25-76(L)
Waters v. Kory

In the
United States Court of Appeals
for the Second Circuit

August Term 2025
Argued: January 12, 2026
Decided: August 26, 2026

No. 25-76(L), 25-524(XAP)

PIERRE KORY, M.D.,
Defendant-Appellant-Cross-Appellee,
v.
EDWARD WATERS, JR., ADMINISTRATOR OF THE ESTATE OF EDWARD JAMES WATERS,
Plaintiff-Appellee-Cross-Appellant.

Appeal from the United States District Court
for the District of Connecticut
No. 24-cv-858, Kari A. Dooley,
District Judge.

Before: LIVINGSTON, PÉREZ, and KAHN, *Circuit Judges*.

Defendant-Appellant-Cross-Appellee Pierre Kory, M.D., prescribed a drug called prednisone to treat Edward James Waters for COVID-19. It is well known that high doses of drugs like prednisone can contribute to peptic ulcer disease, especially in elderly patients like Waters. Kory failed to prescribe the medicines used to mitigate such side effects.

Waters ultimately suffered from a perforated ulcer and died due to organ failure. His estate sued Kory for negligence, a lack of informed consent in Waters's treatment, and violations of the Connecticut Unfair Trade Practices Act ("CUTPA").

At issue in this appeal is 1) whether the immunity provision of the Public Readiness and Emergency Preparedness Act (the "PREP Act") precludes the claims for negligence and lack of informed consent, and 2) whether Waters's CUTPA claims are, at their core, claims for professional negligence and thus barred under Connecticut law. We answer both questions in the affirmative, and thus, all of Waters's claims must be dismissed.

First, the negligence and lack of informed consent claims fall within the PREP Act's immunity provisions. Though this Court has not yet had the opportunity to articulate the PREP Act's causal relationship requirement, the statute's text makes clear that a wide range of claims based on the use or administration of covered countermeasures are barred. Today, we hold that there is "a causal relationship" between Kory's prescription of prednisone and Waters's death, and thus, the allegations are sufficient to trigger the PREP Act's immunity provision.

Second, the CUTPA claim is foreclosed by Connecticut law. CUTPA claims against medical professionals must be targeted at the business or entrepreneurial aspects of the professionals' practices. Waters's CUTPA claim instead seeks to recover for harms caused by Kory's alleged professional negligence.

Therefore, we **AFFIRM** the District Court's dismissal of the CUTPA claim, **REVERSE** the District Court's order denying Kory's motion to dismiss based on PREP Act immunity, and **REMAND** for further proceedings consistent with this opinion.

STEVEN M. WARSHAWSKY, The Warshawsky Law Firm, Mount Kisco, NY, *for Defendant-Appellant-Cross-Appellee.*

AUSTIN BERESCIK-JOHNS, Law Office of Austin B. Johns, LLC, Hartford, CT, *for Plaintiff-Appellee-Cross-Appellant*.

MYRNA PÉREZ, *Circuit Judge*:

Defendant-Appellant-Cross-Appellee Pierre Kory, M.D., prescribed a drug called prednisone to treat Edward James Waters for COVID-19. It is well known that high doses of drugs like prednisone can contribute to peptic ulcer disease, especially in elderly patients like Waters. Kory failed to prescribe medicine used to mitigate these side effects.

Waters ultimately suffered from a perforated ulcer and died due to organ failure. His estate sued Kory for negligence, a lack of informed consent in Waters's treatment, and violations of the Connecticut Unfair Trade Practices Act ("CUTPA").

At issue in this appeal is 1) whether the immunity provision of the Public Readiness and Emergency Preparedness Act (the "PREP Act") precludes the claims for negligence and lack of informed consent, and 2) whether Waters's CUTPA claims are, at their core, claims for professional negligence and thus barred under Connecticut law. We answer both questions in the affirmative, and thus, all of Waters's claims must be dismissed.

First, the negligence and lack of informed consent claims fall within the PREP Act's immunity provisions. Though this Court has not yet had the

opportunity to articulate the PREP Act's causal relationship requirement, the statute's text makes clear that a wide range of claims based on the use or administration of covered countermeasures are barred. Today, we hold that there is "a causal relationship" between Kory's prescription of prednisone and Waters's death, and thus, the allegations are sufficient to trigger the PREP Act's immunity provision.

Second, the CUTPA claim is foreclosed by Connecticut law. CUTPA claims against medical professionals must be targeted at the business or entrepreneurial aspects of the professionals' practices. Waters's CUTPA claim instead seeks to recover for harms caused by Kory's alleged professional negligence, and thus, we affirm the District Court's dismissal of the claim.

