KAMIE F. BROWN (8520)
RAY QUINNEY & NEBEKER P.C.
36 South State Street, Suite 1400
P. O. Box 45385
Salt Lake City, UT 84145-0385
Tel: (801) 532-1500
Fax: (801) 532-7543
kbrown@rqn.com

ARTHUR E. BROWN (*pro hac vice forthcoming*)
ALEXANDER COUSINS (*pro hac vice forthcoming*)
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
Tel: (212) 836-8000
arthur.brown@arnoldporter.com
alexander.cousins@arnoldporter.com

Attorneys for AstraZeneca AB and AstraZeneca Pharmaceuticals LP

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' MOTION TO DISMISS PLAINTIFF'S COMPLAINT** Case No. 2:24-cv-00337-RJS-CMR Judge Robert J. Shelby Magistrate Judge Cecilia M. Romero

Defendants AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca") move to dismiss Plaintiff's Complaint, Dkt. # 1 ("Compl"). Plaintiff's action is barred by the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. §§ 247d-6d *et seq*., time-barred, and fails to state a claim upon which relief can be granted, Fed. R. Civ. P. 12(b)(6).

INTRODUCTION

Plaintiff's claims fail on multiple grounds. *First*, this action is barred by the PREP Act, which renders AstraZeneca "***immune from suit and liability under Federal and State law with respect to all claims for loss*** caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure," such as AstraZeneca's COVID-19 vaccine. 42 U.S.C. § 247d-6d(a)(1) (emphasis added). The PREP Act was an integral component of the United States' response to the COVID-19 pandemic, providing pharmaceutical companies immunity from suit and liability to supercharge the rapid development and deployment of vaccines and treatments for the novel virus. *See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,198 (Mar. 17, 2020). With the protections of the PREP Act in place, AstraZeneca and its partners successfully developed a lifesaving vaccine in a matter of months, an unprecedented scientific achievement.

Plaintiff concedes that the PREP Act applies to her case, which alleges personal injuries relating to the administration of AstraZeneca's COVID-19 vaccine in a clinical trial. Compl. ¶¶ 32, 62-63. Attempting to avoid the Act, however, Plaintiff argues that AstraZeneca waived its statutory immunity by agreeing in the clinical trial Informed Consent Form ("ICF") to "pay the costs of medical treatment" for injuries caused by the vaccine. *Id.* ¶ 58 (quoting Dkt. # 1-1 at 14 (Exhibit A (ICF) at 13)). Plaintiff's argument fails under Utah law, which requires an "explicit[] state[ment]" of clear and unmistakable intent to find that a party waived a statutory right. *Pioneer Builders Co. of Nev. Inc. v. K D A Corp.*, 437 P.3d 539, 542 (Utah Ct. App. 2018) (citation omitted). Plaintiff not only fails to allege an explicit statement of AstraZeneca's clear and

unmistakable intent to waive its PREP Act immunity, but expressly pleads that the ICF *referenced* the PREP Act and informed trial participants that it "may limit your right to sue." Compl. ¶ 61 (emphasis omitted); *see also id.* ¶¶ 62-63.

Second, although styled as a breach of contract action, the Complaint makes clear that this is a product liability case alleging personal injuries from the administration of AstraZeneca's COVID-19 vaccine. Accordingly, Plaintiff's claims are time-barred under the Utah Product Liability Act's two-year statute of limitations, which "applies to actions, ***in both tort and contract***, arising from injury caused by a defective product." *Utah Loc. Gov't Tr. v. Wheeler Mach. Co.*, 199 P.3d 949, 957 (Utah 2008) (emphasis added); *see* Utah Code Ann. § 78B-6-706. Plaintiff has framed her claims artfully in an attempt to plead around the PREP Act, but "Utah courts look to the nature of the action and not the pleading labels chosen" when "characterizing a cause of action." *Failor v. MegaDyne Med. Prods., Inc.*, 213 P.3d 899, 905 (Utah Ct. App. 2009) (quoting *Records v. Briggs*, 887 P.2d 864, 868 (Utah Ct. App. 1994)).

Plaintiff alleges neurological injuries caused by AstraZeneca's COVID-19 vaccine and is seeking to recover economic and non-economic damages, including medical expenses, lost wages, childcare costs, and compensation for emotional harm. Those are precisely the types of injuries and damages alleged in a typical product liability case. Moreover, Plaintiff fails to allege any provision in the ICF – the purported contract at issue – where AstraZeneca committed to compensate trial participants for lost wages, childcare costs, or emotional harm. Thus, Plaintiff is seeking damages far beyond what could be recovered in a breach of contract action. Indeed, Plaintiff seeks to recover medical expenses paid by her *insurer*, which allegedly has a "contractual right to subrogation" of any damages award in this case. Compl. ¶ 168. That argument further

demonstrates that Plaintiff's claims sound in tort, as "a subrogation claim is derived from an injured party's claim against a ***tortfeasor***." *State Farm Mut. Auto. Ins. Co. v. Green*, 89 P.3d 97, 101 (Utah 2003) (emphasis added). Because Plaintiff alleges that she was injured in November 2020 and requested compensation from Defendants in early 2021, *see* Compl. ¶¶ 1, 11-12, 70, 107, her claims are time-barred under the Utah Product Liability Act's two-year statute of limitations, Utah Code Ann. § 78B-6-706.

