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The Voice

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This Week's Feature

Federal "Right to Try Act" Becomes Law: What Your Risk Management Team Needs to Know

By Sarah A. Westby

On May 30, 2018, Congress enacted the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017. *See* Pub. L. No. 115-176, §204, 132 Stat. 1372 (2018). The act allows eligible terminally ill patients to access prescription drugs that have passed Phase 1 clinical trials but that the U.S. Food and Drug Administration (FDA) has not yet approved for general use (termed "investigational drugs"). As of May 30, 2018, 40 states had adopted variations on "Right to Try" laws. Yet state law protections and immunities offer little comfort to manufacturers, providers, and patients without a federal law counterpart.

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New Member Spotlight

Rebecca R. Thornton, Teague Campbell Dennis and Gorham

Rebecca R. Thornton is a partner with Teague Campbell Dennis & Gorham LLP in its Raleigh, North Carolina, office. She represents small and large businesses and helps them navigate lawsuits filed by customers, personnel, and other third parties as a result of accidents and contractual disputes...

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Quote of the Week

"I do feel a responsibility to society because of going into print: a writer has the duty to be good, not lousy; true, not false; lively, not dull; accurate, not full of error."

—E.B. White, "The Art of the Essay No. 1," The Paris Review, Issue 48, Fall 1969.

This Week's Feature

Federal "Right to Try Act" Becomes Law: What Your Risk Management Team Needs to Know

By Sarah A. Westby

On May 30, 2018, Congress enacted the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017. *See* Pub. L. No. 115-176, §204, 132 Stat. 1372 (2018). The act allows eligible terminally ill patients to access prescription drugs that have passed Phase 1 clinical trials but that the U.S. Food and Drug Administration (FDA) has not yet approved for general use (termed "investigational drugs"). As of May 30, 2018, 40 states had adopted variations on "Right to Try" laws. Yet state law protections and immunities offer little comfort to manufacturers, providers, and patients without a federal law counterpart.

The new law aims to fill that void. It provides broad-based, civil tort immunity and prohibits the FDA from using adverse clinical outcomes to delay or deny drug approval. Though lauded by some as the saving grace for terminally ill patients, and derided by others as a threat to patient safety, one thing is certain: implementing the act poses legal, ethical, and administrative challenges for pharmaceutical manufacturers and health-care providers alike.

Key Provisions of the Act

Under the act, patients can gain access to eligible investigational drugs if they (1) have "been diagnosed with a life-threatening disease or condition," (2) have "exhausted [FDA] approved treatment options and [are] unable to participate in a clinical trial," and (3) provide "written informed consent" to a treating physician. Pub. L. No. 115-176, §204. Pharmaceutical manufacturers may choose to provide access to such investigational drugs, but they are not required to do so.

Significantly, the act insulates drug manufacturers and providers from liability for any claim arising from the provision of an investigational drug to an eligible patient, unless their actions constitute "reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law." Pub. L. No. 115-176, §204. The law provides comprehensive immunity from civil tort liability, stating, in relevant part:

> (b) NO LIABILITY—
>
> (1) ALLEGED ACTS OR OMISSIONS.—With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to section 561B of the Federal Food, Drug, and Cosmetic Act and in compliance with such section, no liability in a cause of action shall lie against—
>
> (A) a sponsor or manufacturer; or
>
> (B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

Id. Previously, courts adjudicating this issue held that terminally ill patients did not have a fundamental right to access investigational drugs. *See Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 701 (D.C. Cir. 2007) (en banc) (holding that terminally ill individuals do not have "a fundamental right to experimental drugs that have passed [initial phase] clinical testing"). The act renders decisions such as *Alliance* moot. Legal challenges to the act likely will center on the patient population included in the definition of "life-threatening disease or condition" and informed consent requirements.

The act also prohibits the FDA from using clinical outcomes to delay or otherwise adversely affect approval of the investigational drug, unless it determines that the use of such clinical outcomes is "critical" to determining drug safety. Pub. L. No. 115-176, §204.

Although these provisions remove many barriers to providing access to investigational drugs from the manufacturer's standpoint, manufacturers still have an obligation to report "serious adverse events" to the FDA in the form of an annual report. *Id.* In addition, the law leaves many important terms undefined, and several open questions remain. Before permitting eligible patients to access investigational drugs, manufacturers and providers should consider the incentives, risks, and open questions discussed below, among others, in their risk-benefit calculations.

