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PREP Act Immunity and Its Application in Shareholder Derivative Litigation: A Modest Proposal

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Much has been published recently about the Public Readiness and Emergency Preparedness Act ("PREP Act" or "Act") in the COVID-19 era.[1] Its protections, including broad immunity from liability, have been extended to individuals and companies involved in the design, manufacture, distribution and administration of "countermeasures" against the SARS-CoV-2 virus. Although the PREP Act has been around for more than 15 years, its defensive application in litigation *before* COVID-19 was limited. Now, more than a year into the pandemic, application of the PREP Act is being more actively litigated, primarily in the context of COVID-19 deaths in skilled nursing and assisted living facilities.[2]

Still unresolved, however, is whether there is any basis for using the PREP Act defensively in shareholder derivative suits which allege that "materially deceptive statements" made by companies trying to make vaccines and other "countermeasures" are covered by the PREP Act. While there has been no definitive judicial assessment of this question, there are reasons that companies facing such claims should consider seeking such a determination.

The PREP Act: Background

In 2005, Congress passed the PREP Act as a tool to combat public health emergencies. It empowered the Secretary of the U.S. Department of Health and Human Services ("Secretary") to issue a "Declaration" that "a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency."[3] If such a Declaration is issued, immunity from liability will apply to persons and companies engaged in providing "countermeasures" to combat the perceived public health threat. Such a Declaration was issued by the Secretary of Health and Human Services in March 2020 in response to the COVID-19 pandemic. Through various subsequent amendments to the Declaration, as well as guidance and advisory opinions, the scope of immunity was further illuminated and in some ways expanded.

Historical Application of the PREP Act

Prior to COVID-19, few cases invoked the PREP Act. Among those that did, most favored supporting immunity despite various forms of harm. Unsurprisingly, most of the cases focused on the vaccine for the H1N1 virus.

In *Parker v. St. Lawrence County Public Health Department,*[4] the claim was that a child was immunized against the H1N1 virus without parental consent. The court disposed of this claim, holding that the PREP Act "preempts plaintiff's state law claims for negligence and battery."[5]

In *Kehler v. Hood,*[6] a plaintiff sued a physician and the physician's employer, claiming that the defendants failed to obtain the plaintiff's informed consent before administering the H1N1 vaccine. This led to the development of "a severe case of transverse myelitis."[7] The defendants then brought a third-party action against the vaccine manufacturer, Novartis Vaccines and Diagnostics. Novartis moved to dismiss all claims against it under the PREP Act. The court agreed, held that Novartis enjoyed absolute immunity from liability pursuant to the PREP Act, and dismissed those claims.

Not all cases allowed a defendant to benefit from the PREP Act. In *Casabianca v. Mount Sinai Medical Center,* [8]the claim centered on the *failure to administer* a flu vaccine, which allegedly led to various serious medical consequences. The Trial Order—not an officially published opinion—determined that withholding a vaccine (as opposed to administering it) was not covered by the statute. In the COVID-19 context, this reasoning may not apply since the amendments of the Declaration related to the COVID-19 pandemic make clear that failure to administer a covered activity may still be covered by the PREP Act if withholding from one person is related to the need to administer to another.[9]

Application of the PREP Act During the COVID-19 Pandemic

COVID-19 has seen a plethora of lawsuits in which the PREP Act has been invoked. Many involve skilled nursing or assisted living facilities where COVID-19 countermeasures were *not* administered and patients/residents passed away.[10] Some decisions hinged on a determination as to whether the withholding of countermeasures was causally related to the administration of countermeasures to another person. In other words, were there limited resources and the sued entity made decisions about who would have access to those limited resources? In most cases, courts ruled that such withholding was not a resource issue and declined to rule that the PREP Act applied.[11]

In *Haro v. Kaiser Foundation Hospitals,*[12] an employee of a Kaiser Foundation Hospital was required to report for work 15 minutes before her shift began for COVID-19 medical screening, without compensation for that extra time. Here, the court also held that the PREP Act did not apply.[13]

PREP Act Immunity and Shareholder Derivative Suits

An unresolved question is whether the PREP Act provides protection to companies and their executives who are sued in shareholder class action suits. A number of recently filed cases allege that manufacturers who engaged in efforts to formulate COVID-19 vaccines and other therapies, but failed to achieve regulatory approval in the U.S., committed violations of the Securities and Exchange Act of 1934 ("Securities Act"). These complaints allege generally that (a) the companies and key executives made intentionally false and misleading statements that led investors to purchase securities; (b) the value of the securities was artificially inflated by the allegedly fraudulent statements; and (c) the value then declined upon the failure of the promised vaccine or other countermeasures to obtain regulatory approval.[14]

Undoubtedly, these companies can assert a number of different arguments which may militate in favor of dismissal of these putative class action complaints, most prominently that any statements made were not intentionally false, as required by the Securities Act. One argument that has not been a traditional defense in

shareholder derivative suits is PREP Act immunity. The argument will need to focus on whether the terms of the PREP Act contemplate immunity to the type of injury alleged in shareholder derivative suits.