BACKGROUND

Edward James Waters contracted COVID-19 around November 25, 2021.[1] After testing positive for COVID-19, Waters or his family[2] contacted Defendant Pierre Kory, M.D., who initiated treatment on December 5, 2021. Kory "held himself out as a counter-culture expert regarding COVID-19 treatment" and had

[1] The facts are drawn from the operative complaint and are accepted as true for purposes of our review. *See Schiebel v. Schoharie Cent. Sch. Dist.*, 120 F.4th 1082, 1092 (2d Cir. 2024).

[2] The operative complaint does not allege precisely who contacted Kory. Instead, it merely states that "Mr. Waters or his family reached out to Dr. Kory." *See* J. App'x at 72.

a "tele-health" practice for treating patients. J. App'x at 78. All of Kory's sessions with Waters were conducted remotely.

Around the same time that he contracted COVID-19, Waters experienced a flare-up of gout and was treated with a drug called prednisone, which is a corticosteroid. Kory was aware that Waters had recently taken prednisone. Nevertheless, Kory prescribed Waters additional prednisone to treat his COVID-19 infection, along with ivermectin (an antiparasitic), spironolactone (a diuretic), and dutasteride (a 5-alpha reductase inhibitor).

Despite Kory's treatments, Waters was admitted to a hospital emergency room a week later for shortness of breath and low oxygen levels. Waters was hospitalized for four days and was treated with additional corticosteroids. Notably, he was also given a "proton pump inhibitor," J. App'x at 73, which is used to "counteract the well-known risk of developing peptic ulcer disease through a protracted course of high dose corticosteroids," J. App'x at 75.

After he was released from the hospital, Waters's condition improved. On December 18, 2021, Kory prescribed another round of prednisone, which Waters was instructed to take after the initial prescription from the hospital ran its course. In doing so, Kory did not personally review the details of Waters's hospitalization

and treatment. Nor did Kory prescribe a treatment, such as a "proton pump inhibitor," to mitigate the harmful side effects of the prednisone.

On December 29, 2021, Waters's daughter called Kory to report that Waters was experiencing worsening abdominal pain. Kory proposed reducing the amount of prednisone Waters was taking.

The next day, Waters was again taken to the emergency room due to worsening abdominal pain and abdominal distension. Doctors "immediately suspected a perforated ulcer of the stomach or duodenum" and their suspicions were confirmed through "an emergency exploratory laparotomy." J. App'x at 75. Waters died as a result of multiple organ failure, and Plaintiff-Appellee-Cross-Appellant Edward Waters, Jr. was named the Administrator of his estate.

The estate filed suit in Connecticut Superior Court, and Kory removed the case to the District of Connecticut based on diversity. In the operative Amended Complaint, the estate asserts three claims: 1) negligence, 2) lack of informed consent, and 3) a violation of CUTPA. Kory moved to dismiss the claims based on the immunity provided in the PREP Act, as well as on a theory that the Amended Complaint failed to state a viable CUTPA claim. The District Court dismissed the CUTPA claim but concluded that PREP Act immunity does not apply, and thus

denied the motion to dismiss as to the remaining claims. Kory properly noticed an interlocutory appeal regarding the denial of PREP Act immunity. Upon the parties' request, the District Court certified a partial final judgment as to the CUTPA claim pursuant to Fed. R. Civ. P. 54(b), and Waters appealed the dismissal of that claim.

DISCUSSION

I. Appellate Jurisdiction

We must first assure ourselves that we have jurisdiction to consider these appeals. *See Maye v. City of New Haven*, 89 F.4th 403, 406 (2d Cir. 2023).

Per statute, we generally have jurisdiction over "final decisions of the district courts," *see* 28 U.S.C. § 1291, which are decisions that "conclusively determine[] all pending claims of all the parties to the litigation, leaving nothing for the court to do but execute its decision," *Petrello v. White*, 533 F.3d 110, 113 (2d Cir. 2008). The District Court's order on appeal is plainly not a final decision, as it dismissed only one of three claims.

However, there are exceptions to the general rule. Two are relevant to this case: the collateral order doctrine and the District Court's ability to certify a partial final judgment pursuant to Federal Rule of Civil Procedure 54(b).

A. Collateral Order Doctrine

We hold that the denial of a motion to dismiss on PREP Act immunity grounds is an immediately appealable collateral order.

