

Morgan Lewis

**NOW. NORMAL.
NEXT.**

The PREP Act and Other Immunities – Provider Relief for COVID-19 Related Claims

Greg Etzel and Katie McDermott
August 6, 2020

The PREP Act and Other Immunities – Provider Relief for COVID-19 Related Claims

Topics to be discussed today include



**An overview of the PREP Act
and its protections**



**State initiatives to provide
immunity from liability to
healthcare providers**



**A deeper analysis of the HHS
Advisory Opinion and available
guidance relating to the PREP
Act in the context of the
COVID-19 public emergency**



**Legal and practical risk
management considerations
for providers continuing to
manage their operations in the
crisis**

Key Policy Issues For COVID-19 Immunity

- Any global pandemic requires public and private collaboration and the taking of significant legal and business risks to develop vaccines, new testing models, new ventilators or respiratory models and personal protective equipment. Who bears the legal risk and reward of this response and the innovation?
- Public health protocols for COVID-19 infection and control measures are evolving with many healthcare providers managing vulnerable populations and employees with new or no updated guidance or resources. How does current tort liability principles or enforcement priorities address new standard of care issues?
- Healthcare professionals and institutions will be on the frontline to administer medical countermeasures. What is the scope of immunity for healthcare professionals that fall under a PREP Act declaration as it is modified and evolves?
- Given the interpreted preemption of local law, what is the role of states in assuring that PREP Act immunity advances its key objectives?
- How does PREP Act change insurance or waiver of liability considerations, if at all?
- How should procurement and contracting practices and forms change?

PREP ACT Baseline

- Public Readiness and Emergency Preparedness (PREP) authorizes the HHS Secretary to issue a declaration that provides liability immunity-except for willful misconduct for:

Claims of loss caused, arising, relating or resulting from administration or use of countermeasures to disease, threats, conditions, determined by the Secretary to constitute a present or credible risk of future public health emergency (PHE) for entities and individuals involved in development, manufacture, testing, distribution administration of such countermeasures and their officials, agents and employees

PREP ACT Baseline

- Covered countermeasures may be a pandemic or epidemic product (vaccine), security countermeasure, emergency use of unapproved drug, biological product or device
- Immunity exists for claims: wrongful death, physical, mental or emotional injury, medical monitoring, property damages, including business interruption loss
- Immunity applies to Covered Persons defined in the Declaration, including manufacturers and distributors of the countermeasures, program planners administering the countermeasures, other qualified persons who may prescribe, administer or dispense countermeasure such as healthcare providers
- Importantly, officials, agents and employees for covered entities or persons; and, the United States

PREP ACT and COVID-19



January 31, 2020

HHS Public Health
Emergency Declaration



March 10, 2020

PREP Act Declaration issued for medical countermeasures against COVID-19, effective February 4, 2020 to October 1, 2024 or end of PHE whichever date is earlier. Protects covered persons engaging in recommended activities for covered medical countermeasures



April 10, 2020

Amended to add countermeasures pursuant to CARES Act related respiratory protective devices and any successor regulations deemed necessary



April 14, 2020

HHS Advisory Opinion 02-02 On PREP Act and COVID-19 Declaration



June 8, 2020

Declaration further amended to include qualified pandemic and epidemic countermeasures that limit harm COVID-19 might otherwise cause including certain drug shortages

➤ **PREP ACT COVID-19 Declaration likely to evolve so good to keep on ticker**

HHS Advisory Opinion on COVID-19 PREP Act

- Specific to the COVID-19 PREP Act Declaration issued on March 10, 2020, HHS issued advisory guidance on interpreting the Declaration on April 17, 2020 and modified this guidance on May 19, 2020.
- Addresses scope of PREP Act immunity but does not have the force of law and is subject to change. Explains provisions of Declaration
- Allows immunity for reasonable belief standard for entities and persons that undertook action in good faith belief and otherwise in compliance with PREP Act the countermeasure was covered or that person was covered under Declaration. Example: Purchaser of counterfeit PPE
- Provides a helpful list of recognized covered countermeasures. This list is not exhaustive. www.fda.gov/media/136832/download

