Nos. 125,151
125,268

IN THE COURT OF APPEALS OF THE STATE OF KANSAS

M.T. and M.T., as next friend of her minor daughter, M.K.,
Plaintiffs-Appellees,

v.

WALMART STORES, INC., et al.,
Defendants-Appellants.

M.T. and M.T., as next friend of her minor daughter, M.K.,
Plaintiffs-Appellants,

v.

WALMART, INC., and MARK SCHUKAR,
Defendants-Appellees.

SYLLABUS BY THE COURT

1.

The Public Readiness and Emergency Preparedness (PREP) Act immunizes "covered persons" from liability for any claim for loss that has a causal relationship with the administration of a "covered countermeasure." 42 U.S.C. § 247d-6d(a), (d) (Supp. 2020).

2.

Failure to obtain parental consent by a covered person before administering the Pfizer COVID-19 vaccine to a minor has a causal relationship with the administration of the vaccine and is thus covered under the PREP Act.

Appeal from Johnson District Court; JAMES F. VANO, judge. Opinion filed April 28, 2023. Affirmed in part, reversed in part, and remanded with directions.

Linus L. Baker, of Stilwell, for plaintiffs-appellees and plaintiffs-appellants.

Samuel E. Hofmeier and *Grace E. Colato Martinez*, of Bryan Cave Leighton Paisner LLP, of Kansas City, Missouri; *Barbara A. Smith*, pro hac vice, and *Samual A. Garner*, pro hac vice, of Bryan Cave Leighton Paisner LLP, of St. Louis, Missouri; and *D'Lesli M. Davis*, pro hac vice, of Norton Rose Fulbright US LLP, of Dallas, Texas, for defendants-appellants and defendants-appellees.

Zach Chaffee-McClure, of Shook, Hardy, & Bacon L.L.P., of Kansas City, Missouri, and *Cary Silverman*, of the same firm, of Washington, D.C., for *amicus curiae* The Chamber of Commerce of the United States of America.

Before CLINE, P.J., ISHERWOOD, J., and PATRICK D. MCANANY, S.J.

CLINE, J.: This case tests the scope of immunity provided by the Public Readiness and Emergency Preparedness (PREP) Act, a federal statute that protects those who administer pandemic countermeasures from liability. 42 U.S.C. § 247d-6d (Supp. 2020). Other than providing a federal cause of action "for death or serious physical injury proximately caused by willful misconduct," the Act immunizes "covered persons" from liability for any claim for loss that has a causal relationship with the administration of a "covered countermeasure." 42 U.S.C. § 247d-6d(a), (d).

M.T. (Mother) sued Walmart Stores, Inc., and one of its pharmacists, Mark Schukar, after Schukar administered a Pfizer COVID-19 vaccine to her minor child, M.K., without parental consent. The district court dismissed most of Mother's claims after finding they were barred by the PREP Act. But it did not dismiss Mother's claims based on defendants' failure to obtain parental consent before administering the vaccine.

We find the district court erred in not dismissing all Mother's claims. The PREP Act immunizes "covered persons" such as Walmart and Schukar from "all claims for loss caused by, arising out of, relating to, or resulting from the administration to [M.K.] of a covered countermeasure," such as the COVID-19 vaccine. 42 U.S.C. § 247d-6d(a)(1). Mother's claims for vaccination without parental consent arise out of or relate to defendants' administration of the Pfizer vaccine to M.K. and thus fall within the broad scope of PREP Act immunity. We therefore affirm the district court's dismissal of most of Mother's claims and reverse its denial of defendants' motion to dismiss as to the rest of the claims.

MOTHER'S LAWSUIT

In the fall of 2021, 15-year-old M.K. visited a Walmart pharmacy seeking to be vaccinated for COVID-19 without parental consent. She came with her 21-year-old brother-in-law. Mother claimed Schukar, whom she described in her lawsuit as an "employee pharmacist of Walmart," "injected M.K. with a substance labeled a Pfizer covid vaccine . . . according to a vaccination record provided" to M.K.

Mother alleged a Walmart employee told M.K. she could receive the vaccine without parental consent because she was 15 years old. This advice was incorrect because Kansas law requires parental consent for medical treatment or procedures if the minor is under the age of 16. See K.S.A. 38-123b.

Mother asserted claims for: (1) invasion of the right of privacy, by intruding on the private relationship between Mother and her child and violating Mother's parental right of control; (2) battery against Schukar; (3) negligence against Schukar, based on his failure to secure consent, warn of the vaccine's risks, and inform of acceptable alternative treatments, among other alleged failures; (4) negligence against Walmart based on vicarious liability and the failure to train employees and institute proper policies; (5)

consumer protection violations, based on defendants' deceptive practices about consent and the experimental nature of the vaccine; and (6) punitive damages. She sought compensatory damages for unspecified physical injuries allegedly suffered by M.K., including an increased risk of developing adverse physical conditions, as well as physical pain, mental anguish, emotional distress, anxiety, loss of sleep, future inconvenience, and loss of enjoyment. Mother also sought to recover for her own mental distress and anguish, anxiety, loss of sleep, future inconvenience, and loss of enjoyment, and injuries to her intimate association with her daughter, her parental right of control, and her overall relationship with her daughter.

DEFENDANTS' MOTIONS TO DISMISS

While this case has a convoluted procedural history, the pertinent decision on appeal is the district court's disposition of defendants' essentially identical motions to dismiss Mother's petition. In those motions, Walmart and Schukar contended they were immune from liability under the PREP Act since all Mother's claims were causally related to their administration of the vaccine to M.K.

The district court agreed with defendants for the most part. It found the PREP Act barred all Mother's "claims for loss causally related to the covered countermeasure and its actual introduction by injection into" M.K.'s body, which included Mother's battery claim and "any claimed losses or damages . . . causally related to the Pfizer COVID-19 vaccination, *e.g.*, sickness, anxiety . . . ." It dismissed those claims as well as the claims based on "allegations of misleading or deception as to the efficacy of the vaccine and its approval status."

But the district court then pointed out the PREP Act "does not cover failing to do something or losses that are unrelated or not causally connected to a covered countermeasure." It determined Mother's claims involving "interference with parental

rights, deception as to parental consent needed, and professional negligence in failing to obtain informed consent" fell within this category and, as such, were not barred by the Act.

