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MEDICAL DEFENSE AND HEALTH LAW

MAY 2020

IN THIS ISSUE

Robert G. Smith summarizes a few examples of liability protections for health care providers and risk management and defense strategies in the context of the COVID-19 crisis.

Viral Impact: Liability Protections and Considerations in a Pandemic

ABOUT THE AUTHOR

Robert G. Smith is a shareholder of Lorance Thompson PC in Houston, Texas. Rob currently serves as the Vice Chair of Programs and Projects for the International Association of Defense Counsel Medical Defense & Health Law Committee, and is a member of the Product Liability and Business Litigation Committees. Rob has worked on many types of health care related matters, including defending medical device manufacturers and distributors against product liability claims as well as defending physicians, hospitals, and nursing homes in medical liability lawsuits. Rob graduated Phi Beta Kappa with a degree in mathematics from Louisiana State University and attended law school at the University of Houston College of Law. He is Board Certified in Personal Injury Trial Law by the Texas Board of Legal Specialization and has tried a wide variety of cases during his 24+ years of practice. He can be reached at rgs@lorancethompson.com.

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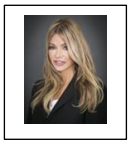

Constance A. Endelicato
Vice Chair of Newsletters
Wood Smith Henning & Berman
cendelicato@wshblaw.com

The COVID-19 pandemic has impacted health care practice and medical liability in countless ways, many of which may not be appreciated for months or years. This brief summary provides a glimpse of statutory, regulatory, and practical changes caused by the virus that may impact your medical practice and/or health law practice.

Liability Protection for Health Care Providers

CARE Act Protection for Volunteer Health Care Workers

The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") includes liability protection to volunteer health care professionals providing health care services during the current public health emergency from liability under federal or state law for harm caused by an act or omission, unless caused by willful or criminal misconduct, gross negligence, reckless misconduct, conscious flagrant indifference, or under the influence of alcohol or intoxicating drugs. *See* Section 3215, Coronavirus Aid, Relief and Economic Security Act, Pub. L. 116-136 (March 27, 2020).

PREP Act Protection for Health Care Providers Providing Countermeasures to the Pandemic

The 2005 Public Readiness and Emergency Preparedness Act ("PREP Act") provides that the Secretary of Health and Human Services may issue a written Declaration that a qualified person who prescribes, administers, or dispenses pandemic countermeasures shall be immune from liability under State or Federal law for claim arising out of, related to, or resulting from the administration to or the use by an individual of a covered countermeasure during a declared disease-related public health emergency. *See* 42 U.S.C. 247d-6d. Countermeasures include qualified pandemic products such as drugs or devices (both FDA-approved or authorized for investigational or emergency use), and biological products manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause. A Declaration was issued by the Secretary of HHS on February 4, 2020 invoking the PREP Act and providing immunity to qualified persons against claims related to covered countermeasures other than claims involving willful misconduct.

State Statutes may Provide Some Protection

Texas' Medical Liability Act, for example, provides that a person who administers emergency care in good faith is not liable for civil damages unless the act was done with willful or wanton negligence (except where the person's act caused the emergence for which care is being administered or where the act was in expectation for remuneration). *See* Tex. Civ. Prac. & Rem. Code Sec. 74.151. In a health care liability claim against a health care provider arising from the provision of emergency medical

care in a hospital emergency department, OB unit, or surgical suite immediately following evaluation or treatment in the ER, the willful and wanton negligence standard applies (except where the health care provider's negligence caused the patient to need emergency care). *See* Tex. Civ. Prac. & Rem. Code Sec. 74.153.

Many States have Issued Executive Orders that Provide Protection

For example, in New York, Executive Order No. 202.10, Continuing Temporary Suspension and Modification of Laws Relating to the Disaster Emergency, provides that as of March 7, 2020, health care providers shall be immune from civil liability for any injury or death alleged to have been sustained directly as a result of an act or omission in the course of providing medical services in support of the State's response to the COVID-19 outbreak unless caused by gross negligence.

The nursing home industry is seeking immunity from lawsuits related to COVID-19, arguing they are more understaffed than normal, there is not a thorough understanding as to how COVID-19 is spread and prevented, and they do not want to be liable for unpreventable events. Some form of legal immunity has already been implemented in Connecticut, Illinois, Massachusetts, Michigan, New Jersey, and New York.

Risk Management Considerations

The pandemic has, in many instances, impacted the environment in which health care providers practice to such an extent that the standard of care is arguably different. On March 18, the Centers for Medicare & Medicaid Services (CMS) announced that elective surgeries, non-essential medical, surgical, and dental procedures be delayed during the COVID-19 outbreak. For example, New York's Executive Order No. 202.10 provides that health care providers are relieved of recordkeeping requirements to the extent necessary to perform tasks necessary to respond to the COVID-19 outbreak, including requirements to maintain medical records that accurately reflect the evaluation and treatment of patients or requirements to assign diagnostic codes or maintain records for billing purposes. Health care workers acting in good faith under this provision shall be afforded absolute immunity from liability for any failure to comply with any recordkeeping requirement. Texas' governor directed the Texas Medical Board and Texas Board of Nursing to fast-track temporary licensing of out of state physicians and nurses, and on March 22 issued an executive order that health care providers shall postpone surgeries and procedures that are not immediately medically necessary to correct a serious medical condition or to preserve life until April 21, which has been extended to May 8 subject to hospital capacity.

Where a health care provider has revised their procedures or methods because of the pandemic, or they are acting pursuant to an executive order, etc., it is important to document why their actions or techniques are different, *i.e.*, what is the basis or authority for their departure from normal protocol. If a medical malpractice lawsuit is filed a year and a half from now, the plaintiff attorney may argue a health care provider postponed a surgery that should have been considered immediately medically necessary, or failed to provide appropriate care, order a test, etc. because there is no record. It would be helpful to the defense of a civil lawsuit if the medical chart included information the health care provider considered in deciding a course of action, when to schedule a surgery, or that the records may not reflect all medical care provided pursuant to Executive Order No. 202.10.

There are so many executive orders, emergency legislative changes, rule suspensions, etc. at the federal, state, and local level that it is critical to document what may have been considered when making a medical decision at a particular place and time.

Lawsuit Considerations

The COVID-19 pandemic affects how medical liability cases are filed and defended. For example, the Supreme Court of Texas has issued orders as of April 27, 2020 that include:

"3. Subject only to constitutional limitations, all courts in Texas may in any case, civil or criminal—and must to avoid risk to court staff, parties, attorneys, jurors, and the public— without a participant's consent:

> b. Allow or require anyone involved in any hearing, deposition, or other proceeding of any kind—including but not limited to a party, attorney, witness, court reporter, or grand juror, but not including a petit juror—to participate remotely, such as by teleconferencing, videoconferencing, or other means;
>
> c. Consider as evidence sworn statements made out of court or sworn testimony given remotely, out of court, such as by teleconferencing, videoconferencing, or other means;
>
> d. Conduct proceedings away from the court's usual location with reasonable notice and access to the participants and the public;

4. Courts must not conduct in-person proceedings contrary to guidance issued by the Office of Court Administration regarding social distancing, maximum group size, and other restrictions and precautions. Courts should use all reasonable efforts to conduct proceedings remotely.

