STATE OF MINNESOTA IN COURT OF APPEALS A24-1339

Jaclyn Roos, Appellant,

Carol Naumann, Plaintiff,

VS.

HealthPartners, Inc., et al., Respondents,

Richard Mahr, et al., Defendants.

Filed May 5, 2025 Reversed and remanded Larson, Judge

Ramsey County District Court File No. 62-CV-23-6340

Andrew W. Barnhart, Barnhart Law Office, PLLC, Long Prairie, Minnesota (for appellant)

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Considered and decided by Slieter, Presiding Judge; Cochran, Judge; and Larson, Judge.

SYLLABUS

When a plaintiff alleges a medical-negligence claim based upon a misdiagnosis, a defendant covered under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d (2018) (PREP Act), is not entitled to immunity because they used a treatment that is a covered countermeasure to treat the misdiagnosed medical condition.

OPINION

LARSON, Judge

Appellant Jaclyn Roos challenges the district court's decision to dismiss her amended complaint on the ground that respondents HealthPartners, Inc., and Regions Hospital are immune from suit under the PREP Act. Because Roos's complaint alleged a claim for which respondents are not immune from suit and the district court failed to draw all reasonable inferences from those allegations in Roos's favor, we reverse and remand.¹

FACTS

In reviewing a district court's decision to grant a motion to dismiss, "we accept the factual allegations in the complaint as true." *Abel v. Abbott Nw. Hosp.*, 947 N.W.2d 58, 64 n.2 (Minn. 2020). The following facts are derived from Roos's amended complaint.

On November 18, 2020, Roos's husband (decedent) was admitted to Regions Hospital "with shortness of breath, fever, weakness, and fatigue." Decedent had community-acquired pneumonia when admitted. "Known causes of community-acquired pneumonia are bacterial, viral, fungi or Covid-19, and are typically ruled out in that order." Decedent, a licensed pharmacist, "immediately and repeatedly" told hospital staff "that he

¹ In response to respondents' motion to dismiss the amended complaint, Roos filed a motion for leave to file a second amended complaint, which the district court denied. Roos argues alternatively that the district court abused its discretion when it denied this motion. Because we reverse the district court's decision to grant the motion to dismiss, we need not decide whether the district court abused its discretion when it denied Roos's motion to amend. But had we reached this issue, we would have reversed because amendments to the pleadings should be liberally granted, and respondents failed to show any prejudice. *See Voicestream Minneapolis, Inc. v. RPC Props., Inc.*, 743 N.W.2d 267, 272 (Minn. 2008) ("Leave to amend should be freely granted unless it results in prejudice to the other party.").

believed he had bacterial pneumonia." Roos also "repeatedly reminded [hospital staff] that [d]ecedent believed he had bacterial pneumonia" and Roos "repeatedly asked [hospital staff] what they were doing to test for and treat it."

Without any testing, hospital staff diagnosed decedent with COVID-19 and viral COVID pneumonia. They administered antiviral medications and anti-inflammatory immunosuppressants to treat those conditions. Hospital staff also administered "financially incentivized" COVID-19 treatments.

On November 23, 2020, decedent's sixth day in the hospital, hospital staff began treating decedent with antibiotics to combat bacterial pneumonia. After 28 hours, hospital staff stopped giving decedent antibiotics, but they resumed antibiotic treatment 33 hours later. The medical records attached to the complaint indicate that these treatments were administered simultaneously with the COVID-19 and viral COVID pneumonia treatments.

On November 27, 2020, hospital staff tested decedent for bacterial pneumonia, and he tested positive. On December 2, 2020, decedent experienced a cardiac arrest and was transferred to another hospital. Decedent received treatment at the second hospital until his death on December 23, 2020.

On November 29, 2023, Roos and a now-dismissed plaintiff filed the original complaint in this action. Respondents moved for a more definite statement. On February 12, 2024, Roos filed an amended complaint. The amended complaint alleged one cause of action against respondents: "survival action and wrongful death medical negligence." The amended complaint asserted that because respondents failed to treat decedent's bacterial pneumonia upon his admission and failed to treat it properly throughout his time at the

facility, decedent's "bacterial infection . . . spread throughout his body and caused his death." Respondents moved to dismiss the amended complaint, arguing that they were immune from suit under the PREP Act. On June 26, 2024, the district court granted respondents' motion to dismiss.

Roos appeals.

ISSUE

Did the district court err when it granted respondents' motion to dismiss the amended complaint on the basis that respondents are entitled to immunity under the PREP Act?

