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# FEEDING A HEALTHIER AMERICA: CURRENT EFFORTS AND POTENTIAL OPPORTUNITIES FOR FOOD IS MEDICINE

## HEARING

BEFORE THE

SUBCOMMITTEE ON PRIMARY HEALTH AND RETIREMENT SECURITY

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING FEEDING A HEALTHIER AMERICA, FOCUSING ON CURRENT EFFORTS AND POTENTIAL OPPORTUNITIES FOR FOOD IS MEDICINE

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# C O N T E N T S

STATEMENTS

TUESDAY, MAY 21, 2024

# FEEDING A HEALTHIER AMERICA: CURRENT EFFORTS AND POTENTIAL OPPORTUNITIES FOR FOOD IS MEDICINE

**Tuesday, May 21, 2024**

U.S. SENATE,
SUBCOMMITTEE ON PRIMARY HEALTH AND RETIREMENT SECURITY,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
*Washington, DC.*

The Subcommittee met, pursuant to notice, at 2:32 p.m., in room 430, Dirksen Senate Office Building, Hon. Ed Markey, presiding.

Present: Senators Markey [presiding], Murphy, Smith, Hickenlooper, Marshall, and Braun.

## OPENING STATEMENT OF SENATOR MARKEY

Senator MARKEY. The Senate Health, Education, Labor, and Pensions Subcommittee on Primary Health and Retirement Security will come to order. Thank you all for joining us today for the hearing, Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine. Thank you, Ranking Member Marshall, for partnering to bring together this very distinguished hearing.

In 1941, President Franklin Delano Roosevelt convened his first White House conference on nutrition. At that conference, he stated that the food an individual eats fundamentally affects his strength, stamina, nervous condition, morale, and mental functioning. And today we would say the benefits flow to all in our society.

Food security played an essential role in the reforms of the New Deal and the Great Society. As we moved towards a more equitable and just society, access to food was and is essential.

In 1946, Congress passed the National School Lunch Act to safeguard the health and well-being of our Nation's children. In 1964, Congress created food stamps now called SNAP, or the Supplemental Nutrition Assistance Program to support improved levels of nutrition for low-income households. And in 1965, Congress passed the Older Americans Act, which would later include and support nutrition programs for seniors. Food programs were core to the New Deal and Great Society because basic food security as a source of nutrition, health, and basic necessity is a key component of building a more just society. And at each point in history, it is the fight for a healthier, more just society that played an integral role in improving access to nutritious healthy foods.

In the late 1960's in Mound Bayou, Dr. Jack Geiger wrote prescriptions for malnourished children to get food from Black owned grocery stores in Mississippi and were paid for by the clinic's pharmacy. When the Federal Government pushed back on this, he said, "The last time I checked my medical textbook, the specific therapy for malnutrition was, in fact, food."

Civil Rights leaders demanded an end to hunger as part of the Poor People's March on Washington in 1968. And in the late 1980's and early 1990's, in response to the HIV AIDS epidemic, programs like Community Servings represented here today and others, developed Food is Medicine programs to make sure that people living and dying from HIV AIDS receive care and support even when many were disowned by their own families.

As David Waters said, "Community Servings showed up for them and said, you're not alone, we're here for you and we've made this beautiful meal for you."

Food is Medicine, an outgrowth of this movement for greater food security and healthier communities is a basic concept. It is the concept that the food that we eat impacts our overall health and well-being. And today, we see Food is Medicine in medically tailored meal programs that address an individual's medical diagnosis, symptoms, allergies or medications.

Produce Prescription Programs are allowing people to get financial support, to buy produce, to treat a health condition or risk. These programs are being integrated across hospitals and community health centers. Lowell Health Center in Massachusetts partners with Mill City Groves to ensure patients with chronic conditions can access healthy, locally sourced produce.

East Boston Health Center is serving groceries to hundreds of families each week, providing prepared meals for seniors through their home delivery meal program, and providing onsite Special Supplemental Nutrition Program for Women Infants and Children support.

We've heard time and time again that an ounce of prevention is worth a pound of cure. And a pilot conducted by Blue Cross Blue Shield in North Carolina, food delivery and health coaching for low-income members with type 2 diabetes was associated with $139 per month less in medical costs per month.

A recent Tufts study found that if medically tailored meals were implemented for everyone with diet related diseases and for people with limitations on activities of daily living, we could save $13 billion in the first year alone.

By comparison, Ozempic costs about a thousand dollars a month. Medicare spending for Ozempic, Rybelsus, and Mounjaro, reached $5.7 billion in 2022, up from $57 million in 2018. To fully deliver on the cost savings promised by Food is Medicine, we need to feed programs by funding research and supporting community organizations like our local health centers and nonprofits who are running and developing these programs.

We need to make sure that there is no separation between our food systems and our health systems. Health providers must know

they can prescribe Food is Medicine, that their patients can access easily and affordably.

But Food as Medicine is more than just cost savings. Food is Medicine is a stop in the continuum of food justice to guarantee that from the farms to dinner tables, people can get the food they need to sustain themselves in their communities.

What our planet can produce is as essential to our health as what our health systems can provide. With Food is Medicine, we can nourish a healthier America.

Thank you all, all of our witnesses. And now, I will turn to recognize Ranking Member of the Primary Health Subcommittee, Senator Marshall.

## OPENING STATEMENT OF SENATOR MARSHALL

Senator MARSHALL. Well, thank you, Chairman Markey, for convening this hearing on Food Is Health. A special welcome to our panel and we have rescheduled this once. So thanks for turning your schedules again around to come back and help us out to understand this issue out a little bit more. I want to say a special thanks to the majority staff for all your help putting this together as well.

But I'm often asked, most days I get asked what can we do to drive the cost of healthcare down? What can we do to save Medicare? What can we do to impact maternal morbidity? What can we do to impact the diabetes epidemic that we're seeing, ADHD, cancer incidents, all those, what can we do to impact all of those? And I would make the case that sound nutrition is not just part of the answer. It is the answer to those dilemmas. Food isn't just medicine, food is health. And I look forward to the testimonies today.

I think the challenge before us is how do we turn these ideas, these concepts, the research you've all done, how do we turn it into practical programs, the policy from the Federal Government, but also how can we put wind beneath your wings as you all try to solve this problem at the local level? So welcome everybody and we look forward to your testimony.

Senator MARKEY. Thank you, Senator Marshall, very much. And now we're going to turn to our witnesses. Our first witness is Ms. Jean Terranova. Thank you for being here today. Ms. Terranova is the Senior Director of Policy and research at Community Servings in Boston, an organization which provides medically tailored meals to individuals and families facing chronic illness of food insecurity.

She currently serves as a principal investigator for two NIH studies examining the impact of Community Servings, meals on health outcomes and quality of life for individuals with diabetes and food insecurity. She also serves on the policy committee of the Food is Medicine Coalition and as a board member for the Aspen Institute's Food is Medicine initiative.

Ms. Terranova, thank you so much for being here. Whenever you feel comfortable, please begin.

**STATEMENT OF JEAN TERRANOVA, SENIOR DIRECTOR OF POLICY AND RESEARCH, COMMUNITY SERVINGS, BOSTON, MA**

Ms. TERRANOVA. Thank you so much. Chairman Markey, Ranking Member Marshall, and Members of the Subcommittee, thank you for the opportunity to testify in this hearing.

My name is Jean Terranova, I am the Senior Director of Policy and Research for Community Servings. Our organization was founded in Boston in 1990 by a diverse coalition of activists, faith groups, and community organizations, to provide home-delivered meals to individuals living with HIV/AIDS at the height of the crisis. We were founded based on the simple principle, although perhaps revolutionary at the time, that food is medicine and that we can drastically improve health simply by changing an individual's diet.

In the last 34 years, Community Servings has grown from a neighborhood to a regional program serving medically tailored meals, MTMs to thousands of people across Massachusetts and our neighboring states. We have grown to serve diverse populations experiencing critical illnesses like diabetes, cancer, and many others.

Over our history, we have delivered over 13 million meals, including over 1.1 million last year. And with our nationwide partners in the Food is Medicine Coalition, we have learned that nutrition plays a crucial role in the healthcare space.

I want to thank the Subcommittee for shining a light on this important issue. Since the 2022 White House Conference on Hunger, Nutrition, and Health, healthcare stakeholders have been paying closer attention to nutrition, and specifically how nutrition can be better integrated into health care delivery. We have great experience with this in Massachusetts. Since 2020, our Medicaid program has provided reimbursement for nutrition services through an innovative model funded under an 1115 waiver.

Community Servings now maintains contracts with 12 of the 17 Accountable Care Organizations participating in this program. We have been able to achieve this integration because our programs have been rigorously studied, including in a peer-reviewed 2019 study published in JAMA, which I have submitted with my written testimony. That study found, among other benefits, that MTMs helped achieve a 16 percent net savings on total health care spending due to decreased emergency room visits, hospital admissions, and emergency transportation services. And the net savings factors in the cost of the meals.

The Aspen Institute has just released its updated Food is Medicine Action Plan showing that there are many other studies demonstrating that MTMs can significantly reduce healthcare utilization and costs.

Medically tailored meals are a simple concept but are complicated to implement. At Community Servings, our nutritionists evaluate each client individually for their health and dietary needs, their community access to food, and their ability to provide for themselves.

The client is then assigned one or a combination of Community Servings' 16 meal plans to meet their food preferences and dietary

requirements. We provide a week's worth of meals at a time, often for both the client and their family.

In addition to the meals, the weekly delivery includes snacks of fresh fruit and yogurt, and a quart of milk. We also provide nutritional education and counseling to those we serve, so that they have the tools to continue on a healthy path once they've moved on. The results are powerful.

Chuck, a 66-year-old with diabetes and vascular issues, has lost over fifty pounds and avoided a foot amputation since receiving a Cardiac Diabetic diet from Community Servings.

Janet, a 60-year-old with an autoimmune disease and cancer, credits Community Servings with taking an intimidating burden off her plate by providing her with nutritious foods, allowing her to focus entirely on her other health needs.

Our impact goes beyond the patients we serve; Food is Medicine Programs also benefit local food supply chains. Our local foods program intentionally sources as much food we can from local providers, totaling over 50,000 pounds of local fish, fruit, and vegetables every year. We have made great strides in increasing access to integrated food with medicine, but more can still be done.

Congress should increase research funding through the National Institutes of Health to explore the benefits of MTMs, and should seek other avenues to integrate nutritional interventions into programs like Medicare. We thank Chairman Markey and Ranking Member Marshall for their brand-new trio of bills that would task Federal agencies with publishing nutrition best practices, and to increase access to MTMs through community health centers.

We strongly support the bipartisan, bicameral, MTM pilot bill led by Senator Booker and Ranking Member Marshall. We need to be increasing such connections between the health care system and the food system.

Again, I thank the Subcommittee for the opportunity to testify today and welcome any questions you may have.

[The prepared statement of Ms. Terranova follows.]

PREPARED STATEMENT OF JEAN TERRANOVA

Chairman Markey, Ranking Member Marshall, and Members of the Subcommittee: Thank you for the opportunity to testify in this hearing. My name is Jean Terranova, I am the Senior Director of Policy and Research for Community Servings. Our organization was founded in Boston in 1990 by a diverse coalition of activists, faith groups, and community organizations to provide home-delivered meals to individuals living with HIV/AIDS at the height of the crisis. We were founded based on the simple principle, although perhaps revolutionary at the time, that food is medicine and that we can drastically improve health simply by changing an individual's diet. In the last 34 years, Community Servings has grown from a neighborhood to a regional program serving medically tailored meals (MTMs) to thousands of people across Massachusetts and our neighboring states. We have grown to serve diverse populations suffering from critical illnesses like diabetes, cancer, and many others. Over our history, we have delivered over 12 million meals, including over 1.1 million last year. And with our nationwide partners in the Food is Medicine Coalition, we have learned that nutrition plays a crucial role in the healthcare space.

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vided reimbursement for nutrition services through an innovative model funded under an 1115 waiver. Community Servings now maintains contracts with 12 of the 17 Accountable Care Organizations participating in this program. We have been able to achieve this integration because our programs have been rigorously studied, including in a peer-reviewed 2019 study published in JAMA, which I have submitted with my written testimony. That study found, among other benefits, that MTMs helped achieve a 16 percent net savings on total health care spending due to decreased emergency room visits, hospital admissions, and emergency transportation services. The Aspen Institute has just released its updated FIM Action Plan showing that there are many other studies demonstrating that MTMs can significantly reduce healthcare utilization and costs.

Medically tailored meals are a simple concept but are complicated to implement. At Community Servings, our nutritionists evaluate each client individually for their health and dietary needs, their community access to food, and their ability to provide for themselves. The client is then assigned one or a combination of Community Servings' 16 meal plans to meet their food preferences and dietary requirements. We provide a week's worth of meals at a time, often for both the client and their family. In addition to the meals, the weekly delivery includes snacks of fresh fruit and yogurt, and a quart of milk. We also provide nutritional education and counseling to those we serve, so that they have the tools to continue on a healthy path once they've moved on. The results are powerful. Chuck, a 66-year-old with diabetes and vascular issues, has lost over fifty pounds and avoided a foot amputation since receiving a "Cardiac Diabetic" diet from Community Servings. And Janet, a 60-year-old with an autoimmune disease and cancer, credits Community Servings with "tak(ing) an intimidating burden off (her) plate" by providing her with nutritious foods, allowing her to focus entirely on her other health needs.

Our impact goes beyond the patients we serve; food is medicine programs also benefit local food supply chains. Our Local Foods Program intentionally sources as much food as we can from local providers, totaling over 50,000 pounds of local fish, fruit, and vegetables every year.

We have made great strides in increasing access to integrated food with medicine, but more can still be done. Congress should increase research funding through the National Institutes of Health to explore the benefits of MTMs and should seek other avenues to integrate nutritional interventions into programs like Medicare. We thank Chairman Markey and Ranking Member Marshall for their brand new legislation to increase access to food through community health centers and primary care physicians, and we strongly support the bipartisan, bicameral, MTM pilot bill led by Senator Booker and Ranking Member Marshall; we need to be increasing such connections between the health care system and the food system.

Again, I thank the Subcommittee for the opportunity to testify today and welcome any questions you may have.

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Senator MARKEY. I thank you so much, Ms. Terranova. Next, we're going hear from Erin Martin, who is a gerontologist, and serves as founder and director of FreshRx, a produce prescription program which collaborates with primary care clinics and local farmers to provide free nutritious produce to people living with diabetes. Ms. Martin serves as president of the Urban Ag Coalition, and co-leads the Oklahoma Food Is Medicine Policy Coalition.

We welcome you, Ms. Martin. Whenever you feel ready, please begin.

## STATEMENT OF ERIN MARTIN, MASM GERONTOLOGIST, FOUNDER AND DIRECTOR, FRESHRX OKLAHOMA, TULSA, OK

Ms. MARTIN. Chairman Markey, Ranking Member Marshall, Members of the HELP Committee, thank you for this opportunity to discuss the transformative power of the FreshRx Oklahoma program. My name is Erin Martin. I'm a gerontologist, the director of FreshRx Oklahoma, the co-lead of Oklahoma's Food is Medicine Policy Coalition, and a proud member of the National Produce Prescription Collaborative.

I started working in long-term care when I was 15 years old. Since then, I have worked in all levels of long-term care, including HUD housing for 62 and older where I saw people on 15 to 32 prescription drugs per year. During that time, I attended the first and leading school of gerontology in the world, at the University of Southern California. And in Italy with USC, I studied death and dying and begin to study the blue zones where people die of something called old age on zero prescription drugs.

I started to understand deeply the connection of food and health. When the pandemic hit, a physician from North Tulsa shared that his diabetic patients were compliant in their medications and their doctor's visits, but that their health was still declining.

To try to address this, we co-founded FreshRx Oklahoma, a produce prescription program that launched in North Tulsa; a community with an eight and a half year, sometimes longer lifespan difference from South Tulsa, a community without a grocery store for 14 years, and a community with the highest mortality rates of diabetes in our county.

Our program empowers individuals with type 2 diabetes by providing them with biweekly locally grown produce for 12 months, along with four to six cooking and nutrition classes per month, and quarterly health metric checkpoints.

Participants or members as we call them, are either self-referred or referred from healthcare professionals at one of our 22 partnering primary care clinics. This also includes federally Qualified Health Centers, PACE clinics and clinics even serving the uninsured.

Provider Partners utilize a prescription form to refer the patient and verify their diagnosis. From there, we enroll the member and they begin the program at the very next food distribution cycle where they receive a starter kit complete with cooking utensils, cookbooks, and more.

This program has significantly shown success in reducing A1C levels and weight, enhancing both quality of life and reducing medical costs. With our first 300 patients, 80 percent have shown a reduction in their A1C level with an average reduction of 2.2 points.

Our largest reduction we've seen went from a 13.6 to a 5.4 in less than 6 months, and our record weight loss was just hit at 116 pounds fully reversing her type 2 diabetes and coming off all of her medications. Many of our members report having had diabetes for over a decade, but experiencing improvements in just a matter of weeks in our program.

I'm extremely proud of what FreshRx has accomplished, but I'm also proud of my colleagues across the country who are leading other successful produce prescription efforts.

There are many ways to provide these services, including prepaid debit cards that can be used in retail, farmer's market vouchers, and even online shopping models that work well for different communities.

Programs must reflect the communities for which they serve, providing food that is culturally relevant and supporting dignity of choice. Our specific model supports local agriculture, stimulates

local economies, and most importantly transforms lives through improved health.

I'm pleased to share that since its beginning, FreshRx has expanded into beyond North Tulsa to five rural cities with the Muscogee Creek Nation to serve their diabetic and pre-diabetic populations.

Implementing Food is Medicine is a smart economic decision with an enormous return on investment. Our program success is a testament to the power of integrating a Food is Medicine approach with our healthcare framework and providing a regenerative cost-effective solution to our Nation's health crisis.

The Senate Health Committee has an opportunity to integrate produce prescriptions across Federal health programs. Doing so offers a promising pathway to not only manage and prevent chronic disease, but to save on healthcare spending and resurrect local economies. Again, thank you for considering the potential of Food is Medicine.

I'm eager to answer any questions and discuss how we can expand these vital services to enhance health outcomes across our Country.

[The prepared statement of Ms. Martin follows.]

PREPARED STATEMENT OF ERIN MARTIN

Chairman Markey, Ranking Member Marshall, Members of the Subcommittee, thank you for allowing me the opportunity to testify before you today.

My name is Erin Martin. I am a Gerontologist and the Founder and Director of FreshRx Oklahoma,[1] a non-profit committed to providing nutrient dense, locally grown produce to help people manage their diabetes and improve their overall health. We do this by running a Produce Prescription program which first launched in North Tulsa, a community that hadn't had a grocery store in over 14 years with the highest rates of mortality from diabetes in the county. There is a significant longevity gap between residents of North and South Tulsa, with data indicating an approximate 8.5-year difference in average life expectancy.

FreshRx is a member of the National Produce Prescription Collaborative (NPPC). Since 2019, NPPC has worked to catalyze the vital role of food and nutrition in improving health outcomes by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness. The collaborative's diverse membership of over 60 organizations includes program operator representatives from various geographies, research, education, healthcare policy, and national networks working to embed and institutionalize Produce Prescriptions as a health intervention tool.

The annual burden of diabetes on the U.S. economy is staggering, costing approximately $412.9 billion in 2022. This includes $306.6 billion in direct medical costs and an additional $106.3 billion stemming from lost productivity.[2] The evidence is clear: diet-related interventions can dramatically reduce these costs. In Tulsa, our Produce Prescription program has already made significant strides. Participants, especially those with Type 2 diabetes and other diet-related diseases, have shown remarkable health improvements—ranging from reduced A1c levels to significant weight loss.

**The Produce Prescription Journey**

Our program, and other programs like ours, eliminate barriers to healthy food while empowering people to create long lasting behavioral change. Produce Prescriptions are a viable medical intervention and should be prioritized for those with diet-related diseases and as a supportive measure to a wider array of medical conditions. A few insurers and health systems are beginning to adopt it as a preventative service for patients who are eligible due to diet-related health risk or condition and food

[1] *https://www.freshrxok.org/*.
[2] *https://pubmed.ncbi.nlm.nih.gov/37909353/#:?:text=Results*.

insecurity or other documented challenges in accessing nutritious foods. These prescriptions can be fulfilled through farmers markets, food retail, and CSAs (farm subscription models) to enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. Produce Prescriptions are designed to improve health outcomes, optimize medical spending, and increase patient engagement and satisfaction.

While the Produce Prescription intervention model began just over a decade ago, today, more than 100 organizations administer programs across the country. The impacts of these programs have been undeniable and warrant serious consideration by all who wish to improve the health and the lives of vulnerable Americans in a cost-effective way.

My journey to Produce Prescriptions began through my extensive experience in long term care starting at the age of fifteen. After working in all levels of long-term care by the time I was 24 years old, I realized the importance and innovation of food as medicine as a mechanism to give people more ways to stay healthy. While learning about the natural biological processes of aging in my Masters program at the premier and world leading Leonard Davis School of Gerontology, I discovered serious discrepancies between the way we are supposed to age biologically, the ways people are aging in other countries, and the way we are aging in the United States. If you are 65 and older in the U.S., you are on an average of 15 or more prescription drugs per year. If you are over 50 in the U.S., you have at least one chronic condition. In fact, I saw clients who were on anywhere between 15 and 32 prescription drugs at one time. I studied Death and Dying with the University of Southern California in Italy and then, began to study the Blue Zones of the world.

The concept of "Blue Zones" refers to regions in the world where people have unusually long lifespans. Five regions have been identified as Blue Zones: Okinawa (Japan), Sardinia (Italy), Nicoya (Costa Rica), Icaria (Greece), and Loma Linda (California, USA). Despite the geographical and cultural differences, their diets share several common traits that contribute to their longevity. Their diet has an emphasis on whole, minimally processed foods. This means less sugar, fewer refined grains, and fewer processed foods. Diets are rich in healthy fats, primarily from sources like olive oil, nuts, and seeds. In Okinawa, for instance, the consumption of fish provides omega–3 fatty acids. Many of the Blue Zones practice some form of caloric restriction or mindful eating. This can be through cultural habits of eating until only 80 percent full or fasting practices. I found that people in these areas, unlike Americans, were dying of something called "old age" on zero prescription drugs.

**Produce Prescription Model in Oklahoma**

My venture into Food is Medicine was furthered once I moved back to Tulsa, Oklahoma, a city where I had grown up, just before the COVID–19 pandemic hit. I saw firsthand the dire need for food access, improvements in the healthcare system, and the vast longevity difference between a North and South Tulsa. A physician, Dr. Kent Farish from Crossover Health Services in North Tulsa came forward and expressed that his patients were compliant in their medications and their doctors visits but they were not getting better and he knew it was the food they had access to and were consuming that was the culprit.

Like many areas across the United States, parts of Oklahoma face economic and community factors that have led to food shortages and highlighted the vulnerabilities within our overtaxed healthcare system. North Tulsa had been without a grocery store for over 14 years plagued by a history of health and racial inequities.