5. Any deadline for the filing or service of any civil case that falls on a day between March 13, 2020, and June 1, 2020, is extended until July 15, 2020."

See Twelfth Emergency Order Regarding the COVID-19 State of Disaster (Misc. Dkt. No. 20-9059).

This order effectively extends the statute of limitations for two and half months and provides that courts can require remote hearings and depositions. Based on this order, on April 22, 2020, a Harris County District Court judge in Houston, Texas conducted a one-day bench trial on the videoconferencing service, Zoom. The judge reported that over 2,000 viewers watched parts of the trial.

This crisis will cause many lawsuits to be filed and now is the time to anticipate new theories of liability and damages. A plaintiff frequently alleges lost wages. There are many occupations that will be negatively impacted by the pandemic generally and may prevent someone from working without regard to any claimed injury.

There are many reports of anxiety and depression related to the virus and it may be difficult for a plaintiff to convince a jury that they are suffering mental anguish because of a defendant health care provider rather than the pandemic and subsequent loss of a job, or illness or death of a friend or loved one.

This is an opportunity for all of us to pause and reconsider how we think and why we do certain things. As communities begin to open up, people may reset their priorities to focus more on family, relationships, and staying closer to home. The pandemic may change jurors' attitudes in ways we cannot anticipate today.

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DRUG, DEVICE AND BIOTECHNOLOGY

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IN THIS ISSUE

Heather Heiskell Jones and James E. Simon report on the "Preventing Essential Medical Device Shortages Act of 2020", a new Senate bill responding to current essential medical device shortages that could have lasting impacts on the medical device manufacturing industry.

The "Preventing Essential Medical Device Shortages Act of 2020": COVID-19 Side Effect That Could Permanently Harm Medical Device Manufacturers

ABOUT THE AUTHORS

Heather Heiskell Jones is a Member in Spilman Thomas & Battle, PLLC's Charleston, West Virginia office. She is Chair of the firm's Insurance Defense Practice Group and Co-Chair of the firm's Medical Monitoring, Product Liability Litigation, and Toxic Tort Litigation Practice Groups. Her primary practice is litigation, including toxic tort matters, medical monitoring and other class actions, product liability matters, employment discrimination and employer liability claims, deliberate intent claims, and insurance bad faith claims. Heather also is experienced handling cases in the West Virginia Business Court Division and has completed advanced mediation training with the West Virginia State Bar. She can be reached at hheiskell@spilmanlaw.com.

James E. Simon is an Associate in Spilman Thomas & Battle PLLC's Charleston, West Virginia office. His primary area of practice is civil litigation, with particular emphasis on business and commercial litigation. James' business litigation practice includes breach of contract, fraud, construction, eminent domain, and constitutional law disputes. He also defends clients in insurance and bad faith litigation, personal injury and products liability lawsuits, and deliberate intent, premises, and products liability claims in toxic tort actions. He can be reached at JSimon@spilmanlaw.com.

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Stephen G.A. Myers
Vice Chair of Publications
Irwin Fritchie Urquhart & Moore LLC
smyers@irwinllc.com

I. Introduction

The ongoing COVID-19 pandemic crisis—infecting more than 2.7 million people worldwide, with almost 870,000 cases in the United States alone as of the writing of this article[1]—has thrown nearly every industry into chaos as the world struggles to adjust to the new reality of social distancing and self-quarantining. Shortages of personal protective equipment (PPE) such as N95 masks, surgical masks, gloves, and gowns have become commonplace, as medical professionals struggle to ensure that they have the equipment they need for the daily treatment of patients, and ordinary citizens scramble to obtain the protective equipment they feel is necessary to keep them protected. Heartbreaking stories abound of ventilator shortages forcing hospitals and governments to contemplate incredibly difficult decisions, such as choosing to withhold treatment from the elderly in favor of younger, stronger patients with a better chance of survival.

Faced with an infected population and a shortage of medical equipment, PPE, and other life-saving devices, some state governors have even invoked their emergency powers to authorize their police forces to confiscate medical resources from private citizens and businesses.[2] Such drastic measures, once considered unthinkable outside of the wartime realm, are now necessary so that hospitals can be re-supplied and re-equipped as COVID-19 patients continue to flow in. Amidst these unprecedented circumstances, many in the media and elsewhere have expressed their frustration and bewilderment as to how the United States could have been caught so unprepared and lacking in vital medical resources, devices, and equipment.

II. The FDA's Frustration with Lack of Regulation of Medical Device Manufacturers

One of these frustrated parties is the Food and Drug Administration (FDA), which has indicated in multiple statements and budget proposals that it will seek to drastically increase its regulation of medical device manufacturers in the wake of the COVID-19 pandemic. In early 2020, the FDA began notifying the United States Congress of a lack of regulation on medical device manufacturers that it considered crucial in the United States' COVID-19 response. In doing so, the FDA used the opportunity to highlight differences between regulations imposed on medical drug manufacturers and regulations imposed on medical device manufacturers—differences that it wants to change.

According to an FDA statement submitted by Stephen M. Hahn, M.D., Commissioner of Food and Drugs for the FDA, at the outset of the virus the FDA acted proactively to monitor the medical drug and device supply

[1] *Coronavirus Map: Tracking the Global Outbreak*, NEW YORK TIMES, last updated Apr. 24, 2020, https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html.

[2] *See, e.g.*, Executive Order No. 113 (New Jersey).

chain between the United States and China, recognizing correctly that the COVID-19 pandemic would likely affect the availability of critical medical resources, and may lead to potential disruptions in their supply.[3] In furtherance of these efforts, beginning on January 24, 2020, the FDA contacted over one hundred eighty (180) pharmaceutical drug manufacturers, reminded them of their legal obligations to "notify[] the FDA of any anticipated supply disruptions," and asked them to "evaluate their entire supply chain" with China.[4] These efforts were successful, as the FDA was able to promptly identify a coronavirus-caused drug shortage after the manufacturer reported the shortage as required.[5]

In contrast, manufacturers of medical devices—which include N95 masks and ventilators, devices that are critically important in preventing transmission of the COVID-19 virus and in treating serious cases—are not legally required to report any anticipated shortages, actual shortages, or supply chain issues to the FDA.[6] Thus, although the FDA was early aware of "63 manufacturers which represent 72 facilities in China that produce essential medical devices," including several facilities "adversely affected by COVID-19," it could only request that these manufacturers report shortage issues to the FDA, without being able to enforce this request.[7] As Dr. Hahn explained,

[N]o law exists requiring medical device manufacturers to notify the FDA when they become aware of a circumstance, including discontinuation of a product, that could lead to a potential shortage, and manufacturers are not required to respond when the FDA requests information about potential supply chain disruption.[8]

As noted in its March 28, 2020 Update, the FDA is taking measures to adapt and to encourage medical device manufacturers to report anticipated shortages promptly, but remains legally limited to requesting that manufacturers participate in reporting voluntarily.[9]

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[3] Stephen M. Hahn, M.D., *FDA Statement - Coronavirus (COVID-19) Supply Chain Update*, FDA.gov, Feb. 27, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update. As the past several months have shown, the FDA's projections were indeed correct, as the medical resource supply chain between the United States and China has been significantly affected by COVID-19.