ANALYSIS

Roos challenges the district court's decision to dismiss the amended complaint for failure to state a claim under Minn. R. Civ. P. 12.02(e) on the ground that respondents are entitled to immunity under the PREP Act. Specifically, Roos argues the district court improperly drew inferences from the complaint in favor of respondents to reach its decision that respondents are entitled to immunity.

When reviewing the dismissal of a complaint for failure to state a claim, "we review the legal sufficiency of the claim de novo to determine whether the complaint sets forth a legally sufficient claim for relief." *Graphic Commc'ns Loc. 1B Health & Welfare Fund* "A" v. CVS Caremark Corp., 850 N.W.2d 682, 692 (Minn. 2014). "We accept the facts alleged in the complaint as true and construe all reasonable inferences in favor of the nonmoving party." *Walsh v. U.S. Bank, N.A.*, 851 N.W.2d 598, 606 (Minn. 2014). A claim survives "a motion to dismiss for failure to state a claim if it is possible on any evidence

which might be produced, consistent with the pleader's theory, to grant the relief demanded." *Id.* at 603.

To address Roos's argument, we begin with an overview of the PREP Act. We then address the allegations in the amended complaint and whether respondents are entitled to immunity at this stage of the litigation.

Α.

"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 [United States Secretary of Health and Human Services (secretary)] to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." *Cannon v. Watermark Retirement Cmtys., Inc.*, 45 F.4th 137, 139 (D.C. Cir. 2022) (quotation omitted). The PREP Act creates an immunity "from suit and liability from claims related to the administration of a covered countermeasure" during a public-health emergency. *Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 400-01 (3d Cir. 2021). "The immunity is triggered by a declaration from the

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² Although we are bound only by U.S. Supreme Court and Minnesota Supreme Court decisions interpreting the PREP Act, other federal court and state court decisions provide persuasive authority. *See Citizens for a Balanced City v. Plymouth Congregational Church*, 672 N.W.2d 13, 20 (Minn. App. 2003) (recognizing that we are "bound by decision[s] of the Minnesota Supreme Court and the United States Supreme Court," but not "by any other federal courts' opinion[s]" though such "opinions are persuasive and should be afforded due deference"); *Mahowald v. Minn. Gas Co.*, 344 N.W.2d 856, 861 (Minn. 1984) (noting that although decisions from courts of other states are not binding, they may be persuasive).

[s]ecretary identifying the threat to public health, the period during which immunity is in effect, and other particulars." *Cannon*, 45 F.4th at 139.

The PREP Act provides, in relevant part, that

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 U.S.C. § 247d-6d(a)(1). From this statute, federal courts have discerned that a defendant is entitled to PREP-Act immunity if: (1) the treatment at issue is a covered countermeasure; (2) the defendant is a covered person; and (3) the plaintiff's claim bears a causal relationship to the administration of the covered countermeasure. *See Maglioli*, 16 F.4th at 400-01; *Maney v. Brown*, 91 F.4th 1296, 1300 (9th Cir. 2024).

Relevant to this case is the secretary's invocation of the PREP Act in response to the COVID-19 pandemic. The secretary issued a declaration invoking the PREP Act on March 10, 2020, based on his determination that "the spread of SARS-CoV-2 or a virus

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³ The parties agree that respondents and their employees are "covered person[s]" under the statute. See 42 U.S.C. § 247d-6d(i)(2) (defining "covered person" to include "a person or entity that is . . . a qualified person who prescribed, administered, or dispensed such countermeasure"), (i)(5) (defining "person" as "an individual, partnership, corporation, association, entity, or public or private corporation"), (i)(8) (defining "qualified person" as "a licensed health professional or other individual who is authorized to prescribe, administer, or dispense . . . countermeasures").

⁴ Some courts treat "loss" as a fourth element. *See Baghikian v. Providence Health & Servs.*, 715 F. Supp. 3d 1265, 1272 (C.D. Cal. 2024); *De Becker v. UHS of Del., Inc.*, 555 P.3d 1192, 1201-02 (Nev. 2024); *State ex rel. Clinton No. 1, Inc. v. Baker*, No. SC 100099, 2024 WL 942543, at *2 (Mo. Mar. 5, 2024). The complaint alleged a "loss" as that term is defined under the PREP Act—decedent's death. *See* 42 U.S.C. § 247d-6d(a)(2)(A)(i) (defining "loss" as "any type of loss, including . . . death").

mutating therefrom and the resulting disease, COVID-19, constitute[d] a public health emergency."⁵ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,198, 15,203 (Mar. 17, 2020). In a December 3, 2020 amendment, effective retroactively to February 4, 2020, the secretary declared that the PREP Act's immunity applied to "the manufacture, development, distribution, administration, and [c]overed testing, use of [c]ountermeasures." Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 79,190, 79,190, 79,195, 79,198 (Dec. 9, 2020). "Covered [c]ountermeasures" included, in relevant part:6

- (a) Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:
- i. [t]o diagnose, mitigate, prevent, treat, or cure COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
- ii. to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause[.]

