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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH

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BRIANNE DRESSEN,

Plaintiff,

v.

ASTRAZENECA AB, a SWEDEN  
corporation; ASTRAZENECA  
PHARMACEUTICALS LP, a Delaware  
Limited Partnership,

Defendants.

**MEMORANDUM DECISION AND  
ORDER DENYING ASTRAZENECA'S  
MOTION TO DISMISS**

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

Chief District Judge Robert J. Shelby

Magistrate Judge Cecilia M. Romero

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Now before the court is Defendant AstraZeneca AB and Defendant AstraZeneca Pharmaceuticals LP's (together, AstraZeneca) Motion to Dismiss for failure to state a claim.<sup>1</sup>

The court DENIES AstraZeneca's Motion for the reasons stated below.

**BACKGROUND**

At the motion to dismiss stage, the court accepts as true all well-pleaded factual allegations in the complaint and views them in the light most favorable to the nonmoving party.<sup>2</sup> The following background facts are drawn from Plaintiff's Complaint.<sup>3</sup>

On November 4, 2020, Plaintiff Brianne Dressen received AstraZeneca's experimental COVID vaccine as part of a clinical trial in Salt Lake County.<sup>4</sup> Velocity Clinical Research, Inc. (Velocity) administered the trial on AstraZeneca's behalf.<sup>5</sup> Before receiving the inoculation,

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<sup>1</sup> Dkt. 24, *AstraZeneca Defendants' Motion to Dismiss Plaintiff's Complaint (Motion to Dismiss)*.

<sup>2</sup> *Sinclair Wyo. Ref. Co. v. A & B Builders, Ltd.*, 989 F.3d 747, 765 (10th Cir. 2021).

<sup>3</sup> Dkt. 1, *Complaint with Jury Demand (Complaint)*.

<sup>4</sup> *Id.* ¶¶ 7, 10.

<sup>5</sup> *Id.* ¶¶ 42–44.

Dressen signed an informed consent form (ICF) that outlined her rights and responsibilities as a trial participant and disclosed possible side effects of the vaccine.<sup>6</sup> Under the terms of the ICF, the parties agreed AstraZeneca would “reimburse[] for time and travel in the amounts of \$125.00 per each completed study visit and \$30.00 for each completed phone call.”<sup>7</sup> The parties also agreed that a “study doctor” would “provide medical treatment or refer [Dressen] for treatment” if Dressen became ill or injured while participating in the study.<sup>8</sup> Additionally, AstraZeneca disclosed that it had an insurance policy to “cover the costs of research injuries as long as [Dressen] followed [the] study doctor’s instructions.”<sup>9</sup> AstraZeneca confirmed it would “pay the costs of medical treatment for research injuries, provided that the costs are reasonable, and [Dressen] did not cause the injury [her]self.”<sup>10</sup> At the same time, the parties agreed federal law may limit Dressen’s right to sue for injuries caused by the vaccine:

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

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<sup>6</sup> *Id.* ¶¶ 8–9; Dkt. 1-1, *Informed Consent Form (ICF)*.

<sup>7</sup> *ICF* at 12.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 13. The ICF also noted a participant’s dismissal from the clinical trial would not jeopardize the availability of medical care and reimbursed expenses.

<sup>10</sup> *Id.*

for injuries may be available to you under this Countermeasures Injury Compensation Program.<sup>11</sup>

Within an hour of receiving the vaccine, Dressen's right arm began tingling.<sup>12</sup> The sensation, a condition called paresthesia, soon spread to her right shoulder and left arm.<sup>13</sup> Later the same day, Dressen began experiencing a host of other symptoms, including blurred vision, tinnitus, nausea, and sound sensitivity.<sup>14</sup> Dressen first visited an emergency room three days after receiving the vaccine.<sup>15</sup> The doctor who treated her diagnosed her with a "vaccine reaction."<sup>16</sup> She returned to the emergency room four days later, and the next day she visited a nurse practitioner at Utah Valley Neurological who diagnosed her with an "immunization reaction."<sup>17</sup> Thirteen days after receiving the vaccine, Dressen visited an otolaryngologist to seek care for "acute sensitivities to light and sound."<sup>18</sup> The doctor noted Dressen was suffering from "a likely side effect due to an increased immune response to the vaccine."<sup>19</sup>

After seven months of seeing different doctors, the National Institute of Health (NIH) invited Dressen to their Bethesda, Maryland campus for testing and treatment.<sup>20</sup> The NIH diagnosed Dressen with "Post Vaccine Neuropathy."<sup>21</sup> This condition caused Dressen to develop

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<sup>11</sup> *Id.*

<sup>12</sup> *Complaint* ¶ 11.

<sup>13</sup> *Id.* ¶¶ 12, 70.

<sup>14</sup> *Id.* ¶¶ 13, 70.

<sup>15</sup> *Id.* ¶ 73.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* ¶¶ 74–75.

<sup>18</sup> *Id.* ¶ 77.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* ¶¶ 28, 82.

<sup>21</sup> *Id.* ¶ 29.

dysautonomia and chronic inflammatory demyelinating polyneuropathy (CIDP).<sup>22</sup> Dressen alleges the “net result” is “constant, abnormal, and painful sensations, including the feeling of an electric shock coursing in her body.”<sup>23</sup> While the acute symptomology has improved, Dressen alleges she remains disabled three years after the inoculation and is “unable to work, unable to do any athletic activity, unable to parent the way she had, and unable to drive more than a few blocks at a time.”<sup>24</sup>

Dressen’s need for medical care and medication “skyrocketed” after receiving the vaccine.<sup>25</sup> Dressen and her husband repeatedly sought reimbursement for these costs from AstraZeneca to little or no avail. These efforts included 17 calls and emails between the Dressens and Velocity representatives from January 15, 2021 to July 13, 2021, resulting in a payment from AstraZeneca to Dressen of \$590.20.<sup>26</sup> However, Dressen informed Velocity that she intended to refuse the \$590.20 payment because it was “far less” than what she had sought, unless AstraZeneca confirmed additional payments would be forthcoming.<sup>27</sup> Dressen sought an update on her claim in August and again in November 2021.<sup>28</sup> Dressen allegedly received no response until December 17, 2021, when Velocity asked Dressen to accept a final settlement of all claims related to her clinical trial in exchange for \$1,243.30.<sup>29</sup>

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<sup>22</sup> *Id.* ¶ 30.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* ¶ 18.

<sup>25</sup> *Id.* ¶ 31.

<sup>26</sup> *Id.* ¶¶ 107–31.

<sup>27</sup> *Id.* ¶¶ 130–31.

<sup>28</sup> *Id.* ¶¶ 133, 135.

<sup>29</sup> *Id.* ¶¶ 133–39.

