Right to Try Investigational Drugs Signed Into Law

On May 30, 2018, S. 204, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Pub. L. No. 115-176, “Right to Try Act”) was signed into law. The Right to Try Act amends the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”) to establish national standards and rules by which certain investigational drugs may be provided to terminally ill patients. Under the Right to Try Act, a patient diagnosed with a life-threatening disease or condition, who has exhausted approved treatment options and is unable to participate in clinical trials involving certain investigational drugs, may seek the opportunity to drug treatments that are not approved by the U.S. Food & Drug Administration (FDA).

The Right to Try Act exempts the provision of eligible investigational drugs to eligible patients from a number of requirements and restrictions under the FD&C Act and other laws. The manufacturer or sponsor of an eligible investigational drug must report annually to the FDA on any use of drugs dispensed under the Right to Try Act. The FDA will post an annual summary report of such use on its website.

The Right to Try Act incorporates the regulatory definitions of “life-threatening” diseases that are: (1) a disease or condition where the likelihood of death is high unless the course of the disease is interrupted, and (2) a disease or condition with potentially fatal outcomes, where the end of clinical trial analysis is survival.

Under the new law, a sponsor or drug manufacturer may only recover the direct costs of making its investigational drug available. Direct costs are costs that can be specifically and exclusively attributed to providing the drug for the investigational use under the Right to Try Act. Direct costs include costs per unit to manufacture the drug (e.g., raw materials, labor, and non-reusable supplies and equipment used to manufacture the quantity of drug needed for the use for which charging is authorized) or costs to acquire the drug from another manufacturing source, and direct costs to ship and handle (e.g., store) the drug. Direct costs exclude costs incurred primarily to produce the drug for commercial sale (e.g., costs for facilities and equipment used to manufacture the supply of investigational drug, but that are primarily intended to produce large quantities of drug for eventual commercial sale) and research and development, administrative, labor, or other costs that would be incurred even if the clinical trial or treatment use for which charging is authorized did not occur.

The FDA announced that it stands “ready to implement this legislation in a way that achieves Congress’ intent to promote access and protect patients. The FDA is dedicated to achieving the goals that Congress set forth in this legislation, so that patients facing terminal conditions have an additional avenue to access promising investigational medicines.”