"The collateral order doctrine . . . is a judicially created exception to the final decision principle; it allows immediate appeal from orders that are collateral to the merits of the litigation and cannot be adequately reviewed after final judgment." *In re Décor Holdings, Inc.*, 86 F.4th 1021, 1026 (2d Cir. 2023) (per curiam) (quoting *Germain v. Conn. Nat'l Bank*, 930 F.2d 1038, 1039–40 (2d Cir. 1991)). "An order is final under the collateral order doctrine if it '(1) conclusively determine[s] the disputed question, (2) resolve[s] an important issue completely separate from the merits of the action, and (3) [is] effectively unreviewable on appeal from a final judgment.'" *Id.* (alterations in original) (quoting *EM Ltd. v. Banco Cent. de la República Arg.*, 800 F.3d 78, 87 (2d Cir. 2015)).

"[O]rders rejecting absolute immunity" are immediately appealable under the doctrine. *See Will v. Hallock*, 546 U.S. 345, 350 (2006). We have applied the doctrine to claims of immunities in various contexts. *See, e.g.*, *Gingras v. Think Fin., Inc.*, 922 F.3d 112, 119–20 (2d Cir. 2019) (tribal sovereign immunity); *Rogers v. Petroleo Brasileiro, S.A.*, 673 F.3d 131, 136 (2d Cir. 2012) (immunity under the

Foreign Sovereign Immunities Act); *see also Mitchell v. Forsyth*, 472 U.S. 511, 530 (1985) (qualified immunity). That is because in such cases, "the central benefits" of "avoiding the costs and general consequences of subjecting public officials to the risks of discovery and trial" would be "effectively lost if a case is erroneously permitted to go to trial." *See P.R. Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 143–44 (1993) (quoting *Mitchell*, 472 U.S. at 526).

However, not every appeal seeking review of a claimed right to avoid trial justifies application of the collateral order doctrine. *See Van Cauwenberghe v. Biard*, 486 U.S. 517, 524 (1988) ("[I]n some sense, all litigants who have a meritorious pretrial claim for dismissal can reasonably claim a right not to stand trial."). Instead, "it is not mere avoidance of a trial, but avoidance of a trial that would imperil a substantial public interest, that counts when asking whether an order is 'effectively' unreviewable if review is to be left until later." *See Will*, 546 U.S. at 353. But "[w]hen a policy is embodied in a constitutional or statutory provision entitling a party to immunity from suit (a rare form of protection), there is little room for the judiciary to gainsay its 'importance.'" *See Digit. Equip. Corp. v. Desktop Direct, Inc.*, 511 U.S. 863, 879 (1994).

We have not yet decided whether an appeal of an order refusing to apply immunity under the PREP Act is subject to the collateral order doctrine. *See Solomon v. St. Joseph Hosp.*, 62 F.4th 54, 59 (2d Cir. 2023) (stating "we need not decide whether Defendants' interlocutory appeal is proper under the collateral-order doctrine"). We do so today.[3] The District Court's denial of PREP Act immunity satisfies each of the three requirements for the collateral order doctrine.

First, the PREP Act bestows complete immunity from suit. *See* 42 U.S.C. § 247d-6d(a)(1). Thus, by denying PREP Act immunity, the District Court "purport[ed] to . . . conclusive[ly] determin[e] that [Kory] ha[s] no right not to be sued in federal court." *Cf. P.R. Aqueduct & Sewer Auth.*, 506 U.S. at 140 (concluding that denials of Eleventh Amendment immunity are appealable collateral orders).

Second, as discussed below, Kory's PREP Act immunity defense is completely separate from the merits of Waters's claim, as the immunity defense hinges on the use of a covered countermeasure. And the Supreme Court has explained the importance of an issue of immunity when such a policy "is embodied in a constitutional or statutory provision," as it is here. *See Digit. Equip.*

[3] In recognizing that a denial of PREP Act immunity is an appealable collateral order, we agree with the circuits that have decided the issue in a precedential decision. *See Dressen v. AstraZeneca AB*, 182 F.4th 1232, 1240 (10th Cir. 2026); *Hampton v. California*, 83 F.4th 754, 762 (9th Cir. 2023); *see also Goins v. Saint Elizabeth Med. Ctr.*, No. 22-6070, 2024 WL 229568, at *4–5 (6th Cir. Jan. 22, 2024) (unpublished).

Corp., 511 U.S. at 879. Thus, the merits of Waters's claims have little to do with the important issue of the application of PREP Act immunity.

Third, because the statute bestows absolute immunity from suit, the entitlement it bestows is "effectively lost" if the defendant is made to "face the . . . burdens of litigation." *See Mitchell*, 472 U.S. at 526–27; *see also Liberty Synergistics Inc. v. Microflo Ltd.*, 718 F.3d 138, 147 (2d Cir. 2013) (explaining that "we must 'examine the nature of the right asserted with special care,' . . . to determine whether an 'essential aspect of the claim' is the right to avoid the burdens of litigation" (quoting *Van Cauwenberghe*, 486 U.S. at 525)). Thus, the District Court's order is "effectively unreviewable on appeal from a final judgment." *Mitchell*, 472 U.S. at 527.

