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Skadden

Coronavirus/COVID-19 Update

As health organizations and governments around the world work to contain the coronavirus (COVID-19), businesses should be mindful of the various ways the virus may impact their operations and employees. The wide range of potential issues includes complications in transactions and contracts, incidents that trigger regulatory obligations, and personnel concerns stemming from illness or remote workforces, among many others. While we don't yet know the full extent to which the coronavirus will impact us on a variety of levels, we offer the following considerations for those navigating coronavirus-related legal challenges.

Coronavirus and M&A

Contributor

Paul Schnell, Partner

History has shown that periods of uncertain economic and market conditions, if prolonged, will reduce M&A activity. If the 2019 novel coronavirus meaningfully disrupts the global economy and markets, there is every reason to think that this would lead to a slowdown in M&A. What could be different this time around is that, in addition to the virus' impact on M&A activity if it triggers an economic slowdown, the harmful effect that a serious outbreak could have on almost all businesses could further discourage buyer interest in pursuing M&A transactions.

The coronavirus could become a complicating factor in every phase of an M&A process:

- The challenge in due diligence of understanding and evaluating the many potential ways, some obvious and others difficult to identify or quantify, in which the coronavirus can affect the target company's strategy, business, financial condition, liquidity, customers, suppliers, costs, contracts and prospects.
- The need to advise the board of directors on the risks associated with the virus, with input from internal or external health experts, so that directors can make an informed decision, consistent with their duties.
- The availability of acquisition financing, including bridge facilities and permanent/takeout financing, and the cost, "market flex" provision and other terms of such financing; the particular diligence requirements a financing source may have concerning the target and, in some cases, the buyer. (See "Uncertainty in Leveraged Financings.")
- The negotiation of various terms of the acquisition agreement that allocate the risk of the virus' harmful impact on the target as between the buyer and seller, such as:
  - The "material adverse change" (MAC) provision;
  - Representations and warranties, such as disclosure of undisclosed liabilities relating to the virus, the status of material contracts and other business relationships, the accuracy of financial statements including the adequacy of reserves, and the adequacy of internal controls monitoring the effects of the coronavirus;
  - The ability of the target company to conduct business in the ordinary course between signing and closing, and the extent to which the target would have the right to take extraordinary measures to combat the virus;

- The health and safety rights the target's employees will retain post-closing, such as policies for working remotely and for employees who contract the virus (see "Employment Considerations");
- Closing conditions relating to the virus' adversely affecting the target company;
- Limitations on the buyer's obligation to obtain financing, and remedies if the buyer fails to come up with the financing; and
- In the case of private companies, the need for any special post-closing indemnity provisions concerning the virus.

The particular wording of MAC provisions in pending and future deals will significantly affect how the risk of adverse developments from the coronavirus will be allocated between the buyer and seller. We reviewed the MAC provisions of 31 purchase agreements that were publicly filed between January 27, 2020, and March 2, 2020. Although MAC provisions are thought to be reasonably well-settled and uniform, there was both considerable variation and some ambiguity in terms of the ability of the parties to argue whether the coronavirus' impact on a company would be a MAC (giving the buyer the ability to terminate) or an exception from what would otherwise be a MAC (giving the seller the ability to force the buyer to close). Of the 31 agreements, only one explicitly refers to coronavirus, listing it as an exception to what would otherwise constitute a MAC. One would expect that many future agreements will specifically address the extent to which the negative impact of the virus can be considered the basis for claiming a MAC.

Other provisions will take some sorting through based on the facts of a particular situation, perhaps sometimes with the help of litigators. Some 13 of the 31 acquisition agreements refer to "pandemics," "epidemics," "disease outbreaks" or "outbreak of illness or other public health event" as an exception to what would otherwise be a MAC. Other agreements have exceptions for developments such as: a change in "general economic conditions" or "financial markets," "events generally affecting the industries in which the company operates," "national emergencies," "natural or man-made disaster," "natural disasters," any "national or international calamity or crisis," "the declaration by the United States or another country of a national emergency," "acts of God," and "*force majeure*" events.

Potential compromises in negotiating future MAC clauses could include:

- Deciding how long the coronavirus' impact on the target's business must continue in order to declare a MAC.
- The buyer accepting as its risk the level of harm caused by the virus at the time the deal is signed, but not a material worsening of such impact occurring after signing (similar to a "no sandbagging" provision).
- The buyer assuming the coronavirus risk so long as the adverse impact on the target is not disproportionate to that experienced generally by the target's industry.

