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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION**

BRIANNE DRESSEN,

Plaintiff,

v.

ASTRAZENECA AB; ASTRAZENECA
PHARMACEUTICALS LP; and VELOCITY
CLINICAL RESEARCH, INC.,

Defendants.

**ASTRAZENECA DEFENDANTS'
REPLY IN SUPPORT OF MOTION TO
DISMISS PLAINTIFF'S COMPLAINT**

Case No. 2:24-cv-00337-RJS-CMR

Judge Robert J. Shelby

Magistrate Judge Cecilia M. Romero

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Plaintiff's brief in opposition ("Opp.") to AstraZeneca's Motion to Dismiss ("Br.") is a litany of misconstrued precedent, mischaracterizations of the Informed Consent Form ("ICF"), and misapprehensions of AstraZeneca's arguments. Plaintiff characterizes her claims as arising from an ordinary breach of contract dispute, but the Complaint makes clear that this is a quintessential product liability case that was filed too late. Plaintiff does not deny that she is alleging *personal injuries* resulting from administration of AstraZeneca's COVID-19 vaccine, nor does Plaintiff dispute that the Public Readiness and Emergency Preparedness Act ("PREP Act") immunizes AstraZeneca "from suit and liability under Federal and State law with respect to *all* claims" arising from "the administration to or the use by an individual of" its COVID-19 vaccine. 42 U.S.C. § 247d-6d(a)(1) (emphasis added). Plaintiff's claims fall squarely within the scope of AstraZeneca's PREP Act immunity and should be dismissed.

In an effort to salvage her case, Plaintiff attempts to rewrite the PREP Act's immunity provision to exclude all claims styled as breach of contract, even if they arise from the administration or use of a covered countermeasure. That argument contradicts the plain language of the statute. Indeed, Plaintiff relies solely on cases involving non-immunized commercial contract claims that did *not* arise from the "administration to or the use by an individual of a covered countermeasure," and thus fell outside the PREP Act for reasons that do not apply here. To support her argument that AstraZeneca *waived* its PREP Act immunity, Plaintiff strikingly ignores the recent, controlling Utah authority cited in AstraZeneca's motion, instead relying on outdated precedent. As for her attempt to avoid dismissal for untimeliness, Plaintiff does not seriously dispute that Utah courts classify causes of action by their substance, not their labels, and

that the Utah Product Liability Act’s two-year statute of limitations applies to both tort and contract claims alleging injury from a defective product.

Plaintiff makes a host of other meritless arguments, including asserting that the ICF is an insurance contract, that an ICF provision that merely describes AstraZeneca’s insurance policy somehow imposes sweeping obligations to pay her household expenses in perpetuity, and that she is entitled to recover costs for medical treatment that her insurer paid on her behalf. None of these claims creates any obstacle to dismissal. This is a straightforward case alleging personal injury from a COVID-19 vaccine, and it should accordingly be dismissed under the PREP Act—precisely the outcome Congress intended when it adopted the statute. The Court should reject Plaintiff’s arguments in opposition and grant AstraZeneca’s motion to dismiss.

ARGUMENT

I. THE PREP ACT BARS PLAINTIFF’S CLAIMS.

A. AstraZeneca Is Immune From This Action.

Plaintiff’s claims are barred in full by the PREP Act. *See* Br. 9-12. Plaintiff does not dispute that the PREP Act immunizes AstraZeneca from claims of injury allegedly caused by its COVID-19 vaccine, though she misconstrues the statute and AstraZeneca’s position. The text of the PREP Act is clear and unambiguous: “covered persons” like AstraZeneca are immune from suit and liability “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) (emphasis added); *see, e.g., Politella v. Windham S.E. Sch. Dist.*, --- A.3d ---, 2024 WL 3545717, at *1 (Vt. July 26, 2024) (finding PREP Act immunizes school district from parents’ claims arising from accidental administration of COVID vaccine to student). Plaintiff’s claims

indisputably allege loss caused by administration of AstraZeneca’s vaccine, so this case is barred under a straightforward application of the PREP Act. *See* Br. 12.

Plaintiff attempts to invent a bright-line rule that PREP Act immunity applies only to claims that sound in tort and does not extend to contract claims. Opp. 1-3. That is not the law. Courts have recognized that the immunity “covers claims for loss **sounding in tort or contract**, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements.” *Keyfman v. West Hills Hosp.*, No. 23VECV03136, 2023 WL 11781969, at *1 (Cal. Super. Ct. Nov. 27, 2023) (unpublished) (emphasis added); *see Hopman v. Sunrise Villa Culver City*, No. 20STCV25558, 2021 Cal. Super. LEXIS 2107, at *5 (Cal. Super. Ct. Jan. 5, 2021) (unpublished) (same); *see also, e.g., Maney v. Brown*, 91 F.4th 1296, 1302 (9th Cir. 2024) (“The PREP Act covers ‘all claims for loss’ related to the administration or use of covered countermeasures. ‘The use of “all” indicates a sweeping statutory reach.’” (quoting *AK Futures LLC v. Boyd St. Distro, LLC*, 35 F.4th 682, 690-91 (9th Cir. 2022))). That interpretation correctly adheres to the statute’s immunity provisions, which draw no distinctions between types of claims.

