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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Rm. 1061
Rockville, MD 20852

Re: Comments on the Food and Drug Administration's Proposed Ban on Electrical Stimulation Devices, Docket No. FDA-2023-N-3902

The Consortium for Constituents with Disabilities (CCD) is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration, and inclusion of children and adults with disabilities in all aspects of society, free from racism, ableism, sexism, and xenophobia, as well as LGBTQIA+ based discrimination and religious intolerance. CCD members include disability professionals, national organizations, provider associations, self-advocates, and other allies of individuals with disabilities.

For decades, disability professionals, provider associations, family groups, consumer-run organizations, State legislatures, and even the United Nations have unequivocally disavowed the use of contingent electric shock for the care and treatment of people with disabilities. The Judge Rotenberg Center (JRC) is the only program in the United States where these shock devices are manufactured and used, even for individuals with the most complex needs. Contingent electric shock is not "treatment." It is not supported by modern treatment theories, and as determined by the Food and Drug Administration (FDA), devices like the Graduated Electronic Decelerator (GED) create a substantial and unreasonable risk of illness and injury with no reliable evidence of long-term efficacy.

For the reasons set out below, the undersigned members of the CCD strongly support the FDA's Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior.¹

I. The FDA Properly Incorporated and Relied Upon the Prior Administrative Record

In March of 2020, the FDA issued a final rule banning the use of Electrical Stimulation Devices (ESDs) on individuals who experience self-injurious or aggressive behaviors.² In so doing, the FDA reaffirmed its conclusion in 2016 that ESDs presented an "unreasonable and substantial risk to public health"³ and should not be used, even in individual cases where other treatments may

¹ 89 Fed. Reg. 20,882-97 (proposed 3/26/24) (to be codified at 21 CFR 882, 895).

² 85 Fed. Reg. 13,312, <https://www.federalregister.gov/documents/2020/03/06/2020-04328/banned-devices-electrical-stimulation-devices-for-self-injurious-or-aggressive-behavior>.

³ U.S. FOOD & DRUG ADMIN., *FDA News Release* (April 22, 2016), <https://www.fda.gov/news-events/press-announcements/fda-proposes-ban-electrical-stimulation-devices-intended-treat-self-injurious-or-aggressive-behavior>.

not completely reduce or eliminate these behaviors.⁴ The supporting FDA record was exhaustively compiled over six years and two administrations, and included public testimony, feedback from a panel of clinical experts, complaint data from JRC and DDS, comments from national disability organizations and provider associations, and a comprehensive literature review. Evidence underpinning the agency's decision was collected between 2014 and 2016, extensively cited in the proposed rule, and later updated and incorporated into the 2020 rulemaking. That combined administrative record was more than sufficient to support the promulgation of the 2020 regulation, and it is properly re-incorporated here in support of the 2024 Notice of Proposed Rulemaking (NPRM).

The FDA's prior administrative record clearly demonstrated that the overwhelming weight of professional research, and virtually all peer-reviewed scientific literature, supports a ban on ESD's and the use of contingent electric shock in response to aggressive or self-injurious behavior by people with disabilities. The undersigned CCD members highlight several key aspects of the FDA's extensive findings of fact in the comments below.

First, the FDA determined that ESDs (like the GED) create "unreasonable and substantial risks of illness and injury," with little or no credible evidence of efficacy or long-term benefit.⁵ Risks of harm include pain, skin burns, loss of sensitivity to fatigue or pain, and injuries from falling, as well as psychological harms, including depression, PTSD, anxiety, fearfulness, suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, and hypervigilance.⁶ It also found that ESDs may worsen underlying clinical conditions, replacing one negative behavior with another, and result in a loss of agency or "learned helplessness."⁷