Of course, if the coronavirus becomes significantly more serious, it will be hard for buyers and sellers to find acceptable compromises. While buyers and sellers can often (but not always) agree on a sharing of a low-risk issue or the risk of the unknown issue, the more likely and material the risk, the harder it will be for either party to accept enough of that risk to make an agreement possible.

During economic slowdowns, market observers often predict an increase in the number of stock-for-stock deals. One of the reasons given for this is that stock deals can be easier to price in a down market: If the share prices of both companies have declined by a similar amount, then their relative values remain the same for purposes of negotiating an exchange ratio. Yet, these predictions generally have not come to pass, with stock deals declining along with those for cash.

What one does see when stock prices are depressed is more shareholder activism and selected unsolicited bids. Companies should consider assessing and preparing for such risk.

It's true that sometimes the best deals are done by buyers willing to take more risk during challenging economic periods, when other potential bidders have gone to the sidelines, the seller may be more motivated to do a deal and pricing is more favorable. But, more often, executives and boards of directors may not have the business confidence in troubled times to make an opportunistic bet on the future.

Impact on Public Company Disclosures and Other Considerations

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The coronavirus outbreak, which has become a global concern, raises complex disclosure and other considerations for companies subject to the U.S. Securities and Exchange Commission's (SEC) reporting and disclosures rules.

Company Responses

Significant developments related to the coronavirus outbreak followed or coincided with the release of fourth quarter and annual earnings information and investor conference calls for many companies. As a result, companies were forced to consider whether disclosures were required to address the potential impact of the outbreak on the company's future results or operations. Companies also considered whether 2020 earnings guidance should be disclosed and restrictions should be placed on trading in company securities by insiders.

Disclosures

While approaches varied, consistent themes emerged in the way companies addressed the coronavirus outbreak in public disclosures.

- **Risk Factors.** Many companies included risk factor disclosures in their 2019 Annual Reports on Form 10-K addressing risks related to the coronavirus outbreak, such as:
  - Disruptions to business operations resulting from quarantines of employees, customers and suppliers in areas affected by the outbreak, and closures of manufacturing facilities, warehouses and logistics supply chains;
  - Disruptions to business operations resulting from travel restrictions and reduced consumer spending; and
  - Uncertainty around the duration of the virus' impact.

  Some of the companies that included these disclosures were clear that they expected the situation to have a material impact on their results of operations. Other companies stated that, while a material impact was possible, at the time of the disclosures a clear determination could not be made.
- **Management's Discussion and Analysis (MD&A).** A number of companies mentioned the coronavirus outbreak in the MD&A sections of their Form 10-K. While the outbreak began in late 2019 and, as a result, was not reflected in many companies' results of operations, a number of companies identified potential trends, uncertainties and projections regarding the expected impact of the outbreak on future periods.
- **Proxy Statements.** While most calendar year-end issuers have not yet filed their proxy statements in connection with

annual meetings, in the past we have seen enhanced disclosure of material risks in the board risk oversight section of proxy statements. Moreover, in recent guidance, the SEC has emphasized that companies should discuss how their boards oversee the management of material risks. Accordingly, we expect that companies experiencing a material impact due to the coronavirus outbreak will address the board of directors' oversight, if any.

- **Forward-Looking Statements**. Companies that addressed the coronavirus outbreak in their periodic reports or earnings guidance also generally updated their forward-looking statement disclaimer language to address the outbreak.

Earnings Guidance

Due to the unpredictable nature of the coronavirus outbreak, certain companies that have normally disclosed expected 2020 earnings decided to discontinue the practice at this time. Other companies forecasted the impact of the coronavirus outbreak on first quarter earnings but excluded the potential impact from their full-year 2020 guidance. Some companies that had already issued 2020 guidance rescinded that guidance as news about the outbreak worsened. Many companies were careful to note that they did not intend to provide updates to the guidance unless required to do so. Some companies, however, committed to update it as additional information became available. As noted below, those companies should carefully monitor developments to determine when an update may be required.

Insider Trading

While companies ordinarily open their trading windows 24 to 48 hours after earnings are released, given the extreme fluidity of this situation, some affected companies suspended this practice and kept the trading window closed as they considered developments related to the outbreak. Other companies opened the trading windows but continued to monitor developments to determine if the decision should be revisited. In a statement issued March 4, 2020, the SEC highlighted this concern, observing that when companies "become aware of a risk related to the coronavirus that would be material to its investors, it should refrain from engaging in securities transactions with the public and to take steps to prevent directors and officers (and other corporate insiders who are aware of these matters) from initiating such transactions until investors have been appropriately informed about the risk."

