COVID-19: Product Liability and Potential Protections Under the PREP Act (and Other Legislation/Proposed Legislation)

Skadden

March 31, 2020

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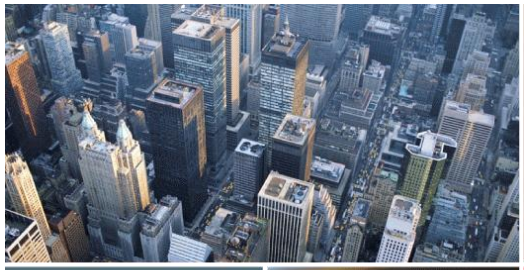

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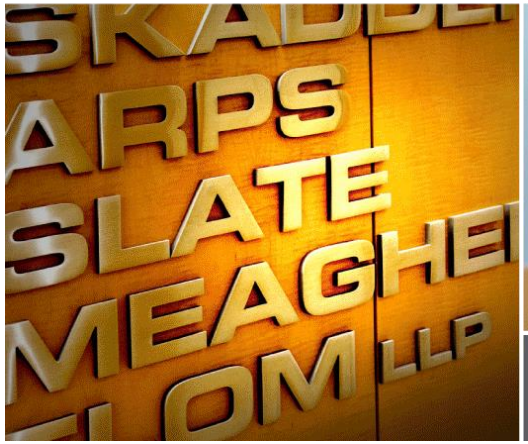

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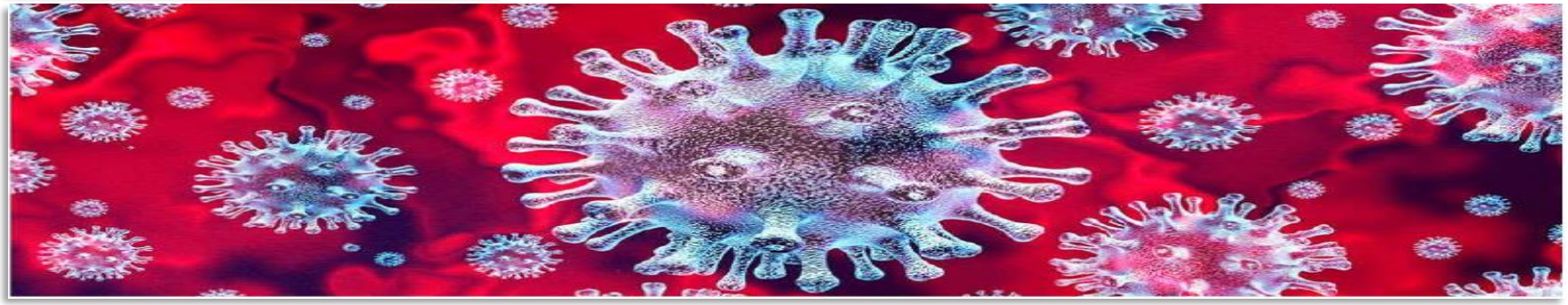

Attorney Addressing Civil Liability in COVID-19 Coronavirus Disease Cases in Cook County and Surrounding Areas

The Wuhan coronavirus, which is officially known as COVID-19, has affected tens of thousands of people around the world. As the number of coronavirus cases in the United States continues to increase, people may be wondering about their legal options if they contract this disease or if a family member dies from an infection. Specifically, victims and their families will want to know whether they can pursue a **personal injury** or **wrongful death** claim and recover compensation from those who were responsible for an infection.

https://www.newlandlaw.com/personal-injury-lawyer/coronavirus-covid-19-injury-death-lawyer

And So It Begins . . . .

MONSOUR LAW FIRM

COULD CORONAVIRUS LEAD TO PERSONAL INJURY LAWSUITS?

MARCH 18, 2020

Personal Injury Lawsuits After Coronavirus Infection

It does feel like the whole world has gone crazy, and we're going to see plenty more where that came from. Employers are asking whether staff could bring a personal injury lawsuit if they get infected at work. Restaurants and retailers ask if customers could find them at fault if they get sick.

