



Nothing about us without us!

May 4, 2023

Xavier Becerra
Secretary
U.S. Department of Health and Human Services

Robert Califf
Commissioner
Food and Drug Administration

Samuel Bagenstos
General Counsel
U.S. Department of Health and Human Services

Sent via electronic mail

Re: FDA reissuing the rule banning electrical stimulation devices

Dear Secretary Becerra, Commissioner Califf, and General Counsel Bagenstos

We the undersigned write to urge the Federal Drug Administration (FDA) to reissue its ban of electrical stimulation devices (ESDs) used to treat self-injurious or aggressive behavior. In 2020 the Food and Drug Administration (FDA) banned the use of these devices as aversive therapy, a well-reasoned position that is consistent with the overwhelming weight of the scientific literature and treatment practices across the country.¹ Unfortunately, FDA's proposed ban was reversed on a technicality related to the FDA's regulatory authority. However, Congress has recently clarified the FDA's authority to issue such a ban.²

For two years since the FDA's original ban on these devices was overturned by the courts, -eight years after a panel of experts recommended that they be banned- children and adults with disabilities have continued to suffer from

¹ Food and Drug Administration. 21 CFR Parts 882 and 895. Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior; Proposed Rule <https://www.govinfo.gov/content/pkg/FR-2016-04-25/pdf/2016-09433.pdf>

² Consolidated Appropriations Act of 2023, H.R. 2617 (Dec. 2022) SEC. 3306. <https://www.congress.gov/bill/117th-congress/house-bill/2617>

painful and dangerous electric shocks. We urge you to end this abuse. The disability community has worked for years to ban ESDs. This past December, Congress affirmed that the FDA has the authority to do so. The medical evidence that this is an ineffective and harmful intervention is clear. When the FDA's judgment was questioned, the American Academy of Pediatrics, the American Academy of Developmental Medicine and Dentistry, the American Association on Intellectual and Developmental Disabilities, the International Association for the Scientific Study of Intellectual and Developmental Disabilities, the National Association for the Dually Diagnosed, the National Association of State Directors of Developmental Disabilities Services, and the National Association of State Directors of Special Education all agreed that the evidence supported an ESD ban.³ As Manfred Nowak, the UN's Special Rapporteur on Torture, has bluntly stated: "This is torture."⁴

On April 22, 2016, the FDA announced that it had determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. This followed outcry from concerned members of the public and advocacy organizations dating back more than 13 years to our first outreach in March 2010. As the FDA found, use of these devices

Present[s] a number of psychological and physical risks: Depression, fear, escape and avoidance behaviors, panic, aggression, substitution of other behaviors (e.g., freezing and catatonic sit-down), worsening of underlying symptoms (e.g., increased frequency or bursts of self-injury), pain, burns, tissue damage, and errant shocks from device misapplication or failure. Based on literature for implantable cardioverter defibrillators, FDA has determined that ESDs present the risks of posttraumatic stress or acute stress disorders, shock stress reaction, and learned helplessness. That literature provides additional support for the risks of depression, anxiety, fear, and pain. Experts in the field of behavioral science, State agencies that regulate the use of ESDs, the sole current manufacturer and user of

³ No. 20-1087 JRC v FDA, Brief of Amici Curiae (Jan. 22, 2021), <https://www.iassidd.org/wp-content/uploads/2021/02/As-filed-Amicus-Brief.pdf>

⁴ <https://abcnews.go.com/Nightline/shock-therapy-massachusetts-school/story?id=11047334>

ESDs, and individuals who were subject to ESDs corroborate most of these findings, and they attest to additional risks.⁵

We were pleased that the FDA agreed with what the United Nations, disability advocates, researchers, psychiatrists and psychologists, families and people with disabilities have long known – these are devices of torture and abuse.

The FDA is mandated to protect the health and safety of these individuals and must not delay further. In the years since this issue was first raised with the FDA, many vulnerable people with disabilities were subjected to electric shocks for behaviors such as getting out of one's seat, interrupting, whispering, slouching, swearing, or failing to maintain a neat appearance. As the previously-issued rule recognized, vulnerable children and adults are experiencing dramatic short and long-term effects from this abusive treatment every day.

We, the undersigned, urge HHS to prioritize and take all actions necessary to ensure this critical rule is reissued. Secretary Becerra and Commissioner Califf, we ask that you devote any and all resources necessary to swiftly reissue the rule with an immediate effective date and no further delays.

If you have any questions about this letter, please contact Larkin Taylor-Parker of the Autistic Self Advocacy Network at ltaylorparker@autisticadvocacy.org.

Signed,

Access Ready

22Q Texas, Inc.

ADAPT Montana

ADAPT National

⁵ U.S. Food and Drug Administration, Final Rule: Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 85 Fed. Reg. (Mar. 6, 2020), 13,312 <https://www.govinfo.gov/content/pkg/FR-2020-03-06/pdf/2020-04328.pdf>.