SEC Response

On January 30, 2020, while discussing a rule proposal relating to MD&A requirements, SEC Chairman Jay Clayton noted that he asked the staff of the SEC to "monitor and, to the extent necessary or appropriate, provide guidance and other assistance to issuers and other market participants regarding disclosures related to the current and potential effects of the coronavirus." Chairman Clayton also observed that "how issuers plan for that uncertainty and how they choose to respond to events as they unfold" can be material to an investment decision.

On February 19, 2020, Chairman Clayton, SEC Division of Corporation Finance Director Bill Hinman, SEC Chief Accountant Sagar Teotia and Public Company Accounting Oversight Board (PCAOB) Chairman William D. Duhnke III issued a joint statement on the impact of the coronavirus outbreak on audit firms and potential filing relief. The joint statement indicated that, in recent discussions with the senior leaders of the largest U.S. audit firms, the SEC and PCAOB discussed the potential effects of the outbreak on financial disclosures and audit quality, including access to information and company personnel. In those discussions, the SEC and PCAOB emphasized the need for companies to consider potential disclosure of subsequent events in the notes to financial statements in accordance with guidance included in Accounting Standards Codification 855, *Subsequent Events*.

On March 4, 2020, the SEC issued an order granting relief for certain filing obligations under the federal securities laws. Specifically, the SEC's order provides publicly traded companies with an additional 45 days to file certain disclosure reports that would otherwise have been due between March 1, 2020, and April 30, 2020, subject to certain conditions.

To qualify for relief, companies must furnish to the SEC a current report on Form 8-K (or, if eligible, a Form 6-K) by the report's deadline with a statement that the company is relying on the SEC's order, a brief description of why the company could not file its required material on a timely basis, an estimate of when the late material will be filed and, if appropriate, a risk factor explaining the impact of COVID-19 on the company's business, among other conditions. In circumstances where a company's filing is late due to the inability of a third party to furnish a required opinion, report or certification, the company's current report must attach as an exhibit a statement signed by such person stating the specific reasons why he or she could not provide the required opinion, report or certification.

The SEC's order also provides relief for companies required to furnish proxy statements, annual reports and other soliciting materials where the company's security holder has a mailing address in an area where, as a result of the coronavirus outbreak, delivery service has been suspended and the company or other person making a solicitation has made a good-faith effort to furnish applicable materials to the security holder.

In addition, the SEC's Division of Investment Management issued a statement on March 4, 2020, extending relief where fund boards do not adhere to certain in-person voting requirements in the event of unforeseen or emergency circumstances affecting some or all of the directors between March 4, 2020, and June 15, 2020.

Next steps

Public companies should continue to monitor developments related to the impact of the virus and the potential need to take further action. If a company discusses the impact of the outbreak with investors, it should be mindful of its obligations under Regulation FD. In this regard, the SEC's March 4, 2020, statement noted that "[w]hen companies do disclose material information related to the impacts of the coronavirus, they are reminded to take the necessary steps to avoid selective disclosures and to disseminate such information broadly."

Depending on the facts and circumstances, companies also may need to update prior disclosures and implement restrictions, or continue restrictions, on insider trading. As explained by the SEC in its March 4, 2020, statement, "[d]epending on a company's particular circumstances, it should consider whether it may need to revisit, refresh, or update previous disclosure to the extent that the information becomes materially inaccurate." While no federal securities law, rule or regulation expressly imposing a duty to update a forward-looking statement exists, courts have analyzed the possible duty under Exchange Act Section 10(b) and Rule 10b-5. Courts are divided as to whether or not a duty to update exists for a forward-looking statement that becomes inaccurate or misleading after the passage of time. Those that recognize a duty to update a forward-looking statement generally have found that such a duty arises when a company makes a statement that remains "alive" in the minds of reasonable investors as a continuing representation.

Potential Securities Litigation Issues

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Increasingly, securities litigation is triggered by the announcement or occurrence of a significant adverse event — sometimes referred to as event-driven securities litigation — such as undisclosed cyber-attacks, underlying regulatory or criminal investigations or violations (*e.g.*, FCPA violations), or environmental disasters. We anticipate that the uncertainties created by the current outbreak of the coronavirus and its impact on companies across all industries, from travel and leisure to technology, likely will give rise to securities litigation. While only a handful of securities cases followed the SARS outbreak, COVID-19 appears to be having a more significant impact on corporations and the markets more generally. Because most securities cases traditionally follow stock declines, volatile markets tend to lead to increased securities litigation. However, the volatility of the market also could pose challenges for plaintiffs — the uniformity of stock price declines across industries could create difficulty in overcoming arguments that the losses were caused by factors other than the issuers' public statements.

