Written Public Comments Submitted to PCAST

September 2, 2023 to November 22, 2023

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GENERATIVE AI PUBLIC COMMENTS

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Section 1: Juniper Gore

Hi Anne-Marie Mazza,
Knowledge Management, infused with Artificial Intelligence, is that one technology that can elevate most—if not all—metrics in the customer contact center. No wonder Gartner ranks it as the #1 technology that can transform CX, EX (employee experience), and operational performance (Source: Managing the Customer Service Experience by Jim Davies). Among the metrics that can be impacted include:

- First Contact Resolution (FCR)
- Average Handle Time (AHT)
- Annual Agent Training Hours (ATH)
- Agent Speed to Competency (STC)
- Deflection of requests for human-assisted service (e.g., calls, emails, chat) with self-service
- Unwarranted returns and exchanges
- Unwarranted field service

We can prove it with real-world customer examples and numbers, and it is all here in this article. **Read** it to know how AI-infused KM can transform your contact center and bring breakthrough value to the employee and customer experience, that is, EX and CX.

Section 2: Yonah Welker

Materials, photos, projects, recent appearances are attached, including this year Unesco, WHO, OECD, governmental taskforces

/ disability, zero exclusion.

Recent publications and open letters:

- >https://www.weforum.org/agenda/2023/08/sovereign-funds-future-assistive-technology-disability-ai/<
- >https://oecd.ai/en/wonk/eu-ai-act-disabilities<
- >https://www.weforum.org/agenda/2023/04/how-cognitive-diversity-and-disability-centred-ai-can-improve-social-inclusion<
- >https://horasis.org/disability-peace-center-ai-policy/<
- https://www.forbes.com/sites/forbestechcouncil/2023/05/09/algorithmic-diversity-mitigating-ai-bias-and-disability-exclusion/?sh=423428b8417d

Recent roundtables:

- Worldbank - closed, neurodiversity
- Unesco - >https://www.unesco.org/sites/default/files/medias/fichiers/2023/08/2023-digital-learning-week-programme-en_1.pdf<
- OECD - >https://www.oecd-events.org/ai-wips-2023/speaker/e2df6466-89c1-ed11-9f73-6045bd8890e4/yonah-welker<

Recent technology repository:

- OECD AI for assistive technologies (helped to curate - over 120 applications)

Recent government public AI programs and courses (author):

- **Human-Centered AI** (funded by EU Commission, author contract) >https://tech.eu/2021/10/29/focusing-on-the-human-shop4cf-offers-an-online-course-in-ai-and-ethics/<

In process:

- Disability-Centered AI and ethics for Linkedin (paid contract, author)

Recent frameworks:

- Unesco - AI ethics in education (will be released soon)
- WHO - Generative AI in health (will be released soon)
- AI for cognitive disabilities - >https://yonah.org/technology_research_neurodiversity_lens.pdf<
- Algorithmic cities - in the process

Recent hackathons I've curated:

- Women in AI US - >https://www.womeninai.co/usa<
- Women in AI APAC - >https://www.womeninai.co/wai-hackathon-apac<
- MIT's future of work/health
- Saudi smart cities hackathon (slightly helped at the beginning + curated the launch during the Summit) - >https://www.arabnews.com/node/2162326/business-economy<

Recent EU Commission Evaluator (expert contract):

AI Coalition, AI4EU, Horizon 2020, EIC, ISDI EdTech, TruBlo. Shop4CF, BonsApps

Recent speaking (presented by agencies - All American Speakers etc):

Unesco, AI Summit New York, AI Summit London, Responsible AI, ML Con, Dublin Tech Summit, RightsCon, World Humanitarian Forum, Times Higher Education, Women in AI, Women in IT, Wonder Women Tech, Women In Tech, She Loves Tech, IWIB, MozFest UK, Spark Fest Australia, ML Innovation, Datalift, Pondering AI, Digital AI Conclave, Disability Tech UK, Way Davos, Diversity In Tech Awards, AWE US, FWD 50, London Tech Advocates, Human Rights Copenhagen, Formwelt Institute, Horasis Summit AI US (*chairing AI for longevity panel with Hussain Al Mahmoudi), etc (2021-22)

Examples of technologies:

Beme.ai - AI for autism (advisor)
- Eyejustread - AI for dyslexia (adopting with EU Commission)
- Robokind - social robotics for emotional training (exhibitions)

Curating, evaluating, scouting for funds, EU Commission projects,
governmental and multilateral agencies, startup and inno. ecosystems:
- Open Bionics, Axiles Bionics - bionic limbs
- Scewo - smart wheelchairs
- Lea Care, Gogoa - rehabilitation and assistive robotics
- Luxai, Robokind - social robotics for autism
- SignAll - computer vision for sign language
- Audicus - hearing impairment

- FeelIf - special adaptive tactile tablets for blind kids
- Braibook - braile reading support
- Brainpower - emotion recognition smart glasses for autism
- Eyejustread - dyslexia, other examples - Bookbot, Speechify
- Ginger - chatbots for mental health
- Neuromascular support (eg. Multiple Sclerosis or paralysis) - Loro
- E-cars - Kenguru
- EEG brain systems - Emotiv, Cortex, Neurable, Melomind, VR headsets - Muse, Psious, Limbix and
- Biofeedback and interactive devices – eg. Brainwaves, Remidi

Section 3: Jose Arteaga

"*The definition of excessive income is any income greater than my income.*"

It has been said Congress doesn't want to pay WNS Sherman act violation fines because the Sherman act violation fines are too expensive.

Since 2014, WNS has been trying to work with the Federal government to control the escalating cost of cyber-security. If the Federal government is trying to save money, why did the Federal government allow the cost of cyber-security to escalate for nine (9) years?

As of June 2023, the cost of Sherman act fines is $625 billion per hour per device per 50,000 employees from June 2014 to June 2023. As explained in the email address, "WNS operating costs explained", $625 billion per hour per device per 50,000 employees is a legitimate expense when the tax payers are receiving effective cyber-security in return. The problem with Sherman Act violation fines is that the tax payers are paying $625 billion per hour per device per 50,000 employees but they are not receiving anything in
return. The Sherman Act violation fines are a penalty paid for by the tax payers because the Federal government has been criminally negligent since June 2014.

If the Federal government disagrees with this amount, since the Federal government allowed the cost of cyber-security to escalate for nine (9) years and counting, what does the Federal government believe the cost of cyber-security should be? How did the Federal government calculate that amount?

WNS is the only organization in the world that can provide an effective cyber-security product that can immediately detect and prevent all forms of URA?

"*The cyber-attacks will continue until cyber-security improves.*" ~ a cyber-attacker

Until this cost issue is resolved, the following problems will continue...

Cyber-attacks continue to plague API (Application Programming Interface), ChatGPT, EINSTEIN, VMware, Cloud, AI (artificial intelligence), AV (anti-virus), 2FA (two-factor authentication), Firewall, Encryption, Biometrics, Attestation, Google, Edge, Safari, Foxfire, Blockchain, Opera, and Log4j.

Cyber-attacks continue to plague water organizations, DoD (Department of Defense), FBI (Federal Bureau of Investigation), law enforcement organizations, judicial organizations, correctional facilities, retail **organizations, e-commerce organizations,** PoS devices (point of service), credit cards, IoT devices (internet of things, in class, in office, remote **location), children's hospitals, pediatricians, insurance organizations, hospitality organizations, airports, rail organizations, construction organizations, manufacturing organizations, supply chain organizations, critical infrastructure organizations,**

energy organizations, public transportation organizations, healthcare organizations, COVID-19 vaccine production, distribution, and administration organizations, GPS (global positioning system), RDP (remote desk protocol), autonomous vehicle technology, semiconductors, education organizations, FAFSA (Free Application for Federal Student Aid), FERPA (Family Educational Rights and Privacy Act), virtual events, IoT devices (in class, in office, and remote locations), CBPAMO (United States Customs and Border Protection), ICE (U.S. Immigration and Customs Enforcement), elections, Naval vessels, National Guard, all levels of government, the Democratic party, the Republican party, and...

- over 560 of your fellow Americans will continue to become victims of daily nation-wide cyber-attacks on automobiles and ventilators;
- Congress continues to violate:
  - House and Senate ethics laws;
  - Criminal Negligence law;
  - WNS's Sherman Act rights;
  - five (5) Presidential Executive Orders;
  - FAR (Federal Acquisition Regulations) Part 3: Improper Business Practices and Conflicts of Interest;
- your children's education continues to be adversely affected by cyber-attacks on schools and remote learning;
- your employment, financial, medical, and personal information continues to be vulnerable to data breaches potentially leading to identity theft;
- your IoT devices, websites, and virtual events continue to be vulnerable to cyber-attacks;

- cyber-crime in the U.S. has been declared a national emergency fifteen (15) times;
- businesses continue to fraudulently misrepresent their software products as cyber-security products;
- over $45 trillion per hour continues to be wasted on unnecessary and ineffective R & D;
- the average cost of a data breach has reached and possibly exceeded $116 million;
- over 60% of small businesses close within six (6) months of a data breach; and
- your fellow Americans continue to lose their jobs as a result of a data breach.

DARPA: Nobody's safe on the Internet

(February 8, 2015) Meet the man the Department of Defense has put in charge of inventing technology to secure the Internet: Dan Kaufman, a former video game developer turned cyber warrior.

What has improved in cyber-security since 2015?

It is imperative Congress pay WNS Sherman act violation fines immediately so WNS can begin the process of securing American citizens from all forms of URA. WNS looks forward to working with Congress and President Biden to secure American citizens from all forms of URA.

WNS is free to download. Contact your Representative, Senator, or Web Network Shield to protect your virtual events from all forms of URA (unauthorized remote access).

Section 4: Yonah Welker

Emerging national AI strategies (eg. France, Germany, UK, US, Japan, China), bringing focus to national safety and access to data to avoid silos, ensure fair technology competition and practices, improve literacy and capacity, and bring privacy and ethics standards. In addition, multilateral agencies such as WHO, Unesco, OECD work on area-specific guidelines to addresshealthcare, education, literacy and capacities-oriented recommendations (eg. Unesco - AI competence framework for students and teachers, 2023).

However, research and development of disability-centered generative AI systems is still a complex task both from a technology and policy perspective. It includes its intersectional nature, spectrums, comorbidities, gender and age-specific parameters, modular and multistakeholder scenarios - when families, caregivers, several devices and interfaces can be involved simultaneously, the necessity of condition-specific adoption and literacy guidelines across segments, sectors and cases.

It's increasing the role of non-AI-specific laws, and digital frameworks - the EU Digital Market and Services Acts, Accessibility Act, regional data and privacy regulation, Convention on rights of persons with disabilities

In particular, Digital Services and Digital Market Acts are aimed to affect "gatekeepers" - big technology companies and platforms, including specific articles addressing fair competition and minimizing silos, improving accountability and reporting system, transparency of algorithmic outcomes and user consent, minors and designated groups protection, identification of dark patterns and manipulation.

Can such frameworks along with the Accessibility Act complement the EU AI Act and The European AI Act to better protect groups with disabilities, bring more transparency and accountability, and minimize technological and economic silos?

Disabilities, AI systems, policies and regulation

It's important to remember that AI systems regulation addressing designated groups or persons with disabilities is not limited to one legal document but rather presented by the spectrum of legal frameworks, laws, conventions, and policies. In particular, such cases can be regulated or affected by "AI"-specific acts, related data, consumer and human rights frameworks, memorandums and conventions.

For instance, assistive technology used to support dyslexia or autism can be affected by articles of the AI Act, data regulation, specific laws protecting children and designated groups such as

the Convention of the Rights of Persons with Disabilities, and country-specific equality and non-discrimination laws.

In particular, the US is known for its "Americans with Disabilities Act", UK - 'Equality Act", France - Bill N2005-102 "for equal rights and equality of opportunities and the inclusion and citizenship of persons with disabilities", Germany - "General Equal Treatment Act ". There are similar examples in other countries.

It can accompanied by local data regulation. For instance, a recent case of temporary suspension of the ChatGPT in Italy or a series of cases in France and Ireland associated with GDPR, demonstrate how non-AI specific regulation may affect digital platforms involving AI algorithms, data collection and privacy.

However, an even bigger impact can be driven by the emerging Digital Services and Market Act, which aimed to "create a safer digital space where the fundamental rights of users are protected and to establish a level playing field for organizations", which already brought public attention related to "misinformation" cases.

Digital Services/Market Acts - digital space and fundamental rights

Digital services and Market acts present parallel sets of rules, one - addressing the side of user protection, mechanisms of the feedback loop, transparency, accountability, flagging and mitigation, and another - the organizational and economic side, including mechanisms of reporting, fair participation, competition and compliance. The initial Commission's proposal of acts was made at the end of 2020, following such frameworks as Electronic Commerce Directive. The rules and obligations presented by the Acts are set to fully apply to all regulated entities at the beginning of 2024.

There is a set of reasons why DSA/DMA comes in parallel with the EU AI Act to better regulate digital platforms and associated algorithms behind it.

- *It designates high-influence / high-risk companies and platforms* which may unfairly use market advantage, create data silos and lack transparency. In particular, DSA identifies 4 tiers of digital platforms using the number of users as a threshold. Currently, Tier 4 relates to over 45M users. So far, 19 platforms (17 very large online platforms and 2 - search engines) have been affected, including eight social media platforms: Facebook, TikTok, Twitter, YouTube, Instagram, LinkedIn, Pinterest, and Snapchat. There are also five online marketplaces impacted: Amazon, Booking.com, China's Alibaba AliExpress, and Germany's Zalando. In comparison to Tier 1-3 which is overseen by member states and designated "competent authorities", Tier 4 is under supervision by the Commission. At the same time, the DMA introduces the definition of the "gatekeepers", using market influence, business leverage and economic position (turnover, number of users and business agents) as a threshold to identify

particular market players such as Alphabet, Amazon, Apple, ByteDance, Meta, and Microsoft

- *It brings the legal and oversight framework* in parallel to the AI Act and data regulation. In particular, it aims to achieve similar objectives, including fair competition and accountability, protecting users' rights and vulnerables groups such as minors, avoiding misinformation, manipulation, keeping transparency and user consent. Similar to the AI Act, it uses the 4-tiers logic, identifying different levels of platforms, risks, associated monitoring, assessment and compliance measures. Similar to data regulation, it keeps the role of the member states, specifically for local cases and entities with less economic leverage, but it keeps the direct Commission involvement for systemic issues, large-scale cases, anti-trust proceedings, DSA's Tier 4 and DMA's gatekeeper's lists;
- *It doesn't replace existing legislation.* It doesn't directly identify what is illegal but rather proposes a framework that helps to identify risks, rules and actions, since what constitutes illegal content or actions is defined in other laws either at the EU level or at the national level. In particular, DSA leverages the concept of "trusted flaggers" - specialized entities that may identify illegal content or actions. It also provides users with better mechanisms to complain to the platform, seek out-of-court settlements, complain to their national authority in their language, or seek compensation for breaches of the rules.
- *It addresses specific AI-based mechanisms and algorithms.* It includes recommendation engines, personalization, profiling and targeting. In particular, it requires providing an explanation of the recommendation engines and mechanism why particular content or product was recommended. It also bans targeted advertising on online platforms by profiling children or based on special categories of personal data such as ethnicity, political views or gender
- *It highlights less visible but high-impact violations such as misinformation, manipulation or privacy breaches.* It also brings more focus to dark patterns' on the interface of online platforms, referring to misleading tricks that manipulate users into choices they do not intend to make which also can be connected to the use of generative AI
- *It helps to not only "regulate", but "facilitate" the digital ecosystem, bringing formats to user rights, agency, oversight and reporting.* It's known that Very Large Online Platforms and Search Engines (tier 4) already started to publish transparency reports under the DSA, at least 5 platforms participated in a "stress test" related to harmful content and actions, users, experts and institutions provided their feedback related to flagging and feedback loop.

How DSA and similar frameworks can bring more protection to the disability-centered AI ecosystem

Disabilities present combinations of spectrums, conditions, involved stakeholders and technologies, making it difficult to regulate it from the point of view of the general AI regulation, but can be complemented by consumer, digital and data-protection acts, overseeing distortions and violations behind the algorithms.

Digital Services and Market Acts (and their further evolution) could specifically improve mitigation of:

- **Multiple stakeholders and minors protection.** Not only assistive technologies but digital platforms for individuals with disabilities can be used by several users, including caregivers. It specifically finds its place in platforms targeting cognitive disabilities such as autism when one interface can be dedicated to the child and another - to the parent. DSA/DMA brings different categories of actors and an opportunity for flagging harmful actions or additional minors' protection
- **Invisible risks, misuse, manipulation.** Generative AI can be used for a variety of cases of digital accessibility from speech-to-text or image-to-speech systems, accessible design and interfaces involving adaptive texts and fonts to knowledge and education platforms that may serve the purpose of assistive accommodation, social protection and micro-learning, equality training and policing. However, similar algorithms can be used to spread misinformation among patients, create deepfakes or manipulate users. DSA/DMA's articles highlighting "dark patterns", misinformation and other harmful techniques
- **Privacy breaches, transparency, consent.** In some countries, governmental agencies were accused of using data from social media without consent to confirm patients' disability status for pension programs. The code of conduct or mechanisms of consent used by social networks, learning, assistive and other digital platforms which lack transparency or may mislead users and their decisions, can be regulated by DSA/DMA
- **Profiling, generalizations.** Medical and social services are known to use "profiling" - grouping people on their interests instead of personal traits - which may lead to discriminatory outcomes. Similar to the GDPR's articles addressing profiling, DSA/DMA introduces additional requirements in this field, specifically towards minors and designated groups
- **Participation.** Finally, algorithmic distortions and errors related to disabilities are largely related to historical and statistical underrepresentation. For instance, it's known that some facial recognition systems were created without acknowledging some facial impairments, legal and judicial systems to be trained on publicly available data sets, beyond their specific jurisdiction, overlooking the participation of particular groups and populations, language models - containing negative sentiment towards "disability" keywords, assessment platforms to be trained using standards of "normality". Designation of more specific actors and stakeholders, active participation and agency could bring more opportunities to protect groups with disabilities.

Accessibility Act and the Way Forward

As we discussed previously, algorithms do not create biases, but rather mirror social and historical distortions presented in society, statistics, existing practices and approaches. DSA/DMA logically complements the AI Act's categories of systems, but categorizes platforms, organizations and market players behind the algorithms, their economic position and influence, the potential scale of risks and responsibility, and mechanisms of oversight.

It brings the opportunity to better address non-algorithmic distortions, including social and market factors, competition and silos. It also brings a critical component of participation of different types of designated stakeholders, feedback loop between developers and users, creating a consistent set of values and expectations, transparent reporting.

