

RESPONDING TO CORONAVIRUS: TEN AREAS THAT SHOULD BE TOP OF MIND FOR IN-HOUSE COUNSEL

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Welcome



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CURRENT STATE OF PLAY

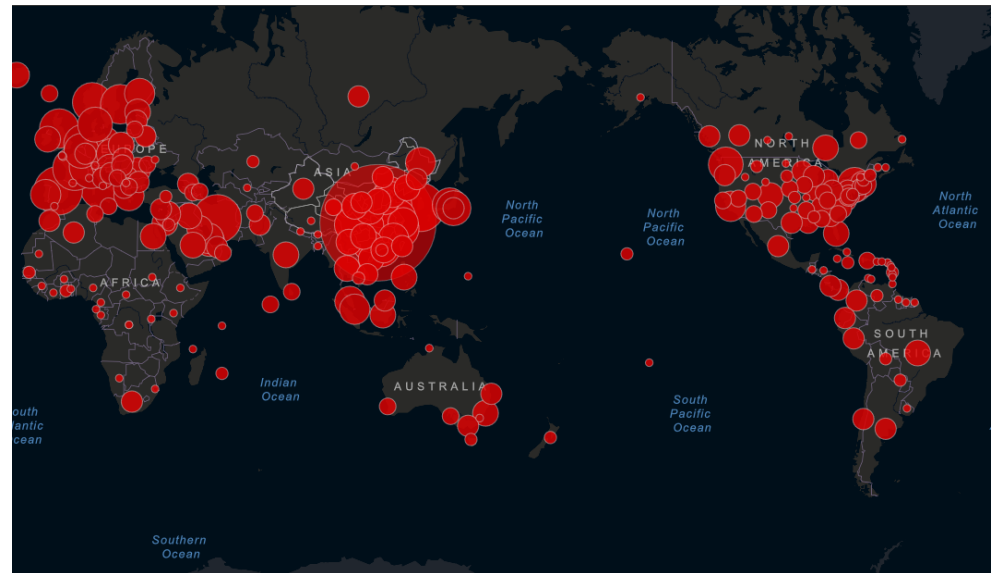
Global Statistics

✓ Total Confirmed Cases: 205, 452

- China: 81,002
- Italy: 31, 506
- Iran: 17, 361
- South Korea: 8,413
- Spain: 13, 910

