WINSTON & STRAWN LLP

WEBINAR

The Perils of Overpromising: Managing Exposure When Your Product Doesn't Live Up to the Hype

JANUARY 13, 2021

AGENDA

INTRODUCTION TO THE PANEL AND THE SCENARIO

- Winston's cross-practice approach to managing product liability exposure for companies

SCENARIO ELEMENTS

1. The Short Seller Attack / Derivative Demand
2. Product Liability and Negligence Suits
3. Securities Class Action / Shareholder Derivative Suits

TAKEAWAYS/QUESTIONS

Setting the Stage: The Scenario

- CleanCo announces its testing PathoBegone to determine effectiveness against coronavirus.
- Promising events follow: FDA grants EUA. CleanCo receives promising preliminary data.
- Sales rep tells hospital that CleanCo has data showing PathoBegone kills COVID-19, leading hospital to place largest order to date.
- CleanCo's marketing highlights this order, and other large orders come in. Revenues are up 85%, and stock jumps 50%.
- Sales rep tells his boss, the VP of Sales for Northeast, about how he shared news of promising data to hospital to close a deal. VP does not report it upwards.
- Senior executives' public comments: cautious, but optimistic.

RECOVERY

THREAT SCENARIOS

1. The Short Seller Attack / Derivative Demand

Repelling the Short-Seller Attack

- Implement early warning system
  - Pay attention to mounting short position in your stock
- IR/PR is first line of defense
  - Have crisis management PR firm on tap
- Sometimes, identity of short-sellers is public but more often, they hide behind a cloak of anonymity, obfuscating critical facts about their campaigns
- Short-sellers may leverage regulatory agencies by casting accusations that can result in investigations or enforcement actions—events that, in turn, are leaked and subsequently publicized
- Effectively combatting short short-selling campaigns requires coordinated legal and communications advice and strategy
- Range of responses: (1) the Conventional Wisdom; (2) Intermediate Level Response; (3) Aggressive Response

The Conventional Wisdom: "Keep Your Head Down"

PROS	CONS
• Avoids adding fuel to fire • Provides flexibility options (in the short term) • Companies with no "hidden skeletons" can recover from even blistering attacks	• Creates information vacuum that allows for rumors/speculation • Anxious employees; anxious investors • Continued stock drop • Increased investigation into company

Intermediate Level Response: Seek to Kill Short-Seller Narrative/Planted Stories

- *Strong responsive statements*
- *Steps to stop planted stories/ place your own story in the press*
- *Hire private investigators*
- *Public conference call (no Q&A, scripted)*
- *Communicate with largest investors to reinforce message*
- *Other*

PROS	CONS
• Corrects misinformation • Controls the narrative • Reassures investors (and employees)	• May not be an option based on substance of allegations • Risk of losing control of narrative

Aggressive Response: Enlist Regulators and/or Litigate

- *Report potential market manipulation to SEC/ask other regulators to investigate*
- *Combine communications counter-attack with lawsuit (or threat of lawsuit) against short-sellers for conspiring to devalue Company's stock and market manipulation under federal securities laws*

PROS	CONS
• Sense of "justice" • Powerful public statement • Turns the tables • Short-seller on the defensive/facing threat of discovery may stand down	• Glass house problem • May not resolve the actual allegations or issue at hand • Can lead to damaging reputations of others and costing people money

Investigation Announcements (aka “Shareholder Alerts”)

- Press releases by plaintiff’s firms trolling for potential clients in wake of short-seller “reports,” precipitous stock drop, announcement of government investigation/enforcement action or other “corporate trauma”
- Essentially a reflex on the part of a certain segment of the plaintiffs’ bar
- Handicapping the “Usual Suspects”
  - *The “Wolf-Criers”*
    - Some firms, not top-shelf players in the federal securities class action/derivative suit area, frequently issue “investigation announcements,” but fall into a cohort that rarely follows through and actually files a case

Investigation Announcements

- *The "Frequent Filers"*
  - Often the first to sue, but routinely unseated as lead counsel by more serious firms that tend to have larger institutional investor clients
  - Notorious for quantity over quality, often filing weak complaints
- *The Serious Players*
- Document retention implications?
- Possible connection between short-sellers and law firm "investigation announcements
  - Coordinated multipronged attack against selected target in an effort to magnify the short-term market impact of the short report

Derivative Demand Response 101

- Predicate to a derivative suit
- Demand typically precipitated by some “corporate trauma” and requests Board investigation of possible breaches of fiduciary duty based on allegations that directors failed to recognize or take action in the face of “red flags” and the Company had inadequate system of controls
- Sometimes preceded by demand to inspect corporate books & records
  - Should be recognized as harbinger of full-blown derivative demand or lawsuit
  - Delaware Section 220
    - Board minutes/emails
    - Must state a “proper purpose” and documents requested must be “necessary and essential” to that purpose
    - Summary proceeding

Derivative Demand Response 101

- May be addressed to the Board c/o the GC or the Chairman
- To form a committee or not to form a committee?
  - Demand concedes majority board independence/disinterestedness
  - Demand review committee ("DRC") vs. Special Litigation Committee (or "SLC")
  - No single blueprint
    - Board's obligation is to make a fully informed, good faith, reasonable determination as to how to respond to demand
      - Factors go beyond whether there is evidence to support a claim
      - Exercise of business judgment to weigh potential benefits of bringing claims versus cost and distraction, potential impact on company's business operations, etc.

