[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., 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

BRIEF FOR THE FEDERAL RESPONDENTS

ROBERT P. CHARROW
General Counsel
Department of Health and Human Services

JAMES LAWRENCE
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel for Litigation

NOAH T. KATZEN
Associate Chief Counsel

SETH I. HELLER
Associate Chief Counsel
Department of Health and Human Services
Office of the General Counsel
Food and Drug Administration

JENNIFER B. DICKEY
Acting Assistant Attorney General

SCOTT R. MCINTOSH
DANIEL AGUILAR
Attorneys, Appellate Staff
Civil Division, Room 7266
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-5432

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

Except for the following, all parties, intervenors, and amici appearing in this Court are listed in the opening brief for The Judge Rotenberg Educational Center, Inc, and the opening brief for Luis Aponte, on behalf of himself and on behalf of his ward, L.A., et al. On December 10, 2020, this Court granted petitioners' voluntary motion to dismiss Elizabeth Mesa, Ricardo Mesa, Donna Oldham, Malcolm Oldham, Pam Prunckun, and Edward Prunckun as petitioners from these consolidated cases.

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 seek review of that rule.

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

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulations:

Other Authorities:

GLOSSARY

Act	Federal Food, Drug, and Cosmetic Act
APA	Administrative Procedure Act
Center	The Judge Rotenberg Educational Center, Inc. petitioner in No. 20-1087
FDA	U.S. Food and Drug Administration
JA	Joint Appendix
Parents	The parent and guardian petitioners in No. 20-1088

STATEMENT OF JURISDICTION

The U.S. Food and Drug Administration (FDA) promulgated a final rule banning electrical stimulation devices for self-injurious and aggressive behavior on March 6, 2020. JA_[85.Fed.Reg.13312]. Petitioners filed petitions for review in this Court on March 26, 2020. The petitions were filed within the time allowed by 21 U.S.C. § 360g(a), and this Court has jurisdiction under 21 U.S.C. § 360g(a)(5).

STATUTORY AND REGULATORY PROVISIONS

The addendum to this brief includes the pertinent statutes and regulations.

INTRODUCTION AND STATEMENT OF THE ISSUES

A significant number of people in the United States exhibit self-injurious and aggressive behavior, which can cause those people to harm themselves or others. These behaviors tend to occur more often in people with intellectual or developmental disabilities, like autism. Treatment of these behaviors varies and can include behavioral therapy, teaching the person different ways to communicate and express their emotions, treating the underlying condition that causes the behavior, and taking prescription medications.

This case concerns electrical stimulation devices, which apply an electric shock to a person's skin to cause them pain, in an attempt to interrupt self-injurious or aggressive behavior. The use of electrical stimulation devices to treat these behaviors has raised numerous ethical considerations among scientific researchers and led dozens of States to ban their use for treating people with intellectual and

developmental disabilities. JA__[85.Fed.Reg.13341-42]. FDA undertook a rigorous years-long review of these devices, convening a panel of experts to consider their use, canvassing the scientific literature, examining state regulatory actions, and soliciting public comment.

Through that review, FDA determined that electrical stimulation devices pose a number of risks, including significant pain, tissue damage, burns, increased hostility and retaliation, panic, anticipatory fear, learned helplessness, anxiety, crying, and the potential to develop post-traumatic stress disorder. Against those substantial threats to health and well-being, there was hardly any rigorous evidence that electrical stimulation devices were effective at treating self-injurious and aggressive behavior, especially when compared to alternative treatments that had no risks or far fewer risks along with proven effectiveness. Ultimately, FDA determined that electrical stimulation devices used to treat these behaviors pose "an unreasonable and substantial risk of illness or injury" that cannot be "corrected or eliminated by labeling or change in labeling" of the devices. 21 U.S.C. § 360f. Accordingly, FDA exercised its statutory authority under 21 U.S.C. § 360f to ban these devices.

The issues presented are:

1. Whether FDA's determination in the final rule—that electrical stimulation devices used for self-injurious and aggressive behavior present an unreasonable and substantial risk of injury that cannot be corrected or eliminated by labeling—is arbitrary and capricious.

2. Whether FDA may ban a device that is intended for a specific kind of use.

3. Whether the final rule otherwise comports with the Administrative Procedure Act.

STATEMENT OF THE CASE

I. Statutory and Regulatory Framework

As originally enacted, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, (the Act) provided only limited federal regulatory oversight of medical devices. The need for federal regulation "changed in the 1960's and 1970's, as complex devices proliferated and some failed." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). "Most notably, the Dalkon Shield intrauterine device" was "linked to serious infections and several deaths," which in turn led to "[t]housands of tort claims." *Id.* Congress responded by amending the Act in 1976 to "impose[] a regime of detailed federal oversight." *Id.* at 316.

As amended, the Act created "various levels of oversight for medical devices, depending on the risks they present," including a classification system. *Riegel*, 552 U.S. at 316. Class I devices, like elastic bandages, are subject to "general controls" like labeling requirements. *Id.* (citing 21 U.S.C. § 360c(a)(1)(A)). Class II devices, like powered wheelchairs, require "special controls" like "performance standards and postmarket surveillance measures." *Id.* at 316-17 (citing 21 U.S.C. § 360c(a)(1)(B)). Class III devices, like "implanted cerebella stimulators[] and pacemaker pulse

generators," receive the "most federal oversight." *Id.* at 317 (citing 21 U.S.C. § 360c(a)(1)(C)).

Even with this new system of oversight, however, Congress was concerned that FDA had limited "existing authority" to "protect the American public from dangerous or fraudulent medical devices." H.R. Rep. No. 94-853, at 18 (1976). Accordingly, Congress enacted 21 U.S.C. § 360f, which authorizes FDA to ban those kind of medical devices. Under that statute, 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 and, as such, is subject to the restrictions that the Act imposes on adulterated articles. *See id.* § 351(g).

Before starting a rulemaking to ban a device, FDA "may consult with" a panel established under 21 U.S.C. § 360c(b) that "has expertise with respect to the type of device under consideration" in order to obtain their views. 21 C.F.R. § 895.21(b). Afterwards, if FDA decides to initiate a rulemaking, it publishes a notice of proposed rulemaking that summarizes "the reasons why the Commissioner initiated the proceeding," the agency's "evaluation of data and information," including data "submitted by the manufacturer," and "[a]ny other data and information that the Commissioner believes are pertinent to the proceeding." *Id.* § 895.21(d). The public

then has an opportunity to provide comments, *id.* § 895.21(d)(8), and the agency can afterwards determine whether the device should be banned or whether the rulemaking should be terminated, *id.* § 895.21(e). If the device is banned, FDA may later reconsider the ban either *sua sponte* or on a petition that demonstrates that "the conditions that constituted the basis" for the ban "are no longer applicable." *Id.* § 895.21(h).

FDA has been judicious with its banning authority and exercised it only twice before. First, in 1983, FDA banned prosthetic hair fibers "intended for implantation into the human scalp to simulate natural hair or conceal baldness." 21 C.F.R. § 895.101. In promulgating that ban, FDA explained that prosthetic hair fibers presented an unreasonable and substantial risk of illness and injury because they can cause infections, facial swelling, severe pain, scarring, permanent, additional loss of natural hair, and because the fibers can break "at the scalp line" making it "difficult to extract the fibers remaining below" the scalp. 48 Fed. Reg. 25126, 25127-28 (June 3, 1983). Second, in 2016, FDA banned powdered surgical and examination gloves, and powder intended for lubricating those gloves. *See* 21 C.F.R. §§ 895.102-895.104. These devices were banned because they can cause "severe airway inflammation, hypersensitivity reactions, allergic reactions (including asthma), allergic rhinitis, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue." 81 Fed. Reg. 91722, 91724 (Dec. 19, 2016).

II. FDA's Rulemaking For Electrical Stimulation Devices

A. Background on electrical stimulation devices used for self-injurious and aggressive behavior

Self-injurious and aggressive behavior are "among the most striking and devastating conditions associated with intellectual and developmental disabilities." JA__[81.Fed.Reg.24389]. Self-injurious behavior can lead to serious, permanent bodily damage, and aggressive behavior can "involve repeated physical assaults." *Id.* These behaviors "are often present in individuals with intellectual or developmental disabilities," like Autism spectrum disorder, Down syndrome, and Fragile X syndrome. *Id.* Studies vary on how prevalent these behaviors are, but a "commonly reported" estimate is that 10% of people with developmental or intellectual disabilities exhibit these behaviors, or about 330,000 people in the United States. *Id.* Extreme cases of self-injurious and aggressive behavior are less common, and a "reliable, conservative estimate" for people with extreme cases is about 25,000. JA__[85.Fed.Reg.13317].

Starting in the 1960s, these behaviors were sometimes treated by using aversive techniques, including electrical stimulation, JA__[81.Fed.Reg.24404], and in 1979 FDA classified electrical stimulation devices as Class II devices, JA__[81Fed.Reg.24391]. Electrical stimulation devices are a kind of "aversive conditioning device" that apply electrical shocks "to a person's skin upon the occurrence of a target behavior in an attempt to reduce or cease the behavior."

