

REPORT OF THE ADVISORY COMMITTEE ON MEDICAL MARIJUANA PETITIONS

Introduction and Background

In November 1998, Oregon voters passed the Oregon Medical Marijuana Act (OMMA) by initiative ballot (the original Act was subsequently amended by the 70th Legislative Assembly through chapter 825, Oregon Laws 1999 [HB 3052] and is now codified in Oregon Revised Statutes at ORS 475.300 to 475.346). The Oregon Health Division (the Division, or OHD) has been given the responsibility of and authority for implementing various sections of the OMMA. Among other things, this Act directs OHD to issue registry identification cards to any person (and to his/her designated primary caregiver) who has been diagnosed with a “debilitating medical condition”(DMC), who has written documentation from his/her attending physician that the medical use of marijuana may mitigate the symptoms or effects of that person’s medical condition, and who meets and fulfills various other requirements, for the purpose of exempting that person (and his/her designated primary caregiver) from criminal prosecution resulting from possessing, producing (growing), or using marijuana for medical purposes. (NOTE: see *Appendix A* for relevant sections of this statute.)

The Act defines “debilitating medical condition” as any one of three conditions (cancer, glaucoma, or positive status for HIV or AIDS) or the treatment of any of these conditions, as well as any other medical condition or its treatment that produces, for a specific patient, one or more specified sequellae (cachexia, severe pain, severe nausea, seizures, or persistent muscle spasms). The OMMA further specifies that any other medical condition or treatment for a medical condition or its treatment may be added to the definition of a DMC if it is adopted by OHD by rule or approved by OHD by rule pursuant to a petition for such inclusion submitted by any person. Pursuant to and consistent with Oregon Administrative Procedures, OHD promulgated and filed Administrative Rules (OAR 333-008-090) on April 29, 1999 for reviewing and acting on such petitions. (NOTE: see *Appendix B* for OAR 333-008-090).

As of mid-January 2000, OHD had received 9 petitions requesting that 8 conditions be added to the list of DMCs; all 8 of these are psychiatric in nature: schizophrenia, schizo-affective disorder, bipolar disorder, anxiety disorder (with depression), post traumatic stress disorder [2 petitions], insomnia/sleep disorder with anxiety, attention deficit disorder, and agitation/anxiety accompanying Alzheimer’s Disease. (NOTE: *Appendix C* contains the petitions and accompanying material submitted by petitioner: this Appendix is **Confidential**.)

In mid-January 2000, OHD contracted with the Oregon Health Policy Institute (OHPI) to assist the Division (1) by fleshing out and developing procedures and protocols for its promulgated Administrative Rules for reviewing petitions to add specific medical conditions to the list of DMCs, (2) by convening an expert panel to advise OHD on these petitions pursuant to the Division’s Rules, (3) by managing and facilitating the work of this panel, and (4) by delivering a report to the Division containing the panel members’ advice and recommendations regarding these 9 petitions in order to assist the Division’s in reaching its final determination to add or not add any of the petitioned-for conditions to the list of DMCs under the OMMA.

Process and Protocol

The contract with OHPI directed it to develop a process and protocol for OHD's review and approval that would (a) guide the expert panel's work, (b) bring relevant available science-based and other valid evidence to the panel for its review, (c) encourage a comprehensive and objective review and evaluation of that evidence, and (d) help assure that panel members based their recommendations regarding adding or not adding a petitioned-for condition to the list of DMCs on their individual evaluation of that evidence.

Based on OHD's directive, OHPI prepared a draft written *Charge* to the expert panel along with additional written materials that outlined a protocol for the panel to follow in carrying out that *Charge*. This material was designed to guide the panel's work and help assure that the panel would provide the Division with the advice and recommendations called for in its Rules and needed by it to make an informed final determination regarding adding or not adding the any of the petitioned-for conditions to the list of DMCs. The State Health Officer/Deputy Administrator of the Division, and the Manager of the Division's Medical Marijuana Program, both reviewed and approved this material for distribution to and use with the panel.

