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Medical Foods: Managing Disease through Nutrition

Medical foods straddle the gap between drugs and conventional foods by targeting the nutritional deficiencies that underlie disease.

Given the large body of research linking chronic diseases and nutrition[1] as well as the rapid increase in lifestyle-related diseases, there is a growing need for highly specific, medically formulated nutritional interventions to support a disease treatment plan.

Medical Foods: Effective Nutritional Management for Disease

Medical foods are nutritional therapies designed for specific, sick populations. They are distinctly different from dietary supplement formulations, which are designed to support healthy populations. Medical foods are a vital, irreplaceable component of many treatment plans, including:[2]

- ***Early-Onset Genetic Abnormalities.*** These include amino acid processing mutations, lipid processing mutations, and glucose transport deficiencies. For example, as pancreatic insufficiency is associated with reduced amounts of digestive enzymes, dietary management of this condition

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1 Harvard School of Public Health, The Nutrition Source, "Vegetables and Fruits: Get Plenty Every Day," http://www.hsph.harvard.edu/nutritionsource/vegetables-full-story, accessed December 9, 2013.

2 Bruce P. Burnett, "The Rise of Medical Food: Why, Where, When," PowerPoint presentation, Primus Pharmaceuticals.

requires a reduced fat diet (to assist food absorption) and enzyme replacement.[3]

- ***Late-Onset Genetic Abnormalities.*** These include diabetes, cardiovascular disease, renal disease, cancer, and osteoporosis. For example, elderly people suffering from osteoporosis are often deficient in vitamin D, calcium, and zinc, which can upset the normal balance of bone resorption and formation for bone mineralization.[4]

- ***Lifestyle-Induced Abnormalities.*** These could include diabetes, cardiovascular disease, arthritis, cachexia, and respiratory diseases. For example, a nutritional intervention for diabetes would include a formulation of vitamins, cinnamon, and plant sterols.[5]

- ***Drug-Induced Abnormalities.*** These abnormalities arise from autoimmune, oncology, and gastrointestinal treatments. For example, methotrexate (used to treat conditions such as rheumatoid arthritis, lupus, and inflammatory bowel disease) can cause a deficiency in folate, while isoniazid (an antibiotic used to treat tuberculosis) can deplete pyridoxine levels in the body.[6]

Diseases can initiate nutritional deficiencies that may result, over time, in structural alterations in the tissue and intracellular changes in biochemical function and structure. Medical foods can prevent deficiencies via disease-specific formulations that go beyond tweaking a patient's existing diet.[7]

Just a small sample of vital medical foods currently being marketed include:

- **Lofenalac:** An infant formula—the first medical food created—designed for babies suffering from phenylketonuria (PKU). The formula contains phenylalanine and other essential nutrients for those infants lacking sufficient enzymes to metabolize phenylalanine (amino acids).

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[3] Frost & Sullivan white paper, "The Promise of Medical Foods: Nutritional Management of Disease State," http://www.orthohealing.com/wp-content/uploads/2011/03/PromiseofMedicalFoods.pdf, accessed December 9, 2013.

[4] Mary Franz, "Medical Foods—Learn How They Manage Disease and Ways to Incorporate Them in Practice," *Today's Dietitian* 14(9):68, http://www.todaysdietitian.com/newarchives/090112p68.shtml, accessed December 9, 2013.

[5] Alliance of Natural Health USA, "FDA Attempting to Restrict Medical Foods," *Pulse of Natural Health*, http://www.anh-usa.org/fda-attempting-to-restrict-medical-foods, accessed December 9, 2013.

[6] "The Promise of Medical Foods," op. cit.

[7] Ibid.

- **Ultrase MT®:** Formulated to manage exocrine pancreatic insufficiency as a result of cystic fibrosis or chronic pancreatitis by providing digestive enzymes (such as lipase, protease, and amylase).

- **Limbrel™:** Formulated to nutritionally manage metabolic processes associated with osteoarthritis. Damaged joints can lead to inflammatory responses, and Limbrel contains naturally occurring ingredients that inhibit the enzymes associated with inflammatory irritants.

- **Folgard RX 2.2®:** Contains folic acid, vitamin B6, and vitamin B12 to lower plasma homoycsteine levels for patients suffering from hyperhomocysteinemia (associated with a number of diseases, including cardiovascular disease and stroke).

As illustrated above, medical foods can help address the nutritional deficiencies inherent in a wide range of diseases and conditions. As such, and as nutrition science continues to evolve, access to and investment in medical foods are increasingly important public health requirements.

