ORAL ARGUMENT HELD APRIL 23, 2021
DECISION ISSUED JULY 6, 2021

Nos. 20-1087, 20-1088

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

The Judge Rotenberg Educational Center, Inc., et al.

Petitioners,

v.

United States Food And Drug Administration, et al.

Respondents.

On Petitions for Review of a final rule of the
United States Food and Drug Administration

PETITION FOR REHEARING EN BANC FOR THE FEDERAL RESPONDENTS

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GLOSSARY

Act	Federal Food, Drug, and Cosmetic Act
FDA	U.S. Food and Drug Administration
JA	Joint Appendix
Op.	Slip opinion in *Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food and Drug Admin.*, Nos. 20-1087, 20-1088 (D.C. Cir. 2021).

INTRODUCTION AND RULE 35(b) STATEMENT

This case concerns the U.S. Food and Drug Administration's (FDA's) authority to ban dangerous medical devices that present an "unreasonable and substantial risk of illness or injury" that cannot be corrected by labeling. 21 U.S.C. § 360f. Banned devices are deemed adulterated, 21 U.S.C. § 351(g), and are subject to the prohibitions on distributing adulterated products in interstate commerce.

A divided panel of this Court held that if a medical device has multiple uses, FDA lacks statutory authority to ban a device for a particular intended use because that would impermissibly regulate the practice of medicine. Op. 2. That holding erroneously limits FDA's authority to prevent the sale and distribution of medical devices intended for uses that pose unjustifiable risks of pain, injury, and psychological trauma. The majority based its conclusion on its reading of 21 U.S.C. § 396, which allows physicians to prescribe legally marketed devices for off-label use. But nothing in the banning statute or the banning rule forbids physicians from using legally marketed medical devices for off-label uses or otherwise impermissibly regulates a physician's practice of medicine.

As Chief Judge Srinivasan noted in his dissent, nothing in the statutory scheme compels the "counterintuitive" result that FDA "must

either ban a device across all its potential uses or refrain from banning it at all." Op. 20. The panel majority's decision mistakenly and unnecessarily constrains FDA's ability to use this critical tool that Congress enacted to protect the public health.

That error is palpably demonstrated here. The medical devices at issue are electrical stimulation devices intended for use on patients with self-injurious and aggressive behavior, many of whom have intellectual and developmental disabilities. Those devices are attached to a person's skin to inflict a painful electrical shock. After an exhaustive review of the scientific evidence, FDA determined that those devices present unreasonable and substantial risks of both physical and psychological injury. The electrical shocks can burn the skin, JA682-84, and deliver "excruciating[] pain[]," JA1748, like "a dentist drilling on an un-anesthetized tooth," JA682. And particularly for patients with intellectual disabilities—who may not be able to communicate their pain, control the application of the shocks, or fully understand why they are receiving the shocks—the devices can cause psychological harms, including post-traumatic stress disorder, depression, anxiety, substitution of negative behaviors, learned helplessness, chronic stress, and suicidality. JA1739. Against those serious risks, FDA and

multiple experts agreed that there was at best weak evidence that the devices were effective at all. JA550-59, 686-88.

Based on those conclusions, FDA banned the devices for self-injurious and aggressive behavior. Electrical stimulation devices intended for other uses (*e.g.*, smoking cessation) do not pose the same kind of risks and so were not banned. JA1739, 1744. That is a reasonable and appropriate use of FDA's statutory authority to protect public health.

The panel majority's decision invalidates that rule and categorically prohibits FDA from banning medical devices for particular dangerous uses. Because judicial review of any banning rule may be sought in this Court, 21 U.S.C. § 360g(a)(5), the majority's decision will restrict FDA's authority regarding every future banning rule. This is an issue of exceptional importance to public health that warrants en banc review.

STATEMENT

I. Statutory Framework

A. The Federal Food, Drug, and Cosmetic Act provides "various levels of oversight for medical devices, depending on the risks they present," including a classification system. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Class I and Class II devices, generally speaking, receive less oversight than Class III devices, like "implanted cerebella

stimulators[] and pacemaker pulse generators," *id.* at 316-17, which present "a potential unreasonable risk of illness or injury," 21 U.S.C. § 360c(a)(1)(C)). If a Class III device does not receive FDA's premarket approval, it is deemed to be adulterated, *id.* § 351(f)(1)(A), and cannot be lawfully sold or distributed in interstate commerce, *id.* § 331, and is subject to condemnation, *id.* § 334.

Congress also granted FDA authority to ban medical devices. Under 21 U.S.C. § 360f, when FDA determines that (1) "a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury," and (2) the deception or risk cannot "be corrected or eliminated by labeling or change in labeling," then FDA "may initiate a proceeding to promulgate a regulation to make such device a banned device." 21 U.S.C. § 360f(a). A banned device is deemed to be adulterated, *id.* § 351(g), and cannot be lawfully sold or distributed in interstate commerce, and is subject to condemnation, *id.* §§ 331, 334.

B. FDA has substantial authority to regulate drugs and medical devices, but Congress has not granted FDA authority to generally "regulate the practice of medicine." *United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981). Congress partially codified the practice-of-medicine limitation in 21 U.S.C. § 396, which provides that the Act does not "limit or interfere

with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient." But § 396 preserves FDA's authority "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." *Id.* Section 396 has been commonly understood to protect the ability of physicians to prescribe legally marketed devices for "'off-label' usage," *i.e.*, "for some other purpose than that for which [a device] has been approved by the FDA." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 766 (3d Cir. 2018).

II. FDA Rulemaking To Ban Electrical Stimulation Devices For Self-Injurious and Aggressive Behavior

A significant number of people exhibit the clinically diagnosed conditions of self-injurious and aggressive behavior, which can cause those people to harm themselves or others. These behaviors "are often present in individuals with intellectual or developmental disabilities," like autism or Down syndrome. JA676. These behaviors have at times been treated with electrical stimulation devices, which apply electrical shocks "in an attempt to reduce or cease the behavior." JA677.

A. The scientific literature "contains many reports of tissue damage or burns" from the devices, JA682, which have been corroborated by

reports and patient testimony, JA683-84, JA1750. The shocks cause pain that has been described as "extremely painful," "excruciatingly painful," "like a dentist drilling on an un-anesthetized tooth," like a "bulging and a ruptured disc," like "a thousand bees stinging you in the same place for a few seconds," and as "the most painful thing I've ever experienced." JA682, 685; JA1748-49.

Patients subjected to repeated electrical shocks that they cannot control are at risk of "psychological trauma such as an anxiety or panic reaction," or the development of post-traumatic stress disorder. JA680. The devices can cause "screaming, crying, or shivering upon device application; grimacing; flinching; perspiring; and escape behavior." JA681.

After being shocked, some patients will "resort[] to hostility and retaliation," while others may have "muscular freezing or melting." JA681. Other patients may increase their own attempts at self-injury, sometimes "reaching the point that extended treatment with the [devices] became impossible to maintain." *Id.* The shocks can also create "a perfect paradigm for" instilling learned helplessness in patients, since the devices "produc[e] pain in people who have no control over the pain." JA683.

