SHIPMAN & GOODWIN LLP®
COUNSELORS AT LAW

DRUGS AND MEDICAL DEVICES
A SHIPMAN & GOODWIN® ALERT

June 21, 2016

Connecticut's New "Right to Try" Law Provides Hope for Patients and Providers, but FDA Remains in the Driver's Seat

Authors and Contributors:

Sarah A. Westby
(860) 251-5503
swestby@goodwin.com

Adam M. Masin
(860) 251-5154
amasin@goodwin.com

Connecticut has recently joined the wave of states enacting a so-called "Right to Try" law, which ostensibly permits terminally ill patients access to investigational drugs (including biologics) and medical devices as a last-resort treatment option. *See* Public Act No. 16-214, *available at* https://www.cga.ct.gov/2016/act/pa/pdf/2016PA-00214-R00SB-00371-PA.pdf. These "Right to Try" laws have been enacted in over thirty states to date. *See* http://righttotry.org/faq/. Current FDA regulations permit the use of such drugs and devices under limited circumstances, but despite state-law attempts to increase access, the reality is that FDA, rather than the states, still largely controls access to these investigational products. FDA regulations which would unlock the effect of state laws by eliminating significant barriers to this access are in the queue but have not yet been enacted. Connecticut's new law, therefore, offers limited hope to patients, providers, and the medical product companies who wish to help them, at least for now, but the new law does lay the groundwork for future expanded access.

On June 10, 2016, Governor Malloy signed Public Act 16-214 into law, along with several supporting laws designed to encourage investment in the biomedical sphere. *See* Public Act Nos. 16-201(designed to speed up the process of granting land use permits for bioscience projects and facilities), 16-204 (encouraging investment in Connecticut bioscience entities), 16-20 (establishing a health data collaborative working group), and 16-21 (encouraging tax credits for bioscience research and development). These laws take effect **on October 1, 2016.**

Connecticut's "Right to Try" law permits patients suffering from a terminal illness to obtain drugs and medical devices which have successfully completed a Phase 1 clinical trial, but have not yet been approved for general use by the FDA. The law is designed to encourage use of investigational drugs and devices by terminally ill patients by providing a number of safeguards and incentives to patients, healthcare providers, pharmaceutical manufacturers, and insurance carriers.

First, the law offers patient protection in two ways: eligibility restrictions and robust informed consent requirements.

A patient is eligible to receive treatment with an investigational drug or device only if he or she meets each of the following requirements:

1. The patient has considered all other treatment options approved by FDA;
2. The patient has been unable to participate in a clinical trial within 100 miles of his/her home or has not been accepted into a clinical trial;
3. The patient has received a recommendation to try the investigational drug or device by

his/her treating physician;
4. The patient has provided written informed consent, as described in the law; and
5. The patient has obtained written documentation from his/her treating physician stating that the patient meets the above requirements.

In addition, the patient, or parent/guardian of a minor or incompetent patient, must sign a written document, which, at a minimum:

1. Explains the currently approved products used to treat the patient's terminal illness;
2. Confirms the patient's agreement with his/her treating physician that all currently approved products are unlikely to prolong the patient's life;
3. Clearly identifies the specific investigational drug or device at issue;
4. Describes the potentially best and worst outcomes of using the investigational drug or device, including the possibility that the drug or device could hasten the patient's death;
5. States that the patient's health insurance carrier is not obligated to pay for treatment associated with the investigational drug or device;
6. States that the patient's eligibility for hospice or in-home health care may be withdrawn upon use of the investigational drug or device; and
7. States that the patient understands that she is liable for the costs associated with the investigational drug or device, and that his/her estate may be held accountable for such cost.

The law contemplates a significant role for the patient's treating physician, but provides a healthy dose of protection as well. For example, neither the State Department of Public Health nor the Connecticut Medical Examining board shall revoke, fail to renew, suspend or take any disciplinary action against a physician based solely on the treating physician's recommendation to use an investigational drug or device. In addition, the law immunizes providers (including physicians, hospitals, treatment centers and private practices) from lawsuits based upon harm done to the patient resulting from the patient's use of an investigational drug or device.

