

December 21, 2016

Dr. Robert M. Califf, MD, MACC
Commissioner, U.S. Food and Drug Administration
10902 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2014-N-0238

Dear Commissioner Califf,

We are writing again to urge the FDA to take action now to finalize the rule banning electrical stimulation devices. We urge you to take this action now before the change of administration.

On July 14, 2016 we met with leadership from the U. S. Department of Health and Human Services, including representatives from the Secretary's Office, Office of Civil Rights and Administration on Community Living. This meeting was in follow up to a June 4, 2016 letter signed by seventy national and state disability organizations, urging the FDA to act expeditiously on the recommendations of the FDA's Medical Devices Advisory Committee's Neurological Devices Panel to ban aversive conditioning devices used for contingent electric shock and urging the FDA to finalize the rules banning these devices before the end of this Administration (copy attached).

We are writing to once again urge you to finalize these rules before the Administration ends. The FDA has now spent literally years gathering evidence, holding hearings and allowing the public to comment. The FDA rules were proposed on April 22, 2016 nearly eight months ago and a full two years after the Panel's recommendations to ban the devices on April 14, 2014. 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 more than twenty weeks since the extended comment period ended and time is running short.

At our July 14 meeting, representatives from the Secretary's Office assured us that these rules were on the Department's priority list to get completed by the end of this Administration. We hope you will hold to this commitment. As you are well aware, it is not only the disability community that is urging you to finalize these rules. On September 22, 2016, six U.S. Senators wrote to you expressing their strong support for the proposed rule to ban electrical stimulation devices to be finalized (copy attached).

We again urge you to stand by your commitment to us and take all necessary steps to finalize these rules before the end of this Administration. This Administration must swiftly take action to finally put an end to this unacceptable abuse and torture of people with disabilities. Please do not hesitate to contact us if you have any further questions.

Sincerely,

Nancy R. Weiss, MSW
Director, National Leadership Consortium on Developmental Disabilities
University of Delaware
443-318-4879; nweiss@udel.edu

with:

Julia Bascom, Incoming Executive Director,
Autistic Self Advocacy Network
jbascom@autisticadvocacy.org

Alison Barkoff, J.D., Director of Advocacy
Center for Public Representation
abarkoff@cpr-ma.org

And the organizations below:

Organization Name	City	State	Country
A Better Life, LLC	Denver	CO	USA
A Better Way of Living Inc	Albuquerque	NM	USA
Alliance for Person-Centered Accessible Technologies	Tempe	AZ	USA
American Association on Intellectual and Developmental Disabilities (AAIDD)	Washington	DC	USA
The American Association of People with Disabilities	Washington	DC	USA
American Network of Community Options and Resources (ANCOR)	Alexandria	VA	USA
ao Strategies	Palatine	IL	USA
The Arc of Massachusetts	Waltham	MA	USA
The Arc of the United States	Washington	DC	USA
Arc of New River Valley	Blacksburg	VA	USA
ARC Rutland Area	Rutland	VT	USA
Asperger/Autism Network	Watertown	MA	USA
Association for Autistic Community	Alexandria	VA	USA
Autism Delaware	Newark	DE	USA
Autism Women's Network	Lincoln	NE	USA
Autistic Self Advocacy Network of Greater Boston	Boston	MA	USA
Bazon Center for Mental Health Law	Washington	DC	USA
Branches of Life	Chester	VA	USA
Capital Recovery Center	Olympia	WA	USA
Center on Disability and Community Inclusion	Burlington	VT	USA
Children's Freedom Initiative	Atlanta	GA	USA
Colorado Bluesky Enterprises, Inc.	Pueblo	CO	USA
Colorado Developmental Disabilities Council	Denver	CO	USA
Community Haven for Adults and Children with Disabilities	Sarasota	FL	USA
Community Link	Boulder	CO	USA
Community Living Victoria	Victoria	BC	Canada
Council of Parent Attorneys and Advocates, Inc.	Towson	MD	USA
The Council on Quality and Leadership CQL	Towson	MD	USA
Creative Supports Institute	Boothwyn	PA	USA
Disability Law Center	Boston	MA	USA
Disability Rights Center	Seattle	WA	USA
Disability Rights Vermont	Montpelier	VT	USA
Douglas J Cartan & Associates Consultants	Brockville	ON	Canada