Derivative Demand Response 101

- Populating the DRC
  - “Committee of One”
  - Counsel considerations
- Timeline
  - No mandatory period within which Board must respond under Delaware law
    - Some states differ
- Challenge to Board’s determination: The “wrongful refusal” standard
  - Very high bar
    - Stockholder must allege with specificity that Board’s process was grossly negligent.
      - Focus on independence and disinterestedness/process vs. substance

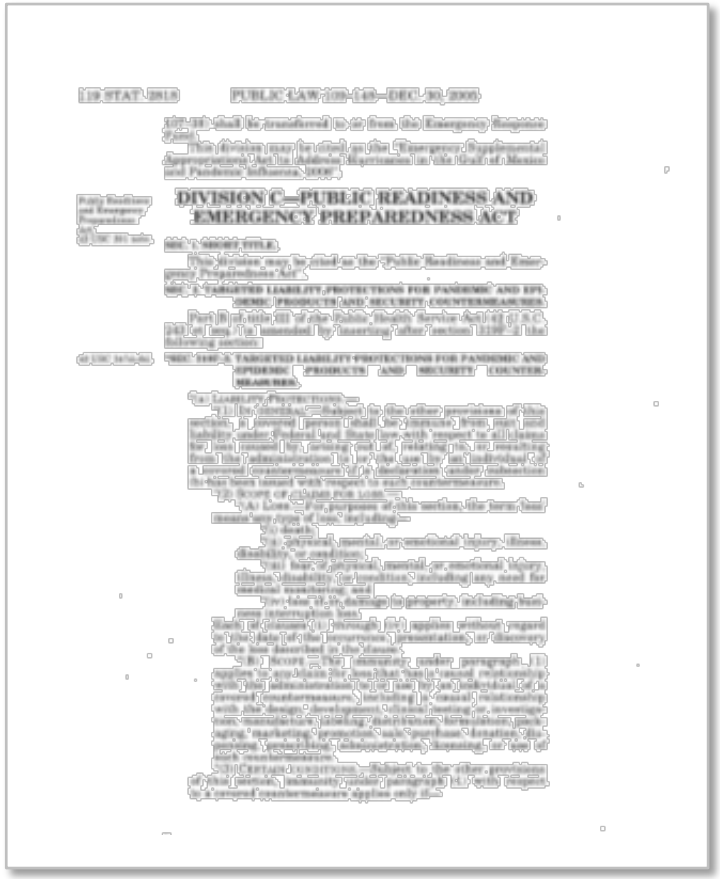
2. Product Liability and Negligence Suits

Setting the Stage: The Scenario Continued

- Philadelphia Metropolitan Hospital sees the coronavirus rate of infection for both patients and personnel significantly increasing.
- Data analysis links the increase in coronavirus mortality to the hospital's use of PathoBegone.
- Citing allegations of corner-cutting in the testing process and fabrication of data provided to FDA, the hospital and individuals who contracted COVID-19 file product liability and negligence suits against CleanCo.
- CleanCo considers whether it is immune from product liability claims under the PREP Act.

What is the PREP Act?

- Public Readiness and Emergency Preparedness Act (2005) (42 U.S.C. § 247d-6d)
- Provides liability immunity against state and federal law claims to covered entities and individuals for covered countermeasures
- Preempts state law
- Authorizes Secretary of HHS to issue a PREP Act Declaration identifying covered diseases that constitute a public health emergency and scope of product immunity