✓ Total Deaths: 8, 248

✓ Total Recovered: 82, 091

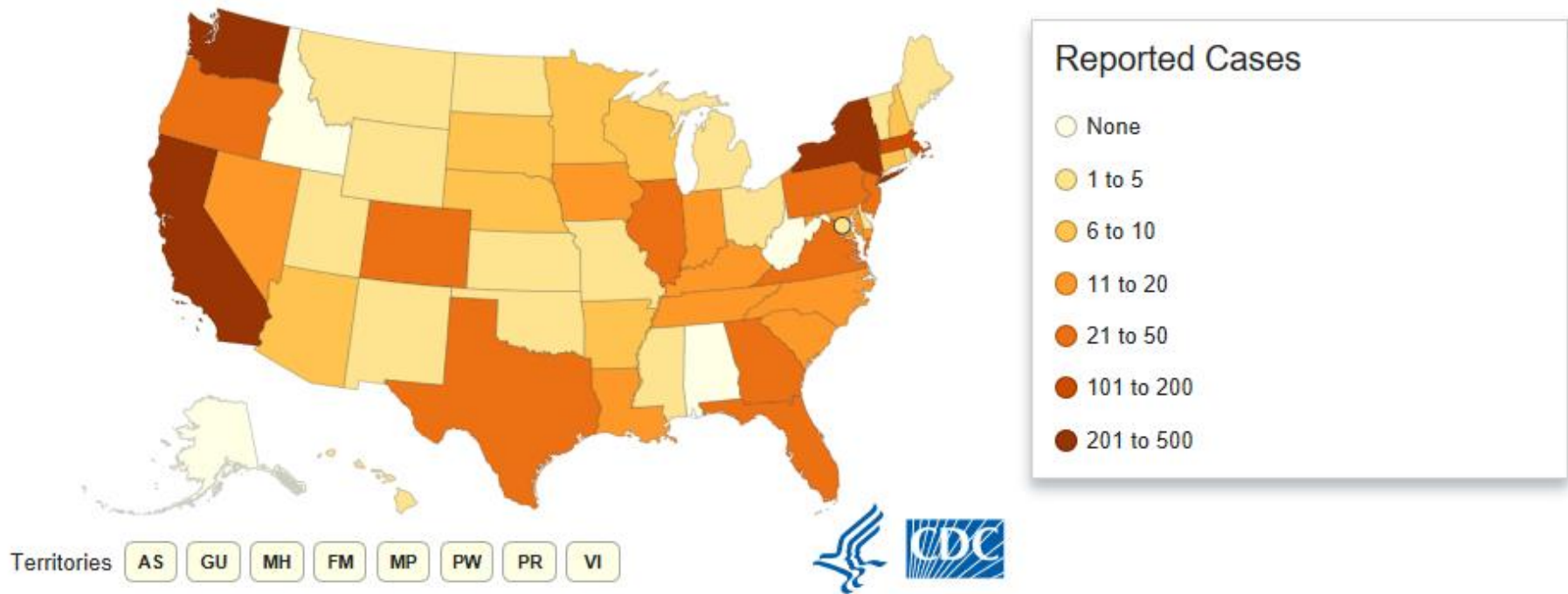


Remember that the numbers are changing rapidly, as increased availability and use of test kits uncover additional cases.

Source: Coronavirus COVID-19 Global Cases by Johns Hopkins CSSE (last updated March 18, 2020)

U.S. Confirmed COVID-19 Cases

Over 4,226 confirmed U.S. cases – 100 deaths



Sources: Coronavirus COVID-19 Global Cases by Johns Hopkins CSSE (last updated: March 18, 2020)
Centers for Disease Control and Prevention (last updated: March 18, 2020)

Webinar Roadmap

1. Crisis Management: The Basics

- ✓ Five-Step Checklist
- ✓ Best Practices

2. Employment

- ✓ Employment Law Issues
- ✓ Guidance for Employers

3. Privacy

- ✓ Privacy Considerations
- ✓ Privacy Safeguards

4. Tort Liability

- ✓ Duty to Warn
- ✓ Marketing Claims
- ✓ Common Question

5. Life Sciences

- ✓ FDA: Supply Chain and Shortages
- ✓ FDA: Product Safety
- ✓ FDA: Diagnostic and Treatment Innovations

6. Contracts

- ✓ Commercial Contract Issues
- ✓ Action Items on Contracts

7. Cybersecurity

- ✓ Remote access vulnerabilities
- ✓ Preventive measures

8. Securities + Financial Regulation

- ✓ Disclosure obligations
- ✓ Insider trading

9. Fraud/Corruption Risks

10. Government Contracts

Recap: Global Perspectives

- ✓ Lessons learned



CRISIS MANAGEMENT: THE BASICS

Crisis Management: Five-Step Checklist

Step One: Determine Who Will Be Responsible for Making Decisions and Coordinating Your Response

- ✓ Once you identify both an individual leader and a supporting team, members of your company will know who they should listen to about the unfolding crisis – consider creating a “RACI” chart to assign roles and responsibilities.
- ✓ This will increase effectiveness and mitigate the prospect of and harm caused by conflicting messages and misinformation.

Step Two: Assess the Situation and Develop a (Flexible) Plan of Action

- ✓ While you should respond as quickly as possible, it is important not to rush.
- ✓ Take time to learn the facts and develop a flexible plan based on what you know and what you know could change.

Crisis Management: Five-Step Checklist

Step Three: Act Decisively

- ✓ Begin to take action consistent with your plan.

Step Four: Create Clear Communication Channels

- ✓ Designated communication lines for incoming and outgoing communications will make executing your plan and managing workforce and public expectations easier.
- ✓ You will be able to deliver updates and reduce panic and confusion.

Step Five: Remain Adaptable

- ✓ The facts will change, and so should your response. Be sure to remain open to changing your plan as events unfold.

Crisis Management and Coronavirus

Best Practices and Key Things to Do

Leadership

Ensure clear responsibilities for both crisis response and day-to-day operations

Communication

Speak in a coordinated way with a consistent message across different audiences

Contracts

Begin looking at contracts and anticipating disputes and supplier delays

Disruptions

Review business continuity plans and alternatives in case facilities close or vendors go offline



EMPLOYMENT

Employment Law Issues

Work Place Health and Safety Regulations

- ✓ Review policies and practices to ensure compliance with the Occupational Safety and Health Administration (OSHA) standards (or the state or local equivalent).
- ✓ Coronavirus is a “recordable illness” that should be reported in accordance with the OSHA Injury and Illness Recordkeeping and Reporting Requirements.

Workers' Compensation Laws

- ✓ Generally, exposure through work should be covered by workers' compensation and should not result in other liability for employers.
- ✓ Exposure resulting from non-compliance with OSHA standards could lead to an enhanced award not covered by workers' compensation insurance.

