United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 23, 2021 Decided July 6, 2021

No. 20-1087

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC.,
PETITIONER

v.

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

Consolidated with 20-1088

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

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

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

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

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

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

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

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

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

Dissenting opinion filed by *Chief Judge* SRINIVASAN.

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

I. Background

A. Factual background

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

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

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

B. Procedural background

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

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

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

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

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.