In 2021, we started the first-of-its-kind PRx in the state of Oklahoma with 52 patients, providing a trifecta of access to local, fresh food, engaging and empowering education, and utilizing health metric checkpoints. We are proud to receive funding from private donors, private philanthropic organizations such as St. John Ascension, MorningCrest Health Foundation, Fazel Family Foundation, the Zarrow Commemoration Fund, and the Federal Government. Our Federal funding comes from the USDA NIFA GusNIP programming. GusNIP supports projects that demonstrate the impact of PRxs on fruit and vegetable consumption, food insecurity and healthcare usage for vulnerable populations.

Physicians and other healthcare providers send a referral to FreshRx Oklahoma verifying their diagnosis and starting metrics (HbA1c, weight, and blood pressure). Our team enrolls the patient by conducting a full survey that captures additional data like mental health, pain management, socialization, medical adherence, hospitalizations, and more. The patient then starts the program at the next bi-weekly

distribution date and receives a starter kit including cooking utensils, a cookbook, and a produce storage sheet. They receive free, local fruits and vegetables bi-weekly for 12 months along with 4–6 cooking and nutrition classes per month. We measure health metrics quarterly to mark the patient's progress and engage patients in ongoing feedback to ensure the program is meeting their needs.

As part of our GusNIP requirement, we work with an Internal Review Board (IRB) at Langston University in Oklahoma to provide ethical oversight, and help us to maintain HIPAA compliance, and review patient documents. We also contract with Oklahoma State University to act as our data partner, evaluating our pre-and post-survey data, to determine whether or not we are achieving our program goals (i.e. calculating if increased consumption of fresh produce by our patients is actually correlated to better health).

**Patient and Community Impact**

Our typical patients are people living with Type 2 diabetes in North Tulsa experiencing food insecurity and most recently, we are serving those with prediabetes in the Muscogee Creek Nation. We are deeply honored to serve the Muscogee Creek Nation while this program fits into their larger plan for public health and food sovereignty. 39 Native American nations call Oklahoma their home. Diabetes plagues Native Americans at a higher rate than any other group of people. In fact, 1 out of 2 Native American children born after the year 2000 will be diagnosed with Type 2 diabetes.

We had a participant who was a veteran who slept on the floor of his apartment who hadn't had produce in over 2 years. He cried every time he got food from our program. He made a soup with all of the greens we gave him and he reported that the "floaters" in his eyes had disappeared in a few short weeks.

We had another participant who was feeling lethargic and unhappy. She was diagnosed at age 60 with Type 2 Diabetes. In our program, she lost 50 pounds and her HbA1c level went from a 9.6 to a 5.4. She now reports feeling happier, treating others with more kindness, exercising daily, and being able to keep up with her grandkids. Our greatest HbA1c reduction has been from a 13.6 to a 5.4 in 6 months! Recently, we had a record weight loss of 111 pounds!

These examples are not unique. Through our work, we have consistently improved intake of fruits and vegetables, improved overall dietary consumption, reduced the gap between actual consumption and the national daily recommendations, lowered weight, lowered blood pressure, and lowered Hemoglobin A1c among program participants.

In fact, our program targets key risk factors like blood glucose levels, blood pressure, and weight. On average, our patients see a 2.2 percent decrease in A1c levels, 13-point reduction in blood pressure, and an average weight loss of 9 pounds with many weight losses above 20 to 72 pounds. Patients in our program, many who have struggled with diabetes for 15 to 20 years, start experiencing improvement in a matter of weeks. Every meal impacts our health.

We have shown a significant statistical correlation between the increased consumption of fruits and vegetables with the overall improvement of health. We have shown a significant statistical increase in the consumption of garden salads and vegetable soup. At the same time, we have shown a significant statistical decrease in the consumption of soda.

**Potential Economic Benefits**

This program is making an impact on health care spending in our state. For example, if we scaled to 1,200 participants, it would cost $3 million and the cost savings would be $25 million for the state of Oklahoma. Let's say we have a 70 percent success rate, a cost of $5,000 per patient, along with the national average cost of diabetes care, and the number of Oklahomans with diabetes, the net savings for Oklahoma could be close to $2.6 billion when scaled statewide. And that is just in Oklahoma!

At the same time, Produce Prescriptions support local economies through the agriculture purchases and jobs being created. We have supported 27 small-scale farming businesses and expanded the volume, diversity, and seasonal production at 15 farms. In fact, the Food is Medicine movement has an economic ripple effect in the healthcare industry, the agricultural industry, and workforce development that can transform lives and restore communities.

In the last 4 years, we have tripled in size and expanded to serve patients at 22 primary care clinics including federally Qualified Health Centers, PACE clinics, and

clinics serving the uninsured. We mostly serve those over 50 years of age, we see success at all ages, including participants all the way into their 90's finding success. We have received national attention for the innovative way we systematically address food and health.

I am extremely proud of our program and all that it has accomplished. I am also proud of my colleagues across the country who are leading the way on produce prescription efforts. FreshRx Oklahoma is one of many models that work. There are many ways to provide these services, including prepaid debit cards for retail like AboutFresh or in Kansas there is an online ordering model called Attane Health.

The results we are seeing are not unique to our state. Research has shown that prescribing healthy food to patients could prevent as many as 3.28 million medical conditions such as heart attacks and strokes and save more than $100 billion in healthcare costs. Subsidizing fruits and veggies would prevent 1.93 million cardiovascular events such as heart attacks and 350,000 deaths.[3],[4] Time and again, these, relatively low-cost interventions have been found to yield improved health outcomes over time, including lowering weight, blood pressure, and HbA1c levels with an incredible health cost savings return on investment. This is not only an intervention that works, but an economic and viable business investment. Moreover, patients achieving these results through PRx have also reduced their reliance on more costly medications and other medical interventions (and increased medical adherence).

**Congressional Opportunities**

While investments in PRx are starting to happen at the Federal level, including at USDA and Indian Health Services, there are a number of opportunities to infuse Produce Prescriptions into health programs not only across the Department of Health and Human Services, including the Administration on Aging, Centers for Medicare and Medicaid Services, and the Health Resources and Services Administration, but across the Federal Government, including within the Department of Veterans Affairs.

One near-term opportunity for this Committee to consider to advance access to Food as Medicine programs is through the upcoming reauthorization of the Older Americans Act (OAA). Since its inception in 1965, the OAA has provided a broad range of critical services and support for older adults, including nutrition services. Today's OAA has an opportunity to further encourage healthy aging, by strengthening the connection between food and health interventions for diet-related disease through PRx.

Given the breadth of their reach in urban and rural areas, OAA programs have the potential to engage program participants and provide meaningful interventions earlier that will lead to improved quality of life and healthier aging. Produce Prescriptions, Medically Tailored Groceries, and Medically Tailored Meals, as well as other Food is Medicine programs, would complement meals on wheels and congregate meal services being provided under OAA. These programs truly have the potential to elevate current programs and produce measurable health outcomes.

Another place where this Committee could help advance Food as Medicine access is within the Health Resources and Services Administration (HRSA) community health center program. A growing number of local Produce Prescription programs are beginning to partner with community health centers to bring this nexus of healthy food and health care together for low income and underserved individuals living with or at risk of chronic conditions. Including Food as Medicine among the allowable health services provided within the community health center setting would enable these programs to flourish at the local level.

I appreciate the Committee examining current and future opportunities of food as medicine funding pathways and implementation. The food we consume not only serves as a source of energy, but also contains nutrients that positively impact our bodies and promote healing to enhance our overall health and well-being. When we eat whole, unprocessed foods rich in essential nutrients, vitamins, minerals, antioxidants, and phytochemicals, these foods work to reduce inflammation and boost immunity, promoting more wellness and resilience.

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[3] *https://www.nih.gov/news-events/nih-research-matters/prescribing-healthy-foods-could-bring-cost-effective-benefits.*

[4] *https://www.fastcompany.com/90323580/prescribing-fruits-and-veggies-would-save-100-billion-in-medical-costs.*

A good diet plays a crucial role in maintaining a balanced immune system, reducing the risk of chronic diseases such as heart disease, diabetes, and certain cancers, and supporting optimal bodily functions. By being intentional with what we eat, we can harness the healing power of food to improve health outcomes, and prevent, manage, and even treat various health conditions.

The best part is that food as medicine recognizes the uniqueness of each person's specific dietary and cultural needs. It encourages people to explore different foods and customize what they eat in a way that works for them with dignity.

It can be difficult for anyone to stay compliant with doctor's orders, let alone those living with food insecurity and poverty. Produce Prescriptions get patients the nutrient-dense food they need to be back in control of their disease. Integrating Produce Prescriptions into the Federal health system provides the opportunity to transform public health.

Again, thank you. I look forward to answering your questions.

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Senator MARSHALL. Good. Mr. Chairman, next I want to introduce Dr. Dariush Mozaffarian, who's the director of the Food is Medicine Institute at Tufts University, located in Boston, Massachusetts. Dr. Mozaffarian is a cardiologist, a scientist and globally recognized expert in nutrition, medicine and public health.

I've had the opportunity to work collaboratively with him since being a freshman in the House of Representatives where we cofounded the Food is Medicine Working Program. As one of the leading experts on Food is Medicine, Dariush was invited here today to share the vast contribution he's made in making Food as Medicine, something we can apply successfully across our health system.

Dr. Mozaffarian is also proof of the American dream. He's the child of immigrants. He couldn't get into Kansas State, so he went to Stanford University to get his bachelor's degree, an M.D. at Columbia University and a doctorate in public health at Harvard University.

Thank you for agreeing to testify and sharing your expertise with us.

Dr. Mozaffarian.

**STATEMENT OF DARIUSH MOZAFFARIAN, M.D., DRPH, DIRECTOR, FOOD IS MEDICINE INSTITUTE, TUFTS UNIVERSITY, BOSTON, MA**

Dr. MOZAFFARIAN. Chairman Markey, Ranking Member Marshall, and distinguished Committee Members, thank you for the opportunity to share what I've learned and what I've seen from Americans across our great nation.

As a heart doctor, I see firsthand people of all ages and backgrounds suffering from diet related diseases. As a public health expert, I see the incredible challenges Americans face every day to obtain and eat nourishing food. And as a researcher, I study the science on how foods affect health and I study the effect of policy changes to achieve well-being and health equity over the course of any given year.

I see and speak with thousands of people, thousands of Americans, who know in their gut that our food is making them sick and yet feel helpless to do anything about it. This inability to eat well is literally lethal. Poor nutrition is the top cause of death and disability in the United States. I should drop the mic there, causing

more harms than tobacco use, alcohol, opioids, physical inactivity and air pollution.

Each week, the food we eat is estimated to kill 10,000 Americans, cause 1,500 new cases of cancer, and cause 16,000 new cases of diabetes, each week. These likely underestimate the full harms given what we're now learning about the effects of our food on the gut microbiome, the brain depression and mental health, child development, autoimmune diseases, immune function and more.

This is also driving societal discord. Each year, 40 million Americans, one in eight households, experience food insecurity, which is linked to worse nutrition, more diet related disease, and greater healthcare spending. Americans with lower incomes in rural communities and from marginalized racial and ethnic groups are at highest risk.

Our food is also an urgent matter of National Security. Eight in 10 young Americans don't qualify for the military and the leading medical disqualifier is overweight and obesity.

Poor nutrition is crushing our economy causing $1.1 trillion in economic losses every year from preventable healthcare spending and loss productivity. For diabetes alone, the U.S. Government alone spends nearly $200 billion each year on direct medical costs for a disease that is almost entirely preventable and treatable with better food.

As detailed in my written testimony, the economic costs of diet related diseases are also crushing U.S. families, U.S. businesses, the Federal budget and the National debt. The lack of attention to these harms of our food explains so much about the problems our Country faces today. Tens of millions of sick Americans, hundreds of billions of dollars in preventable healthcare costs, suffering U.S. businesses, exhausted state and Federal budgets, and frankly, exhausted policymakers fighting over the shrinking remainder.

Senators, if you want to do the things that you believe are important for the American people, you will never have the resources you need until we reduce healthcare spending.

This will not happen until we fix food. The nation state of diet related disease is not Okay, it's not normal and we can fix it. Nutrition is the top cause of poor health and yet historically has been ignored by the healthcare system. This is finally changing with Food is Medicine interventions.

My written testimony describes the various types of Food is Medicine therapies, you've heard from the preceding witnesses on these, their efficacy and their cost equivalence or even cost savings compared to traditional medical treatments.

As shown in many states and in private healthcare demonstration projects around the country, Food is Medicine can improve health and save money, there's almost nothing in healthcare that can do both of those things.

Food is Medicine programs can also support local farmers and regional food systems serving as an economic engine for rural communities. With the current evidence and progress, the Nation is at a tipping point to potentially accelerate Food is Medicine, action is needed.

Today, the vast majority of Americans cannot access these therapies and more research and implementation are critical to assess which programs work best for which patients.

My written testimony summarizes potential congressional actions in this area. For example, advancing Food is Medicine at community health centers serving the most vulnerable Americans who will benefit such as through S. 2840 introduced by Senator Sanders and Marshall. Advancing Food is Medicine in Medicare such as through S. 2133, introduced by Senators Marshall, Cassidy, Booker, and Stabenow.

Integrating Food is Medicine into the older Americans Act, including Produce Prescriptions and medically tailored meals. Providing meaningful funding to NIH to launch Food is Medicine Centers of Excellence, a concept which has already received NIH clearance and is ready to go. And even utilizing report language to encourage Food is Medicine and Medicaid 1115 waivers, Food is Medicine pilots at CMMI, food and nutrition security screening and care referrals in the electronic medical record.

Meaningful nutrition education for doctors, speaking to the national accreditation and licensing organizations that oversee U.S. medical education, healthcare systems, payers, doctors, patients, public and private vendors, food retailers, pharmacies, advocacy and clinical groups, and even from our national polling, the American people all support Food is Medicine.

It's time for congressional action to help bring Food is Medicine to the American people. Thank you for the opportunity to testify.

[The prepared statement of Dr. Mozaffarian follows.]

PREPARED STATEMENT OF DARIUSH MOZAFFARIAN

Dear Chairman Markey, Ranking Member Marshall, and distinguished Members of the Committee:

I am grateful for the opportunity to testify and share what I have seen and learned from Americans across our great Nation. I would also like to extend my thanks to Senators currently advancing innovative Food is Medicine legislative and policy proposals that are supported by diverse stakeholders.

**My Expertise**

My testimony reflects my expertise and experiences as a cardiologist, scientist, and public health expert. I serve as Director of the Food is Medicine Institute at Tufts University, an institute dedicated to understanding how to effectively integrate food-based nutritional treatments into healthcare. As a doctor, I see firsthand people of all ages and backgrounds suffering from diet-related illnesses. As a public health scientist, I see the incredible challenges Americans face, every day, to obtain and eat nourishing food. As a researcher, I focus on the science and practice of what we need to eat to keep our bodies healthy; and on the most effective policy and systems changes to support good nutrition, well-being, and health equity.

Over the course of any given year, I see and speak with thousands of people who are not as healthy as they could be. They are doing their best to care for themselves, and their families, patients, constituents, and employees. Most feel a vague unease about the harm our food is doing—and have no idea what the remedy is. Ordinary Americans face food-fad whiplash. Doctors watch their patients grow more obese and ever sicker. Policymakers with good intentions continue to make decisions based on dangerously outdated science. Social media adds to the confusion: thousands of influencers are now paid by the worst elements of the food industry to cynically pitch anti-nutrition messages—"advice" that can be literally lethal.

I'm here to say: *This is not okay. We can fix this. And you and your colleagues across the Senate and House have a responsibility to do so.*

Some ask me: how did a cardiologist become so focused on food and nutrition? My response: why isn't *every* cardiologist focused on food and nutrition? During my years of training in medical school, internal medicine residency, and cardiology fellowship, it was obvious that poor nutrition was the top driver of disease in most of my patients. And yet, we didn't learn anything meaningful on nutrition and health throughout my medical school training.

Think about that: the *top cause of poor health* in the United States—nutrition—is largely ignored by our healthcare system. This explains so many of the problems we face today.

**The Facts**

- Poor nutrition is the leading cause of death and disability in the United States—causing more health harms than other major risk factors such as tobacco use, alcohol, opioids, physical inactivity, or air pollution (see *Figure 1* at the end of this testimony).
  - The food we eat is estimated to kill 10,000 Americans each week, cause 1,500 new cases of cancer each week, and cause 16,000 new cases of diabetes each week.[1, 2, 3]
  - These horrifying statistics likely *underestimate* the harms of our food, given what we are learning about effects of nutrition on the gut microbiome, brain health, depression, child development, autoimmune diseases, immune function, and more.
- When I entered medical school in 1991, we *did not have* these national epidemics of obesity or diabetes.
  - This has happened in our adult lifetimes, under our noses—under our watch.
  - This is very new: and the main driver is the recent changes to our food.
- Americans are *failing nutrition*. The average score on the Healthy Eating Index (HEI)—a measure of adherence with the Dietary Guidelines—is 58 out of 100. You don't have to be a college professor to know that's an F.
  - The problem is two-fold. First, we eat too much refined starch, sugar, salt, and other additives. These come from highly processed foods, especially in the form of "*acellular nutrients*." For the first time in human history, we are breaking down food into its molecules components that we shape and manipulate, devoid of all natural cell structure. This is harming our cells, causing a rush of rapidly digested nutrients into our bloodstream; and also starving our gut bacteria, leaving too few nutrients to reach our large gut. This "double hit" is driving obesity, diabetes, and more.
  - The second problem is that we eat too few fruits, vegetables, nuts, beans, whole grains, seafood, and yogurt (see *Figure 2* at the end of this testimony). These minimally processed foods are rich in fermentable fibers, bioactive phytonutrients, and other compounds that nourish our bodies and our gut bacteria.
  - Critically, when these harms are tabulated, both are important, but *the lack of healthy foods* is causing more health problems than the excess of harmful compounds. This is important: we can't only fight food like tobacco, aiming to regulate, tax, and penalize unhealthy items. *We must also reward, incentivize, and value healthy food for its true health and economic benefits*. We will return to this when we discuss Food is Medicine.

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[1] U.S. Burden of Disease Collaborators, Mokdad AH, Ballestros K, et al. The State of U.S. Health, 1990–2016: Burden of Diseases, Injuries, and Risk Factors Among U.S. States. *JAMA*. 2018;319(14):1444–1472.

[2] Zhang FF, Cudhea F, Shan Z, et al. Preventable Cancer Burden Associated With Poor Diet in the United States. *JNCI Cancer Spectr*. 2019;3(2):pkz034.

[3] O'Hearn M, Lara-Castor L, Cudhea F, et al. Incident type 2 diabetes attributable to suboptimal diet in 184 countries. *Nature medicine*. 2023;29(4):982–995.

- Poor nutrition is crushing our economy. Poor nutrition is estimated to rack up *$1.1 trillion* in economic losses every year from preventable healthcare spending and lost productivity.[4]
  - For just one condition, type 2 diabetes—a malady almost entirely preventable and treatable with good nutrition—the U.S. Government spends *$187 billion annually* on direct medical costs.[5] This is more than the entire budgets of many agencies and departments.
  - The costs of diet-related diseases are crushing families. Over the last 30 years, the average family on employer-sponsored insurance has *lost $125,000 in cumulative wages* due to rising healthcare premiums.[6] Today, the leading cause of household bankruptcy is catastrophic medical expenses. And relative losses are highest for rural, low-income, Black, and Hispanic families.
  - The costs of diet-related diseases are crushing U.S. businesses. The average premium for employer-sponsored healthcare has risen *50 percent in just 10 years*.[7] Warren Buffet has called rising healthcare premiums "the tapeworm of American economic competitiveness." And the food we eat is feeding that worm.
  - The costs of diet-related diseases are crushing the Federal budget and national debt. In 1969, the year I was born, 5 percent of the Federal budget was spent on healthcare. Today, it's 30 percent. This is by far the *fastest rising discretionary cost* in the Federal budget—crowding out every other priority including defense, border control, infrastructure, education, and more.
  - **Senators, if you want to do the things that you believe are important for the American people, you will never have the funds you need until we reduce healthcare spending. And healthcare spending will never go down until we fix food**.
- This is also an *urgent matter of national security*.[8] Don't take my word for it, listen to Mission: Readiness, a group of more than 700 retired U.S. generals and admirals who have been making this case for more than a decade.
  - In 1941, President Franklin D. Roosevelt convened the National Nutrition Conference on Defense,[9] to create urgent new policies to fix the food supply, when 1 in 3 young Americans did not qualify for the draft due to nutritional deficiencies.
  - Today, nearly *8 in 10* young Americans don't qualify for military service, and the top medical disqualifer is overweight and obesity.
  - For our Nation's sake, our elected leaders today must have the same vision and urgency as FDR to fix our food system.
- Today, *being healthy is the exception*. Far more Americans are sick than well. Poor diets are the primary reason that 7 in 10 adults have overweight or obesity, and 1 in 2 have diabetes or prediabetes.[10] Adding blood pressure and cholesterol levels, only *1 in 15 adults* has optimal cardiometabolic health.[11]

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[4] The Rockefeller Foundation. True Cost of Food: Measuring What Maters to Transform the U.S. Food System. 2021. *https://www.rockefellerfoundation.org/report/true-cost-of-food-measuring-what-maters-to-transform-the-u-s-food-system/*. Accessed June 17, 2022.

[5] Parker ED, Lin J, Mahoney T, et al. Economic Costs of Diabetes in the U.S. in 2022. *Diabetes Care*. 2024;47(1):26–43.

[6] Hager K, Emanuel E, Mozaffarian D. Employer-Sponsored Health Insurance Premium Cost Growth and Its Association With Earnings Inequality Among U.S. Families. *JAMA Netw Open*. 2024;7(1):e2351644.

[7] Center for American Progress. Federal Solutions To Address Rising Costs of Employer-Sponsored Insurance. 2024.*https://www.americanprogress.org/article/Federal-solutions-to-address-rising-costs-of-employer-sponsored-insurance/*. Accessed April 12, 2024.

[8] Mission: Readiness, Council for a Strong America. Breaking point: Child malnutrition imperils America's national security. 2020. *https://www.strongna.on.org/articles/1335-breaking-point*. Accessed September 30, 2022.

[9] National Nutrition Conference for Defense. National Nutrition Conference for Defense. *JAMA*. 1941;116(23):2598–2599.

[10] Task Force on Hunger, Nutrition, and Health. Ambitious, Actionable Recommendations to End Hunger, Advance Nutrition, and Improve Health in the United States: Executive Summary. 2022. *https://informingwhc.org/wp-content/uploads/2022/08/Informing-White-House-Conference-Task-Force-Report-Aug22-Executive-Summary.pdf*. Accessed June 21, 2023.

[11] O'Hearn M, Lauren BN, Wong JB, Kim DD, Mozaffarian D. Trends and Disparities in Cardiometabolic Health Among U.S. Adults, 1999–2018. *J Am Coll Cardiol*. 2022;80(2):138–151.

- Most American adults are walking around sick, many without even realizing it.
- For the first time in U.S. history, life expectancy has been declining—and diet-related chronic diseases are a leading contributor.
- This starts young. Among 2–5 year-olds, more than 1 in 8 have obesity. Among teens, nearly 1 in 4 have obesity, and 1 in 4 have prediabetes.

