Todd&Weld LLP

Max D. Stern
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April 21, 2017

Via Federal Express Overnight Delivery
and Electronic Mail (sarah.kotler@fda.gov)

Sarah B. Kotler, J.D.
Director
Office of the Executive Secretariat
Division of Freedom of Information
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857

RE: Freedom of Information Act Requests - Reference Nos. 2016-7106, 2016-7184, 2016-7308, 2017-1440

Dear Ms. Kotler:

I represent the parents and legal guardians of patients at the Judge Rotenberg Educational Center, Inc. ("JRC") who currently receive treatment with electrical stimulation devices ("ESDs") as part of their Massachusetts Probate and Family Court-approved treatment plans. I also represent the JRC Parents and Friends Association, Inc.,[1] the association that represents all of the JRC parents, including those whose children are currently receiving treatment with ESDs and those who could be eligible to receive it if deemed necessary by their parents, medical professionals, and a court in a "substituted judgment" proceeding. By letters dated July 25, 2016, August 15, 2016 and February 27, 2017, I notified the U.S. Food and Drug Administration ("FDA") that I represent these individuals in their interactions with the FDA, including their Freedom of Information Act ("FOIA") requests to the FDA and associated requests for expedited processing.

On July 19, 2016 and August 23, 2016, Paul Peterson ("Dr. Peterson") sent eight letters to the FDA requesting records in accordance with FOIA. On December 27, 2016, Attorney Flammia submitted a letter to the FDA's Chief Counsel, Elizabeth Dickinson. That letter contained a request for certain records, which the FDA is treating as a FOIA request. In my February 27, 2017 letter to Ms. Dickinson, which is attached for your reference as Exhibit A, I incorporated by reference Attorney Flammia's December 27, 2016 letter to Ms. Dickinson, thereby joining as a requestor in the FOIA request contained therein. Both Dr. Peterson's

[1] Formally known as the B.R.I. Parents and Friends Association, Inc., but doing business as the JRC Parents and Friends Association.

FOIA requests and Attorney Flammia's letter will hereinafter be collectively referred to as the "FOIA Requests."

This letter is to notify you that Michael P. Flammia, Esq. and I jointly represent the following parents and legal guardians of patients at JRC in connection with the FOIA Requests: Lauren Emmick, Louisa Goldberg, Ricardo Mesa, Dr. Peterson, Marie Washington, Peter Biscardi, Leo Soucy, and Mitchell Shear.

Attorney Flammia and I look forward to speaking with you about the FOIA Requests on **Wednesday, April 26, 2017 at 10:00 am**.

Please feel free to contact me in the interim if you have any questions.

Sincerely,

Max D. Stern, Esq.

cc: Elizabeth H. Dickinson, Esq., Chief Counsel *(via electronic mail and Federal Express)*
Michael P. Flammia, Esq. *(via electronic mail)*

EXHIBIT A

Todd&Weld LLP

Max D. Stern
E-mail: mdstern@toddweld.com

February 27, 2017

Elizabeth H. Dickinson, Esq.
Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2016-N-1111;
Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior

Dear Ms. Dickinson,

We represent the parents of students at the Judge Rotenberg Educational Center, Inc. ("JRC") who currently receive treatment with electrical stimulation devices ("ESDs") as part of their probate court-approved treatment plans, and the JRC Parents and Friends Association, Inc.,[1] the association that represents all of the parents, including those whose children are currently receiving the treatment and those who could be eligible to receive it if deemed necessary by their parents, medical professionals, and a court in a "substituted judgment" proceeding.

We write to express our grave concern with the FDA's Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior (the "Proposed Ban"), and with the process that had been used by the FDA thus far in connection with the Proposed Ban. Specifically, we believe the FDA lacks authority to institute the Proposed Ban; that in any event, the Proposed Ban violates our clients' substantive and procedural due process rights; that the majority of the comments the FDA has received are inaccurate, biased, and highly unreliable; and that the Proposed Ban is arbitrary and capricious. Indeed, it accomplishes no more than to take away from our clients' children the best chance they have at leading happy, productive, and – perhaps most importantly – *safe* lives.

Before turning to the legal implications of the Proposed Ban, it is important that you understand the people it affects.[2] All are over the age of 20. All have multiple diagnoses across a

[1] Formally known as the Behavioral Research Institute ("BRI") Parents and Friends Association, Inc., but doing business as the JRC Parents and Friends Association.

[2] There are currently only 53 people in the United States for whom ESDs are used to treat self-injurious or aggressive behavior, and each treatment plan has received court approval prior to implementation. JRC has already provided the FDA with treatment records for all of these

broad spectrum of conditions.[3] While their individual diagnoses may differ, however, they all have several things in common: 1) they all exhibit severe self-injurious and/or aggressive behaviors ("SIB" and "AB"), to such a degree that they routinely put their health and safety, and/or the health and safety of others, at profound risk; 2) they have all been treated at multiple facilities by well-respected professionals using a variety of behavioral and pharmacological techniques; 3) they have all been discharged or rejected from multiple facilities because those facilities were ultimately unable to handle their severe SIB and/or AB; 4) they were all eventually admitted to JRC for care, education and treatment; and 5) they have all shown marked improvement in their SIB and AB with use of ESDs – they have made significant behavioral, academic and social improvements, and are happier and safer.

The choice to use ESDs to treat these individuals was not made lightly. As explained more fully in JRC's letter to you of December 27, 2016, there is a rigorous process in place in Massachusetts for the approval of the use of ESDs to treat SIB and AB. Aside from these bureaucratic safeguards is perhaps an even more fundamentally sound check on any potential misuse of the device: the love parents have for their children. Our clients have been through decades of turmoil, pain, and stress when it comes to managing their children's severe SIB and AB. They have, in every case, tried their best to get their children the most appropriate treatment in order to improve their children's quality of life. All have endured numerous setbacks, rejections, and injuries – both physical and emotional – because of the severity of their children's SIB and AB and their inability to find methods to effectively reduce the behaviors (without sedating or inflicting an array of negative side effects on their children).

But all have now found improvement with ESD treatment. They have all seen that ESDs do far more for their children than any other treatment method their children have received, including the Positive Behavioral Support ("PBS") the FDA now touts as "state-of-the-art" treatment for SIB and AB (but which does not benefit the refractory population whose one and only effective treatment is now at risk of being taken away from them due to the Proposed Ban[4]).

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individuals, including behavior charts, behavior modification treatment plans, and Court orders approving the same. The FDA has never acknowledged receipt of this data, which we believe is invaluable in assessing the safety and efficacy of ESDs.

[3] These include, but are not limited to: Psychotic Disorder NOS; Post-Traumatic Stress Disorder; Pervasive Developmental Disorder NOS; Asperger's disorder; Mood Disorder NOS; Reactive Attachment Disorder; Bipolar Disorder; Obsessive Compulsive Disorder; Anxiety Disorder NOS; Schizoaffective Disorder; Disruptive Behavior Disorder NOS; Mild Mental Retardation; Cognitive Disorder NOS; Attention Deficit Hyperactivity Disorder NOS; Pervasive Developmental Disorder NOS; Landau-Kleffner Syndrome; Severe Intellectual Disability; and Autism Spectrum Disorder.

[4] In 1990, a group of PBS authors, led by Dr. Edward Carr, reviewed 95 published papers in 21 journals covering the period from 1969-1988. They found that positive-only procedures were

And they have all been able, for the first time in decades, to feel at ease, knowing their children are no longer regularly attacking their peers, teachers and family members; biting their own flesh; repeatedly smashing their heads into hard, immovable objects; pulling out their own teeth; ripping out their hair; or removing tissue from various parts of their bodies with their own fingernails.

We urge you to consider the effects the Proposed Ban will have on the 53 to whom it would apply today, and the effects it will have on their families, who have long suffered the collateral effects of their children's SIB and AB, and who – along with their children's treatment providers – are best able to judge what medical interventions are most appropriate and most humane for their children.

Legal Limitations

JRC has already set forth, in their letter to you of December 27, 2016, a variety of reasons the Proposed Ban does not pass legal muster. We made many of the same arguments in the Comment we submitted on July 25, 2016 (a copy of which is attached hereto as Exhibit 1), but will briefly review those points here, paying particular attention to those issues specific to our clients.

First, this is not a "ban" under 21 U.S.C. §360f. That is, the FDA has not determined, "on the basis of all available data and information," that *all* ESDs present "an unreasonable and substantial risk of illness or injury." Rather, it has proposed that when ESDs are used on a very small subset of people for the specific purpose of treating SIB and AB, that *use* presents such a risk. This is not only an incorrect conclusion, it is an unprecedented application of 21 U.S.C. §360f. To *ban* a device is to prevent it from entering into commerce *for any purpose*; the FDA's proposal is to ban the particular use of an otherwise legally marketed device. Congress has not authorized the FDA to regulate the particular circumstances under which health care practitioners may (and may not) use such a device. Yet that is precisely what the Proposed Ban purports to do.

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effective in only 37% of the cases where self-abuse was involved and in only 35% of the cases involving aggression. *See* Carr, E.G., Robinson, F., Taylor, J. & Carlson, J. (1990). Positive approaches to the treatment of severe behavior problems in persons with developmental disabilities. In: *National Institutes of Mental Health Consensus Development Conference,* (pp. 231-341). NIH Publication No. 91-2410. Nine years later, Carr and colleagues completed another review examining 216 published studies from 36 journals (109 were selected for analysis), covering the period from 1985-1996. Carr, E.G., Horner, R.H., Turnbull, A.P., Marquis, J.G., Magito McLaughlin, D., McAtee, M.L., Smith, C.E., Anderson Ryan, K., Ruef, M.B. & Doolabh, A. (1999). *Positive behavior support for people with developmental disabilities: A research synthesis.* Washington, D.C.: American Association of Mental Retardation.) They concluded that positive programming was effective in only 51.5% of the cases. These studies show that even in published studies, PBS is far from universally effective.

Second, the medical practice exemption, 21 U.S.C. §396, prohibits the FDA from interfering with the authority of health care practitioners to prescribe or administer legally marketed devices to their patients. If the FDA were proposing to ban ESDs, categorically, then health care practitioners could no longer prescribe or administer them. But the FDA cannot pick and choose which medical applications it approves of and which it does not – that decision falls squarely with the health care practitioners who regularly see and treat their patients and clients, and who are familiar with each individual patient's and client's unique medical needs.

Third, even if the FDA had the authority to enact the Proposed Ban, it smacks of arbitrary and capricious decision-making. As the FDA makes clear on its website, it "very rarely acts on" its authority to ban devices.[5] It is therefore highly disturbing that in one of the only three instances in which the FDA has moved to ban a device, it has not even bothered to follow its own basic processes for banning the device. Most specific to our clients, the FDA has not interviewed *any* of the parents of JRC clients currently receiving treatment with ESDs, despite claiming in its own website that the agency is "committed to assuring that our decisions and actions are informed by patient perspectives"[6] and that the analysis it undertakes in connection with a proposed device ban includes "[r]eviewing information submitted by health care professionals and patients."[7]

Rather than employing this "patient-centric" approach to regulation by gathering our clients' perspectives, the FDA has instead merely patronizingly dismissed – as naïve or anecdotal – the thoughtful views expressed by the JRC parents in letters they have written to the FDA concerning the Proposed Ban. It is unclear from whom the FDA could get better information concerning the safety or efficacy of ESDs, however, since it is these parents who have a depth of knowledge based upon decades of firsthand experience with their children's SIB and AB, and with the methods used to treat those conditions.

