

February 12, 2024

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear President Biden:

As a community of clinicians, researchers, and thought leaders collaborating on many fronts alongside people with the epilepsies, family members, caregivers, and advocates, to improve epilepsy healthcare and outcomes, we respectfully **request increased federal investment for research into the epilepsies**, as part of your FY 2025 budget proposal. Collectively, the epilepsies are among the most common conditions affecting the brain and range in impact from profoundly debilitating to manageable with therapy. More significant government investment is needed to advance understanding of these various epilepsies, develop more effective and targeted therapies, and establish new, transformative models of patient care.

One in 26 people will develop a form of epilepsy in their lifetime¹ and 3.4 million Americans currently live with active epilepsy, including 470,000 children and teenagers.² The epilepsies can be deadly, with one out of every 1,000 people dying from sudden unexpected death in epilepsy (SUDEP).³ Delayed recognition of seizures and inadequate or delayed treatment increases a person's risk of subsequent seizures, brain damage, disability, and death. Moreover, the epilepsies that lack a definitive biological cause are some of the most burdensome neurological disorders in the US, based on a recent survey.⁴

Epilepsy is a spectrum disease that affects infants, children, young people, working adults, seniors, wounded warfighters, veterans, and persons impacted by traumatic brain injury. At the fundamental level, epilepsies are disorders of the brain characterized by abnormal nerve cell signaling. This causes seizures, which are driven by uncontrolled bursts of electrical activity that change sensations, behaviors, awareness, and muscle movements. The epilepsies consist of many diagnoses, including an ever-growing number of rare epilepsies. Due to this vast spectrum, there are many different types of seizures and varying levels of seizure control. Furthermore, the health challenges of the epilepsies extend far beyond seizures to include cognitive, behavioral, and psychiatric mood disorders, as well as mobility, gastrointestinal, and respiratory issues.⁵

We deeply appreciate your administration's efforts to prioritize access to innovation and eliminate disparate health outcomes across disease states, especially for epilepsies and other neurological disorders. This is exemplified by the U.S. Department of Health and Human Services' statements

¹ Hesdorffer et al., Estimating risk for developing epilepsy. A population-based study in Rochester, Minnesota *Neurology* 2011;76:23-27

² Zack MM and Kobau R, National and State Estimates of the Numbers of Adults and Children with Active Epilepsy — United States, 2015 *MMWR Morb Mortal Wkly Rep* 2017;66:821-825

³ CDC, <https://www.cdc.gov/epilepsy/communications/features/sudep.htm>.

⁴ GBD 2017 US Neurological Disorders Collaborators, Burden of Neurological Disorders Across the US From 1990-2017 A Global Burden of Disease Study, *JAMA Neurol.* 2021;78(2):165-176.

⁵ <https://www.sciencedirect.com/science/article/abs/pii/S0022347618309600>

of support for the World Health Organization (WHO) Intersectoral Global Action Plan (IGAP) that was unanimously approved in May 2022. IGAP envisions a future where “brain health is valued and protected across the life course; neurological disorders are prevented, diagnosed and treated; premature mortality and morbidity are avoided; and people affected by neurological disorders have equal rights, opportunities, respect, and autonomy.”⁶ Your administration’s commitment to encouraging the development of breakthrough areas of medicine and transformative new therapies is commendable and can position the U.S. to realize the vision outlined in the IGAP. By investing strategically in epilepsy research, new therapies, and data surveillance through agencies such as ARPA-H, AHRQ, NIH, CDC, CMS, HRSA, FDA, DoD, and the VA, we can drive forward innovative approaches backed by robust science to elevate the level of healthcare for people with the epilepsies. Collaborative efforts across government will also be key to addressing the challenges related to increasing data tracking and translating data into solutions to help people with the epilepsies and save lives.

