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

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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
Nutrition Across the Continuum of Care

<table>
<thead>
<tr>
<th>Conventional Food, The mainstay of the diet</th>
<th>Foods for Special Dietary Use</th>
<th>Medical Foods</th>
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<tbody>
<tr>
<td>Maintaining health and reducing the risk of disease</td>
<td>Meets a special dietary need</td>
<td>Dietary management of a disease</td>
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<tr>
<td>Diseases or conditions that result in a special dietary need</td>
<td>Must also follow FDA food labeling regulations (NLEA).</td>
<td>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.</td>
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<tr>
<td>Acute or Chronic disease that requires dietary management</td>
<td>Additional labeling related to the special dietary usefulness in disease is not explicitly defined or clarified today.</td>
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Dietary Supplements, To supplement the diet

FDA has clearly defined labeling regulations for foods (NLEA) and dietary supplements (DSHEA).
Disease Management AND Disease Compatibility

How do we help people with disease not only live, but live BETTER?
Potential Path Forward in Distinguishing Therapeutic Foods?

**Disease Management**
- 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.

**Disease Compatible**
- 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.
A Modern Approach to “DNR”

Putting the patient’s nutritional needs and quality of life at the forefront
Healthcare Nutrition Council’s take on “DNR”

“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.
Four Key Pillars to this Interpretation

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

- 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.

Patient feasibility must be considered

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 public-health 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.