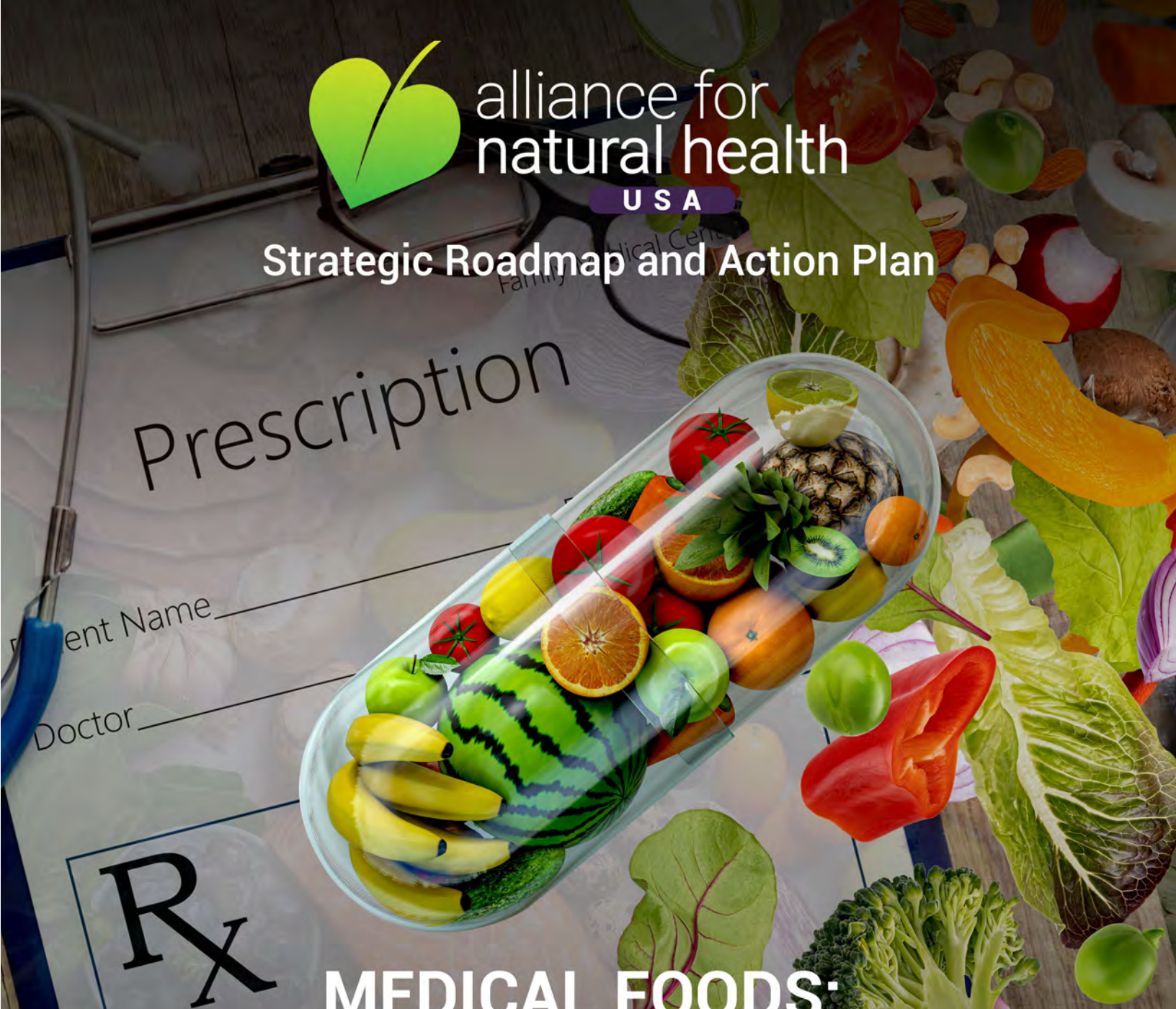
alliance for natural health USA

Strategic Roadmap and Action Plan



MEDICAL FOODS: UNLOCKING ACCESS AND VALUE

Removing barriers to therapeutic nutrition

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About the Alliance for Natural Health USA

ANH-USA is a non-profit advocacy organization dedicated to protecting access to natural health options, promoting sustainable health freedom policies, and empowering consumers with truthful, science-based information to make informed choices about their health.

Find out more at: www.anh-usa.org

Find out more about ANH-USA's Corporate Leadership Circle

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Foreword

This Roadmap and Action Plan set out a practical path to re-position medical foods (MFs) as a mainstream, clinician-supervised tool for earlier, patient-specific management of disease. Sections 2 and 3 present the Strategic Roadmap and Action Plan itself; Section 4 provides the heavily referenced background—the legislative history, scientific rationale, and market/practice barriers—so policymakers, payers, clinicians, and innovators can act on firm evidence.

The timing is critical. The U.S. spends about 16% of GDP on healthcare yet lags shockingly on healthy life expectancy compared with other industrialized countries. Chronic and metabolic conditions continue to skyrocket and an aging population further intensifies demand for care. Properly formulated, GRAS-based, food-derived therapies can help manage these conditions earlier and more safely—often at lower total cost—yet today's framework suppresses access, reimbursement, and innovation.

There is also a policy window. The current administration's national focus on ending chronic disease and reducing anti-competitive barriers creates momentum to align MF regulation with science and patient need. That means clarifying intended use for diseases with distinctive nutritional requirements, restoring clear prescription pathways (including NDC assignment) so payers can adjudicate fairly, broadening qualified supervision beyond physicians, and replacing warning-letter-driven enforcement with clear, evidence-based guidance and safe-harbor routes for innovation.

This document is both blueprint and brief. The Roadmap explains what must change; the Action Plan details how to change it; and Section 4 equips readers with the citations and context to defend those changes in Congress, at FDA and CMS, and within payer and clinical systems. If we act on these recommendations, we can widen access to therapeutic nutrition, spur innovation, and bend the chronic-disease curve—moving American healthcare from late, high-cost rescue to earlier, patient-centred management that improves outcomes and lowers total costs.

We invite companies to join our Corporate Leadership Circle and partner with us in a shared mission: to transform Americans' health by lifting the regulatory constraints embedded over decades of pharmaceutical dominance.

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Alexandria, VA

1. Executive Summary

- **Medical foods (MFs) can unlock major health and economic gains.** Science-based, food-derived formulations can slow or better manage chronic, metabolic, and age-related conditions—often at lower cost and with fewer side-effects than branded drugs, yet remain underused outside hospitals, and under-developed in terms of their potential to unlock health gains.

- **The opportunity is urgent.** The U.S. spends ~16% of GDP on healthcare yet has the lowest healthy life expectancy of any developed nation; Baby Boomers and Gen X intensify demand for effective healthcare. MFs can shift care from late, high-cost interventions to earlier, patient-specific dietary management.

- **Structural barriers suppress access and innovation.** FDA interpretations narrow the MF category beyond statute, exclude common chronic conditions (e.g., diabetes, CVD, OA, metabolic syndrome), and trigger "unapproved drug" findings when diseases are named as required for MF use—deterring companies and confusing payers.

- **Research has been chilled.** Since 2013, FDA's Investigation New Drug (IND) and MF guidance have effectively pushed nutrition studies into drug pathways, leading academics and institutions to abandon promising MF research and leaving the U.S. at a global disadvantage.

- **Prescription ambiguity and physician-only supervision block reimbursement.** Pharmacy Benefit Managers (PBMs) and insurers often treat MFs as over-the-counter (OTC) drugs, denying coverage; many physicians lack nutrition training, while qualified nutrition professionals are side-lined.

- **Strategic aim: modernize the statutory framework.** Update the MF definition under the Orphan Drug Act (ODA) to clarify intended use for diseases/conditions with *distinctive nutritional requirements* that cannot be met by diet modification alone—including metabolic diseases and conditions of aging.

- **Compliance standards that reflect medical necessity.** Establish a non-arbitrary standard anchored in generally recognized (peer-reviewed) evidence;

require GRAS ingredients to ensure safety; recognize MFs as specially formulated products not typically available in the ordinary diet.

