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Rep. Lynn Wachtmann, Chairman
Ohio House Health, Human Services and Aging Committee
77 S. High Street, 13th Floor
Columbus, Ohio 43215

Chairman Wachtmann and members of the House Health, Human Services and Aging Committee:

During the hearings on House Bill 259, an assertion was put forth that nutritional consultants could make “wild and gigantic claims” for herbs and supplements with no overseeing authority. This assertion was not answered during the hearings. I would like to take this opportunity to answer that assertion.

The claim is false. Here is why:

Cure and similar claims are forbidden by 2 Federal agencies

- A. The U.S. Food and Drug Administration (FDA) permits ONLY structure-function claims, i.e., informational claims regarding the nutritional support afforded to the body by a given supplement.
 1. You can't claim that you can cure or control diabetes with a dietary supplement. Such claims constitute what FDA calls New Drug claims, putting them under pharmaceutical regulations.
 2. You can claim to provide adequate nutritional support for the body in support of maintaining a healthy blood glucose level if there is a long-standing record of such use.
- B. Cure claims are also subject to Federal Trade Commission (FTC) action. NOTE: The FTC has been pressing such cases rather vigorously since the Dietary Supplement Health Education Act (DSHEA) was passed in 1994 to rein in FDA abuse of the supplement industry.
- C. Direct disease treatment and cure claims are already covered by existing Ohio law, and are thus subject to proper regulatory scrutiny and action by various agencies.
 1. Anyone who is an unlicensed consultant that claims he/she can “treat” or “cure” any metabolic disorder is already:
 - a. Practicing medicine without a license, and/or
 - b. Practicing dietetics without a license
 2. If he/she claims that the “treatment” or “cure” can be done with a specific nutrient, herb, etc., that person is also dispensing a “New Drug” (see above) meaning he/she is practicing pharmacy without a license
- D. All “cure” and “treatment” claims are also subject to scrutiny by the Ohio Attorney General's Consumer Fraud Division based on the above.

Consultants are NOT asking to be allowed to treat disease with impunity. They ARE asking to be allowed to give advice to their clients about optimal nutrition for their individual bodily and dietary issues without being accused by overzealous regulatory agencies. Any diminution of disease condition as a result of the adoption of a healthier lifestyle is a side benefit and not the primary target.

Thank you for your consideration of the above, and for your consideration of House Bill 259. I look forward to the report of the successful passage of the bill from your committee.

Respectfully,

Charles Michaelis, President
Rocky Fork Formulas, Inc.