

STATE OF MICHIGAN
IN THE 22ND CIRCUIT COURT (WASHTENAW COUNTY)

MARK NOWACKI, As Legal Guardian
and Conservator for DANIEL
NOWACKI, and KATHLEEN P. NOWACKI,

Case No. 22-001761-NP

Plaintiffs,

v.

GILEAD SCIENCES, INC., and
ST. JOSEPH MERCY CHELSEA, INC.,
d/b/a ST. JOSEPH MERCY CHELSEA,

Defendants.

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DEFENDANT GILEAD SCIENCES' MOTION FOR SUMMARY DISPOSITION
BEFORE THE HONORABLE CAROL KUHNKE

Ann Arbor, Michigan - Wednesday, July 12, 2023

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Ann Arbor, Michigan

Wednesday, July 12, 2023 - 3:50 p.m.

THE CLERK: Mark Nowacki as legal guardian and conservator for Daniel Nowacki, et al, versus Gilead Sciences, Incorporated, et al. 22-1761-NP.

MR. KHAHRA: Good afternoon, Your Honor. Ken Khahra here on behalf of Plaintiffs.

MR. DESMOND: Good afternoon, Your Honor. Chris Desmond on behalf of the Plaintiff as well.

MR. BUCHOLTZ: Good afternoon, Your Honor. Jeffrey Bucholtz on behalf of Gilead Sciences.

MR. SULLIVAN: Good afternoon, Your Honor. Tom Sullivan on behalf of Defendant St. Joseph Chelsea.

THE COURT: All right. Go ahead when you're ready. I should say, I'm going to say first that I have had so far two arguments over special legislation that related to COVID and they were both today.

MR. KHAHRA: Sounds like an immunity day, Judge.

THE COURT: Yes. Yes. Definitely.
Go ahead.

MR. BUCHOLTZ: So, thank you, Your Honor. Again, Jeffrey Bucholtz for Defendant Gilead Sciences. We're here on our motion for summary disposition as to Counts 1 through 4, which are the only counts that remain against Gilead after the Federal District Court's order

1 that remanded, that dismissed Count 5 and then remanded
2 Counts 1 through 4.

3 And as Your Honor noted, this is a case about a
4 very special immunity statute, the PREP Act, is, you know,
5 a statute that Congress enacted for, for good reason,
6 where Congress took, you know, unusually lengthy,
7 unusually strong steps to bar claims that related to the
8 administration of covered countermeasures in the context
9 of a, the national emergency like a pandemic, and there
10 aren't that many cases out there that involve the PREP
11 Act. It may be a new issue for a lot of courts, including
12 Your Honor, but I think the issues here that are raised by
13 our motion are pretty straightforward, and I'm going to
14 try to be brief. Your Honor has already had a very long
15 calendar today. There's really only one issue in dispute.
16 Let me take a step back first and just make sure that
17 we're clear about the context.

18 So, this is a case that alleges injuries to Mr.
19 Nowacki from the administration of remdesivir for COVID-
20 19. There's a lot of things that are not in dispute:

21 It's not in dispute that Gilead is a covered
22 person entitled to protection under the PREP Act as the
23 manufacturer of remdesivir;

24 It's not in dispute that the Secretary of Health
25 and Human Services issued a declaration triggering the

1 PREP Act's protections as relevant to this case;

2 It's not in dispute that remdesivir, which is an
3 anti-viral drug approved by the FDA to treat COVID, is a
4 covered countermeasure. In fact, it's the epitome of a
5 covered countermeasure.

6 The only thing that's in dispute -- and I'm
7 sorry. One other thing that is not in dispute is, and
8 this is where this case is different from some of the
9 cases that were addressed in the Federal District Court in
10 the context of removal, what's not in dispute here is the
11 Complaint alleges very clearly, very directly, that the
12 injuries were caused by the administration of a covered
13 countermeasure. And on some of the cases that maybe Your
14 Honor has seen in the papers here that came up in the
15 context of removal of federal court and different issues
16 about federal jurisdiction, were cases where the claims
17 were, that a nursing home, for example, failed to take
18 adequate precautions, didn't require masks, didn't
19 segregate residents, didn't provide enough distancing, et
20 cetera, and that failure to take, to use countermeasures
21 caused an injury. So the courts in those cases have
22 decided, you know, whether those claims have enough of a
23 nexus to the administration of a covered countermeasure.

