Medical Foods: Their Role in Therapeutic Nutrition

March 2, 2021

Sponsored by the Healthcare Nutrition Council
## Disclosures

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<td>Employee</td>
<td>American Society for Nutrition</td>
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Medical Foods: Science, Regulation, and Practical Aspects. Summary of a Workshop

Jennifer L Holmes, Alexandre Biella, Timothy Morck, Jena Rostorfer, Barbara Scheineman

Published: 01 January 2021 Article history ▼

ABSTRACT

On August 13–14, 2019, the Healthcare Nutrition Council and the ASN held the Medical Foods Workshop: Science, Regulation, and Practical Aspects. Medical food products help patients manage their disease and improve their quality of life. Yet many hurdles exist to getting patients new products. In this workshop, participants addressed some of these hurdles, with specific emphasis on topics like the statutory term distinctive nutritional requirements, the regulatory term modification of the diet alone, the role of clinical guidelines, the requirement that medical foods be used under medical supervision, and differentiation of foods for special dietary use from medical foods, as well as product innovation and future research. Real-world examples were discussed for intractable epilepsy, diabetes, end-stage renal disease, and inflammatory bowel disease.
Learning Objectives

At the end of this webinar, learners will be able to:

1. Define medical foods and describe their role in nutrition therapy and how they are different from foods for special dietary uses (FSDU).

2. Identify research gaps and other opportunities to get involved in the scientific and regulatory aspects of medical foods.

3. Describe highlights and next steps from the HNC-ASN Medical Foods Workshop.
Speakers

• **Jessica O’Connell, JD**, Covington & Burling LLP
  *A 101 on medical foods*

• **Barbara Schneeman, PhD**, University of California, Davis
  *Themes from the 2020 Dietary Guidelines Advisory Committee*

• **Patrick Stover, PhD**, Texas A&M University
  *Research considerations for medical foods*

• **Tim Morck, PhD**, Spectrum Nutrition LLC
  *Proposed next steps*
CPE Credit

• ASN designates this educational activity for a maximum of 1 CPEUs. Dietitians and Dietetic Technicians, Registered should only claim credit commensurate with the extent of their participation in the activity.

• To claim credit, please take the post webinar evaluation provided after the webinar.
Asking Questions

- Please use the “questions” box on your “Go To Meetings” screen to submit questions to our presenters.

- Please submit your questions at any time during today’s webinar.
Medical Foods 101: Regulatory Framework and Key Considerations

Jessica P. O’Connell, JD, MPH
Partner, Covington & Burling LLP
Food: Range of Possibilities

- Conventional Finished Foods
- Dietary Supplements
- Specially Formulated Foods
- Food Components
**Food: Range of Possibilities**

### Food
- articles **used for** food or drink for man or other animals
- chewing gum
- articles **used for** components of any such article

### Dietary Supplement
- **intended to** supplement the diet that contains a dietary ingredient
- **intended for** ingestion
- **not represented for use** as a conventional food
Food: Range of Possibilities

**Food for Special Dietary Use**
- Uses for supplying **particular dietary needs** due to a **physical, physiological, pathological or other condition**, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
- Uses for supplying particular dietary needs due to age;
- Uses for **supplementing or fortifying the ordinary or usual diet** with any vitamin, mineral, or other dietary property

**Medical Food**
- 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
Brief Definitional History

• “Medical Food” defined in 1988 amendments to Orphan Drug Act
  • 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

• Nutrition Labeling and Education Act (1990)
  • exempted medical foods from nutrition labeling, nutrient content claim, and health claim requirements
1993 FDA rulemaking to implement NLEA exemption
21 CFR 101.9(j)(8) - Food is subject to exemption only if:

• It is a specially formulated and processed product for the partial or exclusive enteral feeding of a patient;

• It is intended for the dietary management of a patient who 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 through dietary modification alone;

• It provides nutritional support specifically modified for the management of unique nutrient needs that result from the specific disease or condition;

• It is intended to be used under medical supervision; and

• It is intended only for a patient receiving active and ongoing medical supervision
## Notable Differences