Corporate disclosures relating to performance, projections and the potential impact of the virus often will be viewed in hindsight; and the context — that is, the specific disclosures and factual circumstances underlying each case — may significantly affect potential liability. Careful attention to the drafting of disclosures can help avoid potential liability. In particular, companies should pay close attention to updating risk factors and cautionary language, especially those surrounding forward-looking statements in order to maximize the protections of the PSLRA's safe harbor. Management's keen focus on projections and guidance in this rapidly changing environment is imperative and may include updating or disavowing prior guidance depending on the situation. It is also important to signal clearly when an issuer expresses an opinion or belief about the virus' potential impact (*e.g.*, say "we believe"), as opinion statements often are afforded greater protection against securities claims than pure statements of fact. (See "Impact on Public Company Disclosures and Other Considerations.")

Commercial Agreements Implications

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The global economic and regulatory impacts of the coronavirus are likely to create significant ramifications for many companies' commercial agreements. Some companies already are asserting that the outbreak constitutes a *force majeure* event or gives rise to another legal basis excusing nonperformance. The impact of the virus on a particular business and under a particular contract will be fact-specific and depend on the contract's specific provisions.

The circumstances may require a company to:

- Review and evaluate which contracts may be affected by the coronavirus and identify relevant clauses, such as:
  - representations/warranties
  - covenants
  - conditions precedent
  - *force majeure* clauses or "material adverse event" clauses
  - clauses relating to a "change in law"
  - notice requirements
  - termination rights and conditions
  - dispute resolution provisions;
- Assess whether the circumstances and applicable law permit any party to assert any basis for avoiding or pausing performance under the contract;
- Review whether applicable notice or other provisions exist within the contract that may need to be triggered in order to assert the contractual right or defense;
- Analyze the potential consequences of a breach and/or default;
- Formulate a plan for managing communications with counterparties, bearing in mind that strategic considerations may be involved when deciding whether to take certain steps;
- Understand local regulatory actions, including by reviewing existing regulations (*e.g.*, on health and safety) and monitoring new edicts in real time to determine whether they require the company to take steps or make decisions that may affect contractual commitments;
- Consider whether financial contracts or debt instruments may be affected, and whether such contracts may require "prompt" notice of a material adverse event or permit the lender to accelerate payment obligations and/or declare an event of default; and
- Consider whether insurance may cover any losses suffered due to the coronavirus outbreak.

As an example of the type of clause that may be relevant, a joint venture agreement may require all shareholders to use their "best efforts" to promote the business of the joint venture and/or require periodic capital contributions or supply commitments. A shareholder who is impacted by the coronavirus outbreak may face arguments from the other shareholders that it failed to fulfill one or more of these obligations, thereby triggering the remedies provided under the agreement for an "Event of Default." These remedies could include, for example, a forced sale of the allegedly breaching shareholder's shares.

The contract review described above and any actions undertaken may require global or multijurisdictional coordination in order to ensure a consistent response, and a company's response may be fluid depending upon the changing regulatory and health/safety circumstances. For additional details on these types of issues, see our February 26, 2020, mailing, "Coronavirus/COVID-19: Implications for Commercial and Financial Contracts."

Revisiting Virtual Annual Meetings

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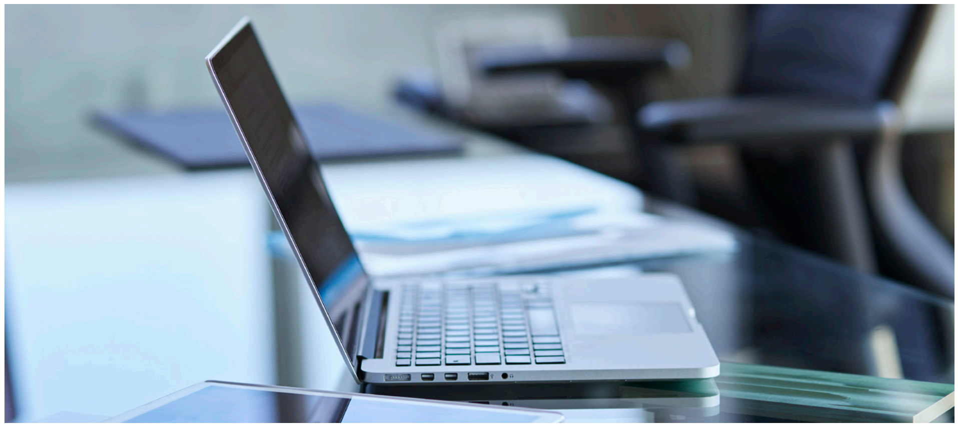


According to Broadridge Financial Solutions, Inc., 326 companies held virtual annual meetings using Broadridge's platform in 2019, an increase of 15% from 2018. On one hand, this increase represents the growing acceptance of the virtual meeting format. On the other, the total number of companies represents a small percentage of U.S. public companies, reflecting in part skepticism among some investors regarding whether technology is being employed as a barrier between directors and shareholders and in part companies' desire to stick to what has worked well.