For related reasons, the devices pose risks of causing depression, acute stress, and "possible suicidal ideation." JA683, 685. One

psychologist reported that her patients would "wak[e] up screaming from nightmares" after earlier being shocked, while other patients experienced "waking nightmares, in which horrible memories of shock, pain, and restraint suddenly over[came] them." JA685-86. These risks may be underreported because many of the affected patients have intellectual and developmental disabilities that impair their communication. JA682.

B. Given these substantial risks, FDA convened an expert panel, undertook an extensive review of the medical literature, and determined that there was a lack of evidence that electrical stimulation devices were effective at treating self-injurious and aggressive behavior. JA686. While the devices could be used as an immediate crisis-control measure, there was little evidence that repeated electrical shocks were effective as a "continuous management technique." JA691. FDA reviewed numerous studies, case reports, and other data and determined that there was not credible evidence of effectiveness. JA686-88, 1760. And that conclusion was shared by the majority of the expert panel who examined the underlying evidence. JA550-59.

C. Based on that analysis, FDA banned "[e]lectrical stimulation devices for self-injurious or aggressive behavior." 21 C.F.R. § 895.105. FDA explained that the ban did not apply to electrical stimulation devices

"intended for other purposes, such as smoking cessation" because those different uses "in different patient populations * * * present different benefit-risk profiles." JA1739, 1744. A smoker could choose to stop using the device or easily say that the shock is too painful, but many people with self-injurious and aggressive behavior have disabilities that make it difficult to communicate "pain and other harms caused by" the devices, or even to understand the cause-and-effect relationship between their behavior and the electric shocks. *Id.*

FDA explained that the ban was consistent with the practice-of-medicine limitation in 21 U.S.C. § 396. Section 396 "makes clear" that "a doctor may prescribe an approved device for a use different from those for which it has been approved; it does not, however, in any way limit FDA's ability to determine which devices can be legally marketed and the uses for which they can be legally marketed." JA1773. FDA further explained that under the Act's general regulatory provisions for medical devices, the same physical instrument is often regulated differently depending on its intended medical use, because different uses present different risks and benefits. JA1772.

III. The Panel's Decision

A. A divided panel of this Court held that the ban was *ultra vires*. The majority held that 21 U.S.C. § 396 unambiguously prohibits FDA from banning a medical device for some but not all uses. Op. 8-14. The majority recognized that to ban a device, FDA must "determine whether the risks a device presents are reasonable" and that determination can differ depending on a device's "multiple possible uses." Op. 9. But the majority held that a "use-specific ban" violates 21 U.S.C. § 396 because it "limits or interferes with a practitioner's authority by restricting the available range of devices through regulatory action." Op. 9. The majority reasoned that because FDA cannot prevent a physician from prescribing or administering "any legally marketed device," 21 U.S.C. § 396, FDA could not prevent physicians from prescribing an otherwise legally marketed device for a particular, banned use. Op. 10.

FDA argued that, as a regulatory matter, an instrument intended for one medical use is one medical device, and the same instrument intended for a different medical use is a different medical device—the first device might present unreasonable risks and be banned, while the second device might not. Op. 10-11. The majority acknowledged that Congress likely contemplated that a device with multiple uses would "constitut[e] a

different device for purposes of classification or other regulation." Op. 11. Nevertheless, the majority held that this understanding of device "would allow the FDA to escape the constraints of section 396 whenever it bans a device," because it could look to the device's intended use. Op. 11. And although the majority noted that 21 U.S.C. § 396 does not limit FDA's ability to "establish and enforce restrictions on the sale or distribution" of medical devices, the majority held that this only applied to some restrictions on conditions for selling medical devices, and not to bans of medical devices. Op. 12 (citing 21 U.S.C. § 360j(e)).

B. Chief Judge Srinivasan dissented, concluding that there was no sound reason why FDA could not ban a device with one intended use that had "limited effectiveness and pose[d] an acute risk of injury," while simultaneously declining to extend that ban to a different use where "the device proves highly effective and presents only a negligible risk of injury." Op. 18. Chief Judge Srinivasan did not interpret FDA's statutes to "compel [the] counterintuitive result" that FDA "possesses only an all-or-nothing banning power." Op. 20. Instead, he would defer to FDA's reasonable interpretation of the statutory interplay between § 360f and § 396: a banned device is considered adulterated and "cannot be 'legally marketed'

for that [banned] purpose," and thus 21 U.S.C. § 396's provisions regarding the practice of medicine would not apply to that device. Op. 22-23.

Chief Judge Srinivasan explained that this understanding—that an instrument with multiple intended medical uses constitutes different devices—is consistent with FDA's general regulation of medical devices. Op. 23. FDA classifies the same instrument, such as cranial electrotherapy stimulators, as a Class II or a Class III device depending on its intended use. *Id.* (citing 21 C.F.R. § 882.5800(b)).

Chief Judge Srinivasan disagreed with the majority's conclusion that the banning rule here would affect a physician's ability to prescribe electrical stimulation devices for any use, citing FDA's explanation that "a doctor may prescribe an approved device for a use different from those for which it has been approved." Op. 24. And he explained that "FDA's ability to tailor a ban to a device's most problematic uses will enable the agency to avoid affecting state regulation of the practice of medicine more than is necessary." Op. 25. Against that backdrop, Chief Judge Srinivasan would defer to FDA's interpretation of its authority under *Chevron*. Op. 25.

REASONS FOR GRANTING REHEARING EN BANC

I. The Panel Majority's Decision Improperly Constrains FDA's Authority To Ban Unreasonably Dangerous Medical Devices And To Protect The Public Health

A. Congress granted FDA authority to ban medical devices when they "present[] substantial deception or an unreasonable and substantial risk of illness or injury" that cannot be corrected by labeling. 21 U.S.C. § 360f(a). A device's intended use is critical to that determination of risk. And if a physical instrument intended for one medical use presents substantial and unreasonable risks that cannot be mitigated, but other uses of the same instrument are safe, FDA acts appropriately and the public health is best served by banning the instrument for that dangerous use.

That evaluation of intended use is a hallmark of the general regulatory framework for medical devices established by the Federal Food, Drug, and Cosmetic Act. The Act defines a "device" as an "instrument, apparatus," or similar article, "which is * * * *intended for* use" in the diagnosis or treatment of diseases. 21 U.S.C. § 321(h) (emphasis added). The Act further excludes from the definition of "device" any item that "achieve[s] its primary *intended purposes* through" chemical or metabolic action. *Id.* (emphasis added). In enacting those definitions, Congress recognized that "there may be instances in which a particular device is

intended to be used for more than one purpose," and Congress intended that "each use may * * * be treated as constituting a different device for purposes of classification and other regulation." H.R. Rep. No. 94-853, at 14-15 (1976).

