

United States Senate
WASHINGTON, DC 20510-0609

October 25, 2021

The Honorable Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, Maryland 20993

Dear Acting Commissioner Woodcock,

We are writing to thank the U.S. Food and Drug Administration (FDA) for acting to protect some of our most vulnerable citizens. We are disappointed with the recent decision by the U.S. Court of Appeals for the D.C. Circuit to overturn the FDA's ban on the use of electrical stimulation devices (ESDs), also known as electric shock devices, on people with intellectual or developmental disabilities. We understand the agency, along with the U.S. Department of Justice (DOJ), has filed an appeal seeking a rehearing en banc. We appreciate your defense of the rule and ask that you continue to prioritize the protection of people with disabilities by ending this dangerous practice.

As you know, FDA has the authority to ban devices if it finds that the device presents substantial deception or an unreasonable and substantial risk of illness or injury. It is clear after hearing from individuals with intellectual and developmental disabilities, their families, and their advocates that ESDs meet those criteria. The FDA's final rule last year also acknowledged that the medical literature shows there are psychological and physical risks associated with the use of these devices, including worsening of underlying symptoms, depression, anxiety, posttraumatic stress disorder, pain, burns and tissue damage.

In addition, when issuing the final rule, FDA noted that of the 1,500 comments received, the overwhelming majority of comments supported this ban.¹ For these reasons, we encourage the FDA, along with the DOJ, to continue to take every step necessary to protect children and adults with disabilities.

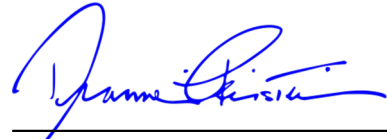
Thank you for your consideration.

Sincerely,

¹ 85 FR 13312, <https://www.federalregister.gov/d/2020-04328>



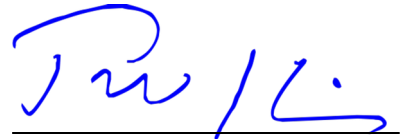
Christopher S. Murphy
United States Senator



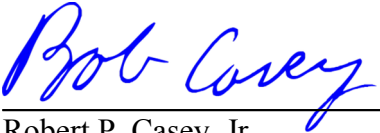
Dianne Feinstein
United States Senator



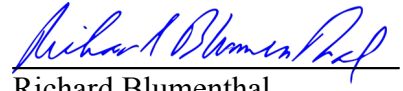
Tina Smith
United States Senator



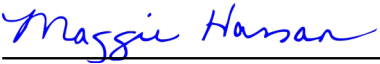
Tim Kaine
United States Senator



Robert P. Casey, Jr.
United States Senator



Richard Blumenthal
United States Senator



Margaret Wood Hassan
United States Senator