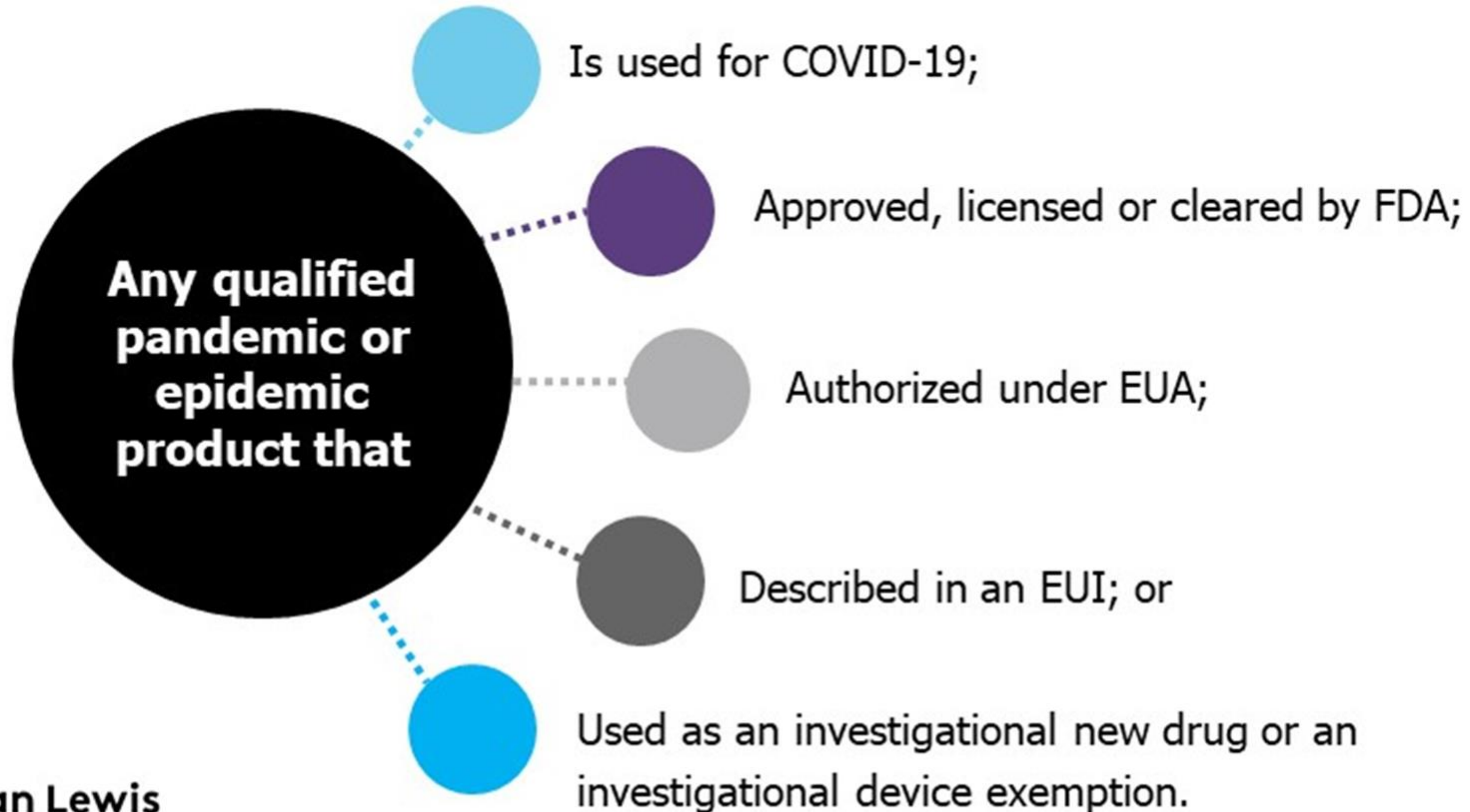
HHS Advisory Opinion on COVID-19 PREP Act

- Advises Covered Persons to take and document reasonable precautions under the “current emergent circumstances” to facilitate the safe use and administration of covered countermeasures and to make such documented precautions publicly available. This advice is applicable to covered persons that are healthcare professionals or entities.
- Explains that PREP Act immunity covers claims for losses in tort or contract as well as claims for loss relating to compliance local, state or federal law requirements “or other legal requirements”, noting PREP Act preempts state and local law in conflict with its objectives.
- Confirms that immunity applies when a Covered Person engages in activities related to an agreement or arrangement with the federal government or acts according to an Authority Having Jurisdiction to respond to a declared emergency.
- Interprets immunity conditions broadly to mean: 1. Any arrangement with the federal government; and 2. Any activity that is part of an authorized emergency response at the federal, regional, state or local level.