Over the coming weeks, many companies will finalize their annual meeting proxy statements. Given the outbreak of the coronavirus — and related limitations on travel and personal preferences to avoid large gatherings — some companies may consider holding a virtual-only shareholder meeting (or a hybrid meeting permitting both in-person and online attendance). In addition to logistical considerations relating to holding a virtual annual meeting and the possibility for greater shareholder participation, companies should consider, among other matters, state corporate law, stock exchange requirements, the company's corporate governance documents, proxy statement disclosure and investor relations considerations.

State Corporate Law

The starting point for a company is to consider the laws of the state in which it is incorporated. The majority of states, including Delaware, permit companies to hold virtual-only shareholder meetings. Some states, such as New York, permit hybrid annual meetings, with the virtual component supplementing a required in-person annual meeting, and other states require a physical meeting to be held.

Stock Exchange Requirements

The New York Stock Exchange requires that companies hold an annual meeting and does not limit or impose conditions on the ability to hold a virtual meeting. Nasdaq permits virtual meetings, noting the importance of providing shareholders the opportunity to ask questions of management at the meeting.

Corporate Governance Documents

For a company incorporated in a state that permits virtual annual meetings, the company should review its governance documents, in particular the bylaws, to confirm that a physical meeting is not required. In some instances, a simple bylaw amendment may be needed to permit a virtual meeting.

Proxy Statement Disclosure

A company holding a virtual meeting will need to disclose in its annual proxy statement how shareholders can access and participate in the meeting. Proxy disclosure also often addresses the ability to submit questions in advance of the meeting, the availability of technical assistance, whether a replay of the meeting will be available and whether answers to questions not addressed during the meeting will be posted online. Companies often disclose the rationale for choosing to hold a virtual annual meeting.

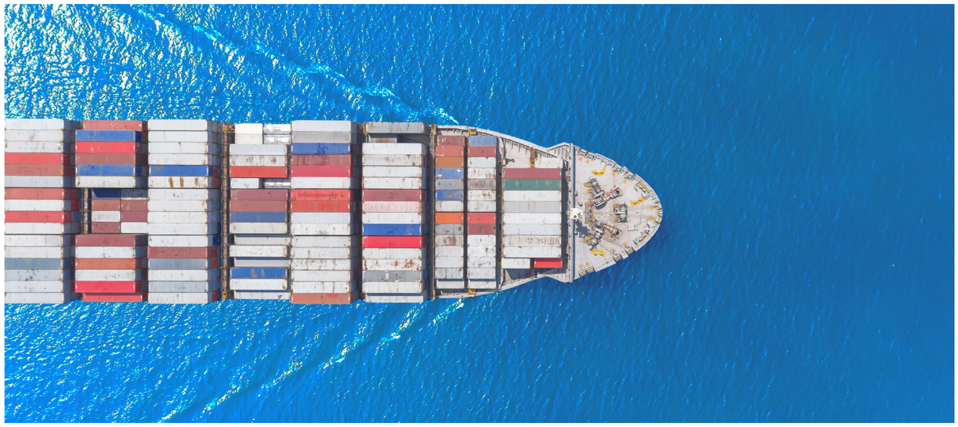
Proxy Advisory Firms and Investor Groups

Currently, ISS does not have a formal policy on virtual shareholder meetings in its U.S. guidelines. Glass Lewis adopted a policy on virtual shareholder meetings in 2019 providing for adverse voting recommendations against director nominees who serve on the governance committee of a company that holds virtual-only meetings without sufficient disclosure about shareholder participation rights. Such disclosure would include:

- procedures for allowing shareholders to vote during the meeting;
- location of posted questions and answers; and
- instructions on how to access the virtual meeting platform.

Companies should also note that, generally, most investor groups have opposed virtual-only meetings of shareholders while acknowledging the potential benefits of supplementing in-person meetings with virtual meetings. In this regard, in 2017 the New York City Comptroller began to vote against all incumbent directors of governance committees subject to election at virtual-only meetings, stating that virtual meetings deprive shareholders of the opportunity to engage with senior management and directors face-to-face at least once per year. The Council of Institutional Investors and California Public Employees' Retirement System also have opposed virtual-only meetings. Whether investors that are generally opposed to virtual-only meetings suspend those views during the coronavirus outbreak remains to be seen.

