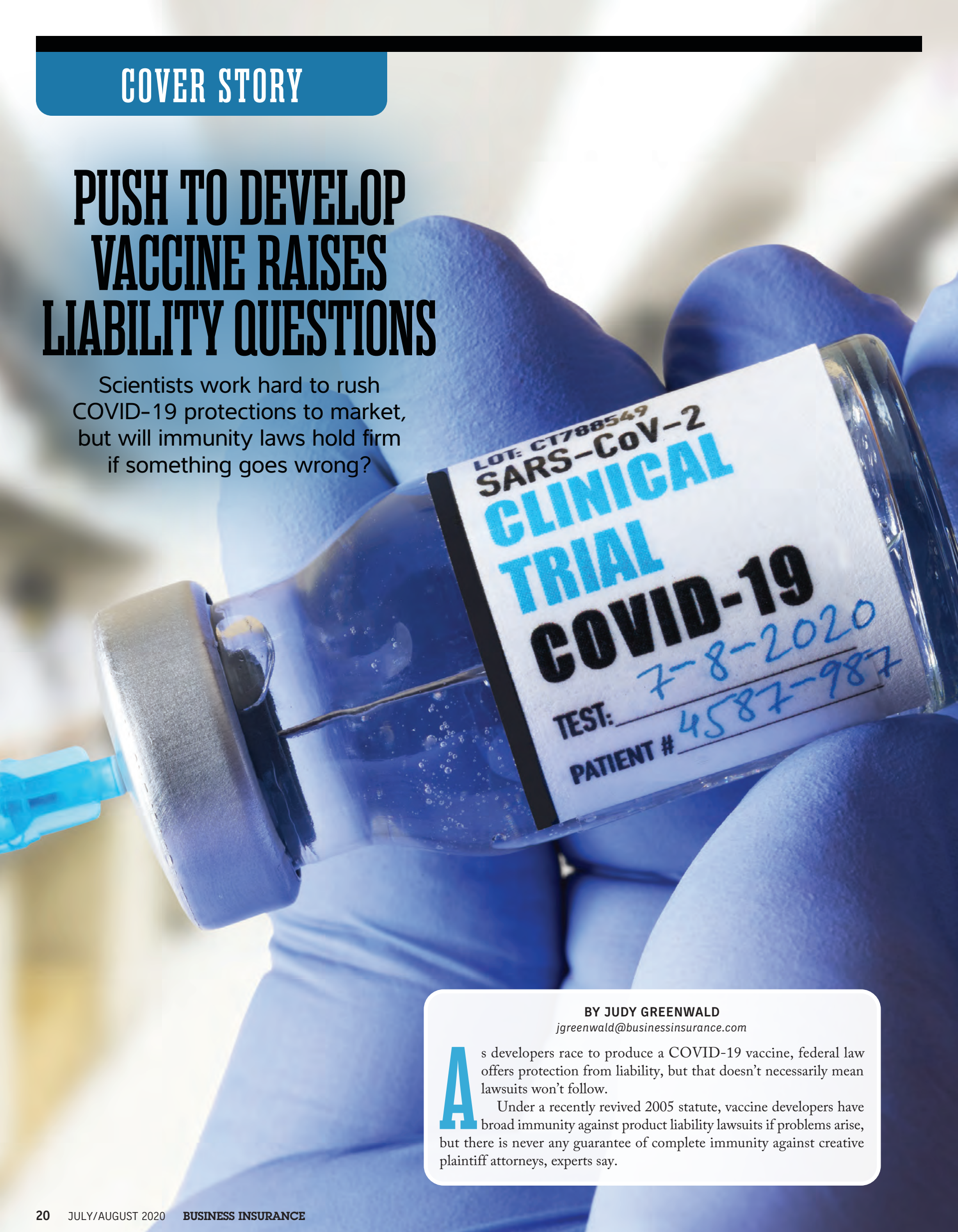
PUSH TO DEVELOP VACCINE RAISES LIABILITY QUESTIONS

Scientists work hard to rush COVID-19 protections to market, but will immunity laws hold firm if something goes wrong?



BY JUDY GREENWALD
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As developers race to produce a COVID-19 vaccine, federal law offers protection from liability, but that doesn't necessarily mean lawsuits won't follow.

