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**VIA E-FILING (WITHOUT EXHIBITS)**

**VIA FEDERAL EXPRESS AND CERTIFIED MAIL (WITH EXHIBITS)**

Stephen M. Hahn, M.D.  
Commissioner, U.S. Food and Drug Administration  
c/o Division of Dockets Management  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

Re: **PETITION FOR STAY OF ACTION PURSUANT TO 21 C.F.R. § 10.35;**

Final Rule Banning Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior, 85 Fed. Reg. 13312 (March 6, 2020)  
(Docket No. FDA-2016-N-1111)

**DECISION REQUESTED BY 12:00 P.M. (EST) ON MARCH 27, 2020**

Dear Commissioner Hahn:

We represent the parents and guardians (“Parents”)<sup>1</sup> of certain patients at the Judge Rotenberg Educational Center, Inc. (“JRC”), as well as the patients themselves.<sup>2</sup> We also

<sup>1</sup> Luis Aponte as guardian of L.A.; John Asare and Ophelia Asare as guardians of G.A.; Nelson Bernardo as guardian of N.B.; Richard Bevins as guardian of M.D.; Richard Bevins as guardian of W.R.M.; Indra Biggs as guardian of D.B.; Carlo Casoria and Judy Casoria as guardians of J.A.C; Gail Cornish as guardian of D.R.; Cornnis Crawford and Patricia Crawford as guardians of J.C.; Prudence Dellamano as guardian of M.R.; Kathy Dion as guardian of S.T.S.; Angela DiSisto as guardian of L.D.; Richard Doherty as guardian of M.D.; Lauren Emmick and Martin Emmick as guardians of L.E.; Stacy Engels as guardian of H.S.; Bruce Freeman as guardian of B.W., B.S., and L.J.; Lance Giuffrida and Jackie Giuffrida as guardians of E.G.; Robert Goldberg and Louisa Goldberg as guardians of A.G.; Stephen Hanna as guardian of C.M.; Judith Honore and Mathurin Honore as guardians of J.H.; Erick Kemp as guardian of D.K.; David Lewis as guardian of E.L.; Cheryl Lloyd as guardian of C.L.; Alfred Lopez and Carline Lopez as guardians of J.L.; Mary Marini as guardian of G.M.; Rick Mesa and Elizabeth Mesa as guardians of N.M.; Trisha Moeder as guardian of J.B.; Jean Murphy as guardian of R.M.; Lainie Murphy as guardian of BRA.S.; William Murphy and Jean Murphy as guardians of R.M.; Cheryl Murray as guardian of K.A.; James Myrick and Dollie Myrick as guardians of M.M.; Malcolm Oldham as guardian of A.O.; Carmen Pena as guardian of G.T.; Robin Pisano and Joseph Pisano as guardians of A.P.; Edward Prunckun as guardian of R.P.; Colman Reaney and Bridget Reaney as guardians of N.R.; Ana Rivera as guardian of E.R.; Edgardo Sanchez as guardian of BRA.S; Mitchell Shear and Marcia Shear as guardians of SA.S; James Shields as guardian of M.S.; Amjad Siddiqi as guardian of H.S.; Raul Sierras as guardian of J.S.; Melody Simpson as guardian of C.S.; Ilana Slaff-Galatan as guardian of MA.S; Leo Coucy and Caludis Soucy as guardians of B.S.; Ellen Stahler as guardian of H.S; Carmen Torres as guardian of A.G.; Carlos Vollenwieder as guardian of E.V.; Kelly Walker and Laura Walker as guardian of B.W.; Jenkin Washington and Marie Washington as guardians of JAW.; Michele Winters and Charles Winters as guardians of E.W.; Sharon Wood and Roger Wood as guardians of J.W.; Maria Augusto as guardian of S.P.; Roger Forbes and Barbara Forbes as guardian of D.F.; Lee Higgins as gaurdian of S.H.; Luis Pereira as guardian of S.P; Paul Peterson and Carol Peterson as guardians of D.P.; Gary Tam and Jamie Tam as guardians of S.T.; Corine Watson as guardian of S.W.

<sup>2</sup> The aforementioned patients are those who currently receive court-ordered treatment with the Graduated Electronic Decelerator (“GED”)-3A or GED-4 device as part of their probate court-approved treatment plans, as well as those whose parents will seek and receive the court’s approval for such treatment.

represent the JRC Parents and Friends Association, Inc. (the “Parents Association”)<sup>3</sup>, the association that represents all of the parents (hereinafter, collectively, “Petitioners”). We are filing this Petition for Stay of Action (hereinafter “Petition”) with the U.S. Food and Drug Administration (“FDA” or the “Agency”) pursuant to 21 C.F.R. §§ 10.35 and 10.20, among other provisions of law.<sup>4</sup>

Based on the reasons and authorities set forth in this Petition, FDA must immediately and indefinitely stay both of the two effective dates for its final regulation banning electrical stimulation devices (“ESDs”) used to treat self-injurious behavior (“SIB”) or aggressive behavior (“AB”).<sup>5</sup> JRC treats a small percentage of its patients who engage in the most severe and the most treatment-resistant SIB and AB – our clients – with a specific type of ESD known as Graduated Electronic Decelerator (“GED”) devices as part of a comprehensive, court-ordered and court-monitored Applied Behavior Analysis (“ABA”) behavioral treatment plan. As detailed below, without a stay, Petitioners will suffer irreparable harm, including the catastrophic, permanent physical or psychological injuries, and possibly even death, of the Parents’ children.

### **FDA’S OPTIONS FOR PROCEEDING**

Because time is of the essence for those who either need or receive the GED treatment that is the subject of these proceedings, Petitioners request expedited consideration of this Petition and confirmation from FDA that an administrative stay has been entered by 12:00 p.m. (EST) on March 27, 2020. Petitioners specifically seek a stay of the final rule’s effective dates for any individual with a treatment plan with GED that has been or will be approved and monitored by a court. Should FDA fail to confirm that FDA will stay the final regulation banning ESDs pending judicial review by noon on March 27, 2020, Petitioners will seek such interim relief from the United States Court of Appeals for the District of Columbia Circuit (the “D.C. Circuit”) on March 27, 2020, in order to protect the rights, interests, and health and safety of their children.

Alternatively, and in light of the recent presidential declaration of a national emergency concerning the novel coronavirus disease (COVID-19)<sup>6</sup>, FDA can have as much time as it requires to review and respond to this Petition, and respond to the coronavirus (COVID-19) pandemic, so long as FDA agrees to stay the effective dates in the interim, and further agrees that Petitioners will be permitted adequate time and a reasonable opportunity following any adverse decision by FDA within which to obtain a ruling from the D.C. Circuit on a stay motion, during which time the effective dates of the regulation will remain stayed.

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<sup>3</sup> Formally known as the Behavioral Research Institute (“BRI”) Parents and Friends Association, Inc.

<sup>4</sup> Petitioners also incorporate by reference the entire petition for stay, including exhibits, filed with FDA by JRC on March 20, 2020 (hereinafter “JRC Petition”).

<sup>5</sup> See Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 85 Fed. Reg. 13,312, 13,312 (Mar. 6, 2020).

<sup>6</sup> See Donald Trump, President, United States, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020).

## **PETITION FOR STAY OF ACTION**

The undersigned submit this Petition requesting that the Commissioner of FDA (“Commissioner”) stay the effective dates of the following matter.

### **A. DECISION INVOLVED**

Through this Petition, Petitioners request that the Commissioner stay both of the two effective dates of FDA’s final regulation banning electrical stimulation devices used to treat self-injurious or aggressive behavior (the “Final Rule” or “Ban”) published in the Federal Register on March 6, 2020 at 85 Fed. Reg. 13312. The Final Rule sets forth two separate effective or “compliance” dates (both, collectively, the “Effective Dates”).

First, FDA demands that any ESDs which are currently “in use on specific individuals as of the date of publication” be discontinued subject to a physician-directed transition plan beginning on April 6, 2020.<sup>7</sup> Without further detail or explanation – and disregarding the fact that JRC’s patients receive treatment with GED as a result of comprehensive, court-ordered, clinician-directed, individualized behavioral treatment plans and specific findings by a court that GED is the least restrictive, most effective treatment for the patient and that the patient is suffering no side effects from GED treatment – FDA directs that all individuals currently on ESDs be transitioned to some other form(s) of treatment, with all ESD treatment ceasing within 180 days of the publication of the Final Rule, or by September 2, 2020.<sup>8</sup>

Second, the Ban becomes effective for all other ESDs, including those not currently in use on individuals, within 30 days of the publication of the Final Rule, or by April 6, 2020.<sup>9</sup> Petitioners understand this portion of the Ban, if it occurs, would preclude any individuals who do not currently receive ESDs from seeking them after April 6, 2020, even if recommended by medical providers and approved by a court.

This Petition is timely as it is submitted within 30 days of the date of the publication of the Ban in the Federal Register.<sup>10</sup> The Petition is also submitted prior to both of the Effective Dates of the Ban.

### **B. ACTIONS REQUESTED**

Petitioners request that the Commissioner immediately issue an indefinite stay of both Effective Dates of the Ban, and that the administrative stay remain in place until the latest of the following:

- 1) the full and final adjudication or resolution of all legal challenges to the Ban, including the Appeal of the Ban filed, or to be filed, with the D.C. Circuit by Petitioners and JRC; or

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<sup>7</sup> See Final Rule, 85 Fed. Reg. at 13,312, 13,349.

<sup>8</sup> See *id.*

<sup>9</sup> See *id.*

<sup>10</sup> See 21 C.F.R. § 10.35(b), (g).

- 2) in the alternative, Petitioners request that the Commissioner stay the Effective Dates of the Ban until such time as the Commissioner rules on the instant Petition and, in the event the Petition is denied, such time as is necessary for Petitioners to seek and obtain a stay from the D.C. Circuit in connection with the Appeal.

In addition to the relief requested in paragraphs 1-2 above, Petitioners request an indefinite stay of the September 2, 2020 compliance date as it relates to each of JRC's fifty-five (55) patients who are currently court-authorized to receive treatment with GED pursuant to a court-ordered treatment plan,<sup>11</sup> and any other individuals who may receive court-approval for treatment with GED.

As FDA expressly acknowledged when proposing the Ban in 2016, the Ban must be stayed with respect to any individuals currently receiving GED for SIB or AB unless and before effective alternative treatments and therapies can be developed, and successfully and fully implemented, due to the serious risk of harm to those individuals (and others) which would likely result from an immediate ban or abbreviated compliance period as opposed to transition periods dictated by the medical needs of each individual. Specifically, in 2016, FDA stated:

“... FDA recognizes that, for certain individuals currently subject to ESDs, immediate cessation could possibly result in a significant increase of SIB or AB before appropriate alternative therapies are in effect, and a more gradual reduction toward complete removal may be necessary for some patients, especially those who have been subject to ESDs for a considerable amount of time. Thus, to account for this possibility, FDA does not intend to enforce the ban for a limited period of time with respect to ESDs that continue to be used on patients after the effective date.”<sup>12</sup>

In the Final Rule issued in March 2020, nearly four years – 1,412 days – after the Proposed Ban was published in April 2016 (and just shy of six years – 2,144 days – after the Panel meeting was held to evaluate the contemplated Ban in April 2014) FDA again recognized the concern raised by Petitioners and others “that [an] improper transition [off of GED] would be potentially life-threatening and likely to cause a return to behaviors and result in direct and immediate harm; [and that] any transition must happen under the care of a physician.”<sup>13</sup> Indeed, “in light of concerns about thorough assessments of the behaviors’ functions and corresponding

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<sup>11</sup> Two JRC patients who are court-authorized to receive GED treatment no longer receive GED treatment because GED successfully, safely and effectively brought to zero all of those patients' SIB and AB. Those two patients have been completely faded from the GED, are not currently wearing a GED, and will be reviewed at their next court treatment plan reviews for potential discontinuation of court authority given the complete success of the GED treatment in their cases. Notwithstanding these two patients' remarkable success with GED, a stay is still necessary in their cases to the extent GED treatment becomes necessary due to a slight regression such as an occasional isolated SIB or AB, which has occurred for other patients before and in which case the GED device is put back on immediately to avoid further regression and then removed again as part of a new fading protocol as soon as indicated. The probate court judge will ultimately decide if the fading for these two individuals has been successful long enough to discontinue the court approval of the GED for those individuals.

<sup>12</sup> See *Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior*, 81 Fed. Reg. 24,386, 24,413 (proposed Apr. 25, 2016) (hereinafter “Proposed Ban”).

<sup>13</sup> See Final Rule, 85 Fed. Reg. at 13,349 (Comment 65).

development of appropriate treatment plans,” FDA “agree[d] that transition off of ESDs should occur under the supervision of a physician” and over an appropriate “period of time to establish or adjust treatment plans” as dictated by each individual’s needs.<sup>14</sup> These same concerns acknowledged by FDA with respect to individuals who currently receive GED apply equally to individuals for whom other treatments have failed and who, in the opinion of their medical providers and an independent judge reviewing such individuals’ treatment options and medical histories, need treatment with GED to prevent serious self-injury and/or aggression. All current and future treatment should continue until the dangerous behaviors have been eliminated or an effective, less restrictive treatment is available.

In sum and in accordance with FDA’s articulated positions set forth in the Proposed Ban and Final Rule, Petitioners seek an indefinite stay of the Ban for all individuals who receive court authorization for treatment with GED. At a minimum, Petitioners seek an indefinite stay of the Ban pending the gradual, full and successful transition of all JRC patients from their current, court-approved behavioral treatment plans which include GED to effective alternative therapies – whatever and whenever that may be for each affected individual – or the dangerous behaviors are effectively eliminated for the patient.

In light of the seriously harmful – perhaps fatal – consequences and irreparable injuries faced by the Parents’ children as a result of the Ban, and to allow Petitioners the opportunity to seek emergency judicial relief should the Commissioner deny this Petition and decline to enter an administrative stay, Petitioners respectfully request that FDA issue a decision on this Petition by 12:00 pm EST on March 27, 2020.

### **C. STATEMENT OF GROUNDS IN SUPPORT OF PETITION FOR STAY**

The Commissioner must grant this Petition and stay the Effective Dates of the Ban because, for the reasons and authorities set forth in detail below, Petitioners: (1) will otherwise suffer irreparable injury; (2) raise issues and claims that are not frivolous and are being pursued in good faith; (3) demonstrate sound public policy grounds supporting a stay and, further, (4) demonstrate that any delay resulting from a stay is not outweighed by public health or other public interests. Because all of the foregoing four factors are met, a stay is mandatory.<sup>15</sup>

Alternatively, and in the event a mandatory stay is not entered, the Commissioner should exercise his discretion to grant a stay because a stay “is in the public interest and in the interest of justice” for the reasons stated in this Petition.<sup>16</sup>

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<sup>14</sup> See *id* (FDA Response to Comment 65).

