana may be a therapeutic alternative.
- 18 I looked at several pieces of
- 19 literature that did support that. One was by
- 20 Russo who most certainly made that relationship
- 21 established. So my conclusion was most
- 22 certainly that this was definitely a modality
- 23 that could be used for patients in an effective
- 24 and therapeutic manner. So I vote yes.
 - DR. BEKKER: Thank you, Dr. Johansen.

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1	I just would like to add that most of	1	confusion, tiredness. In some people it causes
2	therapy recommendations in our purview and in	2	nightmares, difficulty thinking and remembering
3	our making this type of decision smoking is not	3	stuff. It affects memory and actually use this
4	the only way to deliver cannabis as a route.	4	drug to for amnesia. So it definitely will
5	So, again, it's not our goal to figure out how	5	affect memory.
6	to deliver. There are other methods of	6	So my review of literature suggests
7	delivery. So I just want to make clear we are	7	that it might alleviate some of the symptoms
8	not advocating smoking or not smoking. This is	8	with less side effects than commonly accepted
9	not our job.	9	medical treatment. So based on this fact, I
10	Dr. Levounis.	10	approve I will recommend to approve marijuana
11	DR. LEVOUNIS: Yeah, I opine that the	11	for treatment of anxiety primary and secondary.
12	medical condition of migraine, cluster headache,	12	I guess we'll start from here.
13	headaches of unknown origin are certainly	13	Dr. Johansen.
14	debilitating and they are heartbreaking stories.	14	DR. JOHANSEN: So again, Dr. Bekker
15	We heard that they truly are (indiscernible).	15	mostly gave a broad overview of anxiety. I
16	So on the issue the second	16	would like to add that anxiety in a mild form is
17	question of the potential being beneficial will	17	generally treated with like a type of therapy or
18	be the same as before, I vote no on that because	18	a counseling. It's not always a primary measure
19	some of the components (indiscernible) migraine	19	to go to pharmacotherapy to treat patients. So
20	and other headache, then we should	20	patients that do have these kind of issues
21	(indiscernible). There are many other medicine	21	actually wind up having to go through a
22	in the United States.	22	progression before anything is prescribed to
23	DR. BEKKER: Thank you, Dr. Levounis.	23	them and then when they are prescribed, it's
24	Any member from the audience would	24	
25	like to comment, let's do it now.	25	or Benzodiazepine and many of these can be

Page 31 (No response.) 1 2 DR. BEKKER: No comments. Okay. We'll go to next condition. 3 4 Next condition on my list is primary and secondary anxiety, and we'll collaborate a little bit what it means, secondary anxiety. We 7 had three petition on this issue. Some of them 8 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 12 Alzheimer. However, anxiety, and it's very 13 critical, just bear with me, anxiety associated with autism, either autism or Alzheimer's can be treated with marijuana. We treat the disease, 16 but we addressing the symptom. Okay. Now, anxiety is a debilitating 17 18 disorder. Usually medication -- medication generally may not alleviate symptom and 20 pharmacotherapy usually include anti-depressant. This adversely affect such like nausea, vomiting, insomnia, some lead to suicidal

Benzodiazepine is another class of

drug. Common side effect include headache,

1 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 13 14 anxiety. 15 DR. BEKKER: Thank you, Dr. Johansen. 16 Dr. Kennedy. DR. KENNEDY: Thank you. 17 Yes, anxiety is a debilitating and 18 disabling condition in many cases and yes, there 19 are mild forms that can be treated with non-pharmacologic intervention. 21 However, when the anxiety does 22 require a pharmacologic intervention, whether it's primary or secondary in nature depending on

the origin of the anxiety, my review of the

Page 33

ideation, weight gain.

23

1

Page 36

literature and	of the available	information
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- 2 about these conditions tells me that the
- 3 conventional therapies are unacceptable in many
- 4 cases because of the side effects and I'd like
- 5 to point out that the Benzodiazepines, which are
- 6 the primary go-to gold standard for treating
- 7 anxiety disorders, are known to be controlled
- 8 substances. They are widely abused in the
- 9 community. This is well known and follows the
- 10 opioid crisis in some ways. Although it is
- 11 difficult to overdose purely from
- 12 Benzodiazepine, the actual withdrawal from these
- 13 medications can be life threatening and requires
- 14 medical supervision if people become dependent
- 15 or addicted upon them.
- So there are some serious adverse
- 17 effects related to the primary treatment
- 18 modality and many patients are unwilling or
- 19 unable to tolerate these medications because of
- 20 these problems, and it is apparent through the
- 21 review of literature already cited by some of my
- 22 colleagues that these conditions, these types of
- 23 anxiety conditions can be possibly effectively
- 24 treated with the medicinal marijuana and, as we
- 25 know, there are a variety of delivery forms

- 1 more ambivalent than half of my colleagues with
- 2 regard to my evaluation of anxiety as an
- 3 indication. I absolutely appreciate the
- 4 attention and the evidence that was supported
- 5 with regards to these claims and my assessment
- 6 was really based on sort of a risk benefit
- 7 analysis here.
- 8 I think the evidence for anxiety as
- 9 an indication is a little bit more limited than
- 10 the clinical evidence, which is very robust for
- 11 chronic pain and the indication we spoke of.
- 12 There is limited clinical evidence
- 13 that cannabis and cannabinoids, and especially
- 14 cannabidiol is effective in managing anxiety
- 15 symptoms and in my evaluation of the literature
- 16 it was in particular social anxiety disorder
- 17 which seemed to have the most robust evidence at
- 18 this time.

