STATE OF MICHIGAN

COURT OF APPEALS

DN, a legally incapacitated person, by Guardian/Conservator MARK NOWACKI and KATHLEEN NOWACKI,

Plaintiffs-Appellees,

v

GILEAD SCIENCES, INC.,

Defendant-Appellant,

and

ST. JOSEPH MERCY CHELSEA, INC., doing business as ST. JOSEPH MERCY CHELSEA,

Defendant.

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No. 367271
Washtenaw Circuit Court
LC No. 22-001761-NP

DN, a legally incapacitated person, by Guardian/Conservator MARK NOWACKI and KATHLEEN NOWACKI,

Plaintiffs-Appellees,

v

GILEAD SCIENCES, INC.,

Defendant,

and

ST. JOSEPH MERCY CHELSEA, INC., doing business as ST. JOSEPH MERCY CHELSEA,

Defendant-Appellant.

No. 368026
Washtenaw Circuit Court
LC No. 22-001761-NP

Before: BOONSTRA, P.J., and LETICA and RICK, JJ.

RICK, J.

The Spanish flu pandemic of 1918 and the recent COVID-19 pandemic of 2020-2021 constituted two devastating global health crises. According to the Pan American Health Organization, by the time it was contained, the Spanish flu spread around the world in a matter of four months, bringing death and destruction to an estimated 21 million lives.[1] Witnesses described unthinkable circumstances: in some instances, the dead were left in their homes for days; indigenous populations, particularly those in remote areas, were entirely snuffed out; large urban areas depleted proper burial equipment and turned streetcars into hearses to hold the dead.[2]

In contemporary times, the World Health Organization reports that the COVID-19 pandemic was responsible for more than 1 million deaths in the US, and over 7 million deaths globally.[3] The magnitude of the disruption is still being experienced, long after the pandemic itself was declared over. Many lost loved ones, some of whom died alone because of restrictions that prevented anyone from visiting them. Some individuals who contracted the disease now live with "long COVID."[4] The Mayo Clinic reports that persons afflicted with long COVID also see an increased risk of diseases, including heart disease, stroke and blood clots, myalgic encephalomyelitis-chronic fatigue syndrome, also called ME-CFS, to name a few.[5] There is much debate now, and will likely be in the future, about the governmental response and courses of treatment provided as the world grappled with the COVID-19 healthcare crisis.

These consolidated appeals[6] arise out of the alleged dissemination of contaminated doses of remdesivir, an antiviral medication, to plaintiffs' ward, DN. DN was designated a legally incapacitated individual. He was hospitalized and treated for COVID-19, and allegedly received two contaminated doses of the FDA-approved medication. He thereafter suffered two strokes. In

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[1] Sarah Francis Fujimura, *Purple Death: The Great Flu of 1918*, <https://www.paho.org/en/who-we-are/history-paho/purple-death-great-flu-1918> (accessed March 25, 2025).

[2] *Id.*

[3] World Health Organization, *World Health Organization COVID-19 Dashboard* <https://data.who.int/dashboards/covid19/deaths?n=o> (accessed March 25, 2025).

[4] Mayo Clinic, *Long COVID: Lasting Effects of COVID-19* <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351> (accessed March 25, 2025).

[5] *Id.*

[6] *DN v Gilead Sciences, Inc*, unpublished order of the Court of Appeals, entered March 8, 2024 (Docket Nos. 367271 and 368026).

Docket No. 367271, defendant-appellant, Gilead Sciences, Inc. (Gilead), appeals by leave granted[7] an order denying its motion for summary disposition under MCR 2.116(C)(8) (failure to state a claim). In Docket No. 368026, defendant-appellant, St. Joseph Mercy Chelsea, Inc., doing business as St. Joseph Mercy Chelsea (St. Joseph), also appeals by leave granted[8] an order denying its motion for summary disposition under MCR 2.116(C)(8). We reverse and remand.