- The burdens of our food are also *driving societal discord*. Americans of all incomes, races, and ethnicities—and all political parties, states, and cities—are experiencing high and risings levels of diet-related diseases. But those with lower incomes, living in rural communities, and from historically marginalized racial and ethnic groups are at even higher risk.
  - Forty million Americans—about 1 in 8 households—also experienced food insecurity at some point during the year. Food insecurity is associated with worse nutrition, higher rates of diet-related diseases, and greater healthcare spending.
- **The lack of attention to our food explains so much about the problems we face today: hundreds of millions of sick Americans, hundreds of billions of dollars in preventable healthcare costs, suffering U.S. businesses, exhausted Federal and state budgets—and exhausted policymakers**.

**The Power of Food is Medicine**

Having devoted my career to understanding what we need to eat to stay healthy, and to studying private and public food systems changes to empower people to eat that way, I've been on the front lines helping people sort through the confusion and make better decisions. My work brings me face to face with everyday Americans, patients, doctors, and healthcare executives. I meet CEOs and dynamic entrepreneurs who grow, package, and prepare our food; community activists fighting for health and food justice; and elected officials charged with fixing our food and health problems.

My testimony today brings together my training, the newest science, and these real-world experiences to provide effective, practical solutions to our national nutrition crisis. One of the top solutions sweeping the nation is: Food is Medicine.

- Food is Medicine (FIM) refers to food-based nutritional therapies to manage disease within healthcare.[12] FIM includes:
  - Physician screening and referral for appropriate medical conditions.
  - Treatment with medically tailored meals, medically tailored groceries, or produce prescriptions.
  - Accompanying nutrition and culinary education, delivered by RDNs, telehealth, or digital counseling.
  - EMR screening for food and nutrition insecurity.
  - Links to healthcare payers and reimbursement.
  - Medical nutrition education for doctors.
- Importantly, FIM can be used to *treat and manage disease*—not just for long-term prevention.
  - Commonly targeted conditions include type 2 diabetes, high-risk pregnancy, heart failure, and cancer.
- While FM is a medical therapy, not a social program, it also helps address important social determinants of health like food insecurity and poverty.
  - This makes FM a unique "dual purpose" intervention—an executive medical treatment that also addresses social determinants of health and advances health equity, giving all Americans a fair opportunity to achieve their top level of health.
- Whether using meals, groceries, or produce, FIM provides nutritionally curated items, covered in part or full by healthcare, to treat a patient's diet-sensitive condition. These programs can cut through barriers such as cost, transportation, and inadequate knowledge around healthy food.

[12] Mozaffarian D, Aspry KE, Garfield K, et al. "Food is Medicine" Strategies for Nutrition Security and Cardiometabolic Health Equity: JACC State-of-the-Art Review *J Am Coll Cardiol*. 2024; in press.

- Research we and others have conducted shows that FIM programs work.
  - They increase the intake of healthy foods, reduce food insecurity, and improve health outcomes.
  - Observed benefits include lower hemoglobin A1c, body mass index, and blood pressure, as well as improved mental health and disease self-management.
- When targeted to high-risk patients with complex medical conditions, FIM programs also save money. Careful analyses indicate that FIM interventions will be either *highly cost-effective or even cost-saving* compared to many other common medical interventions.
- 1 percent of Americans produce 25 percent of healthcare costs; and 5 percent of Americans produce 50 percent of healthcare costs.[13] Medically tailored meals are an effective, cost-saving treatment for such high-risk, high-utilization patients.
  - In one state analysis, a medically tailored meals program resulted in net annual savings of $9000 for each patient treated—even after accounting for the costs of the program.
  - Our research estimates that about 6 million Americans qualify for medically tailored meals, and that providing this treatment to these patients will save nearly $14 billion annually—even accounting for the costs of the program (see *Figure 3* at the end of this testimony).[14]
- Medical groceries and produce prescriptions are also highly cost-effective or even cost-saving.
  - North Carolina recently evaluated their Medicaid 1115 waiver experience, which included prominent FIM programming, delivered to 20,000 Medicaid beneficiaries across 33 mostly rural counties in the state. They found that, even accounting for the costs of the program, the intervention resulted in net cost savings for Medicaid.[15]
  - Our new research estimates that if about $45 per month of produce prescriptions were provided to Americans with diabetes and food insecurity, the program within 5 years would prevent 65,000 cardiovascular events and—due to healthcare cost savings—have no additional net cost. Over a lifetime, the program would prevent nearly 300,000 cardiovascular events and save more than $3 billion.
- FIM programs can also support local food systems, farmers, and rural communities.
  - Several FIM programs, such as Recipe4Health in Alameda County, California, focus on procuring food from local small and mid-sized farmers. This serves as an economic engine for farmers, their families, and their communities.

**Food is Medicine is Accelerating—But Much More is Needed**

Based on these health and cost benefits, FIM is accelerating across the nation.

- Ten states now have section 1115 waivers to implement FIM in Medicaid: California, Delaware, Illinois, Massachusetts, New Jersey, New Mexico, New York, Oregon, North Carolina, and Washington. Groups in other states are pushing for similar waivers, such as in Oklahoma, Florida, and others.
- Medicare Advantage programs across the country are implementing FIM based on Congress' 2018 expansion of Special Supplemental Benefits for the Chronically Ill (SSBCI). In 2020 when the program launched, 71 plans covered medically tailored meals, and 101 plans covered medical groceries and produce prescriptions. Today, 422 plans cover medically tai-

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[13] Kaiser Family Foundation. How do health expenditures vary across the population? 2024. *https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population/* Accessed April 14, 2024.

[14] Hager K, Cudhea FP, Wong JB, et al. Association of National Expansion of Insurance Coverage of Medically Tailored Meals With Estimated Hospitalizations and Health Care Expenditures in the U.S. *JAMA Netw Open*. 2022;5(10):e2236898.

[15] Healthcare Innovation. North Carolina Plans to Expand Medicaid SDOH Pilot statewide. 2024 *https://www.hcinnovationgroup.com/population-health-management/social-determinants-of-health/news/55002542/north-carolina-plans-to-expand-Medicaid-sdoh-pilot-statewide*. Accessed April 12, 2024.

lored meals, and 929 plans cover medical groceries and produce prescriptions.

- The Department of Veterans Affairs and the Indian Health Service have launched FIM pilot programs.
- The Department of Health and Human Services recently held its first FIM Summit, and CMS and CMMI are together developing toolkits and definitions for FIM programs.
- Large commercial payers are implementing FIM, including Elevance, Blue Cross Blue Shield, Geisinger Health, and Promedica.
- Kaiser Permanente, the largest nonprofit integrated health system in the nation, is coordinating its 5 years of growing FIM programs into the nation's first healthcare FIM Center of Excellence.
- EPIC and other large commercial EMRs are integrating food insecurity screening into their applications.
- Nonprofits across the nation are implementing FIM, including within coalitions like the Food is Medicine Coalition and National Produce Prescription Collaborative.
- Private sector companies are launching FIM programs, like Instacart, Walmart, Kroger, and more.
- Venture capital is investing in exciting FIM startups, like Season Health, Territory Foods, NourishedRx, Good Measures, Farmbox Rx, and more.
- The Rockefeller Foundation and American Heart Association have committed $250 million to FIM research.
- The National Institutes of Health has approved a plan to launch FIM Networks or Centers of Excellence, similar to the NIH-funded Cancer Centers of Excellence that have been so critical to advance cancer research and treatment.
- The American Academy of Pediatrics and American College of Lifestyle Medicine have committed to FIM training for all their members.
- The Accreditation Council for Graduate Medical Education (ACGME) has announced plans to make medical nutrition education mandatory for all residency and fellowship programs by 2026.

**These American Innovations Require Policy Updates**

With the evidence and progress, the nation is at a tipping point to accelerate FIM. More research and implementation projects are critical to assess which FIM programs work best for which patients—especially in Community Health Centers, Medicare, Medicaid, and the VA. This includes:

- Optimal dose ($/month), program duration, and intensity of nutrition and culinary education.
- Meals vs. groceries vs. produce; hospital pick-up vs. retail shopping vs. home delivery.
- Eligible disease conditions and social criteria.

Today, the vast majority of Americans cannot access FIM therapies.

- Most states have not applied for Medicaid 1115 waivers to implement FIM.
- Medicare Part A & B—which cover more than two-thirds of Medicare enrollees—do not cover FIM.
- Many commercial plans are awaiting greater clarity in Federal healthcare around FIM.
- FIM vendors and suppliers are not available in most parts of the country.
- Most doctors remain poorly educated around nutrition and FIM.

*It's time for congressional action to catalyze the scaling and success of FIM. Congress should*:

- Include support for FIM programs at Community Health Centers (such as proposed in S. 2840, introduced by Senators Sanders and Marshall). These Centers serve the most vulnerable Americans and are most likely to benefit from collaborations and support in this space.
- Encourage CMS to continue to release guidance and toolkits to make it easier for states to apply for Medicaid 1115 waivers that include FIM.

- Advance FIM in Medicare, such as through S. 2133, the Medically Tailored Home-Delivered Meals Demonstration Pilot Act, introduced by Senators Marshall, Cassidy, Booker, and Stabenow in the Senate Finance Committee.
- Encourage CMMI to incorporate and test FIM approaches in their existing pilots.
- Appropriate at least $40 million to the NIH Office of the Director for the specific purpose of launching the FIM Networks or Centers of Excellence, a concept which has already received clearance at NIH. This initiative will combine cutting-edge research with patient care, advancing FIM just as the NIH Cancer Centers of Excellence have advanced cancer treatment and control.
- Provide a meaningful increase in support for the NIH Office of Nutrition Research, which is today woefully underfunded compared to other NIH Office of the Director offices (*see* Table 1 on following pages) despite the pressing importance of its research mission for the American people.
- Support continuing FIM pilots at the Department of Veterans Affairs and Indian Health Service.
- Initiate FIM pilots for military personnel and their families at the Department of Defense.
- Expand support for produce prescriptions within the USDA GusNIP program.
- Ensure meaningful nutrition education for doctors by contacting accreditation and licensing bodies to indicate that it's time for change, including the American Association of Medical Colleges (AAMC), Accreditation Council for Graduate Medical Education (ACGME), Accreditation Council for Continuing Medical Education (ACCME), and American Board of Internal Medicine (ABIM).
- Incorporate report language to encourage NIH to implement FIM research across its institutes and centers, coordinated by the Office of Nutrition Research.
- Incorporate report language to encourage CMS to accelerate food and nutrition security screening and clinical care and referral pathways in the EMR.
- Incorporate report language to ensure Health Savings Account can be used for accepted FIM therapies.

Healthcare systems, payers, doctors, patients, public and private sector vendors, and advocacy and clinical groups all support FIM. **It's time for Congressional action to bring FIM to the American people**. Thank you for the opportunity to testify.

**Figure 1. Modifiable causes of death in the United States**. Source: JAMA. 2018;319(14):1444–1472. doi:10.1001/jama.2018.0158/.

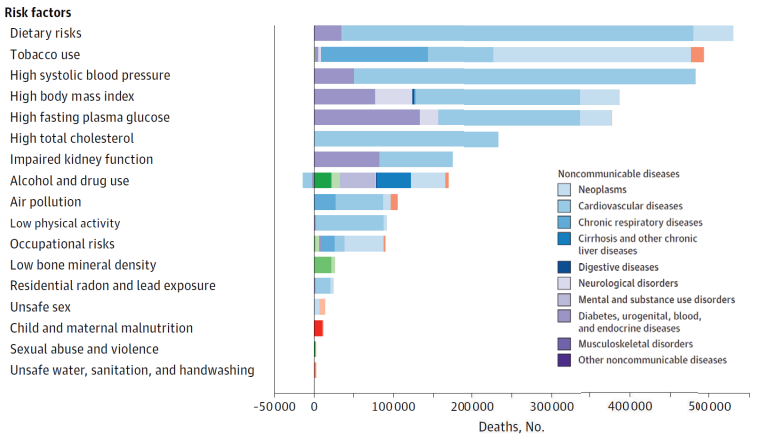

**Figure 2. Dietary intakes of Americans compared to goals (Dietary Guidelines for Americans)**. Source: *https://www.dietaryguidelines.gov/sites/default/files/2021-11/DGA-202-2025-CurrentIntakesSnapshot.pdf*.

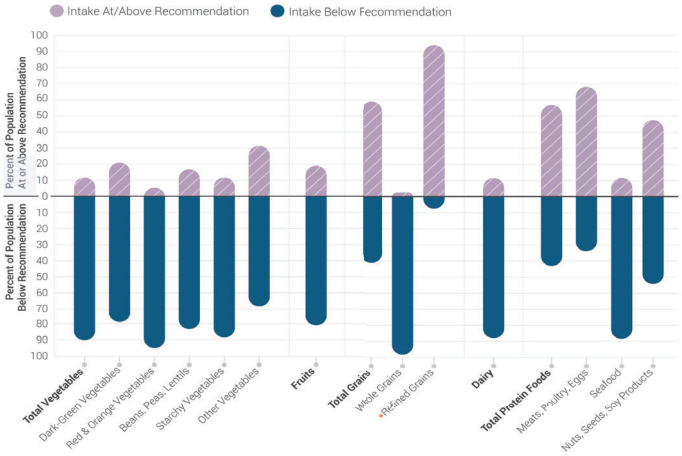


**Figure 3. Estimated health effects, costs, and net savings of providing medically tailored meals to the approximately 6.3 million eligible Americans with high-risk, complex medical conditions and limited activities of daily living**. Source: *https://tuftsfoodismedicine.org/true-cost-fim-case-study-report/*.

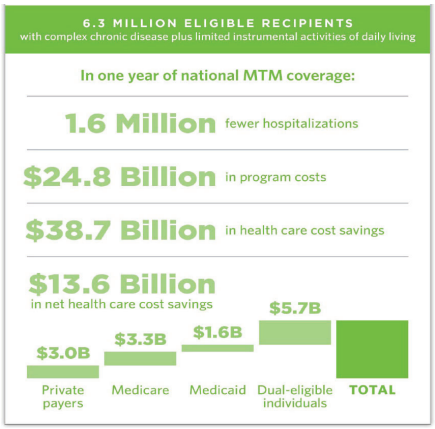

**Table 1. Fiscal year 2023 and fiscal year 2024 Funding for Offices within the NIH Office of the Director**. Source: *https://officeofbudget.od.nih.gov/pdfs/FY25/insti-center-subs/27-OD-FY25-CJ-Chapter.pdf*.

**Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)**
**Budget Summary**
(Dollars in Thousands)

| | FY 2023 Final | FY 2024 CR | FY 2025 President's Budget | FY 2025 +/- FY 2023 |
|---|---|---|---|---|
| Office of the DPCPSI Director | 28,426 | 28,426 | 41,026 | 12,600 |
| Office of Behavioral & Social Sciences Research | 40,845 | 40,845 | 40,845 | 0 |
| Office of AIDS Research | 67,589 | 67,589 | 67,806 | 217 |
| Office of Research on Women's Health | 77,557 | 77,557 | 153,909 | 76,352 |
| Office of Disease Prevention | 17,873 | 17,873 | 17,873 | 0 |
| Office of Dietary Supplements | 28,500 | 28,500 | 28,500 | 0 |
| Office of Data Science Strategy | 85,000 | 85,000 | 85,000 | 0 |
| Office of Research Infrastructure Programs | 309,393 | 309,393 | 259,393 | -50,000 |
| Office of Nutrition Research | 1,313 | 1,313 | 1,313 | 0 |
| Common Fund | 735,001 | 735,001 | 722,401 | -12,600 |
| **Total** | **$1,391,497** | **$1,391,497** | **$1,418,066** | **$26,569** |

Senator MARSHALL. Thank you, Dr. Dariush.

Next, Mr. Chairman, I'd like to introduce James Carter Williams, the CEO and managing principle of iSelect Fund, a venture capital firm that invest in technology that bridges the gap between food, health and AgTech.

Mr. Williams has an extraordinary career problem solving complex systems. An engineer by training, had a long stint in developing innovative cost saving solutions for Boeing's technology planning process that brought the F–18 in under budget. He successfully invested in early stage ventures and corporate research. He's now working to problem solve a more complex system healthcare, with a unique mission centered on food as health.

Our goal is to learn about the intersection of innovation and investment that will help combat the obesity and diabetic epidemic. He has an MBA from MIT Sloan School of Management and a BS in Mechanical Engineering from Rensselaer Polytechnic Institute.

Thank you, Carter, for being here, and the floor is yours.

## STATEMENT OF JAMES CARTER WILLIAMS, CEO AND MANAGING PRINCIPAL, ISELECT FUND, ST. LOUIS, MO

Mr. WILLIAMS. Thank you. Chairman Markey, Ranking Member Marshall, and distinguished Members, it's my pleasure to appear before you today to reflect on the innovations reducing the healthcare cost of poor nutrition. My name is Carter Williams. I'm an engineer with a degree from Rensselaer and MIT.

Over the last 35 years, I've focused on innovation and complex systems, spanning aerospace, energy, agriculture and health. I served in senior roles in Boeing's Phantom Works and several successful startups. Since 2014 I have led iSelect the venture fund focused on the theme, Food is health, investing in more than 70 AgTech and health tech startups. Over those 10 years, we have also met with more than 5,000 entrepreneurs and this is what we have learned.

The U.S. spends 1.7 trillion on food and 1.9 trillion on the healthcare cost of poor nutrition. Type 2 diabetes kills 283 Americans every day. Goldman Sachs has concluded that the U.S. GDP would grow 1 percent annually if we cured obesity. In 2000, the U.S. sequenced the human genome launching companies with breakthroughs in immunotherapy and vaccines, reshaping treatments in healthcare. But we still have a problem that can be solved with similar thinking.

For 350,000 years, humans were thin. In the last 50 years, we're fat and diabetic. Innovation is stepping in. In the near future, grocery stores will offer seamless access to a nutritional coaching to get you better food, through medically tailored meals or natural low cost forms of Ozempic.

You eat what you enjoy, and what you enjoy is better and affordable. Your calorie intake is 25 percent less than your parents, 45 percent less from processed food. You lose weight and gain muscle mass. Regenerative vegetables, frozen or fresh are tasty nutrient dense and affordable. Beef managed on grasslands with virtual fences, are net carbon positive, deliver balanced omega–3s and omega–6s, in reducing clogged arteries.

Processed foods are sweet and tasty, but zero diabetic impact, made with healthy sugars from agricultural waste. Prebiotics fuel your gut microbiome; you sleep better and you have less depression. Medical care is now functional medicine for stalling disease, easily accessed. Health data is part of the grocery store mobile apps. The app knows your genome, your blood work, your blood pressure, and the food you purchase. Integrated into your health insurance, reminding you of quality choices.

Everyone gets the standard of care. Comorbidities are a distant memory. Your health data is protected by the blockchain, anonymized, integrated into synthetic control arm models, comparing your genetics and health to peer groups, improving the work at FDA. Inspired by the original Human genome Project Innovation is driven by the Human Microbiome Project, the Human Nutrition Project, the Soil Microbiome Project, all working to improve the quality of the data we use for our science.

Not all crops are healthy. Their nutrients vary. In field spectroscopy reveal their array of nutrients and meat, fish, vegetables and grains form nutritional quality control, empowering farmers, ranchers, CPGs and processors to optimize nutrient density and cost. Product labels are accurate and complete.

Startups use AI to scan every journal and historical artifact to find natural solutions that improve health. Testing thousands of natural products against digital twin of human nutrition and billions of configurations and speeding the development of new technology. Replacing an array of pharmaceuticals with quality nutrients.

Farmers have transitioned to biologics that rebuild the soil microbiome improving crop nutrient intake crops are robust against disease, drought and weeds. UVs use precision sprayers and lasers to reduce chemicals, improving farmer profits, increasing yield and safer food. These technologies are all real. They all

exist today. Some are controversial, some more affordable, but more than enough to reduce the healthcare costs of poor nutrition.

American entrepreneurs in agriculture, food and health working with FDA, USDA, NIH, and other NGO's, can solve this problem, lowering cost, improving sustainability, increasing longevity, and driving GDP growth. Thank you.

[The prepared statement of Mr. Williams follows.]

PREPARED STATEMENT OF CARTER WILLIAMS

**Introduction**

Chairman Markey, Ranking Member Marshall, and distinguished Members of the Subcommittee, it is my pleasure to appear before you today to discuss the innovations that are transforming healthcare and addressing the costs of poor nutrition. Across the country, 1000's of entrepreneurs are working on the agriculture, food and health innovations that will reduce the health-related costs of poor nutrition, improving longevity, and increasing the United States' competitive advantage. Their work is central to the country's effort to improve nutrition for every aspect of our society. Achieving this promise will require innovation, policy, and regulatory coordination to accelerate the opportunity.

My name is Carter Williams. I am managing director and CEO of the iSelect Fund. I have spent my entire career developing and implementing technology. An engineer by training, I did my graduate work at MIT concentrating on innovation, R and D and system dynamics. My first job was on the shop floor working on F/A–18s at McDonnell Douglas in St. Louis. I spent 15 years at Boeing in aerospace and defense in Phantom Works, where we worked on very complex engineering efforts designed to protect the Nation 10–20 years into the future. While at Boeing, I managed the technology strategy for more than $2.5B in annual R and D investment. In 2004, I entered the realm of startups, successfully developing one of the first internet of things (IoT) frameworks for building energy management, reducing energy usage by 20 percent with software. That company was ultimately bought by Johnson Controls. With deep practical experience driving innovation in companies large and small, I decided to dedicate my efforts to accelerating innovation across the economy. Since 2014, I have led a venture fund that has met with more than 5,000 entrepreneurs and backed more than 70 AgTech and HealthTech startups. Meeting that many entrepreneurs of all different forms has taught me a lot about what is possible.

My practical expertise is to look out 20+ years and marshal the forces of innovation to solve tough problems. Problems too hard to solve with one answer, but solvable when you leverage the innovation of 100's of startups focused against a common objective.

**Innovation**

Innovation is the creation of new businesses and systems to satisfy customer needs. Innovation does not invent; it adapts technology to build better and less expensive products. Great innovation makes our lives simpler and better in ways we did not know possible the moment before.

In a sense we have seen this happen already in computers. In 1980, I tried to persuade my father to buy an IBM PC, arguing it could help balance his checkbook. He demurred. He ultimately became an active power user of computers, for work. He died of a sudden heart attack in 1998. Now, I can buy a $99 device linked to my mobile phone to take my own EKG. I can order my own labs at Quest, for cholesterol, but also for inflammation markers. My watch reports my resting heart rate and hours of sleep. I have a record of my time series heart rate for every bike ride since 2009. I have a low-cost automatic defibrillator in my home. Each product is better and cheaper than the alternative.

We need to do many things to eliminate the healthcare cost of poor nutrition. Some policy, some regulatory, and some innovation. Near term we need to intervene with medically tailored meals.[1] Long term we need to improve nutrition.

[1] Medically Tailored Meals Could Save U.S. Nearly $13.6B Per Year *https://nutrition.tufts.edu/news/medically-tailored-meals-could-save-us-nearly-136b-year*.