Second, the FDA found no systematic investigations of the effectiveness of ESDs for self-injurious and/or aggressive behavior.⁸ Existing studies were outdated and methodologically flawed, and many were silent as to any attempts to assess negative side effects.⁹ Concerns about the accuracy of adverse event reporting were compounded by the age and scientific rigor of the studies themselves.¹⁰ No randomized controlled trials were identified by the FDA or its expert panel.¹¹ Articles identified by or presented to the FDA in support of ESDs did not "adhere to current, more exacting peer-review standards for study conduct and reporting."¹² The FDA also considered the potential for bias in case studies reporting only ESD benefits and no side effects, including the possibility that some investigators may have been "pre-disposed to see only positive

⁴ *Banned Devices; Proposal To Ban Electrical Stimulation Devices*, 81 Fed. Reg. 24,406 (Apr. 25, 2016); <https://www.federalregister.gov/documents/2016/04/25/2016-09433/banned-devices-proposal-to-ban-electrical-stimulation-devices-used-to-treat-self-injurious-or>.

⁵ 85 Fed. Reg. 11,315.

⁶ 85 Fed. Reg. 13,315; *see also*, 81 Fed. Reg. at 24,389.

⁷ 81 Fed. Reg. at 24,389.

⁸ FDA Executive Summary, Neurological Devices Panel ("Panel Summary") (April 2014) FDA-2016-N-1111-1748 at 44, 58; Table 4: Articles Reviewed for Adverse Events Associated with ESDs for Aversive Conditioning for Patients with SIB and Assaultive/Destructive Behavior associated with Developmental Disabilities at 59-61; <https://bit.ly/3Z4EbBc>; *see also* 81 Fed. Reg. at 24,406.

⁹ Panel Summary at 44, 58.

¹⁰ Panel Summary at 58, 64-65. In its Final Rule, the FDA notes that "the only article specifically about JRC's GED device was published in a peer-reviewed journal over a decade ago, and it studied only nine subjects at JRC (Ref. 7). Studies of ESDs more generally have been published in peer-reviewed journals, but many of them are decades old. In the intervening decades, the understanding of pathophysiology has evolved as has the ability to identify and systematically record AEs. [Adverse Events]. These developments are alongside heightened peer-review standards for study and reporting. Accordingly, it is reasonable to assign these studies less weight than more modern studies." 85 Fed. Reg. 13319.

¹¹ Panel Summary at 57.

¹² *Id.* at 64-65; 81 Fed. Reg. at 24,401 (the majority of articles did not "adhere to current, more exacting peer-review standards for study conduct and reporting.")

side effects.”¹³ This potential for bias in overlooking adverse events included the largest case study -- a retrospective review conducted by JRC.¹⁴

Third, the FDA record demonstrated the existence of effective, less restrictive alternatives to electric shock resulting in “durable, long-term benefits” including the reduction or elimination of challenging behaviors.¹⁵ The FDA identified a substantial body of peer reviewed literature and empirical research showing that Positive Behavior Supports, as well as other evidenced-based treatments and therapies, can reduce and eliminate harmful behaviors through environmental modification and the teaching of adaptive, replacement behaviors. As noted in the FDA’s 2016 proposed rule:

scientific advances have yielded new insights into the organic causes and external (environmental or social) triggers of SIB [self-injurious behaviors] and AG [aggressive behaviors], allowing the field to move beyond intrusive punishment techniques such as aversive conditioning with ESDs.¹⁶

This evolution in treatment standards is now well-established. As the FDA noted, “[s]urveys show the [Applied Behavior Analysis] field as a whole moved away from intrusive physical aversive conditioning techniques such as ESDs 2 decades ago.”¹⁷

The undersigned members of CCD believe that these three findings were correct then and remain correct today. We strongly support the FDA’s proposed ban based upon these findings and believe they provide ample, in fact compelling, scientific evidence to support the proposed rule.

