United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 23, 2021 Decided July 6, 2021

No. 20-1087

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC.,
PETITIONER

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
RESPONDENTS

Consolidated with 20-1088

On Petitions for Review of an Order
of the Food & Drug Administration

Max D. Stern argued the cause for petitioners Luis Aponte, et al. With him on the briefs were *Joseph M. Cacace*, and *Alexandra H. Deal.*

Michael P. Flammia argued the cause for petitioner The Judge Rotenberg Educational Center, Inc. With him on the

briefs were *Christian B. W. Stephens, Matthew D. Rodgers, Edward J. Longosz, II,* and *Jeffrey N. Gibbs.*

Richard A. Samp was on the brief for *amicus curiae* The New Civil Liberties Alliance in support of petitioners.

Daniel Aguilar, Attorney, U.S. Department of Justice, argued the cause for respondents. With him on the brief were *Sarah E. Harrington*, Deputy Assistant Attorney General, and *Scott R. Mcintosh*, Attorney.

Felicia H. Ellsworth was on the brief for *amici curiae* American Academy of Pediatrics, et al. in support of respondents.

Before: SRINIVASAN, *Chief Judge*, KATSAS, *Circuit Judge*, and SENTELLE, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* SENTELLE.

Dissenting opinion filed by *Chief Judge* SRINIVASAN.

SENTELLE, *Senior Circuit Judge*: The Judge Rotenberg Educational Center and the parents and guardians of its patients both petition for review of a Food and Drug Administration (FDA) rule banning electrical stimulation devices used to treat aggressive or self-injurious behavior. In its rule, the FDA determined that the devices present an unreasonable and substantial risk of illness or injury, but only when used to treat aggressive or self-injurious behaviors. The petitioners contend that banning a medical device for a particular purpose regulates the practice of medicine in violation of 21 U.S.C. § 396. We agree, grant the petitions for review, and vacate the FDA's rule.

I. Background

A. Factual background

The Judge Rotenberg Educational Center is a facility in Massachusetts that treats patients with severe mental disabilities. The Center admits patients that other facilities could not successfully treat. According to the Center, some of its patients suffer from severe self-injurious and aggressive behaviors that are difficult or impossible to treat using conventional behavioral and pharmacological techniques. The most common self-injurious behaviors include head-banging and self-biting. The behaviors of some patients are extreme enough that they have suffered self-inflicted brain trauma, broken and protruding bones, and blindness.

Before the ban at issue in this case, the Center treated some of its patients exhibiting severe self-injurious or aggressive behavior with an electrical stimulation device. The device, called a graduated electronic decelerator, briefly shocks patients causing them to reduce or cease their self-injurious behaviors. *Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior*, 85 Fed. Reg. 13,312, 13,314 (March 6, 2020). The Center is the only facility in the country that uses electric shock therapy to treat individuals who severely self-injure or are aggressive. Other health care practitioners not affiliated with the Center, however, 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. *Id.* at 13,317. The Center manufactures its own devices. The Center treats approximately 20% of its patients with this treatment at any given time.

The devices are subject to extensive federal and state regulation. The FDA regulates aversive conditioning devices, including ones that use electrical shocks, as Class II devices. 21 C.F.R. § 882.5235. That classification includes all medical devices that the FDA determines are reasonably safe and effective when subject to special controls like postmarket surveillance and patient registries. 21 U.S.C. § 360c(a)(1)(B). In addition to the federal regulation, Massachusetts requires several entities to approve electrical shock treatment. *See Judge Rotenberg Educ. Ctr. v. Comm'r of the Dep't of Dev. Servs.*, Dkt. No. 86E-0018-GI, at 2–8 (Bristol, Mass. Prob. & Fam. Ct., June 20, 2018). Before the Center treats a patient with the devices, Massachusetts requires multiple health care practitioners to certify that no other treatments were effective or that the shock treatment is not contraindicated. It further requires that peer review and that human rights committees ratify the treatment. Further, a state court must determine that the treatment was appropriate. *Id.* The intricate system of state regulation arose as a combination of state statutes, regulations, and a consent decree that the Center and Massachusetts entered in 1987. *Id.*

B. Procedural background

In April 2016, the FDA proposed banning electrical stimulation devices for self-injurious or aggressive behavior. *See Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior*, 81 Fed. Reg. 24,386 (Apr. 25, 2016). The notice of proposed rulemaking stated that the therapy presented several "psychological and physical risks: Depression, fear, escape and avoidance behaviors, panic, aggression, substitution of other behaviors (*e.g.*, freezing and catatonic sit-down), worsening of underlying symptoms (*e.g.*, increased frequency or bursts of

self-injury), pain, burns, tissue damage, and errant shocks from device misapplication or failure." *Id.* at 24,387. Literature addressing other electrical devices that shock patients further suggested treatment with such devices could result in posttraumatic stress disorder. *Id.*

The FDA also reviewed the evidence of the devices' effectiveness and concluded that the evidence was weak. According to the FDA, some studies showed that the devices immediately interrupt the targeted behavior, but that the evidence was inconclusive as to whether the devices "achieve[d] durable long-term reduction of [self-injurious or aggressive behaviors]." *Id.* at 24,387. In reaching those conclusions, the FDA reviewed the medical literature at large and data from the Center itself. *Id.* Based on the evidence of harm to patients, and what it regarded as weak evidence of durable effectiveness, the FDA determined that the devices presented a substantial and unreasonable risk to self-injurious and aggressive patients, justifying banning the devices for that purpose. In 2020, the FDA promulgated its final rule. *See* 85 Fed. Reg. 13,312. The final rule adopted the conclusions set forth above on the risks and efficacy of electrical stimulation devices to treat self-injury and aggression. *Id.* at 13,315. The FDA, in reviewing comments, also concluded that it had the legal authority to ban a device for a particular purpose. *Id.* at 13,345.

Both the Center and parents and guardians of patients who receive or seek to receive treatment using an electrical stimulation device now petition this court to review the FDA's ban raising several issues. We determine that a single issue is determinative of the case. That issue is: Does the FDA have legal authority to ban an otherwise legal device from a particular use? The other arguments will not require separate analysis.

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