Id. at 79,196.

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⁵ Decedent was admitted to Regions Hospital on November 18, 2020, and transferred to another hospital on December 3, 2020. The secretary's declaration was most recently amended on December 6, 2024, to extend its duration to December 31, 2029. *See* 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99,875, 99,876, 99,883 (Dec. 11, 2024) [hereinafter "12th Amendment"]. Accordingly, it is undisputed that the PREP Act was in effect during the events underlying Roos's claim.

⁶ "Covered [c]ountermeasures" continues to have the same definition. *See* 12th Amendment, 89 Fed. Reg. at 99,880.

With these provisions in mind, we turn to Roos's argument.

B.

Roos challenges the district court's decision to grant respondents' motion to dismiss the amended complaint on the basis that respondents are entitled to immunity. Specifically, Roos argues the district court: (1) improperly construed the complaint to allege that respondents' decision to use covered countermeasures caused decedent's death and (2) made unreasonable inferences when it determined the complaint alleged only conduct with a causal relationship to the use of covered countermeasures. We address each argument in turn.

1. Covered Countermeasures

Roos first argues the district court improperly dismissed the amended complaint on the basis that some of the alleged negligent conduct constituted the administration of "covered countermeasures." In particular, Roos observes that, despite her clear argument that "the gravamen of her [complaint] . . . was that the harm arose from the failure to treat [decedent's] bacterial pneumonia with antibiotics," the district court determined that the complaint's "express[] reference [to] COVID-19 and the alleged negative impact countermeasures had on decedent's likelihood to recover" meant that respondents were entitled to immunity.

We first address the district court's determinations with which we agree. In two paragraphs of the amended complaint, Roos made allegations specifically regarding the administration of covered countermeasures to decedent. Paragraphs 18 and 19 provide:

- 18. During the time [respondents] should have been treating [d]ecedent for bacterial pneumonia, they were instead treating him for Covid-19 with antiviral medications as well as for viral covid pneumonia with anti-inflammatory immunosuppressants which impeded [d]ecedent's ability to fight the bacterial pneumonia.
- 19. [Respondents] were administering financially incentivized Covid-19 treatments to [d]ecedent despite never testing him for Covid-19.

We agree with the district court that, to the extent these allegations relate to the administration of COVID-19 treatments generally, and antiviral medications specifically, both fall plainly within the scope of covered countermeasures. *See id.* (defining "[a]ny *antiviral*, any *drug*, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine . . . used . . . [t]o *diagnose, mitigate, prevent, treat, or cure COVID-19*" as covered countermeasures (emphases added)).

Where we depart from the district court's determination is its inference from these two paragraphs that the amended complaint alleges that the use of covered countermeasures caused decedent's death. Instead, the allegations of medical negligence in the amended complaint are not limited to negligent treatment; Roos's primary allegation is misdiagnosis—respondents failed to test and treat decedent for the condition that led to his death (bacterial pneumonia). Removing paragraphs 18 and 19, Roos's complaint reads:

- 10. Decedent's medical records from [respondents] state unequivocally that [d]ecedent had community-acquired pneumonia at the time of his admission to their hospital.
- 11. Known causes of community-acquired pneumonia are bacterial, viral, fungi or Covid-19, and are typically ruled out in that order.

- 12. [Respondents] tested [d]ecedent for Influenza A and B within several hours of taking him under their care, and he was negative for both.
- 13. [Respondents] never tested [d]ecedent for Covid-19.
- 14. [Respondents] failed to give [d]ecedent a sputum test for bacterial pneumonia for the first 8 days he was under their care.
- 15. Decedent, having had bacterial pneumonia years prior and being familiar with its symptoms, upon being placed under [respondents'] care, immediately and repeatedly told them that he believed he had bacterial pneumonia.
- 16. Immediately after [d]ecedent was placed under [respondents'] care, [Roos] repeatedly reminded [respondents] that [d]ecedent believed he had bacterial pneumonia and repeatedly asked them what they were doing to test for and treat it.
- 17. Defendants withheld antibiotic treatment from [d]ecedent for his bacterial pneumonia during the first five days that he was under their care.

. . . .