I. FACTUAL BACKGROUND

In November 2021, 83-year-old DN presented to St. Joseph Hospital, where he was diagnosed with COVID-19. Hospital staff administered monoclonal antibodies and discharged him. DN went to the emergency room the following day because his symptoms were worsening. DN received two doses of remdesivir. Within the next week, he suffered a stroke. DN was discharged to a skilled nursing facility, where he began suffering from hematomas and swelling of the face, thighs, and arms. DN suffered another stroke in December 2021.

In April 2022, DN's guardian received a letter from St. Joseph confirming that DN had received remdesivir during his hospital stay. The letter indicated that two of the five doses of remdesivir administered to DN involved recalled lot numbers of the drug. The voluntary recall was dated December 3, 2021, and pertained to two lots—approximately 55,000 vials—of remdesivir. The recall was published on the Food and Drug Administration's (FDA) website, warning:

> Gilead Sciences Inc. received a customer complaint, confirmed by the firm's investigation, of the presence of glass particulates.
>
> Risk Statement: The administration of an injectable that contains glass particulates may result in local irritation or swelling in response to the foreign material. If the glass particulate reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Gilead Sciences Inc. has not received any reports of adverse events related to this recall.

Plaintiffs sued St. Joseph and Gilead in December 2022, asserting claims for breach of implied warranty, breach of express warranty, negligence, gross negligence, intentional misrepresentation, and loss of consortium. They argued that, although the FDA had approved remdesivir to treat COVID-19, the remdesivir administered in this case "was not in accordance with Gilead's FDA approval for the drug in terms of its manufacturing quality" because it contained glass particles. They alleged that the glass particles in the drug caused DN to suffer two strokes and that he later had to have a leg amputated. Plaintiffs stated that as a result, DN was left bedridden and required around-the-clock care.

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[7] *DN v Gilead Sciences, Inc*, unpublished order of the Court of Appeals, entered March 8, 2024 (Docket No. 367271).

[8] *DN v Gilead Sciences, Inc*, unpublished order of the Court of Appeals, entered March 8, 2024 (Docket No. 368026).

In February 2023, Gilead, with consent from St. Joseph, removed this action to the federal district court on the basis that the federal Public Readiness and Preparedness (PREP) Act, 42 USC 247d-6d, preempted plaintiffs' state-law claims against Gilead. The federal district court determined that the PREP Act completely preempts state-law claims that fall within its scope. It further observed that "[t]he sole cause of action created by the PREP Act is an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct . . . by [a] covered person[.]" *Nowacki for Nowacki v Gilead Sciences, Inc*, unpublished order of the United States District Court for the Eastern District of Michigan, entered June 13, 2023 (Case No. 23-10276), p 13 (quotation marks and citation omitted, first alteration in original). Taking that into account, the court determined that the only claim over which it had original jurisdiction was plaintiffs' claim for intentional misrepresentation because the federal PREP Act "completely preempts"[9] claims alleging death or serious injury caused by willful misconduct. *Id*., unpub order at 14. However, the court noted that under the PREP Act, a plaintiff asserting a willful misconduct claim is required to first exhaust all administrative remedies before bringing the claim in the U.S. District Court for the District of Columbia. See 42 USC 247d-6e(d)(1) and (e)(1). *Nowacki*, unpub order at 21. The court thus opined that dismissal of that claim without prejudice was required because plaintiffs had not yet exhausted their administrative remedies for the claim. *Id*. The court declined to exercise supplemental jurisdiction over plaintiffs' remaining claims. *Id*., unpub order at 22.

