

Final Application



FACULTY OF MEDICINE

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March 30, 1999

Dr. R. J. Fessenden
President, Alberta Science and Research Authority
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Post-it Fax Note 7571E
To: Dr. Fessenden
From: B. Kaplan
Phone #: 403-229-7365
Fax #: 403-543-9100

Dear Dr. Fessenden:

Science and Research Fund Proposal for the Nutraceutical Treatment of Mental Disorders

Thank you for being willing to consider a revision of the above-named proposal. This letter is being FAXed, along with the attachment from Melaleuca (because I have only a hardcopy of the attachment); however, the text of the proposal and the budget are being sent by email to Bill MacDonald.

Four specific items were mentioned in Bill MacDonald's March 4 letter:

- We have responded to the comments from the independent reviewers. A summary of the resulting changes is on the first page of the text, so I will not repeat them all here.
The request is now for only one trial, a sort of pilot study for this entire endeavour. Please note that the revised budget is a bit more than 1/3 of the previous budget for three trials. This is simply because there is a certain economy of scale that means that three trials would have been less expensive than three times a single trial. Also, we note that the current budget is still somewhat modest. Apparently pharmaceutical companies routinely budget \$10-15,000 per patient when doing a clinical trial on psychosis. Since our proposed sample consists of 96 patients...
We were also asked about ethics approval. The University of Calgary's Conjoint Health Research Ethics Board has taken the position that it does not want to review protocols until they are funded. Exceptions can be made if the potential funding agency requires it (as some U.S. agencies do). We saw no need to request exemption from their rule, however. For instance, in the enclosed revision we mention that the Health Research Fund of AHFMR has just funded the clinical trial of the Melaleuca supplements in the treatment of fibromyalgia; consequently, this

month we are finalizing our consent form, etc., and submitting the protocol to the Conjoint Health Research Ethics Board. This is the normal sequence, and we would prefer to follow it.



I look forward to hearing from you regarding our proposal.

Sincerely,

*Bonnie Kaplan*  
Bonnie J. Kaplan, Ph.D.