Indeed, the PREP Act applies to “*all* claims for loss” that relate to “the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1) (emphasis added); *see also id.* § 247d-6d(a)(2)(B). PREP Act immunity thus turns on the *source* of the alleged loss—*i.e.*, whether it relates to the administration or use of a covered countermeasure—not the pleading label chosen by the plaintiff. In the routine commercial cases that Plaintiff relies on, *see* Opp. 3, PREP Act immunity did not apply because the contractual claims at issue did *not* arise from the administration or use of a covered countermeasure. For example, in *Fusion Diagnostic Laboratories, LLC v. Atila Biosystems, Inc.*, No. 2:24-cv-00184, 2024 WL 3024915 (D.N.J. June

17, 2024) (unpublished), a clinical laboratory offering testing services sued a supplier of COVID test kits that were faulty. *See id.* at *1. The court rejected the defendant’s invocation of the PREP Act because the plaintiff “d[id] not allege loss from the ‘administration to or the use by an individual’ of a covered countermeasure.” *Id.* at *2. Instead, the plaintiff merely “sue[d] as a buyer seeking to hold the seller liable for the sale of allegedly defective Covid tests.” *Id.* The PREP Act was therefore inapplicable. Contrary to Plaintiff’s description, *Fusion Diagnostic* did not purport to construe the PREP Act as excluding immunity for *all* contract claims. *Contra* Opp. 4. The court’s holding was narrow, stating only that “[n]othing in the language of the PREP Act suggests that a manufacturer is immune from suit brought by the buyer in a commercial breach of contract dispute over the quality of goods sold.” 2024 WL 3024915, at *2.

So too with *WorkCare, Inc. v. Plymouth Med., LLC*, No. 8:21-cv-00864, 2021 WL 4816631 (C.D. Cal. Aug. 20, 2021) (unpublished), which like *Fusion Diagnostic* was a commercial action by a buyer of unusable COVID tests. *See id.* at *1. As in *Fusion Diagnostic*, the court denied the defendant immunity because “there has been no administration or use of covered countermeasures here.” *Id.* at *5. The court noted in dicta that “[t]he PREP Act does not on its face provide immunity for state contract claims,” but relied on unrelated case law addressing whether assisted living facilities can use the PREP Act to remove state-court actions alleging wrongful death from COVID. *See id.* (citing *Padilla v. Brookfield Healthcare Ctr.*, No. 21-cv-2062, 2021 WL 1549689, at *4 (C.D. Cal. Apr. 19, 2021)).¹ In the dispositive part of its analysis, the court explained that

¹*Haro v. Kaiser Foundation Hospitals*, No. CV 20-6006, 2020 WL 5291014 (C.D. Cal. Sept. 3, 2020) (unpublished), involves the same unrelated issue concerning the “complete preemption” doctrine of removability, and has no bearing on the scope of PREP Act immunity for personal injury claims. *Contra* Opp. 3.

“[u]nder a common-sense reading of the statute, Defendant has not engaged in the ‘administration’ of covered countermeasures,” and so “the PREP Act does not confer immunity on Defendant.” *Id.*

Plaintiff would have the Court treat this case identically to these run-of-the-mill commercial disputes that plainly do not involve administration or use of a covered countermeasure, the trigger for immunity. In contrast to those cases, Plaintiff’s complaint alleges claims for personal injury arising from administration of AstraZeneca’s COVID-19 vaccine, Compl. ¶ 68, which fall squarely within the scope of PREP Act immunity. Plaintiff’s contrary arguments conflict with the purpose of the statute, which Plaintiff agrees is “[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency” by limiting liability for alleged injuries. Opp. 4 (quoting Br. 9); *see, e.g., Maney*, 91 F.4th at 1298 (“Congress passed the PREP Act in 2005 to encourage during times of crisis the development and deployment of medical countermeasures (such as diagnostics, treatments, and vaccines) by limiting legal liability relating to their administration.”). Withholding immunity from covered persons for any claims arising from administration or use of covered countermeasures would run directly counter to Congress’s intent. It would also create precisely the disruption to the business environment that Plaintiff asserts would result from a mistaken interpretation of the PREP Act. Opp. 4-5. The Court should heed Plaintiff’s warning, apply the PREP Act’s immunity provisions as written, and dismiss this case with prejudice. *See* Br. 12.²

² Because this case falls squarely within the scope of the PREP Act, the Court need not assess the outer bounds of the immunity provision or evaluate the hypothetical scenarios Plaintiff lists. Opp. 4. Nor does the Court need to address the constitutional issue Plaintiff raises. Opp. 5 n.3. Whatever interaction PREP Act immunity may have with the Fifth Amendment’s Takings Clause, it assuredly is irrelevant to Plaintiff’s claims of personal injury.