Employment Law Issues

Employment Discrimination Laws

- ✓ As the Centers for Disease Control have stated:
 - ✓ “Do not make determinations of risk based on race or country of origin, and be sure to maintain confidentiality of people with confirmed Coronavirus infection.”
- ✓ Be mindful of the possible need to provide accommodations under the Americans with Disabilities Act (ADA) and similar state laws.

Labor Laws

- ✓ Employees working in concert or on behalf of others based on ascertainable objective evidence are protected from discrimination or retaliation under the National Labor Relations Act

Employee Attendance

- Voluntary Leaves
 - Family Medical Leave Act (and state equivalents)
 - State Paid Family Leave and Medical Leave Acts
 - State or Local Sick Leave
 - Employer vacation, paid-time-off, and sick leave policies
 - Americans with Disabilities Act Accommodations
- Mandatory Leaves
 - Travel from high risk areas, displaying symptoms, or worksites at risk of exposure
 - Worker Adjustment Retraining Notification Act (“WARN”) and state equivalents
- Paying for Leave
 - Exempt vs. Non-Exempt Employees
 - State Income Supplementation
- Mandatory Attendance
 - Symptomatic vs. Asymptomatic Employees
 - Anti-retaliation and discrimination laws

Working From Home

Employers may encourage employees to work from home to control infection but should consider the following issues:



Families First Coronavirus Response Act

H.R. 6201

- Pending Senate Approval
- Emergency Family Medical Leave Expansion
 - Fewer than 500 employees
 - 12 weeks leave, first two possibly unpaid, remainder 2/3 regular pay
 - Coronavirus related public health guidance to self-quarantine, quarantine family member, or coronavirus related school or child care provider closure
 - Job reinstatement unless 25 or fewer employees
 - No mandatory substitution of other leaves
- Emergency Paid Sick Leave
 - Fewer than 500 employees (private companies), 1 or more (public agencies)
 - 80 hours (or average pay for 2 weeks if part-time)
 - Full pay or 2/3 if caring for family member or child
 - Self-quarantine or diagnosis, family member quarantine or diagnosis, or coronavirus related school or child care provider closure
- Financial Assistance

Employer Liability

- **Workers' Compensation**
 - **Exceptions**
 - **California**
 - Conduct that exceeds the risk inherent in the employment relationship
 - Violations of public policy
 - Serious and willful enhancements for violation of health and safety standards or orders, or other knowing or reckless exposure to risk
 - **Other Jurisdictions (e.g., NY and WA)**
 - Intentional torts with the desire to cause harm
 - **Independent Contractors**
 - Some states allow businesses to elect to cover non-employees through workers' compensation, such as independent contractors, if all parties consent