Restructurings Could Increase Amid Supply Chain Disruptions



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The coronavirus outbreak has hit global supply chains hard and could result in an uptick in restructuring activity in 2020. China, the world's largest exporter, has placed work and travel restrictions on more than half a billion people to help contain the spread of the virus, which in turn has had severe repercussions on manufacturing and transportation activities throughout the country. Dun and Bradstreet estimates that around 22 million businesses in the region — or 90% of all active businesses in China — have been impacted by the coronavirus, and that more than 50,000 companies around the world have one or more direct or tier 1 suppliers in the region. Given China's central role in the global economy, COVID-19 could result in massive supply chain disruptions around the world.

Valeritas Holdings, Inc. provides a recent example of the impact of the virus on global businesses. Valeritas, a commercial-stage medical technology company headquartered in New Jersey, filed for bankruptcy in February, citing a supply chain disruption exacerbated by coronavirus as one of the catalysts. Like many global companies, Valeritas' flagship product, an insulin patch for adults with Type 2 diabetes, is manufactured in China; the company's primary suppliers are also in China. Valeritas' supply chain was shut down during the Lunar New Year holidays, and the Chinese government extended the shutdown due to the coronavirus epidemic. The work stoppage worsened a supply chain problem that started in December 2019, substantially reducing Valeritas' inventory levels and in turn negatively impacting the company's liquidity and leading to a Chapter 11 filing. Valeritas' global supply chain problems are not unique. Thousands of companies, in particular in the automotive, electronics and pharmaceutical industries, remain exposed to massive supply chain disruptions if the virus continues to spread.

On a macro level, the impact of the virus on global supply chains has increased the risk of a recession in 2020. The global stock market plunged during the week of February 24-28, 2020, with the S&P 500 Index and Dow Jones Industrial Average each suffering their worst weekly losses for stocks since the 2008 financial crisis. Global interest rates are dropping amid fears of the virus, and on March 3, 2020, the Federal Reserve lowered the federal funds rate to a range of 1-1.25%. With rates close to 0%, economists fear that the Federal Reserve has little room to maneuver if the economy worsens.

Uncertainty in Leveraged Financings

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The uncertainty created by the coronavirus could impact borrowers' ability to forecast future business performance and lenders' ability to predict market conditions, which will affect the terms of any new commitments. In addition, the business disruption caused by the virus could impact borrowers' ability to comply with covenants in their existing credit agreements.

New Commitments

Given the uncertainty, a borrower or sponsor seeking a new financing commitment should pay particular attention to any financial covenants included in the terms of the financing. Borrowers and sponsors may seek additional cushion to their current models when setting covenants in order to be better prepared to absorb any business impact of the virus. In addition, companies in industries that are deeply affected may require longer covenant holidays so that compliance is not required in the near term. We also anticipate that lenders will carefully consider market flex provisions given the expected volatility in the markets as a result of the coronavirus.

Existing Credit Agreements

Any borrower with an existing credit agreement will need to review its ability to comply with existing covenants and may need to seek amendments or short- to medium-term financial covenant waivers to address disruptions in its business. In addition, given increasing travel restrictions, financial reporting may be impacted if boards have to reschedule meetings or accountants are unable to obtain necessary access for their reviews. Borrowers also will need to carefully review their representations and warranties, including any "no material adverse effect" representations, in light of the impact of the virus on their businesses. In order to constitute a material adverse effect, an event must generally be both significant and durational. While the durational impact of the coronavirus remains unknown, companies in affected industries should continue to monitor its impact on their ability to perform under existing loan agreements.

Equity Derivatives and Market Volatility

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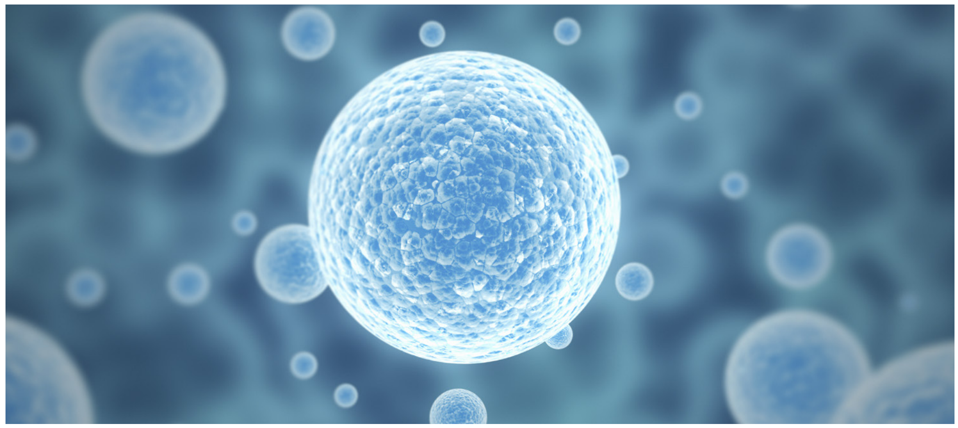
As the coronavirus outbreak continues to impact the capital markets globally, volatility in the markets and declining stock prices present new challenges.