- **Pro-innovation FDA policy.** Replace warning-letter-driven enforcement with clear guidance and safe-harbor pathways; clarify prescription access; allow National Drug Code (NDC) assignment; enable manufacturer self-certification backed by substantial scientific/clinical evidence to support fair reimbursement.

- **Broaden supervised access and workforce capacity.** Extend supervision to qualified healthcare professionals (e.g., PAs, NPs, CNS/CNS-S, RDs, NDs, DCs, PTs) and embed medical nutrition (including MFs) across health-profession curricula.

- **Coverage and payment reforms.** Add MFs to Medicare/Medicaid/VA formularies when supported by clinical and economic data; restore TRICARE reimbursement parity.

- **Expected outcomes.** Broad patient access, lower total costs of care, renewed competition and innovation, and measurable reductions in chronic-disease burden—aligning regulation with current science, patient need, and the Make America Healthy Again (MAHA) agenda.

2. Strategic Roadmap

2.1 The Opportunity

Our country has an important regulatory category comprised of often life-changing medical products which historically have been used in hospitals. Products in this category offer tremendous potential for reducing the burden of chronic diseases were they broadly available in community settings, commonly prescribed by healthcare practitioners and distributed through retail pharmacies. These products contain food-based therapeutic ingredients that cannot be derived from the ordinary diet. This is the **medical food (MF) category** established by U.S. Congress in 1988 and regulated as prescription drugs prior to that change in the law. They include the best of nature's offerings: purified, concentrated, and in combinations.

MFs are processed ingredients usually delivered in powder or liquid forms as shakes for oral consumption or liquids for enteral (tube) feeding in hospitals, although they can be in tablet or capsule forms. MFs are not dietary supplements because they follow a different regulatory pathway and are intended to manage physiologic disease processes through clinically proven, targeted nutrition rather than maintaining structure or function *per se*.

'Baby boomers' (born 1946-1964) and Generation X'ers (1965-1979) are placing ever greater demands on healthcare systems. For thus aging population, MFs offers the potential of slowing down the onset of age-related disease and enabling disease management with less consequence and cost, while lessening the occurrence of emergency-based interventions and hospitalizations.

Reactive healthcare that waits for the public to become sick and then relies on often costly drug treatments with side effects as the primary means for managing disease care is a major driver of runaway healthcare costs and poor outcomes.

With a new administration committed to eliminating chronic disease as part of its Make America Healthy Again (MAHA) agenda, it is timely to reconsider how MFs can play a vital part in transforming American healthcare from sickness and costly emergency interventions to wellness and affordable disease prevention and management.

The United States faces a chronic disease epidemic that threatens public health and economic stability. Despite spending over 16% of its GDP on healthcare, the U.S. ranks a lowly 80th in global healthy life expectancy, with projections worsening by 2050.

Medical foods—science-based nutritional products specifically formulated to manage nutrient deficiencies and imbalances often associated with existing disease states or aging—should be a critical part of the solution.

MFs offer the opportunity to use nutrition science to deliver cost effective solutions to unmet needs of compromised patients when traditional drugs are not effective or safe. MFs generally offer such solutions less expensively and with fewer side effects than branded drugs.

This affordable approach to improving public health is compromised by outdated, overly restrictive regulations that impair access to MFs and discriminate against MFs in favor of more costly drug treatments. **Outdated and biased regulatory policies and practices effectively limit the use of MF products when sometimes they are the most effective and impactful options helping to bring life-changing outcomes to patients.**

The MF category has been a low priority, under-resourced, category at FDA. FDA has made some advances over the 35+ years that MFs have been regulated. But the agency has taken some offsetting steps backward along the way, such as issuing a draft Advanced Notice of Proposed Rulemaking (ANPR) in 1996 to move the category forward only to withdraw the ANPR and offer nothing in its place in 2004. Not following through with clear and timely regulatory relief for MFs and, instead, taking restrictive and inconsistent MF enforcement actions has led to stagnation in the category with some MF manufacturers going out of business.

Recognizing the critical role of foods in health, past government initiatives have focused on (1) national nutrition strategies which strangely exclude nutrition science in favor of public health advice on diet that is over 30-years-old and now widely rebuffed, e.g., low fat diets or the elimination of sodium (salt) from the diet is always beneficial, or (2) Food Is Medicine concepts and media events which oddly ignore the one category of food-based products which literally offers food as medicine – namely MFs.

Some isolated attempts have been made by MF manufacturers to draw attention to MFs, but these efforts have not gained public policy traction or acceptance by government payors like the Centers for Medicare & Medicaid Services (CMS) or commercial insurance pharmacy benefit management companies (PBMs), which control drug pharmacy reimbursement formularies to exclude MF.

Often, patients who need MFs are denied access and left to fend for themselves. Some players in the adjudication process even mistakenly identify MFs as OTC products and

act as *de facto* regulatory agencies to block MF access. The aforementioned discriminatory practices deny the potential of MFs.

From a product perspective, the U.S. healthcare system is structured to favor drugs and discount, and even disregard other types of solutions such as healthy foods or MF. MFs have been marginalized to the point where advances in nutrition science which could be translated into finished products that deliver substantial health gains are never commercialized because of arbitrary and biased regulation, and no opportunity for reimbursement. Regulatory practices and pharmaceutical market structure block life-changing products from reaching the public so that drugs with big trade-offs remain the mainstay of healthcare delivery and swathes of the public are forced to suffer unnecessarily. By contrast, other countries have made advances in medical nutrition products in their healthcare systems by expanding patient access to MF.

The 'food as medicine' potential of MFs compels a thorough re-evaluation of the category and its U.S. regulatory framework.

2.2 The Problem: Structural Barriers to Medical Foods Use

2.2.1 Regulatory Mismatch to the Law Defining Medical Foods

MFs are defined under the 1988 amendments to the Orphan Drug Act (ODA) (Section 4.3, p. 20), a statute intended to incentivize drug development and commercialization for rare diseases. The ODA thus aims to provide more therapeutic products for special public health needs and populations that are not adequately served by conventional drugs.

Contrary to ODA intentions, regulatory MF practices and enforcement do not align with satisfaction of unmet special dietary needs or with the current definition of a MF in the ODA. Regulatory practices of the FDA, as proposed in its guidance (e.g., "Frequently Asked Questions About Medical Foods (Third Edition): Guidance for Industry" [March 2023]) exceed the statute by imposing restrictions on what can be offered as a MF, on MF uses, and on MF standards instead of enabling and supporting scientific innovation in the treatment of special medical conditions and chronic diseases.

FDA's regulatory narrowing of the scope of what constitutes a MF structurally discourages, even penalizes, food and pharmaceutical companies from developing and

commercializing MF products that are needed to satisfy unmet medical needs with often life-changing and affordable MF interventions.

In response to regulatory constriction of the MF category, government and commercial insurance organizations such as CMS and the PBMs Caremark, Optum, and Express Scripts all systematically block access to MF on their reimbursement formularies. This has caused MF products to be discriminated against in favor of more costly, and often harmful, drugs to the detriment of patients and the burden of healthcare systems.

Our healthcare distribution system is generally administered through reimbursement adjudication systems which respond to the regulatory constriction on MFs by largely ignoring the category. This leaves physicians and patients often unaware that MF product options exist, and when they do ask for them or want them to be reimbursed, they are almost universally denied coverage. “Hiding” a whole class of safer and more affordable products undermines competition and disincentivizes companies from investing in the medical advancement and commercialization of nutrition science.

2.2.2 Arbitrarily Narrow Scope of Regulatory Product Classification: FDA interpretations and guidance exclude common chronic conditions from the MF category—such as diabetes mellitus, cardiovascular disease, osteoarthritis, and metabolic syndrome. This is despite strong evidence favoring nutrition interventions in the management of these diseases. FDA has taken enforcement action against manufacturers when they name diseases and conditions on MF labels that have distinctive nutritional requirements, as is legally required in the ODA statutory definition and explicitly permitted under the Nutrition Labeling and Education Act. Provided the disease or condition has a special need (i.e., a distinctive nutritional requirement) which can be managed with medical nutrition, it would align with best practices to name the medical use for the MF to avoid discouraging innovation and causing confusion. However, that is not the general practice due to FDA regulatory constriction of the category.

