PHILADELPHIA TRIAL LAWYERS ASSOCIATION EST. 1959

VERDICT

Volume 2020-2021 - Issue 5

The PREP Act & COVID-Era Claims

Sarah F. Dooley, Esq.
Duffy + Fulginiti

As if it were not enough that we were in the midst of an international pandemic, enter the Public Readiness and Emergency Preparedness (PREP) Act, a Federal mandate that, on its face, offers broad immunity.

> . . . a covered person 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 if a declaration [by the Secretary of Health and Human Services] has been issued with respect to such countermeasure.[1]

In March 2020, the Secretary of Health and Human Services issued a declaration under the PREP Act regarding the COVID-19 pandemic, which has since been amended five (5) times, most recently on February 2, 2021. Since the very first PREP Act emergency declaration, a wide variety of defendants deployed its language in an effort to both deny state courts jurisdiction and fully immunize themselves from COVID-related negligence and product liability.

Whether or not a plaintiff's claim falls within the PREP Act has a massive impact on a plaintiff's potential recovery. Where the PREP Act is applicable, it limits a plaintiff's recovery to only those administrative remedies outlined in a subsection of the Act itself.[2] This subsection, titled "Covered countermeasure process," outlays the sole process for compensation to an ". . .eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure. . ."[3] This subsection offers the "exclusive remedy" for all personal claims falling into its provisions. Those claims may only recover where the plaintiff suffered "serious physical injury" or "death," and the recovery is limited to only medical benefits, lost wages and, where applicable, death benefits. The compensation amount is set by the Secretary of Health and Human Services. This subsection denies federal and state courts jurisdiction to review any of the Secretary's decisions.

Plaintiff lawyers need to anticipate exactly how the defense may attempt to hide behind the PREP Act's protections. One scenario is when a defendant has sold, distributed, marketed, or manufactured a product that it claims is a "covered countermeasure," such as hand sanitizer. In a case currently pending in the Eastern District of Pennsylvania,[4] big box store defendant BJ's argued it was immune, under the PREP Act, from state law product liability claims arising from its sale of defective and illegal hand sanitizer because of the ongoing COVID-19 pandemic. Unwilling to grant such broad immunity, Judge Mark Kearney wrote:

> Consumers claiming harm from ingesting hand sanitizers following the onset of the COVID pandemic may sue the sanitizer's manufacturer and retailer for product defect or negligence. They must do so aware Congress afforded immunity from liability to certain retailers qualified under a fifteen-year-old federal law and present Declaration from the Secretary of Health and Human Services which, among other qualifies, defines the method of distribution responsive to a defined health risk which may afford immunity for a retailer. Not every retailer of hand sanitizer is covered under the limited immunity. The consumers do not necessarily know if the retailer obtained the hand sanitizer for re-sale before the pandemic or to assist in mitigating the spread of the pandemic. The allegedly injured consumer can generally plead only the purchase and resulting harm. We are mindful immunity both frustrates recovery from possibly responsible parties but also incentivizes manufacturers and sellers to create and market

> products which the Government approves to mitigate the pandemic. But we cannot grant immunity from liability and summarily dismiss a complaint based on the face of the consumer's allegations which do not allow us to find the retailer obtained the hand sanitizer in response to the pandemic or under specific distribution channels directed by the Secretary.[5]

A "covered countermeasure" under the PREP Act is defined as a qualified pandemic or epidemic product, among other things.[6] A qualified pandemic or epidemic product is further defined as a drug (as such term is defined by the Federal Food, Drug & Cosmetic Act (FD&C)), a biological product (as such term is defined by the PREP Act), or a device (as such term is defined by the FD&C Act), that is a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, cure, or limit the harm of a pandemic/epidemic.[7] While there are other definitions of covered countermeasure, the defendant in *Avicolli* only focused on the above. The defendant took a broad leap, without any legal or statutory support, and argued that all hand sanitizers, in general, were a "covered countermeasure" in that they are a qualified pandemic/ epidemic product, despite the fact that companies have been selling hand sanitizer and other such products long before the pandemic hit. However, before doing so, the defendant failed to look at the Federal FD&C Act's definitions of drug and device, and the PREP Act's definition of biological product, as is specifically instructed to do so in the PREP Act. Therefore, before reaching the insupportable conclusion that in general, hand sanitizer is a covered countermeasure under the PREP Act, one must determine if the particular product at issue actually fits into one (1) of three (3) categories of qualified pandemic/epidemic products.