<sup>15</sup> See 21 C.F.R. § 10.35(e)(1)-(4) (providing that “[t]he Commissioner *shall* grant a stay in any proceeding if all [four factors] apply[.]” (emphasis added)).

<sup>16</sup> See 21 C.F.R. § 10.35(e) (“[t]he Commissioner *may* grant a stay in any proceeding if it is in the public interest and in the interest of justice.” (emphasis added)).

## **I. FACTUAL BACKGROUND**

The basic facts in this matter are addressed in, among other sources, the documents and submissions in Docket No. FDA-2016-N-1111.<sup>17</sup> Petitioners therefore generally discuss the relevant factual background by reference to documents within the administrative record, copies of which are generally attached to JRC’s Petition.<sup>18</sup> In addition, attached hereto are the following:

- a. Declaration of John Asare (Exhibit 1);
- b. Declaration of Richard Doherty (Exhibit 2);
- c. Declaration of David Lewis, Ph.D. (Exhibit 3); and
- d. Declaration of Carmen Pena (Exhibit 4).

As permitted by FDA regulations, Petitioners incorporate by reference herein all arguments put forth previously in the administrative record with respect to the Proposed Ban.<sup>19</sup>

### **A. Overview of the JRC GED population<sup>20</sup>**

FDA’s Final Rule enacting a ban of ESDs for treatment of SIB and AB is targeted solely at and affects a single facility in the United States, JRC, and the patients who currently receive GED treatment there (as well as those residents who might receive it in the future).<sup>21</sup> Altogether, approximately 240 persons have received it in the 25 years JRC has been authorized to use it; just 53 currently receive it.

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<sup>17</sup> See 21 C.F.R. § 10.35(h) (confirming that “[t]he record of the administrative proceeding consists of ... [t]he record of the proceeding to which the petition for stay of action is directed[,]” among other categories of information).

<sup>18</sup> These include:

- a. The documents and submissions in Docket No. FDA-2014-N-0328;
- b. The documents and submissions in Docket No. FDA-2016-N-1111;
- c. All correspondence between FDA and/or its counsel and JRC, the Parents Association, JRC parents, and/or their counsel, including, but not limited to, the correspondence attached to JRC’s Petition as Exhibit A;
- d. All records produced and/or to be produced in connection with FOIA Request Nos. 2016-7308, 2016-7184, 2016-7106, 2017-1440, 2018-5569, and 2019-11744, including but not limited to, the records attached to JRC’s Petition as Exhibit B;
- e. All records produced and/or to be produced in connection with the lawsuit known as *The Judge Rotenberg Educational Center, Inc., et al. v. U.S. Food and Drug Administration, et al.*, No. 1:17-cv-02092-BAH (D.D.C.) (the “FOIA Litigation”), including but not limited to, the records attached to JRC’s Petition as Exhibit B;
- f. Supporting expert declarations, attached to JRC Petition as Exhibits D–I.
- g. FDA’s April 25, 2016 Proposed Ban; and
- h. FDA’s March 6, 2020 Final Rule.

<sup>19</sup> See 21 C.F.R. 10.20(c) (permitting a petitioner to “incorporate [] by reference” in a petition information “previously submitted in the same proceeding” or where copies of sources cited are included with the submission).

<sup>20</sup> For a more detailed recitation of these facts, see JRC Petition at pp. 9-13.

<sup>21</sup> See Final Rule, 85 Fed. Reg. at 13,313 (“We expect that the rule will affect only one entity); *id.* at 13,314 (“Only one facility in the United States has manufactured these devices or used them on individuals in recent years.”), and *id.* at 13,349 (“We expect that the final rule will only affect one entity that currently uses these devices on residents of its facility.”).

JRC treats that very small portion of individuals who have the most extreme form of SIB and AB – those behaviors involving the most horrific, violent and lethal forms of self-injury. The dangerous behaviors in which these patients were frequently engaged, prior to their treatment with the GED device, included head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, destroying furniture and school equipment, punching their fists through glass windows, running into traffic, jumping out of windows, and violently attacking family members, teachers, staff and others with punches, kicks, bites and sharp objects such as razor blades and utensils. FDA acknowledges the severity and lethality of these behaviors.<sup>22</sup>

The only patients who receive GED treatment – a fraction of JRC’s total patient population – are those who have been determined by JRC and found by the Massachusetts Family and Probate Court (the “Court”) to be resistant to all other available therapies. FDA maintains that the other therapies, such as positive behavioral supports (“PBS”) and pharmacotherapies, are available instead, but can only say that they are “typically”<sup>23</sup> or “generally”<sup>24</sup> successful for extreme cases. In fact, FDA concedes that they “may not be always completely successful for all patients,”<sup>25</sup> and an FDA’s Neurological Devices Panel of the Medical Devices Advisory Committee (the “Panel”) unanimously concluded that there is a subpopulation of refractory patients who do not respond to other available treatments.<sup>26</sup> In closing the door on this safe and effective GED treatment, FDA correctly concludes that “a small subpopulation of people who manifest SIB or AB” – the Parents’ children – now “may simply have no adequate treatment option.”<sup>27</sup>

Overall, JRC has been extraordinarily successful at reducing or eliminating these dangerous behaviors, enabling the patients for the first time to make educational and vocational progress, develop daily living and self-care skills, integrate in the community and spend quality time with loved ones. FDA concedes that ESDs immediately reduce SIB and AB.<sup>28</sup> Furthermore, the Agency acknowledges that “the case reports and other information submitted by JRC appear to indicate that patients’ SIB and AB decreased substantially once they began wearing the GED and remained at low levels for years[.]”<sup>29</sup> and that since 2002 more than half – 58% – have been “faded” from the GED entirely.<sup>30</sup> FDA also acknowledges that numerous scientific articles

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<sup>22</sup> See *id.* at 13,317. FDA estimates the number of persons who exhibit extreme SIB to 25,000, without explaining how it got that number. In any event, it makes no estimate of how many of these are resistant to all other therapies

<sup>23</sup> See *id.* at 13,315.

<sup>24</sup> See *id.* at 13,322.

<sup>25</sup> See *id.* at 13,338.

<sup>26</sup> See *id.* at 13,332. Moreover, the studies cited in Reference 8 in the Final Ban show that even the psychological therapies endorsed by FDA do not come close to eliminating the dangerous behaviors. See *id.* at 13,351 citing LaVigna, G.W. and T.J. Willis, “The Efficacy of Positive Behavioural Support with the Most Challenging Behaviour: The Evidence and its Implications.” *Journal of Intellectual & Developmental Disability*, 37(3):185–195, 2012.).

<sup>27</sup> See Final Rule, Fed. Reg. at 13,332.

<sup>28</sup> See *id.* at 13,332, 13,334.

<sup>29</sup> See *id.* at 13,335.

<sup>30</sup> See *id.* 13,335-36. In November 2019, JRC provided FDA with a lengthy summary of a long-term retrospective clinical analysis, which demonstrates that ESD treatment is quickly effective, produces dramatic results, and leads to lasting benefits. JRC followed 193 patients who received GED treatment between 2000 and 2019. These patients were tracked every minute of every day both before receiving GED treatment and while on GED treatment. The

“report a reduction in the target behavior ranging from a few months up to several years, particularly with continued (less frequent) ESD use.”<sup>31</sup> In fact, half of the Panel agreed that there was a benefit to the therapy.<sup>32</sup>

## B. Regulatory History<sup>33</sup>

ESDs have continuously been used by JRC since 1994 when they were cleared by the FDA through a 510(k) premarket notification<sup>34</sup>; that is, the device was found substantially equivalent to a predicate device. Then, in 2000, FDA concluded that JRC was entitled, in any event, to use the GED-3A and GED-4 devices because their use was exempted from regulation under the practice of medicine doctrine. However, in 2011 FDA changed its position without explanation, informing JRC that it now contended it had jurisdiction to regulate the devices, and that the two versions in use were sufficiently modified that they needed new 510(k) clearance. While JRC disagreed with FDA over the exemption issue, it worked extensively with FDA scientists with the goal of obtaining 510(k) clearance for two new devices.

Then, in March 2013, FDA suddenly shut down all communication. After years of relentless political pressure, and with the 510(k) process on the “one-inch line” of moving forward, FDA decided to terminate the 510(k) process altogether and, instead, propose to ban all ESDs used for SIB and AB under 21 U.S.C. § 360(f). The first step was a meeting on April 24, 2013, with a panel of outside persons chosen by FDA for the purpose (the aforementioned “Panel”). JRC was furnished with less than a month’s notice of the meeting and was allowed a total of 30 minutes to present its case; four parents of children with current GED treatment were given just three minutes each and a representative of the Parents’ Association was given four. Panel members were provided an extensive briefing document written by FDA, without any input from JRC. JRC did not see this lengthy document until it was posted on FDA’s website after the Panel meeting.

The Proposed Rule was issued on April 25, 2016.<sup>35</sup> After FDA granted an extension, JRC and the Parents were given 90 days to present comments. Both JRC and the Parents requested an evidentiary hearing, which was denied by FDA on June 3, 2016.

## C. Information and data produced or offered to FDA.

Throughout the period prior to the Proposed Rule, during the 90-day comment period, and until the promulgation of the Final Rule, Petitioners and JRC undertook to provide FDA with all of the information and access to all of the persons necessary for the Agency to make, first, the 510(k) decision, and thereafter to reconsider its proposed ban. Information submitted included:

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results are clear: the frequency SIB and AB dropped significantly. The introduction of GED treatment resulted in more than a ninety-seven percent reduction in SIB and AB after the first full month of GED treatment, followed by continued deceleration, and the reduction was durable, lasting for years.

<sup>31</sup> See Final Rule 85 Fed. Reg. at 13,333.

<sup>32</sup> See *id.* at 13,336.

<sup>33</sup> For a more detailed summary of the regulatory history, see JRC Petition at 13-64.

<sup>34</sup> See 21 U.S.C. § 360(k).

<sup>35</sup> See Proposed Ban, 81 Fed. Reg. at 24,413.

- Individual narrative patient case summaries for all JRC patients receiving GED treatment;
- Charts, graphs and spreadsheets showing overall patient summary data with GED and trends for patients since 2000;
- Findings of Fact and Orders from the Court;
- Most Recent Case Conference Reports for all GED Patients;
- Quarterly report of GED misapplications;
- Retrospective review of “complaints” related to GED<sup>36</sup>; and
- Manuals, policies and protocols.

The Parents also submitted accounts of their children’s experience with SIB and AB both before and after the GED was applied. The testimony of five parents of JRC patients receiving GED treatment from the Massachusetts trial, each reviewing his or her child’s history, was also submitted.

The documents submitted did not include the voluminous years of raw data maintained by JRC on each patient which undergirded both the individual summaries and the macro-level aggregation of data. JRC repeatedly made clear that all of this data and information was open to inspection by FDA. In particular, on numerous occasions,<sup>37</sup> JRC, on behalf of itself and the parents, invited FDA to review all of its data, observe application of GED treatment at the facility, meet the patients and parents, and otherwise access all of the personnel and documentation the Agency needed to see.<sup>38</sup>

In fact, JRC maintains an extraordinarily comprehensive trove of records concerning its GED patients,<sup>39</sup> all of which was open to FDA by invitation of JRC and, in any event, upon FDA’s request under 21 CFR § 895.2 (Submission of data and information by the manufacturer). This collection of records includes, for every patient:

- Medical records, including annual examination reports, psychiatric evaluations, ongoing nurses’ notes, and nursing body check sheets;
- Medical reports, notes and other documentation related to hospital and outside medical provider visits;
- Ongoing clinician notes;

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<sup>36</sup> These purported “complaints” were, in actuality, records JRC had willingly provided to FDA in November of 2011 documenting “[t]rouble reports” such as required recalibration, misplaced transmitters, and activation failures, all of which FDA’s scientific staff characterized as “underwhelm[ing].” See FOIA documents, CDRH\_Production\_4-008106, at Exhibit B to JRC Petition.

<sup>37</sup> See letters of January 16, 2013, February 1, 2013, May 14, 2013, August 7, 2018.

<sup>38</sup> These invitations were for FDA to make an unannounced visit.

<sup>39</sup> For many patients, the record spans decades and provides a complete account of the course of medical and behavioral treatment. The medical record is comprised of digital nursing notes, annual medical summaries, annual physical examinations, psychiatry notes, reports from specialists (neurology, cardiology, endocrinology etc.), laboratory results, vital signs, height, weight, sick visits, emergency room visits. JRC also requests records from hospitals, residential programs, day programs, and other providers that previously treated current JRC patients in order to form a complete record. In addition, nearly all JRC patients receiving treatment with ESDs had an independent neuropsychiatric evaluation within the last 3 years. See supporting declaration of Nathan Blenkush, Ph.D., BCBA-D, at Exhibit D to JRC’s Petition, at ¶ 50.

- Daily recording sheets, recording all behaviors, treatments, including every application of the GED and the targeted behavior that triggered the application, and impressions on the JRC patient throughout each day<sup>40</sup>;
- Incident reports;
- Communications with parents and funding agencies;
- Records received in connection with the patient’s admission from the funding agency (e.g., school district) and prior treatment programs;
- Treatment Team meeting notes;
- Educational and Vocational Evaluations and Assessments;
- Functional Behavior Assessments and Behavior Intervention Plans;
- Documentation of Treatment Program Changes; and
- Progress Reports prepared for the Court.

All of the offers of further information were declined or ignored.

#### **D. FDA’s Rejection of information submitted by JRC and parents as non-probative evidence**

Despite the evidence submitted by Petitioners and JRC that the GED causes immediate and long-term cessation or marked reduction of dangerous behaviors, FDA concludes, in the Final Rule, that “the risk of illness or injury posed by ESDs for SIB or AB is substantial and unreasonable.”<sup>41</sup> In coming to this conclusion, FDA finds that the evidence submitted by Petitioners and JRC did not establish, or even support, the effectiveness of the device, the absence of serious risks, or that the benefits outweighed the risk of harm. Specifically:

- As to effectiveness, FDA concludes that although the records submitted by Petitioners and JRC showed reductions of dangerous behaviors “in some individuals,” the results could not be “generalized” and did not support a finding of “durable” results because the data collection methodology did not control for “conflict of interest” or “bias” by JRC staff, because it did not exclude the possibility that other factors, such as concurrent therapies, were responsible for the favorable results; and because it “lack[ed] key details,” including adequate diagnostic assessments, time applied, specific behaviors targeted, triggering behaviors, frequency and duration of data collection, and the like.<sup>42</sup>
- As to risk, the FDA “believes” that it is “likely” that JRC underreports adverse events, since it had seen no indications that clinicians look for such instances.

