

United States Senate

WASHINGTON, DC 20510

September 22, 2016

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

We write today to express our strong support for the proposed rule to ban electrical stimulation devices (ESDs) used to treat self-injurious or aggressive behavior. The use of these electric shock devices as aversive therapy for individuals with developmental disabilities is inhumane, especially since many of these individuals have difficulty communicating and alternative effective treatment options are available. Put simply, it is outrageous that this practice is allowed in the United States for this vulnerable population and it should be stopped immediately. As such, we urge you to finalize the proposed rule as quickly as possible.

As the proposed rule states, the FDA is authorized to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury. Furthermore, the proposal lays out in a clear and concise manner that these devices pose substantial risk. Specifically, it states that the FDA has determined that ESDs present a number of psychological and physical risks, including depression, fear, panic, aggression, pain, burns and errant shocks from device misapplication or failure. Moreover, ESDs have been associated with additional risks such as suicidality, chronic stress, acute stress disorder and hypervigilance. It is not surprising that this is the case because as Dr. Margaret Nygren from the American Association of Intellectual and Developmental Disabilities noted during the April 2014 advisory committee meeting, *“These devices are explicitly intended to inflict pain. The pain is not an unfortunate risk or byproduct of the intervention. With these devices, the pain is the intervention.”*

While individuals with a history of self-injurious or aggressive behavior may present challenges for treatment providers and educational personnel, clear alternatives to ESDs are widely known and available. As the proposed rule notes, positive behavioral therapies that do not inflict physical pain or harmful side effects exist. These treatments represent the best practice by experts in the field and often achieve much more durable long-term results than ESDs. One such therapy is positive behavioral support, which begins with a comprehensive functional behavior assessment to identify and address environmental and social triggers of the behaviors and then teaches the individual to replace those behaviors with others that do not cause harm. Positive behavioral support and a similar approach, called dialectical behavioral therapy, have been shown to be effective in numerous studies and could be deployed immediately as a substitute to ESDs.

For these reasons, we commend the FDA for proposing a ban on ESDs and believe that the rule should be finalized expeditiously. The harmful, antiquated, and inhumane use of ESDs as part of aversive conditioning has no place in the 21st Century. Thank you for your consideration and we look forward to your prompt response.

Sincerely,



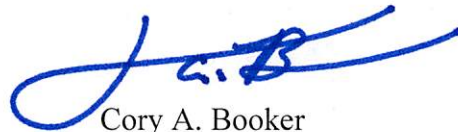
Christopher S. Murphy
United States Senator



Tammy Baldwin
United States Senator



Richard Blumenthal
United States Senator



Cory A. Booker
United States Senator



Robert P. Casey, Jr.
United States Senator



Al Franken
United States Senator

[Faint handwritten signature]

[Faint handwritten signature]

[Faint handwritten signature]

[Faint handwritten signature]

[Faint handwritten signature]

[Faint handwritten signature]