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FDA Seeks Targeted Congressional Reversal of Judicial Checks on Agency Abuses of Discretion

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The Food and Drug Administration (FDA) has been privately lobbying Congress to overturn recent judicial decisions that curb the agency's discretion. While Congress can override federal court decisions, use of that authority to concentrate further power in a single executive-branch agency—and doing so without notice to or input from the public—is contrary to our Constitution's separation of powers and undermines the carefully crafted administrative process.

Every five years, Congress must reauthorize the User Fee Acts, which empower FDA to collect market-authorization fees from companies that manufacture drugs, devices, biologics, and biosimilar products. Because user fees provide significant agency funding, the User Fee Acts are "must-pass" legislation. Knowing that, FDA prevailed on friendly legislators to slip provisions into the User Fee Acts that would legislatively overturn three major agency losses in federal court: *Genus v. FDA*,[1] *Catalyst Pharms., Inc. v. Becerra*,[2] and *Judge Rotenberg Educ. Ctr., Inc. v. FDA*.[3] In each of these cases, the court told FDA that its interpretation of the Federal Food, Drug, and Cosmetic Act (FDC Act) was in violation of its plain language, and thus the agency exceeded its discretion. However, unlike the litigation, which provided both parties with equal opportunities to present its view, FDA is asking Congress to reverse its losses, often relying on arguments dismissed by the courts, without the plaintiffs' knowledge or the public's participation.

Genus v. FDA

The FDC Act defines both drugs and devices in part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." However, the key distinction under section 201 of the FDC Act is that a device neither achieves "its primary intended purposes through chemical action within or on the body of man" nor is "dependent upon being metabolized for the achievement of its primary intended purpose."[4] With this, FDA typically classifies a product as a device where the sponsor demonstrates that a proposed product does not achieve its primary intended purposes through chemical action.[5]

This distinction is significant for industry: Drug marketing approval is far more rigorous than device manufacturing. While the highest risk devices—Class III—require the submission of substantial data, the data requirements are even greater for drugs. *See* 21 U.S.C. § 360e. A higher regulatory burden comes with higher

[1] 994 F.3d 631 (D.C. Cir. 2021); 427 F.Supp.3d 74 (D.D.C. 2019).

[2] 14 F.4th 1299 (11th Cir. 2021).

[3] 3 F.4th 390 (D.C. Cir. 2021).

[4] 21 U.S.C. § 321(g), (h).

[5] FDA, Guidance for Industry, Classification of Products as Drugs and Devices & Additional Product Classification Issues (Sept. 2017) ("Classification Guidance").

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costs of development and compliance, along with significantly higher application and maintenance user fees for drugs than devices.[6]

Despite the statutory distinction, however, FDA decided in 1997 to regulate all contrast agents as drugs regardless of their mechanism of action so that the Agency could regulate all contrast agents under the same regulatory scheme.[7] Consequently, FDA sent Genus a Warning Letter alleging that its contrast-agent product, barium sulfate, was an unapproved drug. Though FDA admitted that barium sulfate meets the statutory definition of "device," FDA claimed authority to regulate contrast agents as drugs based on the overlap in the "intended use" prong of the drug and device definitions in section 201 of the FDC Act. The overlap, FDA argued, permits the Agency to choose whether to regulate a device as a drug and that FDA may choose to do so merely for administrative convenience.

For Genus Medical Technologies, regulation of barium sulfate as a drug would be devastating, so Genus sued FDA. In *Genus Medical Technologies v. FDA*, Genus argued that the plain language of the device definition in the FDC Act foreclosed FDA's claimed discretion, as the statute must be read so that the specific language governs the general; any reading that would afford FDA such discretion would render the distinction between drugs and devices superfluous to the statute. Both the District Court and the Court of Appeals found for Genus and held that the statutory scheme directed FDA to treat products meeting the definition of "device" as devices. The District Court held that FDA's interpretation renders the device distinction superfluous, while the Court of Appeals relied on the long-accepted adage that specific statutory language supersedes general statutory provisions.[8]

FDA set out to implement the courts' decisions, publishing in the Federal Register a Notice that "Going forward, in accordance with *Genus*, FDA intends to regulate products that meet both the device and drug definition as devices, except where the statute indicates that Congress intended a different classification."[9] Meanwhile, FDA lobbied—based on legal precedent that the court rejected—to covertly amend the statute so that imaging agents and OTC monograph products fell into that statutory exception. Rather than comply with the D.C. Circuit's ruling, FDA has been trying to have the statute changed while leading Genus to believe the issue is settled.