Dressen’s husband expressed dismay at the offer, replying via email “[w]e have a contract stating that they will cover medical bills, we have been waiting for this long to be insulted like this?”<sup>30</sup> In response, Velocity requested an updated accounting of Dressen’s medical expenses, and AstraZeneca eventually contacted Dressen directly to seek her authorization for the release of medical records and copies of her uninsured medical expenses.<sup>31</sup> Beginning April 8, 2022, AstraZeneca corresponded several times with Dressen, confirming receipt of medical records, seeking more information about Dressen’s providers, and informing Dressen AstraZeneca was “in the process of evaluating” her claims.<sup>32</sup> But all correspondence ceased on September 26, 2022.<sup>33</sup>

Dressen initiated this lawsuit against Velocity and AstraZeneca on May 13, 2024, bringing claims for breach of contract and breach of the duty of good faith and fair dealing.<sup>34</sup> Dressen voluntarily dismissed Velocity from suit on August 7, 2024.<sup>35</sup> AstraZeneca filed the present Motion to Dismiss on June 28, 2024 seeking to dismiss the Complaint for failure to state a claim.<sup>36</sup> The Motion is ripe for review.<sup>37</sup>

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<sup>30</sup> *Id.* ¶ 140.

<sup>31</sup> *Id.* ¶¶ 145–46.

<sup>32</sup> *Id.* ¶¶ 147–57.

<sup>33</sup> *Id.* ¶ 158.

<sup>34</sup> *Id.*

<sup>35</sup> Dkt. 27, *Plaintiff’s Notice of Voluntary Dismissal of Defendant Velocity Clinical Research, Inc.*

<sup>36</sup> *Motion to Dismiss.*

<sup>37</sup> *Motion to Dismiss*; Dkt. 26, *Plaintiff’s Opposition to AstraZeneca’s Motion to Dismiss (Opposition)*; Dkt. 38, *AstraZeneca Defendants’ Reply in Support of Motion to Dismiss Plaintiff’s Complaint (Reply)*; Dkt. 45, *Plaintiff’s Sur-Reply to AstraZeneca’s Motion to Dismiss (Sur-Reply)*; Dkt. 46, *AstraZeneca Defendants’ Notice of Supplemental Authority*; Dkt. 47, *Plaintiff’s Response to AstraZeneca Defendants’ Notice of Supplemental Authority*; Dkt. 48, *Minute Entry for 10/29/24 Motion Hearing (Minute Entry)*.

## LEGAL STANDARD

A motion to dismiss for failure to state a claim tests the sufficiency of the allegations within the four corners of the complaint after taking those allegations as true.<sup>38</sup> A complaint need not set forth detailed factual allegations, yet “[a] pleading that offers ‘labels and conclusions’ or a ‘formulaic recitation of the elements of a cause of action’” is insufficient.<sup>39</sup> “Under Rule 12, a defendant may raise an affirmative defense by a motion to dismiss for the failure to state a claim. If the defense appears plainly on the face of the complaint itself, the motion may be disposed of under this rule.”<sup>40</sup>

## ANALYSIS

AstraZeneca’s primary argument is that Dressen’s claims are barred by the Public Readiness and Emergency Preparedness Act (PREP Act),<sup>41</sup> which limits the liability of certain covered entities during public health emergencies.<sup>42</sup> The court disagrees. The court finds the text of the PREP Act exempts contractual violations from its scope of immunity. PREP Act immunity requires a causal link between the claim and a tangible medical countermeasure, and breach of contract claims arise from one party’s failure to perform a legal obligation without regard to any countermeasure. The PREP Act’s statutory scheme and purpose support this construction. Furthermore, Dressen’s breach of contract claim is not time-barred by the Utah Product Liability Act because Dressen does not allege the vaccine was defective and because

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<sup>38</sup> Fed. R. Civ. P. 12(b)(6); *Mobley v. McCormick*, 40 F.3d 337, 340 (10th Cir. 1994) (citing *Williams v. Meese*, 926 F.2d 994, 997 (10th Cir. 1991)).

<sup>39</sup> *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

<sup>40</sup> *Miller v. Shell Oil Co.*, 345 F.2d 891, 893 (10th Cir. 1965).

<sup>41</sup> 42. U.S.C. § 247d-6d.

<sup>42</sup> In the alternative, AstraZeneca argues the ICF expressly preserved its PREP Act immunity and any contractual language purporting to bind AstraZeneca to “cover the costs” of Dressen’s research injuries did not operate as a waiver of statutory immunity. *Motion to Dismiss* at 13–16. Because the court finds the PREP Act does not apply to claims for loss based on breach of contract, the court need not consider whether AstraZeneca waived its immunity.

there is express contractual privity between Dressen and AstraZeneca.<sup>43</sup> Finally, Dressen properly states a claim for breach of the duty of good faith because the duty is inherent in all contracts, and Dressen pleaded sufficient facts to state a plausible claim on this basis. Because Dressen’s causes of action are properly characterized, the court need not yet consider the extent or type of damages available to her.<sup>44</sup>

**I. The PREP Act Does Not Immunize Claims for Breach of Contract.**

**a. PREP Act Immunity Requires a Causal Link Between the Claim for Loss and the Covered Medical Countermeasure. That Link Is Missing in Breach of Contract Claims.**

The PREP Act authorizes the Secretary of Health and Human Services to limit a covered entity’s legal liability for losses caused by the “design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use” of a medical countermeasure by or to an individual during a public health emergency.<sup>45</sup> Dressen does not dispute that AstraZeneca is a covered entity, that the AstraZeneca vaccine is a covered countermeasure, nor that she received the vaccine during a public health emergency while the PREP Act was operative.<sup>46</sup> However, the parties dispute whether Dressen’s breach of contract claim falls within the scope of immunity afforded to AstraZeneca under the PREP Act.<sup>47</sup>

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<sup>43</sup> The court declines to take a position on whether the three-year statute of limitation for insurance contracts or six-year statute of limitation for breach of a written instrument applies to Dressen’s claim because AstraZeneca’s Motion rests on its view that the Utah Product Liability Act applies. AstraZeneca reserves the right to challenge Dressen’s timeliness based on the three-year statute of limitation for insurance contracts. *See Reply* at 12 n.6.

<sup>44</sup> *Daniels v. Thomas*, 225 F.2d 795, 797 (10th Cir. 1955) ([T]he prayer for relief is no part of the cause of action.”); *see also Cassidy v. Millers Cas. Ins. Co. of Texas*, 1 F. Supp. 2d 1200, 1214 (D. Colo. 1998) ([T]he only issue on a motion dismiss is whether the claim as stated would give the plaintiff a right to any relief, rather than to the particular relief demanded.”).

