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Letter to the Editor

Note to Readers: The *Food and Drug Law Journal* welcomes responses to articles, and encourages dialogue and analysis from diverse perspectives.

Re: Response to Burnett B and Levy R, "Proposed Industry Best Practices in Development and Marketing of Medical Foods for the Management of Chronic Conditions and Diseases while Awaiting Regulation"

The undersigned organizations submit this letter in response to the article by Bruce Burnett and Robert Levy, "Proposed Industry Best Practices in Development and Marketing of Medical Foods for the Management of Chronic Conditions and Diseases while Awaiting Regulation," which appeared in Volume 72, Number 1 of the *Food and Drug Law Journal*. Given our concerns with the article, we request this alternative viewpoint be published in the next edition of the Journal.

The undersigned organizations represent producers of medical foods that have decades of experience researching, developing and marketing these products. Medical foods have helped countless patients manage complex conditions and remain nourished. Therefore, we were surprised to learn of the Burnett Levy article only after it was published in the *Food and Drug Law Journal*.

The article proposes best practices that claim to be representative of the broader medical foods industry, yet it appears that no other stakeholders were consulted when the article was developed. We are concerned that the authors' narrowly defined best practices and standards are not representative of broader medical foods industry practices or interpretation of the statute and existing guidance. We also question the scientific rigor of some of the proposed practices. Finally, we caution that adoption of the proposed best practices could restrict patient access to many existing medical foods products on which they rely.

While development of best practices for medical foods is worth further discussion as a broader industry, we believe this dialogue must include all stakeholders. Any best practices should be reflective of products that have been used by patients for decades and that are currently on the market. Development of industry best practices is, by definition, a collaborative process that requires the consolidation of a multitude of views and experiences to ensure the final product truly represents activities supported by the entire industry. We welcome the opportunity to work with the authors, other medical food producers and all relevant stakeholders on such an effort. It is vital that researchers, medical foods producers, regulators, patients and other stakeholders recognize that the authors' best practices outlined in this article are not representative of the majority of the medical foods industry.

Respectfully submitted by:

Council for Responsible Nutrition
Healthcare Nutrition Council
Infant Nutrition Council of America