Freedom to Innovate: Lessons From the COVID-19 Pandemic

By Eric M. Kraus and Lisa L. Smith
Phillips Lytle LLP

Innovation demands freedom – freedom to be creative and to think outside the proverbial box. Sometimes, it also requires freedom from litigation threats and unnecessary regulatory roadblocks that can stifle the creative, innovative process. The race to find an effective vaccine against the COVID-19 virus is a prime example of just how such freedom has contributed to life-saving innovation and created a path back towards normalcy.

Eric M. Kraus
Partner

Lisa L. Smith
Partner

Finding a vaccine for a virus typically takes years, even decades. For COVID-19 vaccines, the timeline was measured in months – an astounding scientific achievement. Before the end of 2020, the first two vaccines were granted emergency use authorization (EUA) by the Food and Drug Administration (FDA). The EUA authority allows the FDA to expedite its approval of life-saving therapies. Of course, the obstacles to getting the vaccines into the world's population continue to be challenging, but the job of the scientific innovators – to come up with the vaccine and to secure governmental approval – was facilitated by a series of laws and regulations intended to provide protections to those working on the vaccines and other virus "countermeasures."

The 2005 Public Readiness and Emergency Preparedness Act (PREP Act), invoked by the March 2020 declaration by the Secretary of Health and Human Services that COVID-19 constituted a public health emergency, conveyed broad immunity from liability for those who provided "countermeasures" to the virus. Such immunity has served the scientific community well by insulating vaccine manufacturers from personal injury liability, and thereby encouraging many companies and their scientists to enter the race to discover life-saving medicines to fend off this pandemic, notwithstanding the uncertainties of success. Despite the financial burdens on companies willing to undertake vaccine development, at least one potential costly risk was essentially removed by virtue of the PREP Act and subsequent declaration that insured application of PREP Act protections to COVID-19 countermeasures.

The PREP Act does allow for some limited financial recovery, but only in cases of "willful misconduct." It imposes a variety of stringent procedural hurdles that further limit the circumstances under which a lawsuit might be successful.

The push to get vaccines into the arms of the population had other help as well, with EUA demonstrating how clearing the regulatory underbrush can quickly move a product from the lab to the public without sacrificing safety or efficacy. All three currently available vaccines have benefited from the accelerated EUA process.

The federal government has provided significant liability protections to almost any person or entity involved in providing vaccines to the public, including supply chains (air carriers transporting the vaccines) and those administering the vaccines. Moreover, vaccines are not the only products that have benefited by these extraordinary measures. Therapies to treat the COVID-19 virus such as the use of monoclonal antibodies or convalescent plasma have likewise been granted speedy regulatory approval under the EUA process and are also protected by the litigation immunity granted by the PREP Act.

One reason such immunity does not result in massive and catastrophic failures in the therapies approved under these circumstances is the protections that still exist in the scientific and drug discovery communities, regardless of any special modifications in the litigation or regulatory landscape made during a pandemic: academic institutions and their scientists still function within a set of ethical guidelines; clinical trials are still required by the FDA to demonstrate safety and efficacy; Institutional Review Boards still provide independent oversight over such human trials; and internal corporate compliance rules still govern the process by which investigational new drugs are brought to market.

It is critical to acknowledge that the scientists and physicians on the front lines of drug discovery are among the heroes in the fight against the COVID-19 virus. Their efforts have been granted a huge assist by virtue of a streamlined regulatory process and the special litigation protections established to insulate those who are trying to bring life-saving therapies to the world.

Eric M. Kraus is a partner at Phillips Lytle LLP and co-leader of the firm's Life Sciences Practice. He focuses his practice on complex civil litigation matters, including mass torts and class actions involving pharmaceutical product and medical device liability, as well as toxic torts. He can be reached at ekraus@phillipslytle.com or (212) 508-0408.

Lisa L. Smith is a partner at Phillips Lytle LLP and co-leader of the firm's Life Sciences and Class Action Practices. She handles complex litigation across multiple jurisdictions, with a focus on the defense of pharmaceutical, chemical and other product liability cases, as well as environmental claims. She can be reached at lsmith@phillipslytle.com or (716) 847-8336.