June 4, 2015

Dr. Stephen Ostroff  
Commissioner  
U.S. Food and Drug Administration

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

Dear Commissioner Ostroff,

We are writing to urge the FDA to act on the recommendations of the Neurological Devices Panel of the Medical Devices Advisory Committee at a public meeting convened last year on April 24 that the harms of aversive conditioning devices used for contingent electric shock outweigh any potential benefits.

According to 21 C.F.R. § 895.21, the FDA may ban a device upon finding that “the continued marketing of the device presents a substantial deception or an unreasonable and substantial risk of illness or injury.” After hearing testimony from numerous individuals and organizations with significant expertise serving and advocating for people with the most significant disabilities, the FDA’s panel determined that aversive conditioning devices used for contingent electric shock present precisely such an unreasonable and substantial risk of injury.

We note that the FDA has refrained from making any final determination as to the status of these devices since last year’s hearing. Over the past year, the only institution in the nation known to use contingent electric shock as “treatment,” the Judge Rotenberg Center, continues to use this harmful form of behavioral modification on dozens of children, youth, and adults with disabilities. We remain concerned for the welfare of those currently receiving contingent electric shock while a ruling remains pending. These individuals spend every day wired to electric shock devices, unsure when they may next be shocked against their will.

As many experts and disability rights advocates presented at last year’s hearing, contingent skin shock devices pose a substantial risk of skin burns and long-term trauma responses. This risk is unreasonable in light of the limited evidence supporting their efficacy for treating intensive behavioral support needs, their high potential for misuse and accidental activation, and the well-established body of evidence in favor of alternative options that do not rely on pain and fear. Moreover, the original pioneer of contingent electric shock as a behavioral modification method on autistic children, O. Ivar Lovaas, has publicly repudiated use of the method over twenty years ago in 1993. This practice is unjustifiable under any acceptable standards of treatment for people with disabilities today and there is no reason to allow it to continue.

1 21 C.F.R. § 895.21(a) (2011).  
The FDA has an excellent opportunity to demonstrate a firm commitment to safe, humane, and evidence-based treatments for people with disabilities by banning the types of devices used for this appalling and thoroughly unsupported practice. While there is only one institution using contingent electric shock at present, we are concerned that any decision short of a total ban might allow for the future expansion of contingent electric shock to other institutions and programs, thus subjecting additional people with disabilities to an unnecessarily painful and dangerous “therapy.”

We call for the FDA to issue a total ban on any aversive conditioning devices used for contingent electric shock, in order to protect the public’s right to safe, evidence-based treatment and the inherent human rights and dignity of people with disabilities.

National Organizations

Access Living
ADAPT
Advocacy Institute
Access Living
The Arc of the United States
Association of University Centers on Disabilities
Association of Programs for Rural Independent Living
AutCom
Autistic Self Advocacy Network
Autism Society of America
American Association of People with Disabilities
American Network of Community Options and Resources
Bazelon Center for Mental Health Law
Boston Center for Independent Living
Council of Parent Attorneys and Advocates, Inc.
Children and Adults with Attention Deficit Hyperactivity Disorder
Disability & Pride
Disability Rights Center
Disability Rights Education and Defense Fund
Disability Rights International
Higher Education Consortium for Special Education and Teacher Education of the Council for Exceptional Children
Family Alliance to Stop Abuse and Neglect
Family Voices
Lead On Network
Little People of America
Mental Health America
National Association of Councils on Developmental Disabilities
National Association of the Deaf
National Association of State Directors of Special Education
National Autism Association
National Council on Independent Living
National Disability Rights Network
National Down Syndrome Congress  
National Down Syndrome Society  
National Federation of Families for Children's Mental Health  
National Organization of Nurses with Disabilities  
Not Dead Yet  
Parent to Parent USA  
Respect ABILITY Law Center  
TASH  
United Spinal Association

State and Local Organizations

ADAPT Montana  
ADAPT New York  
AIM Independent Living Center (Corning, NY)  
Access to Independence of Cortland County, Inc.  
Autistic Self Advocacy Network of Greater Boston  
The Arc of Illinois  
Boston Center for Independent Living  
Center for Disability Rights (New York)  
Directions in Independent Living (Olean, NY)  
Disability Law Center of Massachusetts  
Disability Rights Wisconsin  
Easter Seals Massachusetts  
Family Voices of New Jersey  
Family Voices of Illinois  
Family Voices of Tennessee  
INCLUDEnyc  
Not Dead Yet Montana  
PEAK Parent Center  
Regional Center for Independent Living (Rochester, NY)  
Second Thoughts Massachusetts  
Self Advocacy Association of New York State  
Southern Tier Independence Center, Binghamton, NY  
Statewide Parent Advocacy Network (New Jersey)  
Support for Families (California)  
TASH New England  
Tennessee Disability Coalition  
Vermont Family Network  
Washington Metro Disabled Students Collective  
Westchester Independent Living Center

Cc: Sharon Lewis, Maria Town