The district court went beyond the parties' arguments in supporting its decision to deny defendants' motions in part. It noted that parenting is a fundamental constitutional right and issues of consent and the age of majority are traditionally state law issues. It determined the PREP Act could not interfere with or preempt parental rights or state laws over minority or parental consent since the Act did not express a specific intention to do so. It thus denied the motions to dismiss "as to any claims based upon the age of consent under Kansas law or the fundamental rights of the parent with regard to the care and upbringing of her child."

The district court certified its decision as final under K.S.A. 2021 Supp. 60-254(b) as to the portion of Mother's claims that it dismissed. It also certified two questions for interlocutory appeal under K.S.A. 2021 Supp. 60-2102(c):

> (1) "Is the [PREP Act] and its immunity provision completely preemptive of all state law causes of action, regardless of the theory, so long as there is any connection or involvement whatsoever with a covered countermeasure?"; and
> (2) "Does the [PREP Act] give covered persons absolute immunity to violate Kansas parental consent or age of medical consent for minors law?"

Both parties timely appeal from this order, but through different procedural vehicles. Mother directly appealed the portion of the district court's decision that it certified as final. Defendants, meanwhile, filed an application for interlocutory appeal on the certified questions, which this court granted.

While Mother's direct appeal (case No. 125,268) was docketed separately from defendants' interlocutory appeal (case No. 125,151), we have consolidated these appeals

for purposes of this decision since we find the relevant facts, issues, and legal standards are identical in both cases. See Supreme Court Rule 2.06 (2023 Kan. S. Ct. R. at 19).

ANALYSIS

In her direct appeal, Mother argues the district court erred in granting the motions to dismiss in part. She contends the allegations in her petition did not provide sufficient basis for the court to find the PREP Act applied and, even if they did, her claims fell outside the scope of its immunity provision.

Defendants, in their interlocutory appeal, argue the district court erred in denying the motions to dismiss in part. They contend the PREP Act applies to all Mother's claims, including those based on the failure to secure parental consent, as they are all causally related to the administration of a vaccine.

In short, Mother seeks to have all her claims reinstated while defendants seek to have all her claims dismissed.

I. *Did the district court err in granting defendants' motions to dismiss in part?*

Our first task is to determine whether the district court properly dismissed some of Mother's claims. In doing so, we owe no deference to the district court's analysis of these claims or the PREP Act since a district court's decision on a motion to dismiss and its statutory analysis are subject to de novo review. *Lozano v. Alvarez*, 306 Kan. 421, 423, 394 P.3d 862 (2017). We apply this standard of review because we are in the same position as the district court when reviewing both the pleadings and the statute.

Just like the district court, we review the allegations of Mother's petition to determine whether she has stated a legal claim—based both on her theory of relief or any

possible theory. We must accept all alleged facts as true, along with any inferences that can reasonably be drawn from those facts. *Cohen v. Battaglia*, 296 Kan. 542, 545-46, 293 P.3d 752 (2013). But we need not accept as true any conclusory allegations on the legal effects of events Mother has set out if these allegations do not reasonably follow from the description of what happened, or if these allegations are contradicted by the description itself. *312 Education Assn. v. U.S.D. No. 312*, 273 Kan. 875, 881, 47 P.3d 383 (2002).

Our analysis of Mother's claims necessarily involves interpretation of the PREP Act. To that end, we adhere to the key rule of statutory interpretation: The Legislature's intent controls. This means we examine the statute's text and apply plain and unambiguous language as written. We must consider the entire act, reconciling different provisions to make them consistent, harmonious, and sensible, and we cannot consider provisions in isolation. *In re Tax Protest of Ann W. Smith Trust*, 272 Kan. 1396, 1404, 39 P.3d 66 (2002).

A. *The PREP Act*

The PREP Act was enacted on December 30, 2005. It authorizes the Secretary of Health and Human Services—in response to a public health emergency—to issue declarations recommending the manufacture, testing, development, distribution, administration, or use of "covered countermeasures." 42 U.S.C. § 247d-6d(b)(1). "Covered countermeasures" include, among other things, vaccines authorized for emergency use to combat a public health emergency. See 42 U.S.C. § 247d-6d(i)(1)(C).

When the Secretary has issued such a declaration, the PREP Act grants "covered persons" 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 . . . ." 42 U.S.C. § 247d-6d(a)(1). This immunity applies only if the countermeasure is used or administered: (1)

during the effective period of the declaration; (2) for the category of diseases specified in the declaration; and (3) to an individual in the population and geographic area specified by the declaration. 42 U.S.C. § 247d-6d(a)(3).

The immunity granted under the PREP Act is broad and 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).

The Act defines "'loss'" as "any type of loss, including—(i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss." 42 U.S.C. § 247d-6d(a)(2)(A).

The preemption clause is similarly sweeping, stating that during the effective period of a declaration of a public health emergency:

> "[N]o State . . . may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> "(A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> "(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered

countermeasure under this section or any other provision of this chapter . . . ." 42 U.S.C. § 247d-6d(b)(8).

This language includes tort claims. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008) ("[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties"); *Jenkins v. Amchem Products, Inc.*, 256 Kan. 602, 616-17, 886 P.2d 869 (1994).

The sole exception to this immunity is a federal action for death or serious physical injury caused by willful misconduct. 42 U.S.C. § 247d-6d(d)(1). Any such claim must be brought exclusively in the United States District Court for the District of Columbia. 42 U.S.C. § 247d-6d(e)(1). This exception does not apply to negligent or reckless conduct resulting in loss. 42 U.S.C. § 247d-6d(c)(1)(B).

Alongside the PREP Act's grant of immunity, Congress established an alternative administrative process for redressing the harm caused by covered countermeasures—the Covered Countermeasure Process Fund. See 42 U.S.C. § 247d-6e (2018). This fund provides compensation to "eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to [a declared public health emergency] . . . ." 42 U.S.C. § 247d-6e(a). The fund furnishes monetary damages, including unreimbursed medical expenses, lost-employment income, and survivor death benefits to eligible individuals. 42 U.S.C. § 247d-6e.

In early 2020, the Secretary issued a declaration determining that COVID-19 was a public health emergency and activating the PREP Act's liability immunity for activities related to medical countermeasures against COVID-19. This declaration identified the covered countermeasures for which liability immunity is in effect as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19" that also meets the definition of "covered

countermeasure" provided in the Act. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15202 (March 17, 2020).