[4] *Id.*

[5] *Id.*; *see also* Sarah Owermohle and David Lim, *The First Coronavirus-Linked Drug Shortage*, POLITICO, February 28, 2020, https://www.politico.com/newsletters/prescription-pulse/2020/02/28/the-first-drug-coronavirus-linked-drug-shortage-488435.

[6] Hahn, *FDA Statement - Coronavirus (COVID-19) Supply Chain Update.*

[7] *Id.*

[8] *Id.*

[9] Stephen M. Hahn, M.D., *FDA Statement - Coronavirus (COVID-19) Update: FDA takes further steps to help mitigate supply interruptions of food and medical products*, FDA.gov, Mar. 28, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-further-steps-help-mitigate-supply-interruptions-food-and.

III. The FDA's Proposed Regulations of Medical Device Manufacturers

In large part due to this situation, the FDA has taken affirmative steps to increase its regulatory authority over the entire medical device industry, using the COVID-19 pandemic as justification. As detailed in the FDA's FY 2020 Budget Request, the agency is pursuing a detailed legislative proposal that would have long-lasting effects on medical device manufacturers nationwide. Noting that "[n]o law requires medical device manufacturers to notify the FDA when they become aware of a circumstance that could lead to a device shortage," the FDA has requested that Congress authorize it to:

1) require firms to notify the FDA of an anticipated significant interruption in the supply of an essential device;

2) require all manufacturers of devices determined to be essential to periodically provide the FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and

3) authorize the temporary importation of devices whose risks presented when patients and healthcare providers lack access to critically important medical devices outweigh compliance with U.S. regulatory standards.[10]

Additionally, the FDA requested that Congress "clarify FDA's authority to require information that would improve FDA's ability to assess critical infrastructure as well as manufacturing quality and capacity."[11] As Dr. Hahn noted, this proposal would "empower" the FDA to require detailed manufacturing and supply information from medical drug and device manufacturers to the extent necessary to improve the FDA's "ability to recognize shortage signals."[12]

IV. Congressional Response to the FDA's Proposed Regulations

On March 12, 2020, within two weeks of Dr. Hahn's statement, U. S. Senators Bob Casey (D-PA) and Kelly Loeffler (R-GA) introduced Senate Bill 3468, titled as the *Preventing Essential Medical Device Shortages Act of 2020* ("Medical Device Act").[13] The Medical Device Act directly addresses the FDA's concerns, and, among other things, would take the following actions:

- Require the Secretary of the Department of Health and Human Services ("HHS") to issue public regulations defining the term "essential device";

[10] *Overview of Legislative Proposals*, Budget Exhibit to Food and Drug Administration's Fiscal Year 2020 Justification of Estimates for Appropriations Committees, at p. 37 (available at https://www.fda.gov/media/121408/download).

[11] *Id.*

[12] Hahn, *FDA Statement - Coronavirus (COVID-19) Supply Chain Update.*

[13] *Preventing Essential Medical Device Shortages Act of 2020*, S. 3468, 116th Cong. (2020).

- Add essential devices to the drug shortage list in the Federal Food, Drug and Cosmetic Act;

- Require essential device manufacturers to notify the Secretary about anticipated permanent discontinuance or interruption in an essential device manufacturing supply chain;

- Make information publicly available about disruptions in order to inform physicians, health providers and patient organizations about anticipated shortages;

- Allow the Secretary to exempt certain device shortages from public disclosure if it may lead to hoarding, price spikes and other issues that could adversely affect public health;

- Allow the Secretary to expedite the review of medical device applications to help mitigate anticipated shortages;

- Authorize the Secretary to expedite the inspection or re-inspection of establishments that could help mitigate or prevent shortages; and

- Require a Government Accountability Office report to examine the intra-agency coordination process that assesses risks associated with the essential device supply chain and identify ways to mitigate these risks.[14]

The Medical Device Act has since been referred to the Committee on Health, Education, Labor, and Pensions, where it remains pending.[15]

V. Potential Effects on Medical Device Manufacturers

Although the purpose of the Medical Device Act may be laudable, medical device manufacturers should be wary of the increased power and authority that would be granted to the FDA through its parent agency HHS, as such regulatory powers could have permanent, expensive side effects for the industry. For example, broad-based authority to impose reporting requirements on all essential medical device manufacturers would necessarily result in significant regulatory compliance burdens. The actual depth of these burdens would depend on the breadth of the information that the FDA would seek, the detail requested, and the frequency of reporting requirements, but in any event would result in increased time and expense for all device manufacturers, to say nothing of the

[14] *See id.*; *see also Casey, Loeffler Introduce Legislation to Address Shortages of Essential Medical Devices*, casey.senate.gov, Mar. 12, 2020, https://www.casey.senate.gov/newsroom/releases/casey-loeffler-introduce-legislation-to-address-shortages-of-essential-medical-devices.

[15] *S. 3468: Preventing Essential Medical Device Shortages Act of 2020*, govtrack.us, last visited Apr. 24, 2020, available at https://www.govtrack.us/congress/bills/116/s3468/text.

incidental scrutiny that the FDA would be allowed to apply.

Another negative effect would be the required assessment of the "essential device supply chain"—defined by the FDA as the critical infrastructure, manufacturing quality, and capacity of each manufacturer of essential medical devices—that would seemingly provide agency authority to interject regulatory objectives into every aspect of the manufacturing process. This is a result that no private entity desires.

VI. Potential Response Opportunities

For these reasons, the medical device manufacturing industry would be well-advised to deter the FDA from achieving these goals, both by voluntarily cooperating in COVID-19 shortage reporting and by exercising its lobbying power against the Medical Device Act.