I am told you cannot eliminate the healthcare cost of poor nutrition because you can't change people's behavior. As if behavior does not change. We changed our behavior with mobile phones. We went from healthy diets to poor diets. We stopped smoking. We drink less alcohol.

The simplest way to change people's behavior is to build a better product. 60 percent of people today make their decisions based on price. If entrepreneurs develop food that is tasty, nutritious, and affordable, behavior will change. Easy to say, hard to do. We live in a large, complex commodity system.

Food and Health are a system,[2] driven by market forces. It needs to serve everyone. Many things will change, but frankly many things have changed before. The world has driven large changes. Looking at the efforts of 1000's of startups we see a new food system emerging that we call "System C". Built on the foundation of the existing food systems:

> **System A—Tasty and Nutritious**: Our original food system. The garden of Eden so to speak. Tasty and nutritious. It works when there are two humans, but it does not scale to 8.5B. Built on 4.5B years of evolution. System A is still available to the wealthiest in society, and selectively in some cultures.
>
> **System B—Scalable and Cheap**: 19M people died of famine in World War 2.[3] We sought to scale calories globally. We started the green revolution, monoculture, UNICEFs, the World Food Program, and launched global scale. It delivered calories, removed famine as a tool of war, and extended life, but increased diabetes. 3B people remain under nourished.
>
> **System C—Tasty, Nutritious, and Affordable**: The system we now seek takes the best of A and B to create a new system built on modern nutrition science, that is tasty and nutritious, but affordable and scalable. In one part fresh, but also low-cost forms that deliver quality nutrition without causing additional health problems.

It took 4.5B years to build system A, then 60 years to scale System B. We are now 10 years into building System C.

**Background**

In the U.S. we spend about $1.7T on food, and $1.9T on the healthcare cost of poor nutrition. The number is $14T globally. Type 2 diabetes kills 283 Americans every day.[4] A recent Goldman Sachs study[5] found that U.S. GDP would be 1 percent higher per year if we cured obesity.

Despite 350K years of human evolution, and all our innovations in healthcare, the healthcare cost of poor nutrition continues to weaken our economy, burden our communities, and shorten lives.

At the end of World War II, the U.S. decided to end global starvation, leading to the green revolution.[6] Farms went from producing 20 bushels of corn per acre to more than 173 bushels today. We saw similar gains in livestock and fresh vegetables, fruits, and nuts. In 2010, global agriculture with American technology ended the calorie famine. A combination of U.S. innovation, science, policy and farmers, led by the U.S. but implemented globally, changed global production.

Our collective focus on yield and calories is now not enough. 3B people remain under-nourished today. People who would have died of starvation now live long enough to die of diabetes, cardiovascular disease, and cancer.

In 2000, the U.S. sequenced the human genome. That launched 1000's of new companies and created solutions for immunotherapy, vaccines, heart disease, blindness, and more. The world followed U.S. leadership to create a global shift in healthcare.

We have the same opportunity today in nutrition. The same sort of foundation that led to discoveries in the human genome can lead to a world where food is un-

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[2] History of modern nutrition science—implications for current research, dietary guidelines, and food policy *https://www.bmj.com/content/361/bmj.k2392*.

[3] Famines, Our World in Data *https://ourworldindata.org/famines*.

[4] Statistics About Diabetes: *https://diabetes.org/about-diabetes/statistics/about-diabetes*.

[5] Obesity drugs are among health breakthroughs forecast to boost GDP, *https://www.goldmansachs.com/intelligence/pages/obesity-drugs-are-among-breakthroughs-forecast-GDP.html*.

[6] The Green Revolution: Norman Borlaug and the Race to Fight Global Hunger *https://www.pbs.org/wgbh/americanexperience/features/green-revolution-norman-borlaug-race-to-fight-global-hunger/*.

derstood to be synonymous with health. With all our efforts in nutrition, we still do not really understand whether a ketogenic diet is good or bad. With all our efforts in agriculture, we still are unsure of the ideal balance of microbes, genetics, and fertilizers. We have come a long way, but we can do better.

**A Future Vision of Health**

Sometime in the future, you will walk into a grocery store. You may be pre-diabetic, obese, have cancer, or seek to run a marathon. But the experience will be different than it is today.

By then we will live in the realm of System C. You will have seamless access to a nutritionist nudging you as you shift your behavior. Maybe a clinical intervention like medically tailored meals [7] or a nutraceutical form of Ozempic. You still eat what you enjoy, but what you enjoy is now better for you. Your calorie intake is 25 percent less than your parents', and 45 percent less of those calories come from ultra-processed foods. Less fat, and more lean muscle mass without going to the gym every day. Co-morbidities are a rare medical burden.

The vegetables, frozen or fresh, are nutrient dense, boosting vitamins and micronutrients. A product of regenerative agriculture. The grass-fed beef, net carbon positive, managed on grass lands with virtual fences, [8] deliver better taste and balanced omega 3/6, reducing vascular inflammation. The processed foods are sweet and tasty, but zero glycemic impact. [9] Full of prebiotics, fueling your gut microbiome. The center of the store offers packaged bioactives [10] for those genetically at risk of diabetes, leaky gut, high blood pressure, or cholesterol. Your microbiome [11] is back in balance. You sleep better, are less depressed, and enjoy life without medical fears.

It all seems fanciful. It was slow at first, then things happened all at once, because innovation, policy and regulations found the way to reduce the healthcare cost of poor nutrition.

Medical care moved from sick care to functional medicine, [12] forestalling disease. Medical software applications became part of the grocery store mobile apps. It is your data, not theirs. The app knows your health history, it tracks your purchases, it recommends products. It is integrated into your health insurance. [13] It nudges you with recipes, reminds you of a higher quality pasta, or offers a protein dense gluten free bread.

The software runs on deep analytics and AI. Your DNA is sequenced, covered by the grocery store because you are a loyal customer. Your health data is protected by the blockchain, allowing integration into a synthetic control arm model comparing your genetics and health to peer groups based on race, age and social determinants.

Inspired by the original human genome project, we now have data from The Human Microbiome Project, The Human Nutrition Project, and The Soil Microbiome Project. Each built by government, academia, and industry as a foundational, science-backed model guiding health. This foundational data is integrated into Health Shift, [14] a comprehensive human synthetic control arm built from the health data of 1M people who have donated their data to science.

Other commercial software data systems gather blood tests, radiology, and new assays. The data base continues [15] to grow, to train the AI systems that lead to new medical discoveries, new health treatments, new understanding of nutrition, and rapidly adapting regulatory frameworks. Monitored over decades, these longitudinal data sets capture, as one example, the correlation between childhood viruses and late-stage health conditions like MS and Alzheimer's.

We understand the nutritional value of the food in the grocery store because we now use a real-time, low-cost spectroscopy assay that determines the macro and

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[7] Eatwell Meal Kits—*https://www.eatwellmealkits.com/*.
[8] Vence *https://www.merck-animal-health-usa.com/species/cattle/vence*.
[9] Bonumose, Inc.—healthy sugar for the mass market: https://bonumose.com/.
[10] Bright Seed *https://www.brightseedbio.com/*.
[11] Meet the Psychobiome: *https://www.science.org/content/article/meet-psychobiome-gut-bacteria-may-alter-how-you-think-feel-and-act*.
[12] https://www.functionhealth.com/.
[13] Uber and Instacart expand their health plan partnerships *https://endpts.com/uber-and-instacart-expand-their-health-plan-partnerships/*.
[14] *https://www.linkedin.com/pulse/healthshift-empowering-people-transforming-healthcare-carter-williams*.
[15] *https://flywheel.io/*.

micro-nutrients in meat, fish, vegetables, and grains.[16] Over time this reveals the wide variability in nutrition, from sweet potatoes to beef. Farmers, ranchers, CPGs, processors, and others realize the variability and implications, improving quality in production. Consumer labels accurately represent nutritional quality.

Bioactive innovators have built computational models of human nutrition.[17] The models determine the metabolic effect of a nutrient on human health. They use AI to scan every journal, story, and historical artifact to find natural solutions that improve health. They take 1000's of natural ingredients and test their benefit, in billions of configurations, to find the key ingredients that improve health. They convert these discoveries into products, integrated into processed foods or standalone supplements to improve individual health.

Precision fermentation is used to develop new ingredients from food waste. These new products replace animal collagen in food,[18] or protein in animal feed.[19] We have new sugars that offer sweetness with low glycemic impact, a direct replacement for sugar without the danger of diabetes.[20]

Livestock feeding operations are more efficient with software[21] that assure animal husbandry, improves nutrition efficiency, and manage operations to minimize and reverse carbon footprint. Protein dense soy and improved feed conversion ratios reduce the cost of protein in human diets and eliminate the need for antibiotics.

Crop genetics companies apply deep learning and computational intensity to reveal every genetic trait.[22] For decades, improvements in yield reduced taste and nutrition. Now we have the engineering tools to breed crops that improve yield, taste, and nutrition. Corn, soy, wheat and 100's of other crops, all with better quality at a lower cost.

After deep research into the soil microbiome, farmers have transitioned to biologics that create a consortium of microbes in the soil.[23] These microbes improve crop nutrient intake. They naturally fixate nitrogen from the air to feed the crops.[24] Our command of the soil microbiome improves crop nutritional density, making crops robust against disease, drought, weeds, and heat.

Autonomous systems using precision spraying, lasers[25] and mechanical means care for the crops through the season, augmented with biologic-based herbicides.[26] Limiting the application of chemicals to precise applications. The advances in biologics reduce production costs dramatically. These new tools for soil health are validated with ground penetrating radar,[27] imagery, and other sensor systems to train AI models and validate climate and nutritional gains. Financial services, in the form of insets,[28] allow Consumer Package Goods companies to offer price premiums for better nutrition.

Protein engineering, built on breakthroughs like protein folding, develops peptides that protect food and crops from pests. These biologic solutions decay naturally. The rapid design tools allow for seasonal solutions. The approach is integrated with EPAs safety systems, to assure fast engineering of nature-based solutions to protect crops and reduce the cost of crop loss.

**Recommendations**

The technology listed above is all real. These are all emerging companies we and other investors are supporting today. With increased interest rates, venture investing is today at an all-time low, but the ecosystem will adapt, building even stronger companies. The work happening now around medically tailored meals is vitally important in the immediate term, while the innovations outlined above will become commercially successful over the coming years, reducing the need for such meals in time. We do need to think about two key pillars to match these entrepreneurial efforts:

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[16] *https://www.edacious.com/*.
[17] *https://agfundernews.com/meet-the-founder-brightseeds-dr-jim-flatt-illuminates-the-dark-matter-of-nutrition*.
[18] *https://geltor.com/*.
[19] *https://www.bondpets.com/ https://bensonhill.com/*.
[20] *https://bonumose.com/*.
[21] Livestock Management Software *https://www.agriwebb.com/*.
[22] CropOS Technology Platform *https://player.vimeo.com/video/534843655*.
[23] *https://www.holganix.com/ https://www.plutonbio.com/*.
[24] *https://kulabio.com/ https://www.pivotbio.com/*.
[25] *https://carbonrobotics.com/*.
[26] *https://harpebio.com/*.
[27] *https://earthoptics.com/*.
[28] *https://arvaintelligence.com/*.

1. We spent $1B in R and D to unlock the human genome. Industry and government need to set a plan, in the context of today's AI, to do the same in Soil Health, Human Microbiome, and Nutrition Science.

2. The FDA, USDA and EPA need room to rethink how they regulate safety. Using big data and synthetic control arms to speed solutions and stop harms.

We need to do 1,000 different things well. Which will happen. Our economy is perfectly suited to advance society and technology to improve nutrition better and faster than expected. But we do need to decide to take the steps necessary to eliminate the healthcare cost of poor nutrition, as a national mission, like we did to end famine.

"If you want to build a ship, don't drum up the men to gather wood, divide the work, and give orders. Instead, teach them to yearn for the vast and endless sea."

-Antoine de Saint-Exupéry.

**Conclusion**

Looking back to this day, to this room, we will come to see our shift in focus to eliminate the healthcare cost of poor nutrition as a joint mission aligning policy, innovation, research and NGO's. When we are done, the healthcare cost of poor nutrition will be $0. This will happen as we build System C. We will increase the scientific understanding of the human microbiome, human nutrition, soil microbiome, and crop science. Our regulations will adapt to advanced food, bio-actives, and nutraceuticals. The speed of entrepreneurs and innovation will step in, delivering more than expected, better quality products, at a lower cost to society and individually.

Looking ahead, this seems hard but the reality is the net effect of science, regulation and innovation will eliminate the healthcare cost of poor nutrition, increase longevity, improve productivity, and make life better.

**Addendum**

There are 1000's of companies developing innovations to reduce the healthcare cost of poor nutrition. These are a few of those companies that inspire the content of this testimony. Many come from our portfolio. Not all of these will succeed. They do represent examples of the innovation in progress.

1. **EatWell Meal Kits**—Food as medicine meal kits, education, and analytics to address food insecurity and reduce costs for insurers (*https://www.eatwellmealkits.com/*.)

2. **Vence**—virtual fence for livestock management that enables the scaling of the sustainable production of grass fed and pasture raised livestock (*https://www.merck-animal-health-usa.com/species/cattle/vence*.)

3. **Bonumose**—commercializing low-glycemic index, natural sugars through a proprietary, cost-effective enzymatic process (*https://bonumose.com/*.)

4. **Brightseed**—AI powered nutrition discovery company that identifies unique micronutrients in the plant kingdom and maps them to specific human health conditions where they can have the highest impact (*https://www.brightseedbio.com/*.)

5. **Holobiome**—platform for microbiome-based therapeutics to treat diseases of the central and enteric nervous systems (*https://holobiome.org/*.)

6. **Function Health**—Developed by Mark Hyman, a blood testing platform that pairs you with a doctor for review of key blood analytes twice a year. (*https://www.functionhealth.com/*.)

7. **Noom**—Easy nutrition tracking with recommendations (*https://www.noom.com/*.)

8. **Flywheel**—research workflow solution that provides cloud-scale data management and computational analysis (*https://flywheel.io/*.)

9. **Edacious**—accessible low cost nutritional measurement using a suite of spectroscopy tools for the agrifood supply chain (*https://www.edacious.com/*.)

10. **Geltor**—platform technology that enables it to cost effectively produce sustainable and beneficial proteins for the cosmetic, food, beverage, nutritional supplement, and healthcare industries (*https://geltor.com/*.)

11. **Bond Pet Foods**—Using precision fermentation to manufacture animal cells without the animal (*https://www.bondpets.com/*.)

12. **Bonumose**—commercializing low-glycemic index, natural sugars through a proprietary, cost-effective enzymatic process (*https://bonumose.com/*.)

13. **Agriwebb**—building the digital backbone of the livestock industry, connecting animal and land management to the supply chain and the consumer (*https://www.agriwebb.com/*.)

14. **Benson Hill**—combines machine learning and big data with genome editing and plant biology to accelerate the product development process (*https://bensonhill.com/*.)

15. **Vestaron**—biological crop protection products that address resistance and safety/ environmental externalities (*https://www.vestaron.com/*.)

16. **Kula Bio**—nitrogen fixing microbe that replaces 50–80 percent of applied nitrogen at or below the cost of synthetic nitrogen (*https://kulabio.com/*.)

17. **Autonomous Pivot**—noninvasive soil/crop sensor network that feeds AI decision support engine for autonomous irrigation, fertigation, and crop protection (*https://www.autonomouspivot.com/*.)

18. **Harpe Bio**—natural, sustainable, biological weed control solutions (*https://harpebio.com/*.)

19. **EarthOptics**—measurement and modeling of key soil attributes (*https://earthoptics.com/*.)

20. **Arva Intelligence**—provides carbon insetting and offsetting solutions by connecting growers to buyers in the carbon markets (*https://arvaintelligence.com/*.)

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Senator MARKEY. Thank you very much. And now we'll turn to questions from the Subcommittee.

The Older American Act includes essential nutrition programs for older adults, including meals at congregate sites like senior centers, or delivered to their homes. As a member of the working group to reauthorize this law, I remain committed to this sacred responsibility. Ms. Martin, can you elaborate on how Food is Medicine can be incorporated into the Older Americans Act?

Ms. MARTIN. Yes, thank you. I think that these federally Qualified Health Centers, Rural Health Centers and other congregate meal programs would be drastically enhanced and produced incredible health outcomes by being integrated in those systems.

Senator MARKEY. Okay. And can you discuss how pilot projects in the Old Americans Act could demonstrate the benefits of integrating medically tailored meals or Prescription Food Programs for older Americans?

Ms. MARTIN. Yes, and we see old—most of the people we serve actually are over 50 and experiencing these outcomes consistently. There is a federally Qualified Health Center that has a diabetic program. They offer some food bank boxes, but we also get referrals because we really enhance that program from that federally Qualified Health Center. So we believe that having it more integrated in that system would be way more beneficial for the older Americans.

Senator MARKEY. This is such a great bipartisan issue. You're not often going to have the Democratic witness from Oklahoma and

the Republican witness from Massachusetts case, so the recombinant political DNA here shows that many things are possible.

[Laughter.]

Senator MARKEY. Ms. Terranova, you have served as the principal investigator for two large scale NIH studies examining the impacts of Community Servings meals on health outcomes. Why is investment in NIH for research like this so important?

Ms. TERRANOVA. Well, thank you Senator. It's really critical.

Senator MARKEY. Could you turn on your microphone please?

Ms. TERRANOVA. Thank you. Yes, it's really critical because policy leaders are feeling that there is a gap in research and particularly in communities such as rural communities.

Community Servings, as you know has published five peer reviewed journal articles on the impacts of medically tailored meals on health outcomes and healthcare costs. And there have been other studies that were also cited in the Aspen Institutes recently updated report on Food is Medicine. But there still do exist gaps and in particular in multi-site settings, in rural settings and for specific Populations. And so, investing in research for NIH is really critical to addressing these gaps.

Senator MARKEY. Okay. So, Dr. Mozaffarian, what further research in your opinion, needs to be done on this subject?

Dr. MOZAFFARIAN. I think there's a lot of questions, like anything in medicine, right? We know enough to get going and do things now, but we also need more research. I really like the NIH concept of these Food is Medicine Centers of Excellence that's built on the Cancer Centers of Excellence model.

I think in the 1960's, the NIH launched these Cancer Centers of Excellence—maybe later, I'll have to check the date, but now almost every state has one. And these Centers of Excellence integrate patient care with research, with community outreach, and with education.

I think having these hubs of knowledge generate in regions across the country would be really important. There are questions we need to ask, what's the right dose? Is it $50, is it $100? How important is sharing with the family. If the family's bigger, how much more food do you have to give? What should the duration of the program be? Some people may need these programs for just a few weeks, some people may need it for a few months. And like other things in medicine, some people may need it for their whole life, and we have to understand that.

I think those are all really critical questions that need to be answered with better research. That could be done by NIH, it could be done by USDA, it could be done directly through CMMI and Medicaid.

Senator MARKEY. Dr. Mozaffarian, how do you think the cost savings in Food is Medicine Programs relative to the growth of expensive medications like Ozempic that are used to treat diabetes and weight loss?

Dr. MOZAFFARIAN. One of the dirty secrets of healthcare is almost nothing saves money. If it did, we wouldn't have a $4.3 tril-

lion healthcare system. And so, blood pressure screening control, cancer screening control, cholesterol screening control, none of those things save money. They cost money. We get a good buy for the dollars we spend, but they cost money.

Food is Medicine is exciting because for the right patients, particularly very sick patients who receive medically tailored meals or produce prescriptions, the research suggests we might actually save money, net of the program. So I think that's really exciting. I don't think they'll save money in every case. I think there'll be other cases where it'll be a good buy, just like giving a generic cholesterol lowering drug is a good buy. So, we shouldn't expect cost savings in every case.

think this is a really exciting area. And compared to GLP–1s, which Senator Sanders produced a report this week out of the HELP Committee, that if half of Americans eligible for the drug went on the drug, we would double our national pharmacy spend on all prescription drugs combined.

We just can't afford those drugs, as effective as they are. And so, we need to integrate nutrition and Food is Medicine and lifestyle together with GLP–1 to be able to mitigate that cost.

Senator MARKEY. Okay. Thank you.

Senator Marshall.

Senator MARSHALL. I'll defer to Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman, Ranking Member. I ran a company for 37 years prior to coming here, and I remember in 2008 how it got to a point where our health insurance premiums were going up to where we were lucky, it was only 5 to 10 percent. That was a line I'd get every year. It got to a point where I couldn't raise deductibles anymore, couldn't change underwriters any more often.

Had to look and the insurance companies basically told me, they said, we are a system of expensive remediation, and we pay no attention to wellness and prevention. That sounded kind of philosophical.

Then I dug into how that was going to work for me to lower costs and have healthier outcomes. Well, we did that all-in-one day. I took their advice created healthcare consumers out of all my employees to where they watch what they eat. We give them every tool to do that and we have not had premium increases now in 16 years.

A lot of it is watching what you eat, because the foods that are the worst for you generally got the most calories in them. And then you've got to work hard to shed the bare weight that you accumulate, and then you're not necessarily replacing it with good wholesome foods.

My question will start with Mr. Williams. I'd like each witness to give me your opinion. How did we get here? How much of it is a system of healthcare that they don't even give much study to nutrition. It is an expensive business of remediation.

Then about our food supply production, which is more on processed foods as opposed to wholesome ones. I'd like to know who's more at fault when we really know that you should be eating bet-

ter? Is it the healthcare industry that's not being voiceful enough, or is it big food processing that gives us generally many foods that just aren't nutritious for you?

Mr. WILLIAMS. It's a lot in there.

[Laughter.]

Senator BRAUN. Yes, there is.

Mr. WILLIAMS. I think from an economic standpoint it's notable that at the end of World War II we said we don't like famine, and we've got to boost calorie production. And we set down the path to the Green Revolution really to stop worldwide famine. American innovation drove the cost down of those calories. Those calories tended to be, for various reasons, cheap, low nutrition calories. And that sort of set this up.

I think that same level of innovation with a different focus around nutrient density can change the food system itself so that when you go to the grocery store, those kinds of calories have been moved around a little bit.

There's a lot more in there, but the basic food is moving too nutrient dense, as Erin is working with, when she uses regenerative crops, people like them better, they taste better and they lead to an improvement. So the technology's moving in that direction.

I think a challenge for healthcare is, over time, healthcare has been maybe more about healthcare, not about making people. Well, I think the movements by Dr. Hyman around areas like functional medicine in terms of getting in before you get sick are big shifts and we're seeing that kind of new care delivery mechanism. It's unclear how to pay for it correctly. But when we take some of these solutions into the healthcare community, our entrepreneurs find it's very difficult to get them properly covered. You get into the morass of everything.

Dr. MOZAFFARIAN. I want to agree with what Carter said about how we got here. And I would add the evidence vitamin deficiency diseases were rampant in this country in the 1920's and 1930's, disease like pellagra and rickets and all these diseases.

In addition to the concern about getting enough calories for a booming world population, there was concern about vitamin deficiency diseases. So, when you walk down the cereal aisle today, and you see starchy inexpensive calories from monocrop, crops fortified with vitamins, that was a conscious creation of meeting the two scientific goals of the 20th century.