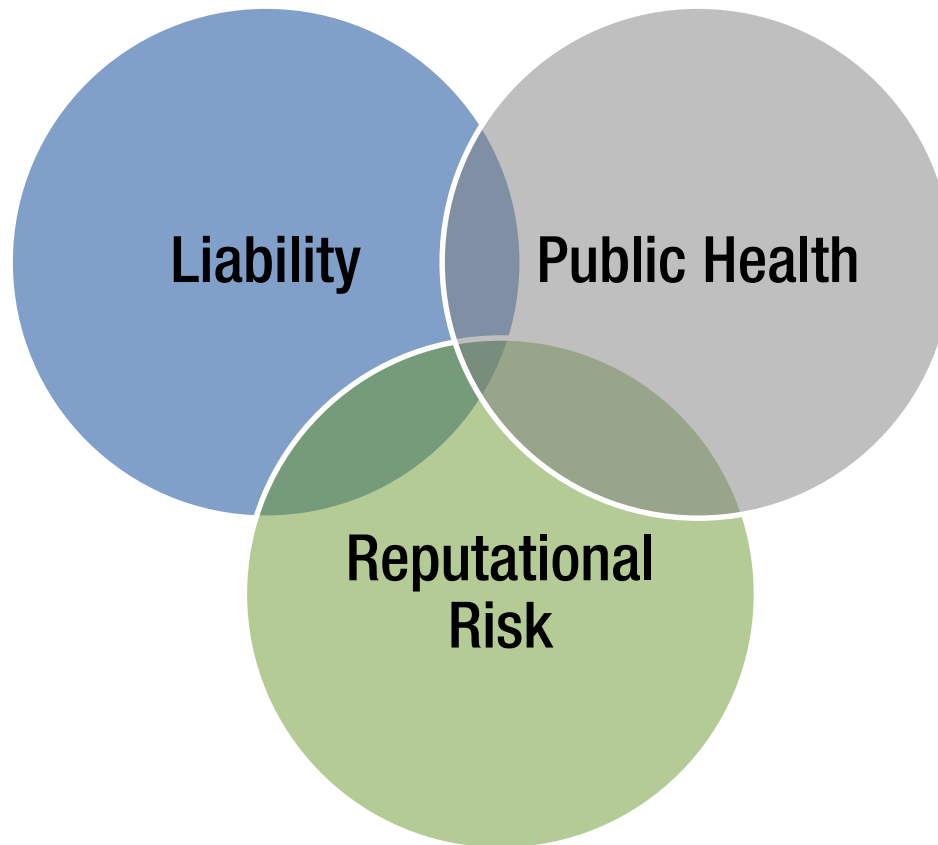
Best Practices for Employers

- ✓ Encourage sick employees to stay home.
- ✓ Employers may also wish to:
 - ✓ Prohibit or restrict business travel to or from high-risk areas
 - ✓ Limit non-essential travel
 - ✓ Postpone large gatherings, use telecommunications as an alternative
 - ✓ Reduce non-essential contact with business partners and clients
 - ✓ Educate employees about risks and precautions, as recommended by public officials
 - ✓ Recommend, or require, that employees with elevated risks of exposure work remotely
 - ✓ Permit other sick and high-risk individuals, such as those with other medical conditions, to work remotely, take time off, or work flexible hours as reasonably necessary
 - ✓ Regularly clean commonly used surfaces
 - ✓ Provide employees with sanitation resources, such as tissues, surface wipes, and trash receptacles
- ✓ Several companies have publicly announced policy changes which others may look to as potential industry specific best practices



Assessing Specific Activities

Evaluating Whether to Go Forward with Specific Activities





PRIVACY

What are the Privacy Considerations?

Legal restrictions on health-related inquiries or exams by employers

- ADA and state medical confidentiality laws (e.g., CMIA)
- HIPAA, where acting as a covered entity for group health plans
- Common-law privacy claims

Other HR considerations

- Protecting confidentiality to encourage other employees to self-report
- Communicating with workforce to maintain trust and promote health and safety
- Preventing discrimination or harassment

Risk of future backlash/claims if employer seems in hindsight to have failed to protect employee privacy

General Principles Under the ADA

ADA generally prohibits medical examinations or inquiries of employees

- Inquiries: questions likely to elicit information about a disability
- Medical examinations: procedure or test that seeks information about an individual's physical or mental health

Exception if employer has reasonable belief, based on objective evidence, that:

- Employee's medical condition will impair ability to perform essential job functions, or
- Employee will pose a direct threat due to a medical condition



What Is a Medical Exam or Inquiry Under ADA?

Likely to be a medical exam/inquiry under the ADA:

- Taking the temperature of employees entering the workplace
- Requiring employees to take their own temperature and self-report it
- Asking if an employee has been diagnosed with COVID-19
- Asking if an employee has medical conditions that may compromise the employee's immune system or make the employee more vulnerable to COVID-19
- Requesting a doctor's note or test verifying an employee does not have COVID-19

Likely not to be a medical exam/inquiry under the ADA:

- Asking an employee about symptoms of a cold or seasonal flu
- Asking an employee about where he/she recently traveled
- Requiring a doctor's note merely verifying an employee is fit to return to work, under standard company policy
- But note advice from health officials re: burden on healthcare system

Remember that ADA is just one consideration in privacy analysis

What Can Employers Ask?

Inquiries about where
an employee has
traveled in past 14
days?

Requests to self-
report diagnosis of
COVID-19?

Inquiries of employees
returning from sick
leave?

Requiring medical exams
or doctors' notes?

Taking temperature of
employees visiting the
office?

What Can Employers Disclose to Coworkers?

Both EEOC and CDC have cautioned about the need to protect confidentiality under the ADA

ADA requires specific confidentiality measures

- Maintaining medical information in separate confidential medical files
- Limiting disclosures

General principles:

- Avoid revealing the identity of the affected employee to coworkers
- Maintain medical information separately, outside of usual HR files
- Restrict access on needs-to-know basis, consistent with ADA



Privacy Safeguards

Steps to help avoid inquiries or actions that may run afoul of privacy laws:

- ✓ Develop internal FAQs based on job role
- ✓ Maintain and enforce standardized procedures requiring centralized approvals for inquiries related to potential exposure or vulnerability to coronavirus
- ✓ Restrict access to such information on an appropriate need-to-know basis
- ✓ Identify regional counsel to provide time-sensitive assistance on local country/state privacy law requirements



TORT LIABILITY

Tort Liability: Duty to Warn

Failure to Warn

- ✓ Common-law duty of care and duty to warn of known, or reasonably knowable, risks
- ✓ Potential duty to warn where exposure to COVID-19 is reasonably foreseeable

