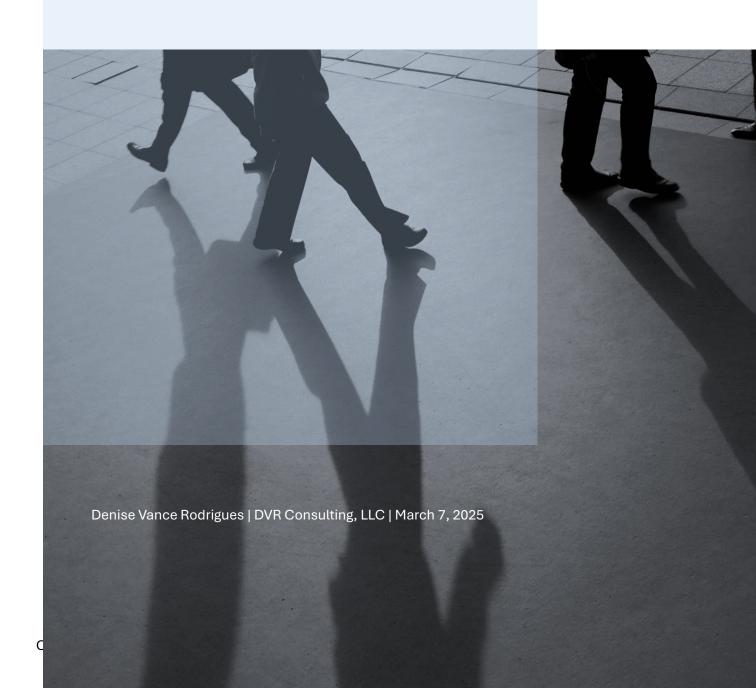
REIMAGING HEALTHCARE

ADDRESSING A BROKEN PRIMARY CARE HEALTH SYSTEM



Contents

Executive Summary	3
The Case for Change:	
A Vision For Change:	е
Model Framework:	7
Three-Pronged Approach: Transitioning to a Primary Care Model Augmented with Functional Medicine	
Unified Market Focus: Integrating Government Leadership Across All Segments	10
Roadmap to Success:	12
Call to Action:	13
Summary:	14
References for Clinical Data Supporting Functional Medicine	166

Executive Summary

The U.S. healthcare system faces escalating costs and poor outcomes due to its reactive, symptom-focused approach. Functional medicine offers a transformative solution by addressing the root causes of illness, emphasizing prevention, and integrating personalized, patient-centered care.

Lifestyle changes over the past several decades have significantly influenced health outcomes. In the 1950s and 1960s, diets were predominantly home-cooked with minimal processed foods, physical activity was naturally integrated into daily life, and chronic disease prevalence was considerably lower. However, today's sedentary lifestyles and increased consumption of caloriedense, nutrient-poor foods have contributed to a surge in chronic diseases. Obesity rates, for example, have risen from approximately 13% in the 1960s to over 40% today. This shift underscores the urgent need for a healthcare model that prioritizes prevention and sustainable lifestyle changes to combat these trends.

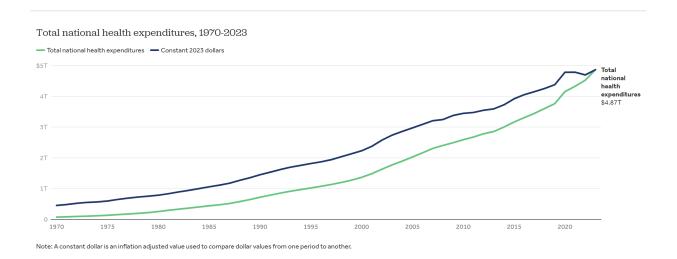
This model outlines a three-pronged approach to reimagine primary care:

- 1. **Functional Medicine-First Model**: A proactive framework addressing underlying conditions through advanced diagnostics, personalized treatment plans, and lifestyle interventions.
- 2. **Empowering Individuals**: Tools, education, and support to enable individuals to take control of their health and implement sustainable lifestyle changes.
- 3. **Community Resources**: Partnerships and initiatives to create accessible, equitable solutions that reduce health disparities and foster long-term wellness.

The model prioritizes key areas such as the gut-brain connection, mental health, chronic disease prevention, and health equity, leveraging clinical evidence to improve physical and mental health outcomes. This innovative approach has the potential to significantly reduce healthcare costs and improve quality of life for all populations, including underserved communities.