Finally, to better address the needs of the population with disabilities, it's important to connect algorithms, platforms and topology of assistive and accessibility as connected ecosystems. This objective could be better achieved with European Accessibility Act - a directive that aims to improve the functioning of the internal market for accessible products and services, by removing barriers created by divergent rules in Member States. It covers products and services that have been identified as being most important for persons with disabilities. This directive could be complemented by repositories, reports and guidelines driven by OECD and WHO.

Following our session with Unesco in Paris this September, WEF - in October and formed ministry task force and WHO's framework.

Recent publications and open letters:

- >https://www.weforum.org/agenda/2023/08/sovereign-funds-future-assistive-technology-disability-ai/<
- >https://www.weforum.org/agenda/2023/11/generative-ai-holds-potential-disabilities/<
- https://oecd.ai/en/wonk/eu-ai-act-disabilities
- >https://www.weforum.org/agenda/2023/04/how-cognitive-diversity-and-disability-centred-ai-can-improve-social-inclusion<
- >https://horasis.org/disability-peace-center-ai-policy/<

NUTRITION PUBLIC COMMENTS

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Section 1: Abby Bownas

Written: 9/6/2023

Please find attached comments from members of the National Produce Prescription Collaborative. We appreciate your interest in nutrition research and look forward to the opportunity to respond. Please reach out with any questions.

Best,

Abby Bownas

NPPC Federal Policy Workgroup

>https://www.nppc.health/<

National Produce Prescription Collaborative
Response to the President's Council of Advisors on Science and Technology
Request for Information About Nutrition Research

September 5, 2023

Dear Co-Chairs Woteki and Colón,

The National Produce Prescription Collaborative (NPPC) appreciates the opportunity to support nutrition science. We wish to reiterate our support for the below NPPC member comments that were recently submitted in response to the PCAST request and/or the National Institutes of Health's (NIH's) Request for Information (RFI): Food is Medicine Research Opportunities.

A Produce Prescription (PRx) is a medical treatment or preventative service for eligible patients due to diet-related health risks or conditions, food insecurity, or other documented challenges in access to nutritious foods, and are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, PRx is designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction. This definition was established through a detailed community consensus process at NPPC and we encourage PCAST, the NIH, and others to utilize this definition.

The NPPC is a collaborative of stakeholders working to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for PRx to improve health outcomes, equity, and costs within the healthcare system. Our member organizations are committed to federal and state policy change that leverages PRx as a clinical treatment or preventative service for diet-related conditions and further embeds this effective model into healthcare and food retail systems.

The NPPC member organizations represented in the attached comments recognize the fundamental importance of continued research into and evaluation of Food is Medicine (FIM) models, including PRx, to advancing uptake of these beneficial programs across health plans and health care systems.

Additional nutrition research is needed. Despite 50+ publications in peer-reviewed literature and hundreds of programs being subject to independent academic evaluation, "insufficient research" is frequently cited as a primary barrier to healthcare coverage for the PRx benefit by health plans and policymakers alike. NPPC's goal is to "Embed PRx as a covered benefit for members of all government-sponsored health plans…" and thus we urge NIH to fund research that (a) closely aligns with research methods criteria utilized by FDA to demonstrate safety and effectiveness of prescription pharmaceuticals and medical devices and (b) is replicable in the current healthcare economics within the United States.

PRx programs have already benefited from extensive and voluminous research relative to other FIM interventions, but would nonetheless benefit from targeted investigation utilizing methods that are familiar to the healthcare industry (i.e., similar to clinical trials that measure safety and effectiveness of pharmaceutical interventions). Though robust, current research is only minimally available using methods such as control groups, or with cohorts of sufficient size and power to infer results to populations of tens, if not hundreds of thousands. Additionally, a more narrow examination of diagnosis and eligibility criteria, as well as PRx dosage and duration, are research gaps that would benefit from more extensive analysis. Lastly, improved research design across the FIM intervention spectrum would be valuable as little is known about the differences in the interventions and how a patient may effectively taper or move from one form of FIM treatment to another.

In terms of translating this research into coverage, represented NPPC members would further encourage the Administration partners, including the members of PCAST, to consult with MEDPAC and MACPAC, the bodies responsible for executing coverage and cost share analysis for clinical treatments in the Medicare and Medicaid programs, as well as analogous partners at the Veterans Health Administration, Indian Health Service, and TRICARE, when determining research study design and methods for research designed to advance the knowledge and utilization of FIM in the clinical setting.

Replicability should also be an essential consideration for NIH-FIM research. Despite repeated success that PRx and other FIM interventions have had in reducing HbA1c and blood pressure while improving patient satisfaction and engagement, many of the funded studies are not evaluating a program that is replicable, primarily due to administrative expenses. Health plans have been willing to consider the cost of the patients' food with no more than $1 or $2 per member per month in administrative fees. We urge NIH-FIM research to prioritize investigation of FIM models that can be replicated under current health economics.

The below member comments further elaborate on many of the points included in this letter. Thank you for this opportunity to share these views in response to the request for information. We look forward to future opportunities to engage with the agency on this important work.

Sincerely,

Abby Bownas

National Produce Prescription Collaborative Federal Policy Working Group

NPPC Member Comments

- The Center for Health Law and Policy Innovation (CHLPI)
- Point 32 Health
- Reinvestment Partners - Response to PCAST
- Tufts University
- UC San Francisco Seligman Lab

Section 2: Erika Hanson

Written: 9/12/2023

Dear PCAST Nutrition Working Group Co-Leads Woteki & Colón:

Please see the attached comments in response to the President's Council of Advisors on Science and Technology's (PCAST's) *Request for Public Input on Nutrition Research*.

We appreciate the opportunity to provide feedback on this important issue and would be happy to work with PCAST to further address any of our comments.

Sincerely,

Erika Hanson

CENTER *for* HEALTH LAW *and* POLICY INNOVATION
HARVARD LAW SCHOOL

September 12, 2023

Catherine Woteki & Frances Colón
Nutrition Working Group Co-Leads
President's Council of Advisors on Science and Technology
1600 Pennsylvania Ave. NW
Washington, DC 20500

Submitted via email to pcast@ostp.eop.gov

Re: President's Council of Advisors on Science and Technology (PCAST) Request for Public Input on Nutrition Research

Dear PCAST Nutrition Working Group:

The Center for Health Law and Policy Innovation of Harvard Law School (**CHLPI**) appreciates the opportunity to provide comments in response to the President's Council of Advisors on Science and Technology's (**PCAST**'s) *Request for Public Input on Nutrition Research*.

CHLPI advocates for reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. We have an active portfolio dedicated to addressing unmet health-related social needs (**HRSN**) through health care delivery and financing. For a number of years, CHLPI has worked with stakeholders including health systems, private and public health plans, community-based organizations (**CBO**s), and government officials across the country to address the damaging impact of food insecurity on health outcomes through health system reform that better supports innovative and equitable health care solutions, including Food is Medicine interventions such as medically tailored meals, medically tailored groceries, and produce prescriptions.

We applaud PCAST – as well all federal agencies and departments collaborating on the Request – for their efforts to better understand current opportunities to advance nutrition research and ensure equitable access to the benefits of that research. We urge continued momentum on this topic to further accelerate much-needed policy change and to expand access to these critical interventions.

1. **How can the United States obtain the greatest return from federal investment in nutrition research?**

A large and steadily growing body of research shows the power of Food is Medicine (**FIM**) – treatments such as medically tailored meals, medically tailored groceries, and produce prescriptions, that are designed to respond to the nutrition needs of patients with diet-sensitive diseases – to produce statistically significant improvements in food security, diet quality, disease

management, and health care costs.[1] Still, crucial gaps remain. A focused research effort on FIM interventions provides important opportunities, not only to examine clinical and cost outcomes, but also to glean key learnings on program implementation to strengthen the nutrition and health care landscape as a whole. Quantitative data on health markers, readmissions, and health care use and cost are crucial to prove that FIM interventions improve health outcomes and help to control the cost of care; however, assessing the practicability of FIM interventions is crucial to provide context to quantitative data. Acceptability to participants; operational details such as access mechanisms; and resource and infrastructure capacity at the health care provider and CBO levels are just a few of the many implementation considerations that may contribute to the merits or challenges of different FIM strategies. We encourage analysis of process, implementation, and engagement metrics to illuminate the experiences of patients, health care providers, and CBO partners across the FIM spectrum.

a. What are the crucial evidence gaps in nutrition research and what steps could PCAST recommend that would substantially fill those gaps?

In considering high priority research gaps, we offer three opportunities to deepen our collective understanding of FIM.

First, key research questions remain open across the spectrum of FIM interventions. More robust research is needed to determine the appropriate intensity and duration of FIM interventions to support desired health outcomes, and to determine the value of scaling FIM interventions to the household level. Further research is also needed in multi-pathway interventions; for example, examining the efficacy of interventions that include food and nutrition education as compared to food-only interventions. Finally, questions surrounding the end of FIM interventions remain largely unexplored: further research is needed on the efficacy of 'step downs' to less intensive FIM interventions, as well as the maintenance of health outcomes following the conclusion of FIM services.

Second, there are opportunities to deepen areas of existing research on specific FIM interventions. While a well-developed body of research supports the efficacy of Medically Tailored Meals (MTM) in improving health outcomes and reducing health care utilization and spending, interventions such as Medically Tailored Groceries (MTG) and Produce Prescriptions

[1] *See, e.g.*, Aspen Institute and Center for Health Law and Policy Innovation of Harvard Law School, FOOD IS MEDICINE RESEARCH ACTION PLAN (Jan. 2022), https://www.aspeninstitute.org/wp-content/uploads/2022/01/Food-is-Medicine-Action-Plan-Final_012722.pdf [hereinafter "FOOD IS MEDICINE RESEARCH ACTION PLAN"]; Kurt Hager et al., *Impact of Produce Prescriptions on Diet, Food Security, and Cardiometabolic Health Outcomes: A Multisite Evaluation of Produce Prescription Programs in the United States*, 16 CIRC. CARDIOVASC. QUAL. OUTCOMES e009520 (2023), https://doi.org/10.1161/CIRCOUTCOMES.122.009520; Huong Q. Nguyen et al., *Association of a Medicare Advantage Posthospitalization Home Meal Delivery Benefit with Rehospitalization and Death*, 4 JAMA HEALTH FORUM e231678 (2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2806411; Lu Wang et al., *Health and Economic Impacts of Implementing Produce Prescription Programs for Diabetes in the United States: A Microsimulation Study*, J. AM. HEART ASSOC. e029215 (2023), https://doi.org/10.1161/JAHA.122.029215; Kurt Hager et al., *Association of National Expansion of Insurance Coverage of Medically Tailored Meals with Estimated Hospitalizations and Health Care Expenditures in the US*, 5 JAMA NETW. OPEN e2236898 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797397; Alan S Go et al., *Effect of Medically Tailored Meals on Clinical Outcomes in Recently Hospitalized High-Risk Adults*, 60 MED. CARE 750 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9451942/pdf/mlr-60-750.pdf.

would benefit greatly from similarly rigorous study design focused on key clinical outcomes. While existing research on MTG shows improvement in health outcomes including blood pressure, further exploration of the acceptability of the intervention and its non-clinical benefits at the individual and household levels are needed. Produce Prescriptions benefit from the most voluminous research of any FIM intervention, but would nonetheless benefit from targeted investigation of efficacy in specific patient populations; cost-effectiveness; and the role of nutrition education as part of the intervention. Improved research design across the FIM intervention spectrum is also valuable: appropriately powered research that includes process and engagement metrics is vital to ensure that research is not extractive, and that results may be translated into policy and practice.

Lastly, a coordinated, whole-of-government approach to FIM research creates an important opportunity to center equity as a research focus. We encourage the PCAST to act purposefully in using its influence as a policy advisor to drive toward more equitable FIM research. Equity-focused FIM research must take into account the diverse experiences and broader context of the populations who receive FIM interventions. It must include qualitative data alongside quantitative measures to provide meaningful context. It must also include perspectives from key stakeholders, such as CBOS with strong connections to study participant populations, and meaningful opportunities for contribution from people who use FIM interventions.[2]

b. What tools, methods, or other resources (in addition to funding) are needed to conduct that research?

Prioritized research, as laid out above, that can be successfully translated into policy and practice should be paired with infrastructure development – for CBOs providing research-based nutrition interventions (e.g., specialty providers such as medically tailored meal and produce prescription organizations, food pharmacies co-located in hospitals and clinics, food banks), health care providers (e.g., physicians, nurses, physicians assistants, dentists, registered dietitian nutritionists, doulas, community health workers) screening and referring for nutrition interventions, and patients and communities utilizing nutrition interventions.

Community-based organizations: Integration into health care system processes, policies, and procedures is new for many CBOs that are otherwise poised to offer their Food is Medicine services. Infrastructure investments are therefore necessary in order to support CBOs as they develop the necessary building blocks for health care partnership and related research. Common core features of relationships between a health system and a FIM CBO that create demands for staffing, resources, and other investments include:

- Health care-CBO partnership development and relationship management (including responsibilities such as contracting and credentialing)
- Provider and beneficiary outreach
- Referral systems and care management
- Billing (claims or invoicing) and reimbursement
- Quality improvement

[2] Additional information on all of these priorities can be found in the *Food is Medicine Research Action Plan*, a comprehensive report prepared by the Aspen Institute and CHLPI in 2022. FOOD IS MEDICINE RESEARCH ACTION PLAN, *supra* note 1.

- Compliance with health care laws
- Reporting and evaluation

To this end, several Medicaid 1115 waivers experimenting with food- and nutrition-related services (e.g., in California, Massachusetts, and Oregon) allow states to claim federal financial participation in infrastructure investments. The funding is available for activities such as:

- **Technology** (e.g., electronic referral systems, shared data platforms, EHR modifications or integrations, screening tools, case management systems, databases/data warehouses, data analytics and reporting, data protections and privacy, accounting and billing systems)
- **Development of business or operational practices** (e.g., procurement and planning, developing policies and workflows for referral management, privacy, quality improvement, trauma-informed practices, evaluation, and member navigation)
- **Workforce development** (e.g., cultural competency training, trauma-informed training, traditional health worker certification, training staff and volunteers on new policies and procedures)
- **Outreach, education, and stakeholder convening** (e.g., potential beneficiary engagement and coverage coordination, design and production of outreach and education materials, translation, obtaining community input, investments in stakeholder convenings)[3]

In doing so, these demonstration projects recognize and respond to the important role of infrastructure in ensuring implementation and research success. As PCAST and other federal agencies pursue a vision for the future of nutrition research, especially implementation science research, it will be critical to similarly acknowledge and include funding provisions for infrastructure development.

Health care providers: As knowledge of the connections between food and health has grown, health care payers and systems have increasingly required health care providers to screen for food and/or nutrition security and connect patients to responsive services. However, many health care providers receive little or no training regarding these functions during their formal education. It is therefore critical that training on patient nutrition and responsive services be built into training curricula for providers across the health care team.

This training should accurately reflect the specific steps that health care providers may need to complete as part of high-quality patient care. This includes not only education on the connection between nutrition and health across the life span, but also training on the practical skills needed to identify and respond to nutrition needs. For example, health care providers are increasingly expected to screen for food and/or nutrition insecurity, provide basic nutrition counseling, make referrals to specialists (e.g., registered dietitian nutritionists (RDNs), social workers, etc.), connect patients to responsive services in the community, and accurately record patient nutrition needs in the medical record. Therefore, to adequately prepare health care providers, curricula must incorporate training on each of these steps – e.g., training on validated screening tools (e.g.,

[3] CENTERS FOR MEDICARE & MEDICAID SERVICES, *Addressing Health-Related Social Needs in Medicaid* (Dec. 6, 2022), https://www.medicaid.gov/sites/default/files/2023-01/addrss-hlth-soc-needs-1115-demo-all-st-call-12062022.pdf.

the Hunger Vital Sign™), responsive resources available in their community, tools that can be used to find services (e.g., online inventories and social services platforms), and the steps needed to make effective referrals.

In providing this training, training programs should consider using strategies that help reinforce key points over time via varied modalities. For example, incorporating nutrition-related training longitudinally across the curriculum (e.g., incorporating elements of nutrition training in both classroom and clinical components of the curricula) can give students greater practice and confidence in applying nutrition-related skills. Additionally, incorporating team-based care (e.g., bringing RDNs or RDN trainees into medical and dental curricula) can prepare students to work more effectively with specialists across the care team in professional settings.

Finally, it is important to recognize that in the absence of policy change, the curricula of health care training programs may be slow to adapt. Given competing demands, health care training programs may be hesitant to build new nutrition-related content into their curricula without the resources and incentives to do so. The Food Law and Policy Clinic of Harvard Law School has therefore outlined a range of policy options that could create these incentives, especially through changes to the accreditation requirements and required testing.[4]

Patients and communities: There are significant opportunities to provide nutrition training to individuals and families through community programs and institutions. For example, educational institutions (K-12, colleges, and universities) have the potential to provide services to either connect students to FIM services or prevent the need for such services in the long-term. First and foremost, these institutions can use their curricula to provide training to students on the connection between food and health and on practical skills (e.g., cooking skills) needed to maintain their nutrition. In doing so, such institutions can help to prevent the onset of diet-related disease, thereby reducing the need for FIM interventions over time. Additionally, these institutions can act as a connector for students and their families – by developing capacity to identify and connect students to nutrition resources in the community such as SNAP, WIC, SNAP-Ed, food pantries, and FIM programs. In doing so, educational institutions can provide not only the education, but also the access to nutritious foods needed to maintain health.

Additionally, though, many individual community members may already be experiencing diet-related disease. For these individuals, more specific education and training may be required. A number of such training programs – such as Medical Nutrition Therapy (MNT), Diabetes Self-Management Training (DMST), and the Diabetes Prevention Program (DPP) – already exist. However, access to these programs is often limited by issues related to health insurance coverage. Federal and state agencies and other health care leaders therefore have an opportunity to expand access to disease-specific nutrition education by identifying gaps in coverage and other barriers, and taking action to respond. For example, in previous sessions of Congress, proposed legislation such as the Medical Nutrition Therapy Act of 2021 (H.R. 3108, S. 1536) has identified and sought to address gaps in insurance coverage for MNT.

[4] HARVARD LAW SCHOOL FOOD LAW AND POLICY CLINIC, *Doctoring our Diet: Policy Tools to Include Nutrition in U.S. Medical Training* (Sept. 2019) https://chlpi.org/wp-content/uploads/2013/12/Doctoring-Our-Diet_-September-2019-V2.pdf.

c. Are there other barriers to research (other than inadequate funding)?