2.2.3 FDA “Unapproved Drug” Claims: FDA has accused companies naming diseases on their MF labels to be marketing “unapproved drugs” under the Food Drug & Cosmetic Act despite meeting the ODA statutory definition. Moreover, FDA discourages use of MFs by referencing good examples as products for genetic disorders rather than for other common chronic diseases.

It appears FDA is conflicted against medical foods because of its entrenched drug culture where CDER has historically advanced the interests of pharmaceutical companies at the expense of MFs, and because MFs do not pay PDUFA fees. For

perspective, the 2025 fee for FDA to review a new drug application (NDA) with clinical data is $4.3M whereas a MF does not have a prior approval *per se* and pays no fees to FDA.

FDA enforcement under narrow MF regulatory interpretations has reduced competition and deterred innovation, creating artificial gaps between patient needs/demand and market supply. Over time, this standard practice has effectively stifled competition and made the business of MF complicated and risky, discouraging innovation and product availability to satisfy unmet needs.

2.2.4 Outdated & Bogus Physician Supervision Standard: Current law requires physician supervised MF product administration, yet many physicians do not have any nutrition training, and, if they do, that training is limited either in undergraduate or medical school, and generally does not include medical nutrition training. Moreover, FDA has changed its position from considering these products to be prescription products to avoiding the question of whether a prescription is required. Avoiding the prescription status question puts MFs at a disadvantage and disincentive, causing patients and practitioners to regard them as of lesser value and as illegitimate medical options compared to drugs.

2.2.5 Urgent Need for Modernization: The only way one knows a product is under the active and ongoing supervision of a healthcare professional as specified in the ODA is for the product to be distributed by prescription via a pharmacy, dispensed out of the office, or administered in a hospital or care facility. By not requiring a prescription, this physician supervision loophole is misinterpreted, either causing PBM companies to categorize the MF as an over-the-counter (OTC) drug or as one for which "no federal prescription is required," disabling reimbursement. Lessening such reimbursement reduces competition for PBM formulary drugs that pay big rebates and fees, ultimately driving up healthcare costs.

The regulatory supervision standard should extend to all qualified healthcare professionals with appropriate nutritional training, enabling them to: (1) make competent product-selection decisions; (2) provide supportive counseling tailored to patients' dietary medical needs; (3) explain how a medical food (MF) addresses those needs; and (4) instruct on proper use while monitoring adherence and outcomes. Physicians face declining reimbursement and rising patient loads, leaving less time per visit; reduced incomes are also discouraging new entrants, contributing to a national physician shortage. This is occurring just when the U.S. could improve healthcare outcomes by encouraging earlier, proactive management of health risks with effective, affordable interventions that prevent or delay age-related disease and improve chronic-disease management. Medical foods offer a key solution: they are generally recognized

as safe (GRAS) and can help restore or rebalance the physiological processes underlying disease.

By restoring and rebalancing metabolic and physiological systems in the body, MFs generally work on the underlying causes of diseases and conditions rather than treating disease symptoms. Consequently, MFs can be used for dietary management of disease in ways that can maintain or restore function by supporting the healthy functioning of physiological processes essential to a restoration of wellness or function.

To ensure effectuation of the MAHA agenda in this area of unmet need, the MF category needs to be modernized through a national program of medical nutrition training for all relevant professional audiences. Therefore, training should be provided in medical, physician assistant, nurse practitioner, dietetic, pharmacy, chiropractic, and physical therapy schools coupled with opening the physician supervision standard to all qualified healthcare professionals with nutrition training. Licensed physician assistants, nurse practitioners, dieticians, naturopathic doctors, pharmacists, certified nutrition practitioners, chiropractors, and physical therapists should also be qualified to prescribe or dispense a MF product.

These actions will unlock access to MFs by making them more available by broadening the prescriber base and clarifying prescription status so PBMs and insurance companies will include MFs in reimbursement. Payers need clarity about MF medical necessity standing and prescription status in order for MFs to be paid using pharmacy reimbursement benefits (they usually are already paid by historical practice as a part of medical benefits in hospitals). These actions will open much-needed access to therapeutic nutrition to satisfy unmet needs and improve health outcomes.

2.2.6 Regulatory Policy Disincentivizes Nutrition Science Research: In 2013, FDA reversed course with its Investigational New Drug (IND) and Medical Food guidance: rather than considering scientific intent to determine whether a study is nutritional, the agency moved to automatically deny nutritional studies unless the product is already recognized as a MF. That reversal has stifled MF innovation, ensuring manufacturers halt or fail to initiate the very research needed to qualify a product as an MF by clinically establishing the distinctive nutritional requirements associated with disease states and chronic conditions. In effect, FDA has created a default presumption that any new MF is an unapproved new drug and therefore unlawful.

This interpretation—disallowing MF innovation except through the IND pathway—has forced medical institutions and companies to abandon promising research. In 2013, more than 50 MD and PhD academic medical and nutrition-science researchers, along

with a multi-organization front led by the American Society for Nutrition, wrote to then-CDER Director Janet Woodcock, MD, opposing FDA's position (Section 4.7, p. 25).

FDA's constriction of the MF category has put the United States at a competitive disadvantage relative to Europe, Asia, and Canada, where nutritional studies have been permitted for decades. Even China, which approved medical foods (foods for special medical purpose) as a category in 1995, updated its food safety law in 2015 to allow provinces to register for nutrition research. Ironically, NIH's practice of funding nutritional research is at odds with FDA's approach.

2.3 The Solution

2.3.1 This strategic roadmap and action plan calls for a revised regulatory framework and interpretation that aligns with original intent of the statutory definition of medical foods in the Orphan Drug Act. This shift as proposed in the present Strategic Roadmap and Action Plan opens the market to MFs to satisfy therapeutic demand while ensuring patient safety and removal of regulatory barriers that discriminate against MF in favor of prescription drugs. The result would unlock nutrition science innovation and commercialization to satisfy unmet medical needs and restore medically justified prescription status and fair market reimbursement practices for MFs, thereby lowering healthcare costs. This expanded category would be able to provide community-based healthcare professionals and patients with new, more affordable, and less risky medical options—clinically validated products for diseased populations, including those in underserved communities, to help reduce age-related diseases and to enhance the management of chronic and degenerative diseases.

3. Action Plan

3.1 **Bolster the statutory framework for medical foods (MFs)**—including updating the definition in the Orphan Drug Act (ODA)—to increase legal clarity and confirm intended use for patient-specific dietary management of diseases or conditions with distinctive nutritional requirements that cannot be met by modification of the normal diet alone, as established by medical evaluation and recognized scientific principles. Intended uses should include metabolic diseases and conditions associated with aging.

3.2 **Update compliance standards to support the medical necessity of MF therapies as the basis for returning them to prescription status**, and adopt a non-arbitrary standard for the distinctive nutritional requirements associated with them. What constitutes a medically necessary MF intervention should reflect the general recognition (peer-review) standard for meeting the distinctive nutritional requirements of the disease or condition at issue, and all ingredients should be Generally Recognized As Safe (GRAS). MFs are specially formulated products not available in the ordinary diet.

3.3 **Revise the framework to reflect modern science and allow MFs to address chronic and metabolic diseases**, aligning with principles discussed at the 2018 National Academies workshop on special nutritional requirements (sponsored in part by FDA) (Rodgers AB (Rapporteur). "Examining Special Nutritional Requirements in Disease States: Proceedings of a Workshop". Washington, DC: The National Academies Press. https://doi.org/10.17226/25164). The new framework should reduce barriers and discrimination against MFs to ensure ubiquitous patient access, lower care costs, and greater innovation to meet unmet special nutritional needs.

