MAYO CLINIC

ORIGINAL

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Brent A. Bauer, M.D.
Director, Complementary and
Integrative Medicine Program
Mayo Clinic
Baldwin 4
(507) 284-8913 Fax (507) 284-5370
bauer.brent@mayo.edu

March 7, 2005

FTC
Office of the Secretary
Room H-159
600 Pennsylvania Avenue NW
Washington, DC 20580

RE: Request for public comment regarding consent agreement with Hi-Health Corporation

Dear Sir or Madam:

I am responding to the request for public comment regarding the consent agreement with Hi-Health. As Director of the Complementary and Integrative Medicine Program at Mayo Clinic, I am keenly aware of the need to bring evidence-based information to the marketplace to enable consumers to make informed decisions about dietary supplement purchases. I proposed in a letter to Mr. Chalpin in October 2004 (see attached) that consideration might be given to applying any awards paid by Hi-Health to establish a fund to enable a qualified academic center to help provide guidance regarding claims for dietary supplements. Such a move would provide consistency and accuracy for judging such claims, providing a service to the FTC, manufacturers, and consumers..

Thus, I am writing to suggest that consideration be given to directing funds resulting from this settlement to support a process whereby existing scientific studies can be evaluated in a critical and rigorous fashion. The goal will be to provide clarity in what constitutes legitimate claims for specific supplements. Claims data would be rated according to the amount and quality of evidence available for each given dietary supplement and each purported use. Creation of such a systematized approach to this complex realm seems to me to be an excellent way to bring the resources of industry, the FTC, and academic medicine to bear on a common challenge.

I would be most happy to see the Mayo Clinic Complementary and Integrative Medicine Program be considered as a potential participant, should such an endeavor be undertaken.

I appreciate the opportunity to share my thoughts on this important topic.

Sincerely,

Brent A. Bauer, M.D.

BAB/jsc

Brent A. Bauer, M.D.
Director, Complementary and
Integrative Medicine Program
Mayo Clinic
Baldwin 4
(507) 284-8913 Fax (507) 284-5370
bauer.brent@mayo.edu

March 7, 2005

Mr. Sy Chalpin
CEO, Hi-Health
7428 East Karen Drive
Scottsdale, AZ 85260

Dear Mr. Chalpin:

I have been giving some careful consideration to the recent issues you have shared with me regarding knowing which claims are appropriate for dietary supplements. It strikes me that your problem from a manufacturer/supplier standpoint is a problem also held by the FTC and by physicians wishing to counsel patients. From your standpoint, you have difficulty in knowing exactly what you can and cannot state regarding most dietary supplements. From the FTC perspective, I suspect they lack resources to comprehensively evaluate the literature in order to give a clear directive regarding use of any individual dietary supplement. And physicians are faced with patients wishing to know which supplements are safe and appropriate to incorporate into their daily health care practices, yet lack a simple and authoritative database to address such questions. Thus, dietary supplement manufacturers, the FTC, and conventional physicians all are in the same situation (i.e. needing unbiased, evidence-based, systematically reviewed evidence for individual dietary supplements).

To a small degree, this is what the Complementary and Integrative Medicine Program at Mayo Clinic has been attempting to address via ongoing clinical studies as well as through educational efforts. However, our efforts our hampered by the limited resources available to apply to evaluation of existing literature. Given more time, it would be a relatively straight forward approach to develop a systematic review process. Then, all existing literature regarding a given dietary supplement could be analyzed in a systematic fashion, with the results made public via an Internet site or some other mechanism as deemed appropriate by the FTC. Such a public resource would:

- provide patients with the information they need
- provide physicians with the information they need
- would give clear direction to manufacturers in terms of guidance regarding what they could and could not claim for a given product
- would enable the FTC to have a clear point of reference for their decisions regarding when claims have crossed the line beyond that which is substantiated.

I have been thinking of this in the context of what might be a beneficial outcome from your interactions with the FTC. Perhaps it would be possible to create a fund to finance the formal and systematic review as outlined above. This could be an ongoing research endeavor for the Mayo Clinic Complementary and Integrative Medicine Program which could perhaps be funded indefinitely through industry contributions, etc. I share this with you as a preliminary concept, but one which I would encourage you

to feel free to share with the FTC representatives you are meeting as well as other interested individuals. It appears to me to offer a tangible benefit to all parties concerned, with the patient/consumer the major beneficiary.

Sincerely,

Brent A. Bauer, M.D.

BAB/jsc