Potential Scenarios Where Duty to Warn May Arise

- ✓ **Employee interacts with products** has COVID-19 (*e.g.*, food stations)
- ✓ **Employee had close contact clients/customers** has COVID-19 (*e.g.*, cashier)
- ✓ **Products used in the healthcare industry**

Tort Liability: Marketing Claims

Products Associated with Protecting Against COVID-19

- ✓ Surgical masks, latex gloves, hand sanitizer, and household cleaning products

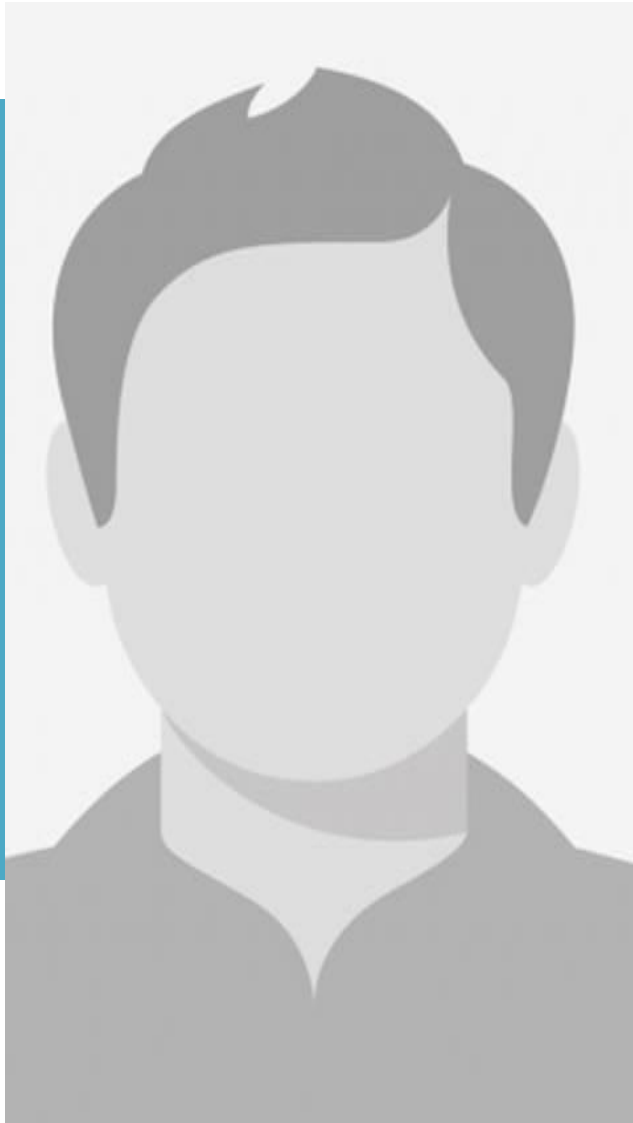
Marketing Claims Must be Substantiated

- ✓ “Truth in Advertising” laws cover false or misleading marketing claims
- ✓ Violations create exposure to enforcement actions and class action litigation

Claims that product can protect against COVID-19

- ✓ Likely false or misleading
- ✓ Retailers have begun contacting manufacturers/sellers about such claims
- ✓ Some product listings being removed from online retailer websites
- ✓ Regulatory agencies have also taken action to investigate and address fraudulent claims relating to coronavirus in products

Tort Liability: Common Question



“

My company is planning to host a small dinner in connection with a major sales conference. What is my liability if it turns out someone at the dinner has coronavirus and infects others? Is there anything I can do to mitigate my risk?

”

SMALL BUSINESS CEO



LIFE SCIENCES

FDA: Supply Chain and Shortages

FDA has strong supply chain authority and shortage management over the drug industry, but NOT over the medical device industry

- ✓ FDA has made requests of almost 200 drug companies since late January, with 20 of those focused on the availability of active pharmaceutical ingredients

- ✓ FDA contacted 63 Chinese medical device firms considered to have the essential devices

FOCUS IS ON FACILITIES IN CHINA AND REPORTS CONFIRM THAT SHORTAGES ARE DEVELOPING AND THERE ARE MATERIAL IMPACTS TO FACILITIES

Firms obtaining components or API from China should be actively engaging with their contractors to understand the impact and seeking to qualify alternative suppliers

FINISHED DRUG AND DEVICE MANUFACTURERS HAVE OBLIGATIONS UNDER GMP FOR SUPPLIER CONTROLS

Expect delays in supplier validations or annual reviews – could lead to FDA inspectional deficiencies in the future

FDA: Product Safety

All foreign inspections have transitioned to record requests or been postponed across all regulated product areas

- ✓ Foreign-based firms are still held responsible for compliance and quality
- ✓ Future focus of inspections will be on safety issues during the outbreak period