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<th>Statute</th>
<th>Regulation</th>
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<tr>
<td>Dietary management of disease or condition</td>
<td>Dietary management of patient with limited capacity to ...</td>
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<tr>
<td>“Distinctive Nutritional Requirement” established by medical evaluation</td>
<td>“Unique Nutrient Needs” that result from disease or condition</td>
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<tr>
<td>No mention of dietary modification</td>
<td>Dietary management cannot be achieved through dietary modification alone</td>
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FDA’s Guidance – FAQ About Medical Foods
Final Guidance issued May 2016

• FDA generally would not consider pregnancy or diabetes to be diseases/conditions for which medical foods should be marketed
  • No distinctive nutritional requirements for either condition because needs can be met through dietary modification alone

• IEMs that medical foods could be used to manage involve amino acid/protein, organic acid, or fatty acid metabolism

• Note: FDA has never defined “distinctive nutritional requirement”
FDA’s Final IND Guidance
issued September 2013

• Generally, human research studies must be conducted under an investigational new drug application (IND) if the research involves a drug.

• This requirement applies to human research studies intended to evaluate the effect of a food (including medical foods) on a disease.

• If medical food is being fed to subjects for nutritional purposes during a study examining the effects of another intervention, the use of the medical food in the study would not trigger the need for an IND.

**FDA stayed certain parts of this guidance in 2015; however, the above principles remain in effect**

2017 IND-Related Warning Letter

• March 29, 2017 Warning Letter from CDER – Targeted Medical Pharma, Inc.
• Result of FDA inspection of clinical research site as part of FDA’s BIMO Program

• **Charge**: “Failure to submit an IND for the conduct of clinical investigations with an investigational new drug”
  • Company 483 response: Research was of “Medical Food used to treat the nutritional deficiencies associated with pain and inflammation”
  • FDA:
    • No distinctive nutritional requirements
    • Clinical endpoint was comparison to a drug
    • Because studying effects of product on disease, product being evaluated as a drug and IND required
Looking to Future: Key Questions

- “Distinctive nutritional requirement” – what does it mean?
- Potential for FDA rulemaking on IND requirements for foods
- Will FDA provide guidance on other categories?
- Key consideration for developing claims within FDA’s current framework
What can we learn from the Dietary Guidelines process?

Barbara Schneeman, PhD
## Disclosures

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<td>McCormick Science Institute; International Food Information Council Trustee; International Advisory Board for Saudi Arabia National Nutrition Committee</td>
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<td>Employee</td>
<td>N/A-Retired from UC Davis and Federal government</td>
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<td>Other</td>
<td>2020 Dietary Guidelines Advisory committee, chair WHO NUGAG Diet and Health subcommittee WHO NUGAG Policy Actions subcommittee NASEM: Food and Nutrition Board Speaker at Healthcare Nutrition Council Workshop</td>
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Main Question

• What can we learn from the *Dietary Guidelines for Americans* process?

• Topics
  • Populations addressed by the *Dietary Guidelines for Americans*
  • Evidence considered in the scientific report for the Dietary Guidelines Advisory Committee
Dietary Guidelines for Americans

• Published every 5 years since 1980 by USDA and HHS and reflects the 'preponderance of scientific evidence'

• Serves as the cornerstone of Federal nutrition programs and policies

• Provides food-based recommendations to reduce risk for diet-related chronic diseases and promote overall health.

• Used by government as well as non-government organizations to support policies and programs
Make Every Bite Count With the Dietary Guidelines
Dietary Guidelines for Americans: What It Is, What It Is Not*

• Quantitative Guidance on Foods, Not Nutrient Requirements
  • Dietary Reference Intakes for nutrients and food components are established by the National Academy of Sciences, Engineering, and Medicine
  • The DGA translates nutrient requirements into food and beverage recommendations.

*From the 2020-2025 Dietary Guidelines for Americans
Dietary Guidelines for Americans: What It Is, What It Is Not*

• Health Promotion, Not Disease Treatment
  • Participants in the scientific evidence evaluated includes healthy individuals, people at risk of diet-related chronic conditions and diseases, and people living with diet-related chronic illness.
  • Not intended as clinical guidelines for treating chronic diseases
  • Health professionals may adapt the Dietary Guidelines to meet the specific needs of their patients.

