# POST COVID-19 LEGAL UPDATE

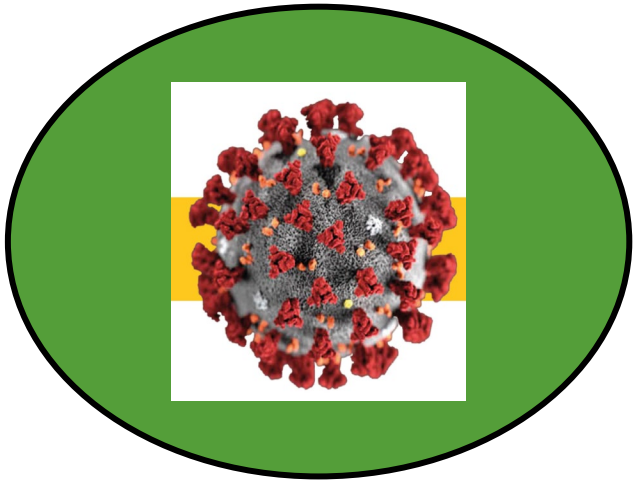
BY: DYLAN BRAVERMAN



The Drowning Dog
by Francisco Goya
(1819)

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# POST COVID-19 LEGAL ANALYSIS

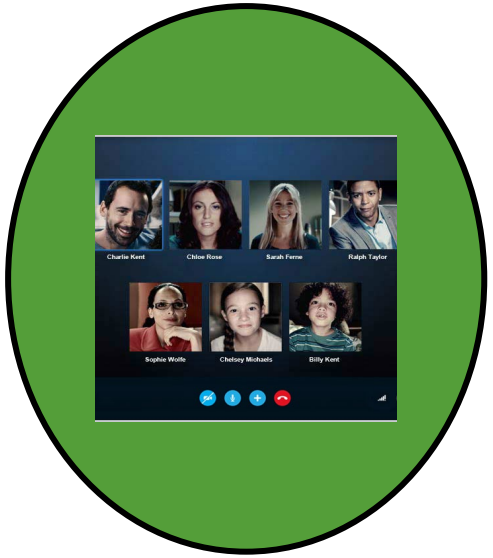


**NATIONAL IMMUNITY:** PREP ACT



**NY STATE IMMUNITY:** EDTPA

(Emergency Disaster Treatment Protection Act)

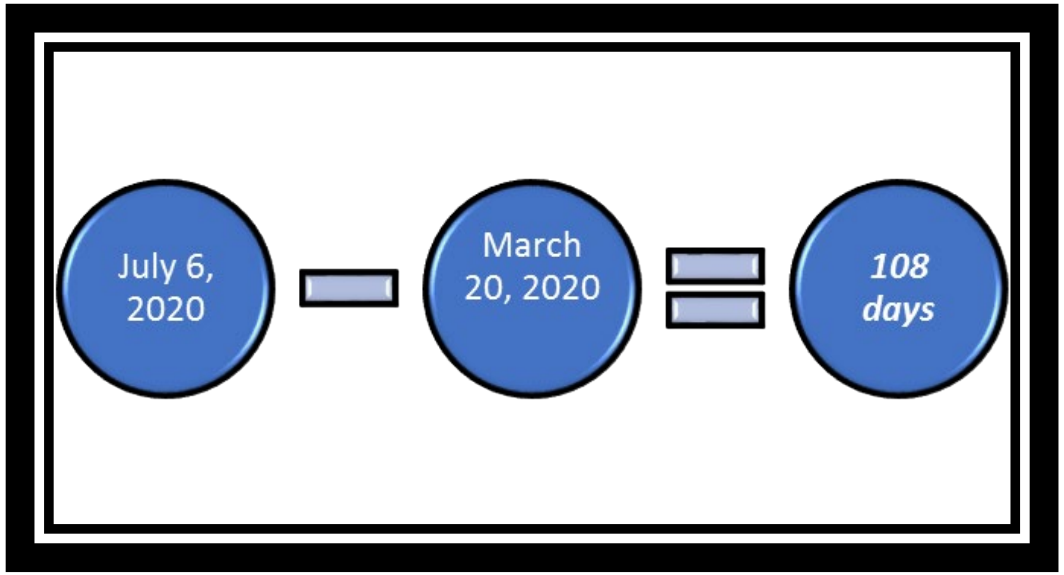



**FACE OF LITIGATION**

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# THRESHOLD ISSUE: STATUTE OF LIMITATIONS