24 This case is all about the administration of a
25 covered countermeasure, remdesivir. The only thing that's

1 in dispute in the Plaintiffs' opposition to our motion,
2 the only argument they make is the same argument they made
3 in federal court that Judge Victoria Roberts, in denying -
4 - in -- in upholding our removal and then exercising her
5 discretion to remand the remaining state law claims, an
6 argument they made at federal court that the plain- --
7 that Judge Roberts rejected, and that's that, that because
8 the remdesivir that Mr. Nowacki received was allegedly
9 contaminated with glass particles because of a
10 manufacturing problem, that it's no longer a covered
11 countermeasure.

12 Remdesivir, in general, undisputed that it's a
13 covered countermeasure. The argument here is because
14 there was a manufacturing problem, and the remdesivir that
15 Mr. Nowacki received allegedly did not conform to the
16 approved manufacturing specifications, that transforms it
17 into something other than a covered countermeasure.

18 Plaintiffs made the same argument in federal
19 court. Judge Roberts addressed it at length, pages 18 to
20 21 of her opinion, and rejected it in what we think is a
21 very well-reasoned opinion that Your Honor should follow.

22 The same issue was directly relevant in federal
23 court because in order to decide the propriety of our
24 removal to federal court, Judge Roberts had to decide
25 whether -- this is at page 16 of her opinion -- whether

1 the claims here were for a loss with a causal relationship
2 to the administration of a covered countermeasure. It's
3 the same issue presented here. And this case really
4 turned, this motion really turns on a very simple
5 provision of the PREP Act. The PREP Act is 42 U.S. Code
6 247d-6d. That's the section provision. And then
7 subsection (a) is entitled Liability Protections.
8 Paragraph (1) is the basic liability protection in the
9 Act. It says:

10 "...a covered person shall be immune
11 from suit or liability under Federal and
12 State law with respect to all claims for
13 loss caused by, arising out of, relating
14 to, or resulting from the
15 administration...a covered
16 countermeasure..."

17 And then, after that, immediately after that you
18 get to paragraph (2). Paragraph (2)(B) says Scope;
19 entitled, Scope. It says:

20 "The immunity under paragraph (1)..."

21 That's the provision that I just read to Your
22 Honor:

23 "...applies to any claim for loss
24 that has a causal relationship with the
25 administration...of a covered

1 countermeasure..."

2 I'm leaving out some words that are inapplicable
3 here. And then it goes on to say, "...including..." and
4 it goes through a whole list of attributes of a covered
5 countermeasure that someone could conceivably argue caused
6 an injury. And it says, "When we say," you know, "When
7 we, Congress, say, 'All claims with a causal relationship
8 to the administration of a covered countermeasure are
9 barred,' we really mean all, and here's a long list of
10 attributes that -- that are included within that causal
11 nexus." And one of those is manufacture.

12 So Congress specifically provided that claims
13 alleging that the manufacture of a covered countermeasure,
14 something about the manufacture of it caused an injury,
15 are barred. And that's what this case is.

16 This is a case alleging that there was something
17 wrong with the manufacturing of the particular doses of
18 remdesivir that Mr. Nowacki received, and the argument is
19 that takes remdesivir from being a covered countermeasure
20 to not being a covered countermeasure. As Judge Roberts
21 explained, pages 18 to 21 of her opinion, that's contrary
22 to the plain text of the PREP Act. Courts are not
23 supposed to read statutes in ways that nullify important
24 provisions of the statutes. Here, Congress went to great
25 lengths to specify all of the different attributes, all

1 the different types of causal relationships that are
2 within the liability bar within the immunity provision,
3 and it says specifically that manufacture is one of them.