Incentives to Providing Access

The incentives to providing access include that it will build good will, generate useful data, and potentially create a market advantage.

Good Will and Social Capital

Pharmaceutical manufacturers should consider the potential opportunities for good will among providers, patients, and the media that comes with providing access to investigational drugs.

Additional In-Vivo Data

Use of investigational drugs will generate additional data on the safety and efficacy of the drug outside of the clinical trial setting. This data may inform decisions on drug improvement, dosing, and administration. In addition, the manufacturer can report positive patient outcomes to the FDA to consider in approving the drug for general use. While the act does not allow the FDA to use clinical outcomes to delay or deny drug approval in most cases, the FDA may consider clinical outcomes at the request of the drug's sponsor. *See* Pub. L. No. 115-176, §204.

Early Brand Visibility and Recognition

Providing investigational drugs to patients and healthcare providers may help prime patients, providers, and purchasers to buy the drug before general marketing efforts have begun, generating brand loyalty and a competitive advantage prior to market entry.

Risks to Consider

Risks to consider include potential litigation and preemption, the vague written informed consent requirement, and "bad press," among others.

Tort Litigation and Preemption of State Law

The act does not expressly address preemption of state law tort claims arising from the provision and use of investigational drugs. Although the letter and legislative history of the act tend to suggest implied preemption (164 Cong. Rec. H1738-05, H1743), manufacturers and providers must consider the uncertainty of immunity from litigation in states where there is no concomitant Right to Try law.

Vague Written Informed Consent Requirement

The written informed consent requirement is vague. The act does not define the term "written informed consent," leaving manufacturers and providers guessing about the level of disclosure required. This gap becomes apparent when comparing the federal act to certain state Right to Try laws, such as the law in Connecticut, which provides detailed informed consent requirements. *See* Conn. Pub. Acts No. 16-214.

Bad Press and Reputational Damage

Investigational drug manufacturers and sponsors must report "known serious adverse events" on an annual basis, and the FDA may publish the annual report on its website.

Open Questions

Four open questions immediately come to mind.

- **"Life threatening disease or condition" is broad:** The eligible patient population, as defined, may result in confusion and administrative challenges for manufacturers and providers and sweep in unintended patient populations.
- **Cost and insurance coverage:** Providing investigational drugs free or at cost may not be feasible, but market pricing could deny access to all but the wealthiest patients. In addition, the law provides no guidance on insurance coverage.
- **Physician oversight and input regarding use of investigational drugs:** The law is silent on dosing, administration, and monitoring requirements for investigational drugs, leaving providers exposed and without guidance.
- **Providers' obligation to report adverse events:** The law addresses reporting requirements for manufacturers and sponsors of investigational drugs, but it is unclear whether health-care providers have any federal reporting obligations.

Conclusion

Pharmaceutical manufacturers and health-care providers need to consider the ambiguities in the law and anticipate the ways in which they can materialize into real risks for the business and professionals before providing access to investigational drugs. Well-organized administration and thorough record keeping, as well as robust informed consent protocols will help the manufacturer or provider minimize the risks of increased use of investigational drugs,

while capturing the benefits to the business and fulfilling the ultimate goal of expanding patients' access to life-saving treatment.

Sarah A. Westby is an associate in the Product Liability Group at Shipman & Goodwin LLP in Hartford, Connecticut. She defends pharmaceutical and health-care clients in complex product liability and medical malpractice litigation in state and federal court. Ms. Westby brings significant trial experience in service of her clients, including the trial of cases involving multi-billion dollar claims to verdict. She frequently advises clients on issues concerning privilege, HIPAA compliance, and trial practice. In addition, she regularly represents pro bono clients through partnerships with Lawyers for Children America and the ACLU. She sits on the Board of Simply Smiles, Inc., a nonprofit dedicated to providing homes, health care, and education to impoverished children living on the Cheyenne River Reservation in South Dakota, and in Oaxaca, Mexico. Ms. Westby is a member of the DRI Young Lawyers Committee, among others.

Member News

Pamela Carter Receives DRI Diversity Award

Pamela W. Carter, founder and partner-in-charge at the Carter Law Group LLC, in New Orleans has been named the 2018 recipient of the DRI Sheryl J. Willert Pioneer Diversity Award. The award was presented during the annual DRI Diversity for Success Seminar last month in Chicago.