Recent research developments have pushed the envelope on multiple fronts. There is now a more robust understanding of the genetic underpinnings of a growing number of epilepsies. The use of rapid genome sequencing to diagnose genetic epilepsies has enabled precision medicine in the clinical care of infants with new-onset epilepsy, with implications for the wider population.^{7,8} Other notable breakthroughs in the last year include the development of a novel seizure mitigation therapy using stem cells that has progressed to clinical testing in people with epilepsy^{9,10} and the creation of an electronic medical record model to predict seizures and minimize invasive procedures.¹¹

Despite these advances and valuable support from the NIH over several decades, the everyday lives of people living with epilepsy remain largely unchanged. A vast number of patients (more than 30% of adults and 20-25% of children) don’t respond to treatment.^{12,13} This number is much higher for patients with rare, genetic epilepsies. For example, nearly 60% of tuberous sclerosis complex (TSC) patients with focal seizures exhibit drug resistance, while a small-scale study of patients with mutations of the *SCN8A* gene, demonstrated nearly 90% being unresponsive to treatment.^{14,15} There has been no decrease in premature deaths due to the epilepsies, especially

⁶ <https://iris.who.int/bitstream/handle/10665/371495/9789240076624-eng.pdf?sequence=1>

⁷ <http://epilepsygenetics.net/2023/05/10/five-novel-concepts-in-epilepsy-genetics-you-need-to-know-in-2023/>

⁸ D’Gama AM, Mulhern S, Sheidley BR, et al. Evaluation of the feasibility, diagnostic yield, and clinical utility of rapid genome sequencing in infantile epilepsy (Gene-STEPS): an international, multicentre, pilot cohort study. *Lancet Neurol.* 2023;22(9):812-825. doi:10.1016/S1474-4422(23)00246-6

⁹ Bershteyn M, Bröer S, Parekh M, et al. Human pallial MGE-type GABAergic interneuron cell therapy for chronic focal epilepsy. *Cell Stem Cell.* 2023;30(10):1331-1350.e11. doi:10.1016/j.stem.2023.08.013

¹⁰ <https://classic.clinicaltrials.gov/ct2/show/NCT05135091>

¹¹ Barsh GR, Wusthoff CJ. Can electronic medical records predict neonatal seizures?. *Lancet Digit Health.* 2023;5(4):e175-e176. doi:10.1016/S2589-7500(23)00041-9

¹² Chen et al., Treatment Outcomes in Patients with Newly Diagnosed Epilepsy Treated With Established and New Antiepileptic Drugs A 30-Year Longitudinal Cohort Study *JAMA Neurol* 2018;75(3):279-286,

¹³ <https://www.epilepsy.com/treatment/medicines/drug-resistant-epilepsy#:~:text=Studies%20suggest%20that%20epilepsy%20fails,20%2D25%25%20of%20children.>

¹⁴ Jeong A, Nakagawa JA, Wong M. Predictors of Drug-Resistant Epilepsy in Tuberous Sclerosis Complex. *J Child Neurol.* 2017;32(14):1092-1098. doi:10.1177/0883073817737446

¹⁵ Larsen J, Carvill GL, Gardella E, et al. The phenotypic spectrum of SCN8A encephalopathy. *Neurology.* 2015;84(5):480-489. doi:10.1212/WNL.0000000000001211

among children. There are no biomarkers for the vast majority of the epilepsies and few effective technologies to track real-time data from patients. Clinicians cannot predict drug efficacy, adverse side effects or long-term prognosis for any given patient. These intractable issues are further complicated by barriers that patients face in accessing care and participating in research. As the Chief of the Dell Children’s Comprehensive Epilepsy Center, Dr. Dave Clarke has stated, “There are still huge swaths of the population affected by the epilepsies that have no access, no voice and are unheard and not part of the research community. You have these vast differences in care.”

Funding for epilepsies research is disproportionately low compared to other health conditions, including other major neurological disorders. For context, \$24.5 billion in direct U.S. healthcare spending is attributable to epilepsy or seizures, with the total healthcare burden being at least \$54 billion.¹⁶ However, only half of a percent of the more than \$42 billion the NIH spends on medical research each year, goes to epilepsy.¹⁷ This disparity has worsened since 2007 and cannot be explained by differences in the incidence or the overall impact of these diseases on Americans. Another significant challenge to understanding the epilepsies and developing new therapies is the lack of comprehensive, timely, representative data. The nation has insufficient surveillance data on the spectrum of the epilepsies, which could contribute to some of the disparity in funding that the epilepsies receive. The cause of the disease is unknown in about 50% of cases, according to the WHO. This underscores the need for federal investment to better understand the root causes of the disease and its progression, and facilitate translation of acquired knowledge into therapies that can improve the quality of life for those impacted by the epilepsies.

