Legal Backgrounder
Vol. 39 No. 5 March 22, 2024

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

FDA's Misguided Quest to Regulate the Practice of Medicine Implicates Serious Federalism Concerns

by Jeffrey N. Gibbs and Christian B.W. Stephens

For over a decade, the Food and Drug Administration (FDA) has devoted extensive resources to banning the use of an FDA-cleared medical device that is being successfully used by medical doctors and other licensed health care professionals at one facility to treat approximately 50 patients in the nation who had failed all other therapies and are now healthy and thriving thanks to the device. Despite having lost once already in a federal Court of Appeals and despite having been provided with comprehensive real-world data showing the safety and effectiveness of the treatment, FDA has doggedly continued its unrelenting pursuit of this ban. Yet FDA's efforts to ban one specific use of the device are not supported by science, impermissibly intrude on the ability of physicians to practice medicine and run afoul of the Tenth Amendment.

Aversive Treatment at JRC. FDA has sought to ban the way a particular device is used at The Judge Rotenberg Educational Center, Inc. (JRC) in Canton, Massachusetts to treat patients with severe self-injurious behavior (SIB) or aggressive behavior (AB). Patients with SIB/AB engage in extremely dangerous and life-threatening behaviors, ranging from head-banging to biting off large parts of their tongue and other acts of self-mutilation, and can cause grave injuries to themselves, their families, and their caregivers.

All patients who are admitted to JRC with SIB/AB have first been unsuccessfully treated with multiple other therapies at other facilities, including facilities widely considered among the best in the nation. These other treatments include both powerful—and hazardous—psychoactive drugs and behavioral therapies. When these treatments failed, patients were frequently put into physical restraints, isolated, and/or sedated to prevent them from harming themselves or others. As a result of this "warehousing" by other facilities, these patients essentially had no quality of life and were deprived of the benefits of community living most others take for granted.

JRC successfully treats most of its SIB/AB patients with medication and positive behavioral approaches. Sometimes, though, these methods are insufficient. In that case, JRC's clinicians may seek authorization from a Massachusetts Probate and Family Court judge to treat the patient with a graduated electronic decelerator (GED) device—a medical device manufactured for JRC and used only at JRC which FDA now characterizes as a type of "electrical stimulation device" (ESD). This device—a type of physical "aversive," or "aversive conditioning device" under FDA's regulations[1]—is placed on the patient's body. When staff observes a patient engaging in a pre-specified dangerous behavior, they can administer a two-second shock to the surface of the patient's skin to condition the patient to not engage in the behavior and thereby "decelerate" (reduce the frequency of) the undesirable behavior. Although FDA claims that JRC is the only facility in the country that uses contingent skin shock therapy to treat individuals who severely self-injure or are aggressive, as noted by the D.C. Circuit Court of Appeals,

[1] *See* 21 C.F.R. § 882.5235.

Jeffrey N. Gibbs is a Director in the Washington, D.C. office of Hyman, Phelps & McNamara, P.C. **Christian B.W. Stephens** is a Member in the Boston, Massachusetts office of Eckert, Seamans, Cherin & Mellott, LLC. Both represent JRC and were JRC's counsel in the prior D.C. Circuit litigation described herein.

"[o]ther health care practitioners not affiliated with [JRC] … administer electrical stimulation devices to treat a wide variety of other conditions, including tobacco, alcohol, and drug addictions, as well as inappropriate sexual behaviors following traumatic brain injuries."[2]

Before the GED can be used on JRC's patients, the treatment goes through a rigorous planning and review process. Treating and outside clinicians, a peer review committee, and a human rights committee review the medical file and patient's treatment history and decide whether GED is, in fact, appropriate for that patient. The treatment plan must identify the specific behaviors that can result in the use of GED. Appropriate legal informed consents must be obtained. Ultimately, GED can be used only with the approval of a Massachusetts Probate and Family Court judge. The patient is represented by his or her own independent court-appointed counsel who may retain an independent expert in those legal proceedings, and court-authorization for GED treatment must be reviewed and renewed on an annual basis. Before GED can be used to treat a patient, numerous individuals, including an impartial state court judge, must determine both that it is in the best interests of the patient and that other therapies have been, or are likely to be, unsuccessful and the patient would consent to the treatment applying the Massachusetts substituted judgment criteria.