The FD&C Act defines a "drug" as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or articles (other than food) intended to affect the structure or any function of the body of man or other animals.[8] Specifically, the PREP Act **only** references Section 321(g)(1) of the FD&C Act in defining the term "drug." This is an important distinction, as unapproved "drugs," such as the hand sanitizer in the *Avicolli* case, are considered "new drugs" under Section 321(p), and not a "drug" under Section 321(g). "New drugs" are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling, per the FDA. The PREP Act does not include Section 321(p) in its accepted definition of a drug, only Section 321(g)(1).9 As such, be mindful of whether or not your product qualifies as a "drug" or a "new drug" if you are facing this argument.

Nevertheless, even assuming the product does qualify as a "drug" under the FD&C Act, it then needs to fit the next requirement: that it be a product specifically used to mitigate, prevent, treat, cure, or limit the harm of the COVID-19 pandemic.[10] In *Avicolli*, the FDA's website specifically indicated that claims of hand sanitizers preventing the spread of COVID-19 are false, misleading, and unproven. The FDA also found that the labeling and branding of the specific hand sanitizer at issue as "hand sanitizer" was false and misleading due to the high concentrations of methanol, which can be dangerous to health when used as a hand sanitizer – skin exposure can lead to systemic absorption and substantial exposure can lead to blindness or death. As such, the "hand sanitizer" at issue in *Avicolli* did not conform to the requirements of the PREP Act's definition of a covered countermeasure as the product is not even a hand sanitizer – as argued by the plaintiffs therein.

A "biological product" is defined as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.[11] There was no evidence, nor could there be, that the hand sanitizer was a "biological product."

The FD&C Act lastly defines "device" as an instrument, apparatus, etc., including any component which is: 1) recognized in the official National Formulary, or the United States Pharmacopeia; 2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or, 3) intended to affect the structure or any function of the body of man and which does not achieve its primary intended purposes through chemical action and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[12] There was no evidence, nor could there be, that the hand sanitizer was a "device."

In agreeing with the plaintiffs that the PREP Act did not apply, Judge Kearney ruled that the facts were distinguishable in a case where, for example, a distillery began obtaining and selling hand sanitizer as part of a specific and coordinated effort to mitigate the spread of COVID-19. Plaintiffs beware: if Judge Kearney had found that the PREP Act did apply, then the case would have been subject to transfer to the District of Columbia, and, state law product liability claims may have been preempted, with the potential that only federal claims of willful misconduct being permitted to proceed.

Even though the PREP Act expressly set forth its limitation to deployment

of "countermeasures," defendants nationally are attempting to extend it into claims relating to negligent workplace/nursing home COVID-19 exposure. Defendants argue that their following (or, often, failure to follow) CDC guidance and deployment (or, often, nondeployment) of COVID-19 countermeasures place these claims within the ambit of PREP Act immunity and related federal preemption. It is under this pretense that these defendants remove cases to federal court, arguing both that the PREP Act completely preempts plaintiffs' claims and that it makes the defendants "federal officers" for the purposes of jurisdiction under *28 U.S.C. §1442*. As a result, nearly all of the rulings related to the scope of the PREP Act's immunity arise in the context of plaintiffs' motions to remand back to state court.

By a large majority, these courts have ruled that the PREP Act does not confer either federal question jurisdiction or federal officer jurisdiction. The courts, however, have gone beyond answering just these jurisdictional questions. In addition, a number of the involved courts have held that the PREP Act is not applicable to negligent COVID-19 exposure cases at all. These cases have nearly unanimously concluded that "the PREP Act applies to action, not inaction."[12] The Federal Court for the District of New Jersey explained that the PREP Act "is designed to protect those who employ countermeasures, not those who decline to employ them."[13] To date, there is only one case where the court found the PREP Act applied to negligent COVID-19 exposure.[14] Every other case, to date, has rejected PREP Act's applicability in this context.[15]

In support of their arguments, defendants have heavily relied on an Advisory Opinion issued by a lawyer in then-President Donald Trump's Department of Health and Human Services, in the sunset days of his administration. The opinion concludes, without legal support, that (1) The PREP Act offers complete federal preemption; and (2) PREP Act immunity also applies to any defendant's inaction, as well as action. These defendants argue that this executive administrative opinion is controlling and dispositive on the applicability of the PREP Act here.