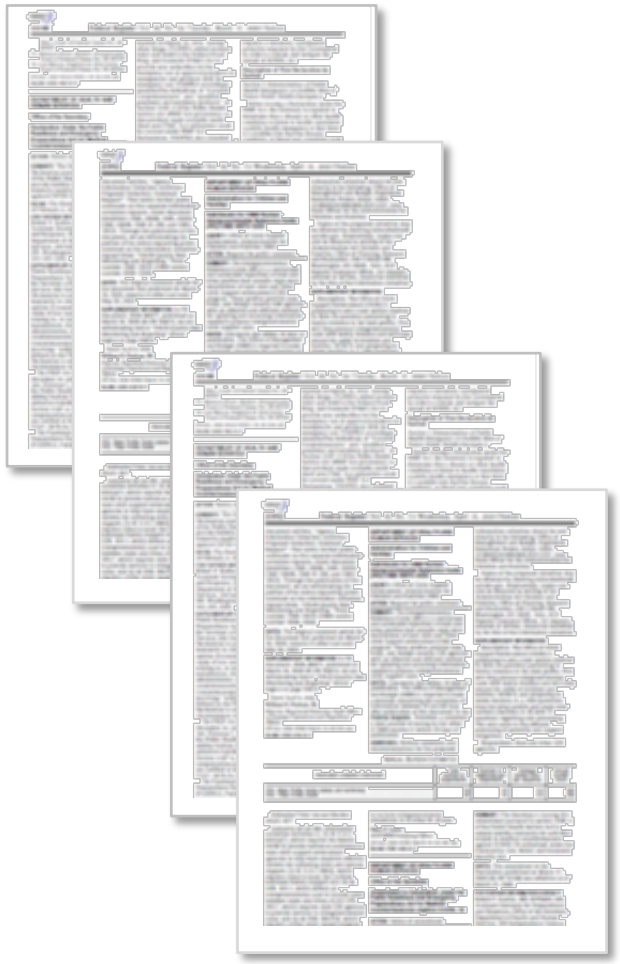
DIVISION C—PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT

Declared Public Health Emergencies

- Acute Radiation Syndrome (2008)
- Smallpox (2008)
- Anthrax (2008)
- Botulism (2008)
- Influenza Viruses (2008), including H1N1 Flu (2009)
- Ebola (2014)
- Nerve Agent Poisoning (2017)
- Zika (2017)
- COVID-19 (2020)

Public Readiness and Emergency Preparedness Act: Current Declarations, available at https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

COVID-19 Declaration and Amendments



March 17, 2020: PREP Act COVID-19 Declaration

- Provides immunity to "**Covered Persons**" against all claims of loss "caused by, arising out of, relating to, or resulting from" the "manufacture, testing, development, distribution, administration, and use" of medical countermeasures against COVID-19 ("**Covered Countermeasures**") for "**Recommended Activities**"

April 15, June 8, August 24, and December 3, 2020 Amendments

- Expands "covered countermeasures" to include respiratory protective devices, products that "**limit the harm**" that COVID-19 might otherwise cause, and childhood vaccinations
- Expands "covered persons" to include licensed **pharmacists** and **telehealth professionals**
- Expands "recommended activities" to include products in **private distribution channels**

What are “Covered Countermeasures”?

- **Drugs, biological products, or devices used** to:
  - Diagnose, mitigate, prevent, treat or cure COVID-19 or limit its harm
  - Diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by COVID-19 or COVID-19 product
- **A product or technology** intended to enhance the use or effect of the above products
- **Respiratory protective devices** approved by NIOSH are included within the definition as codified by the CARES Act

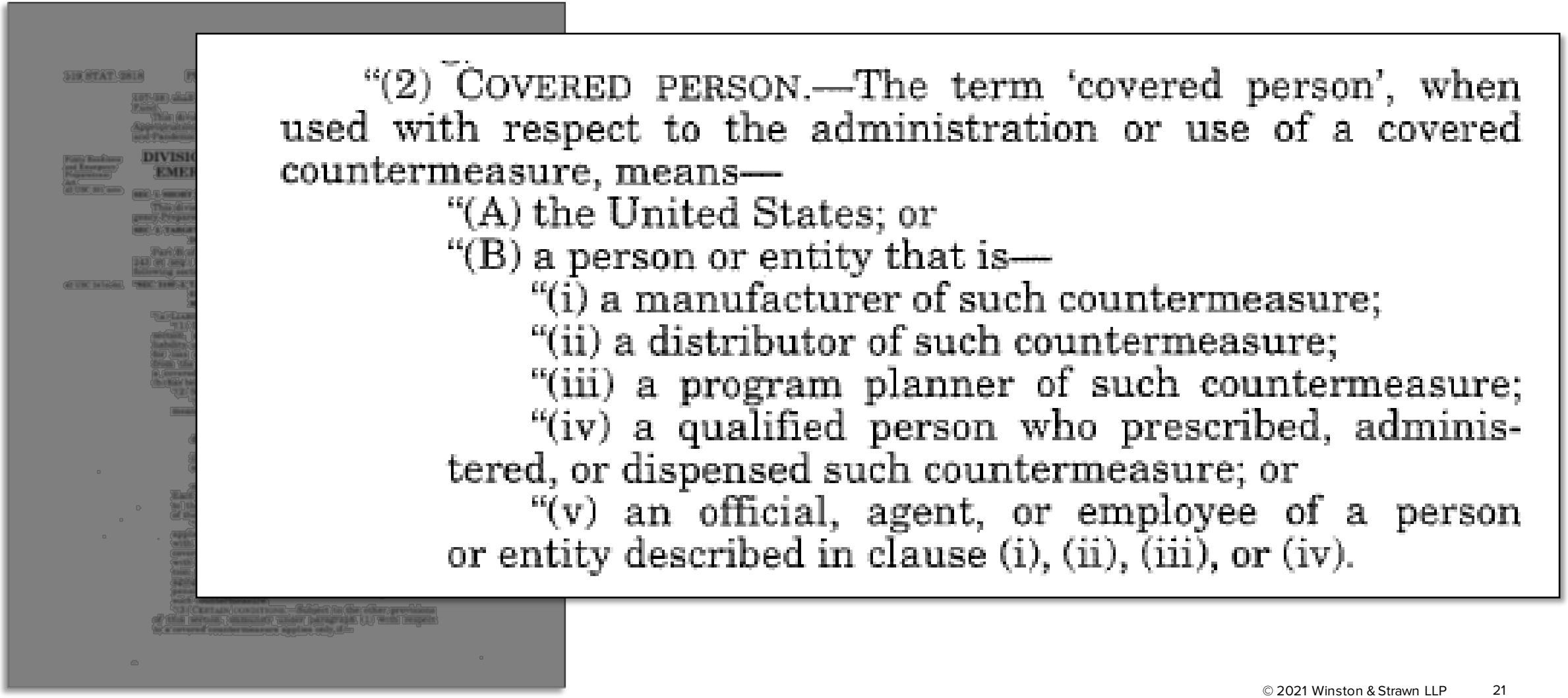
42 U.S.C. § 247d-6d(i)(1)(A); 4/14/20 Advisory Opinion p. 3

