ADVISORY COUNCIL ON ALZHEIMER'S RESEARCH, CARE, AND SERVICES

Washington, DC and Virtual Meeting

May 8, 2023

Advisory Council Members in Attendance

- *Non-Federal Members Present*: Cynthia Carlsson (Chair), Randall Bateman, Venoreen Browne-Boatswain, Matthew Janicki, Keun Kim, Helen Bundy Medsger, Adrienne Mims, Carrie Molke, Joe Montminy, Maria Ortega, Joanne Pike, Rhonda Williams

- *Federal Members Present*: Arlene Bierman (Agency for Healthcare Research and Quality), Bruce Finke (Indian Health Services, IHS), Sarah Fontaine (U.S. Department of Defense), Richard Hodes (National Institutes of Health, National Institute on Aging, NIH/NIA), Shari Ling (Centers for Medicare & Medicaid Services, CMS), Erin Long (Administration for Community Living, ACL), Lisa McGuire (Centers for Disease Control and Prevention, CDC), Joan Weiss (Health Resources and Services Administration), Tisamarie Sherry (Office of the Assistant Secretary for Planning and Evaluation, ASPE)

- *Quorum present?* Yes

- *Advisory Council Designated Federal Officer*: Helen Lamont (ASPE)

General Proceedings

Chair Cynthia Carlsson called the meeting to order at 9:30 a.m. Eastern Daylight Time.

Welcome, Logistics, Introductions, and Announcements
Dr. Carlsson welcomed meeting participants and reviewed the meeting agenda. She responded to submitted public comments by noting that ASPE screens Council members for conflicts of interest and is updating processes for making potential conflict of interest information public. She also noted that the Council's research subcommittee had invited industry representatives to present, but not participate in deliberations, at its next meeting. A proceedings recording and notes will be available to the public.

Payment for Comprehensive Dementia Care: Five Key Recommendations

***Rani E. Snyder**, MPA, John A. Hartford Foundation*
***David Reuben**, MD, University of California, Los Angeles*
***Gary Epstein-Lubow**, MD, Education Development Center*
***Nora Super**, MPA, Long-Term Quality Alliance*

In October 2019, the John A. Hartford Foundation convened experts to discuss payment for dementia care and actionable next steps for current and new comprehensive care payment models. The group convened again in October 2022 to review evidence on quality, costs, and outcomes of scalable payment models, to discuss questions payers must be able to answer in order to provide coverage of comprehensive dementia care models, and to make recommendations for answers to these questions. Recommendations were published in *Health Affairs* February 2023.

Comprehensive dementia care focuses on both patients and caregivers, and includes continuous monitoring and assessment, ongoing care plans, psychosocial interventions, self-management, medication management, treatment of related conditions, and care coordination. Six models of comprehensive dementia care that have varied services and staffing have been developed, all of which have demonstrated patient and caregiver benefits.

The first recommendation for comprehensive dementia care payment models is “The payment model should cover comprehensive dementia care that meets quality outcomes measures.” In a study comparing quality across practice conditions, only 18% of physicians providing usual care met quality standards, whereas 92% offering comprehensive care met these standards.

Recommendation Two is “The payment model should address both beneficiary and caregiver needs.” Caregivers are at increased risk for adverse health outcomes, which can decrease the quality of care they offer.

Recommendation Three is “To be eligible, beneficiaries must have a diagnosis of dementia.” It is crucial to distinguish dementia from mild cognitive impairment in order to support appropriate treatment planning and cost containment. Palliative care should be available to beneficiaries when indicated. Beneficiaries of the Program for All-inclusive Care of the Elderly, people living in long-term residential nursing homes, and people enrolled in hospice care should not be eligible beneficiaries of the proposed comprehensive care models.

Recommendation Four is “Comprehensive dementia care models should be widely available to Medicare beneficiaries, especially those living in rural and underserved communities who have traditionally had difficulty accessing health care systems.” CMS should provide incentives for small community health care providers and rural practices to participate. Payments could be adjusted based on social determinants of health that

affect beneficiaries' communities. Model participants should collaborate with trusted community-based organizations.