3.4 **Broaden medical supervision criteria to include qualified healthcare professionals**, such as physician assistants, nurse practitioners, naturopathic medical doctors, chiropractors, certified nutrition specialists, clinical nutrition specialists, registered dietitians, physical therapists, and other qualified health-care professionals.

3.5 **Create a pro-innovation regulatory environment for MFs**. FDA should replace reliance on warning-letter-driven enforcement with clear, science-based guidance and safe-harbor pathways for innovation, making it clear that MF availability and innovation are encouraged rather than discouraged in favor of drug interventions.

3.6 **Clarify that MFs are accessed by prescription and allow assignment of National Drug Code (NDC) numbers**, enabling fair competition with drugs in the prescription adjudication system. MF manufacturers should self-certify that products meet statutory

definitional elements, with validation by substantial scientific and clinical evidence. This will establish the structural elements needed so valid MFs are not excluded from insurance coverage.

3.7 **Strengthen education by adding medical nutrition (including MFs and dietary supplements) to health-profession curricula** so clinicians understand product categories, can prescribe MFs when appropriate, and better counsel patients.

3.8 **Implement coverage pathways at CMS and the Department of Veterans Affairs (VA) to include MFs in Medicare, Medicaid, and VA formularies** where products have substantial clinical data and an economic basis (e.g., acquisition costs below branded drugs and pharmacoeconomic analyses demonstrating lower total costs of care). Require TRICARE to restore MF reimbursement on equal footing with preferred drug brands, adjudicating MFs through its drug benefit in retail pharmacies, as written into law (FY2016 NDAA).

Conclusions: By enacting these reforms, HHS and its agencies (including FDA and CMS) can expand the MF market to meet current and growing therapeutic demand in an affordable, accessible, and effective way—contributing to reductions in chronic disease and health-care savings.

4. Medical Foods — Background and the Need for Reform

4.1 Introduction

A 2022 study revealed that the U.S. ranks 80th globally in healthy life expectancy and is projected to rank 108th by 2050.[1] That is irrespective of the allocation of 16% of GDP to healthcare.[2] While government-led initiatives like the "Make America Healthy Again" (MAHA) movement are helping to address the drivers of conditions like diabetes, obesity, and mental health issues, much more needs to be done not only to stop but to reverse this powerful, destructive trend against American health and longevity.[3]

In 1988, Congress created the "medical food" definition in the Orphan Drug Act.[4] That Act caused the U.S. regulatory system to parallel the European Union's (EU's) where "medical foods" are deemed "food for special medical purposes" (FSMP).[5] Despite FDA allowance of broader categorization of "medical foods" prior to the Orphan Drug Act[6,7], Congress and FDA thereafter opted for a highly restrictive definition and interpretation.[8]

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[1] Institute for Health Metrics and Evaluation. Increases in U.S. life expectancy forecasted to stall by 2050, poorer health expected to cause nation's global ranking to drop. https://www.sciencedaily.com/releases/2024/12/241206002146.htm#:~:text=Nationally%2C%20mortality%20rates1%20declined,to%20108th%20by%202050. Accessed October 27, 2025.

[2] Health expenditure as a percentage of gross domestic product (GDP) in selected countries as of 2023. https://www.statista.com/statistics/268826/health-expenditure-as-gdp-percentage-in-oecd-countries/. Accessed October 27, 2025.

[3] Make America Healthy Again. https://www.maha.vote/. Accessed October 27, 2025.

[4] The definition was first introduced in 1988 as part of the Orphan Drug Amendments of 1988 (Public Law 100-290, §3(b)(6), April 18, 1988).

[5] The concept of a medical food was first recognized in the European Economic Community (the precursor to the EU) with the passage of Council Directive 89/398/EEC of 3 May 1989 — the Framework Directive on foodstuffs intended for particular nutritional uses (PARNUTS).

[6] The Research Office proposed that medical food be defined as *"[A] term employed to indicate commercially prepared or other products consumed or administered enterally under direct or indirect medical supervision".* Although this definition lacks specificity and does not capture every facet of what constitutes a medical food, it is commendable in that it does not impose a narrow requirement of direct physician supervision.

[7] Dr. Miller suggested that medical food include "*both foods and drugs . . . administered enterally . . . used under the supervision of a physician. In addition, they are represented for the dietary management of a specific disease, disorder or medical condition"* While this definition is also limited as it insists on medical supervision, however it recognised the potential for dual classification of certain products as both a food and drug.

[8] The definition and application of medical food is detailed in paragraph 3.0. Also, this definition was further narrowed by the FDA regulation in 21 C.F.R. §101.9(j)(8) explaining conditions for a product qualifying for medical food exemption.

FDA implemented that restrictive definition in 21 C.F.R. §101.9(j)(8), including a rigid separation of food and drugs. As seen in the 1938 Federal Food, Drug, and Cosmetic Act (FDCA), the FDA has consistently reinforced this divide: drugs can treat, mitigate or prevent disease, foods and supplements cannot.[9] The reality, of course, is that foods—essential to life—are also essential to disease prevention, treatment, and recovery. The examples are so obvious as to be commonplace in a number of areas: water treats dehydration; prune juice treats chronic constipation; nicotinic acid treats hypertension; chromium treats Type II diabetes, etc.

After eventually acknowledging the unique potential of medical foods to exert therapeutic effects—despite their food status—the FDA acted to protect the drug monopoly from competition.[10] While stating that medical foods are "foods" within the meaning of the Food Drug and Cosmetic Act, it simultaneously subsumed them under the Orphan Drug Act, a statute intended to incentivize drug development for rare diseases.[11] Although the FDA commendably exempts medical foods from premarket approval and standard nutrition labeling requirements, its decision to tether them to a drug-based regulatory framework has led to barriers that prevent patients from accessing medical foods essential for health and survival.

Although medical foods are not regulated as drugs, their inclusion under the ODA qualifies them for orphan drug designation—bringing with it benefits such as tax credits and market exclusivity.[12] This creates a semi-drug market structure that inflates costs, restricts competition, and undermines access for those who likely could benefit most from the products.

In April 2025, President Trump issued an Executive Order on "Reducing Anti-Competitive Regulatory Barriers," directing federal agencies to identify and reform regulations that artificially insulate incumbents, suppress innovation, or raise consumer costs.[13] The following month, Executive Order 14297 tackled drug affordability by calling for

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[9] Section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (FFDCA).
[10] [Federal Register Volume 61, Number 231 (Friday, November 29, 1996)]. https://www.govinfo.gov/content/pkg/FR-1996-11-29/html/96-30441.htm Accessed October 27, 2025.
[11] Section 5b of the Orphan Drug Act of 1988.
[12] Seoane-Vazquez E, Rodriguez-Monguio R, Szeinbach SL, *et al*. Incentives for orphan drug research and development in the United States. *Orph J Rare Dis 2008;* 3(1): 33.
[13] DCPD-202500460 - Executive Order 14267—Reducing Anti-Competitive Regulatory Barriers. https://www.govinfo.gov/app/details/DCPD-202500460/. Accessed October 27, 2025.

international price benchmarking and expanded drug importation.[14] Both orders reflect a new Executive Branch policy to lower healthcare costs and promote consumer access—principles that apply just as urgently to medical foods.

Despite FDA's acknowledgment in 1996 of the need to revisit the regulatory framework for medical foods, no essential reforms have been adopted.[15] Instead, the agency has relied on a patchwork of guidance documents and regulatory interpretations that are inconsistent with nutritional science and impose barriers to medical food availability and therapeutic potential.

A more balanced approach is essential and must begin with removing medical foods from the Orphan Drug Act and revisiting their statutory definition to reflect their food-based, therapeutic role. While appropriate professional oversight remains important, regulation should not hinge solely on physician supervision. Instead, licensed nutrition professionals who now form an enormous part of the health care market enable medical foods to be prescribed and administered to a broader class of patients in need expertly and far more affordably than delimiting access solely through physicians. That is particularly true given the prevailing absence of nutrition education among licensed physicians nationwide.

