

April 23, 2018

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 once again urge the Federal Drug Administration (FDA) to finalize its proposed ban of electrical stimulation devices (ESDs) used to treat self-injurious or aggressive behavior. For two years since the FDA initially released its Proposed Rule to ban these devices, and for four 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 urge you to take action now to end this abuse.

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 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. For a month before and a month after that meeting – from March 27 to June 24, 2014 – the FDA gave the public the opportunity to comment, and the FDA received almost 300 comments at that time (posted on Docket FDA-2014-N-0238, available at <https://www.regulations.gov/document?D=FDA-2014-N-0238-0001>).

The FDA took 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. We were pleased that the FDA finally recognized 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 – and that their use would finally be ended. However, despite having already had multiple public comment periods related to the device, FDA allowed an extension of the comment period on the rule from a deadline of May 25 to July 25, 2016. It has now been nearly twenty-one months since that comment period ended. This delay raises significant concerns.

The FDA is mandated to protect the health and safety of these individuals and must not delay further. In the eight years since this issue was raised to the FDA and in the two years it took for the FDA to release a proposed rule in response to the April 2014 hearing, many vulnerable people with disabilities were 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, innocent and vulnerable children and adults are experiencing dramatic short and long term effects from this abusive treatment every day.

We the undersigned urge HHS and the White House to prioritize and take all actions necessary to ensure these critical rules are finalized. 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 final rule is shepherded through the Office of Information and Regulatory Affairs.

If you have any questions about this letter, please contact Sam Crane of the Autistic Self Advocacy Network at scrane@autisticadvocacy.org, (202) 509-0135.

Sincerely,

A Better Life, LLC	Denver	CO
ACHIEVA	Pittsburgh	PA
ACCSES	Washington	DC
Access Living	Chicago	IL
ADAPT	Rochester	NY
ADAPT Chicago	Chicago	IL
ADAPT DC Metro	Washington	DC
ADAPT Georgia	Decatur	GA
ADAPT Kansas	Topeka	KS
ADAPT Montana	Missoula	MT
ADAPT Utah/ Disabled Rights Action Committee	Salt Lake City	UT
The Advocacy Institute	Marshall	VA
Advocates	Framingham	MA
Alliance	Denver	CO
The Alliance for the Betterment of Citizens with Disabilities (ABCD)	Hamilton	NJ
Alliance for Citizen Directed Supports	Philadelphia	PA
Alliance for Person-Centered Accessible Technologies	Tempe	AZ
Allies for Independence	Washington	DC
American Academy of Developmental Medicine and Dentistry	Louisville	KY
American Association of People with Disabilities	Washington	DC
American Association on Health and Disability	Rockville	MD
American Association on Intellectual and Developmental Disabilities	Washington	DC
American Civil Liberties Union	Washington	DC
American Foundation for the Blind	New York	NY
American Network of Community Options and Resources	Alexandria	VA
American Occupational Therapy Association	Bethesda	MD
ao Strategies	Palatine	IL
The Arc Arapahoe & Douglas	Centennial	CO
The Arc Michigan	Lansing	MI
The Arc of Adams County	Northglenn	CO
The Arc of Colorado	Denver	CO
The Arc of Hunterdon County	Annandale	NJ
The Arc - Jefferson, Clear Creek & Gilpin Counties	Lakewood	CO

The Arc of Massachusetts	Waltham	MA	
The Arc Mesa County	Grand Junction	CO	
The Arc of Tucson	Tucson	AZ	
The Arc of the United States	Washington	DC	
The Arc of Virginia	Richmond	VA	
The Arc of Weld County	Greeley	CO	
The Arc of West Central Colorado	Delta	CO	
The Arc of Wisconsin	Stoughton	WI	
Architects of Diversity	Cody	WY	
Association of Developmental Disabilities Providers of Massachusetts	Framingham	MA	
Association of Programs for Rural Independent Living	Little Rock	AR	
Association of University Centers on Disabilities	Silver Spring	MD	
AutCom	Arlington	MA	
Autism Society of America	Bethesda	MD	
Autism Society of Los Angeles	Los Angeles	CA	
Autism Women's Network	Lincoln	NE	
Autistic Self Advocacy Network	Washington	DC	
Bazelon Center for Mental Health Law	Washington	DC	
Blue Peaks Developmental Services	Alamosa	CO	
Boston Center for Independent Living	Boston	MA	
Brain Injury Association of America	Vienna	VA	
Broadreach Training and Resources, Ltd.	New Westminster	BC	Canada
California Down Syndrome Advocacy Coalition	Danville	CA	
Camphill Soltane	Glenmoore	PA	
Center for Behavioral Education and Research, University of Connecticut	Storrs	CT	
Center for Disability Rights	Rochester	NY	
Center for Public Representation	Northampton	MA	
Center on Human Policy, Syracuse University	Syracuse	NY	
Cerebral Palsy of North Jersey	Livingston	NJ	
Children's Freedom Initiative	Atlanta	GA	
Coalition for Juvenile Justice	Washington	DC	
Collaboration to Promote Self-Determination	Washington	DC	
Colorado Bluesky Enterprises, Inc.	Pueblo	CO	
Colorado Developmental Disabilities Council	Denver	CO	
Community Connections, Inc.	Durango	CO	
Community Link	Boulder	CO	
Community Options, Inc.	Montrose	CO	
Community Outreach	Colorado Springs	CO	
Community Systems, Inc.	McLean	VA	
The Coordinating Center	Millersville	MD	
The Council of Parent Attorneys and Advocates, Inc.	Towson	MD	
The Council on Quality and Leadership	Towson	MD	
Delaware Developmental Disabilities Council	Dover	DE	
Dept. of Counseling and Special Education, Virginia Commonwealth Univ.	Richmond	VA	
Different Dream Living	Boone	IA	
Disability Health Access	Los Altos	CA	
Disability Inclusion Guild, Inc.	Rockville	MD	

