

Addendum to comments submitted re: Docket No. FDA-2014-N-0238

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24 June 2014

We urge the FDA to issue a complete ban on electric shock aversive conditioning devices. While much of the testimony and comments about the possibility of a ban have centered on the Judge Rotenberg Center (JRC) as the only entity that uses such a device at present, this issue is larger and of greater significance than the JRC alone. Many may propose that issuing more stringent and rigorous regulations could be an alternative to an outright ban, especially as the abuses of the JRC could theoretically be attributed merely to that specific facility. However, we believe that nothing short of an absolute and total ban on all such devices, past, present, and future, will achieve the goals of protecting consumers and patients, and preventing all unreasonable risks of injury.

Possible regulations might address a.) restrictions on level of milliamperes, other output parameters, and placement of electrodes; b.) definition of the subpopulation that may receive shocks, limited by age and disabilities; c.) preconditions for the use of electric shock aversives, such as long-term failure of multiple other interventions first or documented severity level of self-injurious behavior; d.) conditions on who is allowed to administer shocks, such as requiring devices to be used by licensed medical professionals who personally witnessed the targeted behavior; e.) requirement to disclose safety risks and lack of data on effectiveness prior to use; or f.) restriction on use prior to thorough demonstration of safety and effectiveness through clinical trials with control groups obtaining new data over a fixed duration, specific to particular disabilities and the strength of existing devices, gathered by an objective entity.

Nevertheless, **no amount of regulations will eliminate the substantial and unreasonable risk of injury from any electric shock aversive conditioning device.** Regulations may very well reduce this risk, but will not diminish the risk to the point that it is below the threshold of the substantial and unreasonable standard set forth in the FDA's regulations for banning devices.¹

- Even if the FDA imposes limits on where and how many electrodes can be placed, there is still a substantial and unreasonable risk of burns, seizures, post-traumatic stress, and severe pain, among other possible injuries caused by the device, as the advisory panel noted during the April 24 hearing.²
- Regardless of *any* regulations imposed, there will remain a substantial risk of misfirings and other signal interference with these devices. This would severely undercut the ostensible purpose of the device (to provide highly controlled aversive stimuli) as well as pose an unreasonable risk to those on whom the device is used.
- There is no good data for defining a specific subpopulation that would be eligible to receive shocks.

¹ 21 C.F.R. § 895.21(a) (2011).

² Transcript of Record, Electrical Stimulation Devices for Aversive Conditioning: Hearing Before the Neurological Devices Panel, of the Medical Devices Advisory Comm., of the U.S. Food & Drug Admin., (2014) (discussion of panel members) 331.

- Even if the subpopulation that can receive shocks is limited, someone will still be receiving these shocks at substantial and unreasonable risk of injury.
- **No labeling, warnings, advisements, or other safety information will be made available to those receiving the shocks.** The decisions are made by others rather than by informed consent of the individual patient on their own behalf.

It concerns us further that the only entity currently using these devices is not complying even now with user manual restrictions that require the device to be used by or under the direct supervision of an appropriate licensed professional.³ This admission was made by that entity's executive director personally during the April 24 hearing.

In addition, a recent decision by the Massachusetts Bristol County Probate and Family Court severely undercuts the authority of the Massachusetts Department of Developmental Services (DDS) regulations limiting the use of aversives.⁴ The court's decision outright refused to enforce the DDS regulations. This creates the possibility that more individuals will be shocked against their will, and further emphasizes the need for federal intervention.

Given the flagrant violations of existing regulations and the apparent difficulties in enforcing them, it is obvious that even the most stringent regulations validated by the best scientific data would fail to eliminate the substantial and unreasonable risks of injury that these devices pose.

The FDA must act on its mandate to protect people with disabilities from unsupported treatments that clearly meet the regulatory standard for banning devices. Electrical stimulation devices used for aversive condition a.) are marketed deceptively to those who actually make decisions about their use, b.) pose a substantial and unreasonable risks of injury, and c.) would still pose substantial and unreasonable risks of injury even with further labeling or restrictions on use. Failure to issue a complete ban would strike us not merely as potentially wrong but as wrong with the force of an entire pile of two-month-old unrefrigerated dead fish.

We urge the FDA to issue a total ban on electric shock aversive conditioning devices.

Respectfully submitted,

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³ *Id.* at 269-270.

⁴ In re Guardianship of S.B., 01D-1299-DV1 (Mass. Prob. & Fam. Ct. May 14, 2014).