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The 21st Century Cures Act Will Exacerbate Life Sciences Pharmaceutical Risk

Modern medicine and biotechnology accomplish amazing feats with cutting edge technology, but they are confronting complex and changing regulations.

Onco-Immunotherapy, CRISPR, Cybernetic Implants, Regenerative Medicine, Gene Therapy, Robotics – many of these recent life sciences breakthroughs sound like science fiction.

But they are very real. And the impact of discoveries such as these could redefine what it means to be human.

Although these advancements are being realized through the most cutting-edge science, the greatest risk associated with marketing these products remains one of the oldest challenges.

Regulations.

"Of all the underwriting factors, and there are many given the complexity of the life sciences industry, laws and regulations are not within our control," said Ryann Elliott, Vice President, Underwriting, Life Sciences, CNA Healthcare.

The 21st Century Cures Act (the "Act"), signed into law in December 2016, is a perfect example of how regulatory risk may create destabilization and vulnerability for life sciences companies and their insurers.

Ryann Elliott
Vice President, Underwriting, Life Sciences, CNA Healthcare

While establishing an almost $9B dollar slush fund for the National Institutes of Health to tackle major biomedical research, the law also revised the drug approval process with the goal of expediting production and getting new drugs to consumers faster and at more affordable prices. But not all the changes are positive for the industry. For example, Section 1028 focuses on high-risk, high-reward research outcomes that inevitably will increase liability for the drug companies.

Specifically, the provision requires the director of each national research institute, as appropriate, "to establish programs to conduct or support research projects pursuing innovative approaches to major contemporary challenges in biomedical research involving inherent high risk, but have the potential to lead to breakthroughs."

The measure also was subject to several revisions proposed by the FDA. Importantly, its implications for the industry remain unclear and continue to evolve, especially with a new administration establishing different regulatory goals for the years ahead.

"The industry is sitting on the fence, waiting to see what will happen, but regardless of how it shakes out, there will certainly be changes in the liability and risk landscape for drug manufacturers and insurers in the life science marketplace," said Steven Pendergast, Industry Group Leader, Life Sciences, CNA Healthcare.

Four significant risks to the life sciences industry are presented by the 21st Century Cures Act:

1. Accelerating Drug Development Dramatically Changes Risk Profile

Steven Pendergast
Industry Group Leader, Life Sciences, CNA Healthcare

A core focus of the Act is its effort to reduce regulatory hurdles for pharmaceutical companies in order to speed drug development and reduce costs.

The bill encourages a shift to patient-focused drug development in order to capitalize on the patient experience in clinical trials, rather than focus primarily on adverse events in consideration of a drug's benefits and risk (Subtitle A, Section 2001).

The Act also calls for expedited approval requirements for drugs "as early as possible" in the research, development and clinical trial testing process provided that the drug meets the standards of evidence of safety and effectiveness, thus enabling drug makers to "fast-track" new breakthrough therapies. (Subtitle E, Section 2081).

"Marketing and distributing drugs more expeditiously may reduce costs and enhance patient access, but it will increase risk as drugs spend less time in clinical trial and market surveillance, which means less time to identify potential adverse events," Elliott said.

While expediting the development and commercialization of affordable drugs offers theoretical benefits for patients, notwithstanding the Act's directive to require evidentiary standards for safety and effectiveness, it may potentially compromise safety as the drug latency impact period can be significantly protracted — ultimately creating litigation risk for pharmaceutical companies.

A jury listening to the drug manufacturer's case might consider it reckless and irresponsible for speeding up processes without spending sufficient time monitoring a medication's effects despite the governance process. Moreover, adherence to the new regulatory regime may not provide an adequate defense in the event that a liability claim arises.

"Risk management programs must adjust by contemplating the risk created by fast-tracking drugs," Pendergast said. "If a company reduces its sample population from 3,000 to 1,500 participants and shortens the time span from seven years to five, how does that change its risk profile? How will insurers approach that risk if they provide coverage for the product when it is marketed?"