Though the HHS opinion is fairly recent, courts have already rejected its importance in this analysis. In *Dupervil v. All. Health Operations, LCC,* the court held that this advisory opinion had no control, was owed no deference, and was not persuasive:

> …the Advisory Opinion here expressly states that it 'does not have the force or effect of law.' Thus, even assuming that Congress intended to delegate authority to the Secretary and HHS's Office of the General Counsel 'generally to make rules carrying the force of law,' the Office of the General Counsel interpretation … was not 'promulgated in the exercise of that authority'
>
> Moreover, the Court finds that the interpretation lacks the 'power to persuade.' The Advisory Opinion cites no cases for its proposition that an exclusive federal administrative remedy is sufficient for complete preemption.[16]

At present there are at least three of these cases up on appeal in the circuit courts. Until those appellate cases are decided, and any circuit splits resolved in the United States Supreme Court, plaintiffs bringing a COVID-19 or COVID-19-related case should expect the PREP Act to be a prominent focus of the defendants' strategy. That strategy will include removal to federal court and PREP Act Immunity arguments.

The case law to date underscores the importance of careful pleading. Unlike other more expansive federal law, courts are willing to recognize and enforce the PREP Act's statutory limits, where plaintiffs' claims are pled outside its scope. ◆

1 42 U.S.C. §247d-6d(a)(1).
2 42 U.S.C. §247d-6e(a).
3 42 U.S.C.A. §247d-6e.
4 Avicolli v. BJ's Wholesale Club, Inc., 2021 U.S. Dist. LEXIS 67096 (E.D. Pa. 2021).
5 Id. at 1-2.
6 42 U.S.C. §247d-6d(i)(1)(A).
7 42 U.S.C. §247d-6d(i)(7)(A).
8 21 U.S.C. §321(g)(1).
9 42 U.S.C. §247d-6d(i)(7).
10 42 U.S.C. §247d-6d(i)(1)(A).
11 42 U.S.C. §262(i)(1).
12 21 U.S.C. §321(h).
13 Avicolli supra, 2021 U.S. Dist. LEXIS 67096 at 10-11.
14 Jackson v. Big Blue Healthcare Inc., 2020 WL 4815099, 7 (D. Kan. 2020).
15 Estate of Maglioli v. Andover Subacute Rehabilitation Center, 2020 WL 4671091, 9 (D. N.J. 2020).
16 Garcia v. Welltower OpCo Group LLC, 2021 WL 492581 (C.D. Cal. 2021).
17 See also Dupervil v. Alliance Health Operations, LCC, 2021 WL 355137, 10 (E.D. N.Y. 2021); Anson v. HCP Prairie Vill. KS OpCo LLC, 2021 WL 308156, 9–11 (D. Kan. 2021); Estate of Smith ex rel. Smith v. The Bristol at Tampa Bay Rehab. & Nursing Ctr., 2021 WL 100376, 1–2 (M.D. Fla. 2021); Gunter v. CCRC OPCO-Freedom Square, LLC, 2020 U.S. Dist. LEXIS 201622, 9–15 (M.D. Fla. 2020); Saldana v. Glenhaven Healthcare LLC, 2020 WL 6713995, a2 (C.D. Cal. 2020); Martin v. Serrano Post Acute LLC, 2020 WL 5422949, 2 (C.D. Cal. 2020).
18 Dupervil v. supra, 2021 WL 355137 at 10 (internal citations omitted).

Editor's Note: *Elizabeth A. Bailey is an Asssociate at Saltz, Mongeluzzi & Bendesky, PC, where she focuses on catastrophic personal injury cases resulting from construction and workplace accidents, aerial lift accidents, electrical accidents, and product defects, and malfunctions in Pennsylvania and New Jersey. Ms. Bailey can be reached at: ebailey@smbb.com.*

Sarah Dooley is a Partner at Duffy + Fulginiti, where she focuses her practice on representing the catastrophically injured. Sarah also serves as Editor-in-Chief of the Verdict. You may contact Ms. Dooley at: sdooley@duffyfirm.com.