The FDA’s finding that the risks of ESDs outweighed any evidence of potential benefits was supported by policy statements from leading disability organizations and professional associations around the country, many of whom are CCD members. In 2010, The Arc of the United States and The American Association of Intellectual and Developmental Disabilities (AAIDD), the oldest and largest interdisciplinary organization of professionals and citizens concerned about the human rights of persons with intellectual and developmental disabilities, issued a joint policy Statement against the use of painful aversives and in favor of positive behavioral supports.¹⁸ In 2016, the National Association of State Directors of Developmental Disabilities Services (NASDDDS) which represents State I/DD agencies in 50 jurisdictions, Puerto Rico, and the District of Columbia, submitted formal comments to the FDA, rejecting the use of interventions that cause pain and harm for the purpose of modifying behavior and instead promoting the use of Positive Behavioral Support.¹⁹ In 2019, AAIDD renewed their long-standing call for the “immediate elimination and permanent discontinuation of electric skin shock as an intervention for the behavior of people with intellectual and developmental disabilities.”²⁰ Taken together, these statements reflected a well-established, emphatic, and widespread rejection of contingent electric shock as a form of behavior modification.

¹³ Panel Summary at 65 (citing Carr and Lovaas (1981) (“in light of the intrusive nature of shock treatment, it is puzzling that so few negative side effects have been reported”).

¹⁴ Panel Summary at 58 (citing Israel *et al.*, 2008).

¹⁵ 81 Fed. Reg. at 24,410; 85 Fed. Reg. 13,315.

¹⁶ 81 Fed. Reg. at 24,387.

¹⁷ 85 Fed. Reg. 13,317 (“the professional field, with the sole exception of JRC, has moved beyond the use of ESDs for SIB or AB”)

¹⁸ *Joint Position Statement of AAIDD and the Arc on Behavioral Supports* (August 23, 2010, extended 2015), <https://www.aaid.org/news-policy/policy/position-Statements/behavioral-supports>.

¹⁹ NATIONAL ASSOCIATION OF STATE DIRECTORS OF DEVELOPMENTAL DISABILITIES SERVICES (NASDDDS), *Comment on Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior*, <https://www.nasddds.org/nasddds-offers-comments-to-ban-electrical-stimulation-devices/>.

²⁰ THE AMERICAN ASSOCIATION OF INTELLECTUAL AND DEVELOPMENTAL DISABILITIES (AAIDD), *Position Statement on Electric Shock*; <https://www.aaid.org/news-policy/policy/position-Statements/electric-shock>.

The FDA also properly relied on evidence that the majority of States have severely limited or banned the use of contingent electric shock and other painful aversive interventions. In 2015, the National Association of State Developmental Disability Directors (NASDDDS) surveyed States about their rules, policies, guidelines, contracts, or practices that governed aversive interventions. Of the 45 States responding, 82% reported that aversives are disallowed for use in service for people with I/DD.²¹ A more recent search has found that at least twenty-eight States have enacted prohibitions against the use of electric shock and other painful aversive procedures.²²

The undersigned members of CCD believe these policy statements, adopted by the leading disability professional organizations, represent the most informed and scientifically valid positions concerning the use of behavior interventions generally, and aversive conditioning specifically. We consider the actions of state legislators and disability policymakers to be highly relevant to whether ESDs are appropriate and safe interventions to respond to SIB and AB for persons with disabilities. We note that since the 2020 rule was issued, even more professional organizations have adopted similar policy statements, further supporting the evidence previously relied upon the FDA in promulgating the prior rule.

Taken together, the extensive record created in support of the 2020 ban, and incorporated in the 2024 NPRM, provides comprehensive and compelling evidence in support of the proposed ban, including the substantial and unreasonable risk of injury presented by ESDs when used to reduce aggressive or self-injurious behaviors, and the existence of safe, effective, and less restrictive alternatives in use around the country. This evidence rightly led the FDA to conclude that the risks associated with electric shock are not worth taking, even if other treatment may not completely reduce or eliminate self-injurious or aggressive behaviors in all patients.²³ The undersigned members of CCD endorse this conclusion and considers the extensive record more than sufficient to support the FDA's proposed rule.