<sup>45</sup> 42. U.S.C. § 247d-6d(a)(2)(B).

<sup>46</sup> *Complaint* ¶ 32.

<sup>47</sup> *Motion to Dismiss* at 9–12; *Opposition* at 2–5.

Thus, the question before the court concerns the meaning of § 247d-6d(a), a PREP Act provision defining the scope of immunity provided to covered entities. In interpreting a statutory provision, the court “begins where all such inquiries must begin: with the language of the statute itself.”<sup>48</sup> Section 247d-6d(a) reads, in relevant part:

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure...

(2)(B) Scope

The immunity under paragraph (1) 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.

No court has definitively determined whether § 247d-6d(a) immunizes breach of contract claims against covered entities.<sup>49</sup> However, courts interpreting the statute have concluded the “all claims” language in § 247d-6d(a)(1) “indicates a sweeping statutory reach.”<sup>50</sup> This is consistent with “administration to or use,” which seemingly invites a wide range of possible

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<sup>48</sup> *Republic of Sudan v. Harrison*, 587 U.S. 1, 8 (2019) (citations omitted).

<sup>49</sup> Defendant cites an unpublished case from a California state trial court in which the court wrote the PREP Act “covers claims for loss sounding in tort or contract.” *Reply* at 3 (citing *Keyfman v. West Hills Hosp.*, No. 23VECV03136, 2023 WL 11781969, at \*1 (Cal. Super. Ct. Nov. 27, 2023) (unpublished)). However, the *Keyfman* court merely cited to the PREP Act itself for this assertion; it did not explain why the Act covers claims for loss sounding in contract. *See id.* In any case, that court’s discussion of the Act’s applicability to contract claims was ancillary to its holding because there was no contract disputed in the case.

<sup>50</sup> *Maney v. Brown*, 91 F.4th 1296, 1302 (9th Cir. 2024) (quoting *AK Futures LLC v. Boyd St. Distro, LLC*, 35 F.4th 682, 690–91 (9th Cir. 2022)).



activities to which immunity will extend.<sup>51</sup> A plain reading of § 247d-6d(a)(2)(B) broadens the scope of immunity even further by detailing the types of claims for loss to which immunity will apply, such as claims that have a causal relationship with the “marketing,” “promotion,” “purchase” or “sale” of covered countermeasures. The rule against surplusage mandates, if possible, every word in a statute must be given effect, and that none should needlessly be given an interpretation that causes it to have no consequence.<sup>52</sup> Accordingly, § 247d-6d(a)(2)(B) must be interpreted as adding to the nature of activities to which immunity will extend beyond “administration to or use” of a covered countermeasure, should there be a claim for loss causally related to those activities.<sup>53</sup> Indeed, § 247d-6d(a)(2)(B) repeats the word “administration” and “use” within the list of additional activities that can give rise to immunized claims for loss, which indicates losses causally related to “marketing,” “promotion,” “purchase” and “sale” of covered countermeasures are on similar statutory footing to claims for loss causally related to the “use” or “administration” of the covered countermeasure.

Notably, § 247d-6d(a)(1), titled “In general,” does not limit immunity to claims for loss that have a causal relationship with the “administration” or “use” of a covered countermeasure. Instead, it encompasses claims for loss that “relat[e] to” the “administration” or “use” of a covered countermeasure. Insofar as the terms “administration” or “use” are given special emphasis in the statute, it is that the other activities must be causally related to the claim for loss

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<sup>51</sup> *Use*, Black’s Law Dictionary (12th ed. 2024) (“To employ for the accomplishment of a purpose; to avail oneself of . . . .”); *see also Encompass Ins. Co. v. Coast Nat. Ins. Co.*, 764 F.3d 981, 986–87 (9th Cir. 2014) (interpreting “use” of a car broadly to encompass “unloading” a car).

<sup>52</sup> *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1039 (10th Cir. 2006).

<sup>53</sup> *See Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 401 (3d Cir. 2021) (“The scope of immunity is broad. Covered persons are immune from ‘any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure.’ That includes claims relating to ‘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.’”) (internal citations omitted).

to confer immunity, whereas it is arguable the “administration” or “use” of a covered countermeasure need only be related to the claim for loss.

However, § 247d-6d(a)(2)(B), titled “scope,” limits statutory immunity to claims for loss that have a causal relationship with covered countermeasures, including claims for loss caused by the “administration” or “use” of the countermeasure. Thus, because § 247d-6d(a)(2)(B) defines the “scope” of immunity, as opposed to § 247d-6d(a)(1), which describes the act’s “general” application, the court assumes causality is a necessary condition in all cases for the PREP Act to apply.<sup>54</sup> Indeed, the Supreme Court has explained if the “relate to” language, as used in § 247d-6d(a)(1), “were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes there would be no limits, as really, universally, relations stop nowhere.”<sup>55</sup> The Ninth Circuit applied this precise reasoning to the “relate to” language in the PREP Act, determining the phrase “takes on a more targeted meaning . . . The surrounding verbal phrases—‘caused by,’ ‘arising out of,’ and ‘resulting from,’—all connote some type of causal relationship.”<sup>56</sup>

Finally, § 247d-6d(a)(2)(B) also requires an *individual* to be associated with the statutorily listed activity for immunity to apply. For example, an individual’s “use” or “purchase” of the countermeasure, or the “administration” or “marketing” of the countermeasure “to” an individual, must be the basis for the causal relationship between the statutorily listed activity and the claim for loss. Of course, non-person entities may still be barred from bringing

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<sup>54</sup> See *Padilla v. Brookfield Healthcare Ctr.*, No. CV 21-2062-DMG (ASX), 2021 WL 1549689, at \*4–6 (C.D. Cal. Apr. 19, 2021) (declining to expansively read the “relate to” language to encompass a covered entity’s inaction regarding covid countermeasures). This construction is also consistent with the statute’s purpose as discussed in more detail below.

<sup>55</sup> *Dubin v. United States*, 599 U.S. 110, 119 (2023).

