ORAL ARGUMENT HAS NOT YET BEEN SCHEDULED
Nos. 20-1087, 20-1088

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC.,
Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,
Respondents.

LUIS APONTE,
on behalf of himself and on behalf of his ward, L.A., et al.,
Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,
Respondents.

On Petitions for Review of a Final Rule of the
United States Food and Drug Administration

BRIEF OF AMICI CURIAE AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ASSOCIATION ON INTELLECTUAL AND DEVELOPMENTAL DISABILITIES, AMERICAN ACADEMY OF DEVELOPMENTAL MEDICINE AND DENTISTRY, INTERNATIONAL ASSOCIATION FOR THE SCIENTIFIC STUDY OF INTELLECTUAL AND DEVELOPMENTAL DISABILITIES, NATIONAL ASSOCIATION OF STATE DIRECTORS OF DEVELOPMENTAL DISABILITIES SERVICES, NATIONAL ASSOCIATION OF STATE DIRECTORS OF SPECIAL EDUCATION, AND NATIONAL ASSOCIATION FOR THE DUALLY DIAGNOSED IN SUPPORT OF RESPONDENTS AND AFFIRMANCE

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January 22, 2021

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), undersigned counsel for amici curiae the American Academy of Pediatrics, American Association on Intellectual and Developmental Disabilities, American Academy of Developmental Medicine and Dentistry, International Association for the Scientific Study of Intellectual and Developmental Disabilities, National Association of State Directors of Developmental Disabilities Services, National Association of State Directors of Special Education, and National Association for the Dually Diagnosed certifies as follows:

A. Parties And Amici

Except for the following amici curiae in this Court, all parties, intervenors, and amici appearing before the district court and in this Court are listed in the Certificates as to Parties, Rulings, and Related cases filed by Petitioners.

B. Rulings Under Review

References to the rulings at issue appear in the Certificates as to Parties, Rulings, and Related Cases filed by Petitioners.

C. Related Cases

Counsel is unaware of any related cases before this Court.

/s/ Felicia H. Ellsworth
Felicia H. Ellsworth

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1, amici curiae certify that none of them is a publicly held corporation, that no amicus has a parent company, and that no publicly held corporation owns a 10% or more ownership interest in any of the amici.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

RULES AND REGULATIONS

OTHER AUTHORITIES

GLOSSARY

A	Case No. 20-1087: Amended Certified List of Record Materials for FDA-2014-N-0238, Doc #1868914 (D.C. Cir. Oct. Oct. 29, 2020)
AAP	American Academy of Pediatrics
AADMD	American Academy of Developmental Medicine and Dentistry
AAIDD	American Association on Intellectual and Developmental Disabilities
FDA	Food and Drug Administration
Final Rule	*Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior*, 85 Fed. Reg. 13,312 (Mar. 6, 2020)
IASSIDD	International Association for the Scientific Study of Intellectual and Developmental Disabilities
JA	Joint Appendix
JRC	Judge Rotenberg Center
NADD	National Association for the Dually Diagnosed
NASDDDS	National Association of State Directors of Developmental Disabilities Services
NASDSE	National Association of State Directors of Special Education
Proposed Rule	*Banned Devices; Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior*, 81 Fed. Reg. 24,386 (Apr. 25, 2016)

INTEREST OF AMICI CURIAE

The ***American Academy of Pediatrics (AAP)***, founded in 1930, is an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. Members include pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. As part of its mission, AAP develops clinical guidance for the optimal care of children and youth with disabilities. AAP also engages in education and research and provides expertise and advocacy on local and national issues related to children and youth with disabilities. AAP offers continuing education courses, annual scientific meetings, seminars, and publications. It publishes a monthly scientific journal (*Pediatrics*), a continuing education journal (*Pediatrics in Review*), manuals on topics such as infectious diseases and school health, patient education brochures, and a series of childcare books written by its members. AAP works to ensure children's health needs are considered in the development of legislation and public policy. AAP submitted a comment to the notice of proposed rulemaking. JA__[A2155].

The ***American Academy of Developmental Medicine and Dentistry (AADMD)*** is a national non-profit organization of interdisciplinary medical professionals, including physicians, dentists, optometrists, neurologists, nurses, and other clinicians, committed to improving the quality of healthcare for people with

intellectual and developmental disabilities. Since 2002, AADMD has been at the forefront of national efforts to improve the quality of care for people with intellectual and developmental disabilities, through the evolution of medical treatments, clinical practices, and public policy. AADMD provides a forum in which clinicians identify, develop, and disseminate scientific literature on the best care practices for people with intellectual and developmental disabilities, and has produced medical school curricula adopted by top universities. AADMD is resolved, among other things, to ensure everyone with neurodevelopmental disorders has access to quality health services, to prepare clinicians to face the unique challenges in caring for people with these disorders, to increase the body and quality of patient-centered research regarding these disorders, to disseminate specialized information to families, and to establish alliances between advocacy and healthcare organizations to achieve better outcomes. Where scientific literature is unclear or controversial, AADMD helps to resolve competing conclusions by providing consensus opinion from informed and highly experienced clinicians. AADMD submitted a comment to the notice of proposed rulemaking. JA__[A1983].