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[5] *See* http://www.fda.gov/MedicalDevices/Safety/MedicalDeviceBans/default.htm

[6] Found at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf (page 7, "Partner With Patients"); *see also* http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm361864.htm ("Public Workshop - The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes, September 18-19, 2013").

[7] *See* http://www.fda.gov/MedicalDevices/Safety/MedicalDeviceBans/default.htm. *See also* December 27, 2016 letter from Michael P. Flammia, Esq. and Jeffrey N. Gibbs, Esq. to FDA Counsel (the "December 27, 2016 letter"), setting forth health care professional opinions from trial. While the FDA did interview known opponents of ESD, it did not contact any current parents for their perspective.

Moreover, these parents are not, as some commenters have recently (and offensively) suggested, supporters of "torture" – no parent relishes the thought of his or her child receiving a skin shock from an electrical device. At the same time, however, they relish even less the thought of their children gouging their own skin, eyes, throats, and rectums, so they have made the reasonable choice that a two-second shock employed, on average, once a week, is far less harmful to their children's wellbeing than constant, violent self-injurious and aggressive behaviors.[8] In a recently issued guidance document, the FDA noted that risk tolerances will vary by subjects, and that some individuals will be willing to take on a higher level of risk. The same document notes the importance of considering alternatives.[9] Here, the risk tolerance of parents who have spent decades dealing with their profoundly ill children and have exhausted all other options takes precedence over those third parties who can safely and sanctimoniously advocate that the children be deprived of their only effective treatment.

Nor were our clients coerced by JRC to agree to ESD treatment for their children, as the FDA seems to suggest in the Proposed Ban.[10] Quite the opposite: our clients include doctors, professors, clergy, well-known authors, and sophisticated business people who are perfectly capable of analyzing for themselves the pros and cons of agreeing to ESD treatment for their children.

Just as the FDA has ignored the perspectives of some of the most knowledgeable stakeholders (who have the most at stake in these proceedings), it has simultaneously ignored the large body of evidence at its disposal, collected over some 26 years, that suggests PBS is in fact *ineffective* in treating the very people the Proposed Ban directly affects, and that ESDs are the *only* effective treatment for this refractory population. This willful blindness on the part of the FDA is particularly remarkable in light of the Neurological Devices Panel's conclusion that other treatments – including pharmacological, behavioral, alternative, and experimental therapies – are not "adequate to address SIB and aggressive behavior."[11] Indeed, "the panel also noted the challenge in treating a refractory patient population, and due to treatment gaps, treatment

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[8] It also bears noting that despite the FDA's dogged efforts to portray the ESD as a dangerous device, none of our clients has ever observed any of the nefarious side effects cited by the FDA in support of the Proposed Ban. In fact, the only side effects that our clients (and JRC) have observed, or that a client has reported to JRC during the course of ESD treatment, are temporary redness of the skin after an application, and temporary anxiety and avoidance response before an application. *See* Comment by JRC, Pages 24-25, comment identifier FDA-2016-N-1111-1637 (July 25, 2016).

[9] *See* "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemption."

[10] *See* 81 Fed. Reg. 24409.

[11] *See* Summary of Neurological Devices Panel Meeting, April 24, 2014, at p. 3.

therapies are not completely effective in this population."[12] ESD helps fill in those treatment gaps.

Nevertheless, for purposes of supporting the Proposed Ban, the FDA has chosen to rely on clearly biased and unqualified experts who have a long history of campaigning against ESDs for the proposition that "the weight of the evidence indicates the state of the art for the treatment of SIB and AB relies on multi-element positive methods, especially positive behavioral support (PBS), sometimes in conjunction with pharmacological treatments, and has evolved away from the use of ESDs."[13] As JRC has already detailed in its letter to you, the hundreds of public comments that have now been submitted on the record echo, in large part, these anti-aversive advocates' one-sided messages, and they do so without having any direct knowledge of, or expertise in, the careful and controlled implementation of ESD treatment for patients who exhibit severe SIB and AB.[14]

Consequently, given the staggering breadth of information the FDA has either overlooked or discarded without reason, as well as the biased nature of the information upon which it has chosen to rely, the only conclusion one can draw is that the Proposed Ban is an ideologically driven action pursued in a truly arbitrary and capricious manner.

Fourth, the Proposed Ban violates our clients' substantive due process rights. A long history of Supreme Court cases makes clear that the "care, custody and control of [one's] children" is "perhaps the oldest of the fundamental liberty interest recognized by [the Supreme] Court." *Troxel v. Granville*, 530 U.S. 57, 65 (2000). "[T]his includes a 'high duty' to recognize symptoms of illness and to seek and follow medical advice." *Parham v. J.R.*, 442 U.S. 584, 602 (1979). The JRC parents thus have a fundamental liberty interest in choosing a happy, productive life for their children – even if that life includes an occasional painful, two-second superficial skin shock – over a life of misery in which their children are in constant physical and emotional pain, or in which their children are so heavily medicated (by drugs that have never been shown to be safe or effective for their children) that they cannot function and are segregated from the community because their behaviors are too dangerous for them to be in public.[15] The Proposed

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[12] *Id.*

[13] 81 Fed. Reg. 24404.

[14] It would therefore be a grave mistake for the FDA to consider the majority of these comments, at least without a critical eye towards their motivation and veracity. *See* December 27, 2016 letter; *see also* http://www.fda.gov/MedicalDevices/Safety/MedicalDeviceBans/default.htm ("The FDA considers *any* comments it receives on the proposed ban" (emphasis added)).

[15] In a somewhat ironic twist, the FDA, in the Proposed Ban, suggests that our clients' children be subjected to off-label use of pharmaceuticals to treat their severe SIB and AB – uses the FDA itself has not approved, and for which there have been no studies confirming efficacy or safety.

Ban would selectively deprive our clients' dependent children of critical, life-altering (and in some cases, life-saving) medical treatment, deprive them of community integration, and would substitute the FDA's judgment for the judgment of those who are intimately familiar with these children's particular needs, challenges, and capabilities. This is untenable.

On the other hand, as set forth above, the Proposed Ban is not even supported by the available data and information, let alone a compelling governmental interest that would justify abrogating our clients' rights. In fact, it is no more than an ideological intrusion – devoid of concrete evidentiary support – into our clients' private lives, and it *removes* a life-saving treatment from these highly vulnerable individuals, which is antithetical to the government's interest in protecting this population. Making matters even worse, and illustrating the FDA's disregard for the wellbeing of these patients, the FDA callously proposes that the Ban take effect in 30 days. This proposed timeline shows complete indifference to how the abrupt termination of treatment would affect the individuals the FDA is purportedly protecting.

Fifth, the Proposed Ban would deprive our clients of their fundamental liberty interest without the procedural protections required by due process. The Proposed Ban at issue here is quite clearly "a proceeding that in form is couched as rule making, general in scope and prospective in operation, but in substance and effect is individual in impact and condemnatory in purpose." *American Airlines, Inc. v. C.A.B.*, 359 F.2d 624, 631 (D.C. Cir. 1966). Indeed, throughout the text of the Proposed Ban, the FDA repeatedly makes factual judgments and findings specifically concerning the medical care and treatment of a small subset of students at just *one* institution: JRC.

As JRC noted in the December 27, 2016 letter, the process leading to the Proposed Ban – and the process since the Proposed Ban – has allowed for completely irrelevant, harmful, and erroneous information to make its way into the record. What is more, this information exists in the record without having been subjected to any sort of fact-finding process. Neither JRC nor the JRC parents has had an adequate opportunity to respond to or challenge the information in any meaningful way.

Thus, the JRC parents and their children – the only individuals actually affected by the Proposed Ban – are entitled to more than simply the paper submissions they have thus far been afforded. In fact, given that these are the *only* people affected by the Proposed Ban, and given the grave interests at stake, it is extraordinarily troubling that the FDA has actually consciously chosen *not* to gather "all available data and information" on ESDs, 21 U.S.C. §360f(a), and instead selectively relies upon, and in many cases mischaracterizes, just a portion of the information available to it.

See 81 Fed. Reg. 24406. This is despite the fact that the FDA cautions the public, on its website, to "remember," when a healthcare provider decides to use a drug "off-label," that "FDA has not determined that the drug is safe and effective for the unapproved use." *See* https://www.fda.gov/ForPatients/Other/OffLabel/ucm20041767.htm.

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It is for these reasons – and the reasons set forth in our Comment, our clients' letters to the FDA, JRC's Comment, and JRC's December 27, 2016 letter, all of which are incorporated herein by reference[16] – that we join in JRC's request for a meeting with you to discuss the Proposed Ban, and look forward to your reasoned consideration and prompt response.

Sincerely,

Max D. Stern

Max D. Stern
Alexandra H. Deal

[16] We note that JRC will also soon be submitting to the FDA a Comment on the Comments. We incorporate that document herein as well.

Exhibit

1

Todd&Weld LLP

Max D. Stern
E-mail: mdstern@toddweld.com

July 25, 2016

BY ELECTRONIC SUBMISSION
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments of JRC Parents in Opposition to FDA's Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior, Docket No. FDA-2016-N-1111, and Request for Hearing

This comment registers the objections of parents of students at the Judge Rotenberg Center ("JRC") who currently receive treatment with electrical stimulation devices ("ESDs") as part of their treatment plans,[1] on behalf of themselves and their children, for whom they are legal guardians, and the JRC Parents and Friends Association, Inc.,[2] the association that represents all parents of children attending JRC, including those whose children are currently receiving the treatment and those who could be eligible to receive it if deemed necessary by their parents, medical professionals, and a court in a "substituted judgment" proceeding (collectively, "the Parties"). In addition to the objections raised in this comment, the Parties join and incorporate by reference all of the objections, arguments, and factual material contained in JRC's Comment in Response to the FDA's Proposed Ban.

The Parties also hereby request that the FDA hold an evidentiary hearing before determining whether the Proposed Ban will become a final rule.

Introduction

Our clients strongly oppose to the adoption of the Proposed Ban as a final rule, and they do so in order that none of them may be forced to suffer because of the arbitrary and capricious actions of a government agency gravely overstepping its bounds and adjudicating facts related to the psychological treatment of roughly 50 individuals, rather than objectively evaluating medical device safety.

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[1] Lauren Emmick, Louisa Goldberg, Ricardo Mesa, Paul Peterson, Marie Washington, Peter Biscardi, Leo Soucy, and Mitchell Shear.