By transitioning to this new model of care, the aim is to empower individuals, reduce healthcare costs, and provide sustainable, preventive solutions for government-supported care systems. This is a unique opportunity to lead a paradigm shift in healthcare, making it more effective, equitable, and sustainable for future generations.

The cost of care tells the story. According to <u>KFF</u> the following chart depicts the continued increase in healthcare costs.



The Case for Change:

Traditional primary care is predominantly reactive, focusing on symptom management through medication and episodic care, often neglecting the interconnectedness of bodily systems. This approach has contributed to the growing prevalence of chronic illnesses, including:

- Autoimmune disorders: Affecting over 24 million Americans.
- Mental health issues: Depression, anxiety, and related conditions impact 20% of adults annually.
- Gastrointestinal disorders: Affecting 60–70 million Americans each year.

This system has resulted in:

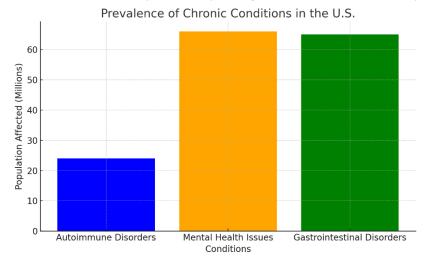
- Increasing rates of chronic diseases across diverse populations.
- Inefficient use of healthcare resources, leading to high costs and suboptimal outcomes.
- Limited access to preventive care and equitable healthcare services for underserved populations.

Emerging research underscores the vital link between gut health and brain health, known as the **gut-brain axis**, which is largely overlooked in traditional care models. This neglect leaves many patients with unresolved or recurring health issues, amplifying healthcare disparities.

Additionally, traditional insurance models do not typically cover comprehensive, advanced diagnostic services for preventive care. As a result, many individuals delay care until chronic conditions develop, which are then treated predictably with pharmaceuticals rather than through lifestyle modifications. Even when lifestyle changes are recommended, they are often introduced too late, leaving patients to navigate these challenges without adequate support.

Economically disadvantaged and underserved communities are disproportionately affected. These populations often lack financial resources, live in areas with limited access to healthy food, and face systemic barriers that perpetuate health inequities.

The chart below shows the number of Americans affected by autoimmune disorders (24 million), mental health issues (66 million), and gastrointestinal disorders (65 million).



Functional Medicine as a Solution

Prominent advocates such as Dr. Daniel Amen and Dr. Mark Hyman have pioneered functional medicine as a holistic approach to prevent and reverse chronic conditions:

- **Dr. Daniel Amen**: A brain-centric approach using advanced imaging to understand and treat mental health issues like depression and anxiety.
- **Dr. Mark Hyman**: Emphasizing personalized treatments, nutrition, and lifestyle changes to address chronic disease root causes.
 - Co-created The Daniel Plan with Dr. Amen and Pastor Rick Warren, integrating faith, food, fitness, focus, and friends into a comprehensive health strategy.
 - Founded the UltraWellness Center and developed the Functional Health platform to promote proactive, preventive care.

While these approaches demonstrate significant benefits, they remain cost-prohibitive for many individuals, particularly those in underserved communities. Addressing this gap requires innovative solutions that prioritize accessibility and equity in healthcare delivery.

The published study: Association of the Functional Medicine Model of Care With Patient-Reported Health -Related Quality-of-Life Outcomes by Michelle Beidelschies, PhD, Marilyn Alejandro-Rodriguez, GSAS, Xinge Ji shows the improvement in chronic conditions for the study group for the first 6 months. Which provides validation for the reasoning functional health should be an option for consumers.

Table 2. Characteristics of Propensity Score–Matched Patients With PROMIS GPH Scores at 6 Months				
No. (%)				