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<sup>40</sup> To create its behavior charting database, JRC relies on recording sheets assigned to each patient, and carried by the staff member assigned to that patient. Each recording sheet is designed to record a 24-hour period of behaviors and other data for each patient, and as such, a new recording sheet is used every day. These recording sheets are used to document frequency counts of patient behaviors, and any GED applications. At the end of each day, a completed recording sheet is provided to the secretarial staff who input the data recorded by the staff member into the computer charting database, resulting in a database with the most up to date and accurate information on the behavior progress of each patient, each day. *See id.* at ¶ 51.

<sup>41</sup> See Final Rule, 85 Fed. Reg. at 13,313.

<sup>42</sup> *See id.* at 13,332-35.

Therefore, it says, the lack of any significant evidence of harm in the documents – including FDA’s own MDR database – does not prove that all sorts of harms do not in fact occur. Accordingly, FDA reasons, there is a risk that such harms actually do or might occur.<sup>43</sup>

- As to the balance of benefit and risk, FDA says the records submitted by Petitioners and JRC failed to document that other therapies, such as positive interventions and pharmacologic therapies, had been adequately tried, and therefore, Petitioners and JRC have not proven that such alternatives would not work in the case of any particular patient.<sup>44</sup> FDA finds that there are no risks of harm from positive behavioral supports,<sup>45</sup> and that although drugs do have serious side effects, those risks would always be outweighed by the risks of GED, since Petitioner and JRC have not proved the GED is effective.<sup>46</sup>

FDA makes no assessment of the harms that would take place if patients are removed from the GED, since it does not credit evidence that the GED prevents any harm. Further, the Parents’ information is dismissed as anecdotal and not scientific, and the Parents themselves are characterized as misinformed and possibly even “pressured.”<sup>47</sup>

## II. BASIS OF THE PETITION FOR STAY

### A. The Petition For Stay is Not Frivolous and is Being Pursued in Good Faith, and Indeed, Petitioners Have a Likelihood of Success on the Merits.

#### 1. The Final Rule Violates the APA

An agency action cannot stand if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law; . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; . . . [or] without proper observance of procedure required by law.” 5 U.S.C. ss. 706(2)(A)-(D). Here, Petitioners make a good faith argument – and, indeed, will be able to show – that the Ban violates the APA because it is not based on the objective assessment of “all available data and information” required by 21 U.S.C. § 360f(a); because FDA departed from past agency practices without explanation and was improperly influenced by political motivations; and because the Ban is enacted in bad faith.

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<sup>43</sup> See *id.* at 13,312, 13,322-24, 13,329-331.

<sup>44</sup> See *id.* at 13,339. See also, e.g.: “With regard to the use of positive interventions prior to ESD use, whether at JRC or before an individual was brought to JRC, the available data and information lack critical details necessary to assess whether those treatments were adequately or appropriately administered. For example, the documents do not provide detail on what specific therapies were attempted, how long they were tried, or that the effects were. We cannot determine from the JRC resident charts and summaries which, if any, treatments were tried prior to placements at JRC, *id.*; “[The information submitted] also cast doubt on JRC’s assertions that pharmacological alternatives were adequately attempted prior to GED use on individuals. For example, the resident summaries excluded information on dosage, regimen (e.g., how many, how often, and for what duration), and both positive and negative effects,” *id.*

<sup>45</sup> See Final Rule, 85 Fed. Reg. at 13,337.

<sup>46</sup> See *id.*

<sup>47</sup> See *id.* at 13,340.

Notably, and as set forth in more detail below, this case bears striking similarities to *Saget v. Trump*, 375 F. Supp. 3d 280 (E.D. N.Y. 2019), in which the Court considered then-Acting Secretary of Homeland Security Elaine C. Duke’s determination to terminate Haiti’s Temporary Protected Status (“TPS”) designation “based on her assessment that Haiti had sufficiently recovered from a 2010 earthquake and there were no longer ‘extraordinary and temporary conditions’ preventing Haitian nationals residing in the United States from safely returning to Haiti.” *Id.* at 295. The Court determined that the plaintiffs were likely to succeed on their claim that the decision to terminate Haiti’s TPS was not in accordance with the law because the Acting Secretary “did not conduct the periodic review in accordance with the dictates of the statute – her decision was preordained and pretextual, and it was made in part due to political influences.” *Id.* at 346. Moreover, it was “not purely evidence-based, as the statute requires. In fact, it ignored much of the evidence in the record.” *Id.* The Court acknowledged that while the Secretary “exercises discretion to make the determination she sees fit,” she must base that discretion on the statutorily-required factors. *Id.* at 347. The Court found significant evidence that, instead:

- The Secretary “reverse engineered the TPS review process to achieve a desired political outcome,” *id.*;
- The Secretary, in coordination with other agencies and officials, “undertook the TPS review process with the explicit goal of terminating TPS for Haiti,” *id.*, including emails from the Secretary stating that she “need[ed] to rationalize conflicting info” because “all agree[d] [TPS] must end,” *id.* at 348;
- “The manner in which the Secretary, DHS, and the Department of State undertook the review process . . . strongly suggests the decision was pretextual,” *id.* at 349, including evidence that:
  - “Defendants manipulated the facts in the record to gradually minimize, omit, or deem unrelated to the hurricane ‘negative’ information about Haiti,” *id.*, while “[p]ositive information, however tangential or isolated, became the sole focus and the stated basis for the decision,” *id.* at 350;
  - “Defendants changed their interpretation of the TPS statute,” *id.* at 349;
  - Defendants “intentionally edited” a critical memorandum “to support the case for termination,” *id.*, because it was “weighted for extension which [they did] not think [was] the conclusion [they were] looking for,” *id.* at 351;
  - “high-ranking officials directed staffers to uncover data they believed would weigh toward termination,” *id.* at 349, because

- they “‘want[ed] a stronger response beginning to build a case for not extending’ TPS to Haiti,” *id.* at 351; and
- the Department of State “conducted a ‘highly unusual’ process that departed from past practices,” *id.* at 349.

For largely the same reasons, the Court also found that plaintiffs were likely to succeed on their claim that the decision to terminate was arbitrary and capricious. *Id.* at 359 (Secretary’s decision arbitrary and capricious due to departure in agency practice), 360 (Secretary’s decision arbitrary and capricious due to political influence), 362 (decision to terminate was arbitrary and capricious because it was pretextual).

Similarly, in a case involving FDA, *Tummino v. Torti*, 603 F. Supp. 2d 519, 519 (E.D. N.Y. 2009), the Court held that FDA’s decisions concerning the availability, without age restrictions, of the emergency contraceptive known as “Plan B” were arbitrary and capricious because they were not the result of reasoned and good faith agency decision-making. Specifically, the Court agreed that, among other things, FDA “repeatedly and unreasonably delayed issuing a decision on Plan B for suspect reasons,” *id.* at 523; the decision was tainted by improper political influence, *id.*; and “FDA’s course of conduct departed in significant ways from the agency’s normal procedures” regarding similar “switch applications,” *id.* See also *id.* at 544.

The cases both illustrate why FDA’s actions with respect to the Ban violate the APA.

#### **a. The Rule is Not in Accordance with the Law**

Under 21 U.S.C. § 360f(a), in order to ban a device, FDA must first review “all available data and information” and find, by a preponderance of evidence, that “the device presents . . . an unreasonable and substantial risk of illness or injury” that cannot be corrected or eliminated by labeling changes. FDA has not complied with these obligations here: it has not made a review of all available evidence (including, but not limited to, evidence that Petitioners could provide in the form of interviews and other personal data going directly to the question of the benefits of ESDs for their children), thereby failing to support its case by a preponderance of evidence, and indeed, it has improperly reversed the burden, imposing it instead on Petitioners (and JRC) to prove that ESDs are beneficial.<sup>48</sup>

FDA’s entire approach to the Ban suffers from a fundamental flaw. It has adopted a rule which affects an exceedingly small group of persons: 53 JRC patients who currently receive the GED, plus those JRC residents who may need the therapy in the future. FDA is poised to take away from every one of these persons the only treatment that has ever successfully reduced or eliminated their painful and life-threatening behaviors, and to put them all at serious risk of harm – on the backwards theory that FDA is somehow protecting them from theoretical risks of harm that they have either not experienced or which, on balance, are far outweighed by the benefits provided to them by ESD treatment.

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<sup>48</sup> See, e.g., 85 Fed. Reg. at 13,322, 13,344-45; see also *id.* at 13,315, 13,319, 13,321-23, 13,326, 13,332-36.

Remarkably, FDA has made this decision even though it concedes that for some of these individuals, there “may simply [be] no” other “adequate treatment option[s].”<sup>49</sup> In other words, FDA has determined that theoretical risks trump real-world benefits. Moreover, it has made this determination without making an individual assessment of the history, diagnosis, condition, or prognosis of a single one of these persons. Indeed, in the six years FDA has taken to consider this rule, it has not seen fit to examine any of the patients presently being treated by the GED (the only individuals affected by the Ban). It has not seen any need – or had the decency – to interview any of the Parents. It has not spoken with any treating clinician. It has not reviewed the clinical treatment records of any individual patient who has received or is currently receiving GED treatment. It has never even observed the application of the GED, the very device it has now banned. Nor does the Agency claim that any of these 55 patients, their guardians, or their court-appointed counsel have informed FDA that they have suffered any adverse effects from GED treatment over the six years FDA has considered this rule.

How does FDA arrive at its conclusion, then? Its logic is this: JRC and Petitioners have not proven that the treatment is effective, because they have not shown that other factors are not responsible for their children’s transformative results at JRC, and because they have not shown that these life-changing results are sufficiently “durable.”<sup>50</sup> According to FDA, JRC and Petitioners have not proven that there are no serious risks associated with GED use, because FDA “believes” that JRC’s records – which do not reveal any significant harm to any of its patients – “underreport” adverse events.<sup>51</sup> Further, FDA claims JRC and Petitioners have not proven that the risks of GED are reasonable because their records do not show that adequate available alternative therapies were attempted, and that those therapies were not successful.<sup>52</sup>

JRC’s charts and its case summaries are deficient, FDA says, because the data was collected by conflicted and biased staff; because the documents lack details which would show whether proper assessments were made of the patients, or specifics about how the GED was applied, or that other treatments were adequately tried first (or if they were, the details of what they involved); or because the records do not establish that other concurrent therapies do not actually account for the favorable outcomes. At every turn, FDA equates an asserted inability to find some particular fact or detail in the documents JRC and Petitioners produced or offered to produce – which fact or detail could assure a lack of harm – with proof that a risk of harm must therefore exist. This is utterly inconsistent with the well-supported principle that “[t]he burden remains on the agency to show that risks associated with [the device] outweigh benefits and are, therefore, unreasonable.”<sup>53</sup>

FDA’s entire analysis is infected by its shifting of the burden of proof, premised upon the notion that the proponents of a device already cleared by FDA must prove its safety and effectiveness (and it is not up to FDA to prove the contrary). That proposition turns the law on its head. It is also important to note that this is not a case in which a manufacturer seeks approval for a new device which has never been authorized for human use and as to which it is entirely

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<sup>49</sup> See *id.* at 13,322.

<sup>50</sup> See *id.* at 13,336

<sup>51</sup> See *id.* at 13,320-21.

<sup>52</sup> See *id.* at 13,332.

<sup>53</sup> *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1039 (10th Cir. 2006).

proper to require the manufacturer to establish safety and effectiveness. Here, FDA has condoned the use of ESDs for 44 years and allowed JRC to use ESDs for 25 years, and has thus caused Petitioners to rely on it for the treatment of their children's otherwise unmanageable conditions. To ban a device which is currently in legal usage, FDA is required to shoulder the burden and it must do so based on a preponderance of the evidence, "the standard traditionally applied in administrative cases."<sup>54</sup> Indeed, since the day FDA originally promulgated the banning regulations in 1979, it has explicitly recognized that "[t]he agency is obligated to sustain the burden of proof and to provide substantial evidence to sustain its burden."<sup>55</sup>

Moreover, FDA rejects the value of Real World Evidence ("RWE") in the form of interviews with the Parents and clinicians or observations of the device's use because, according to FDA, nothing these persons could say, and nothing it might see at JRC, would remedy the purported factual deficiencies concerning the benefit of ESDs, and therefore no input from the only true stakeholders in this process could possibly overcome this absence of proof. Highly-educated Parents are said to be ill-informed or pressured, and the clinicians conflicted and therefore biased because they are, of course, associated with JRC.<sup>56</sup> These outright dismissals fly in the face of FDA's publicly-stated position that RWE is "not a thing that is 'nice to have,' it is a 'need to have.'"<sup>57</sup> Cf. *Tummino*, 603 F. Supp. 2d at 547 (FDA acted arbitrarily and capriciously when it "refus[ed] to extrapolate actual use study data from the older age group to the 16 and younger age group" where there is evidence FDA "routinely extrapolated such data when reviewing the safety and effectiveness of various other contraceptives").

FDA does not, and could not contend that individualized, real-world data about the benefits of ESDs for Petitioners would be irrelevant. Rather, it says that it already knows that this information does not contain the proof it seeks and therefore would not be useful. But the statute does not allow FDA to make *a priori* determinations that relevant information would not be productive and therefore may be ignored without examination. Rather, the law requires FDA to make its decision on the basis of all available data and information, which certainly means it must at least review relevant evidence before dismissing it. The failure here is all the more problematic where the information offered is the very type of information employed by medical practitioners to make treatment decisions. The FDA's refusal to consider that information on the basis of a pre-judged lack of value renders the Ban invalid as a matter of law.

Nor is it even true that the evidence that could be provided by the Parents, by patients themselves, or by clinicians, along with data found in individual patient records at JRC, would not be probative of the very facts FDA asserts are lacking. The Parents are not unintelligent, misinformed, or susceptible to pressure as to treatment choices for their children. They include, among other knowledgeable, capable and involved parents, a senior Harvard professor, a holder of two Pulitzer Prizes, and a medical doctor. They have spent their lives "in the weeds" of their children's treatment, forcefully insisting on care that would actually work to protect their

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<sup>54</sup> See *id.* at 1039-1040, 1041, 1041 n.6 (holding FDA to preponderance of evidence standard in determining whether dietary supplements present "a significant or unreasonable risk of illness or injury").

