OMMP Expert Panel Recommendations 2009 Report

Submitted on behalf of the Expert Panel by Jana Fussell, Expert Panel Process Monitor October 20, 2009

Background Information

On January 26, 2009, Edward Glick submitted a petition to the Oregon Medical Marijuana Program ("OMMP") to add Clinical Depression, Depressive Symptoms, Post-Traumatic Stress Disorder ("PTSD"), Severe Anxiety, Agitation and Insomnia to the list of diseases and conditions that qualify as "debilitating medical conditions" under the Oregon Medical Marijuana Act. In response, the Department convened an expert panel in conformance with ORS 475.334 and OAR 333-008-0090(4) to review this petition. The petitioner waived the requirement found in ORS 475.334 and OAR 333-008-0090(6) that the Department make a determination within 180 days of receipt of the petition. A copy of ORS 475.334 and OAR 333-008-0090(4) are attached to this report as "Exhibit #1."

Description of Review Process Employed by the Expert Panel

The expert panel was asked to consider three bodies of knowledge:

- Scientific research gathered through a structured literature review
- Materials submitted by the petitioner which included research
- Testimony provided by individuals selected by the petitioner, individuals identified by panel members and interested members of the public

Three expert panel sessions were held. The first expert panel session held on July 27, 2009, included introductory remarks by the petitioner and the scientific review process led by Dr. Donald Austin. Attached to this report as "Exhibit #2" is the written material submitted by Mr. Glick as a part of his introductory remarks. Prior to the first meeting,

the panel was provided with materials to review and consider that were submitted by Mr. Glick in support of inclusion of the conditions. This material included research findings, descriptions of patient experiences with cannabis, comments from physicians, and a Psychiatric Benefit Survey 2005 authored by Mr. Glick and entitled "Patients Report Mood and Emotional Benefits Result from Cannabis Use." The second session, held on August 13, 2009, also focused on the scientific review process lead by Dr. Austin. The third and final session held on August 24, 2009, included a presentation by the petitioner along with testimony from individuals whom he invited; testimony from individuals invited by the panel to speak and other public testimony from interested individuals. Written testimony continued to be accepted until September 3, 2009, at 5:00 p.m. Petitioner has the option to submit a written rebuttal to this report.

As a part of this process, immediately following the discussion led by Dr. Austin on a proposed condition, panel members were asked to individually complete a US Preventative Grading Services Task Force ("USPTF") grading sheet for the condition. A discussion of the scientific review process employed in the first two panel sessions is provided in a document prepared by Dr. Austin and attached to this report as "Exhibit #3."

Following the third session, the panel members were asked to submit their final recommendation sheet by September 11, 2009, at 5:00 p.m. In making their recommendations, panel members were instructed to consider all three bodies of knowledge and any additional information received prior to the September 3, 2009 deadline. The final recommendation sheet allowed the panel members to explain any discrepancies between the USPTF grade and the final recommendation to include, or not to include, the condition under consideration. Attached to this report as "Exhibit #4" is each panel member's final recommendation sheet for each condition. These sheets were individually completed by expert panel members after considering all of the evidence presented to the committee.

Summary of the Third Expert Panel Session

As previously noted, a discussion of the scientific review process is attached to this report. This section of the report will provide a summary of the themes that came out of the third session.

The petitioner, Mr. Glick, focused on the materials that he prepared for this panel session entitled "Patient's <u>are</u> Human Research." This document is attached to this report as "Exhibit #5." Mr. Glick opined that "The paucity of research that you panel members received in the literature search portion of this proceeding is a direct result of seventy years of research suppression . . . These comments will hopefully rely on the research that does exist: that of patient experience, history of use, physician writings and animal research. While none of these alone is enough to justify approval of cannabis for use as a treatment, combining the four goes some distance toward explaining the consistent benefits that patients report." Mr. Glick also opined that "the assertions of some panel members that the safety profile of cannabis forbids its use in mental health is not supported by my evidence."