Recommendation Five is "The payment model should be capitated based on the severity of symptoms and available resources." Existing codes are insufficient to support comprehensive dementia care, especially services that do not fit into fee-for-service structure, such as caregiver services. Capitation provides the most flexibility for providers and assures that CMS can meet budget requirements.

The presentation team noted that developing, testing, and implementing models for high-quality dementia care is a current federal policy priority. On April 18, 2023, President Biden issued an Executive Order to consider testing a new dementia care model that includes support for respite care. In addition, CMS is considering adopting measures of geriatric surgery and hospice quality, which the presenter team endorses. The team encouraged Council members to submit comments in favor of adoption.

Discussion

- Comprehensive care includes treatment of comorbidities, including multiple chronic conditions, and requires care coordination with a health care team. Payment models should consider severity of comorbidity symptoms.
- Comprehensive dementia care currently has bipartisan support in Congress.

Federal Updates

- ***Tisamarie Sherry***, *ASPE*. HHS has implemented policies to improve professional and unpaid caregivers' working conditions, improve access to community-based services, and expand programs to address veterans' needs for caregiving. HHS is working with the U.S. Department of Labor to expand and improve long-term care provider workforce data.

- ***Lisa McGuire***, *CDC*. CDC published an article on promoting healthy aging to reduce dementia risk in the *Generations* Spring 2023 issue and a *Morbidity and Mortality Weekly Report* article on racial and ethnic disparities in subjective cognitive decline, which found that less than half of people experiencing subjective cognitive decline had discussed it with a health care provider and that rates were highest among American Indians and Alaska Natives and lowest among Asians and Pacific Islanders. CDC will host the first Dementia Risk Reduction Summit on May 16-17, 2023, in Atlanta, Georgia. The agency has a new Notice of Funding Opportunity (NOFO) for the Building Our Largest Dementia (BOLD) Infrastructure Public Health Programs to Address Alzheimer's Disease and Related Dementias. It will fund approximately 35 new 5-year awards among state, local, and Tribal public health departments. CDC currently is updating the Healthy Brain Initiative Road Map Series on public health strategies to promote brain health, address dementia, and support caregivers. CDC plans to update the Road Map for Indian Country. CDC also is updating BOLD

infographics. CDC is collaborating with the Alzheimer's Association on the Data for Action Project to train state agencies, including public health departments, to interpret and utilize data to improve public health. CDC continues to offer free resources through the Healthy Brain Resource Center. Finally, CDC highlighted new partner resources on reducing risk of dementia developed by the International Association for Indigenous Aging (IA^2).

- ***Bruce Finke***, *IHS*. The IHS grant program supports education and training efforts to build capacity, outreach efforts to increase dementia awareness, and infrastructure to support data and programs. Most funding supports Tribal efforts to address Alzheimer's disease directly through evidence-informed models of care that leverage community resources and reflect community values. IHS and ACL grantees recently met to share lessons learned and insight. In Spring 2023, IHS issued NOFOs for models of care to address dementia in Indian Country.

  IHS is collaborating with the Northwest Portland Area Indian Health Board to develop and disseminated two new ECHO programs: Indian Country Dementia Clinical ECHO, targeted to the primary care workforce, and Indian Country Caregiver Support ECHO. Other IHS education and training programs include the Indian Health Geriatrics Scholars Pilot to build capacity in primary care by mentoring and offering experiential training to scholar cohorts that contribute to local improvement efforts; the Early Dementia Detection Initiative in Dental Clinics, which aims to improve dental care quality for patients with dementia and to train dental care providers to assist patients with dementia in getting the dementia care services they need; the Geriatric Emergency Department Accreditation Initiative, which has resulted in nine emergency department accreditations to date; and the U.S. Department of Veterans Affairs (VA) Geriatric Scholars Program.

