Where Nutrition Becomes Therapy

Personalised Nutrition: Therapeutic Potential & Regulatory Challenges

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Personalised nutrition for better health - targeting the microbiome
OECD EWI Workshop, Brussels, October 10-11, 2017

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What next?

- **Nutrition & ‘Healthy Consumer-Patient’ Continuum**
- **Personalised Nutrition**
  - Untapped, targeted potential for health *and* disease management
- **Gut Microbiome**
  - Complex, not a fad, a partner re: healthcare solutions
- **Regulatory Considerations**
  - Innovation & investment ‘friendly’, with the consumer & patient in mind
- **Future of Personalised Nutrition**
  - Already here // still plenty to do & more future to come

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How much can Nutrition do for Health & Disease? To what extent - can we personalise nutrition? is the regulatory framework fit-for-purpose?

Challenges & Paradigms Shifts in Health & Healthcare

- Societal issues: aging population / overweight / rare & chronic diseases & malnutrition / *costs*

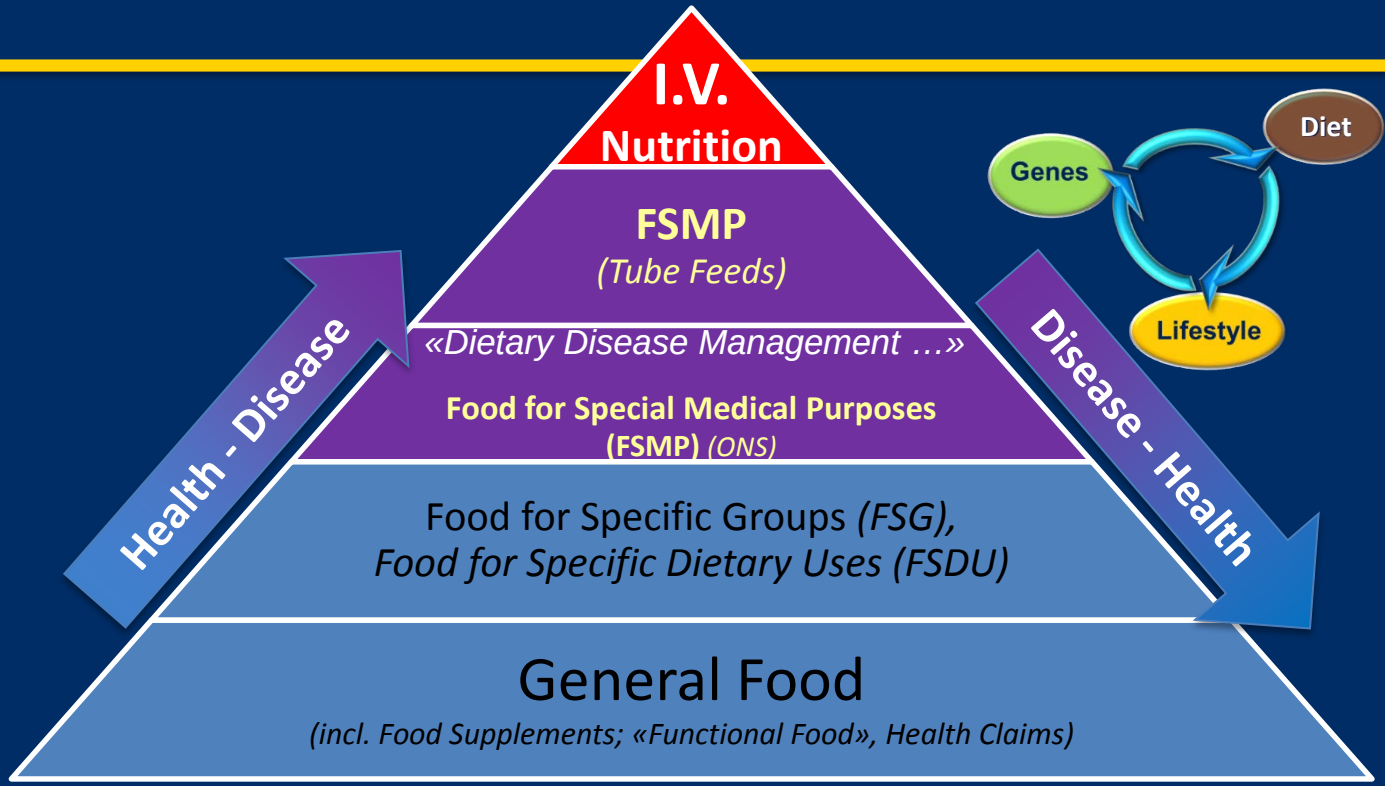
Health & Therapeutic Solution Potential ➔ encompasses Microbiome, Nutrition & Diagnostics

- New science (incl. microbiome) & technology («omics», IVD, apps …) ➔ faster; increased complexity
- Nutrition potential for health / as disease prevention / disease-related malnutrition / dietary disease management/ even (symptomatic) «therapy»
- Personalisation («targeted») ➔ none of us is in the «average» // yet no «over-personalization» either

Ways Forward – Balanced Evidence & Multistakeholder Dialogue ➔ Efficient Healthcare «Logistics»

- Regulatory Framework interpreted/enforced 'fit for purpose' ➔ ROI; acceptable «uncertainty»
  1. Product development: reduce unnecessary technological barriers ➔
     Nutrients: quality/safety, not disease based (CMC: analytics, GMP, stability, …; global harmonization)
  2. Broad based evidence (RCTs, RWE, «citizen research»…), post-marketing shift when possible
  3. Balance precautionary approach vs. innovation benefits

