ORAL ARGUMENT NOT YET SCHEDULED

Nos. 20-1087, 20-1088

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

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC.,
Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,
Respondents.

LUIS APONTE, on behalf of himself and on behalf of his ward, L.A., *et al.*,
Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,
Respondents.

On Petitions for Review of a Final Rule of the Food and Drug Administration

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BRIEF OF THE NEW CIVIL LIBERTIES ALLIANCE AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS, URGING VACATUR

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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Parties and *Amici*. All parties, intervenors, and *amici* appearing before this Court are listed in the Certificates as to Parties, Rulings, and Related Cases filed by Petitioners, except for the New Civil Liberties Alliance (NCLA), which is filing this *amicus curiae* brief in support of Petitioners.

Rulings Under Review. The rulings under review are set forth in the Certificates as to Parties, Rulings, and Related Cases filed by Petitioners.

Related Cases. Counsel for NCLA is unaware of any related cases before this Court.

/s/ Richard A. Samp
Richard A. Samp

Dated: November 23, 2020

CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Circuit Rule 29(b), Fed.R.App.P. 26.1, and Circuit Rule 26.1, the undersigned counsel states that *amicus curiae* New Civil Liberties Alliance (NCLA) is a non-profit corporation; it has no parent corporations, and no publicly-held company has a 10% or greater ownership interest.

Pursuant to Circuit Rule 26.1(b), NCLA describes its general nature and purpose as follows. NCLA is a nonpartisan, nonprofit public-interest organization that has appeared in this Court on a number of occasions in cases raising public policy issues. NCLA has no financial ties with any party to this appeal.

/s/ Richard A. Samp
Richard A. Samp

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GLOSSARY

ADD	Addendum
The Center	The Judge Rotenberg Educational Center, Inc.
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
GED	Graduated Electronic Decelerator
JRC	The Judge Rotenberg Educational Center, Inc.
MDA	Medical Device Amendments of 1976
NCLA	New Civil Liberties Alliance

INTERESTS OF *AMICUS CURIAE*

The New Civil Liberties Alliance (NCLA) is a nonpartisan, nonprofit organization devoted to defending constitutional freedoms from violations by the administrative state.[1] The "civil liberties" of the organization's name include rights at least as old as the U.S. Constitution itself, such as jury trial, due process of law, the right to be tried in front of an impartial and independent judge, and the right to live under laws made by the nation's elected lawmakers through constitutionally prescribed channels. Yet these self-same rights are also very contemporary—and in dire need of renewed vindication—precisely because legislatures, executive branch officials, administrative agencies, and even sometimes the courts have neglected them for so long.

NCLA aims to defend civil liberties—primarily by asserting constitutional constraints on the administrative state. Although Americans still enjoy the shell of their Republic, there has developed within it a very different sort of government—a type, in fact, that the U.S. Constitution was designed to prevent. This unconstitutional administrative state within the federal government is the focus of NCLA's concern.

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[1] NCLA states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than NCLA and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties have consented to the filing of the brief.

Petitioners have made a compelling case that the Food and Drug Administration's (FDA) March 6, 2020 rule (the "Final Rule") violates the Administrative Procedure Act because it is unsupported by substantial evidence and reflects arbitrary and capricious decisionmaking. But NCLA is filing this brief to focus on more fundamental defects in FDA's decision. Congress authorized FDA to utilize rulemaking proceedings to ban commercial distribution and sale of certain medical devices, 21 U.S.C. § 360f, but that provision is inapplicable to devices (as here) manufactured many years ago for the sole use of the manufacturer and its health-care providers. FDA's resort to that statute denied Petitioners their due process rights to a hearing on their claims.

FDA's rulemaking proceeding also runs afoul of Congress's decision to reserve to the States authority to regulate the practice of medicine. NCLA is concerned that FDA has run roughshod over Petitioners' procedural rights and has arrogated to itself powers not delegated to it by Congress.