Equity derivatives, including issuer derivatives such as call spreads, capped calls and ASRs (accelerated share repurchase programs), are impacted by both short- and long-term market movements and are sensitive to changes in volatility and other market conditions. These instruments typically include provisions triggered by various market disruption events, such as trading disruption, exchange disruption and early closure of the relevant stock exchanges, all of which may affect the value of such instruments and result in changes to their terms or mechanics of settlement. Similarly, margin loans, which incorporate many equity derivatives elements, may also be impacted by significant market movements, including market-wide events. For example, a stock price decline may result in margin calls or mandatory prepayments — regardless of the creditworthiness of the borrower or the long-term fundamentals of the issuer of the pledged shares.

Given declining stock prices, companies may seek to repurchase shares at favorable prices or, to support the price of their stock, may wish to engage in open market repurchases. Open market purchases are typically somewhat limited, however, because companies usually avail themselves of securities laws safe-harbor provisions, which impose volume limitations in the case of purchases in accordance with Rule 10b-18 under the Securities Exchange Act. Structured buyback programs are priced taking into account volatility-based considerations, making them unique among monetization options in the current market volatility. Because of their relatively long-term nature, however, such buyback programs may not be well-suited to capture short-term stock price movements. At the same time, equity tender offers, which are often disfavored compared to other stock buyback methods, may present a relative advantage in the current market environment given their relative shorter term.

Challenges for Life Sciences Companies



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COVID-19 creates potential issues on several fronts for life sciences companies and their interactions with the U.S. Food and Drug Administration (FDA). First, many of the drugs and devices sold in the U.S. are manufactured using components and raw materials sourced in China. As Chinese production is slowed — or Chinese imports into the U.S. are denied entry or slowed on public health grounds — many pharmaceutical and device manufacturers face the prospect of interrupted production of finished product. Shortages of life-saving drugs trigger government reporting obligations, and efforts to identify alternative sources of raw material and/or finished medical products will raise complex regulatory issues related to licensure, supply chain and manufacturing compliance. Potential shortages may also exacerbate current political tensions surrounding the prospect of importing prescription drugs and other medical products from non-U.S. sources, including Canada.

In addition to these challenges, shortages also create significant issues for other entities in the health care system, from governmental public health agencies to hospitals, pharmacies and wholesale distributors. These include securing the drug supply chain, ensuring that adequate testing is available, preventing price gouging and grey market diversion of therapies intended to treat the virus, and addressing potential hoarding of such therapies by local health systems or wholesale distributors. In an effort to facilitate more coronavirus testing locations, on February 29, 2020, FDA issued, effective immediately, guidance titled, "Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency." This guidance describes an accelerated policy enabling laboratories to use tests they develop faster in order to achieve more rapid testing capacity in the United States, and it is likely to raise questions from the regulated companies that develop diagnostics.

Moreover, as the specter of a global outbreak increases, life sciences companies may rush to be part of a therapeutic solution. A group of biologics companies is now working with the federal government to develop a vaccine, and the exigencies in finding one will likely trigger complex legal questions related to Emergency Use Authorization, licensing and intellectual property. Similar questions/issues are likely to arise for the pharmaceutical and device industries. Finally, life science companies may want guidance navigating the specific claims that may be made for current products in light of the potential outbreak. For example, companies will have significant incentives to make coronavirus-specific claims for devices (like surgical masks) and medicines that may address symptoms. All of these issues implicate complex regulatory requirements that companies must be prepared to address.

Employment Considerations

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The outbreak of the coronavirus in the United States and internationally presents a number of employment-related considerations. Employers should prioritize the health- and safety-related impacts on the workforce. The U.S. Occupational Safety and Health Administration (OSHA) requires employers to maintain a workplace that is "free from recognized hazards that are causing or are likely to cause death or serious physical harm." Employers should continue to monitor coronavirus updates from OSHA as well as the World Health Organization and the U.S. Centers for Disease Control and Prevention (CDC). The CDC provided interim guidelines in February 2020 that, among other things, advise employers to: actively encourage employees with symptoms of acute respiratory illness to stay home, not require a health care provider's note from employees who are sick with acute respiratory illness to validate their illness or return to work (as medical facilities may not have capacity to provide such notes), maintain flexible sick leave policies, separate and send home employees who appear to have acute respiratory illness symptoms, perform "routine environmental cleaning," advise employees before traveling to take certain steps and check CDC travel notices and guidelines, and consider creating an infectious disease outbreak response plan.