Even though the proposed legislation would have an enormous impact on regulated industry and the imaging-agent market, Congress did not publicly share the legislation until committee mark-ups began, held no hearings on the policy, and never solicited industry or patient feedback. FDA is using Congress here to circumvent the courts to further its claim to unfettered discretion, regardless of the necessary limitations found in the statute. FDA's actions suggest that there is no longer a reason to even have a statutory distinction between drug and device, as FDA can upend that statutory definition by fiat. This removes any semblance of regulatory certainty for industry and undermines trust in the regulatory process.

Catalyst Pharms., Inc. v. Becerra

FDA is urging Congress to make a similar legislative fix for *Catalyst v. Becerra*. There, the Eleventh Circuit interpreted the FDC Act such that FDA must award orphan drug marketing exclusivity to an entire disease or condition rather than to the approved indication. In this case, innovator-drug sponsor Catalyst sued FDA for approving the "same drug for the same disease or condition" as its orphan drug-designated

[6] *Compare* Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5 Billion*, Sci. Amer. (Nov. 24, 2014) *with* Josh Makower, *FDA Impact on Medical Technology Innovation* (Nov. 2010); *compare also* 86 Fed. Reg. 40,582 (July 28, 2021) (setting application fees for generic drugs) *with* 86 Fed. Reg. 41,477 (Aug. 2, 2021) (setting application fees for medical devices with significant fee reductions for small businesses).

[7] Not all contrast agents meet the definition of "device," as they may be metabolized or rely on chemical action.

[8] *See Genus*, 994 F. 3d 631 (D.C. Cir. 2021); *see also Genus Med. Techs., LLC v. FDA*, 427 F.Supp.3d 74 (D.D.C. 2019).

[9] 86 Fed. Reg. 43,553, 43,554 (Aug. 9, 2021).

product, Firdapse (amifampridine), during its seven-year orphan drug exclusivity period. FDA approved Firdapse for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in adult patients in November 2018 with orphan drug exclusivity but nonetheless approved a second amifampridine product, Ruzurgi, in May 2019 for the treatment of pediatric patients with LEMS—a condition with a patient population of fewer than 30 patients. After FDA, of its own volition, "administratively divided" the Ruzurgi application into separate applications for pediatric and adult patients, the agency reasoned that the Firdapse orphan drug exclusivity only protected the approved indication—adult patients—so Ruzurgi could come to market immediately for pediatric patients.

Catalyst sued FDA in June 2019 alleging that the plain language of the Orphan Drug Act precludes FDA's approval of Ruzurgi in *any* LEMS patients until the expiration of the orphan drug exclusivity period covering Firdapse. In September 2021, the Eleventh Circuit determined that the term "same drug or condition" in the Orphan Drug Exclusivity statutory provisions refers to the "rare disease or condition" for which the drug "was designated." Thus, the scope of the Orphan Drug Exclusivity protects the entire designated disease or condition rather than the indication approved. Because the disease for which Firdapse was designated was LEMS—not LEMS in adults—and because LEMS is the same disease in adult and pediatric patients, the Court held that FDA could not approve another sponsor's New Drug Application (NDA) for amifampridine for the treatment of LEMS in any patient population. As a result of this decision, FDA withdrew approval of the Ruzurgi NDA in February 2022. A Petition to the Supreme Court by Ruzurgi's sponsor, intervenor Jacobus, is pending.

In the interim, FDA has intensely lobbied Congress to overturn the *Catalyst* decision—without ensuring a similar platform for plaintiffs. In so doing, Congress has included in the User Fee Act an amendment to the FDC Act such that Orphan Drug Exclusivity applies to the approved "indication or use" within the rare disease or condition rather than the general "same disease or condition."

Judge Rotenberg Educ. Ctr., Inc. v. FDA

FDA has also asked Congress to overturn a third decision the agency lost: an attempt to ban the use of an electrical stimulation device (ESD) to treat self-injurious behavior (SIB) or aggressive behavior (AB) at the single site in the country that provides life-saving therapy to a small number of patients treated for severe SIB and AB who failed multiple other therapies.