Healthy Consumer ⇔ Patient Continuum



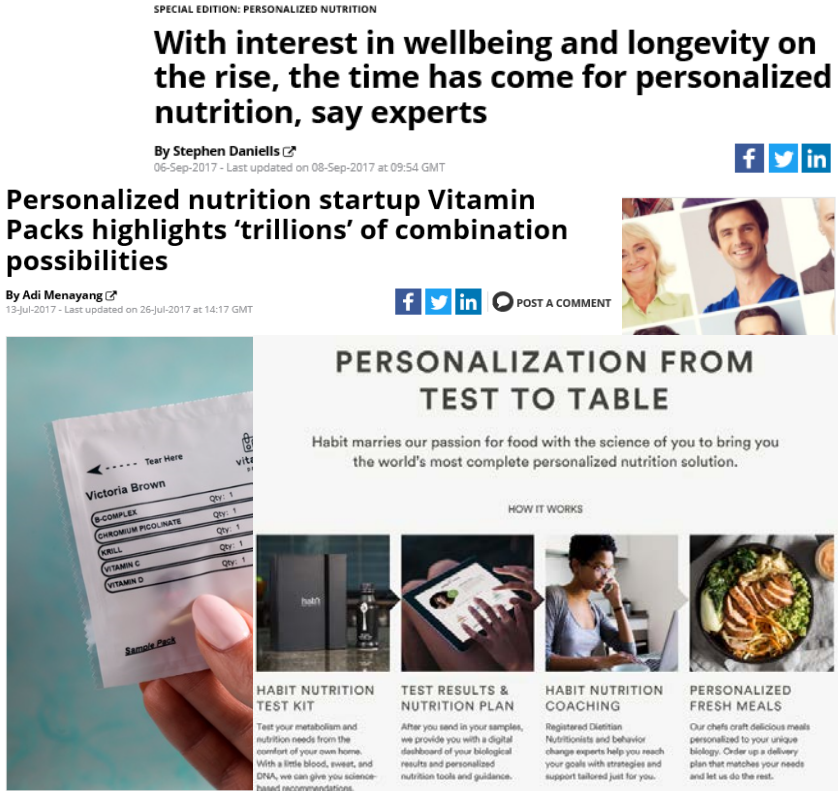
PERSONALISED NUTRITION

Who benefits from Targeted/ Personalised Nutrition?

- Physiological needs of an individual may differ from group needs
- Personalisation requires to meet measured individual nutrient needs
- Personalised nutrition with a demonstrated potential to improve health, wellbeing, patient care.

Personalisation everywhere?

- Personalised & customised approaches are big trends, a potential “tool” for increased customer loyalty & engagement
- Personalised (or “targeted”) Nutrition: Reality or Fiction?
  - Selected micronutrients adjusted per individual, eating habits, differentiation by gender, age/life situation (pregnancy, kids, 50+), gut microbiome/ genome/ biomarker analysis-based nutrient cocktails
  - Healthcare professionals adapt nutrition care to their patient needs



The Future for Medical Foods *(S.Bigelow, 2013)*

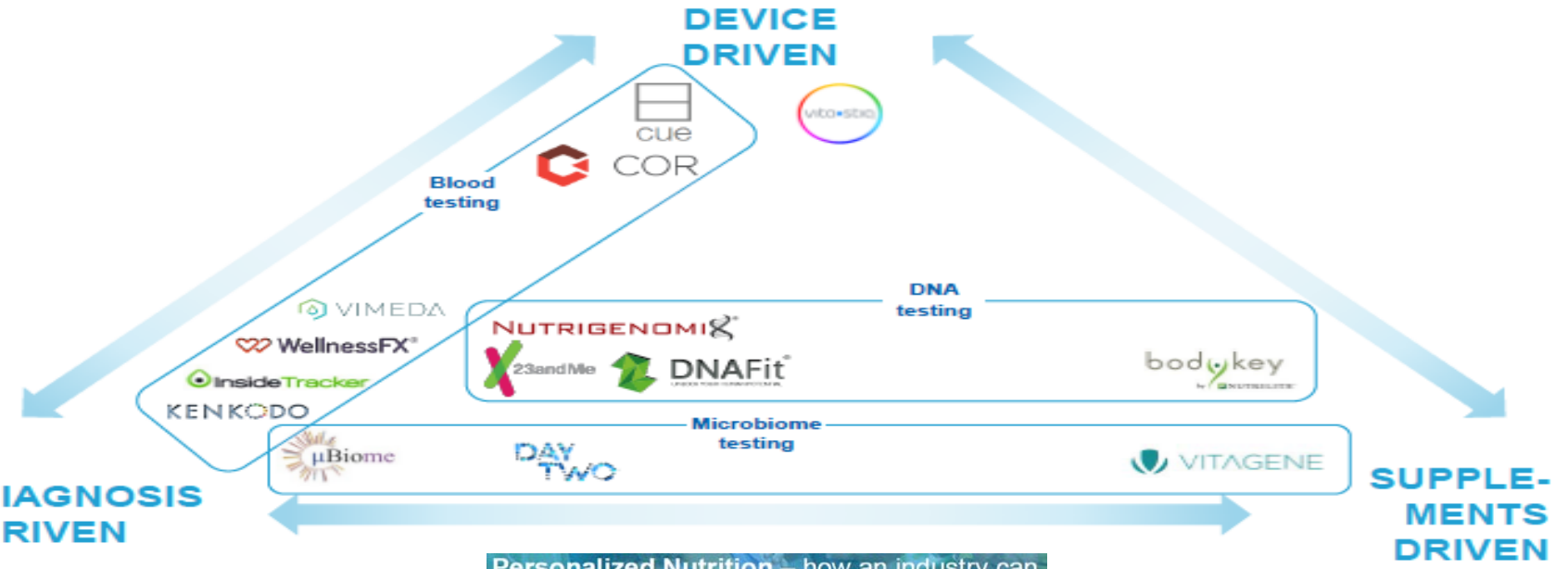
Genomic scientific findings on genetic polymorphisms related to disposition of dietary components/nutrients have been shown to have an effect on the risk, progression and clinical outcome for many diseases. For each of the diseases listed below, medical foods can be developed to address the biological effects of each nutrient-related human polymorphism.