II. The FDA Properly Considered New Information Made Available Since the 2020 Administration Record Closed and Correctly Concluded that Nothing of Significance Has Occurred Which Would Justify Modifying the Prior Regulation

As part of the 2024 NPRM, the FDA conducted an updated literature survey, including published studies, articles, and policy statements related to the risks and effects of ESDs when used for self-injurious or aggressive behaviors.²⁴ This record also incorporated a comprehensive literature review conducted as part of the 2016 and 2020 rule making process. Results from the FDA's updated survey underscore the reliability of its past rulemaking and demonstrate that no further modification of the proposed rule is necessary.

Publications identified since promulgation of the 2020 rule: 1) reaffirm the FDA findings of unreasonable risks of harmful side effects associated with the use ESDs on persons with disabilities and the availability of state of the art alternatives; 2) raise similar questions regarding the durability and long term efficacy of contingent electric shock; and 3) identify ethical and

²¹ See NASDDDS, *supra note* 19.

²² Jurisdictions banning skin shock or other painful aversive techniques include California, Colorado, Illinois, Indiana, Maine, Maryland, Michigan, Missouri, Montana, Nebraska, Nevada, New Mexico, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

²³ 81 Fed. Reg. at 24,406.

²⁴ 89 Fed. Reg. at 20,887.

methodological issues which continue to undermine the credibility of existing research on contingent electric shock for self-injurious and aggressive behaviors.²⁵

The FDA specifically considered four new publications authored or jointly authored by the Judge Rotenberg Center (JRC), three of which involved retrospective studies (at least two concerning the same group of 173 individuals),²⁶ and one which focused on the experiences of an individual client.²⁷ As noted in the NPRM, these studies were based on information available prior to 2020, and are subject to many of the same design and methodology limitations identified in the 2016 and 2020 literature reviews.²⁸ These limitations were also noted in an external review of ESD use at JRC conducted by a taskforce of the Association for Behavior Analysis International (ABAI). Taskforce authors observed that the JRC papers “involve retrospective analyses of clinical data and, thus, do not utilize controlled experimental designs or include measures of reliability or procedural integrity.”²⁹

With regard to its own 2023 overview of the literature on Contingent Electric Shock (CESS), the ABAI taskforce concluded:

No peer-reviewed studies on the therapeutic use of CESS to treat severe behavior disorders in individuals with developmental disabilities have been published in a behavior analytic journal for 20 years; exceptions include six retrospective analyses of data collected at the JRC and a 2004 case study in which the Self-Injurious Behavior Inhibiting System (SIBIS) – a helmet that delivers shocks contingent on certain head movements – was used successfully to treat the self-injury of a 3-year-old child (Salvy et al., 2004). No studies on CESS have been published in the field’s flagship journal (Journal of Applied Behavior Analysis) in more than 30 years. With the exception of individuals affiliated with the JRC, no researchers or clinicians have presented data on the therapeutic use of CESS at recent behavior analytic conferences. No contemporary textbooks used by faculty in undergraduate and graduate applied behavior analysis programs describe the therapeutic use of CESS to treat problem behavior. The most commonly used and cited text (Cooper et al., 2020) states that a punisher such as CESS “no longer meets the standards of least restrictive alternative or best practice.”³⁰

²⁵ See, e.g., Zarcone, J.R., M.P. Mullane, P.E. Langdon, et al.. *Contingent Electric Shock as a Treatment for Challenging Behavior for People With Intellectual and Developmental Disabilities: Support for the IASSIDD Policy Statement Opposing Its Use*, Journal of Policy and Practice in Intellectual Disabilities, 17(4):291–296, 2020; <https://doi.org/10.1111/jppi.12342>; Jennifer R. Zarcone, et al., *Response to ABAI Task Force on the Use of Contingent Electric Skin Shock*, Perspectives on Behavior Science, 46:349–354 (June 2023); <https://doi.org/10.1007/s40614-023-00381-2>.

²⁶ See Blenkush, N.A. and J. O'Neill, *Contingent Skin-Shock Treatment in 173 Cases of Severe Problem Behavior*, International Journal of Psychology & Behavior Analysis, 6:167, 2020; <https://doi.org/10.15344/2455-3867/2020/167>; Yadollahikhales, G., N. Blenkush, and M. Cunningham, *Response Patterns for Individuals Receiving Contingent Skin Shock Aversion Intervention To Treat Violent Self-Injurious and Assaultive Behaviours*.” BMJ Case Reports CP, 14(5):e241204, 2021; <http://dx.doi.org/10.1136/bcr-2020-241204>.