STATEMENT OF THE CASE

Petitioner The Judge Rotenberg Educational Center, Inc. (the "Center" or "JRC") operates a state-licensed treatment facility in Massachusetts that provides treatment and educational services to nearly 300 patients from throughout the United States with severe disabilities and a history of engaging in dangerous, life-

threatening behavior. The Center serves the most seriously ill patients; each of its patients has undergone multiple treatments at multiple facilities before coming to the Center because those facilities were unable to control the patients' dangerous behavior—*e.g.*, gouging their eyes, banging their heads, chewing off body parts.

The Center is the nation's only facility that employs "electrical stimulation devices" (a category that includes the Center's GEDs) as part of a comprehensive Applied Behavior Analysis treatment plan to treat patients' self-injury and aggression. This therapy, administered to fewer than 20% of the Center's patients (all adults), entails administering a skin shock to a patient's arm or leg to modify undesirable behavior. The Center has employed skin-shock therapy with a small minority of its patients for more than 30 years, and contends that the therapy has led to significant reductions in undesirable behavior.

To administer the treatment, the Center has manufactured a device known as a Graduated Electronic Decelerator (GED), which FDA cleared for marketing in 1994.[2] The Center is the sole manufacturer of GEDs, and it does not distribute them to others. Indeed, while it continues to use its GEDs, it has not manufactured a new one in a decade.

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[2] The GED falls within a category of medical devices known as "aversive conditioning devices," which FDA classified as Class II devices in 1979 because their potential risks were "well known." *See* 21 C.F.R. § 882.5235.

For many years, FDA voiced no objections to the Center's use of aversive therapy. In 2000, FDA determined that the Center's reliance on its own GEDs constituted the practice of medicine and thus was exempt from the Food, Drug, and Cosmetic Act's (FDCA) premarket notification requirements, citing 21 C.F.R. § 807.85. FDA conducted inspections of the Center in 2000, 2010, and 2012 and observed no reportable incidents regarding GED use.

By 2013, however, FDA had become openly hostile to contingent skin shock and began planning a lawsuit against the Center. It eventually abandoned plans for a lawsuit and instead initiated this rulemaking proceeding under 21 U.S.C. § 360f. That statute authorizes FDA, under specified conditions, to issue a regulation that declares a device to be "a banned device."

FDA issued its proposed regulation in April 2016 and its final regulation in March 2020. The ban applies to electrical stimulation devices used to deter self-injurious or aggressive behavior. It does not apply to electrical stimulation devices used for other purposes, such as to deter smoking. The Final Rule states:

> FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. This ban includes both new devices *and devices already in distribution and use*.

ADD01, 85 Fed. Reg. 13,312 (March 6, 2020) (emphasis added).

The Final Rule has no effect on anyone other than the Center and its patients; no other treatment facility uses electrical stimulation devices to treat self-injurious or aggressive behavior. FDA has temporarily stayed its Final Rule, which was initially scheduled to take effect on April 6, 2020.

FDA's determination that contingent skin shock presents unreasonable risks to patients directly conflicts with determinations made by Massachusetts's courts. In 2018, after a 44-day evidentiary hearing, a Massachusetts Probate and Family Court judge ruled that aversive therapy using the GED (which entails administering two-second skin shocks) is both safe and effective. ADD254-ADD304. The ruling kept in place a consent decree under which Massachusetts permits the Center to employ its GED treatment to selected patients—but only if the Center first prepares a detailed, personalized treatment plan and if a state judge determines (after an adversarial hearing) that the procedure is safe and in the patient's best interests. *Id.* at ADD290-ADD291. Employing that procedural framework, Massachusetts judges in hundreds of cases spanning several decades have approved the use of the Center's skin-shock therapy to treat patients who have failed other therapies.

The Center seeks review of the Final Rule in this Court. A large group of parents whose children are patients at the Center have also petitioned for review.

Those parents contend that the Center's GED treatment has dramatically reduced the incidence of their children's self-abusive and aggressive conduct, and they are concerned that the Final Rule will deprive their adult children of the only treatment that has proven effective for them.

SUMMARY OF ARGUMENT

FDA seeks to prevent the Center from continuing to use medical devices it manufactured long ago for its own use. FDA has sought to do so by initiating a rulemaking proceeding, during which it concluded that the Center's devices "present an unreasonable and substantial risk of illness or injury" when used to treat patients for self-injurious or aggressive behavior, ADD001, even though (1) substantially similar devices may continue to be used to treat other medical conditions; and (2) the Center is the only treatment facility in the country that uses the devices banned by FDA's rule.