There were no villains in that original goal, right? This was a very positive goal, and we did it. We probably prevented a billion people from starving, and we essentially eliminated vitamin deficiency diseases in most countries in the world. But we created unintentionally this hyper processed, very mono cropped food culture that has made us metabolically sick.

It's that same mix of what got us here in the 20th century, we can now use to go to the next phase, which is to combine government policy with private sector innovation with the best science, and we can do all that together and, and move forward.

Senator BRAUN. Before I run Out of time let's move down the line. Ms. Martin.

Ms. MARTIN. Thank you. I think it's definitely a combination of both. I think having local and fresh food is really important because when it's being shipped from long distances, it's prematurely picked and artificially ripened. And by the time it's in somebody's kitchen, it's very devoid of a lot of the nutrients. So having local food systems to support this Food is Medicine Programs, I think are vital.

Then on the healthcare side, when we are enrolling these participants who, like I said, have had type 2 diabetes for a decade, we tell them that food, what all problems are you having? Oh, pain, depression, diabetes, all these other issues. Food could actually fix all that. And it's the first time that they're hearing about this. So a combination of both. Thank you.

Ms. TERRANOVA. Senator, I will just say, with respect to the medically tailored meal intervention, we have a dual focus that specifically address marginalized communities that for people who experience both food insecurity and diet related illness.

We are not talking about people who are in a job, who can prevent their disease necessarily through food. We are talking about people who have cancer, HIV, diabetes, very critical illnesses, the 5 percent of people who are accounting for 50 percent of healthcare costs.

We're really in the business, I suppose, at Community Servings and within the Food is Medicine Coalition of addressing these illnesses as a treatment as opposed to really a prevention.

Senator BRAUN. Thank you so much. I'll note that when we started producing food that had a lot of vitamins and kind of empty calories, that's when the healthcare industry really started to shoot up, which is now the biggest industry in our Country, nearing 20 percent of our GDP. Thank you.

Senator MARKEY. Senator Smith from Minnesota.

Senator SMITH. Thank you so much. Senator Markey, and Senator Marshall, thanks to our panelists also for being here. This is super interesting. So, you all are describing a healthcare system where costs are going up dramatically, at the same time that poor health is increasing, and food, which arguably has the biggest impact on good health and is the biggest cause of poor health, is sort of like knocking on the door of this system saying, let me in, I can be a part of the solution here.

I think it's also true—I think you were alluding to this a little bit Dr. Mozaffarian, that at the same time that this system is functioning so poorly, you have some big companies that are making a lot of money off of it, insurance companies, big food companies that are making a ton of money off of selling unhealthy food.

I think that bears understanding as we try to figure out what to do here. There's so much that we could talk about, the research side of it, the side about developing products and therapies, and then the kind of the utilization side, the adoption piece of it, how do you get these products and therapies adopted?

I want to actually focus on that a little bit as we think about what we can do in Congress to support this. Maybe I'll start with Ms. Terranova and Ms. Martin. Could you talk a little bit, just like

hone in on one thing, I think, we know that we can get—we're getting better adoption when you have medically tailored meals compared to a specialized dietary plan.

I think I read that, I'm not sure if that's true, but could you just tell us if there's anything we can learn from those two products or therapies about how we can increase utilization or adoption by patients or consumers?

Ms. TERRANOVA. I think Senator, that it really gets to the question of what is a medically tailored meal, and how are we defining it? And it's really important that there be uniformity and agreement around the standards and definitions and the National Food Is Medicine Coalition has just released an accreditation criteria and requirement that standardizes what is this intervention?

It was developed by a committee of registered dietician nutritionists. And this is the model that has really been tested in the research that we've published. And so, it's just very important that we all come to a consensus on what is a meal, how many meals a week, what is the proportion——

Senator SMITH. You're all talking the same language, what it is that you are prescribing or what the therapy—I'm using the kind of medical terms here. Ms. Martin, how do you see the issue of getting improved adoption or utilization for, say we've agreed on what the therapy should be?

Ms. MARTIN. From the studies that I've read and how we've enacted this program is that, I think the best results come from programs that are a hybrid model and having both education and food. And we really curate the food offerings that we provide. And so, I think having these very well-defined programs and accredited education that they're going through, like just, just delivering food yes has impact, but really empowering people to have the knowledge to continue those behavioral changes.

Senator SMITH. In my home State of Minnesota, we have many East African immigrants, we have many Latino people, we have many Hmong people. We have many Swedish people. Everybody's cultures and food are quite different. How do you consider people's cultural preferences and their culture, broadly speaking, as you think about what that medicine, what that food is, that they're getting?

Ms. MARTIN. That's a great question. So the majority of people that we serve are from the Black community and indigenous, and we ask them what they would like. And no farmers at that time were growing collard greens. And so, we commissioned the farmers to grow collard greens, and now we have more collard greens than we know what to do with.

We're asking the people, and we also hire people from the community that reflect those that we serve. And we are asking for that input. We give a survey that says, what food do you like? What do you not like? What kind of indigenous varieties of food? And we also look for growers that reflect that. So we have home growers, Black growers.

Senator SMITH. Integrated system.

Ms. MARTIN. Absolutely. Yep. Building a community.

Senator SMITH. Right. Mr. Williams, before I ever was a senator, I worked for General Mills, and I was a marketing person. And so, as I'm thinking about you working on you, what you do from a venture capital perspective, a business perspective, how do you see this question of implementation or kind of utilization or uptake? I mean, in marketing language, you'd be talking about how you get trial. Yes.

Mr. WILLIAMS. When you're dealing with an entrepreneur, you're trying to get customers to adopt the product.

Senator SMITH. Right.

Mr. WILLIAMS. The main thing here is everybody wants to be healthier, and you really have to build a product that's so much better in a sense that people adopt it despite the friction.

In many ways, what Erin's doing, she is doing that in the community. Most of the patients that she deals with had no idea that they could feel better if they ate better, a very basic thing.

From the standpoint of the way we see it, I would say that it's the people who will compete against General Mills introducing products that do meet the needs of consumers who want to be healthier, and that you're getting into that part of their psychology and that they adopt it and that General Mills follows in time.

I'll say that the Ozempic is driving processed food demand down by about 45 percent in certain patient populations. The cost of Ozempic is going down. So there, if that gets bigger, General Mills of the world are going to be under a lot of challenge.

General Mills has been focused on sort of value engineering product to lower cost. They're going to start running into some challenges where they got to think differently about how they design the products. So they've got a lot of challenges to face.

Senator SMITH. Thank you, Mr. Chairman. I've gone over my time. Appreciate very much.

Senator MARKEY. I'll just say that when I was a boy watching Superman, and all of a sudden, I'm told that if I can send three box tops from Frosted Flakes, this new product that they had Tony to Tiger, I would get a Superman t-shirt at home. And so, we were moving from Corn Flakes and Cheerios and Pep to Frosted Flakes, and I got a Superman t-shirt. So they knew what they were doing in marketing for sure. And that t-shirt, by the way, completely shrunk in the first wash. So I learned about consumer rip-offs, immediately.

[Laughter.]

Senator MARKEY. Senator Hickenlooper from Colorado.

Senator HICKENLOOPER. Thank you, Mr. Chairman, and thank all of you for being here. I appreciate your time and all your effort here. Community health centers have consistently led the way in a lot of the efforts around this. Colorado has a group of community health centers called Peak Vista Community Health Center, and they partner with Care and Share Food Bank.

They serve 29 counties in southern Colorado, it's almost half the size of the state. They've got a number of events where Care and Share will show up with a tractor trailer full of food and they will

demolish it. These are things like back-to-school events or school physicals.

Ms. Terranova, what role have you seen in terms of community health centers within Food is Medicine and how can we implement a model like that outside of, beyond community health centers?

Ms. TERRANOVA. Community health centers really do play a vital role in both innovation as well as in continuity of programs that exist. Community health centers are really key referral partners for our medically tailored home-delivered meal programs.

As you said, they can also offer pantry and programs right onsite and our trusted advisors for the patients that they serve. So they can play really a critical role in maintaining and continuing these programs.

Senator HICKENLOOPER. Right. And I think it is amazing. I am a lifetime lover of sweet things. I was in the brew pub business for a long time, so I've learned the hard way that moderation is the choice here, in a lot of these things that genetically, for various reasons, are inclined toward things that aren't necessarily good for us.

I guess I was going to—we have a company in Colorado called Virta that actually provides coaches. It uses technology, keeps records, monitors glucose and other easily traceable biologic indicators, allows people to every day be conscious of what they're eating and allows them to eat things in moderation. Maybe not as much as they did before, but at least in some cases, matches Ozempic.

Without their supervision, I actually got to the point where I was pre-diabetic a year ago. And so, I basically almost quit sugar completely as close as I could come and dramatically reduced my alcohol consumption. And I lost 10 percent of my body weight in the course of 7 months. I thought I was sick, and yet that shows how much excess is there.

In terms of how do we get this more accessible, and I raised the question or the example of Virta, just because they engage people, people are coaching and they're engaged they want to solve this issue for themselves.

How do we get people to do something assuming that we've got the resources that isn't naturally their inclination? And obviously, the people that are very sick can resolve issues of pain and depression, I'm not worried about that. It's those people that are going downhill, consistently, but slowly. And I guess let's start down at the end with Mr. Williams and then Dr. Mozaffarian.

Mr. WILLIAMS. I think things like Verta, there are a lot of people in the medical community that don't even realize it works? So there is a bit of an education process of the medical community getting a better understanding that there are other interventions than putting somebody else——

Senator HICKENLOOPER. But they use no drugs. I mean, that's, Virta uses no pharmaceuticals at all. It's all just food and rearranging when you eat food and what food you eat in some level of moderation.

Mr. WILLIAMS. Yes. So it's a multifaceted challenge, but I think that one is the way doctors act, they need to learn more about these solutions, what we're saying here on the panel, there are doc-

tors I think, that really don't believe that these kinds of solutions can step in.

The second is, you'll see the first wave of things like this, then you'll get a bandwagon effect. First one person started using a computer, nobody else used it, then everybody else became more obvious. We haven't got into that bandwagon effect. And when we get to that bandwagon effect, we're going to start seeing simpler versions of it. So we're on the pathway to it.

I don't know if I can give you a trick to it other than to recognize the Virta system does not scale to every 200 million people, so we've got to move to that next level of better information exposure to everybody else, that it's the art of the possible. Right.

Dr. MOZAFFARIAN. I'd add that the way I look at it, Willie Sutton, the bank robber from the 1930's, he was arrested and they said, why do you rob banks? He said, that's where the money is. And so, when I look at solutions to the food system, we've been driving toward cheaper calories, cheaper food, we need to flip that and reward farmers, producers, consumer packaged, good companies, retailers that are selling healthier food through dollars that we're already spending, particularly dollars in healthcare.

I have a vision that the Food is Medicine Movement, which is built into healthcare, also then starts to shift the incentives for how we produce food from the ground up. And really just creates a virtuous cycle instead of a negative vicious cycle, so that ultimately Americans that aren't even in a Food is Medicine Program, they have healthier choices at the grocery store. The cereals are better, the snack bars are better. We need processed and packaged food. We're not going to get rid of that, but we can make those healthier with better science and with investment.

Right now we're pouring money down into healthcare and taking money away from every other priority, including food. If we put some money into food, we can start to reverse that cycle and make food healthier for everyone.

Senator HICKENLOOPER. Yes, great. Ms. Martin.

Ms. MARTIN. I think the health coaching aspect is great. Like, you really can get that referral from the doctor and then have someone handhold them through that process. And that's what the doctors love, that champion this program. They feel like this isn't an extra shot or another pill. This is someone who will really walk through this with you.

There's some great online shopping models for produce prescription. One called Attane Health, that's out of Kansas City and serving many states, and they have a health coach model on their platform. And that's pretty much all you need. And then you've, you've got it all fixed right there.

[Laughter.]

Senator HICKENLOOPER. Ms. Terranova, last word?

Ms. TERRANOVA. Just a last word to emphasize the importance of trusted relationships. And so, those community health centers and organizations like ours have that trusted advisor, the registered dietician, nutritionist, the other community members who

really play such an important role in that coaching. Coaching is only as good as people will listen to it.

Senator HICKENLOOPER. That was in my mind to say, at the very beginning as a framing element, but I appreciate that. You're exactly right, Mr. Chairman.

Senator MARKEY. Yes. Thank you. And first let me ask unanimous consent to enter into the record seven statements outlining stakeholder Food is Medicine priorities. Without objections, so ordered.

[The following information can be found on page 42 in Additional Material:]

Senator MARKEY. I recognize Senator Marshall.

Senator MARSHALL. Thank you, Mr. Chairman. I'll start with Mr. Williams. What obstacles exist that block us from harnessing personalized medicine today?

Mr. WILLIAMS. I think that building on the last point, when we look at least from a entrepreneurial standpoint, the startups that we see, when you're a startup in this space, you have to make a decision whether you're going to be in the CMS lane or not.

If you're going to be in the CMS lane, then you got to comply with how it works. And there are things I know the entrepreneurs do that are not what they know is right for the patient, but is right because of the structure of how CMS works. It's not a criticism of CMS, it's they are there to deal with sick people, not proactive.

I think that the front end on CMS and also on FDA standpoint in terms of what is nutrition, the medical claims that we see in the new products that have more nutritional density that can't be made. Because when you go into FDA, it falls into a level of approvals that make it very difficult for an entrepreneur bringing new products to market to get through that buzz saw.

I think both FDA and CMS and that front end, if we're expecting stuff to come from the innovators into the space, they need that pathway cleaned up a little bit or they got to go to it alone and it's got to take longer.

Senator MARSHALL. Okay. Ms. Martin, how would you handle the reimbursement part of this? What would you suggest that, that we should do to better reimburse for the Food is Medicine component?

Ms. MARTIN. The reimbursement should absolutely be integrated into the healthcare model. There are about 14 states that are either pending or have already passed 1115 waivers that are implemented into state Medicaid. And there's already Medicare and in Medicare Advantage programs offering this as a reimbursable.

I would think that it would need to be a pre-authorization for at least a year, and that would be paid upfront to cover the food and the education.

Senator MARSHALL. Are you seeing with any ACOs?

Ms. MARTIN. I have not.

Senator MARSHALL. All right. Dr. Mozaffarian, we got to talk about milk just for a second I'm kind of the champion of whole milk up here.

[Laughter.]

Senator MARSHALL. Can you just speak a little bit, have you done any research about whole milk, which by the way, tastes better and the kids actually drink it, and we're going to have a whole new generation of boys and girls that develop osteopenia, osteoporosis at a much younger age. How do you feel about whole milk and what does your research show?

Dr. MOZAFFARIAN. I mean, one of the reasons I got into nutrition was in the nineties when I was doing my medical training, it was the height of the low fat diet recommendations. And when I read the science to educate myself as a doctor who wasn't receiving training on nutrition, the science in the nineties didn't support a low-fat diet.

We were doing the best we could, but the science was—the policy was 10, 20 years behind the science. And so I knew right then that I had to really understand dietary fats. And so, I've done a lot of research on dietary fats. And I think, although most Americans don't realize this, the dietary guidelines have quietly dropped the focus on low total fat. There is no longer a focus on low total fat in the dietary guidelines, which is appropriate.

There's still a focus on low saturated fat, which I think is misguided and not actually supported by the evidence. And I hope the current dietary guidelines fixes that. But what that does is make recommendations for low fat or non-fat dairy. And we've done research using observational studies, using biomarker studies, using meta-analysis looking at a range of types of studies, and there's no evidence that low fat or non-fat dairy is healthier than whole fat dairy. There's some evidence that whole fat dairy may be healthier than non-fat dairy even the other way. And so, from my perspective, we don't have enough evidence to only recommend low fat or non-fat dairy. We should be telling people to eat what they choose, and we need more science.

I think the second point I would make is there's more interesting evidence about the type of dairy. And so, fermented dairy like yogurt with probiotics or cheese, which is actually the top fermented food consumed in the U.S. may be particularly helpful. And so, I think we need more research on fermented dairy foods.

Senator MARSHALL. Yes. And remind everybody that with the whole milk, you can absorb the fat-soluble vitamins A, D, E, and K. So it just makes sense to me, says she'll find pregnant moms to let them have whole milk. Let me go back to Mr. Williams. Talk a little bit more about regenerative crops and nutrient dense food. What does that mean to you, and how do we get to them and do they taste better?

Mr. WILLIAMS. Yes. So you can imagine that, evolution says if something is more nutrient dense, you would want it to taste better, so you remember to eat it like 200,000 years ago.

It's the case that taste and nutritional density tend to correlate with each other in crops. What we have found is that nutritional quality tends to come from the soil. So if you enhance the soil microbiome, you tend to have more nutrients available, the more nutrient uptake. Farmers are learning a lot better how to balance both synthetic fertilizer and that the microbiome and shifting into a mindset where regenerative is working.

Further, what Erin has been seeing is that you can grow those crops in amongst existing agricultural products. So someone, a 200,000 acre row crop farmer can also put two or three acres and work around regenerative. And then that supply chain is more local. It can be done 10 months out of the year, and then directly supply rural areas with more nutrient dense, but ultimately, that nutrition comes from the soil.

Senator MARSHALL. Well, Mr. Chairman, I just want to say again, thank you for letting us have this hearing. I've got to circle back to one of the statements you made that FDR was concerned about the malnutrition incidents in this country.

I would postulate our incidence of malnutrition today is higher than it was in the 1940's. We have plenty of calories. That's not what I'm talking about. But the nutrition quality of our diet has deteriorated for a lot of reasons.

I wish I could wave my hand and fix this. This is something I've worked on for 30 years and still struggle to find that perfect place and congratulations to, the folks that are finding success, doing and implementing, that's not easily done. So congratulations to you all. Thanks, again, to all of our participants today for your testimony.

Senator MARKEY. Thank you, Senator. Very much. And my father was actually a milkman. So the one thing we got was whole milk. Butternut margarine ice cream. My wife is a physician and she does say that one thing that my brothers and I don't have to worry about is osteoporosis.

[Laughter.]

Senator MARKEY. We were definitely fed the preventative medicine as children. And if I may, Dr. Mozaffarian, when I was a boy growing up with Tufts University, a mile from my house, we had Jean Mayer writing a column and probably 200 newspapers every week on nutrition. He became the president of Tufts University. He died in 1993, but he was the world's leading nutritionist. And to a certain extent that's why you were there because of the legacy of Jean Mayer.

Could you tell us, in the 30 years since Jean Mayer passed, what would he learn today that he didn't know back then? In 1993, what has the research developed that the greatest nutritionist in the world didn't know?

Dr. MOZAFFARIAN. I'm the Jean Mayer Professor at Tufts, and so it's quite a legacy to, and actually one of the reasons I actively try to bring science into action, which is what Jean Mayer's legacy was. He was not an armchair academic. Right. He fought at the Battle of Dunkirk as a French infantryman and helped the British escape across the channel and then fought in the French Underground and in North Africa.

I think what has changed since Jean Mayer passed is the unbelievable biologic complexity of how food affects our bodies. When Jean Mayer was in his prime and training as an excellent scientist, we thought about macronutrients and vitamins and kind of energy processing. And that's how a lot of Americans still think about

food. They look at the back of the package and look at the calories and the vitamins.

But food is more than vitamins and calories. Food is biologic information. You know, everything we eat is biologic information that affects almost every cell in our body.

Jean Mayer would be amazed at how foods affect our gut microbiome. The fermentable fibers, the phytonutrients, the phenolics. He would be amazed at discoveries of things epicatechin in apples, or oleocanthal and extra virgin olive oil, or EGCG, and T these molecules that at nano microgram quantities have biologic effects. In the public literature, we've measured about 100,000 compounds in food, known compounds in food.

There are startups like Bright Seed that I advise in California that have now documented 2 million previously unknown compounds in plant foods and their biologic effects. And so, I think John Meyer would be amazingly gratified and excited about this future where we really start to unpack all of these unbelievable biologic effects of food and how they can be our medicine and improve our health.

Senator MARKEY. That is so great. And as a precursor to this hearing, back in 1986, I was able to include language in a bill with the support of Governor John Sununu, Republican of New Hampshire, and proud Tufts graduate into the bill, which then helped Jean Mayer to build a new facility for research.

I think he'd be very gratified of the research that has now been conducted at the building that he recommended be constructed, and that you are the Jean Mayer Professor advancing his science and helping us all to understand much better the impact which food has upon all of us, and how ultimately food can be and should be medicine for every person on this planet.

I thank Senator Marshall for recommending this hearing and his staff and all of our great witnesses for all of your very, very helpful testimony here today.

With that, this hearing is adjourned. Thank you.

# ADDITIONAL MATERIAL

Written Statement for the Record
Prepared by Kevin Volpp, MD, PhD, FAHA

Scientific Lead, Health Care by Food™, American Heart Association (AHA)
Director, Center for Health Incentives and Behavioral Economics (CHIBE)
Mark V. Pauly Presidential Distinguished Professor, Perelman School of Medicine and the Wharton School, University of Pennsylvania

Submitted to the Senate Health, Education, Labor, and Pensions Committee
Subcommittee on Primary Health and Retirement Security

Hearing on Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine

May 21, 2024

Chairman Ed Markey, Ranking Member Roger Marshall, and members of the Senate Health, Education, Labor, and Pensions Subcommittee on Primary Health and Retirement Security, thank you for holding this hearing, "Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine." My name is Dr. Kevin Volpp, and I currently serve as the scientific lead for the American Heart Association's food is medicine (FIM) initiative, Health Care by Food. I am also the founding Director of the Penn Center for Health Incentives and Behavioral Economics (CHIBE) and the Mark V. Pauly President's Distinguished Professor at the University of Pennsylvania's Perelman School of Medicine and the Wharton School.

For 20 years, I served as a part-time primary care doctor and hospitalist taking care of patients at the Philadelphia Veterans Affairs Medical Center. Many of my patients struggled with chronic diseases such as diabetes and congestive heart failure, which were exacerbated by their challenges finding affordable healthy food. As a behavioral economist, my work has largely focused on testing innovative ways of applying insights from behavioral economics in improving patient health behavior and clinician performance. Through my work with a variety of health plans, health systems, consumer companies, and individual patients, I have developed a deep understanding about what physicians, individuals, and families need to promote health, prevent disease, cure illness, and manage chronic health conditions. As a member of the American Heart Association's advocacy committee, I have worked to advance the organization's mission to be a relentless force for a world of longer, healthier lives for all.

About Health Care by Food™ (HCXF)
In conjunction with the White House Conference on Hunger, Nutrition, and Health in 2022, the American Heart Association and The Rockefeller Foundation launched the Health Care by Food initiative to strengthen the evidence base for FIM. Our vision is to accelerate a future in which millions of patients receive the benefit of a more holistic approach to diet and health, health care professionals and practitioners know how FIM programs can help prevent and manage disease, and payors have sufficient, objective cost-effectiveness evidence for reimbursing FIM programs. The initiative will provide the large-scale clinical evidence required to help identify, support and implement the most viable FIM strategies as a covered benefit through public and private health insurance.