²⁷ Blenkush, N. and M. Cunningham, *Elimination of Refractory Aggression and Self-Injury With Contingent Skin Shock*, The Journal of Neuropsychiatry and Clinical Neurosciences, 35:264–268, 2023, <https://doi.org/10.1176/appi.neuropsych.21020049>.

²⁸ 89 Fed. Reg. at 20,887.

²⁹ Perone, M., D.C. Lerman, S.M. Peterson, et al., *Report of the ABAI Task Force on Contingent Electric Skin Shock*. Perspectives on Behavior Science, 46(2):261–304, at 268 (2023); <https://doi.org/10.1007/s40614-023-00379-w>.

³⁰ See *id.* at 348.

As part of their review, the ABAI taskforce also interviewed clinical directors at nine facilities across the United States that treat severe problem behavior in individuals with developmental disabilities, none of whom used painful aversive stimuli, including CESS.³¹ Finally, the Taskforce acknowledged that CESS is a form of punishment and that advances in the field of behavior analysis have drastically reduced reliance on punitive interventions while increasing the number of individuals with severe behavior problems who can be treated effectively in programs based on principles of positive reinforcement:

As matters stand today, these principles constitute the foundation of the professional practice of applied behavior analysis, and they are essential to ethically sound and effective treatment programs. Today, CESS is not the standard of care for the treatment of problem behavior.³²

Taken together, the limitations of existing studies of ESD use, the identified absence of peer reviewed research on the durability and efficacy of ESDs, and evidence of the effective use of state-of-the-art alternatives led the FDA to correctly conclude that “while the publication process lends some reassurances to the credibility of information and data, presenting previously submitted data in a different form does little to add to overall knowledge about the risks and effects of ESDs for SIB and AB.”³³

As evident in the 2024 NPRM footnotes, there also has been an increase in the number of professional associations publicly disavowing the use of ESDs, including providers specializing in Applied Behavior Analysis. The Association for Behavior Analysis International (ABAI) voted in November of 2022 to “strongly oppose the use of contingent electric skin shock (CESS) under any condition.”³⁴ In so doing, it expressly repudiated the final recommendation of its appointed task force (which was to preserve the CESS option only in “extraordinary circumstances”) and determined instead that insufficient evidence demonstrating the efficacy of CESS compared to state of the art alternative treatments, a lack of social validity, the potential for harm to vulnerable populations, and ethical concerns all necessitated a total ban, as proposed by the FDA.³⁵

Months earlier in June of 2022, the Association of Professional Behavior Analysts (APBA) Board of Directors issued its own Statement concluding that contingent electric shock “is generally not the accepted standard of care in the behavior analytic treatment of severe or challenging behavior,” and that its use “goes against the profession’s overarching ethical principles of maximizing benefits for clients, doing no harm, and treating others with compassion, dignity, and

³¹ *Id.* at 268.

³² *Id.* at 263.

³³ 89 Fed. Reg. at 20,887.

³⁴ ASSOCIATION FOR BEHAVIOR ANALYSIS INTERNATIONAL (ABAI), *Position Statement on the Use of CESS* (November 2022); <https://www.abainternational.org/about-us/policies-and-positions/position-statement-on-the-use-of-cess-2022.aspx> (“CESS can suppress behavior; however, as a treatment, it does not address the function of a behavior, and does not support the acquisition of prosocial or adaptive behavioral repertoires. In fact, the short- and long-term emotional side effects and likelihood of trauma produced by the procedure may interfere with the acquisition of such repertoires. The published literature based in applied behavior analysis does not support CESS as an evidence-based treatment. There is limited evidence that the treatment produces long-term maintenance of behavior change, promotes generalization of behavior change to naturalistic conditions, or enhances important quality of life outcomes during or after treatment. Moreover, there are limited studies published on CESS in behavior analytic journals, limited replication studies across multiple sites, and limited studies published by leading researchers with expertise in the assessment and treatment of challenging behavior. Finally, relatively few of those studies were methodologically rigorous or published after the year 2000, given that CESS is not a commonly accepted or socially valid practice”).