Again, any personal injury lawsuit related to Coronavirus will have to prove the injury or infection resulted from someone else's negligence. If the employer or business did everything reasonably possible to disinfect, protect public health and educate on the dangers, they're probably okay. However, if the victim can prove they got sick or became injured because that business was careless, they might have a case.

When to Call a Personal Injury Attorney

If you became sick or injured because of someone else's negligence, Monsour Law Firm is here to help. Schedule a free, no-obligation consultation today.

https://monsourlawfirm.com/could-coronavirus-lead-to-personal-injury-lawsuits

And So It Begins . . . .

https://seniorjustice.com/corona-virus-in-nursing-homes/
https://www.lipcon.com/blog/lawyers-for-cruise-ship-coronavirus-lawsuits/

Personal Injury: Current Cases

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Cruise Ship Cases

- **In February, Grand Princess cruise ship reported COVID-19 cases among passengers and staff**
- **Plaintiffs have filed 5 cases alleging negligence and gross negligence against Princess Cruise Lines in the Central District of California**
- **Current Cases Filed:**
  - *Weissberger v. Princess Cruise Lines Ltd.*, No. 2:20-cv-2267 (C.D. Cal.)
  - *Dalton v. Princess Cruise Lines Ltd.*, No. 2:20-cv-02458-GW-PJW (C.D. Cal.)
  - *Kurivial v. Princess Cruise Lines Ltd.*, No. 2:20-cv-02361-JFW-AS (C.D. Cal.)
  - *Abitbol v. Princess Cruise Lines Ltd.*, No. 2:20-cv-02414-CBM-KS (C.D. Cal.)
  - *Austin v. Princess Cruise Lines Ltd.*, No. 2:20-cv-02531-DSF-RAO (C.D. Cal.)
- **General Allegations:**
  - Princess allowed passengers to board the ship its previous voyage included passengers symptoms of COVID-19;
  - Princess allowed 62 passengers from the previous voyage – who had been exposed to infected – to join the plaintiffs' voyage;
  - Princess failed to warn plaintiffs before they boarded potential exposure; and
  - Princess did not properly screen the passengers for COVID-19

Potential Cases: Personal Protective Equipment

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Respirator Litigation

- Historically, there has been significant personal injury litigation against manufacturers of respirator masks.
  - **Examples: Mining - "Black Lung" Litigation** (allegations that respirator manufacturers knew or should have known that their products didn't adequately protect coal miners from black lung-causing dust particles); **Construction – Silicosis** (allegations that plaintiffs were overexposed to respirable silica when cutting or drilling concrete even though they wore respirator masks); **Asbestos Removal** (allegations that respirators failed to protect workers form asbestos-related disease)

1 Class Actions and Economic Loss

Current Cases: Class Actions Against a Foreign State

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Class Actions Against The People's Republic of China and Chinese Government Entities

- ***Alters v. People's Republic of China*, No. 1:20-cv-21108 (S.D. Fla.)**
  - » Putative class action filed on behalf of individuals and businesses in the United States claiming negligence, infliction of emotional distress, strict liability and public nuisance
  - » Defendants "failed to report the outbreak as quickly as they could have; underreported cases; and failed to contain the outbreak despite knowing the seriousness of the situation."
- ***Buzz Photos v. The People's Republic of China*, No. 3:20-cv-00656-K (N.D. Tex.)**
  - » Class action lawsuit seeking $20 trillion.
  - » "This is a complaint for damages and equitable relief arising out of the creation and release, accidental or otherwise, of a variation of coronavirus known as COVID-19 by The People's Republic of China and its agencies and officials as a biological weapon in violation of China's agreements under international treaties…."
- ***Bella Vista LLC v. The People's Republic of China*, No 2:20-cv-00574 (D. Nev.)**
  - » Putative class action filed on behalf of "small businesses" in the United States seeking compensation for "hundreds of Billions or Trillions of dollars in financial damages and/or economic [losses]"
  - » Defendants "engaged in a campaign of misinformation and lies" and "engaged in a campaign of intimidating and arresting any Chinese doctors, scientists, attorneys and/or reporters who tried to alert the public about this dangerous 'new' coronavirus," despite knowing that it was "very contagious, deadly and capable of causing a pandemic."