B. *Does the PREP Act apply to this situation?*

Mother contends her petition does not allege enough facts from which the district court could determine the PREP Act applies. *Crosby v. ESIS Insurance*, No. 121,626, 2020 WL 6372266, at *2 (Kan. App. 2020) (unpublished opinion) ("When presented with a motion to dismiss, a district court's consideration is generally limited to the petition itself."). She claims her allegations do not establish the substance injected into M.K. qualifies as a covered countermeasure nor do they establish that Walmart and Schukar qualify as covered persons.

1. *Whether the substance injected was a covered countermeasure*

A "covered countermeasure" is defined under the PREP Act as: (1) a qualified pandemic or epidemic product; (2) a security countermeasure; (3) a drug, biological product, or device that is authorized for emergency use; or (4) a qualifying respiratory device. 42 U.S.C. § 247d-6d(i)(1). The term "biological product" includes vaccines. 42 U.S.C. § 262(i)(1) (2018).

Along with the declaration of COVID-19 as a public health emergency, the Secretary has declared any vaccine manufactured, used, designed, developed, modified, licensed, or procured to mitigate, prevent, or treat COVID-19 which also meets the statutory definition in 42 U.S.C. § 247d-6d(i)(1) to be a covered a countermeasure. Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of

the Declaration, 85 Fed. Reg. 79190, 79196 (December 9, 2020) (clarifying definition given in original declaration).

In finding that the substance injected into M.K. qualified as a covered countermeasure, the district court took judicial notice of declarations by the Department of Health and Human Services Secretary which proclaimed the Pfizer vaccine a covered countermeasure under the PREP Act and noted Mother alleged her child received the Pfizer vaccine after the declarations were issued.

a. *Mother alleged M.K. was injected with the Pfizer COVID-19 vaccine.*

Mother argues the district court misconstrued the petition as alleging that M.K. was injected with the Pfizer COVID-19 vaccine. She claims her petition only alleges the substance injected was *labeled* as the Pfizer COVID-19 vaccine and she directly disputed whether the Pfizer COVID-19 vaccine was actually a vaccine.

To begin, we agree with the district court that Mother's claims about the efficacy of the vaccine are beside the point. Application of the PREP Act does not turn on the effectiveness of the countermeasure. Next, while Mother alleged the Pfizer vaccine is not actually a "vaccine," she did not allege that M.K. was injected with anything but the Pfizer COVID-19 vaccine. And her opposition to the motions to dismiss depended solely on her contention that her petition alleged claims of inaction, which are outside the scope of the Act. She did not argue the Act did not apply because there was a question about what substance was injected into her child.

Mother does not explain why we can or should consider her claim for the first time on appeal. Thus, we find she has waived it. *State v. Williams*, 298 Kan. 1075, 1085, 319 P.3d 528 (2014).

That said, even if we considered Mother's argument for the first time on appeal, it is unsupported by the record: Mother's petition does not claim the substance administered to M.K. was anything but a COVID-19 vaccine and, in particular, the Pfizer COVID-19 vaccine. Mother alleged that M.K. went to the Walmart pharmacy to receive a COVID-19 vaccine, she was injected with a substance labeled a Pfizer COVID-19 vaccine, and she claimed losses specifically from injection of the Pfizer COVID-19 vaccine. For example:

- She alleged Schukar "injected M.K. with [a] substance labeled a Pfizer covid vaccine . . . according to a vaccination record provided to [M.K.]."

- She claimed M.K.'s ability to develop long lasting natural immunities to COVID-19 is permanently diminished and that she faces a higher risk of developing myocarditis or pericarditis as a result of receiving a COVID-19 vaccine.

- Both her negligence and consumer protection claims are based in part on her allegation that Schukar failed to disclose dangers associated with Covid vaccines and her consumer protection claim is also partly based on her allegations that defendants did not inform M.K. that the Pfizer COVID-19 vaccine M.K. received was not fully licensed but only authorized for emergency use and that the "Pfizer FF2589 is experimental and not FDA approved."

- She alleged M.K. was "damaged by the vaccine injection," and she claimed various supposed harms associated with COVID-19 vaccines generally and the Pfizer vaccine in particular.

We find these alleged facts—which we accept as true—and the inferences that can reasonably be drawn from these facts support the district court's finding that the substance injected into M.K. was the Pfizer COVID-19 vaccine.

b. *The Pfizer COVID-19 vaccine is a covered countermeasure.*

Mother also claims one cannot determine from the allegations in her petition whether the Pfizer vaccine qualifies as a covered countermeasure. Again, she did not raise this issue below nor does she explain why we can or should consider it now. Thus, we would be within our discretion to decline to consider it for the first time on appeal. Yet because there is clear legal authority contrary to Mother's position, we will instead rely on that authority to dispatch Mother's claim.

Mother's primary complaint on this issue appears to be the district court's reliance on the declarations issued by the Secretary and FDA declaring the Pfizer COVID-19 vaccine "as a vaccination contemplated under" the PREP Act when finding it is a covered countermeasure. But both Kansas and federal caselaw allow a district court to take judicial notice of matters outside the pleading in ruling on a motion to dismiss when those matters are proper objects for judicial notice. *Rodina v. Castaneda*, 60 Kan. App. 2d 384, 387, 494 P.3d 172, *rev. denied* 314 Kan. 855 (2021); see also *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018) (courts may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment). And a district court may take judicial notice of federal administrative regulations. *Fasse v. Lower Heating and Air Conditioning, Inc.*, 241 Kan. 387, 394, 736 P.2d 930 (1987); see also K.S.A. 60-409(b) (courts may take judicial notice of specific facts "capable of immediate and accurate determination by resort to easily accessible sources of indisputable accuracy"). As a result, the district court committed no error in taking judicial notice of these declarations.

Next, Mother argues the allegations in her petition do not establish whether the substance injected was administered to mitigate, prevent, or treat the ongoing pandemic, as is necessary to meet the definition of a covered countermeasure under the declarations issued by the Secretary. On this point, we agree with defendants that, as a matter of

common sense, the Pfizer COVID-19 vaccine qualifies as a vaccine developed and used to mitigate, prevent, or treat COVID-19.