B. AstraZeneca Did Not Waive Its Immunity.

Plaintiff’s argument that AstraZeneca waived its PREP Act immunity misstates Utah law and misreads the ICF. At the outset, Plaintiff simply ignores governing Utah precedent setting a high bar for waiver of statutory rights. *See* Opp. 6-8. Utah courts require that “waiver of any statutorily guaranteed right must be *explicitly stated*, so that the parties’ intent is *clear and unmistakable*,” *JENCO LC v. SJI LLC*, 541 P.3d 321, 333 (Utah Ct. App. 2023) (quoting *Pioneer Builders Co. of Nev. Inc. v. K D A Corp.*, 437 P.3d 539, 542 (Utah Ct. App. 2018)) (emphases added). Courts “will not infer from a general contractual provision that the parties intended to waive” statutory rights, *id.* at 333 (quoting *Pioneer Builders*, 437 P.3d at 542), and “failure to reserve a statutorily protected right is not the equivalent of a waiver of that right,” *Pioneer Builders*, 437 P.3d at 543.

Plaintiff inexplicably disregards these governing standards in favor of decades-old precedents that have long since been superseded. Opp. 9-11 (citing *Am. Sav. & Loan Ass’n v. Blomquist*, 445 P.2d 1 (Utah 1968); *Webb v. R.O.A. Gen., Inc.*, 773 P.2d 834 (Utah Ct. App. 1989); *Metro. Edison Co. v. NLRB*, 460 U.S. 693 (1983); *Teamsters v. Lucas Flour Co.*, 369 U.S. 95 (1962)). Applying black-letter common law is not an exercise in deriving some original intent of a doctrine; courts look to the most recent controlling precedent, which here forecloses Plaintiff’s arguments for waiver.³ Nothing in the ICF comes close to an “explicit[] state[ment]” of “clear and

³ Plaintiff’s waiver argument fails even under the historical standards she points to, derived from *Teamsters v. Lucas Flour Co.*, 369 U.S. 95 (1962). *See* Opp. 10. In *Metropolitan Edison Co. v. NLRB*, 460 U.S. 693 (1983), the Supreme Court explained that an implied waiver was recognized in *Lucas Flour* “*only because of the unique conjunction between*” two bespoke clauses in a collective bargaining agreement. 460 U.S. at 708 n.12 (citing *Lucas Flour*, 369 U.S. at 105) (emphasis added). Other than that exceptional situation, “the waiver of a protected right must be expressed clearly and unmistakably” and “*explicitly stated*.” *Id.* at 708 & n.12 (emphasis added).

unmistakable” intent to waive AstraZeneca’s PREP Act immunity from suit and liability. *JENCO LC*, 541 P.3d at 333 (quoting *Pioneer Builders*, 437 P.3d at 542). The operative language of the ICF—stating that “Sponsor will pay the costs of medical treatment for research injuries, provided that the costs are reasonable, and you did not cause the injury yourself”—is a “general contractual provision” that cannot plausibly communicate an unmistakable “intention” to relinquish AstraZeneca’s immunity, particularly since the very same page of the ICF expressly *acknowledges* AstraZeneca’s immunity. *Id.*; see ICF at 13.

Even less reasonable is Plaintiff’s claim that AstraZeneca intended to waive the PREP Act in stating that it “has an insurance policy to cover the costs of research injuries as long as you have followed your study doctor’s instructions.” Opp. 6-7 (quoting ICF at 13).⁴ That sentence does not pledge or commit to any action at all, let alone clearly and unmistakably; it merely identifies the source of any compensation that may be provided. It is the very next sentence of the ICF—stating that “Sponsor will pay the costs of medical treatment for research injuries” under certain conditions—that defines the scope of compensation potentially available to participants who experience a research injury. ICF at 13. By reading the first sentence in isolation and insisting that it creates contractual obligations, Plaintiff impermissibly asks the Court to insert words into the ICF. *See, e.g., Equine Holdings LLC v. Auburn Woods LLC*, 482 P.3d 880, 892 (Utah Ct. App. 2021) (“[C]ourts must attempt to construe the words chosen by the parties, and may not, as part of that exercise, make alterations that materially change the meaning of the instrument’s text.”).