20

25

- 19 I do want to just express the fact
 - that there are some concerns and there is some
- 21 evidence in the literature that cannabis may
- 22 also exacerbate anxiety symptoms or an adverse
- 23 effect related to cannabis may be associated
- 24 with anxiety.
 - So sort of weighing out exacerbating

Page 35

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- 1 including non-smoking forms that are available
- 2 in New Jersey, and so I continue to come to the
- 3 conclusion that this -- these conditions, that
- 4 is primary and secondary anxiety should be
- 5 approved for use by the Commissioner.
- 6 Thank you.
 - DR. BEKKER: Thank you, Dr. Kennedy.
- 8 Dr. Zarus.

7

- 9 DR. ZARUS: Thank you.
- 10 I too support the conclusion of my
- 11 colleagues that medicinal marijuana can be a
- 11 coneagues mai medicinai manjuana can c
- 12 benefit in anxiety, particularly in those
- 13 patients that suffer anxiety at its worst, which
- 14 can even conclude in suicide or lead people
- 15 towards suicide.

16 I think there are a number of things

- 17 we already heard and again the risks can be
- 18 intolerable in some people and there is
- 19 significant evidence to demonstrate that there
- 20 is a place for medicinal marijuana in the
- 21 primary care of fighting anxiety in those who
- 22 have it in the worst possible condition.
- DR. BEKKER: Thank you, Dr. Zarus.
- 24 And Dr. Bridgeman.
- 25 DR. BRIDGEMAN: I think I'm a little

- 1 anxiety versus the limited evidence, I did come
- 2 to the conclusion that there wasn't enough
- 3 evidence to support a recommendation for use in
- 4 those patients refractory to traditional
- 5 pharmacotherapy.
- 6 I also just want to point out that
 - we've never had an FDA-approved medication that
- 8 was administered via smoking and I'm not an
- 9 advocate of smoking as drug administration here
- 10 as well, but there are alternative dosage forms
- 11 available and as a pharmacist I'm remiss if I
- available and as a pharmacist rin remi
- 12 don't mention that.
- DR. BEKKER: Dr. Kennedy would like
- 14 to add a comment.
- DR. KENNEDY: Yes. I would agree
- 16 with Dr. Bridgeman's statements about you can
- 17 have anxiety produced from the use of medicinal
- 18 marijuana and one would certainly hope that if
- 19 the condition one is trying to treat is
- 20 exacerbated, you would no longer seek that
- 21 treatment.

- 22 Additionally I would like to say that
- 23 all the petitions were supported by licensed
- 24 healthcare professionals.
 - DR. BEKKER: Dr. Levounis.

					_,
		Page 38		F	age 40
	1	DR. LEVOUNIS: Yes, I agree with my	1	MR. MILLER: Are you taking	
	2	colleagues that the medical condition is	2	comments?	
	3	debilitating for both primary and secondary	3	DR. BEKKER: I'm sorry. Please. I	
ŀ	4	anxiety. In terms of being beneficial, exactly	4	apologize. It's time for public to comment on	
١	5	as I mentioned before, I vote no.	5	this condition. Again, my apologies.	
	6	There is benefit profile in favor of	6	MR. MILLER: Thank you.	
	7	marijuana at this point at least and I wish to	7	James Miller, co-founder of Coalition for	
	8	reserve the ability to analyze the components of	8	Medical Marijuana in New Jersey. I want to	
	9	marijuana in the future (indiscernible).	9	point out two things to what you were just	
	10	I just want to make one more	10	talking about.	
	11	clarification. It was mentioned before the gold	11	Dr. Johansen, you mentioned	
	12	standard treatment for anxiety was in 2017	12	Dr. Russo's studies for migraines. The	
	13	Benzodiazepine. (Indiscernible).	13	interesting point about one of his studies is he	
:	14	DR. BEKKER: Thank you, Dr. Levounis.	14	could not get FDA approval for the he	
:	15	Yes, Dr. Kennedy would like to	15	couldn't get the cannabis with National	
	16	respond, please.	16	Institute on Drug Abuse approval because they	
	17	DR. KENNEDY: Right. Thank you,	17	released the marijuana for efficacy citings. He	
1	18	Dr. Levounis, and I do appreciate that current	18	had to wait a period of time and submit the	
	19	recommendation for anxiety. However, in cases	19	exact same protocol saying he was worried it	
1	20	of acute anxiety anti-depressants, which may be	20	might harm them in some way and then he did get	
:	21	effective in some patients with anxiety,	21	to proceed with that.	
:	22	anti-depressants are not effective initially in	22	So my point is is when there are not	
:	23	an acute condition; panic, etcetera. They take	23	efficacy studies done, unless you can say that	
	24	anywhere from two to six weeks at the right dose	24	you know how many were turned down and not	
	25	to provide an effective dose, if they're going	25	allowed, you know, it's very important.	
			ļ		
- 1		D 00	1	F	3000 A1