The facts alleged in Mother's petition, combined with the declarations which the district court properly relied, are sufficient to reasonably infer that the substance injected into M.K. was a vaccine, authorized for emergency use by the FDA, developed and used to mitigate or prevent COVID-19. 42 U.S.C. § 247d-6d(i)(1); Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190, 79196 (December 9, 2020); *U.S.D. No. 312*, 273 Kan. at 881 (In ruling on a motion to dismiss, a court must accept the plaintiff's factual description, along with any inferences reasonably to be drawn from those facts, as true.).

Finally, Mother notes that nothing in her petition establishes where or how Walmart obtained the injected substance, analogizing her case to *Avicolli v. BJ's Wholesale Club, Inc.*, No. 21-1119, 2021 WL 1293397, at *4 (D. Pa. 2021) (unpublished opinion) (PREP Act's applicability at motion to dismiss stage could not be decided where plaintiffs did not allege, and defendant did not provide a basis for court to infer, that defendant obtained hand sanitizer at issue through one of the two means of distribution specified by the Secretary, i.e., under agreement with the federal government or in response to the COVID-19 pandemic). Mother argues that "nothing in the petition states that Walmart obtained the injection substance through one of the two means of distribution specified by the Secretary of Health and Human Services."

Again, we agree with defendants that Mother's argument is off base because she references an earlier set of requirements enacted at the outset of the pandemic that applied to countermeasures other than vaccines. See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15200 (March 17, 2020) (setting out limitations on

distribution). As defendants point out, these requirements have now been loosened. See Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190, 79196 (amending limitations on distribution to include countermeasures authorized by the FDA to prevent COVID-19).

Additionally, unlike in *Avicolli*, there is no evidence the countermeasure here was sold commercially before the pandemic. In *Avicolli*, which involved product liability claims based on tainted hand sanitizer, the plaintiffs purchased the hand sanitizer at issue from a retail store in May 2020, shortly after the Secretary's declaration of COVID-19 as a public health emergency. Because the plaintiff's allegations could be plausibly read to infer that the defendant retailer obtained and sold hand sanitizer before the onset of the COVID-19 pandemic, the court could not determine that the hand sanitizer sold to the plaintiffs qualified as a covered countermeasure at the motion to dismiss stage. *Avicolli*, 2021 WL 1293397, at *4. We cannot plausibly read Mother's petition the same way.

2. *Whether Walmart and Schukar qualify as covered persons*

Mother also argues the allegations in her petition are insufficient to establish that Walmart and Schukar qualify as covered persons under the PREP Act. Essentially, she contends that because she did not specifically allege defendants were covered persons, the district court could not find that they were. Additionally, while she does not specifically address Walmart's status, she also points out that she never alleged Schukar was a "licensed health professional," a term used to define one type of covered person.

The PREP Act defines "covered person" in relevant part as a person or entity that is a distributor of a covered countermeasure, a qualified person who administered a covered countermeasure, or an employee or agent of a distributor or qualified person. 42 U.S.C. § 247d-6d(i)(2). The term "distributor" is defined as including retail pharmacies.

42 U.S.C. § 247d-6d(i)(3). The term "qualified person," in turn, is defined to include licensed health care professionals or other individuals who are authorized to prescribe, administer, or dispense a covered countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed. 42 U.S.C. § 247d-6d(i)(8).

Again, Mother did not dispute whether Walmart or Schukar qualify as "covered persons" under the Act in her opposition to the motions to dismiss—she only argued that her claims fell outside the scope of the Act because they were claims of inaction. Since she does not explain why we can or should consider her argument disputing their status as "covered persons" under the Act for the first time on appeal, we find she has waived it. *State v. Williams*, 298 Kan. 1075, 1085, 319 P.3d 528 (2014).

While we do not address the substance of Mother's arguments, we pause to clarify that the motion to dismiss standard does not require a plaintiff to specifically plead that a defendant is a covered person under the PREP Act. Instead, it only requires a plaintiff to allege sufficient facts to show the defendants meet the Act's definition of the term. Thus, if Mother had preserved her claim by raising it in the district court, then that court would be required to determine whether Mother's petition alleged sufficient facts to establish defendants are both covered persons, not whether Mother's petition specifically alleged that defendants were covered persons under the Act.

As a result, under the circumstances presented we find the PREP Act applies to the situation described in the petition.

C. *Are Mother's battery, negligence, and consumer protection claims outside the scope of the PREP Act?*

Mother next argues that, even if the substance injected into M.K. was a covered countermeasure and Walmart and Schukar are covered persons, the PREP Act does not apply to her battery, negligence, and consumer protection claims, as these claims fall outside the scope of the Act's immunity provisions.

1. *Mother's negligence and consumer protection claims*

The district court dismissed Mother's negligence and consumer protection claims to the extent that they were based on her allegations that information or data was not provided about the safety or efficacy of the Pfizer vaccine, including her allegations that M.K. was deceived into engaging in "'a medical experiment.'" Mother contends the court erred because she characterizes these claims as "claims of inaction." She contends courts across the country have ruled such claims are outside the scope of the PREP Act. In the alternative, she argues her negligence claims are not covered because several courts have found the Act's federal cause of action for willful misconduct was not intended to displace state law claims for negligence and recklessness. We find her arguments without merit because she miscasts her claims and mischaracterizes the holdings of the cases she cites.

a. *The "claims of inaction" Mother references are claims for a failure to administer a covered countermeasure, not for improper administration of the covered countermeasure like Mother alleges occurred here.*

Mother cites a plethora of federal district court cases to support her contention that the PREP Act does not apply to "claims of inaction." See *Khalek v. South Denver Rehab., LLC*, 543 F. Supp. 3d 1019, 1027-28 (D. Colo. 2021); *Gwilt v. Harvard Square Ret. & Assisted Living*, 537 F. Supp. 3d 1231, 1240 (D. Colo. 2021); *Mackey v. Tower Hill*