JA__[81.Fed.Reg.24390]. The device generates an electric current that travels to electrodes placed on a person's skin, causing a painful shock. *Id.* The device can be manually triggered by an operator, or automatically triggered if, for example, the device determines that a person's head or arm is accelerating quickly, which may be indicative of self-injurious or aggressive behavior. *Id.*

The devices are intended to be used during or immediately after a targeted behavior in order to interrupt the behavior, or condition the person against it, by causing pain. JA__[81.Fed.Reg.24390]. If the device uses a small electrode, it will deliver shocks that feel "sharp, cutting, or lacerating," while devices with larger electrodes cause shocks that feel "pinching, pressing, or gnawing." *Id.* Electrodes placed on the hands, feet, torso, neck, underarms, and face "will be particularly sensitive to shocks," and "[r]epeated shocks to the same location will" alter a person's perception of the shock, "increasing [its] intensity or pain." *Id.*

B. Risks presented by electrical stimulation devices

In its analysis of the scientific literature, case studies, reports, consideration by a panel of experts convened under 21 C.F.R. § 895.21(b), and other materials, FDA determined that electrical stimulation devices pose risks to a person's physical and psychological well-being.

1. *Physical risks.* The scientific literature "contains many reports of tissue damage or burns" from the devices, JA__[81.Fed.Reg.24395], which have been corroborated by expert reports, JA__[81.Fed.Reg.24396], and reports from state

agencies, JA__[81.Fed.Reg.24397]. In one case, a state investigation report described that a person's "skin was off of the area" where the device had shocked him, and the device had to be removed "because the area on was too bad to keep the device." JA__[81.Fed.Reg.24397]. FDA also received testimony from patients and patient's parents who "reported burns that they attributed to the use of" electrical stimulation devices. JA__[85.Fed.Reg.13323].

The electrical shocks delivered by the devices can cause substantial pain for the duration of the shock. That pain was described by those who experienced it 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." JA__[81.Fed.Reg.24395, 24398; 85.Fed.Reg.13321-22].

2. *Psychological risks.* 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. JA__[81.Fed.Reg.24393]. Several scientific articles have reported that these devices can cause "screaming, crying, or shivering upon device application; grimacing; flinching; perspiring; and escape behavior." JA__[81.Fed.Reg.24394]. Increased sweat and fear reactions were particularly concerning, because sweat can increase electrical conductivity and further exacerbate the pain caused by an electric shock. JA__[81.Fed.Reg.24390, 24394].

Those psychological responses can change patient behavior. Some patients will "resort[] to hostility and retaliation," while others may have a "pseudocatatonic sit-down, *i.e.*, muscular freezing or melting." JA__[81.Fed.Reg.24394]. The scientific literature also reports that patients may increase their own attempts at self-injury in response to the electric shocks, sometimes "reaching the point that extended treatment with the [devices] became impossible to maintain." *Id.* The device's shocks could also create "a perfect paradigm for" instilling learned helplessness in patients, since the devices would be "producing pain in people who have no control over the pain." JA__[81.Fed.Reg.24396].

For related reasons, the devices pose risks of causing depression, acute stress, and "possible suicidal ideation." JA__[81.Fed.Reg.24396, 24398]. Patients reported experiencing "nightmares, freezing up upon hearing certain sounds associated with" the electrical shock, and "flashbacks." JA__[81.Fed.Reg.24398]. One psychologist reported that her patients would "wak[e] up screaming from nightmares, which only happened after [electrical stimulation devices] were used on them," while other patients experienced "waking nightmares, in which horrible memories of shock, pain, and restraint suddenly over[came] them, even during an otherwise happy event." JA__[81.Fed.Reg.24398-99]. As one patient treated with the devices reported to a state agency, "[t]here are days when I am scared to even say a word to anyone. I am afraid to wake up because I never know what is going to happen to me. I think I

should not have to live in fear and be scared. * * * I get so depressed here I wish my life by fast." JA__[81.Fed.Reg.24397].

3. *Underreporting of risks*. These documented risks were compounded by the fact that "the medical literature suffers from some significant limitations and has likely underreported" adverse events associated by electrical stimulation devices. JA__[81.Fed.Reg.24395]. Most of the available research articles were 40 to 50 years' old, "before significant advances in the ability to diagnose and classify psychological" adverse events like post-traumatic stress disorder, and before the implementation of "modern standards for [adverse event] monitoring." *Id.* There was also a unique problem posed by the fact that many patients with self-injurious and aggressive behavior have intellectual and developmental disabilities, which "diminish[]" their ability to communicate. *Id.* Thus, a patient may not be able to effectively express "feedback indicating injuries," or the disability itself (*e.g.*, autism) "may impair expressions of pain." *Id.* FDA also recognized that the scientific literature might have a bias against reporting adverse events and risks. Indeed, one review of scientific studies noted that it "might be wise to consider the possibility that some investigators have been predisposed to see only the positive side effects." *Id.*

C. The data on whether electrical stimulation devices are effective

Given these substantial risks, FDA undertook an extensive review of the medical literature to determine whether electrical stimulation devices were effective at

treating self-injurious and aggressive behavior. FDA reviewed "45 studies, including 41 case reports or case series, a case-control study conducted outside the United States, a within-subjects comparison trial conducted outside the United States, a retrospective review of 60 patient charts, and a questionnaire followup study of 22 subjects," as well as "12 articles reviewing some of these 45 studies that included specific clinical information on individual subjects and examined the effectiveness of" the devices on "various pathologies," including self-injurious and aggressive behavior. JA__[81.Fed.Reg.24399].

Those studies and articles demonstrated that electrical stimulation devices "can have some immediate impact on the targeted behaviors in some patients," in that they can immediately stop a patient who is exhibiting self-injurious or aggressive behavior. JA__[81.Fed.Reg.24399]. There was evidence too, though, that some patients would "adapt" to electrical shocks, meaning they would "no longer respond[] at a particular level of stimulation," which may be "evidence of ineffectiveness" even "with respect to immediate interruption or cessation of the targeted behavior." *Id.*

There was substantially less evidence that electrical stimulation devices produce a durable conditioning effect, which causes a person not to exhibit self-injurious or aggressive behavior for a clinically meaningful period of time. While some studies reported apparent durable conditioning effects of months or years, JA__[81.Fed.Reg.24399], those studies came with significant limitations. One review of those studies explained that the durable effect existed "as long as the punishment

contingency remains in effect," indicating that the durable effect depended on the continued presence and application of electrical shocks. *Id.* Accordingly, that review recommended that until further research was carried out, "practitioners and caregivers should not assume punishment will remain effective over the long run." *Id.*

FDA also concluded that these studies "suffer[ed] from a number of deficiencies that limit confidence in the results." JA__[81.Fed.Reg.24400]. For instance, none of the studies were randomized controlled trials designed to directly examine the effectiveness of electrical stimulation devices for self-injurious and aggressive behavior. *Id.* Without such randomized controlled trials, the studies necessarily "yield[ed] weaker conclusions, and thus more uncertain predictions" of effectiveness. *Id.* That was particularly true of retrospective studies, which did "not include a control group," and case reports that concern "the experiences of single individuals." *Id.*

Thus, for example, a series of case reports detailed reductions in self-injurious and aggressive behavior with electrical stimulation devices. JA__[85.Fed.Reg.13333]. Those patients, however, were also "given concomitant treatments such as positive reinforcement or time-outs," and it was "unclear how much, if anything, the use of" electric shocks contributed to their change in behavior. *Id.* Other case studies failed to explain "whether concomitant treatments were given" and lacked discussion of "baseline behavior measurements, device output and electrode locations, and shock administration protocols," further diminishing their value. *Id.*

Other methodological problems limited the quality of these studies. Most of the studies (26 out of 45) were conducted over 40 years ago and "do not adhere to current, more exacting peer-review standards for study conduct and reporting." JA__[81.Fed.Reg.24400-01]. Even a more recent publication "failed to explain, among other standard disclosures, data collection procedures, whether it was retrospective or prospective, and why and how staff made certain decisions that differed from patient to patient." JA__[81.Fed.Reg.24401]. Another article that reviewed case reports "failed to describe how [it] chose the specific case reports, meaning that the authors may have overlooked or omitted individuals for whom punishment-based techniques" were ineffective. *Id.* Other papers, published in 2008 and 2010, were printed in a journal that appears to no longer exist, did not conduct peer-review of its published papers, and whose editorial board included the author of the papers, Dr. Israel, the founder of petitioner Judge Rotenberg Educational Center (Center). *Id.*

Based on these methodological limitations, FDA determined that the scientific literature provides "generally weak" evidence of effectiveness for electrical stimulation devices, particularly for long-lasting durable effects. JA__[81.Fed.Reg.24401].