Page 41 Page 39 The second thing is as to yes, 1 to be effective. marijuana will cause anxiety in some people. So 2 Thank you. it's counterintuitive to let somebody with DR. BEKKER: I also would like to anxiety have it. Sometimes weirdly enough it's comment and say that also conceptually I like minus two times minus two isn't minus four, absolutely agree with Dr. Levounis that in the future if we can determine what component of you know. 7 Another thing though the FDA-approved marijuana are useful, we should definitely drugs for anxiety also have anxiety as a pursue this venue. 8 potential side effect, yet they have other FDA-However, currently we don't know what approved drugs to counteract. You know, it's exactly -- how marijuana works. You know, kind of it's always better to be wealthy and healthy 11 bizarre. 12 So I appreciate Dr. Bekker taking -than poor and sick, yes, I agree with you, but 12 especially making a point to take the side 13 right now we don't have this medication. So we effects into account because from a patient kind of -- at least at this current state of point of view, FDA-approved side effects are no science. My approval may change in future, but better than unapproved side effects. They hurt right now we don't have this medication. 16 16 17 So I just want to put it for the 17 just the same. record. We don't have this piece, which 18 So that's it. DR. BEKKER: Thank you, Mr. Miller. 19 extract, particular component, chemical which If there are no other comments, we deal with this anxiety or this chronic pain. 20 20 21 will move on. 21 Okay. So I think we done with Our next condition is Tourette comments on anxiety and our next condition is --22 22 syndrome. Give me one second. Give me one MS, STARK: Wait. 23 23 24 second to find my recommendation. 24 MR, MILLER: Excuse me, Doctor. (Dr. Bekker confers with colleagues.) 25 DR. BEKKER: Oh, yeah. 25

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1	DR. BEKKER: Oh, okay. I'm sorry. I		1	conclusion on indicating or expanding use for	
2	apologize. Next condition we will consider will		2	these conditions in New Jersey.	
3	be chronic pain of visceral origin.		3	There is evidence that suggests that	
4	There are three petitions related to		4	the endo-pathway system plays a role in	
5	this condition, which include chronic acute		5	modulating these disorders and in my mind from a	a
6	pancreatitis, pain related to neurogenic bladder		6	pharmacological perspective, use of cannabis	
7	and bowel disfunction, and irritable bowel		7	sort of intuitively would make sense based on	
8	syndrome.		8	some sort of pathophysiology that's been	
9	This is rare condition, but extremely		9	described.	
10	painful and extremely difficult to treat. Any		10	DR. BEKKER: Thank you,	
11	pain of visceral origin well documented is		11	Dr. Bridgeman.	
12	extremely difficult condition to treat and my		12	Dr. Zarus.	
13	recommendation based partially on partially		13	DR. ZARUS: Yes, thank you.	
14	on available literature but partially simply on		14	Well, I concur. I mean we this is	
15	compassionate kind of use of this drug.		15	a condition in which internal organs are	
16	It appears that it relieves pain and		16	distended in some way. The pain related to	
17	even if evidence here is not as clear or as		17	that, while there is some pharmacological	
18	clean as what chronic back pain or chronic pain		18	benefit available today, in many cases people	
19	of muscle origin, it's not I admit it's not		19	are refractory to that and the condition can be,	
20	as clear-cut evidence. However, I believe that		20	you know, retractable and debilitating and there	
21	part of being a doctor is to appreciate the		21	is evidence, as you heard, of the benefit that	
22	suffering of people. So partially my decision		22	medicinal marijuana can play from a	
23	is based just on that. So based on that I will		23	pharmacological perspective on the ability	
24	recommend to approve marijuana for pain		24	for or quality of life for an individual.	
25	secondary to visceral origin.		25	So I do concur that including pain of	
-		Page 43			Page 45

1 visceral origin should be added to the list of Let's go the other way around. acceptable conditions for medicinal marijuana. Dr. Bridgeman. 2 DR. BEKKER: Thank you, Dr. Zarus. 3 DR. BRIDGEMAN: So, you know, 3 4 Dr. Kennedy. undoubtedly chronic pain of visceral origin is a 5 DR. KENNEDY: Thank you. condition that's accepted by the medical I'd like to do a partial correction community as being potentially severe and 6 debilitating and we realize that there are both to the record regarding my previous remark about visceral pain which I addressed earlier when we non-pharmacologic interventions in the case of were addressing musculoskeletal pain. irritable bowel syndrome or some of these So regarding musculoskeletal pain, conditions as well as drug therapies that may 10 have a role in alleviating symptoms of chronic just to make sure the record is clear, I agree 11 with my colleagues who spoke on that, that yes, pain associated with either irritable bowel or it is actually known as the top five medical 13 chronic pancreatitis. 13 conditions that disables people, this chronic 14 You know, when we think about the 14 adverse effects associated with the medications pain syndrome of musculoskeletal origin. 15 Now, to address the pain of visceral including the opioids which can be used for 16 origin, many of the pains that come from 17 these conditions, they can be severe and 17 debilitating. We've already discussed that. 18 visceral origin are actually related to muscles 18 There is evidence to suggest that 19 19 and other tissue within the internal organs or surrounding the internal organs which sometimes medicinal use of cannabis may have efficacies of 21 expands due to congestion and inflammation and treatment of chronic pain syndrome and we do 21 these can cause severe and debilitating pain have some limited clinical evidence to suggest 22 22