***Executive Order 202.8***: In accordance with the directive of the Chief Judge of the State *to limit court operations to essential matters during the pendency of the COVID-19 health crisis*, any *specific time limit* for the commencement, filing, or service of any legal action, notice, motion, or other process or proceeding, as prescribed by the procedural laws of the State, including but not limited to the Criminal Procedure Law, the Family Court Act, the Civil Practice Law and Rules, the Court of Claims Act, the Surrogate's Court Procedure Act, and the Uniform Court Acts, or by any other statute, local law, ordinance, order, rule, or regulation, or part thereof, is hereby tolled from the date of this Executive Order until April 19, 2020 [since extended to July 6, 2020 pursuant to EO 202.38].




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# Recommended Defense Arguments

| | |
|---|---|
| If the SOL would have expired during the 108-day toll: | Defense counsel should argue that the deadline for commencement is July 6, 2020 (the day the toll expires). |
| If the SOL did not expire during the 108-day toll: | Defense counsel should argue that there is no toll, and the SOL is not extended. The claim must be commenced as per the CPLR and there is no COVID-19 extension. |
| ***Alternative Argument*** | If the Courts interpret the EO to permit a uniform 108-day extension of the SOL to commence an action, the extension should only be provided to claims where the SOL would have expired during the 108 day toll. *In other words, any SOL that did not expire during the toll should not be extended and the SOL set forth in the CPLR should apply.* |

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# National Immunity: PREP ACT

42 U.S.C. §247d-6d, known as the Public Readiness and Emergency Preparedness Act ("PREP Act"), provides immunity to "covered persons" providing "medical covered countermeasures, pursuant to an Emergency Declaration."

On March 10, 2020, Alex M. Azar II, Secretary of the U.S. Department of Health and Human Services ("HHS") issued the requisite Emergency Declaration triggering the protections of the PREP Act. The Declaration is retroactive to February 4, 2020. It specifically states that, *"(i)n each case, whether immunity is applicable will depend on the particular facts and circumstances*." (emphasis added).

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# THE PREP ACT'S Q&A SETS FORTH "WHO MAY BE AFFORDED IMMUNITY":



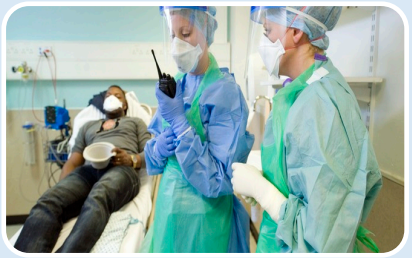
Manufacturers (includes PPE and vaccines)



Distributors



Program Planners



"Qualified Persons"

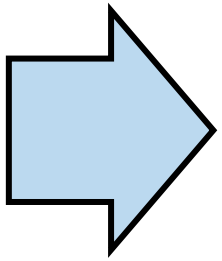


Officials, agents, employees of people listed previously

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# THE PREP ACT Q&A GLOSSARY OF TERMS DEFINES A "QUALIFIED PERSON":