Advocacy Institute

Alabama Disabilities Advocacy Program (ADAP)

Alliance Against Seclusion and Restraint

Alliance Colorado

Allies for Independence

American Academy of Developmental Medicine & Dentistry (AADMD)

American Academy of Pediatrics

American Association on Health and Disability

American Association on Intellectual and Developmental Disabilities

American Civil Liberties Union (ACLU)

American Foundation for the Blind

ANCOR (The American Network of Community Options & Resources)

Arc of Alabama

Arizona Center for Disability Law

Atlantis ADAPT

Autism Society of America

Autism Speaks

Autistic People of Color Fund (APOC)

Autistic Self Advocacy Network

Autistic Women & Nonbinary Network

Barbara L'Italien

Bazelon Center for Mental Health Law

Blue Peaks Developmental Services
Boston Center for Independent Living
Broadreach Training and Resources Ltd
Broadreach training ltd
Caldwell Family Services Inc.
California Down Syndrome Advocacy Coalition
Callisto Services LLC
Caring Across Generations
Central Wisconsin ADAPT
Chattanooga Autism Center
Children and Adults with Attention-Deficit/Hyperactivity Disorder
CommunicationFIRST
Council of Parent Attorneys and Advocates
CQL | The Council on Quality and Leadership
Developmental Disabilities Coalition, Inc.
DisAbility Rights Idaho
Disabilities Law Program, CLASI
Disability Law Center
Disability Law Center of Alaska
disAbility Law Center of Virginia
Disability Law Colorado
Disability Policy Consortium

Disability Right Idaho
Disability Rights Arkansas
Disability Rights California
Disability Rights Center -NH
Disability Rights Center of Kansas
Disability Rights Education & Defense Fund
Disability Rights Florida
Disability Rights Iowa
Disability Rights Maine
Disability Rights Maryland
Disability Rights Michigan
DISABILITY RIGHTS MISSISSIPPI
Disability Rights New Jersey
Disability Rights New York
Disability Rights North Carolina
Disability Rights of West Virginia
Disability Rights Ohio
Disability Rights Oregon
Disability Rights Pennsylvania
Disability Rights South Carolina
Disability Rights Tennessee
Disability Rights Wisconsin

Disabled Queers in Action

Down Syndrome Association of Central Florida

Dreamweavers, Inc. Supported Living

End The TTI

Epilepsy Foundation

Equip for Equality

Family Voices

Georgia ADAPT

Georgia Advocacy Office

Georgia Council on Developmental Disabilities

Gulf Coast Adapt

Hawaii Disability Rights Center

HELEN, The Journal of Human Exceptionality

Human Services Research Institute

ICAPA Network

IGNITE Collective, Inc.

Imagine

Institute on Disability at the University of New Hampshire

International Coalition Against Restraint and Seclusion (ICARS)

InVision Human Services

Japanese Speaking Parents Association of Children with Challenges
(JSPACC)

Juvenile Law Center

Kentucky Protection and Advocacy

Lakeshore Foundation

MARC, Inc.

Maryland Coalition for Inclusive Education

Maryland Coalition of Families

Massachusetts Advocates Standing Strong (MASS)

Michigan Developmental Disabilities Council

Michigan Developmental Disabilities Institute

Michigan Disability Rights Coalition

National ADAPT

National Alliance on Mental Illness (NAMI)

National Alliance on Mental Illness, Massachusetts

National Association of Councils on Developmental Disabilities

National Association of State Directors of Developmental Disabilities Services

National Association of the Deaf

National Council on Severe Autism

National Disability Rights Network (NDRN)

National Down Syndrome Congress

National Health Law Program

National Organization of Nurses with Disabilities

Native American Disability Law Center

Neighborhood Access

Neighbours, Inc

Nevada Disability Advocacy & Law Center

New Haven Voices

North Dakota Protection & Advocacy Project

Not Dead Yet

Oklahoma Disability Law Center, Inc

Ollibean

Options in Community Living, Inc.

Place of Mind

Quality Trust for Individuals with Disabilities

RespectAbility

RespectABILITY Law Center

RISE Services, Inc

RISE UP, Inc.

Second Thoughts MA: Disability Rights Advocates Against Assisted
Suicide

Shared Support Maryland

Syntiro

TASH

TASH New England

The Alliance for Citizen Directed Supports

The Arc - Jefferson, Clear Creek & Gilpin Counties

The Arc Michigan

The Arc of Alabama

The Arc of Hunterdon County

The Arc of Massachusetts

The Arc of the United States

The Arc of Virginia

The Collaborative For Citizen Directed Supports New Jersey

The National Leadership Consortium on Developmental Disabilities

The Partnership for Inclusive Disaster Strategies

Thinking Person's Guide to Autism

Unsilenced Project Inc.

Uplift, Inc.

Values Into Action -New Jersey

Values Into Action -Pennsylvania

West Virginia Center of Excellence in Disabilities

Wildflower Alliance

Wings to Fly Therapy

WV Developmental Disabilities Council