³⁵ *Id.*

respect.”³⁶ Similarly, the Massachusetts Association for Applied Behavior Analysis (MassABA), an organization that represents the interests of behavior analysts in the State, issued a 2021 position paper stating that contingent electric skin shock is “an unnecessary and demonstrably harmful tactic with possible long-term negative physical and emotional effects,” whose use is “immoral, inhumane, and unethical” and “outside the scope of practice of behavior analysis.”³⁷

III. The FDA Properly Analyzed the Risks and Benefits of ESDs and Did Not Attempt to Assess Whether or Not There Was a Professional Consensus with Regard to ESDs.

Whether a device presents an unreasonable risk of illness or injury is not dependent on either unanimity of professional opinion or professional consensus about its use. The FDA’s responsibility, pursuant to its statutory mandate, as set forth in Sec. 516 of the FD&C Act and Sec. 3306 of the FDORA, and its regulatory mandate, as set forth in 21 CFR § 895, is to compare the risks and benefits of a device to the risks and benefits of alternative treatments used in state-of-the-art medical practice. This responsibility is informed by reliable clinical research, the advice of expert panels, the experience of medical professionals, and documented evidence of clinical effectiveness, but it is not dependent on a professional consensus about the utility of any given treatment or intervention.

Devices are not banned simply because most professionals do not approve of them; nor are devices permitted simply because a few professionals prefer them. Rather, the FDA is charged by Congress with the duty to determine if, based upon valid and reliable scientific evidence, that a device does not present an unreasonable and substantial risk of illness or injury, in light of well-established and proven alternatives. The FDA’s purpose in considering effective, alternative treatments is “to assess and compare the risks and benefits of the device that is the subject of the ban, not to determine whether the device ... is part of the standard of care or state of the art.”³⁸

The outcome of this balancing test is clear in the administrative record. The use of contingent electric shock has not been proven to be effective in reducing aggressive and self-injurious behavior, and the risks associated with the use of ESDs are unreasonable given the existence of modern, state of the art treatments including functional behavioral assessments, positive behavioral supports, and pharmacology. Therefore, we strongly support the framework that the FDA applied here, and the conclusion it reached that ESDs present an unreasonable and substantial risk of illness or injury, in light of state-of-the-art alternatives.

IV. The FDA Properly Concluded that Massachusetts State Court Decisions Are Not Relevant to, and Certainly Not Controlling of, Whether ESDs Should Be Banned.

Neither the 2018 Massachusetts Probate court decision concerning termination of a JRC consent decree, nor the Commonwealth’s Supreme Judicial Court review of that decision in *Judge Rotenberg Center v. Commissioner of the Department of Developmental Services*, 492 Mass. 772, 808 (2023) have any bearing on the FDA’s proposed 2024 rulemaking. First, the probate court’s conclusion that there was no professional consensus regarding the use of ESDs to reduce self-injurious and aggressive behaviors was based on a trial record that closed in 2016 – four years

³⁶ APBA BOARD OF DIRECTORS, *Position Statement on the Use of Electric Skin Shock*, (June 2022), https://cdn.ymaws.com/www.apbahome.net/resource/collection/1FDDBDD2-5CAF-4B2A-AB3F-DAE5E72111BF/APBA_Position_Statement_on_Contingent_Skin_Shock_June2022.pdf.

³⁷ MASSACHUSETTS ASSOCIATION FOR APPLIED BEHAVIOR ANALYSIS, *Position Statement on the Use of Electric Shock as an Intervention in the Treatment of Individuals with Disabilities* (October 2021), https://www.massaba.net/wp-content/uploads/Position-Statement_Electric-Shock_2021.pdf.