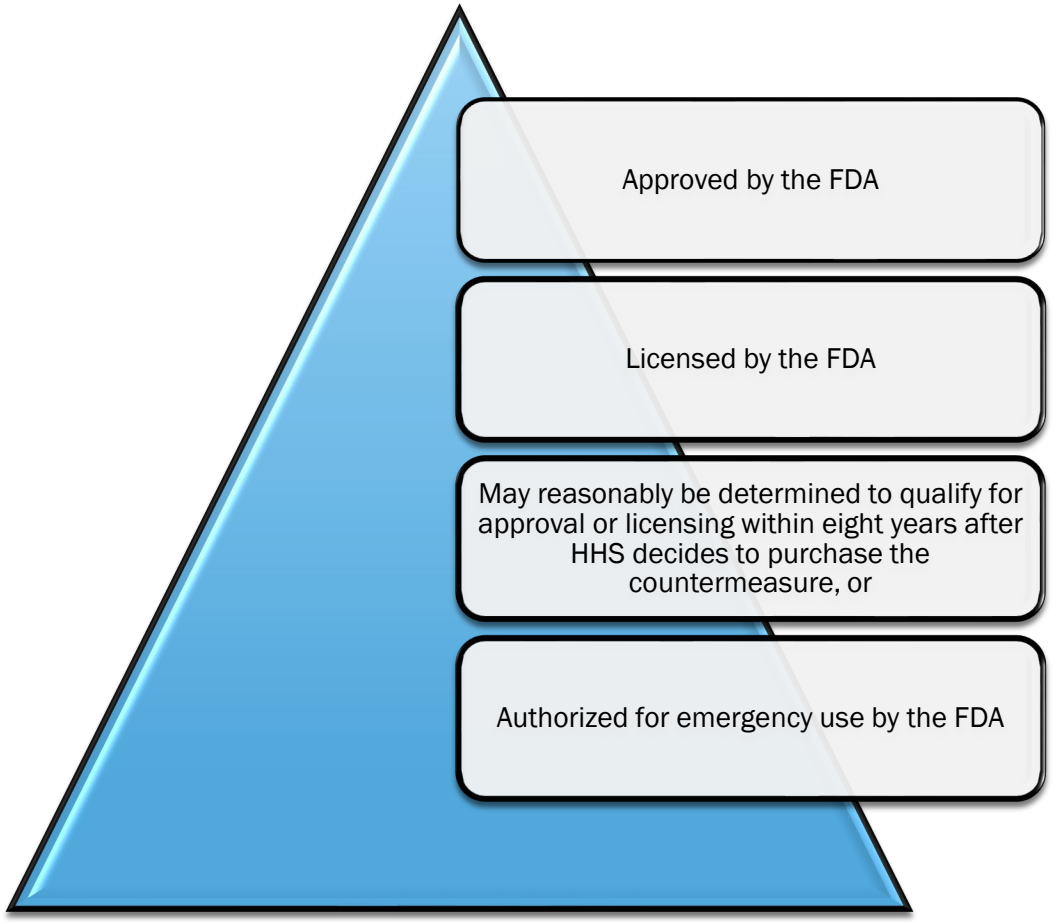
A licensed health professional or other individual who is authorized to prescribe, administer, or dispense covered countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or



A person within a category identified as "qualified" in a Declaration, such as volunteers.

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# THE Q&A GLOSSARY OF TERMS DEFINES A “SECURITY COUNTERMEASURE AS FOLLOWS:




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# CONGRESSIONAL RESEARCH SERVICE ("CRS")

- The CRS memorandum refines the definition of "covered countermeasures" to include: (i) a pandemic product, defined as "any drug, biological product or device developed "to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic" that that the U.S. Food and Drug Administration ("FDA") authorized for emergency use; (ii) a security countermeasure, which includes drugs, products or devices used to address biological, chemical, nuclear or radiological agents as identified by Homeland Security; and (iii) a drug, biological product or device authorized by the FDA for emergency use. As pertinent to COVID-19, this includes respirators and devices modified as ventilators.

- The CRS memorandum further states that the immunity under the PREP Act is afforded to a "covered person" (defined as agents, employees and individuals): (i) the United States; (ii) manufacturers and distributors of "covered countermeasures"; (iii) "program planners;" and (iv) "qualified persons" who prescribe, administer, or dispense covered countermeasures. The "administration" of a "covered countermeasure" includes, "physical provision" to patients, as well as "activities and decisions directly related to … delivery, distribution and dispensing of the countermeasures."

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# CAUSAL LINK FOR PREP ACT:

- To qualify, the alleged loss must have a *causal connection* to the administration/use of a covered countermeasure. This causal connection includes "the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use" of a "covered countermeasure.