The law extends similar protection from liability to pharmaceutical manufacturers, in that a patient cannot sue the manufacturer for any alleged harm done to the patient resulting from the investigational drug or device which the manufacturer has made available. In addition, participation on the part of the manufacturer is voluntary, as there is no requirement that a manufacturer must provide access to its investigational drug or device. Pharmaceutical manufacturers may, but need not, provide access to investigational drugs and devices free of charge or at cost.

Finally, insurance carriers are protected in terms of coverage and liability, in that 1) a health carrier may deny coverage to an insured patient from the time that patient begins treatment with the investigational drug to a period not exceeding six months from the date the patient ceases treatment with said drug or device, and 2) a patient cannot sue the insurance carrier that chooses to provide coverage or denies coverage for an investigational drug or device. Covering the cost of investigational treatment is an expensive endeavor for the insurance carrier, and the new laws do not purport to offer any incentives for coverage. Yet an insurance carrier's reluctance to provide coverage, for both the investigational drug or device and overall patient care while treating with the drug or device, may effectively cut off access to all but the wealthy.

Connecticut's Right to Try law attempts to strike a balance between patient protection and reduction of barriers to access. The law, however, must be read within the patchwork of

pertinent FDA regulations. Currently, FDA permits "expanded access" to investigational drugs in three situations:

- For individual patients, including for emergency use (21 CFR 312.310);
- For intermediate-size patient populations (generally smaller than those typical of a treatment Investigational New Drug ("IND") or treatment protocol — a treatment protocol is submitted as a protocol to an existing IND by the sponsor of the existing IND) (21 CFR 312.315); and
- For widespread treatment use through a treatment IND or treatment protocol (designed for use in larger patient populations) (21 CFR 312.320).

Each of these categories of expanded access requires a regulatory submission, which means time for review and approval -- time that the terminally ill patient may not have -- and carries the possibility of rejection. As things currently stand, healthcare providers must continue to report adverse events occurring while a patient is using an investigational drug or device. Connecticut's Right to Try law does not impose any additional reporting requirements.

Despite the protection given under PA 16-214, mindful manufacturers must consider several pitfalls of participation. First, providing access to investigational drugs and devices to terminally ill patients creates the risk of delays or denial of FDA approval due to the inevitable increase in adverse event reports. Ironically, the good intentions of the law may prove to be a worse development for the overall patient population. Likewise, although state-law immunity is a significant step in the right direction, PA 16-214 (or any state law standing alone, for that matter) may not offer sufficient legal assurance to the pharmaceutical manufacturer without concomitant immunity from suit under federal law arising from distribution, sale, or use of an unapproved drug or medical device.

FDA has proposed regulations aimed at eliminating the threat of liability and the use of adverse events to hinder approval. *See* Trickett Wendler Right to Try Act, S. 2912. If approved, these regulations, read in conjunction with Connecticut PA 16-214, remove significant threats to pharmaceutical manufacturers in making their investigational products available to those in need. Nevertheless, the manufacturer must consider the possibility that some clever plaintiff's lawyer may find a way to admit evidence of adverse events through the back door. Neither PA 16-214 nor the proposed FDA regulations address the admissibility of evidence concerning adverse events in court.

Pharmaceutical manufacturers should consider the potential opportunities for good will among healthcare providers and patients that comes with providing access to investigational drugs and devices, as well as additional data on the efficacy of its drug or device, outside of the clinical trial setting.

While these potential gains may help offset the potential cost of litigation, the manufacturer must carefully weigh these considerations. Be on the lookout for enactment of the proposed Trickett Wendler Act, which may be the weight that tips the scale.

Questions or Information:

For more information about Connecticut's "Right to Try" Law, please contact Sarah A. Westby at swestby@goodwin.com.

289 Greenwich Avenue
Greenwich, CT 06830-6595
203-869-5600

One Constitution Plaza
Hartford, CT 06103-1919
860-251-5000

265 Church Street - Suite 1207
New Haven, CT 06510-7013
203-836-2801

400 Park Avenue - Fifth Floor
New York, NY 10022-4406
212-376-3010

300 Atlantic Street
Stamford, CT 06901-3522
203-324-8100

1875 K St., NW - Suite 600
Washington, DC 20006-1251
202-469-7750

www.shipmangoodwin.com