SIB and AB are dangerous behaviors that can cause serious injuries to patients or caregivers. While most patients with SIB or AB can be treated successfully, existing treatments fail to provide relief for a small minority. FDA and its expert panel agree that a subset of SIB/AB patients cannot be successfully treated with behavioral therapy or drugs. JRC has shown that ESD was able to reduce sharply—or eliminate—dangerous behaviors in many of these patients.

The Judge Rotenberg Center (JRC) in Massachusetts is the only facility in the U.S. where ESD is used to treat SIB/AB patients. Massachusetts has developed a rigorous program for reviewing and overseeing the administration of ESD to SIB/AB patients, including determinations by clinicians that the treatment is needed; a Massachusetts court hearing where independent counsel represents the patient; and identification of the specific behaviors that can result in the use of ESD. After its approval of ESD treatment, the court will periodically assess whether the patient should continue the treatment.

ESD usage has been controversial: several years ago, Massachusetts sued to terminate JRC's use of ESD. FDA issued a proposed rule to ban the use of ESDs to treat SIB/AB in 2016, citing the filing of the Massachusetts lawsuit as evidence against that particular use. Though FDA has the power to ban devices, the ESDs ban marked only the third time FDA had invoked its authority.

Four years later, FDA issued a final rule banning the device. During the rulemaking process, FDA held no hearings nor took any witness testimony; while FDA solicited the views of ESD opponents, it did not contact any proponents. While the proposed ban was pending, the Massachusetts court, after a 44-day trial with multiple witnesses and hundreds of exhibits, found that ESD was safe for and the only effective option for these patients. While FDA used the Massachusetts lawsuit to support the proposed rule, it dismissed as irrelevant the findings of the Massachusetts court that heard from witnesses. FDA also ignored comments from the parents of JRC patients, who explained that no other therapy had provided relief.

JRC and the parents filed a petition for review of FDA's regulation in the D.C. Circuit citing several different grounds, including multiple violations of the APA. For example, FDA relied heavily on anecdotal and outdated reports, ignored expert testimony, and dismissed evidence showing that the number of events of SIB/AB dropped by over 90% in the first month of ESD treatment. JRC and the parents also alleged that FDA had violated the FDC Act by banning a particular use of a device rather than the device itself. While ESD can be used for other purposes, such as smoking cessation, the FDA rule would have banned only this use of ESD, which violates the principle that FDA cannot regulate the practice of medicine or prohibit the off-label use of a device.

In a 2-1 decision, the D.C. Circuit held that FDA's ban was inconsistent with the FDC Act's explicit prohibition on FDA regulating the practice of medicine. Because the Court found that banning a single intended use was impermissible, it never considered the APA or other significant factual issues raised by JRC. The court denied FDA's motion for rehearing en banc. And that was that.

Except it wasn't. Without notifying JRC, FDA asked Congress to add language to the User Fee Acts relating to bans. The new provision would make two changes at FDA's behest: First, it amends the banning provision to permit FDA to ban a specific intended use, not just a device. Second, the provision bans ESDs when intended to treat SIB/AB. With this provision, Congress is seeking to ban ESD to treat SIB/AB without hearing from a single witness or making any findings of fact and without allowing a court the opportunity to review whether FDA's position was factually sound or compliant with FDA.

Instead, Congress, on behalf of FDA, is imposing an unfair and abusive ban to deprive patients of therapy that has been effective, according to their doctors and Massachusetts judges.

Conclusion

In each of these cases, a federal court found FDA's position untenable under the plain language of the statute; in so doing, three courts determined that FDA violated the rights of three separate plaintiffs and dismissed FDA's legal theories. Yet rather than exhausting its appeals, FDA decided to use a backdoor approach: privately lobbying Congress to overturn the cases without giving the plaintiffs the opportunity to preserve their hard-fought victories.

Ultimately, if the provisions discussed above remain in the must-pass legislation, each legal challenge was for naught. Such successful lobbying will reflect FDA's ability to moot almost any APA litigation filed against it and do so by presenting Congress with the exact arguments that judges rejected in the lawsuits filed against the agency. In effect, Congress is simply accepting FDA's findings without any public scrutiny or legislative hearings. As a result, the courts and APA provide no check on an agency that uses congressional action to gain the unfettered discretion that courts rejected.