Under a recently revived 2005 statute, vaccine developers have broad immunity against product liability lawsuits if problems arise, but there is never any guarantee of complete immunity against creative plaintiff attorneys, experts say.

FEDERAL SHIELD DATES BACK TO LIABILITY CRISIS ERA

The National Childhood Vaccine Injury Act of 1986, which was later amended as the National Vaccine Injury Compensation Program, effectively revived an insurance market for vaccines, after insurers fled to escape rising litigation.

The compensation program is funded by the Vaccine Injury Compensation Trust Fund from a 75-cent excise tax on vaccines recommended by the Centers for Disease Control and Prevention.

More than $4 billion in compensation has been paid over the program's life, according to the Health Resources & Services Administration.

The National Childhood Vaccine Injury Act is similar to the Public Readiness and Emergency Preparedness Act in that both established no-fault systems, said Christina Harris, Tampa, Florida-based product manager, life sciences, with IronHealth, a Liberty Mutual Insurance Group unit.

Its impetus was the swine flu scare of the late 1970s, when President Gerald Ford embarked on a program to vaccinate the U.S. population and it was discovered "there was no coverage, because the (insurance) industry was still rebounding from polio vaccine cases, where the courts imposed strict liability," Ms. Harris said.

"When it was enacted back in the '80s (litigation) was a big problem," to the point where some manufacturers had abandoned the vaccine business, and there was concern about not having vaccines that saved millions of lives, said Jim Walters, Philadelphia-based managing director of Aon PLC's life sciences and chemicals industry group.

The act "became the first line of defense," he said. "The incidence of litigation dropped off a cliff and really reduced significantly."

The U.S. Supreme Court held in its 2011 ruling in *Bruesewitz et al. v. Wyeth et al.*, for instance, that the vaccine act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury.

Judy Greenwald

The insurance market for life science companies, though, remains robust, even as the price of coverage firms.

Biopharmaceutical companies, manufacturers, academic institutions and others are rushing to develop vaccines to prevent the COVID-19 disease, which has killed more than 500,000 worldwide.

The World Health Organization had listed 17 "candidate vaccines" that were under clinical evaluation as of late-June, and another 132 that are in preclinical evaluation.

Vaccines must go through a three-step approval process, and it is likely more than one company will produce one, said Lee Farrow, Whitehouse Station, New Jersey-based executive vice president, life sciences industry practice leader, for Chubb Ltd.

"When you're talking about making a million vaccines or more, it's going to require more than one company to do that," he said.

Health care providers have immunity from tort liability under the 2005 Public Readiness and Emergency Preparedness Act that becomes effective once the Secretary of Health and Human Services declares a public health emergency, which Alex Azar did with respect to COVID-19.

The law, which has been invoked several times previously, confers immunity on manufacturers and authorizes a fund to provide compensation for physical injury or deaths caused by vaccines, drugs or medical devices.

Observers say the comparable no-fault Vaccine Injury Compensation Program, which was created by the National Childhood Vaccine Injury Act of 1986 and established a special vaccine court, has been effective in reducing litigation in connection with previously developed vaccines (see related story).

Pharmaceutical manufacturers may also face patent infringement litigation, experts say (see story page 22).

Pharmaceutical companies did not respond to requests for comment.

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>
> Jim Walters, Aon PLC

The PREP Act, which is intended to encourage companies to explore developing and manufacturing vaccines, is good for manufacturers, said Jim Walters, Philadelphia-based managing director of Aon PLC's life sciences and chemicals industry group.

The act provides broad liability immunity on a federal level "and it supersedes state laws and even other federal laws" to provide incentives for companies to work on vaccines and other treatments "without the fear of litigation," Mr. Walters said.

"Those protections will be afforded, in all likelihood, to any company that's working on a vaccine," he said. While companies must still apply for U.S. Food and Drug Administration approval, "there's a tremendous amount of confidence that the vaccine would be subject to this and the companies would have immunity protection," he said.

The PREP Act will protect manufacturers "completely, unless somebody deliberately misrepresents something in an application," said James Beck, life sciences policy analyst with Reed Smith LLP in Philadelphia. "The PREP Act has only one exception and that's deliberate misconduct," and is written very broadly, he said.