⁴ Plaintiff puzzlingly asserts that AstraZeneca’s opening brief failed to acknowledge this provision, Opp. 9, but AstraZeneca quoted it in full, *see* Br. 6. For her part, Plaintiff’s opposition only once includes the actual operative language in its entirety, *i.e.*, “Sponsor will pay the costs of medical treatment for research injuries, provided that the costs are reasonable and you did not cause the injury yourself.” Opp. 7.

Furthermore, Plaintiff's interpretation fails to properly "examine the *entire* contract and *all* of its parts in relation to each other [to] give a reasonable construction of the contract as a whole." *Thatcher v. Lang*, 462 P.3d 397, 405 (Utah Ct. App. 2020) (citation omitted) (emphases added). Reviewing the ICF as a whole makes clear that the PREP Act is a statutory overlay that shapes the meaning of the agreement's "general contractual provision[s]," *JENCO LC*, 541 P.3d at 333, including the statement that AstraZeneca "will pay the costs of medical treatment for research injuries" in certain cases, ICF at 13. The ICF defines "research injuries" as (1) "[i]njuries that have been caused by the vaccine;" (2) injuries that have been caused by "tests"; and (3) injuries that have been caused by "procedures." *Id.* The PREP Act immunizes AstraZeneca from suit and liability for the first category, in which Plaintiff's alleged injury falls, but not necessarily for the remaining categories, which may or may not have "a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). The ICF accordingly provides that the PREP Act "*may* limit" trial participants' "right to sue" for research injuries sustained in the trial, depending on the circumstances. ICF at 13 (emphasis added).

This plain interpretation of the ICF properly considers the agreement as a whole and harmonizes the provisions that address compensation for research injuries. *See Thatcher*, 462 P.3d at 405. Contrary to Plaintiff's contention, no language in the agreement, properly understood, is rendered "superfluous and meaningless." Opp. 9 n.6. Further, the ICF's extensive description of the PREP Act explicitly *reserves* AstraZeneca's right to immunity for claims arising from certain research injuries. *See* ICF at 13. The Court should not "infer from [the ICF's] general contractual provision[s] that the parties intended to waive" AstraZeneca's PREP Act immunity, particularly

when the ICF contains express language to the contrary. *JENCO LC*, 541 P.3d at 333 (quoting *Pioneer Builders*, 437 P.3d at 542).

II. PLAINTIFF’S CLAIMS ARE TIME-BARRED.

The Utah Product Liability Act’s two-year statute of limitations applies to Plaintiff’s complaint—and has long since expired. *See* Utah Code Ann. § 78B-6-706. Plaintiff insists that Utah’s six-year period for breach of written contracts governs, but that is incorrect. Though styled as a contract case, Plaintiff’s claims sound exclusively in product liability and are accordingly out of time.

Plaintiff does not dispute that the Utah Supreme Court held in *Utah Local Government Trust v. Wheeler Machinery Co.*, 199 P.3d 949 (Utah 2008), that “[t]he Utah Product Liability Act applies to actions, *in both tort and contract*, arising from injury caused by a defective product.” *Id.* at 957 (emphasis added). While Plaintiff tries to avoid that pronouncement, the court’s analysis of the Product Liability Act was clear and sweeping: “product liability encompasses *all actions* seeking money damages for injury to people or property resulting from defective products.” *Id.* at 951 (discussing Utah Code Ann. § 78B-6-706) (emphasis added). That describes the allegations in this case precisely. The fact that Plaintiff styled her complaint as a contract action to plead around AstraZeneca’s PREP Act immunity, *see* Compl. ¶¶ 32-34, is irrelevant.

Plaintiff also does not dispute that Utah courts take a holistic approach to determining “which of ... two [statutes of limitations] provisions applies” to a plaintiff’s claims. *Jensen v. Sawyers*, 130 P.3d 325, 333 (Utah 2005). The Utah Supreme Court “pay[s] little heed to the labels placed on a particular claim, favoring instead an evaluation based on the essence and substance of the claim.” *Id.*; *see also Failor v. MegaDyne Med. Prods., Inc.*, 213 P.3d 899, 905 (Utah Ct. App.

2009) (“Utah courts look to the nature of the action and not the pleading labels chosen”).⁵ Plaintiff here seeks compensation for personal injuries allegedly caused by a defective pharmaceutical product. *See, e.g.*, Compl. ¶¶ 165-69, 174-77. Under *Wheeler Machinery*, that brings her complaint squarely within the Utah Product Liability Act’s two-year statute of limitations. Plaintiff counters that she can “elect” to sue under the ICF rather than bring a tort action, Opp. 12-13, but that principle applies only when a plaintiff actually has viable tort and contract claims. Here, “look[ing] to the nature of the action and not the pleading labels chosen,” Plaintiff has only a product liability claim, so there is nothing to elect. *Failor*, 213 P.3d at 905.

