Nutrition for the Full Spectrum of Disease Differentiating Medical Foods and FSDU

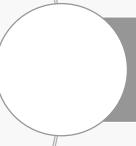
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Science, Regulation and Practical Aspects

What does dietary management of a disease mean to the patient?

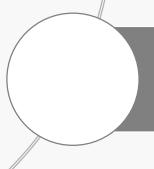
Nutritional Support Needs

- -Determined by either physiological manifestations or physical impairments
- Classical nutrients, other substances of biological value, and total dietary management



Changes to Lifestyle

- Complexity of dietary adaptation to meet nutritional needs
- Oral and/or tube feeding



Identifying practical, safe, and effective choices for Dietary Management

- -Modification of the diet
- Commercially available products

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Maintaining health and reducing the risk of disease

Diseases or conditions that result in a special dietary need

Acute or Chronic disease that requires dietary management

Nutrition Across the Continuum of Care

Conventional Food, The mainstay of the diet

Dietary Supplements, To supplement the diet

FDA has clearly defined labeling regulations for foods (NLEA) and dietary supplements (DSHEA)

Foods for Special Dietary Use

Meets a special dietary need

Must also follow FDA food labeling regulations (NLEA).

Additional labeling related to the special dietary usefulness in disease is not explicitly defined or clarified today.

Medical Foods

Dietary management of a disease

Exempt from NLEA labeling to enable labeling tailored to the needs of the medical community. Labeling related to the dietary management of the disease is permitted.

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Disease Management <u>AND</u> Disease Compatibility

How do we help people with disease not only live, but live BETTER?

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Potential Path Forward in Distinguishing Therapeutic Foods?

<u>Disease</u> <u>Management</u>

Medical Foods

For the dietary management of a disease or condition.

Must be used under medical supervision.

"Distinctive Nutritional Requirements", or "DNR", based on recognized scientific principles, established by medical evaluation

<u>Disease</u> <u>Compatible</u>

Sub category of Foods for Special Dietary Use (FSDU)

For the particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases

For the everyday health of a person living with disease.

Special Dietary Need

Modified nutrition (i.e., fulfilling a special dietary need) would provide benefits to a person's nutritional status, health outcomes or quality of life as part of living with disease

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A Modern Approach to "DNR"

Putting the patient's nutritional needs and quality of life at the forefront

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Healthcare Nutrition Council's take on "DNR"

Healthcare Nutrition Council

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Definition of Distinctive Nutritional Requirement

"Distinctive nutritional requirement" refers to the clinical need for a specific nutritional intake (compared to the intake of healthy populations) which may exist by reason of abnormal physiological manifestation or physical impairment" associated with a disease or condition, the dietary management of which results in clinically meaningful improvements, including but not limited to nutritional status, health outcomes, or quality of life.

*"Abnormal physiological manifestation or physical impairment" includes the following conditions associated with acute and chronic diseases or health conditions:

 a limited, impaired or disturbed capacity to ingest, digest, absorb, metabolize or excrete ordinary food or certain matrients or metabolites, or (ii) other medically-determined requirements for nutrients/other food substances of biological value.

Four Key Pillars to ensure a patient-centric approach to the Medical Foods category:

- i) Focus on patients' complete sutritional requirements, beyond just matrient levels: Our proposed definition of 'distinctive nutritional requirement', as indicated above, appropriately narrows the category of Medical Foods to products formulated with a high standard of scientific rigor and quality, while also providing sufficient flexibility to address overall patient needs, and supporting innovations in nutrition science. While necessary adjustments to the intake of essential nutrients is an example of a distinctive nutritional requirement, it should not be the energy accepted criteris for the classification of a product as a Medical Food. This restrictive interpretation creates a scenario where other products, like standard enteral tube feedings, are excluded from the same regulatory category despite their critical role in the dietary management of the disease or medical condition and their benefit to patients (see below for proposed types of distinctive nutritional requirements).
- 2) This definition of "Distinctive nutritional requirement" is intended to be taken in a context in which it is impossible, impractical, unsafe or nutritionally or clinically disadvantageous for patients to meet their nutritional needs through the exclusive consumption of foods other than Medical Foods.
- 3) Keep positive health outcomes for patients as the core goal: The definition should inform the development of Medical Foods that are specifically formulated to meet the "distinctive nutritional requirements" of patients in order to maintain/improve nutritional status and overall health status, clinical outcomes and quality of life. The definition should also inform the development of Medical Foods when it is impossible, impractical or unsafe for these patients to meet their "distinctive nutritional requirements" exclusively through the normal diet and/or the patients would have a nutritional or clinical disadvantage from consuming the normal diet alone rather than Medical Foods. In other words, the definition

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Four Key Pillars to this Interpretation

Focus on Patients' complete nutritional requirements, beyond just nutrient levels

Patient feasibility must be considered

DNR should encompass more than adjustments to essential nutrient DRIs.

- 1) Mode of delivery
- 2) Conditionally essential (no DRI)
- 3) Other food substances of high biological value Etc.

Is it impossible, impractical, unsafe, or nutritionally or clinically disadvantageous to meet needs through diet alone?

Keep positive health outcomes for patients as the core goal

DNR should be publichealth promoting: consider benefit to patients' nutrition status, clinical outcomes, and quality of life (rather than just necessity).

All of these will translate to benefits to the healthcare system as well, such as reductions in cost of care or reductions in readmissions.

Recognize disease severity can amplify a patient's need for a Medical Food

Patients presenting with higher severity and multiple co-morbidities also necessitating nutritional changes need access to Medical Foods even if the "healthiest" patient can successfully modify diet

and Practical Aspects