In its opinion and order, the federal district court rejected plaintiffs' argument that the remdesivir doses were not a covered countermeasure under the PREP Act as a result of a manufacturing defect. The court explained:

> This argument is unsupported by any authority and contrary to the plain text of the PREP Act. The Act's broad grant of immunity from suit and liability with respect to all claims relating to the administration to or use of a covered countermeasure, see 42 USC 247-6d(a)(1), makes clear that a product's alleged departure from FDA-approved manufacturing specifications does not remove it from the Act's protection.
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> Plaintiffs' argument also runs counter to the PREP Act's purpose: to encourage the expeditious development and deployment of medical countermeasures during a public health emergency by allowing the [Health and Human Services (HHS)] Secretary to limit legal liability for losses relating to the

[9] Complete preemption is distinct from the concept of ordinary preemption. "Complete preemption, really a jurisdictional rather than a preemption doctrine, confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim." *Franciscan Skemp Healthcare, Inc v Central States Joint Bd Health & Welfare Trust Fund*, 538 F3d 594, 596 (CA 7, 2008).

> administration of medical countermeasures such as diagnostics, treatments, and vaccines. The Act's broad immunity provisions were intended, in part, to remove uncertainty and risk for individuals and organizations on the front lines combating a pandemic. [*Nowacki*, unpub order at 18, 20. (quotation marks and citations omitted.)]

Following remand to the state circuit court, Gilead moved for summary disposition under MCR 2.116(C)(8). Gilead argued that the PREP Act provided it with immunity from suit because remdesivir was a covered countermeasure.[10] Gilead further argued that, as remdesivir's manufacturer, it was immune from liability with respect to all claims for loss caused by the use of remdesivir. Gilead noted that the PREP Act's plain language granted immunity from manufacturing defect claims, such as the allegedly contaminated remdesivir administered in this case. St. Joseph moved for summary disposition under MCR 2.116(C)(8) on essentially the same grounds, arguing that under the PREP Act, the hospital was a "covered person" immune from liability for injuries related to the administration of a "covered countermeasure" such as remdesivir.

Plaintiffs responded to Gilead's motion, arguing that the PREP Act did not afford protection to Gilead. Plaintiffs reasoned that because the FDA did not approve or license remdesivir in a form that contained glass particles, the allegedly contaminated remdesivir doses did not constitute a covered countermeasure. Following a hearing, the trial court denied Gilead's motion for summary disposition, reasoning as follows:

> While Congress sought to protect companies who were developing treatments and putting them on the market without the rigorous testing requirements that usually are in place, the government, I don't believe, sought to protect a negligent manufacture of the product. And when the product has some contaminant in it, it is not meeting the requirements to avail itself of the PREP Act. It is no longer a covered countermeasure. It is an attempt at a covered countermeasure, but it is contaminated, and that's different from it being a formula that, for whatever reason, ends up harming a person because it hasn't been well tested or there's some—some problem with the formula itself. That's—it's not claimed here that there was a problem with the formula; it's claimed that there was a problem with the product that was ultimately delivered. And under those circumstances I don't see that the PREP Act applies here to bar the claims that are made by the Plaintiff of a negligent manufacture.

[10] It bears noting that the federal district court's application of the complete preemption doctrine to plaintiffs' intentional misrepresentation claim does not mean that the PREP Act only applied to that claim; rather, preemption may still apply as a defense to the remaining claims in state court, as Gilead and St. Joseph alleged here. See *Franciscan Skemp Healthcare, Inc*, 538 F3d at 601 (quotation marks, brackets, and citation omitted) ("A federal court's order remanding a case to state court based on the inapplicability of the complete preemption doctrine leaves open the question whether the plaintiff's claims are nevertheless defensively preempted").

The court thereafter entered an order denying the motion "for the reasons stated on the record . . . ."

Plaintiffs subsequently responded to St. Joseph's motion for summary disposition, arguing that because St. Joseph brought essentially the exact same motion as Gilead, and Gilead's motion was denied, St. Joseph's motion should also be denied. At a hearing on St. Joseph's motion, the court again agreed with plaintiffs, largely for the same reasons it denied Gilead's motion. An order to that effect was later entered. This appeal followed.