Launched in Spring 2023, the HCXF initiative is made up of over 55 leading researchers across the country in diverse academic fields, guided by the support of dozens of experts who comprise nine volunteer task forces that are examining issues ranging from health equity and common

measures for FIM, community engagement and implementation science, behavioral science, cost effectiveness, human-centered design, and evaluation of the Medicaid waivers, among other issues. Already the HCXF initiative has funded nearly $8 million in 19 research grants that will test the clinical effectiveness of different FIM interventions in diverse patient populations with diabetes, hypertension, cardiovascular disease, and high-risk pregnancy. The initiative is also funding an implementation analysis of the high and low redemption rates in the Gus Schumacher Nutrition Incentives Program (GusNIP) program through the Gretchen Swanson Center for Nutrition. Together, these grants involve researchers from more than 20 academic institutions, 27 community-based organizations, and a number of national corporations with participation throughout much of the United States. These promising short-term and smaller studies will inform larger, scalable research studies.

As laid out in the AHA's presidential advisory on FIM,[1] AHA developed a call to action for the organization, as well as for the rest of the FIM research field, as we look toward strengthening the overall body of the work. Our call to action is the following:

- Define and determine the scope of FIM and its role in health care and strengthen the FIM evidence base across diverse populations to inform our collective understanding of the limitations to the existing evidence and the opportunities for incremental impact.
- In partnership with others, lead efforts to increase the rigor of FIM studies so that the field moves away from predominantly conducting pre–post studies in which causal inferences are difficult to draw to one that leads the field of nutrition research by using experimental and quasi-experimental designs that support more robust and reliable conclusions.
- Bring behavioral science and human-centered design into FIM trials more systematically to increase engagement and ultimately both efficacy among those who choose to participate and population health effectiveness of interventions.
- Make concerted efforts to obtain funding for more rigorous, adequately powered longer-term studies to affect measured clinical outcomes. Conduct comparative effectiveness and cost-effectiveness studies, capturing tradeoffs between intervention costs and effectiveness to inform decisions on which FIM approaches to choose for different populations, outcomes, and settings.
- Use rapid-cycle innovation principles to improve program enrollment and engagement and to study design innovations such as adaptive study designs to accelerate learning from research studies.
- Embed FIM principles of research, including equity, transparency, rigor, quantitative/qualitative balance, dignity, and incorporating lived experience of patients and practitioners, to ensure that effective FIM interventions have reach, adoption, acceptability, and sustainability within the populations served.
- Create common data platforms and standardize data elements and metrics in FIM studies to facilitate comparisons across studies that could support the translation of research into policy.
- Catalyze partnerships across communities, food systems, health systems, commercial entities, and funding agencies to empower a patient-driven, health-for-all approach to mitigate food insecurity and to improve diet quality and health outcomes among the most disenfranchised.
- Leverage implementation science to examine questions on enrollment, dose, engagement, and adherence inclusive of health system or health plan integration.

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[1] Volpp KG, er al. Food Is Medicine: A Presidential Advisory From the American Heart Association. Circulation. 2023;148:1417-1439.

Identify and develop strategies to examine predictors of implementation success of individuals and incorporate these into program design.
- Expand complementarities of advocacy and policy work through cross-sector, community-engaged, inclusive coalitions at the regional and national levels, as well as governmental partnerships to create dialogue and build trust, collaboration, and collective action.
- Standardize professional education nationally to include nutritional science and FIM research to facilitate adoption of FIM best practices in clinical practice by the next generation of health professionals.

Why take a FIM approach to health care?
The connection between chronic disease and nutrition is undeniable. Our diets not only play a role in our risk of developing chronic diseases, but also can prevent, manage, and treat these diseases. Cardiovascular disease is the leading cause of death in the United States, and chronic diseases affected by nutrition including cardiovascular disease, stroke, and diabetes account for most of the nation's $4.3 trillion in annual health care costs.[2] Cardiovascular disease alone accounts for 12 percent of total U.S. health expenditures, considerably more than any other disease.[3] Heart disease and stroke cost the U.S. health care system $216 billion annually and cause $147 billion in lost job productivity.[4] Nutrition insecurity and unhealthy diets—characterized by a high intake of calories, sodium, added sugars, and saturated fat, and low intake of vegetables, fruits, and whole grains—significantly contributes to the development of cardiometabolic disease and chronic diseases more broadly. There are significant equity disparities as well, with higher rates of chronic disease mortality among those with low income, less education, and across different racial/ethnic populations. Black, Latino, and Native populations and low-income households, have higher rates of poor diet quality compared with the overall population.[5] The COVID-19 pandemic has only exacerbated these disparities. Stable availability, access, affordability, and use of nutritious foods across the lifecycle can help reduce the risk of chronic diseases and help treat and manage chronic diseases. Unfortunately, many individuals in the United States are nutrition and food insecure[6] and do not have access to affordable, nutritious food. There is a growing body of evidence that the health care system can be used to help patients access and consume healthy foods. To help address unhealthy diets and nutrition insecurity, evidence-based, cost-effective nutrition and food programs can be integrated into the health care system.

What is FIM?
FIM refers to a medical treatment or preventive intervention for patients with a diet-related health risk or condition and/or nutrition and food insecurity, to which they are referred by a health care provider, health care organization, or health insurance plan.[7] Often these FIM interventions are coupled with medical nutrition therapy (MNT) and efforts to increase enrollment or participation in other federal and state safety net programs, and programs that

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[2] Martin AB, et al. National Health Expenditure Accounts Team. National health care spending in 2021: decline in federal spending outweighs greater use of health care: study examines national health care expenditures in 2021. Health Aff (Millwood). 2023; 42:6–17.
[3] Tsao CW, et al. Heart Disease and Stroke Statistics—2022 Update: A Report From the American Heart Association. Circulation. 2022;145:e153–e639.
[4] Centers for Disease Control and Prevention. Health and Economic Costs of Chronic Diseases. Accessed online April 15, 2024. https://www.cdc.gov/chronicdisease/about/costs/index.htm.
[5] Tsao CW, ibid.
[6] Coleman-Jensen A, et al. Household Food Security in the United States in 2020. Economic Research Report No (ERR-298) pp. 2021.
[7] Harvard University Center for Health Law and Policy Innovation. Accessed online April 15, 2024. https://chlpi.org/project/food-is-medicine/.

address other social determinants of health (housing, education, transportation, social services, etc). There are distinct approaches that are described broadly as FIM, including but not limited to:

- Medically Tailored Meals (MTMs). MTMs are used to address diet-related diseases and food access among higher-risk individuals. MTMs provide home delivery of fully prepared meals designed by a registered dietician to meet the specific dietary needs of an individual living with one or more chronic diseases. This intervention is ideal for patients living with chronic diseases who are unable to shop for or prepare meals for themselves, such as patients following a hospitalization for congestive heart failure who are frail and have difficulty ambulating.
- Medically Tailored Groceries (MTGs). MTGs include a selection of groceries, such as vegetables, fruits, grains, beans, lean proteins and/or dairy prescribed by a registered dietitian nutritionist for a broader range of patients—those with diet-related acute and chronic conditions who can shop or pick up and prepare food at home. MTGs are part of a treatment plan for an individual with a defined medical diagnosis, confirmed by a health care provider or health plan. Food sourcing varies across programs and often incorporates community partners.
- Healthy Food Prescription Programs. Food prescription programs (also called produce prescription programs) incorporate food access directly into the patient-provider relationship which better enables patients to follow their providers' dietary advice. In these programs, providers "prescribe" fruits and vegetables, or other healthy foods, to at-risk patients in the form of coupons or vouchers for local farmers' markets, grocery stores, or mobile markets. These programs are also typically accompanied by nutrition education and/or counseling and can be paired with services provided by registered dieticians or community health workers. Food prescription programs are typically offered to people living with chronic diseases that are exacerbated by unhealthy food and who have nutrition and food insecurity. Some food prescription programs have been funded through the farm bill reauthorization process. The 2018 farm bill provided $250 million of mandatory funding for GusNIP, some of which is allocated for produce prescription pilots.

It is important to note that FIM complements other critical efforts to address food and nutrition security needs, such as supporting Supplemental Nutrition Assistance Program (SNAP), Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the charitable food system (food banks and pantries), among others. However, it is distinct from these programs in that it is specifically targeted for people living with or at high risk of chronic disease, due in large part to diet, through health care settings.

The interest in FIM programs and their increasing use within health care has been in part ahead of the research, driven in large part by organizations and advocates who have worked to develop service delivery programs to meet the nutritional needs of people living with chronic diseases. Within the past several years, health care integration of FIM interventions has become increasingly common. FIM programs are growing, which allows for more researchers to assess the effectiveness of the implementation of different FIM approaches.

Already there has been tremendous momentum at the state and federal level. State Medicaid agencies may currently apply for waivers (i.e., Section 1115 demonstration waiver and 1915(b) waiver) to test new FIM approaches, including MTMs and produce prescription programs, and nearly a dozen states have begun to take advantage of these opportunities for innovation. The administration has called for testing MTMs in Medicare, expanding and enhancing Medicare coverage of nutrition and obesity counseling (MNT), and increasing funding for nutrition research, and have held multiple convenings on FIM as part of the National Strategy on Hunger,

Nutrition, and Health. The Centers for Medicare and Medicaid Services (CMS) now requires hospitals to screen patients for needs related to food insecurity, housing, transportation, and other social determinants of health. Medicare Advantage plans already voluntarily offer supplemental benefits that include food assistance and FIM-like benefits (MTMs, MTGs, produce prescription), but this is an emerging area with limited information about its utilization. The Department of Health and Human Services (HHS) is currently developing common measures and a framework for evaluating FIM set to be released by the fall. Finally, produce prescription programs and pilots continue to grow in numbers, including at the Indian Health Service and Department of Veterans Affairs.

Strengths and Room for Improvement in FIM Research

FIM programs have commonly been evaluated as part of small-scale studies and pilot projects conducted using local resources that are generally not scalable. The HCXF initiative is funding smaller studies with a goal of addressing implementation challenges that would limit the potential for scalability and then will fund larger studies. HCXF has also identified populations to prioritize in research, including the acutely ill, patients with recent hospital discharges, high-risk pregnant women, and alternative paths or wrap-arounds for glucagon-like peptide 1 drugs (GLP-1), drugs. We are also prioritizing having geographically and ethnically and racially diverse populations as participants in the initiative.

Of the studies on FIM programs, the literature on MTMs is the most well-developed, with a number of rigorous study designs and results that examine clinical outcomes and health care utilization and spending. MTMs are associated with improved health outcomes for people living with chronic diseases such as diabetes, heart failure, HIV, and chronic liver disease. Patients on medically tailored meals have reported higher quality of life scores, lower rates of food insecurity, and improved diet quality.[8,9] MTM are also associated with reduced hospital admissions and overall health care costs.[10,11] The research suggests that produce prescription programs are effective at increasing fruit and vegetable consumption[12,13] and reducing household food insecurity.[14] The studies conducted on food prescription programs have found that some of these programs are associated with improved health outcomes and reduced health care burden including decreased hemoglobin A1C levels[15] and lower body mass index.[16] While modeling studies have suggested that food prescription programs may prevent cardiovascular

[8] Ishaq O, et al. Food as medicine: A randomized controlled trial (RCT) of home delivered, medically tailored meals (HDMTM) on quality of life (QoL) in metastatic lung and non-colorectal GI cancer patients. Journal of Clinical Oncology. 2016;34.
[9] Berkowitz SA, et al. Medically Tailored Meal Delivery for Diabetes Patients with Food Insecurity: a Randomized Cross-over Trial. J Gen Intern Med. 2019;34:396-404.
[10] Berkowitz SA, et al. Association Between Receipt of a Medically Tailored Meal Program and Health Care Use. JAMA Intern Med. 2019;179:786-793.
[11] Berkowitz SA, et al. Meal Delivery Programs Reduce The Use Of Costly Health Care In Dually Eligible Medicare And Medicaid Beneficiaries. Health Aff (Millwood). 2018;37:535-542.
[12] Bhat S, et al. Healthy Food Prescription Programs and their Impact on Dietary Behavior and Cardiometabolic Risk Factors: A Systematic Review and Meta-Analysis. Advances in Nutrition. 2021.
[13] Marcinkevage J, Auvinen A and Nambuthiri S. Washington State's Fruit and Vegetable Prescription Program: Improving Affordability of Healthy Foods for Low-Income Patients. Prev Chronic Dis. 2019;16:e91.
[14] Ridberg RA, et al. A Pediatric Fruit and Vegetable Prescription Program Increases Food Security in Low-Income Households. J Nutr Educ Behav. 2019;51:224-230.e1.
[15] Bryce R, et al. Participation in a farmers' market fruit and vegetable prescription program at a federally qualified health center improves hemoglobin A1C in low-income uncontrolled diabetics. Prev Med Rep. 2017;7.
[16] Cavanagh M, et al. Veggie Rx: an outcome evaluation of a healthy food incentive programme. Public Health Nutr. 2017;20:2636-2641.

disease and diabetes, these have typically had to make assumptions about the longer term effects of short-term interventions that may or may not end up being confirmed.[17]

In general, many of the FIM studies that have been conducted using pre-post examination of a group that received an intervention without comparison groups; the measured impact of such interventions may be overstated since they do not account for the general tendency of measured outcomes to regress to the mean.[18] Furthermore, only a small number of randomized controlled trials have been done and those that have been done with few exceptions are small and typically not tested using a scalable infrastructure. More broadly, there are important questions to answer regarding the intensity of FIM interventions, the duration, delivery, the role of patient preferences and choice, the incorporation of educational or behavioral strategies or coaching in addition to food permission, the testing of comparative effectiveness of ways to change behaviors and habits, and of cost effectiveness. More testing using infrastructure that can be replicated and scaled will be particularly important in determining ways to create solutions that could be deployed widely across the United States.

While there have been studies showing no significant results, this further illustrates the importance of carefully considering study design, and various implementations that take into account the lived experience of the populations most likely to benefit. The recent negative study by Doyle et al tested a very specific intervention, in which participants had to drive to an on-site food farmacy to pick up their food on a bi-weekly basis and did not have a great many options with regards to their meal choices.[19] Lack of effectiveness in one specific intervention does not negate that other differently designed interventions may be effective, and both negative and positive studies provide important learnings that inform future research studies.

A common challenge and barrier to system transformation has been that among the wide variety of programmatic interventions at the intersection of food and health, most exist on a small and siloed scale. Different hospitals, payors, and health care providers have approached these programs in various ways, without any clear or standardized set of implementation approaches likely to be capable of scaling nationally. To create more generalizable approaches, there would ideally be coordination between HHS and the United States Department of Agriculture (USDA) with support for research from the National Institutes of Health (NIH) and involvement of public-private partnerships both to facilitate the testing of scalable ideas and to provide financial support. Current FIM interventions do not consistently include the perspectives and voice of potential participants, which can reduce engagement by those who are offered the programs and thereby diminish their impact. In FIM studies that are focused on improving health outcomes or reducing health care utilization, careful assessment of cost effectiveness should be conducted as this will be important in informing decisions about public or private health insurance coverage. Finally, research can also help us understand how to increase uptake and engagement, and thereby full utilization of FIM programs, to maximize their potential impact on health and health care costs.

*Strengths of Medical Nutrition Therapy Research*

As noted previously, MNT is often part of a FIM intervention. MNT research has shown it to be a cost-effective, evidence-based intervention to manage chronic conditions, especially obesity,

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[17] Lee Y, et al. Cost effectiveness of financial incentives for improving diet and health through Medicare and Medicaid: A microsimulation study. PLoS Med. 2019;16:e1002761.
[18] Doyle J, et al. Effect of an Intensive Food-as-Medicine Program on Health and Health Care Use: A Randomized Clinical Trial. JAMA Intern Med. 2024;184:154-163.
[19] Doyle J, ibid.

diabetes, and cardiovascular disease.[20,21,22] CMS defines MNT as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management, which is usually conducted by a registered dietitian (RD) or nutrition professional." MNT services involve in-depth individualized nutrition assessment and use the Nutrition Care Process (NCP) to manage disease. This intervention is also designed to improve a patient's nutritional knowledge of their health condition and diet behavior. Coverage for MNT varies depending on the insurance provider. For Medicare and Medicaid, MNT services are reimbursable for certain populations. Medicare Part B only covers MNT and other related services for patients diagnosed with diabetes, non-dialysis kidney disease or patients within 36 months post kidney transplant, who are referred by a physician and when services are provided by a registered dietician (RD) who is enrolled as a Medicare provider. Medicare covers three hours of MNT the first year of treatment and up to two hours of MNT for each subsequent year. While the costs for these services are reimbursable for patients with diabetes or chronic kidney disease, MNT services are not reimbursed through Medicare for patients with pre-diabetes or other chronic conditions (e.g., hypertension, obesity, CVD, etc.). Medicaid coverage for MNT for adults and children varies from state to state and some states do not recognize RDs as approved Medicaid providers. States are required by federal law to provide "mandatory" benefits including services like inpatient and outpatient hospital services, physician services, laboratory and x-ray services, and other "optional" benefits like prescription drugs, case management, physical therapy, and occupational therapy, which can also be covered by Medicaid. However, coverage for nutritional services is not outlined specifically by Medicaid on the list of mandatory or optional benefits.

MNT is used in a variety of programs that may include FIM interventions or could be augmented with FIM interventions in various programs that counsel on diet for people with or at risk of developing diabetes or heart disease. Efforts are being made at the federal level to increase access of MNT to vulnerable populations. For the past few Congresses, legislation has been introduced to expand MNT access. The first of which was introduced in 2017. As noted previously, the administration has called for expanding coverage of MNT in Medicare.

Conclusion

Chronic conditions and unhealthy diets are inextricably linked, and health disparities remain all too pervasive. FIM interventions within the health care system is a promising approach in helping patients access and consume healthy foods that could improve health outcomes for people living with chronic diseases. Important research gaps, however, continue to exist in our knowledge base on what FIM interventions would be the most effective.

The AHA's HCXF initiative is committed to helping generate the evidence and tools needed in the health sector to design and scale cost-effective FIM programs. Working with patients and partners in government, academia, health care, industry, and community-based organizations, the HCXF initiative will accelerate the rate of innovation to unlock solutions to these most complex challenges.

The AHA supports efforts to increase prioritization of nutrition and equitable access to healthy, affordable food in the health care delivery system and to connect patients with community

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[20] Anderson JM. Achievable Cost Saving and Cost-Effective Thresholds for Diabetes Prevention Lifestyle Interventions in People Aged 65 Years and Older: A Single-Payer Perspective. Journal of the Academy of Nutrition and Dietetics. 2012;112:17471754.

[21] Sikand G, et al. Clinical and cost benefits of medical nutrition therapy by registered dietitian nutritionists for management of dyslipidemia: A systematic review and meta-analysis. Journal of Clinical Lipidology. 2018;12:1113-1122.

[22] Troyer JL, McAuley WJ and McCutcheon ME. Cost-effectiveness of medical nutrition therapy and therapeutically designed meals for older adults with cardiovascular disease. Journal of American Dietetic Association. 2010;110:1840-1851.

resources that improve access to and consumption of healthy food.[23] By increasing coverage for nutrition services through health insurers like Medicare and Medicaid and expanding existing food and nutrition programs, patients can be connected with the resources they need to prevent, treat and manage chronic diseases that drive health care costs across the United States. The AHA further supports efforts to expand investments in nutrition and FIM research, and in existing programs that address food and nutrition insecurity.

[23] American Heart Association. Strategies to Address Socioeconomic and Racial and Ethnic Disparities in Chronic Diseases by Incorporating Food and Nutrition Programs into the Primary Healthcare Setting. June 2022. Accessed online April 15, 2024. https://www.heart.org/-/media/Files/About-Us/Policy-Research/Policy-Positions/Access-to-Healthy-Food/Medical-Nutrition-Therapy-Policy-Statement-2022.pdf.

May 21, 2024

The Honorable Ed Markey
Chairman
Subcommittee on Primary Health
& Retirement Security
428 Dirksen Senate Office
Building Washington, DC

The Honorable Roger Marshall
Ranking Member
Subcommittee on Primary Health
& Retirement Security
428 Dirksen Senate Office
Building Washington, DC

**Statement for the Record**
**Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine**

Dear Senators Markey and Marshall,

Thank you for the opportunity to provide comments for the record of your May 21, 2024, hearing, *Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine* on behalf of the Food is Medicine Coalition (FIMC). The Food is Medicine Coalition (FIMC) is the national coalition of nonprofit organizations that provide medically tailored meals (MTMs) and groceries (MTGs), medical nutrition therapy and nutrition counseling and education to people in communities across the country living with severe, complex, and chronic illnesses. FIMC agencies created the medically tailored meal model as a response to community need nearly 40 years ago and maintain the nutrition standards for the intervention. As longtime advocates for promoting policy initiatives that address the connection between diet-related diseases and the food we eat, we are deeply appreciative of the Subcommittee's leadership and bipartisan work to explore the various options for the federal government to improve access to food is medicine interventions. As you review the myriad food is medicine initiatives that have been introduced in the 118th Congress, we urge you to give S. 2133, the Medically Tailored Home-Delivered Demonstration Pilot Act, which was introduced by Sens. Stabenow, Marshall, Booker and Cassidy, your strong consideration and support.

This bipartisan and bicameral legislation will expand access to Medially Tailored Meals (MTMs), bend the health care cost curve, and provide medically vulnerable seniors with healthy and delicious medically tailored meals in their homes. More importantly, the Biden administration included funding in the FY26 Medicare budget for a 3-year legislative pilot to cover the delivery of medically tailored meals to enrollees' homes. The administration's FY26 budget request builds upon its prior commitments in the 2022 National Strategy on Hunger, Nutrition and Health, which set a goal to work with Congress to pilot coverage of medically tailored meals in Medicare and increase access to this important health care intervention.

As drafted, S. 2133 would use funding from Medicare Part A to establish MTM pilot programs in geographically diverse communities across the country (urban, rural, and frontier) that operate in partnership with hospitals. The bill also gives the Health and Humans Services Secretary strong deference to design pilots in support of the best outcomes possible. S. 2133 sets a foundation for the Centers for Medicare and Medicaid Services (CMS) to gather robust data that will help to quantify how medically tailored meals benefit diverse populations and to build the most effective access for

Medicare enrollees. This data includes: the number of inpatient admissions at hospitals and skilled nursing facilities (SNFs), Medicare expenditures, costs to run pilots, food costs, improvements in participants' health outcomes, increases in patient satisfaction, and savings attributed to the pilots. This 5-year pilot would provide participants with at least two medically tailored meals each day that would be made from healthy ingredients, matched to their medical needs by a Registered Dietitian Nutritionist (RDN) similar to FIMC's MTM Model and nutrition standards, and delivered to their homes. To help improve participant's health outcomes and reduce the likelihood of hospital admissions, each recipient of MTMs would also receive nutrition education and counseling and medical nutrition therapy as indicated to monitor their progress over the course of the pilot.