The terms of the PREP Act provide a starting point for this defense. The PREP Act provides a list of the kinds of claims it seeks to limit by virtue of the grant of broad immunity. Certainly, "garden variety" personal injury claims are covered, including when the harm alleged includes:

(i) Death;

(ii) Physical, mental or emotional injury, illness, disability or condition;

(iii) Fear of physical, mental or emotional injury, illness, disability, or condition, including any need for medical monitoring.[15]

However, the PREP Act also includes an additional category of loss that, by its terms, clearly goes beyond personal injury:

(iv) **Loss of or damage to property**, including business interruption loss.[16]

The question is whether shareholder damages, *e.g.*, the loss in share value alleged in recent shareholder claims, could be a "loss of or damage to property" under the PREP Act.[17]

Shareholder claims generally allege that false or misleading statements by a company and its executives induced a member of the public to purchase shares at inflated value, which subsequently diminished in value when the falsity of the statements became known. Although there are several cases alleging shareholder losses due to allegedly "false or misleading" claims by companies involved in the manufacture or sale of COVID-19 "countermeasures,"[18] none of the cases considered the question whether "loss of or damage to property" could include diminution in value of the shares in such a company. Indeed, none of the defendants appear to have pleaded the PREP Act as a defense. There are arguments to be made as to why they should consider doing so.

Like personal injury claims, fraud is a tort, albeit an intentional one.[19] The PREP Act certainly envisions that some types of covered claims might not merely be ones of negligence or accidental torts since the compensation scheme provides for special treatment of conduct that constitutes "willful misconduct."[20] The section on "willful misconduct" makes clear that the only injuries for which there may be an exception to the blanket immunity otherwise granted by the Act, is willful misconduct that results in *serious* physical injury or death.[21] The plain meaning of the text shows that for other kinds of "willful misconduct"—for example, willful misconduct causing "loss of or damage to property"—immunity still applies and no damages will be permitted outside of the limited compensation scheme under the PREP Act.[22]

The question remains whether the statute applies to any harm—intentional or otherwise—other than personal injury. Rules of statutory construction require that any such inquiry starts with the terms of the statute and whether the language "has a plain and unambiguous meaning with regard to the particular dispute in the case."[23] The United States Supreme Court has made clear that ''[o]ur inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'''[24] Here, the statute unambiguously creates a category of harm that is clearly different from the descriptions of personal injuries (or fear of personal injury) described in the preceding three definitional sections. "Loss of property" suggests a pecuniary loss and supports the notion that the kinds of harm contemplated by the statute is broad enough to include the financial harm described in the shareholder suits.[25]

The terms of the PREP Act are further illuminated by the Declaration, which is statutorily required to invoke the PREP Act to combat a public health crisis.[26] In his Declaration of March 17, 2020, the Secretary

acknowledged that COVID-19 constituted a public health emergency and declared PREP Act immunity to be in effect to encourage "the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and the use of the Covered Countermeasures."[27] Thus, the "desirability of encouraging"[28] these activities lends credence to the argument that statements made in the course of "design, development, clinical testing or investigation"[29] are related to these countermeasures and fall within the purview of the grant of PREP Act immunity. Clearly, the record shows that Congress recognized the need to impose limits on liability across a range of matters to encourage private industry participation in addressing the current public health crisis. Extending immunity for shareholder derivative suits is consistent with this goal.[30]

Even the legislative history of the PREP Act provides evidence that the broadest interpretation of the kinds of harm that are covered by the statute's grant of immunity is appropriate. While the legislative history surrounding the PREP Act is sparse, particularly regarding the provision regarding "loss of or damage to property," there is certainly some evidence to support the idea that the immunity should be read broadly. Although there does not seem to be any specific consideration as to whether allegedly fraudulent statements by "covered persons" are covered by the PREP Act, several opponents of the Act voiced their concern about the breadth of immunity contemplated by the Act and, in doing so, provide guidance as to the legislative intent behind the statute. For example, then-Senator Joe Biden stated:

[T]his is no typical grant of immunity. No, the breadth of this provision is staggering. A drug maker can be grossly negligent in making or distributing a drug, and still escape liability. It can even make that drug with wanton recklessness and escape scott-free after harming thousands of people.[31]

Then-Senator Hillary Clinton also weighed in on the scope of immunity and implicitly acknowledged that the PREP Act applied to more than just physical injury:

Mr. President, I would like to take this opportunity to object to insertion of a provision in the Department of Defense appropriations bill that would provide sweeping immunity protections to pharmaceutical manufacturers . . . . [T]his provision would grant immunity to **all claims of loss**, including death and disability, for a broad range of products, including any drug that the Secretary designated as one that would limit the harm caused by a pandemic—a definition so broad as to encompass nearly any drug.[32]

Senator Patrick Leahy also expressed alarm at the breadth of the grant of immunity:

Knowing violations as well as gross negligence would be immunized from accountability. Even if the drug company acted with the intent to harm people, it would nevertheless be immune from criminal conduct unless the Attorney General or Secretary of Health and Human Services initiates an enforcement action against a drug company that is still pending at the time a personal claim is filed.[33]

While it may be true that some opponents of this broad immunity were mainly concerned about immunizing conduct that resulted in *physical injury* to people, the conduct covered by the immunity granted by this legislation is clearly more than just conduct that causes physical injury. As Senator Clinton's comment reflects, there are reasons to conclude that it covers claims of allegedly fraudulent statements made by "covered persons" involved in the manufacture, distribution and administration of "countermeasures."

Reasons to think otherwise do exist. For example, the Act does not specifically mention loss of share value as a covered "loss." Nor does it reference "fraudulent conduct" as protected by immunity. And, viewed as a whole, some might argue that the PREP Act seems mostly concerned with protecting "covered persons" from liability for personal injury claims. Indeed, it might seem counterintuitive that Congress would have wanted to immunize a company or its executives in the face of knowingly false and misleading statements. This argument, however, misses an important point. Such conduct would not be completely immunized since the

federal government would still be empowered to prosecute such false statements under various laws, including the Securities Act of 1933 and the Securities Act of 1934, pursuant to a carve-out in the PREP Act:

Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law . . . .[34]

Thus, the intent of the PREP Act would actually be promoted by protecting companies involved in trying to create vaccines or other types of treatment for COVID-19 from the burdens placed on those companies by shareholder derivative suits; while preserving the possibility of criminal prosecution by the U.S. Department of Justice and civil liability through governmental action mainly through the U.S. Securities and Exchange Commission.[35]

Conclusion

Until this is tested in the courts, no one can be sure if the hypothesis is correct—that PREP Act immunity should cover certain shareholder derivative suits. But there appears to be good reason to put this to the test. Asserting the Act's immunity in affirmative defenses and moving for dismissal is the best way to find out if the courts will agree.

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[1] *See, e.g.*, Erik K. Swanholt, John J. Atallah & Jessica N. Walker, *HHS Expands and Clarifies Scope of Immunity under the PREP Act*, The National Law Review (Dec. 28, 2020), https://www.natlawreview.com/article/hhs-expands-and-clarifies-scope-immunity-under-prep-act; *See also* Eric Kraus & Jennifer Shah, *COVID-19 Vaccines Unlikely to Create Litigation Opportunities*, Law360 (Dec. 7, 2020)

[2] *See, e.g., Estate of Smith ex rel. Smith v. Bristol at Tampa Rehab. & Nursing Ctr., LLC*, No. 8:20-cv-2798-T-60SPF, 2021 WL 100376 (M.D. Fla. Jan. 12, 2021).

[3] 42 U.S.C. § 247d-6d(b).

[4] *Parker v. St. Lawrence Cnty. Public Health Dep't,* 102 A.D.3d 140 (3rd Dep't 2012).

[5] *Id.* at 142.

[6] *Kehler v. Hood*, 2012 WL 1945952, No. 4:11CV1416, 2012 WL 1945952 (E.D. Mo. May 30, 2012).

[7] *Id.* at *1

[8] *Casabianca v. Mount Sinai Med. Ctr.,* No. 112790/10, 2014 WL 10413521 (Sup. Ct. N.Y. Cnty. Dec. 2, 2014).

[9] 42 U.S.C. § 247d-6d; Fourth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 79,190-01, 79,197 (Dec. 9, 2020). *See also* Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf (Jan. 8, 2021).

[10] *Anson v. HCP Prairie Vill. KS OPCO LLC*, No. 20-2346, 2021 WL 308156 (D. Kan. Jan. 29, 2021).

[11] *See, e.g.*, *Baskin v. Big Blue Healthcare, Inc.*, No. 2:20-cv-2267, 2020 WL 4815074 (D. Kan. Aug. 19, 2020); *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184 (D. Kan. 2020).

[12] No. 20-CV-6006, 2020 WL 5291014 (C.D. Cal. Sept. 3, 2020).

