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NCLA Warns FDA's Over-regulation Will Adversely Affect Public Health During Crisis

NCLA Comments in Support of Citizen Petition Filed on Behalf of the Coalition to Preserve Access to Pharmacogenomics (PGx) Information, Docket No. FDA-2020-P-0152

Washington, DC (April 14, 2020) – If we've learned anything from the COVID-19 pandemic, it is that federal agencies that overstep their authority hinder the health and safety of Americans. Other recent regulatory actions by the Food and Drug Administration (FDA) threaten to undermine the ability of clinical laboratories to provide healthcare professionals and patients with information critical to optimizing drug usage and avoiding adverse events. The New Civil Liberties Alliance is especially concerned that the FDA's decision to prevent the dissemination of information related to the impact of genetic variants on drug response (Pharmacogenomics or PGx) will adversely affect public health.

Today NCLA, a nonpartisan, nonprofit civil rights group, filed **comments** in support of the **Citizen Petition** filed on January 9, 2020, by Hyman, Phelps & McNamara, P.C. on behalf of the Coalition to Preserve Access to Pharmacogenomics (Pgx) Information. NCLA's comments focus on two concerns: (1) FDA's efforts to suppress truthful speech violate the First Amendment rights of clinical laboratories as well as of those doctors and patients who wish to receive PGx information from those labs; and (2) FDA's defense of its speech suppression cannot be reconciled with the U.S. Constitution's separation of powers. FDA claims unlimited administrative discretion to prohibit the operation of all clinical laboratories, but it does not have the power to prosecute only those laboratories that disseminate truthful information of which FDA disapproves.

FDA's position also raises significant due-process concerns because it deprives the regulated community of fair notice of how to conform its conduct to FDA's expectations and permits enforcement officials to make up the rules on the fly. Laboratories have long been at the forefront of efforts to quickly develop tests for detecting the presence of new pathogens; they need considerable flexibility to meet the public's time-sensitive need for such tests. FDA should rescind its speech-suppression policy for laboratories that engage in PGx testing. Any new FDA policy on PGx tests should be developed through a notice-and-comment rulemaking proceeding that complies with the Administrative Procedure Act.

NCLA released the following statements:

"FDA simply lacks constitutional authority to adopt legislation of its own accord and then proceed to apply that legislation to the regulated community. Only Congress may adopt federal laws restricting individual liberty. FDA should grant the Citizen Petition filed by the Coalition."

—Rich Samp, Senior Litigation Counsel, NCLA

"Although the FDA claims its speech-suppression policy protects patients, FDA's restrictions on laboratories marketing LDTs are far more likely to cause harm than to benefit public health. Laboratories are in a unique position to disseminate truthful information about gene-drug associations for new drugs. FDA's policy denies patients optimal treatment."

—Jared McClain, Staff 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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