

The Promise of Medical Foods in Age Management Medicine

Jeff Morris

Physicians, as well as most people in general, are undoubtedly aware of two categories of products over which the U.S. Food and Drug Administration (FDA) has regulatory authority: Drugs, and Dietary Supplements. But there is a third category of products regulated by the FDA, and perhaps the most amazing thing about this category is that the great majority of people—including most medical professionals—are not even aware that it exists. More surprising still is that this relative obscurity remains despite the fact that the FDA recognized the Medical Foods category back in 1972.

What are medical foods? They are defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." That one sentence is packed with meaning, identifying several key requirements that differentiate medical foods from both drugs and dietary supplements. Included in the Orphan Drug Amendments of 1988, Congress not only incorporated that definition by reference into the Nutrition Labeling and Education Act (P.L. 101-535) of 1990, but exempted medical foods from the nutrition labeling, health claim, and nutrient disclosure requirements applicable to most other foods. In order to further clarify the statutory definition of a medical food, the FDA issued these additional guidelines:

The following criteria that clarify the statutory definition of a medical food can be found in the agency's regulations at 21 CFR 101.9(j) (8). A food is a medical food exempt from nutrition labeling only if:

- a. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
- b. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
- c. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
- d. It is intended to be used under medical supervision; and

It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

At this point, Age Management Medicine practitioners may well wonder what relevance medical foods have to their practice—especially when the emphasis of Age Management Medicine is, in theory at least, a proactive approach to the prevention of disease, rather than treating the disease itself. To answer that question, we turned to the head of one of a number of specialty pharmaceutical companies that has developed medical foods for specific conditions. William Shell, M.D., is CEO of Physician Therapeutics, based in Los Angeles. The company provides a range of prescription medical food products and convenience packed medical foods that address the nutrient requirements of diseases including fibromyalgia, pain syndromes, sleep disorders, metabolic syndromes, hypertension, and asthma.

Dr. Shell points out that in addition to fully developed disease states, there are often disease precursors that are revealed through patient testing, which is even more likely with the comprehensive testing conducted by Age Management practitioners; and that such precursors may indicate conditions that would normally be of most concern in aging patients. For example, a product that is labeled "for the

dietary management of diabetes and pre-diabetic states,” or one that is designed for the dietary management of osteoarthritis and its precursors, would be especially helpful in an Age Management practice. The key is that a medical food must meet the distinctive nutritional requirements that have been determined, through scientific research, to exist when a particular medical condition is present. “We lay out the nutritional deficiencies associated with the disease,” says Dr. Shell. “That data has to exist for us to meet the requirements.” And, explains Dr. Shell, medical foods are not intended as a complete diet; “they are supposed to be a nutritional supplement to meet the nutritional requirement of a particular disease.”

It is important to note, however, that though the role of a medical food is as a nutritional supplement, there are distinct and extensive differences between those products that are classified by the FDA as Medical Foods and those products that fit into the FDA category Dietary Supplements. These are spelled out in the following chart:

Medical Food products are NOT Dietary Supplements. The following is a comparison of the differences between Medical Foods and Dietary Supplements

	MEDICAL FOODS	DIETARY SUPPLEMENTS
INTENDED USE	Nutritional or dietary management of a specific disease (e.g., sleep disorders).	To support the structure and function of normal, healthy physiology (e.g., maintain restful sleep).
SAFETY	Ingredients must be GRAS (Generally Recognized As Safe)	Ingredients are considered safe as evidenced by having been sold or widely used in the U.S. market prior to October, 1994.
CATEGORY OF USER	A patient who is under the care of a physician and has distinctive nutritional requirements of a specific disease as assessed by medical evaluation and determination.	Normal, healthy adult
EFFICACY & CLINICAL and/or SCIENTIFIC SUPPORT	The distinctive nutritional requirements of the specific disease and its response to the Medical Food product must be assessed by medical evaluation and determination.	No requirements for pre-market approval.
MEDICAL CARE	Must be used while the patient is under the ongoing care and supervision of a physician.	No requirements for medical care. Products are sold directly to consumers.

source: *Physician Therapeutics*

In addition, Medical Food products have distinct differences from Prescription Drugs:

Medical Food products are NOT Prescription Drugs. The following is a comparison of the differences between Medical Foods and Prescription Drugs

	MEDICAL FOODS	Rx DRUG
INTENDED USE	For the dietary management of the metabolic process of a specific disease	To cure, treat, prevent, or mitigate a specific disease or symptoms of disease.
SAFETY	Ingredients must be GRAS (Generally Recognized As Safe)	Drug ingredients do not have to be GRAS listed. All drugs must be pre-approved by FDA for safety
EFFICACY & CLINICAL and/or SCIENTIFIC SUPPORT	The distinctive nutritional requirements of the specific disease and its response to the Medical Food product must be assessed by medical evaluation and determination.	The efficacy and disease specific claims must be supported by clinical/scientific studies and pre-approved by the FDA
PRESCRIBING & DISPENSING	Must be used under a physician's supervision.	Must be used under a physician's supervision.
MANUFACTURING	FDA Good Manufacturing Practices for foods are required.	FDA Good Manufacturing Practices for drugs.