Third, even if the ICF had waived AstraZeneca's PREP Act immunity (it did not), any waiver would be strictly confined to "the ***costs of medical treatment*** for research injuries, provided that the costs are reasonable, and you did not cause the injury yourself." ICF at 13 (emphasis added).[1] The PREP Act would still preclude Plaintiff from recovering economic or non-economic damages other than her reasonable "costs of medical treatment." *Id.* In addition, Plaintiff's emotional damages claim fails on the merits, as emotional damages are available for breach of contract only when "'specific language' and 'obligations' in the contract . . . 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, 1217 (Utah Ct. App. 2022) (citing *Gregory & Swapp, PLLC v. Kranendonk*, 424 P.3d 897 (Utah 2018)). No such language exists in the ICF.

Therefore, AstraZeneca's Motion to Dismiss should be granted with prejudice.

[1] The ICF defines "research injuries" as "[i]njuries that have been caused by the vaccine, tests or procedures." ICF at 13.

ALLEGED FACTS

"In 2020, the COVID pandemic was raging." Compl. ¶ 4. On March 17, 2020, then-U.S. Secretary of Health and Human Services Alex M. Azar II declared that the pandemic constituted "a public health emergency." 85 Fed. Reg. at 15,198; *see* Compl. ¶¶ 32, 62 (citing declaration). The federal declaration stated that the pandemic represented "a significant public health challenge that require[d] a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread" of the deadly virus. 85 Fed. Reg. at 15,198. To that end, the Secretary urged the "manufacture, testing, development, distribution, administration, and use" of COVID-19 vaccines and activated the PREP Act to help ensure that safe and effective vaccines could be made available to the public as soon as possible. *Id.* at 15,201-02; *see* Compl. ¶¶ 32, 62 (citing declaration).

By the fall of 2020, COVID-19 vaccines were in development, and a clinical trial for AstraZeneca's vaccine was taking place in Salt Lake County. Compl. ¶ 6. The trial was administered by Defendant Velocity Clinical Research, Inc. ("Velocity"). *Id.* ¶ 43. Plaintiff alleges that she enrolled in the Salt Lake trial and went to Velocity's clinic on November 4, 2020. *Id.* ¶¶ 6-7, 64, 67-68. As alleged by Plaintiff, within an hour of receiving the vaccine, her right arm began "tingling and prickling," and the sensation spread over the next few hours. *Id.* ¶¶ 11-12, 70. That evening, Plaintiff experienced blurred and double vision, headaches, sound sensitivity, tinnitus, nausea, vomiting, fever, and chills. *Id.* ¶¶ 13, 70. The following day, Plaintiff's fever and chills had ended, but her other symptoms worsened. *Id.* ¶¶ 14, 71. Plaintiff alleges that the next morning she called the Velocity clinic, which asked her to come in for evaluation. *Id.* ¶ 94. Plaintiff did so on November 6, 2020. *Id.* Following the evaluation, Velocity's lead investigator for the

trial, Dr. Barbara Rizzardi, told Plaintiff that she may have Multiple Sclerosis ("MS") and referred her to a neurologist for further testing. *Id.* ¶ 95.

Plaintiff alleges that her symptoms worsened over the next several months and that she sought medical care on several occasions, including a three-day hospital admission. *Id.* ¶¶ 15-16, 73-81. Plaintiff alleges experiencing various neurological symptoms, but her precise medical condition is not clearly defined. The Complaint alleges a variety of possible diagnoses including: postural orthostatic tachycardia syndrome ("POTS"), *id.* ¶ 84; post-vaccine neuropathy, *id.* ¶ 85; dysautonomia, including chronic inflammatory demyelinating polyneuropathy, *id.* ¶ 30; vaccine-induced demyelinating disease, *id.* ¶ 92; and "Post Acute Covid Vaccine Syndrome," *id.* ¶ 88. At present, Plaintiff alleges that "some of [her] acute symptomology has improved," but she continues to experience pain and remains unable to work, engage in athletic activity, drive a vehicle further than short distances, or "parent the way she had." *Id.* ¶ 18. Plaintiff alleges that she requires ongoing medical consultations with various specialists and has been prescribed a significant number of medications. *Id.* ¶¶ 163, 165.

When Plaintiff first enrolled in the clinical trial, she received an ICF that identified the steps involved in the study, potential side effects, and procedures if she suffered any adverse reaction. *Id.* ¶¶ 8, 50, 65. The ICF further addressed the extent to which Plaintiff may be entitled to receive "[c]ompensation for study related injury" from AstraZeneca. *Id.* ¶ 9. Specifically, the ICF stated:

> The Sponsor has an insurance policy to cover the costs of research injuries as long as you have followed your study doctor's instructions. 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.

Id. ¶ 9 (quoting ICF at 13) (emphasis added). In addition, the ICF provided that if a participant is injured during the study, then Velocity's "study doctor will provide medical treatment or refer you for treatment." *Id.* However, the ICF also stated:

> Due to the coronavirus public health crisis, the federal government has issued an order that **may limit your right to sue** if you are injured or harmed while participating in this COVID-19-related clinical study.