<sup>55</sup> See 44 Fed. Reg. 29,214, 29,218.

<sup>56</sup> See Final Rule, 85 Fed. Reg. at 13,340.

<sup>57</sup> See <https://www.ncbi.nlm.nih.gov/books/NBK540114/> (statement attributed to Dr. Jeffrey E. Shuren, director of the Center for Devices and Radiological Health at FDA).

children (and their children's caregivers and family members) from the many terrifying effects of SIB and AB. They are well-informed about their children's experiences and needs and are accurate historians about the myriad other treatments that have been tried and failed. They can relate in detail the harms their children suffered during and despite the use of these other treatments, including, specifically, the side-effects caused by other therapies such as powerful pharmacotherapies and ineffective positive-only interventions. They can describe just how the GED treatment changed their children's lives, how durable the changes have been, and whether there were any "adverse events" associated with ESD use, and they can explain, from actual experience, what will happen when their children are taken off of the device and returned to the prior status quo.

Nor may FDA assume that the Parents' children cannot themselves communicate their feelings. Most can in one way or another, and as to those that cannot easily do so, their response to application of the GED can be readily observed and understood by trained medical professionals.<sup>58</sup> FDA could monitor the devices in action and the measures taken to protect the safety of the patients, and its investigators could find out for themselves the nature and degree of pain caused by the device rather than accepting the subjective characterizations made by confirmed opponents of the treatment. In fact, several patients have begun GED treatment during the last six years while FDA considered the Ban; FDA could well have accepted JRC's invitation to observe, or, on its own, requested data about their courses of treatment from inception pursuant to their authority under 21 CFR § 895.2.

The clinicians treating JRC's patients are committed professionals who, for example, can shed enormous light on the assessments they have made, and why and how they can determine that addition of the GED was responsible for an ensuing reduction of behavior rather than something else. They can explain how they monitor their patients for adverse effects. The detailed clinician notes, daily recording sheets and many other forms of data kept by JRC concerning these patients – all made available for FDA's inspection – would likewise show, in any and every individual case, the basis for assessments, the extent and context of favorable outcomes, and the non-existence of adverse effects. Further, the records from prior institutions document, in the very detail FDA seeks, what therapies were tried with the Parents' children before they were admitted to JRC.

These are not the only reasons the Ban is not in accordance with the law, however. As the record clearly demonstrates, instead of adhering to its statutorily-required duty to obtain and consider all available data as to whether a device should be banned as creating an unreasonable risk, FDA embarked on a calculated campaign designed to reach a particular result, and did so at least in part because of political and other outside influences. There is evidence that, in order to get to this result, FDA did exactly what the Secretary did in *Saget*, and which the Court said likely violated the APA:

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<sup>58</sup> See JRC Petition, Exhibit I (Declaration of James R. Miner, M.D.), ¶ 38 ("As I have experienced in my practice and research, there are common ways to assess pain experienced by patients, even if the patient cannot express it verbally. These methods include assessing the patient for agitation or cringing in response to a painful treatment or procedure, or other physical reactions or non-verbal cues which are easy to pick up on."); see also JRC Comment, comment identifier FDA\_2016-N-1111-1637 (July 25, 2016), Att. 18-1, at A009120.

- FDA, “in coordination with other agencies and officials,” undertook the process “with the explicit goal” of banning JRC from using GEDs on Petitioners (*see, e.g.*, JRC Petition at pp. 17-21, 25-37, 38<sup>59</sup>, 44-48, 54-61, 63);
- FDA “manipulated the facts in the record to gradually minimize, omit, or deem unrelated” the evidence JRC and Petitioners submitted proving that GEDs are highly effective in treating the most severe cases of SIB and AB, without significant risks to the health or well-being of the people on whom they are used, as well as FDA’s own research into the safety and effectiveness of the GED, which did not demonstrate the conclusion FDA now reaches, i.e., that the risks outweigh the benefits (*see, e.g.*, JRC Petition at pp. 21-23, 39-41, 42-43, 46-51, 58-59, 61-62);
- FDA cherry-picked from data and omitted or whitewashed data the agency itself had obtained in order “to support the case” that the risks associated with GEDs did not outweigh the benefits because that data did not “support the case” FDA was making (*see, e.g.*, JRC Petition at pp. 22-23, 39-41, 42-43, 46-51);
- FDA and other government officials “directed staffers to uncover data they believed would weigh toward” a ban (*see, e.g.*, JRC Petition at 32<sup>60</sup>, 47<sup>61</sup>, 51<sup>62</sup>, 59<sup>63</sup>); and
- FDA “conducted a ‘highly unusual’ process that departed from past practices” (*see, e.g.*, JRC Petition at pp. 39<sup>64</sup>-42).

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<sup>59</sup> FDA’s Chief Counsel and other “key officials” met with NCD and actively encouraged NCD to consider filing a Citizen Petition to request that FDA ban JRC’s GED and to be in direct contact with FDA. *See* FOIA documents, CDRH\_Production\_5-006204, at Exhibit B to JRC Petition.

<sup>60</sup> “[T]o get an injunction we’ll likely need to convince a judge that continued use . . . of these devices would do more harm than good, so the more [anecdotal stories] we have from . . . patients to support this position and counter JRC’s success stories the better.” *See* FOIA documents, CDRH\_Production 9-004201, at Exhibit B to JRC Petition.

<sup>61</sup> Ms. Howard wrote to the Acting Commissioner, explaining that that OCC was “concern[ed] about legal vulnerability”, and that CDRH “want[ed] to work with HHS to see if they can help . . . fill in some gaps that might make [FDA’s] case stronger.” *See* FOIA documents, CDRH\_Production 7-009558, at Exhibit B to JRC Petition.

<sup>62</sup> The day after Mr. Amatrudo learned that FDA could not credibly assert that seizures are a risk of ESDs, he recommended that FDA consider relying on the scientific literature about the pain from shocks by implantable cardioverter defibrillators (“ICDs”) causing acute stress disorder (“ASD”) and posttraumatic stress disorder (“PTSD”)<sup>62</sup>, in the hope that this research “might correlate with the ESDs we want to ban.” *See* FOIA documents, CDRH\_Production 9-006515 (emphasis added), at Exhibit B to JRC Petition.

<sup>63</sup> CDRH’s scientific staff met with OCC’s lawyers for “guidance on how to beef up the record” to support FDA’s foregone conclusion concerning “JRC.” *See* FOIA documents, CDRH\_Production 7-009124, at Exhibit B to JRC Petition.

<sup>64</sup> FDA’s scientific staff admitted the Panel Meeting was “very atypical” in every way. *See* FOIA documents, CDRH\_Production 6-006546, at Exhibit B; *see also* FOIA documents, CDRH\_Production 6-006415 (agreeing that the Panel Meeting was “unusual . . . in so many ways”), at Exhibit B to JRC Petition.

Just like the decision to terminate in *Saget*, then, the Ban is clearly not in accordance with the law.

### **b. The Rule is Arbitrary and Capricious**

An agency decision will be set aside as arbitrary and capricious if the agency “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 465 U.S. 29, 43 (1983).

#### **i. FDA Failed to Consider All Available Data and Evidence and Articulate Satisfactory Explanation**

“Ultimately, ‘the agency must examine the relevant data and articulate a satisfactory explanation between the facts found and the choice made.’” *Saget, supra*, at 353, quoting *Motor Vehicle Mfrs. Ass’n, supra* (additional citation omitted). As previously noted, under 21 U.S.C. § 360f(a), in order to ban a device, FDA must first review “all available data and information” and find, by a preponderance of evidence, that “the device presents . . . an unreasonable and substantial risk of illness or injury” that cannot be corrected or eliminated by labeling changes.

As set forth in detail above (*see* section II(A)(1)(a), *supra*), FDA utterly failed in its duty to review “all available data and information,” and in fact, declined multiple invitations to collect highly relevant data related to Petitioners’ success stories. Just as this failure violates the APA because it is not in accordance with the law, so, too, does it violate the APA because it is arbitrary and capricious.

#### **ii. FDA Departed from Agency Practices**

“An agency cannot simply disregard inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate.” *Saget, supra*, at 353-354, quoting *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009) (Kennedy, J., concurring). “When an agency changes course, it must ‘provide a reasoned explanation for its action . . . .’” *Id.* at 354, quoting *Fox, supra*, at 515. Thus, agency action is considered arbitrary and capricious when it “departs from prior policy” without such an explanation. *Id.*, citing *Encino Motorcars, LLC v. Navarro*, -- U.S. --, 136 S. Ct. 2117, 2126 (2016) (noting an “unexplained inconsistency in agency policy is reason for holding an interpretation to be an arbitrary and capricious change from agency practice” (internal quotation marks, citation, and modifications omitted)). Further, the agency must “show that there are good reasons for the new policy.” *Id.*, quoting *Fox, supra*. “This requirement is not limited to formal rules or official policies and applies equally to practices implied from agency conduct.” *Id.* at 355.

Here, the record demonstrates<sup>65</sup> that as early as the 1970s, FDA recognized that the scientific evidence proved that ESDs safely and effectively treat SIB and AB. In 1979, FDA categorized aversive conditioning devices (“ACDs”), including ESDs, as Class II medical devices.<sup>66</sup> FDA never promulgated any performance standard specific to ESDs, including any performance standard concerning any purported potential psychological adverse effects associated with ESDs. Over the next two decades, FDA cleared numerous ESDs from multiple manufacturers<sup>67</sup> after determining that such devices were at least as safe and effective as the predicate ACDs initially categorized as Class II devices.<sup>68</sup>

FDA cleared JRC’s original GED device in 1994 (K911820).<sup>69</sup> JRC began treating its patients with the GED-4, a stronger version of the original FDA-cleared GED device, by 1992,<sup>70</sup> and with the GED-3A, a more reliable version of the original FDA-cleared GED device,<sup>71</sup> by 2000.<sup>72</sup> In January and February of 2000, based on its first-hand observations during a thorough inspection of JRC,<sup>73</sup> FDA determined that these GED devices were safe. Furthermore, FDA informed JRC that JRC was exempt from establishment registration requirements pursuant to 21 C.F.R. § 807.65(d), and that the GED-3A and GED-4 were exempt from the premarket notification requirements pursuant to the practice of medicine exception at 21 C.F.R. § 807.85.<sup>74</sup> FDA repeated this determination to NYSED in 2006<sup>75</sup> and in the Health Risk Assessment that it prepared after its 2010 inspection, in which it found only a “[r]emote [p]robability” of “serious adverse health consequences.”<sup>76</sup>

Without explanation or justification, FDA, in enacting the Ban, reversed its long-held positions and incorrectly concluded that it has jurisdiction over JRC and the GED devices, and that the GED devices are unsafe and ineffective. Nowhere in the Final Rule does FDA contend with this about-face. Its failure to do so renders the Final Rule arbitrary and capricious. *See Saget, supra*, at 359. *Cf. American Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017) (Forest Service’s unexplained change in its “longstanding practice” of treating certain land as if it were part of the Wild Horse Territory was arbitrary and capricious, in part because it failed to acknowledge or explain its reversal in course).

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<sup>65</sup> For a more detailed explanation of FDA’s treatment of ESDs, *see* JRC’s Petition at pp. 53-82.

<sup>66</sup> *See Neurological Devices; Classification of Aversive Conditioning Devices*, 44 Fed. Reg. 51,726, 51,765 (Sept. 4, 1979); *Aversive Conditioning Device*, 21 C.F.R. § 882.5235 (1979) (defining an aversive conditioning device as “an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics”).

<sup>67</sup> *See* FOIA documents, CDRH\_Production\_2-000153 (indicating that there are at least five ESD manufacturers), at Exhibit B to JRC Petition.

<sup>68</sup> *See* Proposed Ban, 81 Fed. Reg., at 24,391.

<sup>69</sup> *See id.*

<sup>70</sup> *See Judge Rotenberg Educ. Ctr., Inc. v. Comm’r of the Dep’t of Mental Retardation (No. 1)*, 424 Mass. 430, 436 (1997).

<sup>71</sup> *See* FOIA documents, NWE-DO&DFOI00040, at Exhibit B to JRC Petition.

<sup>72</sup> *See* FOIA documents, NWE-DO&DFOI00059, at Exhibit B to JRC Petition.

<sup>73</sup> *See* FOIA documents, NWE-DO&DFOI00058, at Exhibit B to JRC Petition.

<sup>74</sup> *See* FOIA documents, NWE-DO&DFOI00060, at Exhibit B to JRC Petition; *see also* FOIA documents, JRC OES Supplemental 1 000007, at Exhibit B to JRC Petition.

<sup>75</sup> *See* JRC Comment, JRC Responses to Allegation in NYSED June 9, 2006 Report, Docket No. FDA-2016-N-1111, Exh. 17 (July 25, 2016).

<sup>76</sup> *See* FOIA documents, CDRH\_Production\_2-000480-CDRH\_Production\_2-000489, at Exhibit B to JRC Petition.

### **iii. The Rule was Prompted by Improper Political Influence**

“Agency action may also be arbitrary and capricious when the action is the product of bad faith and improper political influence.” *Saget, supra*, at 354, citing *Tummino*, 603 F. Supp. 2d at 544-545. “To support a claim of improper political influence on a federal administrative agency, there must be some showing that the political pressure was intended to and did cause the agency’s action to be influenced by factors not relevant under the controlling statute.” *Id.* at 359, quoting *Town of Orangetown v. Ruckelshaus*, 740 F.2d 185, 188 (2d Cir. 1984).

The record in this matter is replete with evidence of a lengthy and coordinated campaign waged by a number of entities, including other government agencies and officials, to pressure FDA to target JRC and its GED devices.<sup>77</sup> In fact, the significant shift in FDA’s position on ESDs was, in FDA’s own words, precipitated by “outside inquiries” specifically targeting JRC and its GED devices.<sup>78</sup> Bookending this change, FDA announced the Final Ban on the day before its deadline to report on its progress in finalizing the Proposed Ban to several U.S. Senators, one of whom had expressly discussed the issue on and off the record with the newly-appointed Commissioner in connection with his recent confirmation hearing.

The fact that FDA also considered relevant factors in addition to the biased and skewed information with which it was inundated by sources outside the agency is of no moment: “An agency’s consideration of some relevant factors does not ‘immunize’ the decision; it would still be invalid if based in whole or in part on the pressures emanating from [political actors].” *Id.*, quoting *Tummino, supra*, at 544 (internal quotation marks and additional citation omitted). Indeed, “[e]ven if the [agency] had taken every formal step required by every applicable statutory provision, reversal would be required . . . [where] extraneous pressure intruded into the calculus of considerations on which the [agency’s] decision was based.” *Id.*, quoting *D.C. Fed’n of Civic Assocs. v. Volpe*, 459 F.2d 1231, 1245-1246 (D.C. Cir. 1971). That is, of course, precisely what occurred here.