	No. (%)		
Characteristic	Center for Functional Medicine	Family Health Center	Standardized Difference ^a
Patients, No.	398	398	
Age, mean (SD)	52.70 (13.54)	51.81 (16.25)	0.06
Women	302 (75.9)	301 (75.6)	0.006
White race	363 (91.2)	363 (91.2)	0.001
Married	267 (67.1)	272 (68.3)	0.027
Household income, median (IQR), \$	62 776.0 (48 244.0-76 831.0)	65 052.0 (46 432.0-72 874.0)	0.056
Diabetes	100 (25.1)	97 (24.4)	0.017
Depression	118 (29.6)	104 (26.1)	0.078
Hypertension	107 (26.9)	104 (26.1)	0.017
Baseline score, mean (SD)			
PROMIS GPH	46.18 (8.67)	46.30 (8.85)	0.014
PROMIS GMH ^b	46.37 (8.98)	47.88 (9.29)	0.165
Total visits, mean (SD), No.	2.58 (0.94)	2.59 (1.28)	0.004
Functional medicine diagnostic category ^c			
Infection	27 (6.8)	26 (6.5)	0.01
Autoimmune	55 (13.8)	52 (13.1)	0.022
Allergen	14 (3.5)	12 (3.0)	0.028
Cancer	22 (5.5)	16 (4.0)	0.071
Hormones	116 (29.1)	108 (27.1)	0.045
Energy mitochondria	41 (10.3)	34 (8.5)	0.06
Nutrition	4 (1.0)	5 (1.3)	0.024
Mood	6 (1.5)	6 (1.5)	0.001
Neurology	59 (14.8)	53 (13.3)	0.043
HEENT	8 (2.0)	11 (2.8)	0.049
CVD	51 (12.8)	44 (11.1)	0.054
Gut	64 (16.1)	58 (14.6)	0.042
Skin	22 (5.5)	23 (5.8)	0.011
Structure	64 (16.1)	57 (14.3)	0.049
Genitourinary	42 (10.6)	38 (9.5)	0.033
Trauma	2 (0.5)	3 (0.8)	0.032

Abbreviations: Center for Functional Medicine, Cleveland Clinic Center for Functional Medicine; CVD, cardiovascular disease; Family Health Center; Cleveland Clinic Twinsburg Family Health Center; HEENT, head, eyes, ears, nose, and throat; IQR, interquartile range, PROMIS GMH, Patient-Reported Outcome Measurement Information System Global Mental Health; PROMIS GPH, PROMIS Global Physical Health.

A Vision For Change:

This white paper lays out a model to transform primary care by integrating a **functional medicine-first approach** that addresses the root causes of illness, prioritizes prevention, and empowers individuals to take control of their health. By combining advanced diagnostics, personalized care, and community-driven resources, the aim is to reduce chronic disease prevalence, improve health outcomes, and create equitable access to sustainable wellness solutions for all populations.

This model reflects a commitment to fostering a healthcare system that emphasizes proactive care, reduces disparities, and builds resilient, health-conscious communities.

^a Difference in means or proportions divided by SE; imbalance defined as absolute value greater than 0.10.

^b Not included in propensity score match.

^c Definitions provided in eTable 2 in the Supplement.

Model Framework:

To address the shortcomings of the current primary care model, a **functional medicine-first approach** that focuses on prevention, personalized care, and addressing the root causes of chronic illnesses moves the needle in addressing care needs. By prioritizing the critical link between gut and brain health while emphasizing sustainable, patient-centered practices is recommended to begin the movement in the healthcare system to lowering cost and improving patient outcomes.

Key Components of the Solution:

1. Root Cause Focus:

- Shift from symptom management to identifying and addressing underlying conditions, such as microbiome imbalances, nutrient deficiencies, and chronic inflammation and mental health conditions.
- Utilize advanced diagnostics to guide evidence-based interventions that target long-term health improvements.

2. Prevention-Centric Care:

- Proactively reduce the risk of chronic diseases through lifestyle optimization, including nutrition, stress management, and physical activity.
- Empower individuals with tools and education to make informed, health-promoting decisions.

3. Enhanced Health Outcomes:

- o Improve physical, mental, and cognitive well-being by leveraging the gut-brain connection and other systemic interdependencies.
- Reduce reliance on pharmaceuticals that continue to add cost to the healthcare system.

4. Community-Driven Resources:

- Build ecosystems that support wellness through accessible resources like community gardens, health education programs, and partnerships with local organizations.
- Address health disparities by ensuring equitable access to care, particularly for underserved populations.

This solution reimagines primary care as a comprehensive, integrated system that not only treats existing conditions but also fosters long-term wellness through prevention, education, and community engagement. By prioritizing these principles, we can create a healthcare model that is sustainable, cost-effective, and impactful for diverse populations.