Through a community-based participatory research approach, individuals who are affected by policy change can best identify the problems they face and the best solutions for those problems. For example, in one California produce prescription pilot with a research-evaluation component, a CBO identified that some of its clients may prefer the produce prescription program's paper vouchers, which tend to be more likely to be accepted at local corner and ethnic markets than produce prescription cards. The produce prescription program is trying to secure funding to expand this option.[5]

Our CBO partners have also identified geography as a common participation barrier. CBOs scaling FIM programs frequently encounter delivery barriers for beneficiaries in rural areas, those with limited transportation, and/or in geographic areas without sufficient access to healthy food retailers. Programs have addressed these challenges by offering home delivery, shipping, and mobile markets. For example, Corbin Hill Food Project in New York is developing a home delivery model and is also exploring covering transportation costs. About Fresh in Massachusetts deploys Fresh Truck mobile produce markets to 18 sites. In some instances, however, these barriers have been insurmountable, leaving many without access to community-driven services. To address these challenges, states and health plans could provide funding for delivery and shipping through reimbursement rates. Rate guidance could also allow for increased rates for rural areas and local providers seeking to address expanded geographies, populations, or other unmet needs. Finally, states and health plans can cover beneficiary transportation to access benefits. North Carolina's 1115 Healthy Opportunities Pilot Program covers public and private transportation to facilitate the provision of HRSN services. This includes transportation to a grocery store or farmer's market.

d. Are there models from other fields of science that could be employed to fill nutrition research evidence gaps?

As emphasized in the Aspen Institute and CHLPI's *Food is Medicine Research Action Plan*, "provision of something so essential and meaningful as food coupled with a complex health care system that is often difficult to navigate – and, for some, difficult to trust" demands that research and interventions center equity and the identity and perspectives of research participants and the intended intervention recipients.[6] Individuals with lower-incomes disproportionately suffer from diet-related chronic conditions. This includes a disproportionate number of people of color, immigrants, and people with disabilities, who are over-represented in lower socio-economic income brackets due to policies and systems that have historically denied equal opportunity for employment, health care, and nutrition supports. These factors demand a heightened level of attention to ensuring community participation in research conception, design, execution, interpretation, dissemination, and translation in order to avoid missteps and potential harms.

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[5] Erika Hanson et al., Center for Health Law and Policy Innovation of Harvard Law School, *Building Partnerships to Advance Nutrition in California's CalAIM Waiver: Vouchers 4 Veggies, Health Net, and El Concilio* (June 29, 2023), https://www.healthlawlab.org/wp-content/uploads/2023/06/CalAIM-Case-Study-V4V-El-Concilio-Health-Net-FINAL.pdf.

[6] FOOD IS MEDICINE RESEARCH ACTION PLAN, *supra* note 1, at 38.

A key research strategy for obtaining local community input is a community-based participatory research (CBPR) approach. CBPR is a research approach in which researchers, those with lived experience, and organizations providing relevant services to community members collaborate equitably on all aspects of the research process, including identifying and defining the problem, developing the research design, conducting the research, interpreting the results, and determining how the results should be used for action. Building on this approach, the *Food is Medicine Research Action Plan* contains nine concrete recommendations for centering equity and obtaining community input throughout the Food is Medicine research continuum.[7] For example, researchers should establish fair compensation policies for research advisors or co-investigators with lived or local experience, allow for flexibility in research timeline and planned activities so that the research plan can be adjusted in accordance with feedback and input from these individuals, and integrate long-term skills and capacity building efforts. Additionally, researchers and funders should seek out perspectives and potential partnerships with CBOs that provide services or support the study's target population. These organizations can leverage local expertise and help to illuminate opportunities or barriers to scaling access to FIM interventions.

FIM researchers and implementers throughout the country have been putting these strategies and recommendations into practice. For example, in California, Medicaid managed care plans, CBOs and researchers are working together to develop evaluations for their programs under the state's Medicaid section 1115/1915(b) waiver, which allows managed care plans to provide optional FIM services to Medicaid beneficiaries.[8] CBOs have emphasized their ability to provide health plans and researchers with qualitative information from members, such as testimonials and outcomes-related measures from pre- and post-intervention surveys that include questions regarding general health, hospital admission, medication adherence, and food insecurity.

2. How could/should research-based interventions for primary and secondary prevention of diet-related chronic diseases be introduced into federal programs?

Historically, financial support for research-based nutrition interventions has been provided through public and private grants on a limited or pilot basis. These programs provide critical resources for launching, evaluating, and expanding access to nutrition interventions. But they are typically not long-term solutions. However, as focus on the social determinants of health and as outcomes from pilot programs have shown their ability to improve health outcomes and health care costs, support through sustainable funding pathways has grown.

While research-based FIM interventions have yet to be included under baseline coverage in Medicaid or Medicare, a growing number of flexibilities in these programs have enabled some inroads for reimbursement. These innovations tend to create broader access to and more sustainable funding for the actual food provided to qualifying health care beneficiaries through these programs.

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[7] *Id.* at 81-88.

[8] Erika Hanson et al., Center for Health Law and Policy Innovation of Harvard Law School, *Building Partnerships to Advance Nutrition in California's CalAIM Waiver* (June 29, 2023), https://www.healthlawlab.org/2023/06/building-partnerships-to-advance-nutrition-in-californias-calaim-waiver-a-case-study-series/.

- In Medicaid, a growing number of states have incorporated access to FIM interventions into section 1115 waivers. Medicaid Managed Care also presents a key reimbursement opportunity in Medicaid. With recent guidance and proposed regulations from CMS on the scope of flexibilities to provide FIM under In Lieu of Services, many state Medicaid departments and their managed care providers are beginning to blaze a trail down this exciting pathway.[9]
- In Medicare, the rapid growth of new policy pathways, such as coverage for food, produce, and meals under Special Supplemental Benefits for the Chronically Ill (SSBCI), shows promise for nationwide scaling of FIM interventions for beneficiaries who need them most. SSBCI coverage of food and produce ballooned rapidly, from 101 Medicare Advantage plans in 2020 to 929 in 2023, and coverage of meals beyond a limited basis has increased from 71 to 422 Medicare Advantage plans during the same period.[10] These offerings represent a key opportunity to address diet-related chronic illnesses in some of the highest-need patient populations.

Each of these reimbursement strategies would benefit greatly from increased visibility and more robust reporting on best practices and key outcomes. These innovative policies create natural experiments for FIM interventions, and we encourage the PCAST to consider its role – in partnership with its collaborating agencies – in incentivizing CMS, Medicaid agencies, individual plans, and other stakeholders to capture data and evaluate the impact of their implementation.

Continuing to advance policy changes to allow payment for FIM services through health care programs such as Medicaid and Medicare is critical to expanding access. However, we recognize that even with these changes, some populations will be left without access to much-needed FIM services (e.g., uninsured populations, the broader household of FIM recipients, etc.). We therefore encourage policymakers to consider these gaps when developing programs and research, and identify opportunities to collaborate across sectors (e.g., federal, state, health care, and philanthropic) to address them.

For example, for maximum and equitable service access, impact, and research value, policymakers and other across-sector stakeholders can help ensure success and scale of research-based nutrition interventions by (1) ensuring fee schedules and reimbursement rates are developed to promote equity and service access, (2) streamlining and adjusting health care processes to respond to the realities of community-driven services, and (3) investing in CBO infrastructure and capacity building. These adjustments and investments are critical. In states with Medicaid section 1115 waivers, CBO providers of FIM services have noted that low reimbursement rates have created equity issues where rates do not cover attempts to provide services in additional and/or rural geographies where providers are looking to fill unmet needs. CBOs also have to expend sizable, repeated infrastructure funds to address the same or similar legal questions (such as HIPAA compliance) and practical barriers (such as referral software)

[9] More information on each of these pathways can be found in CHLPI and DC Greens' recent report, Kristin Sukys et al., Center for Health Law and Policy Innovation of Harvard Law School & DC Greens, MAINSTREAMING PRODUCE PRESCRIPTIONS IN MEDICAID MANAGED CARE: A POLICY TOOLKIT AND RESOURCE LIBRARY (June 2023), https://chlpi.org/wp-content/uploads/2023/06/Mainstreaming-Produce-Prescriptions-in-Medicaid-Managed-Care-V6.pdf.

[10] *See* ATI Advisory, *New, Non-Medical Supplemental Benefits in Medicare Advantage in 2023* (Feb. 2023), https://atiadvisory.com/resources/advancing-non-medical-supplemental-benefits-in-medicare-advantage/.

across multiple different partnerships where guidance is unclear or standards are not aligned. Clarifying and streamlining these processes would increase efficiency and allow these funds to be directed elsewhere. In many instances, federal agencies such as Department of Health and Human Services have the jurisdiction, expertise, and opportunity to provide this clarity.[11] Finally, CBOs need infrastructure and capacity building funds to implement changes. Reimbursement rates in Medicaid and Medicare do not cover these administrative costs. Both public and private actors – government, health plans, food retailers, foundations, and nonprofits – can assist CBOs with the above to implement sustainable and scaled community-driven FIM programs with maximum and equitable research value.[12,13]

3. **What can be done to assure equitable access to the benefits of the federal nutrition research investment?**

Food is Medicine services have a tremendous role to play in our country's ability to address nutrition disparities and unequal access to nutritional foods. Participants in Food is Medicine services are offered a range of tools – from education to supplies to food – that support improved diet quality, dietary intake and food security, and health outcomes.

Factors that may impact effectiveness among excluded and marginalized groups include:

- Cultural competency
- Diversity of foods available and whether they are acceptable to individuals with different cultural backgrounds and across different geographies and seasons
- Geographic reach of Food is Medicine services
- Stigma
- Circumstantial and relational barriers (e.g., whether the success of the service depends on having access to transportation or childcare, on having time, knowledge, and equipment to prepare food, on stable housing, on the presence of other family members in the household across which food will be divided, etc.)
- Eligibility barriers (e.g., whether the service relies on someone having health insurance or regular access to health care, legal status in the United States, etc.)

The Aspen Institute and CHLPI's *Food is Medicine Research Action Plan* includes several concrete recommendations for ensuring that research is conceived, designed, executed, implemented, and disseminated using equity principles. At a high level, those recommendations are:

[11] *See* Letter to Director Melanie Fontes Rainier, Letter to HHS Office for Civil Rights re: HIPAA and Enabling WHC Commitments (Jan. 11, 2023), https://www.healthlawlab.org/wp-content/uploads/2023/01/Letter-to-HHS-Office-for-Civil-Rights-re-Role-Enabling-WHC-Commitments-2022.pdf.
[12] S*ee* Milken Institute, *Market Solutions for Scaling Food Is Medicine Prescriptions* at 10-14 (June 2023), https://milkeninstitute.org/report/scaling-food-medicine-prescriptions-market-solutions.
[13] For a comprehensive discussion of these issues, with recommendations informed by a survey of on-the-ground implementers, participants, and evaluators of Medicaid section 1115 demonstrations from 19 states, see Letter to The Honorable Chiquita Brooks-LaSure, Food is Medicine Section 1115 Demonstrations – Implementation Survey and Recommendations (Apr. 24, 2023), https://www.healthlawlab.org/wp-content/uploads/2023/04/Letter-to-CMS-re-1115-Waiver-Survey-2023.pdf.

- Understand the diverse experiences and broader context of the population that will receive or has already received the intervention.
- At all stages of the research, plan to include the perspectives of potential study participants and the broader population that will receive or has already received the intervention.
- In addition to including the perspectives of individuals with lived and/or local experience, researchers and funders should seek out perspectives and potential partnerships with community-based organizations that either provide similar services or support the study's target population in other ways.
- Investigate the composition of the research team, including the team's perspectives and potential biases. Fully engage all team members in planning and decision-making.
- Monitor study recruitment and retention.
- All Food is Medicine researchers and funders should encourage academic research institutions to change policies that inhibit equity-centered research.
- Research funders and researchers must ensure they adjust timelines and funding amounts to reflect the additional effort and investment of resources that may be required to do research that is truly equity-centered.
- Whenever possible, qualitative research should be used to complement quantitative data.
- Food is Medicine research design should reflect the reality of household composition and household equipment, with particular attention to the household member who buys and prepares most of the household's food.

More information on each of these recommendations can be found in the *Research Action Plan*.[14]

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CHLPI applauds the President's Council of Advisors on Science and Technology's commitment to advancing nutrition research with an emphasis on equitable service access. We appreciate this opportunity to offer our feedback and would be happy to work with PCAST to further address any of the comments above. Please contact Erika Hanson at ehanson@law.harvard.edu with questions.

Sincerely,

Erika Hanson, JD
Clinical Instructor

on behalf of

The Center for Health Law and Policy Innovation
Harvard Law School
www.chlpi.org

[14] FOOD IS MEDICINE RESEARCH ACTION PLAN, *supra* note 1, at 81-88.

Section 3: Susan Backus

Written: 9/12/2023

Good afternoon,

Please see the attached comments submitted on behalf of the North American Meat Institute in response to the July 18 request for public input on advancing nutrition science. I look forward to participating in the September 26 workshop. Please contact me with any questions. Thank you.

Regards,

Susan

Susan Backus

Vice President, Regulatory and Scientific Affairs

North American Meat Institute

NORTH AMERICAN MEAT INSTITUTE

September 12, 2023

Submitted via email to pcast@ostp.eop.gov

President's Council of Advisors on Science and Technology
Frances Colón, Ph.D., Nutrition Working Group Co-Lead
Catherine Woteki, Ph.D., Nutrition Working Group Co-Lead

Re: PCAST Welcomes Public Input on Nutrition Research, July 18, 2023.

Dear Drs. Colón and Woteki:

The North American Meat Institute (NAMI or Meat Institute) is the leading voice for the meat and poultry industry. The Meat Institute has a rich, century-long history and provides essential member services including legislative, regulatory, scientific, international, and public affairs representation. Together, the Meat Institute's members produce the vast majority of U.S. beef, pork, lamb, and poultry, in addition to the equipment, ingredients, and services needed to produce the safest and highest quality products.

Consumer health is a driving force in the production of meat and poultry products, which not only includes offering nutrient-dense protein food products but also improving and maintaining the safety of the meat and poultry supply. The meat and poultry industry is committed to offering diverse nutritional products. The Meat Institute supports the premise that eating a balanced, healthful diet from all food groups and engaging in moderate exercise are the keys to a healthy lifestyle.

Although the meat and poultry industry is regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), many nutrition and labeling policies originate from the Food and Drug Administration (FDA). Policies developed by FDA may be applied by FSIS or consumers to meat and poultry products. Additionally, many NAMI members operate dual jurisdiction facilities. As such, NAMI supports strong collaborative interagency efforts to ensure consistency of recommendations and guidance to consumers and industry. Absent that collaborative effort, there may be confusion. NAMI is hopeful that the President's Council of Advisors on Science and Technology's (PCAST) recommendations embrace a robust interagency collaborative approach.

PCAST is the sole body of advisors from outside the federal government charged with making science, technology and innovation policy recommendations to the President and the White House. As such, PCAST members are distinguished individuals from industry, academia and nonprofit organizations with a range of perspectives and expertise. The National Strategy on Hunger, Nutrition and Health tasks PCAST to identify scientific opportunities, gaps, and priorities to continue to advance nutrition science. PCAST is working with the Interagency Committee on Human Nutrition Research, the Office of Science and Technology Policy, and the Interagency Policy Council on Nutrition to respond to three questions to inform a vision for advancing nutrition science. The Meat Institute appreciates the opportunity to provide comment on the questions, specifically question 1.

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1. **How can the United States obtain the greatest return from federal investment in nutrition research?**
    a. **What are the crucial evidence gaps in nutrition research and what steps could PCAST recommend that would substantially fill those gaps?**
    b. **What tools, methods, or other resources (in addition to funding) are needed to conduct that research?**
    c. **Are there other barriers to research (other than inadequate funding)?**

Using All Peer Reviewed Nutrition Science When Developing Policy Increases the Return on Federal Investment.

Federal investments in nutrition research play an integral role in advancing the overall body of nutrition science. In the absence of federal funding on specific food groups or components of healthy dietary patterns, external funding is required. However, the results of that research regardless of rigor are not being considered when it comes to federal policy. All research results that meet the scientific rigor for developing federal policy should be included. Excluding industry funded research may not provide the full body of evidence to make sound nutrition policy or recommendations. Collectively the breadth of scientific evidence available to make sound policy delivers additional value to federal nutrition investments by demonstrating that all credible peer-reviewed science is used as support and that specific findings are not being tailored to meet policymaking needs.

Evidence Should be Weighted According to Scientific Rigor.

To build upon using all scientific evidence to develop policy, it is critical that the strength of the evidence be recognized. Scientific studies should be weighted according to the study rigor. The evidentiary standards for unfiltered research place randomized critical control trials at the top as the most rigorous form of research, followed by controlled clinical trials; observational studies; and case studies. Ensuring the highest quality evidence is used to inform policy delivers value on the federal investment. Building policy on the most rigorous forms of evidence – both federally- and privately-funded – instills confidence in the decisions made. Greater faith in policy from federal institutions is invaluable in the nutrition sphere.

Nutrition Policies Should be Evaluated to Demonstrate Impacts on Health Outcomes.

Nutrition science is in its infancy and verifying findings is important to advancing the knowledge base. As much of nutrition policy is informed by research, the impact of nutrition policies and programs should be assessed on a regular basis. However that basis should allow for an adequate time to demonstrate impacts on health outcomes. It's a common axiom that you manage what you measure. Yet, there is no publicly-available measurable evaluation of nutrition policies and programs. For example, the *Dietary Guidelines for Americans (Guidelines)* are developed every five years without any internal or external metrics to determine what has been effective and what areas have been ineffective. Collectively, government and industry, are developing initiatives and programs around *Guidelines* that have never been evaluated for efficacy. Further, practical implementation and achievability of dietary patterns have not been tested for feasibility. As public health data show, dietary outcomes have not improved over the last four decades of dietary guidance.

Metrics for evaluating the effectiveness of the nutrition research based polices are critically needed. Metrics would identify specific areas that need improvement and help focus resources, *i.e.* development of programs targeting specific issues. Metrics could also help determine future areas of research and provide data that could identify if certain sub-populations have specific needs. For instance, developing metrics could tell us whether developing *Guidelines* every five years is effective or whether the process should occur more or less frequently, *e.g.,* every 10 years as is the case with other public health initiatives such as *Healthy People* objectives.

Such a change would be a fundamental shift, but it is a necessary and critical step to improve the effectiveness of the nutrition policies and programs and achieve what is needed – measurable improvement of the health of Americans.

Clarity Should be Provided on Meat References in Nutrition Research.

Rigor and reproducibility are critical when conducting all types of research, including nutrition. Standardizing nutrition research methods, measures, and data elements would allow for more relevant comparisons across studies. There are challenges when collecting accurate consumption and intake data from food frequency questionnaires, dietary recalls, *etc*. when food group terminology is inconsistent.

Dietary guidance must be based on high quality scientific evidence. Understanding how and what the American population consumes are key elements for programs aimed at improving health. Intake data should reflect foods available in the marketplace and how they are consumed to ensure accuracy in dietary assessments. Developing more consistent approaches and practices to defining dietary patterns will allow for study results to be more applicable and relevant.

