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COVID

# 'Historic': Federal Court Says AstraZeneca Not Immune From Liability in Case Involving Woman Injured by

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A **federal court ruled** Monday that a lawsuit filed by a woman injured by AstraZeneca's COVID-19 vaccine during a U.S. clinical trial can continue. The court rejected the drugmaker's claim that a federal liability shield protects it from breach-of-contract claims.

**Brianne Dressen sued AstraZeneca** in May, alleging she was injured and became **disabled by the company's vaccine** in 2020 when she participated in the company's clinical trial.

According to the **complaint**, AstraZeneca's consent form for trial participants promised enrollees medical treatment in the event of illness or injury suffered during the study.

In its **motion to dismiss**, filed in June, AstraZeneca said that under the Public Readiness and Emergency Preparedness Act (**PREP Act**) of 2005 — which grants manufacturers of emergency countermeasures such as **COVID-19 vaccines** immunity from legal liability — Dressen could not sue the vaccine maker for her **injuries**.

But in his Nov. 4 ruling, Chief Judge Robert J. Shelby of the U.S. District Court in Utah said the PREP Act's liability shield does not extend to breach-of-contract claims. He said the basis of Dressen's claim "is a broken promise, not a countermeasure."

The ruling stated:

“PREP Act immunity requires a causal link between the claim and a tangible medical countermeasure, and breach of contract claims arise from one party’s failure to perform a legal obligation without regard to any countermeasure. The PREP Act’s statutory scheme and purpose support this construction.”

Shelby’s ruling could result in more lawsuits challenging the PREP Act, according to Ray Flores, senior outside counsel for **Children’s Health Defense**.

Flores, an expert on the PREP Act, told **The Defender**:

“The court sent an unmistakable signal by issuing this ruling six days after the motion was argued. It is historic since this is the first time a federal court determined that a COVID-19 vaccine injury may be compensable in any way.

“It is refreshing to see that the PREP Act’s unprecedented invincibility now at least has one limit — breach of contract. Battery, fraud and false advertising must be the next exceptions.”

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### **‘PREP Act is public enemy No. 1’**

According to **Dressen’s lawsuit**, AstraZeneca’s consent form for trial participants stated, “If you become ill or are injured while you are in this research study, you must tell your study doctor straight away. The study doctor will provide medical treatment or refer you for treatment.”

Dressen, who since co-founded **React19**, a nonprofit that seeks to help people injured by COVID-19 vaccines, alleged her **vaccine-related injuries and disability** resulted in prohibitive medical costs. One medication alone costs \$432,000 a year.

AstraZeneca offered her only \$1,243.30 in compensation, prompting her to file the breach-of-contract claim.

“For AstraZeneca to have relied on the PREP Act in its motion to dismiss explains why its \$1,243.30 settlement offer was so insultingly low,” Flores said. “PREP appears to be AstraZeneca’s main justification for its failure to live up to the terms of a written contract. This is just one more example of why the PREP Act is public enemy No. 1.”

**Astra Zeneca claimed** its contract with trial participants did not waive its PREP Act immunity and that Dressen’s lawsuit was not a breach-of-contract claim but a product liability claim — which would then preclude Dressen’s claim under the Utah Product Liability Act’s two-year statute of limitations.

The court rejected those claims, finding there was “express contractual privity between Dressen and AstraZeneca” and citing two cases involving buyers of defective COVID-19 tests who successfully sued the manufacturers based on a breach-of-contract claim.

Dressen also argued that AstraZeneca waived its immunity “by clearly and unmistakably promising to pay the cost of research injuries.” The court agreed.

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“AstraZeneca made a contractual promise to her that happened to involve the effects of a covered countermeasure. Accordingly, Dressen’s claim for loss was not ‘caused’ by a covered countermeasure,” the ruling stated. “The PREP Act has a broad scope, none of which involve any breach of express contract.”

According to the ruling, shielding drug manufacturers from breach-of-contract claims was not the intent or purpose of the PREP Act.

“The PREP Act drafters could not have intended to allow pharmaceutical companies to make illusory promises to clinical trial participants because doing so would erode public trust and undermine the ability to recruit willing participants, which in turn would erode and undermine pandemic preparedness,” the ruling said.

The court also rejected AstraZeneca's claim that Dressen's lawsuit was a product liability claim, not a breach-of-contract claim.

"The court is unpersuaded. The plain text of the Utah Product Liability Act does not apply because Dressen does not allege AstraZeneca's vaccine was defective," the ruling said.

Dressen, who was 39 when she was vaccinated, was previously a preschool teacher. She is now unable to work due to her injuries.

Flores predicted that Dressen's lawsuit would ultimately succeed.

"When this case was filed, I went on record stating that my money was on the plaintiff. After this ruling, I predict that Ms. Dressen will take an eight-figure jury award to the bank," Flores said.



### Michael Nevradakis, Ph.D.

Michael Nevradakis, Ph.D., based in Athens, Greece, is a senior reporter for The Defender and part of the rotation of hosts for CHD.TV's "Good Morning CHD."

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