For decades, JRC has been closely monitoring its aversive treatment using the GED and the behaviors of all its patients. A record is created every time a patient engages in SIB/AB and when a GED stimulation is applied. As a result, JRC is able to scientifically measure and demonstrate the effectiveness of GED in treating patients. The results have been remarkable. The data, as reported in recent peer-reviewed medical literature, shows there has been on average a 97% reduction in SIB/AB one month after ESD therapy is initiated.[3] Because there is no other change in therapy, this dramatic reduction in harmful behaviors can only be attributed to the aversive therapy using the GED. This outcome is more notable considering the inability of other institutions to effect improvement despite years of trying.

Notably, the Massachusetts Supreme Judicial Court (SJC)—Massachusetts' highest court—recently upheld JRC's use of so-called "aversives" as a treatment methodology, including specifically GED, under the state regulatory scheme in a September 2023 ruling.[4] In its ruling, the SJC relied upon Massachusetts' close judicial oversight and court-approval process for the use of GED in an individual's treatment plan and cited testimony that "for many families with children at JRC, its [GED] treatment methods were not only effective, but also considered more humane than the course of restraint and pharmacological sedation to which their children had previously been subjected."[5]

JRC v. FDA. We and others have already written about FDA's prior failed efforts to ban the use of JRC's GED devices, and FDA's subsequent efforts to legislatively overturn its court loss.[6]

Succinctly, in March 2020, FDA issued a final rule declaring that ESDs create an alleged "unreasonable and substantial risk of illness or injury" when used for aversive therapy in SIB/AB cases—but not for any other use. JRC challenged the ban in the U.S. Court of Appeals for the District of Columbia Circuit, which issued a decision invalidating the regulation in July 2021. The Court of Appeals ruled that FDA had impermissibly attempted to regulate the practice of medicine in violation of the provision in the Federal Food, Drug, and Cosmetic Act (FDC Act) protecting the practice of medicine, 21 U.S.C. §

[2] *JRC v. FDA*, 3 F.4th 390, 393 (D.C. Cir. 2021).

[3] *See* Blenkush, N.A. & O'Neill, J. (2020). *Contingent Skin-Shock Treatment in 173 Cases of Severe Problem Behavior*. International Journal of Psychology & Behavior Analysis, 6:167. *See also* Blenkush, N.A. & Cunningham, M. (2023). *Elimination of Refractory Aggression and Self-Injury with Contingent Skin Shock*. The Journal of Neuropsychiatry and Clinical Neurosciences (case report) ("The introduction of the GED intervention immediately and nearly completely eliminated [the patient's] severe behavior problems that were refractory to all previous treatments.").

[4] *JRC v. Comm'r of the Dep't of Dev. Servs.*, 492 Mass. 772 (2023).

[5] *Id.* at 802, 804-05.

[6] *E.g.,* Jeffrey N. Gibbs & Sara W. Koblitz, *FDA Seeks Targeted Congressional Reversal of Judicial Checks on Agency Abuses of Discretion*, Washington Legal Foundation "Legal Backgrounder", Vol. 37, No. 11 (June 3, 2022).

396, and the Tenth Amendment to the U.S. Constitution. FDA thereafter unsuccessfully sought *en banc* review of the ruling by the D.C. Circuit,[7] but did not appeal the court ruling to the Supreme Court.

Instead, FDA used informal backchannels to lobby Congress. First, FDA asked Congress to simply ban ESDs when used to treat SIB/AB to prevent JRC's use of the GED devices[8]—a request that Congress refused. As a fallback position, FDA then requested that Congress expand the agency's powers so that FDA could ban not only specific medical devices, but also specific *intended uses* of medical devices. Ultimately, Congress purported to give FDA this new power to ban specific intended uses of medical devices through 19 lines of legislation buried within a 4,000+ page omnibus funding bill hastily enacted in late 2022 to avoid a government shutdown.[9] There is no indication that Congress ever considered the ramifications of the legislation FDA lobbied to obtain; indeed, no hearing or formal congressional debate was even held on this provision of the omnibus funding bill. Through aggressive lobbying, therefore, FDA was able to use the 2022 omnibus funding bill to slip an amendment into the banning provision of the FDC Act to try to circumvent the Court of Appeal's decision.