4 Now, that's really all the Court needs to know.
5 In my view it's really as simple as the claims here are
6 about the manufacture of a covered countermeasure. The
7 argument that something wrong with the manufacturing means
8 it's not a covered countermeasure is contrary to Congress'
9 explicit inclusion of manufacture in the Scope provision
10 (B) that I just read, Your Honor. But there is more;
11 there is double and triple confirmation in other parts of
12 the PREP Act if that's necessary. The same provision (B)
13 that includes manufacture, also includes a causal
14 relationship with labeling, packaging, marketing,
15 promotion, and various other attributes; even here are
16 things relating to a covered countermeasure.

17 And here, the Complaint also talks about
18 labeling. This is paragraph 45 of the Complaint. It says
19 the labeling approved by FDA of remdesivir didn't say
20 anything about glass particles, it wasn't supposed to
21 contain glass particles; that the remdesivir here didn't
22 conform to the labeling. Well, again, Congress
23 specifically provided that claims that are about something
24 to do with the labeling of a covered countermeasure are
25 barred. And if Plaintiffs were right, that if there's a

1 problem with the labeling or with the manufacture, or with
2 anything else in that list in paragraph (B), then that
3 means it's not a covered countermeasure to begin with,
4 then that provision doesn't make any sense; that provision
5 has been nullified. And that's what Judge Roberts
6 explained. Plaintiffs make the exact same argument here,
7 and the answer is the same; it's that courts are not
8 supposed to read statutes in ways that nullify their
9 provisions, except in Plaintiffs' argument here would
10 nullify that provision.

11 I said there's triple confirmation of the PREP
12 Act, and that comes in in a somewhat complicated context
13 relating to the PREP Act's federal cause of action for
14 willful misconduct. The short version of it is, the PREP
15 Act explicitly contemplates that there could be claims
16 about products that have been recalled by FDA, or FDA
17 regulated products that have been voluntarily recalled by
18 the manufacturer, which is what happened here. And in
19 that, in those provisions, and we cite these provisions in
20 our briefs, in those provisions Congress clearly
21 contemplates, explains that -- that something that led to
22 a recall of a product, such as a manufacturing problem,
23 which is the very kind of thing that could lead to a
24 recall on an FDA regulated product, are also within the
25 scope of the PREP Act.

1 So what you have is Congress drawing a
2 distinction between voluntary recalls, which is what
3 happened here, and mandatory recalls where the
4 manufacturer has refused to do a voluntary recall, and
5 that comes in in that provision because of the willful
6 misconduct cause of action that Congress provided as a
7 replacement, a very narrow replacement for the very broad
8 universe of state law claims that it barred.

9 And what you can tell the -- the details of the
10 federal cause of action for willful misconduct are not
11 relevant at this point, but you can tell from those
12 references to recalls that Congress very clearly intended
13 that claims about recalled products are within the scope
14 of the PREP Act.

15 So here, again, we think it's clear that if you
16 were to accept Plaintiffs' argument that an allegation of
17 a manufacturing defect in a covered countermeasure means
18 it's no longer a covered countermeasure, you nullify
19 multiple provisions of the statute in ways that it's not
20 proper to do.

21 The final thing that I will say is, and we make
22 this point in our papers as well, like, I understand that
23 it's unusual for Congress to bar claims as broadly, as
24 widely, as firmly as Congress did in the PREP Act. And
25 here, Congress recognized that it was doing so, it barred

1 a very broad universe of claims, it created a very narrow
2 substitute federal cause of action for a small subset of
3 the claims that it was otherwise barring; that's the claim
4 that was in Count 5 of Plaintiffs' Complaint that Judge
5 Roberts held gave rise to removal of jurisdiction in
6 federal court, and then dismissed because it didn't comply
7 with all of the requirements of the PREP Act's willful
8 misconduct cause of action.

