Right to Try Laws

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SUMMARY

Under Right to Try laws, terminally ill patients may be granted the right to access and use investigational products (i.e., medications or treatments) that are not yet publicly available because they are being investigated by the US Food and Drug Administration (FDA). This dataset explores state laws that govern the criteria a patient must meet to be eligible to access the products. It also addresses insurance coverage for these investigational products, specifically whether insurers are required to pay for coverage, and whether patients may have to forfeit coverage or care if they choose to use Right to Try laws to access these treatments.

ABOUT RIGHT TO TRY LAWS & THE DATA

In 1987, the FDA instituted the Expanded Access Program to provide early access to unapproved drugs to meet the needs of patients seeking alternative treatments for terminal illnesses. The program established a new application process for investigational drugs that allowed pharmaceutical companies to apply to give specific groups access to unapproved drugs under limited circumstances. Since then, for the past 30 years, the FDA has refined its process for granting limited access to medical treatments or products that are not yet publicly available. In 1997, individuals suffering terminal illnesses could now apply for individual early access under the “single patient IND” program. Subsequently, in 2009, the FDA revamped the application process for compassionate use, whittling down the process to three small forms, which could be read over the phone in an emergency situation.

In early 2014, as criticisms of the inefficient regulations of the FDA gained steam, the Goldwater Institute released a model for Right to Try legislation. This model legislation authorized the access to and use of experimental treatments for patients with an advanced illness, established conditions for the use of experimental treatments, and prohibited sanctions of health care providers solely for recommending or providing experimental treatment. The basis of the

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2 Id.
3 Id.
4 http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/Default.htm#Statutory_Background
Goldwater Institute’s argument is that the right to choose investigational drugs is a fundamental right protected by the United States Constitution. A few months after the Goldwater’s model was released, Colorado passed the first Right to Try legislation in the United States. Since then 31 states have passed Right to Try laws with Connecticut becoming the 31st state in July 2016.

Right to Try legislation, according to its proponents, is an attempt to provide terminally ill patients with access to prescription drugs and products that are still undergoing clinical trials and are therefore unapproved by the FDA. Proponents believe that Right to Try laws remove unnecessary bureaucracy and have the potential to save lives. According to detractors, since 99 percent of submitted applications for the FDA’s expanded access program are accepted, criticism by the Goldwater Institute that the program is too slow to be useful to patients is overstated.

Under Right to Try laws, investigational products include drugs, products and devices that have passed through Phase I of the FDA approval process, and are under active investigation. While all states with Right to Try laws use Goldwater Institute’s model legislation as a template, each state has tweaked the legislation in different ways, leading to variation. For example, states vary on how they define “terminal illness”: The majority of the states (24) avoid establishing a firm time requirement; instead, they use language subject to interpretation such as “a condition that will soon result in death.” Only six states define a “terminal illness” as one where the patient has a specific prognosis, of less than either 6, 12, or 24 months. Indiana does not explicitly define “terminal illness.” Another example of variation lies in whether manufacturers are required to cover the costs associated with investigational products, when they are provided. Only Texas requires that manufacturers cover these costs, all 30 remaining states do not.

Some findings from the dataset include:

- In order to be considered an eligible patient in nine of the 31 states, you must be ineligible for a clinical trial, usually within a specified geographic area. What this means varies from state to state. Arkansas, Colorado, Connecticut, Maine, North Dakota, Oklahoma and West Virginia require that eligible patients apply for clinical trials within 100 miles of their home, and require that they not be accepted to those clinical trials within a week of applying. Tennessee has the same requirement, but only requires patients to apply for clinical trials within 50 miles of their home. Mississippi requires that patients apply for clinical trials within their state.

- As of October 1, 2016, patients in seventeen states may have their eligibility for hospice care withdrawn while they are using investigational products.

- In Colorado, Connecticut, North Dakota, Oklahoma, and West Virginia individuals receiving inpatient care do not qualify for access to investigational products.

NAVIGATING THE DATA

There are two ways to navigate the data by clicking the Filter tab or the Explore tab — for each option, the data can be visualized in a map and table format or in jurisdiction profiles.

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7 http://righttotry.org/about-right-to-try/
8 Id.
9 Id.
Filter
The dataset homepage will default to the Filter tab. Here, users may answer a series of questions to learn more about the characteristics of the laws. Answering more than one question will show all the jurisdictions that meet the combined criteria. Criteria selected will be listed above the questions, and can be removed by clicking the white X or by clicking “Reset” above the questions.

