
FOOD IS MEDICINE
IN CLINICAL CARE
DECEMBER 3, 2025 | 9-10:00 AM
RAYBURN, ROOM 2060
For
Enteral
Use Only
ORAL
NUTRITION
SUPPLEMENT
MEDICAL
FOOD
PRESENTED BY
HEALTHCARE
NUTRITION
COUNCIL
With support from
NPKUA
national PKU alliance
CROHN'S
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HCU
NETWORK
AMERICA
IMPROVECARENOW™

Welcome

- HNC represents manufacturers of enteral nutrition formulas and oral nutrition supplements (ONS), including those categorized as medical foods, and parenteral nutrition.
- The mission of HNC is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access for people who require or benefit from advanced and specialized nutrition.
- Thank you! – Reps. Murphy, MD (R-NC-3), Schrier, MD (D-WA-8), and Kiggans (R-VA-2).

With support from

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HEALTHCARE NUTRITION COUNCIL

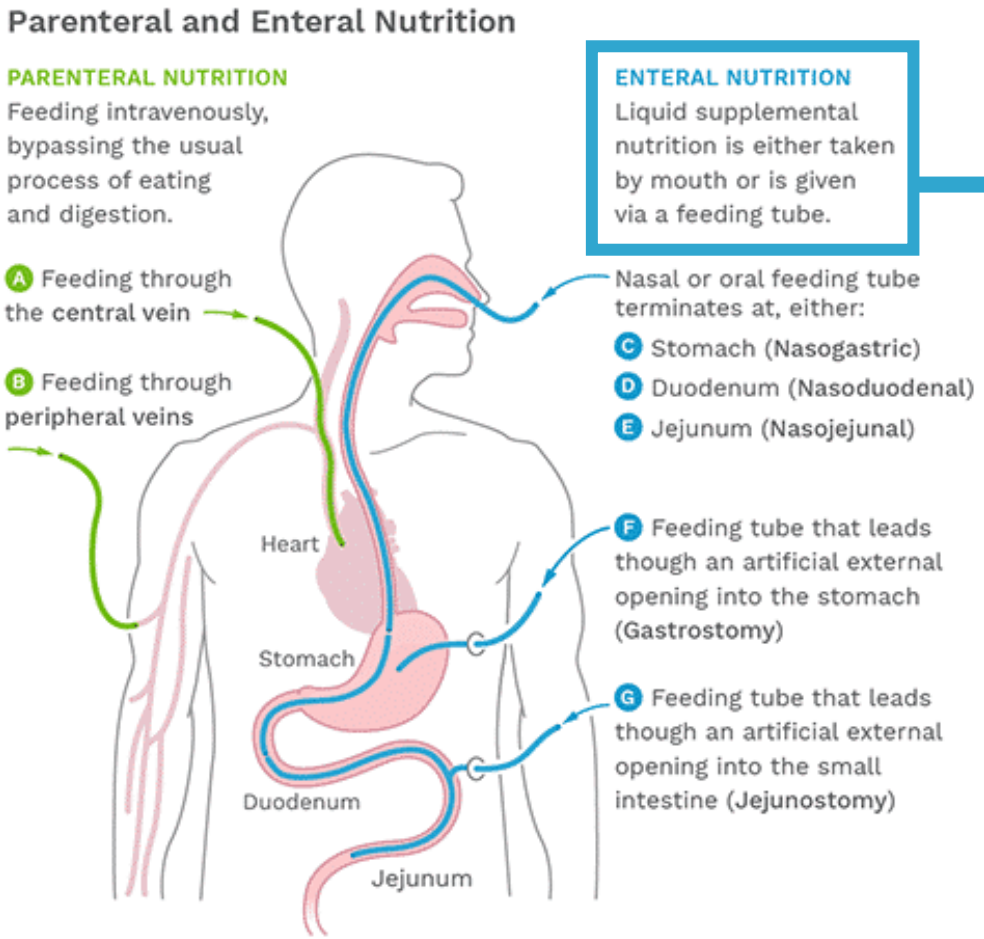
Objectives

- Identify the differences between medical foods, oral nutrition supplements, and conventional foods.
- Recognize the necessity for medical foods and oral nutrition supplements and some of the challenges for patient access.
- Explain why oral nutrition supplements (ONS) should be included in food is medicine legislation.

HEALTHCARE NUTRITION COUNCIL

Overview

- The spectrum of specialized nutrition for certain populations is life-saving; it is their medicine.



Medical Foods

Foods for Special Dietary Use (FSDU)

Oral Nutrition Supplement (ONS)

Different than:

Conventional Food

HEALTHCARE NUTRITION COUNCIL

Image courtesy of Crohn's & Colitis Foundation, www.crohnscolitisfoundation.org

Overview

- Medical foods (21 USC 360ee(b)(3)) and oral nutrition supplements (ONS) (21 CFR Part 105 as “foods for special dietary use”) have their own **unique regulations**; different from conventional foods, dietary supplements, and pharmaceuticals.
- These products are formulated for specific nutritional needs and may be used as **sole-source nutrition**.
- They are lifesaving products that are considered both food and medicine by the people who use them and they should be included in any **“food is medicine”** initiative.
- Medical foods and ONS help prevent **malnutrition**.
- Disease-associated malnutrition costs the U.S. **$156.7 billion** annually.[1]

HEALTHCARE NUTRITION COUNCIL

1. Snider J, et al: Economic burden of community-based disease-associated malnutrition in the United States. JPEN J Parenteral Enteral Nutr. 2014;38:55-165.