D. Other forms of treatment

Although electrical stimulation devices were often used along with other aversive conditioning techniques decades ago, the state of the art has evolved away from these devices "and toward positive interventions." JA__[81.Fed.Reg.24404]; *see*

also 44 Fed. Reg. 29214, 29215 (May 18, 1979) (in determining whether risk is "unreasonable," FDA "will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users"). By 1990, there were well-documented ethical concerns with using aversive conditioning techniques based on "physical pain" that "result in harm," particularly when a treatment best designed for "crisis intervention" and "infrequent use" was being used instead as an "on-going restraint." JA__[A592.at.6-7]. Since then, medical practice and scientific analysis have "shifted away from" these aversive techniques. JA__[85.Fed.Reg.13341]. Today, only one facility in the United States uses electrical stimulation devices to treat self-injurious and aggressive behavior—petitioner Judge Rotenberg Educational Center. JA__[81.Fed.Reg.24391]. And of all published papers on the effectiveness of electrical skin shock, only ten have been published in the last 20 years, and only one has been published in the last decade. JA__[85.Fed.Reg.13341]. Most of those papers have been written by Center employees and consultants, which raised FDA's concerns "regarding their impartiality." JA__[81.Fed.Reg.24406].

Corresponding with this decline in use of aversive conditioning techniques, medical practitioners have been treating self-injurious and aggressive behavior more often with positive interventions and prescription medication. JA__[81.Fed.Reg.24404-05]. Positive interventions can incorporate multiple elements, like "educative programming, functional communication training, and non-

aversive behavior management." JA__[81.Fed.Reg.24403]. These treatment strategies often "account for emotions and self-invalidation (rejecting the validity of one's own thoughts or emotions), which can be underlying factors associated with challenging behaviors." *Id.* Positive behavioral support, for example, seeks to have a person with self-injurious or aggressive behavior channel their actions and communicative intent into "a functionally equivalent, but non-problematic, behavior." JA__[81.Fed.Reg.24404]. Similarly, dialectical behavioral therapy can be used to treat the underlying conditions that give rise to self-injurious and aggressive behavior, and can teach the patient "mindfulness, distress tolerance, interpersonal effectiveness, and emotion regulation." *Id.*

These positive interventions have been shown to be successful in scientific studies. A review of multiple studies for positive behavioral support that treated 423 patients "concluded that [this behavioral treatment] appears to be successful for the most challenging behaviors." JA__[81.Fed.Reg.24404]. And randomized controlled trials for dialectical behavioral therapy "have demonstrated that [this behavioral treatment] successfully reduces self-injury in patients with borderline personality disorder and adolescents with" self-injurious behavior. JA__[81.Fed.Reg.24404-05]. For example, a review of studies examining 66 adolescents with autism and self-injurious behavior found that behavioral interventions produced positive outcomes for 51 patients, mixed outcomes for 12, and negative outcomes for two. JA__[A2630.at.522-25]. And in contrast to electrical stimulation devices, these kinds

of interventions appear to achieve durable results and reduce the targeted behaviors. JA__[81.Fed.Reg.24405].

Current medical practice also sometimes supplements these positive interventions with medication, including risperidone and aripiprazole, both of which are used to treat "irritability associated with autistic disorder" in adolescents. JA__[81.Fed.Reg.24406]. A review of "randomized, placebo-controlled studies" found that these and other drugs can reduce "aggressive behaviors and irritability" in children with autism. JA__[85.Fed.Reg.13343]. While these drugs are "not uniformly effective" for treating self-injurious and aggressive behavior in all patients, FDA concluded that these medications, in conjunction with positive behavioral interventions, are "generally successful for the treatment" of these behaviors. *Id.*

E. FDA's final rule

Based on the evidence before it, FDA concluded that the statutory criteria for banning electrical stimulation devices had been met. JA__[85.Fed.Reg.13312]. FDA found that electrical stimulation devices present significant risks of psychological and physical harms to patients with self-injurious and aggressive behavior, while at the same time there was weak evidence that the devices produced a durable, long-term effect on the patients' behaviors. *Id.* Moreover, state of the art positive interventions had been demonstrated to be successful with minimal risks of harm. *Id.* At bottom, FDA concluded that "the risk of illness or injury posed by [electrical stimulation devices] for" self-injurious and aggressive behavior "is substantial and unreasonable

and that labeling or a change in labeling cannot correct or eliminate the unreasonable and substantial risk of illness or injury." JA__[85.Fed.Reg.13313].

Accordingly, 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," JA__[85.Fed.Reg.13312], because those different uses "in different patient populations * * * present different benefit-risk profiles," JA__[85.Fed.Reg.13317]. For example, a smoker who chooses to use an electrical stimulation device "can immediately communicate pain to the device's controller or remove the device themselves," can "communicate symptoms of other harms * * * to their healthcare provider," and can choose to stop using the device. *Id.* By contrast, many people who exhibit self-injurious and aggressive behavior have disabilities that make it difficult to communicate "pain and other harms caused by" the devices, or to even understand the cause-and-effect relationship between their behavior and the electric shocks. *Id.* Based on those different risk assessments, FDA tailored its regulation to address the unreasonable and substantial risks posed by electrical stimulation devices for self-injurious and aggressive behavior. JA__[85.Fed.Reg.13313].

III. Proceedings In This Court

The final rule generated two petitions for review, which this Court consolidated. The first, No. 20-1087, is a petition by the Judge Rotenberg Educational Center, a facility that uses electrical stimulation devices to treat self-

injurious and aggressive behavior. The second, No. 20-1088, is a petition by parents and guardians of patients at the Center (parents). After the petitions were filed, FDA granted a partial administrative stay of the rule based on the public health emergency caused by the coronavirus pandemic. Doc. No. 1835818, at 6 (Mar. 27, 2020). The Center had also petitioned FDA for an administrative stay of the rule, and FDA explained that it would consider the merits of that petition after the public health emergency ended. *Id.*

Petitioners then moved this Court for a remand of the administrative record and for extra-record discovery. Doc. Nos. 1844326, 1844333 (May 26, 2020). FDA opposed that motion, explaining that there was no statutory or other basis for extra-record discovery, and that there was no need for a remand of the administrative record. Doc. No. 1845945, at 1-2 (June 5, 2020). A motions panel of this court referred the matter to the merits panel. Order (D.C. Cir. July 29, 2020).

SUMMARY OF ARGUMENT

I. FDA's decision to ban electrical stimulation devices for self-injurious and aggressive behavior is well-supported by the evidence and FDA thoroughly explained its reasoning for promulgating the rule. Electrical stimulation devices pose substantial physical risks—indeed, they are designed to stop targeted behavior by inflicting pain on the patient. And that repeated infliction of pain and potential tissue damage is associated with a host of substantial psychological risks, including anxiety, panic, and

post-traumatic stress disorder. Those risks are supported by the scientific literature and expert opinion.

In contrast, there is a lack of credible scientific research to demonstrate that the devices are effective in treating self-injurious and aggressive behavior. Most of the research on the question is decades old and suffers from methodological deficiencies. There is no randomized, well-controlled trial that demonstrates the effectiveness of electrical stimulation devices, and the expert panel convened by FDA to examine the devices largely agreed that the evidence of effectiveness was weak at best. There are alternative methods of treating self-injurious and aggressive behavior, such as positive behavioral interventions (where there are no risks) and medication (where the benefits from well-controlled studies outweigh the risks). Against those findings, FDA reasonably concluded that electrical stimulation devices pose substantial and unreasonable risks of injury and illness that cannot be corrected by proper labeling.

II. FDA appropriately crafted the regulation to ban electrical stimulation devices only when intended to treat patients exhibiting self-injurious and aggressive behavior, because of the unique and unreasonable risks the devices present to that population, who generally have intellectual and developmental disabilities. In looking to the device's intended use, FDA acted consistently with its statutory and regulatory authority. The Federal Food, Drug, and Cosmetic Act defines medical devices based on their intended use, 21 U.S.C. § 321(h), and FDA regulations are consistently contoured to devices' intended uses in determining whether and how they are

regulated. The rule is an appropriate exercise of FDA's authority under 21 U.S.C. § 360f and does not regulate the practice of medicine.

III. The final rule comports with the APA's procedural and substantive requirements. FDA considered all relevant evidence and provided a reasoned explanation for its promulgation of the rule. Petitioners make conclusory allegations that FDA in some way acted in bad faith by promulgating the rule to eliminate the substantial and unreasonable risks posed by electrical shocks from the devices. Petitioners fail to identify any basis for their claim of bad faith and fail to demonstrate that any extra-record discovery is appropriate.

STANDARD OF REVIEW

The Court reviews FDA's final rule to determine whether it is arbitrary and capricious or otherwise not in accordance with law. 5 U.S.C. § 706. A rule is arbitrary and capricious if the agency: "(1) has relied on factors which Congress has not intended it to consider, (2) entirely failed to consider an important aspect of the problem, (3) offered an explanation for its decision that runs counter to the evidence before the agency, or (4) is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 605-06 (D.C. Cir. 2016) (per curiam) (quotation marks omitted).

The Court also reviews the rule to determine whether it is supported by substantial evidence. 21 U.S.C. § 360g(c).