[2] Formally known as the Behavioral Research Institute ("BRI") Parents and Friends Association, Inc., but doing business as the JRC Parents and Friends Association.

This is a very unusual proceeding for what the FDA asserts to be a rulemaking. The FDA here proposes to prohibit a single entity – JRC – from using a device it has allowed JRC to use for more than 25 years for the successful treatment of extraordinarily difficult and physically dangerous behaviors in about 20 percent of the children at that school. Although the rule is asserted to be a ban, it applies only to a single use of the device at issue, while allowing use of this device for any purpose other than the one for which JRC uses it. Moreover, unlike virtually every other FDA proceeding involving medical devices, this one is not directed at a manufacturer who either is selling or wishes to sell the device in commerce. JRC does not sell the device to anyone.[3] It developed the device to use as one treatment option – after many others have been tried and have failed, and normally in conjunction with other treatments – to try to stop or at least reduce otherwise uncontrollable and very self-destructive behavior in a very small patient population, presently numbering only in the dozens.

What JRC has been doing, with the express approval of its students' physicians, parents, and the court, has been to use these devices for students for whose medical treatment providers have concluded all else has failed. This activity clearly falls within the medical practice exemption,[4] which forbids FDA from interfering with the judgment of state-licensed clinicians who decide that ESD treatment at JRC is in the best interests of these individuals. In fact, the Commonwealth of Massachusetts – where JRC is located and where its students receive ESD treatment – has in place a judicially approved and monitored Consent Decree that JRC has faithfully followed for 30 years which requires a number of protections (described fully in JRC's Comment) that are far more expansive than the medical practice exemption. Massachusetts is actually closely supervising JRC and its medical personnel so that there is in *fact*, not just in theory, an alternative congressionally-sanctioned procedure to what FDA seeks to do here.

Mischaracterizing the instant action as a "ban" also leads FDA to employ a flawed procedure, and it results in a grossly flawed outcome. The parents here have a fundamental right to make choices related to the care and medical treatment of their children, to be limited only by a compelling governmental interest. FDA proposes to eliminate this prerogative by purporting to issue a categorical "ban," but in reality, the agency's Proposed Ban would do no more than override the constitutionally protected choices of a small group of persons. This proceeding is not about whether manufacturers of these devices can make and sell them for a profit in interstate commerce, but whether the devices can be used when the health care providers for our clients' children conclude that no other treatment will work as well. This is not a case where Congress has chosen to ban a product or substance entirely, because here, the FDA agrees that these

[3] For this reason, it is highly doubtful that the FDA even has jurisdiction to regulate or ban this use because there is no interstate commercial sale, which is the lynchpin of FDA's regulatory power.

[4] 21 U.S.C. §396.

devices *can* be used – just not for what may be the literally life-saving purpose JRC employs them to control otherwise uncontrollable behavior in a very small subset of dependent children.

Moreover, even if this proceeding fits the technical definition of a rulemaking, which is doubtful, it is a "rule of one," directed solely at one entity that wishes to continue to use these devices. As such, the Supreme Court's decision in *Londoner v. Denver*, 210 U.S. 373 (1908), makes clear that JRC and the parents whose children are benefitting from the use of these devices have a procedural due process right to have a hearing in which the sharply contested issues of fact can be decided after live witnesses are examined and cross-examined.[5]

The importance of a hearing when facts such as these are being adjudicated is perfectly illustrated by the current court proceeding in Massachusetts. Massachusetts, responding to many of the same (erroneous) concerns expressed by FDA in the Proposed Ban, has sought to re-open the Consent Decree based on alleged new evidence that alternative treatments for these almost-impossible-to-treat children are equally if not more effective and safer than these devices. As a result, the Commonwealth and JRC have recently concluded testimony in a 44-day trial before a Probate and Family Court judge. That proceeding examined what JRC providers should and should not be doing in light of other available treatment options – precisely what the FDA seeks to do in this proceeding. It is highly doubtful that the act authorizing FDA to ban medical devices[6] allows it to make the kind of comparative medical judgments that it claims to be doing here, because its only authority is to decide whether a device meets the standards of the law, not whether one lawful treatment is better than another. But the fact that FDA is doing precisely what Massachusetts is doing underscores that this case is about the practice of medicine, not whether a medical device can be banned from interstate commerce.

There is another reason why the Massachusetts proceeding is significant. The court there recognized that the dispute is not one of law or one that could be settled only by looking at randomized controlled, double-blind studies, published in peer reviewed journals, because there are no such studies on either side, in large part because of ethical issues involved in using such studies in the treatment of highly vulnerable populations. The court also recognized that there are sharply divergent views on this question, and so it did what it should have done: it conducted a trial with live witnesses who could be examined and cross-examined, under oath, rather than doing what the FDA is attempting here – to decide disputed issues of material fact by reviewing paper submissions that refer to a variety of written and oral hearsay without an opportunity to cross-examine key witnesses opposed to JRC's use of these devices.

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[5] The legislative kind of proceeding, approved in *Bi-Metallic Investment Co. v. State Bd. of Equalization*, 239 U.S. 440 (1915), and envisioned in Section 553, is constitutionally inadequate for resolving these disputed issues of fact.

[6] 21 U.S.C. §360f.

The predictable outcome of an unfair process is an incorrect result. In order to override the considered choice of these parents for the medical treatment of their children, FDA bears the burden of demonstrating a paramount and compelling state interest. Yet, in the Proposed Ban, it barely acknowledges any burden at all, largely resting its conclusion on the proposition (itself incorrect) that the proponents of ESDs have not proven their case and by relying upon speculation, misinformation, mischaracterizations, double standards, and one-sided analysis.

The Interested Stakeholders

The interested stakeholders described below are the parents of JRC clients, and they have submitted letters to the FDA expressing their support for ESDs and their concerns about such therapy being taken away from their dependent children. Some of these parents testified before the Advisory Panel Meeting in April of 2014. Five of these parents also testified and were subject to cross-examination at a recent trial in Massachusetts which concerned, among other things, whether ESD treatment is still within the standard of care: Lauren Emmick, Ricardo Mesa, Paul Peterson, Marie Washingon, and Mitchell Shear.

Individual Parents and Students[7]

Lauren Emmick

Lauren and Martin Emmick are the parents of L.E. L.E. was born in China on April 12, 1991. Lauren and Martin adopted L.E. in 1992, when she was 11 months old. From the time that L.E. was 18 months old, she exhibited aggressive behaviors, including hitting, biting, scratching, and hair-pulling. L.E.'s primary diagnosis is mild mental retardation, but she suffers from a range of problems, resulting in multiple additional diagnoses.[8] She also has odd fears and obsessions. L.E. was asked to leave a small family daycare program because of her problem behaviors. Thinking L.E.'s aggression could be the result of a language deficit, Lauren Emmick

[7] These summaries are supported by the 2016 individual parent comments submitted to the FDA by Peter Biscardi, Lauren Emmick, Louisa Goldberg, Paul Peterson, Mitchell Shear, Leo Soucy, and Marie Washington; the 2014 letters submitted by parents in conjunction with the 2014 Executive Summary of the BRI Parents and Friends Association, Inc., Docket No. FDA-2014-N-0238; the testimony of Lauren Emmick, Ricardo Mesa, Paul Peterson, Marie Washingon, and Mitchell Shear, and supporting exhibits, at Attachment 18 to JRC's Comment; and individual case studies of the dependent children, at Attachments 3, 5, 6 and 7 to JRC's Comment.

[8] Over the course of L.E.'s treatment history, the following diagnoses have been assigned to her: Psychotic Disorder NOS, Post-Traumatic Stress Disorder, Pervasive Developmental Disorder NOS, Asperger's disorder, Mood Disorder NOS, Reactive Attachment Disorder, Bipolar Disorder, Obsessive Compulsive Disorder, Anxiety Disorder NOS, Schizoaffective Disorder, Disruptive Behavior Disorder NOS, and Mild Mental Retardation.

took her daughter to Boston Children's Hospital to be evaluated, and L.E. began receiving early intervention speech therapy. L.E. was also evaluated by an occupational therapist and received sensory integration therapy.

L.E.'s parents next had her evaluated by a pediatric neurologist, who recommended continuing early intervention with L.E. and having L.E. seen by a behaviorist or child psychologist. After that recommendation, in or about 1994, L.E.'s parents hired Dr. Richard Bromfield, a child psychologist, who worked with L.E. on a weekly or bi-weekly basis, until about 1998.[9] In Dr. Bromfield's opinion, "there is hardly a DSM-IV childhood diagnosis that cannot be considered for L.E.." Dr. Bromfield recommended a consultation with a psychiatrist, Dr. Elizabeth Childs, and L.E. saw Dr. Childs from ages five to ten. During that period, Dr. Childs prescribed multiple medications in order to help L.E., including Ritalin, Zoloft, Lithium, Clonidine, Depakote, Olanzapine, Clozaril, Klonopin, Cogentin, and a PRN for Ativan. Some of the side effects L.E. suffered from these medications included overstimulation, drooling, urinary incontinence, tremors, headaches, and sedation.

Despite these interventions and therapies, L.E.'s aggressive behaviors worsened over time. From a young age, L.E. would attack others and pull their hair. L.E.'s aggressive behavior towards others in first grade resulted in the school separating her from the class and her peers and putting her with a teacher's aide and a desk in a closet to work. Even with this seclusion, L.E.'s mother received calls to bring L.E. home whenever L.E. became aggressive. L.E.'s was aggressive at home as well – her parents would have to physically restrain her almost nightly. L.E. received after-school assistance at home from teachers and a teacher's aide. Despite the medications prescribed by Dr. Childs, L.E. continued to be exhibit aggression towards others and to require frequent restraint. There were many days where she simply could not go to school because her aide was not available to help her and no one else could manage her.

From 1998 until her placement at JRC in 2008, L.E. attended multiple day and residential programs, none of which could handle her behavior problems. These residential programs include the Latham School, the Colburn School, and the Protestant Guild Learning Center. During these residential placements, L.E. was on various medications, including Risperdal, Depakote, Thorazine, Zyprexa, Lexipro, and Abilify. She was also hospitalized on numerous

[9] Dr. Bromfield summarized the efficacy of behavioral interventions used to address her problem behaviors in the following way: "We have tried many differing behavioral strategies, some of which work at differing times. However, there are many more times when she just seems to be swamped by feelings that she cannot otherwise manage. Though she has progressed in many ways here – the how or frequency of such outbursts – that she is getting bigger and stronger only makes them seems so much worse. We have tried several medications with limited success. In fact, it seems that as L.E. gets sufficiently medicated to be calmed, she loses her access to feelings, feels cut off from herself and others, becomes dull cognitively and just plain feels bad and irritable."

occasions due to her increasingly aggressive and disorganized behavior. Despite receiving constant behavioral and pharmacological intervention, L.E. was not getting any better.[10] L.E. ended up spending hours a day in a time-out room and having many restraints, some of which resulted in L.E. suffering serious knee injuries.