Disability Law Center of Alaska	Anchorage	AK
Disability Law Center of Virginia	Richmond	VA
Disability Law Center- MA	Boston	MA
Disability Policy Consortium	Malden	MA
Disability Power & Pride	Washington	DC
DQIA Disabled Queers in ACTION!	Washington	DC
Disability Rights Center	Rhododendron	OR
Disability Rights Center of Kansas	Topeka	KS
Disability Rights Center- NH	Concord	NH
Disability Rights DC at University Legal Services	Washington	DC
Disability Rights Education & Defense Fund	Berkeley	CA
Disability Rights California	Sacramento	CA
Disability Rights Connecticut	Hartford	CT
Disability Rights Florida	Tallahassee	FL
Disability Rights Maine	Portland	ME
Disability Rights Maryland	Baltimore	MD
Disability Rights Mississippi	Jackson	MS
Disability Rights North Carolina	Raleigh	NC
Disability Rights North Dakota	Bismarck	ND
Disability Rights New Jersey	Trenton	NJ
Disability Rights New York	Albany	NY
Disability Rights Oregon	Portland	OR
Disability Rights Pennsylvania	Harrisburg	PA
Disability Rights Wisconsin	Madison	WI
Down Syndrome Alliance of the Midlands	Omaha	NE
Down Syndrome Association of Central Florida	Winter Park	FL
Down Syndrome Association of Delaware	Middletown	DE
Down Syndrome Association of Middle Tennessee	Nashville	TN
Down Syndrome Association of West Michigan	Grand Rapids	MI
Down Syndrome Awareness Group of East Tennessee	Knoxville	TN
Down Syndrome Connection of the Bay Area	Danville	CA
Easterseals	Washington	DC
Education Advocacy Coalition	Baltimore	MD
Endless Possibilities In The Community	Newark	DE
Epilepsy Foundation	Landover	MD
Equip for Equality	Chicago	IL
Exceptional Parent Magazine	Chattanooga	TN
Families of Children on the Autism Spectrum (FOCAS)	Westminster	MD
Family Residences and Essential Enterprises, Inc.	Bethpage	NY
Family Voices	Washington	DC
Frontier Community Services	Soldotna	AK
Gail Jacob and Associates	Madison	WI
Georgia Advocacy Office	Decatur	GA
Governor's Advisory Council for Exceptional Citizens (GACEC)	Dover	DE
HIGH IMPACT Mission-based Consulting & Training	Northbrook	IL
Hills & Dales Child Development Center	Dubuque	IA
Hope House Foundation	Norfolk	VA
Human Services Research Institute	Cambridge	MA