Three-Pronged Approach: Transitioning to a Primary Care Model Augmented with Functional Medicine

This model outlines a transformative shift from the traditional primary care model to one augmented by a **functional medicine-first approach**. This approach focuses on addressing root causes, empowering individuals, and fostering community-driven wellness resources. By

integrating these three pillars, the model delivers a comprehensive solution to enhance health outcomes, lower costs, and promote sustainable well-being.

1. Functional Medicine-First Model: Addressing Root Causes

At the heart of this approach is a focus on uncovering and addressing the underlying causes of chronic illness rather than merely treating symptoms.

Key Features:

- Advanced Diagnostics: Comprehensive testing to identify microbiome imbalances, nutrient deficiencies, and inflammation along with brain health testing to helps identify key stressors/injuries that can be treated effectively.
- **Personalized Treatment Plans**: Evidence-based interventions targeting nutrition, stress management, and lifestyle modifications to optimize health. This would also include clinical intervention to support brain/gut disorders.
- **Preventive Focus**: Proactive measures to reduce chronic disease risks and long-term healthcare costs.

Impact:

- Reduced dependency on medications and costly acute care.
- Improved outcomes for conditions such as autoimmune diseases, mental health disorders, and metabolic syndromes.

2. Empowering Individuals: Taking Control of Health

Functional medicine equips individuals with the tools, education, and resources necessary to take ownership of their health journey.

Key Features:

- **Health Education**: Workshops, online courses, and seminars on nutrition, stress management, and the gut-brain connection.
- **Digital Tools**: Apps and wearables to monitor sleep, diet, exercise, and other health metrics while offering personalized recommendations.
- **Personal Wellness Plans**: Individualized guidance from practitioners to implement sustainable, long-term changes.
- Access to Healthy Food: Address disparities in food access and affordability to promote better health.

Challenges in Food Accessibility:

- **Per Calorie Costs**: Healthier foods cost approximately \$18.16 per 1,000 calories, compared to \$1.76 for calorie-dense, nutrient-poor options.
- Daily Expense Gap: A healthy diet costs an additional \$1.48 per day, or \$540 annually.

• **Income Allocation**: Low-income households would spend up to 50% of their income on healthy diets compared to 11% for higher earners.

• **Food Deserts**: Limited access to healthy options exacerbates disparities, leading to increased risks of obesity, diabetes, and diet-related diseases.

Impact:

- Enhanced patient accountability and engagement.
- Greater adoption of preventive practices, improving both physical and mental health.

3. Community Resources: Building a Sustainable Ecosystem

A strong community support system is essential for equitable access and long-term success in health improvement.

Key Features:

- **Community Gardens**: Local initiatives to grow fresh, organic produce, improving nutrition access.
- Government Assistance Programs: Subsidies for food would be applied to healthy
 options this would necessitate the need to increase the subsidies to allow individuals to
 access healthy options.
- **Healthcare Education Programs**: Community-driven workshops and outreach on preventive care and chronic disease management.
- **Collaborative Partnerships**: Engage local nonprofits, schools, and organizations to expand access to health resources.

Impact:

- Addressing disparities through accessible resources and education.
- Establishing a supportive, health-conscious community for lasting wellness.
- Providing financial support to allow individuals to access healthy options.

Why This Three-Pronged Approach Works

- 1. **Root Cause Resolution**: Functional medicine addresses underlying drivers of chronic disease, improving outcomes and lowering costs.
- 2. **Individual Empowerment**: Providing education and tools reduces reliance on reactive care models.
- 3. **Community Engagement**: Equitable access and sustainable health practices are achieved through local initiatives and partnerships.

This approach represents a paradigm shift in healthcare—integrating functional medicine, empowering individuals, and leveraging community resources to create a healthier, more equitable, and sustainable future.

Unified Market Focus: Integrating Government Leadership Across All Segments

The \$4.3 trillion U.S. healthcare market must transition from a reactive, symptom-based model to one that emphasizes prevention and functional health. A functional health-first approach addresses the root causes of illness through personalized, holistic care, offering a transformative solution that benefits health consumers, employers, and underserved populations. By involving the government in all segments, this approach ensures widespread adoption, equitable access, and sustainable impact.

1. Health Consumers

Hypothesis: A functional health-first model empowers individuals to take ownership of their health, leading to improved outcomes, reduced personal healthcare costs, and enhanced quality of life.