FDA collaborates with Customs and Border Patrol to inspect regulated products

- ✓ Relying on PREDICT screen tool for risk-based screening
- ✓ Firms with product claiming to address or prevent the virus should expect import holds

FDA created a cross-agency task force to address fraudulent claims

- ✓ “bad actors” “taking advantage” – claims to prevent, or treat, the virus or disease
- ✓ Retailers have been contacted and removal of online listings requested
- ✓ FDA reiterates that there are no approved drugs, over-the-counter products or devices with SARA-CoV-2, or COVID-19, approved claims (with exception of 2 EUA diagnostics)
- ✓ Manufacturers and distributors are cautioned against changing label or marketing claims without FDA authorization

FDA: Diagnostic and Treatment Innovations

Currently six tests authorized by FDA for COVID-19 detection

- ✓ Under Emergency Use Access (EUA) process
- ✓ EUA tests are real time Reverse Transcriptase polymerase chain reaction (PCR), designed to detect and measure RNA
 - ✓ Small amounts of DNA required (compare to molecular and genetic analysis)
 - ✓ Need to be conducted in high complexity laboratory
 - ✓ No point of care or home-testing mechanisms available

NO FDA APPROVED VACCINES OR THERAPEUTICS

NIH clinical trial utilizing Remdesivir, developed by Gilead Sciences – investigational broad based antiviral treatment (prior human testing for Ebola and SARS)

OPPORTUNITIES EXIST FOR FIRMS TO DEVELOP INNOVATIONS FOR DIAGNOSTICS OR THERAPEUTICS THAT CAN TAKE ADVANTAGE OF FDA'S CURRENT USAGE OF EXPEDITED DISCUSSIONS AND REVIEWS FOR PRODUCTS ADDRESSING COVID-19



CONTRACTS

Commercial Contract Issues: Key Topics

Conduct a review of contracts to understand your risks, obligations, and options:

Identify Affected Supply and Service Contracts

- ✓ Identify and prioritize key service and supply arrangements. Assess whether and how those might be affected. A systematic review of contracts is critical to understanding the risks, obligations and options.
- ✓ Do the contracts require a business continuity plan or resilience plan? Do they say anything that would affect your ability to have employees work remotely? Check the text of each key agreement to determine what contractual rights and obligations apply.

Material Adverse Change (MAC) and Force Majeure Clauses

- ✓ Start with the text of your agreement to determine if a force majeure or MAC clause is included. In general, if an objectively unforeseeable event – perhaps a public-health crisis – occurs, parties to a contract *may* be partially or completely exempt from performance.

“Frustration of Purpose” and “Impracticability”

- ✓ These are two common-law doctrines to keep in mind. Even if a force majeure clause is not included in your agreement, it is possible – albeit more challenging – to exempt contract performance in some circumstances.

Commercial Contract Issues: Key Topics

Notice

- ✓ Determine if, and when, you need to provide notice about delayed performance to any of the parties to your agreement

Insurance Coverage Contracts

- ✓ Review your insurance policies to determine to what extent your insurance might cover damages that result from the outbreak

Renegotiate

- ✓ If necessary, be prepared to amend the terms of existing contracts

* Remember to think about choice-of-law provisions and how relevant courts might interpret these concepts. *

Action Items on Contracts

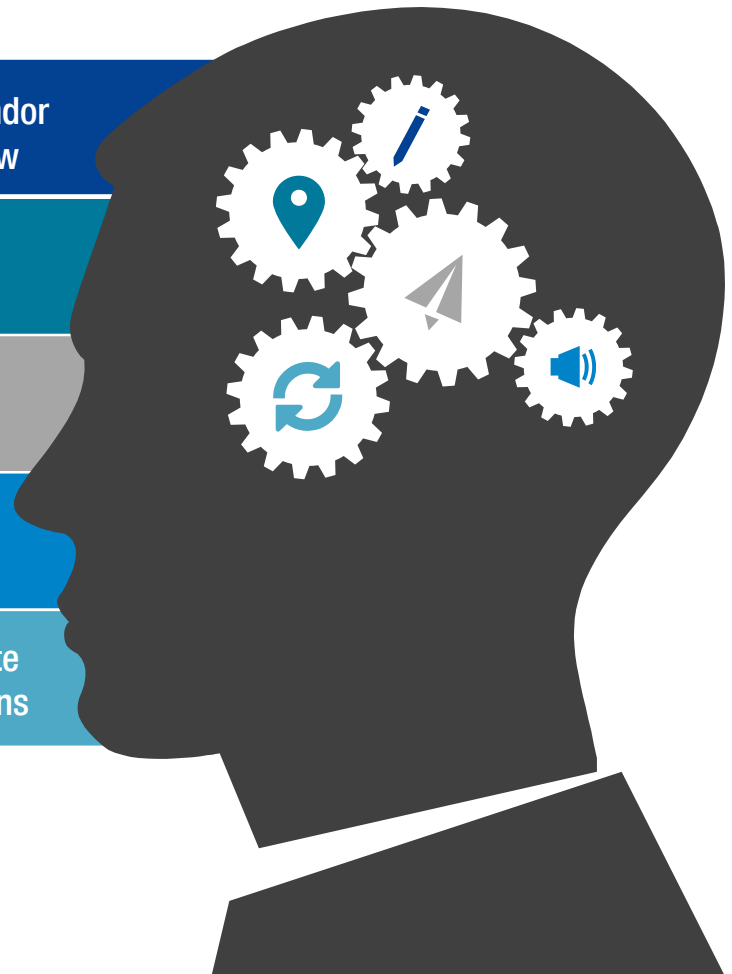
1 If you have standard customer or vendor agreements, have counsel review now