- ***Richard Hodes****, NIH*. NIH appropriations for research on Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) have increased steadily since 2015, with a 5.6-fold increase over that period. One-third of awardees were new or early-stage investigators and one-fifth were new to the field, indicating that NIH funding facilitates the growth of the AD/ADRD research workforce. NIH is soliciting proposals to develop the AD/ADRD Real-World Data Platform, which will provide a data infrastructure to the research community, integrating real-world data from multiple sources to support research and trial design, improve data accessibility and quality, and maintain the research and knowledge base for AD/ADRD research using real-world data. NIH continues to support exposome research. NIH plans to improve its efforts to address social determinants of health through organizational redesign efforts such as founding a Dementia Care Coordination Research Center and a Consortium for Payment, Utilization, and Access for Dementia Care. NIH recently announced funding opportunities for projects to update estimates of the monetary costs of dementia in the United States, to the Edward R. Roybal Centers, and to the Health and Retirement Study and Harmonized Cognitive Assessment Protocol. NIA's Healthy Aging

Start-Up Challenge funds aging research and innovation in the business arena. NIH hosted the National Research Summit on Care, Services, and Supports for Persons Living with Dementia and Their Care Partners/Caregivers March 20-22, 2023. NIH continues to support the UNITE initiative to address structural racism in biomedical research and recently published its 5-year strategic plan for diversity, equity, inclusion, and accessibility. The National Institute of Neurological Disorders and Stroke has announced funding for AD/ADRD training, research on disease mechanisms, clinical trials and clinical research, and translation from research into practice.

Discussion

- It is important for people whom federal programs are designed to serve to be aware of these programs and how to access them. Effective outreach and dissemination should be a high priority. Messaging should be clear and culturally competent. Direct service providers are a critical audience.
- It would be useful to have a central point of access to comprehensive information about dementia and related programs. Keeping such resources up to date can be challenging.
- Many rural communities do not have access to digital media. It is crucial to share information through non-digital media.
- Communication efforts should apply adult learning principles.

Drug Approval and Coverage Decision Processes

"Therapies in Alzheimer's Disease: The Approval Process and Implementing Scientific Discoveries and Advances in Patient Health"

Teresa Buracchio, *MD, Acting Director/Deputy Director, Office of Neuroscience, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)*

Traditional FDA drug approval requires substantial evidence of effectiveness in achieving a clinically meaningful outcome or validated surrogate as well as being safe to use under conditions prescribed, recommended, or suggested by proposed labeling. Accelerated approval may be considered for drugs with potential to treat serious or life-threatening diseases for which there is an unmet need for treatment. To receive accelerated approval there must be substantial evidence that a drug is effective in achieving an outcome that is reasonably likely to predict a clinical benefit. The drug also must meet standards for safety. Validated surrogate endpoints are supported by a clear mechanistic rationale and can be used to support traditional approval without requiring additional efficacy information. A reasonably likely surrogate endpoints are supported by a clear mechanistic and/or epidemiologic rationale but has insufficient data for validation; these endpoints can be used for accelerated approval. Substantial evidence is defined by the Food, Drug, and Cosmetic Act Section 505(d). To meet this definition, evidence must be gathered from well-controlled studies conducted by qualified expert scientists and support the conclusion that the drug is effective in achieving purported

effects. In most cases, reviewers require evidence from at least two adequate and well-controlled studies. A single study with clinically meaningful, statistically robust, and very persuasive effects may be adequate for FDA consideration of effectiveness. In some cases, a single qualified study with additional confirmatory evidence is sufficient. FDA may apply regulatory flexibility in the case of life-threatening and severely debilitating illnesses with unmet need.

Alzheimer's disease is a serious and disabling disease with substantial unmet need for treatment, and which is not addressed adequately by currently available treatment options. Monoclonal antibodies aducanumab and lecanemab have received accelerated approval based on evidence that they reduce amyloid beta plaques. A clinical trial to confirm clinical benefit has been initiated for aducanumab. A trial to verify clinical benefit of lecanemab has been completed. Results are under FDA review.

The FDA engages with stakeholders through meetings, workgroups, and other approaches to learn about scientific advances; participates in data sharing initiatives and offers clinical trial simulation tools; and participates in formal advice meetings, reviews protocols and plans, qualifies biomarkers and clinical outcome assessments, and publishes guidance.