Accordingly, FDA looks to a device's intended use to determine its classification and accompanying regulatory status. For example, some knee prosthetics are regulated as Class II devices if they are "intended for treatment of degenerative and posttraumatic patellar arthritis," but are regulated as Class III devices "when intended for" other uses. 21 C.F.R. § 888.3580(b). Similarly, contact lenses are regulated as Class II devices if they are "intended for daily wear only," while contact lenses "intended for extended wear" are Class III devices with additional restrictions. *Id.* § 886.5916(b). Thus, the same physical instrument may be subject to multiple device classifications, effectively treating it as multiple devices subject to different regulatory requirements, depending on the instrument's intended medical use. No one would think that these classifications impermissibly regulate the practice of medicine by differentiating devices on their intended use. And if a Class III device does not receive pre-market approval from FDA, it may not be lawfully sold or distributed in interstate commerce because it is an adulterated device. 21 U.S.C. § 351(f)(1)(A).

B. Consistent with the role of intended use in the Act's general regulatory requirements for medical devices, FDA looks to a device's intended use to determine if it poses a "substantial" and "unreasonable" risk that warrants banning. 21 U.S.C. § 360f. And if an instrument has multiple intended medical uses, FDA acts appropriately in differentiating between those uses as constituting different medical devices, and not unnecessarily banning safe and effective devices.

But under the majority's holding, FDA cannot pursue that reasonable and tailored course. Instead, FDA must either decline to ban the instrument for any medical use—and thereby allow an unreasonably dangerous device to flow through interstate commerce—or ban the instrument categorically and thereby deprive physicians from even accessing the instrument for safe and effective medical uses (which might be challenged as arbitrary and capricious). Nothing in the statute compels that feast-or-famine reading of FDA's authority.

C. The majority's conclusion to the contrary was based on its mistaken construction of the practice-of-medicine provision in 21 U.S.C. § 396. The majority held that under § 396, FDA cannot ban a device intended for a particular use from being sold and distributed because that would impermissibly interfere with a practitioner's ability to prescribe that

device. Op. 10-11. But that reasoning inappropriately conflates two different measures: (1) regulating the sale and distribution of a device intended for a particular medical use, and (2) prohibiting physicians from prescribing a legally marketed device off-label. Section 396 is directed at the second kind of regulation, not the first.

Once a device is banned, the manufacture, sale, and distribution of that device for that intended use is unlawful. 21 U.S.C. §§ 331, 334, 351(g). That regulation of manufacturers and distributors affects the general market for medical devices, but it in no way regulates a physician's practice of medicine—the underlying instrument may still be lawfully sold and distributed for other intended uses, and physicians remain free to use such devices off-label. *Cf. United States v. Regenerative Sciences, LLC*, 741 F.3d 1314, 1319 (D.C. Cir. 2014) (FDA's "comprehensive, uniform regulatory scheme for the distribution of drugs" does not regulate the practice of medicine).

Section 396 does not limit FDA's authority to regulate manufacturers and distributors, but recognizes that physicians may prescribe medical devices for off-label use, something that FDA reiterated in its rulemaking. JA1773 (explaining that § 396 "makes clear * * * that a doctor may prescribe an approved device for" an off-label use). Thus, rather than

conflict with § 396, the banning rule here "reaffirms that very protection" for off-label prescriptions. Op. 24.[1]

D. The majority correctly recognized that 21 U.S.C. § 396 allows FDA to promulgate "restrictions on the sale or distribution" of devices through rulemaking, but erred in holding that such restrictions do not extend to a ban of a device. Op. 12. The majority mistakenly construed § 396's reference to "restrictions" to refer exclusively to 21 U.S.C. § 360j(e), which permits FDA to "require that a device be restricted to sale, distribution, or use" on certain conditions, and held that it did not include the banning authority in § 360f, which "would be surplusage" if covered by § 360j(e). Op. 12. But Congress knows how to refer exclusively to § 360j(e) by cross-reference, *e.g.*, 21 U.S.C. §§ 352(q), 360d(a)(2)(B)(v), 360bbb-3(e)(3)(C), 360e(d)(1)(B)(ii), and did not choose to so limit its reference to "restrictions" in § 396. Moreover, even if the ban here were considered a restriction under § 360j(e), that would not make § 360f superfluous.

[1] Section 396 protects a physician's ability to prescribe medical devices off-label, but it does not immunize physician conduct that independently violates the Act. *See United States v. Kaplan*, 836 F.3d 1199, 1209-11 (9th Cir. 2016) (affirming conviction of physician who adulterated devices by re-using single-use needle guards on patients, notwithstanding an argument that this was permissible off-label use). And in the same vein, a physician's ability to prescribe a legally marketed device off-label does not limit at the threshold FDA's authority to ban unsafe medical devices.

Restrictions under § 360j(e) are "condition[s] upon which a device may still be sold," Op. 12, and they do not authorize FDA to prohibit the sale of a device for all purposes. By contrast, § 360f indisputably authorizes such complete bans, while also permitting FDA to ban a device for a specific use.

E. The panel majority also expressed concerns about federalism and the States' role in regulating the practice of medicine. Op. 14-16. But those concerns are misplaced. If FDA refused to approve a drug for a particular condition, that refusal would not raise any federalism concerns, even though it would prohibit marketing the drug for that condition. Similarly, FDA does not tread on States' regulation of medicine by banning absorbable powder made from cornstarch, 21 C.F.R. § 895.104, even though that ban is limited to powder intended for lubricating surgical gloves—which can pose significant risks of physical harm—and does not ban the use of that powder in other safer applications, 81 Fed. Reg. 91722, 91723 (Dec. 19, 2016).

And if FDA were to ban a device entirely—thereby preventing physicians from obtaining the device at all—that categorical ban would fall within FDA's core authority to regulate the distribution of medical devices in interstate commerce and similarly pose no federalism concerns. "It is

hard to see how allowing the agency to fashion a *less* intrusive ban would give rise to a *more* significant federalism based concern." Op. 25.

F. If there were any doubt about how the statutory provisions here should be construed, the Court should appropriately defer to the FDA's reasonable construction of its statutory authority under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). As Chief Judge Srinivasan recognized, the agency's harmonization of the practice-of-medicine provision in § 396 and its banning authority in § 360f is "a permissible exercise of the agency's interpretive authority" and deserves to be "sustain[ed]." Op. 26. "When an agency interprets a statute it is charged with administering in a manner (and through a process) evincing an exercise of its lawmaking authority, that interpretation is entitled to *Chevron* treatment," even where, as here, the agency did not expressly invoke *Chevron* in earlier stages of litigation. *American Hospital Ass'n v. Azar*, 967 F.3d 818, 828 (D.C. Cir. 2020) (cleaned up) (quoting *SoundExchange Inc. v. Copyright Royalty Board*, 904 F.3d 41, 54-55 (D.C. Cir. 2018)).

II. En Banc Review Is Warranted

The decision to ban a medical device reflects FDA's expert judgment that no other measures are adequate to protect the public health. The

majority's erroneously cramped reading of that weighty authority warrants en banc review.

