Judge Rotenberg Educational Center v. U.S. Food and Drug Administration

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WHY IT MADE THE LIST

The U.S. Food and Drug Administration (FDA) had only exercised its authority to ban medical devices twice by the time it finalized its ban on electrical stimulation devices (ESDs) for patients with self-injurious behavior (SIB) and aggressive behavior (AB). ESDs are aversive conditioning devices that deliver electrical shocks via electrodes attached to a person's skin. They are intended to limit or stop targeted behavior, such as nail biting or smoking. Patients with severe SIB and AB engage in extreme behaviors that can cause harm to themselves or others. This case represented FDA's first attempt to use this authority to ban a device for a particular use while allowing other uses, and the first time a device ban was challenged in court.[1] Plaintiffs, the Judge Rotenberg Center (JRC) and the parents and guardians of patients using ESDs for SIB/AB, sued FDA on multiple grounds, including for violating the practice of medicine exception. The Circuit Court of the District of Columbia agreed with plaintiffs that FDA could not ban a device for a particular use because doing so would "limit or interfere" with a physician's authority to prescribe or administer a "legally marketed device."

DISCUSSION

Legal Background

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (FDCA) grants FDA authority to ban medical devices under 21 U.S.C. § 360f. This section reads:

> Whenever the Secretary finds . . . that (1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and (2) in the case [this deception or risk] could be corrected or eliminated by labeling or change in labeling and with respect

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[1] Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food & Drug Admin., 3 F.4th 390 (D.C. Cir. 2021).

> to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period; he may initiate a proceeding to promulgate a regulation to make such device a banned device.[2]

Banned devices manufactured or introduced into interstate commerce are adulterated and subject to FDA's civil and criminal enforcement authority.[3] In this case, JRC challenged FDA's ban to use ESDs for patients with SIB/AB as an agency action that "limits and interferes" with the practice of medicine. Congress had stated on multiple occasions that FDA lacked jurisdiction over the practice of medicine, and FDA itself had acknowledged that it could not regulate the practice of medicine. Congress codified this so-called "practice of medicine exception" in the Food and Drug Modernization Act of 1997 under FDCA § 396:

> Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations.[4]

Courts have affirmed that regulating the off-label use of a medical device by a physician is "not the province of the FDA."[5] Over the years, the practice of medicine exception has allowed healthcare practitioners the flexibility to prescribe or administer legally marketed drugs or medical devices not just for the approved use, but for any off-label condition or disease.

FDA contended that § 396 in no way constrained its invocation of § 360f. FDA argued that a banned device would not, by definition, be a legally marketed device, and therefore § 396 was not applicable. FDA also argued that that it would be a peculiar construction of the statute if the statute authorized it to ban a device completely, but prohibited the agency from tailoring a ban to those particular intended uses which FDA believed presented a substantial risk.

Factual Background

JRC is a Massachusetts treatment facility offering treatment to patients who exhibit self-injurious behavior and aggressive behavior. To treat refractory (i.e., treatment-resistant) SIB/AB in certain adult patients, JRC uses an ESD called the Graduated Electronic Decelerator (GED) device for aversive conditioning. JRC is the only facility in the country using ESDs for this purpose.

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2 21 U.S.C. § 360f(a).

3 21 U.S.C. §§ 331(a) and (g), 333, 334(a)(1), 351(g).

4 21 U.S.C. § 396.

5 *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 395 (quoting Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1344 (10th Cir. 2015) (alterations omitted)).

Aversive conditioning devices were on the market prior to the passage of the Medical Device Amendments on May 28, 1976. In 1979, they were classified as Class II devices and regulated under the premarket notification (510(k)) process. JRC obtained clearance from FDA for its ESD via the 510(k) process in 1994 for "treatment of patients . . . who exhibit self-injurious behavior of sufficient intensity and frequency to cause serious damage to themselves. The device should be used only on patients where alternate forms of therapy have been attempted and failed."[6]

The GED consists of a stimulus generator, electrodes, and a remote monitor. Upon recognition of SIB/AB in a patient, a trained practitioner can send a signal via the remote monitor to the generator. The generator then triggers a two-second low voltage electrical current to the patient via the electrodes to reduce or stop observed SIB/AB.