ICF at 13 (emphasis added); *see* Compl. ¶ 61. Plaintiff understood the "order" to be Secretary Azar's March 2020 PREP Act declaration. Compl. ¶ 62. Aware of these provisions, Plaintiff "confirmed her agreement by signing" the ICF. *Id.* ¶ 68.

Plaintiff alleges that she sought "assistance or support from AstraZeneca and its research team," as well as from Velocity and its staff, following her initial evaluation at the Velocity clinic in November 2020. *Id.* ¶¶ 19, 101. Specifically, Plaintiff alleges a series of email and phone inquiries in which she and her husband requested reimbursement for her medical expenses, beginning in January 2021. *See generally id.* ¶¶ 106-57.

Plaintiff filed this lawsuit on May 13, 2024, asserting two causes of action against AstraZeneca and Velocity ("Defendants"). The first cause of action, Breach of Contract, alleges that the ICF was a binding contract in which Defendants promised "(1) to 'cover the costs' of the research injury, including but not limited to medical costs; and (2) to provide medical care and/or refer Plaintiff for medical care." *Id.* ¶ 181. Plaintiff alleges that Defendants breached those alleged obligations and delayed and denied provision of timely medical care. *Id.* ¶ 182.

Plaintiff's second cause of action, Breach of the Duty of Good Faith and Fair Dealing, alleges that Defendants breached their duty of good faith and fair dealing by allegedly providing delayed responses to her inquiries; offering $1,833.50 in payment for past and future medical

expenses; attempting to condition the payment on her agreement to release claims for further compensation; and conditioning her access to an evaluation by clinical trial staff on her agreement to sign an amended consent form disclosing a risk of neurological disorders. *Id.* ¶¶ 187-88.

For both claims, Plaintiff seeks identical economic and non-economic damages. *Id.* ¶¶ 184, 189. Specifically, Plaintiff seeks past and future medical expenses, past and future loss of household services, childcare expenses, past and future lost income, and past and future transportation costs. *Id.* ¶¶ 162-69, Prayer for Relief ¶ 1. Plaintiff also seeks emotional damages and attorney fees. *Id.* ¶¶ 174-77, Prayer for Relief ¶¶ 2-3. As set forth herein, both of Plaintiff's claims should be dismissed with prejudice.

STANDARD OF REVIEW

A motion to dismiss "under Rule 12(b)(6) tests the legal sufficiency of the claims asserted in the plaintiff's complaint." *Braun v. United States*, No. 1:22-cv-00108-RJS-CMR, 2023 WL 6158943, at *4 (D. Utah Sept. 21, 2023) (unpublished). To survive dismissal under Rule 12(b)(6), a complaint must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Although the Court must accept as true all well-pled factual allegations in a complaint, it "need not accept '[t]hreadbare recitals of the elements of a cause of action [that are] supported by mere conclusory statements,' or allegations plainly contradicted by properly considered documents or exhibits." *Clinton v. Sec. Benefit Life Ins. Co.*, 63 F.4th 1264, 1275 (10th Cir. 2023) (quoting *Iqbal*, 556 U.S. at 678). Moreover, "[t]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Kerr v. Polis*, 20 F.4th 686, 700 n.9 (10th Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). "A court

may resolve a motion to dismiss under Rule 12(b)(6) on the basis of an affirmative defense, such as the statute of limitations or statutory immunity, when the facts establishing the defense are apparent on the face of the complaint." *Silver v. Quora, Inc.*, No. CV 15-830, 2016 WL 9777159, at *2 (D.N.M. June 13, 2016) (unpublished), *aff'd*, 666 F. App'x 727 (10th Cir. 2016) (not selected for publication).

ARGUMENT

I. THIS ACTION IS BARRED BY THE PREP ACT.

A. The PREP Act Immunizes AstraZeneca From Liability and Suit for All Claims Arising from or Related to Use of Its COVID-19 Vaccine.

As a threshold matter, Plaintiff's claims are fully barred by the PREP Act. Enacted by Congress in 2005, the PREP Act provides complete immunity "from suit and liability" for manufacturers of "covered countermeasures" intended to "diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic." 42 U.S.C. § 247d-6d(a)(1), (i)(1)-(2), (i)(7)(A)(i); *see, e.g.*, *Cannon v. Watermark Ret. Cmtys., Inc.*, 45 F.4th 137, 138-39 (D.C. Cir. 2022); *Bird v. State*, 537 P.3d 332, 336 (Wyo. 2023). Congress adopted the statute "'[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency' by allowing the [U.S.] Secretary [of Health and Human Services] 'to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines.'" *Cannon*, 45 F.4th at 139 (quoting Kevin J. Hickey, Cong. Rsch. Serv., LSB10443, The PREP Act and Covid-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures 1 (updated Apr. 13, 2022), https://crsreports.congress.gov/product/pdf/LSB/LSB10443); *see also* Defs.' Mem. in Supp. of Mot. to Dismiss 3d Am. Compl. at 36, *Smith v. U.S. Health Res. & Servs. Admin.*, No. 3:23-cv-1425 (W.D. La. Apr. 8, 2024), ECF 53-1 ("the federal government's interest

in maintaining PREP Act immunity is . . . to protect the public health by encouraging the availability of countermeasures to combat public health emergencies").

