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Mitigating Product Liability Risk in the Era of COVID-19

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Overview of issues surrounding mitigation of product liability risks posed by COVID-19

- Outlining potential product liability risks involving COVID-19.
- Practical advice and steps businesses can implement now to mitigate and defend against potential product liability claims related to COVID-19.
- Immunities provided by the PREP Act to businesses involved with covered countermeasures to COVID-19, along with a discussion of the Distribution of Limitations provisions.
- Recommendations to protect product manufacturers and distributors from potential price gouging allegations.

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Potential product liability risks of COVID-19

- Potentially successful product liability claims will likely be based on negligence as opposed to strict product liability.
- Strict liability will be a difficult sell (without immunity) in the era of COVID-19 unless the defendant business manufactured or sold a device (a) that was intended to prevent the spread of the virus, (b) that was defective when it left the business's control and (c) then failed to function as intended.

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What types of product liability claims might apply with respect to COVID-19?

- Product defect claims involving:
  - Marketing or advertising representations;
  - Alleged breach of warranties; and
  - Failure to warn.

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Product defect claims of failure to warn

- Failure to Warn:
  - The warning labels found on the product, packaging and owner's manual must be clear and concise.
  - The warning labels must explain all of the possible dangers and risks that may be associated with the use of the product, particularly those dangers that may not be immediately apparent to the consumer.

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Plaintiff's likely high hurdle of causation for a COVID-19 related product liability claim

- Causation: Difficult to prove in COVID-19 cases.
  - Virus spreads quickly and sometimes silently.
  - Not impossible to prove.

- Rebuttable Presumption: Some states have enacted laws creating a rebuttable presumption, for purposes of receiving workers' compensation benefits, that employees who test positive with COVID-19, contracted the virus at work.
  - Illinois' was revoked.

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Plaintiff's likely high hurdle of causation for a COVID-19 related product liability claim, cont.

- OSHA's Objective Standard: Under federal law, OSHA has stated that it will not enforce employers' recordkeeping requirements with respect to an employee having COVID-19 unless:
  - The employee tests positive for the virus, and
  - There is reasonably available objective evidence that the employee's illness is work-related.
  - E.g., a cluster of cases.

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Example of prior disease transmission case

- Example of Objective Standard: A court found that it was more probable than not that a person contracted West Nile virus from a mosquito bite at work, given the time spent at work during incubation.
- With COVID-19, we can expect courts assessing causation to take into account:
  - Incubation periods: no longer than 14 days.
  - Transmission modes: predominantly respiratory droplets (15 minutes of exposure), mainly indoors.
  - Surface stability: has evolved from 2-3 days to up to 7 days in some instances. Smooth surfaces = more stable.

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Evidence standards used by Plaintiffs in COVID-19 cases

- Example of Standard Used:
  - Plaintiff claimed he contracted COVID-19 at a particular location due to a disproportionate percentage of individuals at that location becoming infected.
- Applied to Products:
  - This same approach could apply to a product liability claim, where a defendant had a disproportionate number of persons who came into contact with a particular product.

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Use of scientific sampling to determine causation

- Scientific Sampling Standard:
  - In a Legionnaires' case, the court allowed an expert to opine on the source of the disease by matching the serogroup and subgroup of the particular Legionella bacteria found in the plaintiff with the bacteria found in a particular water source.
- This same approach may apply to COVID-19 via genomics.
  - If samples of the virus are available, one could sequence the genome of the virus from the product and compare it to the sequence of the genome of the virus in the plaintiff.
  - If the sequences are different, there would be a decent defense that the virus was not contracted from that product.
  - But, if the sequences are the same, the plaintiff has some ammunition for proving causation.
  - Additional mutations of the COVID-19 virus will make it harder to match.

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Advice to mitigate potential product liability claims related to COVID-19

- Steps to reduce marketing claims risks:
  - Carefully vet marketing materials.
  - Support marketing claims with sound science.
  - Due diligence suppliers and ensure that they are providing FDA approved products.
  - Follow all requirements for labels, marketing, advertising and promotion that are included in any Emergency Use Authorization. (E.g., face mask umbrella EUA).
  - Stay away from claims that your product protects against COVID-19.

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Advice to mitigate potential product liability claims related to COVID-19, cont.