HHS Advisory Opinion on COVID-19 PREP Act

- Caveats PREP Act immunity. Immunity is not absolute and does not apply to willful misconduct.
- Exempts claims for equitable relief under federal law.
- Exempts administrative, civil and criminal federal government enforcement actions.
- Limits immunity to claims for personal injury or damages to property.
- Replaces traditional damages with different damages model similar to no-fault compensation system.
- Establishes broad preemption scope related to state action different or in conflict with the PREP Act.

Covered Medical Countermeasures



Covered Persons

Covered Persons includes a person or entity that

- Manufactures or distributes the countermeasure;
- Is a program planner;
- Qualified person to prescribe, administer or dispense the countermeasure; or
- An official, agent or employee of a person or entity that is a manufacturer, distributor, program planner or qualified person.

Program Planner can be state or local government, or other person who supervised or administered the program with respect to qualified activity, including persons who provided policy guidance, technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure.

Qualified Person may be a licensed healthcare professional or other individual authorized to prescribe or administer a countermeasure or such other persons identified in the Declaration.

Covered Persons

Other persons identified in the Declaration include any person authorized by the Authority Having Jurisdiction in connection with public health and emergency responses to prescribe, dispense, administer, deliver or distribute Covered Countermeasures and their officials, agents, employees and volunteers.

Clearly, Authority Having Jurisdiction has broad authority to extend PREP Act immunity. *So what is the Authority Having Jurisdiction (AHJ)?*

AHJ can be a public agency or its delegate that has the legal responsibility and authority to respond to an incident, based on political or geographic or functional sphere of authority (city, county, tribal, state or federal). So, not just HHS. It can be a state through its governor. A city, through its mayor.

Limited Case Law

CASE

***Parker v. St. Lawrence County
Pub. Health Dept.*, 102 A.D.3d
140 (N.Y. App. Div. 2012).**

***Casabianca v. Mount Sinai
Med. Ctr., Inc.*, 2014 NY Slip
Op 33583(U), 2014 N.Y. Misc.
LEXIS 5998 (NY Sup. Ct.
2014)**

DETAILS

- Arose from H1N1 outbreak and Secretary Declaration in 2009
 - Claim for the damages to a minor child from the administration of Peramivir (a recommended Countermeasure without parental consent)
 - Court found Prep Act Immunity applied – preemption of state tort law “broad and sweeping”
-
- Another vaccine-related case arising from the Secretary’s H1N1 Declaration
 - Claim for damages for patient who did not receive an H1N1 vaccine in connection with upcoming procedure
 - Court held that the Prep Act did not preempt state malpractice claim because the covered countermeasure was not administered

Limited Case Law, *cont.*

- *Parker and Casabianca* are both New York state court cases
 - Limited precedent beyond New York
- Federal case in Eastern District of Missouri did not reach the merits of the Prep Act
 - Parties agreed Defendant drug manufacturer was covered by Prep Act immunity (*Kehler v. Hood*, Case No. 4:11CV1416 FRB, 2012 WL 1945952 (E.D. Mo. 2012))
- *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 253 (2011)
 - Not a PREP Act case
 - Broad statutory textual decision upholding immunities of National Childhood Vaccine Injury Act of 1986

Other Immunity Initiatives

COVID-19 related litigation is expected to soar, including liability litigation for products, healthcare services and employment. The protections are all over the place.

Defense Production Act – has liability immunity protections related to compelled productions.

New York, New Jersey, and Illinois issued executive orders providing a measure of healthcare provider immunity.

North Carolina – enacted immunity provisions for essential businesses in connection with the contraction of COVID-19. Includes restaurants, pharmacies, hardware stores, banks.

Senate bill, Safe To Work Act – proposes broad immunity from COVID-19 related liability to discourage insubstantial lawsuits against healthcare workers and facilities, among other business activities, services or accommodations.

States have enacted or proposed immunity provisions. Varied exemptions for gross negligence, intentional wrongdoing or recklessness. Not all address medical liability exposures.

Maryland, Indiana, and Louisiana provide statutory immunity upon PHE declarations.

Georgia, Iowa, Kansas, Oklahoma, Wyoming, and Utah have enacted COVID-19 related immunity provisions.

