



Schizophrenia Society of Ontario

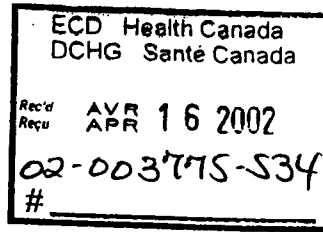
Société de schizophrénie de l'Ontario

Formerly: Ontario Friends of Schizophrenics (OFOS)

Charitable Reg: 0549444-11 • BN: 12990 4058 RR
Honorary Patron: Lincoln M. Alexander
Past Lieutenant Governor

April 8, 2002

The Honourable Anne McLellan
Minister of Health
Brooke Claxton Bldg.
Tunnéy's Pasture
P.L. 0906C
Ottawa, Ontario
K1A 0K9



RE: Schizophrenia Society of Ontario
Report on EM Power + supplement

Dear Minister,

Attached you will find a report commissioned by the Schizophrenia Society of Ontario. Many of our members have been negatively affected by this supplement. We as an organization are extremely concerned that individuals and families living with Schizophrenia have the appropriate information and treatment. We are concerned that the EM Power + supplement may compromise the well being of individuals with Schizophrenia.

We urge you to review this report and would like to request a meeting with you to further discuss our concerns.

Please contact our Executive Director, Mary Alberti at your earliest convenience. If you require further information please do not hesitate to let us be of assistance in this matter.

Sincerely,

Len Wall

Board President

Mary Alberti

Executive Director

CC: Tony Clement, Ontario Minister of Health
Gary G. Mar, Alberta Minister of Health

cc: MD
COM
DMD
EDT

Compassion Through Understanding



Schizophrenia Society of Ontario

Report by the Schizophrenia Society of Ontario on the
Vitamin Supplement

"EM Power +"

Prepared
March, 2002

Report by the SSO on the Vitamin Supplement "EM Power +"

In the Fall of 2000, our current President, Mr. Len Wall, became aware of a sales effort targeting people with schizophrenia and other serious psychiatric disorders. This scheme involved the sale of very expensive vitamin supplements that are claimed to be a cure for many psychiatric disorders, as well as Multiple Sclerosis and Fibromyalgia. Mr. Wall received information that people were being persuaded to take up to 32 capsules a day and advised to go off their psychiatric medications, while being supervised by lay assistants with no medical training.

Mr. Wall warned members of the Schizophrenia Society of Ontario (SSO) about the possible dangers of this marketing scheme and one of our members, Mr. Marvin Ross, who is a medical journalist, began to investigate this issue. With the help of a few other interested people, he documented numerous adverse reactions, hospitalizations, and suicide attempts as the result of the marketing of this product throughout North America. Consequently the SSO decided to have the pills analysed for safety.

For the benefit and protection of our members as well as the concerned general public, we are presenting a brief summary of the results of the analysis we commissioned and the findings of the investigation by Mr. Ross in this report.

What We Learned

Throughout North America, including in Canada, people suffering from various mental illnesses as well as Multiple Sclerosis and Fibromyalgia are being sold a very expensive vitamin and mineral supplement called "EM Power +". The consumers of this product are also advised to abandon their regular medications, on the basis of the argument that there is an adverse reaction between the supplements and the prescribed medication. The pills are manufactured in a laboratory in Utah.

The supplement was being studied for both safety and efficacy at the University of Calgary with funding from the Alberta government. However, due to numerous concerns Health Canada stopped the study at the end of December, 2001. The supplement itself has not been approved by Health Canada as an Investigational New Drug nor does it have a Drug Identification Number (DIN). An evaluation of the ingredients in the supplement was done before the Calgary study that began and it cautioned against the use of this supplement with pregnant women. Women who were pregnant or who might become pregnant were therefore excluded from the study

Despite that initial evaluation and the halting of the research study, the supplements are still being sold to the public.

