

**UNIVERSITY OF
CALGARY****VICE-PRESIDENT (RESEARCH)**

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September 17, 2001

Mr. Marvin Ross
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Dear Mr. Ross:

I wish to take this opportunity to address questions you raised in an August 27 email regarding research being conducted at the University of Calgary. Since there is some overlap with questions raised in letters sent to Dr. D. Kaplan and Dr. D. Addington, this letter will respond to all three inquiries.

In the field of mental health, Dr. Kaplan has conducted two open label studies, and currently is conducting one randomized controlled clinical trial. The fibromyalgia study to which you refer is being conducted by a rheumatologist at the University of Calgary. No presentations of the results of the latter study have occurred because the study is not yet complete. None of the studies referred to above focus on ADHD.

All of the studies referred to above were approved by the University of Calgary's Conjoint Health Research Ethics Board. The study in which Dr. Catherine Field of the University of Alberta is involved was approved by the research ethics committee at the University of Alberta on February 8, 2000.

The supplements used in these studies were evaluated in a number of instances prior to the research being undertaken. First, the Ethics Committee reviews the contents of the supplements for safety concerns. Second, Dr. Kaplan received reviews of the supplements undertaken by Dr. Catherine Field, a nutrition researcher at the University of Alberta. Third, the nature of the supplements were known by the independent reviewers used by the Alberta Science and Research Authority to assess the application for funding for the randomized controlled clinical trial. The purpose of the study, of course, is to assess the efficacy of this treatment.

Health Canada advised at the outset of the studies that neither an IND application nor a DIN was necessary to undertake this research.

The supplements are manufactured by Cornerstone Nutritional Laboratories for Evince International. This manufacturer was selected because they could guarantee a reliable and consistent supply of supplements, a condition that is necessary for this research. Cornerstone is one of the largest contract manufacturers of nutritional supplements in North America. Please contact Cornerstone directly for further particulars.

The University of Calgary has no proprietary interest nor intellectual property rights in the supplement. The supplements used in the study have been donated for the research study. Please contact Synergy directly for further information regarding their business interests and a list of products in which they have an interest.

Dr. Kaplan advises that her interest in this study arose from earlier research on nutrition-behaviour interactions, which has been published in peer-reviewed journals. All such publications are publicly available.

Regarding your question of whether Dr. Kaplan's interest in studying the supplements was triggered by a family member taking them, I am advised that you were misinformed by other sources on this matter. Furthermore, this is not a matter for public discussion.

There has been significant public interest in Dr. Kaplan's research. Her office is not equipped to handle the volume of inquiries received. Many of the people who contacted her office were not eligible to participate in this study. Dr. Kaplan advises that in all cases, it has been recommended that those with an interest in this supplement discuss it with their physician. Furthermore, Dr. Kaplan advises that in no instance have individuals not involved in the research studies been advised or encouraged to use the supplement independent of the advice of their physician. As to the name of the company providing and/or distributing the supplements, this is, of course, public information.

Generally we do not initiate communications with the public or the media until manuscripts have been published. An exception to this is when preliminary results of research are presented at conferences organized by scholarly societies or organizations. While such conferences are attended primarily by members of the scholarly community, they also may be open to members of the public and/or members of the media. This provides the possibility that preliminary research results may receive dissemination beyond the conference participants. The instance to which you refer occurred when a member of the Reuters news agency attended a conference at which Dr. Kaplan reported on the results of her research, and in which Reuters subsequently published a story on the research. We are advised by Dr. Kaplan that she was misquoted in this story. Furthermore, Dr. Kaplan has adopted the practice of corresponding in writing to requests for comments on her research, whenever possible.

As I interpret your comments regarding the Nobel Prize, it is not stated that a member of our faculty has been nominated for a Nobel Prize; rather, that a third party has expressed an opinion that a porcine model of human bipolar disorder might be of significance.

Dr. Kaplan has collaborated with researchers at other institutions on several of these projects. Collaborators include Dr. Catherine Field from the University of Alberta and Dr. Bryan Kolb of the University of Lethbridge. They were involved in the development of one of the Protocols and Dr. Field continues to be involved in aspects of the randomized controlled clinical trial. A psychiatrist on faculty at Harvard University currently has patients in his clinical practice who are using the supplements, and he is sharing data from this experience with Dr. Kaplan.

In order to respond to your questions, we consulted with a number of individuals at the University. I appreciate your patience in allowing us to respond as completely as possible to your questions.

Sincerely,



Keith Archer, Ph.D.
Interim Vice-President (Research)

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Cc: Dr. B. Kaplan, Professor, Department of Pediatrics, U of C and Alberta Children's Hospital