In addition to the written *Charge*, this protocol included a statement of the Duties and Responsibilities of panel members; a list of the intended/desired outcomes to be achieved through the medical use of marijuana (to guide the panel's review of evidence regarding what is known of the impact of marijuana in treating each of the petitioned-for conditions); a set of 6 explicit evaluation criteria (to guide the panel's evaluation of that evidence and to help panel members to decide whether to recommend adding or not adding a petitioned-for condition to the list of DMCs); a grading scheme based on those used by U.S. Preventive Services Task Force and the Agency for Health Care Policy and Research [now the Agency for Healthcare Quality and Research] (to guide the panel's evaluation of the quality of the evidence and the strength of the recommendations that could be made based on that evidence); a worksheet for each panel member to individually fill out for each of the petitioned-for conditions (to guide panel members' written work and help assure comparability and completeness of each member's advice and recommendations); and guidelines for presenting testimony to the panel (to guide petitioners who had a right to address the panel regarding their petitions as well as to guide others who were invited to provide testimony). **[NOTE:** these materials are appended to this report as part of the minutes of the panel's first meeting on February 14, 2000; see ***Appendix D*** for meeting minutes.]

The expert panel consisted of 7 members appointed pursuant to the Division's Administrative Rules which set forth the composition of such panels (OAR 333-008-090(4), which states in part that "*the Division shall appoint an expert panel of five to seven individuals to review a petition. The members of the panel shall include the State Health Officer or designee, other physicians licensed under ORS 677, at least one patient, at least one patient advocate, and other professionals knowledgeable about the condition being considered.*") Since all 8 petitioned-for conditions were psychiatric in nature, the Division decided that one panel could be appointed to review them all. Working with the Manager of the Division's Medical Marijuana Program, OHPI identified panel members selected on the basis of their expertise, interest, experience with similar processes and/or familiarity with the issues involved. The Division reviewed these selections and approved them.

The 7 panel members included 4 licensed physicians (one of whom was the State Health Officer's designee, one of whom is a psychiatrist practicing at OHSU, one of whom is an internist who was active in the medical marijuana ballot initiative, and one of whom is an internist and medical director of the Health Services Commission and the Office for Oregon Health Plan Policy and Research); one registered nurse who has worked with medical marijuana patients and psychiatric patients; one patient who was granted a medical marijuana card for use in treating symptoms of multiple sclerosis and who was a chief petitioner for the ballot measure; and one patient advocate from *Oregonians for Medical Rights* which was also active in the ballot initiative. In addition, a second nurse (who is a psychiatric nurse practitioner interested in the medicinal uses of marijuana) was invited to participate in the panel process and to serve as an unofficial *ad hoc* alternate member.

The panel met 3 times between February 14, 2000 and March 27, 2000; minutes of each meeting are appended to this report (**NOTE:** see *Appendix D*). In addition, a tape recording (unfortunately, of somewhat poor quality) was made of the second meeting on March 20, 2000 at which oral testimony was presented by petitioners and other invited participants; the 3 cassette tapes from that meeting are included in the packet of material submitted to OHD along with this report.

At its first meeting, the panel reviewed and accepted its *Charge* and the duties and responsibilities of members. The panel also reviewed, made minor revisions to, and then accepted the written protocol developed for its use. The State Health Officer was present at the beginning of this meeting to welcome members, thank them for their willingness to participate, remind them of the history and background of the process, and deliver the panel's *Charge* to them. He stated that although the Division will make the final determination on each of the 9 petitions, the panel's role is to advise and make recommendations to the Division regarding approval or denial. He then directed panel members to approach their task objectively and to base their advice and recommendations to the Division on the best scientific evidence available. He further explained that although the panel will review the available evidence as a group, each member is to individually provide his or her recommendations to the Division using the worksheet format in the panel's protocol.