Rehab., LLC, 569 F. Supp. 3d 740, 745-47 (N.D. Ill. 2021); *Robertson v. Big Blue Healthcare, Inc.*, 523 F. Supp. 3d 1271, 1282-83 (D. Kan. 2021); *Anson v. HCP Prairie Village KS OPCO LLC*, 523 F. Supp. 3d 1288, 1293-1302 (D. Kan. 2021); *Brown v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1196, 1201-08 (D. Kan. 2020); *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184, 1192-95 (D. Kan. 2020); *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 531-33 (D.N.J. 2020), *aff'd sub nom. Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021); *Leroy v. Hume*, 554 F. Supp. 3d 470, 476-80 (E.D.N.Y. 2021); *Estate of McCalebb v. AG Lynwood, LLC*, No. 2:20-CV-09746-SB-PVC, 2021 WL 911951, at *5-6 (C.D. Cal. 2021) (unpublished opinion), *appeal filed* March 31, 2021; *Baskin v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2267-HLT-JPO, 2020 WL 4815074, at *3-8 (D. Kan. 2020) (unpublished opinion); *Rodina v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2319-HLT-JPO, 2020 WL 4815102, at *2-8 (D. Kan. 2020) (unpublished opinion); *Parker through Parker v. St. Jude Operating Co., LLC*, No. 3:20-CV-01325-HZ, 2020 WL 8362407, at *5 (D. Or. 2020) (unpublished opinion); *Estate of Jones v. St. Jude Operating Co., LLC*, No. 3:20-CV-01088-SB, 2020 WL 8361924, at *4-10 (D. Or. 2020) (unpublished opinion); *Sherod v. Comprehensive Healthcare Mgmt. Services, LLC*, No. 20CV1198, 2020 WL 6140474, at *7-8 (W.D. Pa. 2020) (unpublished opinion); *Lollie v. Colonnades Health Care Ctr. Ltd. Co.*, No. CV H-21-1812, 2021 WL 4155805, at *3-5 (S.D. Tex. 2021) (unpublished opinion); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, No. 21-CV-387-SCD, 2021 WL 3056275, at *4-5 (E.D. Wis. 2021) (unpublished opinion).

But these cases do not hold that the PREP Act does not apply to claims based on failures to act, as Mother alleges. Rather, the district court in each case found that while the Act applies to claims causally related to the administration or use of covered countermeasures, it does not apply to claims based on the failure to administer or use covered countermeasures.

For instance, in *Mackey*, the plaintiff—the executor of the estate of a nursing home resident who died from COVID-19—filed suit in state court against the nursing home, alleging the resident's death resulted from the nursing home's negligence in preventing and responding to the spread of COVID-19 in the facility. The claims included the nursing home's alleged failure to provide its staff with personal protective equipment and its failure to test the resident for COVID-19 after she got sick. The nursing home then removed the case to federal district court; *Mackey* addressed the plaintiff's motion to remand to state court for lack of jurisdiction. The nursing home argued the PREP Act was a complete preemption statute, providing federal question jurisdiction over the claims.

The court determined remand was required without reaching the question of complete preemption, however, because it found the PREP Act did not apply to the conduct alleged in the plaintiff's complaint. *Mackey*, 569 F. Supp. 3d at 745-46. As the court explained, "although the PREP Act may apply to misfeasance, meaning the improper administration or use of covered countermeasures, it does not directly provide a defense to a claim of nonfeasance, or the failure to use such countermeasures." 569 F. Supp. 3d at 746.

Negligence claims—including those of action and those of omission—are covered by the PREP Act when they are causally related to the administration or use of a covered countermeasure. 42 U.S.C. § 247d-6d(a)(2)(B). The Act did not apply to the plaintiffs' claims in the cases cited by Mother because those claims were not causally related to the administration or use of covered countermeasures—they were causally related to the failure to administer or use covered countermeasures.

Unlike the plaintiffs in *Mackey* and the other cases Mother cites, Mother's claims are not based on defendants' failure to administer a covered countermeasure. Instead, they

all relate to defendants' alleged improper administration of a covered countermeasure. Thus none of these cases support Mother's claim of error.

Mother also argues on appeal that her claims of withholding or misrepresenting information are not covered under the PREP Act because neither action meets the definition of "administration" of a covered countermeasure. She notes that although the Act does not define "administration," the Secretary has defined it through declaration as the "physical provision of the countermeasures to recipients." Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15200 (March 17, 2020) (defining "administration of a covered countermeasure" as "physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures"). Mother contends withholding or misrepresenting information does not constitute the physical provision of anything, nor was M.K. a "recipient."

To begin, Mother did not present these arguments to the district court and does not identify why an exception to the preservation rule applies here. Accordingly, we would be justified in refusing to consider them. But we instead deny these claims on the merits as nonsensical. Mother's claims for withholding or misrepresenting information are properly characterized as claims for the alleged improper administration of a covered countermeasure. That is, they relate to how that covered countermeasure was administered and are thus covered under the Act.

b. *Mother's preemption argument is misplaced.*

Mother also contends her negligence claim is outside the scope of the PREP Act because federal courts have held the Act's federal cause of action for willful misconduct was not intended to displace state law claims for negligence and recklessness. See *Martin v. Petersen Health Operations, LLC*, 37 F.4th 1210, 1213-14 (7th Cir. 2022); *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 586-87 (5th Cir. 2022); *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 688 (9th Cir.), *cert. denied* 143 S. Ct. 444 (2022); *Estate of Maglioli*, 16 F.4th at 410.

While Mother correctly recites the propositions from the cases she cites, those propositions are inapplicable here. First, in each of those cases, the courts were not analyzing whether the PREP Act's immunity provisions applied to negligence claims, but whether federal jurisdiction existed and thus whether removal of the suit to federal court was appropriate. Those removing defendants argued the Act "completely preempted" those plaintiffs' state law causes of action, meaning the claims were governed by federal and not state law.

Complete preemption occurs when a federal law is found to create an "exclusive cause of action" because it "'set[s] forth procedures and remedies governing that cause of action,' such that it 'wholly displaces the state-law cause of action.'" *Martin*, 37 F.4th at 1213 (quoting *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8, 123 S. Ct. 2058, 156 L. Ed. 2d 1 [2003]). In other words, the "federal law displaces all possible liability under state law so that any legal claim necessarily rests on federal law." 37 F.4th at 1213.

In the cases cited by Mother, the federal courts found they did not have jurisdiction because the PREP Act did not completely preempt state law. They noted (1) the Act's immunity provision only created a defense to liability under state law and not a federal claim, and (2) while the Act created a new federal claim, this claim only covered

a subset of potential wrongs and did not preempt any other kind of claim. 37 F.4th at 1213; *Mitchell*, 28 F.4th at 586-87; *Saldana*, 27 F.4th at 688; *Maglioli*, 16 F.4th at 410.