Across the nation, FIMC agencies have worked with private and public insurers and Medicare Advantage plans, foundations, community groups, and state and local government to expand access to lifesaving medically tailored meals. This suite of 1115 Medicaid waivers, risk-based Medicaid financing arrangements, short-term pilots, and transitional service benefits are uniquely designed to meet the health and nutrition needs of specifically designated populations in participating jurisdictions; however, despite the progress food is medicine supporters have made to provide medically-vulnerable seniors with healthy meals in their homes, there still is no federally-designated benefit for MTMs in Medicare Part A or B. As such, we urge you to work with your colleagues to advance S. 2133 as soon as possible.

A plethora of research - largely conducted on FIMC agencies - has already demonstrated the value of this evidence-based health care intervention and major benefits for MTM recipients: (1) improved quality of life; (2) improved mental health; (3) better diabetes management; (4) healthier eating habits; and (5) improved medication adherence, alongside robust cost savings. In fact, if everyone eligible to receive an MTM in America could benefit from this impactful health intervention today, our healthcare system would save $14 billion and prevent 1.6 million hospitalizations in just the first year of access. These savings would largely benefit the Medicaid portfolio as people with diet-impacted diseases, who are low-income/asset limited or disabled, reduce trips to the hospital.

Our national movement is supported by a network of medically tailored meal and medically tailored grocery providers, along with a range of nutrition-focused nonprofit organizations that have participated in the FIMC Accelerator Program – an 11-month training initiative that teaches them how to prepare and deliver a high-quality MTM intervention in communities where there is currently no access. In support of this effort to build a national movement that can replicate the effective work of our membership, FIMC has created a first-in-the-nation accreditation standard for medically tailored meals: The FIMC MTM Accreditation Criteria and Requirements (FIMC MTM ACR). The standard comes at a meaningful moment in the food is medicine movement and helps qualify and quantify the critical intervention as it makes its way into healthcare provision.

Through decades of service, FIMC agencies have perfected the science of layering diets for maximum nutrition effect that receives so much attention today. FIMC agencies are known for the impressive outcomes our nutrition programs produce. We know that these results are only possible with nutritious food, community connection and a client-centered approach. This effort to promote excellence for recipients of MTMs through standardization will ensure that each FIMC-accredited MTM agency provides the same level of service regardless of location, size, or number of clients and meal plans catered for. All FIMC-Accredited agencies are able to provide a medically tailored meal intervention that meets the needs of clients living with severe, complex, or chronic health conditions. The FIMC designation signals to the community, policy makers, healthcare partners, and most importantly - clients - a level of service that can be trusted.

We look forward to working with members of the Subcommittee to advance this evidence-based food is medicine solution that meets the medical and nutritional needs of recipients. Your commitment to

highlighting the power and promise of food is medicine interventions with this hearing today is a testament to your constructive approach to policymaking. As you seek effective solutions or additional policy insights into various food is medicine solutions, we offer the members of the Food Is Medicine Coalition as experts. Any of FIMC's members can speak to the real-world experience of using MTMs to help vulnerable populations lead healthier lives, reduce avoidable health care costs, and improve the experience of care. Should you have any additional questions, please do not hesitate to reach out to me at info@fimcoalition.org.

Sincerely,

Alissa Wassung
Executive Director
Food Is Medicine Coalition

ADVOCATES FOR COMMUNITY HEALTH

Statement for the Record

**Advocates for Community Health**
Amanda Pears Kelly, Chief Executive Officer

**Senate Committee on Health, Education, Labor and Pensions (HELP)**
**Subcommittee on Primary Health and Retirement Security**
hearing on
**"Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine"**

April 17, 2024
2:30 PM ET
Senate Dirksen Office Building Room 430

Advocates for Community Health (ACH) is pleased to submit this statement for the record and applauds the Senate Committee on Health, Education, Labor and Pensions (HELP) Subcommittee on Primary Health and Retirement Security Chair Ed Markey (D-MA) and Ranking Member Roger Marshall, M.D. (R-KS) for holding today's hearing to highlight the importance of food and nutrition in improving health outcomes.

ACH is a member organization of community health centers (CHCs) focused on advocacy initiatives to affect positive change for CHCs, the patients they serve, and the entire nation's health care system. We leverage our members' wisdom, agility, and innovation to spearhead forward-thinking federal policies and drive change to advance and achieve health equity through comprehensive, integrated primary care. This statement aims to underscore the critical role that CHCs play in keeping America healthy, particularly through ways we help our patients access high-quality nourishment to prevent, manage, and treat their health conditions and improve their well-being.

As our nation's largest primary care health system, over 1,400 community health centers nationwide work tirelessly to meet the evolving needs of approximately 31.5 million patients each year, serving all who seek care, regardless of their ability to pay. Over 90 percent of health center patients live at or below the federal poverty line and many face complex and overlapping health challenges while struggling to access food and nutrition services.

As community health centers experienced firsthand, the COVID-19 pandemic highlighted and exacerbated existing challenges in food security, housing, and transportation, essential components of social drivers of health (SDOH). Data shows that more than half of CHCs reported a substantially increased need for services compared to before the pandemic: 69 percent saw an increase in patients seeking housing services, 63 percent in food and nutrition services, and 53 percent in transportation services.[1] This surge underlines the profound impact

[1] Jessica Sharac, Lina Stolyar, Bradley Corallo, Jennifer Tolbert, Peter Shin, and Sara Rosenbaum, "How Community Health Centers Are Serving Low-Income Communities During the COVID-19 Pandemic Amid New and Continuing Challenges," Kaiser

of these factors on community health and the escalating needs that our centers are striving to meet.

In 2021, 32.1 percent of households with incomes below the federal poverty line were food insecure;[2] the issue presents itself at our country's community health centers every single day. Many patients forgo proper nutrition because they are too busy caring for their families. They may need to choose between paying for utilities and housing over spending money on healthy food. Unfortunately, this can make their long-term health problems worse. Therefore, each center tailors its programs to the needs of its local community.

Some examples of how community health centers use food and nutrition to improve public health:

- **Evara Health's Food Pharmacy Program** (Florida) is a pioneering example of directly using food as medicine. In collaboration with Feeding Tampa Bay and funded by Humana, Evara Health's clinicians provide food prescriptions and medically appropriate nutrition and meals to certain patients. To be eligible for their program, patients are screened for food insecurity using the USDA Hunger Vital Sign screening questions. Patients identified as food insecure and diagnosed with chronic conditions of diabetes, hypertension, and/or high BMI are eligible for enrollment in the food intervention program. Patients receive vouchers to use at the Evara Food Rx Pharmacy, where staff assist patients as they choose from a prescribed option set. In addition to Evara's pantries, patients can redeem their vouchers at Feeding Tampa Bay's "Groceries on the Go" bus, which parks at various locations throughout the week, including Pinellas Park and the Lealman Exchange.

- **Lowell Health Center** (Massachusetts) and its partnership with Mill City Grows is a testament to the power of local collaborations. This partnership has enabled patients with chronic conditions at the Health Center to access the healthy foods necessary for their diets. Since its inception in 2021, 56 adults have already enrolled and are benefiting from access to healthy, locally sourced produce.

- **East Boston Neighborhood Health Center** (Massachusetts) takes a four-pronged approach to addressing food insecurity: 1) Food Access programs increase access to healthy foods at Farmers' Markets; 2) the center's Community Resource and Wellness Center serves over 700 families each week with groceries and necessities; 3) an onsite kitchen makes more than 2,000 prepared meals each week for elderly enrolled in its home-delivered meals program through the Senior Care Options or Program of All-Inclusive Care of the Elderly programs; and 4) an onsite WIC program supports thousands of families each year.

- **Peninsula Community Health Services** (Washington) screens all patients for SDOH, including food security. In 2022, they screened 40,007 patients across 88,701 visits and identified 303 patients who needed referrals for food as an immediate need. As a part of their process, PCHS provides emergency food boxes inside their clinic—a service they

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Family Foundation, 2022. Accessed at https://www.kff.org/medicaid/issue-brief/how-community-health-centers-are-serving-low-income-communities-during-the-covid-19-pandemic-amid-new-and-continuing-challenges/.

[2] "Food Security and Nutrition Assistance," Economic Research Service, United States Department of Agriculture, 2023. Accessed at https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/food-security-and-nutrition-assistance/.

offer without any designated funding. Those patients were then sent to work with the center's Community Health Workers for 434 "touches," during which the community health center works to coordinate more stable food resources, another non-billable service the community health center shouldered to ensure their patients' needs are met.

- **North East Medical Services (NEMS) Health Centers** (California) purchase refrigerators for patients who reside in crowded living conditions. They also partner with food pantries to ensure the availability of culturally appropriate food for their predominantly Asian communities, including prescription boxes filled with necessary nutritional foods.

- **Sun River Health** (New York) engages in local events, such as including their Vice President of Operations as a guest chef in community food events, further strengthening the bond between health care providers and the communities they serve.

- **El Rio Health** (Arizona) offers comprehensive nutritional counseling with a team of Nutrition Education Specialists, Registered Dietitians, and a Lactation Consultant. This interdisciplinary approach ensures that diverse nutritional needs are met, from general health maintenance to specific medical conditions.

- **Salud Integral en la Montaña and Tampa Family Health Centers** (Puerto Rico and Florida), along with other members, employ Mobile Health Units to extend the reach of their services, ensuring that nutrition and healthcare access is available even in remote areas or during emergencies.

These efforts align with national initiatives like the White House Challenge to End Hunger and Build Healthy Communities, a nationwide call to action to stakeholders to advance President Biden's goal to end hunger and reduce diet-related diseases by 2030, and the Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health. Notably, the White House Challenge has recognized the work of entities like UTHealth Houston and its partners, whose initiatives are preparing to scale the produce prescription model across school-based health centers nationwide, demonstrating the effectiveness and scalability of food-based interventions in public health settings.

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Community health centers are at the forefront of integrating health care with essential health-related social needs (HRSNs) like food. Proper nutrition is a critical component of medical treatment and chronic disease management. By supporting and expanding such initiatives, we can enhance the health and well-being of communities nationwide. We hope Congress will consider the evidence and enact policies strengthening these vital connections between healthcare providers, food access, and community wellness.

We appreciate your support and the opportunity to exemplify the essential role of food in medicine and public health. We look forward to working with the Committee on these critical issues.
For more information, please contact me at apearskelly@advocatesforcommunityhealth.org or you can contact Stephanie Krenrich, Senior Vice President of Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org.


Statement of:
Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores (NACDS)

For:

United States Senate Committee on Health, Education, Labor & Pensions: Subcommittee on Primary Health and Retirement Security

On:

"Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine"

May 20, 2024

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**Introduction**

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Health, Education, Labor & Pensions Subcommittee on Primary Health and Retirement Security's hearing on "Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine." NACDS lauds your continued partnership and leadership on Food is Medicine and dedication to PBM reform, which remains a top priority for NACDS and our members. There is a pharmacy crisis in America due to PBMs' extremely below-cost reimbursement and avaricious business practices which lead to inflationary effects on drug prices, restrictions on patient access, higher healthcare costs for patients, and an untenable future for community pharmacies in America. NACDS looks forward to continued opportunities to work collaboratively on Food is Medicine, comprehensive PBM reform, and other key issues to better serve the American people and promote health across communities nationwide.

The U.S. healthcare system incurs the highest spending and conversely yields the worst health outcomes, compared to other high-income countries.[1] This data indicates that the U.S. spends about twice as much as our peers on healthcare, with the lowest life expectancy and the highest rate of people with multiple chronic health conditions. In other words, not only are Americans living shorter lives, but they are doing so with more disease and disability.[2] To achieve superior results, the nation desperately needs new solutions, especially those that target improved prevention, management, and treatment of chronic diseases and include the nation's most accessible healthcare providers – pharmacies and pharmacists.

Unfortunately, poor nutrition is annually linked to more than 500,000 deaths[3] and over 50 billion dollars in health costs[4] and nutrition-related chronic diseases remain on the rise with 6 in 10 Americans living with at least 1 chronic disease.[5] Chronic diseases, like heart disease, diabetes, and cancer, are the leading causes of death and the primary drivers of healthcare costs.[6] Healthy

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[1] The Commonwealth Fund. U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes. January 2023, available at: https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022

[2] The Commonwealth Fund. U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes. January 2023, available at: https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022

[3] The US Burden of Disease Collaborators. The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. JAMA. April 2018. https://jamanetwork.com/journals/jama/fullarticle/2678018

[4] Cardiometabolic disease costs associated with suboptimal diet in the United States: A cost analysis based on a microsimulation model. Jardim TV, Mozaffarian D, Abrahams-Gessel S, Sy S, Lee Y, et al. December 2019. https://doi.org/10.1371/journal.pmed.1002981

[5] Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). May 18, 2023. https://www.cdc.gov/chronicdisease/index.htm

[6] https://www.cdc.gov/chronicdisease/index.htm

eating can help prevent and better manage these harmful and costly conditions.[7] In 2022, diagnosed diabetes in the US cost $412.9 billion,[8] and the annual U.S. healthcare spending and lost productivity from suboptimal diets is estimated to be more than $1 trillion.[9] When it comes to U.S. national security, poor diets have a major impact. In 2018, 71% of young people would not be able to join the military and overweight and obesity is a top reason for ineligibility.[10]

Addressing these complex problems requires collaborative solutions that focus on improving access and uptake of healthy foods across diverse communities. Food is Medicine interventions, such as produce prescriptions and medically tailored meals, have demonstrated important benefits in improving health outcomes and controlling health costs by supporting access to healthy food and better nutrition for people either with or at risk for diet-related conditions.[11,12] Importantly, the Community Preventive Services Task Force (CPSTF) recently issued a recommendation for fruit and vegetable incentive programs based on strong evidence of effectiveness in reducing household food insecurity and increasing household fruit and vegetable consumption. Their findings are based on evidence from a systematic review of 30 studies conducted in the United States.[13]

NACDS urges the Subcommittee to take action to improve access to Food is Medicine interventions, leveraging the entire healthcare continuum, including the unique expertise of pharmacies and pharmacists.

About **90% of Americans live within 5 miles of a community pharmacy**[14] and **86%** of adults report that **pharmacies are easy to access**.[15] Pharmacies are open extended hours – including nights and weekends – when other healthcare providers are unavailable. Across populations, people visit pharmacies more often than other healthcare settings. Moreover, **more than 70%** of Americans support pharmacists helping patients prevent chronic diseases, a top driver of healthcare costs.[16]

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[7] https://www.cdc.gov/chronicdisease/resources/publications/factsheets/nutrition.htm#:~:text=Consuming%20unhealthy%20food%20and%20beverages,in%20postmenopausal%20women%2C%20and%20colorectal
[8] https://diabetesjournals.org/care/article/47/1/26/153797/Economic-Costs-of-Diabetes-in-the-U-S-in-2022
[9] https://now.tufts.edu/2023/09/26/report-shows-food-medicine-interventions-would-save-lives-and-billions-dollars
[10] https://www.cdc.gov/physicalactivity/resources/unfit-to-serve/index.html
[11] Health and Economic Impacts of Implementing Produce Prescription Programs for Diabetes in the United States: A Microsimulation Study. Lu Wang, Brianna N. Lauren, Kurt Hager, Fang Fang Zhang, John B. Wong, David D. Kim and Dariush Mozaffarian. July 2023. https://www.ahajournals.org/doi/10.1161/JAHA.122.029215
[12] True Cost of Food: Food is Medicine Case Study. Tufts University Food is Medicine Institute. September 2023. https://now.tufts.edu/2023/09/26/report-shows-food-medicine-interventions-would-save-lives-and-billions-dollars
[13] https://www.thecommunityguide.org/findings/social-determinants-health-fruit-vegetable-incentive-programs.html?ACSTrackingID=USCDCCG_24-DM127084&ACSTrackingLabel=CPSTF%20Recommends%20Fruit%20and%20Vegetable%20Incentive%20Programs&deliveryName=USCDCCG_24-DM127084
[14] https://www.japha.org/article/S1544-3191(22)00233-3/fulltext
[15] https://accessagenda.nacds.org/dashboard/
[16] https://www.nacds.org/pdfs/Opinion-Research/NACDS-OpinionResearch-National.pdf

When the expertise of pharmacies was more fully leveraged during the recent public health emergency, pharmacy interventions averted more than 1 million deaths, prevented more than 8 million hospitalizations, and **saved $450 billion in healthcare costs**.[17] Additionally, a recent study found that a 50% uptake of a pharmacist-prescribing intervention to improve blood pressure control was associated with **$1.137 trillion in cost savings** and could save an estimated 30.2 million life years over 30 years.[18]

The accessibility and clinical expertise of pharmacists and pharmacies lends very well to driving solutions that improve healthcare access, promote innovations, and mitigate preventable spending that results from suboptimal health outcomes. The unique footprint and infrastructure of community pharmacies should be leveraged in advancing healthcare solutions for the American people that prioritize outcomes, prevention, cost-savings, access, and equity. **To better leverage pharmacies in transforming healthcare to help meet the needs of the American people, NACDS strongly recommends the Subcommittee members consider:**

1. **Supporting access to pharmacist services** through the successful passage of the *Equitable Community Access to Pharmacist Services Act* (H.R. 1770/S. 2477) in Medicare Part B – and consider similar opportunities to foster beneficiary access to pharmacist services more broadly. Once enacted, S. 2477 would foster Medicare beneficiary choice to access pharmacist services for common health threats, like influenza and COVID-19, building on the effectiveness and broad reach of pharmacy-based care during the recent public health emergency, including in rural and underserved areas. Following the passage of this critical legislation, NACDS urges the Subcommittee to consider additional opportunities for pharmacies to serve the American people in the future, including to help combat rising rates of diet-related chronic diseases.

2. **Supporting food is medicine access** through the successful passage of key legislation, including the Medical Nutrition Therapy Act (HR 6407/ S 3297), the Medically Tailored Home-Delivered Meals Demonstration Pilot Act (HR 6780 / S 2133), support for the Gus Schumacher Nutrition Incentive Program (GusNIP) expansions, and others. NACDS also looks forward to future opportunities for pharmacies and pharmacy teams to play a role in advancing access and uptake to key Food is Medicine interventions, including referrals for Medical Nutrition Therapy, medically tailored meals, and produce prescriptions.

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[17] https://pubmed.ncbi.nlm.nih.gov/36202712/

[18] Dixon DL, Johnston K, Patterson J, Marra CA, Tsuyuki RT. Cost-Effectiveness of Pharmacist Prescribing for Managing Hypertension in the United States. JAMA Netw Open. 2023;6(11).

**Discussion**

***Support access to pharmacist services to promote better health and control healthcare costs***

Despite their proven ability to improve health outcomes and save downstream healthcare dollars, today, pharmacists are among the only healthcare professionals omitted from Medicare statute as Part B providers. Consequently, pharmacists' accessibility and clinical expertise have been largely untapped in promoting better care quality, value, and access, including in rural and underserved communities. Bipartisan legislation (H.R. 1770/S. 2477) would help address this omission in Medicare by providing payment for essential pharmacist services under Medicare Part B and ensure pharmacists can continue to protect vulnerable senior communities for common threats like flu and COVID-19. As mentioned above, pharmacy interventions during the COVID-19 pandemic averted more than 1 million deaths, prevented more than 8 million hospitalizations, and saved $450 billion in healthcare costs.[19] This legislation builds on that proven success and would help support Medicare beneficiaries with the option to seek routine care for common illnesses from their local pharmacies helps enhance access and quality, in a manner that meaningfully supplements existing care capacity in a tangible and cost-effective way. Consider, for example, individuals who may benefit from having additional access options and the choice to seek routine care services at their local pharmacies, instead of foregoing care until their condition worsens and ultimately leads to a costly hospital visit that could have been avoided. Congress can help the nation achieve a healthier and more sustainable healthcare system, prioritizing access, outcomes, and value by supporting the successful passage of S. 2477.

Also, it is important to consider the connection between diet-related diseases and poor outcomes from common conditions like flu and COVID-19. For example, data reported to CDC from January to May 2020 indicated that COVID-19 hospitalizations were 6 times higher and deaths 12 times higher for people with COVID-19 and an underlying medical condition such as diabetes, or heart disease.[20] There is also a strong connection between influenza and cardiovascular disease.[21]

Throughout the recent public health emergency, pharmacies were a trusted, equitable provider of vaccinations, tests, and antivirals, providing nearly 340 million COVID-19 vaccines to date, in addition to more than 42 million tests, and dispensing more than 8 million antiviral courses.[22] During 2022-2023, more than two-thirds of adult COVID-19 vaccinations were administered at pharmacies[23] and compared to medical offices during the 2023-2024 season, pharmacies provided

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[19] https://pubmed.ncbi.nlm.nih.gov/36202712/
[20] https://archive.cdc.gov/www_cdc_gov/diabetes/library/reports/reportcard/diabetes-and-covid19_1702491562.html
[21] https://www.nfid.org/influenza-vaccination-is-critical-for-patients-with-heart-disease/
[22] https://www.liebertpub.com/doi/10.1089/hs.2023.0085
[23] https://www.liebertpub.com/doi/10.1089/hs.2023.0085

more than 90% of COVID-19 vaccines.[24] With respect to testing, pharmacies provided 87% of the free tests administered through the Improving Community Access to Testing (ICATT) program.[25] Similarly, in considering pharmacies' impact on antiviral access, HHS reported that 87.5% (35,000 of the 40,000) antiviral dispensing sites were pharmacies.[26]

Pharmacies unequivocally demonstrated their ability to meaningfully expand critical access to care across vulnerable communities during the recent pandemic, and the American people have taken notice. According to a poll conducted by Morning Consult and commissioned by NACDS in October of 2023, 81% of adults in the U.S. believe it's important to update policies to ensure that patients permanently have the same access to pharmacy vaccination, testing, and treatment services that were available during the COVID-19 pandemic.[27]

Not only did pharmacies provide unparalleled access to COVID-19 vaccines, tests, and antivirals, pharmacies surpassed expectations when it came to serving vulnerable and underserved communities. For example, 43% of people vaccinated through the Federal Retail Pharmacy Program were from racial and ethnic minority groups, exceeding CDC's goal of 40% — the approximate percent of the U.S. population comprised of racial and ethnic groups other than non-Hispanic White.[28] Additionally, with respect to bivalent COVID-19 vaccinations, pharmacies administered 81.6% and 60.0% of bivalent vaccine doses in urban and rural areas, respectively.[29] Pharmacies also supported concerted efforts to foster testing and antiviral access in vulnerable and rural communities, helping to ensure access points across diverse populations, especially in those communities without other healthcare providers within reach.

**The Subcommittee can help make better healthcare access, improved outcomes, and lower downstream costs a reality by supporting the successful passage of the *Equitable Community Access to Pharmacist Services Act* (H.R. 1770/S. 2477).** More information on this important legislation is available from the Future of Pharmacy Care Coalition here.