- 20. On the sixth day that [d]ecedent was under their care, [respondents] finally began providing him antibiotic treatment for bacterial pneumonia, IV Cefepime, which is actually inferior to Azithromycin for this purpose; however, they discontinued this treatment after only 28 hours and allowed a 33-hour gap in antibiotic treatment until it was recommenced and continued for 5 days.
- 21. [Respondents'] failure to initially treat [d]ecedent's bacterial pneumonia followed by their failure to treat it properly caused the bacterial infection to spread throughout his body and cause his death.

Accordingly, omitting paragraphs 18 and 19, the remaining paragraphs, taken in the light most favorable Roos, form a reasonable inference that the decedent was misdiagnosed.

And to the extent Roos makes allegations regarding the administration of particular treatments, most of those treatments do not fall within the scope of "covered countermeasures" as defined in the secretary's declaration. *See id.* Most obviously, paragraph 20 makes allegations regarding antibiotic treatments, which were plainly not covered countermeasures under the secretary's declaration. *See id.* And paragraph 18 makes allegations regarding decedent's treatment "for viral covid pneumonia with anti-inflammatory immunosuppressants," which also were not covered countermeasures under the secretary's declaration. *See id.*

That leaves Roos's allegations regarding respondents' use of antiviral medications to treat COVID-19 in paragraph 18. The parties engage in extended analyses of the meaning of paragraph 18 in their briefing. Roos concedes that paragraph 18 is ambiguous, but argues that she intended to "allege[] that in addition to treating [d]ecedent for Covid-19 with antiviral medications, [respondents] were treating him for viral covid pneumonia with anti-inflammatory immunosuppressants which impeded [d]ecedent's ability to fight the bacterial pneumonia." Respondents counter that Roos's proposed interpretation is unreasonable. But we agree with Roos that paragraph 18 invites competing inferences. And we are required to settle these competing inferences in Roos's favor at this stage of the proceedings. *See Walmart Inc. v. Winona County*, 963 N.W.2d 192, 196 (Minn. 2021). Accordingly, when reasonable inferences are made in Roos's favor, paragraph 18 alleges that it was the anti-inflammatory immunosuppressants that impeded decedent's ability to

fight the bacterial pneumonia and not the covered countermeasures used to treat COVID-19.

We therefore conclude that, when reasonable inferences are construed in Roos's favor, the amended complaint alleges that respondents' misdiagnosis of decedent's condition and administration of specific treatments not covered by the PREP Act caused decedent's death.

2. Causal Relationship

Because we discern that, taking all inferences in the light most favorable to Roos, the amended complaint alleges that a misdiagnosis and treatments other than covered countermeasures caused decedent's death, we must evaluate whether the allegations in the amended complaint, nonetheless, bear a causal relationship to the administration of the covered countermeasure. *See Maglioli*, 16 F.4th at 400-01. The district court determined that Roos "expressly alleged" that decedent's death "arose out of or related to the administration of a covered countermeasure," such that this element was satisfied.

Application of the causal-relationship element has been well explored outside Minnesota. See Mills v. Hartford Healthcare Corp., 298 A.3d 605, 630 (Conn. 2023). Some courts have described the PREP Act's causation language in broad terms. See, e.g., Maney, 91 F.4th at 1300-01 (describing an "expansive causal relationship" between the administration of covered countermeasures and the plaintiff's claim). Others have taken a narrower approach. See, e.g., Hampton v. California, 83 F.4th 754, 764 (9th Cir. 2023) ("Considered in its context in the PREP Act, 'relating to' takes on a more targeted meaning. . . . It is not enough that some countermeasure's use could be described as

relating to the events underpinning the claim in some broad sense."). But many courts, when considering the causal-relationship element, have determined that PREP-Act immunity does not apply to ordinary negligence claims. *See Est. of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 532 (D.N.J. 2020) ("[T]he [PREP] Act still leaves room for ordinary claims of negligent or substandard care."), *aff'd sub nom. Maglioli*, 16 F.4th at 400; *Mills*, 298 A.3d at 633-34, 633 n.31 (collecting cases).

As indicated above, we conclude that the thrust of Roos's amended complaint is misdiagnosis—that respondents failed to test and properly treat decedent for bacterial pneumonia and those failures caused his death. Yet, we acknowledge that Roos's amended complaint includes allegations that covered countermeasures were used in decedent's treatment—even if they did not *cause* his death. Thus, we must decide whether respondents are entitled to immunity because their treatment of decedent's bacterial pneumonia with a covered countermeasure bears a causal relationship to decedent's death as contemplated by the PREP Act.