ARGUMENT

I. FDA Reasonably Concluded That Using Electrical Stimulation Devices For Self-Injurious And Aggressive Behavior Presents An Unreasonable And Substantial Risk of Injury

In its rulemaking, FDA carefully and thoroughly explained how it collected, considered, and weighed all the available evidence to determine whether it should ban electrical stimulation devices used to treat self-injurious and aggressive behavior. In determining whether risks are substantial and unreasonable, FDA "analyz[ed] whether the risks the device poses to individuals are important, material, or significant in relation to its benefits to the public health, and FDA compar[ed] those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice." JA__[85.Fed.Reg.13315].

Much of petitioners' argument boils down to discrete disagreements with how FDA weighed the evidence and claims that FDA ought to have come to the same conclusion that petitioners reached. At most, petitioners' arguments could suggest that reasonable people might differ on the ultimate conclusion of whether FDA should have banned the devices or taken some other, less restrictive measure. But petitioners fail to demonstrate that the final rule was arbitrary and capricious or that the statutory conditions for the exercise of FDA's banning authority were not satisfied.

As this Court has repeatedly explained, its "role in reviewing agency regulations * * * is a limited one." *Association of Am. Railroads v. Interstate Commerce Comm'n*, 978

F.2d 737, 740 (D.C. Cir. 1992). The Court has explained that it "must be careful not to unduly second-guess an agency's scientific judgments," *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 923 (D.C. Cir. 2013), and that it is "obliged to defer to a reasonable judgment by an agency acting pursuant to congressionally delegated authority," *City of Los Angeles v. U.S. Dep't of Transp.*, 165 F.3d 972, 977 (D.C. Cir. 1999). Thus, the Court will "uphold an agency's action where [the agency] has considered the relevant factors and articulated a rational connection between the facts found and the choice made, and has not relied on [improper] factors." *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 606 (D.C. Cir. 2016) (per curiam) (quotation marks omitted). That is a "highly deferential" standard of review that "presumes the validity of agency action," particularly when the matter "requires a high level of technical expertise" that warrants "defer[ence] to the informed discretion of the responsible federal agencies." *Transmission Access Policy Study Grp. v. FERC*, 225 F.3d 667, 714 (D.C. Cir. 2000) (quotation marks omitted); *see also American Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 533 (D.C. Cir. 2009) ("'This court's role is 'limited to determining if the Administrator made a rational judgment' and is 'not to weigh the evidence anew and make technical judgments.'").

As explained below, FDA's comprehensive anaylsis of electrical stimulation devices' risks and effictiveness, along with the alternative methods of treatment, provide substantial support for the final rule banning those devices for treating self-injurious and aggressive behavior. Petitioners fail to meet their "heavy burden" of

demonstrating that the rule lacks a reasoned basis and explanation. *Transmission Access Policy Study Grp.*, 225 F.3d at 714.

A. Electrical stimulation devices present a substantial risk of injury

1. FDA catalogued a number of significant physical and psychological risks posed by electrical stimulation devices used for self-injurious and aggressive behavior. First and foremost, the devices can cause "intense pain," JA__[85.Fed.Reg.13321], which can be like a ruptured disc, "a thousand bees stinging you," "the most painful thing I've ever experienced," JA__[85.Fed.Reg.13321-22], or a "dentist drilling on an un-anesthetized tooth," JA__[81.Fed.Reg.24395].[1] While the physical pain is temporary and lasts for the duration of the shock, *id.*, those shocks may be given repeatedly to interrupt the targeted behavior, JA__[81.Fed.Reg.24390, 24397-98]. Notably too, this pain is different in kind from pain that might be experienced as a side-effect or collateral measure of another kind of medical device. For electrical stimulation devices, as one expert explained, "the whole purpose of the intervention is to cause pain." JA__[A8368].

The devices can also cause first-degree burns and other tissue damage. JA__[85.Fed.Reg.13323]. Representatives from the Center petitioner have disputed whether the injuries caused by the devices are burns or are instead erythema or

[1] A doctor from the Center petitioner acknowledged that the devices "cause pain," but disputed that pain should be considered a "physical harm." JA__[A8182-83].

"bruise-like mark[s] and discolorations which could last for days," but there is clear evidence that—whatever the terminology—these are examples of tissue damage and that an electrical shock can cause burns. *Id.* Reports from state investigators confirmed that practitioners would rotate the placement of electrodes to "prevent burns that may result from repeated application of the shock to the same contact point," and repeated patient testimony that they had "incurred physical injuries (burns, reddened marks on their skin) as a result of being shocked." JA__[85.Fed.Reg.13323].

Those painful physical risks contribute to and amplify the psychological risks. As FDA reasonably concluded, the repeated application of a painful electrical shock that experts describe as "intense" and "frightening" can contribute to a patient developing "anxiety, stress reactions," post-traumatic stress disorder, and learned helplessness. JA__[85.Fed.Reg.13325]; *see also id.* (explaining that post-traumatic stress disorder can "be based on a series of events rather than a single, discrete event"); JA__[85.Fed.Reg.13326] (recognizing that patients with "an impaired ability to associate cause and effect" are "particularly susceptible to the risk of learned helplessness").

These and other psychological risks were buttressed by the numerous adverse events catalogued in case reports and studies of patients treated with electrical stimulation devices. Those studies reported:

- symptom substitution, including head-snapping, and possible symptom

substitution, including increased incontinence;

• escape behavior;

• possible hostility and retaliation;

• anticipatory fear and avoidance upon observing the experimenter's initial movements to deliver a shock, immediately developing fear of the device itself, and fear (phobic response) of buzzing sounds;

• aggression, including accounts of surrogate retaliation, self-aggression, lesser aggressive action, aggression fantasies, threats and warnings;

• development of episodic bursts of self-injurious behavior and aggression toward others;

• crying, increases in crying, cries of pain, whimpering;

• shivering;

• statements that the shocks were painful and grimacing;

• panic;

• extreme anxiety (consisting of screaming, crying, attack, and escape attempts);

• freezing (generalized behavior suppression) including an observation of pseudocatatonic sitdown;

• initial increase in self-mutilative behavior and emotionality;

• decrease in happiness or contentment and increased dependency;

• slight local tremor in the thigh due to the shock;

• arc burns to the skin;

• lesion or bruise on the skin that resolved in 1 week and slightly reddened areas;

• flinching; and

• perspiration, which can intensify the electric shock.

JA__[85.Fed.Reg.13329-30]; *see also* JA__[81.Fed.Reg.24390].

While FDA did not identify each of these adverse events as a risk of using the electrical stimulation devices, their reporting adds to the substantial base of evidence that the devices present a substantial risk of physical and psychological injury. That concern was heightened particularly given the intellectual and developmental disabilities of many in the patient population, who may not be able to effectively communicate that they are experiencing these harms. As one expert explained, it is difficult to "do a risk/benefit analysis because we really have little ability to recognize the psychological end, the risks, in a nonverbal population." JA__[A8349]. The video included in the administrative record provides further evidence of the substantial pain and psychological harms caused by these electrical shocks. JA__[A633.at.3] (PowerPoint with video link to http://www.youtube.com/watch?v=aAj9W0ntUMI).

Before issuing the proposed rule, FDA convened a panel of experts to consider the devices' risks. JA__[A8060]. Those experts generally agreed that the risks posed by electrical stimulation devices include "burns and other tissue damage, anxiety, acute stress/[post-traumatic stress disorder], fear and aversion/avoidance, pain/discomfort, depression (and possible suicidality), substitution of other negative behaviors (including aggression), psychosis, and neurological symptoms and injury." JA__[A8357]. *See* JA__[A8357-72] (panel members agreeing with this list of risks and explaining that it may be incomplete).

2. Petitioners' objections to this conclusion of substantial risk are mistaken.

The Center argues (at 33-34) that it is inappropriate for FDA to rely on anecdotes and case reports documenting pain and adverse events when FDA considers that kind of evidence to be relatively weak in establishing whether electrical stimulation devices are effective. That argument assumes that all anecdotes and case reports are equally probative, reflecting a fundamental misunderstanding of how experts evaluate the strength of scientific evidence. As FDA explained, randomized and controlled trials continue to be the best kind of evidence for determining whether any device is effective in treating a condition, and anecdotes and case reports are weaker kinds of evidence. JA__[81.Fed.Reg.24400]. But that same kind of evidence "may provide useful risk information" and "be adequate to support certain risks." JA__[85.Fed.Reg.13319]. There would obviously be serious concerns if FDA were to demand that pain, burns, depression, anxiety, and post-traumatic stress disorder be demonstrated with statistical significance before FDA may consider them to be substantial risks. The prevalence of the same kind of risks throughout case reports and testimony demonstrates that the evidence of those risks is substantial enough to warrant their consideration. *See* 21 C.F.R. § 860.7(c)(2) (explaining this difference in the consideration of data).

The Center also wrongly asserts (at 29) that it is entitled to a presumption that electrical stimulation devices are safe, citing *United States v. Undetermined Quantities of All Articles of Finished & In-Process Foods*, 936 F.3d 1341 (11th Cir. 2019). That case concerned completely different statutory provisions that presumed the safety of

dietary supplements but not food additives. *Id.* at 1344-45, 1347-48. It has no application where, as here, the only questions are whether FDA complied with the APA and whether the rule is supported by substantial evidence.

