The Art of Dodging Bullets: How Covid-19 Drug Manufacturers and Providers Plan to Escape Tort Liability

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THE ART OF DODGING BULLETS:
HOW COVID-19 DRUG MANUFACTURERS
AND PROVIDERS PLAN TO ESCAPE
TORT LIABILITY

Ruan Meintjes*

I. INTRODUCTION: AMERICA’S LAST EPIDEMIC SCARE

The 1976 winter at Fort Dix, New Jersey was a cold one—wind chill drove temperatures down to minus forty-three degrees Fahrenheit. On February 4th, Private David Lewis, a new recruit, was forced to undertake a five-mile long march through the cold. Upon his return, Private Lewis collapsed and died. An autopsy revealed that Private Lewis had “severe edema, hemorrhage, and mononuclear infiltrates in the lungs consistent with viral pneumonia.” Private Lewis had no preexisting conditions, and no prior bacterial infection.

Meet the Swine Flu of 1976. The Center for Disease Control (CDC) identified this new strain as H1N1—similar to the Swine Flu that claimed millions of lives in the 1918 pandemic. The revelation that Fort Dix experienced a Swine Flu outbreak caused national consternation—raising “the specter” of the 1918 Pandemic. On March 13, President Ford announced the

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3. Id.
5. Id. at 26.
6. Id.
7. Id. at 24.
start of the National Influenza Immunization Program (NIIP) with the stated goal of “immunizing every man, woman, and child” as quickly as possible.9

To develop the vaccine required by NIIP, pharmaceutical companies and their insurers required the federal government to indemnify the pharmaceutical companies for claims arising from complications due to fast-tracked vaccines.10 Congress obliged, and in August 1976, President Ford signed an amendment to the Federal Tort Claims Act, making a suit against the federal government the sole remedy for claims arising from vaccines administered through NIIP.11

NIIP immunized forty-five million people in ten weeks, but not without negative effects.12 Four hundred-fifty individuals suffered negative side effects from the vaccines, and several died.13 Due to the vaccine complications and because the Swine Flu never developed into an epidemic, federal health officials issued a moratorium on the vaccine on December 16, 1976.14 The ensuing litigation came in legion—totaling over 1,000 individual lawsuits and costing the federal government almost $100 million to settle all the claims.15

In 2020, the federal government again issued liability protection to pharmaceutical companies who rapidly develop a COVID-19 vaccine or treatment through a Notice of Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act).16 Given the lives and the billions of dollars at stake for companies involved with the treatment of COVID-19, a close analysis of the obscure, but soon to be heavily litigated PREP Act is warranted.

II. THE PREP ACT

Unlike the 1976 law in which the federal government indemnified only participating vaccine manufactures, the PREP Act provides tort immunity for all “covered countermeasures.”17 The PREP Act was signed into law by Pres-

9. Id.
10. NEUSTADT & FINEBERG, supra note 2, at 42.
12. NEUSTADT & FINEBERG, supra note 2, at 84.
13. Kim et al., supra note 11.
14. Id.
15. Id. supra note 11.
16. Id.
ident Bush in 2005 for the purpose of inducing companies to “develop products to counter pandemic flu and other disease threat[s].” Senate Majority Leader Bill Frist argued that the bill “strikes a reasonable balance where those who are harmed will be fairly compensated and life-saving products will be available in ample supply to protect and treat as many Americans as possible.” The PREP Act’s opponents, the late Sen. Edward Kennedy being chief among them, countered that the bill was a “Christmas gift to the drug industry and a bag of coal to everyday Americans” because the PREP Act makes it “essentially impossible” to bring claims against drug companies.

On March 17, 2020, the Secretary for Health and Human Services (HHS) issued a declaration, as required under the PREP Act, to trigger the PREP Act’s immunity provisions. Textually, the PREP Act’s scope and extent of liability protection is broad. First, the PREP Act provides that “covered persons” shall be “immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” A declaration from HHS is required to trigger this provision. The definition of a covered countermeasure is broad and includes products authorized by the FDA for emergency use and products that are “manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such pandemic or epidemic might otherwise cause.” A covered person includes the United States, a person or entity that is a manufacturer or distributor of a covered countermeasure, or a program planner or qualified person (medical professionals) in charge of covered countermeasures.