Limitations on "Covered Countermeasures"

- To meet the definition, a COVID-19 product must be:
  - Approved, licensed, or cleared by FDA
  - Cleared for investigational use under an Investigational Drug Application or Investigational Device Exemption by FDA (or otherwise authorized)
  - Described in Emergency Use Instructions issued by the CDC, or
  - Authorized for emergency use under an EUA
- The number of products used "that are approved, licensed or cleared are too numerous to list," but the Declaration links to a list of products covered by EUAs

42 U.S.C. § 247d-6d(i)(7); March 10, 2020 4/14/20 Advisory Opinion at p.4; *FDA Combating COVID-19 with Medical Devices*, Appendix A, available at https://www.fda.gov/media/136702/download; *FDA combating COVID-19 with Therapeutics*, Appendix B, available at https://www.fda.gov/media/136832/download

Who are “Covered Persons”?



“(2) COVERED PERSON.—The term ‘covered person’, when used with respect to the administration or use of a covered countermeasure, means—

“(A) the United States; or

“(B) a person or entity that is—

“(i) a manufacturer of such countermeasure;

“(ii) a distributor of such countermeasure;

“(iii) a program planner of such countermeasure;

“(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

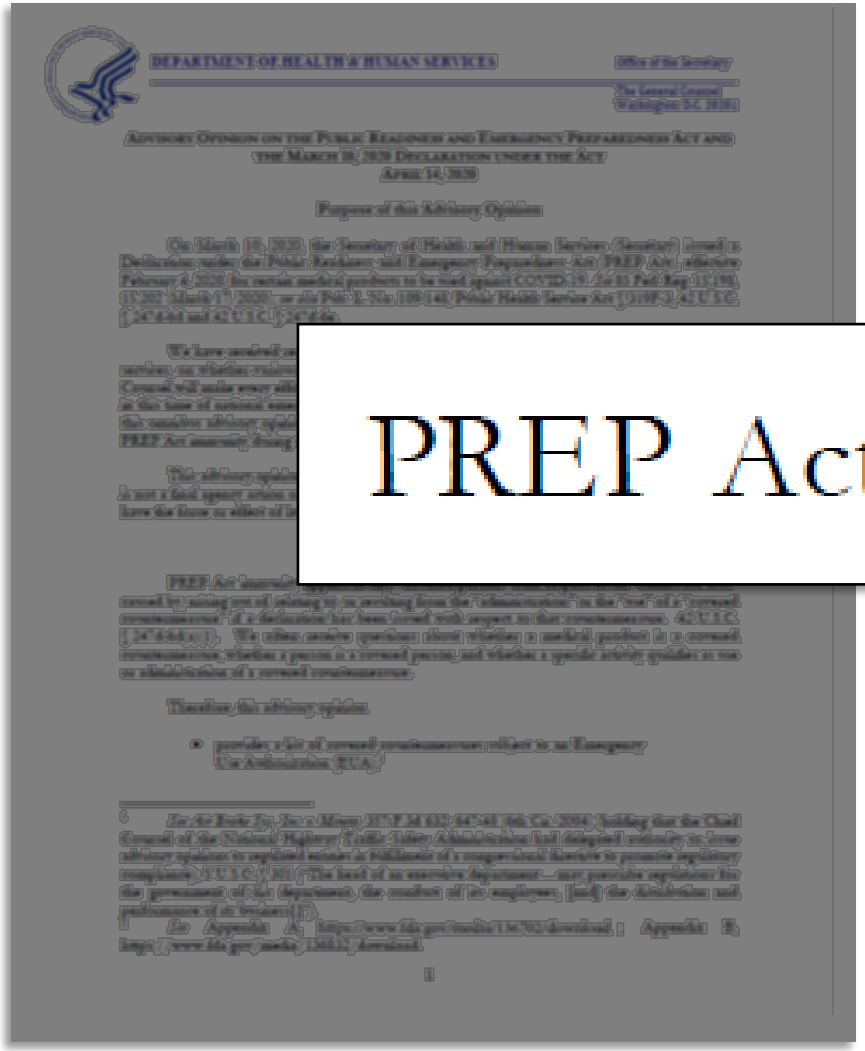
“(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

What are "Recommended Activities" Such that Immunity Applies?