Government Role:

- Provide subsidies or tax credits to individuals who participate in functional health programs, incentivizing proactive health management.
- Expand coverage for functional health services under Medicaid and Medicare to ensure accessibility for all demographics.

Benefits:

- **Personalized Care**: Tailored treatment plans address root causes, such as gut-brain imbalances, nutrient deficiencies, and stress, providing effective and sustainable health solutions.
- **Preventive Focus**: Early interventions prevent chronic diseases, reducing dependence on emergency care and expensive pharmaceuticals.
- **Improved Mental Health**: Addressing the gut-brain connection offers impactful, non-invasive solutions for mental health issues, reducing the societal and economic burden.
- **Long-Term Savings**: Functional health reduces out-of-pocket expenses by decreasing reliance on reactive care models.

2. Employers

Hypothesis: Employers who adopt functional health-first models can reduce healthcare costs, improve workforce productivity, and enhance employee well-being.

Government Role:

 Offer tax incentives to employers who integrate functional health programs and provide access to healthy food options.

• Partner with businesses to create public-private collaborations that scale functional health initiatives across industries.

• Work with existing healthcare systems to shift from reactive to proactive approaches paying physicians to help attain/maintain the health of their patients.

Benefits:

- **Reduced Healthcare Costs**: Preventive care minimizes claims associated with chronic diseases, lowering insurance premiums and overall healthcare spending.
- **Enhanced Productivity**: Healthier employees are more engaged, experience fewer sick days, and contribute to a stronger organizational culture.
- **Talent Attraction and Retention**: Innovative, holistic healthcare benefits set employers apart, making them more competitive in talent acquisition.
- **Measurable ROI**: Functional health programs currently deliver a 20–30% reduction in healthcare costs and significant improvements in employee satisfaction and retention.

3. Underserved Populations / Government-Supported Care

Hypothesis: Functional health addresses health disparities by providing accessible, community-driven solutions that reduce the financial burden on government-supported care systems.

Government Role:

- Fund community-based programs, such as gardens, clinics, and health education workshops, to provide equitable access to resources.
- Expand Medicaid and Medicare to include comprehensive functional health services and preventive care.
- Implement food voucher programs and nutritional education to combat food insecurity and promote healthier diets.

Benefits:

- **Chronic Disease Management**: Proactively addressing conditions such as diabetes and hypertension reduces the strain on public health systems.
- Accessible Resources: Community gardens, education programs, and local health hubs create culturally relevant solutions tailored to underserved populations.
- **Reduced Government Spending**: By focusing on prevention, functional health lowers costs associated with hospitalizations, emergency care, and long-term treatments.
- **Improved Health Equity**: Addressing social determinants of health fosters equitable access and better outcomes for vulnerable populations.

By integrating functional health across all market segments and positioning the government as a central enabler, this approach creates a sustainable healthcare framework that delivers better outcomes, reduces costs, and ensures equitable access. Government leadership in incentivizing prevention, expanding functional health services, and fostering public-private collaborations will accelerate adoption, ultimately transforming the U.S. healthcare system into a model of innovation, efficiency, and equity.

Roadmap to Success:

This model focuses on leveraging government-sponsored programs and providing employers with tools and incentives needed to integrate functional health solutions into their offerings. By prioritizing prevention, personalized care, and equitable access, the following milestones are designed to align with the proposed solution and ensure measurable outcomes:

Year 1: Pilot Phase

Objective: Build credibility, validate the model, and demonstrate early success by targeting Medicaid and Medicare populations.

Actions:

- **Program Implementation**: Launch functional health programs for individuals enrolled in Medicaid and Medicare, focusing on chronic disease prevention and management.
- **Data Collection**: Track health improvement scores and outcomes for participants with chronic conditions, including reductions in hospitalizations and medication use.
- **Digital Infrastructure**: Develop and deploy a robust digital wellness platform to support personalized care, integrate wearable tracking devices, and monitor individual progress.

Outcome:

- Early data to showcase healthcare cost savings, targeting a **15% reduction in claims costs** for government programs.
- Demonstrated improvements in patient outcomes and participant satisfaction.

Year 2: Expansion Phase

Objective: Broaden reach by incentivizing employers to adopt functional health solutions and providing food vouchers for healthier dietary options.