"Willful misconduct" leading to death or a serious physical injury (categorized as life threatening; permanently impairing a body function; permanently damaging a body structure; or requiring medical intervention to avoid such permanent impairment or damage) is the only exception to the PREP Act.

The burden of proof for willful misconduct is "clear-and-convincing evidence" that an act or omission was done: (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard to a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

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# PREP ACT CONTINUED:

- Beyond the PREP Act, there are additional obstacles for a claimant. As a condition precedent to filing suit, the claimant must first seek compensation through the Countermeasures Injury Compensation Program ("CICP"). A lawsuit is barred if the claim is accepted and compensation provided.

- The CICP regulatory process is administered by the HHS. Reimbursement is available for reasonable medical expenses, loss of employment income and survivor benefits (in the case of death). Serious physical injuries under CICP are generally limited to those that warrant hospitalization or led to a significant loss of function or disability.

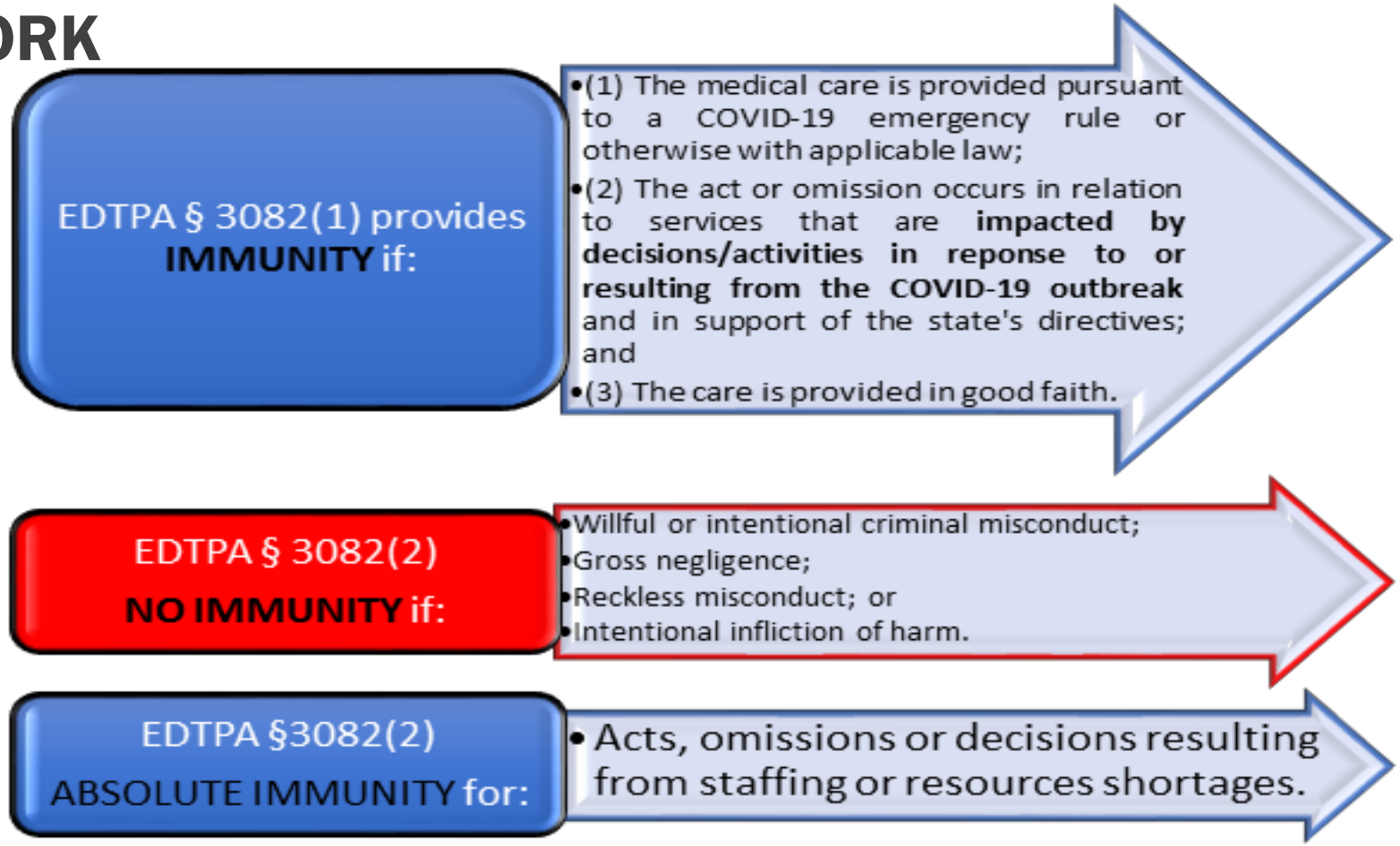
- Defense Recommendations: In the correct factual setting, consideration should be given to removal to Federal Court [per 28 USC §1331; Federal-question jurisdiction and 28 USC §1442(a)(1); Federal Officer Jurisdiction] as well as a pre-Answer motion to dismiss based on: (1) the PREP Act immunity; (2) that the PREP act limits recourse to the CICP; and, (3) that the U.S. District Court for the District of Colombia is the proper venue. Importantly, motions should be made selectively to ensure favorable decisions and case law.