During one serious incident, L.E. physically attacked her mother while Mrs. Emmick was driving on the highway at 65 m.p.h. to take L.E. back to the Protestant Guild; L.E. started to bite Mrs. Emmick and pull out her hair as Mrs. Emmick was driving, and then opened the car door with her seat belt off, requiring Mrs. Emmick to hold onto L.E. in her seat while trying to pull the car off of the highway. L.E. was eventually asked to leave the Protestant Guild. The Emmicks looked for alternative placements for L.E., but the only school that would take L.E. was JRC. L.E.'s parents – after years of attempted treatment with about 25 different psychotropic medications, various behavioral interventions, individual therapy, hospitalizations, and placement within day and residential programs, and fearing for their daughter's safety and the safety of those around her – ultimately chose to send L.E. to JRC.

For the first 30 weeks L.E. was at JRC, the staff tried various treatments to curb her aggression,[11] but these produced only a slight decrease in the frequency of her major problem behaviors. L.E. required over 150 restraints in a six-month period, and about 11% of these restraints injured either L.E. or the staff.

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[10] The following, although not exhaustive, represent the behavioral interventions she received over the years in addition to pharmacological intervention: noncontingent reinforcement (attention) in the form of structured 20-minute sessions with staff in addition to daily appointments with administrative staff; differential reinforcement (providing attention upon request or following appropriate behaviors); attention extinction (including limiting access to preferred staff and male staff in addition to limiting conversation following problem behaviors); response blocking; 1:1 staffing; time out; numerous DRO schedules with conditioned reinforcers; allowing escape from purported "feared stimuli"; behavioral self-management; reinforcer choice; and level systems. These were in addition to emergency physical interventions and associated de-escalation procedures. L.E. also received speech and occupational therapy weekly across programs and, in some cases, counseling.

[11] These treatments included: positive reinforcement, extinction schedule (no verbal pinpoints); differential reinforcement contracts; response cost procedure; higher level of staffing and supervision; verbal pinpoints following inappropriate behaviors; extinction for minor inappropriate behaviors; a hybrid procedure where the first 3 minor behaviors exhibited in an hour were pinpointed and subsequent minor behaviors were ignored; a second hybrid procedure where the first 25 minor behaviors exhibited in a hour were pinpointed and subsequent minor behaviors were ignored; positive attention contingent upon a series of appropriate behaviors; verbal praise; and behavioral counseling.

After Mrs. Emmick tried the ESD herself and discussed it with her husband, the Emmicks decided to allow the addition of ESD treatment to L.E.'s program. L.E.'s program was supplemented with an ESD in or about February of 2009. During the first 60 days of treatment, L.E. received a total of six ESD applications and her major problem behaviors decreased to near-zero levels. As a result of her improved behavior, she was integrated into a normal classroom and her transport restraints were removed, as they were no longer necessary. L.E. was able to eat lunch with the other students in the lunchroom, enter areas that contained other students (with less concern that she would attack other students), and participate in field day and other activities at JRC. L.E. was also able to sit at a computer and learn, go out into the community, have regular lunches out with her mother, come home for overnight visits, and have a roommate. As Mrs. Emmick testified, L.E. was happy, and L.E. herself says that "her whole world opened up" with ESD treatment. L.E. can now be "part of the group," something she never had before the ESD.

In total, L.E. received 92 ESD applications from 2009 to April of 2016, equaling about one application per month. However, there were many months during this seven-year period in which L.E. did not need *any* ESD applications. Due to overall maintenance of appropriate behavior, L.E. continues to benefit from her program and move forward with her goals. L.E. continues to go on field trips every week, including trips for bowling and to the zoo, park and restaurants; she goes to lunch with her mother every week, visits her parents at home, and goes to movies; and she maintains jobs, including working in the JRC kitchen, filling printers, and cleaning residences.

According to Mrs. Emmick, JRC has saved her daughter. She and her husband tried all other available options for L.E., but the addition of ESD to her treatment plan has been the only option that has worked. Mrs. Emmick has observed the change in her daughter with ESD treatment: L.E. "has gone from a person that is isolated and medicated and injured and unhappy to a young person that is happy and able to live in the world and experience what other people experience." Mrs. Emmick is confident that, if ESD treatment is prohibited, L.E. will return to a life of restraints, medication, injuries and hopelessness.

Louisa Goldberg[12]

Louisa and Robert Goldberg are the parents of A.G. A.G. was born on January 14, 1981, and is the oldest of three children. A.G. has been diagnosed with cognitive disorder NOS, attention deficit hyperactivity disorder NOS, pervasive developmental disorder NOS, and obsessive compulsive disorder. Testing in 1996 placed A.G. in the moderate to severe range of mental retardation. A.G. was born with esophageal atresia. He also has a seizure disorder.

[12] Mrs. Goldberg is the treasurer of the JRC Parents Association and serves on the JRC Human Rights Committee.

A.G. received various forms of early intervention from community and school programs between birth and age nine. During this time period, he had difficulties with compliance, hyperactivity, aggression, and other behavior problems. At age nine, the day program he attended recommended residential placement because they could not effectively manage his problem behaviors. A.G. initially did well in a residential setting even though his problem behaviors continued to escalate, but as he grew, and as he became stronger, his aggression became much harder to manage. A.G. required multiple restraints, which caused injuries to staff members and to A.G. He was eventually hospitalized and heavily medicated, to the point where he experienced a toxic reaction to the medication.

After the residential program determined A.G. could no longer stay there because he was a safety threat to staff, he was referred to JRC for treatment and was admitted in February of 2000. He was initially treated with differential reinforcement procedures, but over the first 10 weeks of treatment, he engaged in hundreds of aggressive, health-dangerous, destructive, and major disruptive behaviors.[13] Consequently, an ESD was introduced into his treatment plan in June of 2000. The addition of the ESD eliminated the need for physical restraint, time out, and psychotropic medication, and allowed A.G.'s attending neurologist to treat his seizure disorder with less concern for how seizure control medication changes might impact A.G.'s behavior.

Mrs. Goldberg says that the ESD has been the key to changing A.G.'s behaviors. Prior to having the ESD incorporated into his positive and reward-based program at JRC, A.G. would lash out at his family, staff, and other students, often sending people to the hospital. He was restrained for hours each day at his prior placement, and eventually heavily medicated with psychotropic drugs. He spent his days inside his group home, as the staff felt he was too dangerous to transport to his classroom. He slept most of the day and drooled uncontrollably. His behavior and epilepsy medicines conflicted, causing increased seizures. Despite changes in doses and medicines, nothing stopped A.G.'s aggression. According to Mrs. Goldberg, her son was "merely existing" during this time period. Now, with the help of the ESD, he is back to his funny and congenial self; he is awake, alert, and happy, and is functioning like a "real person." He no longer injures others, is not restrained, and is not heavily medicated. The ESD helps A.G. have a full and rewarding life that could not be accomplished if he was constantly restrained or heavily medicated, and, as Mrs. Goldberg has indicated, it is the most humane way to manage her son's difficult behavior.

Ricardo Mesa

Ricardo Mesa and Elizabeth Mesa are the parents of N.M., who was born on June 24, 1986. N.M. has a longstanding history of aggressive, health-dangerous, oppositional, and

[13] He required emergency physical or mechanical restraint on 55 occasions during his first 114 days of treatment at JRC.

disruptive behaviors. She has been diagnosed with Autism, Pervasive Developmental Disorder and Landau-Kleffner Syndrome (atypical), which affects communication.[14]

N.M. began developing problem behaviors at around three-and-a-half years old; N.M. would pinch and bite herself and others. Over time, as N.M. grew older, her behaviors escalated to the point where they were almost constant. They included: head banging, pinching herself and leaving marks, throwing herself to the floor, hitting herself on the head, and scratching and biting others, including staff, teachers, and peers. N.M. often head-butted her mother and once rendered her unconscious. N.M. also attacked her sister and father. Mr. Mesa has had to pull N.M.'s head out of sheetrock several times because N.M. banged her head through the wall.

Over the years, N.M.'s parents have had N.M. evaluated by various medical professionals, including doctors at Children's Hospital and Massachusetts General Hospital, the LCDC Center with Dr. Arnold Miller (an authority on autism), and Dr. Shane, the head of Children's Hospital's Communication Enhancement Center. N.M. has received one-on-one therapy and speech therapy. N.M. has attended various day programs, but she would often become aggressive. N.M.'s treatment providers have also prescribed various medications for her, including Ritalin, Klonopin, risperidone, Prozac, Paxil, Zoloft, Neurontin, Lithium, Depakote, and prednisone. These medications did not stop N.M.'s aggressive and self-injurious behaviors, however, and she suffered side effects from some of the medications, including drooling and sedation to the point of being "a zombie." Indeed, even at low dosages of risperidone, N.M. was sedated.

Even after N.M.'s parents and doctors discovered she was experiencing seizures, and even after N.M. had brain surgery to treat the seizures, N.M. still attacked others, including head-butting and punching them, and continued to hurt herself by punching herself, throwing herself to the ground, and putting her head through walls. N.M. punched herself in the face with such frequency and force that her eyes were black and blue all of the time.

By the time N.M. was 13, she had been to numerous programs and schools – including the Mattahunt School, the Language Cognitive Development Center, the May Center, the Lighthouse school, Franciscan's Children's Hospital, Boston College Campus School, the Learning Center for the Deaf, and the Perkins School for the Blind – but her dangerous behaviors persisted.

N.M. attended the May Institute for Education and Neurorehabilitation from age 13 until her admission to JRC. N.M. had a detailed behavior plan at the May Institute, and she has

[14] Testing using the Peabody Picture Vocabulary Test found her receptive language to be below two years old.

received a variety of psychotropic medications.[15] While these interventions were in place, N.M. continued to have serious behavior problems, including severe aggression and self-injury. The May Center eventually terminated N.M.'s placement because her self-injurious and aggressive behaviors became more acute and increasingly unmanageable, and her communication skills had not progressed. N.M.'s father recalls that she "cried all the time" and "didn't enjoy anything. She had literally become an eating, sleeping, hurting machine. All she did was eat, sleep, and hurt herself day in and day out."

N.M. was admitted to JRC as a day student in March of 2004. No other school would accept N.M., even though Mr. Mesa called many different programs. N.M. was at JRC for a year before her parents agreed to try ESD treatment. After N.M.'s parents both tried the ESD on themselves, they decided to try it treatment for N.M.; after all, they had tried all available treatments prior to the ESD, and all of them failed. Mr. and Mrs. Mesa noticed a dramatic reduction in self-injury after just one week of ESD treatment.

Once ESD treatment was added to her program, N.M. became attentive and open to instruction, positive behavioral treatments have become meaningful to her, and she is continually improving, spending her days learning, communicating, and developing healthier behaviors. N.M. is now able to sit down for dinner and go on vacation with her family, and can meaningfully participate in vocational work and activities with her peers. In addition, with ESD treatment, N.M. finally learned to use the bathroom facilities, whereas before she needed to wear diapers. Her communication has improved to the point that N.M. can use short sentences to communicate her needs and wants. N.M. continues to work on her communication skills, and can now learn much more because she no longer physically attacks the specialist who helps her with language, as she would do prior to ESD treatment.