As Dr. Hahn explained, the genesis of the FDA's request for more regulatory authority arose out of its realization that the United States was facing multiple potential shortages of essential medical devices, and yet had no authority to compel medical device manufacturers to notify the government of any anticipated shortages. This, combined with the actual essential medical device shortages that did occur (most notably N95 masks and hospital ventilators, as regularly reported by news agencies) catalyzed the proposal of the Medical Device Act. However, as matters currently stand, the medical device industry possesses an opportunity to demonstrate to the FDA and Congress that additional regulations are unnecessary. As detailed in the FDA's March 28, 2020 update, the FDA has developed a voluntary device shortage reporting system that would allow manufacturers to update the FDA regarding any anticipated complications in their individual supply chains. While the FDA cannot enforce this reporting system (as yet), full and complete voluntary participation from all manufacturers would convincingly demonstrate the industry's dedication to providing full assistance in emergency situations such as the COVID-19 pandemic. Thus, both for equitable reasons such as contributing to the effectiveness of the United States' COVID-19 response, as well as economical and business purposes in continuing to operate without potentially oppressive regulation, all medical device manufacturers should be encouraged to fully cooperate with the FDA's COVID-19 information requests in whatever way possible.

The medical device manufacturing industry should also assess the potential for applying lobbying efforts against the Medical Device Act. During these troubling times, the COVID-19 crisis is increasingly being used as justification for almost any level of government oversight, such as the Medical Device Act. Although many members of Congress might have initial, understandable reactions to offer blanket support to any act that might potentially save lives, a reasoned, logical discussion of the actual necessity of the bill might help temper the appetite for

its enactment. In particular, if the industry cooperates with the FDA as recommended above, manufacturing lobbyists would have compelling arguments that it is unnecessary to add additional, onerous regulations to an industry that is already highly regulated, and is already cooperating with all FDA requests for information.

VII. Conclusion

The COVID-19 crisis has presented all aspects of society with unprecedented challenges, and the medical device industry has not been immune. In its ever-evolving response to the COVID-19 pandemic, the FDA has identified certain areas where it is concerned that medical device manufacturers are under-regulated. Certain members of Congress have become alarmed by these concerns, and have responded by introducing a Senate bill with laudable goals that would nonetheless have potentially damaging side effects on all medical device manufacturers making products deemed "essential." Industry members would be well-advised to assuage the FDA's alarms by voluntarily cooperating with its reporting requests, and by employing lobbying efforts as appropriate to highlight the overreaching, unnecessary consequences of the Medical Device Act.

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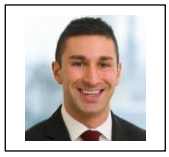
This article explores the ways in which COVID-19 is uniquely affecting all phases of ongoing drug and device litigation, including discovery, motion practice, and trial.

Litigation in the Time of COVID-19: Understanding the Novel Impact on Drug and Device Cases

ABOUT THE AUTHORS

Robin Shah is an attorney in the New York office of Skadden, Arps, Slate, Meagher & Flom, where she is a member of the Mass Torts, Insurance and Consumer Litigation group. Robin represents an array of clients including medical device manufacturers, consumer product manufacturers, and pharmaceutical companies in complex civil litigation. She advises clients on all aspects of litigation including pre-trial discovery, factual investigation, fact and expert witness preparation and trial strategy. She can be reached at robin.shah@skadden.com.



Andrew Karp is an attorney in the New York office of Skadden, Arps, Slate, Meagher & Flom, where he is a member of the Mass Torts, Insurance and Consumer Litigation group. Andrew has experience in various aspects of litigation, including written discovery, fact and expert witness preparation, and trial. He can be reached at andrew.karp@skadden.com.

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Stephen G.A. Myers
Vice Chair of Publications
Irwin Fritchie Urquhart & Moore LLC
smyers@irwinllc.com

The COVID-19 pandemic has affected deadlines, in-person proceedings, and discovery in all pending litigation, but has had particular impact on drug and device cases. For example, the medical professionals who often serve as expert and fact witnesses during discovery are now on the front lines battling the pandemic. In addition, plaintiffs may seek to exclude evidence that manufacturers are researching and developing vaccines to treat the virus. And while many trials are suspended for the short term, the complexity of product liability litigation and related need for a jury trial make it especially difficult for a drug and device trial to proceed in the near future.

Discovery of Medical Professionals

While courts have rather uniformly issued orders addressing court closures and the suspension of jury trials in response to COVID-19, court orders addressing how to approach discovery have been far less uniform. Especially relevant to drug and device litigation is how some courts are singling out medical professionals and excusing them from discovery altogether, which may impact cases where medical professionals are either retained as experts or serve as key witnesses, such as the prescribing or implanting physician.

For example, the Supreme Court of New Jersey suspended "all depositions of and all required appearances for any doctors, nurses or other healthcare professionals who are involved in responding to the COVID-19 public health emergency," except where the deposition or appearance is requested by those individuals or the matters relate to COVID-19, recognizing the "critical need for the uninterrupted services of" doctors, nurses and other healthcare professionals during this time. *See* Order Suspending Depositions and Appearances of Medical Professionals Involved in Addressing COVID-19 (N.J. Mar. 24, 2020); *see also* Omnibus Order on COVID-19 Issues at 2 (N.J. May 28, 2020) (extending original order). A similar order out of Pennsylvania recently suspended such depositions and appearances without exception. *See* Emergency Order of Statewide Judicial Administration Applicable from May 1, 2020, Through June 1, 2020 at 6, *In re Gen. Statewide Judicial Emergency*, Nos. 531 & 532 (Pa. Apr. 28, 2020) ("Depositions of and required appearances for doctors, nurses, or other healthcare professionals who are substantially involved in responding to the COVID-19 public health emergency are suspended for the duration of this Order.").

Other courts have addressed the issue in individual cases. For example, in *DeVine v. XPO Logistics Freight*, plaintiffs filed suit as a result of a motor vehicle collision, and the parties sought to depose various treaters regarding plaintiffs' alleged injuries. In addressing the requests for depositions, the court acknowledged that "the medical community is very, very busy right now," and it was "reasonable . . . to expect that . . . the situation at hospitals and medical offices will be all hands on deck." *DeVine v. XPO Logistics Freight*, Case No. 18 C 1264, 2020

WL 1275087, at *2 (N.D. Ill. Mar. 17, 2020) (to be published in F. Supp. 3d.). In the interest of balancing the burden and expense of the proposed discovery with its potential benefit, Magistrate Judge Gabriel Fuentes imposed a multi-step protocol for the depositions of medical professionals and treatment providers. *Id.* at *3. As a preliminary matter, the court ordered the parties to meet and confer regarding whether each medical provider deposition was actually necessary. For any deposition still sought, the court ordered the party seeking the deposition to submit certain information about the provider, including (i) the provider's "current and anticipated involvement in preparation or response to the COVID-19 public health emergency"; (ii) the nature and extent of the provider's involvement in treating the plaintiff or another party; (iii) the provider's relative importance to the case; and (iv) the extent to which the same or sufficient discovery could be obtained from alternative sources. *Id.*; *see also Lipsey v. Walmart, Inc.*, Case No. 19 C 7681, 2020 WL 1322850, at *4 (N.D. Ill. Mar. 20, 2020) (implementing the same protocol). The court explained that it would use the information to rule on the requests in light of the ongoing need for physician services and the fact that "[a]ll hands cannot be on deck if some of them are at a law office sitting for a deposition in a tort lawsuit." *See DeVine*, 2020 WL 1275087, at *3.