Some employees may be entitled to leave under state or federal Family Medical Leave Acts if they or a family member become ill. In addition, some jurisdictions provide for paid sick leave. All employers should actively consider revising leave policies, at least temporarily, to allow for additional time to address situations in which employees or their family members have coronavirus or symptoms of acute respiratory illness, or employees are otherwise at a certain level of risk of contracting the coronavirus because of travel or other exposure. Employers also should actively consider allowing any such employees to work remotely, to the extent they can perform regular job duties remotely, and requiring or allowing substitute work from, and/or providing other reasonable accommodations to, employees who cannot perform regular job duties remotely because their physical presence at work is required. In this context, employers should also consider the impact of the Americans With Disabilities Act and similar state laws for employees who may be disabled. Likewise, if an employee does become ill, employers must consider how they will communicate this information to potentially exposed employees while protecting the privacy of the employee with the virus. Employees who contract the virus while on business travel or at work may be entitled to benefits under workers' compensation insurance.

At all times, employers must ensure that they do not discriminate against employees on the basis of a legally protected class, including race, color and national origin, which includes implementing workplace policies and practices impartially and consistently.

Managers and supervisors should be trained about such policies and practices and the employment-related implications of coronavirus on such policies and practices. Managers and supervisors, as well as the broader workforce, should be fully and regularly informed about any existing and updated policies, programs and practices that may be impacted by the virus.

Cybersecurity Concerns

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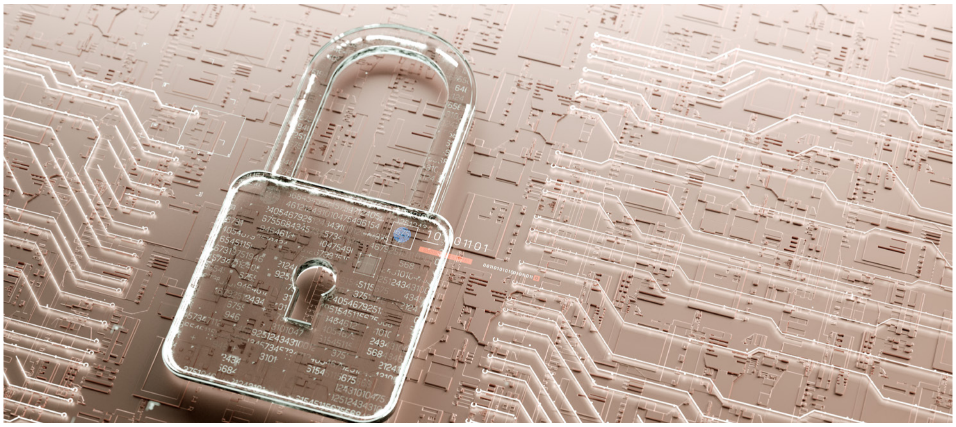

With the potential for additional governments to require or recommend office closures and to close schools in order to prevent or slow the spread of the coronavirus, many companies may decide to implement or expand employee work-from-home programs. While these programs allow for business continuity, they also pose increased cybersecurity risks by creating several additional avenues for unauthorized access to company systems and information. As such, companies must review what cybersecurity controls are in place, or need to be supplemented, prior to initiating or significantly expanding remote working technology. For example, best practices require implementation of two-factor authentication for accessing company networks and webmail and encryption on laptops and mobile devices. Companies should ensure adequate physical security and access controls for information technology assets during preparations for extended office closures.

Employers also should warn their employees that malicious actors will use this opportunity to increase targeted phishing attacks. This might include emails that purport to include medical updates or are "important notices" for those working remotely.

Additionally, policies that govern the acceptable use of company systems and devices as well as the transfer and storage of company information are essential. Employees working remotely are more likely to forward company information to personal email accounts or to store information on unprotected laptops or other devices. Therefore, training or reminders about such policies is critical in the potentially chaotic time of office closures or when employees are working remotely. The ease of using personal services and devices coupled with insufficient cybersecurity protections or noncompliance with company data retention policies can create significant risks of data leakage or unauthorized access.

Finally, companies should be mindful of applicable privacy laws when collecting information about employees or clients they might not have previously collected, such as health information and travel itineraries.

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