

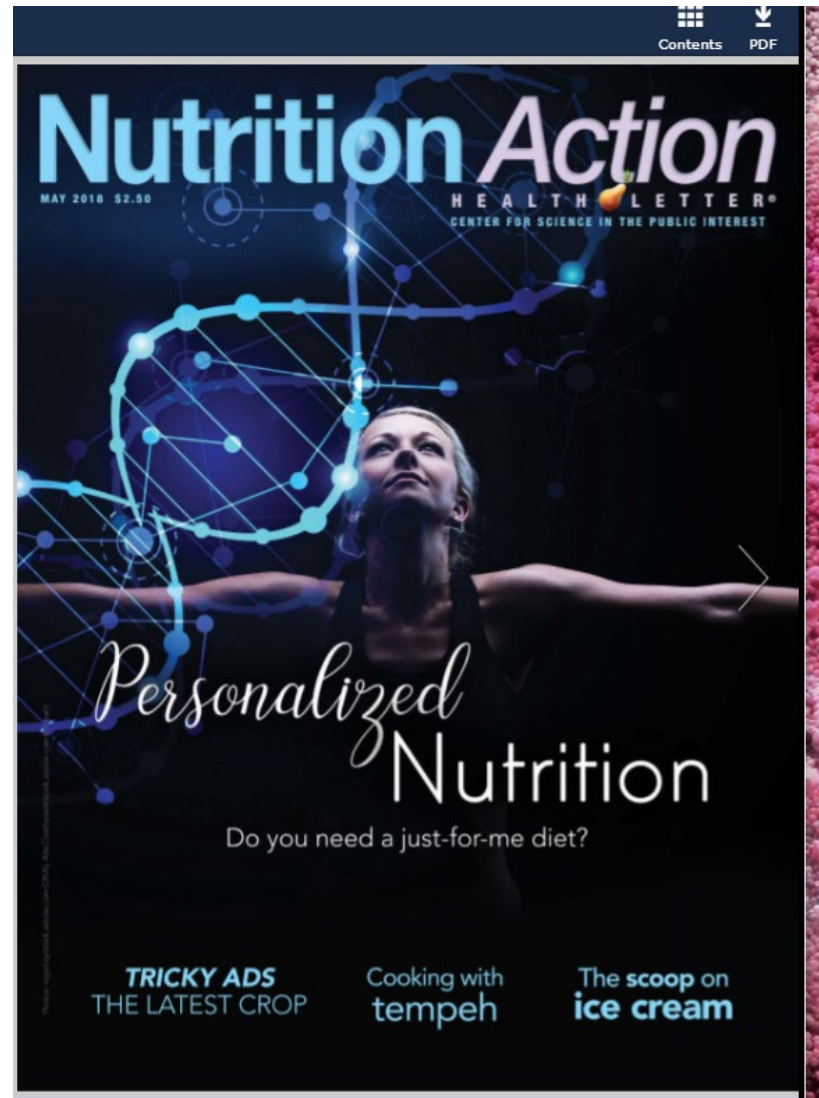
Challenges to Implementing Precision Nutrition: History, Hyporegulation, and Hype

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Disclosure

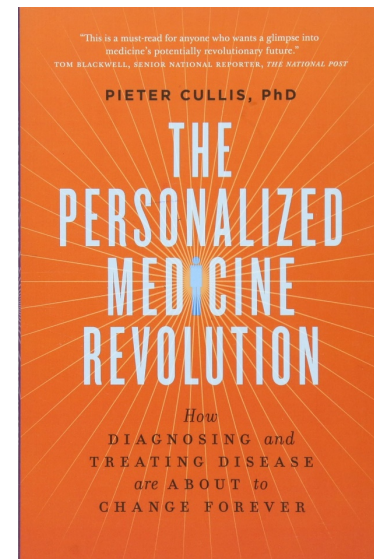
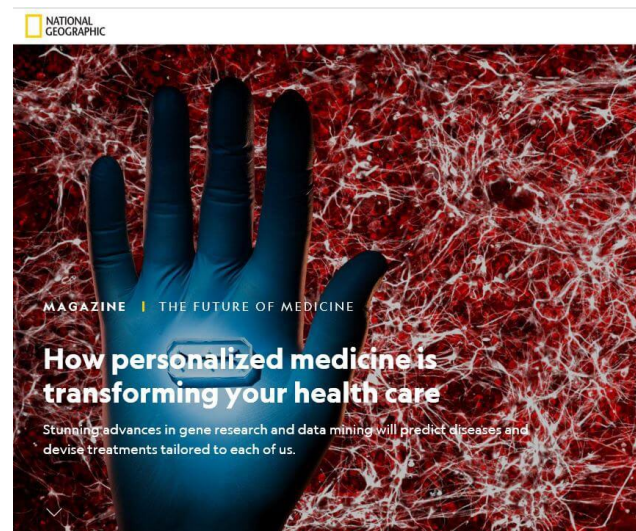
- I have NO conflicts of interests to disclose
- CSPI accepts no donations from either government or industry