Organization Name	City	State	Country
Exceptional Parent Magazine	Chattanooga	TN	USA
F I R S T	Asheville	NC	USA
Georgia Advocacy Office	Decatur	GA	USA
Governor's Advisory Council for Exceptional Citizens (GACEC)	Dover	DE	USA
Hope House Foundation	Norfolk	VA	USA
Human Services Research Institute	Cambridge	MA	USA
Imagine	Blacksburg	VA	USA
Inclusion Alberta	Edmonton	AB	Canada
Inclusion Press	Toronto	ON	Canada
InclusionWorks!	Victoria	BC	Canada
Institute for Community Inclusion, UMass Boston	Boston	MA	USA
Institute on Disabilities	Philadelphia	PA	USA
International Social Role Valorization Association	Harrisburg	PA	USA
InVision Human Services	Wexford	PA	USA
Jewish Family Service & Children's Center of Clifton/Passaic	Clifton	NJ	USA
Kendrick Consulting International	Holyoke	MA	USA
Key Human Services, Inc.	Wethersfield	CT	USA
Keystone Institute	Harrisburg	PA	USA
Keystone Institute India	New Delhi	Delhi	India
The Learning Community for Person Centered Practices	Annapolis	MD	USA
Libraries and Autism: We're Connected	Maplewood	NJ	USA
Linda H. Rammler, Consultants	Middlefield	CT	USA
Loveland Center, Inc.	Venice	FL	USA
Lutheran Services in America Disability Network	Washington	DC	USA
Massachusetts Association for Mental Health	Boston	MA	USA
Massachusetts Developmental Disabilities Council	Quincy	MA	USA
Mental Health Legal Advisors Committee	Boston	MA	USA
Metro Boston Recovery Learning Community	Boston	MA	USA
National Alliance for Direct Support Professionals, Inc.	Albany	NY	USA
Nat. Alliance on Mental Illness - Greater Boston Consumer Adv. Net.	Boston	MA	USA
National Alliance on Mental Illness of Massachusetts (NAMI Mass)	Boston	MA	USA
National Association of Councils on Developmental Disabilities	Washington	DC	USA
National Council on Independent Living	Washington	DC	USA
Neighbours International	Highland Park	NJ	USA
Northeastern University School of Law Disability Justice Caucus	Boston	MA	USA
Not Dead Yet	Rochester	NY	USA
Occupy the Judge Rotenberg Center	Worcester	MA	USA
OHI	Hermon	ME	USA
Ohio TASH	Westerville	OH	USA
Parent to Parent USA	Washington	DC	USA
Partnership for People with Disabilities at VCU	Richmond	VA	USA
Paul V. Sherlock Center on Disabilities	Providence	RI	USA
People First of Georgia	Lithonia	GA	USA
Port Alberni Association for Community Living	Port Alberni	BC	Canada
Respect ABILITY Law Center	Royal Oak	MI	USA
RISE Services, Inc	Mesa	AZ	USA
Self-Advocacy Association of NY State, Inc.	Schenectady	NY	USA

Organization Name	City	State	Country
Self-Advocates Becoming Empowered	Elmhurst	IL	USA
Shared Support Maryland, Inc.	Baltimore	MD	USA
Starpoint	Canon City	CO	USA
Syntiro	Readfield	ME	USA
TASH	Washington	DC	USA
TASH New England	Middlefield	CT	USA
United Cerebral Palsy	Washington	DC	USA
Values Into Action	Media	PA	USA
Vermont Center For Independent Living	Montpelier	VT	USA
Vermont Clinical Training Consortium	Moretown	VT	USA
Vermont Coalition for Disability Rights	Montpelier	VT	USA
Vermont Psychiatric Survivors, Inc.	Rutland	VT	USA
Virginia TASH	Radford	VA	USA
Washington Metro Disabled Students Collective	Washington	DC	USA
Wings to Fly Therapy and Play Center	Chantilly	VA	USA
Wisconsin Board for People with Developmental Disabilities	Madison	WI	USA
Yaldei Shluchei HaRebbe	Brooklyn	NY	USA

Cc: *Bobby Clark*, Counselor to the Secretary for Science and Public Health

Doug Steiger, Counselor to the Secretary for Human Services

Tom Novotny, Deputy Assistant Secretary for Health Sciences and Medicine

Edwin Walker, Acting Administrator and Assistant Secretary for Aging

James Toews, Acting Principal Deputy Administrator, Administration for Community Living

Jocelyn Samuels, Director, Office for Civil Rights

Robinsue Frohboese, Principal Deputy Director/Senior Policy Advisor, Office for Civil Rights

AJ Pearlman, Chief of Staff/Deputy Director for Civil Rights (Acting)