Under those circumstances, the statute on which FDA relies, 21 U.S.C. § 360f, does not provide FDA the rulemaking authority it seeks to exercise. Both its text and context indicate that Congress adopted the statute to permit FDA to move swiftly to prevent manufacturers from continuing to commercially distribute fraudulent or hazardous medical devices during the time it would take for FDA to prevail in a court proceeding. That rationale is inapplicable when, as here, *no*

manufacturer is seeking to commercially distribute the devices targeted by FDA, and the Center's professional staff is using devices the Center manufactured years ago.

The administrative record provides strong evidence of why FDA chose its unorthodox rulemaking path rather than filing a federal-court proceeding against the Center. Because courts in Massachusetts have repeatedly found that the Center's skin-shock therapy is both safe and effective, FDA understandably feared that a federal court, ruling *de novo*, would reject its "unreasonable and substantial risk" claim. By opting for a rulemaking proceeding (for only the third time in its history), FDA was able to serve as both prosecutor and judge, and to prevent the Center from cross-examining FDA's witnesses and effectively responding to the assertions FDA made to support its finding. Those circumstances strongly support Petitioners' claims that FDA has acted in bad faith throughout these proceedings. But quite apart from FDA's bad faith, federal law provides that if FDA seeks to prevent the Center from continuing to use its GED devices in its aversive therapy, it should have done so by filing an action for seizure of the devices, 21 U.S.C. § 334, or for an injunction, 21 U.S.C. § 332, an approach FDA contemplated and abandoned.

The Final Rule should be vacated for the additional reason that FDA is interfering with the practice of medicine by attempting to dictate how the Center must treat its patients. Congress has made clear that the practice of medicine is a matter for state regulation, and Massachusetts courts have repeatedly supported and upheld the Center's use of skin-shock therapy. FDA has *not* banned all uses of electrical stimulation devices such as the GEDs; it concedes that they may continue to be used to treat smoking addiction, for example. Under those circumstances, the practice-of-medicine doctrine bars FDA from interfering with decisions of the Center's clinicians to use the GEDs in any manner they deem medically appropriate.

The practice-of-medicine doctrine would not preclude FDA from barring the *sale and distribution* of electrical stimulation devices for the purpose of treating self-injurious or aggressive behavior. But here FDA is seeking to ban the use of existing devices that were manufactured by the Center for its own use at a time when FDA disclaimed any right to regulate their manufacture or use.

ARGUMENT

I. THE STATUTE AUTHORIZING FDA TO BAN DEVICES VIA RULEMAKING IS INAPPLICABLE HERE

FDA points to 21 U.S.C. § 360f as the source of its authority to engage in rulemaking designed to prohibit use of GEDs and other electrical stimulation devices for self-injurious or aggressive behavior. That statute permits FDA to ban a device by means of a regulation under some circumstances. But the text and context of the statute indicate that it does not permit FDA to proceed by regulatory action under the facts of this case.

A. Rulemaking Bans Are Only Authorized to Prevent *Commercial Distribution* of Unreasonably Unsafe Devices

Congress adopted § 360f, entitled "Banned devices," as part of the Medical Devices Amendments of 1976 (MDA), Pub. L. 94-295. The MDA substantially expanded federal regulation of medical devices. Section 360f authorizes FDA to initiate a proceeding to adopt a regulation declaring a device to be a "banned device" when "a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury."

A report on the MDA by the House Committee on Interstate and Foreign Commerce explained that § 360f was designed to provide FDA with a more

effective means of quickly stopping continued commercial distribution of dangerous or fraudulent medical devices:

> [T]he existing authority of the Secretary to protect the American public from dangerous or fraudulent medical devices is limited to seizure and injunction. To sustain a court action against such devices, the Secretary has the burden of proving that such device is misbranded or adulterated, and throughout the usually lengthy court proceeding, *the device manufacturer may continue marketing his product*. ... The Committee believes that the proposed new authority will enable the Secretary to move quickly to protect the public from fraudulent or hazardous medical devices *in commercial distribution* in a manner that will not compromise the rights of device manufacturers.