Plaintiff alternatively steers the Court toward inapplicable case law that sets out a test for distinguishing claims based on written contracts from actions for *injuries to property*. Opp. 11-12 (citing *Brigham Young Univ v. Paulsen Constr. Co.*, 744 P.2d 1370, 1372 (Utah 1987)). Plaintiff’s claims here involve a written instrument, but a judicially created test cannot override the Product Liability Act, which expressly applies to “any action for damages for personal injury, death, or property damage allegedly caused by a defect in a product.” Utah Code Ann. § 78B-6-703(1). That language unquestionably encompasses Plaintiff’s claims. *See Strickland v. Gen. Motors Corp.*, 852 F. Supp. 956, 959 (D. Utah. 1994) (explaining the text of the Product Liability Act indicates that “the Utah legislature ... intended that all claims against a manufacturer, based on a defective product, be subject to [the Act’s statute of limitations], regardless of the theory alleged”). Moreover, Utah courts hold that “[w]hen two statutes of limitations conflict, the statute applying to a specific type of action”—here, the Product Liability Act—“controls over a more general

⁵ Plaintiff again fails to discuss this on-point case law—which AstraZeneca featured prominently in its brief, Br. 3, 17-18—in favor of passages from older authority that are stripped of context.

statute.” *Veysey v. Veysey*, 339 P.3d 131, 133 (Utah App. 2014) (citing *Perry v. Pioneer Wholesale Supply Co.*, 681 P.2d 214, 216 (Utah 1984)). Plaintiff tellingly avoids addressing the Product Liability Act’s text, to which she has no answer.

Plaintiff also challenges the notion that the type of damages she seeks bears on whether her claims sound in tort or contract. By its terms, the Utah Product Liability Act applies to “any action for *damages for personal injury* ... allegedly caused by a defect in a product.” Utah Code Ann. § 78B-6-703(1) (emphasis added). Plainly, the type of damages Plaintiff is pursuing is relevant to determining the “nature of the action.” *Failor*, 213 P.3d at 905; *see also, e.g., Robinson v. Colo. State Lottery Div.*, 179 P.3d 998, 1003 (Colo. 2008) (en banc) (“Although the nature of the relief requested is not dispositive on the question of whether a claim lies in tort, the relief requested informs our understanding of the nature of the injury and the duty allegedly breached.”). Here, Plaintiff seeks to recover past and future “lost income,” “loss of household services,” “costs of transportation,” and “[p]ast child care expenses,” Compl. ¶ 169, as well as non-economic damages for emotional distress, *id.* ¶¶ 171-77. These are classic product liability damages. *See* Br. 18. Plaintiff alternatively asserts that the proper focus should be the “injury” she seeks rather than “damages,” Opp. 14, but that test points to product liability as well. Plaintiff received AstraZeneca’s vaccine through a process that involved a written ICF, but the injury she alleges is an adverse event resulting from administration of a pharmaceutical product—quintessential product liability harm. Compl. ¶¶ 32, 62-63. In “essence and substance,” *Jensen*, 130 P.3d at 333, this is unquestionably a product liability case.

Plaintiff’s assertion that she qualifies for the six-year statute of limitations under Utah Code Ann. § 78B-2-309(1)(b) also directly conflicts with her unsupported argument that the ICF “qualifies as an insurance contract.” Opp. 16 n.10; *id.* at 17-19. The ICF is not an insurance policy,

see section III.B, *infra*, but even if it were, Plaintiff’s claims would be subject to Utah’s *three-year* statute of limitations “for actions based upon insurance contracts.” *Moore v. Berg Enterprises, Inc.*, 201 F.3d 448 (10th Cir. 1999) (unpublished opinion) (citing Utah Code Ann. § 31A-21-313(1)); *see Veysey*, 339 P.3d at 133 (directing courts weighing conflicting statutes of limitations to use “the statute applying to a specific type of action” over the “more general statute”). Plaintiff’s use of two fundamentally incompatible theories underscores that she lacks a coherent solution to the untimeliness of her claims.⁶

Finally, applying the Utah Product Liability Act statute of limitations here best comports with the Utah legislature’s reasoned determination of the proper period for adjudicating claims of personal injury from defective products, which can require expert evidence of causation that becomes more difficult to obtain over time. *See Vigos v. Mountainland Builders, Inc.*, 993 P.2d 207, 213 (Utah 2000) (“Statutes of limitations are intended to prevent unfair dilatory litigation against a defendant and to *require that claims be litigated while proper investigation and preservation of evidence can occur.*” (emphasis added)). Allowing Plaintiff to proceed here, nearly *four years* after her alleged injury, would undermine the legislature’s clear intent with respect to personal injury claims involving allegedly defective products.

