FOR IMMEDIATE RELEASE **Media Inquiries:** Judy Pino, 202-869-5218

In NCLA *Amicus* Win, D.C. Circuit Vacates FDA Final Rule Wrongfully Regulating 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 (July 6, 2021) – "When Congress has spoken in a statute, we assume that it says what it means and that the statute means what it says," concluded the U.S. Court of Appeals for the D.C. Circuit in an opinion today. In *The Judge Rotenberg Educational Center, Inc. v. U.S. Food and Drug Administration*, the Court declared that the Food and Drug Administration's Final Rule banning one specific use of an FDA-approved medical device improperly interferes with the practice of medicine. The Court further agreed with the New Civil Liberties Alliance that the Food, Drug & Cosmetic Act does not permit FDA to ban an already-approved device for some uses but not other uses. NCLA, a nonpartisan, nonprofit civil rights group, filed a November 2020 *amicus* brief making these two points, as well as arguing that FDA ran roughshod over petitioners' procedural rights and arrogated to itself powers not delegated by Congress.

The Judge Rotenberg Educational Center, Inc. (the "Center") operates a state-licensed facility in Massachusetts that provides treatment and educational services to nearly 300 patients with severe disabilities and a history of engaging in dangerous, life-threatening behavior. The Center is the nation's only facility that employs "electrical stimulation devices" (ESDs) for aversive therapy and has been doing so since 1994, when the Center first manufactured ESDs, which were cleared for marketing by FDA. More than 25 years later, FDA promulgated a Final Rule banning ESD use for self-injurious and aggressive behavior, but not for other uses.

In a 2-1 decision, the Court reasoned that the FDA lacks the statutory authority to enact the Final Rule. Senior Circuit Judge Sentelle wrote in the opinion for the Court, "If no statute confers authority to a federal agency, it has none. If Congress has forbidden an agency from taking an action, the agency cannot so act." The majority determined that the statute in question was not ambiguous, so it saw no need under the *Chevron* doctrine to defer to FDA's legal interpretation of its statutory authority.

Congress authorized FDA to utilize rulemaking proceedings to ban commercial distribution and sale of certain medical devices, but that provision is inapplicable to devices—as here—manufactured many years ago for the sole use of the manufacturer and its healthcare providers. Further, FDA's determination that contingent skin shock presents unreasonable risks to patients directly conflicts with determinations made by Massachusetts's courts. In 2018, after a 44-day evidentiary hearing, a Massachusetts Probate and Family Court judge ruled that aversive therapy using the ESDs is both safe and effective.

FDA sought to prevent the Center from continuing to use its medical devices by initiating a rulemaking proceeding, in which it concluded that the Center's devices "present an unreasonable and substantial risk of illness or injury" when used to treat patients for self-injurious or aggressive behavior, even though substantially similar devices may continue to be used to treat other medical conditions, and the Center is the only treatment facility in the country that uses the devices FDA's rule bans. Under these circumstances, the statute does not provide FDA the rulemaking authority it seeks to exercise, and the Court correctly reined in FDA.

NCLA released the following statements:

"Congress has determined that the practice of medicine should be regulated at the state level. Massachusetts courts have repeatedly upheld the medical procedures at issue here, finding that they are safe and effective. The Court today properly ruled that FDA has no business trying to second-guess that determination."
— **Rich Samp, Senior Litigation Counsel, NCLA**

"At a time when federal regulators are all too keen to micromanage the treatment of disease, this decision properly vindicates the ability of state-licensed physicians to use medical devices as they see fit based on their individual medical training and experience."
— **Mark Chenoweth, Executive Director and General Counsel, NCLA**

For more information visit the case page here.

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.

###