We therefore have jurisdiction over Kory's appeal of the District Court's ruling on PREP Act immunity, which pertains to Waters's negligence and lack of informed consent claims.

B. Rule 54(b)

The appeal of the dismissal of Waters's CUTPA claim is reviewable pursuant to Federal Rule of Civil Procedure 54(b). "Title 28 U.S.C. § 1291 affords federal courts 'jurisdiction to hear timely appeals from final judgments or from

partial final judgments entered pursuant to Fed. R. Civ. P. 54(b).'" *Linde v. Arab Bank, PLC*, 882 F.3d 314, 322–23 (2d Cir. 2018) (quoting *Petrello*, 533 F.3d at 113). Relevant here,

> Rule 54(b) authorizes a district court to enter partial final judgment "when three requirements have been satisfied: (1) there are multiple claims or parties, (2) at least one claim or the rights and liabilities of at least one party has been finally determined, and (3) the court makes an 'express[] determin[ation] that there is no just reason for delay'" of entry of final judgment as to fewer than all of the claims or parties involved in the action.

Id. (alterations in original) (quoting *Acumen Re Mgmt. Corp. v. Gen. Sec. Nat'l Ins. Co.*, 769 F.3d 135, 140 (2d Cir. 2014)).[4] Applied to the CUTPA claim appeal, the first two requirements are straightforwardly satisfied. The CUTPA claim is distinct from Waters's remaining two negligence claims, *see Haynes v. Yale-New Haven Hosp.*, 699 A.2d 964, 972 (Conn. 1997), and the District Court made a substantive determination that Waters's allegations are not cognizable under CUTPA and dismissed that claim.

[4] As part of the third requirement, district courts must generally "provide 'a brief, reasoned explanation'" for their decision to certify partial final judgment. *See In re Energetic Tank, Inc.*, 110 F.4th 131, 148 (2d Cir. 2024) (quoting *Scottsdale Ins. Co. v. McGrath*, 88 F.4th 369, 378 (2d Cir. 2023)). We may excuse the lack of an explanation where the reasons for Rule 54(b) judgment are obvious and a remand "would result only in unnecessary delay in the appeal process." *See id.* (quoting *Brown v. Eli Lilly & Co.*, 654 F.3d 347, 355 (2d Cir. 2011)).

We review the third requirement, a district court's determination that there is no just reason for delay, for abuse of discretion. *See Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 10 (1980). A "district court generally should not grant a Rule 54(b) certification 'if the same or closely related issues remain to be litigated.'" *Novick v. AXA Network, LLC*, 642 F.3d 304, 311 (2d Cir. 2011) (citation modified) (quoting *Harriscom Svenska AB v. Harris Corp.*, 947 F.2d 627, 629 (2d Cir. 1991)). "Certification under Rule 54(b) should be granted only where there are 'interest[s] of sound judicial administration' and efficiency to be served," *see Hogan v. Consol. Rail Corp.*, 961 F.2d 1021, 1025 (2d Cir. 1992) (citation modified) (quoting *Curtiss-Wright*, 446 U.S. at 8), or "where 'there exists some danger of hardship or injustice through delay which would be alleviated by immediate appeal,'" *see id.* (citation modified) (quoting *Cullen v. Margiotta*, 618 F.2d 226, 228 (2d Cir. 1980) (per curiam)).

Here, the District Court's certification under Rule 54(b) was appropriately within its discretion. The District Court explained that refusing to review the dismissal of the CUTPA claim now risks contravening "the policy against piecemeal appeals" given the collateral appeal of the PREP Act immunity issue; by certifying the dismissal of the CUTPA claim, the District Court ensured the

entirety of its order will be reviewed at once. *See Novick*, 642 F.3d at 310; *Hogan*, 961 F.2d at 1025 (citing the "'interest[s] of sound judicial administration' and efficiency to be served" as warranting certification (alteration in original) (quoting *Curtiss-Wright*, 446 U.S. at 8)).

Because we conclude the District Court did not abuse its discretion in certifying partial final judgment of the CUTPA claim for our review, we have jurisdiction to consider that claim as well.