<sup>56</sup> *Hampton v. California*, 83 F.4th 754, 764 (9th Cir. 2023) (internal citations omitted).

suit against covered entities under the PREP Act when they are suing on behalf of individuals that engaged in a statutorily immunized activity.<sup>57</sup> Furthermore, nothing in the statute suggests the claim for loss can only be brought by *the* individual who “use[d]” the countermeasure, or *the* individual to whom the countermeasure was “administ[ered].” Rather, the claim for loss—whether brought by an entity or an individual—must have been caused by *an* individual’s association with the countermeasure through one of the statutorily listed activities.<sup>58</sup>

Despite the statute’s seemingly broad scope, covered entities have twice invoked PREP Act immunity in breach of contract cases, and in both instances the court determined immunity did not apply.<sup>59</sup> Both cases involved buyers of defective COVID tests suing manufacturer-sellers.<sup>60</sup> Although the sellers were covered entities and COVID tests were covered countermeasures, both courts determined PREP Act immunity did not apply because the buyers did not allege loss causally related to the administration of a covered countermeasure.<sup>61</sup>

Neither court provided significant analysis as to why the causal relationship was lacking, nor why the buyer’s claims otherwise did not fit within the scope of § 247d-6d(a)(2)(B). In *WorkCare*, the court opined “the PREP Act does not on its face provide immunity for state contract claims,” but determined “[u]nder a common-sense reading of the statute, Defendant has

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<sup>57</sup> See *Fusion Diagnostic Lab ’ys, LLC. v. Atila Biosys, Inc.*, No. 2:24-CV-00184 (WJM), 2024 WL 3024915, at \*2 (D.N.J. June 17, 2024) (unpublished).

<sup>58</sup> See, e.g., *M.T. ex rel. M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1084 (Kan. Ct. App. 2023) (holding a mother’s claims against a covered entity for its failure to obtain parental consent for its administration of the COVID vaccine to her child fell within the scope of PREP Act immunity, even though she herself was not administered any countermeasure); *Happel v. Guilford Cty. Bod. of Ed.*, 899 S.E.2d 387, 393–94 (N.C. App. 2024) (the “broad scope of immunity provided by the PREP Act applies” to “[p]laintiffs’ claims relating to the administration of the COVID-19 vaccine” without parental consent); *Parker v. St. Lawrence County Pub. Health Dept.*, 102 A.D.3d 140, 143–44 (N.Y. App. Div. 2012) (preemption clause and “sweeping” immunity language of the PREP Act barred all state law tort claims based on defendant’s “failure to obtain [parental] consent” to use of countermeasure).

<sup>59</sup> *Fusion Diagnostic Lab ’ys*, 2024 WL 3024915; *WorkCare, Inc. v. Plymouth Med., LLC*, No. 8:21-cv-00864, 2021 WL 4816631 (C.D. Cal. Aug. 20, 2021) (unpublished).

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

not engaged in the ‘administration’ of covered countermeasures.”<sup>62</sup> The court did not address the fact that § 247d-6d(a)(2)(B) also immunizes claims for losses that have a causal relationship with the “sale” and “purchase” of covered countermeasures.

In *Fusion*, the Plaintiff alleged “extensive” damage to its business reputation resulting from its inability to timely release COVID test results because of faulty test kits provided by the seller.<sup>63</sup> The court dealt with the issue similarly, positing covered entities are “not immune under the PREP Act from Plaintiff’s state law breach of contract claims,” while tethering its holding to the fact the plaintiff did not “allege loss from the ‘administration to or the use by an individual’ of a covered countermeasure.”<sup>64</sup> However, as in *WorkCare*, the court did not explain why Plaintiff’s claim for loss did not fit the statutory examples of immunity outlined in 247d-6d(a)(2)(B), nor why the causal relationship was lacking. Instead, the court relied on a failure to warn case involving the drug Remdesivir to opine that PREP Act immunity is “typically” asserted where the plaintiff asserts harm stemming from the “actual administration, delivery, or distribution” of the countermeasure.<sup>65</sup> It is unclear why the court found there was no “actual administration” in this case, although the court implies that it was relevant that the buyer-plaintiff was not the individual to whom the countermeasure was administered.<sup>66</sup>

In yet another case, *Haro v. Kaiser Foundation Hospitals*, a covered entity unsuccessfully invoked PREP Act immunity where an employee sued her employer under a California minimum

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<sup>62</sup> *WorkCare*, 2021 WL 4816631, at \*5.

<sup>63</sup> *Fusion Diagnostic Lab ’ys*, 2024 WL 3024915, at \*1.

<sup>64</sup> *Id.* at \*2 (relying on the definition of “administration” as provided by the Secretary of Health and Human Services in Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15201, 15202 (Mar. 17, 2020)).

<sup>65</sup> *Id.* at \*2 (citing *Fust v. Gilead Sciences, Inc.*, No. 23-2853, 2024 WL 732965 (E.D. Ca. Feb. 21, 2024)).

<sup>66</sup> *Id.*

wage statute for failing to compensate her for time spent taking mandated COVID tests, which required her to arrive at work 15 minutes before the start of her shift.<sup>67</sup> The court reasoned her claim was not “causally connected to any of [defendant’s] covered countermeasures” because the defendant “could just as easily have implemented the screenings without the requirement that employees show up early. In that case, the screening procedures would simply have occurred while employees were on the clock and [plaintiff] would not have a minimum-wage claim.”<sup>68</sup> Another court in *Redd v. Amazon.com, Inc.* seeking to distinguish *Haro* noted “the employer’s administration and use of the covered countermeasures did not contribute to that financial injury—whether the early arrival was for a COVID-19 screening or another work-related requirement was irrelevant because the cause of the injury was the unpaid time.”<sup>69</sup> In *Redd*, the court determined the PREP Act preempted the Illinois Biometric Information Privacy Act insofar as it purported to afford a cause of action for privacy injuries stemming from the defendant’s use of a COVID countermeasure.<sup>70</sup> There, because the plaintiff’s privacy claim stemmed “exclusively” from defendant’s use of thermal cameras (a covered COVID countermeasure) to screen employees’ temperatures, the court reasoned plaintiff’s claim for loss (a privacy injury) was barred by the PREP Act.<sup>71</sup>

AstraZeneca characterizes *Fusion*, *WorkCare*, and *Haro* as “run-of-the-mill commercial disputes that plainly do not involve administration or use of a covered countermeasure” and therefore argues the courts appropriately determined the PREP Act did not apply.<sup>72</sup> On the other

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<sup>67</sup> 2020 WL 5291014 (C.D. Cal. Sept. 3, 2020) (unpublished).

<sup>68</sup> *Id.* at \*3.

<sup>69</sup> No. 20 C 6485, 2024 WL 2831463, at \* 6 (N.D. Ill. June 4, 2024).

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Reply* at 5.

hand, AstraZeneca contends Dressen's injury is precisely the type of injury immunized by the PREP Act because it arose from the administration of a covered countermeasure.<sup>73</sup> In asserting this causal link, AstraZeneca cites Paragraph 68 of Dressen's Complaint, which states "[Dressen] confirmed her agreement by signing the Consent Form, rolling up her sleeve, and allowing [AstraZeneca's] agent to inject the experimental substance into her arm."<sup>74</sup> Beyond this, AstraZeneca assumes a causal link between Dressen's claim for loss and the covered countermeasure without explaining its basis for the assumption.

