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NCLA Brief Asks DC Circuit to Stop FDA's Improper Attempt to Regulate the Practice of Medicine

The Judge Rotenberg Educational Center, Inc. v. U.S. Food and Drug Administration, et al.;
Luis Aponte, et al. v. U.S. Food and Drug Administration, et al.

Washington, DC (November 24, 2020) – The New Civil Liberties Alliance, a nonpartisan, nonprofit civil rights group, filed an *amicus* brief in the U.S. Court of Appeals for the District of Columbia Circuit supporting a challenge to a Final Rule issued by the Food and Drug Administration (FDA). The Rule bans "electrical stimulation devices" (ESDs) for aversion therapy, currently in use in only one treatment facility in the United States—the Judge Rotenberg Educational Center in Canton, Massachusetts.

NCLA argues that the statute on which FDA relies does not provide FDA the rulemaking authority it seeks to exercise. Congress adopted the statute to permit FDA to move swiftly to prevent manufacturers from continuing to distribute fraudulent or hazardous medical devices *commercially* during the time it would take for FDA to prevail in a court proceeding. That rationale is inapplicable when, as here, no manufacturer is seeking to distribute the devices targeted by FDA commercially.

The Center's professional staff seeks only to continue to use the devices it manufactured many years ago to deter severe self-injurious or aggressive behavior in its own patients. Under those circumstances, the sole enforcement measure available to FDA is a lawsuit seeking an injunction and seizure of the devices—a course of action that would at least have provided Petitioners the hearing rights they were denied in the rulemaking proceeding.

For decades, Massachusetts courts have deemed that the Center's aversion therapy is both safe and effective for hundreds of patients. Thus, fearing that a federal court would reject its "unreasonable and substantial risk" claim, FDA opted to pursue a rulemaking proceeding. By proceeding in this fashion, for only the third time in its history, FDA was able to prevent the Center from cross-examining FDA's witnesses and from effectively responding to the assertions FDA made to support its finding.

FDA seeks to prevent the Center from continuing to use its ESDs, but FDA's rule will allow substantially similar medical devices to continue being used to treat other medical conditions, such as for smoking cessation. NCLA is deeply concerned that FDA has violated the petitioners' procedural rights and has arrogated to itself powers not delegated to it by Congress. NCLA is asking the court to vacate the rule.

NCLA released the following statement:

"Not only is the FDA acting in bad faith, but it's interfering with the practice of medicine by attempting to dictate how the Center must treat its patients. The law that permits hearing-less bans would violate due process rights—and thus would be simply unconstitutional."

— **Rich Samp, Senior Litigation Counsel, NCLA**

ABOUT NCLA

NCLA is a nonpartisan, nonprofit civil rights group founded by prominent legal scholar Philip Hamburger to protect constitutional freedoms from violations by the Administrative State. NCLA's public-interest litigation and other pro bono advocacy strive to tame the unlawful power of state and federal agencies and to foster a new civil liberties movement that will help restore Americans' fundamental rights.

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