This past year, considerable progress was made in raising the profile of the epilepsies, including the establishment of the [Congressional Epilepsy Caucus](#). Our community is united and continues to work collaboratively to improve the lives of people with the epilepsies. We welcome the opportunity to collaborate with government partners to facilitate better outcomes and prioritize development of more effective treatments. Given the high incidence of the epilepsies in the U.S., it is nearly impossible to pass through daily life without encountering persons directly impacted by these disorders. The epilepsies, therefore, merit greater, more strategic investment and attention proportionate to their high personal and economic costs. Moreover, research advances in brain health can catalyze breakthroughs across the wider spectrum of health, which aligns with the priorities of your administration, particularly in improving access to and the quality of care, promoting health equity, bettering understanding of rare diseases, and fostering an innovation ecosystem.

As part of your administration’s forthcoming budget proposal, we strongly encourage you to strategically augment federal investment in the epilepsies including: 1) programs with a high potential for translational payoff that can lead to better health outcomes for people living with the epilepsies and 2) existing funding streams at NIH, CDC, HRSA, VA and DoD to support research needed to further understand the epilepsies. Thank you for your consideration.

Sincerely,

¹⁶ Moura LMVR, Karakis I, Zack MM, Tian N, Kobau R, Howard D. Drivers of US health care spending for persons with seizures and/or epilepsies, 2010-2018. *Epilepsia*. 2022;63(8):2144-2154. doi:10.1111/epi.17305

¹⁷ <https://report.nih.gov/funding/categorical-spending#/>; <https://www.nih.gov/about-nih/what-we-do/budget>



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Joined By:

Alliance to Cure Cavernous Malformation

American Epilepsy Society (AES)

Angelman Syndrome Foundation

Association of University Centers on
Disabilities

ASXL Rare Research Endowment
Foundation

BAND Foundation

BDSRA Foundation

Boston Children's Hospital Epilepsy Center

Bubba's Light

CACNA1A Foundation

Cardio Facio Cutaneous International

Chelsea's Hope Lafora Children Research
Fund

Child Neurology Foundation (CNF)

Children's National Comprehensive
Pediatric Epilepsy Program

Coalition to Cure CHD2

COMBINEDBrain

CSNK2A1 Foundation

CSNK2B Foundation

CTNNB1 Connect & Cure

CURE Epilepsy

Cure KCNH1 Foundation

Cure Sanfilippo Foundation

CureDRPLA

CureGRIN Foundation

CureSHANK

Danny Did Epilepsy Foundation

DEE-P Connections

Dell Children's Comprehensive Epilepsy
Center

Doose Syndrome Epilepsy Alliance

Dravet Syndrome Foundation

Dup15q Alliance

Empowering Epilepsy

Empowering People's Independence

Epilepsies Action Network (EAN)

Epilepsy Advocacy Network	Epilepsy Foundation New Jersey
Epilepsy Alliance America	Epilepsy Foundation New Mexico
Epilepsy Alliance Louisiana	Epilepsy Foundation North Carolina
Epilepsy Association of Western and Central Pennsylvania	Epilepsy Foundation North Dakota
Epilepsy Foundation (National)	Epilepsy Foundation Northern California
Epilepsy Foundation Alabama	Epilepsy Foundation of Colorado & Wyoming
Epilepsy Foundation Alaska	Epilepsy Foundation of Connecticut
Epilepsy Foundation Arizona	Epilepsy Foundation of Delaware
Epilepsy Foundation Arkansas	Epilepsy Foundation of Georgia
Epilepsy Foundation Central & South Texas	Epilepsy Foundation of Greater Chicago
Epilepsy Foundation East Tennessee	Epilepsy Foundation of Greater Orange County California
Epilepsy Foundation Eastern Pennsylvania	Epilepsy Foundation of Greater Southern Illinois
Epilepsy Foundation Florida	Epilepsy Foundation of Hawaii
Epilepsy Foundation Indiana	Epilepsy Foundation of Kentuckiana
Epilepsy Foundation Iowa	Epilepsy Foundation of Minnesota
Epilepsy Foundation Los Angeles	Epilepsy Foundation of Missouri & Kansas
Epilepsy Foundation Louisiana	Epilepsy Foundation of Northeastern New York
Epilepsy Foundation Maryland	Epilepsy Foundation of Virginia
Epilepsy Foundation Metro DC	Epilepsy Foundation of Wisconsin
Epilepsy Foundation Metro New York	Epilepsy Foundation Ohio
Epilepsy Foundation Mississippi	Epilepsy Foundation Oklahoma
Epilepsy Foundation Montana	Epilepsy Foundation Oregon
Epilepsy Foundation Nebraska	Epilepsy Foundation San Diego County
Epilepsy Foundation Nevada	
Epilepsy Foundation New England	