Dressen counters by emphasizing the text of § 247d-6d(a)(2)(B), which she alleges would have necessarily encompassed these "run-of-the-mill" disputes but for the PREP Act categorically denying immunity for breach of contract claims.<sup>75</sup> Dressen notes that, if PREP Act immunity extends to claims for breach of contract, "it is hard to conceive of a contract breach regarding Covid-19 vaccines that is not causally related to the 'use,' 'distribution,' 'marketing,' 'promotion,' 'purchase,' and/or 'sale' of these products."<sup>76</sup>

Dressen highlights a serious problem with AstraZeneca's theory of PREP Act immunity and its interpretation of *Fusion* and *WorkCare*. As discussed above, *Fusion* and *WorkCare* largely ignored § 247d-6d(a)(2)(B)'s broad scope of immunized activities, and so does AstraZeneca. The provision plainly immunizes claims for loss causally related to activities beyond the "administration" or "use" of a covered countermeasure. Even so, the buyer-plaintiff in *Fusion* did engage in the "administration" of COVID tests and alleged reputational damage therefrom. Accordingly, AstraZeneca's attempt to distinguish *Fusion* and *WorkCare* from this

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<sup>73</sup> *Id.*

<sup>74</sup> *Id.* (citing *Complaint* ¶ 68).

<sup>75</sup> *Sur-Reply* at 1–2.

<sup>76</sup> *Id.* at 2.

case because Dressen’s claim plainly involves the “administration” of a COVID countermeasure is unpersuasive.<sup>77</sup>

Still, Dressen does not provide the court a textual basis for her argument that § 247d-6d(a) excludes breach of contract claims from its scope of immunity. And *Fusion* and *WorkCare*—despite their skepticism of whether the PREP Act applies to state law breach of contract claims—did not formally couch their holdings on that foundation.

The court finds textual basis for excluding breach of contract claims from PREP Act immunity in § 247d-6d(a)(2)(B)’s requirement that the claims for loss be *causally* related to the specified set of immunized activities.<sup>78</sup> A contract “is a promise or a set of promises, for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty.”<sup>79</sup> Damages on a contract are triggered by a breach—a party’s unexcused non-performance of a legal duty.<sup>80</sup> The “administration” or “use” of a tangible object like a “covered countermeasure” cannot, by itself, *cause* a breach of contract in the same way it can *cause* tortious injury. Indeed, the causation element in a breach of contract claim requires the breach to have caused damages,<sup>81</sup> whereas the causation element in traditional products liability

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<sup>77</sup> At Oral Argument, AstraZeneca offered an additional theory to distinguish this case from *Fusion* not included in its briefing: the plaintiff-buyer was not the “individual” to whom the countermeasure was physically administered. See *Minute Entry*. Thus, according to AstraZeneca, even though the plaintiff-buyer did administer the countermeasure to *other* individuals, the causation element was not met because the buyer himself was not physically subjected to the countermeasure. This distinction does not resolve the quagmire presented by the plain language in § 247d-6d(a)(2)(B), which does not require the *plaintiff* to have been the “individual” subjected to the countermeasure—only that the claim for loss be causally related to *an* individual’s engagement with the countermeasure through a statutorily listed activity.

<sup>78</sup> Dressen persuasively argues that interpreting the statute to extend total immunity for breach of contract claims may implicate the takings clause which can otherwise be avoided by strictly construing the “causation” requirement. See *Opposition* at 5–6 n.3. The canon of constitutional avoidance thus counsels in favor of this interpretation.

<sup>79</sup> Restatement (Second) of Contracts § 1 (Am. Law Inst. 1981).

<sup>80</sup> *Id.* § 346.

<sup>81</sup> See, e.g., *Hi-Country Ests. Homeowners Ass’n v. Bagley & Co.*, 262 P.3d 1188, 1190 (Utah Ct. App. 2011) (requiring proof that damages were “caused by the alleged breach”).

or failure to warn cases focuses on whether the defective item at issue proximately caused damages.<sup>82</sup> The viability of a breach of contract claim depends first on contractual language, not any tangible items.

Although the court in *Fusion* correctly noted that “state law breach of contract claims” are not immunized by the PREP Act, it is this court’s view that the analysis could have stopped there.<sup>83</sup> The seller of defective COVID tests found no refuge in the PREP Act because the buyer’s claim for loss was caused by the seller’s failure to furnish conforming goods as specified in their contract—not because the buyer was not the “individual recipient[]” to whom the countermeasure was “administered” like the “typical” PREP Act case.<sup>84</sup> It is difficult to see how the reputational harm alleged by the plaintiff in *Fusion* was not “caused” by its “purchase” of a covered countermeasure that was “administered” to “individual” consumers as described in § 247d-6d(a)(2)(B), unless the statute is construed to exempt from its scope of immunity liability caused by breach of contract.

However, even if the *Fusion* court and AstraZeneca are correct that the causal relationship in *Fusion* was lacking because the plaintiff *itself* was not an “individual” subjected to the administration of the countermeasure,<sup>85</sup> an argument that does not precisely align with the text of the PREP Act nor the case law interpreting it,<sup>86</sup> it does not follow that the causation

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<sup>82</sup> See, e.g., *Ahrens v. Food Motor Co.*, 340 F.3d 1142, 1145 (10th Cir. 2003) (“To prevail on their claim based on strict product liability or design defect, Plaintiffs must establish . . . the defect proximately caused Plaintiffs’ injuries.”); *House v. Armour of Am., Inc.*, 929 P.2d 340, 346 (Utah 1996) (“[I]f the event which produced the injury would have occurred regardless of the defendant’s conduct, then the failure to provide a warning is not the proximate cause of the harm and the plaintiff’s claim must fail.” (internal quotations omitted)).

<sup>83</sup> *Fusion Diagnostic Lab’ys*, 2024 WL 3024915, at \*2.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*; *Minute Entry*.

<sup>86</sup> *C.f. M.T. ex rel. M.K.*, 528 P.3d at 1084 (mother’s claims were barred by the PREP Act even though the vaccine was administered to her child).



element is necessarily met whenever there is a plaintiff-individual to whom the covered countermeasure was physically “administered.” In fact, *Haro* counsels the presence of such an individual does not automatically satisfy the causation element in § 247d-6d(a)(2)(B). There, the plaintiff-employee was an individual recipient of an “administered” countermeasure because she was required to report to work 15 minutes early to take COVID tests.<sup>87</sup> However, as the *Redd* court noted, the employee’s legal injury was not *caused* by the countermeasure.<sup>88</sup> This was because the employee would have had a claim against her employer whether she spent the 15 unpaid minutes taking a required COVID test or completing any other required activity not related to a covered countermeasure.<sup>89</sup>

Here, just as in *Haro*, Dressen’s claim is agnostic to the covered countermeasure at issue because her claim for loss would be characterized no differently had the clinical trial been for a drug unrelated to pandemic preparedness. Dressen does not allege her legal injury is causally related to a COVID countermeasure; rather, she alleges it is causally related to AstraZeneca’s failure to perform its bargained-for duty as outlined in the ICF.<sup>90</sup> In other words, the basis of Dressen’s claim is a broken promise, not a countermeasure, just like the basis of *Haro*’s claim was being required to arrive at work early, and not the countermeasure itself.