In addition to his testimony, Mr. Glick had the following seven individuals testify by telephone in support of his petition: David Bearman, MD, Frank Lucido, MD, Jeffrey Hergenrather, MD, Lester Grinspoon, MD, Al Byrne, Mary Lynn Mathre, RN, and Karen Meana. Dr. Bearman has forty years experience providing drug abuse treatment and prevention and has done cannabis assessments for over nine years. He is Vice President for Quality Assurance and Credentials, American Academy of Cannabinoid Medicine. He opined that many of his patients get psychological benefit from the medicinal use of cannabis. Dr. Bearman provided extensive written comments to the committee in addition to his oral testimony. Since 1979 Dr. Lucido has had a general family practice in Berkley, California and his practice is about evenly split between primary care and medical cannabis. Dr. Hergenrather is a "Medicinal Cannabis and General Practice Consultant" who has been active in the practice of cannabis consultation since 1999. He is also based in California and his medical career has focused on primary care both in general practice and in emergency medicine. Dr. Grinspoon is an emeritus professor of psychiatry at Harvard Medical School who has been interested in

marijuana since 1967 and who has come to the conclusion that marijuana is remarkably free of serious toxicity and has enormous medical potential. Al Byrne is a co-founder of Patients out of Time, a charity that educates healthcare professionals about the medicinal use of cannabis. He is particularly focused on PTSD. Mary Lynn Mathre is a registered nurse with extensive experience in addictions nursing and she is the cofounder and president of Patients Out of Time. Karen Menna is a patient who testified that she benefits from the use of marijuana.

The petitioner also had the following three individuals provide inperson testimony on behalf of his petition: Greg Trout has a military service background and has symptoms of PTSD. He testified that the he finds marijuana provides relief without risking the harm to his liver that may be caused by prescribed medicines. Roy Murray is a computer professional who suffers from depression who testified that he has depression and anxiety and has tried Paxil, Effexor and Wellbutrin all of which caused unwelcome side effects. He stated that he has found that while he is not cured, regular use of marijuana has been helpful. Clifford Spencer is a founder and coordinator of "the Co-Op" which has been assisting patients in residential care and/or hospice with implementation of the Oregon Medical Marijuana Act for over 10 years. Mr. Spencer testified that the results of an "informal survey" that he conducted showed that his case study subjects indicated a 50% reduction of symptoms of depression and anxiety with marijuana use for patients who were prescribed prescription drugs for these conditions.

At the invitation of panel members, Susan Elmore, MD and Joshua Boverman, MD presented testimony at the third expert panel session. Dr. Elmore is an addictions psychiatrist who has worked in the field for approximately 8 years who works with people that are trying to get off of THC (the main active chemical in marijuana) and also works with very severe cases of depressive disorder, chronic pain, and PTSD. She stated that: "I did want to make sure that when people talk about it is really helpful, a lot of things are really helpful for PTSD, Konopin, opiates, alcohol for that matter are helpful, but we are definitely going to careful about prescribing anything that is going to possibly create an active dependence that we are then going to be spending possibly years trying to wrestle someone off of." She opined

that there are many other medications that could be prescribed and that this should not be tried first. Dr. Elmore expressed concern that some of the side effects of marijuana are actually very serious symptoms of depression that are struggled with for years to get rid of. In response to a question from a panel member, she stated her belief that good controlled studies have not been done yet on the use of medical cannabis for the treatment of PTSD, depression, anxiety or agitation. Dr. Elmore spoke of the addictive problems that she has seen in patients who have been prescribed Marinol which is a THC drug.

Dr. Boverman is a psychiatrist at OHSU who practices in addictions as well as general psychiatry. He testified that he has seen many patients that he believes are affected negatively by using marijuana: "It impairs their cognition to the point where they would have difficulty in engaging in other therapies. It impairs their ability to maintain sobriety from other drugs which they have developed difficulties from, and there is a preponderance of literature suggesting that it causes anxiety and depression rather than treating it. There is a body of literature that establishes rather firmly that there is a withdrawal syndrome that is associated with cessation of use and heavy marijuana use, and there is a great difficulty in using marijuana for treating chronic medical conditions or mental health conditions, and that it requires use about every six hours, which means that people will go through cycles of intoxication withdrawal which may be more impairing than the condition they are attempting to treat . . . When it comes to treating mental health problems, I have a sense that people can endure great suffering by using marijuana in attempts at controlling their conditions, and I think that making marijuana a treatment for these conditions under the Oregon Medical Marijuana law will mislead individuals and allow them to pursue a path that is absolutely not helpful for them." He stated this it has been his experience as a clinician that many individuals who believe that marijuana is helping their anxiety and depression, for example, are actually physiologically dependent of the drug and suffering as a means of that, and they do not understand it.