The parent petitioners contend that FDA had previously inspected the Center for risks associated with electrical stimulation devices and found no risk. Parent Br. 54 (citing JA__[A4371]). The cited document—which was unrelated to the rule and issued in 2011 before the agency had begun a systematic review of all available evidence of risks—noted that there was "[l]imited information about adverse events [] available at this time." JA__[A4371]. The document still explained, however, that it was "very possible that under reporting has occurred." *Id.* That concern was ultimately borne out by FDA's findings throughout this rulemaking.

B. Those risks are unreasonable given the limited and weak evidence of effectiveness

Given the lack of persuasive evidence that electrical stimulation devices are effective at treating self-injurious and aggressive behavior, FDA appropriately determined that the substantial risks posed by those devices were unreasonable.

FDA considered evidence that the devices were effective at interrupting or stopping self-injurious and aggressive behavior when the patients were shocked, JA__[81.Fed.Reg.24399], and FDA did not dispute that the devices were effective for that limited purpose, which was effectively a crisis-control measure, JA__[81.Fed.Reg.24404]. But, as FDA explained, there are serious implications for

"allowing a crisis intervention procedure to turn into a continuous management technique," *id.*, because repeated shocks could prolong and amplify the risks of physical and psychological injury, JA__[81.Fed.Reg.24397]. FDA therefore rightly examined whether there was credible evidence that electrical stimulation devices produce a durable effect that would treat and mitigate self-injurious and aggressive behavior.

FDA reviewed numerous studies, case reports, and other data to determine whether credible evidence existed, *see supra* pp. 10-13, and it did not. As one expert examining the evidence summarized: "there hasn't been a single randomized study, there hasn't been a single blinded study, there hasn't been a single study that employed an independent rater, there hasn't been a single prospective study, there hasn't been a single study that has used a pre-specified income and a pre-specified outcome. There hasn't been a single multi-center study. There's only been one study that used a control or comparison group. * * * So no, there's no evidence at the present time." JA__[A8346-47].

That conclusion was shared by most of the members of the expert panel that FDA convened, who agreed that the evidence of effectiveness was weak, inconclusive, or nonexistent. JA__[A8345] ("It's still a very difficult one to say yes or no."); JA__[A8346] ("The benefit of the" devices "is really uncertain largely because of the low quality of the evidence"); JA__[A8347-48] (opining that "[i]t's not great evidence" and would recommend "going ahead with a well-designed trial," but had

"no idea * * * what the subpopulation is that would benefit"); JA__[A8348] (opining no effectiveness data due to "the quality of the data that has been provided"); JA__[A8350] ("[T]here's not enough data to really support attribution of this device to the results that have been presented."); JA__[A8350] ("[Y]es, but the evidence base is weak."); JA__[A8351] ("I would give it a weak yes" for effectiveness); JA__[A8352] ("I'll go with a weak yes. I think we are so limited by the quality of evidence that has been presented."); JA__[A8352] ("I think there is weak evidence"); JA__[A8353] ("I say an unequivocal no. It's a firm no."); JA__[A8354] ("[W]hen I apply a higher scientific standard, I would have to say no."); JA__[A8354] ("I would say a firm no."); JA__[A8355] ("I'm not sure.").

As panel member Dr. Karen Weigle explained, the reason why there are no randomized, well-controlled studies regarding the effectiveness of electrical stimulation devices is "the elephant in the room." JA__[A8348]. Namely, it is "considered tortuous to the majority of communities around the word to shock people," particularly those who are "nonverbal or [who] just don't have the capability or the position to be able to report adverse effects and outcomes." *Id.* Against that backdrop, it is unsurprising that there have been so few studies or case reports of any kind in the past 20 years, or that most of that data arose from practitioners or consultants of the Center. JA__[81.Fed.Reg.24400-01]. But even those studies suffered from serious methodological deficiencies that undermined their persuasive value, from failing to explain their data collection procedure and how staff made

decisions across patients, to their publication in journals that were not peer-reviewed and whose editorial board members included the study's author (who was the founder of the Center). *Id.*[2]

As compared to this weak evidence for the effectiveness of electrical stimulation devices, FDA observed that there was at least similar, if not substantially better, data concerning the effectiveness of other treatment methods like positive behavior interventions and medication. JA__[85.Fed.Reg.13316] (explaining that "FDA analyzes the risks and the benefits the device poses" as compared to those "posed by alternative treatments being used in current medical practice").

FDA cited, for example, a 2016 meta-review of 35 randomized, controlled trials that compared medications to placebos in terms of treating irritability and aggression in people with autism. JA__[A2650.at.127]. That meta-review examined how the medications performed in terms of an aberrant behavioral checklist, which measures "emotional and behavioral symptoms" of people with autism, including "aggression toward others, [and] deliberate self-injuriousness." *Id.* And the meta-review concluded that, compared to a placebo, medications like risperidone and aripiprazole

[2] Even under the rule, electrical stimulation devices may be used for approved investigative purposes under 21 U.S.C. § 360j(g) to determine if they are effective at treating self-injurious and aggressive behavior. JA__[85.Fed.Reg.13316]. If the Center petitioner or others wish to develop well-controlled scientific studies to demonstrate the effectiveness of electrical stimulation devices, they may do so.

"were shown to result in significant improvement" on that metric "at the end of treatment." JA__[A2650.at.128].

Likewise, FDA identified multiple studies that demonstrated through random and controlled trials that positive behavioral interventions were effective at treating self-injurious behavior. JA__[81.Fed.Reg.24404-05]; JA__[A753.at.310, 321] ("Controlled randomized research studies have shown that standard outpatient" behavioral therapy "improves anger regulation and interpersonal functioning," and a "patient who regularly dissociates prior to self-injury can be taught to use mindfulness skills to increase voluntary attentional control at critical predissociation moments"); JA__[A758.at.537] (randomized controlled trial of behavioral therapy for 77 "adolescents with recent and repeated self-harm behavior and features of borderline personality disorder" found the therapy "superior to 'enhanced usual care' in reducing self-harm, suicidal ideation, and depressive symptoms"); JA__[A759.at.847] (comparison of 31 patients treated with three months of behavioral therapy, compared to 19 patients who received treatment as usual, demonstrated that the experimental group "improved significantly more" in terms of treating "suicidal behaviors, nonsuicidal self-injury, treatment interfering behaviors, and behaviors that prolong hospitalization"). And a review of a dozen outcome studies for other positive behavioral interventions indicated that, across hundreds of observed patients, those interventions were effective treatments. JA__[81.Fed.Reg.24404]; JA__[A738.at.187, 194].

The presence and availability of those alternative treatments was significant because it demonstrated that there were treatment methods available for self-injurious and aggressive behavior that did not present the same substantial risks as electrical stimulation devices. FDA acknowledged that there might be patients whose self-injurious and aggressive behavior would not be successfully treated with these interventions and medications. JA__[85.Fed.Reg.13332] (noting this possibility and observing that this "subpopulation is difficult if not impossible to define"). Even so, there was no persuasive evidence that such patients could receive an effective and durable treatment from electrical stimulation devices. *Id.* ("[E]ffectiveness has not been established in any population of patients exhibiting" self-injurious and aggressive behavior).

Accordingly, many members of the expert panel agreed that electrical stimulation devices for self-injurious and aggressive behavior pose unreasonable and substantial risks. JA__[A8374] ("[T]he likelihood of injury or illness is virtually 100% if the device is functioning as it should," and given that there are "uncertain benefits" and "certain risks," then there are "substantial and unreasonable risk of illness and injury."); JA__[A8375] ("I think that this represents an unreasonable and substantial risk."); JA__[A8377] ("I think that the risks are unreasonable and substantial."); JA__[A8378] ("I believe that the criteria of unreasonable and substantial risk of illness or injury * * * are met in this case."); JA__[A8379] (same); JA__[A8382] ("I agree that there is evidence of * * * [s]ubstantial and unreasonable risk."); JA__[A8385] ("[Y]es,

there is an unreasonable risk of illness and injury"); JA__[A8387] ("I would say yes to a ban of existing devices"); JA__[A8387-88] (same).

Those unreasonable risks cannot be mitigated by labeling, as many members of the expert panel agreed. JA__[A8394] (nine out of ten experts agreeing that labeling could not mitigate these risks); JA__[A8392] ("[L]abeling would be helpful if we knew what to put on the label, but we don't."). That is because regardless of labeling, the patient will continue to "receive shocks intended to be painful and will continue to be subject to the physical and psychological risks." JA__[85.Fed.Reg.13344]. Petitioners suggest that the devices could be labeled as intended to apply only to a subpopulation of patients for whom no other treatments work. Center Br. 57; Parent Br. 42. FDA considered that possibility and reasonably concluded that such labeling would not mitigate the risks because it was "difficult if not impossible to define" such a patient population, there was no evidence that the devices were effective for any patient, and there was no indication that such labeling would reduce the risks that electrical shocks would still present. JA__[85.Fed.Reg.13332, 13344].