II. PREP Act Immunity

"When a district court denies immunity on a Rule 12(b)(6) motion to dismiss, we review the district court's denial *de novo*, accepting as true the material facts alleged in the complaint and drawing all reasonable inferences in plaintiffs' favor." *Ogunkoya v. Monaghan*, 913 F.3d 64, 67 (2d Cir. 2019) (quoting *Warney v. Monroe County*, 587 F.3d 113, 120 (2d Cir. 2009)). On the merits, we first conclude that Waters's negligence and lack of informed consent claims are barred by the immunity provisions of the PREP Act.

Congress enacted the PREP Act "[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency" by "limit[ing] legal liability for losses relating to the administration of

medical countermeasures such as diagnostics, treatments, and vaccines." Kevin J. Hickey, Cong. Rsch. Serv., LSB10443, The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures 1 (2022).

"The PREP Act provides broad immunity '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' during a public-health emergency." *Solomon*, 62 F.4th at 58 (quoting 42 U.S.C. § 247d-6d(a)(1)).[5]

Only a "covered person" is entitled to immunity. *See* 42 U.S.C. § 247d-6d(a)(1). Most relevant to this appeal, a "covered person" is "a person or entity that is . . . a qualified person who prescribed, administered, or dispensed [a covered] countermeasure." *See id.* § 247d-6d(i)(2)(B)(iv). A "qualified person" includes "a licensed health professional or other individual who is authorized to prescribe, administer, or dispense [covered] countermeasures under the law of the

[5] Individuals whose claims in court are barred by the statute are not left without recompense; "the PREP Act establishes a Covered Countermeasure Process Fund to compensate 'eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration.'" *Solomon v. St. Joseph Hosp.*, 62 F.4th 54, 58 (2d Cir. 2023) (quoting 42 U.S.C. § 247d-6e(a)). Thus, rather than proceeding to court, those harmed by conduct covered by the PREP Act's immunity provisions may seek compensation through the established administrative fund.

State in which the countermeasure was prescribed, administered, or dispensed." *Id.* § 247d-6d(i)(8)(A).

Additionally, the covered person must use a "covered countermeasure" for immunity to apply. The statute provides the Secretary of Health and Human Services ("HHS Secretary") with authority to publish a declaration that "(1) announces a disease or health condition is a public emergency and (2) defines appropriate covered countermeasures." *Solomon*, 62 F.4th at 58 (citing 42 U.S.C. § 247d-6d(b)(1)). As relevant here, "[e]ffective February 4, 2020, the HHS Secretary declared 'COVID-19 . . . a public health emergency' and defined 'covered countermeasures' in part as any 'antiviral, drug, biologic, diagnostic, device, or vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19.'" *Id.* (quoting Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15198-01 (Mar. 17, 2020)). The declaration clarifies that covered countermeasures "must be 'qualified pandemic or epidemic products'" under the PREP Act, or "drugs, biological products, or devices authorized for investigational or emergency use" under the Federal Food Drug and Cosmetic Act and the Public Health Service Act. *See* 85 Fed. Reg. at 15202. In turn, the PREP Act defines "qualified pandemic or epidemic product" as:

> (i) a product manufactured, used, designed, developed, modified, licensed, or procured . . . (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or . . . (II) to limit the harm such pandemic or epidemic might otherwise cause; [or] . . . (ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i).

42 U.S.C. § 247d-6d(i)(7)(A).

Finally, the statute clarifies that immunity applies to

> any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

42 U.S.C. § 247d-6d(a)(2)(B).

In all, in order for immunity to apply to a given claim, the PREP Act generally requires 1) that the defendant be a "covered person," 2) that the defendant used or administered a "covered countermeasure," and 3) that the use or administration of that countermeasure had "a causal relationship" with the alleged loss.[6]

[6] "The PREP Act contains one exception to immunity for claims 'for death or serious physical injury proximately caused by willful misconduct.'" *Solomon*, 62 F.4th at 58 (quoting 42 U.S.C. § 247d-6d(d)(1)).

A. Covered Person

First, we conclude that Kory is a "covered person" under the statute because he is a "licensed health professional . . . authorized to prescribe, administer, or dispense [covered] countermeasures under the law of [Connecticut]." *See* 42 U.S.C. § 247d-6d(i)(8)(A). He therefore may be entitled to immunity.

Kory is not licensed to practice medicine in Connecticut. However, Connecticut law provides that "[a]ny physician or surgeon residing out of this state who holds a current license in good standing in another state and who is employed to come into this state to treat, operate or prescribe for any injury, deformity, ailment or disease from which the person who employed such physician, or the person on behalf of whom such physician is employed, is suffering" may do so on a temporary basis for "a period not to exceed thirty consecutive days." *See* Conn. Gen. Stat. § 20-9(b)(5).

