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Current events in pre-approval access in the United States

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Over the past several years there has been a resurgence of efforts to gain access to investigational products outside of clinical trials. Previously failed attempts a decade or so ago at the federal judicial level has turned advocates' strategy to pushing states to pass variants of so-called "right to try" laws in an effort to circumvent the FDA's expanded access policies. Over the past several years, a majority of states have now done so. While ethicists debate the battle of the good vs. the good of this kind of access, and lawyers debate the state's rights to have these kinds of laws, the FDA and the advocates debate their respective track records. Nevertheless, the issue has gotten the attention of the federal legislators through passed acts as well as putting forth proposed legislation for a national Right to try Act. With the current congress and the executive branch leaning towards the advocates' position, it is likely that we will see continued movement. This session provides a comparison of the varying state "right to try" laws and summaries of the most recently passed and proposed federal laws related to this topic.

Biography

David is a well-known leader and change agent in the clinical research industry. He was born and raised in New Orleans, Louisiana. He has a Masters degree in both Social Work and Business Administration and holds the additional status of Certified IRB Professional (CIP) and Regulatory Affairs Certification (RAC). He is the Responsible Executive for Clinical Research for Hospital Corporation of America (HCA). He is and has been in many industry leader roles both in the United States and globally, including Chair of the Board of Trustees for the Association of Clinical Research Professionals (ACRP). He is also the President of the Nashville Angel Capital Group. He is married with 2 children and lives south of Nashville, Tennessee where he involves himself in work, family life as well as other charitable and entrepreneurial opportunities. David was recently honored with the "Outstanding Speaker" award, presented at the 2015 MAGI West conference.

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