One example of needed standardization in research studies is food group terminology. A review of scientific evidence regarding meat and poultry is an example of how inconsistent food group terminology is utilized by researchers and policy writers. For instance, both the 2015 and 2020 Dietary Guidelines Advisory Committees had difficulty in consistently evaluating meat's role in healthy dietary patterns; it was ambiguous and oversimplified. The inconsistencies were directly related to confusion around food group terminology. The Dietary Guidelines Advisory Committees struggled to define red meat, poultry, processed meat, and lean meat. In fact, the *Scientific Report of the 2020 Dietary Guidelines Advisory Committee* includes the following research recommendation:

> "Design studies with sufficient detail and differentiation of the types and amounts of foods and beverages consumed, including inadequate or excessive intake, to inform an overall assessment of diet quality in the study of dietary patterns and/or diets based on macronutrient proportion. Rationale: Studies often lack or provide limited information on the type and amount of foods and beverages consumed by participants, and this may be due to inconsistency in dietary instruments used to collect data on dietary intake. When information is limited or inconsistent, it is difficult to draw strong conclusions for what types and amounts of foods and beverages to consume or avoid, such as, "processed meat" vs "red and processed meat" vs "meat." More information would allow more detailed guidance to be developed."[1]

[1] Scientific Report of the 2020 Dietary Guidelines Advisory Committee Part E. Future Directions. Research Recommendations, p. 24.

Had such standardization and harmonization been determined, many inconsistencies in evaluating the scientific evidence on meat could have been prevented.

Harmonized research methods and nomenclature will ensure human nutrition research occurs transparently and consistently across federal departments and agencies. Federally funded nutrition research should be the gold standard and demonstrate the leadership, innovation, and quality toward which all research institutions should strive.

Summary.

Meat and poultry products play an important role in healthy, well-balanced dietary patterns. Federal nutrition research plays an integral part in understanding the hows and whys specific foods, beverages, as well as dietary patterns impact health outcomes. Leveraging federal resources with privately funded research, which meets specified scientific criteria, along with basing policy decisions on rigorous evidence can provide greater return on federal nutrition investments. Standardizing nutrition research methods, measures, and data elements would allow for more relevant comparisons across studies. Collectively, these approaches could enhance trust in policy derived from nutrition research by ensuring the most relevant body of evidence is applied.

The Meat Institute appreciates the opportunity to respond to the questions posed by PCAST. If you have questions about these comments or anything else about this issue, please contact me. Thank you.

Respectfully submitted,

Susan L. Backus

Susan L. Backus
Vice President, Regulatory and Scientific Affairs

cc: Julie Anna Potts
Mark Dopp

Section 4: Sarah Ohlhorst

Written: 9/12/2023

Hello,

Attached you will find the American Society for Nutrition's responses to the questions posed by PCAST to identify scientific opportunities, gaps, and priorities to continue to advance nutrition science, emphasizing equitable access to the benefits of research. We appreciate PCAST's efforts and offer ASN's assistance. We look forward to furthering the discussion with PCAST and other stakeholders on September 26th. Please let me know if you have any questions or if you need anything additional.

Thank you,

Sarah D. Ohlhorst, MS, RD
Chief Science Policy Officer
American Society for Nutrition

1. Obtaining the Greatest Return from Federal Investment in Nutrition Research

Nutrition is an important, highly promising, and cross-cutting interdisciplinary research area. Partnerships between academic, federal government, industry, and nutrition professional organizations are essential to meet stakeholder needs and provide the best return on federal investment. The greatest return for federal investment in nutrition research takes place when research is put into practice. Approximately 100 million US adults have obesity, with diet-related diseases, including cardiovascular disease, cancer, and diabetes, accounting for half of the deaths in the US each year. Government spending, including Medicare and Medicaid, to treat cardiovascular disease, cancer, and diabetes accounted for 54% of the $383.6 billion in health care spending, a 30% increase from 2009 to 2018.[1] Slowing or preventing chronic diseases with nutrition and diet-related efforts will provide improved cost-effective outcomes for Americans, as nutrition research is translated into better human health. Nutrition is a modifiable risk factor for numerous chronic diseases, representing a highly viable approach to reduce adverse health outcomes.

a. Crucial Evidence Gaps in Nutrition Research

Due to historical underfunding of nutrition research for decades, nutrition science lags behind other biomedical sciences. Fundamental gaps in our understanding of nutrition science (which are outlined below) and how it relates to altered physiologic states and prevention of chronic disease impede our ability to move forward with nutrition research, policy, prevention, and interventions. Significant increases in nutrition research support are necessary to continue to clarify linkages between diet and health and to enhance nutrition-related disease prevention. Interdisciplinary nutrition research needs to be a funding priority. Increased funding of nutrition research will provide increased fundamental knowledge of diet and nutrition, contributing to evidence-based solutions to the health and economic challenges resulting from diet-related diseases, as well as implementation of nutrition science-based practice and policy.

Relationships Between Nutrients, Foods, Dietary Patterns, Health Promotion and Disease Prevention

Nutrition research is needed to evaluate and strengthen the fundamental evidence underlying the relationships between nutrients, foods, dietary patterns and health and disease prevention. Research to assess the effectiveness and efficiency of nutrition assistance and education programs needs to be undertaken to improve health and nutrition security. In addition, research is needed to better understand what factors impact food and eating behavior, habits, and decision making of people. Nutrition science is vast, encompassing molecular mechanisms all the way to population health. This includes the role of diet on the gut microbiome, exosomes that act as cell-to-cell communicators, epigenetic modifications, and metabolic profiles of chronic disease. These areas all require extensive research and consistent funding across a broad spectrum of interdisciplinary fields.

[1] Government Accountability Office. 2021. Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts. GAO Publication No. 21-593. Washington, D.C.: U.S. Government Printing Office. Retrieved from https://www.gao.gov/assets/gao-21-593.pdf.

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Research on Intake and Health Outcomes, Particularly for High-Risk Subpopulations
Our ability to measure what people consume accurately is essential to all nutrition research and is an area of active study. (See below under c. Tools, Methods, and Other Resources Needed for more about dietary assessment needs.) Research on assessing diet exposure, nutritional status, and impact on health should be considered from a lifespan perspective. The data for younger and older populations and for females are especially inadequate and are crucial evidence gaps in nutrition research.

Foundational and Translational Nutrition Research, Including on Dietary Bioactive Components and Botanicals
More foundational and translational research is needed for all nutrients, including bioactive food components. We still lack fundamental knowledge of nutrition, such as understanding the basic nutrient requirements necessary for various populations to achieve optimal health and understanding how nutrients and bioactives interact and improve human health. Research is needed to identify new and refine existing biomarkers for metabolic and other diet-related disease outcomes. This includes increased understanding of how to add precision to nutrient and bioactive recommendations based on individuals' requirements, responses, and genetic/racial/ethnic backgrounds.

Nutrient Requirement Research
The Dietary Reference Intake (DRI) values, including the Recommended Dietary Allowance (RDA), for several essential vitamins, minerals, and fatty acids, as well as fiber, are either outdated or lacking altogether. The absence of established RDAs is primarily due to insufficient evidence to define optimal intake levels for various populations, a consequence of no federal funding for nutrient requirement research and no federal agency lead for these efforts. We also need more research to estimate Chronic Disease Risk Reduction (CDRR) values where relationships between nutrients and diet-related chronic diseases, such as cardiovascular disease and type 2 diabetes, are established. This will require better and larger prospective cohort studies and randomized controlled trials (RCT).

Food Production and Processing for Increased Nutritional Quality
Agriculture is inextricably linked to food and nutrition and must therefore be an integral part of nutrition research. Research is needed to increase the nutrient density of food crop commodities to positively impact human health and incentives should be provided to increase production of fruits, vegetables, and other specialty food crops. Knowledge gaps persist regarding food production, ranging from innovative farming techniques to advanced processing, efficient packaging, and reliable transportation, which can collectively contribute to the optimization of nutritional content. Furthermore, evidence gaps in nutrition security, its origins, environmental impacts, and how to mitigate its effect on health center on understanding how to create resilient food systems that guarantee access to nutritious foods for all segments of the population, regardless of socioeconomic and other circumstances.

b. Steps PCAST Should Recommend to Fill Evidence Gaps

Establish a National Nutrition Strategy

A federal commitment to support nutrition research, including establishment of nutrient requirements, is vital, as nutrition research dramatically improves the quality of life for Americans while reducing healthcare costs. A coordinated national nutrition science strategy that aims to improve nutrition research coordination, collaboration, and data sharing across all federal agencies will improve nutrition policies and programs. Expanding our investment in federal nutrition research will foster research efficiency, maximize impact, and increase return on investment, while promoting equity, nutrition security, and health.

Improve Coordination of Federal Nutrition Research

PCAST should recommend steps to improve coordination and integration of federal research on food and nutrition. Given nutrition's inherently interdisciplinary nature, an ongoing, strong coordinating mechanism across all government agencies is essential, as recommended by the 2021 US Government Accountability Office (GAO) report[1], Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts, in order to achieve the many promising opportunities in nutrition. The GAO report noted that nutrition currently crosses 21 federal agencies and 200 disjointed efforts. The work of the trans-federal government Interagency Committee on Human Nutrition Research (ICHNR) is critical to achieve this goal but must be further amplified to allow for increased harmonization of and more effective nutrition research initiatives across agencies and cabinet level departments. Currently the ICHNR is composed of knowledgeable experts in positions of responsibility. However, it is structured as a volunteer group with no infrastructure. The ICHNR should be given the staff, authority, and budget needed to align all federal agencies to focus on nutrition research support and coordination across the federal government. Specifically, increased resources and investment are needed for the NIH Office of Nutrition Research and to establish a similar office with a coordinating role for USDA nutrition research.

Catalyze Nutrition Research Public-Private Partnerships

The US government should determine incentives to catalyze public-private partnerships for nutrition research, including private sector and philanthropic research funding, that stimulates high-integrity, transparent, and unbiased research to address the nation's priorities related to hunger, nutrition, and health. In addition, a nutrition science-specific advisory council that would engage stakeholders outside of the federal government, including state, local, and tribal governments, as well as experts from academia and the private sector, would be extremely beneficial to obtain the greatest return from federal investment in nutrition research.

Request a Study Outlining Nutrition Research Needs

Following 50+ years of nutrition research, the field of nutrition remains in a weakened position to advise Americans about the food they should eat to improve health and longevity. A study to establish priority research needs and opportunities in nutrition would guide current and future federal approaches across all federal agencies, similar to the ASN Nutrition Research Priorities that were established in the 2013 publication, "Nutrition research to affect food and a healthy life span[2]," which has been cited by more than 75 publications.

[2] Ohlhorst S, Russell R, Bier D, Klurfeld DM, Li Z, Mein JR, Milner J, Ross AC, Stover P, Konopka E. 2013. Nutrition research to affect food and a healthy life span. *Am J Clin Nutr.* 98(2):620-5. doi: 10.3945/jn.113.180638

Increase the Nutrition Research Workforce
PCAST should also recommend steps to propel efforts to recruit cutting-edge nutrition scientists to the federal agencies and to other institutions and to train the next generation of nutrition scientists and practitioners to usher in new initiatives that will enhance nutrition with profound effects for the health of all Americans.

c. Tools, Methods, and Other Resources Needed

Innovative research tools are needed for the federal agencies responsible for nutrition research and for nutrition researchers at institutions everywhere. A 2020 ASN white paper, "Valuing the Diversity of Research Methods to Advance Nutrition Science[3]," highlights the wide breadth of methods used in nutrition science and how each confer value. The paper also touches on the key considerations and limitations of various methods, as well as needs in nutrition research method evolution.

Improved Dietary Intake Assessment Methods
Current dietary assessment methods need to be improved and validated using biomarker studies in humans. Our limited ability to objectively measure dietary intake and the ability to correct measurement biases in diet and disease association studies using related intake biomarkers hinders progress. For example, studies using doubly labeled water for short-term energy assessment show energy underestimation by about 30-40% among individuals with overweight and obesity, though much less among persons who are not overweight or obese. Systematic biases of this magnitude, if uncorrected, can play havoc with energy intake and disease association analyses. Few nutrients or diet components or dietary patterns have objective methods available for determining intake. Metabolomic signatures, big data, and artificial intelligence may help to identify novel biomarkers of exposure and of disease processes that can propel nutrition research into the future.

Updated Food and Dietary Supplement Composition Databases
Particularly with the current emphasis on moving toward personalized (individual) and precision (subgroup) nutrition, it is essential to know what people are eating and the range of variability for nutrients in common foods. Foundational tools to help nutrition researchers do this include the US Department of Agriculture (USDA)'s food composition databases, such as FoodData Central. However, many food composition database entries do not reflect the realities of the current food supply nor the realities of our increasingly diverse nation, which may negatively impact research, programs, and policies based on this information. Many of the foods within these databases have not been updated for years. Plant and animal breeder practices, as well as industry reformulations, have changed both the macro- and micronutrient contents of many commonly consumed foods. In addition, about half the fruits and vegetables eaten in the US are imported from various other countries, with different soil nutrients, fertilization patterns, and climate conditions, resulting in variable nutrient content for these foods. Similar changes have occurred

[3] Mattes RM, Rowe SB, Ohlhorst SD, Brown AW, Hoffman DJ, Liska DJ, Feskens EJM, Dhillon J, Tucker KL, Epstein LH, Neufeld LM, Kelley M, Fukagawa NK, Sunde RA, Zeisel SH, Basile AJ, Borth LE, Jackson E. 2022. Valuing the Diversity of Research Methods to Advance Nutrition Science. *Adv Nutr*. 13(4):1324-1393. https://doi.org/10.1093/advances/nmac043.

in animal-sourced foods with breeding and feed alterations leading to markedly different nutrient content patterns. Food databases also need to be updated for cultural appropriateness to reflect the common foods and beverages of racially and ethnically diverse populations and immigrant communities in the US to improve the accuracy of nutrient and food intake and dietary exposure estimates among these subgroups.

Reinvigorated Nutrition Surveillance and Data Monitoring

Increased federal investment in health and nutrition surveillance and data monitoring are also crucial. Nutrition monitoring findings are essential for multiple government agencies, as well as the public and private sector, to track what Americans are eating, inform nutrition and dietary guidance policy, evaluate the effectiveness and efficiency of nutrition assistance programs, and study nutrition-related disease outcomes. Nutrition and health data, largely collected through the National Health and Nutrition Examination Survey (NHANES) and What We Eat in America, are essential for tracking the nutrition, health, and well-being of the American population, and are especially important for observing nutritional and health trends in our nation's children and persons 65 and older. The 2023 ASN paper, "Critical Data at the Crossroads: National Health and Nutrition Examination Survey Faces Growing Challenges[4]," provides a comprehensive review of challenges and opportunities for the future of NHANES.

Cutting-Edge Technology and Systems Approaches

Nutrition research should take advantage of the latest technologies and systems approaches to tackle pressing research questions for topics ranging from obesity to food and nutrition security. Metabolomic signatures, big data, and artificial intelligence may help to identify novel biomarkers of exposure and of disease processes. Combining systems approaches with analytical approaches will enable our ability to understand the interactions and pathways (e.g., biological, behavioral, social, and environmental) involved in the complex interactions of diet and health, diet and weight, weight and chronic disease occurrence, and behavior and diet, among others. Systems methods can elucidate the dynamic behavior of systems and help generate hypotheses to explain why systems act in certain ways. For example, systems approaches were advocated to be applied to development of the *Dietary Guidelines for Americans (DGAs)*[5].

Changes to Glean More Information from Federal Nutrition Research

Suggested changes to the federal government grant process may help improve the field of nutrition research. For example, clinical intervention proposals should include planned retrospective analyses to explain potential differences in response, which can inform precision nutrition. This should be required in the initial proposal, rather than as an add-on after the end of the study, to ensure scientific rigor and integrity. This will in turn improve the design of future research studies. Required reporting of baseline study characteristics should be outlined for specific nutrition research study designs. For example, studies examining energy balance (whether positive, negative, or neutral) need to consider activity level and diet intake since both can impact the findings. Other examples that can influence intake-outcome relationships include

[4] Taylor CL, Madans JH, Chapman NN, Woteki CE, Briefel RR, Dwyer JT, Merkel JM, Rothwell CJ, Klurfeld DM, Seres DS, Coates PM. 2023. Critical data at the crossroads: the National Health and Nutrition Examination Survey faces growing challenges. *Am J Clin Nutr* 117, 5, 847-858, https://doi.org/10.1016/j.ajcnut.2023.03.007.

[5] National Academies of Sciences, Engineering, and Medicine. 2017. *Redesigning the Process for Establishing the Dietary Guidelines for Americans*. Washington, DC: The National Academies Press. https://doi.org/10.17226/24883

age, sex, gender, disease status, and baseline nutritional status.[6] Like age or gender, nutrition status should be considered a biological variable as there are many interacting factors affecting and affected by nutritional status.

d. Barriers to Research

Lack of Coordination of Federal Nutrition Research

(See *Improve Coordination of Federal Nutrition Research* above.) At present there is no single source or repository across departments that contains up-to-date information on the nutrition research being funded with federal dollars, making it difficult to avoid duplication or to fill crucial gaps.

Workforce Challenges

Increasing the workforce and the diversity of workforce trained in nutrition research is of utmost importance to progress the field of nutrition research. Both the number and diversity of talent within nutrition research must increase to support the field. Currently, a very small pool of undergraduate students apply for graduate level nutrition training. Graduate school for 4+ years, typically followed by a postdoctoral fellowship must be made appealing to potential students, especially financially, to retain the students needed to build the nutrition research workforce. In ASN's response to an NIH Request for Information regarding re-envisioning postdoctoral research training and career progression in the biomedical research field, ASN highlighted the importance of postdoctoral positions for nutrition research and recommended increasing postdoctoral salaries, especially for starting postdoctoral researchers, and implementing a regional cost-of-living adjustment. The need to address student loan repayment is also emphasized to encourage nutrition students to pursue graduate school and postdoctoral positions.

Infrastructure Challenges

Nutrition research to fill crucial evidence gaps requires infrastructure that is not currently present in many academic nutrition programs. Infrastructure for food and nutrition research and laboratory classroom teaching is lacking at many institutions due to decades of inadequate funding needed to update facilities. Examples include teaching laboratories for nutrition and dietary assessment, whole room calorimeters, and biometric laboratories for assessing anthropometry. A Gordian report found that more than 69% of research facilities at land-grant university colleges of agriculture, a home for some nutrition programs, are at the end of their usefulness[6]. Researchers are often expected to perform 21st century science in facilities constructed in the 1950s and '60s[7]. This is also true at Historically Black Colleges and Universities (HBCUs) and Hispanic-Serving Institutions, contributing to declines in the diversity of the field of nutrition.