Whether the PREP Act completely preempts state law negligence claims for the purposes of federal jurisdiction is different from Mother's argument, which appears to be that her state law negligence claims are *exempt* from the Act's immunity provision. Mother appears to misunderstand the preemption doctrine, so her argument based on that doctrine is misplaced.

Mother's negligence and consumer protection claims all flow from the allegation that a COVID-19 vaccine was administered to M.K. These claims are based on the supposed harms associated with such vaccines, the alleged failure to sufficiently inform M.K. and Mother about the vaccine and its licensing status before its administration to M.K., misrepresentations in the medical charting associated with the administration of this vaccine, negligence in post-vaccination care, and negligence related to the employee training and policies surrounding vaccine administration. These claims would be meaningless had Schukar not administered a COVID-19 vaccine to M.K.

Because Mother's negligence and consumer protection claims are causally related to the administration of a covered countermeasure, we find the district court did not err in dismissing these claims.

2. *Mother's battery claim*

Mother also argues the district court erred in dismissing her battery claim as the PREP Act does not apply to intentional torts, citing *Ravain* v. *Ochsner Medical Center*, No. 21-2365, 2022 WL 3334694, at *5 (E.D. La. 2022) (unpublished opinion) (remanding case to state court, concluding that PREP Act's statutory scheme was not comprehensive enough to completely preempt state-law intentional tort claims). Mother

essentially argues that the Act does not apply to intentional torts because the Act does not completely preempt state law intentional tort claims.

Again, Mother's claim on this point is meritless. As explained above, the doctrine of complete preemption has no applicability to the question before us. That the PREP Act does not completely preempt state-law intentional tort claims does not establish that its immunity protections do not apply to intentional tort claims causally related to the administration of a covered countermeasure.

Mother's battery claim is clearly causally related to the administration of a covered countermeasure. The unprivileged touching alleged by Mother is the injection of the vaccine without parental consent. We therefore find the district court did not err in holding the PREP Act applied to Mother's battery claim as well.

3. *Mother's other claims on appeal are meritless.*

Mother also argues the district court erred by: (1) applying an erroneous burden shifting framework in deciding the motions to dismiss; (2) treating her cases against Walmart and Schukar as one in ruling on the motions to dismiss; (3) deciding causation, as this is a question of fact properly left to the jury; and (4) issuing an advisory opinion.

First, Mother contends the district court misinterpreted the law of affirmative defense burdens in granting defendants' motions to dismiss in part. Mother claims the district court erred by shifting the burden onto her to prove that defendants' affirmative defense of PREP Act immunity did not apply. In support, she points out that the district court, in discussing the applicable standards, mentioned the burden-shifting framework that applies when considering a motion to dismiss based on the statute of limitations. However, although the district court mentioned this burden-shifting framework, it does not appear to have applied it. In its order on the motions to dismiss, the district court

properly placed the burden of proving the Act's applicability on defendants, even finding that defendants failed to meet this burden as to some of Mother's claims. Mother does not identify how the burden was shifted onto her below or how the framework otherwise impacted the district court's ruling. Thus, it appears the district court simply misspoke but did not misapply the burden of proof to establish defendants' affirmative defenses.

Mother next contends the district court erred by consolidating her cases against Walmart and Schukar and ruling on both defendants' motions to dismiss in one order. But, as defendants point out, the parties agreed below that the cases involved identical claims and addressed the same controlling issue. And Mother joined in Schukar's motion to consolidate below, arguing to the district court that "[t]he defendants' preemption arguments in both their motions to dismiss are identical. The Court should consolidate these cases in the interest of judicial economy."

As a result, we need not address the merits of Mother's argument on consolidation, as it is both unpreserved and precluded by the invited error doctrine. *Water Dist. No. 1 of Johnson County v. Prairie Center Dev., L.L.C.*, 304 Kan. 603, 618, 375 P.3d 304 (2016) (a party cannot invite error and then complain of the error on appeal).

Mother also argues that the district court improperly decided a fact question: whether her claims had a causal connection to the administration of a covered countermeasure. She cites the generic proposition that causation is a question of fact usually left to the jury, not a question of law for the district court to decide. But this proposition is not universally true. A district court may decide causation in the context of a motion to dismiss, as it did here. This is because when all the evidence on which a party relies is undisputed and susceptible of only one inference, proximate cause becomes a question of law. *Hale v. Brown*, 287 Kan. 320, 324, 197 P.3d 438 (2008). Based on Mother's allegations, and construing them all in her favor, the district court found her claims for negligence, battery, and violation of the Kansas Consumer Protection Act were

causally related to defendants' administration of a covered countermeasure. We see no error in the district court's resolution of the issue, as explained in detail above.

Finally, Mother argues the district court erred by issuing what she calls an "advisory opinion." She claims that since the district court incorrectly determined the PREP Act applied (according to her), its rulings applying the Act "were not justiciable, advisory, and hypothetical." Mother does not explain her argument, other than citing a general discussion in *State ex rel. Morrison v. Sebelius*, 285 Kan. 875, 896-98, 179 P.3d 366 (2008), explaining why courts cannot and should not issue advisory opinions. Beyond failing to adequately brief her argument, it is meritless. We have found the district court correctly dismissed Mother's claims and this ruling was not advisory.

Having found the district court properly construed the allegations in Mother's petition and applied the PREP Act's immunity provision, we find no error in its dismissal of most of her claims.

II. *Did the district court err in denying defendants' motions to dismiss in part?*

In their interlocutory appeal, defendants argue the district court erred in only partially granting their motions to dismiss. Defendants ask us to reverse this portion of the court's order and direct dismissal of all claims in Mother's petition, as they all fall within the broadly worded loss and causation provisions of the PREP Act.

Mother offers the same arguments in response to defendants' interlocutory appeal that she advances in her direct appeal. That is, she contends the district court correctly concluded the PREP Act does not cover failures to act and thus does not apply to her claims based on the failure to secure parental consent. She also argues that obtaining parental consent is not a covered countermeasure.