9 But then Congress did another thing. It created
10 a no-fault administrative compensation program to make up
11 for the fact that it was barring a lot of claims that
12 would normally be in the court system. Congress said,
13 "We're going to channel those claims instead out of the
14 court system, so that we don't disincentivize or delay the
15 development, the manufacture, the distribution, the
16 administration of covered countermeasures in a national
17 emergency like a pandemic, but we recognize that by
18 barring all those claims, we're leaving some people
19 without compensation, so we're going to create an
20 administrative no-fault compensation program."

21 Now, the Plaintiffs in their papers, you know,
22 say that the compensation program is not generous. If the
23 details of the compensation program and how generous it is
24 or isn't really aren't the issue here. The point is that
25 Congress didn't have to create a compensation program at

1 all. It could have just barred these claims. It did
2 create a compensation program, the Plaintiffs do have a
3 remedy under the compensation program, and the law is
4 clear that the PREP Act bars these claims in court, and
5 leaves Plaintiffs to their remedy under the compensation
6 program.

7 I said that I would be brief. I'm not sure that
8 I have been, but I'll stop there and see if Your Honor has
9 questions. If so, I'd be happy to answer them. But for
10 those reasons, we think the law is clear and the motion
11 should be granted, and the Plaintiffs, if they choose to
12 do so, pursue a claim in the compensation program.

13 Thank you, Your Honor.

14 THE COURT: Thank you.

15 Who's arguing for Plaintiff?

16 MR. KHAHRA: Thank you, Your Honor. Thank you,
17 Your Honor. May I proceed?

18 THE COURT: Yes, you may. Go ahead.

19 MR. KHAHRA: Thank you.

20 Judge, I disagree with brother counsel on quite a
21 bit of the issues that he's raised, but I do agree with
22 him on the issue that this is a novel concept. What you
23 have before you is (C)(8) motion that tests the
24 sufficiency of the Complaint and whether or not we have
25 pled a claim that will allow this case to move forward.

1 You know, a lot has been said about what Judge
2 Roberts did or didn't do, and I think my reading of her
3 opinion is a bit different than what counsel has just
4 articulated today, because Judge Roberts, if she was
5 convinced that this was preempted, she would have
6 dismissed the whole case, not remanded it. But she
7 remanded it back, so now it's before this Court to decide
8 whether or not the PREP Act immunity applies to these four
9 counts that are left. Judge Roberts dismissed the only
10 claim that she felt was preempted by the PREP Act, which
11 was the intentional misrepresentation claim, Count 5.
12 Everything else was remanded back. In fact, on page
13 (unintelligible) of her opinion, and also in the last page
14 of her order she said, "Even if I did not have to dismiss"
15 -- I just want to make sure that I quote the exact
16 language. She stated:

17 "Even if I did not" -- "Even without
18 dismissal of Count 5, the Court would
19 still decline to exercise supplemental
20 jurisdiction of Plaintiffs' other
21 counts..."

22 Which are state law claims, which:
23 "...substantially predominate over
24 the intentional misrepresentation and
25 willful misconduct claim."

1 Meaning, the other claims are not preempted by
2 the PREP Act. The PREP Act applies to covered persons for
3 covered countermeasures.

4 In our Complaint what we have stated is that Mr.
5 Nowacki received two doses of remdesivir that was
6 contaminated, that had glass particles, and hence the
7 cause of -- the injury was caused by the glass particles.
8 There's a distinction. And in order for something to be a
9 covered countermeasure, the Exhibit Number 4, the
10 prerequisite is that the drug, device, or biological
11 product has to be approved, cleared, or licensed by the
12 FDA. And you have -- and we have to look at these
13 remdesivir units that Mr. Nowacki received as an
14 individual unit, and not as remdesivir as a whole.

15 The individual units of remdesivir that Mr.
16 Nowacki received is not something that what the FDA
17 approved. It deviated from it. It had glass particles.
18 Had the FDA known that there was glass particles in it,
19 they would have never approved it. So it's not a covered
20 countermeasure. The analysis starts and ends right there.

21 We're making it way too complex by saying this is
22 all covered under the PREP Act. It's the defense's
23 burden, and they have not cited to a single case that
24 contains contamination where the courts have extended the
25 PREP Act immunity. In fact, the only three cases that

1 they cited to, which I obviously addressed in my response
2 papers, have cases that dealt with reactions to the actual
3 vaccine drugs. That was on page 7 of my response.