- Immunity is afforded only to "Recommended Activities" for Covered Countermeasures that are:
  - Related to an **agreement or arrangement with the federal government** (not limited to written contract),
  - Authorized in accordance with the public health response of an "**Authority Having Jurisdiction"** following a declared emergency (any activity that is part of an authorized emergency response at federal, regional, state, or local level), or
  - Licensed, approved, cleared, or authorized by FDA, even if used in **private distribution channels** (effective Dec. 3, 2020)

Declaration, Section VII; 4/14/20 Advisory Opinion 4/14/20 Advisory Opinion, p. 2

PREP Act Does Not Provide Total Immunity



PREP Act immunity is not absolute.

April 14, 2020 Advisory Opinion, p. 2

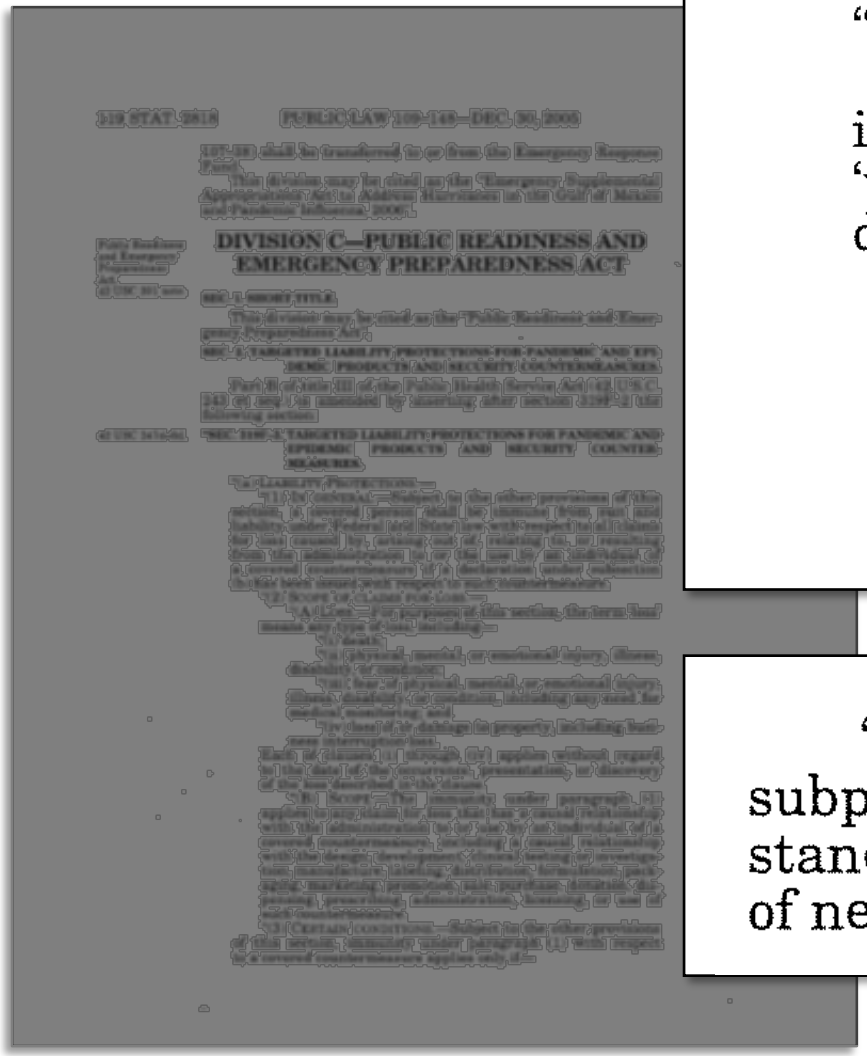
What are the Limits of PREP Act Immunity?

No immunity from/for:

- Claims under **federal law** for **equitable relief**
- Any **governmental enforcement actions**, whether civil, criminal or administrative
- **Foreign claims** where U.S. has no jurisdiction
- **Death or serious injury** caused by **willful misconduct**

4/14/20 Advisory Opinion, pp. 2; 42 U.S.C. § 247d-6d(f); U.S. Dept. of Health and Human Services, PREP Act Q&As, available at https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q3; 42 U.S.C. § 247d-6d(d)

What is "Willful Misconduct"?