II. ANALYSIS

Gilead and St. Joseph argue that the trial court erred by denying their motions for summary disposition because the PREP Act's plain language grants immunity from manufacturing defect claims. We agree.

"We review de novo a trial court's decision on a motion for summary disposition, reviewing the record in the same manner as must the trial court to determine whether the movant was entitled to judgment as a matter of law." *Bronson Methodist Hosp v Auto-Owners Ins Co*, 295 Mich App 431, 440; 814 NW2d 670 (2012). "A motion under MCR 2.116(C)(8) tests the legal sufficiency of a claim based on the factual allegations in the complaint." *El-Khalil v Oakwood Healthcare, Inc*, 504 Mich 152, 159; 934 NW2d 665 (2019). "When considering such a motion, a trial court must accept all factual allegations as true, deciding the motion on the pleadings alone." *Id*. at 160. "A motion under MCR 2.116(C)(8) may only be granted when a claim is so clearly unenforceable that no factual development could possibly justify recovery." *Id*. We likewise review de novo "questions concerning the proper interpretation of contractual or statutory language[.]" *Dobbelaere v Auto-Owners Ins Co*, 275 Mich App 527, 529; 740 NW2d 503 (2007).

Generally, "[a] court's primary purpose in interpreting a statute is to ascertain and effectuate legislative intent. Courts may not speculate regarding legislative intent beyond the words expressed in a statute." *Mich Ed Ass'n v Secretary of State (On Rehearing)*, 489 Mich 194, 217; 801 NW2d 35 (2011) (quotation marks and citation omitted). "As far as possible, effect should be given to every phrase, clause, and word in the statute." *Sun Valley Foods Co v Ward*, 460 Mich 230, 237; 596 NW2d 119 (1999). "[C]ourts must interpret statutes in a way that gives effect to every word, phrase, and clause in a statute and avoid an interpretation that would render any part of the statute surplusage or nugatory. A statute is rendered nugatory when an interpretation fails to give it meaning or effect." *Esurance Prop & Cas Ins Co v Mich Assigned Claims Plan*, 507 Mich 498, 508-509; 968 NW2d 482 (2021). "When the plain and ordinary meaning of statutory language is clear, judicial construction is neither necessary nor permitted." *Pace v Edel-Harrelson*, 499 Mich 1, 7; 878 NW2d 784 (2016).

"Congress enacted the PREP Act in 2005 to encourage the expeditious development and deployment of medical countermeasures during a public health emergency by allowing the [HHS] Secretary to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." *Hudak v Elmcroft of Sagamore*

Hills, 58 F4d 845, 849 (CA 6, 2023) (quotation marks, citation, and alterations omitted).[11] Under the plain language of the Act,

> 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 under subsection (b) has been issued with respect to such countermeasure. [42 USC 247d-6d(a)(1).]

There is no dispute that the HHS Secretary declared COVID-19 a public-health emergency in March 2020. See *Hudak*, 58 F4d at 850. Immunity under the Act was extended through October 1, 2024. *Id*. See also Department of Health and Human Services, Office of the Secretary, *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, Fed Reg 15198, 15202 (March 17, 2020).

As relevant to this appeal, "loss" is defined as including losses caused by death or by "physical, mental, or emotional injury, illness, disability, or condition[.]" 42 USC 247d-6d(a)(2)(A)(*i*) and (*ii*). The PREP Act additionally defines the phrase "covered person" to include entities that manufacture, distribute, prescribe, and administer a covered countermeasure. See 42 USC 247d-6d(i)(2)(B)(*i*), (*ii*) and (*iv*). Plaintiffs agree that Gilead and St. Joseph are covered persons in this case. The PREP Act also defines the phrase "covered countermeasure" as "a qualified pandemic or epidemic product" or "a drug . . . that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act[.]" 42 USC 247d-6d(i)(1)(A) and (C). On this point, plaintiffs agree that in general, remdesivir is considered a covered countermeasure. However, they argue that the remdesivir administered to DN should not be considered a "covered countermeasure" because Gilead manufactured, and St. Joseph administered, a product containing microscopic glass particles. Plaintiffs maintain that it is the glass particles, and not the remdesivir itself, that caused DN's lasting injuries.