The Ban is arbitrary and capricious for this reason as well. Cf. *Tummino, supra*, at 546 (FDA’s decision that unrestricted OTC access to Plan B could not be approved, based in part on pressure from White House and “constituents who would be very unhappy with . . . an over-the-counter Plan B,” was arbitrary and capricious).

## **2. FDA’s Refusal to Allow an Evidentiary Hearing as Requested by Petitioners and JRC Violated Their Rights to Due Process.**

21 C.F.R § 16.60 (“Rule 16”) provides the Commissioner, when considering “any regulatory action . . . to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.” The request of JRC and Petitioners to hold such a hearing was denied. That denial was an abuse of discretion and arbitrary and capricious because it denied Petitioners their rights to due process of law.

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<sup>77</sup> For a more complete summary of the record in this regard, see JRC Petition at pp. 17-21, 25-37, 38, 44-48, 54-61, 63.

<sup>78</sup> See FOIA documents, ORA000228, at Exhibit B to JRC Petition.

“The Due Process Clause of the Fifth Amendment was intended to secure the individual from arbitrary exercises of governmental power.” *ABA, Inc. v. District of Columbia*, 40 F. Supp. 3d 153, 165 (D. D.C. 2014), citing *Daniels v. Williams*, 474 U.S. 327, 330 (1986). Where a party has a protected interest in life, liberty or property, the government cannot knowingly deprive the party of that interest without notice and an opportunity to be heard “at a meaningful time and in a meaningful manner.” *Id.*, quoting *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). *See also Cleveland Board of Education v. Loudermill*, 470 U.S. 532, 542 (1985). What process is due depends upon a balancing of the following factors: 1) the private interest affected; 2) the risk of an erroneous deprivation through the procedures used; 3) the probable value of additional or substitute procedural safeguards; and 4) the government’s interest, including the burden of a hearing. *Id.*, citing *Mathews*, 424 U.S. at 335. Put another way, “to make out a violation of due process, the [affected party] must show the Government deprived [it] of a liberty or property interest to which [it] had a legitimate claim of entitlement, and that the procedures attendant upon that deprivation were constitutionally [in]sufficient.” *Id.* (internal quotation marks and citations omitted).

#### a. Petitioners’ Protected Interests

Here, Petitioners – both the patients and their parents – undoubtedly have a liberty interest in choosing medical treatment absent an overriding interest of the state in denying them that treatment. *See, e.g., Parham v. J.R.*, 442 U.S. 584, 602 (1979) (parents generally “have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations,” which “surely” includes a duty to “recognize symptoms of illness and to seek and follow medical advice” (internal quotation marks and citations omitted); *Emrik v. Chemung Cray Dep’t of Social Servs.*, 911 F.2d 863, 867 (2d Cir. 1990) (“the constitutional liberty interest of parents . . . though not beyond limitation . . . includes a significant decision-making role concerning medical procedures sought to be undertaken . . . upon their children”); *Estate of Bailey by Oare v. York County*, 768 F.2d 503, 509 n.7 (3d Cir. 1985) (parent has “cognizable liberty interest in preserving the life and physical safety of his child from deprivations caused by state action, a right that logically extends from his recognized liberty interest in the custody of his children and the maintenance and integrity of the family”) (abrogated on other grounds, *DeShaney v. Winnebago County Dept. of Social Services*, 489 U.S. 189 (1989)).

Furthermore, Petitioners have a “legitimate claim of entitlement” to GED use which has been recognized for the past 29 years by the very agency that now seeks to strip away that entitlement. *See Alaska Airlines, Inc. v. C.A.B.*, 545 F.2d 194, 199-200 (D.C. Cir. 1976) (airline had “claim of entitlement” to exemption allowing it to operate charters without limitation in Alaska, which Board itself granted, and which ASA relied upon). Cf. *Perry v. Sindermann*, 408 U.S. 593, 601 (1972) (a person’s interest in a benefit is a property interest for due process purposes if there are such rules or mutually explicit understandings that support his claim of entitlement to the benefit”).

Given these protected interests, Petitioners were entitled to sufficient procedures before being deprived of life-saving treatment.

## b. What Process Was Due

“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)).

Although FDA denies that it engaged in adjudication here, the Ban at issue 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). It is undisputed that JRC is the only facility in the United States to manufacture or use ESDs to treat SIB or AB in recent years and JRC, its residents, and their families are the only individuals that will be affected by the Ban.<sup>79</sup> Beyond that, however, there is ample evidence that FDA purposely targeted JRC and understood that its actions with respect to the Rule were adversarial, rather than neutral, in nature. For example, FDA officials have referred to the Rule as the “JRC banning regulation”<sup>80</sup> and the “JRC ban rule.”<sup>81</sup> When an expert FDA retained concluded that ESD “should be restricted but not banned”<sup>82</sup> because their use “reduces or eliminates severe SIB and [AB],”<sup>83</sup> FDA – increasingly “concern[ed] about legal vulnerability” – sought help from HHS to “see if they can help . . . fill in some gaps that might make [FDA’s] case stronger.”<sup>84</sup>

An evidentiary hearing was thus the *only* way to resolve the myriad factual disputes at issue involving this single entity.<sup>85</sup> As the D.C. Circuit has explained, “an oral hearing provides a

<sup>79</sup> E.g., 81 FR 24386 at 24389, 24411 (“ESDs are only used at one facility in the United States with individuals from a small number of States.”), 24413 (“We expect the proposed rule would only affect one entity that currently uses these devices to treat residents of their facility.”). *Accord* 85 FR 13312 at 13313, 13314, 13315, 13349.

<sup>80</sup> See FOIA documents, CDRH\_Production 2-006959, at Exhibit B to JRC Petition.

<sup>81</sup> See FOIA documents, CDRH\_Production 9-006521, CDRH\_Production\_9-006523, at Exhibit B to JRC Petition.

<sup>82</sup> See FOIA documents, CDRH\_Production 6-007775, at Exhibit B to JRC Petition.

<sup>83</sup> See FOIA documents, CDRH\_Production 6-007776-CDRH\_Production 6-007777, at Exhibit B to JRC Petition.

<sup>84</sup> See FOIA documents, CDRH\_Production 7-009558, at Exhibit B to JRC Petition.

<sup>85</sup> *Alaska Airlines* is illustrative. There, 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, intrastate, and charter operations). 545 F.2d 196-197, 198. The Court held that where the “nature of [the] administrative proceeding” did not just involve interpretation of an exemption, but also centered on specific facts concerning the specific entities, it “took on more than an interpretive character, becoming basically adjudicatory and centering on the operations of ASA.” *Id.* at 200. Importantly, even though CAB claimed the proceeding “concerned a class of carriers of which ASA happened to be the only member, the concern of the Board with ASA’s particular operation . . . indicates that the Board was dealing with ASA individually and not in a class context.” *Id.* at 201. “Therefore,” said the Court, “the Board should have provided the parties a hearing to allow them to present and refute evidence concerning the charter operations.” *Id.*

way to ensure accuracy when facts are in dispute, especially if credibility is an issue.” *Gray Panthers v. Schuelke*, 652 F.2d 146, 161 (D.C. Cir. 1980). Furthermore,

[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.

*Id.* at 161-162.

Oral hearings serve another important purpose, too: they “ensure that decisionmakers recognize that their decisions affect the lives of human beings, a fact that is often obscured by a jumble of papers and depersonalized [information].” *Id.* at 169. Here, of course, the human beings in question number just 55, and, as FDA takes great pains to point out, they often cannot speak for themselves. Yet their voices can still be heard through their parents, who have loved them, cared for them, and advocated for them, in some cases for decades, in order to give them the best lives possible under what can only be described as tragic circumstances. Indeed, Petitioners are in many ways far better situated than any other interested party to speak to the benefits of ESDs and how they have truly transformed the lives of their children.

A regulatory hearing under Rule 16 would have provided the essentials of due process. FDA would have been obliged to provide, at the outset, “a full and compete statement of the action which is the subject of the hearing, together with the information and reasons supporting it.”<sup>86</sup> Then, JRC and Petitioners would have then been able to “present any oral or written information relevant to the hearing” and “confront and conduct reasonable cross-examination” of any person presenting FDA’s proffered information and reasoning.<sup>87</sup> Thus, a hearing would have ensured Petitioners the opportunity to, at a minimum:

- Provide individualized evidence concerning their children’s experiences and needs; the myriad other treatments that have been tried and failed; the harms their children suffered during and despite the use of these other treatments, including, specifically, the side-effects caused by other therapies such as powerful drugs; how the GED treatment has changed their children’s lives; how durable the changes have been; and whether there were any “adverse events” associated with ESD use.
- Contest and rebut the evidence relied on by FDA concerning the purported “risks” of GED use.
- Respond specifically to claims that their submissions lack adequate information.

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<sup>86</sup> 21 C.F.R § 16.60(b).

<sup>87</sup> See *id.*

- Present evidence of immediate harm which would be caused by removal of device.

Furthermore Rule 16 requires that the decision be made on the administrative record compiled at the hearing; that the presiding officer be free from bias or prejudice; and generally excludes those who have had prior participation in the investigation of the matter from acting as the fact-finder.<sup>88</sup> These procedural guarantees would have been important in mitigating the effects of the demonstrated long-term and intensive campaign by outside parties and agencies vying for FDA to take action against JRC and its GED devices.

FDA's treatment of the Massachusetts Probate Court case also clearly demonstrates the need for an evidentiary hearing.<sup>89</sup> The claims made by the Massachusetts agency (DDS) as to the alleged ineffectiveness and harmfulness of the GED were identical to those made by the FDA (and, indeed, apparently made in close cooperation with the FDA and other federal departments<sup>90</sup>), but did not withstand the scrutiny of an evidentiary hearing where the proponent bore the burden of proof and its evidence was subject to cross-examination and rebuttal. Here, FDA makes selective use of the plaintiff's evidence in that case, leaving out all of the ways that this evidence was disproven, belied or called into question and making it appear that the evidence actually supported DDS's – and therefore FDA's – assertions.<sup>91</sup>

## B. Irreparable Injury<sup>92</sup>

Petitioners<sup>93</sup> will suffer irreparable harm if FDA does not stay the Ban. Indeed, this case presents an exceptional case for entry of a stay because there is a personal, physical irreparable injury element to FDA's Ban, which distinguishes this case from others routinely presented to FDA. As set forth herein, if the Ban on ESDs is not stayed, the very lives and physical safety of JRC's patients and others (including guardians, families and caretakers) will be placed in immediate danger.

As the declarations attached to JRC's Petition<sup>94</sup> establish, any effort by FDA to prohibit access by JRC's patients to ESD treatment with GED devices will likely result in a return of the patients' self-destructive and violent behaviors, and could require near-constant physical, mechanical and chemical restraint as the only means to attempt to stop them from killing or maiming themselves and hurting those around them. In addition to these obvious health and safety concerns, a forced cessation of GED treatment will result in the loss, possibly forever, of

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<sup>88</sup> See *id.* at §§ 16.42, 16.80.

<sup>89</sup> For a more detailed explanation of the Massachusetts Probate Court case, see JRC's Petition at pp. 69-70.

<sup>90</sup> See *id.*

<sup>91</sup> In fact, FDA appears to credit live testimony it never heard, see Final Rule, 85 Fed. Reg. at 13,336, 13,349, which flies in the face of well-accepted legal principles.

<sup>92</sup> For a more detailed description of the deleterious effects a ban would have on this extremely vulnerable population, see JRC Petition at 96-115.

<sup>93</sup> Pursuant to 21 C.F.R. § 10.20(c)(4), in this publicly available Petition, JRC's patients are referenced by their initials, and not their full names, in order to protect those individuals from an unwarranted invasion of personal privacy.

<sup>94</sup> See Exhibits D-I to JRC Petition.

the significant educational and behavioral progress, independent living skills and vocational progress, and community integration thus far enjoyed by those individuals at JRC.

Following are descriptions of ten representative individual JRC residents who will be specifically impacted by the Ban and face irreparable harm if a stay is not entered. These descriptions are supported by the sworn declarations of medical and psychological experts with decades of combined experience treating residents of JRC.<sup>95</sup>

#### **1. G.A. and Evidence Why Any Forced Transition Will Cause G.A. Irreparable Harm.**

G.A. is a 23-year-old male with an intellectual disability, autism spectrum disorder, and a severe behavior disorder with a long history of engaging in extreme and repeated SIB and AB. Multiple well-respected special education programs, day programs, residential programs, and psychiatric facilities attempted, and failed, to inhibit G.A.'s SIB and AB with non-intrusive ABA interventions and medications. G.A. was also placed on a variety of potent medications and suffered from numerous side effects, including, sedation, agitation, and a possible disinhibition effect associated with flurazepam, haloperidol, Zyrtec, and clonazepam, respectively. He also experienced priapism as a result of clozapine. G.A. was admitted to JRC on November 29, 2016, at the age of 20. With the failure of these other means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to supplement G.A.'s behavior modification treatment plan with aversive interventions, including the GED devices. The GED treatment had an immediate and dramatic impact on G.A.'s SIB and AB, with both dropping to near-zero levels. G.A. has also been successfully tapered off all psychotropic medications. As a result of the decline in his problematic behaviors, G.A. is now a happy and productive individual engaged in his community. The Ban and any attempt to transition G.A. off his current treatment program including GED treatment will cause G.A. grievous and irreversible harm. G.A. would be at imminent risk of physical and emotional harm, including lacerations, broken bones, rhabdomyolysis, abrasions, and other injuries associated with his SIB and AB. G.A.'s injurious behavior will return, including head banging, resulting in additional subconcussive head trauma. G.A. will likely require significant restraint and isolation, denying him safe access to his family and the community, and exposing him to dangerous side-effects and risks associated with restraint. A return to psychopharmacological interventions along with other ineffective treatments would also subject G.A. to potentially serious and detrimental side effects such as sedation, agitation, a possible disinhibition effect, and priapism, while providing little, if any, benefit to him.<sup>96</sup>

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<sup>95</sup> See declarations of Miles Cunningham, M.D., Ph.D., Edward Sassaman, M.D., Nathan Blenkush, Ph.D., BCBA-D, Robert von Heyn, Ph.D., BCBA-D, LABA, and Dawn O'Neill, Ph.D., BCBA-D attached as Exhibits D–H to JRC Petition.

