Exhibit C

From: Katzen, Noah <Noah.Katzen@fda.hhs.gov>
Sent: Thursday, September 10, 2020 11:56 AM
To: Edward Longosz; Anne K. Walsh; Jeff N. Gibbs; Michael Flammia
Cc: Gorji, Perham; Mednick, David; Heller, Seth; Svonkin, Michele
Subject: [External] RE: JRC Petition for Stay - URGENT REVIEW REQUESTED

Ed,

Hope all is well. Just to close the loop on this, FDA does not object to the interpretation of the partial stay you set out below with regard to patients who were authorized to receive treatment with GED but were being faded or not actually wearing the device at the time that FDA issued the partial stay.

Noah

From: Edward Longosz <ELongosz@eckertseamans.com>
Sent: Friday, August 7, 2020 5:44 PM
To: Katzen, Noah <Noah.Katzen@fda.hhs.gov>; Anne K. Walsh <AWalsh@hpm.com>; Jeff N. Gibbs <JGibbs@hpm.com>; Michael Flammia <MFlammia@eckertseamans.com>
Cc: Gorji, Perham <Perham.Gorji@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Heller, Seth <Seth.Heller@fda.hhs.gov>; Svonkin, Michele <Michele.Svonkin@fda.hhs.gov>
Subject: RE: JRC Petition for Stay - URGENT REVIEW REQUESTED

Noah:

Thank you for your recent email and trust you are staying out of harm's way.

Regarding your request for updated information, we note your request relates to data JRC provided to FDA five years ago on June 19, 2015. Currently, of the two hundred and seventy-six patients enrolled at JRC, only fifty-four of these patients are authorized to receive treatment with GED pursuant to a treatment plan approved by a Massachusetts Probate and Family Court (the "Court"). Court approval of these GED treatment plans must be and has been renewed by the Court every year. Three of these fifty-four patients are undergoing a fading process and are not currently wearing the GED. A number of JRC patients have been completely faded from GED treatment, and their Court-approved treatment plans have expired. The agreed partial stay clearly covers those patients that are Court approved for treatment; otherwise, the GED would not be part of a Court-approved treatment plan.

During our July 8, 2020 call, we discussed the distinction between JRC's process of fading a patient with a Court-approved treatment plan from GED treatment and the permanent discontinuation of GED treatment "subject to a physician-directed transition plan." We thought it would be helpful to provide some additional information regarding this distinction.

When JRC attempts to fade a patient with a Court-approved treatment plan from the GED, it is done so pursuant to a patient-specific fading protocol developed by the patient's treating clinicians (Massachusetts-licensed Behavior Analysts, Physicians, etc.). The goal is for the patient to be permanently faded from GED treatment, while maintaining the patient's low rate of aggressive and self-abusive behaviors and thereby not risking the patient's health and safety. Thus, the patient-specific protocols do not have a deadline for the permanent removal of GED treatment and take into account that the patient's behaviors may re-emerge upon removal of the GED and that the GED may need to be re-instated to keep the patient safe from self-harm and to not lose the important behavioral progress accomplished with the Applied Behavior Analysis treatment plan including the GED device. As mentioned in a prior email to you, Court-approved treatment plans specifically state that "[f]ading of an intervention must be done on a highly individual basis, taking into account a variety of factors in the individual's past and present history … [f]ading will take place in a slow and gradual manner … [h]owever, if the behavior appears to return, the intervention may be re-instated to prevent regression…." The GED is always considered in use (even if not currently worn by the patient) because it is part of the treatment plan, approved by the medical care provider and the Court. The fading component is part of the natural progression of the treatment and use of the GED and should not be conflated with the FDA term "physician-directed transition plan."

The "physician-directed transition plan" is FDA's own construct. Under the FDA Ban, Electrical Stimulation Devices ("ESDs") for self-injurious or aggressive behaviors which are "in use on specific individuals" on March 6, 2020 are banned as of September 2, 2020. Those "specific individuals", under the Ban, must begin the process of being faded from ESD treatment starting April 6, 2020 and pursuant to a "physician-directed transition plan." Under the Ban, pursuant to every "physician-directed transition plan," the patient must be removed from GED treatment by a date certain, September 2, 2020. This includes a patient who may not currently engage in aggressive and self-abusive behaviors but whose aggressive and self-abusive behaviors may re-emerge, warranting, if the Ban did not exist, the resumption of GED treatment for the patient's own health and safety. Thus, patients that have a Court-approved treatment plan would be subject to the FDA-imposed transition plan if the Ban were to be upheld, but these patients are currently protected by the partial stay.

As previously stated, we view the partial stay as applying to any patient who, at the time of the publication of the final rule, was authorized to receive treatment with GED pursuant to a treatment plan approved by the Court, even if the patient was undergoing a fading process or not wearing GED devices on March 27, 2020 when the partial stay went into effect.

If you have any questions, please let us know.

Stay safe and have good weekend.

Ed L.

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From: Edward Longosz
Sent: Tuesday, August 4, 2020 10:02 AM
To: Katzen, Noah <Noah.Katzen@fda.hhs.gov>; Anne K. Walsh <AWalsh@hpm.com>; Jeff N. Gibbs <JGibbs@hpm.com>; Michael Flammia <mflammia@eckertseamans.com>
Cc: Gorji, Perham <Perham.Gorji@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Heller, Seth <Seth.Heller@fda.hhs.gov>; Svonkin, Michele <Michele.Svonkin@fda.hhs.gov>
Subject: RE: JRC Petition for Stay - URGENT REVIEW REQUESTED

Thanks Noah—we will review and revert back to you shortly.

