

# United States Senate

WASHINGTON, DC 20510

May 28, 2024

The Honorable Robert M. Califf, M.D.  
Commissioner  
U.S. Food and Drug Administration  
White Oak Office Building 1  
Silver Spring, Maryland 20993

Dear Commissioner Califf:

We write to comment on the Notice of Proposed Rulemaking (NPRM) issued by the Food and Drug Administration (FDA) on March 25, 2024, proposing a ban of electrical stimulation devices (ESDs) intended for self-injurious behavior (SIB) or aggressive behavior (AB).<sup>1</sup> We wish to uplift this important step taken by the FDA reestablishing the ban on ESDs following its ban in 2020 that was reversed. Since then, Congress has clarified the FDA's authority to issue such a ban and the FDA has repropose the rule, an action we fully support.<sup>2</sup>

ESDs deliver a painful electric shock through electrodes attached to skin. The devices are commonly used on children and adults with disabilities as a means to reduce SIB or AB, but evidence has condemned this practice as archaic and inhumane.<sup>3</sup> When used, ESDs present an unreasonable and substantial risk of illness or injury including depression, anxiety, worsening of underlying symptoms, development of post-traumatic stress disorder as well as pains, burns and tissue damage.<sup>4</sup>

If finalized, the proposed rule would remove ESDs from the market and the devices will no longer be considered legally marketed.<sup>5</sup> This proposed rule has been made with careful consideration of the available information and data. The FDA found the weight of evidence indicates that ESDs for SIB or AB present a number of psychological and physical risks while not supporting or improving an individual's behavior.<sup>6</sup> We support the FDA in these findings. We believe that individuals with disabilities who have been subjected to ESDs need alternative treatments and interventions in line with current medical practices.

---

<sup>1</sup> <https://www.govinfo.gov/content/pkg/FR-2024-03-26/pdf/2024-06037.pdf>

<sup>2</sup> <https://www.federalregister.gov/documents/2024/03/26/2024-06037/banned-devices-proposal-to-ban-electrical-stimulation-devices-for-self-injurious-or-aggressive>

<sup>3</sup> <https://www.iassidd.org/wp-content/uploads/2021/02/As-filed-Amicus-Brief.pdf>

<https://www.help.senate.gov/ranking/newsroom/press/murray-murphy-democrats-urge-fda-to-immediately-ban-the-use-of-electrical-shock-devices-on-children-and-adults-with-disabilities>

<sup>4</sup> <https://www.federalregister.gov/documents/2024/03/26/2024-06037/banned-devices-proposal-to-ban-electrical-stimulation-devices-for-self-injurious-or-aggressive>


<sup>5</sup> <https://www.fda.gov/medical-devices/medical-devices-news-and-events/fda-proposes-new-ban-electrical-stimulation-devices-self-injurious-or-aggressive-behavior>

<sup>6</sup> <https://www.federalregister.gov/documents/2024/03/26/2024-06037/banned-devices-proposal-to-ban-electrical-stimulation-devices-for-self-injurious-or-aggressive>

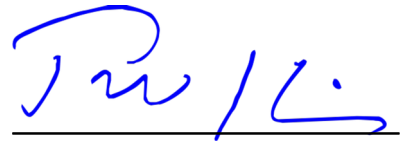
We commend and support the FDA in banning these devices and recognizing the available evidence-based interventions to support.<sup>7</sup> The FDA’s proposed rule is a welcome alignment with the input received from individuals with disabilities themselves, patients and parents of individuals who have been treated with ESDs, disability rights organizations, as well as insight collected from FDA panels.<sup>8</sup>

In closing, we thank you for proposing this rule to eliminate an outdated and harmful treatment used on individuals with disabilities. We urge the FDA to finalize the rule to prevent further pain and trauma to individuals with disabilities who are being subjected to ESDs.

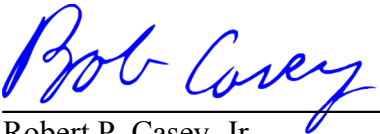
Sincerely,



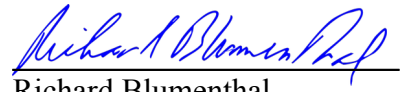
Christopher S. Murphy  
United States Senator



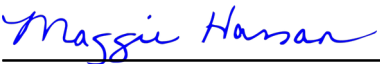
Tim Kaine  
United States Senator



Robert P. Casey, Jr.  
United States Senator  
Chairman, Special Committee  
on Aging



Richard Blumenthal  
United States Senator



Margaret Wood Hassan  
United States Senator



Bernard Sanders  
United States Senator

<sup>7</sup> <https://www.federalregister.gov/documents/2024/03/26/2024-06037/banned-devices-proposal-to-ban-electrical-stimulation-devices-for-self-injurious-or-aggressive>

<sup>8</sup> <https://www.fda.gov/medical-devices/medical-devices-news-and-events/fda-proposes-new-ban-electrical-stimulation-devices-self-injurious-or-aggressive-behavior>