4 The Parker case, on page number 8. There was the
5 T.C. case that had the issues with COVID-19 vaccine where
6 the patient developed some sort of a medical complication
7 and subsequently filed a medical malpractice case.

8 Then there was the case of, in November of 2022
9 out of the Eastern District of Kentucky, the Goins case,
10 that case also did not contain any contamination drug.

11 It is the defense's burden at this point to show
12 to this Court that the contaminated drug, the glass
13 particle, does not fall within the definition of a covered
14 countermeasure. There is not a single case out there that
15 they have cited to, to, for this Court to extend the PREP
16 Act immunity to this case.

17 For those reasons, I think this case should go
18 forward. I certainly believe that under (C) (8), once we
19 start to get into additional discovery and start to learn
20 more about the facts, more will be learned, and obviously
21 we can -- we can be -- we'll be before this Court later on
22 I'm sure on other motions and things of that nature. But
23 at this point I believe this is not a covered
24 countermeasure. The PREP Act immunity could not be
25 extended under these circumstances.

1 Thank you, Your Honor. If you have any
2 questions, I'm happy to address those.

3 THE COURT: I don't.

4 Anything else?

5 MR. BUCHOLTZ: Your Honor, may I have just a very
6 brief opportunity for rebuttal?

7 THE COURT: Certainly.

8 MR. BUCHOLTZ: Thank you.

9 I want to respond to what my friend, Plaintiffs'
10 side, said about Judge Roberts' order and preemption.
11 Preemption is a word of many meanings, and I think that
12 apples and oranges are being mixed up here.

13 The issue in front of Judge Roberts first and
14 foremost was whether removal of jurisdiction was proper;
15 whether federal courts had subject matter jurisdiction.
16 Complete preemption, which is a, the Sixth Circuit says is
17 a misleadingly named doctrine, because it's really not
18 about preemption, it's really about jurisdiction, but
19 nonetheless the term the U.S. Supreme Court has given to
20 it is complete preemption.

21 Complete preemption is about when you plead a
22 claim under state law, as Plaintiffs did here, but
23 Congress has so occupied the field, so thoroughly occupied
24 the field, so thoroughly ousted state law, that there just
25 isn't any claim under state law, and if you plead a claim

1 purportedly under state law, as a matter of law, it's
2 turned automatically into a claim under federal law, that
3 as such, invokes the jurisdiction of the federal courts.
4 That's complete preemption. That has nothing to do with
5 this motion here today. It was the issue in federal court
6 because it's what determined whether the federal court had
7 removal jurisdiction.

8 So Judge Roberts agreed with us that Count 5, the
9 intentional misrepresentation claim, fell within the scope
10 not just of the PREP Act's immunity provision, which is
11 the issue here today, but within the scope of the PREP
12 Act's substitute exclusive federal cause of action.
13 That's what gave rise to complete preemption, meaning
14 federal court jurisdiction.

15 But the only argument the Plaintiffs made in
16 response to the complete preemption, jurisdictional
17 argument, was there's no nexus with the administration of
18 a covered countermeasure, which is another requirement of
19 course for the PREP Act's substitute cause of action under
20 federal law, there's no nexus with the administration of a
21 covered countermeasure because the remdesivir here,
22 because it was allegedly contaminated, wasn't a covered
23 countermeasure. So that's exactly the same argument the
24 Plaintiffs are making now.

25 And by using the word preemption imprecisely, I

1 think I -- there's -- I don't want Your Honor to be
2 confused about it, right? The PREP Act bars, and this is
3 again 247d-6d(a) (1), it doesn't even use the word
4 preemption. It's just an outright immunity from suit and
5 liability provision. That's the provision that's directly
6 at issue here on this motion. It has nothing to do with
7 federal court jurisdiction. It just says that:

8 "...a covered person..."