- Steps to reduce breach of warranty risks:
  - Disclaim all express and implied warranties as appropriate under the law. (Do so conspicuously.)
  - Consider including a specific disclaimer regarding COVID-19.
    - Use the terms COVID-19, Sars-CoV-2 and the viruses mutating therefrom.
  - Consider excluding third-party beneficiary coverage from contracts to the extent allowed by law.
  - Be careful about claims as to effectiveness.

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Advice to mitigate potential product liability claims related to COVID-19, cont.

- Steps to reduce failure to warn risk:
  - For PPE, devices and drugs used to treat COVID-19, consult FDA guidance and consider providing specified warnings (E.g., umbrella EUA for masks).
    - Consider a specific warning: not intended to prevent, treat, cure, or mitigate the spread of SARS-CoV-2 (or any virus mutating therefrom) or COVID-19 (unless you have proper testing and FDA approval).
  - For test kits, consult FDA guidance and consider warning about false positives and false negatives.
  - For drugs and devices not intended or expected to be used with COVID-19, still consider warning about virus transmission based on surface stability.

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Advice to mitigate potential product liability claims related to COVID-19, cont.

- Steps to Reduce All Types of Claims
  - Guidance: Follow the CDC's, OSHA's and the FDA's evolving guidance. Courts will rely on this guidance to inform the standard of care in negligence lawsuits.
  - Immunity: Ensure that your product meets the requirements for immunity under the PREP Act and its companion Declaration.
  - Pre-Emptive Sampling: Consider taking environmental samples of COVID-19 that were present on your product and storing them under appropriate conditions.
    - Sampling and analysis must be performed by someone properly certified and credentialed.

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Advice to mitigate potential product liability claims related to COVID-19, cont.

- Recordkeeping: Keep detailed records regarding employees' work locations and time frames.
- Samples: Maintain numerous samples of manufactured product.
- Sick Employees: If an employee or contractor is suspected to have COVID-19 and is in the work environment, follow OSHA and CDC guidance, including immediate isolation of that individual.
- Insurance Notification: Notify insurers immediately.
  - Inform the insurance company you expect them to obtain all necessary information to defend a claim.

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Advice to mitigate potential product liability claims related to COVID-19, cont.

- Review Policies: Review your insurance policies and amend, if possible, to cover product liability scenarios involving COVID-19 exposure.
  - Assess your business interruption coverage and whether it extends to damages arising from closures necessary to address facilities impacted by COVID-19.
  - Look to exclusions relating to pollution or contamination to determine whether COVID-19 would fall within such exclusions.
- Contract Review: Evaluate supply chain risks and revise contracts with vendors and customers that allocate risk appropriately, including indemnifications.
  - If the current risk allocation is unsatisfactory, evaluate timing of renewals, ability to negotiate modifications and availability of alternative suppliers and vendors.

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Advice to mitigate potential product liability claims related to COVID-19, cont.

- Employee Training:
  - If your employees are handling products or packaging, consider requiring them to wear gloves and masks to increase the likelihood that product leaves your custody or control in a non-contaminated state. (Review OSHA rules.)
  - Train your employees regarding the protective hygiene measures set forth in the CDC's guidance.
- Other Legal Defenses:
  - Lack of duty
  - Defect not cause
  - Contributory/comparative negligence
  - Assumption of risk
  - Disclaimers of warranties
  - Substantial change

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Countermeasures and immunities provided by the PREP Act and HHS Declaration

- Immunity under the PREP Act and Declaration
  - The Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d, ("PREP Act") and accompanying March 17, 2020 Declaration ("Declaration") issued by the Secretary of Health and Human Services provides certain immunity for product manufacturers and distributors from legal action.
  - The PREP Act and Declaration must be read together.
- They provide that "covered persons" engaging in "recommended activities" are immune from suit from an individual that incurs a "loss" caused by the administration or use of a "covered countermeasure."
  - Covered Persons include manufactures and distributors, which are defined broadly.
  - Recommended Activities are "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures."

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Countermeasures and immunities provided by the PREP Act and HHS Declaration, cont.