"(c) DEFINITION OF WILLFUL MISCONDUCT.—

"(1) DEFINITION.—

"(A) IN GENERAL.—Except as the meaning of such term is further restricted pursuant to paragraph (2), the term 'willful misconduct' shall, for purposes of subsection (d), denote an act or omission that is taken—

"(i) intentionally to achieve a wrongful purpose;

"(ii) knowingly without legal or factual justification; and

"(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

42 U.S.C. § 247d-6d(c)(1)(A)

"(B) RULE OF CONSTRUCTION.—The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

42 U.S.C. § 247d-6d(c)(1)(B)

Facts Supporting Willful Misconduct Claim

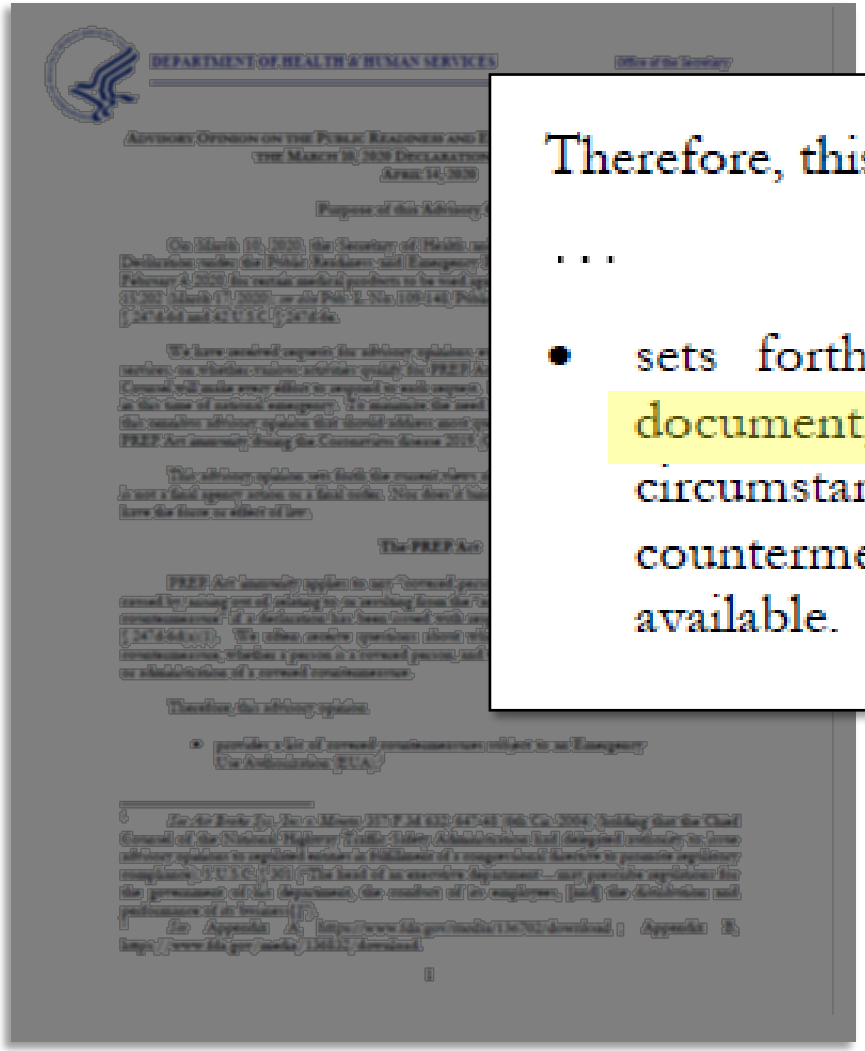
- Manipulation or falsification of clinical data[1]
- Knowledge of faulty materials used in manufacturing[2]
- Fraudulent concealment of health or safety issues[3]
- False or misleading marketing[4]

1 E.g., Blackwood v. Atrium Med. Corp., No. 16-CV-379-LM, 2019 WL 3779698 (D.N.H. Aug. 12, 2019)
2 E.g., Cooper Tire & Rubber Co. v. Tuckier, 826 So. 2d 679 (Miss. 2002)
3 E.g., Kerrivan v. R.J. Reynolds Tobacco Co., 953 F.3d 1196 (11th Cir. 2020)
4 E.g., Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517 (D. Minn. 1989)

Best Practices for Avoiding Willful Misconduct

- Oversight protocols for data generating activities, such as clinical trials
- Quality control checks for new manufacturing processes or suppliers
- Confirm product labels fully reflect known risks
- Promptly update product labels with new safety information
- Ensure marketing statements are accurate and supported by validated data
- Exercise care regarding marketing claims of agency approval

Reasonableness is Key



Therefore, this advisory opinion

. . .

- sets forth HHS's view that covered persons should take, and document, reasonable precautions under the current emergent circumstances to facilitate the safe use or administration of covered countermeasures and to make those documents publicly and easily available.