Need for Comprehensive Mentoring

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[6] Perspective: Nutritional Status as a Biological Variable (NABV): Integrating Nutrition Science into Basic and Clinical Research and Care. Adv Nutr. 2021; 12(5): 1599–1609. doi: 10.1093/advances/nmab046

[7] Reeves P, Mason S, Sanders L. 2021. A National Study of Capital Infrastructure at Colleges and Schools of Agriculture. Retrieved from: https://www.aplu.org/wp-content/uploads/a-national-study-of-capital-infrastructure-at-colleges-and-schools-of-agriculture-an-update-1.pdf

It is important to acknowledge that comprehensive mentoring during training, as well as continued mentoring beyond the graduate and postdoctoral years, plays a pivotal role in advancing research efforts. Mentoring that encompasses a holistic approach to understanding basic, interventional, and community-based research, as well as health outcomes, is imperative. A multifaceted mentoring approach enables researchers to develop a well-rounded understanding of the intricate nuances of the field. It enhances an individual's ability to conduct rigorous and impactful research and equips them with the necessary skills to translate research findings into meaningful interventions and policies that address real-world challenges. Mentoring is particularly important for those underrepresented in the field and necessary for enhancing the pipeline of diverse, well-trained nutrition professionals and researchers.

Need for Cross-Disciplinary Training

The significance of integrated training in nutrition cannot be overstated. While specialized training in nutrition is critical, it should be complemented by in-depth training in biology, physiology, immunology, endocrinology, psychology, biostatistics, etc., as determined by the research questions of interest. Nutrition research is inherently multidisciplinary, and researchers must possess a comprehensive grasp of various aspects ranging from molecular mechanisms to population-level health outcomes. By offering integrated training that spans the diverse dimensions of nutrition, researchers are better equipped to tackle complex issues and drive innovative solutions that cater to the diverse needs of individuals, communities, and societies at large and provide the greatest return from federal investment.

e. Models to Fill Evidence Gaps in Nutrition Research

Medicine is a field that integrates knowledge of multiple systems and may be closest to the diversity that nutrition incorporates but has not always proven to be a good model for nutrition research since food/nutrition and drugs are more different than alike. Implementing standards for rigor in nutrition research for diet composition, well controlled diets, power calculations, inclusion and diversity of subjects, researchers, etc., would benefit the research reputation of nutrition. Many fields have specific criteria for data management, repositories, inclusion and exclusion criteria, genomic data criteria, data reporting, and so on. Research rigor is essential to provide high quality and reliable contributions to the knowledge base, which forms the bedrock for the development of nutrition policy and guidance. Nutrition research has often suffered from the lack of rigor demanded in other fields, the lack of bona fide validated, reliable, and accurate tools and study designs, and should be improved to build more confidence in scientific knowledge that informs public health dietary guidance. As such, ASN has implemented best practice recommendations to ensure better trust in ASN and in nutrition science.

2. Introducing Research-based Interventions into Federal Programs

It is important that federal food and nutrition policies, regulations, and programs be aligned with the *DGAs* and other nutrition standards such as the DRIs to ensure science-based nutrition guidance that will lead to improved health. However, while the DGAs are reviewed on a mandated cyclical basis, there is no dedicated funding for establishing the *DGAs.* It is imperative to secure funding to support the implementation and coordination of forthcoming *DGAs* among federal agencies and to ensure the research gaps and opportunities from previous Dietary

Guidelines Advisory Committee Scientific Reports are addressed. Importantly, dedicated research funds for a comprehensive, multi-armed, multi-site RCT (like the original Dietary Approaches to Stop Hypertension [DASH] study) to assess the impact of the *DGAs* on health outcomes should be considered.

While some food as/is medicine provisions are already being introduced into federal programs, a systematic approach for establishing evidence-based and scalable interventions is required. Evidence-based guidelines should be informed by the totality of the evidence, including consideration of strengths, weaknesses, and knowledge gaps, through the systematic identification and critical appraisal of the evidence. Integration of nutrition experts, healthcare providers, educators, and policymakers will ensure robust engagement of the target public. Targeted community programs should be implemented, when applicable, preferably that offer incentives to bolster healthier lifestyles. Robust evaluation mechanisms must be established to assess effectiveness of programs with flexibility to then refine programs. Through harmonious multi-disciplinary collaboration among stakeholders, a comprehensive and impactful strategy can aid in diet-related chronic disease prevention.

3. Equitable Access to Federal Nutrition Research Investment Benefits

Diet-related chronic diseases are a leading cause of death in the US and research has shown that low-income and other under-served populations, including communities of color and tribal communities, are disproportionately affected by diet-related chronic diseases. One of the nutrition-related challenges faced by low-income and other under-served populations that has far-reaching consequences, including increased incidence of diet-related chronic diseases, is food and nutrition insecurity.

Improve Nutrition Education for Medical and Health Care Professionals

Inherent in any effort is the need to be mindful of nutrition equity and equitable translation of nutrition science to practice. As such, it is important to have a nationally coordinated, sustained approach for nutrition education for medical and health professional students including dentists, nurses, advanced care providers, physical and occupational therapists, and other care providers. The field of medicine requires the integration of knowledge from multiple systems, but medical school graduates receive little or no training in nutrition. Dietary recommendations and counseling must be an integral part of diet-related disease management.

Diversify Nutrition Research Workforce and Institutions

In addition, there must be federal efforts to recruit and nurture wide representation to the field of nutrition research so that the next generation of nutrition researchers more closely resembles the US population, and the research topics and solutions are more equitable and diverse. Ensuring diversity, equity, and inclusion at all levels of the nutrition research continuum, from trainees, researchers, workforce, subjects in specific research projects, and the population served by research translation, should be a priority. ASN supports efforts to establish or expand policies and programs that increase representation in nutrition research, such as the NIH Institutional Research and Academic Career Development Awards (IRACDA) program and USDA's NextGen. Awareness and education about available nutrition research funding, tools, resources, and more should be equitably accessible for all research institutions and researchers. Grant

programs should have a goal to promote research that provides important evidence on how to increase accessibility to healthy diets for all populations. Distribution of awards to minority-serving institutions is imperative, as well as awards for programs engaging in collaborative partnerships and community-based participatory research.

4. Conclusion

The American Society for Nutrition appreciates PCAST's efforts to identify scientific opportunities and priorities to advance nutrition science and we thank you for the opportunity to provide input to inform PCAST's recommendations to the President. ASN welcomes the opportunity to serve as a resource to PCAST as you move forward with the evaluation of nutrition science. The ASN membership has a wealth of expertise in nutrition science across the entire research spectrum from basic science to health policy, from discovery to application. As referenced throughout this response, ASN publishes many documents to inform and advance the field of nutrition research and we would be pleased to help spread the word of PCAST's recommendations. In closing, we reiterate the recommendations put forward above under b. Steps PCAST Should Recommend to Fill Evidence Gaps for your consideration and action. Please contact Sarah Ohlhorst, MS, RD, ASN's Chief Science Policy Officer [240-428-3647; sohlhorst@nutrition.org], should you have any questions or if ASN may provide additional information.

Section 5: Cindy Quezada

Written: 9/16/2023

Dear Nutrition Working Group,

Please find my comments to your request for public input on nutrition research. Thank you for your work on this important subject.

Cindy Quezada, PhD

Farmworker Research Program Director

UC Merced Community and Labor Center

1. **How can the United States obtain the greatest return from federal investment in nutrition research?**

    a. **What are the crucial evidence gaps in nutrition research and what steps could PCAST recommend that would substantially fill those gaps?**

    There exists a significant evidence gap within the realm of nutrition research, specifically concerning the implementation of programs for farmworkers' nutrition and well-being.

    Background

    Despite being instrumental in the nation's food production, farmworkers face alarmingly high rates of food insecurity, ranging from 37% in the Salinas Valley of California to a staggering 100% among indigenous agricultural workers on the central Coast of California (Mora 2022) (Matias 2020) (Hill 2011) (Castaneda 2019) (Minkoff-Zern (2014). The causes of this dire food insecurity situation are multifaceted, encompassing low wages; the seasonal nature of the work; work disruptions caused by extreme weather events, such as drought, floods, rain and fires; the absence of workplace benefits like unemployment insurance that could provide a safety net during these work disruptions; substandard housing that lacks adequate food storage and cooking facilities; and residing in food deserts devoid access to grocery stores offering fresh produce.

    Furthermore, farmworkers are burdened by elevated rates of diet-related chronic diseases. A comprehensive study conducted by UC Merced in 2021 on the health of California's farmworkers determined that nearly 20% of respondents were diagnosed with diabetes, compared to 11.6% of California's general population and 13.4% of its Latino population, as reported by America's Health Rankings. Moreover, approximately 19% of the study's respondents reported hypertension problems and approximately 37% were diagnosed as obese by a physician.

Despite this high incidence of chronic diseases, a meager proportion of farmworkers benefit from federal nutrition programs. According to the National Agricultural Workers Survey (NAWS) 2019-2020, only 13% of farmworkers reported a household member used SNAP in the past two years and 9% reported utilizing WIC during the same period.

The low participation is compounded by the fact that more than half of farmworkers are estimated to be undocumented, rendering them ineligible for programs restricted to US citizens and lawfully present non-citizens, such as SNAP. Even programs like WIC, which lack immigration restrictions, suffer from low participation rates due to income thresholds, lack of information dissemination and misinformation.

To address these pressing issues, it is imperative to conduct in-depth studies to assess the impact and efficacy of nutritional programs among farmworker populations by addressing the following research gaps

- **Longitudinal health studies:** Conduct longitudinal health studies of farmworker families to compare health outcomes related to diet-related chronic diseases between those who participate in programs like SNAP, WIC, Gus Schumacher Nutrition Incentive Program (GusNIP) and Gus Schumacher Produce Prescription Program and those who do not.
- **Examination of Food Insecurity Programs for Farmworkers:** Undertake a comprehensive examination of the performance of food insecurity programs among farmworkers. This analysis should include a deep dive into the low-participation rates of farmworkers in nutritional programs stratified by immigration status. The feasibility of the set income thresholds should also be re-assessed and income allocation patterns in farmworker households studied by geography.
- **Examination of culturally responsive food programs:** Explore effective strategies for providing culturally responsive and healthy food, including

prescription-based options, to farmworker communities. As an example, a foodbank in Tulare County, California, offers samples of meals made from the food bag contents to give recipients ideas for culturally appropriate and healthy recipes to make for their families. They also had a community kitchen, where they offered cooking classes for diabetics and overall healthy eating. This food bank largely serves rural, farmworker communities. It would be worthwhile to explore the effectiveness and scalability of such innovative initiatives for replication.

- **Addressing systemic barriers:** Investigate how food access programs can be tailored to overcome systemic barriers faced by farmworker populations, including the concepts of food prescriptions and culturally relevant food pairings with associated benefits like medical service provision.
- **Role of home and community gardens**: Explore the potential of home and community gardens as spaces that preserve and showcase agricultural, cultural and dietary knowledge of farmworkers.
- **Operational changes and partnerships**: Assess the operational changes and partnerships necessary for the successful scaling of innovative food provision programs. It will be important to analyze how cross-sector partnerships work best to leverage their expertise and resources to yield scalable nutrition programs for farmworkers. Addressing these research gaps and implementing evidence-based recommendations will be pivotal in alleviating the pressing nutritional challenges faced by farmworkers and advancing our understanding of nutrition in this vulnerable population.

An important step for PCAST is to present the federal government with a research agenda and priorities that elevate the needs of all farmworkers, irrespective of their immigration status and ethnicity.

b. What tools, methods, or other resources (in addition to funding) are needed to conduct that research?

The foremost resource required is the active participation and collaboration of farmworkers themselves. Farmworkers, particularly the indigenous, often hail from cultures deeply rooted in food and agricultural practices. Their unique agricultural and nutritional knowledge can enrich the research community's understanding of food insecurity issues. Recognizing farmworkers as both producers and consumers of food, it is imperative to empower them to leverage their involvement in the food system. This empowerment can harness their agrarian and culinary insights, enabling them to make substantial contributions towards addressing the challenges of food security and healthy eating. It is important to note that rather than being a matter of farmworkers making healthy "choices," these challenges often stem from class-based and racial disparities within the food system.

One of the primary challenges in conducting research within farmworker communities is access. To reach the farmworkers most in need, it is critical for researchers to establish connections to trusted messengers within these communities. These trusted messengers need to understand the culture and speak the language. There has been an increase in indigenous farmworkers from Central America who are monolingual and speak languages for which little to no interpretation infrastructure exists. These workers are often among the most vulnerable to human and worker rights violations. Funding allocations should prioritize researchers who have ties to farmworkers and the organizations that serve them. Community-engaged research, conducted by researchers who intend to invest in the community in a non-extractive manner should take precedence. This approach ensures that the research process respects the dignity and needs of farmworkers.

In conclusion, conducting research on farmworker nutrition requires a multifaceted approach that extends beyond financial resources. By actively involving farmworkers, prioritizing access through trusted messengers, and fostering holistic collaboration, scientists can develop research initiatives that not only yield valuable insights but also promote the well-being of this essential workforce.

2. **How could/should research-based interventions for primary and secondary prevention of diet-related chronic diseases be introduced into federal programs?**

The incorporation of research-based interventions for primary and secondary prevention of diet-related chronic diseases into federal programs is a pivotal step toward improving public health outcomes. To facilitate this integration, several key strategies and collaborative efforts should be considered.

Data serves as a potent tool for administrative advocacy. Researchers may establish close partnerships with community, labor, and work organizations to support evidence-based policy advocacy. This collaborative approach can be instrumental in advocating for the incorporation of preventive measures for diet-related chronic diseases into federal programs. By providing robust scientific evidence and working in tandem with these stakeholders, researchers can effectively convey the urgency and necessity of such interventions to policymakers.

Researchers, as part of their grant requirements, should actively engage in public outreach and education initiatives. This involvement may encompass a range of activities, such as presenting research findings to elected officials, offering expert testimony at national, state, and local hearings, and conducting community presentations. These outreach efforts are essential for disseminating research outcomes to a broader audience and informing the public, advocates and decision-makers. They serve to bridge the gap between scientific discoveries and actionable policy changes.By forging these partnerships, researchers can leverage collective expertise and resources, so that interventions are grounded in sound scientific evidence,

Researchers can be active contributors to policy development process. This involvement may include contributing data for the drafting of legislation, regulations, or program guidelines that incorporate evidence-based interventions tailored to the specific needs of the target population.

In conclusion, the introduction of research-based interventions for primary and secondary prevention of diet-related chronic diseases into federal programs demands a multifaceted approach. Researchers must harness the power of data, support advocacy and education, cultivate collaborative partnerships, and contribute towards policy development to effect meaningful change. By combining research excellence with strategic advocacy, researchers can help pave the way for healthier and more resilient farmworker communities nationwide.

3. **What can be done to assure equitable access to the benefits of the federal nutrition research investment?**

Ensuring equitable access to the benefits of federal nutrition research investment is imperative, particularly in the context of vulnerable populations, such as farmworkers, including those who are indigenous and undocumented. Several key strategies can be employed to promote equity in this domain:

Federal nutrition research should encompass a comprehensive understanding of the realities and unique challenges faced by farmworker populations. By ensuring research efforts include these marginalized groups, the research community can generate insights that are directly applicable to their specific needs and circumstances. This inclusivity helps to address the disparities in access and outcomes that may exist and ensures no population is left behind.

One powerful avenue for promoting equity is to utilize research findings to advocate for policy changes that remove barriers and enhance access to federal assistance programs. For instance, lifting immigration restrictions on access to federal assistance programs would have a profound impact on equity. Research results can serve as compelling

evidence to support the advancement of policy modifications, highlighting the benefits of inclusivity and social justice.

Transparency in data collection, analysis, and dissemination is critical. Making research data accessible and understandable to a broad audience, including policymakers, advocates and especially affected communities, promotes accountability and facilitates evidence-based decision-making. Data should also be disaggregated to ensure a complete understanding of needs of particularly vulnerable populations, such as the recent Mayan immigrants This transparency can help bridge the gap between research findings and their practical application, advancing equity.

In conclusion, assuring equitable access to the benefits of federal nutrition research investment necessitates a proactive, inclusive, and advocacy-driven approach. By focusing research efforts on vulnerable populations, supporting the data needs for policy change advocacy, fostering collaborative partnerships, and promoting data transparency and disaggregation, the research community can contribute toward a more equitable and just society where all individuals have access to the benefits of nutrition research.

Section 6: Dr. Mozaffarian/Tufts University

Written: 11/2/2023

Good afternoon,

On behalf of Dr. Mozaffarian and the fellow signatories, please find attached a submission in response to the request for public input to inform a vision for advancing nutrition science.

Thank you for the opportunity to provide ideas and responses to the proposed questions.

Best regards,

Kirsten Deuman, MPH, RDN

Manager, Research Translation & Content Development

Nutrition Policy Initiative, Food is Medicine Institute

Friedman School of Nutrition Science and Policy at Tufts University

Tufts UNIVERSITY | Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy
FOOD IS MEDICINE INSTITUTE

November 2, 2023

President's Council of Advisors on Science and Technology (PCAST), Nutrition Working Group
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Re: PCAST Welcomes Public Input on Nutrition Research

Dear PCAST Nutrition Working Group Co-Leads and Members,

As leading researchers and health professionals with substantial expertise in nutrition science, we are pleased that PCAST and its Nutrition Working Group have asked for public input to inform a vision for advancing nutrition science. We submit this comment in response to the questions posed to assist in identifying scientific opportunities, gaps, and priorities to continue to advance nutrition science while emphasizing equitable access to the benefits of research.

BACKGROUND AND CONTEXT

Poor nutrition is the top contributor to negative health outcomes in America, with billions of dollars spent each year on preventable, diet-related illnesses. In the United States, 1 in 2 adults have diabetes or prediabetes, 7 in 10 have overweight or obesity, and 14 in 15 have suboptimal cardiometabolic health.[1-3] One in 4 adolescents and young adults have prediabetes, and 1 in 5 children and adolescents have obesity.[4,5] Each week, suboptimal nutrition is estimated to lead to the death of 10,000 Americans[6] and 21,000 new cases of diabetes.[7] These burdens disproportionately impact people with lower incomes and lower educational attainment, from rural communities, the southeastern states and tribal reservations, and from certain traditionally marginalized racial and ethnic groups, contributing to growing health disparities.[5] Diet-related illness is also a matter of national security: Nearly 8 in 10 U.S. young adults aged 17-24 cannot qualify for military service; overweight disqualifies 11 percent of youth from serving if they so choose and contributes to the 44 percent of youth who are disqualified for multiple reasons.[8]

Diet-related diseases create major economic challenges for American businesses, families, and individuals through rising health care premiums, out-of-pocket-costs, missed work, and lower productivity. Unhealthy diets are estimated to account for 20% of U.S. health care costs from heart disease, stroke, and diabetes.[9] The yearly combined health care spending and lost productivity from suboptimal diets cost the U.S. economy $1.1 trillion each year.[10] Yet, as rates of diet-related disease and associated health care spending continue to rise, funding levels for nutrition research and training (as a percentage of total NIH spending) have been flat at approximately 5% since FY2015.[11]

A coordinated, accelerated strategy across several federal agencies and institutes is critical to advancing nutrition science. An independent report published in 2020 by leading scientists and policy experts maintained that the current investment and pace of federal nutritional knowledge and discovery are insufficient to address the fundamental nutrition-related challenges facing the nation, and identified the need for an expanded and coordinated nutrition research effort.[12] A 2021 U.S. Government Accountability Office (GAO) report found that the federal government invests in 200 efforts to improve Americans' diets, including 119 federal efforts deemed "research" (e.g., collect and monitor data, conduct or fund studies, review research to develop guidelines on healthy eating), but that the 200 efforts are fragmented across 21 agencies.[13]

The 2020 report recommended leveraging, harmonizing, and catalyzing the existing efforts being led across multiple federal departments and agencies through two complementary strategies: 1) a new authority for robust cross-government coordination of nutrition research and other nutrition-related policies and 2) strengthened authority, investment, and coordination for nutrition research within the National Institutes of Health (NIH).[12] The report's authors concluded that these strategies, taken together, would be complementary and would help create the new leadership, strategic planning, coordination, and investment needed to address nutrition-related challenges in the United States.