Best and stay safe.

Ed L.

From: Katzen, Noah <Noah.Katzen@fda.hhs.gov>
Sent: Monday, August 3, 2020 1:10 PM
To: Edward Longosz <ELongosz@eckertseamans.com>; Anne K. Walsh <AWalsh@hpm.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>; Svonkin, Michele <Michele.Svonkin@fda.hhs.gov>
Subject: [External] RE: JRC Petition for Stay - URGENT REVIEW REQUESTED

Ed,

As further follow up to your email below, we have a couple questions about the numbers reported in the attached letter. Specifically, on page 2, JRC stated that "aversive conditioning is approved for only 61 [students]. Further, only 47 are currently receiving such treatment as several students have been phased off these devices successfully with no return of the initial, otherwise uncontrollable dangerous behaviors."

We would appreciate it if you could provide the updated numbers of patients for each of these two categories. Would you also be able to confirm that your interpretation below applies to all students approved for aversive conditioning, not the subset "currently receiving such treatment," as phrased in the letter?

From: Edward Longosz <ELongosz@eckertseamans.com>
Sent: Tuesday, June 30, 2020 10:19 AM
To: Katzen, Noah <Noah.Katzen@fda.hhs.gov>; Anne K. Walsh <AWalsh@hpm.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

Dear Noah –

I trust that you are staying safe and out of harm's way.

As you know, under Massachusetts law, JRC and the Parents must receive, on an annual basis, re-authorization from the Massachusetts Probate and Family Court for each patient with a treatment plan that includes the GED, including any patient in a fading process. In reviewing the partial stay with this provision in mind, we write to confirm our understanding of the scope of the partial stay FDA granted, which states: "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." We interpret the partial stay to apply to any patient who, at the time of the publication of the final rule, was authorized to receive treatment with GED pursuant to a treatment plan approved by a Massachusetts Probate and Family Court, even if the patient was undergoing a fading process or not wearing GED devices on March 27, 2020 when the stay went into effect. In other words, a court may reauthorize a treatment plan with GED for any patient who was subject to a treatment plan that included GED at the time FDA granted the stay.

This interpretation is consistent with the language in the final rule and petitions for stay. Patients receiving GED treatment often are able to undergo gradual GED fading due to their behavioral improvement, which is an anticipated goal of the treatment in many cases, and also an indication of treatment effectiveness. However, their court-approved treatment plans permit these patients to resume wearing the GED devices if deemed clinically necessary. As written in the court-approved treatment plans (FDA has copies), "[f]ading of an intervention must be done on a highly individual basis, taking into account a variety of factors in the individual's past and present history … [f]ading will take place in a slow and gradual manner … [h]owever, if the behavior appears to return, the intervention may be re-instated to prevent regression…." In this context, we presume that you agree with our interpretation of the partial stay.

As always, we would welcome a call to discuss this further.

Best regards and stay safe.

Ed L.

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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: [External] 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.

From: Anne K. Walsh <AWalsh@hpm.com>
Sent: Wednesday, March 18, 2020 12:50 PM
To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Gorji, Perham <Perham.Gorji@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>
Cc: Edward Longosz <ELongosz@eckertseamans.com>; Jeff N. Gibbs <JGibbs@hpm.com>
Subject: JRC Petition for Stay - URGENT REVIEW REQUESTED

We write as a follow-up to our call yesterday with Perham Gorji and David Mednick. Our client, Judge Rotenberg Educational Center (JRC), plans to seek a stay of the final rule banning electrical stimulation devices for SIB or AB. 85 Fed. Reg. 13312 (Mar. 6, 2020). Because this ban will go into effect on April 6, 2020, JRC plans to file its Petition to Stay with FDA this Friday, March 20. Counsel for the parents of JRC patients will file a separate petition on Monday, March 23. If FDA does not enter a stay ***by noon on March 27***, we intend to file a motion with the court to stay the effective date of the ban pending judicial review of our appeal.

We believe this timing is necessary given the impending effective dates.

Further to our discussion, we are willing to work together for a solution regarding the stay filings to allow the country to get through the national emergency of COVID-19 that President Trump has declared. FDA has the authority to postpone the effective date of the final rule under 5 U.S.C. § 705, or to exercise enforcement discretion on the ban. Given the competing priorities of the Agency to respond to COVID-19, as well as the effect on JRC, its patients, and counsel to conduct business normally, we would be willing to defer the stay filings if FDA is willing to postpone or move the effective date of the ban for 90 days.

Also, we can confirm that our client is amenable to an appropriate format you choose to implement the Agency's decision to exercise discretion. We are suggesting that exercising enforcement discretion through an Agency letter or directive would be the most effective mechanism to achieve this mutual goal without compromise to either parties' current or future position. We are willing to be flexible on the format to alleviate the Agency's workload, including a letter to JRC counsel stating the Agency's position that would be binding on the non-enforcement of the ban.

Separately, as discussed by phone, we intend to appeal the ban on the merits. Also, as we discussed, we are willing to collaborate on a merits briefing schedule to allow for appropriate appellate review of the final rule during the period of enforcement discretion.

We look forward to hearing from you.

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See HPM's FDA Law Blog: http://www.fdalawblog.net/

U.S. News & World Report Law Firm of the Year in FDA Law 2019

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