Nutrition Action Healthletter, May 2018



Learning from the Past: Precision Medicine

- Interest accelerated with sequencing the genome
- Best results have been in oncology where mutations are simpler
 - What is the mutation prevalence?
- Less success in more complex diseases



Companion Diagnostics

- First approval: herceptin for breast cancer (1998)
 - Companion diagnostics detect either HER2 or HER2 alleles in patient's tumor
 - Predicts tumor responsiveness to trastuzumab
- 46 companion diagnostic devices approved by FDA
 - 43 for various cancers
 - Also,
 - Aggressive Systemic Mastocytosis
 - Myelodysplastic Syndrome
 - Non-transfusion-dependent Thalassemia

Laboratory Developed Tests (LDTs)

- FDA has authority to regulate in vitro diagnostics (IVDs) through the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act
 - LDTs are tests where samples are sent out for analysis
 - FDA has exercised enforcement authority over LDTs
 - Industry asserts that the Comprehensive Laboratory Improvement Act (CLIA) provides adequate oversight
 - But CLIA regulates laboratories, not tests
- Deficiencies in LDT oversight:
 - Lack of evidence supporting clinical validity of tests (CLIA assesses analytical validity)
 - Inadequate adverse event reporting
 - No premarket review of performance data
 - Unsupported manufacturer claims
 - Inadequate product labeling
 - Uneven playing field
- 2020 Azar memo: LDTs must be regulated by regulation, device by device, not by guidance

Examples of Problematic LDTs

- PreOvar KRAS-variant Ovarian Cancer Screening Test
 - Variant said to increase risk of cancer and predict therapeutic response
 - Large independent study failed to confirm
 - Risk of unnecessary surgery
- SurePath HPV Collection Medium
 - Prone to false-negative tests for cancerous strains
 - Risk of untreated cervical cancer
- CARE Clinics Autism Biomarkers Test
 - Panel of biomarkers and a heavy metal toxicity test purported to identify the causes of a child's autism
 - Tests linked with clinic's treatment plan, which included disproven treatments such as chelation therapy, hyperbaric O₂, etc.
- 32 Warning Letters for COVID-19 diagnostics

[Source: wayback.archive-it.org/7993/20171115144712/https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf](https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf); <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>

FDA's General Wellness Policy for Low-Risk Devices

- FDA does not intend to regulate general wellness products that:
 - 1) Are intended for only general wellness use
 - Maintain or encourage a general state of health or a healthy activity
 - Relate healthy lifestyle to reducing risk or impact of certain well understood chronic diseases or conditions
 - 2) Present a low risk to the safety of users and other persons (excludes invasive or implanted products)
- Exempts wellness products that do not make reference to treating, diagnosing, or preventing diseases or conditions
 - Not treat or diagnose obesity
 - E.g., claims to promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals
- Exempts wellness products that do make reference to reducing risk of helping live with diseases or conditions
 - Impact of healthy lifestyle choice must be generally accepted (e.g., heart disease, hypertension, type 2 diabetes)
 - E.g., track calories to reduce risk of type 2 diabetes

FDA-Permitted Claims on Food

- Health claim:
 - Characterize the relationship between substance and disease
 - Requires “significant scientific agreement”
 - Preapproval required
- Qualified health claim
 - Characterize the relationship between substance and disease
 - Requires “credible evidence”
 - Preapproval required
- Structure/function claim:
 - Describe the effect on normal structure or function of the human body.
 - Requires “competent and reliable scientific evidence”
 - Disclaimer required (claim not evaluated by FDA; not intended to diagnose, treat, cure or prevent any disease)
- Nutrient content claim
 - Characterize the level of a nutrient compared to official recommendations

[Source: Am J Prev Med 2019;56:622-5](#)

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Brain



DHA w/Vitamin D

- Supports a healthy inflammatory response*
- Helps ease sore muscles after exercise*
- Supports your brain, heart, eyes, and joints*

\$0.22/Day

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Fermented Ginseng

- Helps ease the effects of everyday stress*
- Supports immune health*
- May help with mild memory loss associated with aging*

\$1.00/Day

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Ginkgo Biloba Extract

- Promotes healthy circulation*
- Supports healthy aging*
- Supports cognitive function*

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Omega 3

- Supports a healthy inflammatory response*
- Promotes brain, heart, and eye health*
- Supports joint comfort*



TRU NIAGEN®

- Supports healthy aging*
- Promotes a healthy cellular metabolism*



Vegan DHA

- Supports a healthy inflammatory response*
- Helps ease sore muscles after exercise*
- Supports your brain, heart, eyes, and joints*



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Learn How Your Body Responds to 96 Different Foods




Food Sensitivity Test

★★★★★ 5550

This at-home test measures your body's immune response to 96 foods to help guide you on what types of food may be the best to choose for an elimination diet.