Actions:

- **Tax Incentives**: Partner with government agencies to offer tax credits to employers integrating functional health into their employee wellness programs.
- **Enhanced Tracking**: Refine digital platforms to benchmark Year 1 results and track key ROI metrics, including absenteeism reduction and productivity improvements.
- **Food Access Programs**: Collaborate with local organizations to provide food vouchers and educational resources for healthier food choices.

Key Metrics:

• Initial adjustments in **medical cost spend** are expected as programs scale, with costs trending downward over time.

• Reduced employer healthcare costs, alongside measurable gains in employee satisfaction and productivity. This would include the ability to lower the employee cost sharing that has risen over the last 2 decades.

Years 3-5: Growth Phase

Objective: Establish functional medicine as a standard of care across all market segments, including government-supported programs and employer-sponsored plans.

Actions:

- Market Integration: Expand functional health programs to cover a majority of Medicaid, Medicare, and employer-sponsored insurance plans.
- **Policy Advocacy**: Work with policymakers to recognize functional medicine as a reimbursable and essential part of healthcare offerings.
- **Community-Driven Resources**: Scale initiatives like community gardens, wellness workshops, and local health hubs to ensure widespread accessibility.

Key Outcomes:

- Based on years 1 and 2 results KPI's will be developed for cost reductions through proactive, preventive care models.
- Establish functional health as a front-line standard in U.S. healthcare, creating a sustainable, equitable framework for long-term wellness.

These milestones align with the broader goal of transforming the U.S. healthcare system into one that prioritizes prevention, reduces costs, and ensures equitable access for all populations. By integrating functional health across government and employer channels, this model delivers measurable impacts that benefit individuals, employers, and public programs.

Call to Action:

Functional medicine is not just an enhancement to traditional healthcare—it is a necessary evolution. By integrating a functional medicine-first model that emphasizes prevention, personalized care, and the critical connection between gut and brain health, we can transform healthcare delivery. This approach addresses the root causes of chronic diseases, reduces healthcare costs, and improves outcomes for individuals, employers, and underserved communities.

Join us in leading this transformation by collaborating to implement sustainable, patient-centered healthcare solutions. Together, we can reduce the financial burden on government-supported programs, empower individuals to take ownership of their health, and foster innovation that creates a healthier, more equitable future.

Summary:

This model presents a transformative healthcare model that leverages functional medicine to address the root causes of chronic diseases. By optimizing the gut-brain connection and prioritizing prevention, this approach delivers innovative solutions for rising healthcare costs and improves overall well-being.

Key Highlights:

1. **Opportunity**:

The traditional healthcare system's focus on symptom management has driven escalating costs and poor outcomes for chronic conditions. Functional medicine offers a preventive, personalized alternative that addresses underlying causes, such as gut-brain axis dysfunction, significantly improving mental and physical health.

2. Case for Change:

This model envisions a healthcare system that empowers individuals to take ownership of their health, provides evidence-based care focused on root causes, and engages communities to create equitable, sustainable solutions. For the government, this means reduced healthcare spending, particularly for underserved populations.

3. A New Vision:

- A three-pronged approach involving individual empowerment, root cause care, and community engagement.
- Services include advanced diagnostics, personalized treatment plans (e.g., nutrition, stress management, mental health and microbiome optimization), and digital tools to monitor outcomes.
- Improved access to healthy foods through policy interventions to reduce cost disparities for low-income populations.

4. Focus:

- Encourage employer-sponsored programs to shift healthcare toward prevention and provide resources that reverse trends in chronic disease healthcare costs.
- Highlight government incentives and support to facilitate the adoption of functional medicine in underserved areas.

5. Roadmap to Success:

- Build a robust infrastructure with certified healthcare providers and digital platforms to track engagement and outcomes.
- o Collaborate with government programs and employers to implement incentives for adopting preventive healthcare measures.

6. Expected Outcomes:

- Over time, a healthier population with significantly lower healthcare costs for chronic conditions.
- o Improved national health outcomes, fostering a proactive approach to wellness and reducing reliance on reactive care models.

Why This Matters:

Focusing on functional medicine offers a clear path to improving the cost and quality of healthcare in the United States. It prioritizes prevention, empowers individuals, and fosters community-driven

solutions. For the government, this approach reduces financial burdens on healthcare systems, while ensuring equitable access for underserved populations.

By committing to functional medicine, we can create a healthier, more engaged nation invested in their well-being—an approach that will resonate with current healthcare challenges and provide long-lasting benefits. Together, we can redefine the future of healthcare.

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