Current Cases: Manufacturers and Distributors

Class Action Against Amazon for Price Gouging

- ***Armas v. Amazon.com, Inc.*, No. 2020-5653 (Fla. Cir. Ct.)**
  - Putative statewide consumer class action filed in Florida state court
  - Claims that Amazon charged unconscionable prices for items such as toilet paper and hand sanitizer in violation of Florida's Deceptive and Unfair Trade Practices Act

Lawsuits over unavailable products (subscription) and delivery delays likely as well.

Current Cases: Manufacturers and Distributors

Class Actions for False Advertising (hand sanitizer, vitamins, supplements)

- ***David v. Vi-Jon Inc.*, No. 20-cv-0424 (S.D. Cal.)**
  - Putative statewide consumer class action filed in California federal court against Vi-Jon Inc. (Germ-X manufacturer)
  - Alleges that the company falsely claims that Germ-X provides "'Coronavirus/Flu Prevention'" in advertisements despite the absence of "'adequate and well-controlled studies' supporting" that contention
- Other similar lawsuits may follow:
  - ***See Gonzalez v. Gojo Indus., Inc.*, No. 1:20-cv-00888 (S.D.N.Y. 2020)**
    - Putative nationwide consumer class action alleging that the makers of Purell hand sanitizers falsely marketed their products as effective in protecting against Ebola and other viruses without scientific support
    - Although the allegations are not directly about COVID-19, plaintiffs also claim that "according to some reports, defendant has promoted the Products as a viable means of preventing transmission of Coronavirus."

- Similar lawsuits occurred during prior pandemics:
  - ***See Kammula v. Kellogg Co.*, No. CV09-08102 (MMM) (RZx) (C.D. Cal. 2009)**
    - Putative statewide consumer class action alleging the defendant made false statements in their advertising of Kellogg's Cocoa Krispies by stating the product "boost[ed] a child's immune system." Plaintiffs alleged this was "particularly egregious, especially in light of the current H1N1 ('swine') flu epidemic in California and the rest of the nation."
    - Case ultimately settled.

Consumer Fraud Class Action – Ebola Precedent

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Bahamas Surgery Center LLC v. Kimberly-Clark Corporation, No. CV 14-8390 DMG (PLAx) (C.D. Cal.)

General Allegations:

- Manufacturer of surgical gowns represented that they met certain standards for liquid barrier protection and were safe for use in the treatment of Ebola despite knowing of and failing to disclose "catastrophic" testing failures to the contrary.

Class Definition:

- All California purchasers of surgical gowns (court declined to certify nationwide issues class)

Result:

- Jury returned a $450-million verdict for class on their claim of fraudulent concealment, finding that the omission was material
  - Award slashed to roughly $20 million. Further reduction sought on appeal.

Insights:

- Surgical gowns may be subject to immunity under the PREP Act—a topic addressed later in this presentation—but *Bahamas Surgery Center* foretells lawsuits involving other products that are not exempted from liability by emergency declaration.

Negligent Undertaking

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Many companies have encouraged business by reassuring customers that they are taking extra steps to ensure their health and safety. What if customers are injured because these extra measures were performed carelessly (or not at all)?

Email from Exercise Studio:

We want to assure you that, at . . . we're taking the necessary precautions to prevent the spread of COVID-19. We will continue all routine deep cleaning procedures, and we've added more hand sanitizer and wipe stations in all of our studios. We're dedicated to protecting against coronavirus, while remaining a place that our NYC community can feel welcome and safe.

Although we are confident in these preventative measures, starting tomorrow, we are making some additional adjustments in our New York City studios.

Here's what is changing:

- 50 minute classes
- One round on the tread, one round on the floor
- Our facilities team will clean the entire studio between rounds

Email from Coffee Shop:

What we have done:

*Our condiment stations have been shut down in an effort to avoid potential contamination. We will now complete your entire order for you, no need to visit a condiment cart. All condiments, milks, napkins and the like will now be kept behind the counter and added for you, per request. Order ahead has been updated to allow complete customization of all coffee drinks so the need for condiment carts has been eliminated.