Now, FDA has publicly announced its intention to again propose a ban on ESDs used for aversive therapy in SIB/AB cases using its newfound alleged power to ban specific intended uses of medical devices.[10] FDA's decision to focus so much effort on the banning of one specific use of a device used at one facility to successfully treat the SIB/AB of approximately 50 total patients is baffling. During fiscal year 2022, FDA received nearly 3,000,000 reports of adverse events with devices.[11] During that same year—and for years prior to that—there was not a single reported adverse event with an ESD at JRC. And the ESDs used at JRC, unlike most other medical devices, are subject to intense, ongoing judicial and regulatory scrutiny on the state level. This extensive scrutiny has not revealed any evidence of harm to patients when the device is used as intended, while providing strong evidence of treatment effectiveness.

Tenth Amendment Problems. From a legal perspective, FDA's renewed efforts to ban ESDs when used to treat SIB/AB also represents an ongoing effort by the agency to directly regulate the practice of medicine, which is a historic police power exercised by the States, not the federal government. As the D.C. Circuit appropriately recognized in its 2021 ruling, FDA's actions thus implicate important federalism concerns.

The Tenth Amendment, in particular, confirms the federal government's limited and enumerated powers by guaranteeing that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."[12] As described by the U.S. Supreme Court, the Tenth Amendment "secures the freedom of the individual" by allowing the States to enact "local policies 'more sensitive to the diverse needs of a heterogeneous society …'" than laws passed through "political processes that control a remote central power."[13] "By denying any one government complete jurisdiction over all the concerns of public life, federalism protects the liberty of the individual from arbitrary power."[14] Prominent among the historic police powers reserved to the States is the regulation of the practice of medicine. The U.S. Supreme Court has long recognized that "direct control of medical practice in the

---

[7] *See* Order Denying Petition For Rehearing *En Banc*, *JRC v. FDA*, No. 20-1087 (D.C. Cir. Nov. 22, 2021).

[8] *See* Richard A. Samp, *Proposed Legislation Would Ban Vital Procedure*, New Civil Liberties Alliance (May 13, 2022).

[9] *See* Joel Zinberg, M.D., *The FDA Wants to Interfere in the Practice of Medicine*, The Wall Street Journal "Opinion Commentary" (Jan. 12, 2023).

[10] *See* Biden Administration, 2023 Fall Regulatory Agenda.

[11] *See* Kushal T. Kadakia, et al., *Reforming the Medical Device Recall Process—A Call for Accountability*, Health Affairs "Health Affairs Forefront" (Feb. 15, 2024).

[12] U.S. Const., amend. X.

[13] *Bond v. United States*, 564 U.S. 211, 221 (2011).

[14] *Id.* at 222.

states is beyond the power of the federal government."[15] More recently, the Court has described this notion as "the historic primacy of state regulation of matters of health and safety."[16]

FDA's efforts to ban JRC's use of GED to treat its patients' SIB/AB is an affront to this core component of state sovereignty. FDA's prohibition on medical professionals utilizing this medical device to treat a particular medical condition wholly disregards a patient's unique clinical presentation and histories of failed alternative treatments and directly interjects the federal government into the physician-patient relationship. Remarkably, FDA's ban is not focused on preventing the shipment of new devices but on preventing the use of devices that were manufactured years ago and are now being used per a physician's determination that ESDs should be employed. In essence, FDA seeks to override a medical professional's experience and judgment as to the best course of treatment on a case-by-case basis in favor of a federal medical mandate that a particular treatment methodology should not be used for a certain medical condition. Despite its recognition that for many SIB/AB patients there is simply no other effective treatment, FDA nonetheless endeavors to prohibit an entire treatment methodology supported by scientifically rigorous data over the long term, based primarily on ostensible moral, ethical, or political considerations—factors that are not even part of FDA's statutory authority. FDA also never considers the morality or ethical implications of depriving patients of the only therapy that has caused or may cause them to stop their SIB/AB.