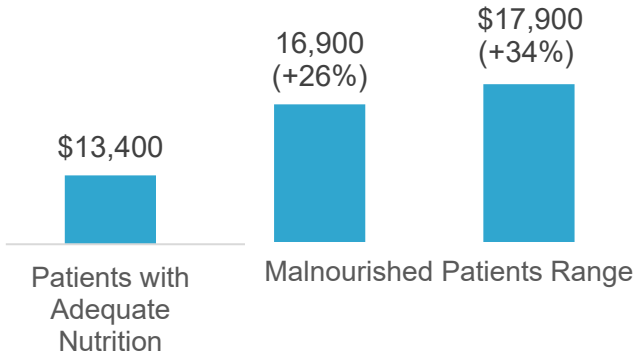
Health Economic Outcome Data on Malnutrition and ONS

Hospital Readmission Rates for Malnutrition in U.S. Patients

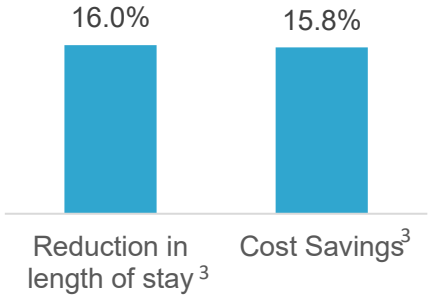
50%

Higher rate of readmission within 30 days.[1]

Average Readmission Costs for Patients with Malnutrition[2]



Medicare Patients Aged 65+ Receiving ONS



Cost-Effectiveness of Standard ONS use in Community and Care Homes

9.2%

Mean cost savings[4]

[1] Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. HCUP Statistical Brief #218. 2018. 1-18.
[2] Fingar et al.
[3] Thomas DR, Zdrowski CD, Wilson MM, et al. Malnutrition in subacute care. Am J Clin Nutr. 2002;75:308-313.
[4] Medical Nutrition International Industry. 'Better care though better nutrition: value and effects of medical nutrition' 4th Edition. 2018. Retrieved on July 1, 2023. https://www.medicalnutritionindustry.com/files/user_upload/documents/medical_nutrition/2018_MNI_Dossier_Final_web.pdf

Overview

- **ONS products are:**
  - Included in clinical guidelines for patient care.
  - Frequently prescribed or recommended by healthcare professionals (HCPs).
  - Proven effective for the target population.
  - HSA/FSA eligible (when prescribed).
  - May be covered by Medicaid and certain health insurance plans.
  - Available with or without a prescription (over-the-counter).
  - Located in a designated retail area, typically near the pharmacy.

Foods for Special Dietary Use (FSDU)

Oral Nutrition Supplement (ONS)

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Overview

- **Medical foods:**
  - Included in clinical guidelines for patient care.
  - Used under the supervision of a physician.
  - Are intended for the specific dietary management of a disease or condition with distinctive nutritional requirements.
  - May be covered by some health insurance plans.

- Access to both medical foods and ONS can be impacted by coverage challenges.

HEALTHCARE NUTRITION COUNCIL

Outline

Rep. Greg Murphy, MD (R-NC-03)

GOP Doctors Caucus Co-Chair

Ways & Means Health Subcommittee

Rep. Kim Schrier, MD (D-WA-08)

Congressional Doctors Caucus Co-Chair

Energy & Commerce Health Subcommittee

Outline

Berit Dockter
MPP, RD, LD

Moderator

HNC

Dr. Eric Kossoff

Medical Director

Johns Hopkins

Becky Woolf

Virginia

Crohn's Disease

Ben Lewis

Massachusetts

HCU

Jessica O'Connell

Partner

Covington & Burling LLP

FDA Product Classification

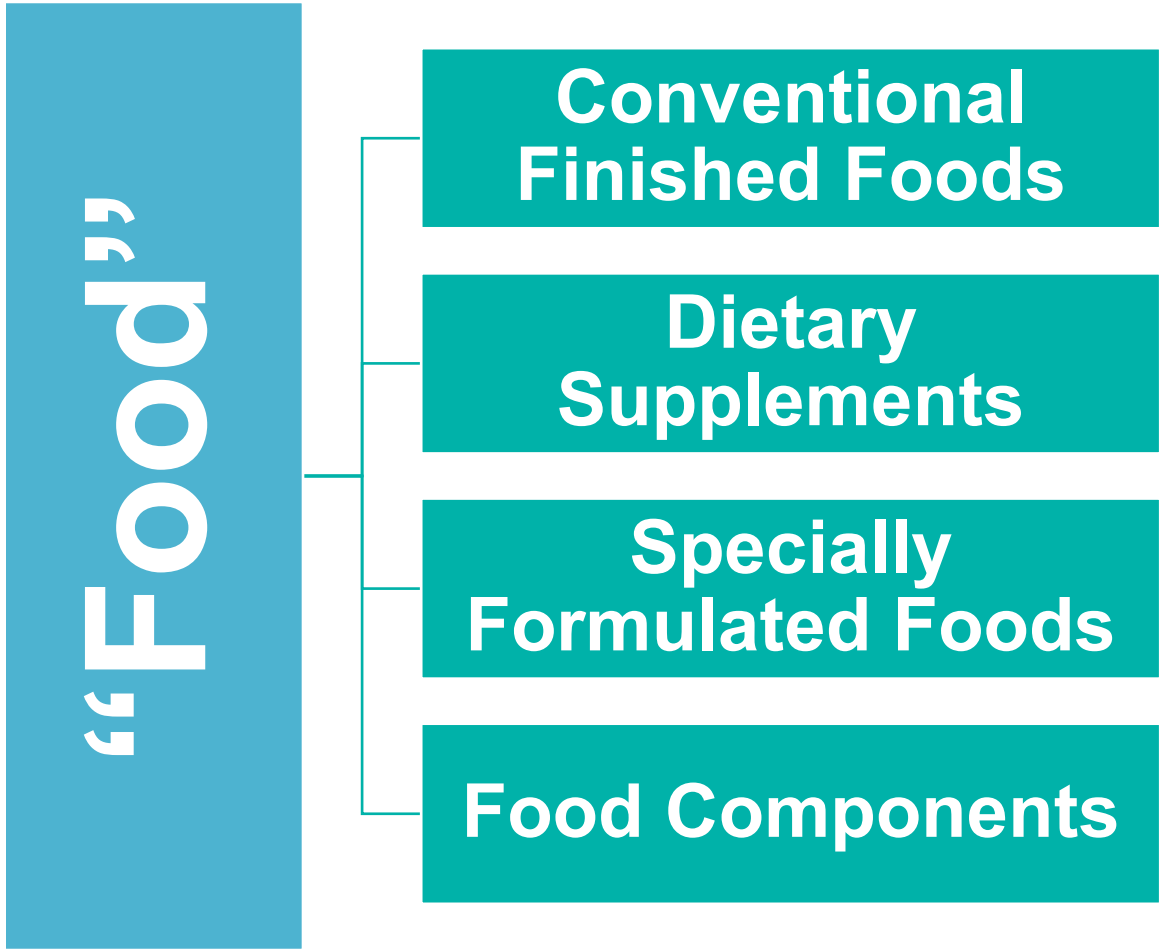
A product is classified under the Federal Food, Drug, and Cosmetic Act (FDCA) according to its "intended use"