*Teams have been instructed to wash hands regularly throughout the day

*Glove use has been implemented at all workstations the CDC has deemed appropriate to do so

*Teams will regularly be sanitizing door handles, bathrooms, table tops and other surfaces

*We are awaiting our shipment of hand sanitizer and sanitizing wipes to be used by our team and made available to all customers to use at their pleasure in our stores

*Employees have been instructed to stay home if they are experiencing symptoms

Potential Cases: Economic Loss

Efforts to stem the spread of COVID-19 have included government-issued prohibitions on gatherings of different sizes. Businesses concerned with the safety of their clients and customers have shuttered, and an increasing number of states have ordered restaurants, gyms and other non-essential businesses to close indefinitely.

Such restrictions and closures could give rise to claims for economic loss premised in a theory of financial injury.

Memberships, Subscriptions and Promotions

Gym and Spa Memberships

- Gyms and spas closed

Prepaid Services

- Sports seasons cancelled
- Theater seasons cancelled
- Cinemas closed
- Concerts canceled
- Service contracts
- Warranties

Frequent Flyer Miles

- Banks offering airline miles as promotion for opening accounts
  - Airlines are not flying
  - Travel restrictions

2 HHS and FDA Response

Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d

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Background

- The PREP Act authorizes the HHS secretary to issue a declaration that provides liability immunity to Covered Persons against claims of loss caused by, arising out of, relating to or resulting from the manufacture, distribution, administration or use of Covered Countermeasures, excluding willful misconduct.
- On March 10, 2020, the HHS secretary issued a Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19, effective as of February 4, 2020.

Liability Immunity

- The Declaration provides Covered Persons immunity from suit under federal and state law for all claims for loss caused by, arising out of, relating to or resulting from the manufacture, testing, development, distribution, administration or use of a Covered Countermeasure.
- Liability immunity does not apply for death or serious physical injury proximately caused by willful misconduct.
  - Such a suit must be filed in the U.S. District Court for the District of Columbia.

PREP Act (cont.)

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Covered Persons

- Liability immunity is only available for Covered Persons.
  - Manufacturers – including contractors or subcontractors, suppliers or licensers, and any and all of their parents, subsidiaries, affiliates, successors and assigns
  - Distributors – those engaged in the distribution of drugs, biologics and devices (e.g., manufacturers, common carriers, brokers, warehouses, retail pharmacies)
  - Program Planners – those supervising the administration, dispensing, distribution, provision or use of Covered Countermeasures
  - Qualified Persons – individuals authorized to prescribe, administer or dispense Covered Countermeasures
- The immunity extends to the officials, agents and employees of Manufacturers, Distributors, Program Planners and Qualified Persons.

PREP Act (cont.)

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Limits on Distribution

- The Covered Countermeasures must relate to:
  - Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memorandum of understanding or other federal agreements;

  or

  - Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

Covered Countermeasures

- Covered Countermeasures include: antivirals, drugs, biologics, diagnostics, devices or vaccines used to treat, diagnose, cure, prevent or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product.
- The Covered Countermeasure must be one of the following:
  - Qualified Pandemic or Epidemic Product
  - Security Countermeasure
  - Authorized for investigational or emergency use
  - Personal respiratory protective device (added by Congress in 2020).

PREP Act (cont.)

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- Qualified Pandemic or Epidemic Products and Security Countermeasures must be approved, cleared, licensed or authorized for investigational or emergency use.
- Qualified Pandemic or Epidemic Product – a drug, device or biological product:
  - 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;
  - Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat or cure a serious or life-threatening disease or condition caused by such a drug, biological product or device; or
  - A product or technology intended to enhance the use or effect of such a drug, biological product or device.

Security Countermeasure – a drug, device or biological product:

- That the HHS secretary determines to be a priority to diagnose, mitigate, prevent or treat harm from any biological, chemical, radiological or nuclear agent identified as a material threat by the secretary of homeland security; or
- To diagnose, mitigate, prevent or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product or device against such an agent; and
- Is determined by the secretary to be a necessary countermeasure to protect public health

PREP Act (cont.)