II. The Final Rule Was Appropriately Targeted At Electrical Stimulation Devices Used For Self-Injurious And Aggressive Behavior

A. The Federal Food, Drug, and Cosmetic Act authorizes FDA to ban a device when it presents an unreasonable and substantial risk of injury. The nature of FDA's authority under this provision turns in significant measure on how the Act

defines "device" and the established regulatory scheme for devices, which are both predicated on a device's intended use and the risks associated with that intended use.

The Act defines a "device" as an "instrument, apparatus," or similar 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 in man or other animals." 21 U.S.C. § 321(h). The Act further excludes from the definition of "device" any item that "achieve[s] its primary intended purposes through chemical action within or on the body" or that is "dependent upon being metabolized for the achievement of its primary intended purposes." *Id.* Thus, FDA's regulatory authority over devices, including its banning authority, depends on the article's "intended [] use" and its "primary intended purposes." *Id.* Indeed, in enacting § 321(h), Congress recognized that "there may be instances in which a particular device is intended to be used for more than one purpose," and in those instances Congress expected that "each use may * * * be treated as constituting a different device for purposes of classification or other regulation." H.R. Rep. No. 94-895, at 14-15 (1976).

In keeping with that definition, FDA has generally defined and regulated devices based on their intended use and has tailored its regulations based on different types of intended use. *See generally* 85 Fed. Reg. 59718, 59721-23 (Sept. 23, 2020) (collecting cases and examples of examining a product's intended use to determine whether it is a regulated drug or medical device). For example, a sound-amplifying

device is regulated as a hearing aid if it "is intended to compensate for impaired hearing," 21 C.F.R. § 874.3300(a), but would not be so regulated if it were intended for another use, such as amplifying natural sounds during outdoor recreational activities. Likewise, a flat piece of balsa wood might be regulated as a tongue depressor if it is "intended to displace the tongue to facilitate examination of the surrounding organs and tissues," *id.* § 880.6230(a), but would not be so regulated if it was intended for another purpose, such as a popsicle stick.

FDA also looks to a device's intended use to determine how it should be classified. *See supra* pp. 3-4. For example, some knee prosthetics (knee joint patellar (hemi-knee) metallic resurfacing uncemented prostheses) 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). In short, the same physical device may be subject to multiple classifications depending on the device's intended use.

Consistent with this regulatory framework, FDA appropriately considers a device's intended use when it analyzes whether a device should be banned under 21 U.S.C. § 360f. As a hypothetical example, if it were shown that contact lenses "intended for extended wear" posed an unreasonable and substantial risk of injury

that could not be corrected by labeling, FDA would have the authority to ban those devices. At the same time, FDA would act appropriately by confining the ban to contact lenses intended for extended wear and by not banning contact lenses "intended for daily wear only," if that intended daily use was not associated with any unreasonable risk of injury. The limited scope of the ban would be appropriate even if both kinds of contacts were physically identical because (in this hypothetical) the different intended uses of the contacts would pose different risks that warranted different regulatory treatment.

For the same reason, FDA acted appropriately here by banning electrical stimulation devices that are intended to treat aggressive or self-injurious behavior and by not extending that ban to electrical stimulation devices intended for other uses. Those different intended uses, FDA explained, "present different benefit-risk profiles" and warrant different treatment. JA__[85.Fed.Reg.13317]. A smoker who wishes to use an electrical stimulation device to help quit smoking can "immediately communicate pain," "remove the device themselves," and otherwise "communicate symptoms of other harms" that can "lead to discontinuation of the device's use." *Id.* By contrast, many people with self-injurious and aggressive behavior can have "difficulty communicating pain and other harms caused by" the devices. *Id.* Worse, many such patients "may not be able to associate cause and effect or," as with some autistic patients, "may express pain atypically or not at all." *Id.* Those substantially different risks based on the device's intended use warrant different regulatory

treatment. Treating the same physical device differently under the banning provision depending on its intended use is no more problematic than the settled regulatory practice of classifying physically identical devices differently based on their different intended uses.

By looking to the device's intended use, FDA's ban here is consistent with the bans that FDA has previously promulgated. For example, when FDA banned powdered surgical and examination gloves, and powder for lubricating those gloves, the scope of the ban was defined by the device's intended use. *See, e.g.*, 21 C.F.R. § 895.102 (banning powdered gloves "intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination"); *id.* § 895.103 (banning disposable powdered gloves "intended for medical purposes that is worn * * * to prevent contamination between patient and examiner"); *id.* § 895.104 (banning certain powder "that is intended to * * * lubricate the surgeon's hand before putting on a surgeon's glove"). FDA made clear that the ban on powder did not extend "to powder intended for use in or on other medical devices, such as condoms," because the agency had "not seen evidence" that powder intended for use in or on different medical devices "presents the same public health risks as that on powdered medical gloves." 81 Fed. Reg. 15173, 15174 (Mar. 22, 2016).

B. Petitioners object to this conclusion, arguing that FDA cannot ban a device based on its intended use. Parent Br. 24-33. In petitioners' view, FDA may only ban devices categorically for all possible intended uses. Nothing in the statute compels

that conclusion. To the contrary, the Act defines a "device" based on its intended use, 21 U.S.C. § 321(h), and, as explained above, FDA has consistently and uncontroversially defined and regulated medical devices based on their intended use, subjecting the same physical device to different regulatory requirements depending on the intended use. Moreover, FDA acts appropriately when it narrowly tailors a ban to address only those uses that present unreasonable risks of harm, as the banning authority "should not be used except when it is deemed necessary to protect the public health." H.R. Rep. No. 94-853, at 20.

For similar reasons, petitioners' reliance on 21 U.S.C. § 396 is misplaced. Center Br. 21; Parent Br. 27-31. That provision recognizes that health care practitioners may prescribe "any legally marketed device to a patient for any condition or disease," even if the device has not been approved for that use. 21 U.S.C. § 396. Thus, the statute recognizes that physicians can 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) (quoting *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001)). That recognition acts as a safe harbor for a practitioners' use of a legally marketed device, and in no way affects FDA's general regulatory authority to promulgate regulatory restrictions on devices themselves. *Id.* at 766-67 (explaining that under 21 U.S.C. § 396, a physician "may use a Class III device for unapproved purposes" but a "manufacturer may not vary the design or manufacture of the pre-approved device,

even in anticipation of such uses"); *see also* JA__[85.Fed.Reg.13346] (making the same point); 21 U.S.C. § 331(a)-(c) (prohibiting adulterated devices from being introduced or received in interstate commerce).

Petitioners are also mistaken in claiming that FDA lacks authority to promulgate the rule because the Act does not authorize the agency to regulate the practice of medicine. Parents Br. 24-33. That argument rests on a basic failure to understand the relationship between FDA's authority under 21 U.S.C. § 360f and the rest of the Act.

Section 360f authorizes the agency, upon prescribed findings, to promulgate a regulation making a device a banned device. A banned device is deemed to be adulterated. 21 U.S.C. § 351(g). As such, it is subject to the prohibitions on adulterated devices set forth in 21 U.S.C. § 331. Among other things, an adulterated device may not be introduced into interstate commerce. *Id.* § 331(a); *see also id.* § 332 (authorizing courts to restrain violations of § 331). In addition, an adulterated device is subject to seizure and condemnation. *Id.* § 334.

None of these restrictions regulates the practice of medicine. Prohibiting the interstate distribution of an adulterated device may keep the device out of a physician's hands, and thereby preclude using it to treat a patient. So too if the adulterated device is seized and condemned. But the fact that those restrictions remove an adulterated article from the market does not amount to a regulation of the practice of medicine any more than a decision by FDA not to approve a new drug

application, which would likewise deny physicians access to that drug. *Cf. United States v. Regenerative Sciences, LLC*, 741 F.3d 1314, 1319-20 (D.C. Cir. 2014) (explaining that FDA's generally applicable regulations for the distribution of drugs does not amount to regulating the practice of medicine).

For purposes of determining whether FDA has authority to promulgate the regulation at issue in this case, it is immaterial that the Center may be the only facility currently using such devices. Even if the Center is not itself distributing the devices in interstate commerce, that does not constrain FDA's statutory authority to prevent manufacturers or distributors from entering the market and introducing banned and therefore adulterated devices. And if the Center receives such devices through interstate commerce and distributes them to its physicians, or if the Center takes actions that render the devices adulterated before its physicians administer them, those actions would also be subject to the Act's restrictions and may be regulated without infringing a physician's practice of medicine. 21 U.S.C. § 331(c), (k); *see also* JA__[A24] (noting that the Center previously "contracted with a third-party manufacturer to re-design and manufacture updated versions" of electrical stimulation devices).[3]

[3] Even if the adulteration of a drug or device is attributable to the actions of a physician, it does not follow that placing restrictions on the adulterated article would amount to an impermissible regulation of the practice of medicine. For example, if FDA authorized a device to be used for investigational purposes, 21 U.S.C. § 360j(g), that device would become adulterated if it were used in a way that "fail[ed] to comply

For similar reasons, the parent petitioners are mistaken in arguing that FDA lacks jurisdiction over the Center's electrical stimulation devices because they "have never been sold or distributed." Parent Br. 22-24. Petitioners' argument might be relevant if FDA were to bring an enforcement action based on one of the Act's prohibitions relating to adulterated articles, *e.g.*, 21 U.S.C. §§ 331, 351(g), but it has no bearing on FDA's unquestioned authority to ban devices under 21 U.S.C. § 360f. The rule is generally applicable to all electrical stimulation devices for self-injurious and aggressive behavior, not just the ones currently used by the Center.