Explore
Users can access Explore by clicking the Explore tab in the bar above the questions. Using Explore, users will see the answers to one question across all jurisdictions.

The primary questions in this dataset are:

1. Does this state have a Right to Try law?
2. How is “terminal illness” defined?
3. What are the criteria for a patient to be eligible for access to investigational products?
4. Are manufacturers required to make investigational products available to eligible patients?
5. Are manufacturers required to cover the costs associated with investigational products?
6. Are insurers required to pay for coverage costs?
7. What coverage or care might patients have to forfeit if they access an investigational product under Right to Try laws?

DISPLAYING THE RESULTS
There are two display modes once criteria have been selected by using either the Filter or Explore tab — Map display mode and Profiles display mode.

Map Display
LawAtlas.org dataset homepages default to the map display mode. When querying the data using the Filter tab, all jurisdictions that meet the criteria selected will display in one tone of yellow. Those jurisdictions that do not meet the criteria selected will be colored gray. When querying the data using the Explore tab, the map will illuminate with colors from yellow to red that are associated with the various answer choices (the color-coding is defined by the key to the left of the map).

Below the map, a table will appear. Using the Filter or Explore tab to navigate the questions will change the display:

- Using the Filter tab, you can select an unlimited number of criteria and the applicable jurisdictions that meet the combined criteria will be displayed in the table below.
- Using the Explore tab, you can isolate a single criterion and the applicable jurisdictions will appear in the table below.

Profiles Display
The Profiles display presents the results of the criteria selected in a text-based format for each applicable jurisdiction. Using the Filter tab, jurisdictions that meet the criteria selected will
display. Using the Explore tab, jurisdictions that meet the criterion selected will display. If no criteria are selected, the full profiles for each state will appear under both Filter and Explore.

Profile Legend
Within each Profile box, above the questions and answers, there are additional options and information useful in exploring the law:

<table>
<thead>
<tr>
<th></th>
<th>Toggle Legal Text – Selecting this option will show all the legal text used to answer questions for this jurisdiction.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Toggle Full Place Profile – Selecting this option will show all questions and answers for this jurisdiction, regardless of what was selected using the Filter or Explore tabs.</td>
</tr>
<tr>
<td></td>
<td>Toggle Size – Selecting this option will make the profile larger, but will not change the information displayed.</td>
</tr>
</tbody>
</table>

Legal Text History – This interactive timeline displays when changes in the law have occurred within a jurisdiction. Using the arrows to the left or right, users may explore how the law has changed over time as new amendments to the law have been enacted. The timeline will change from gray to a shade of yellow when the jurisdiction passed its first relevant law. Each change in the law after that is marked by a break in the timeline.

Map and Profile Legend
There are a few symbols to be aware of in both Map and Profiles display modes:

|   | Section Symbol – Clicking this symbol will open a window that displays excerpts from the law that correspond to the question and answer. |
|   | Caution Note – Clicking on this symbol will open a small window that displays text that describes important caveats about the question and answer. |

DATASET RESOURCES
Each dataset homepage includes the following resources available for download:

- Data: The Data file exports in CSV. format and may contain two tabs. The “Statistical Data” tab contains the legal variables coded in the dataset, displayed as values defined in the accompanying Codebook. The “Summary Data” tab contains the legal variables coded in the dataset in text form, as well as the accompanying citations and any caution
notes that may be included. Note: if there is only one tab available for download it will be the “Statistical Data” as described above.

- Codebook: The Codebook defines all of the coded variables in the dataset. The Codebook lists the question, question type, variable name, variable value and variable label. The Codebook should be used in conjunction with the Statistical Data extract.

- Research Protocol: The Research Protocol is a comprehensive document that outlines the entire methodology of the project, including the scope, inclusion and exclusion criteria, data collection methods, definitions, coding scheme decisions, as well as the quality control process.

- Summary Report: The Summary Report provides a snapshot of important findings from the dataset.

ADDITIONAL INFORMATION

- Goldwater Institute: Right to Try Homepage


This collection of laws does not provide legal advice nor does it address enforcement of laws, administrative policies, case law, or any other sources of law. Should you have a specific question about these laws in your state, please contact an attorney in your jurisdiction.