April 14, 2020 4/14/20 Advisory Opinion, pp. 1-2

PREP Act vs. Typical Product Liability Litigation

	PREP ACT LITIGATION	TYPICAL PRODUCTS LITIGATION
Jurisdiction	Exclusive federal cause of action alleging PREP Act exception before 3-judge panel in D.D.C.	State or Federal Court; jury trial available
Governing Law	State where alleged misconduct occurred; federal law defines "willful misconduct" and "serious injury"	State law (typically where injury took place)
Pleading Requirements	With particularity; affidavits and certified medical records requirements	Notice pleading (FRCP 8) or State equivalent
Discovery	None before interlocutory appeal of MTD; limited to matters "directly related to material issues"	Relevant and proportional to claims and defenses (FRCP 26) or State equivalent
Damages	Reduced by amount of collateral source benefits; Proportional liability for noneconomic damages	Dependent on governing state law
Burden of Proof	Clear and convincing	Preponderance of the evidence

3. Securities Class Action / Shareholder Derivative Suits

Defending the Federal Securities Class Action

- Long fuse/slow burn
- Initial complaint is placeholder
  - “Rush to courthouse”/hastily prepared/almost never responded to
  - Multiple complaints/investigation announcements will eventually be combined in a single consolidated action without need for action by defendants -- and before they ever have to respond
- Short-term action items
  - D&O insurance notice
  - Document retention
  - Internal and external communications strategy
  - Identify former involved employees (friendly, hostile and indifferent)
  - Service issues/scheduling stip

Defending the Federal Securities Class Action

- Initial jockeying among plaintiffs: The lead plaintiff/lead counsel process
  - Dictated by Private Securities Litigation Reform Act of 1995 (PSLRA)
    - Within 20 days of filing, plaintiff must publish notice to other shareholders informing them of right to seek appointment as lead plaintiff
    - Within 60 days of notice, any shareholder can file motion for appointment as lead plaintiff (regardless of whether they previously filed a complaint) asking that their lawyers be appointed "lead counsel"
    - Court has 90 days from the notice—that is, 30 days from the deadline for would-be lead plaintiffs to file motions – to appoint a lead plaintiff and lead counsel
      - NOTE: Different from class certification, which happens later
    - Court must decide any consolidation motions prior to selecting lead plaintiff (but usually in same decision)

Defending the Federal Securities Class Action

- Lead plaintiff/lead counsel often given up to 60 days from appointment to file consolidated/amended complaint
  - Typically, much longer and more detailed
  - Frequently includes allegations from so-called "confidential witnesses" or "CWs" (often disgruntled former employees)
  - Will incorporate any intervening adverse developments/"shoes that fall"
  - May include new defendants/claims and/or a longer class period
- Defendants will typically have 60 days from filing of amended complaint to move to dismiss
  - In other words, ***at least seven months from filings until defendants respond***

Defending the Federal Securities Class Action

- In the meantime, no discovery or other activity pursuant to PSLRA's automatic stay of discovery until motion to dismiss is decided.
- But:
  - Internal self-discovery
  - Coordinate with counsel handling demand response / FDA process / products suit
    - E.g., overlapping document holds, planned interviews of defendants or other key witnesses
  - Seek stay of any "piggyback" derivative suit

Defending the "Piggyback" Derivative Suit Amidst "Corporate Trauma"

- Derivative suits almost invariably follow filing of federal securities fraud class action(s)
  - "Oversight"/"duty to monitor business risk" claims
    - State law breach of fiduciary duty by the Board/corporate waste
- Sometimes filed in same federal court as securities class action, different federal court, state court – or all of the above
- Range of responses
  - "Demand futility"
  - The SLC Option
  - The Stay Option

Demand Futility

- In most jurisdictions, to sue derivatively, stockholder must either first make a demand on Company's board to investigate or plead that such demand would have been "futile"
  - Delaware v. other states
  - To establish "demand futility," stockholder must plead and prove that majority of directors on the board at the time complaint was filed were interested and or lacked independence
  - Fact that director is named as defendant not sufficient; must show that the director faces a "substantial likelihood" of liability based on the claims asserted
- Basis for early-stage motion to dismiss