C. In its brief, amicus supporting petitioners appears to contend that the rule here was an "adjudicatory proceeding[]" that required FDA to afford the Center the procedures associated with a formal adjudicatory hearing. Amicus Br. 21. The Center itself has not made such a claim, and an amicus cannot introduce issues that the parties themselves have not presented. *See, e.g.*, *NACS v. Board of Governors of the Fed. Reserve Sys.*, 746 F.3d 474, 482 (D.C. Cir. 2014). In any event, the claim lacks merit. Section 360f grants FDA authority to "promulgate a regulation" to ban a device, and neither the statute nor the APA requires FDA to use formal hearing-style procedures to promulgate such regulations. *See* 5 U.S.C. § 553(c) (hearing requirements of APA

---

with a requirement" for the investigational use, *id.* § 351(i). Similarly, if a physician failed to refrigerate a vaccine held in office stock, and the vaccine decomposed as a result, the vaccine would become adulterated. *Id.* § 351(a). In both cases, the physician could hardly resist the forfeiture of the adulterated article by arguing that FDA may not regulate the practice of medicine.

apply only "[w]hen rules are required by statute to be made on the record after opportunity for an agency hearing"); *Association of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1160 (D.C. Cir. 1979). Moreover, Congress itself determined that informal hearings were not necessary before FDA promulgated a rule under 21 U.S.C. § 360f. *See* Pub. L. No. 101-629, § 18(d), 104 Stat. 4511, 4529 (1990) (eliminating the statute's prior requirement of an informal hearing). Employing that statutorily prescribed procedure complies with due process, because the rule is "generally applicable to" all such electrical devices, and is not limited to "a particularized order affecting particular owners 'in each case upon individual grounds.'" *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017) (quoting *Bi-Metallic Inv. Co. v. State Bd. of Equalization*, 239 U.S. 441, 446 (1915)).

III. The Final Rule Comports With The Administrative Procedure Act

Petitioners raise several other objections to the rule, but in all instances FDA satisfied the APA's requirements.

A. FDA considered all relevant evidence and explained its reasoning

The parent petitioners contend that in promulgating the final rule, FDA failed to adequately consider Massachusetts probate court procedures concerning "substituted judgment," which they assert can mitigate the risks associated with electrical stimulation devices. Br. 46-47. Petitioners fail to explain how a single state's judicial procedures for certain minors and others who are unable to give consent are

generally applicable to FDA's rulemaking, and fail to explain how these procedures mitigate any of the physical or psychological risks that are presented by the electric shocks from the devices. The Center petitioner also seeks (at 30, 33) to rely on a decision by the Massachusetts probate court, but that case concerned different issues (the application of a consent decree and a decision of whether the decree should be vacated based on changed factual circumstances) that were "not an issue in this ban." JA__[85.Fed.Reg.13314-15]. And in any event, FDA considered testimony and evidence that was presented to the Massachusetts state court. *See, e.g.*, JA__[85.Fed.Reg.13321-22] (summarizing expert testimony from the court proceeding); JA__[85.Fed.Reg.13324-25] (same); JA__[13327] (same).

Petitioners also assert that FDA failed to adequately seek out additional information from the Center that was necessary to complete its rulemaking. Parent Br. 49-52. Notably, the Center does not contend that it should have had a further opportunity to provide this information to FDA, despite its numerous opportunities to provide evidence and comment. The information petitioners point to chiefly concerns the Center's procedures for conducting assessments on its patients and details of patient charts. Parent Br. 50-52. Petitioners fail to explain how or why this information is relevant to the risks and efficacy of electrical stimulation devices. In any event, FDA considered the underlying information as part of the administrative record and explained its deficiencies. *See* JA__[A2661.at.9] (case summaries indicated that patients received electrical shocks "for many years and even decades," making it

"doubtful" that the patients are "truly being successfully conditioned"); JA__[A2661.at.11] (noting "the lack of rigor in evaluating safety, including reporting adverse events in a methodical, consistent manner"))

The parent petitioners wrongly claim (at 58-59) that FDA failed to consider evidence from parents of patients with self-injurious and aggressive behavior who are treated with electrical stimulation devices. But FDA considered evidence, testimony, and comments submitted by parents, who tended to have different opinions on whether electrical stimulation devices should be banned. *See, e.g.*, JA__[81.Fed.Reg.24398] (a parent association stated that they had not seen any side effects, while another parent stated that the devices cause "[b]urns, fear, pain," post-traumatic stress disorder, and catatonia); JA__[81.Fed.Reg.24402-03] (considering parent testimony supporting the use of the devices); JA__[85.Fed.Reg.13320] (summarizing evidence from parents that FDA considered); JA__[85.Fed.Reg.13328-29] (summarizing evidence from state investigators, relaying that "parents and students themselves have reported short-term and long-term trauma effects as a result of use of such devices or watching other students being shocked (*e.g.*, loss of hair, loss of appetite, suicidal ideation)").

Petitioners also repeatedly assert that FDA has failed to explain why it has promulgated the rule to ban electrical stimulation devices for self-injurious and aggressive behavior when FDA had earlier cleared the devices as a Class II device and made earlier regulatory evaluations that did not prohibit use of the devices. But FDA

has provided a reasoned explanation for the difference. As noted in the proposed rule, the agency "now has a better understanding of the risks and benefits presented by these devices than it did 36 years ago when these devices were classified" JA__[81.Fed.Reg.24391]. Based on the current evidence, FDA concluded that a ban was appropriate because there was an unreasonable and substantial risk of injury from the devices for treating self-injurious and aggressive behavior. *Id.*

And in the final rule, FDA again acknowledged that it had previously found that an electrical stimulation device was "substantially equivalent to predicate aversive conditioning devices" and could be marketed in interstate commerce as Class II devices under 21 U.S.C. § 360(k). JA__[85.Fed.Reg.13322]. In the quarter century since that decision, however, new information has allowed FDA to have a better "understanding of the risks posed by this type of device, including the risk of pain, as well as the diagnosis of, and treatment options for" patients with self-injurious and aggressive behavior. *Id.* That is a sufficient and reasonable explanation for why FDA cleared some electrical stimulation devices for use decades ago under different regulatory authority, and why the agency now, based on new information and under the framework set out by 21 U.S.C. § 360f, took a different action based on its changed understanding. *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) ("[A]gencies do not establish rules of conduct to last forever" and "an agency must be given ample latitude to adapt their rules and policies to the demands of changing circumstances") (quotation marks omitted).

B. Petitioners fail to establish any basis for extra-record discovery

"[I]n reviewing agency action, a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." *Department of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019). That is because "judicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government and should normally be avoided." *Id.*

The Center petitioner contends that it is entitled to extra-record discovery because it mistakenly believes that the rule was promulgated as a result of bias and political pressure.[4] The Center bases its belief on the fact that FDA took action here that was arguably different from what the agency had done in the past, that the agency consulted with its attorneys, and that the agency communicated with other federal agencies, state agencies, and other interested parties. Center Br. 58-59. The Center also alleges that FDA was inclined to believe that the devices qualified for a ban under

[4] The Court also has pending before it a motion by the Center for a remand to FDA for extra-record discovery, relying on 21 U.S.C. § 360g(b). Doc. No. 1844326 (May 26, 2020). As FDA explained in it opposition, the fundamental problem with that motion is that § 360g(b) does not allow for extra-record discovery, but instead only permits a remand to FDA to allow a petitioner to "adduce additional data, views, or arguments" if "there were reasonable grounds for the petitioner's failure to adduce" those matters in the rulemaking proceeding. 21 U.S.C. § 360g(b); *see also* Doc. No. 1845945 (June 5, 2020) (opposition to the motion).

the statute, sought out supporting information, and took steps to "beef up" the administrative record to support the rule. Center Br. 60.

Shorn of the Center's hyperbole, none of this amounts to bad faith, or anything close to it, and petitioner has not made the "'strong showing' of bad faith required" for a request to supplement the record. *Hecht ex rel. James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1095 (D.C. Cir. 1996). Petitioner's assertions boil down to an argument that FDA had a preferred policy outcome and consulted with others who shared that preference. But even if that were true, agency decisions are "routinely informed by unstated considerations of politics, the legislative process, public relations, interest group relations, foreign relations, and national security concerns (among others)." *Department of Commerce*, 139 S. Ct. at 2573. Relatedly, agencies regularly consult with other interested departments within the federal government when developing policy or gathering information, and often reach out to state governments that may be addressing the same issues. And it is entirely appropriate for agency staff to confer with attorneys for litigation advice to ensure that agency action comports with legal requirements and can withstand legal challenges. In short, "[i]t is hardly improper for an agency head to come into office with policy preferences and ideas, discuss them with affected parties, sound out other agencies for support, and work with staff attorneys to substantiate the legal basis for a preferred policy." *Id.* at 2574. This is the routine stuff of administrative procedure, not bad faith.