9 There's no dispute that Gilead is one:

10 "...is immune from suit and liability
11 under Federal and State law with respect
12 to all claims for loss caused by, arising
13 out of, relating to, or resulting from the
14 administration...of a covered
15 countermeasure..."

16 The only question is, is remdesivir that
17 Plaintiff allegedly received a covered countermeasure?

18 That's exactly the same question that Judge
19 Roberts asked -- that Judge Roberts had to decide. And
20 she explained on page 16 of her opinion she had to decide
21 that because it went to whether any of Plaintiffs' claims
22 fell within the scope of the exclusive federal cause of
23 action in the PREP Act that gave rise to federal court
24 jurisdiction. She held yes, intentional misrepresentation
25 claim did precisely because it was a claim for loss

1 arising out of the administration of a covered
2 countermeasure, rejecting Plaintiffs' argument that the
3 alleged manufacturing defect means it wasn't a covered
4 countermeasure.

5 Now, she also had to decide additional things,
6 about whether Count 5, alleged willful misconduct within
7 the scope of the PREP Act's definition, that went only to
8 federal subject matter jurisdiction and is not relevant
9 here now. But the key issue that was in dispute, really
10 the only issue that was in dispute in federal court was do
11 allegations of a manufacturing defect mean a covered
12 countermeasure is no longer a covered countermeasure?

13 Judge Roberts squarely addressed that issue
14 because she had to. She wrote three-and-a-half well-
15 reasoned pages about it. The heading on Count (sic) 18,
16 the whole section of her opinion is, "The Recalled
17 Remdesivir Constitutes a 'Covered Countermeasure.'" The
18 exact same issue here.

19 And as to my friend's comment that if Judge
20 Roberts had agreed that Counts 1 through 4 were barred by
21 the PREP Act she wouldn't have remanded them, that's just
22 not correct, Your Honor. Again, we're mixing apples and
23 oranges.

24 The issue in front of Judge Roberts first and
25 foremost was federal subject matter jurisdiction. She

1 found that Count 5 fell within federal subject matter
2 jurisdiction because it was in substance a claim for
3 willful misconduct within the scope of the PREP Act. She
4 found that Counts 1 through 4 were not for willful
5 misconduct; they were for negligence or other things short
6 of willful misconduct; therefore, they didn't fall within
7 the PREP Act's substitute exclusive federal cause of
8 action. That's a different question for whether they fall
9 within the PREP Act's immunity provision.

10 The PREP Act's immunity provision, which is the
11 one I've read Your Honor twice now, is extremely broad.
12 It doesn't have any mens rea in it. It's not limited to
13 claims for willful misconduct or claims for negligence or
14 claims for any other type of claim. Instead, it's quite
15 broad and applies to all claims for a loss that has the
16 required nexus to the administration of a covered
17 countermeasure.

18 So, Judge Roberts didn't decide -- excuse me. I
19 misspoke.

20 What Judge Roberts did decide is that Count 5
21 fell within the PREP Act's exclusive federal cause of
22 action and Counts 1 through 4 didn't. That -- that issue
23 went to federal subject matter jurisdiction. It doesn't
24 relate to the motion here today. The consequence of that
25 was that Judge Roberts had removal jurisdictional, so she

1 exercised jurisdiction and dismissed Count 5.

2 She then had, as a matter of 28 U.S.C. 1367, she
3 had supplemental jurisdiction over Counts 1 through 4,
4 which really are state law claims. They're not
5 transformed into federal law claims by virtue of complete
6 preemption like Count 5 was. They stay state law claims.
7 She had supplement jurisdiction over them, but the way
8 supplemental jurisdiction works is the court has
9 discretion to retain or not retain supplemental
10 jurisdiction. She exercised her discretion not to retain
11 it. That does not in any way mean that those claims are
12 not barred by the PREP Act's immunity provision. And
13 Judge Roberts already found in substance that they are.
14 There's no distinction for that purpose between Counts 1
15 through 5 and Count 5. All of them are just different
16 legal theories that arise out of the same conduct; the
17 administration to Mr. Nowacki of remdesivir to treat his
18 COVID. They're just different legal theories. And the
19 difference in legal theory has no bearing whatsoever on
20 whether they fall within the PREP Act's liability
21 protections in (a)(1)(B). They all do, and they only
22 argument the Plaintiffs have made is the exact same
23 argument that Judge Roberts rejected at length.