Ms. Carter has been a member of DRI for nineteen years and serves as a national director of DRI's Board of Directors. She has served as a member or chair of more than two dozen DRI committees, including the Young Lawyers Committee, Women in the Law Committee, and the Diversity and Inclusion Committee, which organizes DRI's annual Diversity for Success Seminar. She has chaired the selection committee for DRI's Law Student Diversity Scholarships, which annually awards two DRI $10,000 scholarships meant to encourage diversity in the legal profession.

DRI Executive Director John R. Kouris said "Pam Carter and I came to DRI at almost the exact same time, and I have had the benefit of her good advice for almost twenty years. She has been my counsel, colleague, and a tireless and relentless worker on behalf of all issues of diversity. DRI is a stronger organization for it."

The honor is awarded to persons who have pursued

- a commitment to inclusion of persons within the institution who are members of traditionally under-represented groups;
- dedication and commitment to advocating diversity in the legal profession through activity that has a visible, tangible, or measurable impact on the perception of, attitude toward, respect for, and treatment of other persons;
- the development of contemporary measures to fight discrimination and prejudice in the profession; and
- diversity initiatives and actively promoted relations among persons of different races, ages, ethnic origin, gender, sexual orientations, religious backgrounds, or physical and mental abilities.

Keep The Defense Wins Coming!

Please send 250–500 word summaries of your "wins," including the case name, your firm name, your firm position, city of practice, and e-mail address, in Word format, along with a recent color photo as an attachment (.jpg or .tiff), highest resolution file possible (*minimum* 300 ppi), to DefenseWins@dri.org. Please note that DRI membership is a prerequisite to be listed in "And the Defense Wins," and it may take several weeks for *The Voice* to publish your win.

Edward McCambridge and Jason Eckerly


DRI members Edward McCambridge and Jason Eckerly, shareholders in Segal McCambridge Singer & Mahoney's Chicago office, successfully appealed a trial court verdict in *Kinseth v. Weil-McLain, et al.*, on behalf of their client, Weil-McLain. Plaintiff had been awarded $4 million in compensatory damages at trial (with Weil-McLain having been found 25 percent at fault) and $2.5 million in punitive damages. On June 1, 2018, the Supreme Court of Iowa issued a unanimous decision in favor of Weil-McLain, upholding the Court of Appeals' reversal of the trial court's verdict and remanding the case for a new trial.

Plaintiffs Kinseth and his wife brought claims of negligence, product liability, and breach of implied warranty of merchantability against 42 companies based on claims that the eventual death of Kinseth resulted from exposure to asbestos rope and cement used during his work in the heating and plumbing industry during which he worked with boilers. Eventually, only Weil-McLain remained a defendant at trial. On appeal, Weil-McLain pointed to statements made by plaintiffs' counsel during closing arguments that violated defense counsel's motions in limine and argued that the motions for mistrial that they brought should have been granted at that time. The court agreed with counsel for Weil-McLain that, in fact, defense counsel's motion in limine had been violated and further determined that plaintiffs' counsel engaged in improper closing statements.

The case is *Shari Kinseth, et al. v. Weil-McLain*, case number 15-0943, in the Supreme Court of Iowa.

Matthew J. Kelly

On March 14, 2014, 47-year-old Lisa Hurley of Kingston, New York, went to Glens Falls Civic Center to attend the NYS Basketball Championships. A nine-inch snowstorm had ended the day before.

As plaintiff was walking towards the Civic Center, she entered a parking lot for officials and teams. Rather than walking on the sidewalk on generally clear pavement, she cut across the parking lot and fell on a collection of snow suffering a bimalleolar fracture of the right ankle. She required an open reduction internal fixation and her treating doctor indicated that she would likely need an ankle fusion or ankle replacement.

Ms. Hurley contended that the Civic Center was negligent in its maintenance of the premises. She called her treating doctor, as well as an expert orthopedist. She also called a meteorologist, who said that there was sufficient time for the Civic Center parking lot and area to be cleaned from the prior day's nine-inch snow fall.

Defendants called its staff members with regard to the work that they had done clearing the area. They also called an expert snow plow contractor, who testified as well to the precautions that had been taken on the sidewalk area by the defendants.

The case commenced trial on Tuesday, May 29, 2018, before the Honorable Martin D. Auffredou and concluded on June 1, 2018. After one and a half hours of deliberation, the jury returned a verdict in favor of the defendants. Of interest was that of the six deliberating jurors, four were either 20 or 21 years old.

The defendants were represented by DRI member Matthew J. Kelly of Roemer Wallens Gold & Mineaux LLP.

