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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

February 10, 2020

Dr. Stephen M. Hahn
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write to ask for immediate action to finalize the rule to ban the use of electrical stimulation devices on people with disabilities. Nearly four years ago, on April 25, 2016, the Food and Drug Administration (FDA) issued a proposed rule seeking to ban electrical stimulation devices (ESD) used for self-injurious or aggressive behavior.¹ The comment period for the proposed rule ended on July 25, 2016, with 1,209 comments. In the fall of 2018, the FDA announced² it intended to finalize the rule by December 2019. At the time of that announcement, former Commissioner Gottlieb stated, “We believe these products present an unreasonable and substantial risk to public health that cannot be corrected or eliminated through changes to the labeling.”³ In the fall of 2019, the FDA again announced its intent to finalize the rule by December 2019.⁴ Unfortunately, the FDA missed its deadline, allowing the continued use of electric shock on people with disabilities, including children. This is unacceptable.

The proposed rule would end a barbaric – and disproven - practice and prevent punishment using electric shock for self-injurious and aggressive behaviors. The specific devices the FDA has proposed banning use electrodes that attach to the skin and deliver electric shocks. According to the proposed rule, “the effects of the shock are both psychological (including suffering) and physical (including pain),”⁵ and the physical effects can be intensified based on the severity of the shock, which can be adjusted by a person other than the recipient of the shock. The recipient of the shock can experience trauma, especially with prolonged or frequent use of shock. In fact, the FDA determined ESDs used for self-injurious or aggressive behavior “present a number of psychological and physical risks: depression, fear, escape and avoidance behaviors, panic, aggression, substitution of other behaviors (e.g., freezing and catatonic sit-down), worsening of underlying symptoms (e.g., increased frequency or bursts of self-injury), pain, burns, tissue damage, and errant shocks from device misapplication or failure,” as well as “risks of posttraumatic stress or acute stress disorders, shock stress reaction, and learned helplessness.”⁶

¹ 81 Fed. Reg. 24385 (Apr. 25, 2016) (Banned devices; Proposal to ban electrical stimulation devices used to treat self-injurious or aggressive behavior).

² Office of Management and Budget, FDA Unified Agenda of Regulatory and Deregulatory Actions (Fall 2018).

³ FDA proposes ban on electrical stimulation devices intended to treat self-injurious or aggressive behavior, FDA News Release (Apr. 22, 2016).

⁴ Office of Management and Budget, FDA Unified Agenda of Regulatory and Deregulatory Actions (Fall 2019).

⁵ 81 Fed. Reg. at 24387.

⁶ 81 Fed. Reg. at 24387.

After thorough review of the ESDs described in the proposed rule, the FDA determined these devices present an unreasonable and substantial risk of illness or injury, and a ban is appropriate. Indeed, the agency stated “the evidence is inadequate to establish that ESDs improve individuals’ underlying conditions or successfully condition individuals to reduce or cease the target behavior to achieve durable long-term reduction of the target behavior.”⁷ Furthermore, it explained that state-of-the-art treatments for self-injurious and aggressive behaviors “are positive-based behavioral approaches along with pharmacotherapy, as appropriate, and do not include ESDs.”⁸

That ESDs continue to be used on children and adults with disabilities as punishment is unacceptable. In one case, brought to light in an expose, a young man was shocked 31 times, ending up in a hospital due to the trauma and physical effects.⁹ This practice must be stopped without delay. We urge you to finalize the proposed rule and take immediate action to ban the electric shock of people with disabilities. Please provide an update on the agency’s progress toward finalizing the rule by no later than February 28, 2020. For additional information or questions, please contact Kimberly Knackstedt with the HELP Committee at Kimberly_Knackstedt@help.senate.gov.

Sincerely,



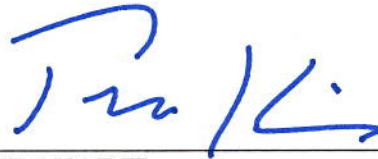
PATTY MURRAY
Ranking Member, Senate Committee on
Health, Education, Labor & Pensions



CHRISTOPHER S. MURPHY
United States Senator



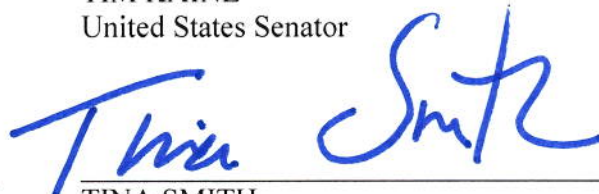
ROBERT P. CASEY, JR.
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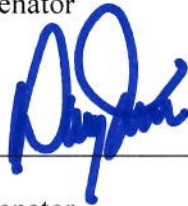
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United States Senator

⁷ 81 Fed. Reg. at 24410.

⁸ 81 Fed. Reg. at 24411.

⁹ Jennifer Gonnerman, “31 Shocks Later,” New York Magazine (Aug. 31, 2012).