2 Consider engaging with key suppliers and counterparts to confirm performance

3 Understand, and track, your notice obligations under key contracts

4 Appreciate that in a volatile market, you may have leverage to renegotiate

5 Be prepared for litigation and anticipate needing counsel in relevant jurisdictions





CYBERSECURITY

Cybersecurity

- ✓ As the coronavirus spreads, more and more institutions are encouraging their workforce members to work remotely.
- ✓ First-time teleworkers and remote operations create a “target-rich environment” for cyber attackers.
- ✓ You should review and update your cybersecurity posture with the following in mind:
 - ✓ Remote operations will increase external access to your internal network
 - ✓ There may be disruptions to your IT team’s ability to serve your workforce
 - ✓ Physical security still matters
- ✓ Protect against coronavirus related phishing attempts





SECURITIES + FINANCIAL REGULATION

Disclosure Considerations for Public Companies

- ✓ A company must evaluate whether it has an affirmative disclosure obligation that would require the company to publicly address the risks and uncertainties arising from the Coronavirus.
- ✓ For upcoming SEC filings, such as Form 10-Ks and Form 10-Qs, the material risks and uncertainties arising from the Coronavirus may need to be addressed in risk factors, MD&A, and/or the subsequent event footnote to the financial statements.
- ✓ If developments with the Coronavirus make it possible that the company will miss its outstanding earnings guidance or analysts' expectations by a significant extent, it may be necessary for the company to consider a "pre-release" of the company's results or disclosure of revised guidance.

Insider Trading

Take Active Steps to Mitigate the Risk of Coronavirus-Related Insider Trading

- ✓ Assess insider trading policies to ensure they guard against trading on the basis of Coronavirus-related material, non-public information by *all* employees.
- ✓ Identify groups within your organization that have, or are likely to have, Coronavirus-related material, non-public information.
- ✓ Disseminate your organization's insider trading policies to all identified employees and require them to acknowledge receipt and review electronically.
- ✓ Consider whether additional preventative measures are warranted.
 - ✓ Special trading blackout periods
 - ✓ Restricted securities lists
 - ✓ Heightened pre-clearance procedures
 - ✓ Additional employee training

Remember that insider trading affects a broad range of organizations, including public and non-public companies.



FRAUD/CORRUPTION RISK

Fraud/Corruption Risks Presented by COVID-19

The business disruption occasioned by the outbreak of COVID-19 may uncover unrelated instances of embezzlement, fraud, and self-dealing affecting your organization and create new risks of bribery and corruption.



- ✓ Challenging economic conditions, unexpected closures, and re-assignment of roles can surface embezzlement, theft, and other misconduct.
- ✓ The slow down and disruption to business could increase the pressure on suppliers and sales teams to achieve targets.
- ✓ Company representatives could be solicited for bribes when they try to get access to emergency services (*e.g.*, to get evacuated from a high risk zone) or seek guidance from authorities.

Addressing Fraud and Corruption Risks

- Be alert for indications of “red flags” suggesting embezzlement, fraud, and weaknesses in internal controls.
- The following are best-in-class practices for ensuring continued commitment to compliance during this COVID-19 wave:
 - ✓ The priority must be ensuring that employees’ health and safety concerns are being addressed.
 - ✓ Messages and training from the compliance function will be more credible if employee welfare was prioritized first.
 - ✓ Use targeted communications to reinforce your existing compliance policies.
 - ✓ Work with senior executives and the board to ensure that business pressures do not overshadow the company’s commitment to compliance.
 - ✓ Encourage senior executives and managers at all levels to set the right “tone from the top”.
 - ✓ Consider temporarily lowering financial thresholds which trigger reviews of transactions, expenses, third-party deals, and other aspects of company business.
 - ✓ Ensure that the critical compliance functions can continue even if employees all work remotely.



