



STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
MARGARET M. O'NEILL BUILDING
410 FEDERAL STREET, SUITE 1
DOVER, DE 19901

VOICE: (302) 739-3620
TTY/TDD: (302) 739-3699
FAX: (302) 739-6704

MEMORANDUM

DATE: May 24, 2016

TO: Food and Drug Administration

FROM: Daniese McMullin-Powell, Chairperson
Delaware State Council for Persons with Disabilities

RE: Docket No. FDA-2016-N-1111 (Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior)

The Delaware State Council for Persons with Disabilities (SCPD) has reviewed The Food and Drug Administration's (FDA's) proposal to ban electrical stimulation devices used to treat aggressive or self-injurious behavior. The FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. The FDA is proposing to include in this ban both new devices and devices already in distribution and use.

SCPD strongly endorses the FDA's proposal to ban electrical stimulation devices used to treat aggressive or self-injurious behavior. The Council supports the FDA's determination that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling and agree that this ban should include both new devices and devices already in distribution and use. The use of devices of this kind is condemned by people with disabilities, family members, disability professionals and advocates, medical professionals, and almost every national disability organization. Additionally their use is condemned by the United Nations Special Rapporteur on Torture.

As the FDA notes, the use of these devices has resulted in countless psychological and physical adverse effects. There is no evidence that they are a valid or effective treatment. People who have experienced the shock from these devices report nightmares, overwhelming fear and anxiety, and Post Traumatic Stress symptoms as a result. The Judge Rotenberg Center, the only facility to use contingent electric shock to control behavior claims that electric shock is used for "self-mutilating or other life threatening behaviors" but there are dozens of testimonies and documents demonstrating that shock is routinely used for non-dangerous, innocuous behaviors such as refusing to follow staff directions, failing to maintain a neat appearance, stopping work for more

than ten seconds, getting out of one's seat, interrupting others, nagging, swearing, whispering, and slouching.

The video that Fox News made public (<https://www.youtube.com/watch?v=ZtRGQRtwh2U>) demonstrates that the shock is not the 'gentle reminder' parents have been made to think is being used, but instead, a devastatingly painful experience. The Judge Rotenberg Center often combines the use of electric shock with prolonged restraint used as a punishment making the use of contingent shock even more dangerous. SCPD is additionally concerned that the shock device used at the Judge Rotenberg center has been demonstrated to malfunction, shocking the wrong person in error or shocking a person wearing the device over and over until the wires are disconnected. The shock delivered by the devices used at the Judge Rotenberg Center (30 – 90 milliamperes) is many times stronger than that delivered by a cattle prod at .4 milliamperes or a dog collar at 4.8-5 milliamperes and both of these devices deliver a shock for only a fraction of a second. The shock delivered by the GED can last for a maximum of two seconds, four times as long as the shock from a cattle prod.

It is important to note that the people at the Judge Rotenberg Center are not the only people in the U.S. with dangerous behaviors; hundreds if not thousands of others are treated across the country using humane and effective approaches. Over the last 30 years there have been constant advances in our ability to understand and support people with dangerous behaviors; shock is neither humane nor necessary. A wide range of methods are available which are not only more effective in managing the dangerous or disruptive behaviors of children and adults with disabilities, but which have more lasting effect and do not inflict pain on or dehumanize people with disabilities.

SCPD is charged in 29 Del.C. Section 8210 with the responsibility of proposing and promoting state and federal laws, regulations, programs and policies to improve the well-being of individuals with disabilities. SCPD and other disability councils have addressed the harmful use of Electroconvulsive Therapy (ECT) in Delaware without success. Endorsing the FDA's proposal to ban electrical stimulation devices is consistent with past efforts and our stated mandate. Moreover, a successful ban to such practices will improve the lives of persons with disabilities and their families.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our position or comments on the proposed ban.