The ***American Association on Intellectual and Developmental Disabilities (AAIDD)*** was founded in 1876 and is the nation's oldest and largest organization of professionals in the field of intellectual disability. AAIDD's focus is on

gathering, maintaining, and disseminating information on the scientific and clinical understanding of intellectual disability, and on providing a forum for professionals focusing on intellectual disability to exchange ideas and information and maintain the scientific and clinical integrity of their work. Through its professional journals, conferences, and publications, AAIDD works diligently to advance the scientific understanding of intellectual disability. Primarily focused on clinical, psychological, scientific, educational, and habilitative issues, AAIDD also has a longstanding interest in legal issues that affect the lives of people with intellectual disabilities. AAIDD submitted a comment to the notice of proposed rulemaking (JA__[A2074]), and AAIDD's Executive Director and CEO testified in front of the 2014 Neurological Devices Panel (JA__[A317 at 153-156]).

The ***International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSIDD)***, founded in 1964, is an international, interdisciplinary, and scientific non-governmental organization that promotes worldwide research and exchange of information on intellectual disabilities. Its mission is to promote the development of new knowledge, research, and other scholarly activities, and to apply such knowledge to improve the lives of people with intellectual and developmental disabilities, their families, and those who support them. IASSIDD stimulates high quality and innovative research encompassing interdisciplinary interests and methodological diversity, and engages

in a worldwide exchange of evidence-based knowledge with relevant stakeholders. This work includes the publication of two scientific journals: the *Journal of Policy and Practice in Intellectual Disabilities*, an international, peer-reviewed journal that provides a forum for description of evidence-based policy and practice related to people with intellectual and developmental disabilities; and the *Journal of Intellectual Disability Research*, devoted exclusively to the scientific study of intellectual disability and reporting original observations to this field. IASSIDD also sponsors international congresses every three to four years to present recent findings in the biological, behavioral, and social sciences related to intellectual disabilities, and holds conferences, webinars, roundtables, and workshops. IASSIDD also published a review of the available literature on electric skin shock, and concluded that electric shock should be banned. *See* Zarcone 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*, 17 J. of Policy & Practice in Intellectual Disabilities 291 (2020).

The ***National Association for the Dually Diagnosed (NADD)*** is a non-profit international organization for persons with both intellectual and developmental disabilities and mental health needs and was founded in 1983. NADD comprises professionals, researchers, families, and individuals dedicated to the expansion of

knowledge, training, and policies that promote quality of life for individuals with dual diagnoses. Its mission is to enhance the understanding and treatment of people experiencing co-occurring intellectual and developmental diagnoses and mental health conditions or mental illness. NADD has been training and consulting with individuals, organizations, and government agencies for nearly 40 years, has hosted annual conferences for 37 years, and has published over 70 books. It also publishes the *Journal of Mental Health Research in Intellectual Disabilities*, which centers on scientific and scholarly research related to mental health and wellness for people with intellectual and developmental disabilities. Through its work, NADD promotes whole-person care through the biopsychosocial approach to treatment. It supports and contributes to research and training, public policy, and the development of supports and treatment approaches that promote best practices, independence, and full inclusion for people receiving services. James Mulick, a member of the editorial board for the *Journal of Mental Health Research in Intellectual Disabilities*, submitted a comment to the notice of proposed rulemaking. JA__[A2219].

The ***National Association of State Directors of Developmental Disabilities Services (NASDDDS)*** is a professional organization comprising the directors of state agencies from all 50 states and the District of Columbia with responsibility for the administration and management of services furnished to individuals with

intellectual and developmental disabilities. NASDDDS members support people with intellectual and developmental disabilities who also have significant behavioral support needs. For nearly 60 years, NASDDDS has promoted and assisted state agencies in developing effective, efficient service delivery systems that furnish high-quality supports to people with intellectual and developmental disabilities. In pursuit of this goal, NASDDDS provides member state agencies with timely analyses of federal statutory and regulatory policies that affect people with disabilities, disseminates information on state-of-the-art programs and service delivery practices, provides technical assistance and support to member states, and offers a forum for the development of state and national policy initiatives. NASDDDS submitted a comment to the notice of proposed rulemaking (JA__[A1608]), as did NASDDDS' Executive Director, Nancy Thaler (JA__[A1972]). Ms. Thaler also testified at the 2014 Neurological Devices Panel. JA__[A317 at 170-173].

The ***National Association of State Directors of Special Education (NASDSE)***, founded in 1938, is a membership organization that supports state special education directors throughout the United States and its territories. Its mission is to improve individual and organizational success for state leaders of special education by providing relevant services that guide positive systemic change and results, thereby ensuring students with disabilities will live, learn,

work, and participate in their communities. In pursuit of this goal, NASDSE strives to create and influence effective public policy by identifying and disseminating best practices for supporting students with disabilities; creating an innovative network for its members and partner organizations that easily connects people, ideas, and resources; and providing specialized professional development services to support all state leaders of special education. NASDSE, as well as many of its member organizations, submitted a comment to the notice of proposed rulemaking. JA__[A1868].