One persuasive case out of Connecticut aids our understanding of the causal-relationship element in the misdiagnosis context. There, the decedent went to the emergency room in March 2020 complaining of a sore throat and headache, and test results indicated that she was having a heart attack. *Mills*, 298 A.3d at 611. Because staff suspected the decedent had COVID-19, the decedent's admission to the catheterization lab was deferred. *Id.* at 612. Staff administered a COVID-19 diagnostic test to the decedent—a covered countermeasure—which returned negative after several days. *Id.* at 612-13, 629. The decedent was admitted to the catheterization lab the next day, but died before treatment

could be administered. Id. at 613. The plaintiff filed a wrongful-death action against the hospital and several physicians. Id. at 610. Applying a rule similar to Minn. R. Civ. P. 12.02, the district court determined that some defendants were immune from suit under the PREP Act and dismissed the claims against those defendants. *Id.* The Connecticut Supreme Court reversed. Id. at 610-11. The supreme court noted that the plaintiff's allegations included failures to timely diagnose the decedent's heart condition, transfer the decedent to the catheterization lab, and properly monitor the decedent. *Id.* at 632. The supreme court recognized the possibility of a causal relationship between "the delay in treatment attendant to the COVID-19 test" and the decedent's death but concluded that "the mere fact that the defendants administered and used a COVID-19 test did not, in and of itself, dictate whether they should or should not proceed with treatment while the test result was pending." Id. at 632-33. Accordingly, the PREP Act did not provide the defendants with immunity for a loss arising from their "treatment of the decedent before the receipt of the negative COVID-19 test result." *Id.* at 634.

⁷ A similar result was reached in *Waters v. Kory.* No. 3:24-CV-00858 (KAD), 2025 WL 20556, at *4 (D. Conn. Jan. 2, 2025), appeal docketed, No. 25-524 (2d Cir. Mar. 6, 2025). There, the decedent was diagnosed with COVID-19 in early December 2021 and sought treatment. *Id.* at *2. The doctor prescribed the decedent a covered countermeasure but neglected to prescribe an additional medication that is typically taken in conjunction with the covered countermeasure to prevent patients from developing a separate disease. *Id.* The decedent thereafter contracted that separate disease and died. *Id.* The federal district court denied the doctor's motion to dismiss a subsequently filed wrongful-death action under the PREP Act. *Id.* at *6. The federal district court noted that the plaintiff alleged the doctor's "failure to take other action . . . caused the decedent's death," rather than the doctor's administration of a covered countermeasure, and that this "other action" could have been taken regardless of the decedent's COVID-19 diagnosis. *Id.* at *4. The federal district court reasoned that "the negligence occurred when [the doctor] failed to mitigate

Here, we reach a similar conclusion that the allegations in Roos's amended complaint do not evince a causal relationship between the covered countermeasure and decedent's death. The amended complaint focuses on respondents' "failure to initially treat [d]ecedent's bacterial pneumonia" and, after diagnosis, "failure to treat it properly." (Emphasis added.) The amended complaint alleges that these "failure[s]"—not respondents' administration of a covered countermeasure—"caused the bacterial infection to spread throughout [decedent's] body and cause his death." (Emphasis added.) Thus, the alleged negligence occurred when respondents failed to treat the condition that ultimately caused decedent's death. Further, there is nothing in the amended complaint or the attendant medical records—that suggests respondents could not have simultaneously treated decedent for COVID-19 and bacterial pneumonia. In fact, the medical records attached to the complaint indicate that decedent received simultaneous treatments for both conditions five days after he was admitted to the hospital. Thus, like in *Mills*, the mere fact that respondents suspected decedent had COVID-19 did not, in and of itself, dictate that they should not also proceed with testing and treatment for bacterial pneumonia under the facts as alleged in the amended complaint. Accordingly, we conclude that, drawing all reasonable inferences in Roos's favor, the amended complaint does not allege a causal relationship between the administration of covered countermeasures and decedent's death.

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against the very condition that ultimately occurred and resulted in [the decedent's] death." *Id.* Because the plaintiff's claims stemmed from a failure to prescribe the additional medication, rather than the administration or use of the countermeasure, the federal district court determined there was no causal relationship, and the PREP Act did not apply. *Id.* at *5.

Because we must allow this case to proceed if "it is possible on any evidence which might be produced" that Roos was entitled to her requested relief, dismissal of the amended complaint was inappropriate. *See Walsh*, 851 N.W.2d at 603. We, therefore, reverse the district court because respondents are not entitled to immunity under the PREP Act at this stage in the litigation.

DECISION

Because Roos alleged a medical-negligence claim for which respondents are not immune from suit under the PREP Act when all reasonable inferences are drawn in Roos's favor, we conclude the district court erred when it granted respondents' motion to dismiss the amended complaint. We reverse and remand with instructions to reinstate the amended complaint and for further proceedings consistent with this opinion.

Reversed and remanded.