In essence, the *Haro* court reasoned that the causation element in the PREP Act can only be met if the administration or use of the countermeasure at issue is an independently sufficient

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<sup>87</sup> *Haro*, 2020 WL 5291014, at \*1.

<sup>88</sup> *Redd*, 2024 WL 2831463, at \*6.

<sup>89</sup> *Id.*

<sup>90</sup> Complaint ¶¶ 33–36.

condition for the asserted claim.<sup>91</sup> Here, Dressen was administered a covered countermeasure, and she was warned that she may suffer from an adverse reaction, but the fact that she suffered from such reaction was not sufficient to ripen her claim. Rather, she only has a claim because AstraZeneca made a contractual promise to her that happened to involve the effects of a covered countermeasure. Accordingly, Dressen’s claim for loss was not “caused” by a covered countermeasure.

Dressen does not allege the AstraZeneca vaccine was defective, that AstraZeneca failed to properly disclose vaccine side effects, the labels on the vaccines were deceptive, nor the way the vaccine was advertised caused her harm. These unasserted claims are likely barred by the PREP Act because they are statutorily listed in § 247d-6d(a)(2)(B) as activities that can give rise to immunity, and because such claims likely involve harm that is causally related to those activities. But because Dressen’s claim for loss was allegedly caused by AstraZeneca’s failure to “cover the costs” of a research injury as required by the ICF,<sup>92</sup> it is not barred by the PREP Act. AstraZeneca fundamentally confuses Dressen’s research injury with her legal injury; the legal injury is not barred by the PREP Act because the research injury is not a sufficient condition for her claim. This construction of the statute’s causation requirement is consistent with every case AstraZeneca relies on for its proposition that the PREP Act has a broad scope, none of which involve any breach of express contract.<sup>93</sup>

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<sup>91</sup> *C.f. Redd*, 2024 WL 2831463, at \*6 (determining that the PREP Act applied because Plaintiff’s privacy injury was “exclusively attributable” to the thermal cameras—a covid countermeasure—unlike the Plaintiff’s financial injury in *Haro*).

<sup>92</sup> *ICF* at 13.

<sup>93</sup> *Motion to Dismiss* at 11–12 (citing a personal injury case allegedly caused by deceptive marketing and advertising, *Fust*, 2024 WL 732965 (E.D. Cal. Feb. 21, 2024); citing a personal injury case involving a slip and fall after the administration of a vaccine, *Storment v. Walgreen, Co.*, No. 1:21-CV-00898 MIS/CG, 2022 WL 2966607 (D.N.M. July 27, 2022); citing a personal injury case caused by a failure of the vaccine administrator to disclose which vaccine manufacturer supplied the vaccine, *Bird v. State*, 2023 WY 102, 537 P.3d 332 (Wyo. 2023); citing a personal injury case dealing with lack of parental informed consent, *M.T. ex rel. M.K.*, 528 P.3d 1067)).

Importantly, even if the broader “relate to” language in § 247d-6d(a)(1) is operative, courts have construed it strictly, such that claims for breach of contract would still not fit the bill. For example, the failure of a nursing home to implement appropriate countermeasures in its facilities did not “relate to” the administration of a countermeasure under the PREP Act,<sup>94</sup> nor did a healthcare center’s failure to properly screen patients for COVID.<sup>95</sup> Indeed, if “relate to” is the operative statutory nexus between the claim for loss and the covered countermeasure, and if AstraZeneca concedes the claim for loss in *Fusion* is outside the scope of the PREP Act,<sup>96</sup> then AstraZeneca impliedly concedes “relate to” ought to be construed strictly. A buyer claiming a manufacturer-seller harmed its business reputation by providing it defective COVID tests which the buyer individually administered to consumers certainly “relates to” the “use” of a countermeasure by an “individual,” unless “relates to” is construed to require a more robust nexus between the claim for loss and the covered countermeasure (*i.e.*, a construction more closely resembling a causal relationship).<sup>97</sup> Thus, under § 247d-6d(a)(1), breach of contract claims—even those involving covered vaccines— do not “relate to” the administration or use of a covered countermeasure.

**b. The Prep Act’s Statutory Scheme Suggests Only Tort-Like Claims for Loss Are Immunized.**

The Supreme Court counsels that courts ought not “construe words in a vacuum” and instead requires that statutes “be read in their context and with a view to their place in the overall

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<sup>94</sup> *Smith v. Colonial Care Ctr., Inc.*, No. 2:21-CV-00494-RGK-PD, 2021 WL 1087284, at \*3–4 (C.D. Cal. Mar. 19, 2021), *aff’d sub nom. Smith v. Colonial Care Ctr.*, No. 21-55377, 2023 WL 4103937 (9th Cir. June 21, 2023).

<sup>95</sup> *Padilla*, 2021 WL 1549689 at \*4–6. (C.D. Cal. Apr. 19, 2021) (relying on Office of the General Counsel’s advisory opinion construing PREP Act immunity to only extend to claims of “inaction” when there were limited countermeasures available, and they were administered to one individual instead of another).

<sup>96</sup> *See Reply* at 5.

<sup>97</sup> *See Hampton v. California*, 83 F.4th 754, 764 (9th Cir. 2023) (“The surrounding verbal phrases—‘caused by,’ ‘arising out of,’ and ‘resulting from,’—all connote some type of causal relationship.”).

statutory scheme.”<sup>98</sup> Reading Section 247d-6d(d) in conjunction with Section 247d-6d(a) sheds light on the types of claims the PREP Act intended to immunize.

Section 247d-6d(d) reads, in relevant part:

the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person.

Willfulness speaks to an individual’s state of mind, and it is an aggravating factor in tort.<sup>99</sup>

Generally, contract law is unconcerned with a breaching party’s state of mind because it seeks to promote value-maximizing transactions, and when a contract ceases to be economically efficient for one party, the law declines to punish a party for willfully breaching it.<sup>100</sup> The fact that Section 247d-6d(d) makes an exception for aggravated tortious conduct from the scope of immunity outlined in 247d-6d(a) suggests that 247d-6d(a) was primarily concerned with non-willful tortious conduct in the first place. Indeed, Section 247d-6d(d) notes willful misconduct “shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.” This provision serves as additional evidence that it was primarily negligent and reckless conduct that the PREP Act sought to immunize, both of which generally have no bearing on contract law.