"Factors and Implementation for Traditional Medicare"

***Joseph Chin**, MD, MS*
***Shari Ling**, MD, CMS*

While CMS has authority distinct from FDA and other federal agencies, CMS consistently works in coordination with other federal agencies to ensure consistent federal policy and regulation. About one in 20 Medicare fee-for-service beneficiaries with Alzheimer's disease has no other chronic conditions. More than half (54%) of this population has four or more additional chronic conditions.

Medicare is a benefit program with services and conditions eligible for coverage defined in Title XVIII of the Social Security Act. National coverage determinations are made through a process defined by statute. The process includes review of published evidence, including peer-reviewed journal articles and professional societies' guidelines, and public comments in order to determine whether an item or service is reasonable and necessary for the Medicare population. Determinations may specify medical conditions and characteristics of patients, providers, and facilities under which the item or service is covered by Medicare.

"Prescribing Policy for Lecanemab and Plans for Future Implementation: Challenges and Opportunities"

Jennifer Martin, PharmD, VA

The VA is a staff model health maintenance organization, which allows rapid system-wide change. Following FDA review of a new molecular entity, the VA conducts a literature and clinical review, which is reviewed and commented on by the subject matter experts of the National Formulary Committee, then disseminated to clinicians for comment. After final review by the National Formulary Committee, a VA National Formulary decision is made, establishing national criteria for use. The VA disseminates documentation of these national decisions to local facilities for implementation. The VA covers all drugs, regardless of formulary status. Physicians may request approval for non-formulary prescription medications with documented rationale. More than 80% of requests have been approved.

VA coverage of monoclonal antibodies aligns with CMS's national coverage determination. Both drugs are classified as non-formulary. Providers can request approval to prescribe. Real-time prospective medication use evaluation is required for each dose of medication to be administered in order to assess safety and appropriateness of use. Manufacturers are not allowed to promote use of either drug at VA facilities. Monoclonal antibodies can be prescribed to VA patients if the provider is a VA neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia; the patient meets diagnostic criteria for mild cognitive impairment or mild Alzheimer's disease based on scores on the Functional Assessment Staging Test and Mini Mental State Examination; amyloid PET imaging or CSF analysis is consistent with Alzheimer's disease; and neuroradiology is available to review serial MRI scans. The VA does not offer monoclonal antibody therapy when any condition other than Alzheimer's disease may be a contributing cause of cognitive impairment; if the patient cannot have an MRI; if the patient has experienced ischemic attack, stroke, or seizures during the past year; if an MRI shows abnormalities related to edema or hemorrhages; or if the patient has untreated bleeding disorders.

The VA has found that it is important to be able to tailor procedures at the local level and to provide centralized education and training regarding medication administration and monitoring. The VA invites input on optimizing standardized operating procedures and training. There is a shortage of geriatric clinicians and neuroradiologists available to ensure adequate capacity for following VA protocols for administering monoclonal antibodies.

Discussion

- It is crucial to consider both risks and benefits of treatment when making clinical decisions.
- Medicare does not consider cost when making coverage determinations.
- Changing FDA determinations requires new scientific evidence.

- CMS cannot determine a drug to be eligible for coverage among the general Medicare population without full FDA approval.
- Agencies serving rural and underserved populations can facilitate clients' access to treatment and also work to ensure that treatment is safe. It is critical to balance both of these concerns.
- HHS agencies prioritize equitable access to treatment and information about treatment. People with disabilities including Down syndrome are a priority population that has been affected by disparities.
- Some stakeholders emphasize that regulatory agencies should not let high standards be obstacles to progress toward treating a currently incurable disease.

Progress, Challenges, and Opportunities in Translating Research into Clinical Impact

"National Alzheimer's Project Act (NAPA) Research Subcommittee Historical Recommendations and Progress"

***Randall Bateman**, MD*

Disease-modifying treatments for Alzheimer's disease recently became available for the first time, and additional treatments and diagnostics are in the pipeline. Policy makers and health care system administrators must consider how to optimize treatment access and utilization. Factors that influence decisions regarding what is optimal include insurance and care access, family and caregiver support, demographics, medical system capacity, education about and implementation of appropriate diagnosis and treatment, and policy and payer restrictions.