There is no question FDA is overtly regulating the practice of medicine by brazenly prohibiting practitioners from using an otherwise permissible and legal medical device *only* when used to treat a specific medical condition (SIB/AB) but not for any other medical condition. Plainly, this is unwarranted federal micromanagement of the medical profession.

Worse, in conjunction with attempting to prohibit ESDs for SIB/AB, FDA has taken the position that practitioners should instead use behavioral therapy, alone or in conjunction with off-label medications, to treat patients experiencing SIB/AB. Both alternative treatments that FDA endorses are well outside of FDA's core competencies and limited legal jurisdiction over products. FDA's expertise does not extend to behavioral therapies or off-label uses. Moreover, these alternatives present dangerous side-effects or may simply be ineffective, or both, as FDA itself has acknowledged. This issue further illustrates the great lengths to which FDA, under the guise of regulating medical *devices*, is attempting to dictate just how medical *professionals* should treat patients. FDA seeks to federalize how a particular medical condition (SIB/AB) is to be treated by proscribing one particular treatment option and endorsing alternatives outside of its jurisdiction. If FDA is permitted to so dictate the medical standard of care and what specific treatments should be used for certain medical conditions, there is essentially no limit to the agency's authority over treatment regimens—and no room for the States to continue to regulate such activities as they have historically done, and as Massachusetts continues to do for JRC's patients.

By endorsing certain alternatives but precluding the use of ESDs for SIB/AB, FDA has exceeded both its expertise and its limited delegated powers. As one federal appeals court recently ruled, such "personalized medical advice" is plainly "beyond FDA's statutory authority": "FDA is not a physician. It has authority to inform, announce, and apprise—but *not* to endorse, denounce, or advise."[17] Indeed, based on the Tenth Amendment, Congress itself lacked the power to delegate the regulation of the practice of medicine to FDA in the first place[18]—to say nothing of 21 U.S.C. § 396, the FDC Act's statutory prohibition on FDA interfering with the practice of medicine, which Congress left fully intact notwithstanding FDA's

[15] *Linder v. United States*, 268 U.S. 5, 18 (1925); *accord F.T.C. v. Simeon Mgmt. Corp.*, 391 F. Supp. 697, 705 (N.D. Cal. 1975), *aff'd,* 532 F.2d 708 (9th Cir. 1976) ("The direct control of medical practice has been left to the states and is beyond the power of the federal government.").

[16] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

[17] *See Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 595 (5th Cir. 2023) (emphasis added).

[18] *See JRC*, 3 F.4th at 399 ("[F]ederal agencies like the FDA are doubly restricted: they may only exercise powers Congress has delegated to them, and that delegation itself must be a lawful exercise of Congress's constitutional authority.").

recent lobbying efforts.

The Supreme Court has been vigilant in policing efforts by federal agencies to expand their regulatory powers into areas traditionally regulated by the States and has insisted that Congress provide explicit authorization insofar as any agency claims a power that could alter the historic balance of powers between the separate federal and state sovereigns. Courts also utilize a presumption against federal preemption of state police power regulations.[19]

FDA's dangerous, renewed attempt to intrude into the practice of medicine by way of a new ESD regulation will undergo close judicial review. Whether it will survive another legal challenge based on these foundational principles of state independence and sovereignty (as well as violations of the Administrative Procedure Act and the FDC Act, among other issues) is doubtful.

Conclusion. Despite JRC's decades of safety and effectiveness data on hundreds of patients, FDA has decided to continue its decade-long quest to ban ESDs only when used to treat SIB/AB in favor of alternative treatments outside of its jurisdiction which FDA endorses. Although FDA holds itself out as a science-based agency, in this case FDA has failed to follow the science. And in seeking to ban the use of ESDs to treat SIB/AB, FDA is also infringing the right of physicians to practice medicine as they deem appropriate, and therefore impinging upon the States' rights to regulate the practice of medicine as protected by the Tenth Amendment.

[19] *E.g.*, *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992).