We understand plaintiffs' argument. Nevertheless, Congress acted to prevent suits like this in the face of a serious public health emergency. Gilead and St. Joseph are ultimately correct: under the PREP Act, no liability can attach here. The immunity granted under the PREP Act

> applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, *manufacture*, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure. [42 USC 247d-6d(a)(2)(B) (emphasis added).]

"The PREP Act creates only one exception to its grant of immunity[,]" *Hudak*, 58 F4d at 849. The sole basis for which liability can be imposed under the PREP act is "for death or serious physical injury proximately caused by *willful misconduct*," 42 USC 247d-6d(d)(1) (emphasis added). The

[11] Opinions of the lower federal courts are not binding, but may be considered for their persuasive value. *Truel v Dearborn*, 291 Mich App 125, 136 n 3; 804 NW2d 744 (2010).

Act defines willful misconduct as " '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.' " *Hudak*, 58 F4d at 849-850, quoting 42 USC 247d-6d(c)(1)(A)(*i*) through (*iii*). Thus, under the plain language of the PREP Act, Gilead and St. Joseph cannot be held liable for any alleged wrongdoing short of "willful misconduct." 42 USC 247d-6d(d)(1). Plaintiffs did not plead in avoidance of the PREP Act by alleging that Gilead or St. Joseph engaged in willful misconduct in this case, nor does it appear that an unintentional error allegedly causing contamination of the remdesivir during the manufacturing process rises to the level of willful misconduct for which Gilead and St. Joseph can be held liable. 42 USC 247d-6d(a)(1); 42 USC 247d-6d(a)(2)(B).

Additionally, as Gilead pointed out in the federal district court, "Congress's explicit extension of PREP Act immunity to claims involving a covered countermeasure's 'manufacture' would be rendered meaningless if, as Plaintiffs suggest, the presence of a manufacturing defect prevented a product from being a covered countermeasure in the first place." *Nowacki*, unpub order at 19. To accept plaintiffs' argument and conclude that manufacturing defects prevent products from being considered "covered countermeasures" under the PREP Act, we would necessarily have to render some of the language of the PREP Act nugatory, in violation of our principles of statutory interpretation. *Esurance Prop & Cas Co*, 507 Mich at 508-509. We decline to do so here.

The plain language of the PREP Act clearly grants Gilead and St. Joseph immunity from all liability for injuries that were not caused by willful misconduct. Because plaintiffs have not alleged that Gilead or St. Joseph engaged in willful misconduct by manufacturing or administering remdesivir to DN, plaintiffs' claims cannot prevail.[12] Congress has unequivocally extended immunity to scientists, pharmaceutical companies, and other healthcare providers who grappled with the unprecedented nature of the COVID-19 pandemic. The PREP Act also extends immunity to those entities vis-à-vis any potential future health crises, barring allegations of willful misconduct. The trial court thus erred by declining to grant summary disposition under MCR 2.116(C)(8). On remand, the trial court shall enter an order granting summary disposition to Gilead and St. Joseph under MCR 2.116(C)(8) and dismissing plaintiffs' claims in their entirety.

Reversed and remanded for further proceedings consistent with this opinion. A public question being involved, no costs may be taxed under MCR 7.219. We do not retain jurisdiction.

/s/ Michelle M. Rick
/s/ Mark T. Boonstra
/s/ Anica Letica

[12] Although the PREP Act generally precludes covered persons from liability, it does not leave injured parties without recourse; under the Act, eligible individuals may seek aid through the "Covered Countermeasure Process Fund," which was established to provide compensation "for covered injuries directly caused by the administration or use of a covered countermeasure[.]" 42 USC 247d–6e(a).