- **Vitamin D receptor.** Vitamin D can be viewed as a master hormone that exerts its metabolic action via a cellular receptor located in most human tissues. While most dietary sources of vitamin D may be found in dairy products, certain populations may not obtain adequate vitamin D to meet their nutritional requirements (Norman and Henry 2012). ts classical nutrition-related actions involve calcium mobilization, especially its deposition to bone tissue, whereas more recent findings involve skeletal muscle and immune system development and maintenance (Girgis et al. 2013, Prietl et al. 2013).Human polymorphisms of the vitamin D receptor affect the ability of vitamin D to exert its biological action, which has been found to be associated with the risk, progression and/or clinical outcome of several diseases including diabetes, rheumatoid arthritis, polycystic ovarian syndrome (PCOS), and ovarian and oral cavity cancers (Gezen-Ak et al. 2012, Hitchon et al. 2012, Larcombe et al. 2012, Levin et al. 2012, Milner 2012, Yokoyama et al. 2012).
- **Folate MTHFR.** Two relatively common human polymorphisms related to dietary folate (vitamin B9) disposition have been characterized for the methylene-tetrahydrofolate reductase (MTHFR) and methionine synthase reductase (MFRR) genes, designated as C677T and A2756G, respectively, which can result in elevated blood levels of homocysteine, a known risk factor for hypertension and vascular disease (Bailey and Caudill 2012). Associations have been characterized between human MTHFR polymorphisms and the risk, progression and/or clinical outcomes for numerous diseases including depression, mild cognitive impairment, heart disease including myocardial infarctions, and spina bifida (Ma et al. 1996, Morita et al. 1997, Schwartz et al. 1997, Lucock et al. 2000, Yates and Lucock 2003, Milner 2012, Smith et al. 2010, Wilson et al. 2013).
- **Dietary fatty acid utilization.** Human polymorphisms affecting energy utilization of dietary polyunsaturated and saturated fatty acids include the genes that code for CALPAIN-10 (Ca-mediated protease), PPAR receptor (peroxisome proliferator-activated receptor), INK4 (a tumor suppressor), lipoprotein lipase, fatty acid desaturase-1 and -2, and endothelial nitric oxide synthase. These human polymorphisms are associated with the progression to metabolic syndrome (a condition that often leads to diabetes and obesity), elevated blood cholesterol levels and asthma (Bendlova et al. 2008, Perez-Rodriguez et al. 2011, Joffe et al. 2012, López-Alarcón et al. 2012, Thompson et al. 2012, Ahmed et al. 2013, Gillingham et al. 2013).
- **Human microbiome.** The microbiome is defined as the total community of microbes that inhabit the human gastrointestinal (GI) tract, of which the microbial community is responsible for aiding the digestive process. he human microbiome has been characterized by the NIH Human Microbiome Consortium in 2012 (Huttenhower et al. 2012). The genetic disposition of human microbiome has been found to be associated with the risk, progression and/or clinical outcome of many diseases including obesity, type 1 diabetes, inflammatory bowel disease, rheumatoid arthritis, muscular dystrophy, multiple sclerosis, fibromyalgia and some cancers (Aomatsu et al. 2012, Clemens 2012, Huttenhower et al. 2012). There is the potential that genetic variations in the members of the microbiome or its human host may have an effect on their interactions in respect to human disease state. Dietary probiotics in the form of cultured dairy products and prebiotic supplements provide positive effects the nature and activity of the human microbiome in respect to digestive process, immunity and perhaps obesity.

Personalisation starts with Measuring

Some companies are on the market or are fundraising right now

BASF
We create chemistry



Personalized Nutrition – how an industry can take part in shaping the future of Nutrition

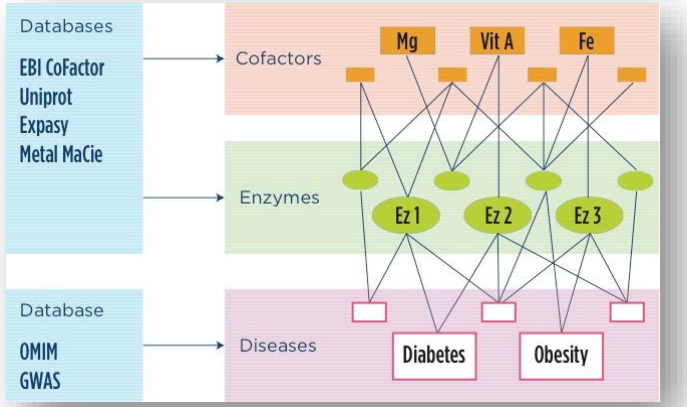
Simon Strauch, Dr. Michael de Marco, Martin Stahljans

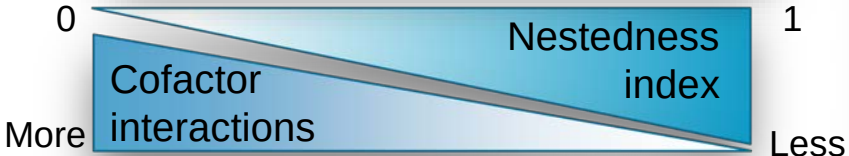
January 2017

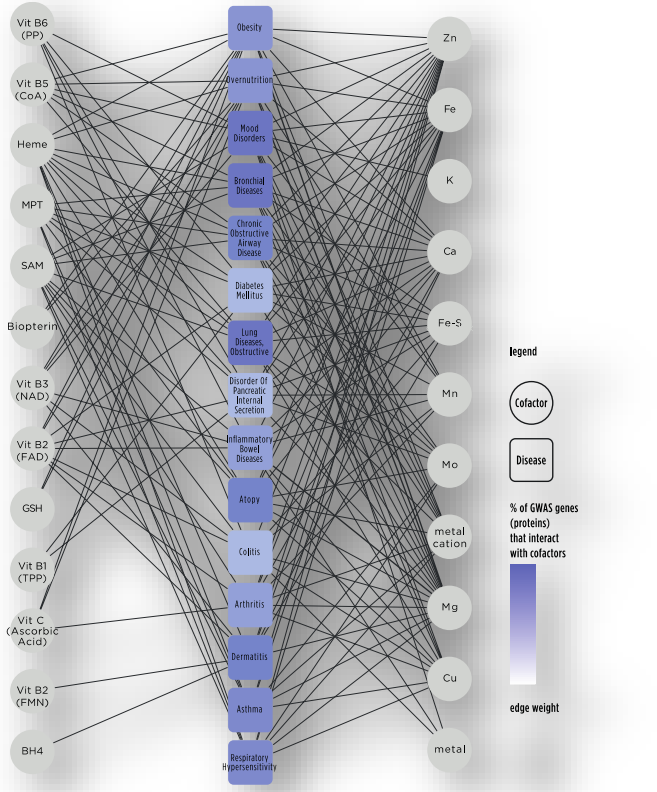
Newtrition

Complexity of Personalising Micronutrients?

Cofactor – Protein Interactions







 J.Kaput (2016)

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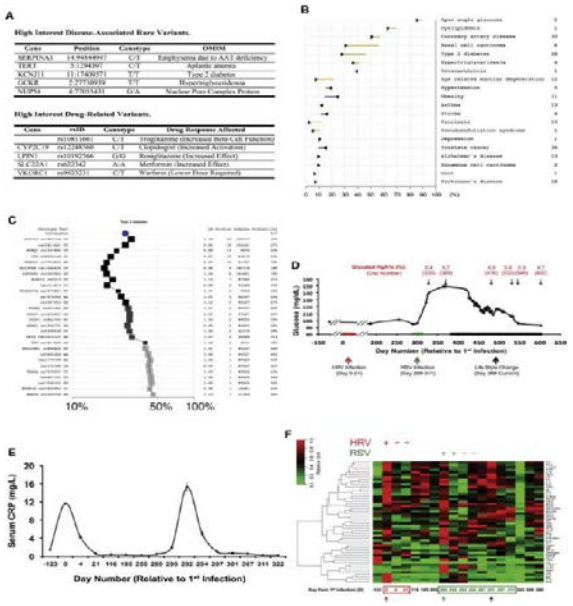
Science Approach towards Targeted Nutrition