These orders reflect an acknowledgment by some courts that medical professionals are in a unique situation where the essential services they are providing during this pandemic necessarily outweigh litigation needs, and if other courts issue similar orders, the impact on deposition requests could be significant. Moreover, the orders may have wider implications for drug and device manufacturers involved in product liability litigation, where the types of company employees routinely asked to testify may be involved in the company's coronavirus response efforts. Although, to date, these orders have been limited to medical professionals, they signal a willingness among courts to excuse certain individuals from the burdens of litigation where they are substantially engaged in responding to the COVID-19 crisis. In that regard, they suggest that courts may be receptive to similar arguments for other professionals on the front lines, such as a company scientist involved in safety testing for a coronavirus vaccine candidate or a company compliance officer tasked with ensuring that new life-saving drugs are properly labeled and approved for emergency use.

Motions to Exclude Evidence of Defendants' Good Conduct

Another way in which drug and medical device cases are specifically impacted by COVID-19 is through the role that manufacturers are playing in the response to the virus. Many clients currently engaged in litigation are working to develop vaccines and other drug therapies to treat the virus, or have ramped up manufacturing efforts to meet the high demand for certain life-saving medical equipment.

As a result, many plaintiffs are proactively seeking to keep any evidence of manufacturers' response efforts out of upcoming trials in order to support their narrative of manufacturer defendants as bad actors. *See, e.g.*, Plaintiff's Memorandum of Law in Support of Her Motion *In Limine* to Preclude Any Reference to Johnson & Johnson or Its Subsidiaries' Efforts to Create A Vaccine for or Otherwise Combat COVID-19 at 1, *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, Case No. 2:14-cv-01379 (S.D. W. Va. filed Apr. 13, 2020), ECF No. 227-1 (motion to preclude defendants from "introducing into evidence or making any direct or indirect mention or reference whatsoever—by counsel, or through witnesses, exhibits, or expert testimony—to [their] efforts to develop a vaccination for, or otherwise combat, Covid-19"). To that end, plaintiffs are claiming that a company's efforts to create a vaccine or otherwise combat COVID-19 are evidence of its good character and should not be admitted to more broadly bolster its reputation. Moreover, plaintiffs contend that where a litigation does not relate to COVID-19, such evidence is irrelevant, having no tendency to make any fact in the case more or less probable than it would be without the evidence. Plaintiffs have also argued that such evidence is unfairly prejudicial because its sole purpose is to evoke an emotional response from jurors and convey that the companies are doing good in the community.

But a sweeping prohibition of the kind sought by plaintiffs would be unfair to defendants. Jurors are likely to have been affected by COVID-19 in one way or another, and although defendants may not be seeking to affirmatively introduce evidence of vaccine development, the notion that all references to COVID-19 must be excluded seems both overbroad and unnecessary. Moreover, there are many circumstances where a pharmaceutical drug or medical device company would have legitimate reason to mention its efforts to develop a vaccine or otherwise combat the virus, such as introducing the company to jurors by way of explaining the types of products it makes, introducing a company witness involved in the company's response efforts, or even describing how a drug gets to market in emergency situations.

Suspension of Jury Trials

Lastly, the complexity of drugs and medical devices makes trials especially difficult in the current environment. As a general matter, many courts have put in-person jury trials on hold due to issues with both jury selection and service. *See, e.g.*, General Order No. 72-2 at 1, *In re Coronavirus Disease Pub. Health Emergency* (N.D. Cal. Apr. 30, 2020) (suspending civil jury trials through June 1, 2020); Further Continuance of Jury Trials and Exclusion of Time Under the Speedy Trial Act at 2, *In re Coronavirus/COVID-19 Pandemic* (E.D.N,Y. Apr. 21, 2020) (Administrative Order No. 2020-15) (suspending civil jury trials through June 15, 2020); Amended General Order No. 2020-05-2 at 2, *In re Coronavirus (COVID-19) Pub. Emergency*

(N.D. Ohio Apr. 20, 2020) (suspending civil jury trials through June 12, 2020).

For instance, jury selection becomes especially difficult while social distancing because potential jurors may need to take public transportation to get to the courthouse, and they may be closely inspected by security personnel while entering the building. *Commonwealth v. Vila*, No. FE-2019-0000939, 2020 WL 1643379, at *5 (Va. Cir. Ct. Mar. 30, 2020, trial order). In addition, while actually serving on a jury, the jurors would be seated in a juror box where it would be a "practical impossibility" to keep everyone six feet apart. *Id.* However, spreading out the jury would make it difficult to police inappropriate interactions between jurors and attendees in the gallery. *Id.* Courts have also raised concerns with compiling a representative sample of the population while excluding those at high risk for COVID-19, ensuring that the jury is focused on the task at hand despite COVID-19 struggles at home, and acknowledging the potential for a mistrial if a juror becomes ill during the trial and others need to quarantine.

With those considerations in mind, some courts are choosing virtual alternatives to trial, but that option is less likely to be successful in drug and device litigation. Generally speaking, a virtual trial is most straightforward in a bench trial, which is rarely the format for drug and device litigation. Furthermore, a virtual trial is least controversial if the verdict is non-binding, but summary jury trials are similarly rare in drug and device litigation. Moreover, product liability litigation against drug and device companies tends to involve document-intensive examinations of several witnesses, some of whom live in other time zones, raising both scheduling and logistical concerns. Finally, as discussed above, to the extent discovery of medical professionals is halted for the foreseeable future, any trial testimony of medical professionals may be similarly suspended.

Conclusion

COVID-19 has been and will continue to be a universal disruptor. While it may not be possible to predict what the world will look like six months from now, taking stock of the ways in which COVID-19 has already manifested itself in ongoing litigation is instructive. As it relates specifically to drug and device litigation, the impact thus far suggests restrictions on requesting the deposition of a medical professional, challenges to the admissibility of evidence concerning defendants' COVID-19 response efforts, and a longer hiatus from trials.

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INSURANCE AND REINSURANCE

June 2020 – Second Edition

IN THIS ISSUE

The mandatory quarantines caused by the COVID-19 pandemic have already resulted in insurance claims for business interruption. This article discusses the challenges to coverage and resulting political and legal pressures on the insurance industry.

COVID-19 Business Interruption Insurance Claims Coverage Issues

ABOUT THE AUTHORS

Doug Vaughn is the Vice Chair of membership of the Insurance and Reinsurance Committee and has been recognized by Best Lawyers as 2020 Lawyer of the Year in Gulfport, MS for litigation - insurance. He is a past president of the Mississippi Defense Lawyers Association and is a current member of the faculty of the IADC Trial Academy. Doug is the head of Deutsch Kerrigan's Gulfport, Mississippi office. He can be reached at dvaughn@deutschkerrigan.com.