23

that cannabinoids in the treatment of

pancreatitis or irritable bowel may have

efficacy and that was largely where I came to my

23

and, as already noted, the current

pharmacotherapy cannot only exacerbate the

problem, especially in the GI tract if people

	Page 4	6		Page 48
1	are suffering with constipation, opioid	:	more detrimental than the pain. Patients have	
2	analgesics continue to worsen that kind of	:	to kind of weigh back and forth, what is the	
3	effect.	:	best modality for them to do.	
4	So these kinds of pains are extremely	4	And so based upon the evidence from	
5	debilitating and very, very difficult to treat	!	the literature and my feelings and experience	
6	even with the opioid analgesics and any other	(with the quality of life with these patients,	
7	kinds of pharmacological intervention.	-	certainly I support the use of marijuana,	
8	So I have found that there are	8	medicinal marijuana for the treatment.	
9	several peer-reviewed publications that speak to		DR. BEKKER: Thank you, Dr. Johansen.	
10	the beneficial effects of cannabis for the	10	And Dr. Levounis.	
11	treatment of pain resulting from inflammation or	1:	DR. LEVOUNIS: Yes, on the issue of	
12	malfunction of the internal organs. They were	1.2	whether the chronic pain of visceral origin is	
13	published in respected peer-reviewed journals in	1:	debilitating, I vote yes, and on the second	
14	2007, 2011 and 2013, to mention three of them.	1.	issue of the benefit of (indiscernible) I vote	
15	So in my opinion there is more than	1.5	5 no.	
16	sufficient evidence to recommend medicinal	1.0	At this point we're hearing something	
17	cannabinoids for visceral pain.	1.	that has come up in the testimony we heard	
18	DR. BEKKER: Thank you, Dr. Kennedy.	1.8	before and as to opioid, some people put forward	
19	And Dr. Johansen.	1.9	the idea that perhaps cannabis use can double as	
20	DR. JOHANSEN: I concur with my	20	a means of curbing the issue of the opioid	
21	colleagues regarding the evidence in the	2:	epidemic somehow in the future in that regard.	
22	literature and I would like to add the	22	There was a very extensive article	
23	following; the individual who has chronic pain	2:	that was published in the American Journal of	
24	related to visceral origin more often than not	24	Psychiatry in September of 2017 and that's why	
25	it could be a bowel malfunction like irritable	2	it's not in my original testimony.	
	Page 4	7		Page 49

1 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

8 impacts the individual's quality of life and

these can be extraordinarily detrimental.

And in addition to the

10

pharmacological treatment for chronic pain

related to bowel malfunction and specifically 12

related to viscera may actually lead to an 13

exacerbation of the individual's symptoms. 14

I also noted that there was no one 15

accepted treatment of pain of visceral origin 16

which is a -- which is not necessarily a 17

18 concern. The management by any provider most

certainly needs to provide optimal situations 19

20 for the patient in terms of quality of life and

pain management, but some of the anticholinergic 21

22 and antispasmodic medication that they use do

indeed provide some painful relief of bowel 23

spasms, but there are pretty significant side 24

effects to that and that really can be almost

(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. 6

DR. LEVOUNIS: Or rather 500 people,

not patients. 34,500. 8

7

DR. BEKKER: Thank you, Dr. Levounis.

I'm not familiar with this study. I guess it 10

just came out. The study which was published in 11

JAMA in 2015 assessed the results of 12

legalization of medicinal marijuana in Colorado 13

14 and they state in JAMA article that deaths

association with opioid overdose went down by 15

about 28 percent, something like this after 16

17 legalization.

There was another study, which is in 18

my evaluation, which shows that patients on 19

chronic opioid -- again this is large study. 20

Patient on chronic opioid who use marijuana, use 21

of opioid went down by about 40 percent and 22

about 10 -- another 10 percent of patient 23

24 completely off opioid.