<sup>96</sup> See generally, Declaration of Nathan A. Blenkush, Ph.D. included in DVD as Exhibit D to JRC Petition; Declaration of Miles G. Cunningham, M.D., Ph.D included in DVD as Exhibit E to JRC Petition; Declaration of Edward A. Sassaman, M.D. included in DVD as Exhibit H to JRC Petition.

**2. J.C. and Evidence Why Any Forced Transition Will Cause J.C. Irreparable Harm.**

J.C. is a 23-year-old male from New York with an intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by extreme and repeated SIB and AB. Prior to admission to JRC, J.C. attended multiple well-respected day programs, including the Stepping Stone Learning Center and Mary Cariola's Children's Center. All of these prior facilities attempted, and failed, to inhibit J.C.'s SIB and AB with non-intrusive ABA interventions and medications. Despite these interventions, J.C. required a protective helmet and emergency restraint up to twelve times a day. During this time, J.C. was also placed on a variety of potent medications, including benzotropine, chlorpromazine, risperidone, doxepin, clonazepam, lorazepam, propranolol, divalproex, and benadryl. On February 10, 2015, J.C. was admitted to JRC at the age of 18, severely sedated and unable to stand without assistance, drooling, and his eyes were rolled back in his head from a wide range of prescribed medications. JRC immediately sent J.C. to the emergency room, where medication dosages were determined to be too high and reduced. With the failure of these other means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to supplement J.C.'s behavior modification treatment plan with aversive interventions, including the GED devices. The GED treatment had an immediate and dramatic impact on SIB and AB, allowing him to progress academically and socially. Furthermore, J.C. no longer requires the constant use of a helmet or physical restraints, and he was successfully tapered off of all psychotropic medications. J.C. has transformed and is now a happy and productive individual. The Ban and any attempt to transition J.C. off his current treatment program including GED treatment will cause J.C. grievous and irreversible harm. J.C. would be at imminent risk of physical and emotional harm, including the risk of death, immediately upon the commencement of any forced transition. J.C.'s SIB and AB would reemerge. J.C.'s head banging would return, thereby risking permanent injuries, including the complete loss of sight and permanent hearing loss, as well as subconcussive head trauma. J.C. will likely require significant restraint and isolation, denying him safe access to his family and the community. A return to psychopharmacological interventions along with other ineffective treatments would also subject J.C. to potentially serious and detrimental side effects while providing little, if any, benefit to him.<sup>97</sup>

**3. M.D. and Evidence Why Any Forced Transition Will Cause M.D. Irreparable Harm.**

M.D. is a 34-year-old male from New York with an intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by extreme and repeated SIB and AB. Multiple nationally-known and well-respected psychiatric hospitals, day programs, and residential treatment programs, including Bellevue Hospital and the Anderson School, attempted, and failed, to inhibit M.D.'s severe SIB and AB with positive non-intrusive ABA interventions and medications. During this time, M.D. was also placed on a variety of potent medications, including Haldol, Klonopin, Zyprexa, Dexedrine, Orap, Thorazine, Risperdal, Depakote, Clonidine, Benadryl, Zoloft, Cogentin and Luvox, and PRNs of Thorazine and Trazadone. M.D. suffered serious side effects from his medications, including tremors, drooling, increased sedation, and neuroleptic malignant syndrome. On December 9, 2004, M.D. was admitted to JRC

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<sup>97</sup> See generally Exhibits D, E, and H to JRC Petition.

at the age of 19. With the failure of these other means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to supplement M.D.'s behavior modification treatment plan with aversive interventions, including the GED devices. By incorporating aversive interventions, M.D.'s SIB and AB dramatically decreased to near-zero levels. M.D.'s behavior has not required the use of emergency physical restraint in 15 years or mechanical waist restraint in over 10 years. Additionally, M.D. has been psychotropic medication-free for over 15 years. M.D. has transformed since receiving treatment with the GED devices and is now a happy, more independent, and productive individual. The Ban and any attempt to transition M.D. off his current treatment program including GED treatment will cause M.D. grievous and irreversible harm. M.D. would be denied his right to the most effective and least restrictive treatment for his SIB and AB and would be at risk of physical and emotional harm, including death while putting care providers at risk of severe injury. M.D. will likely require significant restraint and isolation, denying him safe access to his family and the community. A return to psychopharmacological interventions along with other ineffective treatments would also subject M.D. to potentially serious and detrimental side effects while providing little, if any, benefit to him.<sup>98</sup>

#### **4. E.L. and Evidence Why Any Forced Transition Will Cause E.L. Irreparable Harm.**

E.L. is a 51-year-old man with a severe intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by extreme and repeated SIB and AB. Prior to admission to JRC, E.L. underwent treatment at a number of day programs, residential programs, hospitals, and psychiatric units. Despite significant effort, all of these facilities attempted, and failed, to inhibit E.L.'s severe SIB and AB with less intrusive treatments. Additionally, E.L. was prescribed a variety of potent medications, including Ritalin, Haldol, Thorazine, chloral hydrate, Dilantin, Valproic acid, Mellaril, Elavil, and flurazepam, resulting in negative side effects ranging from intensified aggression to gastrointestinal distress. After the local school district determined it could not meet E.L.'s behavior treatment needs, E.L. was admitted to JRC on December 10, 1987, at the age of 19. JRC sought and received permission from the Massachusetts Probate and Family Court to add the GED devices to E.L.'s behavioral treatment plan. Following the implementation of the device, E.L.'s behavior improved dramatically, reducing instances of violent and destructive behavior to zero and near-zero levels, and he was successfully tapered off all psychotropic medications. Unfortunately, despite this progress, the local school district transferred E.L. out of JRC and into an alternative residential program at Melmark in Pennsylvania on June 14, 2013. Almost immediately after arrival at Melmark, E.L. reverted to his previously dangerous behavior, attacking staff and harming himself and requiring the reintroduction of physical restraints and psychotropic medications. After a successful lawsuit against the local school district by E.L.'s guardians, E.L. was readmitted to JRC on January 30, 2018. JRC is now seeking permission from the Massachusetts Probate and Family Court to re-introduce aversive interventions, including the GED devices, to E.L.'s behavior modification treatment plan. The Ban will deny E.L. the re-introduction of the GED treatment into his treatment program, which will cause E.L. grievous and irreversible harm – just as it did with his first removal from the JRC. E.L.'s SIB and AB will continue, causing E.L. severe pain and

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<sup>98</sup> See generally Declaration of Dawn O'Neill, Ph.D. included in DVD as Exhibit F to JRC Petition; Exhibit E to JRC Petition; Exhibit H to JRC Petition.

suffering and other physical and possible psychological injuries. E.L. will continue harming himself, including hitting his head, resulting in additional subconcussive head trauma. E.L. will require significant restraint and isolation, denying him safe access to his family and the community. The repeated use of psychopharmacological interventions along with other ineffective treatments would also subject E.L. to potentially serious and detrimental side effects while providing little, if any, benefit to him.<sup>99</sup>

##### **5. R.M. and Evidence Why Any Forced Transition Will Cause R.M. Irreparable Harm.**

R.M., a 31-year-old male from Massachusetts with an intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by extreme and repeated SIB and AB. R.M. was admitted to JRC on two separate occasions. Prior to his first admission to JRC, multiple well-respected day programs and specialized programs attempted, and failed, to inhibit R.M.'s SIB and AB with medications and curriculums that prioritized social communication and emotional regulations skills. During this time, R.M. was also placed on a variety of potent medications, including Risperdal, Seroquel, Lithium, Clonidine, Neurontin, Topaz, Anafranil, and Ativan. These treatments ultimately proved unsuccessful and R.M. was admitted to JRC on February 5, 2003, at the age of 14. With the failure of these other means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to supplement R.M.'s behavior modification treatment plan with aversive interventions, including the GED devices. The GED treatment had an immediate and dramatic impact on R.M.'s SIB and AB, allowing him to progress academically and socially. In fact, R.M. emitted an average of under three AB and three SIB per week between August 1, 2003, and August 30, 2010. However, despite this progress, R.M. was removed from JRC on his 22<sup>nd</sup> birthday against medical advice and placed with Hogan Regional Center. While under the care of the Hogan Regional Center, R.M. required increased staffing, chemical restraint and frequent physical/mechanical restraint, and experienced significant behavioral regression. During this time, R.M. was also prescribed the psychotropic medication Ativan that proved ineffective. Eventually, the Hogan Regional Center recommended that R.M. return to JRC since they could not properly care for him. R.M. returned to JRC and resumed GED treatment on July 31, 2003. The GED treatment again had an immediate and dramatic impact on R.M.'s SIB and AB. Between November 29, 2010, and March 7, 2020, R.M. emitted a weekly average of 2.04 AB and 1.1 SIB and no longer required the use of restraint. R.M. has tapered off of all psychotropic medications and is able to provide himself with basic self-care. The Ban and any attempt to transition R.M. off his current treatment program including GED treatment will cause R.M. grievous and irreversible harm – just as it did when he was removed from JRC and placed at the Hogan Regional Center. R.M.'s SIB and AB would again reemerge, requiring significant restraint and isolation, and denying him safe access to his family and the community. A return to psychopharmacological interventions along with other ineffective treatments would also subject R.M. to serious side effects while providing little, if any, benefit to him.<sup>100</sup>

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<sup>99</sup> See *id.*

<sup>100</sup> See *id.*

## **6. S.A.S. and Evidence Why Any Forced Transition Will Cause S.A.S. Irreparable Harm.**

S.A.S., a 26-year-old woman with a severe intellectual disability, autism spectrum disorder, and a severe behavior disorder, has suffered a long history of engaging in severe SIB and AB. Multiple well-respected day and residential treatment programs attempted, and failed, to inhibit S.A.S.'s severe SIB and AB with non-intrusive ABA interventions and medications. S.A.S. was also placed on a variety of potent medications, including risperidone, aripiprazole, quetiapine, lorazepam, valproic acid, guanfacine, buspirone, fluoxetine, diphenhydramine, and naltrexone. After S.A.S.'s local school district found itself unable to meet her behavioral needs in New York, S.A.S. was admitted to JRC on March 7, 2005, at the age of 12. With the failure of these other means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to supplement S.A.S.'s behavior modification treatment plan with aversive interventions, including the GED devices. By incorporating aversive interventions, S.A.S.'s SIB and AB dramatically decreased. S.A.S. no longer requires physical restraints or protective equipment, and has tapered off all psychotropic medications. S.A.S. has been able to have four major eye surgeries to reattach her retinas and her academic and vocational life has flourished. The Ban and any attempt to transition S.A.S. off her current treatment program including GED treatment will cause S.A.S. grievous and irreversible harm. S.A.S. would be at imminent and severe risk of loss of eyesight and subconcussive head trauma. S.A.S. will likely require significant restraint and isolation, denying her safe access to her family and the community. A return to psychopharmacological interventions along with other ineffective treatments would also subject S.A.S. to serious side effects such as tremors, anxiety, insomnia, increased sedation, and gastro-intestinal disturbance, while providing little, if any, benefit to her.<sup>101</sup>

## **7. ST.S. and Evidence Why Any Forced Transition Will Cause ST.S. Irreparable Harm.**

ST.S. is a 36-year-old man with an intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by extreme and repeated SIB and AB. Multiple special needs services programs and well-respected residential treatment programs, including the Grafton Residential School in Virginia and the Kennedy-Krieger Institute in Virginia, attempted – and failed – to inhibit ST.S.'s severe SIB and AB with non-intrusive ABA interventions and medications. ST.S. was also placed on a variety of potent medications, including Haldol, Mellaril, Ritalin, Paxil, Lithium, Naltrexone, Depakote, Valium, Seroquel, Thorazine, Klonopin, Prozac, Benadryl, Ativan, Secretin, Prolixin, Cogentin and Droperidol. ST.S.'s treatment with Haldol resulted in an oculogyric crisis and these treatments were ultimately unsuccessful. ST.S. was thus admitted to JRC on October 12, 2000, at the age of 17. With the failure of these other means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to add aversive interventions, including GED devices, to ST.S.'s behavior treatment plan. The revised treatment successfully reduced the frequency of ST.S.'s serious SIB and AB behaviors to near-zero levels per week over the last six years. Furthermore, ST.S. was successfully tapered off all psychotropic medications. The decrease in ST.S.'s SIB behaviors has led to significant progress in his academic and vocational work, including engagement in

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<sup>101</sup> See generally Exhibits D, E, and H to JRC Petition.

employment tasks (shredding paper, landscaping, and gardening) and participation in community outings. The Ban and any attempt to transition ST.S. off his current treatment program including GED treatment will cause ST.S. grievous and irreversible harm. ST.S.'s aggressive head banging, eye poking, hair pulling, biting and scratching will return, resulting in additional subconcussive head trauma and possibly death. ST.S. will likely require significant restraint and isolation, denying him safe access to his family and the community. A return to psychopharmacological interventions along with other ineffective treatments would also subject ST.S. to serious side effects while providing little, if any, benefit to him.<sup>102</sup>

**8. G.T. and Evidence Why Any Forced Transition Will Cause G.T. Irreparable Harm.**

G.T. is a 26-year-old man with a right-sided hemiparesis, an intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by a long history of extreme and repeated SIB and AB. G.T. first received special education services in a public school setting, and then through psychiatric in-patient treatment at Mount Sinai in New York. This in-patient treatment consisted of ABA treatment and seclusion techniques with the use of a helmet and physical restraints. G.T. was also prescribed a variety of potent medications, including Clonidine, Klonopin, Abilify, Naltrexone, Namenda, Risperdal, Cogentin, and Seroquel. These methods proved unsuccessful in treating G.T.'s severe SIB and AB, and G.T. was admitted to JRC in February 2008 at the age of 14. Since his admission to JRC, G.T.'s treatment has consisted of predominantly positive-only and non-intrusive treatments; however, G.T.'s SIB and AB have gotten more severe. G.T. engaged in 6,635 AB and 2,564 SIB between March 18, 2018, and March 8, 2020, and required 97 emergency restraints. Additionally, G.T. required hospitalization on multiple occasions for injuries resulting from banging his head through both a sheetrock wall and a van window. As a result, JRC is now seeking permission from the Massachusetts Probate and Family Court to add aversive interventions, including the GED devices, to G.T.'s behavior modification treatment plan. The Ban will deny G.T. the introduction of the GED treatment into his treatment program, which could cause G.T. grievous and irreversible harm. G.T. will be at imminent risk of physical and emotional harm, including death from a fatal hemorrhage from his violent head banging. G.T. will require significant restraint and isolation, denying him safe access to his family and the community.<sup>103</sup>

**9. E.W. and Evidence Why Any Forced Transition Will Cause E.W. Irreparable Harm.**

E.W. is a 26-year-old woman with a moderate intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by extreme and repeated SIB and AB. Multiple special needs services programs and well-respected residential treatment programs, including the Maryhaven Center of Hope, attempted, and failed, to inhibit E.W.'s SIB and AB with non-intrusive ABA interventions and medications. During this time, E.W. was also placed on a variety of potent medications, including quetiapine, ziprasidone, olanzapine, risperidone, aripiprazole, Depakote, oxcarbazepine, carbamazepine, Adderall, methylphenidate, clonidine,

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<sup>102</sup> See generally Declaration of Robert von Heyn, Ph.D., included in DVD as Exhibit G to JRC Petition; Exhibit E to JRC Petition; Exhibit H to JRC Petition.