Mr. Mesa testified that N.M.'s treatments have "stopped the madness of her just being an eating, sleeping, hurting machine," and N.M. is now able to learn and enjoy learning, and to find positive behaviors rewarding. N.M. is now "a happy kid" who "enjoys life."

JRC has worked to wean N.M. off of the ESD and Mr. Mesa can often take N.M. out into the community; N.M. can refrain from behaviors simply by having the ESD in a bag nearby, without N.M. having to wear it. However, Mr. Mesa fears that, if ESD treatment is prohibited, N.M. will regress, and he also fears that the Mesas could not continue to keep N.M. at home if she were to revert back to her violent behaviors.

[15] These included Depakote, Buspar, risperidone, Clonidine, Prednisone, and Klonopin.

Paul Peterson

Dr. Paul Peterson, the Henry Lee Shattuck Chair of Government at Harvard University, and his wife, Carol Peterson, are the parents and legal guardians of D.P. D.P. was born on July 9, 1970, and he has been diagnosed with severe cognitive defects and autism. D.P. also has a severe behavior disorder that includes a long history of aggressive, health-dangerous, destructive, disruptive, noncompliant, bizarre and ritualistic behaviors, including smearing feces; running away; gagging himself to induce vomiting; removing tissue from the back of his throat with his fingernails; picking his gums to bleeding; head banging; head butting others; rectal gouging; and forcefully squeezing his genitals or buttocks.

D.P. has been in special education programs since 1975. D.P. was in school placements in England, Chicago, California, Washington DC, and Pennsylvania. Although D.P. had problem behaviors at a young age, including leaving his home unsupervised or wandering into the street, D.P.'s self-injurious behaviors became more pronounced and serious in or around 1983, when D.P. became an adolescent: he would stick his hands in his mouth and make himself vomit; scratch his throat to produce blood; pick at his face and eyes; bang his head; and smear his feces. D.P.'s day program advised that D.P. required a residential program because he needed continuous supervision.

D.P. was then placed at the Devereux School in Philadelphia. Unfortunately, D.P.'s behaviors became worse, and he had to be physically restrained and wear a jacket with mitts covering his hands. D.P. was gouging his rectum, gouging his throat, picking at his eyes, banging his head, and making himself vomit. Devereux tried various medications, including Ritalin and Haldol,[16] and various behavioral modification techniques. Devereux was unable to address D.P.'s issues, however, and after five years, the school told D.P.'s parents that D.P. would have to be removed within one week. D.P. was aggressive during restraints and Devereux was worried about the safety of the staff.

D.P. was then placed at Kennedy Krieger Institute, which tried a variety of drug therapies and behavioral therapies. D.P. continued to try to put his hands down his throat to induce vomiting or scrape up blood, bang his head, or pick at his eyes, gums, and rectum. After four months, it was clear Kennedy Krieger was having difficulty finding an effective treatment for D.P.

When D.P. arrived at JRC (then BRJ) in 1988, the school first used positive reinforcement therapies to help him. These techniques were not effective, unfortunately, and decelerative interventions were used to supplement the positive reinforcement techniques. These interventions included different aversive therapies, which were initially effective in reducing

[16] Other medications used to treat D.P. included Mellaril, Thorazine, and Chloral Hydrate. However, the medications aggravated D.P.'s behaviors in some instances and interfered with D.P.'s ability to function.

D.P.'s major behaviors from the thousands per month to the hundreds. However, D.P. would become aggressive with staff, and the initial effectiveness of these decelerative interventions did not last.

D.P.'s mother tried the ESD, and D.P.'s parents then decided to allow ESD treatment to be added to D.P.'s treatment program. This treatment was added in December of 1990, and the treatment produced an immediate decrease in his targeted behaviors, and the behaviors continued to decelerate over approximately the next five years. Since 2006, D.P. has been free of all protective restraints and responds to ESD treatment. D.P. receives an ESD application about once a week, and he no longer engages in his most serious self-injurious behaviors, such as throat- or rectum-gouging or head banging.

The successful reduction of D.P.'s behaviors with ESD treatment has allowed D.P. to learn skills such as feeding and dressing himself and independently using the bathroom facilities, and to communicate and spend time with his family on home visits. D.P. has hobbies he enjoys with his family, such as listening to music, being read to, and going on walks with his father. D.P. also goes on frequent field trips, like attending the Newport Jazz Festival, going bowling and going to baseball games.

D.P.'s parents state that, if not for JRC, D.P. might not be alive today. Dr. Peterson describes the progress D.P. has made at JRC as quite remarkable, especially when considering that D.P. was in complete physical restraints when he arrived at JRC. D.P. is "happier now than he's ever been." Dr. Peterson fears that, if the FDA bans ESD treatment, D.P. will start engaging in his old behaviors again, and would have to be put back into a straitjacket and other protective restraints.

Marie Washington[17]

Marie Washington is the mother of J.W., who was born on January 2, 1973. J.W. has been diagnosed with autism and mental retardation. At the age of three, J.W. began to exhibit severe temper tantrums; he was reported to be echolalic, hyperactive, and aggressive. By five years old, J.W. was biting and kicking others, and he would roll on the floor and scream without provocation. J.W. attacked his teachers at the Kennedy Center and was discharged from the program. J.W. was then evaluated at Mt. Sinai Hospital as an inpatient; he received medication to the point of sedation. J.W. was homeschooled for a time, but he attacked the teacher. At about 13 years old, J.W. went to the Shield Institute in New York, a day program, but again his aggression resulted in his being discharged. He attacked others, threw tantrums on the bus to school, and broke a nurse's nose. Around that time, he also hit his father with such force that he knocked his father's teeth out.

[17] Mrs. Washington is President of the JRC Parents Association.

J.W. lived at home until he was 13 years old, at which time his violent tantrums became too much for his family to handle. In 1987 he was enrolled in a residential facility, the Anderson School, where he was treated with a behavior modification approach and psychotropic medications. However, this program was ineffective in reducing the number or intensity of his aggressive and other problematic behaviors. The medications sedated him to the point of being vegetative and caused him to gain weight – he ballooned to over 200 pounds and grew breasts.

J.W.'s parents decided to send J.W. to JRC (then BRI) in 1989, after other schools would not accept him. J.W. was admitted to JRC in November 1989. At that time, J.W. would punch and kick others, pull hair, and suddenly disrobe in public. When J.W. first entered the school, his treatment program was comprised of a positive reward system and other positive interventions, but J.W.'s behaviors escalated. In 1992, J.W.'s parents decided, after Mrs. Washington tried the ESD, to allow ESD treatment for J.W. With ESD treatment, J.W.'s aggressive and health-dangerous behaviors decelerated and ultimately reached near-zero rates, and those behaviors remain at near-zero rates today.

Over the past two years, J.W. has received just two ESD applications. The improvements in his problem behaviors have allowed him to access his community more often and live in a duplex with three other men. He gets into the community on a weekly basis to eat in restaurants, go bowling, watch movies and take walks in the park. He can work in the workshop and dress himself. These are things J.W. could not do before he received treatment with ESD, and his family is very pleased with his progress. His parents visit him once a month and they have taken him on trips to Florida. He is, according to his mother, happy, healthy, and "living a life like a human being now, not like a raw animal that he was before when he first came into the program." He is in good physical health, active, and not overweight like he was on medication.

Mrs. Washington observed that ESD treatment, along with JRC's positive rewards, has been the only effective treatment for J.W.. It has saved him from a life on drugs in an institution. J.W. is the best he has been in his life, and as a consequence, Mrs. Washington can "sleep at night now" and the family can live life: "before, there was no life." Mrs. Washington does not want J.W. to have to go back to "take downs" (restraint) and medication, something she fears will happen if the FDA bans ESDs.

Peter Biscardi[18]

Peter and Maureen Biscardi are the parents of P.B., who was born on January 28, 1978. P.B. was diagnosed with Autism at three years of age and subsequently attended at least four schools specializing in the treatment of children with P.B.'s diagnosis. Each school eventually terminated P.B.'s enrollment because his behavior – which included self-injury and aggression –

[18] Mr. Biscardi is a class representative of the class of JRC parents and students in the state action in which the Consent Decree was entered.

was unmanageable. In addition, at home, P.B.'s parents had to take various measures to keep P.B. safe (e.g., locking cupboards and drawers, and adding special latches to exit doors). In spite of his parents' efforts, P.B. continued to endanger himself at home. For example, he cut himself with a razor and ingested Drano. P.B. would also hit himself on the head with his fist and bite himself on the hand and forearm, which resulted in large calluses. At 11 years old, no day school in P.B.'s geographical area would accept him because of his severe behavior problems. P.B. was admitted to JRC (then BRI) in January of 1978.

At JRC, P.B. was treated with a combination of pharmaceutical interventions and behavioral procedures until court-approved ESD treatment was added to his behavior program in March of 1991. Since that time, P.B. has been treated with a combination of applied behavior analysis procedures and the ESD. P.B.'s aggression and self-injury reduced in clinically significant ways after implementation of the ESD. Not only did they reduce in frequency from their pre-ESD levels, but they also declined in their intensity. By the summer of 2014, P.B. was faded from the GED device 24 hours per day, 7 days per week. In September of 2014, P.B.'s court-approved treatment plan, which included the ESD, was allowed to expire. Since that time, P.B.'s behavior intervention program has not included the ESD.

Since progressing as a result of ESD treatment, P.B. is able to visit with his family each month. While he is home with his family, P.B. is, according to his parents, "happy, calm, and playful." Since P.B. has been at JRC and received a combination of reward and punishment therapy, he has improved drastically. According to P.B.'s parents, JRC's program and the ESD treatment have saved P.B.'s life.

Leo Soucy[19]

Leo and Claudia Soucy are the parents and legal guardians of B.S., who was born on November 18, 1967. B.S. has a long history of a severe behavior disorder that includes very serious self-injurious and aggressive behaviors. At the age of three, B.S. began attending day programs that provided special education services, but he eventually required residential placement at the age of seven.

As B.S. grew older, his behaviors worsened. He threw himself to the floor during transitions, destroyed property, threw objects, ingested non-food items, smeared feces, bit his hand, slapped himself, and banged his head. He was also frequently aggressive toward staff and students (*e.g.*, biting, scratching, and pulling hair). B.S.'s behaviors were so disruptive that he could not be maintained in a typical classroom. He was treated with psychotropic medications, including Mellaril and later Thorazine, but his response was erratic and he experienced negative side effects. Behavioral interventions included stimulus control, redirection, and contingent reinforcement, but were ineffective.

[19] Mr. Soucy is a class representative of the class of JRC parents and students in the state action in which the Consent Decree was entered.