In 2021, the NIH Office of Nutrition Research (ONR) was established in the NIH Office of the Director by Dr. Francis Collins, based on the NIH's conclusion that nutrition research and its vast implications would be best served by greater strategic planning and coordination across the NIH's 27 institutes and centers**.** The NIH ONR aims to advance and coordinate federal investments in nutrition science to support and coordinate basic and translational research to ultimately promote health and reduce burdens of diet-related diseases among all Americans. The NIH ONR has the potential to help coordinate and catalyze existing research efforts across not only NIH, but also the multiple other federal departments and agencies that conduct nutrition research. However, only ~$1 million (0.002%) of the NIH's annual $45 billion budget goes to the Office of Nutrition Research (ONR).[14] Full funding for the NIH ONR must be a critical priority.

Additional new investment is also critical to advance nutrition science across NIH, at USDA, and other federal agencies. NIH is the primary driver of our nation's ability to advance research aimed at clarifying the causes and effects of disease and identifying effective prevention and treatment solutions. A 2019 analysis from the NIH Office of Disease Prevention (ODP) compared the amount of dedicated NIH prevention research funding for risk factors of death and disability, and concluded that large gaps exist between the top causes of poor health and the research funding allocated to address them – with poor nutrition at the top.[15] Notwithstanding this pressing need for more investment, overall funding levels for nutrition research and training (as a percentage of total NIH spending) have not increased.[11] In recent years, constant dollars for nutrition research and training at NIH as a percent of actual total NIH obligations have actually declined[11] — despite continuing increases in the prevalence of diet-related diseases, health disparities, and corresponding economic burdens.

USDA is the second largest funder of federal nutrition research, focusing on research specific to healthy diets for the general population. Despite this, USDA investments in research and statistics have fallen below 1980 funding levels. For example, the Agricultural Research Service (ARS) budget for human nutrition research and monitoring has been flat since 1980.[12] Further, the relocation of ERS and NIFA to Kansas City, MO in FY 2020 caused workforce losses of 50% and 71%, respectively.[16] In addition to NIH and USDA, other federal entities also invest in nutrition research such as CDC, FDA, and DoD.

A robust new investment in federal nutrition research, together with increased structure and authority for coordination of federal nutrition research across the government, is critical to allow our nation to pursue exciting new fundamental, clinical, and translational discoveries, reduce the human and economic burdens of chronic disease for all Americans, reduce health disparities, and support national security by addressing a major contributor to military readiness. We are pleased to submit the following responses to the questions posed by PCAST and the Nutrition Working Group to assist in identifying scientific opportunities, gaps, and priorities to continue to advance nutrition science while emphasizing equitable access to the benefits of research.

QUESTION 1: ***How can the United States obtain the greatest return from federal investment in nutrition research?***

Nutrition research is currently funded through more than 10 federal departments and agencies, without sufficient coordination or authority for harmonized goals, data-sharing, or translation.[12] An independent report published in 2020, *Strengthening National Nutrition Research: Rationale and Options for New Coordinated Federal Research Effort and Authority*, concluded: "Greater harmonization and expansion of federal investment in nutrition science, not a silo-ing or rearrangement of existing investments, has tremendous potential to generate new discoveries to improve and sustain the health of all Americans." Strengthening federal nutrition research will enable individuals, health care providers, food system stakeholders, and government policymakers to better improve health through nutrition — particularly in communities that experience severe diet-related health disparities due to constrained access to nutritious foods and other structural barriers that challenge healthy food choices.

The National Strategy on Hunger, Nutrition, and Health highlights the role of nutrition science and education in supporting America's vitality, calling for investment in nutrition research to inform policy and implement a vision for advancing nutrition science. Now more than ever, we should prioritize advancing nutrition science as an effective mechanism to improve health outcomes for all Americans, reduce health care spending, improve national security, promote business innovation, and promote health equity.

Through extensive background research and stakeholder conversations, the independent report published in 2020 identified three strategies to strengthen national nutrition research. Within each of the three key strategies, recommended actions were provided along with the potential advantages, disadvantages, and paths forward, all of which are described in the report. The highlights include:[12]

1. A new authority for robust cross-governmental coordination of nutrition research and other nutrition-related policy
    a. New Office of the National Director of Food and Nutrition (ONDFN)
    b. New U.S. Global Nutrition Research Program (USGNRP)
    c. New Associate Director for Nutrition Science in the White House Office of Science and Technology Policy (OSTP)
    d. New U.S. Task Force on Federal Nutrition Research
2. Strengthened authority, investment, and coordination for nutrition research within the NIH
    a. New National Institute of Nutrition (NIN)
    b. New Trans-NIH Initiative(s) in Nutrition Research
3. Strengthened authority, investment, and coordination at USDA for human nutrition research, food and agricultural research, education, extension, and economics
    a. Increased investment in nutrition research across Research, Education, and Economics (REE)

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b. Expanded USDA research to improve public guidance and education
c. Innovative USDA research to strengthen benefits of nutrition assistance programs

More recently, the Task Force on Hunger, Nutrition, and Health (Task Force) - a diverse, independent multi-stakeholder group of experts, direct service providers, and leaders with varying expertise and perspectives - developed a report of 30 policy recommendations and 200+ associated actions to advance the goals of the White House Conference on Hunger, Nutrition, and Health. The report was based on a review of more than 75 existing policy reports; inputs from a Strategy Group of 26 organizations that provided a broad range of perspectives on relevant issues; three in-person national policy convenings (bringing together more than 240 multi-sector leaders and stakeholders); and more than 15 listening sessions planned with communities around the nation to uplift the knowledge and perspectives of individuals with diverse lived experiences around hunger, poor nutrition, and diet-related diseases. Three recommendations from the Task Force report are directly related to supporting the United States in obtaining the greatest return from federal investment in nutrition research:[17]

1. Create a new national nutrition science strategy,
2. Increase leadership, coordination, and investment in nutrition research at NIH, and
3. Use research and data sharing to improve nutrition policies and programs across Federal agencies.

We support these recommendations and elaborate on each of them below.

→ Recommendation 1 - Create a New National Nutrition Science Strategy

A new national nutrition science strategy would improve coordination and investment in federal nutrition research on prevention and treatment of diet-related conditions. A nutrition science strategy with increased investment in nutrition research across federal agencies will create knowledge and opportunities to strengthen federal food assistance programs and to reduce the human and economic costs of diet-related disease. Improved coordination and funding for research on nutrition, hunger, health, and their social determinants is a critical step towards answering some of the most important scientific questions of our time around human health and health equity, and will enable the federal government to leverage nutrition-related knowledge to benefit the public good, the economy, and national security.

In summary, a coordinated national nutrition science strategy will foster:

- Complementary and amplified nutrition science efforts across multiple federal departments and agencies
- Acceleration of essential basic, clinical, public health, and translational discoveries
- Scientific advances to address topics such as the role of nutrition in preventing and treating illnesses such as obesity, Alzheimer's disease, and certain cancers, and in promoting maternal health and child development
- Development of strategies to address major nutrition-related health disparities by geography, income, education, race, and ethnicity
- Expanded and modernized nutrition-related monitoring and surveillance
- A skillfully trained nutrition science workforce
- Coordinated medical health professional education and training that includes licensing and certification standards for nutrition education

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- An evidence base sufficient for providing necessary updates to each edition of the DGAs and for periodic updates to Dietary Reference Intakes (DRI)
- Strengthened intersections between nutrition science and food products, supply chains, and sustainability
- Improved communication to the public around evidence-based nutrition information and education to inform choice and reduce confusion

Specific actions to advance development of a national nutrition science strategy, consistent with the recommendations of the 2022 Task Force on Hunger, Nutrition, and Health, include:[17]

- The White House could launch a national nutrition science strategy that accelerates and reshapes the way the U.S. government supports and drives innovation across our food and health care systems, including at the NIH, United States Department of Agriculture (USDA), United States Department of Defense (DOD), United States Department of Veterans Affairs (VA), Centers for Medicare & Medicaid Services (CMS) / Center for Medicare & Medicaid Innovation (CMMI), Indian Health Service (IHS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Federal Trade Commission (FTC), Department of Homeland Security, Federal Reserve, National Science Foundation, and United States Agency for International Development.
- The strategy could be guided by an advisory committee of government and non-government stakeholders, including industry, academia, consumers, and advocates. This could be created via a Presidential directive, and direct coordination of existing resources across NIH, USDA, CMS, CMMI, VA, DOD, CDC, and FDA, and include a mechanism providing sustained authority to coordinate federal nutrition research across the federal government.
- Create a new National Institute of Nutrition (NIN) at the NIH, accompanied by meaningful new funding to complement existing NIH activities. The NIN would support basic, translational, and policy research; provide health professional training; coordinate nutrition science across federal agencies; and support updates to the *Dietary Guidelines for Americans* (DGA). The funding should supplement existing NIH research funding and should not supplant funding being provided to existing institutes and centers.
- Congress and the President's budget could double federal funding for nutrition research across agencies to at least $4 billion per year to better support high-impact research on topics related to hunger, nutrition, health, and their social determinants.
- The White House could appoint a new Associate Director of Nutrition Science within the Office of Science and Technology Policy. The Associate Director would advise the President on issues related to nutrition research, provide high-level leadership for federal nutrition science efforts, and promote identification and development of coordinated and innovative nutrition research initiatives.
- Congress could establish a new U.S. Global Nutrition Research Program to improve coordination and integration of federal food and nutrition research. This program would be modeled after the U.S. Global Change Research Program.
- The White House and NIH could create a dedicated system to identify and track federal investments in nutrition research. This coordinated federal nutrition research system would allow for the effective identification and prioritization of scientific discoveries across critical areas. It would also create the capacity to identify and address timely new scientific challenges and opportunities.

Additional suggestions to advance development of a national nutrition science strategy:

The Interagency Committee on Human Nutrition Research (ICHNR), which includes representatives from multiple federal departments, is charged with "improving the planning, coordination, and communication among federal agencies engaged in nutrition research, and with facilitating the development and updating of plans for federal research programs to meet current and future domestic and international needs for nutrition."[18] The ICHNR meets approximately twice per year. While noble in intent, this entity has several limitations that impede its impact and ability to successfully coordinate federal nutrition efforts, including lack of any strong or consistent connection to the White House, no specific budget appropriations, no mechanism for reporting to Congress, and absence of any well-supported infrastructure for external advisory input on cross-governmental strategies for nutrition research.[12]

A possible solution to improve functionality and increase the impact of ICHNR is to adopt a model similar to that of the National Collaborative on Childhood Obesity Research (NCCOR). NCCOR, formally launched in February 2009, was the result of a formal collaboration between three of the major funders of childhood obesity research at that time: the Robert Wood Johnson Foundation (RWJF), the Centers for Disease Control and Prevention (CDC), and NIH. USDA later joined the collaborative in 2010. NCCOR's mission was "to improve the efficiency, effectiveness, and application of childhood obesity research and to halt—and reverse—the current childhood obesity trend through enhanced coordination and collaboration."[19] One of the key components of the collaborative development was agreement that a third-party coordinating center was essential for its success. As a result, FHI 360 became the Coordinating Center and has since supported the work of NCCOR through strategic planning, coordination of NCCOR activities, communication and dissemination of NCCOR outputs, and evaluation. NCCOR has documented its development, successes, and lessons learned in multiple publications.[19,20] ICHNR may similarly benefit from a third-party coordinating center to improve its functionality, reach, and impact.

→ Recommendation 2 - Increase Leadership, Coordination, and Investment in Nutrition Research at NIH

The 2022 Task Force report recommended that NIH, as the leading funder of health research in the United States, make high-quality nutrition research a top priority.[17] We are on the cusp of exciting scientific discoveries to address hunger, improve nutrition, and reduce diet-related diseases for all Americans. Food and nutrition research also have the potential to catalyze innovation in neurological health, immunity against infectious diseases, infertility, auto-immune disease, mental health, autism, and the other chronic illnesses that increasingly burden our society each year. Translational science is essential for testing and furthering implementation of effective strategies to address food insecurity and costly chronic diseases and for addressing inequities across the food system.

Specific actions to increase leadership, coordination, and investment in nutrition research at NIH, which are consistent with the 2020 independent white paper on nutrition research[12] and the recommendations of the 2022 Task Force on Hunger, Nutrition, and Health,[17] include:

- Congress and the NIH could strengthen and expand the NIH ONR, which provides cross-NIH strategy and coordination on nutrition research priorities. This office could sunset upon creation of a National Institute of Nutrition.

- NIH could provide support for investigator-initiated peer reviewed research on topics of critical importance to hunger, nutrition, and health science, education, policy, and practice. This includes, but is not limited to, the connection between diet and the microbiome, food is medicine interventions, improving nutrition through the federal nutrition programs, the impact of hunger and nutrition on health equity, the role of ultra-processed foods on health outcomes, the role of food additives and compounds in food packaging on health and disease, marketing and determinants of food choice, food accessibility and affordability, impact of agricultural practices on food nutritional quality, local implementation of systems and policy changes, and other translational research.
- NIH could invest in more randomized controlled trials in nutrition research, prioritizing studies that have clear mechanisms for impacting dietary intake, to provide advanced insights into mechanisms through which diet impacts biochemical processes, risk factors for illness, and health outcomes in the body.
- NIH could invest in development and validation of new research methods in nutrition sciences, such as leveraging mobile technology (e.g., to assess nutritional intake and to promote behavior change), applying computational approaches (e.g., to explore biomarkers within the microbiome), and using artificial intelligence and machine learning.
- NIH and other funders could require or incentivize researchers to include the perspectives of relevant public, community, and patient stakeholders at all stages in the research process, including defining research questions, collecting quantitative or qualitative data, interpreting findings, and communicating and disseminating results.
- NIH could increase the emphasis on translational and dissemination and implementation research to accelerate implementation of effective food and nutrition security interventions, with an emphasis on those that advance equity. NIH could prioritize research proposals that:
    - Include the voices and perspectives of patients to ensure program designs are effective and equitable at meeting health needs and are convenient to use.
    - Assess the intensity and duration of nutrition programs (including the impacts of scaling benefits by household size).
    - Assess the nutritional composition of food offerings to identify which dietary patterns are most likely to impact health outcomes.
    - Explore the impacts of interventions beyond the target individual, such as the effects on health outcomes for household members, or broader economic impacts.
- NIH could prioritize and provide federal funding to more effectively address research questions to inform updates to the DGA and to other evidence-based dietary guidelines for prevention and management of specific chronic diseases (e.g., the American Heart Association's dietary guidance to improve cardiovascular health and the American Diabetes Association's consensus report on nutrition therapy for adults with prediabetes or diabetes).
- NIH, the Health Resources and Services Administration (HRSA), and CMS could provide support and funding for the training of health care professionals for clinical care and basic and translational science in nutrition through the establishment of nutrition-focused research fellowships and postdoctoral programs.
- NIH could provide for more cross-agency nutrition research initiatives through the Common Fund and the Office of the Director.

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→ Recommendation 3 - Use Research and Data Sharing to Improve Nutrition Policies and Programs Across Federal Agencies.

Federal and state health care and nutrition programs and policies, if designed and implemented effectively, can have enormous impact on poverty reduction, food and nutrition security, health, health equity, and health care spending. Greater investment in research and data transparency are important for improving the effectiveness of programs and policies across federal agencies.

Specific actions to better use research and data sharing to improve nutrition policies and programs across federal agencies, consistent with the recommendations of the 2022 Task Force on Hunger, Nutrition, and Health,[17] include:

- USDA and Congress could encourage and fund multiple rigorous pilot programs in the Supplemental Nutrition Assistance Program (SNAP) to evaluate different innovative approaches to jointly reduce hunger and improve nutrition including different combinations of incentives for more healthful items, disincentives for less healthful items (e.g., increasing the price of certain foods or drinks, similar to a tax, but not an explicit restriction on items), testing increased benefits levels, and behavioral economics and gamification through mobile technology and online retail applications. Pilots can also test the effects of allowing purchases of hot prepared foods, as well as purchases of food preparation tools relevant to improving food safety and meeting federal food handling and preparation guidelines. Pilots should include participant choice to "opt in" to participation in a pilot program. Evaluations should include the perspectives of SNAP participants, be both quantitative and qualitative, and include assessment of the following outcomes: reach, interest in enrollment, stigma, dignity, satisfaction, food security, nutrition security, and health. These pilots should also seek to establish vehicles for collaboration between the public and private sectors.
- USDA, possibly in partnership with CDC and CMS, could examine the relationships between federal nutrition programs and nutrition and health outcomes and use the findings to strengthen federal nutrition assistance programs. Studies could examine the economic impacts of the programs, the impacts of COVID-19 on program outcomes, and consider opportunities to address food insecurity, nutrition insecurity, and health disparities in both the short- and long-term.
- Federal agencies, including NIH, USDA's Economic Research Service (ERS), USDA's Food and Nutrition Service (FNS), CDC, and others, could increase investment in research on policies, food systems, social and commercial determinants of health, nutrition and food security, and evaluation of policies and interventions.
- USDA, possibly in partnership with CDC and CMS, could develop, test, and validate nutrition security screening modules – or issue research grants to develop and test standardized surveys – such as the 2-question nutrition security screener developed by Tufts, Kaiser Permanente, the Los Angeles County Department of Public Health, and the George Institute. While USDA has put forward a working definition of nutrition security, validated metrics for evaluating nutrition security are still needed to assess equitable access, availability, and affordability of nutritious foods and alignment of diet quality with key recommendations in the Dietary Guidelines for Americans, as measured by USDA's Healthy Eating Index score. Once established, nutrition security metrics could be added to ERS food insecurity monitoring surveys.
- CMS could make data publicly available on use of Medicare Part C coverage of Food is Medicine programs under the Special Supplemental Benefits for the Chronically Ill. Utilization data should include the amount spent on Food is Medicine treatments, the type of treatments, the

geographic reach, and quantity of patients served. These data could facilitate research on payors' experiences in implementation, identification of barriers to expansion of these benefits, and patient experience.