The immediate consequences of the panel's decision are sufficiently grave by themselves to warrant further review by the full Court. The use of electrical stimulation devices for self-injurious and aggressive behavior can cause profound physical and psychological harms, as the record graphically demonstrates, and the panel's invalidation of the banning rule will have serious public health consequences for a highly vulnerable population. JA410 (video link to http://www.youtube.com/watch?v=aAj9W0ntUMI). And the decision will preclude FDA from tailoring any future exercise of its banning authority to unsafe uses of multiple-use devices, forcing the agency to an all-or-nothing choice of banning devices for safe uses as well as unsafe ones or forgoing banning altogether.

CONCLUSION

The Court should grant rehearing en banc.

Respectfully submitted.

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SEPTEMBER 2021

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A) because it contains 3,893 words, excluding the parts of the brief exempted under Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), according to the count of Microsoft Word.

/s/ Daniel Aguilar
Daniel Aguilar

ADDENDUM

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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.*

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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.

II. Analysis

The answer to the controlling issue is determined by the application of two statutes: 21 U.S.C. § 360f, which authorizes the FDA to ban medical devices, and 21 U.S.C. § 396, which prohibits the FDA from regulating the practice of medicine. We begin by setting forth the relevant portion of each statute.

Section 360f, which Congress passed in the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act, grants the FDA authority to ban medical devices. The section provides: "Whenever the Secretary finds . . . that a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury," and that risk cannot be "corrected or eliminated by labeling," the Secretary "may initiate a proceeding to promulgate a regulation to make such device a banned device." 21 U.S.C. § 360f(a). "Device" is a defined term within the Food, Drug, and Cosmetic Act, meaning "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." *Id.* § 321(h)(1). A banned device is considered adulterated, authorizing the FDA to seize the device if it has been or may be introduced into interstate commerce and making it a crime to introduce the device into interstate commerce or manufacture it. *Id.* §§ 331(a), (g); 333; 334(a)(1); 351(g).

Section 396 constrains the FDA's authority by prohibiting it from regulating the practice of medicine. In the Food and Drug Modernization Act of 1997, Congress provided:

> 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.

21 U.S.C. § 396. Section 396 ensures that once the FDA permits a device to be marketed for one use, health care practitioners have the flexibility to draw on their expertise to prescribe or administer the device for any condition or disease, not just the use the FDA approved—in short, to practice medicine. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349–50 (2001). Such "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission," and indeed, duty, "to regulate in this area without directly interfering with the practice of medicine." *Id.* at 350. Section 396 protects the liberty of doctors and patients to use approved devices in any manner they wish. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1344 (10th Cir. 2015) (Gorsuch, J.); *see also* H.R. Rep. No. 105-399, at 97 (1997) ("[T]he off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA.").

The FDA argues that section 396 does not restrict its authority under section 360f at all. It argues that section 396 only prohibits the FDA from limiting the authority of a

practitioner to prescribe or administer a legally marketed device, and a device is not legally marketed if it is banned. The FDA also points to the Act's definition of a "device" with reference to its intended use, such that it would be appropriate for the FDA to ban devices with reference to particular uses. Finally, the FDA also argues that it would be a peculiar construction of the statute if the statute authorizes it to ban a device completely, or not approve it in the first instance, but prohibits the FDA from using its expertise to narrowly tailor a ban to those circumstances in which a device presents a uniquely substantial risk.

The petitioners contend not only that section 360f does not authorize use-specific banning, but also contend that the plain text of section 396 prohibits the FDA from banning a medical device for a particular purpose. They further argue that the section reserves the "tailoring" that the FDA suggests is appropriate to medical practitioners, not the FDA. Finally, they note that the FDA's construction is not appropriate because it interferes with states' traditional authority to regulate the practice of medicine.

Ordinarily, we evaluate an agency's interpretation of a statute it administers under *Chevron USA Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984). Under the framework, we first consider "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If so, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. If Congress has not spoken clearly, we defer to an agency's interpretation if it is "based on a permissible construction of the statute." *Id.* at 843. In this case, the FDA did not invoke *Chevron* deference or even cite the case in its briefing. Perhaps this is because the agency concluded that the relevant statutes are unambiguous. We agree that the statutes are unambiguous,

although this does not mandate the FDA's conclusion that the statute authorizes it to take this action.

A. Statutory analysis

We begin our analysis of the scope of the FDA's banning authority with section 360f, the statute that authorizes banning in the first instance. The statute states that the FDA may make "such device a banned device," and the natural reading of that language suggests a device either is banned or it is not. It speaks of no authority to place a device in an intermediate state of "banned in some uses." But the statute also requires the FDA to determine whether the risks a device presents are reasonable, presumably in light of the benefits that the device provides to individuals that use it. If a device has multiple possible uses, each use will present a different benefit-risk profile. The risks a device presents could therefore be reasonable for some uses but not for others. Focusing on "reasonable" in the statute echoes the FDA's reasoning that it should be permitted to tailor a ban to those circumstances in which it applies its expertise to find an unreasonable risk.

However, section 396 expressly denies the FDA authority to construe any part of the Food, Drug, and Cosmetic Act, including its authority to ban devices under section 360f, to permit the FDA to "limit[] or interfere[]" with practitioners' authority to prescribe or administer "legally marketed device[s]" to patients. The questions for us then, are whether a ban "limits or interferes," and whether a device that the FDA has attempted to ban for a particular purpose is "legally marketed."

A use-specific ban limits or interferes with a practitioner's authority by restricting the available range of devices through regulatory action. Rather than being a peculiar interpretation,

as the FDA argues, this understanding is consistent with both the ordinary meaning of the terms "limit" and "interfere," as well as Supreme Court precedent. To limit is "to restrict the bounds or limits of," or "to curtail or reduce in quantity or extent"; to interfere, in turn, is "to interpose in a way that hinders or impedes: come into collision or be in opposition." *Interfere*, *Limit*, *Merriam-Webster.com*; *see also Buckman*, 531 U.S. at 350. Preventing further manufacture of a device and seizing existing devices both "limits" and "interferes" with a physician's ability to prescribe or administer them.

As to the statutory reference to "legally marketed," a device is legally marketed if it is lawful for a manufacturer to sell the device or a practitioner to prescribe or administer it. The statute does not suggest, not should we read into it, a limitation that the device must be marketed for the particular use for which the practitioner wants to utilize the device. Indeed, that would eviscerate the statute's protection of off-label use. *See Buckman*, 531 U.S. at 350. Any device that the FDA attempts to ban for one but not all uses will, accordingly, still be legally marketed. In this case, practitioners can still prescribe or administer electrical stimulation devices for other conditions, like smoking. 85 Fed. Reg. at 13,317. Electrical stimulation devices are therefore legally marketed, and as discussed previously, banning them for a particular use limits or interferes with a practitioner's ability to administer or prescribe them as the practitioner sees fit. The plain meaning of the first sentence of section 396 demonstrates that the FDA does not have the authority to limit practitioners' use of a device for a particular purpose.

The FDA's alternative interpretation of "legally marketed device" is unpersuasive. The agency argues that because the Act requires a device to have a use, the appropriate construction of "device" is a pairing of a particular instrument

with a particular use. It would follow that an electrical stimulation device for self-injurious and aggressive behavior is not a "legally marketed device" once the FDA bans that pairing of an instrument and use. Congress potentially had such an interpretation in mind, as legislative history contains references to the FDA being permitted to treat multiple "use[s] . . . as constituting a different device for purposes of classification or other regulation." H.R. Rep. No. 94-853, at 14–15 (1976). That is not an appropriate interpretation.