B.S. was ejected from facilities in his home state of Massachusetts and rejected by at least five in-state placements, as well as by facilities in Connecticut and Vermont, before being admitted to JRC in August of 1984. B.S. began treatment with an ESD in December of 1991. The extraordinary reduction in the frequency of B.S.'s major problem behaviors has allowed him to lead a more normal life. Each day he commutes between his group home in Randolph, MA and the workshop in JRC's day program in Canton, MA.

Mitchell Shear

Dr. and Mrs. Mitchell Shear are the biological parents and guardians of S.S., who was born on March 21, 1993. S.S. has a history of aggressive, health-dangerous, disruptive, and noncompliant behaviors. Her diagnoses include Autism Spectrum Disorder and Severe Intellectual Disability. From a young age, S.S. would cry, constantly tantrum, kick, smear her feces all over the furniture and walls, and refuse to eat. S.S. would throw herself to the floor and could not be calmed down, and she was always unhappy.

Between 1996 and 2005, S.S. attended various day programs and one residential school and showed very little behavioral improvement during that time. As S.S. grew older, her behaviors grew worse – she began to hit herself and others, pinch herself and others, head-butt people, bite others (including her family and teachers), and scratch. She also continued to smear her feces and refused to eat, resulting in weight loss so severe her body was emaciated. In S.S.'s first residential placement, she had a helmet (to prevent additional damage to her head from slapping and gouging her face), weighted gloves, and a blanket wrap. She was on a positive reinforcement system and was given risperidone, fluoxetine, and valproic acid for behavior control. Other medications doctors tried with S.S. include Prozac, Buspar, Tenex, Xanax, Abilify. None of these drugs was effective in reducing S.S.'s problem behaviors, however. S.S. also experienced side effects from the medications, including drowsiness, drooling, facial tics, and tremors.

In addition, behavioral treatments employed on S.S. included: extinction; differential reinforcement; discrete trial learning; functional communication training (including communication through PECS); antecedent interventions (avoiding crowds, making a wide range of toys available to her continuously); teaching and allowing self-restraint; and increasing response effort through the use of wrist weights.

Despite all of these interventions, S.S. continued to hit her head 700 to 800 times per eight-hour shift. Indeed, she hit her head so often that she detached both of her retinas. At that point it was clear her residential placement was not effective, and she was admitted to JRC in March of 2005. Upon admission to JRC S.S. was blind and required surgeries to try and repair her eyesight, weighed 80 pounds and was covered in bruises and scratches, and had pulled out patches of her own hair.

JRC tried treating S.S. with various interventions, including: numerous permutations of differential reinforcement behaviors contracts; intermittent momentary rewards; extinction; token fines; verbal "no" and verbal redirection; restating reinforcement contingency; manipulation of demands; loss of privilege procedure; restraining reinforcement contingency; antecedent manipulations; response blocking; and protective equipment. These treatments were not sufficient to treat S.S.'s dangerous behaviors, and S.S.'s parents decided to try ESD treatment.

With the addition of ESD treatment, JRC's treatment program has completely transformed S.S.'s life. The reduction in her aggressive and self-injurious behaviors has enabled S.S. to have the multiple surgeries required to re-attach her retinas and restore her vision. S.S. is also able to interact with others, stay calm instead of tantrum, and go out into the community. Her mood improved – as her father describes it, "[s]he went from miserable all the time to happy 95 percent of the time." Whereas S.S. used to be angry and combative with her parents, she is now affectionate and hugs them, and is fun to be with. They can take her on home visits, out to restaurants, out to stores and on walks. In addition, S.S. was able to have a necessary knee surgery, stay in her cast and go through rehabilitation. Her sleep patterns have improved and she works consistently on her academic tasks. Her verbal communication skills have also improved, and she can now use short phrases to ask for things. She is now toilet trained and no longer has to wear diapers. She has literally become a different person. S.S. is happy, healthy, and learning. Without the availability of ESD treatment for S.S., Dr. Shear fears that her self-injurious and aggressive behaviors will all return.

Parents Association

The BRI Parents and Friends Association, Inc. (the "Association") supports the continued availability of aversive conditioning devices to treat severe behavior disorders instances where other therapies have failed.

The Association is a Massachusetts Nonprofit Corporation consisting of parents and guardians of current and former clients of the Judge Rotenberg Educational Center, Inc. ("JRC"), f/k/a the Behavior Research Institute or "BRI", as well as friends and other supporters of JRC and its life saving treatment program.

The Association's mission is to provide assistance and support (both physical and emotional) to the parents and guardians of children who reside at JRC and suffer from the most severe forms of behavior disorders as these parents and guardians secure and monitor the treatment and care necessary to keep their children safe and healthy. The Association's mission is to serve as an advocacy organization for the parents and guardians of all current and former JRC clients, regardless of the clients' treatment needs and whether they receive treatment with ESDs. Members of the Association share information with each other and the public about JRC and its various treatment programs, much of which is acquired during site visits to JRC and through discussions with JRC clinical and administrative staff. Members also sit on JRC's Human Rights Committee, which evaluates the programs of clients who have been prescribed

treatment with ESDs. Members of the Association provide testimony to state legislative committees and information and comment to media outlets regarding JRC's life-saving treatment program including its limited use of ESDs with a minority of its client population that engages in the most aggressive and self-abusive behavior and is highly treatment resistant.

The Proposed Ban

I. The Proposed Ban is Not Authorized by 21 U.S.C. §360f

Under 21 U.S.C. §360f, a device may be "banned" when FDA finds, "on the basis of all available data and information," that the device presents "an unreasonable and substantial risk of illness or injury." 21 U.S.C. §360f(a)(1). That is not what the FDA proposes to do here, however. Instead, it proposes to prohibit the *use* of electrical stimulation devices *for the purpose* of treating aggressive or self-injurious behavior. Indeed, FDA's proposal states explicitly that for "other purposes," there is no prohibition.[20]

This is not a *ban* at all. Congress has used very plain language. Clearly, to *ban* a device is to prevent it from entering into commerce *for any purpose*. Congress has never authorized FDA to regulate how medical devices can be employed in the discretion of health care practitioners (and with the consent of patients or their caregivers) once FDA has permitted them to be lawfully marketed. Indeed, FDA has never before even attempted to utilize this statute to do anything but outlaw a device altogether. In the only previous occasion on which the FDA adopted a final rule banning a device, it prohibited all implanted hair fibers across the board.[21] And the only other time FDA has even *proposed* to ban a device – the pending Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove[22] – it proposed to prohibit certain surgical items *absolutely*, for all uses, without exception.

In short, this whole exercise is wholly without precedent and without statutory authority.

II. The Proposed Ban Offends the Medical Practice Exemption under 21 U.S.C. §396

21 U.S.C. §396 provides:

> Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to

[20] *See* 81 Fed. Red. 24387.

[21] *See* Proposal to Make Prosthetic Hair Fibers a Banned Device, 48 Fed. Reg. 25126.

[22] 81 Fed. Reg. 15173.

a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

As noted above, the Proposed Ban does not ban electrical stimulations devices categorically. Some such devices are already exempted or approved and legally marketed, and others could be approved or cleared for other purposes. In fact, the very devices now used to treat aggression and self-injury are eligible to be considered for clearance or approval for *other* applications. Congress codified the medical practice exemption in 1997 specifically to prohibit FDA from dictating to medical professionals the uses to which otherwise lawful devices can be put. Yet FDA's proposal is almost entirely premised on an assessment of behavioral treatment practice, a task for which the FDA is woefully unequipped. This is precisely the reason for the medical practice exemption.

The legislative history could not be more clear. According to the conference report the "Practice of Medicine" exemption was

> intended by the conferees to emphasize that **the FDA should not interfere in the practice of medicine**. Specifically, the conferees note that **the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA**. It is the intent of the conferees that this provision not be construed to affect medical professional liability.

H.R. CONF. REP. 105-399, 97, 1997 U.S.C.C.A.N. 2880, 2887 (emphasis added). In the case of our clients, ESD treatment is prescribed by each individual's health care provider, consented to by each individual's parent/legal guardian, and approved by a court of law. The FDA simply has no authority to inject itself into this medical decision-making process by dictating what treatment these individuals should and should not receive for their unique medical and psychological conditions.

III. The Proposed Ban Would Violate the Due Process Rights of the Parents Who Have Chosen This Treatment for Their Children and a Decision to Adopt it as a Final Rule Would be Arbitrary and Capricious in Violation of the APA

A. Substantive Due Process

1. Applicable Law

A long history of Supreme Court cases makes clear that the JRC parents have a fundamental liberty interest in choosing the best, most effective medical care for their children, *especially* when those children are so severely impaired that they pose a danger to themselves

and to others, and that any intrusion by the government must be supported by a compelling interest, and narrowly tailored to serve that interest.

The Due Process Clause of the Fifth Amendment provides that "No person shall . . . be deprived of life, liberty, or property, without due process of law . . . ." The Clause

> protects individuals against two types of government action. So-called "substantive due process" prevents the government from engaging in conduct that "shocks the conscience," *Rochin v. California,* 342 U.S. 165, 172 (1952), or interferes with rights "implicit in the concept of ordered liberty," *Palko v. Connecticut,* 302 U.S. 319, 325–326 (1937).

United States v. Salerno, 481 U.S. 739, 746 (1987). The Supreme Court's "established method of substantive-due-process analysis has two primary features[.]" *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). "First, . . . the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, 'deeply rooted in this Nation's history and tradition,' and 'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.'" *Id.* at 720-721 (internal and citations omitted). "Second," the Court has "required in substantive-due-process cases a 'careful description' of the asserted fundamental liberty interest." *Id.* at 721 (citations omitted). The Due Process Clause "forbids the government to infringe . . . 'fundamental' liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Id.*, quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993).

2. The Fundamental Liberty Interest At Stake

The JRC parents have a fundamental liberty interest to choose ESD treatment for their dependent children. Indeed, the interest of parents in the "care, custody and control of their children" is "perhaps the oldest of the fundamental liberty interest recognized by [the Supreme] Court." *Troxel v. Granville*, 530 U.S. 57, 65 (2000). Moreover, "there is a presumption that fit parents act in the best interests of their children." *Id.* at 68. "Accordingly, so long as a parent adequately cares for his or her children (*i.e.*, is fit), there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children." *Id.* at 68-60, citing *Flores*, 507 U.S. at 304. As the Court has explained:

> Our cases have consistently followed that course; our constitutional system long ago rejected any notion that a child is "the mere creature of the State" and, on the contrary, asserted that parents generally "have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations." *Pierce v. Society of Sisters*, 268 U.S. 510, 535 (1925). *See also Wisconsin v. Yoder*, 406 U.S. 205, 213 (1972); *Prince v. Massachusetts*, 321 U.S.158, 166 (1944); *Meyer v. Nebraska*, 262 U.S. 390, 400 (1923). **Surely, this includes a "high duty" to**

> **recognize symptoms of illness and to seek and follow medical advice.** The law's concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions. More important, historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children. 1 W. Blackstone, Commentaries; 2 J. Kent, Commentaries on American Law.

Parham v. J.R., 442 U.S. 584, 602 (1979) (emphasis added).