Frank Barry is a 1973 graduate of Tulane Law School, and a member of the Bars of Louisiana and several federal courts, including the US Supreme Court. He primarily practices maritime and oil & gas litigation, as well as insurance coverage work, in Deutsch Kerrigan's New Orleans office. He can be reached at fbarry@deutschkerrigan.com.

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The Insurance and Reinsurance Committee members, including U.S. and multinational attorneys, are lawyers who deal on a regular basis with issues of insurance availability, insurance coverage and related litigation at all levels of insurance above the primary level. The Committee offers presentations on these subjects at the Annual and Midyear Meetings. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

Bryan D. Bolton
Vice Chair of Newsletters
Funk & Bolton
bbolton@fblaw.com

I. INTRODUCTION

The COVID-19[1] pandemic will engender a huge number of business interruption insurance claims on a scale to surpass the claims following previous catastrophe claims affecting regions of the United States. While Hurricane Katrina and Superstorm Sandy devastated regions, COVID-19 affects the entire world and within North America, every area of every state and province. Insurance coverage issues inherent in the processing of these forthcoming claims will vary depending on the policy conditions and exclusions in each policy and the circumstances and losses of each insured; however, there are several issues that may occur frequently and these are discussed below. As a side note, federal Cares Act legislation provides forgivable loans to small businesses which turn into grants, thereby decreasing but not erasing an insured's business interruption losses.[2]

II. PHYSICAL DAMAGE REQUIREMENT

Most business interruption insurance policies include the condition that the insured premises suffer physical damage and many policies since 2006 contain the specific ISO form CP 01 40 07 06, entitled "Exclusion for Loss Due to Virus or Bacteria." The policy coverage may read that there must be "direct physical loss or damage to property at a premises which are described in the Declarations."

One national law firm often representing insureds argues[3] "nothing in these often unedifying terms rules out the possibly of damage caused by the presence of microscopic organisms or requires that loss or damage be visible to the naked eye, or even visible at all." If the premises of the insured's business are flooded or damaged by fire, or building collapse, then the policy condition of an "occurrence" and definitions of "damage" would be satisfied. But what if there is no physical damage to the property of the insured, and the business interruption is caused by some type of governmental shutdown order sparked by the COVID-19 Pandemic?

There is case law holding that some type of physical damage to the insured's premises which causes the business interruption must occur before policy coverage is triggered. In *Mama Joe's, Inc. v. Sparta Ins. Co*. 2018 U.S. Dist. LEXIS 201852, 2018 WL 3412974 (S.D.

[1] According to the Center for Disease Control, a novel coronavirus is a new coronavirus not previously identified. On February 11, 2020, the World Health Organization announced an official name for the disease causing the 2019 novel coronavirus outbreak, first identified in Wuhan China, as coronavirus 2019, abbreviated as COVID-19. cdc.gov/2019-ncov/faq.html#Coronavirus-Disease-2019-Basics

[2] The Federal Cares Act signed March 27, 2020 created the Paycheck Protection Program regarding SBA-bank loans for small businesses that continued to pay their employees during the pandemic shutdown. Ultimate forgiveness of these loans if the proceeds are used to pay for payroll costs and other designated expenses for eight (8) weeks following the loan origination is provided for in the act.

[3] See Jenner & Block newsletter dated March 12, 2020, by David Kroger and Elin Park.

Fla. June 11, 2018) involving nearby roadwork which caused dust and debris contamination of the insured restaurant, the federal district court held that damage to the property requiring actual damage alteration to the property requiring repairs would be needed to trigger the policy coverage and granted summary judgment for the insurer, thereby denying the restaurant's claim.

In *Mastrellone v. Lightning Rod Mut. Ins. Co.,* 884 NE 2d 1130 (Ohio App. 2008), the court held that mold could be removed by cleaning and did not affect the structural integrity of the building and therefore did not trigger business interruption coverage. In *Source Food Tech, Inc. v, USF&G,* 465 F.3d 834 (8th Cir. 2006), the Court held that beef imports banned for mad cow disease did not amount to "physical loss or damage." In *Newman Myers Kreines Gross Harris PC v. Great American Insurance Company*, 17 F Supp. 3d 323 (SDNY 2014) the court held that a power shutoff in advance of Super Storm Sandy approaching did not amount to physical loss or damage. A federal district court in Michigan held in the case of *Image Products v. Chubb Corp,* 703 F. Supp. 2d. 705 (E.D. Michigan 2010), that strong odors, mold and bacteria in the air and ventilation system in the building did not constitute physical damage to the property necessary to trigger insurance coverage and granted summary judgment to the insurer.

III. ARGUMENTS FOR COVERAGE IN THE ABSENCE OF PHYSICAL DAMAGE

Despite these cases dismissing claims of affected policyholders due to lack of physical damage, case law does exist supporting the inventive argument "non-altering" physical damage is present at the insured premises if there is "contamination" at the location, even if the contamination does not physical cause property damage.

A. TEMPORARY CONDITIONS TRIGGERING COVERAGE

For example, in *Gregory Packaging Inc. v. Travelers Prop. Cas. Co. of Am.,* 2014 U.S. Dist. Lexis 165232 (D. N.J., November 25, 2019), a federal district court in New Jersey held that a release of unsafe amount of ammonia in a facility amounted to a "direct physical loss". That court held property can sustain a physical loss or damage without experiencing structural alteration, and in *Wakefern Food Corp. v. Liberty Mut. Fire Ins. Co.*, 406 N.J. Sup. 524 (N.J. App. Div. 2009), the Court held that property can be "just temporarily unfit" and trigger coverage so the business interruption claim was allowed to proceed.

The *Wakefern Food Corp*. court's reasoning should be of particular interest to those in the food service industries, as restaurant employees are the most severely affected by business shutdowns from COVID-19, with hair and nail salons, hotels, gymnasiums and entertainment venues such as theaters and sporting events similarly affected.

Mississippi's casinos have been given a reopening date of May 21, after being closed by governmental decree for roughly two months. Walt Disney Co. and Universal Studios parks in Florida are gradually reopening in May and in Las Vegas, companies have announced staged plans pointing toward plans to reopen in by summer of 2020, demonstrating the conditions disrupting the business operations were at best temporary but the change in operations when reopening occurs do not suggest a return to "business as usual." Whether and when the ways people interacted before March of 2020 will ever return is a matter of speculation and disagreement.

B. POST COVID-19 ISO ENDORSEMENTS

Even when governmental shutdown orders close the businesses of insured policyholders, traditional business interruption coverage sections on policies usually still require the trigger of a physical damage or loss. However, it has been reported that the Insurance Services Office ("ISO") has responded to the COVID-19 outbreak by issuing endorsements for the use with commercial property forms that do not condition coverage upon direct physical loss or damage to property. The ISO forms provide limitation business interruption coverage due to actions taken by civil authorities to avoid or limit infection or spread by COVID-19. The two ISO forms have been described as "business interruption, limited coverage for certain civil authority orders relating to coronavirus" and "business interruption, limited coverage for certain civil authority orders relating to coronavirus (including orders restricting some modes of public transportation)", respectively. These forms reportedly also include certain exclusions and should be carefully reviewed.

