March 6th, 2019

Alex M. Azar II

Secretary

U.S. Department of Health and Human Services

Scott Gottlieb

Commissioner

Food and Drug Administration

John Michael Mulvaney

Director

Office of Management and Budget

*Sent via electronic mail*

Re: FDA proposed rule banning electrical stimulation devices

Dear Secretary Azar, Commissioner Gottlieb and Director Mulvaney,

We the undersigned write to express our deep appreciation to see that the final rule for the proposed ban of electrical stimulation devices (ESDs) used to treat self-injurious or aggressive behavior has been placed on the Federal Drug Administration (FDA)’s Fall regulatory agenda. For nearly three years since the FDA initially released its Proposed Rule to ban these devices, and for almost five years since a panel of experts recommended that they be banned, children and adults with disabilities have continued to suffer from painful and dangerous electric shocks. We are relieved that the FDA finally plans to formally recognize what people with disabilities, disability advocates, researchers, psychiatrists and psychologists, families, and the United Nations have long known: these are devices of torture and abuse, and their use must end. We are pleased to see that the agency intends to take action in the coming year to end this abuse.

**We further wish to reiterate what we expect from the final rule: a complete, immediate ban of the use of ESDs for behavior modification.** In recognition of the severe harm these devices inflict, and in light of the abundant evidence the FDA has reviewed, we do not believe any sort of “phase-down” period or any form of “grandfathering” is warranted. Given the extensive time the FDA has taken to develop the final rule, as detailed below, we urge that it be released in its final form by the 5th anniversary of the panel--April 24th, 2019. Following the issuance of the rule, we expect the FDA to take prompt action to enforce the ban and ensure the safety and well-being of individuals known to have been subject to ESDs. **Secretary Azar and Commissioner Gottlieb, we ask that you devote any and all resources necessary to swiftly review comments and finalize the rule with an immediate effective date and no further delays**. Additionally, we call on the White House to take all steps necessary to ensure that the rule is expeditiously finalized and released.

As you know, concerned citizens and advocacy organizations first wrote to the FDA in March 2010 and again in January 2013, urging that the FDA ban these dangerous and unnecessary devices. In addition, in December 2012, the Centers for Medicare and Medicaid Services issued a letter making clear that use of the graduated electronic decelerator device, and other Level III aversive techniques, is prohibited for individuals receiving Medicaid-funded home and community-based services. Advocates met with FDA representatives in April 2013. A year later, on April 24, 2014, the FDA held a day-long hearing and convened an advisory panel to seek scientific and clinical expert opinion on the risks and benefits associated with other treatment options, the risks and benefits of ESDs for aversive conditioning, and on whether these devices present a substantial and unreasonable risk of illness or injury. The FDA additionally solicited public comment, and deliberated for a full two years before announcing on April 22, 2016 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. Despite having had multiple public comment periods related to the device, FDA allowed an extension of the comment period on the proposed rule from a deadline of May 25 to July 25, 2016. **It has now been over thirty months since that comment period ended.**

**The FDA is mandated to protect the health and safety of these individuals and must not delay further.** We appreciate the swift action the FDA has taken under Commissioner Gottlieb’s leadership on many products which threaten the health and well being of Americans, particularly young people. Just this past month, the FDA warned against the potential dangers of [teething necklaces and jewelry products](https://www.disabilityscoop.com/2019/01/08/fda-warns-jewelry-sensory/25850/) sometimes used by autistic people for sensory regulation. **We urge you to treat this matter with the same urgency.** In the nine years since this issue was raised to the FDA, some of our nation’s most vulnerable people have been subjected to unbearably painful electric shock for such harmless behaviors as getting out of one’s seat, interrupting, whispering, slouching, swearing, or failing to maintain a neat appearance. As the proposed rule recognizes, disabled children and adults are experiencing dramatic short and long term effects from this abusive treatment every day. They cannot afford to wait any longer. **We the undersigned urge HHS and the White House to prioritize and take all actions necessary to ensure this critical rule is immediately finalized and implemented.**

If you have any questions about this letter, please contact Julia Bascom of the Autistic Self Advocacy Network at jbascom@autisticadvocacy.org, or 205-558-4894.