Personal omics profiling reveals dynamic molecular and medical phenotypes
Chen et al. (2012) Cell 148:1293-1307 – Medical findings



Nutrition & Health Interactions

Socio-economics	Health status
Lifestyle	Medical conditions (drugs)
Dietary habits	Age, gender
Environmental exposures	Genetics (incl. microbiota)

Metabolic Phenotypes & Biomarkers

Dietary assessment & Nutritional status

Nutrition Molecular Epidemiology

Risk factors & prevalence of nutrition-related disease

Quantitative, comprehensive
System Nutrient Profiling
Amino acids, fatty acids, micronutrients

Personalized Nutrition Healthcare

Nutritional patient stratification

Personalized Nutrient Requirements

Proven causality between nutrient deficiency with health and disease status

Targeted Nutrition

IVD & Nutrition
Nutritional efficacy monitoring

Health Maintenance

Healthy aging &
Preventive medicine

Medical Food / FSMPs

Dietary management of disease specific nutrient requirements

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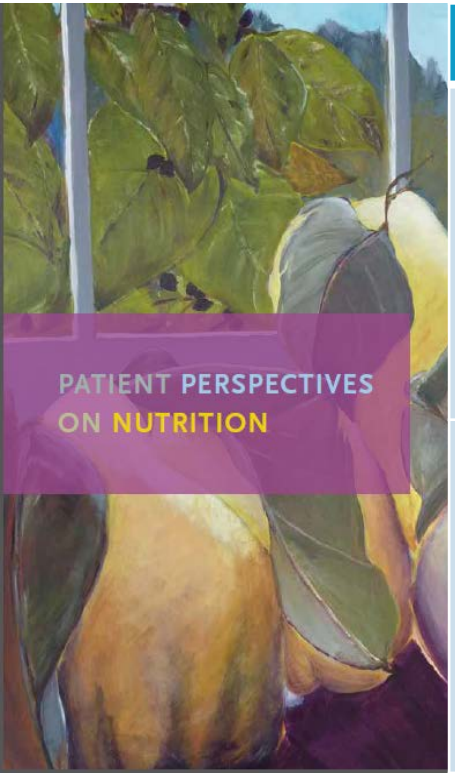
Medical Nutrition: Improving Nutritional Status / Clinical Advantage

Can be a de-facto Disease Prevention/Management/Treatment - Complementing Drugs



	Disease / Medical Condition	Clinical Benefit
Nutrition as Disease-related Malnutrition Management	Short Bowel Syndrome; Stroke	Lifesaving Intervention
	COPD	Increased Ventilatory Capacity
	Surgical Patients	Less Complications
	Older patients	More Active, Better quality of Life, Decreased Mortality
Nutrition as Disease Management («Therapy»)	Crohn's Disease	Induction of Remission
	Cow's Milk Allergy	Reduced Symptoms, Catch-up Growth
	IEMs: PKU, MSUD, FAOD, GSD ..	Normal Growth & Development
	Intractable Epilepsy	Less Seizures; Normal Growth & Development

Adapted from: http://www.eu-patient.eu/globalassets/press/pressreleases/2013-05-24_pr-nutrition_epf-egan-enha.pdf

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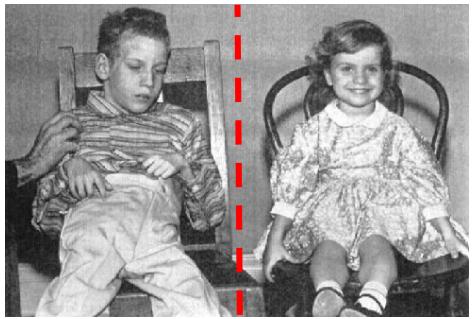
The PKU story

For Inborn Errors of Metabolism (IEM)

Disease / patient need

- **Inborn error of metabolism**



Two siblings with PKU. Only the sister had been diagnosed and treated since birth

Nutritional solution

Clinically proven

- **Nutritional therapy is the gold standard**
- **Vitaflo's portfolio offers "diet for life" solutions**

Ruthsatz - OECD EWI Workshop, Brussels 2017

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THE CHARLIE FOUNDATION
for Ketogenic Therapies

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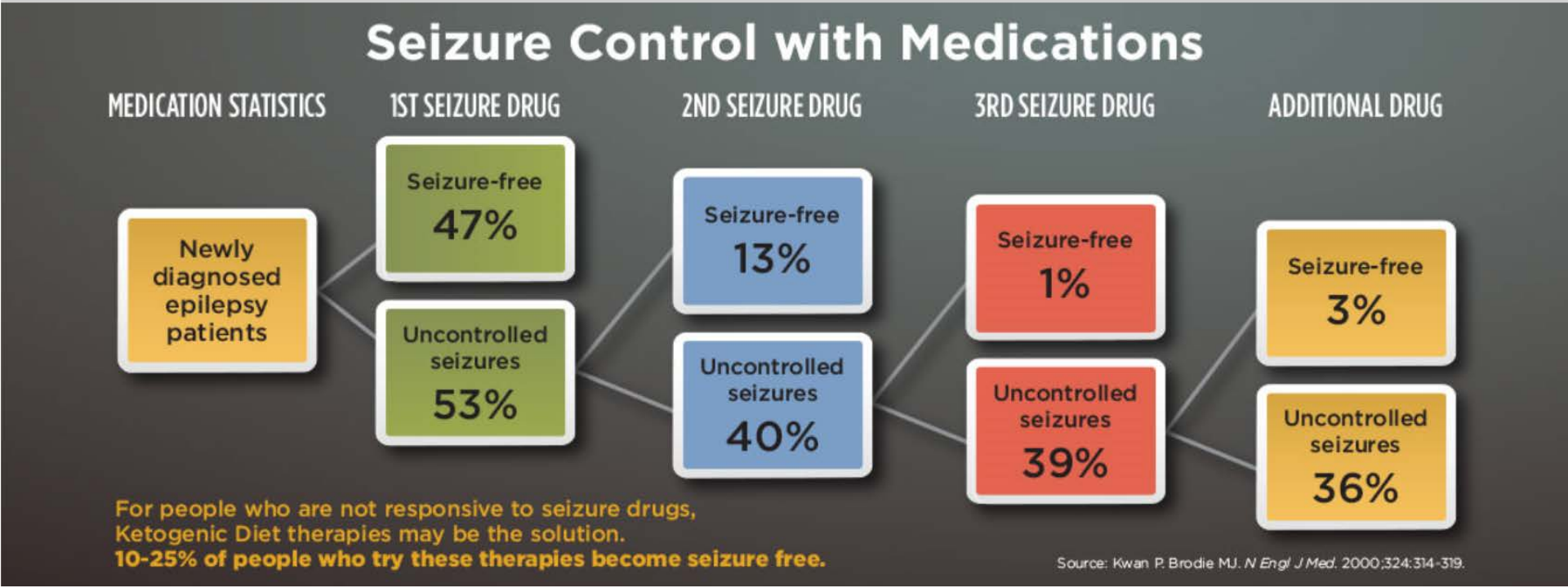