PREP Act immunity is triggered when the HHS Secretary issues a declaration that a disease or other health condition or threat "constitutes a public health emergency," 42 U.S.C. § 247d-6d(b)(1), and applies to "all claims," under "Federal and State law," 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," *id.* § 247d-6d(a)(1). "[T]he sole exception" to the immunity is for "an exclusive Federal cause of action" available for "death or serious physical injury proximately caused by willful misconduct" by a "covered person." *Id.* § 247d-6d(d)(1); *see id.* § 247d-6d(c)(1)(A) (defining "willful misconduct"); *id.* § 247d-6d(i)(2)(B) (defining "covered person" to include manufacturers of covered countermeasures). In lieu of civil claims, the PREP Act established "the 'Covered Countermeasure Process Fund' for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." *Id.* § 247d-6e(a). Seeking relief through the federal fund is a prerequisite to bringing suit under the PREP Act's willful misconduct exception. 42 C.F.R. § 110.1; 42 U.S.C. § 247d-6e(a), (d)(1).

AstraZeneca's immunity for claims concerning its COVID-19 vaccine was triggered by Secretary Azar's PREP Act declaration for the pandemic on March 17, 2020. 85 Fed. Reg. 15,198; *see Cannon*, 45 F.4th at 140; Compl. ¶¶ 62-63. The declaration defines "covered countermeasures," in relevant part, 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, or the transmission of SARS-CoV-2 or a virus mutating therefrom." 85 Fed. Reg. at 15,202 (emphasis

added); *see* 42 U.S.C. § 247d-6d(i)(1), (i)(7) (defining "covered countermeasure"). The definition extends to products "authorized for investigational or emergency use." 85 Fed. Reg. at 15,202; *see* 42 U.S.C. § 247d-6d(i)(7)(B)(ii) (defining a category of covered countermeasure as including products in clinical trials under section 505(i) of the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 355(i)). Though Secretary Azar and his successors have amended the Declaration, the definition of "covered countermeasure" to include COVID-19 vaccines authorized for investigational use is materially unchanged. *See* 85 Fed. Reg. 79,190, 79,196 (Dec. 9, 2020) (Fourth Amendment); 88 Fed. Reg. 30,769, 30,774 (May 12, 2023) (Eleventh Amendment).

As Plaintiff concedes, Compl. ¶ 32, the PREP Act immunizes AstraZeneca, its corporate family, and other countermeasure manufacturers and providers from claims arising from administration and use of COVID-19 vaccines and treatments, including in clinical trials, 42 U.S.C. § 247d-6d(a) (defining scope of immunity and claims precluded); *id.* § 247d-6d(i)(4) (defining "manufacturer" to include parents, subsidiaries, and affiliates).[2] The immunity sweeps broadly, applying 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 . . . or use of such countermeasure." *Id.* § 247d-6d(a)(2)(B). Recognizing the PREP Act's expansive scope, courts across the country have routinely dismissed all manner of claims against covered persons. *See, e.g.*, *Fust v. Gilead Scis.*, No. 2:23-cv-2853, 2024 WL 732965, at *6-7 (C.D. Cal. Feb. 21, 2024) (unpublished) (dismissing

[2] Plaintiff's Complaint names both AstraZeneca Pharmaceuticals LP, a U.S. entity, and AstraZeneca AB, a Swedish entity, as defendants, and defines them collectively as "AstraZeneca." Compl. ¶¶ 38-40. Because PREP Act immunity applies equally to both entities, AstraZeneca similarly does not differentiate between them in this brief.

with prejudice personal injury claim against manufacturer of COVID-19 treatment and collecting cases dismissing claims under the PREP Act); *Storment v. Walgreen, Co.*, No. 1:21-cv-00898, 2022 WL 2966607, at *1-3 (D.N.M. July 27, 2022) (unpublished) (dismissing with prejudice claim against pharmacy alleging injuries from a fall after vaccination); *Bird*, 537 P.3d at 336-37 (affirming summary judgment for defendant in vaccine injury claim against State of Wyoming); *M.T. ex rel. M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1084-85 (Kan. Ct. App. 2023) (remanding with instructions to dismiss claim against pharmacy concerning alleged administration of vaccine to minor without parental consent).

The PREP Act requires dismissal of this case on the same basis. Plaintiff undisputedly brings "claim[s] for loss" that 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), *i.e.*, administration of AstraZeneca's COVID-19 vaccine in a clinical trial, Compl. ¶ 68. AstraZeneca is thus completely immune not only from liability for all of Plaintiff's alleged injuries, but also from *suit*. Because no amendments to the Complaint could impact AstraZeneca's immunity, the Court should dismiss this case with prejudice. *See N. Mill St., LLC v. City of Aspen*, 6 F.4th 1216, 1235 n.22 (10th Cir. 2021) ("dismissal with prejudice is generally appropriate under Rule 12(b)(6) when amending the complaint would be futile"); *Total Quality Sys., Inc. v. Universal Synaptics Corp.*, No. 1:22-cv-00167-RJS-DAO, 2024 WL 2396979, at *14 n.143 (D. Utah May 23, 2024) (unpublished) (same); *see also, e.g.*, *Storment*, 2022 WL 2966607, at *3-4 (unpublished) (dismissing PREP-Act-immunized claims with prejudice).