The NAPA research subcommittee has issued several recommendations since 2012. One recommendation is to develop a scientific road map for preventing, treating, and providing effective care and services for AD/ADRD by 2025. Road maps have been developed, continue to be needed, and should be updated on a regular basis. Another recommendation is to increase federal funding for research and implementation science. There have been substantial increases in funding over the last decade, but further increased future funding continues to be necessary. The recommendation to standardize terminology used for cognition and neurocognitive disorders has been partially addressed; these efforts are ongoing. There also has been progress toward implementing the recommendation to enhance research recruitment efforts. This recommendation should continue to be a priority, with emphasis on equitable inclusion and access. The subcommittee has recommended developing strategy and infrastructure to increase ethical research data sharing. Progress has been made and is still needed. This is also the case for the recommendation to engage stakeholders, including patients and care partners, in all stages of research. Progress toward implementing the recommendation to promote early detection and diagnosis of AD/ADRD has included identification of biomarkers and disease-modifying treatments. More progress should continue to be a priority. Research on care implementation and

improving quality of life has increased and continues to be a priority. The subcommittee's current top priority is for federal agencies to collaborate to design and implement pipelines for faster translation of research findings into clinical care.

"Overview of NAPA Research Progress"

***Ron Petersen**, PhD, MD, Mayo Clinic*

As a result of research findings, the understanding of Alzheimer's disease has evolved defined by biomarkers for amyloid and tau, in which symptoms are a part of the disease continuum but are not definitional. Current therapies work to reduce rate of disease progression by reducing amyloid in the brain. Two drugs have received accelerated FDA approval (aducanumab and lecanemab), with full approval pending for one drug. Adverse events associated with lecanemab include amyloid-related imaging abnormalities. Lecanemab treatment is associated with improved quality of life for patients and reduced caregiver burden. Preserving functioning is a key clinically meaningful outcome. NAPA has made important contributions to the significant progress made since 2011. Stakeholders should consider who should administer therapies and the implications of CMS coverage with evidence development. Coverage restrictions could increase disparities by reducing access.

"Industry's Role in Translating Research into Clinical Impact"

***Amir A. Tahami**, MD, PhD, Eisai*

Alzheimer's disease is a chronic, progressive, irreversible neurogenerative disorder that causes 60-80% of dementia cases. It is the fifth leading cause of death globally, causing approximately 2 million deaths annually. There is a need for treatment that addresses the underlying pathophysiology of Alzheimer's disease in order to delay disease progression and improve health outcomes. Costs of Alzheimer's disease include costs associated with lost productivity, unpaid care, direct medical and service costs, and costs of institutionalization during later stages of the disease. Costs are proportional to disease severity.

Care varies across the disease continuum, from risk assessment to end of life. Currently, there are opportunities for improvement at each stage of care. Research findings should be translated to care quality improvement. Recent developments, such as blood-based biomarkers, allow earlier and more accurate diagnosis of Alzheimer's disease. Earlier diagnosis will allow access to new treatment options and maximize the possibility that treatment will succeed in slowing cognitive and functional decline as well as improving patient safety. Since treatment costs increase with disease severity, early diagnosis and treatment have potential to reduce costs. Neurologists will need to change practice to allow patients to benefit from innovations. The limited number of specialists and capacity for biomarker testing present barriers to early diagnosis.

The Clinical Meaningfulness Framework considers multiple outcomes, not limited to cognition and functioning. An Alzheimer's Association workgroup applied this framework in a study that found patients value the additional time in milder disease stages that results from slowing the rate of disease progression 25%. Models of lecanemab effects indicate that it slows disease progression enough to allow patients more than 2 years in each earlier stage of disease progression prior to severe Alzheimer's disease.