25 So, again, I would be interested to

			Getobel	,
	Page 50	T		Page 52
1	read this publication in American Journal of	1	this type of study should be revalidated given	
2	Psychiatry, but leaving this issue aside, from	2	the current situation we find ourselves in with	
3	all other systematic review in meta-analysis	3	the opioid crisis.	
4	suggest that use of opioid is reduced when in	4	Thank you.	
5	states with the medicinal marijuana or legalized	5	DR. BEKKER: Thank you.	
6	marijuana, as a matter of fact.	6	Members of audience, any comments?	
7	DR. LEVOUNIS: You know, this is	7	Mr. Miller?	
8	based on (indiscernible) and that's why	8	MR. MILLER: Briefly I would like to	
9	(indiscernible) as to what's going on in the	9	add that it was 2014 when the American Medical	
10	association between cannabis use and	10	Association looked at the effects of the first	
11	(indiscernible).	11	13 states with medical marijuana laws. They all	
12	DR. BEKKER: Right. I'm sorry that I	12	included general pain provisions. Unlike	
13	didn't read this article, so I cannot comment.	13	New Jersey, we started very bad perhaps with	
14	They're probably very sure they're correct, but	14	as the 14th state, but in those 13 they found	
15	there are studies on both sides. So one study,	15	there was 24.8 percent reduction in the overdose	
16	you cannot say that this study absolutely denied	16	death rate due to opioids.	
17	all available evidence like (indiscernible)	17	In New Jersey we have a thousand	
18	studies, stuff like that. Science is	18	overdose deaths of opioids both prescribed and	
19	developing.	19	illegal and that would translate statistically	
20	Maturity (indiscernible) studies	20	to 250 lives that could have been saved.	
21	shows that marijuana reduces opioid consumption	21	Now of course the American Medical	
22	and (indiscernible) shows something else. So	22	Association, and rightly so, cannot attribute	
23	until, you know, this should be public should	23	cause and effect to it. We cannot say this is	
24	know about this study and thank you for bringing	24	what we will find, but when it happens in all 13	
25	this particular research to our attention. I	25	states and it combines for a 25 percent	

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1 reduction, people need to be reminded that it is

an additional medicine, adjunct medicine, not a

replacement medicine and The Coalition for

1 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? 7 DR. BEKKER: Yes. Dr. Kennedy would 8 like to comment as well. 9 10 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 17 up, more than 34,000 of them, in 2004 and 2005. 18 19 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 22 23 of opioids now.

So although the study may have valid

conclusions based on the data they reviewed,

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. 7 So thank you for taking that into 8 account. If we really are having the epidemic 9 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. 13 So this is my only -- it's not being used. It's not being talked about. New Jersey 15 does not mention this. So I hope that 16 17 eventually it will work that you folks will bear fruit in New Jersey and we will be better off 19 for it. 20 So thank you very much. DR. BEKKER: Thank you, Mr. Miller. 21 22 If there isn't any other comment, we 23 will move on. 24 (No response.) DR. BEKKER: No other comments. 25

	Page 54			Page 56
1	So next condition on our list is	1	were I think 12 peer-reviewed publications that	
2	Tourette syndrome. Tourette syndrome is a	2	were provided. An additional search that I	
3	neurological disorder which is characterized by	3	conducted as well actually proved that there	
4	repetitive involved in movement and occasionally	4	were clinical trials that actually established	
5	verbal outbursts. There are no accepted	5	that medical marijuana as a treatment for	
6	pharmacological treatment for this condition.	6	Tourette's is clearly effective and based upon	
7	Also all kinds of medication been tried to treat	7	that I recommend it to be used.	
8	Tourette syndrome. Only neuroleptic officially	8	DR. BEKKER: Thank you, Dr. Johansen.	
9	approved by FDA for treating Tourette syndrome	9	Dr. Kennedy.	
10	but treatment is not very successful. It's very	10	DR. KENNEDY: Thank you.	
11	difficult to treat condition, very debilitating.	11	Yes, Tourette's is a well-recognized	
12	Underlying cause of Tourette syndrome	12	debilitating disabling medical condition that	
13	is relatively unknown, uncertain. However,	13	frequently has its onset early in childhood. So	
14	there are number of clinical reports. I found	14	when this condition does affect an individual,	
15	12 peer-reviewed publications which suggests	15	their entire life span can be affected including	
16	that marijuana is helpful and we had, like all	16	the ability to be in conventional educational	
17	of us probably remember, heartbreaking story	17	settings and these some of these individuals	
18	about mother who has 17-year-old kid, very	18	are so disabled by their condition, they cannot	
19	intelligent and smart, but depressed and lonely	19	be in standard schools, even in school settings	
20	simply because he cannot be in a normal	20	that have additional help. Because of the	
21	environment at school.	21	particular nature of the condition, it often	
22	So based on this my review of the	22	makes other people feel uncomfortable and shun	
23	literature and compelling stories, I would	23	them socially and so on.	
24	recommend to approve cannabis for treatment of	24	The tics are involuntarily. They can	
25	Tourette syndrome.	25	include vocalization that can be unpleasant to	
	Page 55			Page 57
1	Dr. Johansen	1	hear by other people and make people feel	

1 Dr. Johansen.

2 DR. JOHANSEN: Thank you, Dr. Bekker.

3 So there is no -- there is no one

4 primary medication or go-to drug that

5 practitioners use to treat this. So there have

6 not certainly been -- there's a varying approach

7 to how it's addressed.