B. AstraZeneca Has Not Waived Its PREP Act Immunity.

Contrary to Plaintiff's conclusory assertion otherwise, Compl. ¶ 35, AstraZeneca has not waived its immunity from suit and liability under the PREP Act. Under Utah law, "[a] 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)). Utah 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); *see also, e.g.*, *Sysco Corp. v. Lab. Comm'n*, 502 P.3d 1242, 1246 (Utah Ct. App. 2021) (same); *Medley v. Medley*, 93 P.3d 847, 849 (Utah Ct. App. 2004) (same). Importantly, "failure to reserve a statutorily protected right is not the equivalent of a waiver of that right." *Pioneer Builders*, 437 P.3d at 543.

In asserting that AstraZeneca waived its PREP Act immunity, Compl. ¶ 35, Plaintiff refers to a sentence on page 13 of the ICF that states: "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." ICF at 13. That language is far from an "explicit[] state[ment]" of clear and unmistakable intent to waive AstraZeneca's PREP Act immunity from suit and liability. *Pioneer Builders*, 437 P.3d at 542 (quoting *Larsen Beverage v. Lab. Comm'n*, 250 P.3d 82, 85 (Utah Ct. App. 2011)). It does not reference the PREP Act at all, let alone explicitly. *Larsen Beverage*, 250 P.3d at 85. As Utah courts have explained, "waiver is 'the intentional relinquishment of a known right[,]' and . . . in order for waiver to occur, 'there must be an existing right . . . , a knowledge of its existence, and an *intention* to relinquish it.'" *JENCO LC*, 541 P.3d at 333 (quoting *Soter's, Inc. v. Deseret Fed. Sav. & Loan Ass'n*, 857 P.2d 935, 942 (Utah 1993)) (emphasis added). The ICF

language Plaintiff relies on is a "general contractual provision," that cannot plausibly communicate an unmistakable "intention" to relinquish AstraZeneca's statutory immunity. *Id.*

At most, that language – read in isolation – does not expressly "*reserve*" AstraZeneca's statutory immunity, which is "not the equivalent of a waiver." *Pioneer Builders*, 437 P.3d at 543 (emphasis added). However, properly reading the contract "as a whole," *Thatcher v. Lang*, 462 P.3d 397, 405 (Utah Ct. App. 2020) (quoting *Gillmor v. Macey*, 121 P.3d 57, 65 (Utah Ct. App. 2005)), AstraZeneca *did* reserve its PREP Act rights in the ICF, using language that Plaintiff herself cites elsewhere in the Complaint, *see* Compl. ¶¶ 53, 173. On the very same page that contains the sentence on which Plaintiff's case hinges, the ICF also states:

> Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19-related clinical study.
>
> If the order applies, it limits your right to sue the researchers, healthcare providers, any Sponsor or manufacturer or distributor involved with the Study. You may be prevented from making claims for injuries that have a causal relationship with the use of the investigational product in this Study, including, but not limited to, claims for death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption loss.
>
> However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. If funds are appropriated by Congress, compensation for injuries may be available to you under this Countermeasures Injury Compensation Program. To find out more about the Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

ICF at 13. This language plainly refers to the PREP Act and Secretary Azar's declaration for the COVID-19 pandemic, 85 Fed. Reg. 15,198, which Plaintiff concedes. Compl. ¶ 62. By informing study participants that their ability to sue AstraZeneca is limited by federal law, AstraZeneca expressly reserved its statutory rights under the PREP Act. In the face of these provisions, Plaintiff cannot plausibly claim that the ICF, properly interpreted as a whole, contains an explicit statement of clear and unmistakable intent to waive AstraZeneca's PREP Act immunity. *See JENCO LC*, 541 P.3d at 333.

Moreover, AstraZeneca cannot possibly have waived its PREP Act immunity with respect to Plaintiff's claim for breach of the duty of good faith and fair dealing. Compl. ¶ 188. Under Utah law, the implied covenant of good faith and fair dealing plays a "limited role" by "inferring as a term of every contract a duty to perform in the good faith manner that the parties surely would have agreed to if they had foreseen and addressed the circumstance giving rise to their dispute." *Young Living Essential Oils, LC v. Marin*, 266 P.3d 814, 816 (Utah 2011); *see also, e.g.*, *Vander Veur v. Groove Ent. Techs.*, 452 P.3d 1173, 1177 (Utah 2019) (same). Plaintiff does not expressly allege that AstraZeneca waived its PREP Act immunity from implied covenant claims, nor could she; a waiver of statutory immunity under Utah law must be "clear and unmistakable," *Pioneer Builders*, 437 P.3d at 542, but the implied covenant doctrine addresses terms that a court "may imply or read . . . into the agreement," *Terry v. Hinds*, 47 F. Supp. 3d 1265, 1274 (D. Utah 2014). Absent a complete waiver of PREP Act immunity, which Plaintiff concedes did not occur, Compl. ¶¶ 32, 63, AstraZeneca could not have clearly and unmistakably waived its immunity for claims under a contract term that exists only by implication. Put differently, Plaintiff cannot plausibly argue that AstraZeneca unmistakably waived its statutory immunity in connection with

circumstances that the contracting parties had not "foreseen and addressed" in the express terms of the ICF. *Young Living Essential Oils*, 266 P.3d at 816.