Industry's role in translating research into clinical impact includes drug discovery and development, conducting clinical trials, obtaining regulatory approval, manufacturing, quality control, pharmacovigilance, distribution, providing education, collaborating with researchers, conducting post-marketing studies, and offering patient support programs. Industry experiences high costs resulting from failed attempts to develop drugs. Public/private collaboration is essential for offering early diagnosis and treatment options.

"Programs Facilitating Integration of Disease-Modifying Therapies and Diagnostic Testing into Clinical Practice"

***Kirk Daffner**, MD, FAAN, Professor of Neurology, Harvard Medical School*
***Seth Gale**, MD, Assistant Professor of Neurology, Harvard Medical School, Clinical Director, Alzheimer's Center, Brigham and Women's Hospital*

Massachusetts General Brigham (MGB) brings together Massachusetts General Hospital and Brigham and Women's Hospital into one hospital and physician network. MGB hosts an Interdisciplinary Dementia Care Center, which offers clinical assessment and evaluation, specialized testing, and treatment plan development and implementation by a team of providers specializing in cognitive neurology, geriatric psychology or neuropsychiatry, neuropsychology, social work, and cognitive therapy. Services include symptomatic medical treatments, cognitive therapy, skills training, counseling, social work referrals, and patient partner support. Some providers are clinical researchers and some patients are research participants, as there are several current Alzheimer's clinical research programs.

Over the first 2 years of delivering these new disease-modifying therapies, there are likely to be bottlenecks due to the challenge of identifying patients for whom treatment is appropriate and ensuring that treatment is safe. MGB developed the Alzheimer Therapeutics Program clinic model with the aim of overcoming these challenges. The Alzheimer Therapeutics Program will offer a specialized therapeutic clinic to identify, evaluate, treat, and monitor patients receiving advanced therapeutics for Alzheimer's disease. Clinicians will share responsibility for patient care and participate in consensus conferences for complex cases.

There are additional opportunities for health systems, federal agencies, and the pharmaceutical industry to build programs for accessible and safe provision of disease-modify therapies. In the short term, health care systems must develop and implement programs that can deliver disease-modifying therapies, monitor patient safety, and train

advanced practice and other providers in how to administer disease-modifying therapies. Over the long term, systems must train a wider range of providers and increase program efficiency. In the short term, federal agencies will need to approve and reimburse appropriate use of disease-modifying therapies and ensure access to all patients who need them. In the long term, agencies will need to support reimbursement for evaluation for Alzheimer's disease and drug safety monitoring and set guidelines for new diagnostic tests and devices. In the short term, pharmaceutical and biotech industries can defray specialist training costs. In the long term, they can support education for patients and caregivers and collaborate with federal agencies and health care systems to sponsor pragmatic research.

In the United States, as many as 80% of people with dementia have not been diagnosed, and as many as 95% of people with mild cognitive impairment have not been diagnosed. This contributes to the bottlenecking challenge of identifying patients for whom disease-modifying therapies are appropriate. Care capacity must be increased to meet need. This can include funding validated models of screening and developing more efficient and accurate screening techniques. Most patients are not eligible for disease-modifying therapies when they are diagnosed, often because they are in the moderate stage of dementia or providers are unable to confirm their stage of dementia. The field needs to determine how best to provide longitudinal care for these patients and how to address the shortage of providers trained to provide this care.

While Black and Hispanic Americans are 1.5-2 times more likely than White Americans to have dementia, they are 65% less likely to be diagnosed and treated. Black and Hispanic Americans are less likely to be prescribed medications that treat Alzheimer's disease, are less likely to adhere to directions for taking these medications and are more likely to discontinue medication use. As many as 40% of patients from racial/ethnic minorities believe their health care providers have not listened to them because of their race or ethnicity. Health care systems must consider how to address barriers to equity in order to ensure equitable access to screening and treatment. Pharmaceutical and biotech industries should develop programs to cover the costs of diagnosis and treatment for those who cannot afford them.