Sincerely,

A Better Life, LLC

ACHIEVA

ACCSES

Access Living

ADAPT

ADAPT DC Metro

ADAPT Chicago

ADAPT Georgia

ADAPT Kansas

ADAPT NY

ADAPT Montana

ADAPT Utah

The Advocacy Institute

Advocates

Alliance

The Alliance for the Betterment of Citizens with Disabilities

Alliance for Citizen Directed Supports

Alliance for Person Centered Accessible Technologies

Allies for Independence

American Academy of Developmental Medicine and Dentistry

AAPD

American Association on Intellectual and Developmental Disabilities

American Association on Health and Disability

American Civil Liberties Union (ACLU)

American Foundation for the Blind

American Network of Community Options and Resources

American Occupational Therapy Association

Autism Science Foundation

The Arc Arapahoe and Douglas

The Arc Michigan

The Arc of Adams County

The Arc of Colorado

The Arc of Hunterdon County

The Arc - Jefferson, Clear Creek & Gilpin Counties

The Arc of Massachusetts

The Arc Mesa County

The Arc Michigan

The Arc of the United States

The Arc of Virginia

The Arc of Weld County

The Arc of West Central Colorado

The Arc of Wisconsin

Architects of Diversity

Association of Developmental Disabilities Providers of Massachusetts

Association of Programs for Rural Independent Living

Association of University Centers on Disabilities

AutCom

Autism Society of America

Autism Society of Los Angeles

Autism Women's Network

Autistic Self Advocacy Network

Bazelon Center for Mental Health Law

Blue Peaks Developmental Services

Boston Center for Independent Living

Brain Injury Association of America

Broadreach Training and Resources, Ltd.

Camphill Soltane

Caldwell Family Services Inc.

California Down Syndrome Advocacy Coalition

Cal-TASH

Center for Behavioral Education and Research, University of Connecticut

Center for Disability Rights

Center for Public Representation

Center on Human Policy, Syracuse University

Central Wisconsin ADAPT

Cerebral Palsy of North Jersey

Chattanooga Autism Center

Children's Freedom Initiative

Collaboration to Promote Self-Determination

Colorado Bluesky Enterprises, Inc.

Colorado Cross-Disability Coalition

Colorado Developmental Disabilities Council

Community Connections, Inc.

Community Link

Community Options, Inc.

Community Outreach

Community Systems, Inc.

The Coordinating Center

The Council of Parent Attorneys and Advocates, Inc.

The Council on Quality and Leadership

Delaware Developmental Disabilities Council

Dept. of Counseling and Special Education, Virginia Commonwealth Univ.

Different Dream Living

Disability Health Access

Disability Inclusion Guild

Disability Law Center- MA

Disability Law Center of Virginia

Disability Law Center of Alaska

Disability Policy Consortium

Disability Power & Pride

Disability Rights Center

Disability Rights Center of Kansas

Disability Rights Center-NH

Disability Rights California

Disability Rights Connecticut

Disability Rights DC at University Legal Services

Disability Rights Education & Defense Fund

Disability Rights Florida

Disability Rights Maine

Disability Rights Maryland

Disability Rights Mississippi

Disability Rights North Carolina

Disability Rights North Dakota

Disability Rights New Jersey

Disability Rights New York

Disability Rights Oregon

Disability Rights Pennsylvania

Disability Rights Wisconsin

Diverse City Press, Inc.

Down Syndrome Alliance of the Midlands

Down Syndrome Association of Central Florida

Down Syndrome Association of Delaware

Down Syndrome Association of Middle Tennessee

Down Syndrome Association of West Michigan

Down Syndrome Awareness Group of East Tennessee

Down Syndrome Connection of the Bay Area

Easterseals

Education Advocacy Coalition

Endless Possibilities In The Community

Epilepsy Foundation

Equip for Equality

Exceptional Parent Magazine

Families of Children on the Autism Spectrum (FOCAS)

Family Residences and Essential Enterprises, Inc.

Family Voices

Frontier Community Services

Gail Jacob and Associates

Georgia Advocacy Office

Georgia Council on Developmental Disabilities

Governor's Advisory Council for Exceptional Citizens (GACEC)

HIGH IMPACT Mission-based Consulting & Training

Hills & Dales Child Development Center

Hope House Foundation

Human Services Research Institute

I CAN Missouri Foundation

Imagine

Inclusion Innovations

Independent Environments, Inc.