Epilepsy Foundation South Carolina	International Foundation for CDKL5 Research
Epilepsy Foundation South Dakota	International SCN8A Alliance
Epilepsy Foundation Southeast Tennessee	Jordan's Guardian Angels
Epilepsy Foundation Texas	Josh Provides Epilepsy Assistance Foundation
Epilepsy Foundation Utah	KCNQ2 Cure Alliance
Epilepsy Foundation Washington	KCNT1 Epilepsy Foundation
Epilepsy Foundation West Virginia	KIF1A.ORG
Epilepsy Leadership Council (ELC)	Koolen-de Vries Syndrome Foundation
Epilepsy Learning Healthcare System	KPTN Alliance
Epilepsy Services Foundation	Lennox-Gastaut Syndrome (LGS) Foundation
Epilepsy Services of New Jersey	Louie's Huwe
Epilepsy Support Network of Orange County	Malan Syndrome Foundation
FACES (Finding a Cure for Epilepsy and Seizures)	Mid-Atlantic Epilepsy and Sleep Center
FAM177A1 Research Fund	My Epilepsy Story (MES)
FamilieSCN2A Foundation	My Kool Brother
Global Organization of Health Education (GOHE)	National Association of Epilepsy Centers (NAEC)
Glut1 Deficiency Foundation	NORSE Institute
GRIN2B Foundation	NR2F1 Foundation
HNRNP Family Foundation	NYU Langone Comprehensive Epilepsy Center
Hope for HIE	Orphan Disease Center
Hope for Hypothalamic Hamartomas	Partners Against Mortality in Epilepsy (PAME)
Hope for ULD	PCDH19 Alliance
Idaho Comprehensive Epilepsy	

Pediatric Epilepsy Learning Healthcare System (PELHS)	Tatton Brown Rahman Syndrome Community
Pediatric Epilepsy Research Consortium	Tbc1d24 Foundation
Pediatric Epilepsy Surgery Alliance	Telethon Kids Institute
Phelan-McDermid Syndrome Foundation	TESS Research Foundation
PPP3CA Hope Foundation	The Cameron Boyce Foundation
Project 8p Foundation	The CASK Gene Foundation
Project Alive	The Charlie Foundation for Ketogenic Therapies
Purple Point Neurodiagnostics	The Coelho Center for Disability Law, Policy and Innovation
PVNH Support & Awareness	The Connected Parent
Rare Epilepsy Network (REN) Coordinating Committee	The Cute Syndrome Foundation
RASopathies Network	The DESSH Foundation
Ring14 USA	The Epilepsy Study Consortium (TESC)
ROW Foundation	The Global Foundation for Peroxisomal Disorders
SATB2 Gene Foundation	The Inchstone Project
Seattle Children's Hospital Epilepsy Program	The MED13L Foundation
SLC6A1 Connect	The Rory Belle Foundation
SMC1A FOUNDATION	The Schinzel-Giedion Syndrome Foundation
SNAP25 Foundation	The SPATA Foundation
Sociedad Puertorriqueña de Epilepsia	The Sturge-Weber Foundation
South Carolina Advocates for Epilepsy	THG1L Families
STXBP1 Foundation	TSC Alliance
SynGAP Research Fund	YWHAG Research Foundation