Charles "Chuck" Deluca

In a decision released May 7, 2018, New Haven Superior Court Judge Robin Lynn Wilson granted the motion for summary judgment briefed and argued by Ryan Ryan Deluca LLP partner and DRI member Charles "Chuck" Deluca, in a lawsuit stemming from the Sandy Hook tragedy of December 14, 2012. The decision in favor of Ryan

Ryan Deluca's clients, the Town of Newtown and its Board of Education, came in the matter of Scarlett Lewis, Administratrix of the Estate of Jesse Lewis, *et al.* v. Town of Newtown *et al.*

The estates of two of the victims of Lanza's attack brought a lawsuit against the Town of Newtown and its Board of Education for allegedly failing to prevent the attack by the shooter on those within the school, including students, teachers, staff, and administrators.

In her 29-page decision, Judge Wilson agreed, finding that, "[i]n the present case, faculty and staff had to make split-second decisions in the face of an armed gunman and subjecting their decisions to scrutiny, aided by hindsight, would no less serve the public interest than subjecting a police officer's discretionary decisions to second guessing." "Emergencies, by their very nature, are sudden and often rapidly evolving events, and a response can never be 100 percent scripted and directed," she wrote. "In an emergency situation, whereby those deemed to react in a discretionary manner are themselves under attack, no reasonable jury could find that anything would have been apparent to these individuals, under such explosive and rapidly evolving circumstances, as a matter of law."

Plaintiffs' counsel has appealed the decision.

2018 DRI Election Update

At the 2018 DRI Annual Meeting in San Francisco, October 17–21, the DRI Board of Directors will elect four individuals to join them as national directors (each serving three-year terms). The final candidates are presented to the board upon the recommendation of the Nominating Committee, chaired this year by DRI Past President J. Michael Weston. In addition, an individual will be elected as the next DRI second vice president, which begins his or her track to the presidency after serving subsequent years as first vice president and president-elect. Also, one candidate will be elected to serve a one-year term as secretary–treasurer. The following DRI members have filed Declarations of Candidacy for this year's second vice president, secretary–treasurer, and national director positions. To read a candidate's declaration, click on the name.

Second Vice President/Secretary–Treasurer

- Douglas K. Burrell, Drew Eckl & Farnham LLP, Atlanta, Georgia
- Daniel W. Gerber, Gerber Ciano Kelly Brady LLP, New York, New York
- Lana Alcorn Olson, Lightfoot Franklin & White LLC, Birmingham, Alabama
- Patrick J. Sweeney, Sweeney & Sheehan PC, Philadelphia, Pennsylvania
- Matthew E. Yde, Yde Law Firm SC, Wausau, Wisconsin

Secretary–Treasurer

- Bryan C. Garcia, Garcia Law Group LLC, Albuquerque, New Mexico

National Director

- Mario J. Delano, Campbell Foley Delano & Adams LLC, Asbury Park, New Jersey
- Matthew S. Foy, Gordon Rees Scully Mansukhani LLP, San Francisco, California
- Thomas E. Ganucheau, Beck Redden LLP, Houston, Texas
- John S. Guttmann, Beveridge & Diamond PC, Washington, D.C.
- Leonor M. Lagomasino, Hinshaw & Culbertson LLP, Coral Gables, Florida
- Jodi V. Terranova, Wilson Elser Moskowitz Edelman & Dicker LLP, Washington, D.C.

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This is a reminder to all DRI members that *For The Defense* magazine is now available in **both** digital and print formats. Through September you will receive a print **and** electronic copy of *FTD* as part of a pilot program designed to get your feedback. Click here to view the latest issue of *FTD* digital edition. We are excited to bring you the next generation of tools for today's defense attorney. Here are just a few of the featured advantages that will make *FTD* digital edition your "go to" publication:

- Electronic magazine delivered via email to **all** DRI members
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- 24/7/365 availability
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Watch your inboxes as the July issue of FTD digital edition will be available soon!

If you have not done so already, please let us know how you like this new member benefit and share your feedback at FTD-feedback@dri.org!

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Previously known as DRI Online, DRI LegalPoint™ is a *free*, members-only service that provides access to a vast online library of DRI articles, books, and materials. DRI members can search thousands of documents and filter them by practice area and resource. DRI LegalPoint™ includes content from *For The Defense*, *In-House Defense Quarterly*, committee newsletters, the Defense Library Series, seminar materials, and the DRI Defense Wins Reporter, just to name a few.