INTRODUCTION

Amici submit this brief in support of the Food and Drug Administration's ("FDA") ban of the use of electrical stimulation devices—a form of electric shock—for aversive conditioning. Amici are national organizations of physicians, researchers, and administrators of state disability and special education systems.[1] They have deep expertise in state-of-the art practices regarding effective and safe treatments for individuals with disabilities who also engage in self-injurious and aggressive behaviors. For decades, amici have played a leading role in developing, identifying, and disseminating the scientific literature regarding positive behavioral supports and other evidence-based treatments for the populations they serve. Amici have an ongoing interest in the issues raised by the FDA's ban, and have shared their expertise and knowledge with the FDA through comments provided during the rulemaking process.

The FDA was correct to ban the use of these devices. Using electric shock for aversive conditioning is painful, psychologically damaging, and often physically harmful. Moreover, there is no justification for subjecting people to such unreasonable risk of injury, pain, and illness, because safe, effective, and less

[1] Pursuant to Federal Rules of Appellate Procedure 29(a)(2) and 29(a)(4)(E), amici state that all parties have consented to the filing of this brief, that no counsel for any party authored this brief in whole or in part and that no party, party's counsel, or other person contributed money that was intended to fund preparing or submitting the brief.

restrictive treatments are available and widely used. The FDA banned these devices for both reasons, and both conclusions are consistent with the overwhelming weight of scientific literature on this topic, and actual treatment practices across the country, including those used by amici's own members. In fact, electric shock is prohibited by state agency rules or legislation in virtually every U.S. jurisdiction. Other than at the Judge Rotenberg Center ("JRC"), every person in this country being treated for self-injurious or aggressive behaviors receives treatment other than the use of electric shock. Because the FDA's decision to ban the last remaining use of these devices is thoroughly grounded in scientific evidence, well-supported by the administrative record, and consistent with current practices, and because it reflects understanding of the state-of-the-art treatment for these conditions, the petition for review should be denied.

ARGUMENT

I. RESEARCH AND LITERATURE SUPPORTS THE FDA'S DETERMINATION THAT ELECTRICAL STIMULATION DEVICES CREATE UNREASONABLE AND SUBSTANTIAL RISKS OF INJURY

The FDA acted in accordance with the weight of professional research and peer-reviewed literature, which supports the FDA's conclusion that electric shock presents an unreasonable and substantial risk of illness and injury. This literature conforms with, and includes, amici's own research and experience. As part of its inquiry into the safety of electrical stimulation devices, the FDA canvassed

scientific literature about treatment outcomes related to electric shock and aversive conditioning, and for adverse events related to electric shock, and reviewed the literature in full for information on the benefits and risks (respectively) of electric shock devices. JA__[A314 (hereinafter "Panel Summary") at 45].[2]

As a supplement to this rigorous review of the scientific literature, the FDA also sought out other evidence bearing on the safety and efficacy (if any) of electric shock devices. The FDA met with many professional organizations with expertise in this area, JA__[Panel Summary at 71-72]; reviewed letters and reports, JA__[*id.* at 71-73]; reviewed patient case summaries and complaint files from the JRC, JA__[*id.* at 74-75]; conducted clinical interviews, JA__[*id.* at 76-78]; and reviewed reports relating to those administered electric shock. JA__[*Id.* at 78-81]. This body of evidence supports the FDA's decision to ban these devices.

A. The FDA's Finding That Using Electric Shock For Aversive Conditioning Poses A Significant Risk Of Harm Is Supported By The Scientific Literature

The scientific literature shows that persons who receive electric shock as aversive conditioning suffer pain, other physical harms, and often psychological

[2] The FDA composed an executive summary of all of the relevant literature and other evidence, which it provided to experts at a panel it convened in 2014, the Neurological Devices Panel of the Medical Devices Advisory Committee. The panel's expertise was wide-ranging and covered a variety of issues concerning whether electrical stimulation devices should be banned. 85 Fed. Reg. 13,312. 13,318 (Mar. 6, 2020) (hereinafter "Final Rule").

harms, such as trauma, as a result of the use of the device. This professional research and peer-reviewed literature supports the FDA's conclusion that the devices pose unwarranted risks of substantial harm.