*From the 2020-2025 Dietary Guidelines for Americans
Food-Based Dietary Guidelines: Understanding nutrition in the context of foods

- Vitamins
- Electrolytes
- Trace Minerals
- Amino Acids
- Minerals
- Carbohydrates
- Fats
- Dietary Fiber
- Protein
- Recommended Dietary Intakes
- Estimated Average Intakes
- Adequate Intakes
- Risk of Chronic Diseases
- Tolerable Upper levels

- Fruits
- Vegetables
- Grains
- Protein Foods
- Dairy
**How are they developed?**

USDA and HHS are mandated to publish the Dietary Guidelines every 5 years based on the preponderance of evidence.

A Federal Advisory Committee is chartered and appointed.

The Advisory Committee reviews scientific evidence to address specific questions from USDA and HHS.

The Advisory Committee submits its findings and conclusions to the government in a technical report.

This report, relevant references, and public comments are used to update the Dietary Guidelines by HHS and USDA.

The document goes through government clearance and replaces the previous guidelines.
• The Committee answered questions on diet and health using one of three approaches.

• Each of these approaches has its own rigorous, protocol-driven methodology, and plays a unique, complementary role in examining the science.

*NESR refers to the Nutrition Evidence Systematic Review Team
Approaches to Examine the Evidence

Data Analysis
A collection of analyses that uses national data sets to help us understand the current health and dietary intakes of Americans. These data help make our advice practical, relevant, and achievable.

Food Pattern Modeling
Analysis that helps us understand how changes to the amounts or types of foods and beverages in a pattern might impact meeting nutrient needs across the U.S. population.

NESR Systematic Review
Research project that answers a question on diet and health by searching for, evaluating, and synthesizing all relevant, peer-reviewed studies.
The Committee looked across all of the conclusion statements – the totality of our scientific review – to develop overarching advice for USDA and HHS to consider as the Departments develop the 2020-2025 Dietary Guidelines.
The NESR systematic review methodology

**NESR Systematic Review**
Research project that answers a question on diet and health by searching for, evaluating, and synthesizing all relevant, peer-reviewed studies.

Information available at the NESR website: https://nesr.usda.gov
The Advisory Committee developed a protocol for each scientific question they answered.

NESR systematic review protocols include:

- Analytic framework
- Inclusion and exclusion criteria
- Literature search strategy
- Literature search and screening results
- Lists of included and excluded articles

Note: Protocols and conclusions were posted at www.dietaryguidelines.gov.
Components of the NESR Analytic Framework

**Intervention/Exposure** vs Comparator

Diet-related intervention/exposure of interest and what it is being compared to

**Population:** Population of interest

**Intermediate Outcomes**

Intermediate health outcome(s)

**Population:** Population of interest

**Health Outcomes**

Endpoint health outcome(s)

**Population:** Population of interest

Key factors that could impact the relationship being examined: confounders, covariates, moderators

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**Legend**

- The relationship of interest in the systematic review
- Factors that may impact the relationship of interest in the systematic review

---

**Key definitions**

[Term] – [definition]
[Term] – [definition]
[Term] – [definition]
NESR Inclusion and Exclusion Criteria

• Established up front to provide an objective, consistent, and transparent framework for identifying articles to include in each review
• Framed around relevancy to U.S. Federal policy
• Standard criteria have been applied to the extent possible
• Some criteria are tailored to the specific review, such as:
  • Diet-related intervention/exposure of interest
  • Health outcomes, endpoint and/or intermediate
  • Date of publication
  • Size of study groups
  • Study duration
  • Age of study participants
## Standard NESR Inclusion and Exclusion Criteria