- Congress could provide additional resources for, and CDC and USDA should prioritize, nutrition monitoring including regular data collection and reporting on nutrition behaviors, environments, and policies, including drivers of and strategies to address health disparities. This should include dedicated regular funding for efforts such as but not limited to the National Health and Nutrition Examination Survey, the National Household Food Acquisition and Purchase Survey, the Behavioral Risk Factor Surveillance System, and the USDA National Nutrient Database for Standard Reference; and new collection instruments on environments and policies.
- USDA could disaggregate all federal nutrition program participation data by key demographic categories, including race, ethnicity, and gender.
- USDA could conduct research on the barriers and facilitators to federal nutrition program participation among individuals who are eligible but not participating.
- USDA could prioritize research on the intersections of production, nutrition security, procurement, and equity across its Research, Education, and Economics agencies.
- The Federal Trade Commission (FTC) could study the effects of marketing foods and beverages that do not align with the latest DGA on children's nutrition and health outcomes (including a focus on traditionally marginalized populations), and on effective ways to reduce negative outcomes.
- FDA could continue investment in research on the effects of food labeling policies such as the updated Nutrition Facts label, health claims, and front-of-package labeling on outcomes such as consumer knowledge, behaviors, or health outcomes. FDA could also evaluate the effects of voluntary limits on additives (e.g., the short-term sodium targets) on outcomes of interest.

QUESTION 1A: What are the crucial evidence gaps in nutrition research and what steps could PCAST recommend that would substantially fill those gaps?

Evidence Gaps to Address

A clear understanding of the nutritional value of our food — as well as the ways in which Americans consume foods and beverages — has proven critical in treating costly, diet-related health conditions such as diabetes, obesity, and heart disease, and in advancing health equity. Nutrition research is advancing quickly, but there is still much left to learn.

The 2020 independent white paper on nutrition research identified nine key areas of opportunity for enhanced federal nutrition research coordination and investment:[12]

1. Cross-governmental strategic planning and prioritization
2. Advance the science for dietary recommendations to the public
3. Leverage new technologies and data science resources and approaches
4. Advance foundational and basic science knowledge and discoveries
5. Understand and address diet-related health disparities
6. Support and enhance translational and implementation science
7. Coordinate key cross-agency research priorities for nutrition-related investments
8. Intersections with food production, supply chains, and sustainability
9. Monitoring and surveillance

Specific recommendations within each of the nine key areas of opportunity can be found in Table 2 of the paper. The nine key areas and corresponding recommendations were identified and adapted from several federal and nongovernmental consensus recommendations on current priority areas for new nutrition research including from the Interagency Committee on Human Nutrition Research, 2015 Dietary Guidelines Advisory Committee, and the American Society for Nutrition.

Since the publication of the above-mentioned 2020 paper, the 2020 Dietary Guidelines Advisory Committee submitted the Scientific Report of the 2020 Dietary Guidelines Advisory Committee that contains a section on "Future Directions" to highlight research recommendations that could advance knowledge in nutrition science and support future activities related to the Dietary Guidelines. Recommendations include support for Federal data, needs for updated Dietary Reference Intakes, and a list of research gaps and needs collated by each chapter of the DGAs.[21]

In response to a spring 2023 NIH RFI on Food is Medicine Research, the Friedman School identified high priority research gaps and opportunities for advancing Food is Medicine (FIM) interventions (e.g., medically tailored meals, produce prescriptions, etc.), including:

1. Best practices for what works and with what conditions, including program dose and duration, specific implementation factors (i.e., context, culture), and patient/population characteristics (i.e., disease state [diabetes] or group [veterans]) that might influence efficacy and costs.
2. Cost of implementing FIM programs in various settings and with a variety of patient populations, as well as cost effectiveness compared to other healthcare-focused and population health-focused interventions.
3. Potential additional benefits on other outcomes such as patient-related quality of life, disease progression, mental health, caregiver well-being, and population-level health equity.
4. Potential health and economic benefits for family members/households of enrolled patients (i.e., spillover effects).
5. Potential economic benefits for local, regional, and national farms, retailers, and related supply chain stakeholders.
6. Potential for integration of FIM programs with other procurement priorities, such as support for small and mid-sized farms, local and regional production, regenerative and organic agricultural practices, fair labor practices, and food sector ownership from traditionally marginalized populations.
7. Potential for improved food system sustainability, including growing and providing local, culturally appropriate foods, economic development for people who live in areas with specialty crop potential, and impact on climate.
8. Process and engagement metrics for translating research results into policy and practice such as intensity, duration, access mechanism, and adherence and participation levels.
9. Datasets that could be made public by Centers for Medicare & Medicaid Services on the use of Medicare Part C coverage of FIM programs under the Special Supplemental Benefits for the Chronically Ill, such as amounts spent on FIM treatments, types of treatments, geographic reach, and types and numbers of patients served.
10. Payers' experiences in implementation and identification of barriers to expansion of these benefits.

Recommended Steps to Substantially Fill Evidence Gaps

→ Recommendation 4 - Ensure Strong Funding for the NIH Office of Nutrition Research (in addition to Recommendations 1-3 listed for Question 1 above).

With such funding, ONR will help answer the foundational scientific questions necessary to improve the nation's health, economic competitiveness, and military readiness, while reducing health care spending and health disparities for all Americans. Investment in nutrition research will also launch new American small businesses and jobs, building on rapidly growing private capital investments in nutrition innovation.

With strong funding, ONR can help drive groundbreaking science with increased capacity to:

- Achieve advances in understanding of the molecular effects of food in the body;
- Catalyze discoveries to help prevent and treat priority disease conditions that have strong links to diet and nutrition but require much more research;
- Ensure access to quality nutrition in a child's first 1,000 days, leading to an optimized diet, increased maternal health outcomes, and successful child development;
- Coordinate and support cutting-edge research in a new series of NIH Food is Medicine Centers of Excellence across the nation, building on the highly successful model of the NIH Cancer Centers of Excellence which have created major breakthroughs in the treatment of cancer;
- Examine structural and social determinants that affect access to healthy food and contribute to disparities in diet-related diseases (namely, through the Community Partnerships to Advance Science for Society [ComPASS] program);
- Ensure successful and efficient implementation of the 2020-2030 Strategic Plan for NIH Nutrition Research and NIH Common Fund's Nutrition for Precision Health initiative;
- Promote the training of the next generation of diverse research scientists to catalyze new discovered around food, nutrition, diet-related diseases, and health disparities;
- Increase the impact, visibility, and dissemination of nutrition science findings so that our scientific learnings quickly, directly lead to healthier communities; and
- Structure a more efficient and effective approach to coordinate research and discoveries in nutrition other federal departments and agencies, and with academic institutions and the private sector.

QUESTION 1B: *What tools, methods, or other resources (in addition to funding) are needed to conduct that research?*

→ Recommendation 5 - Develop a Platform to Support Collaboration and Information-sharing for Food is Medicine Research, e.g.:

- With new investment, establish national Food is Medicine Networks or Centers of Excellence as planned by (but not yet funded within) the NIH ONR.
- Leverage clinicaltrials.gov platform for sharing and standardizing measures relevant to FIM interventions. A number of benefits include sharing metrics and evaluation measures, promoting more efficient allocation of research funds, facilitating systematic reviews and other analyses of the research literature, and providing a public record of basic study results in a standardized format.

- Create a dedicated system to identify and track federal investments in nutrition research and allow for effective identification and prioritization of scientific discoveries across critical areas. An example is the NIH RePORTER system.
- Create a measures registry specific to FIM interventions similar to the National Collaborative on Childhood Obesity Research (NCCOR) Measures Registry, which is a searchable database of diet and physical activity measures relevant to childhood obesity research.

The American Society for Nutrition has recommended development and use of the following five tools for advancing nutrition research:[22]

1. Omics, (especially genomics, proteomics, and metabolomics) to determine how specific nutrients interact with genes, proteins, and metabolites to predict an individual's future health.
2. Bioinformatics - use of computer science and information technology to develop and enhance techniques to make it easier to acquire, store, organize, retrieve, and use biological data. Bioinformatics will enable nutrition researchers to more efficiently manage, analyze and understand nutrition data, and make connections between diet and health that were not previously possible.
3. Databases - food and nutrient databases to track and observe trends related to nutrition and health of individuals and link food and supplement composition and intake data to health outcomes. Nutrient databases should be expanded to cover more foods and their bioactive components, including non-essential nutrients. Nutrition data must also be incorporated into databases related to novel research areas, such as nutrigenomics and the microbiome, to adequately link these areas with nutrition.
4. Biomarkers - biological markers that are responsive to diet and nutrition must continue to be developed and verified to accurately track food and nutrient intake and determine and monitor health and nutritional status of individuals and sub-populations. Biological markers that are responsive to diet and nutrition will help assess disease progression and variability in response to treatment, while improving early diagnosis and prevention. Biomarkers must continue to be developed and verified to accurately track food and nutrient intake given our rapidly changing food supply.
5. Cost-effectiveness analysis - a tool used to calculate and compare the relative costs and benefits of nutrition research interventions. Cost effectiveness analysis helps to determine the most cost effective option that will have the greatest benefit to public health.

QUESTION 1C: *Are there other barriers to research (other than inadequate funding)?*

→ Recommendation 6 - Provide Stronger National Coordination for Nutrition Science Research.

Lack of such coordination is a major barrier to research according to both the 2020 independent white paper and the 2022 report of the Task Force on Hunger, Nutrition, and Health. With more than 10 federal departments and agencies currently investing in nutrition research, a new coordinated federal research effort is required to leverage, harmonize, and catalyze these efforts to help create the new leadership, strategic planning, coordination, and investment needed to address nutrition-related challenges in the United States. As previously stated, the 2020 independent white paper recommends two complementary strategies: 1) a new authority for robust cross-government coordination of nutrition research and other nutrition-related policies and 2) strengthened authority, investment, and coordination for nutrition research within the National Institutes of Health (NIH).[12]

Reiterating points made in response to Question 1, a coordinated national nutrition science strategy will bring:

- Complementary and amplified nutrition science efforts across multiple federal departments and agencies
- Acceleration of essential basic, clinical, public health, and translational discoveries
- Scientific advances to address topics such as the role of nutrition in preventing and treating illnesses such as obesity, Alzheimer's disease, and certain cancers, and in promoting maternal health and child development
- Development of strategies to address major nutrition-related health disparities by geography, income, education, race, and ethnicity
- Expanded and modernized nutrition-related monitoring and surveillance
- A skillfully trained nutrition science workforce
- Coordinated medical health professional education and training that includes licensing and certification standards for nutrition education
- Evidence base sufficient for providing necessary updates to each edition of the DGAs and for periodic updates to Dietary Reference Intakes (DRI)
- Strengthened intersections between nutrition science and food products, supply chains, and sustainability
- Improved communication to the public around evidence-based nutrition information and education to inform choice and reduce confusion

→ Recommendation 7 - Diversify the Nutrition Science Workforce.

Lack of adequately trained, diverse, nutrition science professionals as a barrier to research**.** Current and future investments should prioritize the training of a new generation of scientists and health care professionals for clinical care and basic and translational science in nutrition through the establishment of nutrition-focused research fellowships and postdoctoral programs. For example, adequate funding could be provided to the NIH Office of Nutrition Research to support such expansion and diversification of the nutrition science workforce.

QUESTION 1D: ***Are there models from other fields of science that could be employed to fill nutrition research evidence gaps?***

→ Recommendation 8 - Consider Strategies offered by the 2020 Independent White Paper on Nutrition Research for Strengthening and Accelerating National Nutrition Research, as Modeled by other Fields of Science:[12]

- Create a new Office of the National Director of Food and Nutrition (ONDFN) modeled after the Office of the Director of National Intelligence (ODNI)
- Create a new U.S. Global Nutrition Research Program (USGNRP) modeled after the U.S. Global Change Research Program (USGCRP)
- Create a new Associate Director for Nutrition Science in the White House Office of Science and Technology Policy (OSTP) as modeled after other Associate Director positions and initiatives

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- Create a new U.S. Task Force on Federal Nutrition Research as modeled after other timely U.S. task forces such as on Combating Antibiotic-Resistant Bacteria; Veteran Wellness, Empowerment, and Suicide Prevention; or on Combating Drug Addiction and the Opioid Crisis
- Create a new Trans-NIH Initiative(s) in Nutrition Research modeled after the BRAIN Initiative, "All of Us" Research Program, or the NIH Human Microbiome Project

As described earlier, ICHNR could employ a model similar to NCCOR for better coordination and functionality. NCCOR was modeled after a similar public-private partnership that proved to be successful: the Youth Tobacco Cessation Collaborative established in 1998 and sunsetted in 2011.[23]

QUESTION 2: ***How could/should research-based interventions for primary and secondary prevention of diet-related chronic diseases be introduced into federal programs?***

It is time to fully leverage existing federal investments that can jointly improve food and nutrition security. In 2022, 17 million households experienced food insecurity (about 13% of U.S. households), a burden that disproportionately falls on households with lower income, households with children, people of color, and people living in rural communities.[24] Food insecurity perpetuates health inequities through a cycle of poor nutrition and higher risk of developing diet-related diseases like obesity, diabetes, and heart disease.[25]

In addition, nutrition insecurity is widespread throughout the United States: based on the Healthy Eating Index (HEI), Americans ages 2 years and older have a failing grade on nutrition with an average score of 58 out of 100.[26] Youth ages 5 to 18 years have HEI scores below the population average, and no single population subgroup in the nation (i.e., age, sex, income, or race/ethnicity) has an average score above 65.[26] Low scores are a result of insufficient intake of fruits, vegetables, whole grains, nuts, and seafood, and excess intake of refined grains, added sugars, and sodium.[27]

Food and nutrition insecurity are interrelated challenges that require strategies that address both together, rather than one or the other. A key example of a federal program aiming to address both food and nutrition security is the Gus Schumacher Nutrition Incentive Program (GusNIP). GusNIP provides incentives for SNAP participants to purchase fruits and vegetables with their Electronic Benefit Transfer (EBT) benefits. However, only 3.7% of SNAP beneficiaries participate in GusNIP due to the requirement that GusNIP grantees match all federal resources with local resources, the need for increased technical assistance for applicants and programs, consumer confusion, and other factors.[28] If the program's reach increases, total fruit and vegetable consumption is expected to increase substantially. Furthermore, evaluation of the program has not been sufficiently funded, due to small grants (typically $500,000 max) that do not permit more comprehensive assessment of impacts on health, health equity, or healthcare utilization.

→ Recommendation 9 - Prioritize Food and Nutrition Security in Federal Nutrition Programs, e.g.:

- USDA, possibly in partnership with NIH, could examine relationships between each of the federal nutrition programs and nutrition, health outcomes, and health equity and use the findings to strengthen these programs.
- Congress could allocate at least double the funding for the GusNIP program and decrease or eliminate the non-federal matching requirements for grantees in lower-resourced communities to encourage additional participation; the effects of such changes should be evaluated and publicly reported.

- Congress could require that USDA regularly collect, analyze, and report SNAP purchasing data to analyze the nutritious value of food acquired by participants and non-participants at state and national levels, and to identify the levels of nutrition security, nutrition insecurity, and very low nutrition security among participants and non-participants.
    - A biennial collection of data using science-based metrics, collected at the aggregate level and made available for public use with all participant and store-level identifiers removed, would help policymakers and researchers understand the impact of efforts to support nutrition security, and adjust and improve those efforts as appropriate.
- USDA and Congress could encourage and fund multiple rigorous pilot programs in SNAP to evaluate methods to both reduce food insecurity and increase nutrition security. Pilot programs should seek to establish collaboration between the public and private sectors and should consider options including:
    - Combining incentives for healthy food purchases and disincentives for unhealthy food purchases (e.g., piloting a fruit and vegetable incentive combined with a sugary beverage reduction strategy at the point of purchase). A combination of incentives and disincentives can be cost neutral for the program, providing a practical budgetary solution to improve nutrition security while maintaining choice among SNAP participants.
    - Allowing the purchase of hot and prepared foods consistent with DGA recommendations.
    - Increasing use of mobile technology and online-remote retail applications.

  Pilots should consider the perspectives of SNAP participants in both the design and evaluation, including assessment of reach, interest in enrollment, stigma, dignity, satisfaction, food security, nutrition security, health, program costs, and health care utilization.

→ Recommendation 10 - Prioritize Food is Medicine Interventions in Federal Programs, e.g.: [29]

- Congress could authorize pilot programs that provide eligible individuals with MTMs and produce prescriptions through Medicaid, Medicare, and TRICARE; and include careful evaluations of effects on patient-centered outcomes, health, health equity, and healthcare utilization. (Such pilot programs were established in the Indian Health Service and Veterans Health Administration in 2023.)
- States could apply for, and CMS could approve, Section 1115 Waivers that allow Medicaid Programs to test and scale Food is Medicine programs, including funding for robust evaluations as has been done with the Healthy Incentives Pilot.
- The U.S. Department of Health and Human Services (HHS) and CMS could continue to support efforts to develop the data infrastructure needed for food and nutrition insecurity to be captured in electronic health records and ensure interoperable health information exchange and the collection of demographic information. The HHS Office of the National Coordinator for Health Information Technology could use this data to determine goals and interventions that can support efforts to reduce food and nutrition insecurity.
- Adequate funding could be provided to the NIH Office of Nutrition Research to support the four domains (i.e., research, education and training, patient services, and community outreach and engagement) required to establish a comprehensive Food is Medicine Networks or Centers of Excellence.

QUESTION 3: *WHAT CAN BE DONE TO ASSURE EQUITABLE ACCESS TO THE BENEFITS OF THE FEDERAL NUTRITION RESEARCH INVESTMENT?*

Nutrition science affects individuals' daily decisions, the nutrition guidance that health providers offer to patients, and the nutrition standards that undergird federal, state, and local public health programs and policies. For example, numerous nutrition programs, policies, and educational campaigns are based on nutrition science and evidence with the goal to improve consumer knowledge, promote experiential learning, support healthier food environments, and expedite translation and dissemination of the evidence connecting food, nutrition, and health. These efforts are important for promoting long-term behavior change and reducing prevalence of diet-related diseases. Such reasons support the importance of ensuring equitable access to the benefits of the federal nutrition research investment.