H.R. Report No. 94-853 (1976) at 18-19, ADD140-41 (emphasis added).

There is no hint in the House Report that Congress intended this expedited rulemaking authority to apply to situations, as here, in which *no* manufacturer is commercially distributing the devices in question and in which only a single treatment facility is using the devices—all of which it manufactured many years before. Under such circumstances, requiring FDA to resort to its much more commonly employed tools (court actions for seizures and injunctions) would not create any danger that a manufacturer would continue to commercially distribute its products while court actions were pending. And authorizing FDA to proceed via rulemaking would not eliminate any such danger.

The texts both of § 360f and of the remainder of the MDA demonstrate that Congress did not authorize § 360f rulemaking proceedings for medical devices not being commercially distributed. For example, § 360f includes a lengthy section that addresses whether a device's "unreasonable and substantial risk of illness or injury ... could be corrected or eliminated by labeling or change in labeling." 21 U.S.C. § 360f(a)(2). That discussion only makes sense in the context of commercially distributed medical devices. It contemplates that labeling will play a crucial role in any determination of whether a medical device creates unreasonable and substantial risks. To protect "the rights of device manufacturers," ADD141, the statute provides that if a labeling change would correct or eliminate those risks and the manufacturer makes the necessary changes specified by FDA, then FDA may not ban the device under § 360f.

But that focus on labeling changes makes no sense in the context of a device that, as here, is not commercially distributed but rather was manufactured by the health-care professionals who will be using the device. The FDCA imposes labeling requirements on prescription medical products to ensure that *the treating clinician, not the patient*, has "adequate directions for use." *United States v. Evers*, 643 F.2d 1043, 1051 (5th Cir. 1981) (quoting 21 U.S.C. § 352(f)(1)). For that reason, when the person who manufactures a medical product is also the treating

clinician, it is "nonsensical" to suggest that he should be required to "provide adequate information to himself." *Id.* at 1053. Accordingly, § 360f's mandate that any rulemaking proceeding should focus heavily on product labeling is a strong textual indication that Congress did not authorize FDA to proceed via rulemaking when the adequacy of labeling is not an issue.

Moreover, the entire focus of the MDA is the "commercial distribution" of medical devices. *See, e.g.*, 21 U.S.C. § 360(k) (requiring that FDA be notified before a medical device is "introduced or delivered for introduction into interstate commerce for *commercial distribution*") (emphasis added); 21 U.S.C. § 360c(f)(1) (stating that specified devices should be classified as Class III devices unless they were "introduced or delivered for introduction into interstate commerce *for commercial distribution* before May 28, 1976" or are "substantially equivalent" to Class I or Class II devices that were "introduced or delivered for introduction into interstate commerce *for commercial distribution*" before that date) (emphasis added); 21 U.S.C. § 360e(b). It strains credibility to suggest that Congress intended the abbreviated rulemaking proceedings authorized by § 360f to apply to medical devices that were never commercially distributed when the entire focus of the remainder of the MDA is the commercial distribution of devices. Indeed, FDA determined in 2000 that the Center's GEDs were not subject to § 360(k)'s

notification requirements precisely because the Center was not distributing them commercially but rather was manufacturing them for its own use.[3]

B. The Statute Does Not Permit Bans for Some Uses But Not Others

Nothing in § 360f suggests that it authorizes FDA to issue a regulation that bans one use of a device but permits other uses. The statute authorizes FDA to promulgate a regulation declaring that an unsafe device is a "banned device"; it does not authorize a regulation declaring that the device is only partially banned. FDA itself has previously interpreted § 360f as permitting only complete bans. 48 Fed. Reg. 25,126 (June 3, 1983). On the two prior occasions when FDA relied on § 360f, it imposed a ban on *all* uses of the device in question both times. 21 C.F.R. § 895.101 (ban on prosthetic hair fibers); 81 Fed. Reg. 91,722 (Dec. 16, 2016) (ban on powdered surgical gloves).

