UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC., *Petitioner*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., *Respondents*.	No. 20-1087

NOTICE OF FILING OF ADMINISTRATIVE STAY

Petitioner The Judge Rotenberg Educational Center, Inc. (JRC) hereby provides notice to the Court that on March 27, 2020, the U.S. Food and Drug Administration (FDA) issued, pursuant to 21 C.F.R. § 10.35(e), a partial administrative stay of its regulation banning electrical stimulation devices used to treat aggressive or self-injurious behavior, 85 Fed. Reg. 13312 (Mar. 6, 2020), which regulation forms the basis of this action.

Attached hereto as **Exhibit A** is a March 27, 2020 letter from FDA confirming and regarding the partial administrative stay entered effective March 27, 2020, following JRC's submission of an agency petition for stay to FDA on March 20, 2020 (FDA Docket No. FDA-2020-P-1166) pending judicial review by this Court.

Attached hereto as **Exhibit B** is a March 27, 2020 e-mail from FDA confirming that, in addition to the stay, FDA will exercise enforcement discretion as set forth in the communication.

Notice is respectfully provided at the request of the Court and as the foregoing issues relate to matters that are, or may be, before this Court.

Respectfully submitted,

/s/ *Michael P. Flammia*
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Dated: March 27, 2020 *Attorneys for Petitioner*

CERTIFICATE OF SERVICE

I hereby certify that on March 27, 2020, I caused a copy of the foregoing document to be served on the below counsel by filing it with the Court's electronic-filing system:

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Counsel for Respondents, United States Food & Drug Administration, Stephen M. Hahn, M.D., in his official capacity as Commissioner of Food & Drugs, United States Department of Health & Human Services, and Alex M. Azar, II, in his official capacity as Secretary of Health & Human Services

/s/ *Michael P. Flammia*
Michael P. Flammia

U.S. FOOD & DRUG ADMINISTRATION

March 27, 2020

Michael P. Flammia
ECKERT SEAMANS CHERIN & MELLOT, LLC
Two International Place, 16th Floor
Boston, MA 02110

Re: Petition for Stay of Action
Docket No. FDA-2020-P-1166

Dear Mr. Flammia:

This letter responds to the above-referenced petition for a stay of action you submitted on behalf of your client, the Judge Rotenberg Educational Center, Inc. (JRC), dated March 20, 2020. In this petition, you request that the U.S. Food and Drug Administration (FDA) stay the "two effective dates" for the final rule banning electrical stimulation devices (ESDs) for self-injurious (SIB) or aggressive behavior (AB). We have reviewed the information in your submission and, in accordance with 21 CFR 10.35(e) and for the reasons explained below, we grant your request for a stay in part.

I. Background

On March 6, 2020, FDA issued a final rule banning ESDs for SIB or AB, finding that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling in accordance with section 516 of the Federal Food, Drug, and Cosmetic Act (85 FR 13312). The ban affects both new devices and devices already in distribution and use upon the effective date of the final rule, which is 30 days after publication of the final rule (April 6, 2020). However, for those individuals currently subject to ESDs for the identified intended use, the ban provides time to transition away from the use of ESDs under the supervision of a physician because FDA recognized that affected parties may need some time to establish or adjust treatment plans. Therefore, for devices currently in use on specific individuals subject to a physician-directed transition plan, compliance is required 180 days after the date of publication of the final rule (September 2, 2020). These two dates comprise the effective dates referenced in your petition.

II. Legal Background

Under 21 CFR 10.35, an interested person may request FDA stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period (21 CFR 10.35(b)). Request for a stay must be submitted no later than 30 days after the date of the decision involved. FDA may grant or deny a petition for stay of action, in whole or in part, if it is in the public interest and in the interest of justice (21 CFR 10.35(e)). FDA must grant a stay if all of the following apply: (1) The petitioner will otherwise suffer irreparable injury; (2) The petitioner's case is not frivolous and is being pursued in good faith; (3) The

petitioner has demonstrated sound public policy grounds supporting the stay; and (4) The delay resulting from the stay is not outweighed by public health or other public interests. (21 CFR 10.35(e)).

III. Petition for Stay of Action

Your petition requests an indefinite stay of action for both effective dates of the ban, to "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 JRC and guardians of JRC patients currently receiving GED [(Graduated Electronic Decelerator)] or who will receive GED treatment pursuant to a court order; or . . . (2) until such time as the Commissioner rules on JRC's instant Petition and, in the event the Petition is denied, such time as is necessary for JRC to seek and obtain a stay from the D.C. Circuit in connection with the Appeal." The petition is based on two alternative grounds. First, you state that FDA must grant a stay because "JRC and its patients: (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." Alternatively, you request FDA grant a stay because it is "in the public interest and in the interest of justice." In particular, your petition alternatively poses that "in light of the recent presidential declaration of a national emergency concerning the novel coronavirus disease (COVID-19)," FDA can stay substantively responding to the petition "so long as FDA agrees to stay the effective dates in the interim, and further agrees that JRC 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."