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«Intractable Epilepsy & the Value of formulated Ketogenic Diet Products»* as Nutritional Therapy

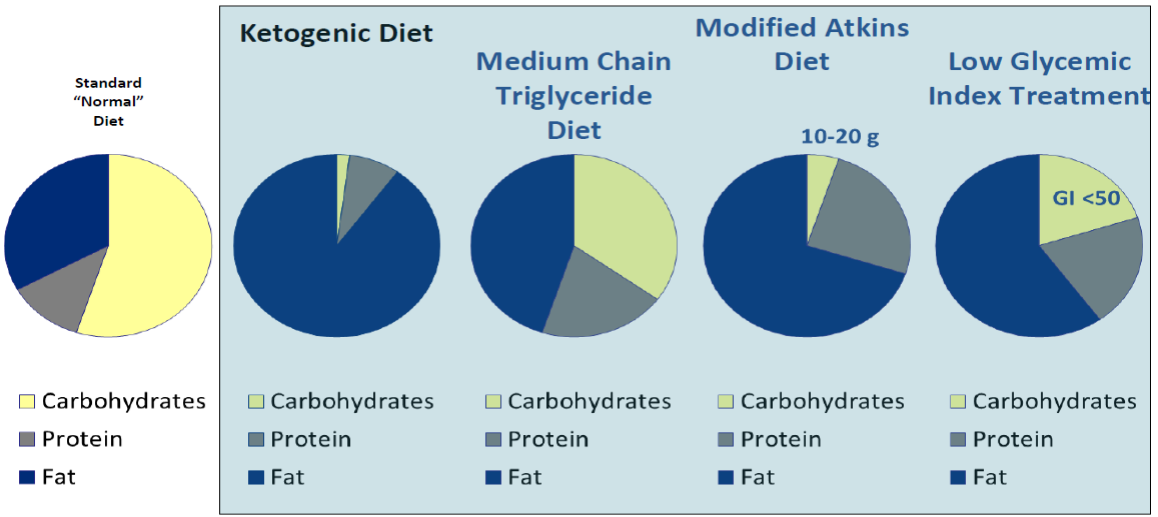
Ketogenic Diet: The Basics

- Traditionally started gradually in the hospital over 2-3 days, after a 24 hour fast
  - Families educated daily
- Ratio (fat: carbs and protein)
  - 4:1 more strict
  - 3:1 for infants and adolescents
- Calories and fluids measured
- Solid foods and/or formula

Case Study: 17 year old female

- 1 week: No change in seizures, likes the fat foods but misses rice and pasta
- 1 month: Seizures reduced 90%! (but not driving…)

Four Ketogenic Diets



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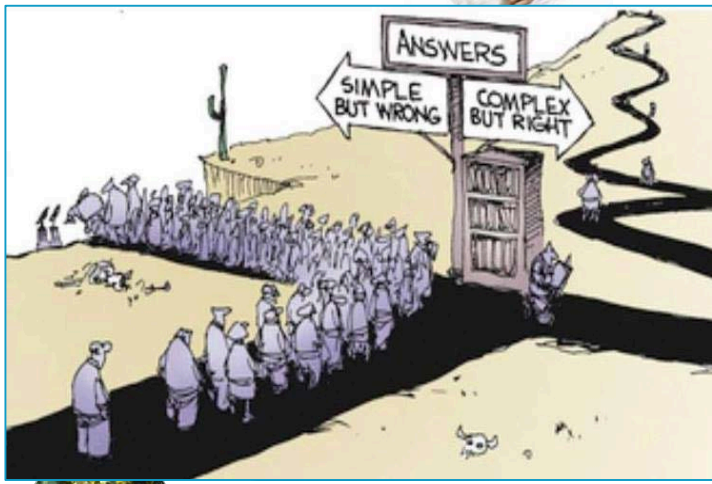
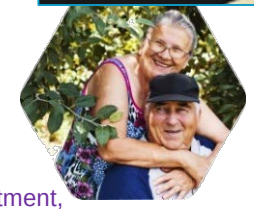
**Adapted from Prof. Eric Kossoff (RAPS Convergence, Sept 2017; Regulatory Focus journal, Oct.2017)*

Personalized Nutrition – A Gut Feeling

- **Nutrition is crucial in health & disease management ➔ Microbiome part of the solution**
  - Nutrition is safe, physiologic, nourishes (!), can be a sole or additional solution to disease prevention, related malnutrition, dietary disease management, symptomatic disease therapy
  - Use untapped nutrition potential in an adapted, «modern» way*
- **Regulatory framework tested by a real world scenario**
  - Aging society, NCDs, healthcare costs, patient empowerment
  - Increased complexity: blurring lines between established food, drug, devices categories (FSMP, nutritional therapy, ‘apps’ ...)
- **We must interpret/enforce regulations in an innovation & consumer/patient friendly way**
  - Eliminate unnecessary technological hurdles (CMC; global)
  - Opportunities will be lost if no investment (ROI)*
  - Accept a ‘certain’ uncertainty (IT/Big data …)





