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.”[[1]](#footnote-1) 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.[[2]](#footnote-2) 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.

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 ResourcesBazelon 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 of Children with Disabilities (San Francisco, CA)

TASH New England

Tennessee Disability Coalition

The Vermont Family Network

Washington Metro Disabled Students Collective

Westchester Independent Living Center

Cc: Sharon Lewis, Maria Town

1. 21 C.F.R. § 895.21(a) (2011). [↑](#footnote-ref-1)
2. Jennifer Gonnerman, School of Shock, Mother Jones, Aug. 20, 2007, *available at* <http://www.motherjones.com/politics/2007/08/school-shock>; Dan Moser & Alan Grant, *Screams, Slaps, and Love: A Surprising, Shocking Treatment Helps Far-Gone Mental Cripples*, in Life Magazine 90-96 (May 7, 1965). [↑](#footnote-ref-2)