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Practical Application

- The PREP Act requires federal and state courts to dismiss claims against Covered Persons related to Covered Countermeasures. Defendants typically have been successful at the motion to dismiss stage, and courts have upheld the broad and sweeping nature of the Act.
  - "[T]he alleged manufacturer of the H1N1 vaccine at issue here[] is protected by the PREP Act and is absolutely immune from liability for any type of loss caused by the vaccine….Accordingly, [the claim] seeking indemnity and/or contribution on account of the H1N1 vaccine's alleged defective condition and/or inherent danger shall be dismissed for lack of jurisdiction." Memorandum and Order, *Kehler v. Hood, et al.*, 11-cv-1416 (E.D. Mo. May 30, 2012).
  - "Considering the breadth of the preemption clause together with the sweeping language of the statute's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary." *Parker v. St. Lawrence County Public Health Department*, 102 A.D.3d 140 (N.Y. App. Div. 2012).

Emergency Use Authorization (EUA) – 21 U.S.C. 360bbb-3

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Background

- Under section 564 of the FDCA, FDA may authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the HHS secretary has made a declaration of emergency or threat justifying authorization of emergency use.
- The medical products subject to EUAs are commonly referred to as "medical countermeasures," or "MCMs," and may be authorized for use to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by a chemical, biological, radiological and nuclear ("CBRN") agent when there are no adequate, approved and available alternatives.
- The purpose of the EUA pathway is to enable the government to authorize the use of MCMs in an expedited fashion based on less evidence than would be required to obtain FDA approval or clearance in the normal course.
- The applicable law was originally amended by the Project Bioshield Act of 2004 to create the EUA authority, but has been further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the 21st Century Cures Act of 2016 and Public Law 115-92 of 2017.
- FDA issued a final guidance, titled "Emergency Use Authorization of Medical Products and Related Authorities" in January 2017, to provide its thinking on implementation of the law.

EUA – COVID-19 (cont.)

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EUA Elements

- Before FDA may issue an EUA, the HHS secretary first must declare that circumstances exist justifying the authorization. This "EUA declaration" must itself be based on an initial determination, made by the secretary of HHS, the director of homeland security or the secretary of defense, of an emergency specified in section 564 of the FDCA.

Criteria for Issuance of Authorization

- Serious or life-threatening condition: such as COVID-19
- The product "may be effective":
  - FDA determines whether the known and potential product benefits outweigh the known and potential product risks
  - FDA evaluates the totality of the evidence:
    - Trial results (foreign or domestic) or *in vitro* data
    - *In vivo* efficacy data from animal studies
- No Alternative: an alternative may be "unavailable" if there are insufficient supplies
- Other Criteria as FDA may prescribe by regulation

Conditions of Authorization: e.g., labeling, adverse event reporting

Termination: In general, EUA remains in effect for the duration of the EUA declaration.

EUA – COVID-19 (cont.)

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Public Emergency Declaration

- On January 31, 2020, Secretary Azar declared a current public health emergency.

Emergency Use Authorization

- On February 4, 2020, Secretary Azar declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics.
- On March 2, 2020, Secretary Azar declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices.
- On March 24, 2020, Secretary Azar declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, such as ventilators.
- Approximately 20 EUAs issued since, including the broad ventilator EUA on March 24.

Related Guidance Documents: e.g., Diagnostic Tests, Hand Sanitizer

3 Legislative Proposals

Federal Action: The CARES Act

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The Coronavirus Aid, Relief, and Economic Security (CARES) Act limits liability for certain, individuals and devices in an effort to encourage actions to address COVID-19 challenges:

Volunteer Health Care Professionals

- Shields volunteer health care professionals aiding COVID-19 patients from liability for any harm caused by an act or omission of the professional in the provision of health care services during the public health emergency
  - "Harm" includes "physical, nonphysical, economic, and noneconomic losses"

Respiratory Protective Devices

- Provides liability protection to manufacturers of masks, respirators and other personal respiratory protective equipment

State Action: Legislative Immunity

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Immunity for Businesses:

- Alabama (Draft Bill)
  - "[A] business entity that is properly licensed to conduct business in this state is not liable for any injury or damages, including death, suffered by any individual, resulting from the individual's actual or alleged contraction of the coronavirus from another patron, an employee or any other individual while on the premises of the business entity."