*Europe invests 97% in treatment, i.e. drugs & devices, 3% in prevention

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GUT MICROBIOME

Innovation Engine – Critical to long-term Success

Partnering in GI Health

SERES THERAPEUTICS

enterome bioscience

axcella

CHI-MED

Ns NUTRITION SCIENCE PARTNERS

Networking with Academia

biopôle

EPFL ÉCOLE POLYTECHNIQUE FÉDÉRALE DE LAUSANNE

CHUV

LUDWIG CANCER RESEARCH

Hôpitaux de Toulouse

MONASH

Tufts UNIVERSITY

Leveraging Venture Funds

Inventages

FLAGSHIP VENTURES

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Partnering in Food Allergy

dbv technologies

aimmune THERAPEUTICS

Partnering in Brain Health / Devices

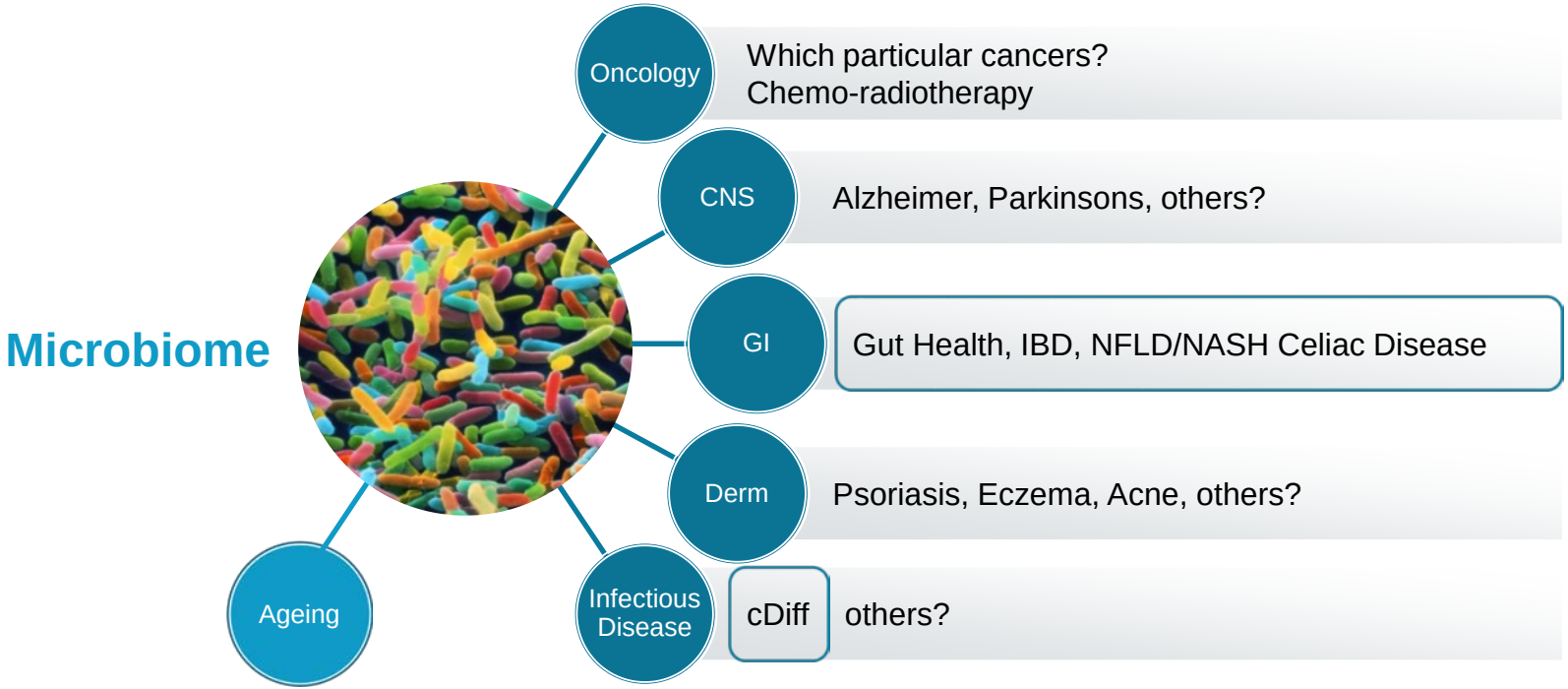
Accera

GE Healthcare

AC IMMUNE

PHAGENESIS

A broad Role of Microbiome



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Critical Path to Microbiome Modulation & Deployment in Multiple Indications

We can influence by….	*...using Differentiating Technologies*
1 Diagnosing the microbiome *How do we measure microbiota status in health & disease*	– Metagenomic ‘footprint’ of microbiota in health & disease – MetaHIT database (10 million bacterial genes) – De-risking CTs & development plans across indication areas
2 Replacing the Microbiome *Restore a healthy microbiome*	– Bacterial cultivation & spore technology – Access to unique bioinformatic tools to generate new Ecobiotics: defined live bacterial engraftments
3 Feed the healthy microbiome *Develop nutrients/molecules enhancing healthy microbiome*	– Developing nutrients/natural derived ingredients to modulate the microbiome (*eg* AAs, oligosaccharides, prebiotics, probiotics, lipids)
4 Kill the unhealthy microbiome *Develop targeted solutions & prevent colonisation of pathogens*	– Nutrients or bacteria derived small molecules – Antagonise attachment / metabolic activity of non-beneficial bacteria
5 Use bacteria as delivery system *Select & develop live bacteria as benefit delivery system*	– Unique delivery system (*eg*. *L. lactis)* for biologics & small molecules – Specific probiotics

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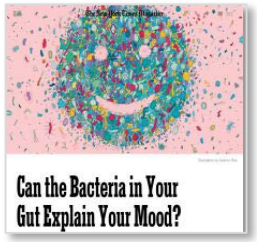
Mastering the Microbiome… a New Health Frontier

Anxiety → **Gastrointestinal Health** → **Allergy, Obesity/Diabetes**

Probiotics (BL 999) in Anxiety Management



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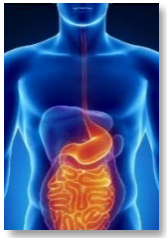
Ecobiotics in the Microbiome



IBD IBS

Crohn's Disease

Ulcerative Colitis

SERES THERAPEUTICS™

enterome bioscience

Targeted Bacteria in Inflammation & Immunity-related Diseases

FLAGSHIP VENTURES

EVELO BIOSCIENCES

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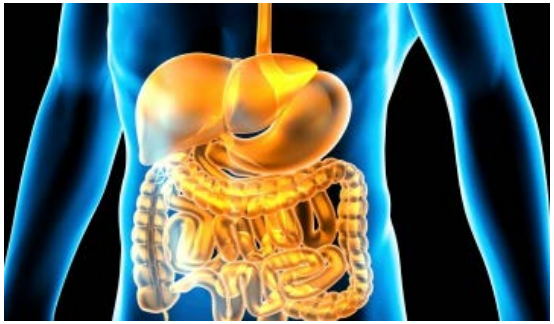
IBD = Inflammatory Bowel Disease IBS = Irritable Bowel Syndrome

Building Leadership in the Microbiome Field

Strategic investment and partnership with Seres



SERES THERAPEUTICS™

- **Microbiome is a fast developing and new health frontier**
- **Exclusive agreement outside North America for Seres' novel class of microbiome therapeutics**
  - Clostridium difficile infections (CDI): SER-109, SER-262
  - Inflammatory bowel disease (IBD): SER-287, SER-301
- **Complementary relationship to support future commercialization**
- **Seres: leader in the microbiome space with most advanced pipeline**
- **Nestlé Health Science: global footprint; strong category expertise in Acute Care & GI; opportunities for co-therapeutic approaches (Dx-Rx-Nx)**