According to the laboratory analysis commissioned by the SSO, this supplement contains 36 ingredients in very high doses. Some of these doses may approach levels of toxicity and 9 of them exceed the tolerable upper intake levels (a measure of the highest amount that can be taken without fear of toxicity for almost everyone) as recently established by a team of US and Canadian scientists. One of the ingredients (Boron) is banned for sale in Canada

The laboratory analysis also revealed significant variances for many of the ingredients between what is actually in the pills and what is stated on the label. For 16 of the 23 ingredients that the laboratory analysis was able to quantify (70% of the total number of ingredients), the variance is greater than + or - 10%, ranging from - 25% to + 70%.

The vitamin supplement "EM Power +" which is being sold to consumers and used in current studies at the University of Calgary is manufactured by Evince International LLC of Farmington, Utah. This company was not incorporated until December 19, 1999; its stated business purposes are producing, marketing, and distributing supplements and investing in real estate.

The trademark of "EM Power +" was registered in the United States on November 29, 1999; the trademark registration states that the product has been commercially available in the US since April 1, 1999. The trademark application for the name in Canada was not filed until May 16, 2001; the application states that it was not used in Canada prior to March 6, 2000.

In Canada this supplement is sold by the Synergy Group of Canada (a for-profit company engaged in the sale of water coolers) who also call themselves the Truehope Institute and, lately, Truehope Nutritional Support Ltd is selling this supplement. On October 29, 2001, the principals of Synergy incorporated Truehope Nutritional Support Ltd as a private non-profit firm with two directors. The two principals are David Hardy, a former animal feed mixer and vitamin/mineral salesman for livestock, and Tony Stephan, a former bankrupt property manager.

The promotional materials from the Canadian marketing of "EM Power +" describe it as a product derived from successful experiments with nutritional supplements used in pig farming. Since under Alberta law private non-profits are set up to promote something, it appears that the non-profit company Truehope is set up to promote the use of vitamins and minerals in the treatment of psychiatric disorders and to support the marketing of "EM Power +" through the for-profit company Synergy.

Claims about the safety of "EM Power +" for use in experimental studies currently being conducted at the University of Calgary are based on results of earlier studies that date back to 1998. However investigation indicates that the results of these earlier studies were not conclusive with regards to efficacy, and as well it is not clear at all that the composition of the nutritional supplement marketed as "EM Power +" is the same as the product tested in these earlier studies.

Furthermore, that 1998 study was never published and the University of Calgary refuses to provide a copy of the study or the informed consents given to the participants even when requested to under the Freedom of Information law.

Our Conclusions and Concerns

First of all we must make clear that any scheme that encourages going off prescribed medications is highly dangerous. We must emphasize that encouraging people with severe psychiatric disorders to go off medications can have severe negative effects. Furthermore it is not clear that people are doing so with the approval of their doctor.

Secondly the SSO is extremely concerned about the potential dangers of the use of this product, given the information we have gathered about adverse reactions to date as well as the results of the commissioned lab tests. Moreover, we must note that any claim that animals exhibit nervous disorders similar to human psychiatric disorders which can be cured with vitamins and minerals is not proven. Nor is there even such a theory proven in veterinary science.

Thirdly we question the legality of the sale in Canada of this product which has not been approved by Health Canada as an Investigational New Drug and does not have a Drug Identification Number (DIN). Based on our investigation, we are not convinced at all that the safety of the product has established scientifically.

Fourthly we must also express our grave concern as to whether the participants in the current experimental studies on this product at the University of Calgary involve true informed consent for the participants, in consideration of the lack of clear documentation for the safety of the product being tested. From a moral and ethical perspective, it is essential that psychiatric patients not be recruited into experiments without being provided with sufficient evidence to properly weigh the consequences of their participation. To act otherwise is in violation of the internationally recognized ethics of conducting human research to which Canada subscribes.

Given the vital and immediate consequences of the marketing of "EM Power +" for the well-being of our members as well as the general issues raised by our

analysis and investigation, SSO will continue to monitor the evidence and provide updates as relevant information becomes available.