Prior to the ISO form endorsement described above, the commentary on COVID-19 business interruption insurance coverages focused upon the 2006 ISO Form-Virus Exclusion.

ISO Form CP 01 40 07 06 is entitled "Exclusion for Loss Due to Virus or Bacteria" and provides ". . . we will not pay for loss or damage caused by or resulting from any virus, bacterium or other microorganism that induces or is capable of inducing physical stress, illness or disease… the exclusion goes on to state that it applies among other things to business income and it is reportedly found in many first party property insurance policies since 2006.

C. REASONABLE EXPECTATIONS DOCTRINE

But even in the face of such an apparently clear exclusion for business interruption due to a virus pandemic, there have been suggestions that such an exclusion may be avoided either by arguing that the governmental closure order is the cause of the damage and not the contamination by the virus or by arguing the "reasonable expectations" doctrine, adopted in

Mississippi in the case of *Bland v. Bland*, 629 So.2d 582 (Miss. 1993), as follows: "The objectively reasonable expectations of applicants and intended beneficiaries regarding the terms of insurance contracts will be honored even though painstaking study of the policy provisions would have negated those expectations." *Id.* at 589 (citing Keeton, *Insurance Law Rights at Variance With Policy Provisions*, 83 Harv.L.Rev. 961, 967 (1970)). The *Bland* decision has not been often cited in Mississippi in the years following its publication but it is noted that more recent court opinions have required a finding that the policy be ambiguous as a condition precedent to invoking the "reasonable expectations" doctrine. *WW Holdings, LLC v. ACE Am. Ins. Co*. 574 Fed Appx. 383, 386 n.2 (E.D. La. 2014). Other states have analyzed factual scenarios wherein a discussion was held between an agent and a prospective policyholder over insurance coverage and where both an ambiguity exists in the contract and the agent's representations created a misconception regarding coverage in the policy, the reasonable expectations doctrine could provide an avenue for recovery. *Talbot 2002 Underwriting Capital, Ltd. V. Old White Charities, Inc.,* 2016 U.S. Dist. LEXIS 52088 (S.D. W.Va April 19, 2016) (*citing Casto v. Northwestern Mut. Life Ins. Co.*, 2009 U.S Dist LEXIS 79385 (S.D. W. Va. Sept. 2, 2009).

D. ARE ALLERGENS POLLUTANTS?

It is also possible that pollution exclusion endorsements in policies might provide a basis for arguments as to coverage. However, in *Westport Ins. Corp. vs. VN Hotel Group, LLC,* 761 F. Supp. 1337 (M.D. Florida 2010)[4] the court held legionella bacteria are not pollutants and thus found the policy exclusion did not apply and in *Johnson v. Clarendon National Insurance Company,* 2009 Cal App. Unpub. LEXIS 972, 2009 WL 252619, (Cal. 4th DCA February 4, 2009) a court held that a pollution exclusion did not apply to mold and "likely would not apply to viral infections" because the court reasoned that the language of the pollution exclusion was unclear and would be interpreted in favor of coverage. In *First Specialty Insurance Corp. v. GRS Management, Inc. ,* 2009 W.L. 254613 (S. D. Fla. 2009) the federal district court held that the virus was a pollutant.

The specific ISO Form "exclusion for loss due to virus or bacteria" provides that "we will not pay for loss or damage caused by or resulting from any virus, bacterium or other microorganism that induces or is capable of inducing physical distress, illness or disease…" the ISO circular dated July 6, 2006 used as part of its filings with State Regulatory Authorities refers to rotavirus, SARS, influenza (such as avian flu), legionella, and anthrax.

[4] Affirmed on appeal, *Westport Ins. Corp. v. VN Hotel Group, LLC*, 513 Fed. Appx. 927 (11th Cir. 2013).

The ISO Form CP 00 30 10 12 entitled "Business Income (and Extra Expense) Coverage Form provides that the insurer will pay for the actual loss of business income sustained due to the necessary suspension of your operations during the period of restoration. The suspension must be caused by direct physical loss of or damage to property at premises which are described in the declarations and for which a business income limit of insurance is shown in the declarations. The loss or damage must be caused by or result from a covered cause of loss. With respect to loss of or damage to personal property in the open or personal property in a vehicle, the described premises include the area within 100 feet of such premises".

ISO Form PROP 12 19 09 17 entitled Ordinance or Law Coverage includes the provision that "coverage under this endorsement applies only if a.) the building sustains only direct physical damage that is covered under this policy and is a result of such damage you are required to comply with the ordinance or law…"

IV. CURRENT LITIGATION

Subsequent to the closure of restaurants in the United States due to the COVID-19 pandemic, in lawsuits filed in New Orleans, *Cajun Conti, LLC v. Certain Underwriters at Lloyds,* Civil District Court, Orleans Parish, and Napa County, California, *French Laundry Restaurants d/b/a French Laundry, et al v. Hartford Fire Insurance Co.,* the policy holders have asserted the respective governmental closure orders and the contamination of the premises by the virus provide a basis for coverage, regardless of any limitations or exclusions in the policy language. Likewise, lawsuits filed by the Chickasaw and Choctaw Nations in Oklahoma against their insurers for business interruption coverage and seeking declaratory judgment of the tribe's casinos and other business which were shut down and impacted in light of the Covid 19 panic are covered claims notwithstanding under the business interruption provisions regarding orders of civil authorities.

From mid-April to present, most new lawsuits filed have been putative class actions with requests to consolidate federal cases for MDL in Chicago, Miami and Philadelphia.

V. CURRENT LEGISLATION

Finally, legislative actions in various states affecting insurance coverage received lavish media attention but have subsequently failed to gain traction to become enacted into law. The New Jersey legislature introduced a bill (A.B. 3844) to force insurers to pay COVID-19 business interruption claims despite the ISO Form Virus Exclusion used in the policies issued to the insureds in that state with businesses of less than 100 employees. The proposed legislation contains language to the effect that "notwithstanding the provision of any other law, rule, or regulation to the contrary insuring against loss or damage to property which includes the loss or use of occupancy

of business interruption enforced in this state…shall be construed" to include coverage for COVID-19 business interruption losses. Similar legislation has been introduced during the month of March in other states including Ohio, Massachusetts, New York, and Louisiana, and in April, Pennsylvania, South Carolina and Michigan but despite the fanfare with which such bills were announced, none of the bills have made much headway in their respective state legislatures. The first such bill, introduced in New Jersey and discussed above, was withdrawn in the month of March without a vote. In mid-May, the Louisiana bill died in committee.