<sup>103</sup> See *id.*

guanfacine, fluoxetine, citalopram, fluvoxamine, buspirone, naltrexone, Xanax as a PRN, and Ativan as a PRN. These treatments failed to successfully manage E.W.'s SIB and AB, resulting in E.W.'s suspension from Maryhaven on August 3, 2010. E.W. was admitted to JRC on December 13, 2010, at the age of 17. With the failure of the less intrusive means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to supplement E.W.'s behavior modification treatment plan with aversive interventions, including the GED devices. E.W.'s SIB and AB dramatically decreased. Over the last 12 months, E.W. has exhibited only 4 AB and 6 SIB, and she has not required emergency restraint on a single occasion. Additionally, E.W. has tapered off all psychotropic medications and no longer requires the use of a helmet, physical restraint, or mechanical restraint. Because of her significant progress with her JRC treatment plan, E.W. is now integrated in the community and enjoys visits with her parents and family both at JRC and the family home. The Ban and any attempt to transition E.W. off her current treatment program including GED treatment will cause E.W. grievous and irreversible harm. E.W.'s biting of her hands, wrists and feet will return, as will her head banging, resulting in additional subconcussive head trauma. The acceleration in problem behaviors would necessitate a resumption of mechanical restraint, protective equipment, and E.W. would be doomed to undergo the same demonstrably ineffective treatments that she attempted for 15 years. E.W. will likely require significant isolation, denying her safe access to her family and the community.<sup>104</sup>

#### **10. J.W. and Evidence Why Any Forced Transition Will Cause J.W. Irreparable Harm.**

J.W. is a 26-year-old man with a moderate intellectual disability, autism spectrum disorder, and a severe behavior disorder characterized by extreme and repeated SIB and AB. Multiple well-respected residential treatment programs and psychiatric facilities attempted, and failed, to inhibit J.W.'s SIB and AB with non-intrusive ABA interventions and medications, including quetiapine, gabapentin, aripiprazole, risperidone, valproic acid, ziprasidone, and chlorpromazine. After J.W.'s local school district found itself unable to meet his substantial educational and behavioral needs in Virginia, J.W. was admitted to JRC on June 21, 2007, at age 13 because JRC would "enable him to make both academic and behavioral progress." With the failure of other means of treatment, JRC sought and received permission from the Massachusetts Probate and Family Court to supplement J.W.'s behavior modification treatment plan with aversive interventions, including the GED devices. J.W.'s SIB and AB dramatically decreased. In fact, J.W. emitted zero AB and SIB for slapping/hitting himself, banging his head, or pulling his hair between July 1, 2018, and June 30, 2019. J.W. no longer requires physical restraints or protective equipment, and has tapered off all psychotropic medications. Because of his significant progress with his JRC treatment plan, J.W.'s academic and vocational life has flourished. J.W. participates in physical activities, including swimming and horseback riding and is regularly able to make home visits. The Ban and any attempt to transition J.W. off his current treatment program including GED treatment will cause J.W. grievous and irreversible harm; including risk of imminent physical and emotional injury as well as a deterioration in his quality of life. J.W. would resume his extreme and repeated SIB and AB, likely requiring significant restraint and isolation and denying him safe access to his family and the community. A return to

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<sup>104</sup> See generally Exhibits D, E, and H to JRC Petition.

psychopharmacological interventions along with other ineffective treatments would also subject J.W. to serious side effects while providing little, if any, benefit to him.<sup>105</sup>

### C. Sound Public Policy

Public policy grounds also favor a stay of the Ban. Public policy supports the administration and receipt of treatment recommended and prescribed to individuals by their doctors and clinicians and requested and supported by their parents and guardians. Public policy, in addition to principles of comity, also disfavors federal interference with state issues such as the practice of medicine and informed consent to medical treatment, as well as state court judgments and rulings such as those issued by the Massachusetts courts for every one of JRC's patients who do or will receive treatment with GED. There is a "longstanding public policy against federal court interference with state court proceedings" and "duplication of legal proceedings ... where a single suit would be adequate to protect the rights asserted" that is based upon "the notion of 'comity,' that is, a proper respect for state functions, a recognition of the fact that the entire country is made up of a Union of separate state governments, and a continuance of the belief that the National Government will fare best if the States and their institutions are left free to perform their separate functions in their separate ways."<sup>106</sup>

Significantly, a stay will ensure that FDA's ostensible goals of protecting the public health and protecting the health of the vulnerable population at issue<sup>107</sup> are actually being promoted by the Final Rule and are not being undermined by other "impacts that have not yet been properly considered."<sup>108</sup> "The public ... has an interest in ensuring that the Final Rule promulgated by the [FDA] does not give way to unintended [] consequences that have not (but should have) been evaluated by [the agency]."<sup>109</sup> Judicial review of the Final Rule, and a stay pending judicial review, will give the public assurance that the Ban is factually and scientifically justified, as FDA claims. It will also maintain a long-standing status quo rather than disrupting these patients' critical medical care.

The public interest squarely favors a stay pending judicial review of the Ban and final adjudication or resolution of the Appeal. "It is in the public interest ... for an agency to implement properly the statute it administers."<sup>110</sup> As the United States District Court for the District of Columbia explained:

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<sup>105</sup> See *id.*

<sup>106</sup> *Younger v. Harris*, 401 U.S. 37, 43-4 (1971). "Indeed, allowing the department to ignore a judge's order would intrude on the function of the courts, for there is no doubt that the ability to enter orders is necessary to the very existence of the court and essential to the maintenance of the court's authority." *Judge Rotenberg Educ. Ctr., Inc. v. Comm'r of the Dep't of Mental Retardation*, 424 Mass. 430, 446-47, 677 N.E.2d 127, 139-40(1997), abrogated on other grounds by *In re Birchall*, 454 Mass. 837, 913 N.E.2d 799 (2009) (approving substituted judgment review of treatment plans for incompetent persons by Massachusetts courts and rejecting effort by State agencies to overrule or bypass court findings that GED treatment at JRC was inappropriate for individuals), quoting *Attorney Gen. v. Sheriff of Suffolk County*, 394 Mass. 624, 631, 477 N.E.2d 361 (1985) ("court must have power to carry out its obligation[s]").

<sup>107</sup> See Final Rule, 85 Fed. Reg. at 13,315.

<sup>108</sup> *Brady Campaign to Prevent Gun Violence v. Salazar*, 612 F. Supp. 2d 1, 26-27 (D. D.C. 2009).

<sup>109</sup> See *id.* at 26.

<sup>110</sup> *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 45 (D. D.C. 2000).

there is ... a strong public policy, expressed in the APA, that federal agencies will exercise their discretion in compliance with their governing statutes and with their regulations, including the publication of adequate explanations for their actions. A delay in the implementation of [a] Final Rule so that the Court may review the record to see if the that [sic] Rule was promulgated in compliance with the APA and the [agency's] own regulations does not, in the Court's view, undermine the policies behind the [governing statute enforced by the agency].<sup>111</sup>

Thus, whatever alleged public benefits of the Final Rule FDA may claim, decisional law is clear that those benefits are outweighed by public policy interests in ensuring the Final Rule was issued in accordance with law including, specifically, the APA (and, in this case, ensuring the Rule is supported by substantial evidence and is not arbitrary or capricious or the result of politically-motivated bad faith).<sup>112</sup>

Any public interest concerns favoring denial of a stay cannot outweigh the needs of JRC's patients for continued or necessary medical treatment in view of the many years it took FDA to consider and issue the Ban at issue, and the fact that treatment with GED has been permissible and performed for decades with FDA's knowledge and express permission.<sup>113</sup> No ascertainable or significant public harm will result while awaiting resolution of an appeal on the merits when FDA-reviewed aversive conditioning devices, and ESDs in particular, have been continuously available for medical use, in one form or another, since 1979 and the patients will continue to be protected by the Massachusetts Probate Court review and monitoring of GED treatment.<sup>114</sup>

Moreover, FDA's ostensible interest in protecting public health is minimal given the particular facts and circumstances of this case.<sup>115</sup> FDA acknowledges, as it must, that the Final Rule impacts only one facility in the country – JRC – and only a few dozen individuals at JRC: the Parents' children.<sup>116</sup> Because FDA's regulatory action targets only JRC, there is no "threat to the public interest in general or to third parties in particular" present in this case, which cuts against any public interest argument by FDA and weighs in favor of a stay.<sup>117</sup> The only persons

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<sup>111</sup> *McGregor Printing Corp. v. Kemp*, Case No. 91-cv-3255 (GHR), 1992 WL 118794, \*1, \*6 (D.D.C. May 14, 1992).

<sup>112</sup> See *id.* See also *People for the Ethical Treatment of Animals v. Nat'l Institutes of Health, Dep't of Health & Human Servs.*, 745 F.3d 535, 543 (D.C. Cir. 2014) (recognizing "the public interest in 'shed[ding] light on an agency's performance of its statutory duties.'"), quoting *U.S. Dep't of Justice v. Reporters Comm. For Freedom of Press*, 489 U.S. 749, 772 (1989).

<sup>113</sup> See *Brady Campaign to Prevent Gun Violence*, 612 F. Supp. 2d at 26 ("Neither the NRA nor MSLF present the Court with any reason as to why, after operating under the firearm restrictions in the previous regulations for approximately 25 years, their members would be substantially harmed while awaiting resolution of Plaintiffs' claims on the merits and ascertainment of whether their members have the right to possess concealed, loaded, and operable firearms in national parks and wildlife refuges based on the regulations amended by the Final Rule.").

<sup>114</sup> See Proposed Rule, 81 Fed. Reg. at 24,386 at 24,391 & Table 1.

<sup>115</sup> See Final Rule, 85 Fed. Reg. 13,312 at 13,346 ("Protecting patients from devices that present an unreasonable and substantial risk of illness or injury is a legitimate governmental interest."), 13,348 ("FDA has no financial or other interest in the outcome of this proceeding other than the protection of the public health.").

<sup>116</sup> See, e.g., Final Rule, 85 Fed. Reg. 13,312 at 13,349 ("We expect that the final rule will only affect one entity that currently uses these devices on residents of its facility.").

<sup>117</sup> See *Smoking Everywhere, Inc. v. U.S. Food & Drug Admin.*, 680 F. Supp. 2d 62, 77 (D. D.C. 2010), aff'd sub nom. *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010) (finding public policy interests favored a

directly affected by the Ban – JRC, JRC’s patients, and the guardians and families of JRC’s patients – are all fighting against the Ban and seek a stay of the Ban so the treatment provided by JRC can continue. Public outcry by advocacy groups which have long endeavored to shutter JRC does not equate to public interest, and those groups are not under any obligation to use the GED treatment. Nor do they know anything about the medical history of these patients, or how harmful the termination of GED therapy would be.

No public policy concerns support FDA’s efforts to override state-level laws and protections already long in place and which are working well to protect the health, safety and welfare of JRC’s patients and other Massachusetts citizens. FDA’s rulemaking rests on the fundamental misconception that individuals who receive treatment with ESDs for SIB or AB do not give adequate consent to such treatment<sup>118</sup> and, as a result, FDA must act to protect vulnerable members of society.<sup>119</sup> Although FDA recognizes in the Final Rule that proper legal consent is obtained for each of JRC’s patients who receive treatment with ESDs, remarkably, FDA still deems such legal consent inadequate.<sup>120</sup>

In Massachusetts – where JRC and all affected patients are located – “[t]he right of incompetent individuals to refuse medical treatment is effectuated through the doctrine of substituted judgment.”<sup>121</sup> In particular, Massachusetts courts utilize the substituted judgment procedure to determine “whether an individual would consent to the use of certain aversive treatments” including, specifically, GED treatment at JRC.<sup>122</sup>

In making a substituted judgment determination, a “court dons ‘the mental mantle of the incompetent’ and substitutes itself as nearly as possible for the individual in the decision making process.”<sup>123</sup> A court endeavors “to determine with as much accuracy as possible the wants and needs of the individual involved” in order to reach the ultimate decision “which would be made

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stay based on these factors and notwithstanding FDA’s claim “that the public interest in health and safety weighs in favor of denying preliminary relief because, by enforcing the FDCA as it sees fit, FDA protects the public from unsafe and ineffective drugs.”).

<sup>118</sup> See Final Rule, 85 Fed. Reg. at 13317; Regulatory Analysis, at pp. 11-13 (“Because the individuals with SIB or aggressive behavior can’t give or withdraw consent for the use of the device, these individuals can’t choose to avoid these risks.”).

<sup>119</sup> See Final Rule, 85 Fed. Reg. at 13,315 (“The vulnerable population subject to ESDs for SIB or AB, like all individuals, are entitled to the public health protections under the FD&C Act.”).

<sup>120</sup> See *id.* at 13317 (“FDA recognizes that, at the facility that still uses ESDs for SIB or AB, legal consent is obtained to use the devices. ... FDA is not questioning the validity or importance of legal consent, but rather pointing out that legal consent does not eliminate concerns related to the shock recipients’ communication difficulties and lack of control over use of the device on them.”).

<sup>121</sup> *Care & Protection of Beth*, 412 Mass. 188, 194, 587 N.E.2d 1377, 1381(1992).

<sup>122</sup> *Guardianship of Brandon*, 424 Mass. 482, 487, 677 N.E.2d 114, 119 (1997). *Accord Judge Rotenberg Educ. Ctr., Inc. v. Comm'r of the Dep't of Mental Retardation*, 424 Mass. 430, 443 (1997) (discussing Consent Decree between JRC and DMR); 115 C.M.R. §5.14(4)(e)(3)(c) (DMR regulation providing that only “a court of competent jurisdiction utilizing the substituted judgment criteria” can authorize a behavior modification plan employing Level II or Level III aversive interventions for adults who are not capable of giving informed consent to such treatment).

