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Lawsuit Alleges COVID Patient 'Died From the Cure and Not from the Disease' After Receiving Contaminated Remdesivir

A Michigan judge ruled that a lawsuit filed by the family of a man who died after receiving remdesivir contaminated with glass particles can proceed, despite claims by the drug's manufacturer, Gilead Sciences, that it is shielded from liability under the Public Readiness and Emergency Preparedness, or PREP, Act.

By John-Michael Dumais

A Michigan judge has ruled that a lawsuit against Gilead Sciences, the manufacturer of remdesivir, can move forward and be tried in the courts, despite claims by Gilead that it is protected under the Public Readiness and Emergency Preparedness (PREP) Act.

Remdesivir, an anti-viral drug sold under the brand name Veklury, was approved in May 2020 by the U.S. Food and Drug Administration (FDA) to treat COVID-19.

In her July 20 ruling, Judge Carol Kuhnke of the Circuit Court for the County of Washtenaw dismissed a motion for summary disposition filed by the defendants, Gilead Sciences and St. Joseph Mercy Chelsea Hospital.

St. Joseph Mercy Chelsea Hospital is where Daniel Nowacki received five doses of remdesivir between Nov. 10-24, 2021, which the lawsuit alleges caused two strokes and a leg amputation, leaving Nowacki unable to care for himself. He later died of complications.

The drug Nowacki received came from one of two lots, comprising 55,000 vials, that were voluntarily recalled by the manufacturer on Dec. 3, 2021, because they were contaminated with glass particles.

Gilead has admitted the glass particles could lead to stroke and other serious health problems.

Nowacki's family filed a lawsuit in December 2022, in an attempt to establish when Gilead knew of the contamination and to hold the hospital accountable for its lack of follow-up once it learned of the problem with the drug.

According to the lawsuit, the hospital's lack of action resulted in "[Nowacki's] subsequent treating physicians including staff at Henry Ford [being] unaware of this fact [i.e., the drug

contamination]" so they "could not appropriately deal with Dan's medical condition."

Judge Kuhnke presided over oral arguments in the case on July 12. Among the key points she made during the proceeding was that, despite the immunity provided by the PREP Act and the emergency situation calling for the rapid development of treatments, she did not feel the law protected Gilead from negligent manufacturing.

She said:

> "When this particular product and the doses ... were administered to Mr. Nowacki, there was a failure, and the failure was that there were some doses that were contaminated with shards of glass, which were recognized by Gilead as being potential causes of stroke, which is what exactly happened to Mr. Nowacki. ...
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> "The product that was approved and that was used in this case was developed and marketed pursuant to a formula, and that formula is what HHS [the U.S. Department of Health and Human Services] approved for emergency use and for the protections of the PREP Act. ...
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> "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."

"Unfortunately he died from the cure and not from the disease," Kuhnke said.

In a press release from the firm representing Nowacki, attorney Ven 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.
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> "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."

The difficulty of prosecuting under PREP Act

Ray Flores, a health freedom rights attorney, told The Defender, "This ruling doesn't create any kind of precedent, but it does let the case move forward."

According to Flores, this is the first time a judge has made arguments that have the potential to chip away at the otherwise impenetrable PREP Act, which allows for a challenge only on the basis of "willful misconduct."

Flores co-authored the article, "Pharma's Gatekeeper: How the PREP Act Protects Everyone Except Those Injured by Vaccines," published in The Defender in February. He wrote:

> "[The PREP Act] grants a 'covered person' immunity from legal liability for all claims for loss relating to the administration or use of covered 'countermeasures,' such as drugs, biological products, medical devices and vaccines. ... [This includes] the U.S.

> government; a manufacturer, a distributor, a program planner; and one who administers, or dispenses such countermeasures."

The only avenue left open to persons injured by such countermeasures — which includes the COVID-19 vaccines — is the Countermeasures Injury Compensation Program.

Although over 12,000 claims for COVID-19-related injuries have been filed in this program through Aug. 1, only four people have received compensation. Flores said their average award was just $2,200.

Highlighting the difficulty of even getting a case to court, Flores discussed the case of a 6-year-old Vermont student, vaccinated against his parents' wishes, that was thrown out by a Superior Court judge based on his understanding of the PREP Act.

"The Vermont ruling is clear and short," Flores wrote. "All state law protections (other than workers' compensation) essentially disappear under the PREP Act."

Nowacki's story and the recall

Nowacki went to the St. Joseph Mercy Hospital on Nov. 9, 2021, complaining of fatigue, cough, shortness of breath and loss of appetite. He was diagnosed with COVID-19, given monoclonal antibodies and sent home.

The next day, he returned to the emergency room with worsening symptoms, and on the same day began receiving remdesivir.

Within days, he had a stroke. He was discharged on Nov. 24 to a skilled nursing facility. While there, he started developing hematomas and reported swelling on his face, thighs and arms. He subsequently was admitted to Henry Ford Hospital, where treating physicians failed to crack the mystery of his symptoms.

On Dec. 14, Nowicki suffered another stroke.

Although Gilead began its recall on Dec. 3, 2021, Nowacki did not receive notification from St. Joseph Mercy Hospital until April 6, 2022, about the doses of remdesivir he received from the recalled batches.

The recall was published on the FDA website, which according to the lawsuit contained the following 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 and can travel to various organs and block blood vessels in the heart, lungs, or brain which can cause stroke and even lead to death.
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> "To date, Gilead Sciences Inc., has not received any reports of adverse events related to this recall."