→ Recommendation 11 - Increase participation of diverse populations in research, so that results are more generalizable to Americans from various population groups. As stated in a 2023 report of recommendations to improve health disparities and health equity research,[30] numerous reasons contribute to the lack of adequate representation of diverse communities in research study populations, but in any case this deficiency results in knowledge gaps and in findings that may not apply or may even be detrimental when applied to, for example, racial and ethnic minority groups. For instance, achieving and maintaining sufficient participation of diverse subgroups in clinical studies is essential so that subgroup analyses can determine whether an intervention leads to different outcomes in different populations. Detecting whether such differences exist can indicate whether population-specific prevention or clinical approaches may be warranted and what additional data needs remain. Of note is that both genetic and racial and ethnic diversity are important, as substantial genetic heterogeneity exists within racial and ethnic groups.

→ Recommendation 12 - Disseminate published research results, translating and communicating the evidence to relevant stakeholders (consumer, policy makers, decision makers, etc.), and use evidence to inform sound policy and program decisions that will positively impact the health, nutrition, and lives of all Americans through the federal nutrition programs, public health and education, and health care sectors. Federal health- and food-related programs that serve Americans with lower incomes such as Medicaid, SNAP, WIC, and school meals must integrate the latest nutrition science evidence so that the participants in these programs benefit from such knowledge. This is currently playing out, for example, via proposals to revise WIC food packages and to update nutrition standards for school meals, both of which aim to help those programs better reflect the latest edition of the Dietary Guidelines for Americans.

→ Recommendation 13 - Provide health insurance coverage for programs such as medically tailored meals, medically tailored groceries, and produce prescriptions for appropriate, targeted populations consistent with the evidence base (e.g., adding coverage for patient populations for which effective program models have demonstrated health impacts), as recommended by the 2022 Task Force on Hunger, Nutrition, and Health.[17] Such Food is Medicine programs have rapidly gained interest among health care providers, health systems, payers, and patients as potential tools to improve clinical care for diet-related illness, especially for patients experiencing food and nutrition insecurity. Specific policy actions to improve access to FIM programs are outlined on pages 40-42 of the Task Force report. An example is promoting universal screening for food insecurity and nutrition insecurity in federal healthcare programs, with appropriate referrals, treatment planning, and follow-up for patients who are identified as food or nutrition insecure.

In closing, we reiterate the following key points:

- In the United States, 1 in 2 adults have diabetes or prediabetes, 7 in 10 have overweight or obesity, and 14 in 15 have suboptimal cardiometabolic health. Even among teens, 1 in 4 have prediabetes and 1 in 4 have overweight or obesity.
- These burdens disproportionately impact people with lower incomes and lower educational attainment, from rural communities, the southeastern states and tribal reservations, and from certain traditionally marginalized racial and ethnic groups, contributing to growing health disparities.
- Poor diets are estimated to account for 20% of U.S. health care costs from heart disease, stroke, and diabetes. The yearly combined health care spending and lost productivity from suboptimal diets cost the U.S. economy $1.1 trillion each year.
- Diet-related illness is a matter of national security: Nearly 8 in 10 U.S. young adults aged 17-24 cannot qualify for military service, and overweight disqualifies 11 percent of youth from serving if they so choose and contributes to the 44 percent of youth who are disqualified for multiple reasons.
- As rates of diet-related disease and associated health care spending continue to rise, funding levels for nutrition research and training (as a percentage of total NIH spending) have been flat at approximately 5% since FY2015.
- A robust new investment in federal nutrition research, together with increased structure and authority for coordination of federal nutrition research across the government, is critical to allow our nation to pursue exciting new fundamental, clinical, and translational discoveries, reduce the human and economic burdens of chronic disease for all Americans, reduce health disparities, and support national security by addressing a major contributor to low military readiness.

We share these comments to assist in identifying scientific opportunities, gaps, and priorities to continue to advance nutritional science while emphasizing equitable access to the benefits of research. We thank PCAST and the Nutrition Working Group for the opportunity to submit this comment for consideration as it develops a vision for advancing nutrition science, and we welcome the opportunity to present ideas to the Nutrition Working Group as part of the evolving process to develop recommendations.

Sincerely,

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These comments represent the recommendations of individual Tufts faculty members. The opinions expressed in this document do not necessarily represent official views or positions of the Friedman School of Nutrition Science and Policy, Tufts University, or its affiliates.

1. Menke A, Casagrande S, Geiss L, Cowie CC. Prevalence of and trends in diabetes among adults in the United States, 1988-2012. *JAMA*. 2015;314(10):1021-9. doi:10.1001/jama.2015.10029
2. Fryar CD, Carroll MD, Afful J. *Prevalence of overweight, obesity, and severe obesity among adults aged 20 and over: United States, 1960–1962 through 2017–2018*. 2020. December 2020. https://www.cdc.gov/nchs/data/hestat/obesity-adult-17-18/overweight-obesity-adults-H.pdf
3. 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. doi:10.1016/j.jacc.2022.04.046
4. Andes LJ, Cheng YJ, Rolka DB, Gregg EW, Imperatore G. Prevalence of prediabetes among adolescents and young adults in the United States, 2005-2016. *JAMA Pediatr*. 2020;174(2):e194498. doi:10.1001/jamapediatrics.2019.4498
5. Stierman B, Afful J, Carroll MD, et al. *National Health and Nutrition Examination Survey 2017–March 2020 Prepandemic Data Files Development of Files and Prevalence Estimates for Selected Health Outcomes*. National Center for Health Statistics; 2021. Accessed June 8, 2023. https://stacks.cdc.gov/view/cdc/106273
6. Mokdad AH, Ballestros K, Echko M, et al. The state of US health, 1990-2016: Burden of diseases, injuries, and risk factors among US states. *JAMA.* 2018;319(14):1444-1472. doi:10.1001/jama.2018.0158
7. O'Hearn M, Lara-Castor L, Cudhea F, et al. Incident type 2 diabetes attributable to suboptimal diet in 184 countries. *Nat Med*. 2023;29(4):982-995. doi:10.1038/s41591-023-02278-8
8. 77 percent of American Youth Can't Qualify for Military Service: Better Nutrition and Physical Activity can Yield Healthier Outcomes for Youth and Bolster National Security. Council for a Strong America - Mission: Readiness. Accessed October 26, 2023, https://strongnation.s3.amazonaws.com/documents/1541/aab5fcd2-74e4-4b76-b260-010a5d9afcc9.pdf?1674578754&inline;%20filename=%2277%20Percent%20of%20American%20Youth%20Can%E2%80%99t%20Qualify%20for%20Military%20Service.pdf%22
9. Jardim TV, Mozaffarian D, Abrahams-Gessel S, et al. Cardiometabolic disease costs associated with suboptimal diet in the United States: A cost analysis based on a microsimulation model. *PLoS Med*. 2019;16(12):e1002981. doi:10.1371/journal.pmed.1002981
10. The Rockefeller Foudation. *True cost of food: Measuring what matters to transform the U.S. food system*. July 2021. https://www.rockefellerfoundation.org/wp-content/uploads/2021/07/True-Cost-of-Food-Full-Report-Final.pdf
11. Flores R, Jury NJ. *NIH Nutrition Research Report 2020-2021*. 2023. Accessed October 26, 2023. https://dpcpsi.nih.gov/sites/default/files/NIH_Nutrition-Research-Report_RF508_FV-05.pdf
12. Fleischhacker SE, Woteki CE, Coates PM, et al. Strengthening national nutrition research: Rationale and options for a new coordinated federal research effort and authority. *Am J Clin Nutr*. 2020;112(3):721-769. doi:10.1093/ajcn/nqaa179
13. Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts. GAO-21-593. Washington, D.C.: August 17, 2021.
14. Frist B, Mozaffarian D. Congress: Close the Gap between Funding for Nutrition Research and the Toll Diet-Related Disease Takes on Americans. STAT; 2022. Accessed October 27, 2023. https://www.statnews.com/2022/12/02/congress-close-the-gap-funding-nutrition-research-toll-diet-related-disease/
15. Vargas AJ, Schully SD, Villani J, Ganoza Caballero L, Murray DM. Assessment of prevention research measuring leading risk factors and causes of mortality and disability supported by the US National Institutes of Health. *JAMA Netw Open*. 2019;2(11):e1914718. doi:10.1001/jamanetworkopen.2019.14718
16. Ogrysko K. Plans to Relocate some 550 USDA Employees Fall Vastly Short of Initial Expectations. Federal News Network; 2019. Accessed October 27, 2023.

https://federalnewsnetwork.com/workforce/2019/10/plans-to-relocate-some-550-usda-employees-fall-vastly-short-of-initial-expectations/
17. Task Force on Hunger Nutrition and Health. *Ambitious, Actionable Recommendations to End Hunger, Advance Nutrition, and Improve Health in the United States*. 2022. Accessed October 27, 2023. https://informingnutritionpolicy.org/2022-task-force-report/
18. Interagency Committee on Human Nutrition Research. USDA National Agriculture Library. Accessed October 27, 2023, https://www.nal.usda.gov/human-nutrition-and-food-safety/interagency-committee-human-nutrition-research
19. Writing Group for the National Collaborative on Childhood Obesity Research (NCCOR). Developing a partnership for change: The National Collaborative on Childhood Obesity Research. *Am J Prev Med*. 2018;54(3):465-474. doi:10.1016/j.amepre.2017.12.001
20. Writing Group for the National Collaborative on Childhood Obesity Research (NCCOR). A national collaborative for building the field of childhood obesity research. *Am J Prev Med*. 2018;54(3):453-464. doi:10.1016/j.amepre.2017.12.007
21. Dietary Guidelines Advisory Committee. *Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services*. 2020. https://www.dietaryguidelines.gov/2020-advisory-committee-report
22. American Society for Nutrition. Tools to Advance Nutrition Research. Accessed October 27, 2023, https://asn-cdn-remembers.s3.amazonaws.com/1206c0a5568382a65a4c044bb83c7176.pdf
23. Orleans CT, Arkin EB, Backinger CL, et al. Youth tobacco cessation collaborative and national blueprint for action. *Am J Health Behav*. 2003;27 Suppl 2:S103-19. doi:10.5993/ajhb.27.1.s2.2
24. Rabbitt MP, Hales LJ, Burke MP, Coleman-Jensen A. *Household Food Security in the United States in 2022*. 2023. https://www.ers.usda.gov/publications/pub-details/?pubid=107702
25. Laraia BA. Food insecurity and chronic disease. *Adv Nutr*. 2013;4(2):203-12. doi:10.3945/an.112.003277
26. U.S. Department of Agriculture Food and Nutrition Service Center for Nutrition Policy and Promotion. How Healthy is the American Diet? Accessed October 27, 2023, https://fns-prod.azureedge.us/sites/default/files/media/file/HEI-2015_Infographic_NHANES2017-2018.pdf
27. U.S. Departments of Agriculture and Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 2020. https://www.dietaryguidelines.gov/
28. The Bipartisan Policy Center. *Making Food and Nutrition Security a SNAP: Recommendations for the 2023 Farm Bill*. 2023. https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2023/01/BPC-Health-Nutrition-Brief_Farm-BillV5.pdf
29. Deuman KA, Callahan EA, Wang L, Mozaffarian D. *True Cost of Food: Food is Medicine Case Study*. 2023. https://tuftsfoodismedicine.org/true-cost-fim-case-study-report/
30. Health Disparities and Health Equity Research Working Group of the NIDDK Advisory Council. *Pathways to Health for All: Health Disparities and Health Equity Research Recommendations and Opportunities*. 2023. https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/pathways-health-all

Section 7: The Society for Nutrition Education & Behavior

Written: 11/10/2023

Greetings Dr. Colon and Dr. Woteki,

Thank you for the opportunity to submit comments to the questions posed by the President's Council of Advisors on Science and Technology. The Society for Nutrition Education and Behavior membership and leadership are submitting the attached document addressing the questions posed in order to create a vision for advancing nutrition science.

If additional information is needed or if the working group would like to consult with the Society please don't hesitate to reach out.

Rachel Daeger, CAE, IOM

Executive Director

Society for Nutrition Education and Behavior

Society for Nutrition Education and Behavior

Input for PCAST on Nutrition Research Opportunities and Gaps
from the Society for Nutrition Education and Behavior

Submitted: November 10, 2023

Prompt: What are the crucial evidence gaps in nutrition research and what steps could PCAST recommend that would substantially fill those gaps?

- Gap: Lack of federal ethical guidelines for nutrition research
    - Recommendation: Create consensus recommendations for rigor, reproducibility, transparency, and accurate reporting of results from research in nutrition science. Utilize the expertise and reporting capabilities of the National Academy of Sciences/Medicine for this purpose.
- Gap: Lack of current research on validity of current diet assessment methods or development of new diet assessment methods, particularly for children
    - Recommendation: Fund validation studies which examine accuracy of diet assessment methods, especially focusing on biomarkers to create causal links for food and nutrition's impact on health outcomes and to better assess the effectiveness of dietary interventions.
    - Recommendation: Improve the reporting of diet assessment results by creating recommendations for standardized use of government nutrient databases.
- Gap: Study samples in nutrition research are often not representative of US populations.
    - Recommendation: Create federal guidelines that help researchers create study samples that reflect the diversity of the US population.
    - Recommendation: Increase the number of research studies that focus on rural populations.
- Gap: Limited research on identification of effective strategies for population-based food behavior change
    - Recommendation: Increase the amount of nutrition research focused on multilevel community interventions to identify which factors in community settings have the most impact on improving food behavior for health promotion and disease prevention at the population level.
    - Recommendation: Incorporate and further study evidence-based factors for food behavior change within food and nutrition programs in broader community systems to increase their reach and sustainability while adapting them to diverse populations.

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- Gap: There are limited studies of long-term effects of diet on health promotion and disease prevention and management.
    - Recommendation: Fund and support longitudinal cohort studies that allow identification of diet and behavioral factors that contribute to disease prevention and incidence (i.e. Framingham Heart Study for cardiovascular disease, Nurses' Health Study for chronic disease in women, etc.).
    - Recommendation: Fund and support multi-center clinical trials that develop evidence for best practices for food and nutrition interventions in disease management (i.e. Dietary Approaches to Stop Hypertension (DASH) Trial, Diabetes Control and Complications Trial (DCCT), etc.).
- Gap: Understudied populations are often excluded from nutrition research, which limits development of evidence-based guidelines for optimal nutrition during lifecycle stages.
    - Recommendation: Add additional understudied populations to the National Health and Nutrition Examination Study (NHANES), in addition to oversampling for groups of 60 and older, African Americans, and Hispanics. Suggested populations to also emphasize in national health surveys include, but are not limited to, older adults, infants and children, and pregnant women.
- GAP: Scientists, researchers, and clinicians in the academic field of nutrition are often excluded in government nutrition research plans and funding.
    - Recommendation: Examine nutrition programs at land-grant universities in all states, which house many of the long-standing US academic programs in nutrition, for faculty experts who may serve on committees that plan research needs (i.e. see the Dietary Guidelines for Americans committee as an example).
    - Recommendation: Ensure that funding is provided to a full and diverse range of academically trained nutrition scientists and researchers at **all** R1 & R2 universities, land-grant universities, HCBUs, non-land grant H.S.I. institutions and research organizations.

Prompt: What tools, methods, or other resources (in addition to funding) are needed to conduct that research?

- Development of more validated nutrition assessment tools appropriate for population studies
- Validated tools for the assessment of food and nutrition security
- Research methods that promote participatory research strategies for improved understanding of cultural food practices

- A clearinghouse that lists consulting biostatisticians available for research studies outside of academia (i.e. healthcare, non-profit organizations, businesses, etc.)
- More staff on journal editorial teams so nutrition research results can be published more quickly in the scientific literature
- Development of policies (with enforcement) within NIH, funders, and journals regarding compliance with reporting and data sharing practices
- Improved methods for dietary assessment including those in current use (24-hour recall, FFQs, etc.), development of new methods and a clearinghouse for greater access to available methods by researchers in varied settings
- Funding and resources to enhance interdisciplinary connections and collaborations among basic researchers whose work directly impacts nutrient metabolism (for example, omics, neurobiology, energy expenditure, etc.)
- A regulatory framework for use of nutrition technology in nutrition education-focused research studies
- Improved methods for blinding diet in RCTs

Prompt: Are there other barriers to research (other than inadequate funding)?

- Upholding of the status quo in nutrition research so that the same research topics often have the most funding.
- Need for an examination of how nutrition research funding is allocated and who it is allocated to in order to better explore novel research ideas.
- The nutrition scientist population does not reflect the diversity of the US, which limits development of research questions focused on nutrition, health promotion, and disease management in diverse communities.
- Partnering with communities is complicated, takes longer and often requires more resources. This makes longer research projects focused on communities less attractive to scientists/researchers/faculty, who often need completed projects for career advancement.
- Researchers must ensure that barriers to change are addressed within nutrition study designs (for example, being able to access healthy foods).
- Minimal translation from research into policy development hinders development of evidence—based interventions.

Prompt: Are there models from other fields of science that could be employed to fill nutrition research evidence gaps?

- Institute of Education Sciences (IES) model for broadening participation
- National Human Genome Research Institute (NHGRI) model for investment in increasing diversity among trainees, tracking trainee outcomes, and increasing diversity among researchers
- American Society for Nutrition (ASN) model for increasing diversity in clinical trials
- Use of randomized studies to determine effectiveness of community-scale interventions (see book 'Randomistas')

Prompt: How could/should research-based interventions for primary and secondary prevention of diet-related chronic diseases be introduced into federal programs?

- Use rigorous assessment methods to assess the effectiveness of federal programs. Many programs just rely on assessing changes in knowledge. Expand assessment to collect anthropometric data, dietary data, etc.
- Prioritize measurement of outcomes-based implementation programs including use of participant-informed feedback throughout implementation.
- Evaluate expanded eligibility for nutrition supplementation programs for primary prevention of diet-related conditions.
- Develop guidelines for what constitutes evidence that supports legislation to reimburse for Food is Medicine programs (e.g. produce prescriptions, tailored meals, etc.).
- Connect federal nutrition education programs with Medicare, Medicaid, and FQHCs in a way that patients are prescribed nutrition education **in addition to** a Food is Medicine program (while also addressing food insecurity as the social determinant of these conditions).
- Create a firewall that prevents pharmaceutical or food corporations from having input into nutrition recommendations for federal programs (i.e. development of Dietary Guidelines for Americans, etc.).
- Policies and regulations for federal programs should focus on prevention and achieving a reduction in diet-related chronic illnesses in addition to food insecurity.

Society for Nutrition Education and Behavior

Prompt: What can be done to assure equitable access to the benefits of the federal nutrition research investment?

- Place a strong focus on implementation outside of major metros and provide funding on a census level to the states for equitable implementation.
- Make (virtually) all federally funded data, accompanying statistical code, and study results publicly available.
- Fund and conduct community-participatory research focused on translation and implementation of research findings within federal programs. Support scientists, researchers, and faculty working in communities heavily affected by diet-related chronic diseases in conducting that research so that federal programs can be tailored to local needs.