IV. Decision Summary

FDA has reviewed your petition and finds that it is in the public interest and interest of justice at this time to grant a stay in part. For the reasons stated below, we are staying the compliance date for devices subject to the ban which are currently in use on specific individuals who would need to obtain a physician-directed transition plan to cease use of such devices.

As your petition recognizes, the nation is experiencing a pandemic of respiratory disease caused by a novel coronavirus. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2), and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, as a result of confirmed cases of COVID-19, and after consultation with public health officials as necessary, Alex M. Azar II, Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (PHS Act), determined that a public health emergency exists and has existed since

January 27, 2020, nationwide.[1] On March 13, 2020, President Donald J. Trump declared that the COVID-19 outbreak in the United States constitutes a national emergency beginning March 1, 2020.[2] FDA plays a critical role in protecting the United States from threats, including emerging infectious diseases like the COVID-19 pandemic, and we advise limiting individual contact with healthcare providers to reduce the potential for exposure to COVID-19 as well as to conserve healthcare delivery resources. Creation or implementation of a physician-directed transition plan has the potential to increase the risk of transmission or exposure to COVID-19, and it may divert healthcare delivery resources from other uses during the pandemic.

This stay is intended to remain in effect for the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act (42 U.S.C. § 247d(a)(2)). Once the public health emergency ends and while your legal challenge to the ban is pending, the stay will continue in effect until: (1) FDA substantively responds to your petition; and (2) if FDA does not grant your petition, you have had adequate time and reasonable opportunity to obtain a ruling from the D.C Circuit regarding a stay of FDA's response to your petition. FDA's partial stay will affect only the effective date for those devices currently in use on specific individuals who have or would need to obtain a physician-directed transition plan; therefore, compliance for these devices will not be enforced either 30 days after the date of publication (April 6, 2020) or 180 days after the date of publication (September 2, 2020). The effective date for all other devices, 30 days after the date of publication (April 6, 2020), remains unchanged.

V. Conclusion

After reviewing your request for a stay of action, we have determined that a partial stay is in the public interest and interest of justice, based on the public health emergency. The stay is limited to those devices currently in use on specific individuals who have or would need to obtain a physician directed transition plan to cease use of such devices. The effective date for all other devices remains unchanged, requiring compliance by April 6, 2020.

Sincerely,

Jeffrey E. Shuren -S

Digitally signed by Jeffrey E. Shuren -S
Date: 2020.03.27 10:06:49 -04'00'

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and
Radiological Health

[1] Determination that a Public Health Emergency Exists (Jan. 31, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

From: Katzen, Noah <Noah.Katzen@fda.hhs.gov>
Sent: Friday, March 27, 2020 12:14 PM
To: Anne K. Walsh <AWalsh@hpm.com>; Edward Longosz <ELongosz@eckertseamans.com>; Jeff N. Gibbs <JGibbs@hpm.com>
Cc: Gorji, Perham <Perham.Gorji@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Heller, Seth <Seth.Heller@fda.hhs.gov>
Subject: RE: JRC Petition for Stay - URGENT REVIEW REQUESTED

All,

As discussed, FDA is issuing the attached partial grant of your stay request. In addition to this stay, FDA will exercise enforcement discretion as described herein.

We understand that the Judge Rotenberg Educational Center (JRC) and a number of others filed appeals on March 26, 2020, challenging the Final Rule to Ban Electrical Stimulation Devices (ESDs) for Self-Injurious or Aggressive Behavior, 85 Fed. Reg. 13312 (Mar. 6, 2020), in the D.C. Circuit. Pending judicial review of the merits of those appeals, FDA does not intend to initiate enforcement action against JRC nor initiate or support a referral for any enforcement action to the U.S. Department of Justice against JRC with respect to patients currently treated with ESDs for SIB and AB. FDA understands that JRC, doctors, and patients will continue the use of ESDs for SIB and AB for existing patients being treated with GEDs while the above-mentioned petitions for review are pending in federal court.

FDA's decision to exercise enforcement discretion does not extend to JRC patients who are not being treated with ESDs for SIB and AB at this time; FDA does not intend to bring an enforcement action with respect to the Final Rule against JRC while the appeals are pending without first completing an inspection of JRC.