HUSCH BLACKWELL

COVID-19 RESEARCH AND LABORATORY TESTING

No industry has had to deal with the COVID-19 pandemic—both operationally and financially—the way healthcare has. COVID-19 has impacted organizations in every segment of the healthcare industry as they strive to contribute to pandemic mitigation efforts through the provision of care, facilitating testing, and participating in the development of vaccines. Husch Blackwell's healthcare and life sciences attorneys have provided comprehensive legal advice to COVID-19 research institutions and testing laboratories (both free-standing and affiliated with hospitals, health systems, and educational institutions) across the United States. Our robust team of attorneys range from former U.S. Food and Drug Administration (FDA) regulators and clinical research institutional review board (IRB) members, to former pharmaceutical manufacturer executives.

The healthcare and life sciences team advises on a full range of routine and complex legal matters impacting research institutions and laboratories including compliance with laws such as the Clinical Laboratory Improvement Amendments (CLIA), FDA requirements and the Emergency Use Authorization (EUA) process, and coverage under the Public Readiness and Emergency Preparedness (PREP Act). Our team also routinely counsels on the laboratory licensure and survey process, reimbursement matters, research collaborations, acquisitions and divestitures, privacy issues, intellectual property, and COVID-19 testing agreements between our clients and the government, employers, institutions of

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higher education, and other organizations.

As research institutions and clinical laboratories attempt to navigate the increasingly complex and ever-evolving regulatory landscape, Husch Blackwell is here to provide more than legal counsel, we are your partners.

Representative Experience

Assisted preeminent research facility with the development of COVID testing innovation and research strategy, including analysis of FDA, EUA, laboratory developed tests, and PREP Act implications and community outreach contracts.

Advised national laboratory on licensing, CLIA, and FDA regulatory issues related to COVID-19 screening and surveillance procedures using its FDA-authorized diagnostic test, and analyzed impact on PREP Act immunity.

Assisted in the conversion of an animal laboratory to a human laboratory in the areas of CLIA, licensure, privacy, and billing matters.

Helped evaluate compliance with federal research regulations (informed consent/IRB issues), National Institutes of Health Grants Policy Statement (NIHGPS), and related federal regulations and investigations in area of pediatric and adult research.

Drafted and reviewed numerous COVID-19 testing agreements for a variety of clients including hospital systems, institutions of higher education, and employers of

all sizes.

Assisted in the sale of a nutrigenomic laboratory to provide healthcare regulatory due diligence guidance to minimize risk.

Provided guidance to a pathology lab in dealings with the CLIA surveyor and achieved a favorable outcome that resulted in no corrective actions.

Assumed role of interim in-house counsel for international pharmaceutical service provider. Reviewed and negotiated contracts for contract research organization (CRO) services, pharmacovigilance services, hub/commercial services, nursing services, and patient assistance program services.