The reason 247d-6d(d) explicitly exempted only willful misconduct from its scope of immunity, as opposed to any mention of contract law, is likely because the drafters did not consider 247d-6d(a) to extend its scope of immunity to claims for breach of contract. To be sure, the PREP Act may still preempt state law affording statutory causes of action that expressly

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<sup>98</sup> *W. Virginia v. Env’t Prot. Agency*, 597 U.S. 697, 721 (2022) (citation omitted).

<sup>99</sup> *Griess v. Consol. Freightways Corp. of Delaware*, 882 F.2d 461, 463 (10th Cir. 1989) (citation omitted).

<sup>100</sup> Robert L. Birmingham, *Breach of Contract, Damage Measures, and Economic Efficiency*, 24 Rutgers L. Rev. 273, 284 (1970).

conflict with the PREP Act or impede its field of regulation, such as when the cause of action directly originates from the deployment of a covered countermeasure through a statutorily listed activity outlined in 247d-6d(a)(2)(B).<sup>101</sup> However, the PREP Act's overall scheme wherein only willful misconduct is exempted from the scope of immunity suggests that claims for breach of contract were not within the contemplated scope of immunity to begin with.

**c. Immunizing AstraZeneca from Breach of Contract Claims Runs Counter to the Purpose of the PREP Act.**

AstraZeneca correctly identifies the PREP Act's vital purpose is "[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."<sup>102</sup> However, AstraZeneca provides no support for its argument that immunizing it against breach of contract claims furthers this purpose.

Indeed, Dressen argues the opposite is true, emphasizing the sanctity of contractual obligations as "the bedrock for a healthy business environment."<sup>103</sup> The sanctity of contract is precisely what allegedly induced Dressen to participate in Velocity's clinical trial involving a "experimental" vaccine.<sup>104</sup> It is generally in the public interest to "enforce valid contracts and make parties live up to their agreements."<sup>105</sup> If the PREP Act immunized deceptive contractual inducement and sanctioned illusory promises, then no one would agree to undertake the high-risk

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<sup>101</sup> *Redd*, 2024 WL 2831463, at \*6.

<sup>102</sup> *Motion to Dismiss* at 9 (quoting *Cannon v. Watermark Ret. Cmty., Inc.*, 45 F.4th 137, 138–39 (D.C. Cir. 2022)).

<sup>103</sup> *Opposition* at 4–5.

<sup>104</sup> *Complaint* ¶¶ 6, 10, 40, 68; *ICF* at 11.

<sup>105</sup> *Rebath LLC v. New England Bath Inc.*, No. CV-16-01700-PHX-DLR, 2016 WL 8670165, at \*6 (D. Ariz. July 15, 2016).

activities that are critical during public health emergency responses. The PREP Act drafters could not have intended to allow pharmaceutical companies to make illusory promises to clinical trial participants because doing so would erode public trust and undermine the ability to recruit willing participants, which in turn would erode and undermine pandemic preparedness. Critically, covered entities will not be hindered in rapidly developing and deploying medical countermeasures during a public health emergency by virtue of being held accountable to their contractual obligations, into which they are free to enter or avoid. To the contrary, requiring covered entities to adhere to their contracts will ensure maximal cooperation between covered entities and consumers during the most critical stages of pandemic response. The speed and agility with which covered entities can operate during public health emergencies due to their widespread tort immunity would be undermined if the *express* promises they make along the way were not enforceable. Accordingly, interpreting the PREP Act as including breach of contract claims in its scope of immunity would be inconsistent with its purpose.<sup>106</sup>

Furthermore, AstraZeneca's construction of the PREP Act produces absurd results contrary to the statute's purpose. For example, under the terms of the ICF, Dressen was entitled to "time and travel" reimbursements in the amount of \$125.00 per study visit during the clinical trial with Velocity.<sup>107</sup> AstraZeneca's theory of immunity would allow it to shirk this and any other promise made to trial participants merely because the promise ultimately relates to the administration or use of a vaccine. Such a theory would invite rank abuse among covered entities to make illusory promises to unwitting consumers. The "absurdity doctrine" is a rule of

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<sup>106</sup> See, e.g., *Leonard v. Ala. State Bd. of Pharmacy*, 61 F.4th 902, 914 (11th Cir. 2023) (considering the PREP Act's purpose in evaluating the scope of preemption); *Forrester v. White*, 484 U.S. 219, 224 (1988) ("[T]he Court has been careful not to extend the scope of [legislative immunity] further than its purposes require.").

<sup>107</sup> *ICF* at 12.

statutory construction counseling that “interpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available.”<sup>108</sup> The doctrine applies “only when it would have been unthinkable for Congress to have intended the result commanded by the words of the statute—that is, when the result would be so bizarre that Congress could not have intended it.”<sup>109</sup> AstraZeneca’s interpretation of the PREP Act must be avoided not only because it is textually suspect, but also because Dressen’s alternative theory prevents the exceedingly bizarre result of encouraging covered entities to lure unwitting consumers through illusory promises.

## II. Dressen’s Breach of Contract Claim Is Not Time Barred.<sup>110</sup>

AstraZeneca next argues Dressen’s breach of contract action is time barred by the Utah Product Liability Act.<sup>111</sup> AstraZeneca avers Dressen’s claim is a product liability action seeking damages for a defective product despite the Complaint “framing this case as a contract dispute.”<sup>112</sup> To support this argument, AstraZeneca relies on Utah case law stating “[t]he Utah Product Liability Act applies to actions in tort and contract, arising from injury caused by a defective product.”<sup>113</sup>

The court is unpersuaded. The plain text of the Utah Product Liability Act does not apply because Dressen does not allege AstraZeneca’s vaccine was defective. The ICF disclosed that adverse reactions may occur,<sup>114</sup> and the fact that Dressen suffered such a reaction did not cause

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<sup>108</sup> *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) (citation omitted).

<sup>109</sup> *Robbins v. Chronister*, 435 F.3d 1238, 1241 (10th Cir. 2006) (quoting *Demarest v. Manspeaker*, 498 U.S. 184, 190–91 (1991)).

<sup>110</sup> Both parties apply Utah law to this claim, and the court finds no reason to apply the law of any other jurisdiction.

<sup>111</sup> *Motion to Dismiss* at 16–19; *Reply* at 9–12.

<sup>112</sup> *Motion to Dismiss* at 16.