Institute for Community Inclusion, University of Massachusetts Boston

Institute on Disabilities, Temple University

Integrated Quality Management Approach (IQMA) Team

InVision Human Services

Jannirose JOY LLC

Japanese Speaking Parents Association of Children with Challenges

Job Path, Inc.

Kentucky Association of Private Providers (KAPP)

Kentucky Protection and Advocacy Division

Keystone Human Services

Kern Down Syndrome Network

Koinonia Homes, Inc.

L'Arche Syracuse

Lakeshore Foundation

The Learning Community for Person Centered Practices, Inc.

Liberty Resources Inc.

LifeShare

Linda H. Rammler, Consultants

Living Well Disability Service

Lutheran Services in America Disability Network

Marbridge Foundation

Maryland Association of Community Services

Maryland Coalition of Families

Maryland Coalition for Inclusive Education

Mental Health America

Mental Health Legal Advisors Committee, Supreme Judicial Court of Massachusetts

Metro Boston Recovery Learning Community

Michigan Protection and Advocacy Service

Mosaic

M-POWER

National Leadership Consortium on Development Disabilities

National Alliance for Direct Support Professionals

National Alliance on Mental Illness

National Alliance for Mental Illness - Greater Boston Consumer Advocacy Network

NAACP

National Association of Councils on Developmental Disabilities

National Association of Nurses with Disabilities (NOND)

National Association of State Directors for Developmental Disabilities Services

National Association of State Directors of Special Education (NADSE)

National Association of the Deaf (NAD)

National Association of State Head Injury Administrators

National Coalition for Mental Health Recovery

National Consumer Voice for Quality Long-Term Care

National Council on Independent Living

National Disability Rights Network

National Down Syndrome Congress

National Down Syndrome Society

National Empowerment Center

National LGBTQ Task Force

National Rehabilitation Association

Native American Disability Law Center

Neighbours, Inc

NorthStar Supported Living Services, Inc.

Not Dead Yet

Occupy the Judge Rotenberg Center

Oklahoma Community-based Providers, Inc.

Ollibean

Options in Community Living, Inc.

Orange Grove Center

Oregon Resource Association (ORA)

Oregon Supported Living Program

Parent 2 Parent USA

Parents of Adults with Disabilities in Colorado

Pastoral Ministry with Persons with Disabilities

Play to Learn...Learn to Play, Inc.

Protection and Advocacy for People with Disabilities - SC

Quality Trust for Individuals with Disabilities

Queerability

Research and Training Center on Community Living, University of Minnesota

The Resource Exchange, Inc.

Respect ABILITY Law Center

RISE Services, Inc.

Riverside Training Centers, Inc.

Rocky Mountain Down Syndrome Association

Second Thoughts MA: Disability Rights Advocates against Assisted Suicide

SEEC

Shared Support Maryland, Inc.

Southeastern Developmental Services

Southern Arizona Network for Down Syndrome

Spaulding Support Services

Starpoint

Statewide Independent Living Council of Alaska

Sunshine Social Club

Support, Inc.

Syntiro

TASH

TASH New England

Teaching Learners with Multiple Needs/Ahern TEC

The THRIVE Network

Topeka Independent Living Resource Center

Transition Consults, LLC

UMKC Institute for Human Development

Unbound Books Autism Acceptance Library

United Cerebral Palsy

United Spinal Association

Uplift, Inc.

Values Into Action, NJ

Values Into Action, PA

Velocardiofacial Syndrome Texas, Inc.

Vision for Equality

Vita Community Living Services

Washington Metro Disabled Students Collective

Western Massachusetts Recovery Learning Community

Wings to Fly Therapy and Play Center

Wisconsin Board for People with Developmental Disabilities

Wisconsin Upside Down

Cc: Jeffrey Shuren
 Director
 Center for Devices and Radiological Health

Roger Severino

 Director

Office of Civil Rights

 Lance Robertson

 Administrator

 Administration on Community Living

Neomi Rao

Administrator

Office of Information and Regulatory Affairs