Judge Rules for First Time Pharma Company Not Immune Under PREP Act After Man Injured by Remdesivir

In a groundbreaking decision, a Michigan judge ruled on Aug. 8 that the PREP Act does not shield a drug manufacturer and hospital from liability in the case of a man who experienced two strokes and a leg amputation after receiving remdesivir contaminated with glass particles.

This is the first time a judge has ruled that a pharmaceutical company and hospital do not have immunity under the PREP Act—and an injured plaintiff has successfully gotten past this roadblock.

Although the ruling is not a binding precedent, this case sets the tone for future lawsuits against the company for injuries potentially incurred by those given Remdesivir. It may also

pave the way for people injured by other COVID-19 products.

Detroit-based attorney Ven Johnson filed a lawsuit on behalf of Dan Nowacki, his wife, and son against Gilead Sciences, Inc. (Gilead), the manufacturer of remdesivir—marketed as Veklury—and the hospital that administered the drug.

The complaint alleges gross negligence, breach of warranty, and loss of consortium—as Nowacki's wife has lost her husband's "society, companionship, and household services."

St. Joseph Mercy Chelsea Hospital and Gilead claimed they could not be sued because they had immunity under the PREP Act. Both the pharmaceutical company and the hospital attempted to get the case dismissed.

Apparently, Gilead thought that when the U.S. Food and Drug Administration (FDA) approved its drug, it also approved the glass particles that mysteriously ended up in as many as 55,000 doses of their product.

"Their argument has been, 'Yeah, we know how we voluntarily recalled. Yeah, we know there are glass particulates in it, and we know that two doses were given to Dan, and we know he had a stroke," Johnson said during an interview. "But since we followed the FDA guidelines and were approved, we have drug immunity. You can't sue us because it was approved by the FDA."

Johnson said he knew it would be an uphill battle, but he is proud of both judges [in state and federal court] who reviewed the case and saw through the charade—that Gilead Sciences Inc. got approval for the drug but not the glass particles contained in it.

For those who don't know, the PREP Act authorizes the Secretary of the Department of Health and Human Services to issue a declaration that gives individuals and entities involved in the "development, manufacturing, testing,

distribution, administration, and use of such countermeasures" like a COVID-19 drug, medical product, or vaccine immunity from liability for the harm "caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions."

The COVID-19 "emergency" was the perfect justification to allow pharmaceutical companies to cut corners with their experimental drugs, pharmacies to give COVID-19 vaccines in parking lots, and hospitals to administer costly, ineffective, and potentially harmful treatments at the expense of inexpensive treatments we know worked.

Even though the COVID-19 emergency ended, HHS extended liability protections under the PREP Act because they care more about protecting pharmaceutical companies and the machine they've created than the people who are being harmed by these products.

Facts of the Case

Remdesivir, first authorized for emergency use in May 2020, is a controversial antiviral drug that supposedly targets the RNA in SARS-CoV-2 to prevent replication and COVID-19 symptoms. It has since been approved for adults and children as young as 28 days who weigh at least 6.6 pounds.

According to the complaint, Nowacki, on Nov. 10, 2021, was admitted to St. Joseph Mercy Chelsea Hospital and diagnosed with COVID-19. During his stay, he received five doses of remdesivir. At least two doses belonged to contaminated lots.

Days later, Nowacki experienced his first massive stroke and was released on November 24 to a skilled nursing facility. There he began to develop hematomas and swelling in his hands, face, and arms and was readmitted to Henry Ford Hospital, where his "symptoms remained a mystery to physicians."

Nowacki suffered a second stroke on Dec. 16 that left him bedridden and in need of permanent round-the-clock care for the rest of his life.

However, according to a company announcement published on Dec. 3, 2021, on the FDA's website, Gilead issued a voluntary recall of two lots of remdesivir after it received a customer complaint of glass particulates in the drug and confirmed through an investigation the claim was true. This was before Nowackie had his second stroke.

In a risk statement, the company admitted that "glass particulates" can "cause stroke or even lead to death" if they reach the blood vessels, travel to various organs, or block blood vessels in the heart, lungs, or brain.

However, Gilead stated at that time it had not received any reports of adverse events related to the recall and was notifying its distributors and customers via UPS next-day air to hospital pharmacies to facilitate the return of any remaining vials from the affected lots.

Yet neither Nowacki nor his family were notified about the recall until St. Joseph Mercy Hospital sent a letter four months later, in April 2022, confirming Nowacki had received at least two doses of remdesivir from lots potentially contaminated with glass particles.

That letter was a response to the family's inquiries to determine whether Nowackie was given remdesivir in the hospital from contaminated lots. Instead of receiving assistance from Gilead, the pharma giant told them to contact the hospital.

"One of the things that we're going to figure out is exactly what Gilead, the FDA, and the hospital knew and when," Johnson said. "How did glass particles that could cause strokes and death in people get into this medication? Why aren't these people approaching us to get our client's medical records to

understand what happened?”

Johnson said he didn’t understand why Gilead and the hospital made no effort to contact people who had potentially received the contaminated lots or help those who may have been harmed.

Instead, they’re trying to hide behind technicalities, he said. “This epitomizes who they [the pharmaceutical industry] are or who they’ve become.”

In a press release, Johnson said:

> *“Dan Nowacki’s case is a tragic example of the devastating consequences that can arise from sheer negligence and greed from pharmaceutical companies and the incompetence of St. Joseph Mercy Chelsea in not giving timely notice of a recalled drug.*
>
> *“Drug manufacturers and medical institutions need to prioritize patient safety above all else. The four-month delay of alerting Nowacki of the recalled remdesivir prevented Mr. Nowacki’s subsequent treaters from administering necessary treatment, which compromised Nowacki’s recovery.”*

Johnson said in his years of experience, it isn’t common for a company to issue a voluntary recall and to do so without having contact with the FDA.

“They had to have had contact with the FDA,” he said. “They claim in their December press release they had evidence of a customer who had some type of reaction, and they confirmed it was accurate—but when was it, where did it happen, and when did they first learn about it, because this process didn’t happen in two to three weeks.”

The next step in the court process is to engage in discovery. This will allow Nowackie’s attorney to obtain answers to these questions—and he plans to depose everyone he can at Gilead to

find out what they knew and when.

Johnson doesn’t believe his client is the only person who suffered injuries from contaminated lots of remdesivir and invites anyone with information on how glass particles may have found their way into the lots or those who experienced similar injuries to contact his law firm.

“We’re going to absolutely go after this recall campaign,” Johnson said. “There is something they could have done to locate the folks to prevent him from having a second stroke. But that’s what happens when you allow drug manufacturers to do whatever they want.”