III. ANY WAIVER OF ASTRAZENECA’S IMMUNITY IS LIMITED TO OUT-OF-POCKET COSTS FOR MEDICAL TREATMENT.

A. At Most, Plaintiff Can Recover Out-Of-Pocket Costs for Medical Care.

Even if Plaintiff’s claims were timely and not barred by the PREP Act, the Court should nonetheless dismiss Plaintiff’s claims for all damages except reasonable out-of-pocket costs of

⁶ AstraZeneca reserves the right to move for dismissal of Plaintiff’s claims as untimely under the three-year limitations period for insurance contracts should the Court find the ICF qualifies as one.

medical treatment. *See* Br. 19-20. No other compensation is available under the operative language of the ICF, which states that AstraZeneca will pay “the costs of medical treatment for research injuries.” ICF at 13. Plaintiff insists that the preceding sentence of the ICF—explaining that AstraZeneca “has an insurance policy to cover the costs of research injuries”—somehow entitles her to a far more expansive scope of damages. Opp. 19-21. That reading of the text is untenable. As described in section I.B, *supra*, the ICF’s reference to AstraZeneca’s insurance merely identifies the source of any compensation that may be provided under the agreement. The following sentence then specifies what compensation may be available: “the costs of medical treatment for research injuries.” ICF at 13. That language clarifies the meaning of the previous sentence, dispelling any doubt about the meaning of “costs of research injuries”; they are “the costs of medical treatment” that a trial participant expends for treating such injuries. *Id.*

Plaintiff’s contrary reading would render the second sentence of the paragraph superfluous and nonsensical. Plaintiff would have the Court find that AstraZeneca took on an immense commitment to pay for a vast range of long-term personal expenses—in a sentence that does not even state AstraZeneca “will” do anything—and then in the next sentence, made a redundant statement about its intention to pay for a narrow subset of those costs. Plaintiff claims that AstraZeneca’s interpretation fails to give the first sentence meaning, Opp. 9, but it is her reading that impermissibly fails to “harmonize[] the provisions and avoid[] rendering any provision meaningless.” *Bennion v. Stolrow*, 550 P.3d 474, 477 (Utah 2024) (citation omitted). The contradictions in Plaintiff’s approach illustrate why contract language cannot be read in isolation, but must be considered in the context of the entire agreement. *See Thatcher*, 462 P.3d at 405.

Plaintiff alternatively claims that the ICF is ambiguous on the scope of available compensation, but that argument falls flat. “[A] provision of a contract is not rendered ambiguous by the bare existence of competing interpretations of it.” *W. Valley City v. Bret W. Rawson, P.C.*, 489 P.3d 191, 197 (Utah 2021) (citation omitted); *see also, e.g., NetDictation LLC v. Rice*, 455 P.3d 625, 631 (Utah Ct. App. 2019) (“A contract is not ambiguous ‘simply because one party seeks to endow [terms] with a different interpretation according to his or her own interests.’” (citation omitted)). Rather, a contract or provision is ambiguous *only* if “it is capable of more than one *reasonable* interpretation because of uncertain meanings of terms, missing terms, or other facial deficiencies.” *NetDictation LLC*, 455 P.3d at 631 (emphasis added) (quoting *Glen v. Reese*, 225 P.3d 185, 189 (Utah 2009)). Importantly, a party’s proposed interpretation “may be ‘ruled out’ as unreasonable based on ‘the natural meaning of the words in the contract provision in context of the contract as a whole.’” *W. Valley City*, 489 P.3d at 197 (citation omitted).

Plaintiff’s reading of the ICF’s compensation provisions is unreasonable on its face because it impermissibly inserts words that are absent in the first sentence, *see supra*, at 7 (citing *Equine Holdings LLC*, 482 P.3d at 892), and would deprive the second sentence of any meaning, as just noted. Plaintiff’s reading thus must be “ruled out.” *W. Valley City*, 489 P.3d at 197. Because there is no ambiguity for the Court to resolve, the Court should find as a matter of law that if AstraZeneca waived its PREP Act immunity in any way (it did not), the waiver is limited to Plaintiff’s out-of-pocket costs of medical treatment for research injuries. *See In re W. Ins. Co.*, 521 P.3d 851, 858 (Utah 2022) (“If the language within the four corners of the contract is unambiguous, the parties’ intentions are determined from the plain meaning of the contractual language, and the contract may be interpreted as a matter of law.” (citation omitted)).