- Manufacturer's intent of how product is to be used by consumers
- Objective intent – express claims, implied claims, circumstances surrounding distribution of the product, and, in some cases, actual consumer use of the product

For drugs, FDA regulations (21 C.F.R. § 201.128) state that

- Objective intent may be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives; and
- It may be shown by the circumstances that an article is offered and used for a purpose for which it is neither labeled nor advertised

Food: Range of Possibilities



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

Medical Foods and Diet Therapy for Patients with Epilepsy

Eric H. Kossoff, MD
Professor, Neurology and Pediatrics
Director, Pediatric Ketogenic Diet Program
Johns Hopkins Hospital
Baltimore, Maryland USA

3 December 2025

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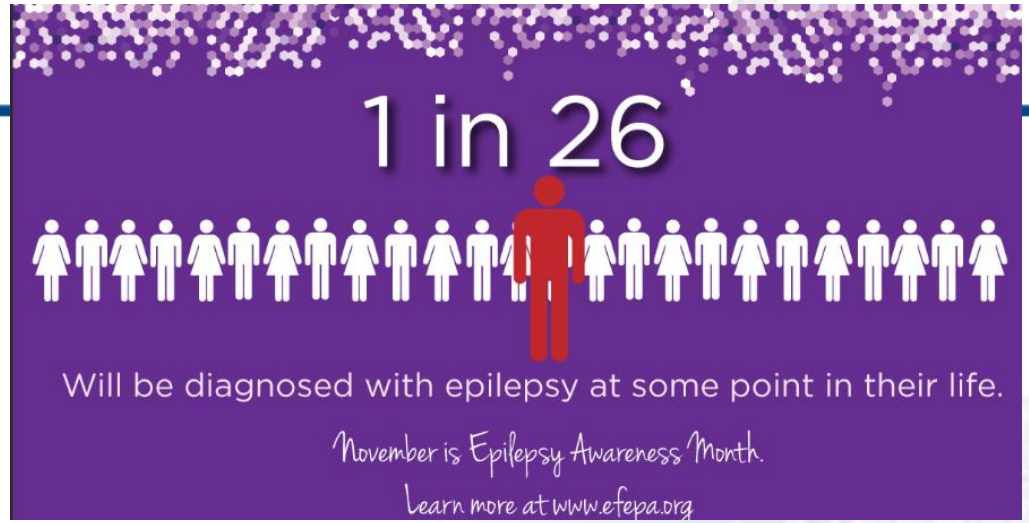
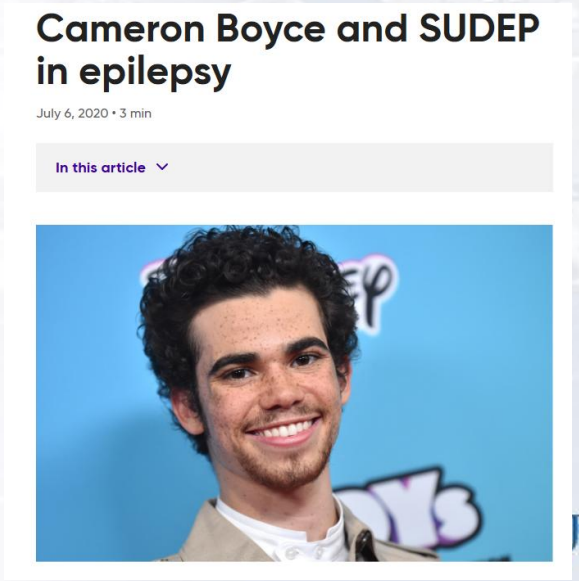
Disclosures

- Consultant: Nutricia, Simply Good Foods, Dr. Schaer, Cambrooke
- Royalties: Springer, UpToDate, Oxford, JHU Press, SNS Press
- I am being compensated for my involvement in this morning's meetings by HNC

Epilepsy

- 1 in 26
- Occurs at any age
- Variety of causes, including “idiopathic/genetic”
- SUDEP rare, but occurs





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Why do we need options besides drugs?

EARLY IDENTIFICATION OF REFRACTORY EPILEPSY

PATRICK KWAN, M.D., AND MARTIN J. BRODIE, M.D.

- 2000 : 47% with 1st drug, 14% with 2nd, 1% with 3rd

Treatment Outcomes in Patients With Newly Diagnosed Epilepsy Treated With Established and New Antiepileptic Drugs

A 30-Year Longitudinal Cohort Study

Zhibin Chen, PhD; Martin J. Brodie, MD; Danny Liew, MD, PhD; Patrick Kwan, MD, PhD

- 2018 : 50% with 1st drug, 12% with 2nd, 1% with 3rd

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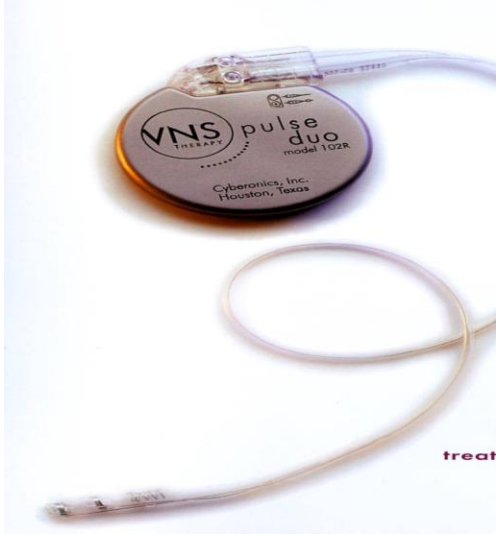

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Our food should be our medicine and our medicine should be our food.