In support of its alleged authority to issue partial-ban regulations, FDA argues, "[I]t is difficult to conceive of a ban of a device divorced from its intended

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[3] FDA argues that it is entitled to regulate an entity's manufacturing activities even if the manufacturer never distributes its medical products commercially and simply uses them internally. But even if such activity might arguably in some circumstances constitute a "prohibited act" (*see, e.g.*, 21 U.S.C. § 331(k), which prohibits doing an act that renders the product adulterated or misbranded while the product is "held for sale"), nothing in § 360f suggests that FDA is permitted to utilize rulemaking proceedings to make such a "prohibited act" determination in connection with a product that has never been distributed commercially.

use since devices are defined and regulated not only according to their technological characteristics but also according to their intended uses." Final Rule, 85 Fed. Reg. at 13,345, ADD34. FDA's response is a *non sequitur*. The issue is not whether FDA may approve of some uses of a device while disapproving others—an action FDA undertakes on a regular basis when it reviews device applications. Rather, the issue is whether § 360f authorizes FDA to do so by issuing a "banned device" regulation. Section 360f's text authorizes FDA to issue a regulation declaring a device to be a "banned device." It says nothing suggesting that a regulation may go halfway—*i.e.*, a declaration that a device is a "banned device" when used for one purpose but not a "banned device" when used for another purpose.

C. FDA Opted for Rulemaking Proceedings Because It Wanted to Hamper Petitioners' Ability to Defend Against FDA's "Unreasonable and Substantial Risk" Claims

Petitioners have made a compelling case that FDA, in adopting its banned-device rule, "operated with animus, bias and bad faith to achieve a predetermined outcome." Center's Page Proof Brief at 58. NCLA will not repeat all that evidence here. Rather, NCLA focuses on one glaring aspect of FDA's bad-faith conduct: its choice to proceed against the Center via a rulemaking rather than a

court proceeding—precisely because FDA knew that doing so would hamper the Center's ability to defend itself.

As noted above, in 2011-12 FDA dramatically shifted its view of the Center's operations; while it previously concluded that those operations were exempt from the notification requirements of 21 U.S.C. § 360(k) and the FDCA's establishment-registration requirements, it thereafter began concerted efforts to shut down the Center's use of the GED device. By 2012-13, FDA made plans to file a judicial proceeding against the Center. Its December 6, 2012 Warning Letter to the Center stated, "Failure to promptly correct [alleged FDCA violations spelled out in the letter] may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties." By early 2013, the federal government selected an attorney to lead the litigation effort and attempted to build a case that the GED devices were unsafe—by instructing FDA scientists to seek evidence "that may be helpful to our case" and explaining that, "to get an injunction" prohibiting the Center's GED use, the more evidence it gathered to "counter JRC's success stories the better." Center's Page Proof Brief at 13 (quoting internal FDA documents).

But by late 2013, FDA had abandoned plans to initiate a court proceeding against the Center and instead began preparations for a regulatory proceeding

under § 360f. After several years devoted to gathering evidence to support a ban that senior FDA personnel already favored, FDA issued its proposed rule in April 2016 and its Final Rule in March 2020.

FDA has never explained why it shifted gears and decided to initiate a rulemaking proceeding rather than follow the much more common path: a court action seeking an injunction and seizure of drugs or devices. Its choice quite obviously had nothing to do with the rationale that motivated Congress to adopt § 360f in 1976: a desire to provide FDA with a speedy remedy so as to prevent medical device companies from continuing commercial distribution of hazardous medical devices while lengthy court proceedings (initiated by FDA) were ongoing. A *speedy* remedy against the Center appears to have been the furthest thing from FDA's mind. It spent several years crafting its case before filing its proposed rule and then waited four more years before issuing the Final Rule.

Nor can FDA plausibly claim that it resorted to rulemaking because it sought to adopt a nationwide policy that would apply to a broad cross-section of manufacturers. FDA was well aware that the Center was the only treatment facility in the nation that employed electrical stimulation devices to treat patients exhibiting self-injurious or aggressive behavior and thus the only facility that would be affected by the rulemaking proceeding. Indeed, the administrative record

is replete with FDA memos referring to the rulemaking as the "JRC ban," the "JRC ban rule," and the "JRC banning regulation."