Imagine	Blacksburg	VA
Inclusion Innovations	Robbinsdale	MN
Independent Environments, Inc.	Eugene	OR
Institute for Community Inclusion, University of Massachusetts Boston	Boston	MA
Institute on Disabilities, Temple University	Philadelphia	PA
Integrated Quality Management Approach (IQMA) Team	Boston	MA
InVision Human Services	Wexford	PA
Jannirose JOY LLC	Yellow Springs	OH
Japanese Speaking Parents Association of Children with Challenges	Los Angeles	CA
Job Path, Inc.	New York	NY
Kentucky Association of Private Providers (KAPP)	Monticello	KY
Kentucky Protection and Advocacy Division	Frankfort	KY
Keystone Human Services	Harrisburg	PA
Kern Down Syndrome Network	Bakersfield	CA
Koinonia Homes, Inc.	Independence	OH
L'Arche Syracuse	Syracuse	NY
Lakeshore Foundation	Birmingham	AL
The Learning Community for Person Centered Practices, Inc.	Annapolis	MD
Liberty Resources Inc.	Syracuse	NY
LifeShare	Manchester	NH
Linda H. Rammler, Consultants	Middlefield	CT
Living Well Disability Service	Eagan	MN
Lutheran Services in America Disability Network	Washington	DC
Maryland Association of Community Services	Columbia	MD
Maryland Coalition of Families	Columbia	MD
Mental Health America	Alexandria	VA
Mental Health Legal Advisors Committee, Supreme Judicial Court of Massachusetts	Boston	MA
Metro Boston Recovery Learning Community	Boston	MA
Michigan Protection and Advocacy Service, Inc.	Lansing	MA
Mosaic	Omaha	NE
M-POWER	Roxbury	MA
National Leadership Consortium on Development Disabilities	Newark	DE
National Alliance for Direct Support Professionals	Albany	NY
National Alliance on Mental Illness	Arlington	VA
National Alliance for Mental Illness - Greater Boston Consumer Advocacy Network	Boston	MA
National Association of Councils on Developmental Disabilities	Washington	DC
National Association of State Directors for Developmental Disabilities Services	Alexandria	VA
NAACP	Baltimore	MD
National Association of State Directors of Special Education (NADSE)	Alexandria	VA
National Association of State Head Injury Administrators	Alabaster	AL
National Association of the Deaf (NAD)	Silver Spring	MD
National Coalition for Mental Health Recovery	Potomac	MD
National Consumer Voice for Quality Long-Term Care	Washington	DC
National Council on Independent Living	Washington	DC
National Disability Rights Network	Washington	DC

National Down Syndrome Congress	Atlanta	GA
National Down Syndrome Society	New York	NY
National Empowerment Center	Lawrence	MA
National LGBTQ Task Force	Washington	DC
National Organization of Nurses with Disabilities	Chicago	IL
Native American Disability Law Center, Inc.	Farmington	NM
Neighbours, Inc	Highland Park	NJ
NorthStar Supported Living Services, Inc.	Placerville	CA
Not Dead Yet	Rochester	NY
Occupy the Judge Rotenberg Center	Worcester	MA
Oklahoma Community-based Providers, Inc.	Oklahoma City	OK
Ollibean	Tampa	FL
Oregon Rehabilitation Association (ORA)	Salem	OR
Oregon Supported Living Program	Eugene	OR
Parents of Adults with Disabilities in Colorado	Parker	CO
Parent 2 Parent USA	Washington	DC
Pastoral Ministry with Persons with Disabilities	Newark	NJ
Play to Learn...Learn to Play, Inc.	Acton	MA
Protection and Advocacy for People with Disabilities- SC	Columbia	SC
Quality Trust for Individuals with Disabilities	Washington	DC
Queerability	Rockville	MD
Research and Training Center on Community Living, University of Minnesota	Minneapolis	MN
The Resource Exchange, Inc.	Denver	CO
Respect ABILITY Law Center	Royal Oak	MI
RISE Services, Inc	Orem	UT
Riverside Training Centers, Inc.	St Helens	OR
Rocky Mountain Down Syndrome Association	Denver	CO
Second Thoughts MA: Disability Rights Advocates against Assisted Suicide	Boston	MA
SEEC	Silver Spring	MD
Shared Support Maryland, Inc.	Baltimore	MD
Southeastern Developmental Services	Lamar	CO
Southern Arizona Network for Down Syndrome	TUCSON	AZ
Spaulding Support Services	East Syracuse	NY
Starpoint	Canon City	CO
Statewide Independent Living Council of Alaska	Anchorage	AK
Sunshine Social Club	Whitestown	IN
Support, Inc.	Aurora	CO
Syntiro	Readfield	ME
TASH	Washington	DC
TASH New England	Boston	MA
Teaching Learners with Multiple Needs/Ahern TEC	Billerica	MA
The THRIVE Network	Brooklyn	NY
Topeka Independent Living Resource Center	Topeka	KS
Transition Consults, LLC	Bala Cynwyd	PA
UMKC Institute for Human Development	Kansas City	MO
Unbound Books Autism Acceptance Library	Modesto	CA

United Cerebral Palsy	Washington	DC	
United Spinal Association	Washington	DC	
Unlimited Possibilities of Colorado LLC	Greeley	CO	
Uplift, Inc	Gardiner	ME	
Values Into Action- New Jersey	Burlington	NJ	
Values Into Action- Pennsylvania	Media	PA	
Velocardiofacial Syndrome Texas, Inc.	Austin	TX	
Vita Community Living Services	Toronto	ON	Canada
Washington Metro Disabled Students Collective	Washington	DC	
Western Massachusetts Recovery Learning Community	Holyoke	MA	
Wings to Fly Therapy and Play Center	Chantilly	VA	
Wisconsin Board for People with Developmental Disabilities	Madison	WI	
Wisconsin Upside Down	Hartland	WI	

Cc:

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