—

Hippocrates

citatis.com

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- Hippocrates ~400 BC
  - Man with body burns and seizures
  - “complete abstinence from food and water”

- Galen ~200 BC
  - Recommended “abstinence from daily use of such food as engenders unhealthy humors”

The Bible: King James version
Mark 9: 14-29

- “he fell on the ground, and wallowed foaming”
- “he asked his father, How long is it ago since this came unto him? And he said, of a child”
- “Jesus took him by the hand, and lifted him up; and he arose”
- “And he said unto them, this kind can come forth by nothing, but by prayer and fasting”

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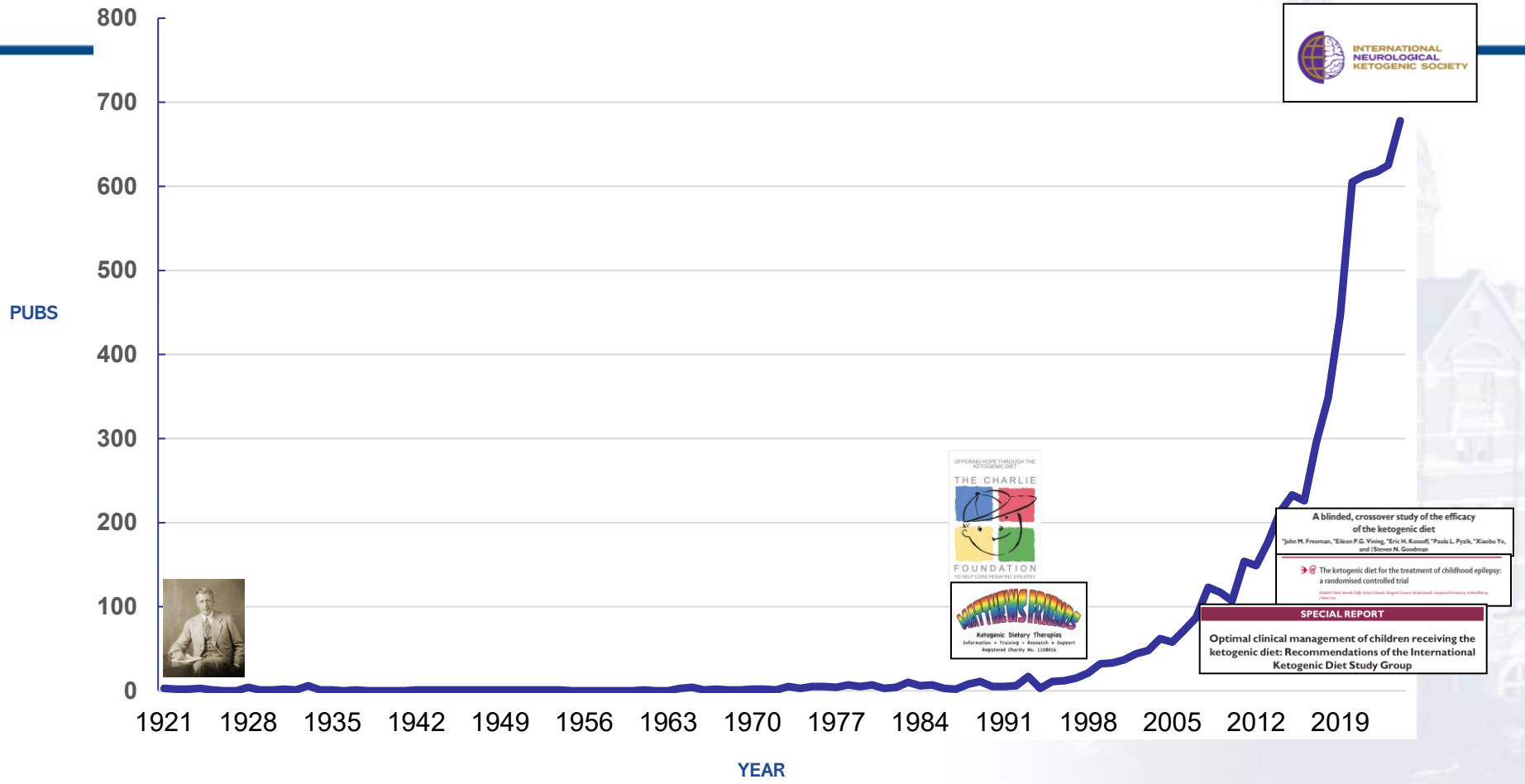

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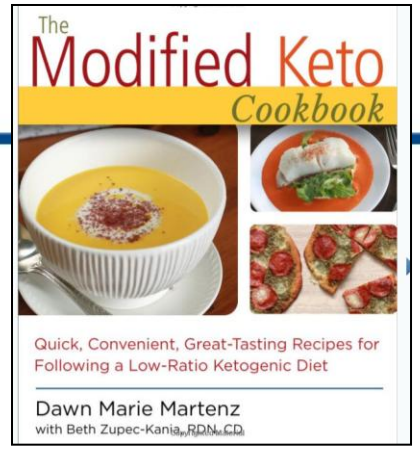