Accordingly, no waiver has occurred, and Plaintiff's claims are entirely barred by the PREP Act. Plaintiff's Complaint should therefore be dismissed with prejudice.

II. THE UTAH PRODUCT LIABILITY ACT BARS THIS ACTION AS UNTIMELY.

Independent of the PREP Act, this action is also time-barred. Despite Plaintiff framing this case as a contract dispute, it is unquestionably a product liability action seeking damages for injuries allegedly caused by a defective product. Accordingly, the Utah Product Liability Act's two-year statute of limitations applies. Utah Code Ann. § 78B-6-706. Because Plaintiff's alleged injury occurred in November 2020 and she requested compensation from Defendants in January 2021 – more than three years ago – this case is untimely.

A. Plaintiff's Complaint Sounds In Product Liability.

While styled as a contract case, the substance of Plaintiff's claims and the damages she seeks make clear that this action sounds in product liability. In *Utah Local Government Trust v. Wheeler Machinery Co.*, 199 P.3d 949 (Utah 2008), the Utah Supreme Court explained that "product liability encompasses all actions seeking money damages for injury to people or property resulting from defective products." *Id.* at 951 (citing 1 David G. Owen et al., *Madden & Owen on Products Liability* § 1:5 (3d ed. 2000)). Accordingly, "[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; *see also, e.g.*, *Mecham v. C.R. Bard, Inc.*, No. 2:19-cv-00750, 2020 WL 2768997, at *3 (D. Utah May 27, 2020) (unpublished) (same). That conclusion flows from the text of the Utah Product Liability Act, which 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); *see Wheeler Machinery*, 199 P.3d at 952 (discussing Section 78B-6-703(1)). In light of the Act's expansive sweep, its statute of limitations has "broad application" and governs any claim concerning a product that is allegedly defective when furnished to the plaintiff. *Wheeler Machinery*, 199 P.3d at 952 (citing *Strickland v. Gen. Motors Corp.*, 852 F. Supp. 956, 959 (D. Utah 1994)); *see also Strickland*, 852 F. Supp. at 959 (explaining the text of the Product Liability Act "suggests 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").

Utah courts' expansive construction of the product liability act is consistent with their general, practical approach to construing the claims in a complaint. "In characterizing a cause of action, Utah courts look to the nature of the action and not the pleading labels chosen." *Failor v. MegaDyne Med. Prods., Inc.*, 213 P.3d 899, 905 (Utah Ct. App. 2009) (quoting *Records v. Briggs*, 887 P.2d 864, 868 (Utah Ct. App. 1994)); *see also Jensen v. Sawyers*, 130 P.3d 325, 333 (Utah 2005) ("[W]hether a claim exists should be based on the 'nature of the action and not the pleading labels chosen.'" (quoting *Davidson Lumber Sales, Inc. v. Bonneville Inv., Inc.*, 794 P.2d 11, 14 (Utah 1990))). In general, courts in Utah "are most concerned with the true nature of the wrong and the injury as evidenced in the substance of the pleadings." *Records*, 887 P.2d at 868 (collecting cases); *see also Lord v. Shaw*, 665 P.2d 1288, 1290 (Utah 1983) ("The substance of the pleading and the nature of the issues which are raised, rather than the pleader's designation of the cause of action, control the issue.").

Here, Plaintiff seeks compensation for personal injuries allegedly caused by a defective pharmaceutical product – just as in a standard product liability suit. *See, e.g.*, Compl. ¶¶ 167-69,

174-77. The fact that Plaintiff styled the case as a contract action to plead around AstraZeneca's PREP Act immunity, *see id.* ¶¶ 32-34, is irrelevant; the Court must "look to the nature of the action and not the pleading labels chosen." *Failor*, 213 P.3d at 905. The "true nature" of this action is confirmed by the personal injuries alleged and the types of damages sought. *Records*, 887 P.2d at 868. The ICF language that allegedly waived AstraZeneca's PREP Act immunity – which Plaintiff concedes is her only possible avenue to sue, Compl. ¶ 35 – covers only "the costs of medical treatment for *research injuries*" when "reasonable" and not self-inflicted. ICF at 13 (emphasis added). The ICF defines "research injuries" as "[i]njuries that have been *caused by the vaccine*, tests or procedures." *Id.* (emphasis added). Thus, to prove her claims, Plaintiff must necessarily establish medical causation, a core element of any personal injury product liability case.

The types of damages Plaintiff requests further confirm that her claims sound in product liability. Plaintiff demands economic damages far beyond the costs of medical treatment, including 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. Plaintiff does not allege any contractual provisions in which AstraZeneca agreed to compensate trial participants for such expenses, which are quintessential product liability damages. Moreover, Plaintiff seeks to recover medical treatment costs paid by her insurer, on the alleged basis that her "insurer has a contractual right to subrogation." *Id.* ¶ 169. Plaintiff's argument lays bare that this is a tort case in all but name, as "a subrogation claim is derived from an injured party's claim against a ***tortfeasor***." *State Farm Mut. Auto. Ins. Co. v. Green*, 89 P.3d 97, 101 (Utah 2003) (emphasis added); *see also GNS P'ship v. Fullmer*, 873 P.2d 1157, 1160 (Utah Ct. App.

