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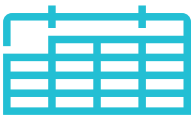
Right-to-Try – An Alternative to the Federal Compassionate Use Program

"Right-to-Try" legislation provides patients access to cutting edge therapies that haven't been formally approved by the FDA. This legislation has been passed at the state level in 41 states and Congress just passed legislation at the Federal level as an alternative to the Compassionate Use program currently in place.

Existing Compassionate Use Programs

- Are limited to patients with a health condition that is life threatening with reasonable likelihood of death within months.
- Require patients to first petition the drug company, through their doctor, to obtain access.
- Require the drug company to agree to provide the drug before patients can apply to the FDA.
- Still require FDA review of the application.

Unfortunately, many patients do not have time on their side to work through this time consuming process. Under the new "Right-To-Try" bill, patients no longer need to petition the FDA for approval to try an unapproved drug. The patient's doctor can contact the drug company directly and if an agreement is reached, the patient can be granted access to the drug.



The recently passed Federal Legislation contains these key provisions:

1. Patients with a life-threatening disease or condition must have exhausted approved treatment options;
2. The FDA cannot use any negative data unless it is critical in determining the safety of the product;
3. The manufacturers and prescribers may be protected from liability if they meet certain requirements set forth in the bill but there could remain potential for private actions under any State or Federal product liability, tort, consumer protection, or warranty law.

There are several questions you should consider regarding patient access to your drug outside of the traditional clinical environment:

- **Legal Protections**
  - How will you verify that the patient meets the eligibility criteria without meeting the patient in person; additionally, if the patient fails to meet all of the inclusion criteria, do you continue the conversation with them?

- **Patient/ Healthcare Practitioner Safety**
  - If the doctor states that the patient is not able to formally participate in the trial, do you consider why the patient does not qualify for an ongoing trial?
  - Does the drug have an inherently adverse safety profile that puts healthcare practitioners at risk for malpractice?

- **Social Pressures**
  - Are you morally obligated to provide access to your drug if it's a patient's last hope of survival?
  - It is not uncommon for social media campaigns to get behind a patient's request for access to a revolutionary therapy. How do you combat the societal pressure to provide access to your drug?

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As the "Right-To-Try" bill goes beyond the states and takes root as Federal Law, formal evaluative criteria and procedures will need to be formalized in order to protect both patients and drug companies from potential liability.

- **Financial Pressures**
  - Who pays the costs?
  - Are third party payers like insurance companies or the government going to cover the costs?
  - How would you as the drug company get compensated for the direct manufacturing costs?
  - How would supply of your drug be impacted if provided outside of planned clinical trials?
  - Would you potentially risk a delay in your trials due to a product shortage?

For further information, consult your agent or broker or speak with a Chubb Life Sciences Specialist.

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