Discussion on Coordination of NAPA Goals: Challenges and Opportunities

- Electronic health records can help primary care physicians to identify people with mild cognitive impairment or dementia.
- Health systems should provide supports that allow primary care physicians to obtain support as needed.
- Patient navigators are a potentially valuable resource for ensuring patients get the care they need.
- Private home-based care providers discharge patients after a dementia diagnosis if their staff does not include a dementia specialist, which is required for reimbursement. Policies are needed to protect patients and caregivers from being harmed by such practices.
- New drugs should be administered by specialists in order to maximize patient safety.

- Patients with younger onset Alzheimer's disease are more likely than older patients to be affected by tau and may need tau imaging for early diagnosis.
- Stakeholders should consider how to decrease the time between research findings and clinical practice.
- ***Ron Petersen*** of the Mayo Clinic said the CMS national coverage determination was the most important decision about reimbursement in the history of Medicare. It is the most important current policy issue related to Alzheimer's disease. It is important for patients to have input on how risks of treatment are weighed. The United States has a history of authorizing risky treatment for dangerous diseases. He pointed out that a phase 3 trial has provided evidence of drug effectiveness and said that CMS should respond by reconsidering its decision.

Public Comments

- ***Laura Cohen*** of Eli Lilly Company advocated for timely and equitable access to therapies targeting amyloid plaques. She said that the CMS decision to restrict access will impede efforts to treat Alzheimer's disease and reduce prevalence. She urged reconsideration based on recent new evidence as soon as possible.

- ***Candace DiMatteo*** of the Partnership to Fight Chronic Disease emphasized the importance of equitable access to treatment. She urged CMS to lift restrictions on access to disease-modifying drugs.

- ***Hampus Hillerstrom*** is father to a son with Down syndrome, was previously co-founder and executive director of an Alzheimer's disease biotech company, and is currently president and chief executive officer of LuMind Foundation, a national non-profit organization that accelerates research related to Down syndrome. He reminded the Council that people with Down syndrome typically get Alzheimer's disease 20-30 years earlier than the general population and have a 90% lifetime risk of getting Alzheimer's disease. Current CMS restrictions to clinical trial participation based on age and cognitive skills exclude people with Down syndrome from access to disease-modifying medications. His organization has convened experts to develop a consensus statement on equivalent access to treatment for adults with Down syndrome. The organization will share this statement with the Council in about 1 month. No adults with Down syndrome were included in clinical trials of monoclonal antibodies, which could delay this population's access to these drugs for as much as 14 years. He urged conducting trials among adults with Down syndrome as soon as possible. He asked the Council to advocate for conducting such trials, to advocate for lifting restrictions on access to treatment that affect people with Down syndrome, and to address needs of people with Down syndrome in the National Plan.

- ***Seth Keller***, neurologist, pointed out that it is difficult to assess neuroatypical people for mild cognitive impairment. Dr. Keller worked with a national team of experts to develop recommendations for how to assess this population for mild

cognitive impairment and dementia. He advocated for implementing these recommendations and for more research in this area.

- Dr. Lamont read comments from ***Leslie Norins***, who urged the Council to require members to disclose conflicts of interest.

- ***Russ Paulsen***, Chief Operating Officer of UsAgainstAlzheimer's, urged action to prevent and cure Alzheimer's as quickly as possible.

- ***Mike and Carol Peterson*** are parents of a daughter with Down syndrome who was diagnosed with Alzheimer's disease when she was 41 years old. They acquired assistive technology, helped their daughter get medical care, and tried to support her in managing symptoms. While the Petersons were able to handle these responsibilities, they noted that this can be detrimental to the health of other older parents of people with Down syndrome and Alzheimer's disease. They proposed including professionals representing the Down syndrome community on Council subcommittees. They also advocated for policies and programs that support caregivers and for the inclusion of people with Down syndrome in research studies and drug trials.

Concluding Remarks

Dr. Carlsson noted that the Council's next meeting will be held July 31, 2023.

The meeting adjourned at 4:34 p.m.

Minutes submitted by Helen Lamont (ASPE).

All presentation handouts are available at https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa/napa-advisory-council/napa-advisory-council-meetings.