The only plausible explanations for FDA's decision to shift its focus from litigation to a regulatory proceeding were FDA's fear that it would lose any case decided by an impartial decision-maker and its desire to gain the home-court advantages that come with a rulemaking proceeding. FDA had good reason to fear that it would lose a court proceeding: the Center's treatment practices have been upheld as safe and effective by numerous courts. Under the terms of a 1987 consent decree entered by a Massachusetts court, the Center does not administer aversive therapy to any of its patients unless a judge in the Massachusetts Probate and Family Court first determines (after an adversarial proceeding at which each patient is represented by separate counsel) that the therapy is in the patient's best interests and that he consents to it. Employing that procedural framework, Massachusetts judges in hundreds of cases spanning several decades have approved the safety and effectiveness of the Center's practices.[4]

Moreover, in June 2018, after a 44-day evidentiary hearing, a Massachusetts Probate and Family Court judge issued a comprehensive, 51-page opinion that

[4] In light of those consistent findings, NCLA is disturbed that the Final Rule does not even mention, let alone discuss, these court proceedings.

rejected an effort to overturn the 1987 consent decree. ADD254-ADD304. Among the judge's findings: that "for many JRC students, physical aversive treatment has been effective at treating the behavior that brought them to JRC," ADD303, and that opponents of aversive therapy failed to establish that the therapy falls outside "the accepted standard of care" for patients exhibiting self-injurious and aggressive behavior. ADD302.

During the Massachusetts court proceedings, the Center had the opportunity to call witnesses, to cross-examine opposing witnesses, to respond to all evidence on which opposing parties relied, and to have factual findings made by an impartial decision-maker. By resorting to a rulemaking proceeding, FDA was able to deny the Center each of those procedural protections. Indeed, during those proceedings, FDA denied the Center's request for a regulatory hearing and repeatedly refused the Center's requests that FDA officials visit the Center, meet with clinicians, evaluate patients, evaluate more data, and ask questions. Center's Page Proof Brief at 17.

A desire to deprive regulated entities of procedural protections they would have enjoyed in a judicial proceeding is not a good-faith reason for a regulatory agency to choose to proceed against those entities via a proposed rulemaking. If FDA had a good-faith basis for its decision, it has yet to articulate it. FDA's

unexplained and unusual decision to initiate a rulemaking under § 360f considerably strengthens Petitioners' claims that FDA has proceeded in bad faith.

D. Interpreting the Statute to Permit FDA to Employ Rulemaking Proceedings Under the Facts of This Case Would Raise Serious Constitutional Concerns

FDA's § 360f proceeding was largely adjudicatory in nature: it decided issues that affected only one regulated entity, and many of its findings were focused on the Center's conduct. The Due Process Clause guarantees significant procedural protections to entities subject to adjudicatory proceedings, yet FDA's § 360f proceeding afforded the Center virtually none of those protections. A ruling that § 360f authorized FDA to proceed as it did would call into serious question the constitutionality of § 360f. To avoid the need to address those constitutional concerns, the Court should interpret § 360f as urged by Petitioners: that it does not authorize FDA to initiate banned-device rulemaking proceedings in connection with devices that are used by only one entity and are not commercially distributed.

In general, an agency is required to provide greater procedural protections to interested parties when it engages in adjudication than when it engages in rulemaking. Because a rule generally treats a large number of people in a like manner, the law is less concerned about procedural protections for each of the many people similarly affected by a rulemaking than it is about protections for

those whose interests are being adjudicated on an individualized basis. But merely because an agency labels a proceeding a "rulemaking" does not preclude the possibility that the agency is exercising adjudicatory powers to which enhanced due process protections apply.

As explained by the Supreme Court:

> The basic distinction between rulemaking and adjudication is illustrated by this Court's treatment of two related cases under the Due Process Clause of the Fourteenth Amendment. In *Londoner v. Denver*, cited in oral argument by appellees, 210 U.S. 373 (1908), the Court held that due process had not been accorded a landowner who objected to the amount assessed against his land as its share of the benefit resulting from the paving of a street. Local procedure had accorded him the right to file a written complaint and objection, but not to be heard orally. This Court held that due process of law required that he "have the right to support his allegations by argument, however brief; and, if need be, by proof, however informal." *Id*., at 386. But in the later case of *Bi-Metallic Investment Co. v. State Board of Equalization*, 239 U.S. 441 (1915), the Court held that no hearing at all was constitutionally required prior to a decision by state tax officers in Colorado to increase the valuation of all taxable property in Denver by a substantial percentage. The Court distinguished *Londoner* by stating that there a small number of persons "were exceptionally affected, in each case upon individual grounds." *Id*., at 446.