1994) ("The doctrine of subrogation allows an insurer . . . to step into the shoes of its insured and *recoup its losses from a tort-feasor* whose negligence caused the loss" (cleaned up)).

For all of these reasons, under well-defined Utah law, Plaintiff's claims sound in product liability and are governed by the Utah Product Liability Act.

B. Plaintiff's Claims Are Time-Barred.

Considering "[t]he substance of the pleading and the nature of the issues which are raised," *Lord*, 665 P.2d at 1290, this case is time-barred under the Utah Product Liability Act's two-year statute of limitations, Utah Code Ann. § 78B-6-706. Plaintiff alleges that her injury occurred in November 2020 and that she first requested compensation from Defendants in January 2021. Compl. ¶¶ 7-12, 64-70, 107-08. Accordingly, she was aware of her potential claim by January 2021 at the latest. Thus, Plaintiff's two-year limitations period expired no later than January 2023. Plaintiff did not file this lawsuit until May 13, 2024, so her claims are time-barred as a matter of law under the Utah Product Liability Act. Plaintiff's Complaint should therefore be dismissed with prejudice.

III. ANY PURPORTED WAIVER OF ASTRAZENECA'S PREP ACT IMMUNITY IS STRICTLY LIMITED TO REASONABLE OUT-OF-POCKET COSTS OF MEDICAL TREATMENT.

Alternatively, if neither the PREP Act nor the Utah Product Liability Act bar this action in full, the Court should nonetheless dismiss Plaintiff's claims for all damages except reasonable out-of-pocket medical treatment costs. Any purported waiver of AstraZeneca's PREP Act immunity would be strictly limited to those costs, as they are the only type of compensation specifically referenced in the ICF. AstraZeneca would remain immune "from suit and liability" for all of Plaintiff's other claimed damages, including economic damages other than medical treatment

costs; emotional damages; and attorney fees. 42 U.S.C. § 247d-6d(a)(1). Further, even if a broader range of damages were available (it is not), Plaintiff is not entitled to emotional damages or attorney fees for an alleged breach of the ICF. Finally, Plaintiff's cause of action for breach of the implied duty of good faith and fair dealing fails to state a claim. Plaintiff articulates no plausible basis for recovery and seeks identical damages as for express breach, so the claim is both meritless and redundant.

A. Any Available Economic Damages Are Limited To Reasonable Out-of-Pocket Medical Treatment Costs.

Any waiver of AstraZeneca's PREP Act immunity is strictly limited to "the costs of medical treatment for research injuries, provided that the costs are reasonable, and you did not cause the injury yourself." ICF at 13. That language cannot plausibly be read to include or provide for any economic damages beyond Plaintiff's out-of-pocket costs of treating her alleged research injury. Nothing in the contract contemplates AstraZeneca paying study participants compensation for lost income, loss of household services, costs of transportation, or childcare expenses. *Contra* Compl. ¶ 169, Prayer for Relief ¶ 1. Thus, claims for damages for those expenses are completely barred by AstraZeneca's PREP Act immunity, limited waiver or not.

Moreover, Plaintiff's attempt to recover medical treatment costs incurred by her insurer fails as a matter of law. *See* Compl. ¶ 168. Plaintiff lacks standing to recover costs incurred by her insurer because she has not alleged that such expenses are the result of "an actual or an imminent harm" to her. *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010); *see also Tennille v. W. Union Co.*, 809 F.3d 555, 563 (10th Cir. 2015) (holding that the Tenth Circuit "share[s] the Supreme Court's 'reluctance to endorse standing theories that rest on speculation about the decisions of independent actors'") (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414

(2013)). Furthermore, Plaintiff fails to attach an insurance policy or identify any contractual language that purportedly establishes her insurer's subrogation rights.

B. Non-Economic Damages Are Unavailable As A Matter of Law.

Moreover, PREP Act immunity aside, emotional damages are presumptively unavailable in breach of contract cases under Utah law. "Normally there is no recovery of damages for mental anguish stemming from a breach of contract" because "an award of damages in a breach of contract case attempts to place the aggrieved party in the same ***economic*** position the party would have been in if the contract was not breached." *Gregory & Swapp, PLLC v. Kranendonk*, 424 P.3d 897, 904 (Utah 2018) (citations omitted) (emphasis added). Utah courts recognize that "'[s]ome type of mental anguish, anxiety, or distress is apt to result from the breach of any contract which causes pecuniary loss.'" *Id.* at 905 (quoting *Cabaness v. Thomas*, 232 P.3d 486, 508 (Utah 2010)). However, "it is well established that these damages are not 'the natural and probable result of the breach' and 'are deemed to be too remote to have been in the contemplation of the parties at the time the contract was entered into to be considered as an element of compensatory damages.'" *Id.* (quoting *Cabaness*, 232 P.3d at 508).