Twenty-two additional individuals provided oral testimony. Some of these individuals also provided written testimony. Twenty-one of these individuals testified that they had found marijuana helpful for

one or more of the medical conditions under review. More than half of these individuals cited their experiences with PTSD. A common thread running through most of the testimony was unwanted side effects encountered with use of conventional medications as compared with marijuana. One individual identified himself as an addict and an alcoholic who is actively working on a very rigorous recovery program who deals with his PTSD and his nightmares without the aid of chemicals. He stated that marijuana does mess with his cognitive abilities and that when he gets stoned, he gets stupid and that leads him back to wanting to use his other drug, alcohol, and that ends him up in jail. In his opinion: ". . . marijuana or not, just so you know, whether you are stoned or not the problem is still there and needs to be addressed. No medication is going to cure PTSD."

Other Written Testimony

A variety of other written testimony was received over the course of the panel's deliberations and prior to the September 3, 2009, deadline. The president of the Oregon Psychiatric Association, Thomas Hansen, MD, wrote that his organization sought input from its members and executive council and takes the position that: "The absence of evidence to support efficacy in treating patients who have one of the listed conditions coupled with the potential risk of harm leads the Oregon Psychiatric Association to oppose the proposed expanded list of diagnoses proposed for treatment with medical marijuana. "Larry Stoune, MD, who is a certified addiction specialist expressed his opposition to adding any of the diseases or conditions under consideration writing that THC is consistently and persistently a part of the history of most every patient he sees with poly- and monosubstance dependency. He opined that group therapy is the treatment of choice for PTSD and that there are multiple natural ways to treat the other conditions noted. A retired former philosophy professor wrote that marijuana is more effective in combating insomnia than sleeping pills. A psychiatric nurse practitioner from New Mexico wrote to strongly recommend that Oregon consider adding psychiatric conditions to the list of approved indications for the treatment with medical marijuana citing his experiences with patients. A number of current OMMP participants voiced their support for adding the conditions under consideration with PTSD being the most

mentioned condition. Michael Karawitz, Director of Outreach for Veterans for Medical Marijuana Access, stated that: "Allowing for the addition of 'Depression', 'Anxiety', 'Insomnia', 'PTSD' and 'Extreme Agitation' to the OMMP will of great benefit to Oregon's disabled military veterans and will by extension offer the veterans hospital the ability to be more flexible in the treatment plans that they can offer." Panel members Cohn and Keane also provided written comments. Dr. Cohn expressed reservations about Dr. Boverman's testimony. He stated that his observations with a number of patients have led him to believe that medical marijuana is useful in treating some individuals with certain psychiatric problems. He opined that additional tools are needed to treat refractory psychiatric conditions. Ms. Keane wrote that in the absence of good solid double blind placebo controlled trials, personal patient testimony and personal clinical experiences become weightier. She opined that the testimony of the physicians who work in cannabis supportive clinics in California is particularly important and that this testimony as well as the studies presented by the petitioner balance out the lack of clinical trials.

Objections to Process

The petitioner had several objections to the process used by the committee most notably to the appointment of Diane Lia, MSW, LCSW, CADC II to the expert panel and also to some articles suggested by panel members Lia and Dodson for the panel members' consideration. Ms. Lia has had experience in counseling patients suffering from mental illness in alcohol and drug agencies, community mental health program, Employee Assistance Programs and a domestic violence agency. She works with clients with cooccurring disorders, specifically PTSD and trauma and has had a lot of training in PTSD. The program believes that Ms. Lia who works for the Addictions and Mental Health Division as a Program Policy and Development Specialist is well qualified to serve on the committee. The petitioner also expressed concern that panel members, Lia, Fireman and Dodson have no clinical experience in cannabinoid therapeutics. It is, however, important to note this background is not a qualification that is required by the governing statute or administrative rule for membership on the expert panel.

Summary of Expert Panel's Final Recommendations

Seven members served on the expert panel:

- Stormy Ray, president of the Stormy Ray Cardholders' Foundation
- Dr. Tom Dodson, psychiatrist
- Teresa Keane, psychiatric nurse practitioner
- Dr. Alan Cohn, psychiatrist
- Dr. Grant Higginson, administrator of the Office of Community Health and Health Planning in the Public Health Division
- Diane Lia, whose background was discussed above
- Dr. Marian Fireman, psychiatrist

Four members (Dodson, Higginson, Lia and Fireman) recommended against adding any of the conditions under consideration to the list of diseases and conditions that qualify as "debilitating medical conditions" under the Oregon Medical Marijuana Act. Dr. Higginson did, however, suggest that the OMMP consider initiating a legislative concept for the 2011 session that would allow research on medical marijuana for PTSD in well-controlled situations. Two panel members recommended that all of the conditions under consideration be added (Ray and Keane). One panel member (Cohn) recommended adding all of the conditions with the exception of clinical depression.