Following the passage of this critical legislation, NACDS urges the Subcommittee to consider additional opportunities for pharmacies to serve the American people in the future, including to help combat rising rates of chronic diseases. Research strongly supports the ability for pharmacists to improve health outcomes and control healthcare costs through better prevention

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[24] https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adult-vaccinations-administered.html
[25] Miller MF, Shi M, Motsinger-Reif A, Weinberg CR, Miller JD, Nichols E. Community-based testing sites for SARSCoV-2 — United States, March 2020–November 2021.MMWR Morb Mortal Wkly. 2021;70(49):1706-1711.
[26] US Department of Health and Human Services. https://www.hhs.gov/about/news/2023/04/14/factsheet-hhs-announces-amend-declaration-prep-act-medical-countermeasuresagainst-covid19.html
[27] https://accessagenda.nacds.org/dashboard/
[28] https://www.gao.gov/assets/720/718907.pdf
[29]https://www.cdc.gov/mmwr/volumes/73/wr/mm7313a2.htm?s_cid=mm7313a2_e&ACSTrackingID=USCDC_921-DM125690&ACSTrackingLabel=%20This%20Week%20in%20MMWR%3A%20Vol.%2073%2C%20April%204%2C%202024&deliveryName=USCDC_921-DM125690

and management of chronic diseases (See Appendix A).

In fact, leveraging the proven ability for pharmacies to make an important impact on chronic disease prevention and management, NACDS has undertaken two recent Food is Medicine projects as commitments to the White House Conference on Hunger, Nutrition, and Health. **First, NACDS' Nourish My Health campaign is a nationwide public education campaign aimed at highlighting the connection between eating nutritious foods and reducing the risk of diet-related heart disease, diabetes, and cancer.** Campaign messaging highlights the following calls to action: (1) Get a baseline health screening (blood pressure, cholesterol, blood sugar/blood glucose, and body mass index) and learn about your risk for nutrition-related diseases; (2) Improve your baseline numbers by adding healthy foods to your diet to live longer and healthier; and (3) Access important information about healthy foods, lifestyle modifications, and health screenings through the campaign website and related resources. In addition to leading health organizations engaging in the campaign, a dozen pharmacy organizations have also activated in the campaign, sharing key messages and resources with their audiences across communities, and providing important interventions, like baseline health screenings. To date, Nourish My Health has achieved **175 million impressions**, reaching Americans across the country, including rural and underserved populations. The campaign has also garnered **more than 6,000 responses** to a nutrition security survey developed by the Food is Medicine Institute at the Friedman School of Nutrition Science and Policy at Tufts University. Please visit nourishmyhealth.org for more information.

**Additionally, the Milken Institute Feeding Change and NACDS are working with multisectoral stakeholders and experts to determine the policy, infrastructure, operational, and programmatic steps necessary to leverage pharmacies in expanding access to Food Is Medicine interventions, especially for communities with high rates of diet-related disease and food insecurity.** The learnings of this work, informed by 30 experts, will be available in early June, and will be leveraged to inform and promote scalable implementation of accessible and sustainable produce prescriptions across diverse communities. This work is part of a commitment by NACDS and the Milken Institute to the White House's Challenge to End Hunger and Build Healthy Communities. NACDS looks forward to continued opportunities for pharmacies to be leveraged more broadly in promoting access and uptake to Food is Medicine interventions that have demonstrated impact in mitigating harms from chronic diseases.

***Support access to Food is Medicine interventions to improve prevention and management of rising chronic diseases***

As described in the introduction, chronic diseases continue to pose a major threat to the health, wellbeing, and resiliency of the American people. Addressing these complex challenges will require collaborative solutions that help advance access and uptake to healthy food and patient

education supported by healthcare providers, including pharmacists, retail dieticians, and many others.

Several key pieces of bipartisan legislation introduced in this year's Congress offer important opportunities to advance access to Food is Medicine interventions and support the growing, robust research and evidence that demonstrates the critical value of Food is Medicine interventions. In particular, the **Medical Nutrition Therapy Act (HR 6407 /S 3297)** would expand eligibility for evidence-based Medical Nutrition Therapy (MNT) services in Medicare Part B from only people with diabetes and renal disease to encompass a more comprehensive array of chronic conditions, including prediabetes, obesity, cardiovascular disease, cancer, and others. The legislation would also allow more healthcare providers to refer Medicare beneficiaries into Medical Nutrition Therapy, including nurse practitioners, physician assistants, clinical nurse specialists, and psychologists, thereby improving needed access to MNT, which is generally provided by a registered dietician expertly trained in nutrition. Research indicates MNT is clinically effective and helps control healthcare costs, including for the conditions outlined in the bill.

Because the majority of Medicare beneficiaries have chronic conditions that can be impacted by nutrition, but may not meet current eligibility criteria for MNT today, this legislation would help fill a serious gap in Medicare Part B coverage to promote better management of chronic conditions. In the future, NACDS would appreciate the opportunity to collaborate on efforts that support pharmacists' ability to refer patients for Medical Nutrition Therapy, especially given that pharmacists see their patients far more often than other healthcare providers and can make a critical impact in expanding referrals for MNT to improve access. Consider, Medicare beneficiaries visit pharmacies significantly more often than primary care providers with 13 visits per year to pharmacies compared to 7 visits per year to primary care. That difference is even more pronounced in rural communities with 14 visits to pharmacies compared to 5 visits yearly to primary care.[30]

Additionally, the **Medically Tailored Home-Delivered Meals Demonstration Pilot Act (HR 6780 / S 2133)** would establish a four-year demonstration pilot under Medicare Part A to test clinical health outcomes and hospital readmissions for high-risk beneficiaries with diet-related chronic conditions who received home-delivered medically tailored meals. The legislation indicates that the pilot would include 20 hospitals providing 12 weeks of Medically Tailored Meals and 1 year of nutrition education for beneficiaries who participate in the demonstration. These meals are specifically designed by nutrition experts to support management of certain conditions, like diabetes, high blood pressure, and renal disease, to name a few.

Currently, medically tailored meals can be offered by Medicare Advantage plans through

[30] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7364370/

supplemental benefits, however, the majority of beneficiaries with traditional Medicare do not have access to medically tailored meals. This legislation offers an important opportunity to test potential impacts of Food is Medicine on a critical population of Medicare beneficiaries to help inform future, permanent changes to strengthen the Medicare program to best meet the current needs of beneficiaries, including changes that specifically addressing rising rates of harmful and costly chronic diseases. Given the accessibility and clinical expertise of pharmacies and pharmacists, NACDS appreciates any future opportunities to leverage pharmacies in advancing access and uptake of Food is Medicine interventions, including medically tailored meals, produce prescriptions, screenings and monitoring for chronic conditions, and other chronic disease prevention and management interventions broadly.

NACDS is also supportive of legislative efforts to fund meaningful programs that extend access to healthy foods for Americans, including the Gus Schumacher Nutrition Incentive Program (GusNIP) which offers incentives to encourage families participating in SNAP, for example, to purchase healthy foods like fruits and vegetables, among other initiatives. However, additional funding is needed to expand the impacts of this program. Legislation includes the GusNIP expansion Act (HR 4856), GusNIP Improvement Act (2. 2577), Opt for Health with SNAP (OH SNAP) Act (S 2015/HR 4149), and Local Farms and Food Act of 2023 (S 1205, HR 2323). These efforts would help support Americans in accessing healthier foods, address nutrition insecurity, advance food is medicine efforts to improve health, and help control downstream healthcare spending related to chronic diseases.

**Conclusion**

NACDS urges the Subcommittee to act on key opportunities to improve health outcomes, advance access, and reduce preventable healthcare spending, including through support for S. 2477, S. 3297, S. 2133, and others, in addition to comprehensive PBM reform. As rates of chronic disease continue to rise unsustainably, the nation needs collaborative solutions that leverage the collective expertise from across the healthcare ecosystem, including pharmacies and pharmacists. For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy at sroszak@nacds.org .

| Appendix A. Key Examples Demonstrating Pharmacists' Ability to Improve Chronic Disease Care | | |
|---|---|---|
| **Results of Pharmacist Care** | **Intervention** | **Source** |
| Statistically significantly higher improvements in the individual areas of A1c, blood pressure, and statin goal attainment – 40% of patients in the pharmacist intervention group achieved all 3 clinical goals after intervention, compared with only 12% of patients in the usual care group. | Study of patients seen in clinics within a Primary Care Network (PCN) during defined period of time. Patients included in the intervention group if they were actively managed by a PCN pharmacist and had a diagnosis of diabetes. A control group included patients without access to a PCN pharmacist and was matched to the intervention group by baseline A1c results. | *Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. (May 2018). The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home. JMCP. 2018;24(5):423-429. (Link)* |
| Results showed 637 drug therapy problems were resolved among 285 intervention patients. HEDIS measures improved in the intervention group compared with the comparison group for hypertension (71% versus 59%) and cholesterol management (52% versus 30%). Total health expenditures decreased from $11,965 to $8,197 per person. 12:1 return on investment. | MTM services provided by pharmacists to BlueCross BlueShield health plan beneficiaries in collaboration with primary care providers. | *Brian J. Isetts, Stephen W. Schondelmeyer, Margaret B. Artz, Lois A. Lenarz, Alan H. Heaton, Wallace B. Wadd, Lawrence M. Brown, Robert J. Cipolle, Clinical and economic outcomes of medication therapy management services: The Minnesota experience, Journal of the American Pharmacists Association, Volume 48, Issue 2, 2008. (Link)* |
| Mean reductions in systolic and diastolic blood pressure were 21.6 and 14.9 mmHg greater, respectively, in participants assigned to the pharmacist-led intervention than in those assigned to the active control. | Barbershops were assigned to a pharmacist-led intervention (in which barbers encouraged meetings in barbershops with specialty-trained pharmacists who prescribed drug therapy under a collaborative practice agreement with the participants' doctors) or to an active control approach (in which barbers encouraged lifestyle modification and doctor appointments). | *Victor RG, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops. The New England Journal of Medicine. April 2018. (Link)* |

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|---|---|---|
| Pilot study displayed improvement in diabetes and hypertension clinical markers associated with pharmacist provision of MTM. A1c goal achievement occurred in 52.84% of patients and hypertension control was reported in 65.21%. Pharmacists identified and resolved more than 1,400 medication-related problems and addressed multiple adverse drug event issues. | Three FQHC sites with distinct models of established pharmacist MTM services to care for patients with uncontrolled diabetes and/or hypertension. | *Rodis JL, et al. (2017). Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. Journal of Primary Care & Community Health.* (Link) |
| In a simulated cost-effectiveness analysis of a 5-state Markov model, 50% uptake of a pharmacist-prescribing intervention to improve blood pressure control was associated with a $1.137 trillion in cost savings and could save an estimated 30.2 million life years over 30 years. | A pharmacist-prescribing intervention including a wallet card, education, and usual care to improve blood pressure control in the US. | *Dixon DL, Johnston K, Patterson J, Marra CA, Tsuyuki RT. Cost-Effectiveness of Pharmacist Prescribing for Managing Hypertension in the United States. JAMA Netw Open. 2023;6(11).* (Link) |

NECPAD

The Honorable Ed Markey
Chair, Health, Education, Labor &
Pensions Committee's Subcommittee on
Primary Health & Retirement Security
U.S. Senate
Washington, DC

Dear Chair Markey,

I wish to thank you so very much for your sponsorship of the Medical Nutrition Equity Act (MNEA) in the previous Congress which is slated for reintroduction by Senator Casey soon and has also be reintroduced in the House by our bill champion, Congressman McGovern (H.R. 6892), as well as Senator Rutherford who has joined as a lead cosponsor. I write to you in the most urgent and sincere manner as the President of the New England Connection for PKU and Allied Disorders, Inc. (NECPAD) and the very proud mother of a 22-year-old amazing young woman with a rare metabolic disorder called Phenylketonuria (PKU).

I wish to commend you and the Subcommittee for its interest in "food as medicine" and for holding the April 17 hearing —"Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine." In the spirit of the hearing's focus, I wish to call your attention to the Medical Nutrition Equity Act again, which has been supported by several members of the Health, Education, Labor and Pensions Committee in previous Congresses. The bill ensures patients with GI or inherited metabolic disorders have access to medically necessary nutrition, which includes specialized foods and formulas, to treat their diseases and disorders. There is a natural connection between the issue of medical nutrition and the issue of "food as medicine" for the patients who rely on specialized foods and formulas as their medical treatment.

Established in 1995, NECPAD is an all-volunteer nonprofit organization. The Board of Directors is currently comprised of adults who live with rare metabolic disorders such as PKU and Maple Syrup Urine Disease (MSUD), PKU parents and caregivers and clinicians from Boston Children's Hospital. As a longstanding and very active nonprofit, NECPAD is deeply committed to fulfill its working mission to inspire learning, social support, research, and public policy to help develop the full potential of people affected by PKU and related Allied Disorders such as MSUD, Homocystinuria (HCU), Organic Acidemias (OA), Tyrosinemia (TYR) and Urea Cycle Disorders (UCD). All these inborn errors of metabolism (IEMs) are detected via the Newborn Screening Program and are extremely rare. NECPAD is proud to support those living with these rare disorders, their families and health care professionals throughout New England and we also join our counterparts across the nation to support our rare community here in the United States.

Nationwide it is estimated that under 20,000 persons live with these IEMs. Each disorder requires a very strict, medically prescribed nutrition regimen – a so called, extremely unique "diet for life" consisting of both specially manufactured, low protein modified foods and specially made, disease specific formula. If you were ever looking for an example of the expression, "you are what you eat", is it certainly true in the case of those with IEMs. Foods high in protein, including much of what exists in the

marketplace such as meat, fish, cheese and dairy products, pasta, rice, bread, tofu, legumes, and the like are considered toxic to those with IEMs, negatively affecting brain development, physical growth, executive functioning and sometimes leading to severe illness, hospitalization, long term disability and death. Therefore, in order to live a healthy life, those with IEMs absolutely must consume only low protein fruits and vegetables, as well as other medical nutrition - only specially made low protein foods and formulas for their lifetime as prescribed and closely followed by a physician.

Although you may not be familiar with the intricacies of each of these rare disorders, suffice it to say, that thanks to the Newborn Screening Program, the lives of each and every one of these 20,000 persons have been dramatically improved. Newborn Screening was introduced in the early 1960s here in Massachusetts and is now a nationwide, widely supported, and successful initiative. Again, thanks to early detection and treatment, a very strict, medically prescribed and physician followed "diet for life" for those with IEMs can lead to a healthy and very well-adjusted life. Without proper access to medically prescribed nutrition, those with IEM will be extremely hungry, will not thrive, will be unable to bear healthy children, will not be productive members of society, and in some cases will suffer irreversible brain damage or death.

Unfortunately, medically prescribed foods and formula are extremely expensive to manufacture, some requiring specially engineered and regulated amino acids and other special ingredients. A low protein specially made loaf of bread costs $14 and box of special pasta almost $12. The medically prescribed metabolic formulas costs upwards of $1000 - $2,500 per month. This is not affordable for the average household and has thus contributed to our community in crisis without proper nutrition. It has also resulted in extreme inequities in our rare community. Nearly 40 states require some level of coverage of medically necessary nutrition, but coverage is highly variable from state to state. Additionally, existing state laws do not reach patients enrolled in health plans covered by the Employee Retirement Income Security Act (ERISA).

Most recently, the essential nature of the importance of the treatments for these disorders was highlighted during the so called "formula shortage crisis". Although the formula shortage crisis brought the importance of access to nutrition to light recently, those with IEM have, frankly, been in crisis for several years. It is estimated, for instance, that in the PKU community we have lost to care a devastating half of our PKU community, in particular (approximately 8,000 out of 16,500), largely attributable to lack of access to proper medically prescribed nutrition due to inconsistent insurance coverage by both private and public insurance plans. This lack of access to medically prescribed nutrition defeats the very purpose of the Newborn Screening program, that is, according to the Center for Disease Control as follows, "Newborn screening identifies conditions that can affect a [person's] long-term health or survival. Early detection, diagnosis, and intervention can prevent death or disability and enable [a person] to reach their full potential."

For well over 15 years, NECPAD has joined our counterparts nationwide to advocate in Congress for the *Medical Nutrition Equity Act* (MNEA H.R. 2587/S. 2013 in the 117th and H.R. 6892 in the 118th). This bill was first introduced by Massachusetts Senator John Kerry and has had bipartisan/bicameral support since. The *Medical Nutrition Equity Act* will ensure that those with inherited metabolic disorders have access to medically necessary nutrition required to treat their condition. During the upcoming HELP subcommittee hearing, NECPAD respectfully requests that you please highlight the need for the *Medical Nutrition Equity Act* during the Subcommittee's hearing and that the Subcommittee closely examines the MNEA and helps to ensure coverage of medically necessary foods and formulas for those covered under Medicare, Medicaid, CHIP and the Federal Employees Health Benefits Program.

The importance of improving access to medically necessary nutrition for patients with GI and metabolic disorders was included in the White House's 2023 National Strategy on Hunger, Nutrition and

Health. Congress has also recognized the importance of improving coverage of medically necessary nutrition by including language similar to the MNEA in the 2016 National Defense Authorization Act for TRICARE beneficiaries. The MNEA builds on the coverage of medically necessary nutrition Congress passed for TRICARE beneficiaries by extending coverage to other payors.It is time to extend that coverage to other insured populations and to ensure there is a federal coverage floor.

Congress has recognized the importance of identifying PKU and other inherited metabolic disorders early in life and has passed and repeatedly reauthorized legislation requiring testing for these conditions through the Secretary of HHS 'Recommended Uniform Screening Panel (RUSP). Disorders are added to the RUSP because they can be treated when diagnosed early. Approximately 2,000 of the babies tested each year are diagnosed with an inherited metabolic disorder. For most of these babies, medical nutrition is their only option to survive. The New England Connection for PKU and Allied Disorders, Inc. (NECPAD) sincerely appreciates this opportunity to share its unique perspectives on what food insecurity looks like for children and adults with PKU and other IEMs.

In closing, I share with you a summary of my personal story as well as my prayer and plea for a brighter future for my family as well as my extended rare family. I am the very proud daughter of an exceptional education teacher with the City of Boston for over 38 years, and a hardworking electrician for over 45 years. My parents sacrificed, to say the least, to put me through college. I had an amazing upbringing in Dorchester – a close-knit neighborhood within the City of Boston. I worked full time while attending law school at night and graduated top 1% of my class. I worked closely for several years with four different Chief Justices within the Massachusetts Trial Court. My law partner and I currently own a small, women owned law firm. I am 29 years married to the most amazing man and an extremely hard-working plumber who has owned a small plumbing business for well over 30 years. We are blessed with two, wonderful children, one of which, our daughter, Caroline, has PKU. My law degree, while useful throughout my career, has served me well especially as I am blessed to help advocate for those in need, including my own family and my extended rare family.

I am thrilled to let you know that our Caroline, thanks to the Newborn Screening Program and her medical nutrition, is much smarter than me and my husband combined. But now that Caroline is almost 23, she is quite anxious about her future, as are we. We started advocating for the *Medical Nutrition Equity Act* when Caroline was entering kindergarten, and it still has not passed as she graduates from college. Because of that, her choices as she enters the work force are quite limited. She must find a job, and live within a state, that has adequate insurance. She is also very concerned as she wants to become a mother someday, although she assures me no time soon ☺. With her PKU, if Caroline is not STRICTLY on her medical prescribed diet before and during her pregnancy, her child, our grandchild, will most likely be born with severe birth defects, and may not survive. We, obviously, will do everything in our power to ensure this does not happen, but not all families have the wherewithal to support their children financially, or otherwise, throughout their lifetime. As a volunteer for NECPAD for well over 20 years, I am honored to help support individuals in dire need on a daily basis, and I see the devastating effects of those who do not have access to medically prescribed nutrition. The very sad part of all of this is that this is completely avoidable! With proper access to medical nutrition, individuals with PKU and IEM can lead very normal, healthy lives. I plead with you, Senator Markey, as our advocate in Congress to please help highlight the importance of this medical nutrition during the upcoming hearing. It is time, it is high time, to see the very purpose of the Newborn Screening Program fully through.

In addition to my personal story, NECPAD would be grateful if you reviewed the patient stories at nutritionequity.org/states. NECPAD also supports hundreds of its members annually and could sit for hours with you sharing their stories of devastation and thankfulness that our nonprofit is there to support them. But, as much as we certainly try, NECPAD's support is not sustainable throughout the lifetime of

an individual. Please, please help us protect our rare, vulnerable, and very deserving patients and families.

For more information or questions, please feel free to contact me anytime at denise@cqlawllc.com .

Thank you very much for taking the time to consider NECPAD's comments and requests, as well as my own personal story and plea.

With sincere gratitude,

Denise Queally, Esq.
Proud PKU Mom and President of NECPAD
The New England Connection for PKU and Allied Disorders, Inc.
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April 15, 2024

The Honorable Ed Markey
Chair, Health, Education, Labor &
Pensions Committee's Subcommittee on
Primary Health & Retirement Security
U.S. Senate
Washington, DC

The Honorable Roger Marshall
Ranking Member, Health, Education, Labor &
Pensions Committee's Subcommittee on
Primary Health & Retirement Security
U.S. Senate
Washington, DC

Dear Chair Markey and Ranking Member Marshall:

The Patients & Providers for Medical Nutrition Equity (PPMNE), a national coalition of 45 patient and provider organizations that represent individuals for whom specialized nutrition is medically necessary for treatment of their gastrointestinal (GI) or inherited metabolic disease or disorder, commend the Subcommittee for its interest in "food as medicine" and for holding the April 17 hearing — "Feeding a Healthier America: Current Efforts and Potential Opportunities for Food is Medicine." In the spirit of the hearing's focus, we call your attention to the *Medical Nutrition Equity Act (MNEA),* which has been supported by several members of the Health, Education, Labor and Pensions Committee in previous Congresses and is poised for reintroduction by Sen. Casey. The bill ensures patients with GI or inherited metabolic disorders have access to medically necessary nutrition, which includes specialized foods and formulas, to treat their diseases and disorders. There is a natural connection between the issue of medical nutrition and the issue of "food as medicine" for the patients who rely on specialized foods and formulas as their medical treatment.

The importance of improving access to medically necessary nutrition for patients with GI and metabolic disorders was included in the White House's 2023 National Strategy on Hunger, Nutrition and Health. Congress has also recognized the importance of improving coverage of medically necessary nutrition by including language similar to the *MNEA* in the 2016 *National Defense Authorization Act* for TRICARE beneficiaries. The *MNEA* builds on the coverage of medically necessary nutrition Congress passed for TRICARE beneficiaries by extending coverage to other payors. The out-of-pocket costs for specialized formulas and foods to treat GI and metabolic disorders can reach thousands of dollars per month, and, for many patients and families, cost is a barrier to access and treatment. It is time to extend coverage to other insured populations.

The 2022 formula shortage highlighted the necessity of specialized formulas for the children and adults who rely on them for both treatment and sustenance. These formulas are not discretionary for patients with Gi and metabolic disorders; they are essential to their medical management and survival. We encourage you to visit nutritionequity.org/category/states to read stories from individuals from across the country which underscore why passage of this legislation is imperative.

Our community has been advocating for passage of some version of this legislation for more than a decade. Our goal is to advance the *MNEA* this year, and we seek your support in that regard. We ask that this letter and the attached fact sheet be submitted for the hearing record. Please contact Megan Gordon Don at 202.246.8095 or mgdon@mgdstrategies.com with questions or requests for additional information.

Sincerely,

Patients & Providers for Medical Nutrition Equity Coalition

[Whereupon, at 3:45 p.m., the hearing was adjourned.]

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