



October 19, 2021

Dr. Cynthia Carlsson  
Chair, Advisory Council on Alzheimer's Research, Care, and Services  
Office of the Assistant Secretary for Planning and Evaluation, Room 415F  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Dr. Carlsson:

The National Down Syndrome Society (NDSS), in partnership with the LuMind IDSC Foundation and the National Task Group on Intellectual Disabilities and Dementia Practices (NTG), is submitting this letter to the Advisory Council on Alzheimer's Research, Care, and Services (the Advisory Council), urging the Advisory Council to take action to address the needs the Down syndrome community, consistent with its charge under the National Alzheimer's Project Act (P.L. 111-375). NDSS is the leading human rights organization for all individuals with Down syndrome. NDSS envisions a world in which all people with Down syndrome have the opportunity to enhance their quality of life, realize their life aspirations, and become valued members of welcoming communities.

The estimated lifetime risk of Alzheimer's disease for people with Down syndrome exceeds 90%<sup>i</sup> and is the leading cause of death for those adults.<sup>ii</sup> People with Down syndrome represent the single largest group with early onset dementia due to Alzheimer's disease; the median age for a diagnosis of Alzheimer's related dementia in this group is approximately 55 years of age.<sup>iii</sup> It is imperative, therefore, that all causal research and treatment studies for Alzheimer's disease include people with Down syndrome.

To advance this effort, we have joined together to thank the Advisory Council for including Down syndrome in its annual plan recommendations issued per the National Alzheimer's Project Act and to recommend further action: **we urge the Advisory Council to establish a special subcommittee to focus on how HHS can improve the diagnostic and clinical supports available to adults with Down syndrome and other intellectual and developmental disabilities.** While the Down syndrome community stands apart in its urgent need for this work, it is our belief that the subcommittee's efforts would benefit the entire intellectual and developmental disability community.

We wish to highlight five specific areas where the intellectual and developmental disability community – and specifically the Down syndrome community – needs the support of the Advisory Council. We ask the Advisory Council to recommend that HHS take the following actions:

Access to Adequate Clinical Care

**Fund opportunities for the education of clinicians, inclusive of both students and practitioners, make substantive recommendations for training curricula, and create resources for technical assistance.**

Correctly diagnosing Alzheimer's disease in an individual with Down syndrome requires a specialized

knowledge of this population, and there is a dearth of clinicians who have the requisite skills, knowledge, and experience. It is estimated that specialty Down syndrome clinics currently meet the needs of only 5% of the population.<sup>iv</sup> Even when a person with Down syndrome is properly diagnosed with Alzheimer's disease, there is a systemic lack of inclusive treatment options and care protocols for managing dementia. To address these needs, we also ask that HHS support the identification and enhancement of existing and potential clinics and diagnostic resources that serve our community.

#### Increased Support for Research for Down Syndrome Associated Alzheimer's Disease:

**Improve the body of research focused on the intersection of and relationship between Down syndrome and Alzheimer's disease.** In order to effectuate this change, we recommend increased coordination between the Advisory Council's annual plan and the NIH Down Syndrome Research Plan. While there have been notable increases in NIH biomarker and biomedical research, there are not enough funded studies focused on health outcomes, diagnostics, or social research, including caregiver impact. Better coordination between the NIH Down Syndrome Research Plan and the NAPA Advisory Council Plan's annual plan, with more attention directed towards areas of research currently un- or under-realized, will dramatically improve the likelihood that individuals with Down syndrome and their families can reach the best possible outcome after an Alzheimer's diagnosis.

#### Access to New Alzheimer's Treatments

**Collaborate with CMS to promote the affordability of new Alzheimer's therapies for individuals with Down syndrome.** Insurance coverage of treatments is a key lever in helping individuals with Down syndrome receive adequate care. In its administration of Medicare and Medicaid, CMS sets a market standard that other insurers follow, so as new treatments for Alzheimer's disease continue to be developed, it is critical that CMS ensure that its policies do not limit physicians' capacity to make individualized assessment, diagnosis, and treatment plans that take persons with intellectual and developmental disabilities into account. Because of the Advisory Council's ability to highlight the needs of this community – and especially those with Down syndrome – and because of its constituent membership, the Advisory Council is uniquely positioned to ensure that inability to pay should not be an impediment to treatment.

#### Inclusion of Individuals with Down Syndrome in Clinical Trials

**Work to ensure that individuals with Down syndrome are included in current and future clinical trials, either through regulation or subregulatory guidance, as appropriate.** Clinical trials lead to new treatments. By excluding people with Down syndrome from trials, investigators are systematically excluding them from clinical care that can markedly improve their quality of life. At the same time, the Down syndrome community is put at risk for adverse reactions to treatments for Alzheimer's that are developed in their absence and may prove inappropriate. A recent example of this problematic practice is Biogen's ongoing trials for aducanumab, a new treatment of early-stage Alzheimer's related dementia. Despite the treatment's promise for adults with Alzheimer's dementia in the general population, because atypical adults were (and remain) omitted from the trials, even Biogen itself has advised against the off-label use of the medication for adults with Down syndrome. Furthermore, an expert panel has concluded that the use of aducanumab in adults with Down syndrome is inappropriate.<sup>v</sup>