An exception to the liability shield is made for willful misconduct by a covered person. To take advantage of this exception, the plaintiff must

19. Id.
20. Id.
23. Id.
24. Id.
25. Id. § 247d-6d(i)(1).
26. Id. § 247d-6d(i)(2).
27. Hickey, supra note 17, at 3–4.
show that the covered person acted with wrongful purpose, knowingly without legal or factual justification, and with disregard to obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.\textsuperscript{28} If a plaintiff is able to clear the hurdle of the willful misconduct exception, the plaintiff must then seek redress through a compensation fund (discussed further below).\textsuperscript{29} The plaintiff’s right to bring suit is waived if the plaintiff elects to receive compensation through the fund.\textsuperscript{30} If the injured person chooses to file a lawsuit, then the plaintiff may sue in the District Court of Columbia, but will face heightened pleading and discovery standards.\textsuperscript{31} The plaintiff will also need to prove willful misconduct with clear and convincing evidence and defeat the affirmative defense the PREP Act affords to covered persons sued under this exception.\textsuperscript{32}

Once the HHS issues a declaration under the PREP Act, the Treasury is required to create and fund a program designed to compensate claims caused by countermeasures or persons covered by the PREP Act.\textsuperscript{33} An individual “seriously injured or killed by the administration of a covered countermeasure, whether or not as a result of willful misconduct, may seek compensation through the Countermeasures Injury Compensation Program [CICP].”\textsuperscript{34} After the 2020 declaration by HHS, Congress allowed HHS to appropriate nearly thirty billion dollars to respond to COVID-19, including the funding of a CICP program.\textsuperscript{35} Note that the CICP is not the same as the National Vaccine Injury Compensation Program (VICP).\textsuperscript{36} Unlike the CICP, the VICP “provides compensation for injuries caused by most vaccines routinely administered in the United States.”\textsuperscript{37} The CICP funds are solely intended for injuries or death resulting from countermeasures covered under the PREP Act.\textsuperscript{38}

\textsuperscript{28} Id.
\textsuperscript{29} Id.
\textsuperscript{30} Id.
\textsuperscript{31} Id.
\textsuperscript{32} Id.
\textsuperscript{33} 42 U.S.C.A. § 247d-6e(a) (LEXIS through Pub. L. No. 116-344).
\textsuperscript{34} Hickey, supra note 17, at 4.
\textsuperscript{35} Id.
\textsuperscript{36} Id.
\textsuperscript{37} Id.
\textsuperscript{38} Id.
III. PRE-2020 PREP ACT LITIGATION

Prior to 2020, due to the lack of a global pandemic in recent years, courts have had little opportunity to produce case law related to the PREP Act.39 Two pre-2020 cases, however, are instructive.

A. Kehler v. Hood

In the case of Kehler v. Hood, the federal court for the Eastern District of Missouri afforded PREP protection to Novartis, a manufacturer of the H1N1 vaccine.40 In mid-2009, Novartis won a contract from the federal government to develop a H1N1 vaccine in an effort to prevent an influenza pandemic in the United States.41 In June 2009, the HHS issued a declaration under the PREP Act declaring the H1N1 virus a public health emergency.42 Consequently, the vaccine developed by Novartis was deemed a covered countermeasure.43

In January 2010, a physician vaccinated Kehler with the Novartis vaccine.44 After the administration of the vaccine, Kehler contracted a severe case of transverse myelitis—a condition that causes painful swelling around the spinal cord.45 The plaintiff brought an action against the physician and the physician’s hospital for negligence and failure to warn.46 In turn, the physician and the hospital brought a third-party claim against Novartis for product liability and failure to warn.47

Novartis asserted a PREP Act defense against the third-party claims.48 The court noted in dicta that, due to the PREP Act, Novartis was “absolutely immune from liability for any type of loss caused by the vaccine.”49 For the physician and the hospital to prevail on a claim against Novartis under the PREP Act, they were required to show willful misconduct by Novartis.50

41. Id. at *2.
42. Id.
43. Id.
44. Id.
45. Id.
47. Id.
48. Id. at *1.
49. Id. at *3.
50. Id.
court dismissed the claims against Novartis on procedural grounds—noting that it did not have federal question jurisdiction due to a provision in the PREP Act that gives sole jurisdiction to the District Court for the District of Columbia.51 Because of the procedure-based dismissal, the court never reached the issues of preemption and liability inherent to a matter such as this.52

B. Parker v. St. Lawrence County Public Health Department

In the 2012 case of Parker v. St. Lawrence County Public Health Department, the Appellate Division for the New York Supreme Court held that the PREP Act preempted state law claims for negligence and battery.53 This case arose from the same 2009 HHS declaration related to the H1N1 vaccine.54 In this case, however, a local New York school administered a covered countermeasure vaccine known as Peramivir in an immunization program to a student without parental consent.55 The parent of the student initiated a claim against the school under state law for negligence and battery.56