First, that construction would allow the FDA to escape the constraints of section 396 whenever it bans a device. If Congress wished to have section 396 apply to everything except the FDA's banning authority, it could have done so. Instead, the statute begins "Nothing in this chapter shall be construed," mandating that this section constrain the FDA's banning authority. Next, interpreting the definition of "device" as requiring a pairing of an instrument with a particular use is inconsistent with the definition of "device" itself. Section 321 defines "device" by reference to "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," focusing on the physical item itself rather than any particular intended use. It then uses the terms "diagnosis of disease or other conditions," and "cure, mitigation, treatment, or prevention of disease," when defining a device, not "*a* condition," "*a* disease," or "*a particular* disease." The plurality and lack of an article in the statute render its ordinary meaning to be that a "device" must be intended to diagnose, cure, mitigate, treat, or prevent some number of conditions or diseases, not necessarily a particular one. Contact lenses, for example, are one medical device even though they treat both nearsightedness and farsightedness.

The second sentence of section 396, which authorizes the Secretary to "establish and enforce restrictions on the sale or distribution . . . of a device that are . . . promulgated through regulations," does not rescue the FDA. Although one could colloquially refer to a ban as a restriction, there is significant space between the definitions of the two terms. A "restriction" is a "limitation or qualification," while a "ban" is a "legal or otherwise official prohibition." Black's Law Dictionary (11th ed. 2019). More important, however, is the fact that the Act structurally segregates bans and restrictions. As usual, we presume that the same words, used in the same act of Congress, have the same meaning. *Atlantic Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932). Congress, in a subsection titled "Restricted Devices," authorized the FDA to "require that a device be restricted to sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or upon such other conditions as the Secretary may prescribe in such regulation." 21 U.S.C. § 360j(e).

The restrictions that the FDA promulgates through section 360j(e) include, for example, requiring the special controls appropriate for Class II devices. *See id.* § 360c(a)(1)(B). By contrast, section 360f, authorizes the FDA to ban a medical device. The two separate sections would be sufficient to demonstrate that restrictions and bans are distinct. Looking more closely at the statute reinforces the point. Reading "restriction" in section 396 to include bans is inconsistent with section 360j(e), which makes clear that a restriction is a condition upon which a device may still be sold. If we somehow overlook the plain language of section 360j(e) and permit a ban as a restriction under section 360j(e), then section 360f itself would be surplusage as the FDA could find all the banning authority it wanted elsewhere.

As we suggested above, we are not persuaded that because the FDA possesses the "greater" power to completely ban a medical device, it must have the "lesser" power to tailor a ban to only certain uses. Courts regularly recognize that a greater power does not imply the existence of a lesser power, especially when the exercise of that claimed lesser power uniquely offends some external constraint. States may hold elections for state judges or they may not, but the First Amendment prohibits them from "conduct[ing] elections under conditions of state-imposed voter ignorance." *Republican Party of Minn. v. White*, 536 U.S. 765, 788 (2002) (quoting *Renne v. Geary*, 501 U.S. 312, 349 (1991) (Marshall, J., dissenting)). States can regulate dentists or allow them to participate in an unregulated market, but they cannot permit dentists to anticompetitively self-regulate in defiance of the Sherman Act. *N.C. State Bd. of Dental Exam'rs v. FTC*, 574 U.S. 494, 505–06 (2015). Congress may provide Medicaid funds to states or it may not, but once states have relied upon those sizeable funds, it cannot condition their receipt on an expansion of Medicaid without running afoul of the Tenth Amendment. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581–83 (2012) (opinion of Roberts, C.J.). As a final example, and most relevant to this case, the Attorney General may ban all uses of certain controlled substances, but he cannot prohibit specific uses that states regard as legitimate medical practice. *See Gonzales v. Oregon*, 546 U.S. 243, 272–73 (2006). In this case too, no one disputes that section 360f permits the FDA to ban a device completely. The FDA could even decline to approve a device in the first instance. The problem is that once the FDA approves a device and then tries to ban it for specific uses, it defies the limitation that section 396 imposes. Just as in other contexts, section 396 operates as an external constraint—preserving the ability of physicians to make professional judgments about off-label uses—that

prevents the FDA from exercising a lesser power merely because it possesses a greater one.

B. Federalism concerns

While our analysis thus far has focused on the text of section 396, the statute's role in preserving the balance of powers between the federal government and the states provides further support for our conclusion. "The Constitution created a Federal Government of limited powers." *Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991). "[T]he general government is not to be charged with the whole power of making and administering laws. Its jurisdiction is limited to certain enumerated objects, which concern all the members of the republic, but which are not to be attained by the separate provisions of any." THE FEDERALIST NO. 14 (James Madison). Courts have recognized this bedrock principle since the earliest years of the republic. *See Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 176 (1803) ("The powers of the legislature are defined, and limited; and that those limits may not be mistaken, or forgotten, the constitution is written.") (Marshall, C.J.).

The Tenth Amendment instructs us that the powers which the Constitution does not delegate to the federal government belong to the states. U.S. CONST. amend. X. The very structure of the Constitution underscores the balance of powers between the federal and state governments "[w]ith its careful enumeration of federal powers and explicit statement that all powers not granted to the Federal Government are reserved." *United States v. Morrison*, 529 U.S. 598, 618 n.8 (2000). Congress may legislate on naturalization, bankruptcy, patents, and copyrights, for example, U.S. CONST. Art. I, § 8, but cannot generally mandate individuals purchase particular goods or regulate the practice of law. *See NFIB*, 567 U.S. at 557–58 (opinion of Roberts, C.J.); *Am. Bar Ass'n v. FTC*, 430 F.3d 457,

471–72 (D.C. Cir. 2005). As a result, before we will construe a statute to permit federal action in an area that is traditionally the province of state law, we require Congress to make its intention to "alter the usual constitutional balance between the States and the Federal Government . . . unmistakably clear in the language of the statute." *Will v. Michigan Dep't of State Police*, 491 U.S. 58, 65 (1989) (internal quotations omitted).

"This principle applies with equal force to the so-called modern administrative state." *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001). Federal agencies are creatures of statute. They possess only those powers that Congress confers upon them. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). If no statute confers authority to a federal agency, it has none. If Congress has forbidden an agency from taking an action, the agency cannot so act. *See FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120, 132–33, 155–56 (2000). Accordingly, federal 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. Just as we require a clear statement when interpreting a statute in the first instance, we require an explicit authorization from Congress before we will permit an agency to regulate in an area that alters the balance of powers between states and the federal government. *See Am. Bar Ass'n*, 430 F.3d at 471–72. In *American Bar Association*, a federal agency, in that case the Federal Trade Commission, attempted to regulate the practice of law. We held that it could not do so absent explicit authorization by Congress. *See id.* In this case, the Food and Drug Administration attempts to regulate the practice of medicine, not only without explicit authorization from Congress, but in the face of an explicit congressional command not to do so.