2. Existing Bespoke Policy Language Could Act as a Liability Multiplier

The current insurance marketplace for life sciences is unique because it consists of customized policies written to meet the complex needs of the pharmaceutical world. While companies can enjoy coverage tailored to their risks, brokers face the challenge of studying and understanding the various policy language and forms that currently exist.

"Not all products are created the same. There is no single standardized offering in life sciences product liability policy forms in the marketplace," Pendergast said.

This policy language incongruence will exacerbate the risk transfer challenges of adapting to the changing liability landscape presented by the 21st Century Cures Act. The lack of standardized and consistent policy language, coupled with changing risk profiles, increases insurance complexities for brokers and insureds exponentially, as new forms are issued in the marketplace.

"Multiply the number of insurers by the number of changes resulting from the 21st Century Cures Act, and the effect is a field of liability land mines, as well as potential errors for insurers, brokers and insureds," Elliott said. "It creates a very complex horizon of shifting risks."

3. Pricing Disruption: Moving Away from Ratable Revenue

Life sciences insurers typically assess risk based upon ratable revenue for sold products and trial subjects for clinical trials. During the Obama administration, the impact of the Affordable Care Act created a definitive move to less costly generic drugs. Furthermore, with drug pricing being hotly debated in Congress, and the new Trump administration immediately calling on big pharma to examine and find ways to reduce pricing, the pharmaceutical top line revenue is under stress.

While the fast-track provisions reflected in the 21st Century Cures Act provision will reduce drug development costs, thereby reducing allowing for reduced drug pricing, it may, however result in a trickle-down effect for insurers.

"Its impact, of necessity, will create a shift away from the ratable revenue-based methodology for insurers, to the point where it may no longer

be a reasonable ratable baseline," Pendergast said. "Instead, insurers will be under significant pressure to find new techniques to tangibly rate the risk associated with drugs in order to keep underwriting and pricing stable and consistent."

Elliott emphasized that pricing also should consider the purpose and criticality of a medication.

"Take a critical drug and delivery system such as epinephrine, as an example. Its effectiveness is literally a matter of life or death. Product failure thus presents an enormous risk," she said. "In this case, the drug's function and delivery is what drives liability. Even if its price point decreases, the risk level remains the same."

While insurers search for a better risk measure, volatile government activity and regulatory uncertainty will exacerbate pricing disruption in the insurance marketplace.

4. Continued Change Requires Constant Vigilance

The only real certainty around the 21st Century Cures Act is that it will continue to drive industry change.

Despite being signed into law with bipartisan support in December of 2016, several components have been rolled back or placed on hold until the new FDA Commissioner, Scott Gottlieb, M.D., settles into the role. The FDA has already introduced almost 1,000 pages that would represent changes to the law.

"However, Dr. Gottlieb has expressed support for the generic pharmaceutical industry, so it's pure speculation at this point what he will do with this regulation and how it will align with the big business-focused perspective of the Trump administration," Elliott said.

Discussion surrounding the potential impact of regulatory change on the life sciences industry and the forward impact on insurers providing coverage for life sciences companies raises more questions than answers.

To stay abreast of changes percolating on Capitol Hill and the consequent shifts in liability and risk, life sciences companies should seek an insurer with dedicated knowledge and experience in the drug development process and pharmaceutical marketplace, and that values long-term commitments with its customers.

With industry-leading experience in medical professional and product liability, as well as the mass tort environment in healthcare and life sciences, CNA is uniquely positioned to identify emerging trends. The insurer writes approximately $900 million in premium for physicians, nurses, hospitals, allied care facilities, life sciences products/services and entire health systems. This significant presence in the healthcare professional liability insurance industry provides the experience needed to recognize emerging problems with drugs or medical devices.

"We are one of a few insurers that write a large amount of medical malpractice in healthcare as well as product liability for life sciences companies, which gives us deep insight into emerging issues and allows us to get out in front of them," Pendergast said. "When there are injuries in a clinical setting, it ultimately spills over into the drug and device world."

That insight and expertise, combined with underwriting discipline, claim expertise and risk control services, makes CNA a leader and stable partner in weathering the regulatory volatility confronting life sciences companies.

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