See for yourself what DRI members are saying about DRI LegalPoint™. DRI member Baxter Drennon of law firm Wright Lindsey Jennings recently said

> DRI LegalPoint has become my 'go-to' first step when doing research on substantive legal issues and for new ideas on improving my legal skills. Recently, I wanted to revamp how I prepare corporate representatives for deposition. Using information I found on DRI LegalPoint, I created a presentation that I now customize to prepare individual corporate representative witnesses. DRI LegalPoint has improved my practice and made my research easier. I highly recommend that other DRI members take advantage of and use DRI LegalPoint.

Don't miss out! Leverage the expertise of leading defense practitioners and find the on-point articles and resources you need with **LegalPoint**™. Please visit https://www.dri.org/legal-resources today for more information.

Cybersecurity and Data Privacy, September 5–7, 2018

Recent developments in technology have spurred issues never before imagined. Cyber threats now include not just hacking, but ransomware attacks, social engineering, and other schemes. Advanced technologies such as blockchain and cryptocurrencies bring a world of questions to previously traditional structures in marketing, banking, and sales. Interconnected and "smart" devices create new concerns about privacy within the "Internet of Things" (IOT), especially in the healthcare world. And autonomous vehicles, once available only to the Jetsons, are now a reality that brings with them a host of concerns that demand the attention of cyber professionals. Governmental regulations on data privacy and security are responding to these new issues and evolving every day. The seminar will appeal to a diverse audience of professionals: in-house counsel, firm attorneys, IT personnel, insurance professionals, and anyone who must understand developments in cybersecurity and data privacy law. Click here to view the brochure, book your room, and register for the program.

DRI Drug and Medical Device Litigation Primer, September 13, 2018

The DRI Drug and Medical Device Litigation Primer has long been lauded by companies and outside counsel alike as the perfect training for junior defense lawyers. For only $250, attendees will learn in an informal classroom style from leading experts in the field. No other training is as comprehensive or cost-effective. Join us—or pass the brochure along to others in your firm who may benefit from this program! Click here to view the brochure and register for the program.

Fire Science and Litigation Seminar, September 13–14, 2018

With four controlled burns the week before the seminar and a flashover burn demonstration the day before, we are literally burning down the house to make this an exciting and relevant seminar. It will take fire science and litigation techniques into the real world, using photographs, video, and data from controlled burns, incorporating them into presentations about fire behavior, fires involving products found in home and office environments, and trial tactics to manage technical and graphic evidence. This seminar is for new and experienced attorneys and will help with every fire case on your docket. Click here to view the brochure and register for the program.

Counseling Drug and Medical Device Companies on Risk Prevention Strategies, September 19, 2018, 12:00pm–1:30pm CST

Pharmaceutical and medical device manufacturers encounter numerous risks that, if not handled properly, could lead to litigation. Risks include the challenges of properly marketing products, complying with numerous regulations, and emerging adverse events. Mass tort litigation, and challenges based on the False Claims Act and the Anti-Kickback Statute among others, pose perpetual risks along with handling the erosion of time tested defenses such as the learned intermediary doctrine. With an ever shifting tide, it is important to stay current on these topics. Register now to learn from top attorneys whose focus is watching for and defending against these risks. Click here to learn more and register for the webinar.

Dumb Things: Eminently Avoidable Legal Ethics Mishaps, September 18, 2018, 1:00 – 2:00pm CST

The presentation will cover various examples of dumb things lawyers do and explains how firms can avoid obvious mistakes arising from unthinking action or inaction (the low-hanging fruit of risk avoidance). Click here to learn more and register for the webinar.

Rebecca R. Thornton, Teague Campbell Dennis and Gorham

Rebecca R. Thornton is a partner with Teague Campbell Dennis & Gorham LLP in its Raleigh, North Carolina, office. She represents small and large businesses and helps them navigate lawsuits filed by customers, personnel, and other third parties as a result of accidents and contractual disputes. Ms. Thornton is admitted to practice in North Carolina, as well as the United States District Courts for the Eastern, Middle, and Western Districts of North Carolina. She is a graduate of Elon University School of Law and of North Carolina State University.

Ms. Thornton lives in Raleigh with her husband, one-year-old daughter, and two black labs. They love to travel and spend time outside, and they are always on the go. Her version of relaxing is distance running, and she just completed her sixth marathon and has a goal to complete 10 marathons by her 40th birthday.