8 There are also non-neuroleptical

9 approaches as well, therapeutic modalities which

10 may or may not be effective, but just as a

11 reminder, these patients with Tourette syndrome

12 have experienced -- their quality of life is

13 huge and depending upon most certainly where

14 they are in their life span, whether they're

15 adolescent, young adults or older adults or

16 someone who's in their -- or an older adult,

17 they can -- will certainly have social

18 isolation, which is very, very common, which

19 then puts them in compliance with depression,

20 anxiety, you know, insomnia and so forth, and so

21 even when they do seek pharmacological

22 treatment, they indeed might have an

23 exacerbation of these symptoms merely as a side

24 effect.

25

So looking at the literature, there

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

6 The approved medication for

7 Tourette's syndrome falls into the category of

anti-psychotic medication, also known as

9 neuroleptics in some places. These medications

10 are actually not being used for psychosis.

11 Tourette's is not generally associated with

12 psychotic symptoms, but are being used because

13 of their effect on what we call the

14 extraforaminal system in the brain which

15 involves structures very deep in the brain, the

16 basal ganglia, which we know are implicated in

17 Tourette's syndrome although we haven't

18 identified the full etiology of the condition,

19 but sometimes these medications can suppress the

20 tic.

21 However, their efficacy is

questionable because they have much less than an

23 80 percent rate of tic suppression and given

24 that, because they have tremendous side effects

25 that are very adverse -- they can cause weight

Page 60 Page 58 1 can present for us and we can deduct that this 1 gain, metabolic syndrome, diabetes, stroke. 2 They can cause other movement disorders. They would be a reason why medicinal marijuana would 3 can have serious cardiac affects that have to be be effective. So yes, I'm all for it with the rest 4 monitored and they may cause drowsiness as do 4 5 of the team. 5 the SRRI, which are the anti-depressant class DR. BEKKER: Thank you, Dr. Zarus. 6 6 that is often used for these -- for this 7 condition, but all of these medications, 7 And Dr. Bridgeman. DR. BRIDGEMAN: So I just want to particularly the anti-psychotics can have very, 8 point out again my assessment was based on risk very debilitating and sometimes dangerous and benefit analysis and we do know that 10 medical adverse effects. 10 neurocognitive development continues up until 11 So given the review of the literature 11 age 25 years. So I am not a pediatric expert, 12 and the number of clinical reports that but I did have some in looking at this therapy 13 describes the successful treatment of this in regards to the developmental effects of 14 condition by using cannabinoids and I reviewed cannabis on the developing brain. So that was 15 12 peer-reviewed publications that were listed one of the sort of risk aspects of my 16 and there are letters of support from physicians 16 evaluation. 17 17 and other licensed healthcare professionals You know, again, according to the 18 18 knowledgeable about the condition, I concluded 19 that medicinal cannabinoids, medicinal marijuana compassion use of medical marijuana, as in New Jersey our state permits use of therapy or may be effective and should be considered for 20 use of cannabis if the condition is resistant to 21 the use of this condition. 21 22 or the patient is intolerant to conventional DR. BEKKER: Thank you, Dr. Kennedy. 22 therapy and Tourette's syndrome in my mind falls 23 23 Dr. Zarus.

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itself, Tourette's is well-recognized, although 3 we don't have clarity on how the neurologic 4 system is causing Tourette syndrome. We're still unclear about the etiology of the 6 condition itself, making it difficult for medication and the therapeutic toolboxes are relatively empty. 8 You heard there's not really a go-to

1 the same direction. We heard that the condition

DR. ZARUS: Thank you.

And all of my colleagues, I concur in

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10 regimen made up of multiple drugs. There's just 11 a few things out there. Only one FDA-approved 12 therapeutic category, and for those of you who 13 follow along with all these meetings, we had an 14 opportunity to meet a young woman who gave a 15 testimonial of not only the difficulty she's quality of life and even other issues that have 18 been brought up as her own personal condition of

16 having handling the condition itself, but the 17 19 So it's really a quality of life 20 21 issue. It's a condition for which there is some -- whether it's peer-reviewed data and 23 literature, evidence to demonstrate the effectiveness and we should also look at the 25 pharmacologic opportunity that the cannabinoid 1 where traditional therapy -- the traditional

in that category where we've heard from -- you

know, my colleague said this is a condition

drug therapies don't often respond.

When I look at the evidence, there is 3

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.

10

There was a review in the Journal of 11 the American Medical Association in 2015 that 12 concluded that there was local quality evidence, 13 but evidence nonetheless to support cannabis in improving symptoms associated with Tourette's

and I would also point out that Tourette's is 16

one of the medical indications for compassionate 17

use of cannabis in the State of Minnesota. 18 So in suggesting that this indication 19

be considered by our Commissioner, the

Department of Health, I think that there's

enough evidence that I can comfortably conclude 22

that this is an appropriate indication. 23

DR. BEKKER: Thank you, 24

Dr. Bridgeman.