Immunity Assessment

- Checklist and confirm all PREP Act requirements and specific Declaration COVID-19 requirements
- Assess and document steps to establish and comply with PREP Act requirements for covered countermeasures and status as qualified person
- Assure that the provider can meet good faith standard of covered persons engaging in recommended activities for covered medical countermeasures.
- Determine any actions through *Authority Under Jurisdiction* that may expand immunity, including for volunteers
- Investigate all state declarations, orders, and benchmark immunity requirements
- Assess use of COVID-19 waivers or contract amendments to incorporate PREP Act or other immunity provisions or establish assumption of risk defenses
- Determine insurer position on whether and how coverage (including duty to defend) is impacted by PREP Act and related immunities

Immunity Scenarios

- Patient comes to the clinic with COVID like symptoms on July 25, 2020, and the Doctor prescribes hydroxychloroquine sulfate to treat. Patient later dies from cardiac complications and the family sues the clinic for malpractice.
- Patient comes to the clinic with COVID symptoms, family believes he is a candidate for HCQ therapy, but it is not prescribed. Patient later dies from COVID-19 and family sues the clinic for malpractice.
- Patient A and his significant other receive free respiratory masks as a handout at local clinic as he arrives for COVID-19 testing. The materials used in making the mask are later found to be defective and causing severe skin reactions. Patient A is screened for testing for COVID-19, but he has no relevant symptoms at the time and is not tested. 2 days later he develops shortness of breath and is hospitalized with COVID-19. His significant other (Patient B) is hospitalized in a separate wing due to the significant allergic reaction to the materials in the mask. Based on the exposure to his COVID-19 partner, he receives a PCR test which returns a (false) negative result. After being treated and released for the rash, he returns home to gather with family to discuss Patient A's status. All members of the family then contract COVID-19 within 5 days of the meeting, two requiring hospitalization. The family now seek to sue the clinic for the damages suffered as a result of their experience.

Selected References

- COVID-19 PREP Act Declaration. *85 Fed. Reg. 15,198 (March 17, 2020) and 42 U.S.C. 247d-6d and 247d-6e. See also, Pub. L. No. 109-148, Public Health Service Act, 319F-3; www.phe.gov/prepact/Pages/COVID19.aspx*
- HHS Advisory Opinion, www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf
- List of COVID-19 countermeasures: See Appendix A, <https://www.fda.gov/media/136702/download>

NOW. NORMAL. NEXT.

QUESTIONS?

Morgan Lewis

Biography



Gregory Etzel

Houston

gregory.etzel@morganlewis.com

+1.713.890.5755

Greg Etzel concentrates his practice on the representation of hospitals and other healthcare providers in a variety of complex legal transactions and regulatory litigation. Prior to joining Morgan Lewis, Greg spent four and a half years in-house as the vice president of legal affairs at The University of Texas Medical Branch (UTMB), providing legal counsel and representing the entire institution on a wide range of issues involving strategic initiatives, hospital and medical school operations, transactions, litigation management, public information, and international affairs.

Biography



Kathleen McDermott

Washington, DC

kathleen.mcdermott@morganlewis.com

+1.202.739.5458

A former Assistant US Attorney and US Department of Justice (DOJ) Healthcare Fraud Coordinator, Katie McDermott represents healthcare and life sciences clients throughout the United States in government investigations and litigation matters relating to criminal, civil, and administrative allegations, including violations of the False Claims Act and its whistleblower provisions. Katie also advises on corporate compliance matters relating to internal investigations, voluntary government disclosures and consent decrees. Katie has handled a wide variety of quality of care enforcement matters for nursing facilities, hospice, home health and hospital providers.

THANK YOU

© 2020 Morgan, Lewis & Bockius LLP
© 2020 Morgan Lewis Stamford LLC
© 2020 Morgan, Lewis & Bockius UK LLP

Morgan, Lewis & Bockius UK LLP is a limited liability partnership registered in England and Wales under number OC378797 and is a law firm authorised and regulated by the Solicitors Regulation Authority. The SRA authorisation number is 615176.

Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan Lewis operates through Morgan, Lewis & Bockius, which is a separate Hong Kong general partnership registered with The Law Society of Hong Kong as a registered foreign law firm operating in Association with Luk & Partners. Morgan Lewis Stamford LLC is a Singapore law corporation affiliated with Morgan, Lewis & Bockius LLP.

This material is provided for your convenience and does not constitute legal advice or create an attorney-client relationship. Prior results do not guarantee similar outcomes. Attorney Advertising.