<sup>123</sup> *Matter of Moe*, 385 Mass. 555, 565, 432 N.E.2d 712, 720 (1982), quoting *Superintendent of Belchertown State School v. Saikewicz*, 373 Mass. 728, 752, 370 N.E.2d 417, 431 (1977).

by the incompetent person, if that person were competent ....”<sup>124</sup> Altogether, “[t]he function of a substituted judgment hearing is to secure to incompetent persons the same right to choose or reject treatment that is accorded to competent persons by the law of consent.<sup>125</sup>

In the case of every JRC patient who is court-authorized to receive treatment with ESDs (GED), the Massachusetts Probate Court has issued substituted judgment determinations that each of those individuals would, if competent, consent to behavioral modification plans that include supplemental aversive treatment with GED or consent to the continuation of those treatment plans after carefully weighing all possible risks of the treatment versus all possible benefits as well as all prior failed or other possible treatments on a case-by-case basis. As a matter of Massachusetts law, the Probate Court’s substituted judgment rulings constitute those individuals’ legal, and actual, consent to such treatment and subjective determination that the treatment should commence or continue having weighed all possible benefits and all possible risks including those FDA claim are associated with the use of ESDs including GED.<sup>126</sup> Massachusetts courts utilize the same substituted judgment process in deciding whether to permit physicians to use antipsychotic medications with incompetent adults because of the high risk of serious medical side-effects of antipsychotic medications, some of which are permanent and lethal.

FDA has absolutely no basis, or legal jurisdiction, to opine that the informed consent provided by all JRC patients in accordance with Massachusetts law – which FDA recognizes is valid legal consent<sup>127</sup> – is still inadequate or insufficient to address potential risks of treatment with ESDs. Informed consent for medical treatment in this context is an issue of state, not federal, law,<sup>128</sup> and thus an issue outside of FDA’s legal authority.<sup>129</sup> In fact, as recognized by the United States Supreme Court, State regulation of the issue of informed consent for medical treatment is squarely “part of the *practice* of medicine, subject to reasonable licensing and regulation by the State.”<sup>130</sup> By second-guessing the legal mechanism Massachusetts has put in place to safeguard the rights and health of its citizens, FDA not only improperly intrudes on an issue of State law but also improperly interferes with how the practice of medicine is conducted in Massachusetts.

FDA’s conclusion that the informed consent provided by JRC’s patients in accordance with Massachusetts law “does not eliminate concerns related to the shock recipients’ communication difficulties and lack of control over use of the device on them” completely

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<sup>124</sup> *Saikewicz*, 373 Mass. at 750, 753-54; *Cohen v. Bolduc*, 435 Mass. 608, 619, 760 N.E.2d 714, 722 (2002) (substituted judgment is used “to approximate best what the incompetent person would have wanted were she able to communicate her wishes.”).

<sup>125</sup> *Guardianship of Brandon*, 424 Mass. at 487, 677 N.E.2d. at 119; *Matter of Hier*, 18 Mass. App. Ct. 200, 207, 392 N.E.2d 549, 963 (1984) (same).

<sup>126</sup> See, e.g., *Brandon*, 424 Mass. at 487, 677 N.E.2d. at 119.

<sup>127</sup> See Final Rule, 85 Fed. Reg. at 13,317 (“FDA is not questioning the validity or importance of legal consent...”).

<sup>128</sup> See *EMW Women’s Surgical Center, P.S.C. v. Beshear*, 920 F.3d 421, n.13 (6th Cir. 2019) (recognizing that a State is entitled to regulate informed consent with respect to abortion even if it has a political “goal” to protect unborn life).

<sup>129</sup> FDA’s regulations relating to informed consent, 21 C.F.R. Part 50, relate solely to clinical investigations.

<sup>130</sup> See *Nat’l Institute of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2373 (2018) (emphasis in original), citing *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 884 (1992).

misses the mark.<sup>131</sup> Massachusetts courts already weigh those specific concerns for each of JRC's patients and take into account each person's individualized medical presentation. As pronounced by the Massachusetts Supreme Judicial Court ("SJC"), any difficulty applying the legal concept of informed consent to medical treatment with an incompetent individual does not justify denying that individual the benefits of the proposed treatment:

We recognize that in situations in which there is an attempt to use substituted judgment for a never-competent person, it is a legal fiction. It is the legal mechanism by which society (at least in Massachusetts) attempts to vindicate liberty interests, albeit through a legal fiction. We are also aware that therefore "the substituted judgment [doctrine] is ... difficult to apply." *Guardianship of Roe*, 383 Mass. 415, 444 n. 16, 421 N.E.2d 40 (1981). That difficulty, however, "provides inadequate justification for denying its benefits...." *Id.* "While it may ... be necessary to rely to a greater degree on objective criteria [in the case of a never-competent person] ... the effort to bring the substituted judgment into step with the values and desires of the affected individual must not, and need not, be abandoned."<sup>132</sup>

The "substituted judgment" standard already applied by Massachusetts courts is driven by a "straightforward respect for the integrity and autonomy of the individual" at issue and already takes into consideration not only such factors as "the probable side effects of treatment" proposed but also FDA's concerns that an individual has "no comprehension of the reasons for the [treatment]" and would experience pain and "fear without the understanding from which other patients draw strength."<sup>133</sup> Otherwise stated, in applying a substituted judgment analysis, Massachusetts courts already recognize and weigh the concerns articulated by FDA to justify the Ban notwithstanding the legal consent FDA recognizes has been provided for ESD treatment; specifically, a "concern that special care be taken to respect the dignity and worth of [an individual's] life precisely because of his vulnerable position."<sup>134</sup>

As confirmed by the SJC, Massachusetts courts specifically have the power to approve GED treatment at JRC in appropriate cases.<sup>135</sup> Massachusetts courts also recognize the lengthy history of bad faith regulation of JRC by Massachusetts state agencies, intended to prohibit or impede GED treatment at JRC, which is akin to FDA's current efforts to ban ESDs in a targeted assault on GED treatment at JRC.<sup>136</sup>

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<sup>131</sup> See Final Rule, 85 Fed. Reg. at 13317.

<sup>132</sup> *Guardianship of Doe*, 411 Mass. 512, 518 (1992) (alterations in original).

<sup>133</sup> See *Superintendent of Belchertown*, 373 Mass. at 754, 373 N.E.2d at 432.

<sup>134</sup> See *id.* at 753-54, 432 (engaging in substituted judgment analysis regarding potential chemotherapy treatment for a noncommunicative, incompetent individual and upholding determination to withhold such treatment, in part, due to a "concern that special care be taken to respect the dignity and worth of [the individual's] life precisely because of his vulnerable position" recognized by lower court judge).

<sup>135</sup> See *Brandon*, 424 Mass. at 487, 677 N.E. 2d at 119; *Judge Rotenberg Educ. Ctr., Inc.*, 424 Mass. at 443-47, 667 N.E. 2d at 137.

<sup>136</sup> See *id.* at 432-33, 448-55, 131-32, 140-45 (1997) (describing lengthy history of bad faith regulation of JRC by Massachusetts state agencies, finding that again "the department did not regulate JRC in good faith," and ordering sanctions and imposing a receivership over the state agency as a result).

Because the risks and benefits of treatment with ESDs and the vulnerabilities of specific patients have already been, and will continue to be, carefully considered for each JRC patient who may receive treatment with ESDs in accordance with a well-developed body of Massachusetts law and decades of application by Massachusetts judges, there is and can be no public interest in FDA's ability to further regulate a field already well-regulated by State authorities or to address concerns already recognized and addressed by State judges who are in a much better position than FDA administrators who have never examined or even met any of the JRC patients to determine what treatment is best for Massachusetts residents. No public policy grounds support the need for duplication of regulatory oversight over the same issues between state and federal governments, let alone impermissible FDA interference with settled Massachusetts law or the practice of medicine in Massachusetts. Indeed, for this very reason, several members of FDA's Panel expressed concerns that FDA was engaging in a "particularly harsh form of paternalism" by telling JRC's patients, guardians, families, and healthcare providers – and Massachusetts judges approving treatment by JRC's patients – "that the FDA knows better than they do"<sup>137</sup> and "for the federal government to tell them no, you can't continue this treatment anymore; we know better than you."<sup>138</sup>

Tellingly, FDA admits that only "*possible* benefits to individuals and to society" may result from the Ban and that, as a general matter, "[FDA] do[es] not know how much society values the ban of this device."<sup>139</sup> From an economic standpoint, as well, FDA agrees that the "final rule is not a significant regulatory action as defined by Executive Order 12866" and "will not have a significant economic impact on a substantial number of small entities."<sup>140</sup> No compelling public interest weighs against a stay of the Ban in this case, where FDA admits the Ban may have limited or no value or impact to the public or society at large. The third factor thus weighs in favor of a stay.<sup>141</sup>

#### **D. Any Delay Caused by a Stay Would Not Be Outweighed by Public Health or Other Public Interests**

Lastly, any delay resulting from a stay is not outweighed by public health or other public interests. In the first place, where there is no "risk of injury to the public or the rights of third parties," there is no effect on "public interest." *See, e.g., McMurray v. United States*, 551 Fed. Appx. 651, 655 (2014), citing *Sylva Shops Ltd. P'ship v. Hibbard*, 175 N.C. App. 423 (2006). Moreover, "the perpetuation of unlawful agency action is not in the public interest." *Saget, supra*, at 377 (emphasis added) (citations omitted).

As detailed in the proceeding section, the public interest supports allowing a stay while the judicial branch reviews the sufficiency of the Ban. Also as outlined above, FDA-approved ESDs have been cleared and available for medical use since the 1970s, and any public health

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<sup>137</sup> *See* JRC Comment, Transcript of Neurological Devices Panel, FDA-2016-N-1111-1756, at 338 (April 24, 2014).

<sup>138</sup> *See id.* at 340.

<sup>139</sup> *See* Regulatory Analysis, at pp. 13, 14 (emphasis added).

<sup>140</sup> *See* Final Rule, 85 Fed. Reg. at 13,349. *Accord* Regulatory Analysis, at pp. 5, 15.

<sup>141</sup> At most, the third factor is neutral. Where, as here, the reach of a potential stay is narrow, limited only to the parties, and has no impact on nonparties, the public interest is "at most a neutral factor in the analysis" rather than one that favors granting or denying a stay. *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138-39 (9th Cir. 2009), quoting *Bernhardt v. L.A. County*, 339 F.3d 920, 931 (9th Cir. 2003).

concerns are minimal in this case involving only a handful of individuals at the one only facility in the nation that uses the device at issue. Although members of the public may have opinions as to the use of ESDs to treat SIB and/or AB, the reality is that a stay of the Ban will not impact the public at large, as conceded by the FDA in its rulemaking. In contrast, the Final Rule in this case will have an immediate and negative impact on the health and welfare of JRC's patients and put those individuals' very lives at risk.

Moreover, the "mere assertion of delay does not constitute substantial harm" that warrants denial of a stay.<sup>142</sup> Any alleged harm to FDA cannot be separated from the public interest in this context (which, as noted, favors a stay).<sup>143</sup> FDA took over six years to finalize the Ban, even though Congress has stated that the purpose of the ban provision was to allow expeditious removal of dangerous devices<sup>144</sup>; any delay associated with a stay pending resolution of the Appeal will be minimized in this case because direct judicial review of the Ban is available at the Circuit Court, and not District Court, level.<sup>145</sup>

Notably, had FDA determined that the "risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals" – including the health of the affected individuals at JRC – FDA could have banned the device effective immediately upon publication of the Proposed Ban in April 2016 via a special effective date.<sup>146</sup> Lacking sufficient evidence and attempting to avoid compliance with the notice and hearing requirements associated with declaring a special effective date, however, FDA chose not to do so.<sup>147</sup> As a result, FDA has already determined that the health of individuals, including JRC's patients, is not in unreasonable, direct or substantial danger as a result of the continued use of GED to treat SIB and AB.

Thankfully, this is not – yet – a case where "[t]he egg has been scrambled and there is no apparent way to restore the status quo ante."<sup>148</sup> FDA must administratively stay the Ban "to protect and maintain the medical status quo" of the affected individuals "until their claims can properly be adjudicated" because "[a]ny substantial delay now in providing necessary treatment of symptoms as they develop may cause considerable permanent damage or make the damage so far incurred irreversible" as confirmed by the affidavits submitted herewith.<sup>149</sup> A stay is also necessary so that individuals who desperately need GED treatment in the opinion of their treating physicians and clinicians and are not precluded from seeking court-approval of the treatment while the sufficiency of the Ban is litigated, putting their own safety and lives at risk. In addition, granting

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<sup>142</sup> *U.S. v. Philip Morris Inc.*, 314 F.3d 612, 622 (D.C. Cir. 2003), abrogated on other grounds, *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100 (2009).

<sup>143</sup> *Nken v. Holder*, 556 U.S. 418, 435 (2009) ("... [T]he traditional stay inquiry calls for assessing the harm to the opposing party and weighing the public interest. These factors merge when the Government is the opposing party.").

<sup>144</sup> See H.R. Rep. No. 94-853, 9th Cong., 2d Sess. (1976) ("House Report"), at 18-19 (emphasis added).

<sup>145</sup> See 21 U.S.C. § 360g(a)(5).

<sup>146</sup> See *id.* at § 360f(b).

<sup>147</sup> See *id.* at § 360f(b) (requiring FDA to "as expeditiously as possible, give interested persons prompt notice of [the special effective date] under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation" following such notice and hearing).

<sup>148</sup> *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002).

<sup>149</sup> *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 87 F.R.D. 560, 567 (D.D.C. 1980).

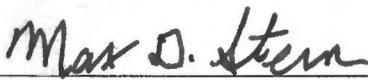
a stay will, during this National Emergency, allow FDA to focus its resources and attention on far more pressing matters than offering GED to a few dozen individuals.

Because all four factors are satisfied, a stay must enter.

### CONCLUSION

Based upon the foregoing, Petitioners have demonstrated all factors necessary for the Commissioner to issue a mandatory or discretionary stay of the Effective Dates of the Ban on ESDs used to treat SIB and AB. Petitioners respectfully request that the Commissioner enter an administrative stay of the Effective Dates in accordance with FDA regulations to avoid irreparable injuries to Petitioners, in the public interest and the interest of justice, pending judicial review, and pursuant to FDA's prior expressed intent to refrain from enforcement of the Ban with respect to any patients currently receiving ESDs in individual cases and unless and until alternative therapies can be developed and fully and successfully implemented for all such individuals.<sup>150</sup> At a minimum, a stay pending the resolution of the Appeal is warranted for the reasons stated. We look forward to hearing from you forthwith.

Respectfully submitted,



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<sup>150</sup> See Final Rule, 85 Fed. Reg. 13,312.

Enclosures

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