JRC has used GED devices for over twenty-five years with hundreds of clients. For a patient to be admitted to JRC, a Massachusetts law requires that a licensed doctoral-level clinician document a comprehensive Applied Behavior Analysis (ABA) plan for that individual. The plan prescribes the GED and discusses how alternative treatments have been attempted and failed. A peer-review committee and a human rights committee must sign off on the treatment plan. The patient or their parent(s)/guardian must provide written informed consent. Additionally, a Massachusetts Probate and Family Court judge must also review the patient consent to the proposed GED treatment; here, the patient is represented by separate counsel. Finally, JRC must collect extensive data regarding treatment and each instance of therapy delivered to the patient.

Over the years, the use of the GED has become increasingly controversial, attracting the attention of multiple groups that were opposed to aversive therapy. FDA inspected JRC in 2000 and "did not observe any indications that the patients/clients were at risk." JRC was also inspected in 2010 and 2012 and each inspection resulted in no "reportable" incidents related to GED use. Nevertheless, in December 2012, FDA issued a warning letter asserting that the models of the GEDs then in use were modified from the originally cleared GED device, thus requiring a new 510(k). In the letter, FDA acknowledged that it had scheduled a meeting in January 2013 to discuss JRC's proposed 510(k) submission and to discuss a transition plan for those patients currently using devices. The meeting was canceled by FDA shortly before it was to be held.

On April 24, 2014, FDA held a meeting of the Neurological Devices Panel, which evaluated the merits of issuing a ban on ESDs for aversive conditioning devices "used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics."[7] The Panel was closely divided on whether to ban the device, but unanimously agreed that there was a subpopulation of SIB/AB patients who could not be adequately treated with existing therapies.

On April 25, 2016, FDA issued a proposed ban. In proposing the ban, FDA asserted a variety of risks, including psychological distress, pain, and burning. The agency also said that there was no evidence that GEDs provided any meaningful benefits. After receiving over 1,000 comments—many of which were form comments supporting the ban—FDA published a final rule on March 4, 2020 to ban ESDs, but only when used to treat SIB/AB. In the final rule, FDA asserted that new or updated device labeling

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[6] K911820.

[7] 21 C.F.R. § 882.5235.

could not address the risks from ESDs. The ban did not include other uses of ESDs (e.g., nail biting or smoking).

DECISION SUMMARY

In March 2020, JRC and the parents and guardians of patients that used or sought to use ESDs petitioned the U.S. Circuit Court of the District of Columbia to review the final rule. (While the case was pending, FDA granted a stay of the ban for patients already using the GED.) Though the petitioners raised multiple issues with FDA's ban, the court decided the case on a single question: whether FDA had the legal authority to ban an otherwise-legal device from a particular use. Writing for the court's 2-1 majority, Judge Katsas answered this question by analyzing the interplay of two statutes: 21 U.S.C. § 360f, which authorizes FDA to ban medical devices, and 21 U.S.C. § 396, which prohibits FDA from regulating the practice of medicine.

JRC argued that the use of § 360f to ban a medical device for a particular purpose constitutes the regulation of the practice of medicine and violates the plain text of § 396. According to JRC, banning ESDs for SIB/AB but not for other uses, such as nail biting and smoking, was an intrusion into the practice of medicine that was inconsistent with § 396.

FDA contended that § 396 has no applicability over § 360f. According to FDA, § 396 only prohibited the agency from limiting the authority of practitioners from prescribing or administering "legally marketed devices"—and a banned device would not, by definition, be a legally marketed device. FDA reasoned that devices are, after all, defined by their intended use, so banning devices with reference to particular uses would be appropriate.[8] FDA also argued that if the agency could completely ban a device, it necessarily has the power to ban specific uses of the same device.