First, the FDA correctly concluded that receiving electric shock is painful. The literature shows that people receiving electric shock often respond by crying, or with cries of pain. *See* JA__[Panel Summary at 59-61] (citing JA__[A529 at 298]; JA__[A558 at 443] (child responded to shock with a "cry of pain")). Another common response reported by people subjected to electric shock is fear. *See* JA__[Panel Summary at 59-61] (citing JA__[A519 at 71] (eleven-year-old boy "soon responded to the experimenter's initial movements by showing signs of fear and avoidance of the oncoming shock"); JA__[A554 at 108]). As the FDA noted in its final rule, "the scientific literature and statements from individuals who were subject to [electrical stimulation devices] (as well as others who have tested [electrical stimulation devices] on themselves) indicate that the pain from such shocks is severe, and it causes distress and fear." Final Rule at 13,324. Several of the individuals who tested electrical stimulation devices on themselves were doctors, who described the experience as excruciatingly painful in sworn testimony. *Id.* at 13,324-13,325.[3] There is no serious argument that receiving

[3] After review of supplemental record information supplied by JRC, including expert witness testimony from a Massachusetts court proceeding involving the

electric shock is *not* painful; indeed, the JRC (the only institution in the United States still using electrical stimulation devices) expressly acknowledges that the shock is *intended* to be painful and that pain is a feature of the devices, not an unintended consequence. *Id.* at 13,324; JA__[A2330]. Although the JRC attempts to discount the significance of that pain and fear, the FDA was well within the contemporary medical and scientific consensus in finding that these adverse events contribute to an unreasonable and substantial risk of illness and injury.

Second, the literature supports the FDA's conclusion that using electric shock poses a serious risk of other physical harms, in addition to physical pain. As the FDA found, "the literature contains reports of tissue damage that ranged from burns to bruises … and errant shocks from device misapplication or failure." Final Rule at 13,322. The FDA also identified numerous studies that reveal physical

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JRC, the FDA concluded in its final rule that the proposed rule in fact "understated pain as a harm caused by [electrical stimulation devices]." Final Rule at 13,322. These behavioral experts testified regarding the level of pain caused by electric shock based on their personal experience being shocked by the devices, describing the experience as "excruciatingly painful," "extremely painful," "quite painful," like a "bulging and a ruptured disc," and "the most painful thing I've ever experienced." *Id.* at 13,321-13,322. The FDA also considered the expert opinion of Dr. James Eason, who opined that different electrical stimulation devices cause varying levels of pain to different people, but that all three devices he analyzed (two of which are used by the JRC) "are capable of inflicting extreme pain on anyone." 81 Fed. Reg. 24,386, 24,396-24,397 (Apr. 25, 2016) (hereinafter "Proposed Rule").

harm inflicted by electric shock.[4] *See* JA__[Panel Summary at 60] (citing JA__[A566 at 61 (device "produced a mark on [the individual's] thigh which resembled a bruise in the shape of the electrode … the mark disappeared in approximately 1 week"); JA__[A530 at 241] (electric shock can result in eventual tissue damage); JA__[A562 at 255] ("[T]here were hundreds of superficial pin-point burn marks on his upper arms, the result of sparks arcing from the shock stick to his skin.")).[5]

Finally, the FDA's conclusion that the use of electric shock poses serious risk of psychological harm is also supported by both the literature and experts in the field. "Most of the reviews acknowledge the possibility of negative emotional reactions such as fear, avoidance, aversion, anxiety and depression." JA__[Panel Summary at 62-64] (citing JA__[A548 at 167-170]; JA__[A529 at 298] (reactions to electric shock include "[p]anic and extreme anxiety (i.e., screaming, crying,

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[4] The FDA received testimony that the device has a "substantially high risk of causing first and second degree burns," and noted that "[n]ot only is it common practice for JRC staff to rotate the position of electrodes to avoid burns from repeated shocks to the same area, but they also use a specific term, 'GED vacation,' to denote a period of time of up to several weeks during which a student is taken off the [device] in order to allow injuries to heal." JA__[A630 at 9].

[5] More anecdotally, the FDA received reports that students at the JRC who had received electric shocks reported "burns that lasted a few days," "many burns," and "burns, scars, paresthesia/loss of sensation/numbness, muscle contractions/spasms, pain, heart palpitations, [and] seizure." JA__[Panel Summary at 76-77]. One student reported experiencing a year-long loss of sensation in one leg as a result of the administration of electric shocks. JA__[*Id.* at 78].

attack, escape)")).[6] The information reviewed by the FDA also reveals that these conditions may worsen over time, leading to the exacerbation of underlying symptoms, the loss of personal agency, and even the potential for suicidal thoughts and conduct. Proposed Rule at 24,389. Based on its review of the scientific literature and the contributions from experts, the FDA concluded that, because electric shock "can also contribute to stress, anxiety, learned helplessness, and posttraumatic reactions [flashbacks of panic and rage; nightmares, and hypervigilance], among other outcomes, we do not believe that it is reasonable to conclude that the risks presented by [the devices] are unrelated to suicidal ideation." Final Rule at 13,319.[7]

These conclusions are entirely consistent with amici's knowledge of and expertise regarding the state of the science on the risks associated with electrical stimulation devices. Indeed, amicus the International Association for the Scientific

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[6] In its consent form, the JRC describes the following possible side effects of electric shock, all well-understood symptoms of post-traumatic stress disorder: "nightmares; intrusive thoughts; avoidance behaviors; marked startle responses; mistrust; depression; flashbacks of panic and rage; anger; hyper-vigilance." Final Rule at 13,321.