Gut Microbiome – Healthcare Potential

- Need to address basic development issues

Baseline Thoughts	•Patient or Microbiome? Symbiosis? Dysbiosis? «Healthy» Microbiome? •Health & disease impact? define gaps
Transformative Science	•Dynamics of gut microbiome: mechanism of action, physiologically relevant endpoints, individual metabolism, e.g. nutrition pheno-typing to quantify “DNR” (nutritional needs)
Quality, Safety, Efficacy	•Regulate what: Safety 1st (pathogen free)? •Large scale production; batch consistency? •Classify non-gut systemic microbiome effect
Gold Standard, Precedent, Analogy, Learning?	•Pro-, Pre-, Symbiotics / Antibiotics •1st 1000 days, functional variability •Access: patients’, payers’ views?

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Microbiome – A Gut Feeling

- Microbiome is a complex adaptive system ➔ not a fad, a ‘quasi organ’ not to be viewed in isolation ➔ a variable in every aspect of host health ➔ the diet has a strong effect on gut microbial composition
- Blurred lines ➔ view in context, good vs. bad over-simplified ➔ only few strains seem important, 1 bacteria present in a certain host environment & a genetic susceptibility can influence health or disease
- Don’t oversell ➔ targeting the microbiome will not affect or cure *all* GI diseases

REGULATORY CONSIDERATIONS

«Modify* the Gut Microbiome for the …

Biological Drug	• **.. prevention, treatment, cure of IBD / … C.diff. »**
FSMP/ Medical Food (tube feeds or ONS)	• **… dietary management of IBD»**
Food Health Claim (EU NHCR Art.14; US)	• **… risk** (factor) **reduction of IBD»** (~«Disease Prevention»)
Food Health, S/F Claim (EU NHCR Art.13; US S/F)	• **… normal bowel function/ increase in faecal bulk»**

* incl. e.g. FMT from healthy to sick individuals

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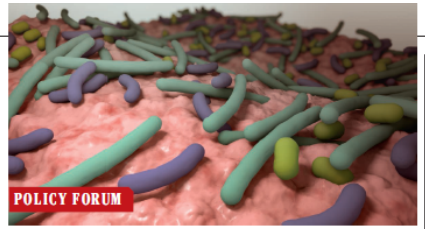
Regulatory framework for personalised nutrition in health & disease

- Current rules & advice based on average requirements & limits (EAR, DRI, UL, …), health, age or gender related ➔ personal needs, safety, claims may deviate ➔ healthy people (homeostasis) vs. disease
- Measuring tests & devices (e.g. IVD, LDTs, apps, wearables) must be validated to ascertain quality & reliable nutritional advice

Science (2017)



SCIENCE AND REGULATION

Food and microbiota in the FDA regulatory framework

How should microbiota-directed foods be regulated?

By Jonathan M. Green,[1,2]* Michael J. Barratt,[3]* Michael Kinch,[1] Jeffrey I. Gordon[3]*

New understanding of how our gut microbial communities (microbiota) transform dietary ingredients into metabolic products that affect human biology is altering our definitions of the nutritional value of foods (*1*, *2*). We are coming to appreciate how much formation of the gut microbiota during early postnatal life and the traits encoded by its several million microbial genes (microbiome) are important determinants of healthy growth and of our metabolic, physiologic, immune, and perhaps neurologic phenotypes (*3*, *4*). These advances are spawning efforts to develop foods that promote healthy microbiota development during early postnatal life, prevent the loss of microbial diversity associated with Western diets, and repair abnormalities associated with various disease states (*5*–*8*). But given the mechanisms by which such microbiota-directed foods (MDFs) may achieve their desired effects, the existing U.S. regulatory framework presents challenges in determining how MDFs should be classified. How these challenges are addressed will affect innovation incentives, product quality, consumer access, and public health. Although approaches to regulation vary among countries (*9*), we focus on the U.S. Food and Drug Administration (FDA) because of its global influence and because the products it regulates are often widely distributed.

It has been more than 20 years since the last major revision of regulatory definitions for food ingredients in the United States. When the Dietary Supplement Health and Education Act of 1994 was signed into law, knowledge of the role of the gut microbiota in health and disease was limited. Growing appreciation of how the microbiota generates biomolecules that are not produced by any of our human cell lineages and that affect our health status is forcing us to evolve our concept of essential nutrients to include some of these microbial products (*10*, *11*). A microbiota that cannot generate these products in adequate quantities may lead to disease and is thus a target for reconfiguration by MDFs, which can be defined as foods designed to alter properties of a microbiota. An MDF could alter existing members of the consumer's microbiota in a deliberate manner to affect the community's functional properties, and/or it may provide a substrate that is transformed by the microbiota to products necessary for a healthy state.

There is rapid growth in the number of products that claim to affect the gut microbiota and benefit health.

POTENTIAL CLASSIFICATIONS

If an MDF is designed primarily to provide nutritive value, a key question is whether such nutritive value has to be provided directly by the MDF for it to be classified as a "conventional food" by the FDA (i.e., substances ingested primarily for their taste, aroma, or nutritive value). For example, if the MDF affects targeted members of the microbiota in ways that increase microbial production of a nutrient necessary for a healthy state, would the MDF be considered a food? One way of distinguishing a conventional food from an MDF is that the former is not designed to specifically alter the properties of the microbiota, whereas the latter is intentionally formulated with this goal in mind. In practice, ingredients that target the microbiota may be present in, or deliberately added to, existing products [e.g., human milk oligosaccharides in infant formula (*12*)].

The distinction between conventional food and an MDF may be inconsequential from a regulatory perspective if the use of the MDF satisfies criteria for being deemed Generally Recognized as Safe (GRAS) and claims fall within the scope allowable for food. Note that it is not the substance itself that underlies GRAS designation but rather its manner of use; moreover, there is no definitive list of substances established as GRAS under conditions of intended use. To establish GRAS status, qualified food-safety experts would have to consider the effects of the MDF, its constituents, and the products of its microbial biotransformation. If an MDF is composed of ingredients with GRAS status, it could be classified as a conventional food. If any components do not have GRAS status, they cannot be added to conventional food without petitioning the FDA for approval as a new food additive. This requires extensive safety testing (*13*).