State Action: Legislative Immunity

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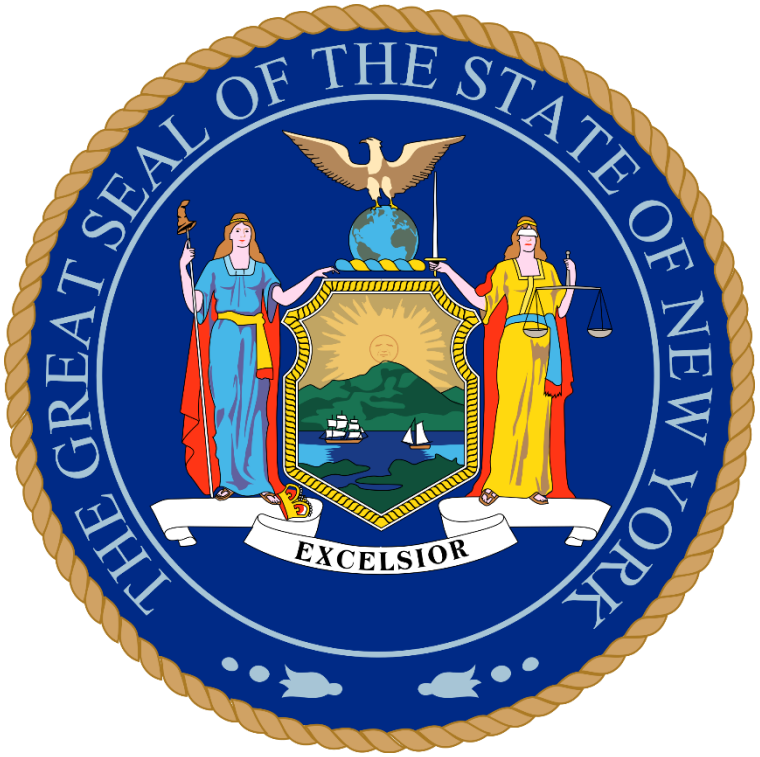
Immunity for Health Care Workers:

- New York (Exec. Order 202.10)
  - "[T]o the extent necessary to provide that all physicians, physician assistants, specialist assistants, nurse practitioners, licensed registered professional nurses and licensed practical nurses 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 by such medical professional in the course of providing medical services in support of the State's response to the COVID-19 outbreak, unless it is established that such injury or death was caused by the gross negligence of such medical professional…."



Other Legislative Proposals?

How could Congress address COVID-19?

- Create federal jurisdiction for all claims relating to COVID-19
  - Consistent and coordinated treatment
- Create immunity against certain actions—*e.g.*, Alabama proposal
  - Include provision for preemption
  - Protect “essential businesses”

Other Legislative Proposals?

How could Congress address COVID-19?

- Create safe harbor for actions taken pursuant to CDC recommendation or directive—*e.g.*, cancelling events and/or closing facilities to avoid gatherings of more than *X* people.
  - Include provision for preemption
  - Exclude certain business-to-business lawsuits
- Expand immunity to cover makeshift manufacturers of hand sanitizer and other products needed to address shortages; exempt egregious conduct
  - "Good Samaritan" rationale

Other Legislative Proposals?

How could Congress address COVID-19?

- Create cause of action for Medicare/Medicaid fraud claims
  - Resemble actions brought under the False Claims Act
    - Exclusive cause of action for COVID-19-related claims regarding government payments
    - Government must agree that lawsuit has merit and intervene
- Establish uniform, exclusive national standard regarding price-gouging for interstate sales of products, perhaps including exhaustion mechanism

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This webinar is for informational purposes only. As this is an evolving situation, we anticipate that the illustrative scenarios presented and the law discussed during the discussion will evolve and change.

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