The court was faced with the sole issue of “whether the PREP Act preempted the plaintiff’s state law claims for negligence and battery.”57 The plaintiff advanced two key contentions: (1) that PREP Act immunity does not extend to qualified persons who administered a covered countermeasure to an individual without consent; and (2) that Congress did not intend the PREP Act to authorize “radical measures” such as immunization without consent.58 After considering the language and the intent of Congress related to preemption, the court concluded that the immunity in the PREP Act is broad and sweeping, and that “Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person.”59 Seeking to bolster its holding, the court pointed to the fact that Congress instituted a compensation fund and created a federal cause of action for willful misconduct, and therefore intended to make these federal actions the sole remedy for losses covered by the PREP Act.60 Moreover, the court

51. Id.
52. See generally Kehler, 2012 WL 1945952, at *3 n.5.
54. Id. at 141.
55. Id.
56. Id. at 141–42.
57. Id. at 142.
58. Id. at 144.
59. Parker, 102 A.D.3d at 143–44.
60. Id. at 144.
reasoned that Congress “fully understood that errors in administering a vaccination program may have physical as well as emotional consequences, and determined that such potential tort liability must give way to the need to promptly and efficiently respond to a pandemic.”

IV. POST-2020 PREP ACT LITIGATION

By way of preface, defendants seeking to shield themselves from liability made little use of the PREP Act prior to 2020. As chronicled below, 2020 vaulted the PREP Act into a place of prominence in the COVID-19 litigation landscape. Because most COVID-19 vaccines and treatment are still in clinical trials, the body of case law is still unripe as to the substance affirmative protections of the PREP Act. Presently, creative attempts to read the PREP Act broadly comprise the current body of PREP Act case law. The selection of cases discussed below, however, are still indicative as to how courts may view affirmative defenses to covered counter measures going awry in the years to come.

A. Estate of Maglioli v. Andover Subacute Rehabilitation Center

After COVID-19 claimed the lives of seniors at an rehabilitation center in New Jersey, the seniors’ estates became plaintiffs in Estate of Maglioli v. Andover Subacute Rehabilitation Center, bringing causes of action for wrongful death against the center. The plaintiffs claimed that the rehabilitation center failed to take “proper steps to protect the residents and/or patients of their facilities from the Covid-19 virus.” Examples of the center’s negligence include allegedly failing to provide masks and allowing support staff to interact with patients without any protective equipment. Following the precedent set in Parker, the rehabilitation center argued that the PREP Act preempts state law. The court, however, found that Parker is distinguishable.

61. Id.
64. Est. of Maglioli, 2020 WL 4671091, at *1.
65. Id. at *2.
66. Id. at *4–5.
67. Id. at *10.
68. Id. at *27.
The district court held that the PREP Act did not preempt state law in the context of *Estate of Maglioli.* The court reasoned that, in *Parker,* the vaccine was developed under a federal government contract that was covered by the 2009 HHS Declaration. This case, the court said, was different from *Parker* because the plaintiffs’ injuries were not alleged to have “arise[n] from Defendants’ administration to them of vaccines or medicines (or for that matter protective gear)—activities that the PREP Act promotes by affording immunity.” Moreover, the plaintiffs’ complaints did not run afoul of the preemption clause in the PREP Act because the cause of action faulted the rehabilitation center for lack of countermeasures. Consequently, the court concluded that such “claims concerning the quality of care do not fall within the scope of the PREP Act.” Had the drafter of the PREP Act meant to provide immunity for failure to care in the course of treating a COVID-19 patient, the court argues, the drafters “could easily have done so.”

The *Estate of Maglioli* court never reached the ultimate question of liability. Instead, it simply found that the PREP Act did not preempt the case and remanded the case to the state courts where it continues in litigation at the time of this writing.

**B. Big Blue Healthcare Cases**

Coming from the U.S. District Court in Kansas, the facts in Eaton v. Big Blue Healthcare, Inc. and its ten sister cases closely mirror that of *Estate of Maglioli,* After a COVID-19 outbreak in Kansas, several residents of the care facility passed away. Several of the deceased estates brought suit against the care facility alleging, among other things, failure to follow proper infection control protocols and guidelines; failure to separate those with symptoms from those without; failure to respond to the presence of COVID-19 in the facility; and failure to follow standing orders, instruction, and protocol regarding COVID-19. As in *Estate of Maglioli,* the care center claimed immunity from liability under the PREP Act.