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# IMMUNITY IN NEW YORK

The immunity was initially provided by way of Governor Cuomo's March 7, 2020 and subsequent executive orders ("EO").

Those EO's were substantively codified in Article 30-D, §3082(2) of the Public Health Law [now known as the Emergency or Disaster Treatment Protection Act ("EDTPA")]. The EDTPA applies to all care on or after March 7, 2020 until the end of the COVID-19 emergency (not defined and ongoing).




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## THE EDTPA APPLIES TO ANY "HEALTH CARE FACILITY", DEFINED AS A HOSPITAL, NURSING HOME OR OTHER FACILITY LICENSED/AUTHORIZED TO PROVIDE HEALTH CARE SERVICES FOR ANY INDIVIDUAL…[AND]…ANY HEALTH CARE PROFESSIONAL." "HEALTH CARE PROFESSIONAL" IS DEFINED AS:

- an individual, whether acting as an agent, volunteer, contractor, employee, or otherwise, who is licensed in New York to practice medicine;
- a Nurse or Nurse's Aide;
- EMTs;
- a home care provider;
- a medical provider performing services within the COVID-19 emergency rule (including out-of-state and Canadian physicians, medical students and foreign-educated unlicensed physicians); or
- a healthcare facility Administrator, executive, Board member, Trustee or other person responsible for directing, supervising or managing a healthcare facility and its personnel or other individual in a comparative role.

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## EDTPA § 3082(1) APPLIES TO:

- The care is provided pursuant to a COVID-19 emergency rule or otherwise according with applicable law;
- The act or omission occurs in relation to “healthcare services” that is impacted by decisions or activities in response to or resulting from the COVID-19 outbreak and in support of the State’s directives; and
- The care is provided in good faith.

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# GOOD FAITH IS DEFINED INDIRECTLY (BY COMPARISON) AND DOES NOT APPLY TO:

- Willful or intentional criminal conduct,
- Reckless misconduct
- Gross negligence
- Intentional infliction of harm

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## EDTPA PROVIDES ABSOLUTE IMMUNITY TO:

- Acts, omissions or decisions resulting from a resource or staffing shortage.
- Thus, even willful or intentional criminal misconduct, gross negligence, reckless misconduct and intentional infliction of harm claims are barred if they involve resource or staffing shortages.

# GROSS NEGLIGENCE DEFINED:

- PJI § 2:10A: Negligence is a failure to exercise ordinary care. Gross negligence/ willful misconduct is more than the failure to exercise reasonable care;
- Willful misconduct occurs when a person intentionally acts, or fails to act, knowing that (his, her) conduct will probably result in injury or damage. Willful misconduct also occurs when a person acts in so reckless a manner, or fails to act in circumstances where an act is clearly required, so as to indicate disregard of the consequence of (his, her) action or inaction.
- Gross negligence means a failure to use even slight care, or conduct that is so careless as to show complete disregard for the rights and safety of others.

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