[13] *Id.*

[14] *See, e.g.*, *Leung v. Bluebird Bio, Inc.*, No. 1:21-cv-00777 (E.D.N.Y. filed Feb. 12, 2021) changed venue to No. 1:21-cv-10335 (D. Mass. filed Feb. 26, 2021); *Monroe Cnty. Emps'. Ret. Sys. v. AstraZeneca PLC*, No. 1:21-cv-00722 (S.D.N.Y. filed Jan. 26, 2021); *Zhukov v. AstraZeneca PLC*, No. 1:21-cv-00825 (S.D.N.Y. filed Jan. 29, 2021). [As of Apr. 29, 2021, *Monroe Cnty. Emps'. Ret. Sys. v. AstraZeneca PLC* and *Zhukov v. AstraZeneca PLC* were consolidated to *In re AstraZeneca PLC Secs. Litig.*, No. 1:21-cv-00722 (S.D.N.Y. filed Jan. 26, 2021)].

[15] 42 U.S.C. § 247d-6d(a)(1)(A)(i-iii).

[16] 42 U.S.C. § 247d-6d(a)(1)(A)(iv) (emphasis added).

[17] The term "loss of or damage to property, including business interruption loss" has been, and continues to be, extensively litigated in COVID-19-related insurance coverage disputes. Although the terminology is similar, these cases do not address the PREP Act but rather focus on the terms of the policies at issue. In some cases, where the policy required "direct physical loss," courts have ruled that the policy requires "tangible damage" and denied coverage. *See, e.g., Turek Enters., Inc. v. State Farm Mut. Auto. Ins. Co.,* 484 F. Supp. 3d 492 (E.D. Mich. Sept. 3, 2020). Other cases denied coverage on the basis of a policy's express "virus exclusion." *See, e.g., Martinez v. Allied Ins. Co. of Am.*, 483 F. Supp. 3d 1189 (M.D. Fla. Sept. 2, 2020).

On the other hand, there are cases where the business plaintiff seeking coverage successfully drew a distinction between "loss of" and "damage to" property. *See, e.g., Studio 417, Inc. v. Cincinnati Ins. Co.*, 478 F. Supp. 3d 794, 800-03 (W.D. Mo. 2020) (insurers' motion to dismiss denied, holding that plaintiff stated a claim, and that "direct physical loss" included the suspension of business due to COVID-19 and related governmental restrictions).

[18] *See, e.g.*, Monroe Cnty. Emps'. Ret. Sys., *supra* note 9; *Leung*, *supra* note 9; *Zhukov*, *supra* note 9.

[19] Restatement (Third) of Torts: Liab. for Econ. Harm § 9 (2020).

[20] 42 U.S.C. § 247d-6d(c).

[21] 42 U.S.C. § 247d-6d(d)(1).

[22]*See* 42 U.S.C. § 247d-6e (which provides for the establishment of an "emergency fund" in the Treasury "designated as the 'Covered Countermeasure Process Fund' [to] provid[e] . . . compensation to eligible individuals").

[23] *See Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997). ''A statute generally 'should be enforced according to its plain and unambiguous meaning.''' *Greathouse v. JHS Sec. Inc.*, 784 F.3d 105, 111 (2d Cir. 2015) (quoting *United States v. Livecchi*, 711 F.3d 345, 351 (2d Cir. 2013)).

[24]*Robinson*, 519 U.S. at 340 (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240 (1989)).

[25] Dictionary definitions provide further support for this view. For example, the *Merriam-Webster* online dictionary defines property as "something to which a person or business has a legal title." https://www.merriam-webster.com/dictionary/property (last visited May 13, 2021). See also *The Oxford English and Spanish Dictionary*, which defines property as "[t]he right to the possession, use, or disposal of something; ownership." https://www.lexico.com/en/definition/property (last visited May 13, 2021).

[26] 42 U.S.C § 247d-6d(b)(1).

[27] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198-01, 15,201 (Mar. 17, 2020).

[28] 85 Fed. Reg. 15,198-01, 15,201.

[29] *Id.*

[30] Albeit in another context, the U.S. Supreme Court agreed that a statutory scheme that provided liability protections to encourage private industry participation in an effort to develop nuclear power was proper and constitutional. *Duke Power Co. v. Carolina Env't Study Grp., Inc.*, 438 U.S. 59 (1978).

[31] 151 Cong. Rec. S14,242-01, S14,242 (daily ed. Dec. 21, 2005) (statement of Sen. Joseph Biden).

[32] *Id.* at S14,243 (statement of Sen. Hillary Clinton) (emphasis added).

[33] *Id.* at S14,247 (statement of Sen. Patrick Leahy).

[34] 42 U.S.C § 247d-6d(f).

[35] *See* 17 C.F.R. §§ 240.10b-5. *See also* Securities Act of 1933 § 24 ("Securities Act"), 15 U.S.C. § 77x; Securities Exchange Act of 1934 § 32, 15 U.S.C. § 78ff(a).

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