B. The ICF Is Not An Insurance Contract.

Plaintiff's remaining arguments largely rely on the Court accepting the false premise that the ICF is an insurance contract. That claim fails from the start. Under Utah law, certain "elements [are] essential to an insurance contract": the agreement must identify "the types of risk [the insured] wants covered, the amount of the indemnity, the duration of coverage, [and] the premium." *Harris v. Albrecht*, 86 P.3d 728, 730-31 (Utah 2004) (citation omitted). *None* of those elements is present in the ICF, ruling out any argument that it qualifies as an insurance agreement. Even if some of those elements could be discerned in the ICF, there is indisputably nothing in the agreement that resembles an insurance premium. That element is essential because the central purpose of insurance is the distribution of risk among individuals paying premiums. *See Utah Funeral Directors & Embalmers Ass'n v. Mem'l Gardens of the Valley, Inc.*, 408 P.2d 190, 194-95 (Utah 1965). No such structure existed for the trial participants who signed the ICF. Nor was the ICF a policy "intended for sale to the public," another identifying feature of insurance agreements. *Dyno Nobel v. Steadfast Ins. Co.*, 85 F.4th 1018, 1026 (10th Cir. 2023) (quoting *U.S. Fid. & Guar. Co. v. Sandt*, 854 P.2d 519, 523 (Utah 1993)).

Sidestepping controlling case law, Plaintiff relies on the Utah Court of Appeals' decision in *Pugh v. North American Warranty Services, Inc.*, 1 P.3d 570 (Utah Ct. App. 2000), for its finding that certain contracts not styled as insurance policies nonetheless qualify as such under Utah law. *See* Opp. 17-18 (citing *Pugh*, 1 P.3d at 574-76). The agreement at issue in *Pugh* was a "service contract" that provided limited warranty coverage for a used vehicle in exchange for payment from the plaintiff. 1 P.3d at 572. Importantly, the parties agreed that "the *sole purpose* of the contract was to shift the risk of financial loss due to vehicle breakdown" from the buyer to the

warranty provider. *Id.* at 574 (emphasis added); *see also id.* (explaining the provider effectively “conceded” that “the contract served the exact same purpose as an insurance contract”).

For these reasons, the agreement in *Pugh* was, in effect, an insurance contract, as subsequent courts have recognized. *See Gardiner v. York*, 153 P.3d 791, 793 (Utah Ct. App. 2006) (describing *Pugh* as “a breach of insurance contract case”); *see also Lewiston State Bank v. Greenline Equip., L.L.C.*, 147 P.3d 951, 956 (Utah Ct. App. 2006) (same). In sharp contrast to the vehicle warranty policy in *Pugh*, the “sole purpose” of the ICF here was not to shift risk for expected expenses, but rather to facilitate a clinical trial of a vaccine that would help liberate the world from the disruption and devastation of a once-in-a-century pandemic. The ICF’s inclusion of additional provisions addressing compensation for any injured trial participants does not remotely render the agreement analogous to the service contract in *Pugh*.

That the ICF is not an insurance contract confirms that Plaintiff cannot interpret “costs of medical treatment” to allow for recovery of expenses paid by her health insurer. Opp. 21-23. The authorities plaintiff cites for that premise involve traditional insurance, and most concern medical payments provisions in automobile policies that cover “incurred” medical expenses, a term of art that the ICF does not use. *See* 11 Jordan R. Plitt et al., *Couch on Insurance* § 158:10 (3d ed. June 2024 update). That includes the insurance treatise Plaintiff cites for the principle that she can reasonably recover expenses she did not pay, which is plainly inapplicable here. *See* Opp. 22 n.13; Donald M. Carley, 6 *New Appleman on Insurance Law Library Edition* § 64.04[2] (2024) (newer edition of Plaintiff’s cited treatise addressing a specific feature of uninsured motorist coverage that allows for double recovery in certain circumstances). Looking to the principles that actually govern the ICF, the compensation provision restricts payments to “costs of medical treatment for research

injuries, provided that the costs are *reasonable*.” ICF at 13 (emphasis added). By any measure, it would not be reasonable for AstraZeneca to make payments to Plaintiff for medical expenses that have already been covered by her health insurer.⁷

IV. PLAINTIFF FAILS TO STATE A CLAIM FOR BREACH OF THE IMPLIED DUTY OF GOOD FAITH OR ATTORNEY FEES.

The Court should dismiss Plaintiff’s claim for breach of the implied duty of good faith, which is both barred by the PREP Act and meritless, as well as her request for attorney fees. *See* Br. 15, 17-19, 23-24. Plaintiff does not dispute that AstraZeneca is immune from implied covenant claims if it retains PREP Act immunity from her express breach claims. Instead, Plaintiff merely states that “the ordinary rules of contract govern, including the implied duty of good faith,” as long as a contractual obligation “waives the immunity to an existing right.” Opp. 15. AstraZeneca has *not* waived its immunity, *see* section I.B, *supra*, so Plaintiff’s implied covenant claim is barred.