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<tr>
<th>Category</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
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<tbody>
<tr>
<td><strong>Study design</strong></td>
<td>• Randomized controlled trials</td>
<td>• Uncontrolled trials</td>
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<td></td>
<td>• Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies</td>
<td>• Case-control studies</td>
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<td></td>
<td>• Prospective cohort studies</td>
<td>• Cross-sectional studies</td>
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<td></td>
<td>• Retrospective cohort studies</td>
<td>• Uncontrolled before-and-after studies</td>
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<td></td>
<td>• Nested case-control studies</td>
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<td><strong>Publication status</strong></td>
<td>Peer-reviewed articles</td>
<td>Non-peer-reviewed articles (e.g., unpublished data, manuscripts, pre-prints, reports, abstracts, and conference proceedings)</td>
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<td>English</td>
<td>Languages other than English</td>
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<td><strong>Country</strong></td>
<td>Very High or High Human Development (based on the year the study was conducted)</td>
<td>Medium or lower Human Development</td>
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<td><strong>Study participants</strong></td>
<td>Humans, males and females</td>
<td>Non-human participants (e.g., animal or in-vitro models)</td>
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<td>Health status of study participants*</td>
<td>Studies that enroll:</td>
<td>Studies that <strong>exclusively</strong> enroll:</td>
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<td>• participants who are healthy and/or at risk for chronic disease, <em>including those with obesity</em></td>
<td>• participants diagnosed with a disease, or hospitalized with an illness or injury (For this criterion, studies that exclusively enroll participants with obesity will <strong>not</strong> be excluded)</td>
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<td>• <strong>some</strong> participants diagnosed with a disease or with the health outcome of interest</td>
<td>• participants with the outcome of interest (i.e., studies that aim to treat participants who have already been diagnosed with the outcome of interest)</td>
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<td>• infants born full-term (≥37 weeks and 0/7 days gestational age), low birth weight (&lt;2500g), and/or small for gestational age</td>
<td>• infants born preterm, low birth weight (&lt;2500g), and/or small for gestational age</td>
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*In each protocol, this criterion has been tailored specifically for the outcomes being examined*
Note: Medical Foods vs Conventional Foods (and dietary supplements)

• Regulations for the 1990 Nutrition Labeling and Education Act defined medical foods and excluded them from certain nutrition labeling requirements.

• Nature of nutrition-related claims for conventional foods and dietary supplements
  • Nutrient Content Claims
  • Health claims (Disease risk reduction)
  • Structure/function claims
Advisory Committee Process

2020 Dietary Guidelines Advisory Committee Timeline

2018
February 28-March 30
Call for comments on the topics and supporting scientific questions

2019
September 6-October 6
Call for nominations to the 2020 Dietary Guidelines Advisory Committee

Spring 2020
Call for comments on Scientific Report

Open public comment period during the Advisory Committee’s work

Meeting 1 Meeting 2 Meeting 3 Meeting 4 Meeting 5

Participate!

2020-2025 Dietary Guidelines for Americans
DietaryGuidelines.gov

* Tentative timeline
† Will include opportunity for oral comments
Future Directions in the DGAC Scientific Report

• “Identify collaborative efforts across the Federal government… [for] consideration of dietary patterns, in treating and managing diet-related conditions and disorders, such as type 2 diabetes, obesity, and cardiovascular disease (CVD).”
  • Identified based on public comments on the need for such guidelines
  • Included the need for weight loss strategies

• “Examine the relationship between nutrition and immune function”

• “Consider the role of genetics and epigenetics in future guidelines (e.g., single nucleotide polymorphisms (SNPs) for fatty acid metabolism; folate metabolism).”
REDUCING RISK FOR DISEASE

- Interventions to Decrease Risk
- Use of Biomarkers to Estimate Risk.

Increasing Risk

Treatment
REDUCING RISK FOR DISEASE

HEALTH

• Interventions to Decrease Risk
• Use of Biomarkers to Estimate Risk.

Increasing Risk

Dietary Management Of Disease

DISEASE

Treatment
Research considerations for medical foods

Patrick J. Stover, Ph.D.
Vice Chancellor, Texas A&M AgriLife
Dean, Texas A&M College of Agriculture and Life Sciences
Director, Texas A&M AgriLife Research
# Disclosures

## AFFILIATION/FINANCIAL INTERESTS  
*(prior 12 months)*

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<td>R37DK58144; ODS Supplement HD059120</td>
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<td>Marabou Foundation, National Academy of Sciences, American Society for Nutrition, ICAAS Scientific Advisory Board; NIH Nutrition Strategic Plan Thought Leader Panel: Chair</td>
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- **Grants/Research Support:** NIH: T32-DK007158 R37DK58144; ODS Supplement HD059120
- **Scientific Advisory Board/Memberships:** Marabou Foundation, National Academy of Sciences, American Society for Nutrition, ICAAS Scientific Advisory Board; NIH Nutrition Strategic Plan Thought Leader Panel: Chair
- **Speakers Bureau:** None
- **Stock Shareholder:** TIAA
Special Nutrient Needs:
Disease can modify nutrient requirements