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1	And Dr. Levounis.	1	Dr. Kennedy.	
2	DR. LEVOUNIS: Yes, I agree with my	2	DR. KENNEDY: Thank you.	
3	colleagues about how debilitating is Tourette	3	Yes, while asthma can be debilitating	
4	syndrome indeed and how the other treatments	4	and indeed life-threatening in an acute	
5	(indiscernible).	5	exacerbation without treatment, there are well	
6	On the second issue of the balance of	6	known and very effective treatments available	
7	the benefits and evidence to support the	7	for this condition and there are no clinical	
8	cannabis, I vote no on the second question.	8	trials that I could find documenting usefulness	
9	DR. BEKKER: Thank you, Dr. Levounis.	9	of cannabis in this condition.	
10	Members of the audience, any	10	So therefore I do not recommend it to	
11	comments?	11	the Commissioner for addition to the medicinal	
12	(No response).	12	marijuana grouping.	
13	DR. BEKKER: Okay. So the next	13	Thank you.	
14	condition is one petition for requesting use of	14	DR. BEKKER: Thank you, Dr. Kennedy.	
15	cannabis to treat asthma.	15	Dr. Zarus.	
16	Asthma is a respiratory condition	16	DR. ZARUS: Thank you.	
17	which characterized by spasm in bronchi causing	17	In addition to the lack of	
18	difficulty breathing and an extreme condition	18	peer-reviewed data, there are no supportive	
19	can lead to death. The onset of this disease	19	healthcare professionals that recommended that	
20	actually is well understood and there are	20	we consider this. It doesn't seem to have	
21	numerous available treatments that can alleviate	21	anyone supporting the use and there is certainly	
22	these symptoms.	22	no data. So I also concur that we should hold	
23	I read the literature on the use of	23	on this one until there's more evidence.	
24	cannabis to treat asthma. I found lot of	24	DR. BEKKER: Thank you, Dr. Zarus.	
25	clinical studies, but unfortunately or	25	And Dr. Bridgeman.	
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DR. BRIDGEMAN: Asthma is an

1 fortunately, I'm not sure, there's no clinical 2 documentation of use of marijuana for asthma. It kind of doesn't make a whole lot of sense to 4 me. 5 So based on my review of literature 6 and other ability of medication to treat this condition, my recommendation would be no. Dr. Johansen. 8 DR. JOHANSEN: So I did go back to 9 the literature as well. The triggers for asthma across the life span for pediatric and for 11 adults and older adults, they are different from 13 person to person, but there is evidence based 14 and medically accepted and effective treatment 15 for long-term control and for quick relief, for 16 short acting relief that are both effective and provide minimal side effects, if any, and so I 17 18 did go back to the literature to see if there were any clinical based trials that would 20 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 24 condition.

DR. BEKKER: Thank you, Dr. Johansen.

25

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. 8 That being said, there is also some evidence to suggest that there may be an anti-inflammatory effect of the cannabinoid. 11 12 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 16 17 asthma. I also want to just point out that 18 inhalation of the byproduct of the combustion is 19 20 one of the known triggers for asthma exacerbation. So with that regard, my 21 assessment was no to expanding use for this 22 23 indication. 24 DR. BEKKER: Thank you, 25 Dr. Bridgeman.

	Page 66			Page 68
1	And Dr. Levounis.	1	expanded an indication in New Jersey.	
2	DR. LEVOUNIS: I fully 100 percent	2	DR. BEKKER: Thank you,	
3	agree with my colleagues that asthma can be	3	Dr. Bridgeman.	
4	debilitating, but I vote no on the second	4	Dr. Zarus.	
5	question of whether it should (indiscernible).	5	DR. ZARUS: And I'm also concluding	
6	DR. BEKKER: Thank you, Dr. Levounis.	6	that we should hold on this. There's not enough	
7	And members of the audience, anybody	7	evidence and while again conventional therapy	
8	would like to comment on our recommendation?	8	doesn't really fix it, which would otherwise	
9	(No response).	9	make me think this is valuable for patients, in	
10	DR. BEKKER: Okay. So our next and	10	this particular case we still don't have enough	
11	last condition, we had one petition for	11	information to be able to say that. So	
12	requesting medicinal marijuana to treat chronic	12	DR. BEKKER: Thank you, Dr. Zarus.	
13	fatigue syndrome.	13	Dr. Kennedy.	
14	Chronic fatigue syndrome is a	14	DR. KENNEDY: Yes, thank you.	
15	debilitating condition which is characterized by	15	I concur with my colleagues. I was	
16	extreme fatigue, tiredness. It does not go away	16	unable to find any clinical evidence that	
17	with rest and cannot be explained by underlying	17	medicinal marijuana or cannabinoids could be	
18	medical conditions.	18	helpful in this condition and although this	
19	The cause of chronic fatigue syndrome	19	condition has been researched for nearly 30	
20	is not clearly understood and there are no	20	years quite extensively by various groups, there	
21	current treatment. People just try whatever is	21	is really not yet a good elucidation of the	
22	possible and each affected person has different	22	etiology of this condition and why people have	
23	symptoms. It's kind of difficult to develop	23	it or what treatment would be helpful.	
24	general kind of recommendation.	24	Many patients use other adjunctive	
25	So I reviewed the literature on use	25	complementary therapy; yoga, acupuncture,	
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Page 67 1 etcetera. However, I conclude that there is not 1 of medicinal marijuana for treating this 2 any sufficient evidence to expand medicinal 2 syndrome. I could not find any clinical studies marijuana use in New Jersey to chronic fatigue 3 which address this disease, indicating conceptually it's very -- neurologically it's syndrome. DR. BEKKER: Thank you, Dr. Kennedy. 5 very difficult for me to imagine how or explain how cannabis can help alleviate this symptom. 6 Dr. Johansen. DR. JOHANSEN: I want to concur with So based on this fact, my recommendation is no. my colleagues and yes, I could not find any So let's go the other way around so 8 evidence to support this and I guess on behalf we kind of equalize forces. 9 of the panel I want to make sure that we Dr. Bridgeman. 10 recognize that this is a medical condition and 11 DR. BRIDGEMAN: Sure. And I'm really there is an issue in that there are most 12 just going to echo Dr. Bekker's comments here. certainly physical, psychological, debilitating 13 We know that chronic fatigue syndrome is -- the associated symptoms that are related with this. treatment approach is largely tailored to the However, in order to support the use of patient's presenting symptoms and just with medicinal marijuana to treat this and be able to 16 regard to the fact that the pathophysiology that modify symptoms, there has to be some evidence 17 explains this disorder hasn't been completely to support that. 18 18 elucidated or current treatment options are 19 So I voted again with my colleagues 19 largely palative and symptom triggered, I also that there was nothing there to support that at 20 found no evidence to support the use of cannabis this time. 21 for this particular condition at this time and, 21 DR. BEKKER: Thank you, Dr. Johansen. 22 again, even from a pathophysiologic And Dr. Levounis. 23 pharmacologic approach, kind of couldn't