Kory is licensed in New York and Wisconsin. *See* J. App'x at 63. Additionally, the decedent or his family enlisted his services, and he provided

---

The United States District Court for the District of Columbia has exclusive jurisdiction over claims brought pursuant to the willful misconduct exception. *See* 42 U.S.C. § 247d-6d(e)(1). In *Solomon*, we found that the PREP Act's willful misconduct cause of action does not constitute field preemption for medical malpractice claims; but contrary to Waters's arguments, that holding has no bearing on this case as there is no preemption issue at bar. *See Solomon*, 62 F.4th at 61 & n.4 ("Instead, the PREP Act principally creates an immunity scheme. And immunity has no bearing on complete preemption, which is a *jurisdictional* doctrine, not a preemption-defense doctrine.").

those services for less than thirty days. *See* J. App'x at 72–74. Under Connecticut law, Kory is a "qualified person," and, if he uses or administers a "covered countermeasure," becomes a "covered person" within the scope of the PREP Act's immunity provision. *See* 42 U.S.C. § 247d-6d(i)(2)(B)(iv), (i)(8)(A).[7]

B. Covered Countermeasure

It is indisputable that Kory used a covered countermeasure to treat the decedent. Indeed, at oral argument, Waters conceded that prednisone, which Kory prescribed to treat the decedent's COVID-19 infection, is a covered countermeasure under the PREP Act. *See* Oral Arg. at 13:50–14:07. And as discussed, the HHS Secretary defined covered countermeasures as any "drug . . . used to treat, diagnose, cure, prevent, or mitigate COVID-19." *See Solomon*, 62 F.4th at 58 (quoting 85 Fed. Reg. at 15198–01).[8]

---

[7] Even if Kory had treated the decedent for longer than thirty days, Waters concedes that a series of executive orders pertaining to the COVID-19 pandemic excused any deficiency in meeting the Connecticut medical licensure requirements. *See* Waters Br. at 34. Therefore, we need not address Waters's argument that Kory's treatment properly continued after the permitted period by virtue of the "continuing treatment doctrine" under Connecticut law. Regardless, the continuing treatment doctrine applies to extend the limitations period for bringing medical malpractice claims, *see Bednarz v. Eye Physicians of Cent. Conn., P.C.*, 947 A.2d 291, 298–99 (Conn. 2008); Waters points to no precedent applying the doctrine in the context of assessing the lawfulness of an out-of-state physician's practice in Connecticut.

[8] Notably, neither the statute nor the Secretary's declaration limits a covered countermeasure to drugs specifically designed and produced to treat a certain disease like COVID-19. Thus, it does not matter that prednisone is also used to treat other ailments; here, it was "used to treat" Waters's COVID-19 infection, and thus, constitutes a covered countermeasure.

C. A Causal Relationship

Finally, based on the face of the complaint, the relevant covered countermeasure (the prednisone) has a sufficient causal relationship with the alleged loss (the decedent's death) to trigger immunity.

Waters alleges that Kory "prescribed an unreasonably high dose of Prednisone and did so without proper consideration for gastrointestinal protection." *See* J. App'x at 75. Waters insists that Kory should have "prescribe[d] [the decedent] a gastrointestinal prophylaxis with a proton pump inhibitor or H2 blocker to counteract the well-known risk of developing peptic ulcer disease." *Id.* Kory's decision to prescribe high doses of prednisone without prophylaxis, Waters alleges, led to the decedent's death. The question is whether these allegations evidence "a causal relationship" between Kory's prescription of prednisone and the decedent's death sufficient to trigger the PREP Act's immunity provision. For the reasons explained below, they do.

1. PREP Act Immunity Does Not Require Sole Causation

First, contrary to Waters's urging, we see no basis for interpreting the PREP Act to require that a covered countermeasure be the *sole* cause of an alleged loss. Nothing in the statute's text indicates that Congress contemplated such a narrow

causal tie between the use or administration of the covered countermeasure and the loss alleged. Instead, several aspects of the statute indicate that Congress could not have had a "sole cause" requirement in mind.