 IgG Reactivity to **96 Foods**

 Finger prick sample collection

 Test a **larger variety of foods**

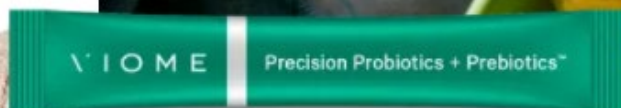
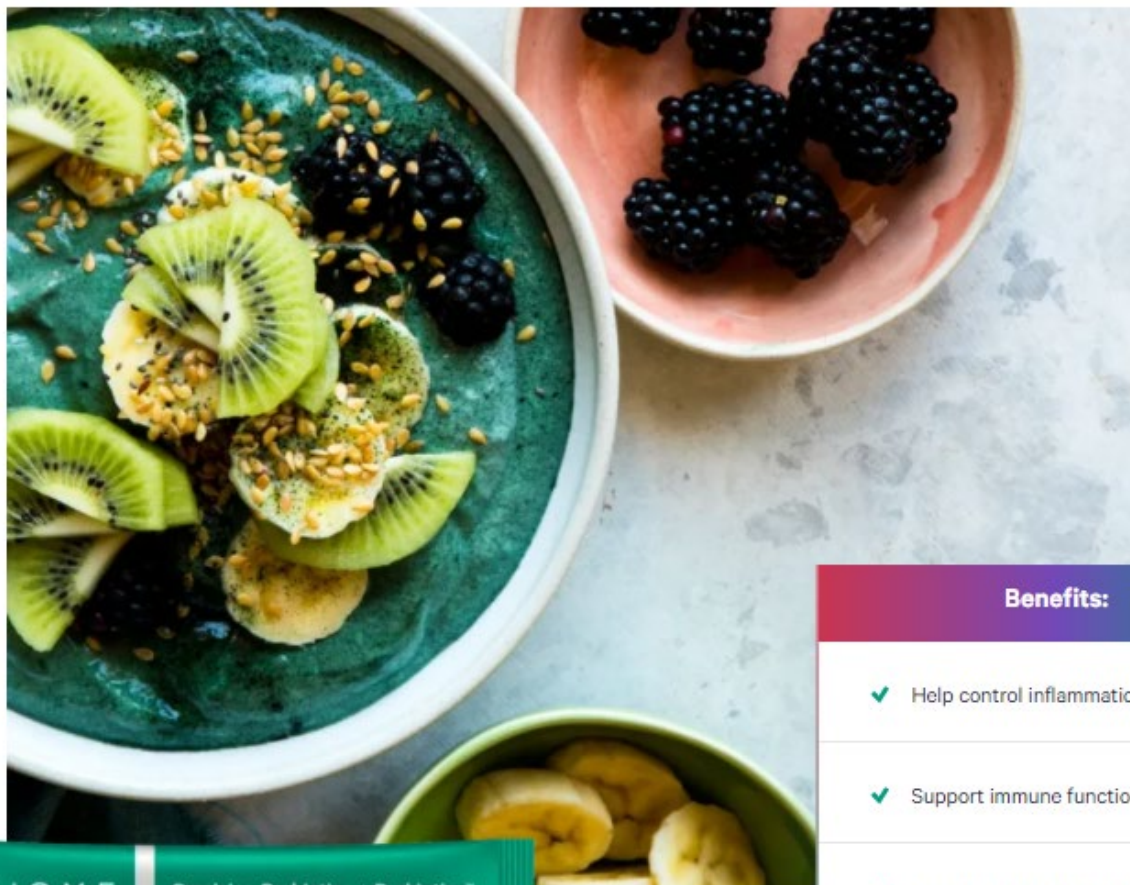
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Benefits:

- ✓ Help control inflammation
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My Results



**Gut Microbiome
Health**
Not Optimal

My Foods



Apple

SUPERFOOD



Kale

AVOID

My Supplements

Bromelain	299 mg / day
Fennel Seed Extract	228 mg / day
L. plantarum 299v	2bn CFU / day
Acacia Fiber	3000 mg / day
Borage Oil	728 mg / day

My Results



**Immune System
Health**
Not Optimal

My Foods



Zucchini

SUPERFOOD



Tomato

AVOID

My Supplements

Resveratrol	122 mg / day
L-Glutathione Reduced	303 mg / day
Fennel Seed Extract	171 mg / day
Ginger Root Extract	43 mg / day
N-Acetyl-D-Glucosamine	256 mg / day

Microbiome-based precision nutrition for metabolic disease.