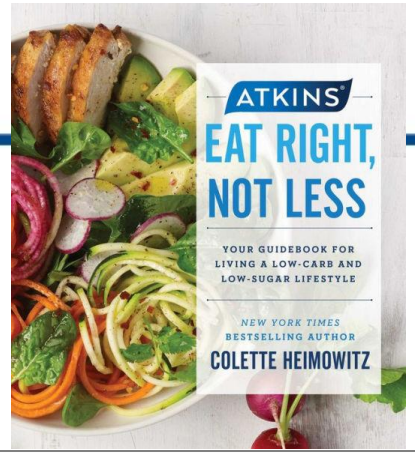

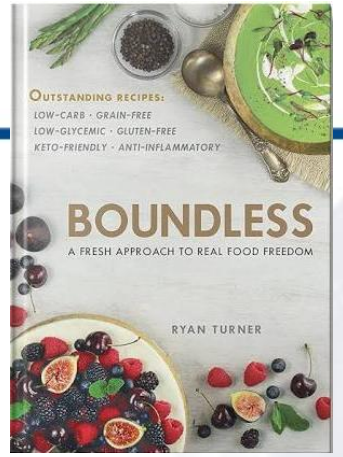

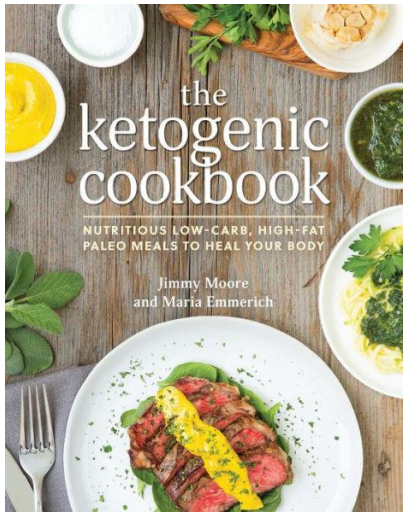

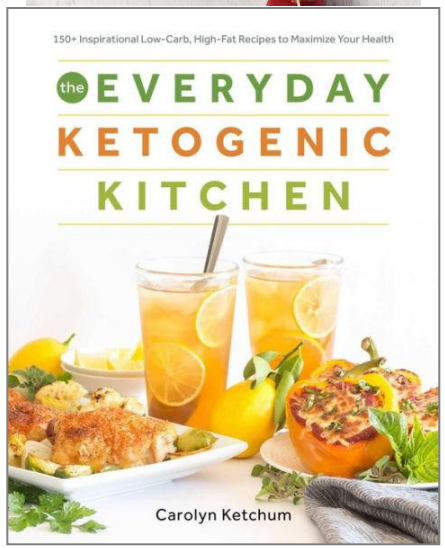

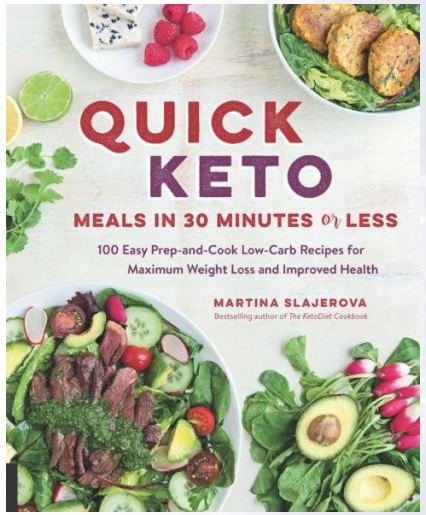

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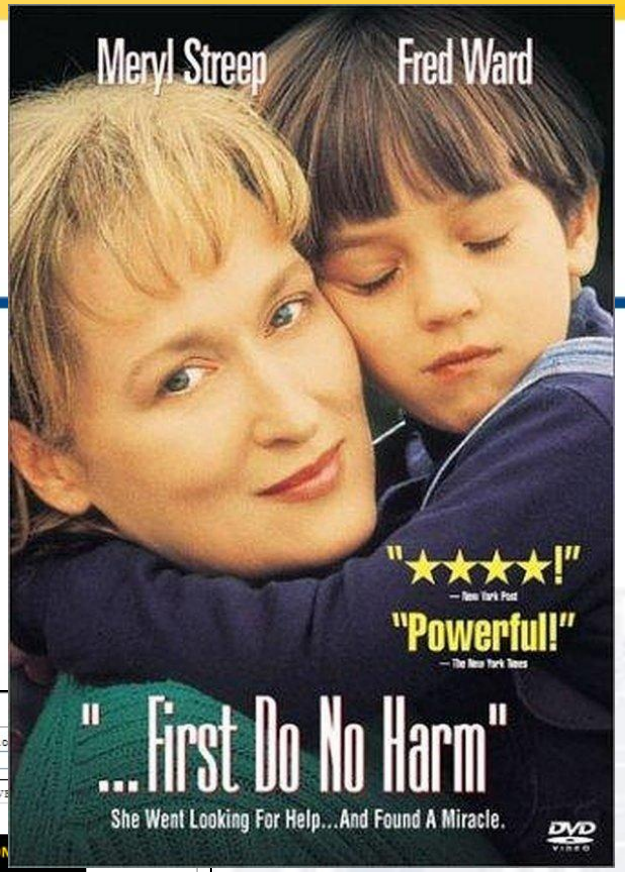
DIET

Sometimes a 90% Fat Diet Is Good For You

By MEREDITH MELNICK | @meredithcm | November 19, 2010 | 17

This weekend, the *New York Times Magazine* has an article written by Fred Vogelstein, a contributing editor to *Wired* and father to a young boy with epilepsy. Sam's condition is severe: at one point, the boy was having up to 130 seizures a day and was not responsive to medication. To treat him, the family has put Sam on a special diet: a typical breakfast consists of eggs mixed



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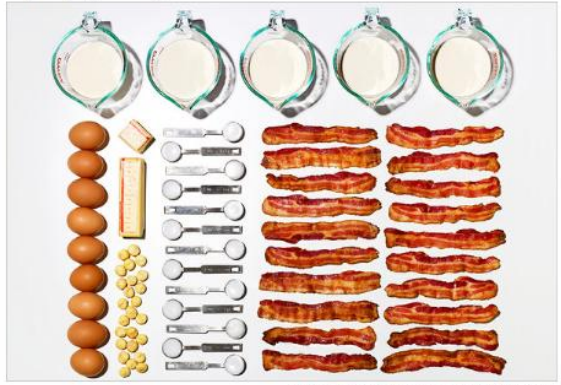
Epilepsy's Big Fat Miracle



Stephen Lewis for The New York Times; Food Stylist: Brett Kurzwell

What's Popular Now

The Yankees, a Summer Symphony in 9 Innings

Seeing Trends, Coalition Works to Help a River Adapt

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Diet is unique amongst epilepsy therapies

- Team approach

- Parents can cook to control their child's seizures

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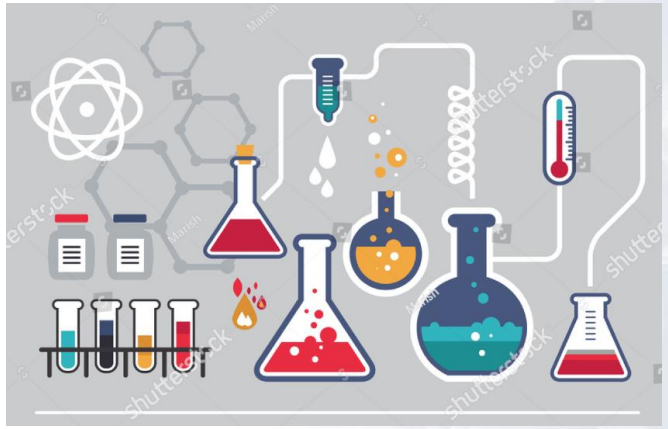
Diet is unique amongst epilepsy therapies

- Different mechanisms of action



- Perceived as a more natural approach

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Table 1. Epilepsy syndromes and conditions (listed alphabetically) for which KDT has been consistently reported as more beneficial (>70%) than the average 50% KDT response (defined as >50% seizure reduction).