[7] The FDA also properly considered additional evidence, including reports by former students of JRC who reported severe psychological harm they experienced as a result of receiving electric shock for aversive conditioning. For example, one student reported living in "constant fear" while wearing the device, because he had no idea when he would be shocked or why. JA__[Panel Summary at 76]. Five years after leaving the facility he reported "panicky moments when reminded of the shocks … ." *Id.*

Study of Intellectual and Developmental Disabilities published a comprehensive review of the available literature on electric shock devices that concluded that the devices should be banned because of, among other things, the physical and psychological harm caused by the devices. *See* Zarcone 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*, 17 J. of Policy & Practice in Intellectual Disabilities 291 (2020), https://onlinelibrary.wiley.com/doi/epdf/10.1111/jppi.12342.

II. THE FDA'S CONCLUSION THAT THERE IS NO CREDIBLE EVIDENCE OF THE EFFICACY OR LONG-TERM BENEFIT OF ELECTRIC SHOCK IS SUPPORTED BY THE WEIGHT OF THE EVIDENCE

Following years of testimony, expert reports, and public comment, the FDA rightly concluded that there is little or no credible evidence of the efficacy or long-term benefit of electric shock. This finding conforms to amici's own research, expertise, and extensive experience in providing treatment, supports, and services to disabled persons with self-injurious and aggressive behaviors. The FDA properly concluded that, as to the literature that JRC contends suggests certain benefits from electric shock, any evidence of efficacy was limited, methodologically flawed, and subject to bias.

As the FDA correctly concluded, aversive punishment techniques are very context specific, meaning that the recipient may associate the punishment with a

particular room or shock provider, and not with the behavior for which he is being punished. Proposed Rule at 24,387; *see* JA__[Panel Summary at 49-53] (citing JA__[A2394] ("[E]ffects of the [electric shock] punishment were usually specific to the setting in which it was administered."); JA__[A2404] ("[M]utilative behaviors were continuing to occur whenever the psychologist was not there to administer shock."); JA__[A562] ("The effects of [shock] were specific to settings and behaviors … [shock application] during learning sessions had no noticeable effect on rate of [self-injurious behavior]."). Moreover, as the FDA also correctly observed, the literature suggests that those repeatedly exposed to electric shock eventually adapt to it, requiring the need for ongoing and stronger shocks over time to achieve the same results:

> [W]ithout durable conditioning the target behavior will recur over time and necessitate ongoing shocks to cause immediate cessation, magnifying the risks. If adaptation occurs, it would render the shocks wholly ineffective and could lead to stronger shocks with no effect.

Proposed Rule at 24,411.[8]

In addition, the FDA observed that many of the studies purporting to find benefits from the use of electric shock were conducted by JRC staff, and did not

[8] *See also* JA__[Panel Summary at 58] ("[P]roblems that may be encountered during the often extended course of treatment are that individuals may adapt to the intensity of the electrical stimulus, that self-restraint may emerge or intensify, that individuals may show [self-injurious behavior] at very low intensities that eventually results in tissue damage, etc.").

attempt to assess negative side-effects, employed no systematic process for identifying these harms, or limited the definitions of adverse events, even excluding pain as a potential harm resulting from application of electric shock. JA__[Panel Summary at 61-64]. As the FDA noted, these methodological flaws cast doubt on the accuracy and usefulness of studies that reported no adverse side effects. *See* Proposed Rule at 24,389.

The FDA concluded that, while electric shock can in some instances reduce self-injurious or aggressive behavior on a short-term basis, any immediate effects are far outweighed by the numerous short and long-term risks associated with electric shock. Indeed, the FDA's survey of the scientific literature revealed little or no reliable evidence of long-term benefits of electric shock as aversive conditioning, or the durability of any resulting change in behavior. JA__[Panel Summary at 47]; Proposed Rule at 24,401. In light of the many more studies showing pain, psychological, and physical harms resulting from receiving electric shock, the FDA correctly concluded that the studies purporting to find only benefits and no harm from the use of electric shock deserved less weight.

In addition to methodological flaws, the FDA identified numerous other deficiencies in the available studies purporting to establish the effectiveness of electric shock, concluding that the studies were outdated, biased, and not representative of the relevant population. *See* JA__[Panel Summary at 64-65].

The FDA properly concluded that, given the limitations of these studies, they should be read cautiously and in the context of more reliable evidence pointing in the opposite direction.

First, the FDA identified the concern that pain was not systematically looked for in these studies and therefore was underreported. For example, one article written by the former director of JRC and reviewed by the FDA reported an "absence of negative side effects" while also reporting "collateral behaviors" such as "attempts to remove the device or grab the transmitter." JA__[A2525 at 158]. Of course, attempts to remove a device or grab the transmitter of electric shock out of the researcher's hands are likely responses to pain, and indicate that for at least some studies pain was not reliably measured as an adverse event.