At the federal level, H.R. 6494, proposed by California Representative Michael Thompson mandates business interruption coverage for viral pandemics or other forced business closures and/or mandatory evacuations under current existing insurance policies. Any such bills that make it into law will be subject to challenges to their constitutionality as ex post facto laws or otherwise in violation of Article One, Section 10 of the United States Constitution, prohibiting state laws impairing the obligation of contracts.

VI. CONCLUSION

All eyes are focused on how courts will respond to arguments that business interruption coverage should provide relief to policyholders whose businesses were forced to close due to the COVID-19 pandemic. The policy language requirement of physical damage as a pre-requisite to coverage is being challenged in numerous ways by affected business owners and governmental entities. Application of the reasonable expectations doctrine to create coverage where none exists in the policy requires at a minimum the finding of an ambiguity in the policy as a matter of law and in some states, additional proof of misrepresentations by the agent in discussing specifics of coverage. While efforts to enact legislation forcing insurance coverage under existing policies containing exclusions may be fizzling, class action lawsuits pending in numerous states will exert pressure on insurance companies. The outcome of these efforts, initiatives and lawsuits is uncertain at this time but as the precedents set forth above illustrate, outcomes may vary, at least in the short term.

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BUSINESS LITIGATION

JULY 2020

IN THIS ISSUE

The current market collapse (the COVID-19 Crisis) is different from prior market crashes because it was not caused by the collapse of a particular market segment or the failure of an ascertainable industry to embrace responsible lending and/or investment practices. The current market collapse will likely spawn litigation that is focused on both particular market segments (e.g., healthcare, oil and gas, airline, airplane manufacturing, restaurant, cruise-line, and tourism, to name a few), and particular investment products. This bulletin focuses on two investment products that likely will be the subject of many investor claims: structured notes and high-yield (junk) bonds.

Potential Investment Litigation and Arbitration Trends Arising out of the COVID-19 Financial Crisis: Two Products that will Likely be the Subject of Claims

ABOUT THE AUTHORS

John Beach is a partner with Adams and Reese LLP in its Columbia, South Carolina office. John is a member of the firm's Business Litigation, Investment Litigation, and Estate, Trust, and Fiduciary Litigation Teams. He has been recognized by Best Lawyers in America®, Martindale-Hubbell® and Super Lawyers® John joined IADC in 2012. He can be reached at john.beach@arlaw.com.

Jack Pringle is a partner with Adams and Reese, LLP in its Columbia, South Carolina office. He counsels clients in matters relating to privacy, information security, information governance, administrative and regulatory law, public utilities, securities and class action litigation. He can be reached at jack.pringle@arlaw.com.

Lyndey Bryant is a partner with Adams and Reese LLP in its Columbia, South Carolina office. Lyndey practices in the areas of business litigation and probate and trust litigation. She has represented both large, multinational, Fortune 100 companies and small, family-run businesses, and their officers, directors, and employees in complex civil litigation, arbitration, administrative proceedings, and appeals. She is a graduate of the IADC Trial Academy (2018), and has received "Rising Star" recognition by the South Carolina Super Lawyers (Thompson Reuters) for her appellate work (2019 and 2020). Lyndey can be reached at lyndey.bryant@arlaw.com.

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Kyle Miller
Vice Chair of Publications
Butler Snow LLP
Kyle.miller@butlersnow.com

Litigation following a global financial crisis often focuses on particular products and/or market segments. Many claims following the 2000 "Technology Crash" focused, not surprisingly, on losses caused by investments in the tech sector. The 2008 "Mortgage Crisis" spawned much litigation over the financial services industry's failure to properly screen mortgage applicants and the related issuance, purchase, and sale of certain financial services products, primarily collateralized debt obligations (CDOs) and mortgage-backed securities (MBSs).

The current market collapse (the COVID-19 Crisis) is different from prior market crashes because it was not caused by the collapse of a particular market segment or the failure of an ascertainable industry to embrace responsible lending and/or investment practices. We can only hope this difference will help financial markets recover more rapidly from the COVID-19 Crisis than the past two.

Regardless, we believe the current market collapse will spawn litigation that is focused on both particular market segments (e.g., healthcare, oil and gas, airline, airplane manufacturing, restaurant, cruise-line, and tourism, to name a few), and particular investment products.

This bulletin focuses on two investment products we believe will be the subject of many investor claims: structured notes and high-yield (junk) bonds.

Structured Notes

A structured note is a debt security issued by financial institutions; its return is based on equity indexes, a single equity, a basket of equities, interest rates, commodities or foreign currencies. So, in addition to being a type of bond, a structured note is also a type of derivative, because its return is derived from the performance of an underlying asset, group of assets or index.

Structured notes are complex and illiquid. When the underlying asset on which a structured note's return is derived drops significantly, as many assets have in the current market, the return and the related value of that structured note is substantially diminished. For these and other reasons, structured notes are unsuitable for many investors.

Underscoring this conclusion, the SEC issued an Investor Alert regarding structured notes in 2015. Nonetheless, throughout the last three years of overall market growth, structured notes have been a tempting product for financial advisors to recommend to customers. As long as the market is strong, structured notes can offer a relatively high return.

Current market conditions will likely cause many investors to lose money unexpectedly on structured notes. Structured notes also often pay relatively high commissions, a

point plaintiffs' attorneys assert demonstrates that defendants are acting in their self-interests when recommending these investments. Several plaintiffs' securities law firms have recently posted information on structured notes in an effort to obtain clients.

"High-Yield" Bond-based Investments

A high-yield (junk) bond is a bond rated below investment grade (i.e., below BBB). These bonds have a higher risk of default and, in exchange, offer higher relative yields in order to attract investors. Despite investors sustaining significant losses from junk bonds in the past, the size of the U.S. high-yield bond market is nearly double its level at the time of the 2008 financial crisis.[1] Indeed, despite many opinions that junk bonds are an unsuitable investment for customers headed toward retirement, many IRAs actually offer high-yield bond funds as one investment option.

While it remains to be seen whether the current financial crisis will cause widespread corporate defaults on high-yield bonds, the specter of that occurring has caused a massive selloff of junk bonds around the world. High-yield bonds with below-investment-grade ratings plunged at their fastest pace in history in March 2020.[2] While it will take more time to learn whether a substantial number of these high-yield bonds will go into default, such an event seems likely, particularly for bonds issued by companies in the most adversely affected market segments.

If widespread default occurs in the wake of the COVID-19 Crisis, we anticipate investors will file claims asserting they were not warned of the potential financial risks posed by high-yield bonds and that such investments were unsuitable for the investors' conservative needs and directives.

[1] [1]Jonathan Rochford, Opinion: The Next Wreck in Junk Bonds Will be Bigger, Longer and Uglier, Market Watch (June 16, 2018).

[2] Serena Ng and Zie Yu, Investors, Fearing Defaults, Rush out of Junk Bonds, Wall Street Journal (March 26, 2020).

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