For emotional damages to be recoverable in a breach of contract action, "[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.* Importantly, that principle holds even when a contract concerns sensitive, personal matters. *See Ward*, 511 P.3d at 1216-17 (holding the fact that a contract pertained to deletion of intimate photos was insufficient to create a factual issue regarding whether it contemplated emotional damages). Stated otherwise, "[d]amages related to emotional distress or mental anguish" must have been "both a foreseeable

result of the breach of contract and *explicitly* within the contemplation of the parties at the time the contract was entered into," *Cabaness*, 232 P.3d at 508, which "seldom happens," *Gregory & Swapp*, 424 P.3d at 905.

Plaintiff has not and cannot allege facts triggering this rare exception. Plaintiff identifies no specific language in the ICF showing that the parties explicitly contemplated emotional damages for breach of contract. Plaintiff points solely to the language discussing the PREP Act, Compl. ¶¶ 53, 173, which states in part that the Act may "*prevent*[]" a trial participant "from making claims for injuries that have a causal relationship with the use of the [study product], including, but not limited to, claims for . . . mental[] or emotional injury," ICF at 13 (emphasis added). At most, that language acknowledges that plaintiffs might bring claims for emotional damages stemming from alleged adverse reactions (and that AstraZeneca is immune from suits on those grounds). Nothing in the ICF suggests that the parties explicitly contemplated emotional damages arising from a *breach of the ICF,* which Plaintiff repeatedly insists is distinct from a product liability claim. Compl. ¶¶ 33-34. Unless a plaintiff shows that "at the time the parties formed the contract, they contemplated that emotional distress damages *might flow from a breach of the contract*," emotional damages are barred. *Ward*, 511 P.3d at 1216 (emphasis added) (citing *Gregory & Swapp*, 424 P.3d at 897). Plaintiff's misinterpretations of the ICF language are unavailing.

Plaintiff's claim for non-economic emotional damages fails as a matter of Utah law, and the Court should dismiss her claim with prejudice. Courts may not consider "[t]estimony and extrinsic evidence" in determining availability of emotional damages for breach, so no discovery or factfinding is appropriate. *Gregory & Swapp*, 424 P.3d at 906. Instead, courts must simply

"analyze[] whether the nature and language of the contract plainly show that non-economic damages were explicitly contemplated by the parties at the time the contract was formed." *Id.* Nothing in the ICF meets that requirement, so Plaintiff's emotional damages claim fails.

C. Plaintiff Fails To State A Claim For Attorney Fees.

Attorney fees are also unavailable as a matter of law. "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)); *accord Busico v. Carver*, 542 P.3d 956, 972 (Utah Ct. App. 2023) ("In Utah, attorney fees are awardable only if authorized by statute or by contract." (citation omitted)). No statute or contract provides for Plaintiff to recover fees here. The Complaint demands fees exclusively by reference to case law that concerns fee awards as a sanction for defendant insurers' bad-faith refusal to pay or settle claims. Compl., Prayer For Relief, ¶ 3. As one of Plaintiff's own cases explains, Utah courts "have carved out a narrow exception" to the no-fees default rule "in the insurance context." *Pugh v. N. Am. Warranty Servs., Inc.*, 1 P.3d 570, 574 (Utah Ct. App. 2000). The exception applies only "[w]hen an insurance company breaches the implied covenant to perform its obligations in good faith." *Id.* (citing *Collier v. Heinz*, 827 P.2d 982, 984 (Utah Ct. App. 1992)). This is not an insurance case, nor did AstraZeneca breach any implied covenant of good faith.

Therefore, the Court should dismiss Plaintiff's request for attorney fees.

D. Plaintiff's Claim For Breach Of The Duty Of Good Faith And Fair Dealing Is Meritless.

In addition to being barred by the PREP Act, Plaintiff's implied covenant claim fails on the merits. Utah courts observe strict limits on the covenant's scope to prevent the "misuse" of judicially implied contractual terms, which "threatens 'commercial certainty and breed[s] costly

litigation.'" *Young Living Essential Oils*, 266 P.3d at 816 (quoting *Kham & Nate's Shoes No. 2, Inc. v. First Bank of Whiting*, 908 F.2d 1351, 1357 (7th Cir. 1990)). The covenant "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); *accord Airstar Corp. v. Keystone Aviation, LLC*, 514 P.3d 568, 580-81 (Utah Ct. App. 2022). Plaintiff flouts those principles here to assert an amorphous, unbounded right to recovery from AstraZeneca. *See* Compl. ¶ 188. Moreover, Plaintiff pleads the same "economic and non-economic damages" for breach of the implied covenant as for express breach. *Id.* ¶¶ 184, 189. Accordingly, this claim is redundant, and Plaintiff's entitlement to recovery (if any) is limited on the same grounds as the express breach claim.

Because there is no basis for Plaintiff's breach of good faith and fair dealing claim, this cause of action should be dismissed.

CONCLUSION

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

DATED this 28th day of June 2024.

RAY QUINNEY & NEBEKER P.C.

/s/ Kamie F. Brown
Kamie F. Brown

ARTHUR E. BROWN (*pro hac vice forthcoming*)
ALEXANDER COUSINS (*pro hac vice forthcoming*)
ARNOLD & PORTER KAYE SCHOLER LLP

Attorneys for AstraZeneca AB and AstraZeneca Pharmaceuticals LP