States, not the federal government, traditionally have regulated the practice of medicine. *See Gonzales*, 546 U.S. at 275. Choosing what treatments are or are not appropriate for a particular condition is at the heart of the practice of medicine. *See State v. Miller*, 542 N.W.2d 241, 246 (Iowa 1995); *State v. Smith*, 135 S.W. 465, 469 (Mo. 1911). Indeed, Massachusetts has taken a very active role in regulating the Center's use of electrical stimulation devices. *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). Therefore, before we would permit the FDA to dictate whether practitioners may administer electrical stimulation therapy to self-injuring and aggressive patients, we would require an explicit statement from Congress to that effect. *Will*, 491 U.S. at 65; *Am. Bar Ass'n*, 430 F.3d at 471–72. When Congress chooses to authorize the FDA to explicitly list what conditions a physician can use a drug or device to treat, it does so. *E.g.*, 21 U.S.C. § 333(e) (requiring human growth hormone to be approved for a particular purpose). In this case, we have quite the opposite of an explicit authorization—an explicit statement from Congress that the FDA cannot act. Section 396 explicitly limits the power of the FDA. The FDA has no authority to choose what medical devices a practitioner should prescribe or administer or for which conditions.

CONCLUSION

In the end, despite the length of our discussion, the resolution of the controlling issue is quite easily expressed. When Congress has spoken in a statute, we assume that it says what it means and that the statute means what it says. In this case, the statute says that the FDA is not to construe its statute so as to interfere with the practice of medicine. That means that the FDA may not enact the regulation at issue before us. Because we conclude that the FDA lacks the statutory authority

to ban a medical device for a particular use, we do not address petitioners' other arguments, including whether the ban was arbitrary and capricious or whether substantial evidence supported the FDA's factual determinations. We grant the petitions for review and vacate the FDA's rule banning electrical stimulation devices for self-injurious and aggressive behavior.

So ordered.

SRINIVASAN, *Chief Judge*, dissenting: The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., grants the FDA various types of regulatory authority over medical devices. The agency, for instance, may classify devices as Class I, II, or III devices, depending on the degree of risk a device poses. *See id*. § 360c(a)(1). The riskier the device, the greater the FDA's power to regulate it. *See id*. The Act also vests the FDA with authority to go further: the agency can outright ban a device upon determining that it presents "an unreasonable or substantial risk of illness or injury." *Id.* § 360f(a)(1). A banned device cannot be manufactured, introduced, or received in interstate commerce. *Id*. §§ 331(a), (c), (g), 351(g). The FDA has exercised the banning power very sparingly in the 45 years of its existence. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified at 21 U.S.C. § 360c *et seq*.). The agency has banned a device on just three occasions, including, most recently, the ban in question in this case. *See* 85 Fed. Reg. 13,312 (Mar. 6, 2020) (Rule); 81 Fed. Reg. 91,722 (Dec. 19, 2016); 48 Fed. Reg. 25,126 (June 3, 1983).

There is no dispute that the FDA has power under the statute to ban a medical device altogether—i.e., across all its potential uses. The issue in this case is whether the FDA can exercise its banning authority in a more tailored fashion: rather than ban a device across the board, can the agency ban the device for a particular intended use while allowing it for other uses? One can readily envision why the FDA might wish to do so. Suppose a device has been approved to treat two distinct conditions, meaning it has two intended uses. When treating the first condition, the device proves to be of limited effectiveness and poses an acute risk of injury. But when treating the second condition, the device proves highly effective and presents only a negligible risk of injury. The FDA presumably would want to ban the device for the first intended use but permit it for the second. And it is hard to perceive why Congress could want to deny the agency that

middle-ground option. Why force the agency to make an all-or-nothing choice—either abolish a highly beneficial use so it can stamp out a highly risky one, or stomach the highly risky use so it can preserve the highly beneficial one?

This case is illustrative. The FDA conducted a years-long examination of whether to ban the use of electrical stimulation devices intended to treat self-injurious or aggressive behaviors. 81 Fed. Reg. 24,386, 24,392–93 (Apr. 25, 2016) (Proposed Rule). Persons who engage in those behaviors often suffer from intellectual or developmental disabilities. *Id.* at 24,389. Electrical stimulation devices deliver a powerful and painful electric shock to the wearer's skin, in an effort to punish and thereby discourage self-injurious and aggressive behaviors when they manifest. *Id.* That type of treatment has fallen into disuse over the past three decades: petitioner The Judge Rotenberg Center is the sole facility in the United States that still uses electrical stimulation devices to treat self-injurious or aggressive behavior in disabled persons. *Id.* at 24,391, 24,409.

The FDA found that use of electrical stimulation devices to treat those behaviors poses a number of health and safety risks—from physical injuries such as severe pain, skin burns, and tissue damage, to psychological injuries such as panic, anxiety, and post-traumatic stress disorder. *See, e.g.*, Rule, 85 Fed. Reg. at 13,323–26. The agency further concluded that the devices are of dubious efficacy in treating self-injurious or aggressive behaviors, and that alternative treatments (not involving the infliction of pain) have proven more effective and less risky. *Id.* at 13,333. The FDA thus decided to impose a ban on electrical stimulation devices intended to treat those behaviors. *See id.* at 13,315.

The agency, though, did not extend its ban to encompass electrical stimulation devices intended to treat other conditions.

The devices, for instance, can be used to treat smoking addiction. When used for that purpose, the agency found, the devices present a different, and acceptable, benefit-risk profile. *Id*. at 13,317. That is in part because a smoker typically controls the device and can stop its use when it causes undue pain, and she can also communicate any harmful symptoms to a healthcare provider. *Id*. By contrast, persons with intellectual or developmental disabilities receiving treatment for self-injurious or aggressive behaviors often do not control the electrical stimulation devices they wear (rather, the devices are controlled by a third party or automatically trigger upon detecting certain movements). *Id.*; Proposed Rule, 81 Fed. Reg. at 24,394, 24,396. Those persons also may lack the ability to discern a causal connection between the devices and physical or psychological harm, or may be unable to communicate the harmful symptoms to others. Proposed Rule, 81 Fed. Reg. at 24,395. Because electrical stimulation devices have varying benefit-risk profiles depending on their intended use, the FDA confined its ban to the intended use determined to pose an unreasonable danger—the treatment of self-injurious or aggressive behaviors. Rule, 85 Fed. Reg. at 13,317.

Again, no one doubts the FDA's statutory authority to impose a blanket ban on electrical stimulation devices covering all their potential uses. The question here is whether the agency could adopt a less sweeping, more tailored approach: banning the devices for treatment of self-injurious or aggressive behaviors while allowing the devices for treatment of other conditions. Petitioners contend, and my colleagues agree, that the agency possesses only an all-or-nothing banning power: it must either ban a device across all its potential uses or refrain from banning it at all. Respectfully, I do not read the statute to compel that counterintuitive result.