This paper makes the case for a new approach to medical food regulation by evaluating its statutory origin, practical consequences, and the need to harmonize intended use with regulatory treatment. The aim is to bridge the current gap between patient need and the availability of affordable, readily accessible therapeutic nutrition.[16,17] Only through far greater patient access to medical foods can the nation significantly advance the goal of ending chronic disease.

4.2 Legislative History of Medical Foods

Prior to 1972, FDA regulated medical foods as drugs under Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(g)(1)(B)). Products like Lofenalac—

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[14] DCPD-202500591 - Executive Order 14297—Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. https://www.govinfo.gov/app/details/DCPD-202500591. Accessed October 27, 2025.
[15] Aldridge ML. *Re: Docket No. 02N-0434 Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent (2003)*.
[16] Hacker KA, Mehta NK, Thorpe LE. The burden of chronic disease—effect of COVID-19 pandemic on the burden of chronic disease in the United States. *Mayo Clin Proc Innov Qual Outcomes*. 2024;8(1):36-47.
[17] Watson KB, Wiltz JL, Nhim K, *et al*. Trends in Multiple Chronic Conditions Among US Adults, By Life Stage, Behavioral Risk Factor Surveillance System, 2013-2023. *Prev Chronic Dis.* 2025;22:E15.

used in the dietary management of phenylketonuria --were regulated as drugs.[18] In 1972, the FDA shifted its regulatory approach, acknowledging that certain nutrient formulations could satisfy unique dietary needs of patients with disease or medical conditions, yet not be classified as drugs.[19] That pivot aimed to reduce regulatory burdens on manufacturers of such products to expand patient access.

Despite the shift, FDA still differentiated "medical foods" from conventional foods. Enteral nutrition, whether orally consumed or administered via feeding tube, was reclassified as "foods for special dietary use" (FSDU), while parenteral (injectable) formulations remained "drugs".[20] Lofenalac, for instance, was reclassified from a drug to an FSDU.

It was not until 1988 that the FDA formally recognized "medical foods," providing its statutory definition under the Orphan Drug Amendments of 1988.[21] Two years later, the Nutrition Labeling and Education Act of 1990 (NLEA) incorporated that definition into Section 403(q)(5)(A)(iv) of the FDCA. The NLEA also exempted medical foods from nutrient content claims, health claims, and standard nutrition labeling requirements imposed on conventional foods.[22]

In January 1993, the FDA released its final rule under the NLEA, establishing the regulatory criteria medical foods must meet.[23] In 1996, the agency published an Advance Notice of Proposed Rulemaking (ANPRM), expressing its intention to re-evaluate that regulatory structure.[24] Most recently, in March 2023, the FDA issued its updated guidance—*Guidance for Industry: Frequently Asked Questions About Medical Foods, Third Edition*—to further clarify the scope and regulatory treatment of medical foods.[25]

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[18] Shiming L, Ho C-T, Lange KW. Medical foods in USA at a glance. *J Fut Foods* 2021; 1(2): 141-145.
[19] Hattan DG; Mackey DR. A Review of Medical Foods: Enterally Administered Formulations Used in the Treatment of Diseases and Disorders," *Food Drug Cos Law J* 1989; 44(5): 479-502
[20] Id.
[21] Section 5b of the Orphan Drug Act of 1988.
[22] Lewis CA, Jackson MC, Bailey JR. Understanding medical foods under FDA regulations." In *Nutraceutical and Functional Food Regulations in the United States and Around the World*, Academic Press, 2019, pp. 203-213.
[23] 21 U.S.C. 343(r)(5)(A).
[24] 61 Fed. Reg. 60661, Nov. 29, 1996.
[25] Frequently Asked Questions About Medical Foods; Third Edition. Guidance for Industry. file:///Users/cex123/Desktop/FDD%20Project%20docs/Guidance-FAQ-Medical-Foods-3rd-Edition-March-2023.pdf. Accessed October 27, 2025.

4.3 Current Legal Definition and Application of Medical Food

The term 'medical food' is defined under 21 USC § 360ee(b)(3) and Section 5b of the Orphan Drug Act of 1988 as:

> *...a food which is formulated to be consumed or administered enterally [orally] 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.*

The Orphan Drug Act does not require MFs to be pre-market approved by FDA, instead they are subject to active post-market oversight and enforcement. Given this status, it would provide more accountability in the regulatory process for manufacturers to certify they are meeting the statutory definition and then submit this self-affirmation with additional compliance information to the FDA.

The 1996 ANPRM was FDA's attempt to address growing calls for clarity in response to ambiguity surrounding this definition.[26] Although withdrawn in 2004, the 1996 ANPRM remains the industry's primary guidance for understanding the FDA's position on medical food.[27]

In the ANPRM—and reiterated in the second and third editions of the Guidance document—the FDA not only distinguished medical foods from other categories like FSDU, but also provided interpretation to statutory language.[28] For example, regarding the requirement that medical foods be *"....administered enterally under the supervision of a physician,"* the agency clarified that this means the patient must be receiving short or long term "active and ongoing" medical supervision in a health care facility or as an outpatient.[29]

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[26] Holmes, JL, Biella A, Morck T, *et al*. Medical foods: Science, regulation, and practical aspects. Summary of a workshop." *Curr Dev Nutr 2021;* 5: nzaa172.

[27] Aldridge, M. L. *Re: Docket No. 02N-0434 Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent (2003)*.

[28] Frequently Asked Questions About Medical Foods; Third Edition. Guidance for Industry. file:///Users/cex123/Desktop/FDD%20Project%20docs/Guidance-FAQ-Medical-Foods-3rd-Edition-March-2023.pdf. Accessed October 27, 2025. See also the Draft Guidance for Industry Frequently Asked Questions About Medical Foods; Second Edition. file:///Users/cex123/Desktop/FDD%20Project%20docs/Draft-Guidance-for-Industry--Frequently-Asked-Questions-About-Medical-Foods--Second-Edition-(PDF).pdf. Accessed July 28th, 2025.

[29] Frequently Asked Questions About Medical Foods; Third Edition. Guidance for Industry. file:///Users/cex123/Desktop/FDD%20Project%20docs/Guidance-FAQ-Medical-Foods-3rd-Edition-March-2023.pdf. Accessed October 27, 2025.

The FDA further emphasized that not every food recommended by a physician, nor every food used in the dietary care of disease, qualifies as a medical food. Instead, medical foods must be specially formulated and processed products—distinct from naturally occurring foodstuffs—intended to serve as the central component of a patient's clinical dietary management.[30]

On the clause requiring use for the "specific dietary management" of a disease or condition, the agency clarified that medical foods do not treat or cure the disease itself, but support the maintenance and management of patients with diseases.[31]

Consequently, medical foods are not weight loss products, nor foods included within a healthy diet (such as low-sodium foods or reduced-fat foods) intended for disease risk reduction. Rather, they are foods reserved for the maintenance of the body already suffering from a disease or condition. This, they stated, was to "favorably influence the disease process" and "positively influence morbidity and mortality (patient outcomes)."[32]

As the law did not define "distinctive nutrition requirements," the FDA proposed two interpretations: a *physiological interpretation*, referring to the body's specific nutrient needs to maintain internal balance and sustain life; and an *alternative interpretation*, which includes both physiological nutrient demands and physical or functional limitations that prevent an individual from ingesting or absorbing conventional foods.[33]

In essence, the current legal definition of medical food narrowly limits products that can qualify as medical foods. It distinguishes them from both conventional foods and FSDUs by requiring enteral administration (oral or tube feeding i.e., specifically not intravenous, via suppository, etc.), by requiring physician supervision, by requiring a defined role in clinical dietary management, and by requiring evidence of distinctive nutritional needs tied to a medically diagnosed disease or condition.

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[30] 21 CFR 101.9(j)(8).
[31] Bagchi D (Ed). *Nutraceutical and Functional Food Regulations in the United States and Around the World*. Elsevier, 2014. Academic Press.
[32] 61 Fed. Reg. at 60668.
[33] Lewis CA, Jackson MC, Bailey JR. Understanding medical foods under FDA regulations. In: *Nutraceutical and Functional Food Regulations in the United States and Around the World*, Academic Press, 2019, pp. 203-213.