If an MDF were classified as a "dietary supplement," it would be possible to make certain claims related to its nutrient content and its effects on health or the structure and function of the body but not claims regarding the treatment, prevention, or diagnosis of a disease. However, if an MDF contains a substance not normally found in food or one that has not been reviewed by the FDA as a new ingredient under a New Dietary Ingredient (NDI) Notification, its classification as a dietary supplement would likely be precluded (*14*).

A "medical food" is designed for dietary management of a disease or condition with "distinctive nutritional requirements" (e.g., for management of inborn errors of metabolism, such as phenylketonuria). If an MDF is designed for a condition where insufficiency of a product of a microbiota—or chemicals generated by host cell metabolism of that product—is recognized to be causally related to the condition, then that product might be considered an "essential nutrient" in the context of that condition. An MDF that promotes microbial production of the

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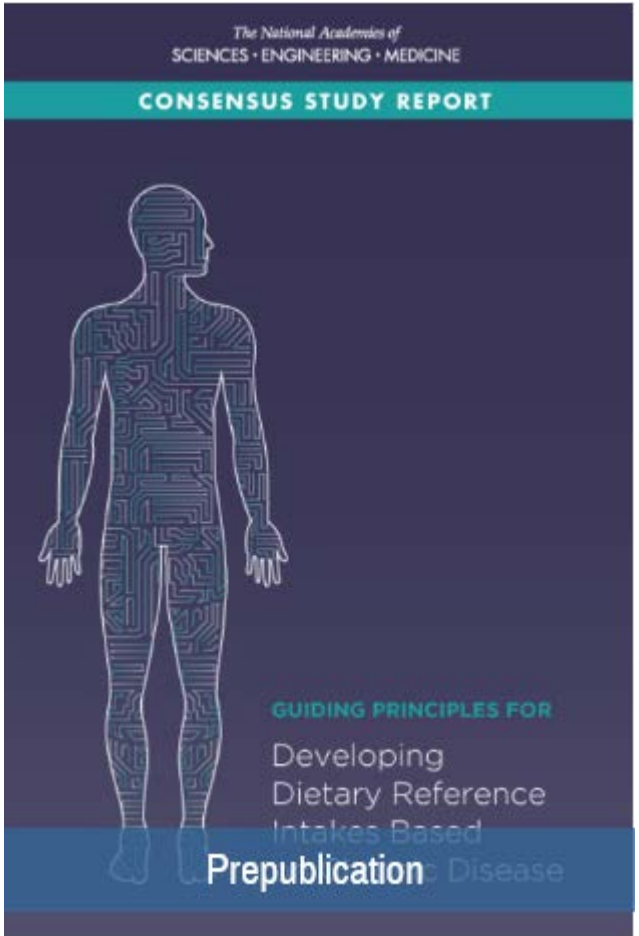
ILLUSTRATION: V. ALTOUNIAN/SCIENCE

NASEM (US, 2017)



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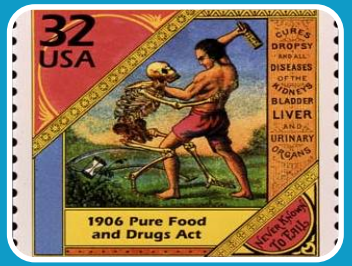
Increase Flexibility between Food & Drug Frames for Innovative Solution-Focused Dietary Disease Management

Regulatory Design & Gaps

Geographical Destination & Food or Drug «Intended use»: Design @ very start of development:

‘ Changing horses midstream? ’ ➔
~Start from scratch to meet compliance requirements



«Disruptive innovations» in dietary disease management:
Difficult to meet all category requirements when switching frames

- *Nutrition vs. drug CMC (monographs; analytics; G(X)P; …); clinical (disease) endpoints*
- *Nutrient «cocktails» not adapted to [mono-]dose-response drug requirements*
- *Health vs. disease dosage continuum: nutritional ➔ pharmacologic ➔ toxic*
- *Patho-mechanism of action («DNR») proof for medical food, yet not drugs*

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Why citizen-driven research strategies

20th century

- Cure
- Religion of the Average
- "We take good care of you"
- You are either sick or healthy
- Reductionist
- Knowledge imperative
- Certainty / uncertainty

21st century

- Prevention
- Uniqueness of the individual
- "I take good care of myself"
- Focus on resilience
- Appreciative of complexity
- Learning imperative
- Curiosity

Gaston Remmers
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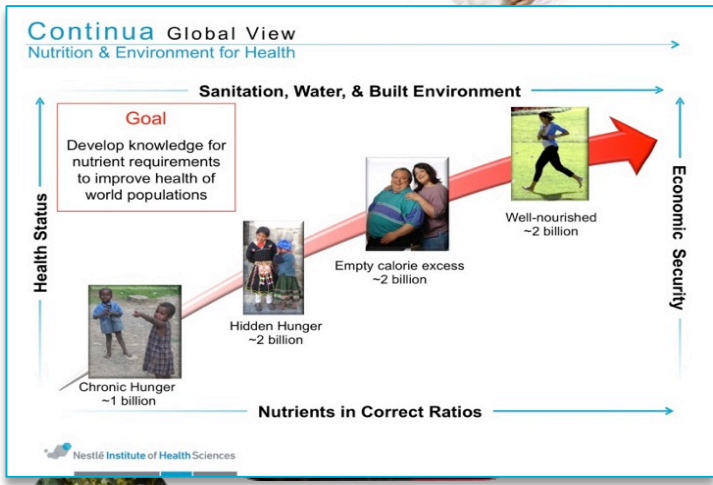
Personalised Nutrition's Future?

- Science is crucial to develop effective regulation & policy, but may not provide answers to all aspects
- Incentives for the development of nutrition solutions is of public interest ➔ Accelerate current thinking & approaches ➔ Prepare for unexpected "disruptive", cost-efficient solutions ("omics", IT/Big data, diagnostics)
- Nutrition approach still largely driven by averaging needs (EAR, DRI, UL …). Personalisation is a general, non-stoppable trend. Personalised Nutrition is already amongst us. Both approaches can co-exist together.
- No «over-personalising» (homeostasis vs. disease)
- Demonstrated, perceived & sustained benefit for consumers, patients, health care systems is key ➔ Need for a continued multi-stakeholder dialogue.



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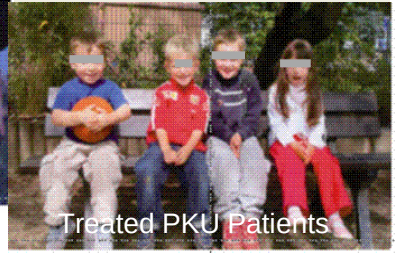
— from LIVING LANGUAGE

Personalised



Nutrition

- Making a Difference

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