The PREP Act's coverage of not only the direct *use* of a covered countermeasure, but also several further removed acts in the *administration* of that countermeasure, all but forecloses a "sole" cause requirement. *See* 42 U.S.C. § 247d-6d(a)(1); *see id.* § 247d-6d(a)(2)(B) (listing "the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use"). "[F]or example, the 'design, development,' 'manufacture,' and 'distribution' of a vaccine are multiple links removed in the chain of events from the ultimate injecting of an individual with a vaccine," yet the PREP Act includes such acts in the scope of immunity, evincing an "expansive causal relationship." *See Maney v. Brown*, 91 F.4th 1296, 1300–01 (9th Cir. 2024) (quoting 42 U.S.C. § 247d-6d(a)(2)(B)). Along the same lines, we struggle to imagine a case in which a countermeasure's labeling, packaging, or licensing can be the *sole* cause of a plaintiff's loss. By expressly indicating that events

"multiple links removed" from the ultimate loss may be covered, Congress plainly intended the statute's causation requirements to be "expansive." *See id.*

Additionally, the statute covers "either an affirmative countermeasure that addresses the public health emergency itself, or medical care to address a side effect of the affirmative countermeasure." *See Goins v. Saint Elizabeth Med. Ctr.*, No. 22-6070, 2024 WL 229568, at *5 (6th Cir. Jan. 22, 2024) (citing 42 U.S.C. § 247d-6d(i)(7)(A)(ii)). Medical care designed to address the side effects of a treatment, by definition, will never be the "sole" cause of a "loss." The initial treatment, in response to which the subsequent care is implemented, will also retain some factual causal connection to the ultimate loss. After all, the subsequent side effects treatment never would have been prescribed absent the initial treatment. Thus, reading the PREP Act to require that the covered countermeasure in question be the "sole" cause of a loss runs contrary to the statute's plain text.

Finally, the statute uses expansive language to describe the causal relationship required to trigger immunity, including claims for loss "relating to" the use or administration of a covered countermeasure. *See* 42 U.S.C. § 247d-6d(a)(1). That broad language is inconsistent with a requirement that the countermeasure be the sole cause of the alleged loss. And in specifying the scope

of the immunity provision, Congress merely required "*a* causal relationship" between the covered countermeasure and the alleged loss. 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added). Courts in a variety of contexts regularly use such language to encompass a broader range of connections than that of a "sole cause" connection. *Cf., e.g., Brown v. Parker Drilling Offshore Corp.*, 410 F.3d 166, 176 (5th Cir. 2005); *Frito-Lay, Inc. v. Loc. Union No. 137, Int'l Bhd. of Teamsters*, 623 F.2d 1354, 1362–63 (9th Cir. 1980); *Morrison v. Ayoob*, 627 F.2d 669, 671–72 (3d Cir. 1980); *Indus. Inv. Dev. Corp. v. Mitsui & Co., Ltd.*, 594 F.2d 48, 55 (5th Cir. 1979).

In summary, a "sole cause" requirement is inconsistent with Congress's intent as gleaned from the text of the PREP Act.

2. The Allegations In This Case State "A Causal Relationship"

Having ruled out a "sole cause" requirement, we need not further define the precise contours of the causal relationship required to trigger PREP Act immunity. Under any remaining possible standard, Kory is entitled to immunity.

The statute's general immunity provision provides a long list of covered connections; it states that immunity applies so long as the alleged claims for loss are "caused by, arising out of, relating to, or resulting from" the administration or use of a covered countermeasure. *See* 42 U.S.C. § 247d-6d(a)(1). The list, especially

the statute's inclusion of claims for loss merely "relating to" the use of a covered countermeasure, indicates that Congress was not particularly concerned with a tight causal relationship.[9] *See Hampton v. California*, 83 F.4th 754, 762–63 (9th Cir. 2023) (explaining that the PREP Act "[a]t the very least" requires that "the underlying use or administration of a covered countermeasure must have played s*ome role* in bringing about or contributing to the plaintiff's injury" (emphasis added)).

Here, as alleged, the prednisone directly and foreseeably caused the ulcers that perforated and led to the decedent's death. *See* J. App'x at 75; *see also* J. App'x at 90 (claiming that the prednisone prescribed by Kory "caus[ed] a large duodenal ulcer which ultimately led to Mr. Waters' untimely death" and that such ulcers are a "well-known" side effect).[10] Thus, Kory's use of a covered countermeasure played more than "some role" in Waters's death; the prednisone was a factual and proximate cause. *See Hampton*, 83 F.4th at 762–63. We have no trouble concluding

[9] Despite the evident broad scope of the statute, we agree with the Ninth Circuit that the statute's inclusion of "relating to" must be read in its context, and that the statute requires at least *some* causal link. *See Hampton*, 83 F.4th at 764 ("It is not enough that some countermeasure's use could be described as relating to the events underpinning the claim in some broad sense.").

[10] Allegations of causation need not be as direct and foreseeable as those here to confer immunity. Again, Congress cast a wide net with the language of the PREP Act, and this case does not present reason to ascertain the minimum relationship required to trigger immunity.

that such allegations more than trigger the PREP Act's immunity provision, and therefore, Kory is entitled to immunity.[11]

III. CUTPA

The District Court appropriately dismissed Waters's CUTPA claim on the merits, and we review the dismissal de novo. *See Elias v. Rolling Stone LLC*, 872 F.3d 97, 104 (2d Cir. 2017).