4.4 Limitations of the Current Regulatory Model

In the 1996 ANPRM, the FDA acknowledged the inadequacies of the then current medical food framework and announced its intent to re-evaluate it, stating: *"The agency believes that there is a need to reevaluate its policy for regulating medical foods*..."[34]

Although the agency received numerous comments in 2004, it withdrew the ANPRM due to limited resources.[35] Nearly three decades later, no new definition has been proposed or adopted. Instead, guidance documents and regulations that do not resolve conspicuous ambiguities in the statutory definition and are inconsistent with a growing body of scientific literature remain.

4.5 Regulatory mismatch of medical foods

Classifying medical foods under the Orphan Drug Act (ODA) lacks a scientific and legal rationale. From a legal and scientific standpoint, the classification is fundamentally flawed and highlights a glaring regulatory misalignment.

Historically, U.S. law has drawn a clear, yet often arbitrary, line between "foods" and "drugs." The 1938 Federal Food, Drug, and Cosmetic Act (FDC Act) explicitly excluded foods from the definition of drugs, thereby precluding the dual categorization of certain products as both foods and drugs. That rigid construction was reaffirmed in *Nutrilab Inc. v. Schweiker* (1982), where the court defined foods as items consumed for "taste, aroma, or nutritional value," and held that a product could be categorized as either a food or a drug, but not both.[36]

That rigid legal construction is at odds with both common sense and scientific reality. It ignores the overlap between nutritional and pharmacological effects, as well as mounting evidence that certain food-based substances can have therapeutic properties.[37]

In 1988, attempting to reduce or eliminate this tension, FDA created the category of "medical food" as a subset of foods for special dietary use in association with the

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[34] 61 Fed. Reg. 60661, Nov. 29, 1996

[35] Holmes JL, Biella A, Morck T, et al. Medical foods: Science, regulation, and practical aspects. Summary of a workshop. *Curr Dev Nutr* 2021; 5: nzaa172.

[36] 713 F.2d 335 (7th Cir. 1983).

[37] Grossman LA. Food, Drugs, and Droods: A Historical Consideration of Definitions and Categories in American Food and Drug Law, *Cornell Law Review* 2008; 93(5): 1091-1148; Wahlqvist ML. The New Nutrition Science: Sustainability and Development, *Publ Health Nutr* 2005; 8(6a): 766-772.

management of disease. That was a recognition that certain foods—particularly those with bioactive compounds—play a unique role in managing disease.[38] However, rather than establishing a hybrid regulatory approach that reflects the dual identity of such products (i.e., their food origin and therapeutic function), the FDA insisted on classifying them solely as foods.

Further complicating matters, the FDA subsumed medical foods under the Orphan Drug Act (a statute intended to promote the development of drugs for rare diseases that lack commercial viability). Medical foods are not, however, drugs. They are specially formulated nutritional products grounded in dietetics and standard nutritional science, not drug research and development.[39] Hence, offering them drug-like privileges (e.g. exclusivity, tax credit) is a regulatory mismatch.

Even the term "medical food" makes the contradiction glaringly obvious. The term presupposes food as its foundational identity — not drug. FDA has effectively placed "medical food" within a regulatory environment built for drugs, not foods.

That decision seems less about scientific reasoning and more about regulatory convenience — or, arguably, a political strategy to have all products capable of treating people regulated under the drug category, thus affording protection to drug markets at the expense of food markets. By failing to adopt a dual classification model that reflects both the food origins and therapeutic relevance of these products, the FDA has trapped medical foods in a legal framework that does little to promote access, innovation, or clinical utility. The short-term fix for this, as proposed in the present Strategic Roadmap and Action Plan, involves statutory change to the MF definition in order to reduce legal ambiguity and excessively narrow interpretation of the definition's scope by FDA.

4.6 Ambiguity and Limitation of the Physician Supervision Requirement

The current definition of medical food requires that it be administered "under the supervision of a physician." That aspect of the definition is restrictive, along a sliding scale of restriction.

For example, it may be construed to require the presence of a professional each time a medical food is administered. That is clearly impractical for many medical foods. While

[38] Bellisle F, Blundell JE, Dye L, *et al*, Functional Food Science and Behaviour and Psychological Functions. *Brit J Nutr* 1998; 80(S1): S173-S193.
[39] Herder M. What is the purpose of the Orphan Drug Act?." *PLoS Med 2017;* 14(1): e1002191.

physicians may help determine appropriate formulations or dosages, they are rarely involved in the daily administration of products such as predigested protein formulas or low-phenylalanine foods used in follow-up to surgeries or for chronic metabolic disorders, or other self-administered medical foods that are necessary for follow-ups to surgery or for serious disease conditions.[40]

In practice, "medical supervision" has often been reduced to minimal, periodic oversight, such as reviewing lab results or prescribing general dietary guidance every few months. For example, in diabetes care, physicians typically monitor HbA1c levels every 3–6 months.[41] Such infrequent involvement hardly constitutes the "active and ongoing" oversight envisioned by the statutory language, especially for conditions requiring adaptive, biomarker-driven dietary adjustments.

Even more problematic is the definition's rigid "physician" requirement, which is anachronistic in the advent of graduate level nutrition expertise, such as that possessed by Certified Nutrition Specialists, Naturopathic Doctors, registered dietitians, and other allied health professionals. Physicians, although trained in medical diagnostics and pharmaceutical treatments, often have minimal formal education in nutrition science.[42] The current framework sidelines those professionals, thereby denying expert nutrition interaction with patients on medical foods issues and access to medical foods sufficient to fill the gap between therapeutic demand and patient supply.

This rigid reliance on physicians undermines interdisciplinary care, delays access to therapeutic nutrition, and places critical dietary decisions in the hands of professionals who may lack the requisite expertise. As a result, the physician supervision requirement imposes an unjustifiable barrier on patient access.

4.7 Inflexibility in Definition Undermines Current Public Health Needs

Medical foods were initially designed to support patients with rare metabolic conditions, such as phenylketonuria (PKU), inborn errors of metabolism (IEM), short bowel syndrome,

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[40] Bass, IS. A legal overview of the status of medical foods in the United States. *Food Drug Cos Law J 1989;* 44(5): 467-477.
[41] Sherwani SI, Khan HA, Ekhzaimy A. Significance of HbA1c test in diagnosis and prognosis of diabetic patients." *Biomarker Insights* 2016: BMI-S38440.
[42] Devries S. A global deficiency of nutrition education in physician training: the low hanging fruit in medicine remains on the vine. *Lancet Plan Health* 2019; 3(9): e371-e372.

tyrosinemia, and urea cycle disorders.[43] However, with the rising chronic disease epidemic, it is evident that most diseases managed with medical foods are no longer rare diseases, but are often chronic or metabolic.[44,45] For instance, medical foods are essential in the treatment of:

a. Early-onset genetic abnormalities: e.g. glucose transport deficiencies, lipid processing mutations and amino acid processing mutations.[46]
b. Late-onset genetic abnormalities: e.g. cancer, renal disease, diabetes, cardiovascular diseases and osteoporosis.[47]
c. Lifestyle-induced abnormalities: e.g. arthritis, respiratory diseases, diabetes and cachexia.[48]
d. Drug-induced abnormalities: e.g. lupus, inflammatory bowel disease and rheumatoid arthritis.[49]

Additionally, as lifestyle and drug-induced abnormalities often occur or progress with age, MFs provide proactive dietary support for the relevant physiological pathways—helping to slow progression and, in some cases, to restore function or rebalance homeostasis.