Angelman syndrome[56,57]
Complex I mitochondrial disorders[51,55]
Dravet syndrome[35,36]
Epilepsy with myoclonic–atonic seizures (Doose syndrome)[34,37,38]
Glucose transporter protein 1 (Glut-1) deficiency syndrome (Glut1 DS)[27,29–32]
Febrile infection–related epilepsy syndrome (FIRES)[44–47]
Formula-fed (solely) children or infants[48,49]
Infantile spasms[10,39,40]
Ohtahara syndrome[50–52]
Pyruvate dehydrogenase deficiency (PDHD)[28]
Super-refractory status epilepticus[44,46,53,54]
Tuberous sclerosis complex[41–43]

Kossoff et al *Epilepsia Open*. 2018;3:175-92.

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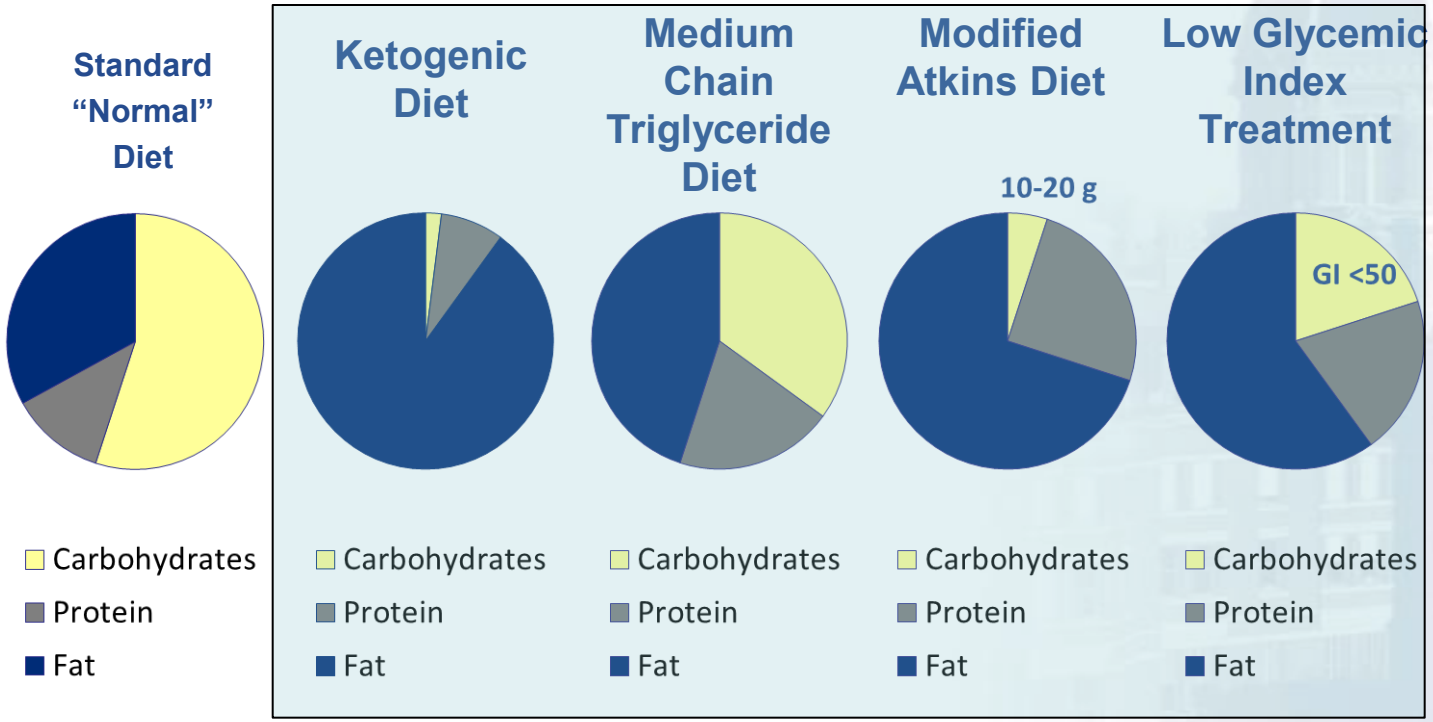
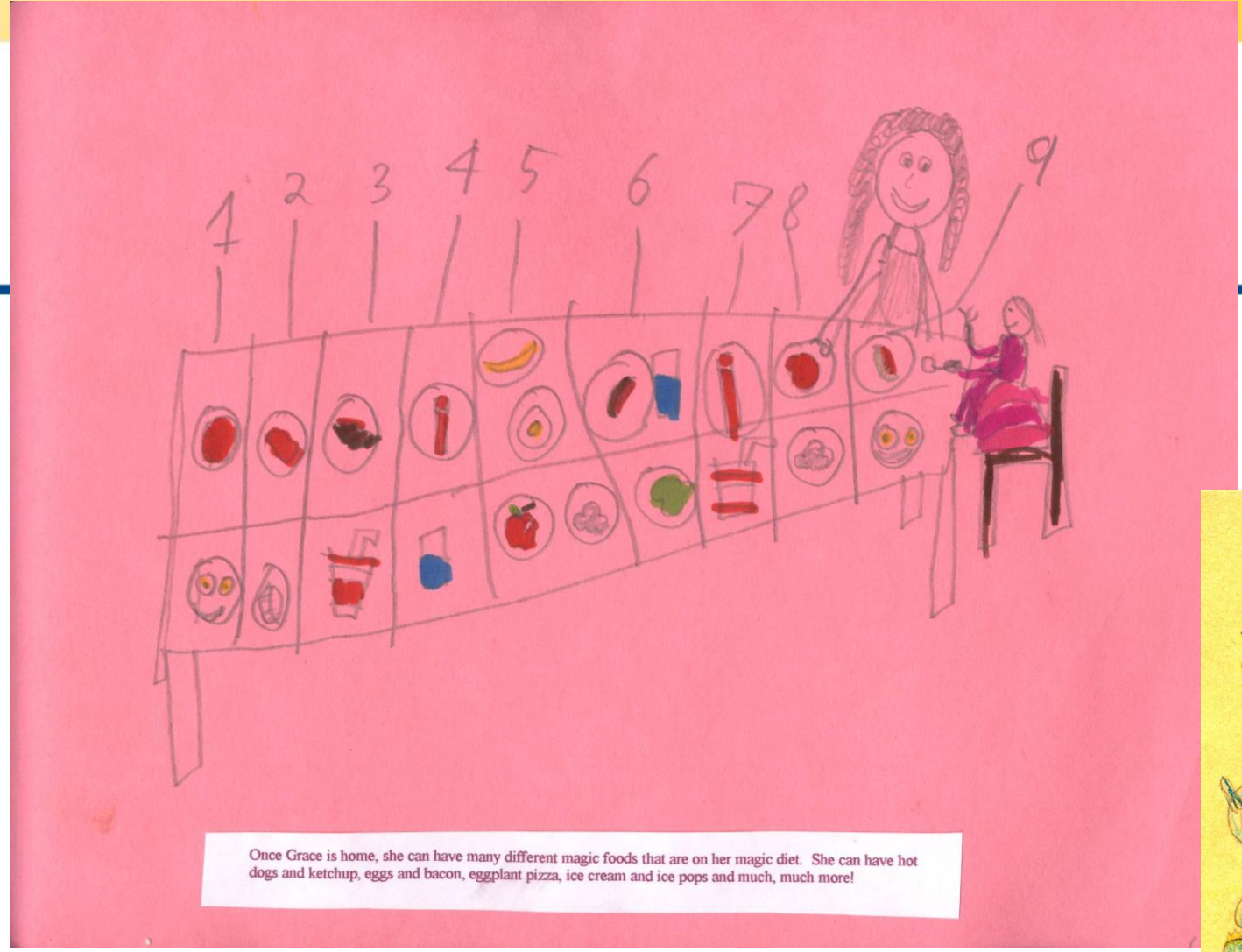
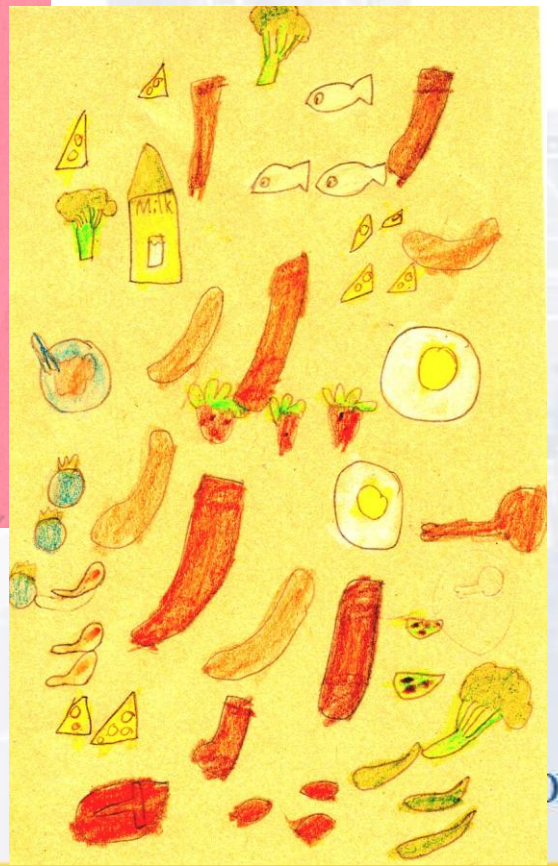
Four Ketogenic Diets







