Introduction to Right to Try Laws:

In stark contrast to states enacting Physician Assisted Suicide legislation for patients suffering from terminal irreversible illnesses who seek to control their date of death, LA is a ‘pro life’ state. LA statutes herald Life begins at conception/ ends with natural death- and strictly forbid “Nothing …shall be construed to condone, authorize, or approve- assistance to suicide, mercy killing or euthanasia or to permit any affirmative or deliberate act or omission to end life other than natural process of dying” LA RS 40:1151.9

In 2014 LA joined a growing # of states, passed an Access to Treatment for Terminally Ill Patients law (Act No. 346 Regular Session 2014) for patients with terminal illnesses who are seeking access to new drugs not yet FDA approved. These laws are popularly known as a ‘Right to Try Laws”.

This Louisiana law is attached

As a matter of introduction and explanation I have summarized below four types of legislation which afford preapproval access. Nos 1 & 2 are existing laws & Nos. 3 & 4 are proposed legislation

1-State Right to Try laws- allow use of investigational new drugs (IND) after drug has survived Phase I clinical trials- early trials which measure basic efficacy & toxicity/ side effects/ safety of IND.

As of July 1, 2015 Right to try laws similar to LA law have been passed in 20 other states (Alabama, Arizona, Arkansas, Colorado, Florida, Indiana, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, North Dakota, Oklahoma, South Dakota, Tennessee, Texas, Utah, Virginia, and Wyoming). Right to Try legislation has been introduced in 18 other states (Alaska, California, Connecticut, Delaware, Georgia, Hawaii, Illinois, Kansas, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, West Virginia, and Wisconsin).

2- FDA Expanded Access/ Compassionate Use Law - provides for seriously ill patients who are not eligible for clinical trials to approach the FDA to access unapproved drugs. Before state Right to Try laws were passed, a patient who sought access to an Investigational New Drug (IND) or device had to work with his/her provider to comply with the following U.S. Food and Drug Administration (FDA) regulations for expanded access.

The FDA regulation requires the patient and provider to submit paperwork to FDA which establishes:

a-The patient has a serious disease or condition associated with morbidity that has a substantial impact on day-to day functioning *or* a disease or condition that is immediately life threatening;

b- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;

c- The patient cannot obtain the drug under another IND or protocol;

d- The potential benefit justifies the potential risks, and those risks are not unreasonable; and

e- The provision of the investigational drug in the expanded access case will not interfere with clinical investigation of the IND that could support the approval or development of the IND.

f- If and after the FDA approves the compassionate use of an IND, the patient still needs to acquire access to the desired drug thru the manufacturer. Because of research requirements, INDs are closely controlled by the manufacturer and not available in pharmacies like normal prescriptions. The drug manufacturer has to agree independent of FDA ‘approval’ to provide the IND to the patient

3-21st Century Cures Act- Omnibus Congressional proposed legislation- to streamline the approval process. Bill is in 2016 session of Congress for review.

This bill provides for annual increases in funding for NIH & FDA to develop new drugs ($8.75 B over 5 years). Some provisions would expedite the approval process for high-priority treatments. For example, one provision would allow FDA to approve certain drugs and medical devices based on case studies and published medical reports rather than data from larger clinical trials. Another would allow the agency to approve drugs to treat rare, life-threatening infections based on smaller clinical trials.

Fast tracking research of course raises concerns and criticisms perhaps best voiced by former FDA Commissioner Margaret Hamburg: “…the misperception that you might be able to speed innovation by lowering standards for safety and efficacy…would be a terrible mistake …shortening review times is not going to create scientific understanding and the research and development that needs to be done…the public would be best served if Congress would give the agencies the support they need to do their job.”

4-Congressional Right to Try Act- proposed legislation

This bill, in its present form, would- a) prohibit the federal government (FDA) from taking any action to prevent patients from accessing INDs; b) effectively bar FDA from denying access under the existing FDA Expanded Use/ Compassionate Use Law and undermine present FDA authority to control introduction of new products; and, c) essentially duplicate currently existing right to approach FDA under states Right to Try Laws in 20 states (+ 18 proposed state statutes.)

Barring a federal government decision that this matter is of such national character that an act of Congress is necessary to unify inconsistent and conflicting state laws, this proposal is unlikely to become law.