In 2013, 50+ academic MD/PhD leaders publicly opposed the FDA's stance as applied to MFs, and other categories of food, that forced them into being considered as Investigational New Drugs (INDs),[50] disqualifying them from being regarded even as New

[43] Meral H, Demirdöven A. The use of medical foods to fight chronic diseases: a narrative review. *J Agr Sci* 2024; 30(3): 424-435.
[44] Morgan SL, Baggott JE. Medical foods: products for the management of chronic diseases. *Nutr Rev* 2006; 64(11): 495-501.
[45] Meral H, Demirdöven A. The use of medical foods to fight chronic diseases: a narrative review. *J Agr Sci* 2024; 30(3): 424-435.
[46] Camp KM, Lloyd-Puryear MA, Huntington KL. Nutritional treatment for inborn errors of metabolism: indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. *Mol Gen Metab* 2012; 107(1-2): 3-9.
[47] Kris-Etherton PM, Hecker KD, Bonanome A, *et al*. Bioactive compounds in foods: their role in the prevention of cardiovascular disease and cancer. *Am J Med* 2002; 113(9): 71-88.
[48] Berthon BS, Wood LG. Nutrition and respiratory health—feature review. *Nutrients* 2015; *7*(3):1618-1643.
[49] Morgan SL, Baggott JE. Medical foods: products for the management of chronic diseases. *Nutr Rev* 2006; *64*(11): 495-501.
[50] Public comment led by Connie Weaver, Ph.D., on Docket No. FDA-2010-D-0503; Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND November 6, 2013). https://downloads.regulations.gov/FDA-2010-D-0503-0019/attachment_1.pdf. Accessed October 27, 2025.

Dietary Ingredients (NDIs). Several nutrition-related organizations, led by the American Society of Nutrition, filed a similar complaint.[51]

As of February 2024, 133 million American live with at least one chronic illness, with 42% of adults having two or more.[52] Similarly, approximately one in three adults have metabolic syndrome, a condition that increases the likelihood of heart diseases, type 2 diabetes, and stroke.[53] In response, FDA has acknowledged that medical foods are needed for broader conditions requiring specialized nutrient intake.[54]

Despite that recognition, the agency has failed to allow broader patient access with huge consequences for health.[55] While medical foods are technically categorized as foods, their inclusion under the ODA invites quasi-drug treatment and incentives such as market exclusivity, tax credits, and waived user fees—designed for pharmaceuticals, not food-based interventions.[56]

That has resulted in a hybrid market structure that drives up prices and restricts access. For example, ODA-driven exclusivity prevents competition, encouraging pricing strategies more akin to those used for orphan drugs than for foods. In many cases, that restriction has led to limited insurance coverage and has placed an undue financial burden on patients who rely on these products for basic disease management.[57]

Moreover, the misapplication of ODA incentives has encouraged market behaviors, such as indication stacking and aggressive branding, that are more about maximizing profit

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[51] American Society of Nutrition comment on Docket No. FDA-2010-D-0503; Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND (November 26, 2013). https://asn-cdn-remembers.s3.amazonaws.com/7ae4fa5a6772968856c8cb8e9466a228.pdf. Accessed October 27, 2025.
[52] Chronic Disease Prevalence in the US: Sociodemographic and Geographic Variations by Zip Code Tabulation Area. https://www.cdc.gov/pcd/issues/2024/23_0267.htm#:~:text=throughout%20the%20US.-,Introduction,least%20affluent%20ones%20(7). Accessed October 27, 2025.
[53] What Is Metabolic Syndrome? https://www.nhlbi.nih.gov/health/metabolic-syndrome#:~:text=Metabolic%20syndrome%20is%20common%20in,health%20problems%20it%20can%20cause. Accessed October 27, 2025.
[54] This FDA's issued guidance in 2007 (later revised in 2016 and 2023) clarifies that medical foods are intended for the dietary management of a disease or condition and not just for rare diseases as long as they are used under medical supervision.
[55] While it is true that not all chronic and metabolic diseases are managed with medical food, a significant portion of the population require medical foods or dietary modification for management. This includes formulas with modified carbohydrate content for diabetes, high-energy and high-protein formulas for cancer, and textured-modified foods for neurological disorders.
[56] Berry SA., Kenney MK, Harris KB, *et al*. Insurance coverage of medical foods for treatment of inherited metabolic disorders. *Gen Med* 2013; 15(12): 978-982.
[57] Id.

than expanding access or supporting patient outcomes. The result is a distorted market where products critical for managing chronic conditions are unaffordable to many and regulated in ways that stifle clinical innovation and patient access.[58]

4.8 'Intended Use' of Medical Foods

Under 21 CFR 101.9, the FDA defines medical foods as products intended for the specific dietary management of a disease or condition with distinctive nutritional requirements, identified through medical evaluation and consumed under active, ongoing physician supervision. Medical foods, while not subject to pre-approval from FDA, must follow FDA compliance guidelines and all good manufacturing practices (cGMPs). They are categorized as Generally Recognized as Safe (GRAS) or approved food additives, and thus should include only ingredients with adequate evidence of meeting GRAS criteria for their intended use. Likewise, although not classified as drugs, medical foods are uniquely permitted to make disease-related claims, such as supporting treatment or management of a condition, provided they meet these strict statutory criteria.[59]

By contrast, dietary supplements are intended solely to supplement the diet and are expressly prohibited from making disease claims.[60] The distinction implies that supplements are meant for healthy individuals seeking to maintain general wellbeing. As a result, they are widely available, affordable, and do not require medical oversight.[61]

Paradoxically, medical foods—intended for individuals with diagnosed medical conditions—are more restricted in access and more expensive, caught in a quasi-drug regulatory model that limits competition, raises costs, and curtails access.[62] If the intended use of medical foods is to support the dietary needs of individuals with serious medical conditions, why are such products less accessible than supplements?

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[58] Medical Foods: Here Are Opportunities, Obstacles For This New Trend. https://www.forbes.com/sites/brucelee/2024/02/18/food-as-medicine-here-are-opportunities-obstacles-for-this-new-trend/?utm_source=chatgpt.com. Accessed October 27, 2025.
[59] US Congress, Orphan Drug Act, 1988 amendment (100th Congress).
[60] 21 U.S.C. 321 (ff) and Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[61] According to the CDC, a survey conducted between 2017-2018 showed that about 57.6% of US adults report using any dietary supplement within the last 30 days. Dietary Supplement Use Among Adults: United States, 2017–2018. https://www.cdc.gov/nchs/products/databriefs/db399.htm. Accessed October 27, 2025.
[62] Medical Foods: Here Are Opportunities, Obstacles for This New Trend. https://www.forbes.com/sites/brucelee/2024/02/18/food-as-medicine-here-are-opportunities-obstacles-for-this-new-trend/?utm_source=chatgpt.com. Accessed October 27, 2025.

The mismatch between purpose and policy distorts access and suppresses innovation. Aligning the regulatory treatment of medical foods with their nutritional role would bring policy into step with intended therapeutic use.

Clarifying prescription status and permitting assignment of NDC numbers, as proposed in the present Strategic Roadmap and Action Plan (Section 3.6), resolves a significant part of this policy conflict. There is also clear and recent scientific evidence that opening up this prescription pathway would fill a substantial gap in unmet needs within the U.S. population.[63,64]

4.9 FDA Enforcement and the Chilling Effect of Regulatory Intimidation

One of the more subtle yet deeply consequential tools used by the FDA to enforce its narrow interpretation of medical foods is the systemic issuance of warning letters. Warning letters, directed at manufacturers attempting to develop or market medical food products for chronic diseases, function as regulatory deterrents because non-compliance can result in seizure of products and prosecution of manufacturers, distributors, and sellers.