United States v. Florida East Coast Ry. Co., 410 U.S. 224, 244-45 (1973).

Under the standard set out in *Florida East Coast*, FDA's § 360f proceeding bears many of the hallmarks of an adjudicatory proceeding, despite being labeled a rulemaking by FDA. As was true in *Londoner*, only one regulated entity (the

Center) was affected by FDA's decision to ban electrical stimulation devices. Indeed, FDA's decision does not ban all electrical stimulation devices, only those used for self-injurious or aggressive behavior—and only the Center uses the devices for those purposes. The Center can hardly be blamed for concluding that FDA's § 360f proceeding *adjudicated* its rights. While FDA's Final Rule nominally applies to any device manufacturer who might seek to market or use an electrical stimulation device for treating the targeted behaviors, FDA knew full well that no one other than the Center contemplated doing so—indeed, FDA officials routinely referred to its § 360f proceeding as "the JRC ban." Moreover, a significant amount of the evidence cited by FDA in support of the Final Rule focused not on qualities of GEDs in the abstract but rather on the manner in which the Center operated its aversive-therapy program.

Because the Center was subject to FDA adjudicatory proceedings, it was entitled to procedural rights afforded by the Due Process Clause, including a "meaningful" opportunity to be heard. *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). As outlined by the Center in its brief, it was provided no such opportunity;

in particular, FDA repeatedly rejected the Center's requests for a live hearing at which it could present its case.[5]

Section 360f's failure to provide hearing rights calls into serious question the statute's constitutionality as applied to the Center. Under the doctrine of constitutional avoidance, the Court should avoid addressing that issue by adopting the reasonable interpretation of § 360f espoused by Petitioners: that § 360f does not authorize proceedings to ban use of devices manufactured in-house by a single treatment provider and never distributed commercially. *See Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. and Const. Trade Council*, 485 U.S. 568, 575 (1988).

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[5] The absence of a hearing severely prejudiced the Center. One of many examples of that prejudice was the Final Rule's determination that "shortcomings" in the records provided by the Center to FDA prevented the agency from determining that the Center's aversive therapy was effective in treating self-injurious and abusive behavior. 85 Fed. Reg. at 13,333, ADD22. The Center attached many patient records to its comments on the proposed rule. FDA apparently decided as early as 2018 that those records were inadequate to establish effectiveness. But it did not inform the Center of that decision until it issued the Final Rule in 2020, despite the Center's repeated offers to provide more records and its invitations for FDA to conduct site visits. Had the Center been granted its requested hearing (either in federal court or before the agency), it could have learned of FDA's determination that the records were considered inadequate and provided additional evidence to substantiate its effectiveness claim.

NCLA has serious constitutional concerns whenever a federal administrative agency seeks to adjudicate core private rights in administrative proceedings.[6] The U.S. Constitution assigns the adjudication of such rights to the judiciary. *See B&B Hardware, Inc. v. Hargis Industries, Inc.*, 575 U.S. 138, 171 (2015) (Thomas, J., dissenting) (noting that "some historical evidence suggests that the adjudication of core private rights is a function that can be performed only by Article III courts, at least absent the consent of the parties to adjudication in another forum"). But at the very least, important constitutional values are threatened when, as here, a federal agency issues adjudicative decisions that adversely affect private rights without providing affected rights-holders a meaningful opportunity to be heard. The Court can eliminate that threat by overturning the Final Rule.

II. FDA IS IMPROPERLY ATTEMPTING TO REGULATE THE PRACTICE OF MEDICINE

The Final Rule should be vacated for the additional reason that FDA is interfering with the practice of medicine by attempting to dictate how the Center

[6] There is little doubt that a core private right is at stake in this case: the right of individuals (or their guardians) to make decisions (in conjunction with their clinicians) regarding their medical care. *See, e.g., Roe v. Wade*, 410 U.S. 113 (1973); *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

must treat its patients. Ever since adoption of the FDCA in 1938, Congress has repeatedly made clear that the practice of medicine is a matter for state regulation.