• As of 2014, 60% of adult Americans had at least one chronic condition, and 40% had more than one. Rand, 2017

• Reviewed evidence for special nutritional requirements in disease states and medical conditions that cannot be met with a normal diet

• The workshop explored how these requirements may apply to the management of chronic or acute conditions or diseases: inborn errors of metabolism, burns or surgical trauma, cancer, inflammatory bowel disease, traumatic brain injury, and other non-communicable diseases or medical conditions.
Disease influences whole-body nutrient status and/or specific tissue nutrient status

Disease-Related Etiology
- Inflammation
- Genetic predisposition
- Autoimmunity
- Mitochondrial dysfunction
- Pharmaceuticals
- Trauma

Physiological Impact on Nutrients & Function
- Gut absorption
- Brain/Nerve Barriers
- Degradation/tturnover
- Excretion
- Metabolism
- Redistribution

Impact on Human Nutrition
- Whole-body deficiencies
- Tissue-specific deficiencies
- Conditionally essential nutrients
- Nutrient toxicities

Impact on Biomarkers
- Function & Status
- Whole-body (serum)
- Tissue-specific (CSF, tissue)
- Predictive Biomarkers
- Cells & Stem cells

Considerations for Distinctive Nutritional Requirements

Examples of factors that affect nutrient status and/or biomarkers of status:

- Increased rates of nutrient catabolism
  - Acquired Arginine Deficiency Syndrome
    - Arginase is elevated in many diseases and cancers and in trauma/surgery Nutr Clin Pract. 2017, 32:30S-47S
  - Inflammation (vitamin B6, vitamin D, others) Mol Aspects Med 53, 10, 2016; AJCN; 2011 93(5):1006

- Tissue redistribution and/or excretion
  - Infection (iron) Semin Cell Dev Biol. 2015 39:35

- Decreased rates of uptake across barriers (gut and blood-brain barrier transport)
  - Genetics, Inflammation, Drug use, Autoimmunity, others

- Stem cell-specific nutrient requirements → Tissue Regeneration
  - Serine auxotrophy in myoblasts BBRC 70: 1085, 1976
A folic acid–enalapril combination was more effective than enalapril alone in the secondary prevention of renal function decline among Chinese adults with hypertension across a spectrum of mild to moderate chronic kidney disease (CKD).


Enalapril treatment alone in the absence of supplemental folic acid increased serum folate by 5.1 ng/mL, with a modest decrease in serum homocysteine (0.2 μM).
How do we establish DNRs??
Analytic framework applicable to assessment of nutrients

I. Association of exposure with clinical outcomes of interest
II. Association of exposure with validated surrogate outcomes of interest (functional biomarker)
III. Association of exposure with intermediate biomarker of interest (to clinical outcome)
IV. Association of exposure indicators to clinical outcomes of interest
V. Association of exposure indicator to surrogate outcome of interest

Russell et al. 2009 Am J Clin Nutr
Inborn Errors of Metabolism (IEM) inform Distinctive Nutritional Requirements in Disease

Medical Foods Address Nutrient Requirements that originate from a Loss of Function

- **IEM**
  - Medical Food
  - Nutrition Compensating for Functional Deficits Caused by Genetics

- **Chronic Disease**
  - Nutrition Compensating for Functional Deficits Caused by Disease
Diet-related interventions and IND applications

Any study that assesses the effect of a food or nutrient on the diagnosis, cure, mitigation, treatment, or prevention of disease requires an IND or an appropriate waiver from the US FDA.

Foods and nutrients used to prevent or treat a nutrient deficiency are exempt

Diet-related interventions and IND applications

IND is not required for the following studies:

- Food or dietary supplement to reduce the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that does not include individuals <12 mo old, those with altered immune systems, or those with serious or life-threatening medical conditions.

- Clinical studies designed to evaluate a nutritional structure/function effect of a conventional food or dietary supplement. (e.g. effect of iron on hemoglobin concentrations)

- A clinical study to evaluate the safety or tolerability of a food or ingredient generally does not require an IND provided the target outcome is not indicative of a treatment or mitigation of a disease or condition.