69. *Id.* at *31.
71. *Id.* at *28.
72. *Id.* at *24.
73. *Id.* at *29.
74. *Id.* at *30.
75. *Id.*
78. *Id.* at 1186 n.1.
79. *See id.* at 1187.
80. *Id.* at 1188.
The plaintiffs argued that the PREP Act did not apply because the claims arose from the center’s omissions and not from the administration of a countermeasure.\textsuperscript{81} The center responded by arguing that the PREP Act must be interpreted more broadly.\textsuperscript{82} They made the case that “administration or use” does not just include the physical dispensing of a covered countermeasure, but also includes “activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to the recipients.”\textsuperscript{83} Moreover, they argued that this includes “the management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.”\textsuperscript{84} Finally, the residential care center insisted that Congress intended to provide broad protection, and the plaintiffs’ reading impermissibly narrowed the scope PREP Act.\textsuperscript{85} The court, however, was not persuaded.\textsuperscript{86}

The court found that the PREP Act is wholly inapplicable to the case of Eaton.\textsuperscript{87} The court was not “convinced that a facility using covered countermeasure somewhere in the facility is sufficient invoke the PREP Act as to all claims that arise in that facility.”\textsuperscript{88} For the PREP Act to provide immunity, there must be a causal connection between the covered countermeasure and the loss.\textsuperscript{89} The court also adopted a narrow reading of the PREP Act and refused to adopt the residential care center’s broad reading of the Act.\textsuperscript{90} The court found that if “Congress intended the PREP Act to apply as broadly as Defendants advocate, it certainly could have written it to clearly apply to inaction as much as action.”\textsuperscript{91}

C. Haro v. Kaiser Foundation Hospitals

Haro v. Kaiser Foundation Hospitals is the most unique attempted use of the PREP Act during the pandemic—the PREP Act was invoked by a hospital to defend against a minimum wage claim.\textsuperscript{92} In the face of the COVID-19 pandemic, a California hospital foundation began requiring some

\begin{itemize}
  \item \textsuperscript{81} Id. at 1193–94.
  \item \textsuperscript{82} Id. at 1194.
  \item \textsuperscript{83} Eaton, 480 F. Supp. 3d at 1194.
  \item \textsuperscript{84} Id.
  \item \textsuperscript{85} Id. at 1195.
  \item \textsuperscript{86} Id.
  \item \textsuperscript{87} Id.
  \item \textsuperscript{88} Id. at 1194.
  \item \textsuperscript{89} Eaton, 480 F. Supp. 3d at 1194.
  \item \textsuperscript{90} Id. at 1195.
  \item \textsuperscript{91} Id.
\end{itemize}
hourly employees to report to work fifteen minutes early to complete COVID-19 screening before the start of their shift.93 The fifteen minutes between the early arrival and the start of work was not paid.94 The plaintiff, an hourly employee of the hospital foundation, brought a putative state class action on behalf of employees similarly situated, asserting that the policy violated state minimum wage laws.95 The hospital foundation removed the case to federal court and asserted a PREP Act defense, arguing that the PREP Act completely preempts state law.96

The hospital foundation argued that their employees “use various personal protective equipment, such as masks and face shields, and therefore its screening process is a use of a covered countermeasure.”97 The court rejected this argument.98 Because the minimum wage claim was “not causally connected to the screening procedures themselves, but rather the requirement that employees show up 15 minutes before their shift starts,” there is no PREP Act immunity for the hospital foundation.99 The case was remanded back to state courts.100

V. DISCUSSION

The Swine Flu outbreak of 1976 infected 200 people while killing only Private Lewis.101 COVID-19, on the other hand, has killed 238,000 Americans at the time of this writing.102 Moreover, the PREP Act is a significantly more sophisticated statutory creature when compared to the 1976 bill hastily put into law by the Ford administration.103

However, the scope of the potential liability may be significantly different than the Swine Flu episode. At the time of this writing, the New York Times reported that there are fifty-two vaccines in clinical trials on humans, and at least eighty-six preclinical vaccines under active investigation in ani-

93. Id.
94. Id.
95. Id.
96. Id.
97. Id. at *3.
99. Id.
100. Id. at *5.
101. Kim et al., supra note 11.
mals.104 Where the Swine Flu program inoculated approximately forty-five million people in the United States, the contemplated scale of global immunization will dwarf the 1976 inoculation figure.105 Realizing this, some members of the medical community have called for the establishment of a global facility to administrate mass claims.106 While such proposals are unlikely to affect legal developments in the United States, U.S. law practitioners and pharmaceutical manufacturers will likely ensure that their litigation war chests are well funded and will be prepared for the inevitable onslaught of claims once vaccines are administered to patients at large.

Indeed, the PREP Act’s protection is nearly as bulletproof.107 As the Parker case highlighted, a school was able to hide behind the PREP Act after it immunized a student with an experimental vaccine without the consent of the parent.108 However, when creative defendants endeavor to shoehorn the PREP Act into affirmative defenses that have little or nothing to do with covered countermeasures, courts are reluctant to extend any PREP Act liability immunity. To date, short of Parker, no court has fully preempted state law using the PREP Act and, as PREP Act cases continue to accumulate in the judicial system, judicial observers might expect to see a sharp rise in these dilemmas.


107. Kim et al., supra note 11.