Moreover, many of the studies (cited in JA__[Panel Summary at 59-61]) report related responses like panic, extreme anxiety, screaming, crying, attack, and escape, JA__[A2496 at 298]; fear, JA__[A2390 at 70-71 and JA__[A554 at 108]]; temporary increase in self-mutilative behaviors, JA__[A2404 at 111-114]; and cries of pain, JA__[A558 at 443]. In its Final Rule, the FDA grappled with this issue, noting that "JRC's Dr. Nathan Blenkush was asked directly whether the stimulus causes pain, [and] he answered 'yes.' People affiliated with [the] JRC … have stated that they observed no harms in many years of observing individuals subject to [electrical stimulation devices], so they appear not to consider certain

adverse effects, including pain, to be harms." Final Rule at 13,322 (internal citations omitted). The FDA correctly determined that, contrary to the JRC's view and the assumptions apparently underlying these studies' designs, "pain caused by the devices is a harm." *Id.*

Second, the FDA found that the harmful side effects of electric shock were underreported in these studies for the additional reason that the disabled youth and adults who are the subjects of these studies were often unable to verbalize their reactions to use of the device precisely because of their disability. Final Rule at 13,329. Self-injurious and aggressive behavior manifest at disproportionately high rates in people with extreme deficits related to intellectual or developmental disabilities, and "many individuals undergoing this type of aversive conditioning find themselves unable to adequately express their consent, emotions, and pain experience with the use of [electrical stimulation devices]." *See* JA__[A2155]; JA__[Panel Summary at 65]; Final Rule at 13,329.

Third, the FDA concluded that the age of the studies—most of which date back to the 1960s and 1970s—meant that they were not subject to the more rigorous, modern publication standards. *See* Proposed Rule at 24,401. These older studies were also even more prone to the methodological flaws discussed above, including the failure to consider short and long term risks, or to recognize psychological traumas as an adverse event, particularly in disabled individuals who

could not "adequately communicate the harms they experience…." *Id*. at 24,411. Reports of the efficacy of electric shock use in the 1960s and 1970s "were published during a time when conceptions and understanding of disease and pathophysiology (particularly psychiatric pathophysiology)" were less well understood. Panel Summary at 64-65. As a result, the FDA concluded, those responsible for these older studies did not identify and report on psychological issues like acute or post-traumatic stress as a result of the use of electric shock. JA__[*Id.* at 65]. Many of these studies simply do not consider some of the most serious harms that can result from use of electric shock, harms the FDA considered and found substantial. *See* Proposed Rule at 24,387.

Fourth, the FDA noted that no randomized controlled trials have been conducted demonstrating any benefits of electrical stimulation devices. Final Rule at 13,315. Likely due to both ethical and practical concerns, there were "[n]o comparison trials directly examining [electrical stimulation devices] for [self-injurious behavior] and/or aggressive behavior." JA__[Panel Summary at 58]. In the studies purporting to find benefits, the use of electric shock occurred in conjunction with other treatments (such as positive treatment programs, behavioral and functional treatment programs, and medications), making it impossible to assess what, if any, positive treatment effect could be attributed to the electric shock alone. Final Rule at 13,315. Relatedly, the sample size for the studies

purporting to find benefits from electric shock was too small to be reliable. JA__[Panel Summary at 49-56]. Many of the studies had only one subject and few had more than ten. *Id.* Conclusions drawn from trials that are not randomized and controlled "are generally considered weaker because they do not rule out other causes for any differences in results, including subject selection bias, as effectively," so the FDA reasonably concluded that "the reliance on weaker study designs for trials on [electrical stimulation devices] limits the conclusions that may be drawn regarding their effectiveness." Proposed Rule at 24,400.

Finally, the FDA also had before it ample evidence of the potential for bias in case studies deliberately structured to report only benefits and no side effects to electric shock, noting that some investigators may have been "pre-disposed to see only positive side effects." JA__[Panel Summary at 65] ("[I]n light of the intrusive nature of shock treatment, it is puzzling that so few negative side effects have been reported."). For instance, the majority of these articles (all but three) did not define a systematic method for assessing adverse effects. *Id.* Indeed, the largest case study—a retrospective review conducted by the JRC—explicitly did not classify "temporary emotional behaviors, a temporary tensing of the body, or attempts to remove the device or grab the transmitter noted during treatment" as adverse effects, instead classifying such reactions as "immediate collateral

behavior." JA__[Panel Summary at 58].[9] Similarly, of the 66 patient case histories submitted to the FDA by JRC, "no systematic methods for short-term or long-term [adverse event] monitoring were defined." *Id.* As a result, it is not surprising that JRC's retrospective review of 60 students receiving electric shock reported only one negative side effect, and that the 66 patient case histories submitted to the FDA by the JRC reported no harm across all patients. These findings suggest that the JRC studies purporting to show benefits were structured by the JRC towards a predetermined outcome.[10]