Food and Nutrition Translation

USDA plays a pivotal role in providing Americans with safe, nutritious, and wholesome foods. This means supplying foods, both fresh and processed, that are of the highest quality and that provide adequate nutrition supporting the entire population life span. This task must address challenges to reduce foodborne illnesses; understand the drivers of poor diets and nutritional choices; provide better access to nutritious foods in low-income households; and reduce the overall cost of foods through more efficient processing, packaging, and repurposing to minimize food waste.
Proposed next steps

Timothy A. Morck, Ph.D.
President/Founder
Spectrum Nutrition, LLC
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Workshop Closing Session: Proposed Next Steps

• Panelists and audience contributed to an extensive list of next steps to address some of the hurdles associated with the medical food regulatory landscape (see Table 2 of the proceedings document)

• Key elements include:
  - Need to clarify key definitions of terms that qualify a product as a medical food
    - “Distinctive nutritional requirements” for various disease conditions
    - Modification of the ordinary diet alone
    - Intended for use under medical supervision
  - Updating an understanding of “dietary management of disease” and how nutrition can improve nutritional status and health outcomes, add to quality of life, and may reduce overall healthcare costs, for certain patient groups
  - Exploring paths to open dialogue around these scientific subjects, with those responsible for establishing policy and regulations having the goal to improve patient care through innovation and research
Need to clarify key definitions in Medical Food regulations

21 C.F.R. 101.9(j)(8)

i. 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 tube;

ii. 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;

iii. 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;

iv. It is intended to be used under medical supervision; and

v. 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.

(Highlighting added)
Keep the patient at the center of regulatory policy

• Safety - preeminent in FDA’s regulations - remains the focus
• Consider updating the medical food definition
  • Specially formulated food using GRAS ingredients
  • Promotes improvements for patients including, but not limited to, nutritional status, health outcomes, and quality of life
  • Not treating the disease pathology, but supporting the body’s metabolic and physiological systems
• Can safe, cost-effective, food products that provide metabolic and physiological support, “normalize metabolic function” impaired by disease, and/or clinically meaningful improvements be allowed to be marketed as “medical food” to benefit patients?
  • Shouldn’t sole source nutrition, given by feeding tube (medical device), be firmly established as a medical food?
• How broadly will “nutritional support” or “nutritional management” be defined?
Suggested ways forward

• Keeping the health, safety, welfare, and quality of life benefits of patients at the heart of any discussion is key

• Collaboration between scientific groups (eg. ASN) and trade associations (eg. HNC)
  • To promote research and publication of responsible, up to date, scientific evidence for the value of nutrition in optimal care of patients with defined conditions
  • Contribute to definitions about “distinctive” and “unique” nutrient needs of patients

• Engagement with FDA staff
  • Share and discuss most current, peer-reviewed, research findings to support patient-centered regulatory policy
  • Helps equip them to promulgate the best regulations

• Legislative Channels
  • Key bills have been introduced to Congress attempting to obtain financial assistance for nutritional support of patients
    • Medical Nutrition Equity Act of 2019-2020 (H.R. 2501)
    • Medical Nutrition Therapy Act of 2019-2020 (H.R. 6971)
What Can I do?

• Read the workshop proceedings publication in “Current Developments of Nutrition” to get the full perspective of the 1.5 day workshop, complexity of the issues, and ideas for moving forward (see next slide)

• Become knowledgeable about medical foods, their benefits, and limitations, in order to promote their true value for patients

• Consider engaging with groups dedicated to improving the lives of patients with diseases and conditions, that could benefit from improved nutritional support provided by targeted medical foods
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ABSTRACT

On August 13–14, 2019, the Healthcare Nutrition Council and the ASN held the Medical Foods Workshop: Science, Regulation, and Practical Aspects. Medical food products help patients manage their disease and improve their quality of life. Yet many hurdles exist to getting patients new products. In this workshop, participants addressed some of these hurdles, with specific emphasis on topics like the statutory term distinctive nutritional requirements, the regulatory term modification of the diet alone, the role of clinical guidelines, the requirement that medical foods be used under medical supervision, and differentiation of foods for special dietary use from medical foods, as well as product innovation and future research. Real-world examples were discussed for intractable epilepsy, diabetes, end-stage renal disease, and inflammatory bowel disease.
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