As explained above, Mother's arguments are misplaced. The cases Mother cites are inapplicable because they addressed the failure to administer a countermeasure rather than the improper administration that we have here. Similarly, the question before us is not whether obtaining consent is a covered countermeasure but whether claims based on the failure to obtain consent for a vaccination are causally related to the administration of that vaccine.

A. *Jurisdiction*

Mother first argues that defendants cannot seek interlocutory appeal from the district court's order, since the district court elected to convert a portion of the order into a final judgment under K.S.A. 2022 Supp. 60-254(b). Mother contends this eliminated the option of an interlocutory appeal from the order, as K.S.A. 2022 Supp. 60-2102(c) only applies if a district court's order is "not otherwise appealable." Thus, Mother argues, this court lacks jurisdiction to hear defendants' interlocutory appeal.

This court, however, has already decided that it has jurisdiction to hear both appeals. As defendants note, Mother presented these same arguments in her Motion to Dismiss Appellants' Appeal. This court considered these arguments and held that jurisdiction exists to hear defendants' interlocutory appeal. In line with this conclusion, this court denied Mother's Motion to Dismiss Appellants' Appeal.

The district court properly certified the portion of its judgment where it dismissed Mother's claims as final under K.S.A. 2021 Supp. 60-254(b), so this portion of its order could be appealed under K.S.A. 2021 Supp. 60-2102(a)(4). And it properly certified the portion of its judgment where it denied defendants' motion to dismiss Mother's remaining claims for interlocutory appeal under K.S.A. 2021 Supp. 60-2102(c). Mother cites no authority which prevents a district court from proceeding this way, which aligns with the guiding principle of Kansas' rules of civil procedure, requiring those rules to be "liberally

construed, administered and employed by the court and the parties to secure the just, speedy and inexpensive determination of every action and proceeding." K.S.A. 2022 Supp. 60-102.

The cases which Mother relies on address the certification of a court's decision as a whole, not its component parts like the way the district court treated its decision here. For example, *DeMelo v. Woolsey Marine Industries, Inc.*, 677 F.2d 1030 (5th Cir. 1982), addressed a situation where a district court disposed of all claims against one defendant but rather than certifying that decision as final under Rule 54(b) of the Federal Rules of Civil Procedure (the federal equivalent of K.S.A. 60-254[b]), it referenced 28 U.S.C. § 1292(b) (the federal equivalent of K.S.A. 60-2102[c]). The 5th Circuit court found it had jurisdiction despite this mistake, noting "'practical, not technical, considerations are to govern the application of principles of finality' and that we should not 'exalt form over substance' to dismiss appeals.'" *DeMelo*, 677 F.2d at 1033. We similarly find Mother has provided no basis to revisit this court's prior decision to deny Mother's motion to dismiss defendants' interlocutory appeal.

B. *Identifying the issues on appeal*

In certifying this case for interlocutory appeal, the district court certified two questions for review:

> (1) "Is the [PREP Act] and its immunity provision completely preemptive of all state law causes of action, regardless of the theory, so long as there is any connection or involvement whatsoever with a covered countermeasure?"; and
> (2) "Does [the PREP Act] give covered persons absolute immunity to violate parental consent or age of medical consent for minors law?"

To begin, we note that courts are limited to answering questions presented in an actual case or controversy between parties; they have no power to issue advisory opinions. *Sebelius*, 285 Kan. at 888.

Defendants argue that we need not address whether the PREP Act covers all claims in all cases, only whether the claims here are covered. They contend that the limited question of this case is whether the PREP Act provides immunity to Walmart and Schukar for Mother's claims—nothing more.

Furthermore, appellate courts have some discretion in recasting the issues on interlocutory appeal from those certified by the district court. The Kansas Supreme Court has held that courts may go beyond the issues certified by a district court for interlocutory appeal where appealable issues are intertwined with nonappealable issues. *Williams v. Lawton*, 288 Kan. 768, 784, 207 P.3d 1027 (2009). This is in part because, as the court in *Williams* noted, interlocutory appeals originate from the district court's order itself, and an appellate court can and should address a different legal question if it controls disposition of the certified order. 288 Kan. at 784 (citing *Paper, Allied-Industrial v. Continental Carbon*, 428 F.3d 1285, 1291 [10th Cir. 2005]).

Therefore, we limit our review in the interlocutory appeal to the limited question controlling disposition of the certified order here: Does the PREP Act apply to Mother's claims based on the failure to obtain parental consent? We need not address the broad questions certified by the district court, as they go beyond the actual controversy below and thus improperly seek an advisory opinion.

C. *Whether the PREP Act applies to claims based on a failure to secure parental consent*

As defendants note, the Act provides immunity for "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." 42 U.S.C. § 247d-6d(a)(1). And it explicitly instructs that this immunity applies to "any claim for loss that has a causal relationship with the administration to . . . an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). Defendants argue that based on this text, as well as basic common-law principles of causation, the Act applies to Mother's claims based on parental consent.

Because the PREP Act applies to any claim for loss that has a causal relationship with the administration to an individual of a covered countermeasure, defendants argue that it must apply to a claim based on a failure to secure parental consent to administer the vaccine. Defendants claim that it is indisputable that all of Mother's claims are causally related to the administration of the Pfizer vaccine here, as the test for causation in fact is a "but for" test. See *Kudlacik v. Johnny's Shawnee, Inc.*, 309 Kan. 788, 793-94, 440 P.3d 576 (2019) (discussing requirements of causation in fact). Defendants note that but for the administration of the vaccine, Mother would have no claim based on the administration of the vaccine without consent or the failure to warn of its effects.

Defendants also point to the fact that other courts, in interpreting similarly worded statutes preempting state causes of action, have described the phrases "relate to" or "'relating to'" broadly. See *Pilot Life Ins. Company v. Dedeaux*, 481 U.S. 41, 47, 107 S. Ct. 1549, 95 L. Ed. 2d 39 (1987) (explaining that "'[t]he phrase "relate to" . . . [has a] broad common-sense meaning, such that a state law "relate[s] to" a benefit plan "in the normal sense of the phrase, if it has a connection with or reference to such a plan"'") (quoting *Metropolitan Life Ins. Company v. Massachusetts*, 471 U.S. 724, 739, 105 S. Ct. 2380, 85 L. Ed. 2d 728 [1985]); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374,

383-84, 112 S. Ct. 2031, 119 L. Ed. 2d 157 (1992) (describing the term "relating to" as "'deliberately expansive'" and "'conspicuous for its breadth'"); *EagleMed, LLC v. Travelers Insurance*, 315 Kan. 411, 424, 509 P.3d 471 (2022) ("The United States Supreme Court has construed the 'relating to' phrase in the [Airline Deregulation Act] to 'express a broad pre-emptive purpose'") (quoting *Morales*, 504 U.S. at 383); *Burnett v. Southwest Bell Tel., L.P.*, 283 Kan. 134, 152, 151 P.3d 837 (2007) (explaining that ERISA's "preemption of any state law which 'relates to' employee benefit plans" is broad). Defendants argue that this shows that both the immunity and preemption provisions of the PREP Act should thus be construed broadly.