DR. LEVOUNIS: I agree with my

colleagues that chronic fatigue is a very

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rationalize that as well.

So I concluded that it should not be

me	dicinal marijuana review panel		October 25, 20
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1	debilitating medical condition, but I don't find	1	DR. BEKKER: Yes. Okay.
2	the profile of medicinal cannabis to be in favor	2	Any other procedural
3	of sufficient sufficient evidence in favor of	3	MS. CARSON: So he just went through
4	yes. So I vote no.	4	the roll for you.
5	DR. BEKKER: Thank you, Dr. Levounis.	5	MS. STARK: Okay.
6	And members of the audience, if	6	DR. BEKKER; So if nobody else
7	anybody would like to comment on chronic fatigue	7	MS. CARSON: Procedurally then she
8	syndrome.	8	took Dr. Bekker's roll call as hers.
9	(No response).	9	MS. STARK: Yeah.
10	DR. BEKKER: So no comments. So I	10	MS. CARSON: That's fine.
11	just need to ask members of the panel if in your	11	DR. BEKKER: So if there are no other
12	deliberation or public comment, you change your	12	comments, is there motion to adjourn?
13	view on the petitions, and I guess you have to	13	DR. KENNEDY: So move.
14	state for the record. Dr. Bridgeman?	14	DR. ZARUS: Second.
15	DR. BRIDGEMAN: I have not changed my	15	DR. BEKKER: Okay. Thank you
		16	everybody for your participation. Members of
17	DR. BEKKER; Dr. Zarus?	17	the panel, thank you so much.
18	DR. ZARUS: I have not changed my	18	(The proceedings are adjourned
19	views.	19	at 11:37 a.m.)
20	DR. BEKKER: Dr. Kennedy?	20	
21	DR. KENNEDY: I have not changed my	21	
22	view.	22	
23	DR. BEKKER: Dr. Johansen?	23	
24	DR. JOHANSEN: I have not changed my	24	
25	view.	25	
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	-	1	CERTIFICATE
1	DR. BEKKER: Dr. Levounis?	2	
2	DR. LEVOUNIS: I have not changed my	3	STATE OF NEW JERSEY)
3	view.	4	: ss.
4	DR. BEKKER: And I did not change my	5	COUNTY OF HUNTERDON)
5	view.	6	,
6	So our deliberation did not change	7	I, BETH RADABAUGH, a Certified
7	*	8	Shorthand Reporter and Notary Public within and
8	So initial recommendation stands as as	9	for the State of New Jersey, do hereby certify
9	presented and depicted on the web site. So our	10	that the within is a true and accurate
10	recommendation stands.	11	transcript, to the best of my ability, of the
11	Any other procedural issues?	12	proceedings taken on October 25, 2017.
12	(Dr. Bekker confers with Ms. Carson.)	1	
13	DR. BEKKER: Okay. Members of panel,	13	I further certify that I am not
14	next vote refers to I guess second vote to	14	related to any of the parties to this action by
15	confirm our initial recommendation.	15	blood or marriage; and that I am in no way
16	DR. BRIDGEMAN: Second.	16	interested in the outcome of this matter.
17	DR. BEKKER: Yes.	17	IN WITNESS WHEREOF, I have hereunto
18	DR. ZARUS: Second.	18	set my hand this 3rd day of December, 2017.
19	DR. BEKKER: Yes.	19	
20	MS. JOHANSEN: Second.	20	Boll R. Sulayed

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DR. BEKKER: Yes.

DR. BEKKER: Yes.

Dr. Levounis.

DR, KENNEDY: Second.

DR. LEVOUNIS: Second.

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