The panel also discussed and accepted some general ground rules at this first meeting. Members agreed that the panel would direct its attention solely to reviewing evidence and making recommendations that bear on the petitions submitted to the Division and that the panel would not deliberate the content or the pros and cons of the OMMA in general. The Act and its provisions, as well as the Division's program for administering it, would be taken as given and would not be topics of discussion. In addition, members agreed that the OMMA permits persons to petition for, and directs the Division to rule on, adding a *condition* to the list of DMCs rather than petitioning for and ruling on granting a *petitioner* a card for the use of medical marijuana for the petitioned-for condition. Members thus agreed that they are not to review and evaluate a petition in terms of permitting the petitioner to be granted a card, but rather in terms of whether or not to add the condition. The review of evidence and the recommendation made to the Division must address the condition rather than the petitioner, and must take account of the safety and efficacy - and the relative benefits and risks - of treating the condition with medical marijuana rather than relying solely on the individual perceptions of the relative benefits and

risks experienced and reported by the petitioner or on the petitioner's particular circumstances. Finally, members agreed on what kind of evidence the panel would review and evaluate as a group and on which each member would base his/her advice and recommendations to OHD.

Evidence was collected which evaluated the medical use of marijuana for each of the petitioned-for conditions as well as for psychiatric conditions in general. This evidence included published research (from the peer-reviewed medical and scientific literature as well as from other sources), published or copyrighted research reviews, government agency reviews (most notably by committees appointed by the Institute of Medicine and the National Institutes of Health), unpublished research and reviews, and personal communications to panel members from clinicians and researchers. All of this evidence was distributed to all panel members for their review. A numbered copy of each of the 9 petitioners' petitions was also distributed to each member at the panel's first meeting. Members were directed to maintain petitioner confidentiality and to return their copies of the petitions at the end of the panel's process. **(NOTE: All evidence reviewed by the panel is appended to this report as *Appendix E* for review by the Division.)**

As part of its review of evidence, the panel heard oral testimony and received written testimony from experts identified by panel members or the Division. The panel also heard from 8 of the 9 petitioners who wished to exercise their right under the Division's Administrative Rules to address the panel [OAR 333-008-0090(4)(a)]; 5 did so in person and 3 did so by telephone during the panel's second meeting. **(NOTE: All written testimony received and reviewed by the panel is appended to this report as *Appendix F*; in addition, cassette tape recordings of all oral testimony accompanies this report for review by the Division.)**

For each petitioned-for condition, each member reviewed the entire packet of evidence, including the actual petition and any oral or written testimony bearing on that petition, and evaluated that evidence in light of the panel's *Charge* and the grading scheme that was part of the panel's protocol. Each member then decided for him/herself which evidence was most compelling, used that evidence to evaluate the petition against the set of evaluation criteria in the panel's protocol, and then completed a worksheet for that condition outlining the reasoning that led to his/her recommendation to add or not add that condition to the list of DMCs and documenting the evidence and rationale that he/she used to arrive at that recommendation. During the panel's third and final meeting, members presented, discussed and answered each other's questions about their individual findings and recommendations for each of the 8 petitioned-for conditions. Following this meeting, each member was given a day and a half to review and possibly revise his/her worksheets in light of other member's findings and recommendations, and then to submit their finalized worksheets for compilation into this final report.

Advice and Recommendations

Rather than attempting to characterize or summarize in any detail the various recommendations of each of the 7 panel members for each of the 8 petitioned-for conditions, along with the reasoning and rationale behind them, members are being allowed to "speak for themselves" through the worksheets they each submitted and which are appended verbatim to this report, unedited and in their entirety **(NOTE: see *Appendix G*)**. A general summary of the individual recommendations is presented in the Table below. Several observations on this set of

recommendations, designed to assist the Division to better understand and more effectively use them in reaching its final determinations on the petitions, then follow.

Panel Member Recommendations (and Strength of Recommendations) for Each Petition to Add [Yes/as Disease or Symptom] or Not Add [No] a Condition to the List of Debilitating Medical Conditions