- Covered Countermeasures must meet two requirements:
  - (1) They must be any antiviral, other drug, biologic, diagnostic, other device or vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or any device used in the administration of any such product, and all components and constituent materials of any such product; and
  - (2) They must meet be a "qualified pandemic or epidemic product," "security countermeasure," or drugs, biological products, or devices authorized for investigational or emergency use.
- Need some sort of FDA approval/authorization in almost all cases.

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Countermeasures and immunities provided by the PREP Act and HHS Declaration, cont.

- Limitations of Distribution: Under Section VII of the Declaration.
- Often overlooked and very important.
- Section VII says activities in question must be:
  - (1) pursuant to a federal contract or other federal agreement or
  - (2) authorized by a "public agency or its delegate," including federal, state, and local governments, that have authority over the pandemic response.
  - The non-binding Advisory Opinion issued on April 14, 2020 by HHS: interpret two conditions broadly to include "(1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level."
    - The HHS Advisory Opinion provided examples of authorization to include "guidance, requests for assistance, agreements, or other arrangements."

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Countermeasures and immunities provided by the PREP Act and HHS Declaration, cont.

- Limitations of Distribution in Practice:
  - This provision obviously applies when a government contract is at issue.
  - May not apply in many other scenarios.
  - Likely worthwhile to enter into a Memorandum of Understanding or obtain a letter from an appropriate governmental entity authorizing you to conduct the activity in question.
  - Includes HHS as well as state and local public health authorities. (See definition of authority having jurisdiction in Section VII of the Declaration: the public agency or its delegate "that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.")

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Recommendations to protect a business from potential price gouging allegations

- Are you price gouging?
  - Your business may be engaging in price gouging without you knowing it, as price gouging can occur when you raise your prices.
  - But, typically does not occur if prices are raised in response to an increase in expenses such as raw materials or transit.
  - Businesses selling PPE and medical supplies are largely permitted to operate, and generate profits, during the COVID-19 crisis.
- What laws apply?
  - You should review both state and federal law when determining whether price gouging is occurring. There is no federal preemption and state laws vary, causing problems for those who conduct business across the U.S.

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Protections from potential price gouging allegations, cont.

- Price gouging laws are often apply during a state of emergency.
  - Each state operates under its own emergency declaration, and state laws vary as to which categories of products are covered.
  - For COVID-19, many state price gouging laws apply to PPE and medical products, as well as some consumer products.
- What are the penalties? Penalties vary.
  - Civil penalties (fines) are often applied per violation and each sale of a product can be deemed to be a separate and distinct violation.

Protections from potential price gouging allegations, cont.

- The Current Federal Law:
  - A federal Executive Order has allowed the HHS to identify scarce and necessary materials and prescribe conditions with respect to the accumulation and sale of such materials.
  - The Executive Order prohibits any person from accumulating designated materials: either (1) in excess of the "reasonable demands" of business, personal, or home consumption, or (2) for the purpose of resale at prices in excess of prevailing market prices.
  - The designated materials list includes medical devices, medicines, PPE, disinfecting devices and products used in a clinical setting.

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Protections from potential price gouging allegations, cont.

- State Laws:
  - Strict Regulation: Connecticut, Georgia, Louisiana and Mississippi's price gouging laws do not allow for any increase in a product's prices from the prices that were charged immediately prior to the state of emergency.
    - Most of these laws allow you to take into account any increase in the costs you incurred in producing or selling the product.
  - Percentage Standard: Some states prohibit the sale of covered products for more than a set percentage above the pre-emergency sale price.
    - California defines price gouging as selling certain covered consumer items for more than 10% of the price charged for those goods or services immediately prior to the declaration of emergency.
  - Reasonableness Standard: Other states apply a reasonableness standard.
    - New York law forbids selling certain products for "an amount which represents an unconscionably excessive price."

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Protections from potential price gouging allegations, cont.

- Tips:
  - No Preemption: If you sell products across the U.S., you need to be aware not only of the federal law, but also the various state price gouging laws.
    - One strategy is to comply with the strictest state standards that do not allow for any price increase, while taking costs into consideration.
  - Your procurement, marketing and sales teams need to be aware of these price gouging issues.
  - In addition, you should discuss this issue with your suppliers if they appear to be price gouging you.

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Questions?

Thank you for your time and attention, and please feel free to contact us if you have any additional questions!

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