24 If Your Honor has any questions, I'd be happy to
25 answer them. Thank you.

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THE COURT: I don't have any.

Anyone else have anything they want to say?

(No response.)

THE COURT: Okay. As we all know far too well, in March of 2020 the -- we experienced a world-wide pandemic. I find it funny to say that because isn't that the definition of a pandemic is that it is completely pervasive?

But anyway, the -- we had the COVID pandemic descend upon us, and as it was ravaging the population and killing hundreds of thousands of people, folks such as those at Gilead were scrambling to develop vaccines and treatments and -- and to save lives. And in recognition of the fact that people are dying as these treatments are being developed, the -- our Congress I think wisely legislated some protections for those companies that were rushing products to market, and I don't say that in a disparaging way. The -- the world was clamoring for -- for products that would help them survive the COVID -- help them survive COVID, and companies such as Gilead, as I said, were doing that, attempting to fill that void.

The product that was approved and that was used in this case was a, developed and marketed pursuant to a formula, and that formula is what HHS approved for emergency use and for the protections of the PREP Act.

1 When this particular product and the doses that
2 were administered to Mr. Nowacki, there was a failure, and
3 the failure was that there were some doses that were
4 contaminated with shards of glass, which were recognized
5 by Gilead as being potential causes of stroke, which is
6 what exactly happened to Mr. Nowacki, and unfortunately he
7 died from the cure and not from the disease.

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

1 Again, we're not talking about a problem with the
2 formula, and that would be the reason to insulate a drug
3 manufacturer from liability is because they're putting
4 something on the market that hasn't been adequately
5 tested. It's not the failure to test that caused a
6 problem in this case. It's not the failure of further
7 investigation or human subjects or anything else that we
8 would typically see that there just wasn't time for. In
9 this case it was, as alleged by Plaintiff, negligent
10 manufacture with contaminants in there that nobody would
11 have ever intended to be in a drug that's supposed to
12 treat someone for a life-threatening disease.

13 I can't find that the legislature intended to
14 insulate a company from its negligence in placing
15 contaminants, or allowing contaminants to be distributed
16 with the product. And for that reason, I'm going to deny
17 the motion for summary disposition.

18 There was some bit of argument in the briefs
19 about causation or the Plaintiffs' ability to prove
20 causation. This is a (C)(8) motion. I'm not going to
21 consider the (C)(10) aspect of -- that was kind of touched
22 upon in the motion for summary disposition. What I'm
23 doing today is determining that under (C)(8) the summary
24 disposition is not appropriate and it's denied.

25 MR. KHAHRA: Thank you, Your Honor.

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THE COURT: Thank you.

MR. BUCHOLTZ: Thank you, Your Honor.

THE COURT: Recess.

(At 4:20 p.m., proceedings concluded; off the record.)

1 STATE OF MICHIGAN

2 COUNTY OF WASHTENAW) ss.

3 I certify that this transcript is a complete, true, and
4 correct transcript to the best of my ability of the digital
5 proceedings in the case of Mark Nowacki as legal guardian and
6 conservator for Daniel Nowacki, et al, versus Gilead Sciences,
7 Incorporated, et al, held July 12, 2023.

8 Digital proceedings were recorded and provided to this
9 transcriptionist by the court and this certified reporter
10 accepts no responsibility for any events that occurred during
11 the above proceedings, for any unintelligible, inaudible,
12 and/or indiscernible response by any person or party involved
13 in the proceeding or for the content of the digital media
14 provided.

15 I also certify that I am not a relative or employee of the
16 parties involved and have no financial interest in this case.

17 DATED: July 14, 2023

18 *s/ Kristen Shankleton*

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22 _____
Transcription provided by:

23 Kristen Shankleton (CER 6785)

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