III. THE FDA RELIED ON AN EXTENSIVE BODY OF EVIDENCE IN DETERMINING THAT THE RISKS POSED BY ELECTRICAL STIMULATION DEVICES ARE UNREASONABLE GIVEN STATE-OF-THE-ART TREATMENT ALTERNATIVES THAT ARE PROVEN TO BE SAFE AND EFFECTIVE

The FDA's conclusion is further bolstered by the availability of alternatives to electric shock that do not carry the same risks. As a wealth of modern, reliable research shows, the use of positive behavioral supports to address self-injurious or

[9] In its Final Rule, the FDA notes that the only article specifically about JRC's device was published over a decade ago and studied only nine subjects at JRC, and that other more general studies of the devices were even older. The FDA noted that "[i]n the intervening decades, the understanding of pathophysiology has evolved as has the ability to identify and systematically record [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." Final Rule at 13,319.

[10] And to the extent these studies and case reports are conducted by the JRC itself, as many are, they are susceptible to additional biases given its financial and reputational interest in the continuing use of electric shock.

aggressive behaviors not only avoids the pain and other negative side effects described above, but is a highly effective treatment for people with self-injurious or aggressive behaviors. Unlike electric shock, use of positive behavioral supports is designed to produce durable, long term improvements. Accordingly, use of positive behavioral supports has been adopted by disability service and special education systems and by doctors, clinicians, service providers and education professionals across the country, leaving the JRC as the single remaining entity in the United States still employing electric shock devices.

A. The Professional Literature Supports the Efficacy of Positive Behavioral Supports

In promulgating its rule, the FDA found not only that the risk of illness and injury posed by electric shock is substantial, and outweighed by any perceived benefit, but also that the availability of safe and effective state-of-the-art treatment alternatives makes assuming those risks unnecessary. In particular, the FDA determined that positive behavioral supports, sometimes alongside pharmacotherapy, have been proven to be effective treatment for self-injurious and aggressive behaviors. Proposed Rule at 24,410.

Using positive behavioral supports involves an instructor reinforcing all behaviors except the behavior he or she is trying to eliminate. Such treatment is rooted in "scientific advances that have yielded new insights into the organic

causes and external (environmental or social) triggers of [self-injurious and aggressive behaviors], allowing the field to move beyond intrusive punishment techniques such as aversive conditioning with [electrical stimulation devices]." Proposed Rule at 24,387. *See also* JA__[A589]; JA__[A587]; JA__[A595]; JA__[759]. Positive behavioral supports are "founded on the assumption that all behavior is a form of communication." JA__[A1608]. The treatment uses behavior assessments to understand why a problem behavior occurs—to identify what the individual is trying to communicate and the underlying medical and psychiatric issues. Proposed Rule at 24,404. The assessment process allows clinicians to formulate and implement effective treatment plans using positive techniques rather than painful punishment like electric shock. These treatment plans feature interventions that "have become state-of-the-art treatments for [self-injurious and aggressive behavior]." *Id*. at 24,387. The FDA record demonstrates that positive behavioral supports are able to "achieve success through environmental modification and an emphasis on teaching appropriate skills," and have generally been successful. Final Rule at 13,313.

As the FDA correctly found, the studies showing the efficacy of positive behavioral supports do not suffer from the same flaws as the studies touting the efficacy of electrical stimulation devices. They have more subjects, systematically record adverse events, and were conducted more recently, so they were subject to

more exacting standards for study conduct and reporting. Final Rule at 13,319. Based on this review of the professional literature, the FDA concluded that positive behavioral supports present state-of-the-art, safe, and effective alternatives to electric stimulation device use. *Id*. at 13,313.

Moreover, positive behavioral supports, unlike electric shock, do not merely seek to suppress certain symptoms and actions, but go on to address the underlying causes of self-injurious and aggressive behavior. Positive behavioral supports thus can achieve durable, long-term benefits of the sort that the scientific community has recognized are the proper objects of medical care. Final Rule at 13,313; *see also* JA__[A2155].

The FDA also considered information from the "biopsychosocial" perspective, which recognizes that behaviors may also have biological or psychological causes. *See* Proposed Rule at 24,403 ("[M]edical approaches now treat [self-injurious and aggressive behaviors] as results of environmental cues and biological processes."). For these reasons, an interdisciplinary approach that uses psychotropic medications to treat co-occurring psychiatric conditions, in coordination with other treatments, is consistent with the state-of-the-art treatment for persons with developmental disabilities and serious self-injurious and aggressive behavior. JA__[Panel Summary at 43, 90-91] ("Pharmacological

interventions are typically used in conjunction with a behavioral treatment program or when patients do not respond to a behavioral therapy.").

The FDA noted that "recent advancements in psychiatric research and clinical care have improved the understanding of psychiatric diagnosis and treatment, particularly in individuals with intellectual and developmental disabilities." Final Rule at 13,315. Psychiatrists are better able to identify and diagnose co-occurring psychiatric disorders in individuals with developmental and intellectual disabilities, thus prescribing medications with greater efficacy and at lower doses. This has facilitated the use of pharmacological treatments that lead to reductions in self-injurious and aggressive behaviors, by improving the underlying condition.