"To now be considered non-diabetic is more than I could have imagined."

David, 51
Saginaw, Michigan

Watch Story



CLINICAL
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MAYO CLINIC

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Our DNA tests

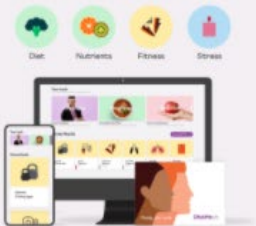
Diet Fit



~~\$189~~ \$132.30

Get Started

Health Fit



~~\$249~~ \$174.30

Get Started

Circle Premium



~~\$629~~ \$440.30

Get Started

Dietary Markers

See Reports +

Diet Type Recommendation

Carbohydrate Sensitivity

Fat Sensitivity

Detox: Toxin Generation Speed

Detox: Toxin Generation Speed

Detox: Cruciferous Vegetable Needs

Salt Sensitivity

Alcohol Response

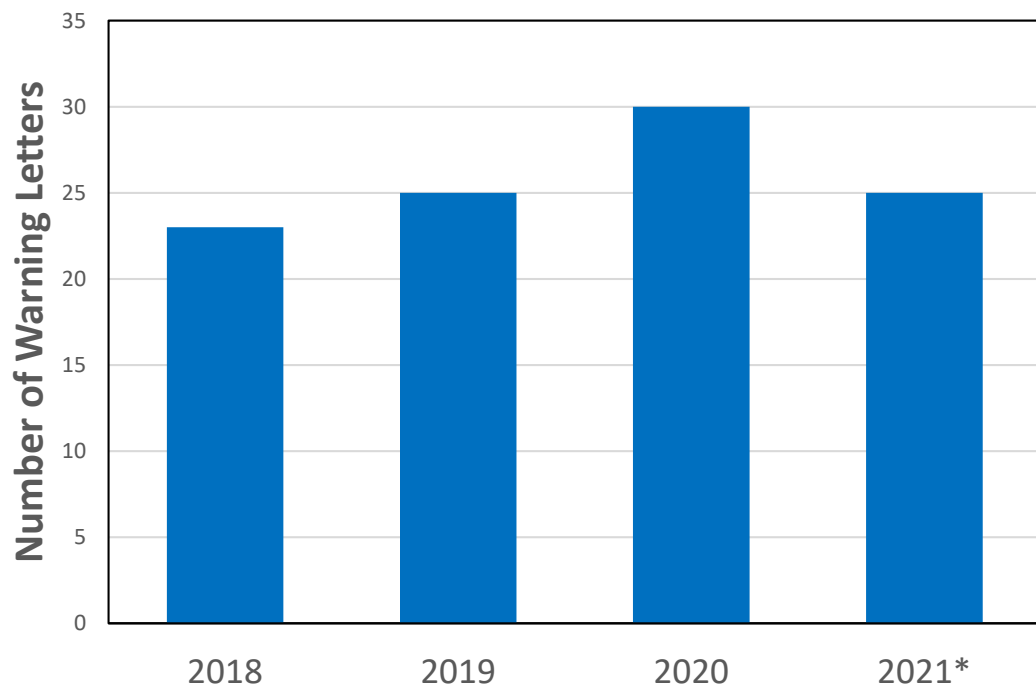
Caffeine Sensitivity

Bitter Taste Perception

Lactose Tolerance

Celiac Predisposition

CFSAN Warning Letters For Misbranding



*Through July

Examples:

- May 2021: 5 letters regarding dietary supplements claiming to treat infertility
- March 2021: 2 letters regarding CBD for pain relief
- February 2021: 10 letters regarding dietary supplements claiming to treat depression and other mental health disorders

Looking Ahead

- Perfect storm of poor regulation
 - High demand, especially among high SES/worried well
 - Largely unregulated LDTs
 - Wellness guidance
 - Plethora of unsupported claims
 - Poorly regulated dietary supplements
 - Lack of prescriber intermediary
- Need for better science
 - Strategic Plan for NIH Nutrition Research
 - Increased risk \neq impact \neq actionable
 - Public health impact must be assessed rigorously