PETITIONED-FOR CONDITION	PANEL MEMBER ^(*)							
	Rick Bayer, MD	Joshua Boverman, MD	Ed Glick, RN	Teresa Keane, PMHNP	Amy Klare	Martin Lahr, MD	Stormy Ray	Kathy Weaver, MD
Schizophrenia	No (Strong)	No (Weak)	Yes/D	No (Weak)	No (Weak)	No (Strong)	Yes	No (Strong)
Schizo-Affective Disorder	No (Strong)	No (Weak)	Yes/D	No (Weak)	No (Weak)	No (Strong)	Yes	No (Strong)
Bipolar Disorder	Yes/S (Weak)	No (Inc)	Yes/D	Yes/D&S (Strong)	Yes/S	No (Inc)	Yes	No (Strong)
Anxiety (with Depression ⁽⁺⁾)	Yes/S (Strong)	No (Inc)	Yes/D	Yes/D&S (Strong)	Yes/D (Strong)	No (Inc)	Yes	No (Strong)
Post Traumatic Stress Disorder	No (Weak)	No (Inc)	Yes/D	Yes/D (Strong)	Yes/D (Strong)	No (Inc)	Yes	No (Strong)
Insomnia (with Anxiety)	Covered under Anxiety	No (Inc)	Yes/D	Yes/D&S (Strong)	Yes (Strong)	No (Inc)	Yes	No (Strong)
Attention Deficit Disorder	No	No (Inc)	Yes/D	Yes/D (Weak)	Yes/D (Strong)	No (Inc)	Yes	No (Strong)
Agitation of Alzheimer's Disease	AD - No Agitation Yes/S	No (Inc)	Yes/D & S	Yes/S (Weak)	Yes/D (Strong)	Yes/D (Weak)	Yes	No (Strong)

(*) Teresa Keane, PMHNP, participated in the panel's process and served as an unofficial alternate member.

(+) Dr. Bayer broke anxiety with depression into 2 separate conditions and completed a separate worksheet for each one. His recommendation for depression is Yes/S (Strong).

These recommendations cannot be properly understood or used without a careful reading of the worksheets which document how they were arrived at and how the individual panel members sees them being applied. The Division is advised to carefully read each worksheet (including any general statements that accompany an individual member's worksheets), taking into account the evidence on which individual recommendations are based (and the quality of that evidence), how that evidence was evaluated and applied, if any opposing evidence (and the quality of that evidence) was omitted in reaching a recommendation, the stated rationale for a recommendation (which may or may not be based on the evidence), any caveats, conditions, or suggested practice guidelines (and the extent to which they can be implemented and enforced) that accompany the recommendations, and the extent to which the worksheet of any given member appears to be a repeat or copy of another member's work. The Division should also note that the wording of Criterion 6 in Section II of the worksheet was changed from the negative to the positive by *some but not all* members (based on discussion at the panel's third meeting); the individual wording of this criterion must be read carefully on any given worksheet in order to properly interpret how it was scored and any accompanying written commentary.

It should be noted that all members took the panel's task seriously and formulated their conclusions and recommendations based on their best understanding and evaluation of the available evidence, but that different members understood and evaluated that evidence differently - frequently being influenced by values and beliefs outside of the panel process. In many instances, different panel members relied on the same evidence to reach opposing conclusions and recommendations. This was due to the different ways in which individual members evaluated and interpreted the available evidence, or to the extent to which they went beyond the evidence and relied on values and beliefs in formulating their recommendations. For some members, the peer reviewed medical literature and expert testimony was most compelling, while for others petitioner testimony and anecdotal evidence from users of marijuana was most compelling, and for still others, other evidence or combinations of evidence proved most compelling. Clinician members tended to rely at least somewhat on their own clinical experience, but often reached opposing recommendations based on that experience and their interpretation of it. In some instances, an overriding belief in patient/physician autonomy or the need to protect patients from the criminal justice system outweighed all else.

Similarly, recommendations were all based on the same evaluation criteria, but these criteria were weighted differently by different members, with some considering evidence-based medical benefits and risks most heavily and others considering patient/petitioner subjective experience most heavily.

In sum, the panel process achieved what it was intended to achieve - to provide the Division not with a consensus of opinions but rather with a representative range of recommendations based on a review of a common set of evidence by 7 informed individuals who differentially approached, interpreted, evaluated, and applied that evidence. This process, then, is providing the Division with a view of the complexity and nuances of the decision it must make regarding approving or denying each of the 9 petitions it received, and of ruling to add or not add one or more of the 8 petitioned-for conditions to the list of "debilitating medical conditions" under the Oregon Medical Marijuana Act. It is now within the Division's hands to review the material accompanying this report and to reach its final determinations.