A Unique Regulatory Category Being Threatened

Before 1972, medical foods were regulated as drugs. However, in recognition of the importance of medical foods, as well as to encourage innovation and increase access, Congress created a distinct regulatory category for medical foods via the Orphan Drug Act amendments.

The Orphan Drug Act defines a medical food as "a food that is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition, for which distinctive nutrition requirements, based on recognized scientific principles, are established by medical evaluation."[8]

In practice, medical foods:

- Are specially formulated for the management of distinctive nutrient needs in connection with a disease or condition;

- Are given to patients who cannot normally metabolize or consume ordinary foods, or their needs cannot be met by an ordinary diet;

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[8] 21 USC § 360ee(b)(3), http://www.law.cornell.edu/uscode/text/21/360ee, accessed December 9, 2013.

- Are administered orally or internally; and
- Must be administered under physician supervision as part of ongoing medical care.

Medical foods are not subject to FDA pre-approval, but must follow FDA compliance guidelines, including good manufacturing practices (cGMPs). All medical food ingredients must either be approved food additives or classified as Generally Recognized as Safe (GRAS). According to some experts, safety standards for medical foods—which are often food-based and incorporate natural ingredients—are higher than for pharmaceutical products evaluated in the context of a risk/benefit analysis (as many drugs have serious side effects).[9]

Medical foods are allowed to make disease management claims with the understanding that they meet the distinctive nutritional requirements to manage a disease or condition, a legal right otherwise reserved for drug products: Congress specifically exempted medical foods from certain requirements in the Nutrition Labeling and Education Act of 1990.[10] However, all disease claims for medical foods must be substantiated by scientific evidence, including clinical investigations.[11]

In 1996, the FDA made an Announcement of New Proposed Regulations (ANPR), expressing concern about the scientific support for medical foods on the market. In 2000, the FDA withdrew the ANPR. While FDA's intentions in this area remain unclear, it is noteworthy that medical foods are administered under the supervision of physicians (therefore, with their implicit endorsement) and are reimbursed by many healthcare plans, including, in some instances, Medicare and Medicaid.[12]

In August 2013, the FDA issued a revised draft guidance for medical foods. The draft guidance greatly narrows the type of diseases and conditions medical foods can help manage, limiting them to "inborn errors of metabolism" (IEMs).[13] However, contrary to the FDA's interpretation, it can be argued that many

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[9] J.D. Weir, "Medical Foods: A Necessary Part of Clinical Practice for Chronic Disease States," National Council for Prescription Drug Programs, *Council Connection* (May 2006): 14.

[10] 21 USC § 343(q)(5)(A)(iv), http://www.law.cornell.edu/uscode/text/21/343, accessed December 9, 2013..

[11] US Congress, Orphan Drug Act, 1988 amendment (100th Congress).

[12] S.L. Morgan and J.E. Baggott, "Medical Foods: Products for the Management of Chronic Diseases," *Nutrition Reviews* 64(11):495-501, http://www.ncbi.nlm.nih.gov/pubmed/17131945, accessed December 9, 2013.

[13] Emord & Assoc., "FDA Issues Draft Medical Food Guidance," http://emord.com/blawg/fda-issues-draft-medical-food-guidance, accessed December 9, 2013.

disease states beyond IEMs impose specific nutritional requirements that can be met with medical foods. The draft guidance excludes diseases resulting from essential nutrient deficiencies such as scurvy and pellagra, and controversially excludes both type 1 and type 2 diabetes. Further, there has been research into the application of medical foods for chronic pain, insomnia, depression, asthma, and many other conditions that would not qualify under the FDA's draft guidance.[14]

The FDA's interpretation of medical foods is a departure from the agency's previous guidance, and would potentially greatly restrict innovation and the number of marketable medical foods, to the lasting detriment of industry, consumer choice, and treatment quality and flexibility.

Preserving Congressional Intent and Consumer Choice

Medical foods play a vital role in our management of disease, and are an important supplement to a well-rounded treatment plant. Congress acknowledged this—as well as the inherent safety of food-based ingredients—by creating a unique regulatory category for medical foods that recognizes the therapeutic benefits of food nutrients. Congress's intent should be honored. This will encourage research and innovation in medical foods for the effective dietary management of disease.

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[14] Richard Isaacson, "Medical Foods: Overview of an Emerging Science," http://www.tmedpharma.com/docs/Medical-Foods-by-issacson.pdf, accessed December 9, 2013.