But other experts warn the PREP Act does not necessarily provide complete immunity.

The declaration invoking the PREP Act for COVID-19 expires in October 2024, or when the Department of Health and Human Services declares the pandemic to be over, whichever comes first. This leaves the question of whether vaccine manufacturers would continue to have immunity, Mr. Walters said.

Immunities "aren't always 100% foolproof effective," said Larry Reback, San Francisco-based managing principal and leader of EPIC Insurance Brokers & Consultant's policy response unit, whose focus is product liability.

See **VACCINE** next page

VACCINE PRODUCT APPROVAL PROCESS

The U.S. Food & Drug Administration's Center for Biologics Evaluation and Research is responsible for regulating vaccines in the United States.

Pre-marketing, or pre-licensure, vaccine clinical trials are typically done in three phases:

PHASE 1

Initial human studies, which are performed on a small number of closely monitored subjects.

PHASE 2

Dose-ranging studies, which may enroll hundreds of subjects.

PHASE 3

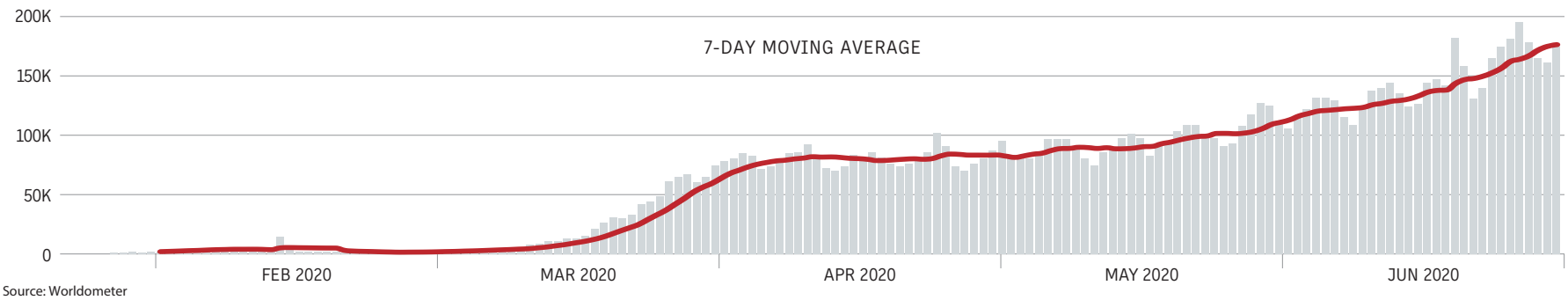
Trials that typically enroll thousands of individuals and provide the critical documentation of effectiveness and important additional safety data required for licensing.

Many vaccines also undergo **Phase 4**, which are formal studies conducted once they are on the market.

Source: U.S. Food and Drug Administration

DAILY NEW COVID-19 CASES — WORLDWIDE

Daily new COVID-19 cases worldwide since the start of the outbreak through June.



Source: Worldometer

VACCINE

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"They can be challenged based on specific factors, and even if they are ultimately upheld, they may cost a lot of money defending," he said.

Under product liability law, there are three principle grounds for liability: design defects, manufacturing defects, and a failure to warn, Mr. Farrow said.

"Usually, what we're most involved in is failure to warn," he said. Because most products are developed under the FDA's guidance and regulatory bodies, "the design is probably fine, unless there's a huge product withdrawal," he said.

As for manufacturing, Mr. Farrow said, "You have to make it correctly," While there are cases of manufacturers producing bad lots, "for the most part" they are made correctly, he said.

"The typical product liability exposure is always present. Bodily injury is a key driver," said Christina M. Harris, Tampa, Florida-based life sciences manager for IronHealth, a Liberty Mutual Insurance Group unit.

The PREP Act's intent "is to wash away that liability to manufacturers, distributors and developers because they want to entice them to develop vaccines themselves and understand in doing so they are open to public scrutiny and litigation," she said.

To be successful in litigation efforts, plaintiffs "would have to do it very creatively and approach with caution, especially if they've got the federal government" seeking to "honor its word, so to speak," by enacting the PREP Act to begin with, she said.