Petitioners, joined by my colleagues, ground their all-or-nothing understanding in 21 U.S.C. § 396. That provision states that "[n]othing 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." 21 U.S.C. § 396. In petitioners' view, because banning a device generally makes it unavailable, a ban naturally "limit[s] or interfere[s] with the authority of a health care practitioner to prescribe or administer" the device within the meaning of § 396. *Id.* (For present purposes, I will assume arguendo the correctness of that understanding.)

The key to petitioners' all-or-nothing conception of the FDA's banning authority lies in their interpretation of the phrase "legally marketed device" in § 396. That provision protects a physician's ability to "prescribe or administer" a device—but only if it is a "legally marketed device." *Id*. According to petitioners, when the FDA bans a device across the board, the device cannot be "legally marketed" at all, rendering § 396 inapplicable. But if the FDA attempts to ban a device only for a particular use, petitioners reason, the device can still be "legally marketed" for other intended uses. And because the device, on petitioners' reading, then counts as a "legally marketed device," § 396 applies, such that the single-use ban impermissibly "limit[s] or interfere[s] with the authority of a health care practitioner to prescribe or administer" the device for the banned use. The upshot of that reading is that the agency must either ban a device for all its uses or not ban it at all.

The FDA construes § 396 differently. The agency specifically addressed (and rejected) petitioners' understanding of § 396 when promulgating the Rule. Rule, 85 Fed. Reg. at

13,345–46. Whereas petitioners believe that a device counts as a "legally marketed device" as long as it can be legally marketed for *any* purpose, the FDA understands that a device can be a "legally marketed device" for some purposes but not others. In the FDA's view, if the agency bans a device for a specific purpose, the device cannot be "legally marketed" *for that purpose*. And because the device then does not count as a "legally marketed device" in connection with that purpose, § 396 is inapplicable to the ban. Consequently, the FDA explained in the Rule, § 396 "does not . . . in any way limit FDA's ability to determine which devices can be legally marketed and the uses for which they can be legally marketed." *Id*. at 13,346. It follows that electrical stimulation devices "manufactured and used at [The Judge Rotenberg Center]" to treat self-injurious and aggressive behaviors "are not legally marketable devices" due to the ban, and that the "FDA's issuing of this rule in no way conflicts with section [396]." *Id.*

The agency's interpretation of § 396 is judged under *Chevron*'s two-step framework. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984); *SoundExchange, Inc. v. Copyright Royalty Bd.*, 904 F.3d 41, 54 (D.C. Cir. 2018). The question at *Chevron*'s first step is whether the statute unambiguously forecloses the agency's interpretation of its banning power, under which it can tailor a ban to a device's most problematic uses. *See Catawba Cnty. v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009). Or put alternatively, does the statute unambiguously compel petitioners' all-or-nothing understanding of the FDA's banning authority? My colleagues believe it does. Maj. Op. 9. In their view, petitioners' interpretation of "legally marketed device" in § 396 is the only possible reading of the statute. In my view, however, while petitioners' reading is certainly a permissible one, the FDA's competing interpretation is permissible as well.

And that is enough to get the agency past *Chevron*'s first step. *See Catawba Cnty.*, 571 F.3d at 35.

The statute does not expressly define what "legally marketed device" means in § 396, or otherwise directly address whether the term accommodates the FDA's use-specific reading. But outside the context of a ban, whether a device can be "legally marketed"—whether it will be approved, what kind of approval process it must undergo, what sorts of labeling requirements it must satisfy, and whether it must meet additional restrictions before sale, *see* 21 U.S.C. §§ 360c(a)(1)(A)–(B), 360e(c)(1), 360j(e)(1)(A)—can vary based on the device's intended use. Indeed, when Congress first granted the FDA authority to regulate medical devices, a House Committee Report expressly recognized that "there may be instances in which a particular device is intended to be used for more than one purpose," and anticipated that "each use may . . . be treated as constituting a different device for purposes of classification or other regulation." H.R. Rep. No. 94–853, at 14–15 (1976). Accordingly, the FDA has long held the position that it can "regulate[] . . . devices . . . based on the intended uses [of] the products." 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994).

As an example, the FDA has assigned the same device differing classifications (Class I, II, or III) depending on its intended use. Consider, in that regard, cranial electrotherapy stimulators. They are Class II devices when intended to treat insomnia or anxiety but are Class III devices when intended to treat depression. *See, e.g.*, 21 C.F.R. §§ 882.5800(b)(1), (b)(2). As a result, whether a cranial electrotherapy device can be "legally marketed" will turn at least in part on its intended use. If the device is intended to treat depression, it can be marketed only after undergoing the rigorous premarket approval process applicable to Class III devices. *See id.* § 882.5800(c); 21

U.S.C. § 360c(a)(1)(C). But if the device is intended to treat insomnia or anxiety, it can be marketed without regard to that process. *See* 21 U.S.C. § 360c(a)(1)(B). To know whether a device may be "legally marketed," then, it may be necessary to consider the device's intended use.

Under the FDA's interpretation of § 396, the same is true of banned devices: when a device is banned for one intended use, it is not a "legally marketed device" in connection with that use. Nothing in the terms of § 396, or in the broader statutory context, unambiguously forecloses that understanding. To the contrary, in light of the use-specific operation of the FDA's regulatory authority over devices more generally, it stands to reason that the agency's banning power can be understood to function in the same way.

My colleagues suggest that the FDA's understanding of the term "legally marketed devices" in § 396 would eviscerate the provision's basic object. *See* Maj. Op. 10. Section 396, all agree, aims centrally to protect a physician's ability to administer devices for "off-label" uses—i.e., uses beyond those for which FDA approval has already been obtained. *See Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985). But in explaining its interpretation of § 396 in the Rule itself, the FDA specifically recognized—as it has for decades—that the provision "makes clear . . . that a doctor may prescribe an approved device for a use different from those for which it has been approved." Rule, 85 Fed. Reg. at 13,346; *see also* 59 Fed. Reg. at 59,821. Far from undercutting § 396's protection of a physician's ability to prescribe off-label uses, then, the Rule's reading of § 396 reaffirms that very protection.

My colleagues also invoke the federalism-based interest in construing federal statutes to avoid unduly impinging on

traditional state prerogatives—here, regulating the practice of medicine. *See* Maj. Op. 14–16. But again, all agree that the agency possesses statutory authority to impose a blanket ban on a device covering all its intended uses. It is hard to see how allowing the agency to fashion a *less* intrusive ban would give rise to a *more* significant federalism-based concern. In fact, recognizing the FDA's ability to tailor a ban to a device's most problematic uses will enable the agency to avoid affecting state regulation of the practice of medicine more than is necessary.

For those reasons, § 396 does not unambiguously foreclose the FDA's reading of the statute at *Chevron*'s first step. We then move on to *Chevron*'s second step, under which we defer to the FDA's interpretation as long as it is "reasonable and consistent with the statute's purpose." *UC Health v. NLRB*, 803 F.3d 669, 675 (D.C. Cir. 2015). I believe it is.