GOVERNMENT CONTRACTS

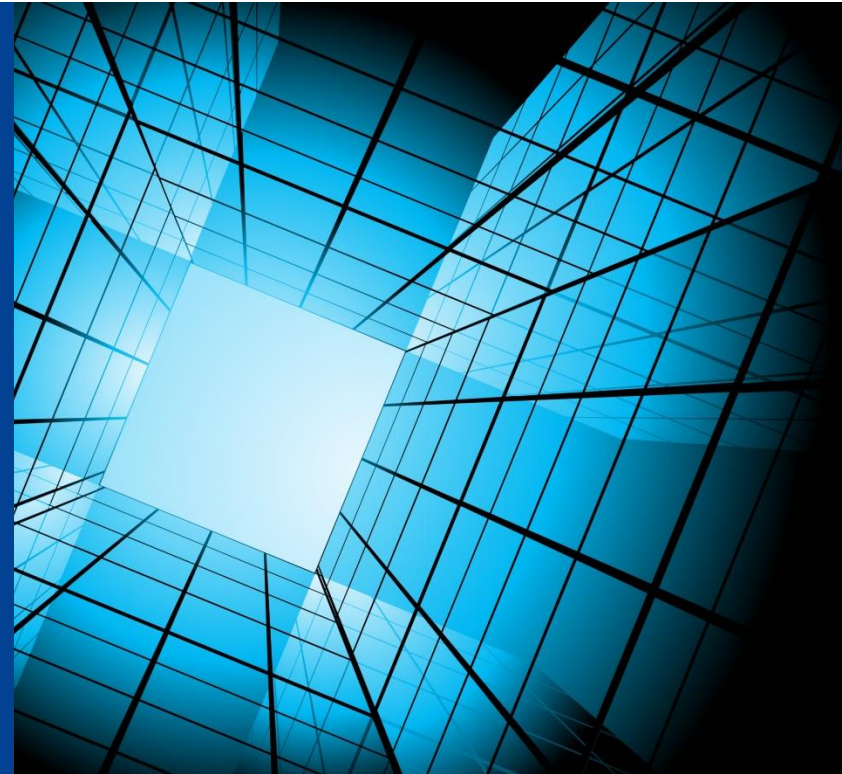
Issues for Government Contractors

- ✓ Government contractors are likely to be affected by Coronavirus, both in their own workforces and throughout their supply chains.
- ✓ Excusable delay provisions in the Federal Acquisition Regulation (FAR) allow for schedule adjustments where failure to perform is the result of epidemic or quarantine restrictions.
 - ✓ Contractors cannot be terminated for default when a failure to perform is out of its control (or the control of its subcontractor or supplier).
 - ✓ These provisions allow for a schedule adjustment, but they do not provide for price adjustments for increased costs, barring additional government direction such as a stop-work order.
- ✓ Defense Priorities and Allocation System (DPAS)-rated orders may require contractors, with both commercial and government contracts to supply certain goods or services to the government first.
 - ✓ May also allow contractors to claim priority in their supply chains for materials for DPAS-rated orders.

Issues for Government Contractors (cont'd)

FOR THOSE WHO ARE NOT GOVERNMENT CONTRACTORS:

Be aware that the federal government may use its authority under the DPAS to “cut in line” and obtain supplies and services related to the response (*e.g.*, protective equipment or medical devices) ahead of you.





GLOBAL PERSPECTIVES

Global Lessons Learned

The response of multi-national companies should be informed by the issues that have arisen across the globe during this crucial early period – and what that suggests for the period ahead.



CONTRACTS

Take the opportunity to consider your contractual arrangements and see how to best future-proof yourselves against similar incidents of this nature.

CRISIS MANAGEMENT

A reminder to stress test your crisis management approach – and to consider now how your organization would respond to a range of difficult scenarios.

LABOR & EMPLOYMENT

Consider your labor law obligations *globally*, as well as your internal processes and protocols to ensure compliance with the same.

Questions



Visit the Morrison & Foerster Coronavirus Resource Center at
<https://www.mofo.com/special-content/coronavirus>

Thank You!



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The background is a dark blue to black gradient, overlaid with a complex network of thin, light blue lines. These lines connect numerous small, glowing blue dots of varying sizes, creating a sense of depth and connectivity, similar to a molecular structure or a digital network map. The dots and lines are more concentrated in the upper right and lower right areas, with some fainter connections extending towards the left.

MORRISON
FOERSTER