CUTPA provides that "[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a). Connecticut courts look to the following factors to determine if a trade practice is unfair: "(1) whether the

---

[11] Kory's failure to prescribe a prophylaxis does not change our conclusion.

The District Court's decision to deny immunity hinged on the distinction between the prednisone prescription and Waters's focus on Kory's failure to prescribe a mitigating prophylaxis. It reasoned that "Dr. Kory's alleged failure to mitigate against the harmful effects of high doses of corticosteroids is sufficiently alleged to be a 'distinct and independent cause' of Mr. Waters' death, even though the corticosteroids were prescribed to treat COVID-19." *See Waters v. Kory*, No. 3:24-CV-00858, 2025 WL 20556, at *5 (D. Conn. Jan. 2, 2025) (quoting *Mills v. Hartford Healthcare Corp.*, 298 A.3d 605, 634 (Conn. 2023)). But Kory's administration of a covered countermeasure "in and of itself, dictate[d]" whether Kory also needed to prescribe a prophylaxis. *See id.* at *4 (quoting *Mills*, 298 A.3d at 632). The failure to prescribe prophylaxis, therefore, cannot be described as distinct and independent of the covered countermeasure: prednisone. We therefore do not need to decide whether a complaint's focus on a distinct and independent cause of the alleged loss matters for purposes of PREP Act immunity.

Moreover, Kory's failure to prescribe a prophylaxis does not mean this case is premised on the *failure* to use or administer a covered countermeasure. Several circuits have agreed that where a plaintiff alleges loss caused by a failure to use or administer a covered countermeasure (like the failure to administer a vaccine or implement masking requirements), the claims are not barred by the PREP Act. *See Schleider v. GVDB Operations, LLC*, 121 F.4th 149, 163 (11th Cir. 2024) (citing cases). But here, unlike in those cases, Waters alleges that the loss is, in fact, causally connected to the affirmative use or administration of a covered countermeasure: prednisone.

practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or other[wise] . . . ; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers . . . ." *See Ulbrich v. Groth*, 78 A.3d 76, 100 (Conn. 2013) (citation modified).

"Medical malpractice claims recast as CUTPA claims cannot form the basis for a CUTPA violation. To hold otherwise would transform every claim for medical malpractice into a CUTPA claim." *Haynes*, 699 A.2d at 974. "[T]he touchstone for a legally sufficient CUTPA claim against a health care provider is an allegation that an entrepreneurial or business aspect of the provision of services aside from medical competence is implicated, aside from medical malpractice based on the adequacy of staffing, training, equipment or support personnel." *Id.*

Here, the CUTPA claim is premised entirely on Kory's medical treatment of the decedent. The sole allegations relating to the entrepreneurial or business aspect of Kory's medical practice explain that Kory was overly focused on growing his brand and business, and that "he could not devote adequate time to providing patients such as the plaintiff with proper medical care." *See* J. App'x at 78. We agree with the District Court that such allegations look nothing like the cases in

which Connecticut courts have recognized viable CUTPA claims against medical professionals. *See Waters*, 2025 WL 20556, at *7 (citing cases). Instead, where claims are premised on the notion that a component of the defendant's business or entrepreneurial efforts weighed on the care that defendant was able to provide to the plaintiff, Connecticut courts have generally concluded that such claims are barred as recast medical malpractice claims. *See, e.g.*, *Hayes*, 699 A.2d at 974–75; *Janusauskas v. Fichman*, 826 A.2d 1066, 1076–77 & n.13 (Conn. 2003); *Est. of Doe v. Pegasus Mgmt. Co.*, No. CV030082729, 2004 WL 944767, at *1–2 (Conn. Super. Ct. Apr. 14, 2004) (granting motion to strike as insufficient an allegation that nursing home management company violated CUTPA because it was motivated by profit to admit new residents to the detriment of the safety of current residents). Therefore, the district court was correct to dismiss Waters's CUTPA claim under Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

CONCLUSION

We hold that 1) we have appellate jurisdiction over both parties' appeals, 2) Kory is entitled to PREP Act immunity in relation to Waters's negligence and lack of informed consent claims, and 3) Waters's CUTPA claim is an improper attempt at recasting a medical malpractice claim. For the foregoing reasons, the District

Court's dismissal of the CUTPA claim is **AFFIRMED**, the denial of Kory's motion to dismiss on the basis of PREP Act immunity is **REVERSED**, and we **REMAND** for further proceedings.