The court found the statutes to be unambiguous. Noting that FDA did not argue otherwise, the court proceeded to analyze the competing statutes and their competing interpretations without employing the *Chevron* framework.[9] Starting with § 360f, the court found that Congress only allowed FDA to ban a device, not ban it "in some uses," potentially supporting JRC. Yet, Congress also required FDA to evaluate the "reasonableness" of a device's risks—presumably in light of its benefits—to ban a device. Because each use of a device has its own benefit–risk profile, the court noted the reasonableness language may support FDA's argument that bans may be tailored only to circumstances that FDA finds unreasonable.

The court then analyzed how § 396 restricted the use of § 360f: would an ESD ban for SIB/AB "limit or interfere" with a practitioner's authority to prescribe or administer a device, and was a device that FDA has attempted to ban "legally marketed?" The court held that a use-specific ban does "limit or interfere" how a practitioner could use the device in the ordinary sense of these words. A device ban would limit ("restrict" and "curtail") and interfere ("hinder" and "impede") with a physician's ability to prescribe or administer the device. The court also held that a device is "legally marketed" if it is lawful for a manufacturer to sell it or for a practitioner to prescribe or administer it. Therefore, banning a device for a particular use will still result in a device that is legally marketed for its other uses. Therefore,

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[8] *See* 21 U.S.C. § 321(h)(1) (defining devices as articles that are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . .").

[9] Chevron USA, Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).

banning ESDs for SIB/AB would interfere with a practitioner's ability to administer or prescribe ESDs based on their own medical judgment for certain conditions while the device is still available for other conditions.

The court also rejected FDA's reasoning that a device is defined as a pairing of a particular instrument with a particular use. According to the court, if it endorsed this position, it would follow that ESDs are not "legally marketed" as soon as FDA bans them for SIB/AB. FDA was essentially asking the court to read into "legally marketed" "a limitation that the device must be marketed for the particular use for which the practitioner wants to utilize the device," which would "eviscerate the statute's protection of off-label use."[10] Finally, in rebuffing FDA's argument that the power to ban a device necessarily includes the power to ban certain uses of that device, the court cited precedents that possession of a "greater" power does not imply the existence of a "lesser" power.[11]

Chief Judge Srinivasan dissented from the decision. In his opinion, the statute was not an "all-or-nothing banning power" and instead gave FDA the power to tailor a ban. Applying *Chevron* to interpret "legally marketed device," Judge Srinivasan concluded that § 396 does not unambiguously foreclose FDA's position, and therefore the court must defer to FDA's interpretation if it was reasonable and consistent with the statute's purpose. Judge Srinivasan found a tailored ban "eminently reasonable" given that Congress already allows a complete ban.

FDA sought rehearing en banc of the decision. On November 22, 2021, this request was denied.

IMPACT OF THE DECISION

This case represented the first ever challenge to an FDA ban on medical devices. FDA had previously banned two devices, but neither ban had been challenged.

The D.C. Circuit Court of Appeals found that in issuing the ban on ESDs for SIB/AB, and not nail biting or smoking or other behaviors, FDA overstepped its authority. Citing § 396's language that "nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease,"[12] the court held that FDA could not interfere with the practice of medicine by proscribing a particular intended use. While the specific legal issue of the intersection of the practice of medicine exemption and FDA's authority to ban may be narrow, this unequivocal support for the practice of medicine exemption may have implications for other situations in which FDA seeks to curb the authority of physicians.

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[10] *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 397. The court noted that Congress may indeed have contemplated such an interpretation based on legislative history, but ultimately dismissed that interpretation based both on the definition of a device and because of how it would nullify the practice of medicine exception. *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 397. The court also noted that FDA's actions that impinge on the practice of medicine implicate the Tenth Amendment of the Constitution because they attempt to regulate the practice of medicine, an unenumerated power that was not delegated to FDA and therefore has always resided with the state. *Id.* at 399.

[11] *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 398.

[12] 21 U.S.C. § 396.