

## **MEDICAL UPDATE MEMO NOVEMBER 24, 2003**

### **RESULTS FROM TWO STUDIES OF MARIJUANA AND MULTIPLE SCLEROSIS**

#### **SUMMARY**

Two recent studies – one conducted in Great Britain and one in Canada – provide new information about the possible effectiveness of marijuana or its derivatives as a treatment for MS symptoms.

- The British study involved 657 people with MS. For 13 weeks, participants received either cannabis oil, synthetic tetrahydrocannabinol (THC, the active ingredient in marijuana) or inactive placebo. Following the treatment period, those on active treatment had no objective improvement in muscle spasticity as measured by a standardized scale. However, treated participants reported improvements in walking speed, another measure of spasticity, and symptoms of spasticity, muscle spasms, sleep and pain.
- The Canadian study investigated marijuana use among people living in southern Alberta. Researchers mailed questionnaires to 780 adults with MS registered with the MS Clinic in Calgary. Of the 420 who responded, 43 percent reported they had used marijuana at some point in their lives, not necessarily related to MS. However, 96 percent said they were aware that marijuana was potentially helpful for MS symptoms, and 72 percent said it should be legal for people to use medicinally. The most common reason for not using marijuana was its illegal status.

#### **DETAILS**

##### **British Study – Cannabinoids for treatment of spasticity and other symptoms related to multiple sclerosis**

The results from the largest clinical trial of marijuana derivatives for the treatment of MS symptoms was published in *The Lancet*, Nov. 8, 2003. The study involved 657 people with MS at 33 clinical centres across the United Kingdom of Great Britain and Northern Ireland. For a 13 week period, participants received either cannabis oil, synthetic tetrahydrocannabinol (THC, the active ingredient in marijuana) or inactive placebo. All substances were taken orally (by mouth). The study was double-blinded so neither participants nor the examining physicians knew who was receiving which treatment.

The primary outcome was the measurement of muscle spasticity as assessed by the standardized Ashworth scale. Secondary outcomes were mobility and participant perception of symptom improvement including irritability, depression, tiredness, muscle stiffness, tremor, pain, sleep, muscle spasms, energy levels and bladder function.

## **Results**

Data was obtained from 630 participants. There was no objective evidence of a treatment effect on muscle spasticity, the primary outcome of the study, using the standardized Ashworth scale. The Ashworth scale, a 5-point scale, measures restriction of movement in specific muscle groups and has been widely used in prior studies of spasticity and its treatment, however, it is known to measure only one aspect of spasticity. At the end of the study, physicians asked participants to rate their own sense of whether the agent they had taken had improved their symptoms. Significantly more participants taking either cannabis oil or THC reported subjective improvements in spasticity, spasms, sleep and pain, but not tremor or bladder symptoms.

Among secondary outcomes studied was the time it took to walk 10 metres. Walking times before and during treatment were obtained from 278 participants; there was a reduction in walking time by 12% in the group taking THC, compared to a reduction of 4% in both the cannabis oil and placebo groups. This difference was statistically significant. There was no improvement on another mobility test.

There were serious adverse events in all three groups: 20 in the placebo group, 18 in the THC group and 12 in the cannabis oil group. More episodes of dizziness/ light-headedness, dry mouth, and gastrointestinal symptoms occurred in the treatment groups.

The investigators also noted there were fewer relapses in the treatment groups. Of the nine MS relapses that occurred during the study period, seven were in the placebo group and one each in the treatment groups. However, the study was not designed to investigate impact on relapses so no conclusions can be drawn from this finding.

## **Canadian Study – Cannabis Use as Described by People with Multiple Sclerosis**

In the Canadian study, researchers at the MS Clinic, University of Calgary, researchers mailed questionnaires to 780 adults in southern Alberta who were registered with the clinic. A total of 480 people (62 percent) completed the questionnaire. Mean sample age was 48 years and 75 percent were women. They level of disability ranged from mildly to severely impaired. The study was reported in *The Canadian Journal of Neurological Sciences*, August 2003. It was funded by the MS Society of Canada.

## **Results**

While 72 percent of respondents said it should be legal to use marijuana for medical use and 96 percent were aware that it might potentially be useful as a treatment, just 43 percent reported having used marijuana. Not all of that use was for medical purposes. For those who had not tried marijuana, 64 percent were concerned that it is illegal, 34 percent were concerned about side effects, 34 percent lacked knowledge of how to obtain it and 24 percent didn't believe it would help symptoms. (Responses add up to more than 100 percent since more than one answer was permitted.)

Of the 176 people who had tried marijuana, 35 percent said it was to help relieve MS symptoms. Sixty-four percent of these were currently using marijuana. Symptoms perceived to be relieved were anxiety/depression (67 percent), spasticity (58 percent), chronic pain (49 percent) and fatigue (40 percent). Of those using marijuana, 54 percent said they felt much better and 39 percent said they felt a little better. As with the British study, fewer said they had experienced improvement in bladder problems.

Of those who had stopped, they mentioned cost, dislike of side effects, legal concerns and lack of effectiveness.

## **Summary**

The British study is the largest examination on the effect of marijuana extracts on MS symptoms. It shows that the oral derivatives of marijuana do not provide objective measures of improvement related to spasticity. However, both the British clinical trial and the Canadian survey, support previous observations by people with MS that marijuana does result in subjective improvements that could not be measured by physicians.

Both research groups noted the dangers of smoked marijuana because of the risk associating with inhaling potentially dangerous substances in the smoke. Commenting in an editorial in *The Lancet* that accompanied the British marijuana research study, Drs. Luanne Metz and Stacey Pace, both involved in the Canadian research, stated:

“Hopefully [this]...study will stimulate further research to develop safe and effective formulation of cannabis, and will inform debate over the social and legal restrictions that limit its use. In the meantime when other treatment inadequately controls spasticity, oral cannabinoids should be considered where law permits their possession and use.”

## **Legal Status in Canada**

In Canada, federal government regulations allow people with certain illnesses including MS to apply for permits to possess and/or grow marijuana for personal medical purposes

or to designate another person to grow it for the person who has the permit. All usages must be prescribed by physicians. Details about how to apply for permits are available at [www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm](http://www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm) Information is also available by calling the Health Canada Cannabis Medical Access Office toll-free: 1-866-337-7705 or 613 954-6540.

In July 2003, federal Minister of Health Anne McLellan announced an interim policy to allow Health Canada to provide dried marijuana and/or marijuana seeds to individuals holding federal permits. This decision was in response to complaints by some permit holders that they were not able to access marijuana. The product and seeds will come from Prairie Plant Systems Inc., the company currently under contract with Health Canada to produce marijuana for clinical trials. Details about how to apply for dried marijuana and/or marijuana seeds are available at [www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm](http://www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm) Information is also available by calling the Health Canada Cannabis Medical Access Office toll-free: 1-866-337-7705 or 613 954-6540.

Some physician organizations have advised their members not to prescribe marijuana because of the lack of information about optimum prescribing and potential legal issues. It is not yet clear if these recommendations will change with respect to oral cannabis given the results of the *Lancet* study.

Individuals interested in the medical use of marijuana should speak to their own physicians or contact Health Canada.

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