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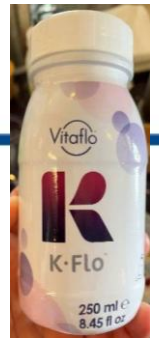

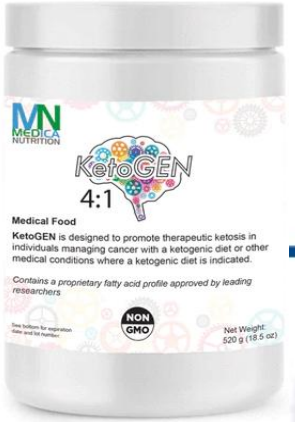

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Other Ketogenic Diet Products Used by Patients

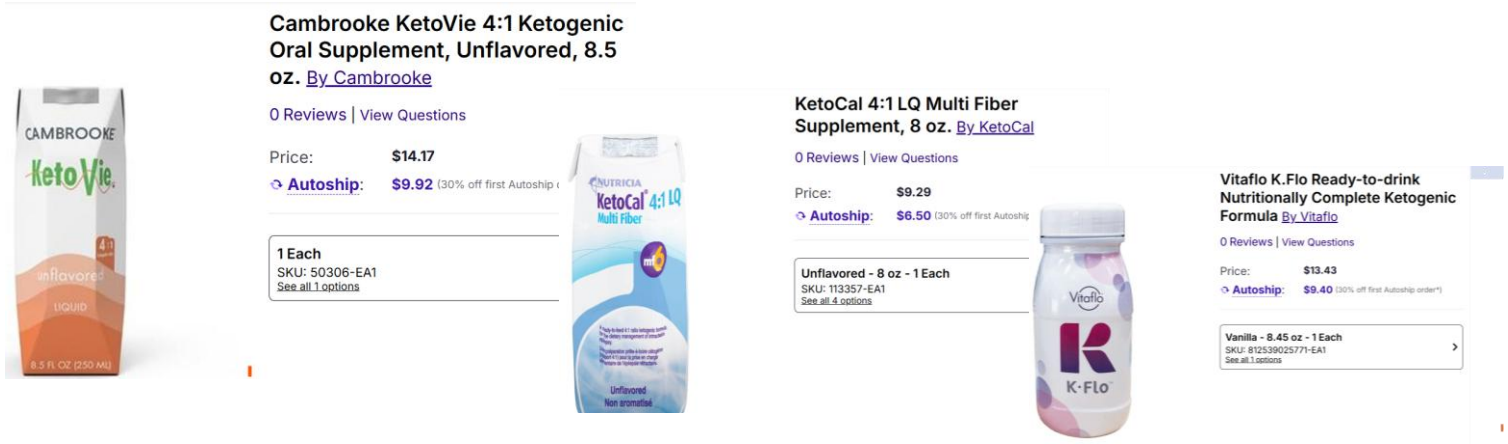
- Ketone supplements (salts, esters)
- Low carb “keto” breads, pizza, cookies to replace foods
- Other low-carb milkshakes