FDA is authorized to regulate the sale and distribution of drugs and devices in interstate commerce. But once FDA has authorized the distribution of a medical device, doctors' decisions on how to administer it to patients are subject to regulation only under state law. Indeed, in response to an FDA effort to regulate off-label prescriptions of devices, Congress (as part of the Food and Drug Administration Modernization Act of 1996) inserted an explicit practice-of-medicine provision into the FDCA:

> 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.

21 U.S.C. § 396.[7]

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[7] Even before adoption of this amendment, FDA itself recognized the limitations on its authority to regulate the practice of medicine. It stated in 1972, in the context of drug prescriptions:

> the physician may, as part of the practice of medicine ... vary the conditions of use from those approved. ... This interpretation of the Act is consistent with Congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to the enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice ... Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice,

Courts have repeatedly recognized that the practice-of-medicine exemption imposes strict limitations on FDA's statutory authority. The Supreme Court has explained that FDA's "mission [is] to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). The Court added, "FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding directly upon decisions statutorily committed to the discretion of health care professionals." *Ibid.*

Numerous courts have recognized that FDA has the authority to "control the availability" of medical products, but not their off-label use as part of the practice of medicine. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998) ("[O]ff-label use of FDA-approved drugs by physicians is an established aspect of the modern practice of medicine"), *appeal dism'd sub nom., Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *United States v. Caronia*, 703 F.3d 149, 180 (2d Cir. 2012) ("Finally, a ban on off-label prescriptions would be no better. Indeed, it would constitute an unprecedented

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> and declined to provide any legislative restrictions upon the practice of medicine.

37 Fed. Reg. 16,503 (Aug. 15, 1972) (quoted in *Evers*, 643 F.2d at 1048).

intrusion into the practice of medicine."); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 226 (S.D.N.Y. 2015) (rejecting FDA's narrow reading of *Caronia*).

Many other regulatory provisions are consistent with the prohibition against FDA's intrusion into the practice of medicine. For example, 21 U.S.C. § 360(g) and 21 C.F.R. § 807.65(d) exclude licensed practitioners who develop or modify their own medical devices for treatment of their patients from annual registration requirements with FDA.

Electrical stimulation devices (such as the Center's GEDs) are classified as Class II medical devices. 21 C.F.R. § 882.5235. They may legally be marketed for a number of medical purposes, such as for assisting with smoking cessation. Accordingly, medical practitioners are entitled to prescribe electrical stimulation devices for other (off-label) uses they deem medically appropriate. By attempting to prevent licensed clinicians at the Center from using these legally marketed medical devices for the treatment of self-injurious and aggressive behavior, FDA is improperly interfering with the practice of medicine. Regulation of medical practice is the province of state authorities, and Massachusetts courts have explicitly endorsed the Center's activities.

The Court's decision in *United States v. Regenerative Sciences, LLC*, 741 F.3d 1314 (D.C. Cir. 2014) is not to the contrary. The defendant doctors in

Regenerative were administering their patients a drug of their own invention that had never been approved by FDA. The Court rejected their claim that the practice-of-medicine statute barred FDA's enforcement action against them, stating that the FDCA authorizes FDA to prohibit doctors from dispensing unapproved drugs. 741 F.3d at 1319-20. In sharp contrast, in our case FDA is attempting to second-guess doctors' decisions regarding how (and for what purpose) they use an FDA-cleared medical device. If FDA's position were upheld, the practice-of-medicine exception would be obliterated. FDA would be free to bring an enforcement action against any doctor who prescribes an approved or cleared medical device for a use of which FDA disapproves.

CONCLUSION

The challenged FDA rule should be vacated.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* New Civil Liberties Alliance. Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of NCLA is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect X8), the word count of the brief is 5,999, not including the certificate as to parties, the Rule 26.1 disclosure statement, table of contents, table of authorities, glossary, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

November 23, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of November, 2020, I electronically filed the brief of *amicus curiae* New Civil Liberties Alliance with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/CF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
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