The JRC parents are educated, involved, loving people who have exhausted every possible option to treat their children – placement in day and residential programs, various forms of therapy, and pharmacological intervention – and have concluded, in consultation with their children's treatment providers, that nothing works better than the addition of the ESD to their children's treatment plans. Indeed, in many cases, they have concluded that the pharmacological interventions their children have received over decades have caused actual *harm*, and have offered no benefits whatsoever in terms of managing their children's dangerous behaviors.

Furthermore, although the FDA suggests that Risperdal and Abilify are a component of state of the art treatment for this population's problems[23], these very drugs – which are approved for treatment of irritability associated with autistic disorder in children and adolescents ages 5-16 – are prescribed off-label for many of our clients' dependents, whose diagnoses encompass a broad range of disorders *not* approved for treatment with Risperdal and Abilify. (That is, they are neither autistic, nor between the ages of five and 16). If the pharmaceutical companies that developed and sold these drugs were to market them for our clients' various disorders, the companies could be criminally prosecuted for off-label promotion.[24] Yet the FDA apparently has no problem promoting these drugs for uses the FDA itself has not approved (and for which there have been no studies confirming their efficacy or safety). Risperdal and/or Abilify were tried with many of the JRC clients receiving treatment with ESDs; these drugs were not effective and also caused harmful side effects.

Many of the parents have explained that the choice to add the ESD to their children's treatment programs was a very difficult one – the idea of allowing a shock to be administered to one's child is terrifying. But more terrifying, as these parents have testified to and written about in firsthand accounts of their experiences, is the damage their children have done to themselves and others without the ESD to regulate their behaviors. They have swallowed Drano. They have banged their heads repeatedly and with such force that they have detached their retinas, blinding themselves. They have gouged their rectums and torn their scrotums. They have pulled out their own teeth and fingernails. They have ripped out their hair. They have bitten through their cheeks

[23] *See* 81 Fed. Reg. 24406.

[24] *See* 21 U.S.C. §331.

and bitten off their tongues. They have scratched themselves raw. They have attacked their caretakers and family members, some of whom have suffered permanent damage, including loss of vision and loss of body parts. And as they grow bigger and stronger, they pose an even greater danger to themselves and others. Yet when the ESD is added to their treatment protocols, the severity and frequency of these behaviors often decrease to zero or near-zero levels. They stop harming themselves. They stop attacking others. And, importantly, they are then in a position to be *receptive* to positive behavioral therapy, and to *learn*. They are also able to undergo necessary medical procedures that were impossible to perform when they were engaging in self-injury and aggression.

The JRC parents have a fundamental liberty interest in choosing a happy, productive life for their children – even if that life includes an occasional painful, two-second shock – over a life of misery in which their children are in constant physical and emotional pain, or in which their children are so heavily medicated (by drugs that have never been confirmed safe or effective for their children) that they cannot function. The Proposed Ban would selectively deprive our clients' dependent children of critical, life-altering (and in some cases, life-saving) medical treatment, and would substitute the FDA's judgment for the judgment of those who are intimately familiar with these children's particular needs, challenges, and capabilities. This is untenable.

3. The FDA has Not Satisfied Any Burden, Let Alone Shown the Ban is Narrowly Tailored to Serve a Compelling Interest.

Such a grave intrusion into the fundamental rights of our clients must be supported by a compelling state interest. *Reno v. Flores*, 507 U.S. at 302. Although it is true that "a state is not without constitutional control over parental discretion in dealing with children when their physical or mental health is jeopardized," *Parham v. J.R.*, 442 U.S. at 603 (citations omitted), "[s]imply because the decision of a parent is not agreeable . . . or because it involves risks does not automatically transfer the power to make that decision from the parents to some agency or officer of the state," *id.*

Here (and as set forth more fully in JRC's Comment), the Proposed Ban is not even supported by the available data and information, let alone a compelling interest. In fact, it is no more than an ideological intrusion – completely devoid of concrete evidentiary support – into our clients' private lives, and it *removes* a life-saving treatment from these highly vulnerable individuals, which is antithetical to the government's interest in protecting this population. Since FDA proposes to ban the use of ESD's for all persons suffering from self-injury and aggression – without exception – it must prove either that there are no cases in which a parent, or a medical professional, or a court, could reasonably conclude that a risk v. benefit analysis supports the use of ESD treatment, or that no procedure is currently employed – or could be employed – to identify which cases are appropriate for ESD and which are not. Yet FDA has not shown either.

FDA concedes that there is a subpopulation for which no other effective treatment is available, and it concedes that ESD treatments "cause the immediate interruption of self-injurious or aggressive behavior[.]"[25] As to the long-term effectiveness of the treatment, all the FDA manages to say is that ESD proponents have not proven it works, and it dismisses the needs of the Parties with the cavalier statement that, "[a]s with other psychological or neurological conditions, there may simply be a subpopulation of patients for whom there is no adequate treatment option." This is a thoroughly flawed, and false, notion. In the first place, it turns the burden of proof on its head. Unless the FDA proves that ESDs are not beneficial enough to outweigh whatever risks they may pose (though, as set forth more fully in JRC's Comment, these risks are actually quite minimal), the parents are entitled to continue to elect the treatment for their children.

Moreover, as extensively reviewed in JRC's submissions, the overwhelming weight of the evidence is that the "adequate treatment option" *is* ESDs. Although the idea of delivering a shock to a human being may be unpalatable, it ought to be far more unpalatable that without ESDs, those human beings will revert to states in which they harm themselves to such a degree that they are bruised, battered, scarred, blind, torn and bloody, or in which they are so drugged by psychotropic medications (many of which would have to be used "off-label" to treat them) that they would cease to lead meaningful lives. It is not enough to shrug and say, "perhaps your sons and daughters are simply untreatable," and leave them to live (or die) in agony.[26] And that is certainly not the expression of a compelling interest in protecting these children.

Furthermore, even assuming FDA has shown a compelling interest in "protecting" a small group of individuals from a particular medical treatment, it has not shown an all-out ban is the only way to do so. For example, the FDA has never addressed the individualized process set forth under the aforementioned Consent Decree, which unquestionably adds several layers of protection before ESD treatment is even available to these individuals. Nor does FDA explain why specific controls would not be effective under the circumstances. This stands in sharp contrast to the way FDA recently treated electroconvulsive therapy ("ECT") devices, which it reclassified from Class III to Class II. FDA acknowledged the risks ECT therapy poses – risks that are *far* greater in number and severity than the risks of ESDs[27] – but nevertheless concluded

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[25] 81 Fed. Reg. 24387.

[26] It is also ironic that any one of these parents could choose to administer ESD to his or her child for purposes of treating that child's smoking or alcohol addiction, but apparently cannot choose to have it administered for life-threatening conditions in a highly regulated setting after it has been prescribed by a doctor and approved by a court of law.

[27] These risks include: adverse reaction to anesthetic agents/neuromuscular blocking agents; adverse skin reactions; cardiovascular complications; cognition and memory impairment; death; dental/oral trauma; device malfunction; manic symptoms; pain/discomfort; physical trauma; prolonged or tardive seizures; pulmonary complications; skin burns; worsening of psychiatric

that "in the specified patient population, and with the application of general and special controls . . . , the probable benefit to health from use of the device outweighs the probable injury or illness from such use."[28]

Consequently, the Proposed Ban is not remotely "narrowly tailored." Rather, it affirmatively harms 50+ vulnerable individuals in ways the FDA refuses to acknowledge or admit, despite the wealth of data and personal experiences available to it that show the device is safe, effective, and the only available means of treatment for this tiny population. Adoption of the ban would violate substantive due process.[29]

B. The Proposed Ban Would Deprive the Parents of Their Fundamental Liberty Interest without the Procedural Protections Required by Due Process

1. Applicable Law

While certain regulatory agencies, when they proceed by general legislative pronouncement, may be excused from the basic requirements of adjudicatory procedure, this does not apply to an individualized decision, applicable to few persons, based on findings particular to those persons. *Alaska Airlines, Inc. v. C.A.B.*, 545 F.2d 194, 200 (D.C. Cir. 1976), citing *Londoner v. Denver*, 210 U.S. 373 (1908); *Bi-Metallic Investment Co. v. State Bd. of Equalization*, 239 U.S. 440 (1915). While it is true that "the line between legislation and adjudication is not always easy to draw," *Gallo v. U.S. Dist. Ct. for the Dist. of Ariz.*, 349 F.3d 1169, 1182 (9th Cir. 2003), quoting *LC & S, Inc. v. Warren County Area Plan Comm'n*, 244 F.3d 601, 603 (7th Cir. 2001),

> [t]he three primary considerations are: (1) whether the government action applies to specific individuals or to unnamed and unspecified persons; (2) whether the promulgating agency considers general facts or adjudicates a particular set of disputed facts; and (3) whether the action determines policy issues or resolves specific disputes between particular parties.

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symptoms. *See* https://www.federalregister.gov/articles/2015/12/29/2015-32592/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-intended-for-use-in#h-14.

[28] *See id.*

[29] For largely the same reasons, the Proposed Ban would not even survive rational basis review – the very lowest level of constitutional scrutiny – as the ban bears no rational relationship to a legitimate state interest. *See, e.g., City of Cleburne, Texas v. Cleburne Living Center*, 473 U.S. 432, 440 (1985).

Id. (citing cases); *see also RR Village Ass'n v. Denver Sewer Corp.*, 826 F.2d 1197, 1204-1205 (2nd Cir. 1987) ("Action is adjudicative when a decision is based on a determination of 'facts about the parties and their activities, businesses, and properties'" (citation omitted)).

2. FDA's Proposed Ban is an Adjudicatory Decision

This is precisely the danger created by the FDA's assertion of a power, not authorized by statute, to rule upon individual medical treatment decisions. In *Alaska Airlines, Inc., supra*, the Civil Aeronautics Board ("CAB") issued an order – without holding an evidentiary hearing or oral argument – prohibiting Alaska Airlines from operating a charter service it had been operating for over two decades (with what it believed to be the blessing of the CAB, which granted the airline an exemption permitting it to conduct interstate, instrastate, and charter operations). 545 F.2d at 196-197, 198. CAB's decision was based on three factual findings, all of which the airline challenged. Further, the airline requested an evidentiary hearing, alleging "the existence of facts which, if established at a hearing, would undermine [the adversary's] position." *Id.* at 198. Nevertheless, "[a]lthough considerable data on these issues was presented to the CAB, no evidentiary hearing was held to establish for the record the quantum and substantiality of the facts relied upon to support petitioners' contentions." *Id.*

The airline contended that its authority to operate the charters constituted "property" within the meaning of the Due Process Clause, "requiring that notice and hearing be afforded before amendment or restriction of that authority." *Id.* at 199. The D.C. Circuit agreed, pointing out that where the Board was concerned with the airline's "particular operation rather than with other similar past operations or conditions in other air markets," it was clearly "dealing with [the airline] individually and not in a class context. Therefore, the Board should have provided the parties a hearing to allow them to present and refute evidence concerning their charter operations." *Id.* at 201. Moreover, the Court held that "the hearing must be an evidentiary one, permitting each party to present and challenge evidence. Having itself interjected factual issues into the proceedings, the Board should have held an evidentiary hearing in order to insure their proper resolution." *Id.* at 203.