The district court seemed to recognize that the PREP Act's broad language implicitly included claims based on the administration of a covered countermeasure without parental consent. But it concluded that Congress would not have made the Act applicable to such claims by mere implication, as they involve a fundamental constitutional right—parents' right to decide their children's care.

The district court concluded that "[i]f Congress intended to interfere with or to preempt [parents' fundamental rights] it would have said so, not left it up to individuals or Courts to guess or read into the statute by rules of construction or implication." Because the Act's preemption provision did not specifically state that the Act preempted claims based on parental consent, the district court found that it had no application to such claims.

Defendants concede the PREP Act does not expressly mention parental consent. But they argue the Act's broad preemption language, the sweeping immunity clause, and the availability of alternative remedies all reflect Congress' intent to preempt all state claims relating to the administration of a covered countermeasure, including those related to the administration of a vaccine to a minor without parental consent. In defendants' view, the text of the Act's immunity and preemption provisions is comprehensive and all-

encompassing, and claims based on the failure to obtain consent cannot be carved out of it. In other words, "all claims" means all claims, not "all claims except for those based on a violation of a fundamental right."

D. *Existing caselaw supports Defendants' position.*

Defendants point out that a New York state appellate court has already squarely addressed this issue, holding that the PREP Act's immunity provisions extend to qualified persons who administer a covered countermeasure to an individual without consent, namely the plaintiff's minor child. *Parker v. St. Lawrence City Pub. Health Dept.*, 102 A.D.3d 140, 143-45, 954 N.Y.S.2d 259 (2012).

While the district court tried to distinguish *Parker* in its decision, we find the distinctions the court identified are inconsequential. The district court said *Parker* was unpersuasive because it involved an earlier version of the PREP Act, a different public health emergency, and a different standard for dismissal from Kansas. But, as defendants note, the analysis in *Parker* turned on the text of the statute's immunity and preemption provisions—which was the same then as it is now—not any unique aspect of New York law or meaningful difference between the emergency declaration at issue there and the one here.

Focusing on the plain text of the Act, the court in *Parker* determined that the broad language of the Act's preemption and immunity provisions revealed a congressional intent to immunize covered persons from all state law tort claims arising from the administration of covered countermeasures, including one based on a defendant's failure to obtain consent. *Parker*, 102 A.D.3d at 143-44. The court also noted this finding was bolstered by Congress' provision of exclusive alternative remedies for injuries stemming from covered countermeasures in the form of the Countermeasures Injury Compensation Program and the Act's separate cause of action for willful misconduct. 102 A.D.3d at

144. And it noted the policy decision made by Congress; namely its determination that potential tort liability arising from errors in administering a vaccine program "must give way to the need to promptly and efficiently respond to a pandemic or other public health emergency." 102 A.D.3d at 144.

Defendants also note that a federal district court has also recently ruled on the scope of the PREP Act, holding that the Act bars claims arising from the administration of a COVID-19 vaccine without consent. *Cowen v. Walgreen Co.*, No. 22-CV-157-TCK-JFJ, 2022 WL 17640208, at *3 (N.D. Okla. 2022) (unpublished opinion).

In *Cowen*, the plaintiff alleged that she had been injected with a COVID-19 vaccine without her knowledge or consent after seeking a flu vaccine from a Walgreens pharmacy. The plaintiff argued that because her injuries could have resulted from any vaccination or other medical procedure, the PREP Act did not apply. In dismissing her claims, the district court held that the PREP Act applied because the plaintiff's alleged injuries were all the result of the administration of a COVID-19 vaccine. 2022 WL 17640208, at *3.

While *Cowen* is not as factually similar to this case as *Parker*, we still find its analysis persuasive and supportive of our decision that the PREP Act applies here. Both cases hold that any claim causally related to the administration by a covered person of a covered countermeasure is covered by the Act, even claims based on the failure to obtain consent.

CONCLUSIONS

In line with *Parker* and *Cowen*, we find the PREP Act applies to Mother's claims based on the failure to secure parental consent. The text of the Act is unambiguous: The Act applies to all claims causally related to the administration by a covered person of a

covered countermeasure. The question presented by this interlocutory appeal is thus whether a claim based on the administration of a covered countermeasure without parental consent is causally related to the administration of a covered countermeasure. Reframed this way, the answer is yes.

Finally, we need not address the district court's unbidden constitutional concerns about the PREP Act. Because this case can be decided on the text of the Act and Mother never advanced any constitutional claim, we adhere to the long-standing doctrine of judicial self-restraint known as constitutional avoidance. As explained in *Butler v. Shawnee Mission School District Board of Education*, 314 Kan. 553, 502 P.3d 89 (2022), "[t]his rule strongly counsels against courts deciding a case on a constitutional question if it can be resolved in some other fashion, especially when the question concerns the validity of a statute enacted by our coordinate branches of state government." 314 Kan. at 554 (citing *Smith v. Kansas Dept. of Revenue*, 291 Kan. 510, 519, 242 P.3d 1179 [2010]) ("declining to reach constitutional concerns over statute authorizing field sobriety tests based on reasonable suspicion, when facts demonstrated probable cause"). Much like the district court in *Butler*, the district court here gratuitously shaped the contours of the PREP Act to accord with its own constitutional concerns when no such controversy was before it.

We reverse that portion of the court's judgment and express no opinion about the PREP Act's constitutionality.

In summary, we find the district court erred in denying defendants' motions to dismiss in part, and we reverse and remand the case with instructions to dismiss all claims.

Affirmed as to case No. 125,268, reversed as to case No. 125,151, and remanded with instructions to dismiss all claims.