The claim also fails on the merits. The implied covenant doctrine “cannot be read to establish new, independent rights or duties to which the parties did not agree *ex ante*,” nor “create rights and duties inconsistent with express contractual terms,” and courts “will not use [the] covenant to achieve an outcome in harmony with the court’s sense of justice but inconsistent with the express terms of the applicable contract.” *1143 Oakwood Village LLC v. Albertsons, Inc.*, 104 P.3d 1226, 1240 (Utah 2004) (citation omitted); *accord Airstar Corp. v. Keystone Aviation, LLC*, 514 P.3d 568, 581 (Utah Ct. App. 2022). In response, Plaintiff resorts to case law involving insurance bad faith. *See* Opp. 15-16 (citing *Beck v. Farmers Ins. Exch.*, 701 P.2d 795, 801 (Utah

⁷ Plaintiff appears to have abandoned the Complaint’s meritless subrogation-based request for double recovery. *Compare* Opp. 23 (“Plaintiff’s right to medical expenses does not depend on subrogation”) *with* Complaint ¶ 168 (stating Plaintiff is entitled to double recovery because her “insurer has a contractual right to subrogation for both past and future expenditures”); *see* Br. 18.

1985)). Because the ICF is not an insurance contract, *see* section III.B, *supra*, that authority is irrelevant and Plaintiff fails to state a plausible claim.

The same reasoning and authorities dispose of Plaintiff's request for attorney fees. As with her implied covenant claim, Plaintiff demands attorney fees based on case law involving insurance agreements. Opp. 17-19. Plaintiff offers no other basis for awarding fees, nor does any exist. "Attorney fees are generally recoverable in Utah only when authorized by statute or contract." *McKitrick v. Gibson*, 541 P.3d 949, 954 (Utah 2024) (quoting *Reighard v. Yates*, 285 P.3d 1168, 1182 (Utah 2012)). Utah courts emphasize that awarding of attorney fees is an "exception" with "narrow application to insurance contracts." *Pugh*, 1 P.3d at 576 n.7. "[A]n expansive view of the exception 'is not reasonable because it would eviscerate the general rule; attorney fees would be awarded virtually every time a party is found in breach of its contract.'" *Id.* (quoting *Collier v. Heinz*, 827 P.2d 982, 984 (Utah Ct. App. 1992)). This case offers no basis to depart from the general rule. The Court should hold that the ICF is not an insurance agreement and dismiss Plaintiff's implied covenant claim and demand for fees.

V. NONECONOMIC DAMAGES ARE CATEGORICALLY UNAVAILABLE.

Plaintiff is not entitled to noneconomic damages of any kind, and her contrary arguments again misconstrue governing law. Setting aside PREP Act immunity, damages for mental anguish are presumptively unrecoverable in breach of contract claims. *See Gregory & Swapp, PLLC v. Kranendonk*, 424 P.3d 897, 904 (Utah 2018). For such damages to be available, "[s]omething in the contract ... must show that the parties contemplated granting relief for more than the typical mental anguish and discouragement that results from a breach of contract." *Id.* at 905. Specifically, a plaintiff must show that "at the time the parties formed the contract, they contemplated that

emotional distress damages *might flow from a breach of the contract.*” *Ward v. McGarry*, 511 P.3d 1213, 1216 (Utah Ct. App. 2022) (emphasis added) (citing *Gregory & Swapp*, 424 P.3d at 897).

Plaintiff has not and cannot make that showing. Nothing in the ICF indicates that the parties explicitly contemplated noneconomic damages for breach of the ICF. *See* Br. 22. Plaintiff resists that clear conclusion by obscuring the controlling precedent and cherry-picking quotations to develop a more favorable test that is not the law. Opp. 23-25. Plaintiff alternatively suggests that the ICF is ambiguous with respect to noneconomic damages, but offers no reasonable alternative interpretation of the agreement. *See* section III.A, *supra*. The Court should reject these arguments. Plaintiff cannot state a claim for noneconomic damages, which in any event are barred by the PREP Act.

CONCLUSION

For the reasons set forth above and in AstraZeneca’s Motion, AstraZeneca respectfully requests that this Court grant its Motion to Dismiss and dismiss Plaintiff’s Complaint with prejudice.

DATED this 16th day of August 2024.

RAY QUINNEY & NEBEKER P.C.

/s/ Kamie F. Brown

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