Accordingly, a court "may not reject an agency's stated reasons for acting simply because the agency might also have had other unstated reasons," which could include "political considerations" or "an Administration's priorities." *Department of Commerce*, 139 S. Ct. at 2573; *see also id.* ("Agency policymaking is not a 'rarified technocratic process, unaffected by political considerations.'"). That is particularly true in this case, where FDA "submitted a substantial explanation for its promulgation of the" rule and compiled an "extensive record," which can and must "serve as the basis for [judicial] review." *Sierra Club v. Costle*, 657 F.2d 298, 390 n.450 (D.C. Cir. 1981). Petitioners' arguments do not raise any "serious doubts about the fundamental integrity of this rulemaking proceeding" that might warrant extra-record discovery. *Id.*

The Center also appears to complain (at 62) that FDA improperly redacted certain documents that were produced in response to Freedom of Information Act requests, where the redactions were based on the privileges for deliberative process and attorney–client communications. It is unclear what relief the Center seeks based on this suggestion. To the extent the Center believes that documents released in response to their requests were improperly redacted, they can (and have) raised that issue in the ongoing Freedom of Information Act litigation—but they cannot collaterally challenge those determinations in this merits challenge to FDA's rulemaking. *See Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 376 F. Supp. 3d 47, 76 (D.D.C. 2019) (granting FDA summary judgment for withholding records under attorney-

client privilege and draft records under deliberative-process privilege). And to the extent petitioners believe documents reflecting FDA's deliberative processes are relevant to the administrative record, they are wrong. This Court has squarely held that "predecisional and deliberative documents are not part of the administrative record to begin with," and they are rightly considered "irrelevant and therefore not otherwise discoverable" on APA review. *Oceana, Inc. v. Ross*, 920 F.3d 855, 865 (D.C. Cir. 2019) (quotation marks omitted).

CONCLUSION

The Court should deny the petitions for review.

Respectfully submitted.

ROBERT P. CHARROW
General Counsel
Department of Health and Human Services

JAMES LAWRENCE
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel for Litigation

NOAH T. KATZEN
Associate Chief Counsel

SETH I. HELLER
Associate Chief Counsel
Department of Health and Human Services
Office of the General Counsel
Food and Drug Administration

JENNIFER B. DICKEY
Acting Assistant Attorney General

SCOTT R. MCINTOSH
/s/ Daniel Aguilar
DANIEL AGUILAR
Attorneys, Appellate Staff
Civil Division, Room 7266
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-5432
Daniel.J.Aguilar@usdoj.gov

JANUARY 2021

CERTIFICATE OF COMPLIANCE

I hereby 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 Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 11,665 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

TABLE OF CONTENTS

21 U.S.C. § 360f. Banned devices

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information, that--

> **(1)** a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and
>
> **(2)** in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

(b) Special effective date

The Secretary may declare a proposed regulation under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

21 U.S.C. § 396. Practice of medicine

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. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

21 C.F.R. § 895.21. Procedures for banning a device.

(a) Before initiating a proceeding to make a device a banned device, the Commissioner shall find that the continued marketing of the device presents a substantial deception or an unreasonable and substantial risk of illness or injury.

> (1) In determining whether the deception or risk of illness or injury is substantial, the Commissioner will consider whether the deception or risk posed by continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing.
>
> (2) In determining whether a device is deceptive, the Commissioner will consider whether users of the device may be deceived or otherwise harmed by the device. The Commissioner is not required to determine that there was an intent on the part of the manufacturer, distributor, importer, or any other responsible person(s) to mislead or otherwise harm users of the device or that there exists any actual proof of deception of, or injury to, an individual.
>
> (3) In determining whether a device presents deception or risk of illness or injury, the Commissioner will consider all available data and information, including data and information that the Commissioner may obtain under other provisions of the act, data and information that may be supplied by the manufacturer, distributor, or importer of the device under § 895.22, and data and information voluntarily submitted by any other interested persons.

(b) Before initiating a proceeding to make a device a banned device, the Commissioner of Food and Drugs (the Commissioner) may consult with the panel established under section 513 of the act that has expertise with respect to the type of device under consideration. The consultation with the panel may occur at a regular or specially scheduled panel meeting or may be accomplished by correspondence or telephone conversation with panel members. The Commissioner may request that the panel submit in writing any advice on the device under consideration. The

Commissioner will record in written memoranda any oral communications with a panel or its members.

(c) If the Commissioner determines that any substantial deception or unreasonable and substantial risk of illness or injury or any unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or change in labeling, or change in advertising if the device is a restricted device, the Commissioner will notify the responsible person of the required labeling or change in labeling or change in advertising in accordance with § 895.25. If such required relabeling or change in advertising is not accomplished in accordance with § 895.25, the Commissioner may initiate a proceeding to ban the device in accordance with § 895.21(d) and, when appropriate, may establish a special effective date in accordance with § 895.30.

(d) If the Commissioner decides to initiate a proceeding to make a device a banned device, a notice of proposed rulemaking will be published in the Federal Register to this effect. The notice will briefly summarize—

(1) The Commissioner's finding under paragraph (a) of this section that the device presents substantial deception or an unreasonable and substantial risk of illness or injury, and, when appropriate, the Commissioner's determination under § 895.30 that the deception or risk of illness or injury presents an unreasonable, direct, and substantial danger to the health of individuals;

(2) The reasons why the Commissioner initiated the proceeding;

(3) The evaluation of data and information obtained under other provisions of the act, submitted by the manufacturer, distributor, or importer of the device, or voluntarily submitted by any other interested persons under paragraph (a)(3) of this section, if any;

(4) The consultation with the panel, if any, under paragraph (b) of this section;

(5) The determination as to whether the deception or risk of illness or injury or the danger to the health of individuals could be corrected by labeling or change in labeling, or change in advertising if the device is a restricted device;

(6) The determination of whether the required labeling or change of labeling, or change in advertising if the device is a restricted device, if any, has been made in accordance with paragraph (c) of this section;

(7) The determination as to whether, and the reasons why, the banning should apply to devices already in commercial distribution or those already sold to the ultimate user, or both; and

(8) Any other data and information that the Commissioner believes are pertinent to the proceeding. The notice will afford all interested persons an opportunity to submit written comments within 30 days after the date of publication of the proposed regulation. All nonconfidential information upon which the proposed finding is based, including the recommendations of the panel, will be available for public review in the Division of Dockets Management, Food and Drug Administration.

(e) (1) If, after reviewing the administrative record of the regulatory hearing before the Food and Drug Administration, if any, the written comments received on the proposed regulation, and any additional available data and information, the Commissioner determines to ban a device, a final regulation to this effect will be published in the Federal Register. The final regulation will amend subpart B by adding the name or description of the device, or both, to the list of banned devices.

(2) If the Commissioner determines not to ban the device, a notice of withdrawal and termination of rulemaking proceedings and reasons therefor will be published in the Federal Register.

(f) The effective date of a final regulation to make a device a banned device, promulgated under paragraph (e) of this section, will be the date of publication of the final regulation in the Federal Register unless the Commissioner, for reasons stated, determines that the effective date should be later than the date of the publication and specifies that date in the notice. Each such regulation will specify whether devices already in commercial distribution or sold to the ultimate user or both are banned.

(g) A regulation promulgated under paragraph (e) of this section is final agency action, subject to judicial review under section 517 of the act.

(h) Upon petition of any interested person submitted in accordance with § 10.30 of this chapter, or as a matter of discretion, the Commissioner may institute proceedings to amend or revoke a regulation that made a device a banned device if the Commissioner finds that the conditions that constituted the basis for the regulation banning the device are no longer applicable. When appropriate, the procedures in this section will be employed in such proceedings.

21 C.F.R. § 895.101. Prosthetic hair fibers

Prosthetic hair fibers are devices intended for implantation into the human scalp to simulate natural hair or conceal baldness. Prosthetic hair fibers may consist of various materials; for example, synthetic fibers, such as modacrylic, polyacrylic, and polyester; and natural fibers, such as processed human hair. Excluded from the banned device are natural hair transplants, in which a person's hair and its surrounding tissue are surgically removed from one location on the person's scalp and then grafted onto another area of the person's scalp.

21 C.F.R. § 895.102. Powdered surgeon's glove

(a) Identification. A powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

21 C.F.R. § 895.103. Powdered patient examination glove

(a) Identification. A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

21 C.F.R. § 895.104. Absorbable powder for lubricating a surgeon's glove

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

21 C.F.R. § 895.105. Electrical stimulation devices for self-injurious or aggressive behavior

Electrical stimulation devices for self-injurious or aggressive behavior are aversive conditioning devices that apply a noxious electrical stimulus to a person's skin to reduce or cease self-injurious or aggressive behavior.