Finally, the FDA correctly found that positive behavior supports are "typically successful, on their own or in conjunction with pharmacotherapy, regardless of the severity of the behavior targeted or the setting, and can achieve durable long-term results while avoiding the risks posed by [electrical stimulation devices]." Final Rule at 13,315. *See also* JA__[A589]; JA__[A587]; JA__[A595]; JA__[A759]. For example, one study demonstrated the success of positive behavior supports with individuals who had previously been subjected to aversive interventions, including electric shock. Those individuals successfully transitioned to more integrated, community-based services. *See generally* JA__[A587].

Given the demonstrated success and efficacy of positive behavioral supports, and their near-universal adoption as a state-of-the-art treatment intervention, the FDA properly concluded that, even if positive behavioral supports cannot eliminate every instance of self-injurious or aggressive behavior in all people, electric shock is neither appropriate nor effective. Proposed Rule at 24,406, 24,411.

B. Physicians, Researchers, Disability Professionals, and Service Providers Recognize That Electric Shock Should Not Be Used

At this point, it is an understatement to say that positive behavioral supports are the most effective, widely used, state-of-the-art treatment. Other than the individuals at the JRC, every disabled person in this country who is being treated for self-injurious or aggressive behaviors is being treated without electric shock. In fact, electric shock has been widely determined to be antiquated and detrimental to individuals with intellectual and developmental disabilities by professionals in the field.

The Executive Director of amicus the National Association of State Directors of Developmental Disability Services testified to the FDA that "the vast majority of state agencies" have issued rules prohibiting the use of aversive interventions like electric shock. JA__[A317 at 171]. She further testified that forty states and the District of Columbia have legislatively outlawed the use of such interventions. JA__[*Id.* at 172]. The same amicus also submitted a comment

to the FDA demonstrating that in 2015, of 45 states who responded to a survey, "82% reported that aversive interventions are disallowed for use in service for people with [intellectual and developmental disabilities]. The vast majority of remaining states that did [allow them] are actively working to change their policies." JA__[A1608]. Similarly, many state education systems (including those represented by amicus the National Association of State Directors of Special Education) have banned the use of aversive interventions like electric shock. Consistent with this professional consensus, numerous amici organizations have adopted position statements opposing aversive treatments like electric shock and supporting the use and efficacy of positive behavioral supports.[11]

[11] *See, e.g.*, *NASDDDS Adopts Position Statement Opposing Aversive Interventions and Promoting Positive Behavior Support* (July 14, 2015), http://nasddds.org/uploads/documents/NASDDDS_Press_Release_final.pdf; AAIDD, *Position Statement: Electric Shock* (Feb. 5, 2019), https://www.aaidd.org/news-policy/policy/position-statements/electric-shock; AAIDD, *Position Statement: Aversive Procedures* (amended Jan. 2020), https://www.aaidd.org/news-policy/policy/position-statements/aversive-procedures; AAIDD, *Joint Position Statement: AAIDD and The Arc on Behavioral Supports* (rev. 2015), https://www.aaidd.org/news-policy/policy/position-statements/behavioral-supports; *IASSIDD Position Statement: Opposing Electric Skin Shock as Treatment* (Aug. 31, 2018), https://bit.ly/38TmgGE; Zarcone 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*, 17 J. of Policy & Practice in Intellectual Disability 291 (2020), https://onlinelibrary.wiley.com/doi/epdf/10.1111/jppi.12342.

Thus, as the FDA noted, "[t]he overwhelming majority of patients exhibiting [self-injurious behavior or aggressive behavior] throughout the country are being treated without the use of [electrical stimulation devices]." Final Rule at 13,315. The FDA estimates there are about 330,000 individuals in the United States who exhibit self-injurious or aggressive behavior. *Id*. at 13,317. Of those, about 25,000 are "the most extreme cases." *Id.* However, as the FDA noted, electrical stimulation devices are currently used on a tiny fraction of that number— "which in 2016 numbered 51 individuals from 12 states"—and all at the JRC. *Id.* Successfully treating self-injurious and aggressive behaviors without using electric shock is not a pipe dream or a distant hope. It is the way that nearly all persons with these behaviors are treated. The FDA thus did no more than act in conformance with the medical and scientific consensus.

CONCLUSION

For the foregoing reasons, the Court should deny the petition for review.

Respectfully submitted.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 29(b)(4) and 32(a)(7)(B)(i).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 6,402 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word for Office 365 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Felicia H. Ellsworth
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Date: January 22, 2021

CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of January, 2021, I electronically filed the foregoing brief with the Clerk of the United States Court of Appeals for the D.C. Circuit using the Court's CM/ECF system. Counsel for all parties are registered CM/ECF users and will be served by the appellate CM/ECF system.

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