Regulatory (insurance) issues for me…

- Helpful…but not required (unless all of nutrition)
  - Not fixing an underlying disorder, nor a cure
- Except for 100% Gastrostomy-tube fed patients, it's not fully reimbursed (and expensive for patients)
- 80% of patients are not on the KD alone
  - However, many can reduce anti-seizure drug dosing and save money

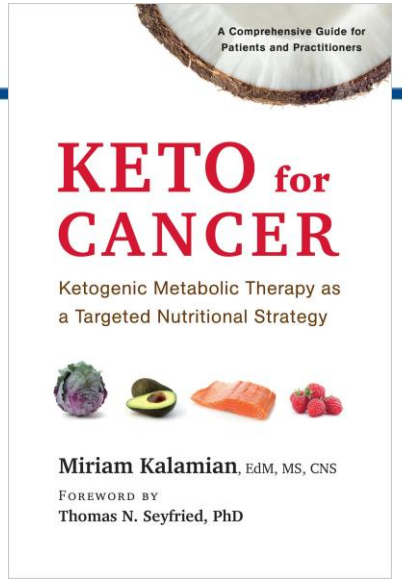
Regulatory (insurance) issues for me…

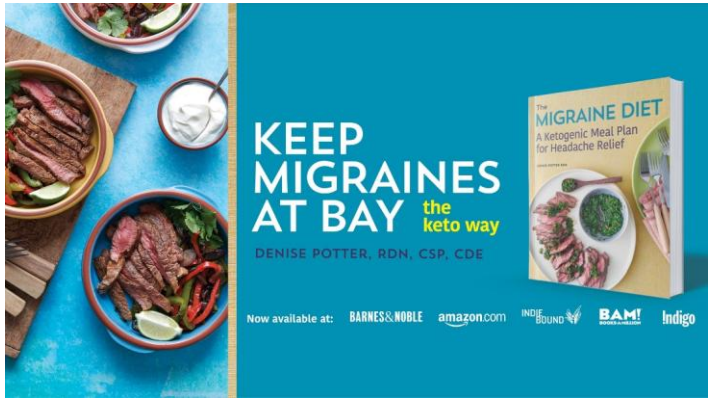
- Most families ask about oral ketone supplements but they cannot afford them
- Vitamins and minerals are required – but also not covered by most insurances
- In some situations we'll use the ketogenic diet for infants as a first-line therapy…insurance denies the admission and the formula…



Usage of formulas depends on the age, weight and condition of the patient and may range between 1-4 tetras/day, totaling an expense of $279–1700 per month*

* Source: Carewell.com. Accessed September 16, 2025. Based on KetoCal 4:1 LQ ($9.29 x 30) and KetoVie ($14.17 x 4/d x 30 days)





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Johns Hopkins Ketogenic Diet Center

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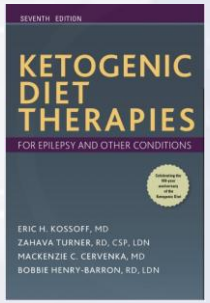

JOHNS HOPKINS MEDICINE

Welcome

Becky Woolf
Virginia
Crohn’s Disease

Ben Lewis
Massachusetts
HCU

Other Key Definitions

Drug: Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

Intended to affect the structure or any function of the body (other than food), or

Intended for use as a component of any of the above

Clinical investigation*:* any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. An "experiment" is any use of a drug except for the use of a marketed drug in the course of medical practice

Investigational new drug*:* a new drug or biological drug that is used in a clinical investigation

Brief History: FDA's Regulation of Medical Foods

Defined by statute in amendments to Orphan Drug Act (1988)

Nutrition Labeling and Education Act (1990)

- exempted medical foods from nutrition labeling, nutrient content claim, and health claim requirements

FDA rulemaking to implement NLEA

- Proposal (11/1991)
  - FDA "considers the statutory definition of medical foods to narrowly constrain the types of products" that are exempt from labeling requirements
  - FDA proposed to "clarify" the statutory definition by providing criteria for use in identifying a medical food
- Final Rule (1/1993)
  - FDA says regulation establishes "criteria that a product must meet to be considered a medical food"

Brief History: FDA's Regulation of Medical Foods

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

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

** Final Rule on IND Exemptions anticipated in coming months

FDA Medical Food Warning Letters

No "Distinctive Nutritional Requirement" for the Disease or Condition

- Most WLs contain this charge, without qualification, for at least some products

No "Distinctive Nutritional Requirement" that cannot be met through dietary modification alone

- Many WLs since 2009 contain this charge
- Even if diet alone "*may not*" meet the distinctive nutritional requirement, still not medical food if no evidence that requirement "*cannot*" be met through dietary modification alone

FDA Medical Food Warning Letters

No Distinctive Nutritional Requirement for

- Mild to moderate Alzheimer's
- Fibromyalgia
- Chronic Fatigue Syndrome
- Macular Degeneration
- Leaky Gut Syndrome
- Inflammatory Bowel Disease
- Metabolic Syndrome
- Eczema
- Protein Calorie Malnutrition
- Irritable Bowel Syndrome
- Pressure Ulcers
- Poor Appetite
- Diarrhea
- Glial Tumors

Dietary Modification Alone for

- Pregnancy
- Diabetes
- Bariatric Surgery Recovery

IND-Related Warning Letters

- *Example:* 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?	• April 2018 NASEM Meeting: "Examining Special Nutritional Requirements in Disease States: A Workshop"
What substantiation is required for medical foods? What are IND implications?	• FDA rulemaking on IND requirements for foods
What is role of FSDU? Dietary Supplements? Other specially formulated foods?	• Will FDA provide guidance on other categories?
How can we distinguish between disease *treatment* or *mitigation* and disease *management?*	• Key consideration for developing marketing claims within FDA's current framework

Conclusion

- Please protect patient access to medical foods and oral nutrition supplements.

- Recognize the important role of oral nutrition supplements in food is medicine legislation.

- Support bills such as:
  - **The Medical Foods and Formulas Access Act of 2025** (H.R. 5684)
    (formerly Medical Nutrition Equity Act)
  - **The Medical Nutrition Therapy Act of 2025** (H.R. 6199)

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Questions?

Thank you for coming!

The slides and materials are available on the HNC website:

https://healthcarenutrition.org/congressional-briefing-food-is-medicine-in-clinical-care/

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