Since the first medical food-related warning letter in 2001,[65] the FDA has issued numerous others, consistently reiterating that the statutory definition of medical food "narrowly constrains" the types of products eligible for this classification. A warning letter issued in August 2013 to Metagenics, a prominent California-based medical food manufacturer, is particularly telling. In rejecting the company's product claims, FDA stated:

> *[A] medical food must be intended for a patient who has a 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. . . .*** *[Y]our*

[63] Watson KB, Wiltz JL, Nhim K, Kaufmann RB, Thomas CW, Greenlund KJ. Trends in Multiple Chronic Conditions Among US Adults, By Life Stage, Behavioral Risk Factor Surveillance System, 2013-2023. *Prev Chronic Dis.* 2025 Apr 17;22:E15.
[64] Pruitt SD, Khan R, Chaiyakunapruk N, Phrommintikul A, Aguilera MAD, Tan NC, Afzal S, da Silva van der Laan A, Weinman J. The silent epidemic of non-adherence - insights from the 2024 a:care congress. *BMC Proc.* 2025;19(Suppl 10):13.
[65] Lewis, CA, Jackson MC, Bailey JR. Understanding medical foods under FDA regulations."
In: *Nutraceutical and Functional Food Regulations in the United States and Around the World*, Academic Press, 2019, pp. 203-213.

products do not meet these requirements and therefore do not qualify as medical foods under either the statute or FDA's regulations.[66]

The narrow interpretation of medical food is borrowed from an FDA promulgated medical food labelling regulation- 21 C.F.R. §101.9(j)(8). In this regulation, the FDA stated that for a product to qualify for medical food exemption, the product must supply "'medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.'" Notably, the requirement does not exist in the statutory definition of a medical food, nor is it implied therein and makes no scientific or medical sense when evaluating how chronic conditions are managed through specialized diets.[67]

Yet, the FDA relies on the regulation to exclude certain conditions like diabetes mellitus (DM), chronic fatigue syndrome, metabolic syndrome, cardiovascular disease, inflammatory bowel disease, and peripheral artery disease from being available for disease management through use of a medical food.[68]

The case of diabetes (which likely represents the largest patient base for medical food products) is particularly instructive. In the second (draft) guidance (2013), the agency acknowledged that type 1 and type 2 diabetes have clear, distinctive nutritional requirements, e.g. insulin-matched carbohydrate counting in type 1, calorie restriction and fiber enhancement in type 2— supporting medical-food interventions. As to whether diabetes qualifies as a condition for which a medical food may be labeled or marketed, however, FDA categorically answered "No."[69]

Recognizing the logical inconsistency of its earlier position, the third (2023) edition then contained a volte face. It claimed that "there are no distinctive nutritional requirements associated with the management of DM…essential nutrient requirements…are no

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[66] Warning Letter to Medical Food Distributor Shows Fault Lines Between Food, Drug Claims. https://www.raps.org/News-and-Articles/News-Articles/2013/9/Warning-Letter-to-Medical-Food-Distributor-Shows-F. Accessed October 27, 2025.
[67] Medical Food Mumbo Jumbo: Confusing FDA Guidance Documents Will Discourage Medical Food Development. https://www.thefdalawblog.com/2013/09/medical-food-mumbo-jumbo-confusing-fda-guidance-documents-will-discourage-medical-food-development/. Accessed October 27, 2025.
[68] Lewis CA, Jackson MC, Bailey JR. Understanding medical foods under FDA regulations. In: *Nutraceutical and Functional Food Regulations in the United States and Around the World*. Academic Press, 2019, pp. 203-213.
[69] Draft Guidance for Industry Frequently Asked Questions About Medical Foods; Second Edition. file:///Users/cex123/Desktop/FDD%20Project%20docs/Draft-Guidance-for-Industry--Frequently-Asked-Questions-About-Medical-Foods--Second-Edition-(PDF).pdf. Accessed October 27, 2025.

different than those for unaffected persons," reiterating that diabetes is not a valid indication for medical foods.[70]

That FDA position rejects the well-established clinical necessity for nutritional management strategies tailored to diabetes care—carbohydrate frameworks, timing, and macronutrient prioritization. That makes it difficult for patients to access diets that are essential to the management of their life-threatening diseases.[71]

The problem created by this regulatory restriction is enormous. There are 2 million Type 1 diabetics in the United States. There are about 35 million Type 2 diabetics in the United States. Of those, 352,000 are juveniles under the age of 20. Complications of diabetes are listed as the 8th most common cause of death in the United States.

Furthermore, FDA's position is arbitrary and capricious. If the FDA accepts dietary management as legitimate for genetic metabolic diseases like PKU—where strict nutrient manipulation is difficult and essential—it is bewildering that it would dismiss the nutritional complexity of diabetes, a condition affecting millions.

By consistently framing such uses as violations—citing misbranding or unauthorized disease claims—the FDA sends a clear message: even scientifically sound, physician-supervised nutritional interventions will not be tolerated if it challenges the dominance of this carefully constructed, drug-focused system of regulation. In other words, FDA will protect the drug industry from competition, even at the expense of the health and lives of Americans.

FDA's "medical foods" restrictions have far-reaching adverse consequences for satisfaction of therapeutic demand, product innovation, and the health and longevity of Americans, contradicting the largest talking points for why medical foods were codified in the ODA in the first place.

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[70] Frequently Asked Questions About Medical Foods; Third Edition. Guidance for Industry. file:///Users/cex123/Desktop/FDD%20Project%20docs/Guidance-FAQ-Medical-Foods-3rd-Edition-March-2023.pdf. Accessed October 27, 2025.

[71] Meral H, Demirdöven A. The use of medical foods to fight chronic diseases: a narrative review. *Journal of Agricultural Sciences* 2024: 30(3): 424-435.

5. Conclusions

Medical foods (MFs) can and should become a pillar of U.S. healthcare's transition from late, high-cost rescue to earlier, patient-specific management of disease through targeted nutrition. The science and the need are clear: properly formulated, GRAS-based, food-derived therapies can help slow, stabilize, or better manage chronic and metabolic conditions—often with fewer side-effects and at lower total cost than branded drugs—yet current policy suppresses access, reimbursement, and innovation.

Today's framework is misaligned with statute and modern nutritional science. FDA interpretations have narrowed the category beyond the Orphan Drug Act (ODA), chilled research by pushing nutrition studies toward drug pathways, created "unapproved drug" traps when diseases are named (as they must be), and fostered confusion among PBMs and payers—resulting in denials of coverage and reduced clinical adoption. The physician-only supervision convention further constricts access despite widespread gaps in physicians' nutrition training and the availability of highly qualified nutrition professionals.

This roadmap sets out a balanced, practical fix. Congress and HHS should modernise the statutory and policy architecture to: (1) update and clarify the ODA definition to embrace diseases and conditions with distinctive nutritional requirements—including common metabolic and age-related conditions—where needs cannot be met by diet modification alone; (2) adopt a non-arbitrary, medically necessary standard anchored in generally recognised (peer-reviewed) evidence, with GRAS ingredients and recognition that MFs are specially formulated products not available in the ordinary diet; and (3) restore clarity on prescription status, allow NDC assignment, and enable manufacturer self-certification backed by substantial scientific/clinical evidence so payers can adjudicate fairly.

Concurrently, FDA should replace warning-letter-driven enforcement with clear, science-based guidance and safe-harbour pathways; reopen nutrition science by correcting the IND posture that has chilled MF research; and broaden supervision to qualified healthcare professionals (PAs, NPs, CNS/CNS-S, RDs, NDs, DCs, PTs) to expand responsible access. Education in medical nutrition—including MFs—should be embedded across health-profession curricula. CMS, VA, and TRICARE should implement coverage pathways where clinical and economic data support lower total costs of care.

Executing these reforms will widen patient access, spur competition and innovation, and generate measurable reductions in chronic-disease burden and healthcare spend—

squarely aligned with the Make America Healthy Again agenda. It will also restore U.S. leadership in medical nutrition science and practice, closing the current gap between therapeutic demand and patient supply. The path is actionable, evidence-based, and affordable; what is needed now is coordinated action by Congress, HHS/FDA/CMS, payers, clinicians, patients, and innovators to unlock the full value of medical foods for American health and longevity.

6. Join the ANH Medical Food Reform Campaign

Public advocacy groups, and practitioner organizations or companies involved with, or with interests in, medical foods who would like to get involved with the Alliance for Natural Health's strategy for medical food regulatory reform, please contact us at: office@anh-usa.org with the subject 'Medical Food Reform'.

Companies are strongly encouraged to join the ANH Corporate Leadership Circle so we can work closely with you to ensure we maximise the opportunities for medical foods as well as our shared vision of transforming the healthy life expectancy of the American people.