source: *Physician Therapeutics*

Here we get into something of a gray area, one that Dr. Shell would like to see clarified by the FDA. “You may not be aware of it,” he says, “but the large drug companies all have their own medical food divisions. However, they use the term Nutritional Supplement, because you can’t sell medical foods directly to consumers without having disease claims spelled out. They sell them in pharmacies, and the pharmacist essentially becomes the physician; these products are kept behind the counter, and the pharmacist will advise a customer to use them when asked about treating a particular condition. Because they are not

marketed for specific diseases, the FDA has looked the other way.” According to Dr. Shell, most of the medical foods sold by the big pharmaceutical companies bear the appellation “Under Medical Supervision” or “Under Physician Supervision”—but he thinks they should be under Rx-only supervision. “A physician would have to monitor the relationship between the product and other medications, and internal dietary absorption,” explains Dr. Shell. “That’s why we have added the Rx-only label to all our medical food products.”

A proponent of the use of medical foods is Derrick DeSilva, M.D., a member of the Medical Teaching Faculty at John F. Kennedy Medical Center in Edison, NJ, and Attending Physician at Raritan Bay Medical Center in Perth Amboy, NJ. “I have always believed there are very specific nutrient deficiencies with people in various disease states,” says Dr. DeSilva. “In my mind the nutritional deficiency may be contributing to the side effects of the disease, and the disease itself. These medical foods may be a solution to either the disease itself or to correct a nutritional deficiency caused by the medications used to treat the disease.” Adds Dr. DeSilva, “Elevated homocysteine levels and their relationship with heart disease and Alzheimer’s are all over the medical literature. Where does it come from? It could come from not eating the right foods, it could come from over the counter medications, it could come from prescription medications; it could be multi-factorial.” The bottom line, say Dr. DeSilva, is that “Medical foods come into play as part of a treatment protocol that should be used by people in treatment for various diseases. And, there’s a role for them in prevention as well.”

In a 2008 white paper, Palo Alto, CA-based consulting firm Frost & Sullivan spelled out some of the reasons to consider inclusion of medical foods in a disease treatment program:

- Most, if not all, illnesses are associated with underlying nutritional requirements, and meeting these distinctive nutritional needs associated with specific diseases is recognized as an essential therapeutic step.
- Many diseases have increased nutritional requirements that cannot be met by normal diet alone, or by merely altering the diet.
- The nutritional requirements of an individual in a disease state can be considerably different from those of a healthy individual; recognizing and managing these increased nutritional requirements should be an integral part of the medical management of clinical conditions.
- If a nutritional requirement of a disease is not met, a nutrient deficiency can develop. The consequences of a nutritional deficiency that has evolved over time can range from structural alterations in tissue to intracellular changes in biochemical function and structure.
- Increased nutritional requirements can be the result of inadequate ingestion of nutrients, malabsorption, impaired metabolism, loss of nutrients due to diarrhea, increased nutritional turnover rates inherent in certain disease states, or the impact of drug therapies.
- Many disease states are known to have disruptions in the metabolic process that alter neurotransmitter production; medical foods that modulate production of neurotransmitters in different disease states have been shown to deliver therapeutic benefits to the patients.

Perhaps the most compelling argument in favor of medical foods, as a benefit to both the patient’s health and overall state of mind, is the minimization of side effects. The products themselves have not been associated with any ill effects; Frost & Sullivan reports that in over 200,000 prescriptions for medical food products, some of which have been co-administered with pharmaceutical agents in the customary practice of medicine, no serious adverse drug events have been observed or reported. But more importantly, by addressing the underlying nutritional requirements of disease states, physicians can prescribe pharmaceutical agents at the lowest FDA approved dosage according to standard medical practice. By using low doses of pharmaceutical agents, patients can obtain relief from symptoms with fewer side effects. Simultaneously, providing the appropriate nutritional support optimizes the effect of prescribed drugs, thus maximizing therapeutic effectiveness while minimizing detrimental effects. “We are not advocating use of medical foods in place of pharmaceuticals,” emphasizes Dr. Shell, “we see these as adding to and increasing the efficacy of those medications.”

The Frost & Sullivan paper concludes that wider utilization of medical foods to meet the distinctive nutritional requirements of commonly occurring disease states, including pain syndromes, sleep disorders, asthma, and other clinical conditions, will improve outcomes for patients—but that the real challenge to the use of medical foods is in encouraging physicians to consider the nutritional status of patients, and enhance their understanding of the altered nutrient requirements inherent in disease states. In practical terms, it would seem that an Age Management practice (where extended patient interviews, detailed histories, and continuing contact are the norm) is the perfect setting for optimal use of medical foods as part of a comprehensive treatment protocol.

William Shell, M.D., will present “The Use of Medical Foods in Clinical Practice” on Friday, November 6th at the Age Management Medicine Conference in Las Vegas. Visit www.agemed.org for details.