Comparative Analysis of Right to Try Access to Innovative Emerging Healthcare Technologies

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ABSTRACT

Because the regulatory process for approval of investigational drugs in the United States can be prolonged, terminally ill patients seek expanded access to experimental medicines from biopharmaceutical companies. Currently, the FDA permits patients to utilize the compassionate use provision which allows seriously ill patients to obtain an unapproved drug under development. Although the existing process allows companies to provide experimental drugs on a case-by-case basis, only a small number of exceptions are granted each year (Whaley, 2015). While studies may identify ways to accelerate the drug approval process in the United States or expand the compassionate use process such as the expanded access programs, an alternative approach to obtain early access to experimental medicines is the controversial right to try legislation being enacted by the individual states. Right to try laws allow terminally ill patients to have access to investigational drugs prior to final FDA approval and without FDA authorization. Currently, such reform legislation has been approved in twenty-six states (Goldwater Institute, 2015). In addition, pharmaceutical companies may take advantage of the reform legislation, further intensifying competition in the healthcare marketplace. Prior research to examine provisions associated with right to try policies within the United States have been limited. To address this gap in the literature, this paper will examine right to try trends including qualification criteria, terminal illness requirement, comparable treatment options, and permission provisions.

Keywords: Expanded access programs, Right to try, Experimental medicines, Unapproved drugs