The SLC Option

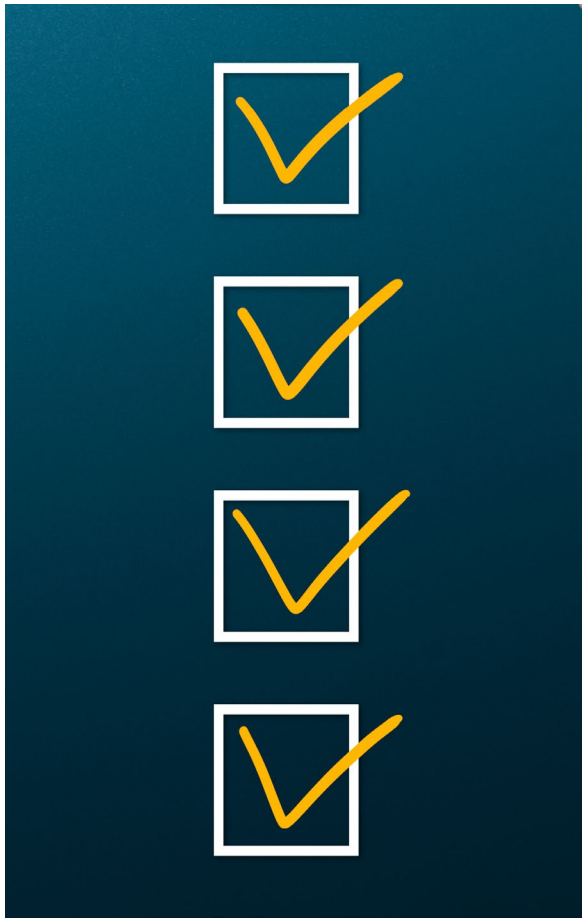
- Displace stockholder plaintiff through formation of SLC to investigate the claims asserted
- Available at any stage of litigation, but most common following denial of motion to dismiss
- Requires at least one independent director
- Probably requires hiring a new, independent law firm
- Derivative litigation generally stayed pending completion of SLC's investigation
- SLC, following investigation, can seek dismissal or take over litigation from shareholder plaintiff
- Considerations: cost; D&O coverage; distraction
  - How does existing demand response investigation factor in?

The Stay Option

- Claimed damages will often be the cost of defending/settling the federal securities class action, any governmental investigations or enforcement actions or, here, the products suit
- Plaintiffs will often be amendable to a stay in exchange for agreement allowing them to participate in certain discovery/settlement discussions or mediation in the securities class action

Takeaways

Takeaways



Short-Seller Attacks

- **Be prepared**
  - Know your stockholder base
  - Have the right suite of advisors on “ready alert”
- **Be situational**
  - The “right” response is not foreordained
    - A spectrum from silent to “smashmouth”
- **Be coordinated**
  - With defense of existing or anticipated related litigation, investigations, regulatory processes, etc.

Takeaways

Derivative Demand Response

- **Be prepared**
  - Look out for and recognize books & records demands as precursors
  - Identify your disinterested independent directors
  - Identify potential independent counsel choices
- **Be situational**
  - No single blueprint
  - DRC investigation may not be necessary – or it may be essential
- **Be coordinated**
- **Be deliberative**

Takeaways

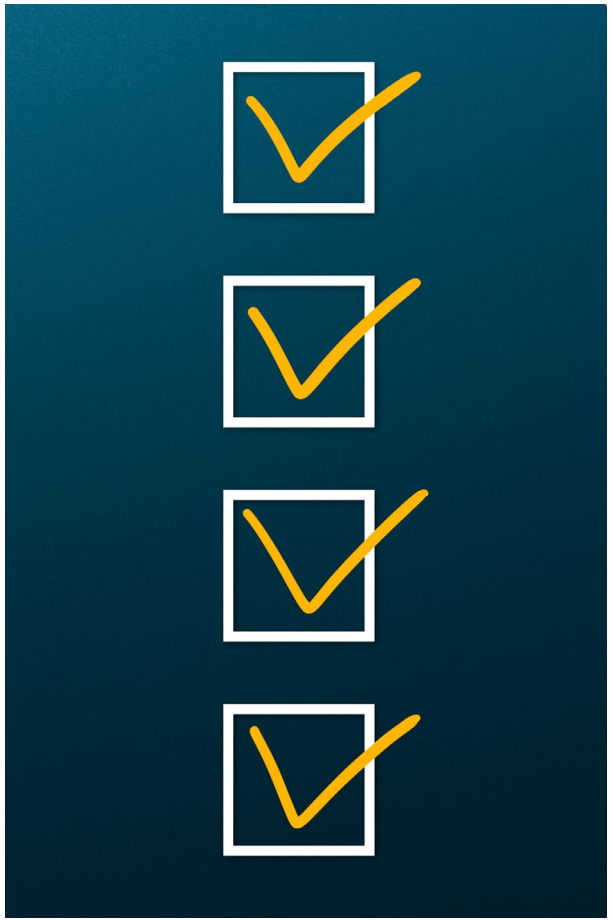
Plaintiff's Firm "Investigation Announcements"

- Maybe something, maybe nothing
  - Gauge threat level based on issuing law firm's "MO"
- Consider document retention

Products Liability/Negligence Suits

- PREP Act immunity is broad but not absolute
- Private distribution channels for COVID-19 countermeasures are now covered
- Prepare protocols and quality control to avoid willful misconduct

Takeaways



Securities Class Actions

- "Out of many, one"
- Slow developing/months of lead time
  - Use it wisely
- Coordination remains the watchword
- Motion to dismiss while discovery stayed

Piggyback Derivative Suits

- Often "derivative" in the truest sense
- Can frequently be backburnered on consent
- Multiple paths to shut down
  - Defense typically stands on shoulders of what has gone before (e.g., DRC, securities class action)