³⁸ 89 Fed. Reg. at 20,885.

before the FDA's final rule was promulgated. That record did not include either the FDA's 2016 proposed rule or its administrative record.

Second, the probate court's findings were focused on whether there was a change in fact or law warranting termination of the consent decree which allowed for the use of aversives at JRC, subject to certain conditions. It did not directly consider whether the device created a substantial and unreasonable risk of illness or injury. Finally, the SJC did not adopt the probate court's finding regarding professional consensus. Instead, it simply held that the decision to deny the Commonwealth's motion for termination was not clearly erroneous, given the actions of a state official in 2010, and that the trial court did not abuse its discretion. At the same time, the SJC indicated that further findings on more recent developments would be useful given the age of the probate court record.

Since there is nothing in either court opinion that directly addressed, or reached factual or legal conclusions regarding, whether ESDs presented an unreasonable and substantial risk of illness or injury compared to alternative treatment interventions, these State court decisions are not relevant to the FDA's analysis.³⁹ Therefore, we strongly support the agency's determination that these decisions have "no legal or scientific bearing on this proposed ban."⁴⁰

V. Transition Period

The FDA seeks comments on whether there should be a transition period of 180 days for the ban of all ESDs after the effective date of the rule.⁴¹ We first note that all of the reasons supporting the ban, and particularly the FDA's conclusion that there is an unreasonable and substantial risk of illness or injury, strongly supports an immediate effective date, with no transition period. When scientific evidence demonstrates that a device is dangerous, that its risks exceed any alleged benefits, and that alternative treatments are safer, more effective, and widely used by treating professionals, even in the most difficult cases, delaying a ban is not warranted. Instead, the transition from ESDs should occur as soon as possible under the supervision of a qualified independent medical professional, trained in the provision of state-of-the-art behavioral support services.

Nevertheless, we recognize that for the approximately fifty individuals with significant disabilities at JRC who are subject to ESDs: 1) there has not been an appropriate functional assessment by a qualified, independent medical professional; 2) there is not a treatment plan that contains alternative interventions; and 3) there is not immediate access to state-of-the-art treatment interventions. Therefore, but reluctantly, we support a 60-day transition period, which would provide up to 30 days to conduct the necessary functional assessments and revise individuals' treatment plans, and an additional 30 days to identify appropriate treatment settings and alternative interventions.

Given the urgency of these issues, and the passage of time since its previous 2020 ban, we urge the FDA to move forward with approval of the proposed rule as soon as possible.

Sincerely,

Access Ready Inc.
American Association of People with Disabilities
American Association on Health and Disability

³⁹ 89 Fed. Reg. at 20,882, 20,886-87.

⁴⁰ 89 Fed. Reg. at 20,882, 20,885.

⁴¹ 89 Fed. Reg. at 20994.

American Association on Intellectual and Developmental Disabilities (AAIDD)
American Civil Liberties Union (ACLU)
American Music Therapy Association
American Network of Community Options and Resources (ANCOR)
American Occupational Therapy Association
American Therapeutic Recreation Association
Association of University Centers on Disabilities
Autism Society of America
Autism Speaks
Autistic Self Advocacy Network
Autistic Women & Nonbinary Network
Bazelon Center for Mental Health Law
Caring Across Generations
Center for Public Representation
Communication 4 ALL
CommunicationFIRST
Council of Parent Attorneys and Advocates
Council of State Administrators of Vocational Rehabilitation (CSAVR)
Disability Rights International
Disability Rights Education & Defense Fund
Eggleston
Epilepsy Foundation
Family Voices
Huntington's Disease Society of America
Justice in Aging
National Association of Councils on Developmental Disabilities
National Center for Learning Disabilities
National Center for Parent Leadership, Advocacy, and Community Empowerment (National PLACE)
National Council on Independent Living
National Disability Rights Network (NDRN)
National Down Syndrome Congress
National Health Law Program
RespectAbility
TASH
The Advocacy Institute
The Arc of the United States
United Spinal Association
United States International Council on Disabilities
World Institute on Disability