#### Access to Long-Term Services and Supports

**Promote processes to ensure that health care providers in congregate care settings serving individuals with Down syndrome are trained in memory care; likewise, work to ensure that providers in dedicated memory care settings are trained in the care of individuals with Down syndrome and other intellectual and developmental disabilities.** The need for alternatives to long-term family-based care

has become more acute because the life expectancy of individuals with Down syndrome has increased dramatically over the past few decades, spotlighting the diminishing capacity of family members who themselves are aging. Individuals with Down syndrome transitioning into congregate settings must have access to professionals who possess specialized expertise. Most memory care clinicians lack the specific training needed to care for individuals with Down syndrome adequately, and most clinicians who care for individuals with Down syndrome are unfamiliar with how to provide memory care. Without alternatives, such as small dementia care group homes, supported apartments, or in-home supports, families will continue to bear the responsibility of providing life-long direct care for their loved ones with Down syndrome living with Alzheimer's disease – all while they themselves face the difficulties of aging.

We thank the Advisory Council for the opportunity to comment on the critical intersection between Down syndrome and Alzheimer's disease and to share our recommendations for addressing the needs of the community. The National Down Syndrome Society and its partners are eager to work with the Advisory Council to promote positive outcomes for all individuals with intellectual and developmental disabilities. For further information regarding these comments, please contact me at [kpickard@ndss.org](mailto:kpickard@ndss.org).

Sincerely,



Kandi Pickard  
President and CEO, National Down Syndrome Society

About the National Down Syndrome Society:

The National Down Syndrome Society (NDSS) is the leading human rights organization for all individuals with Down syndrome. NDSS envisions a world in which all people with Down syndrome have the opportunity to enhance their quality of life, realize their life aspirations and become valued members of welcoming communities. Founded in 1979, NDSS supports and advocates for the Down syndrome community by focusing on three key areas of programming: Resources & Support, Policy & Advocacy and Community Engagement. Within these focus areas NDSS engages in various activities, events and programs to support individuals with Down syndrome, their families and caregivers across the lifespan. Visit [www.ndss.org](http://www.ndss.org) for more information about NDSS.

About the LuMind IDSC Foundation:

The LuMind IDSC Foundation (LuMind IDSC) envisions a world where every person with Down syndrome thrives with improved health, independence, and opportunities to reach his or her fullest potential. By facilitating translational research, LuMind IDSC accelerates the availability of therapeutic, diagnostic, and medical care options for people with Down syndrome while also providing responsive and reliable resources to a vibrant online community of 200,000 people with Down syndrome, their families, and caregivers.

[www.lumindidsc.org](http://www.lumindidsc.org)

### About the NTG:

The 'NTG' is a not-for-profit organization charged with ensuring that the interests of adults with intellectual and developmental disabilities who are affected by Alzheimer's disease and other causes of dementia – as well as their families and friends – are considered in research, public policy, and services development. The NTG's overall mission is to advocate for services and supports for people with intellectual disability and their families who are affected by Alzheimer's disease and dementias.

<https://www.the-ntg.org>

cc: Dr. Helen Lamont, DHHS/ASPE  
Director, Division of Disability and Aging Policy  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

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<sup>i</sup> McCarron, M.; McCallion, P.; Reilly, E.; Dunne, P.; Carroll, R.; Mulryan, N. A prospective 20-year longitudinal follow-up of dementia in persons with Down syndrome. *J Intellect Disabil Res.* **2017**, *61(9)*, 843-852.

<sup>ii</sup> Hithersay, R.; Startin, C.M.; Hamburg, S.; Mok, K.Y.; Hardy, J.; Fisher, E.M.C.; Tybulewicz, V.L.J.; Nizetic, D.; Strydom, A. Association of dementia with mortality among adults with Down syndrome older than 35 years. *JAMA Neurol.* 2019, *76(2)*, 152-160.

<sup>iii</sup> Sinai, A.; Mokrysz, C.; Bernal, J.; Bohnen, I.; Bonell, S.; Courtenay, K.; Dodd, K.; Gazizova, D.; Hassiotis, A.; Hillier, R.; McBrien, J.; McCarthy, J.; Mukherji, K.; Naeem, A.; Perez-Achiaga, N.; Rantell, K.; Sharma, V.; Thomas, D.; Walker, Z.; Whitham, S.; Strydom, A. Predictors of age of diagnosis and survival of Alzheimer's disease in Down syndrome. *J Alzheimers Dis.* 2018, *61(2)*, 717-728

<sup>iv</sup> Santoro SL, Campbell A, Balasubramanian A, Haugen K, Schafer K, Mobley W. Specialty clinics for adults with Down syndrome: A clinic survey. *Am J Med Genet A.* 2021 Jun;185(6):1767-1775. doi: 10.1002/ajmg.a.62169. Epub 2021 Mar 17. PMID: 33729670.

<sup>v</sup> Cummings J, Aisen P, Apostolova LG, Atri A, Salloway S, Weiner M. Aducanumab: Appropriate use recommendations. *J Prev Alzheimers Dis.* 2021;8(4):398-410. doi: 10.14283/jpad.2021.41. PMID: 34585212.