Like the administrative action at issue in *Alaska Airlines, supra*, the Proposed Ban at issue here is quite clearly "a proceeding that in form is couched as rule making, general in scope and prospective in operation, but in substance and effect is individual in impact and condemnatory in purpose." *American Airlines, Inc.*, 359 F.2d at 631. Indeed, throughout the text of the Proposed Ban, the FDA repeatedly makes factual judgments and findings specifically concerning the medical care and treatment of a small subset of students at just *one* institution: JRC. Thus, the Parties – the only individuals actually affected by the Proposed Ban – are entitled to more than simply paper submissions.

3. The Parties Are Entitled to a Hearing

"Where governmental action seriously injures an individual," and the "reasonableness of the action depends on fact findings, the protections afforded by due process of law entitles the individual to a fair opportunity to show that the governmental action was unwarranted" (internal quotation marks omitted)). *Fitzgerald v. Hampton*, 467 F.2d 755, 763 (D.C. Cir. 1972). Consequently, "when governmental agencies adjudicate or make binding determinations which directly affect the legal rights of individuals, it is imperative that those agencies use the procedures which have traditionally been associated with the judicial process." *Hannah v. Larche*, 363 U.S. 420, 442 (1960); *RR Village, supra* ("Proceedings that adjudicate disputed facts in particular cases are subject to the requirements of procedural due process" (internal quotation marks and citation omitted)).

What process is due to any particular party is ultimately determined by balancing three criteria: 1) the private interest affected by the governmental action; 2) the probable value of additional procedural safeguards; and 3) the government's interest in the existing procedure. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). Application of these factors here requires that FDA hold a hearing at which the pivotal findings of the FDA may be fairly evaluated.

The Private Interest Affected

As shown above, the parents have an overwhelming and indisputable interest in FDA's determination. If the device is outlawed, their children will be condemned to suffer the likely consequences: death, at worst; grievous injury, with little doubt; an end to progress and a life of misery, at best.

It bears noting here that FDA appears to have willfully blinded itself to the Parties' interests. In point of fact, FDA has *ignored* the parents' repeated invitations to speak with them, to meet their children, and to see what ESD treatment has accomplished for them. It has likewise *ignored* JRC's repeated invitations to visit the school and gather whatever information is necessary to make a reasoned determination concerning the risks and benefits of ESD treatment. Given that these are the *only* entities affected by the Proposed Ban, and given the grave interests at stake, it is extraordinarily troubling that the FDA has actually consciously chosen *not* to gather "all available data and information" on ESDs, 21 U.S.C. §360f(a), and instead selectively relies upon, and in many cases mischaracterizes, just a portion of the information available to it.

The Probable Value of Additional Safeguards

The paper comment procedure employed by FDA, used to deprive the parents of the only therapy (individually approved by a Massachusetts court) which has ever worked for their children, is a completely inadequate method to provide a fair assessment of ESDs. To support the Proposed Ban, FDA has found "facts" which cannot stand the test of live examination. It relies on speculation, mischaracterization, unidentified and clearly biased sources, impeachable

experts, and evidentiary standards not applied elsewhere, among many flaws that would be revealed by a few questions put to FDA witnesses.

Here, an evidentiary hearing is the only truly effective way to resolve the myriad factual disputes at issue. As the D.C. Circuit has explained, "an oral hearing provides a way to ensure accuracy when facts are in dispute, especially if credibility is an issue." *Gray Panthers v. Schwelker*, 652 F.2d 146, 161 (D.C. Cir. 1980). The Supreme Court has recognized time and again the importance of cross-examination, in particular, in the face of a potential deprivation of liberty or property:

> 'Certain principles have remained relatively immutable in our jurisprudence. One of these is that where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue. While this is important in the case of documentary evidence, it is even more important where the evidence consists of the testimony of individuals whose memory might be faulty or who, in fact, might be perjurers or persons motivated by malice, vindictiveness, intolerance, prejudice, or jealousy. We have formalized these protections in the requirements of confrontation and cross-examination. They have ancient roots. They find expression in the Sixth Amendment . . . . This Court has been zealous to protect these rights from erosion. It has spoken out not only in criminal cases, . . . but also in all types of cases where administrative . . . actions were under scrutiny.'

Goldberg v. Kelly, 397 U.S. 254, 270 (1970), quoting *Greene v. McElroy*, 360 U.S. 474, 496-497 (1959); *see also Flatford v. Chater*, 93 F.3d 1296, 1307 (6th Cir 1996) ("due process requires that a social security disability claimant have the opportunity to cross-examine a reporting physician where reasonably necessary to a full development of the evidence"); *Edgecomb v. Housing Authority of Vernon*, 824 F. Supp. 312, 315-316 (D. Conn. 1993) ("the opportunity to confront and cross -examine witnesses is essential when the information supplied by those witnesses is the reason for the loss of benefits").

By way of examples directly pertinent here, in the Massachusetts Consent Decree case, cross-examination elicited from the Commonwealth's experts – advertised to be among the most qualified in their fields – that PBS is not universally effective for population with the most severe behaviors (Jennifer Zarcone); or that Risperdal and Abilify – the supposed miracle drug alternatives to skin shock – have not been shown to be effective for self-injury (James McCracken); and even that contingent skin shock *should* be available as a treatment option (Phillip Levendusky).

Furthermore, even if there were no full evidentiary hearing, an informal hearing – requested by JRC and denied by FDA – would offer far greater insurance against the risk of mistake than now exists. Among the most basic elements of due process is the right to respond to

all of the evidence. That is impossible here, both because FDA has not revealed all the sources upon which it has relied, and because by definition, under the comment-only procedure, the interested parties have no ability to respond to all of the evidence once it is in, let alone cross-examine the key witnesses that FDA claims support the Proposed Ban. Thus, the D.C. Circuit has observed that

> [e]ven if credibility is not . . . directly in issue, personal, oral hearings are an effective way to eliminate misunderstandings and focus issues. Ambiguities which are not readily apparent on the face of a document can be disclosed and clarified with a few moments of oral exchange between the individual and the decisionmaker.

Gray Panthers, 652 F.2d at 161-162.

The Government's Interest in the Existing Procedure

The FDA's interest in the existing procedure ought to be neutral. Its paramount concern, given the nature of the Proposed Ban, should in fact be *accuracy*. It should not be interested in one outcome or another; the point is to assess the relative benefits and risks of any given device it proposes to ban. Given what is at stake here – that is, the very lives of approximately 50 highly vulnerable individuals – the resources expended on a hearing that would assist FDA in settling very real questions of risk and benefit ought to be of minimal concern.

Moreover, as set forth above, there is very little precedent for this type of action, since FDA has only banned one other device in its history, and proposed to ban just one other. Thus, it is a rare occurrence indeed, and given that the Proposed Ban at issue here only applies to a particular use for a particular population, FDA ought to have no concern that providing a hearing would set a precedent establishing the necessity of a hearing each and every time it proposes to ban a device.

4. The FDA Should Hold a Hearing Before Undertaking any Further Consideration of the Proposed Ban.

Whether or not mandated by statute, the FDA has ample discretionary authority to order a live hearing before a disinterested fact-finder to review the contentions made in its report. Our clients request that FDA order such a hearing now, before further consideration of the ban. This should be an evidentiary hearing. Alternatively, at a *minimum*, it should be an informal hearing at which the Parties may at least respond to contentions made by proponents of the ban.

C. The Process Leading to the Proposal, and the Contents of the Proposal Itself, Are Flawed by Unfairness, Bias, and Pre-Determination.

Both the process leading up to the Proposed Ban, and the contents of the Proposed Ban

itself, have all of the earmarks of a preordained outcome. Indeed, it is clear from the record that this was anything but a fair and unbiased consideration of the evidence on the part of the FDA. By way of example (but by no means a complete summary of the arbitrary and capricious nature of FDA's instant action):

- FDA expressly allowed the use of this device for this purpose for decades, but then abruptly reversed course and asked JRC to make a new 510(k) presentation, which JRC duly prepared, at great expense. Then, FDA terminated the whole process, without explanation, on the eve of a pre-510(k) meeting;

- In the Proposed Ban, FDA patronizingly dismissed, as naïve or merely anecdotal, the thoughtful views expressed by the JRC parents, who have a depth of knowledge based upon decades of firsthand experience. Indeed, FDA has not even bothered to interview the JRC parents, despite claiming in its own literature that: "Patients are committed to contributing their views, data, and resources to increase patient-centric medical product innovation, assessment, and regulatory decision-making, and **we [the FDA] are committed to assuring that our decisions and actions are informed by patient perspectives**" (emphasis added)[30];

- At the same time, FDA, in the Proposed Ban, unquestioningly credited the views of four anonymous former JRC parents in opposition to ESDs, but these parents' accounts and motivations cannot be verified or challenged;

- FDA has failed even to observe the use of ESDs at JRC, despite multiple invitations to visit the facility to do so;

- FDA has held the proponents of ESDs to evidentiary standards not applied to other devices, and has ignored the substantial body of evidence demonstrating the safety and effectiveness of ESDs to treat this refractory population;

- FDA understates the severity and risk of the self-injurious and abusive behaviors for which ESDs are employed by JRC, and the permanent injuries those behaviors can cause, in order to diminish the benefit that ESDs provide to this incredibly difficult-to-treat population;

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[30] Found at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf (page 7, "Partner With Patients"); *see also* http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm361864.htm ("Public Workshop - The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes, September 18-19, 2013").

- FDA drastically inflates the size of the affected population in order to include in its analysis far milder cases of self-abuse and injury which *do* respond to alternate therapies, thus grossly distorting FDA's risk-benefit analysis;

- FDA misstates the literature as to PBS by overstating the effectiveness of PBS, in combination with pharmacotherapy, as a means of treating severe SIB and AB, and at the same time mischaracterizes the literature on ESDs by claiming it is biased, incomplete, and not based on randomized controlled studies (studies that would actually be unethical under the circumstances); and

- FDA relies on clearly biased experts who have a long history of campaigning against ESDs. Ironically, and despite the fact that FDA elevates the opinions of these experts over the substantial body of literature to the contrary, one of the experts, Tristan Smith, actually *supports* the use of ESDs. FDA buried this conclusion in the Proposed Ban in such a way as to make it almost unnoticeable – surely a red flag indicating one-sidedness and a predetermined outcome.

The aforementioned examples provide ample evidence of the arbitrary and capricious nature of the Proposed Ban.

Conclusion

In sum, and for the reasons set forth above, the Parties strongly oppose the Proposed Ban and request an evidentiary hearing (or, at a minimum, an informal hearing) before any final action is taken on the ban.

Sincerely,

Max D. Stern
Alexandra H. Deal