Mr. Beck said he does not believe that litigation against those who develop a COVID-19 vaccine "'are going to be looked upon very favorably by the courts and even juries." He said he is also unconcerned about the declaration's expiration date.

"Society's going to be so grateful to whomever provides a successful vaccine in this circumstance that immunity for the vaccine itself will be extended, if necessary," he said.

Meanwhile, there is a "very robust marketplace" for clinical trial insurance, Mr. Walters said. Underwriters "recognize the value and importance of immunities arising from the PREP Act and are willing to write the coverage," he said.

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>
> Lee Farrow, Chubb Ltd.

"I would describe the market as firm," Mr. Farrow said. "Vaccines are a little more challenging to underwriters generally speaking, so the rates may be a little bit more than other life sciences markets."

A vaccine "is just part of the overall life sciences market," so "we evaluate and underwrite life science companies very similarly, regardless of whether they make vaccines" or other products, said

Linda Schultz, Pittsburgh-based head of life sciences product liability for Hartford Financial Services Group Inc.

"For life sciences companies, we look at their experience with compliance with FDA regulation, their history of FDA inspections of their facilities, their ability to comply with good manufacturing practice guidances, and other regulatory requirements." Hartford also evaluates life sciences companies' supply chains because they often rely on third parties for various aspects of their manufacturing, she said.

Ms. Schultz said Hartford offers up to $10 million in policy limits, but in certain cases $15 million is available.

Vaccines are given to healthy people "and the liability exposure is more significant than if it were someone already sick, for example," Mr. Farrow said.

"We have to feel like we understand the way the products work and what the possible concerns are" to determine the right attachment point and premium, he said.

Mr. Farrow said that despite the urgency in creating a vaccine, "we still need to underwrite, and by that I mean we will review the protocols, which is the blueprint to conduct the clinical trial (and) read through the formal consent documents, which warn test subjects about concerns and potential adverse events, unknown events."

Then, if the protocol is well put together and the informed consent documents acceptable, "and we like the technology and feel good about the company as well," Chubb will write it, he said.

IronHealth's Ms. Harris said insurers will usually insure the clinical trial exposure at relatively lower limits and low retentions, then as the risk grows and the products move into commercialization, they'll modify the terms and conditions accordingly and higher limits may be bought.

Vaccines are excluded in many insurers' policies, but most if not all insurers are willing to carve back to remove the exclusion, Ms. Harris said.

INTELLECTUAL PROPERTY CONCERNS, EXISTING PATENTS MAY POSE HURDLES

As pharmaceutical companies and others strive to find a viable vaccine for the coronavirus, they need to be wary of patent infringement claims, experts say.

"Patents are critical to the success of the biopharmaceutical and pharmaceutical companies," said David Duski, Chicago-based director and national intellectual property practice leader at consulting and accounting firm BDO USA LLP.

Those seeking to develop a vaccine "need to be thinking about, in the back of their minds, whether their efforts infringe on intellectual property rights," Mr. Duski said. Failing to consider this "could drag them into litigation."

One intellectual property risk manufacturers face is whether proposed methods of treatment or steps necessary to manufacture a vaccine infringe on existing patents, said Michael J. Abernathy, Chicago-based co-leader of law firm Morgan Lewis & Bockius LLP's Disputes Practice and Life Sciences Industry Initiative.

"Presumably, as they are working on the vaccine, they are rapidly doing clearance to make sure that doesn't happen," he said.

Another risk is an attempt to invalidate a patent. Courts have been hostile to patents of naturally occurring processes, Mr. Abernathy said. In its 2012 ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the U.S. Supreme Court ruled diagnostic tests must do more than "simply state the law of nature while adding the words 'apply it.'"

Another area of concern is co-development "either between competitors or between companies that have complementary technologies," he said.

Typically, there is an agreement "that spells out the collaboration. There are provisions that describe who gets what IP protection if a drug is developed or a therapy is developed, who then gets license rights and what are the economics of those arrangements," he said.

Mr. Abernathy said that given "the very quick development time," companies should determine whether the agreements foresee and address all possible contingencies.

"These agreements really need to be very, very carefully drafted to capture those rights," he said.

Judy Greenwald