The primary purpose of the Federal Food, Drug, and Cosmetics Act is to "protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948). To that end, the Act undisputedly grants the FDA power to impose a blanket ban on an unsafe device covering all its uses. Viewed in that light, it is eminently reasonable—and entirely consistent with the statute's purposes—to conclude that the FDA may impose a more targeted ban focused solely on a device's unreasonably dangerous intended uses. To be sure, a use-specific ban may be seen to constrain a physician's ability to acquire the device for the banned purpose. But her ability to acquire the device would be equally (if not more) constrained in the case of an across-the-board ban, which all agree the agency can impose. And the FDA's ability to take myriad other actions that can also prevent a device from reaching physicians is well-established: no one disputes that the agency may decline to approve a device in the first place, for instance, or

withdraw its prior approval of a device. *See* 21 U.S.C. §§ 360e(d)(2), 360e(e)(1).

Against that backdrop, the agency's authority to fashion a partial ban on a device is unexceptionable. I would therefore sustain the FDA's understanding of § 396 as a permissible exercise of the agency's interpretive authority. I respectfully dissent from my colleagues' contrary conclusion.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), undersigned counsel certifies as follows:

A. Parties and Amici

Petitioners are the Judge Rotenberg Educational Center, Inc., Luis Aponte, on behalf of himself and on behalf of his ward, L.A.; Ophelia Asare and John Asare, on behalf of themselves and on behalf of their ward, G.A.; Maria Augusto, on behalf of herself and on behalf of her ward, S.P. ; Nelson Bernardo, on behalf of himself and on behalf of his ward, N.B.; Richard Bevins, on behalf of himself and on behalf of his ward, W.M.; Indra Biggs, on behalf of herself and on behalf of her ward, D.B.; Judy Casoria and Carlo Casoria, on behalf of themselves and on behalf of their ward, JA.C.; Gail Cornish, on behalf of herself and on behalf of her ward, D.R.; Hannah Crawford, on behalf of herself and on behalf of her ward, J.C.; Patricia Crawford and Cornnis Crawford, on behalf of themselves and on behalf of their ward, E.C.; Prudence Dellamano, on behalf of herself and on behalf of her ward, M.R.; Angelo Disisto, on behalf of herself and on behalf of her ward, L.D.; Richard Doherty and Richard Bevins, on behalf of themselves and on behalf of their ward, M.D.; Lauren Emmick and Martin Emmick, on behalf of themselves and on behalf of their ward, L.E.; Barbara Forbes and

Roger Forbes on behalf of themselves and on behalf of their ward, D.F.; Bruce Freeman, on behalf of himself and on behalf of his wards, L.J., B.S., B.W.; Yakuline Giuffrida and Lance Giuffrida, on behalf of themselves and on behalf of their ward, E.G.; Louisa Goldberg and Robert Goldberg, on behalf of themselves and on behalf of their ward, A.G.; Lee Higgins on behalf of himself and on behalf of his ward, S.H.; Judith Honore and Mathurin Honore, on behalf of themselves and on behalf of their ward, J.H.; Stephen Hanna, on behalf of himself and on behalf of his ward, D.M.; Erick Kemp, on behalf of himself and on behalf of his ward, D.K.; David Lewis, M.D., on behalf of himself and on behalf of his ward, E.L.; Cheryl Lloyd, on behalf of herself and on behalf of her ward, C.L.; Carline Lopez and Alfred Lopez, on behalf of themselves and on behalf of their ward, J.L.; Mary Marini, on behalf of herself and on behalf of her ward, G.M.; Trisha Moeder, on behalf of herself and on behalf of her ward, J.B.; Jean Murphy and William Murphy, on behalf of themselves and on behalf of their ward, R.M.; Lainie Murphy, on behalf of herself and on behalf of her ward, BRA.S.; Cheryl Murray, on behalf of herself and on behalf of her ward, K.A.; Dollie Myrick and James Myrick, on behalf of themselves and on behalf of their ward, M.M.; Carol Peterson and Paul Peterson, on behalf of themselves and on behalf of their ward, D.P.; Robin Pisano and Joseph

Pisano, on behalf of themselves and on behalf of their ward, A.P.; Carmen Pena, on behalf of herself and on behalf of her ward, G.T.; Bridget Reaney and Colman Reaney, on behalf of themselves and on behalf of their ward, N.R.; Ilana Slaff-Galatan, on behalf of herself and on behalf of her ward, MA.S.; Ana Rivera, on behalf of herself and on behalf of her ward, E.R.; Marcia Shear and Mitchell Shear, on behalf of themselves and on behalf of their ward, SA.S.; James Shields, on behalf of himself and on behalf of his ward, M.S.; Amjad Siddiqi, on behalf of himself and on behalf of his ward, HA.S.; Raul Sierra, on behalf of himself and on behalf of his ward, J.S.; Kathy Dion, on behalf of herself and on behalf of her ward, ST.S.; Melody Simpson, on behalf of herself and on behalf of her ward, C.S.; Claudia Soucy and Leo Soucy, on behalf of themselves and on behalf of their ward, BRE.S.; Ellen Stahler and Stacy Engels, on behalf of themselves and on behalf of their ward, H.S.; Jamie Tam and Gary Tam, on behalf of themselves and on behalf of their ward, S.T.; Carmen Torres, on behalf of herself and on behalf of her ward, AN.G.; Carlos Vollenweider, on behalf of himself and on behalf of his ward, E.V.; Kelly Walker and Laura Walker, on behalf of themselves and on behalf of their ward, B.W.; Jenkin Washington and Marie Washington, on behalf of themselves and on behalf of their ward, JA.W.; Corine Watson, on behalf of herself and on behalf of her ward,

S.W.; Michele Winters and Charles Winters on behalf of themselves and on behalf of their ward, E.W.; Sharon Wood and Roger Wood, on behalf of themselves and on behalf of their ward, J.W.; and The B.R.I. Parents and Friends Association, Inc. d/b/a The J.R.C. Parents and Friends Association, Inc., on behalf of its members.

Respondents are the U.S. Food and Drug Administration, Janet Woodcock in her official capacity as Acting Commissioner of the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services, and Xavier Becerra in his official capacity as Secretary of Health and Human Services.

There have been no intervenors.

Amici appearing in this court are the New Civil Liberties Alliance, the American Academy of Pediatrics, the American Association on Intellectual and Developmental Disabilities, the American Academy of Developmental Medicine and Dentistry, the International Association for the Scientific Study of Intellectual and Developmental Disabilities, the National Association of State Directors of Developmental Disabilities Services, the National Association of State Directors of Special Education, and the National Association for the Dually Diagnosed.

B. Rulings Under Review

On March 6, 2020, the U.S. Food and Drug Administration issued a final rule under 21 U.S.C. § 360f that banned electrical stimulation devices for self-injurious and aggressive behavior. Petitioners sought judicial review of that rule, and respondents seek en banc review of the panel's decision.

C. Related Cases

This case has not previously been before this Court or any other court, and there are no related cases pending in this Court or any other court. *See* D.C. Cir. R. 28(a)(1)(C) (defining "any other court" to mean a U.S. Court of Appeals or a court in the District of Columbia).

/s/ Daniel Aguilar
Daniel Aguilar