<sup>113</sup> *Id.* at 16 (quoting *Utah Loc. Gov’t Tr. v. Wheeler Machinery Co.*, 199 P.3d 949, 957 (Utah 2008)).

<sup>114</sup> *ICF* at 9–11.

her claim to ripen. AstraZeneca relies on inapplicable case law imposing a two-year statute of limitations on *breach of implied warranty* claims. In *Utah Local Government Trust v. Wheeler Machinery Company*,<sup>115</sup> the court reasoned implied warranty claims fit naturally under the Utah Product Liability Act's statute of limitations scheme despite their technical designation as actions in contract because of their factual, historical, and conceptual similarity to product liability actions.<sup>116</sup> Here, Dressen does not allege a breach of warranty claim. There is no allegation of a defective product in the Complaint, and there is express contractual privity between AstraZeneca and Dressen. AstraZeneca's liability will depend on its breach of express ICF terms, not any implied warranties about the vaccine itself.

AstraZeneca attempts to sidestep the text of the Utah Product Liability Act and the caselaw expanding its application to breach of warranty claims by arguing the "substance" of Dressen's pleading "sounds" in product liability and should therefore be subject to the Act.<sup>117</sup> In other words, AstraZeneca asks this court to re-characterize Dressen's claim as a product liability action because the "nature of the action" sounds in tort and the "pleading labels" Dressen chose

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<sup>115</sup> 199 P.3d 949 (Utah 2008).

<sup>116</sup> *Id.* at 955–56.

<sup>117</sup> *Motion to Dismiss* at 16, 19.



are not dispositive.<sup>118</sup> This argument is unavailing because the nature of Dressen’s action is entirely consistent with the breach of contract pleading label she chose. Her Complaint details the contractual promises she alleges AstraZeneca breached but makes no allegation that the vaccine was defective. While Dressen’s prayer for relief may seek damages typically associated with a product liability claim, that does not require the court to re-characterize her Complaint.<sup>119</sup> This is especially true given AstraZeneca concedes the damages Dressen seeks—past and future medical expenses, lost income, emotional damages, and attorneys’ fees—are plausibly consistent with her claim for the breach of the Implied Duty of Good Faith and Fair Dealing and the circumstances surrounding the ICF, even if some of these damages would be awarded in only exceedingly “rare” breach of contract actions.<sup>120</sup>

Furthermore, notwithstanding AstraZeneca’s contention that the Utah Product Liability Act governs this action, it concedes that a plaintiff with “viable” claims in tort and breach of

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<sup>118</sup> *Reply* at 10 (citing *Failor v. MegaDyne Med. Prods., Inc.*, 213 P.3d 899, 905 (Utah Ct. App. 2009)). At Oral Argument, AstraZeneca argued that the “nature” of an action pleaded as breach of express contract—but which actually involves a product that caused physical harm and which does not fit neatly as a contract for a service or a good—is functionally a product liability action (and therefore should be subject to the Utah Product Liability Act statute of limitations). See *Minute Entry*. As already discussed, the case law does not support this expansive construction of the Utah Product Liability Act, but rather focuses the Act’s application to breach of implied warranty cases. See *Wheeler Machinery*, 199 P.3d 949 at 955–56). Nor does the case law support AstraZeneca’s theory of this court’s power to re-characterize a complaint that is “clearly base[d]” on a breach of an agreement. See *Records v. Briggs*, 887 P.2d 864, 869 (Utah Ct. App. 1994) (declining to re-characterize a contract claim into a tort claim when the plaintiff “clearly bases” the claim on a breached agreement). AstraZeneca’s argument would swallow whole the rights of private parties that entered into express contracts that provide legal protection that does not precisely mirror the protections afforded by product liability law. Although Dressen’s suit involves a product that caused her harm, the ICF is plainly a service contract that promised to “provide medical treatment or refer [Dressen] for treatment” and “cover the costs” of the treatment if such harm were to occur. See *ICF* at 13. These express promises impose unique contractual obligations on AstraZeneca that may not be captured by the Utah Product Liability Act. AstraZeneca provides no authority suggesting that such promises can be disregarded merely because they relate to a product that caused harm, especially where there is no allegation that the product was defective.

<sup>119</sup> *Records*, 887 P.2d 864 at 869.

<sup>120</sup> See *Minute Entry*.

express contract can generally elect to sue under either theory.<sup>121</sup> However, this is not so when the “tort alleges a breach of a duty that the contract itself imposes.”<sup>122</sup> In that case, the economic loss rule mandates that the plaintiff seek only contract-based remedies.<sup>123</sup> Here, contrary to AstraZeneca’s contention that Dressen can “only” sue in tort,<sup>124</sup> the opposite is likely true: the economic loss rule would have barred Dressen from bringing any tort action because AstraZeneca’s sole duty with respect to the vaccine was imposed via contract because of its immunity from tort liability under the PREP Act. Accordingly, even if the court were to accept AstraZeneca’s theory that the Utah Product Liability Act governs claims for breach of express contractual agreements whose “nature” involves products that cause harm—which the court does not—the economic loss rule likely would have prevented Dressen from making a claim under the Utah Product Liability Act in the first place. It cannot be that the Utah Product Liability Act’s statute of limitation governs a claim that could not have been brought under the Act in the first place. Still, even if the economic loss rule did not apply, Dressen could freely pursue this contract-based action even though the Utah Product Liability Act statute of limitation expired because she does not allege a claim within the scope of that Act, and because AstraZeneca fails to challenge any element of Dressen’s breach of contract claim. Rather, AstraZeneca only insists

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<sup>121</sup> *Reply* at 10; see *Ward v. Intermountain Farmers Ass’n*, 907 P.2d 264, 267 (Utah 1995) (“Although such a fact scenario could also give rise to a tort claim, it contains all of the elements of a contract action. [Plaintiff] may therefore elect in this case to waive the tort and sue on the contract.”); Restatement (Second) of Torts § 899 cmt. b (Am. Law Inst. 1965) (“An act and its consequences may be both a tort and a breach of contract... When this is so, the injured person, although barred by a statute from maintaining an action of tort may not be barred from enforcing his contractual . . . right or vice versa.”); *Brigham Young Univ. v. Paulsen Const. Co.*, 744 P.2d 1370, 1372–73 (Utah 1987) (holding that negligent failure to perform contractual duties may be brought as contract action and is not barred by tort statute of limitations).

<sup>122</sup> *KTM Health Care Inc. v. SG Nursing Home LLC*, 436 P.3d 151, 170 (Utah Ct. App. 2018).

<sup>123</sup> *Id.*

<sup>124</sup> *Reply* at 10.

that the claim should be re-characterized as a tort claim, but the court declines to do so for the reasons already stated.

### **III. Dressen Plausibly Stated a Claim for Breach of the Implied Duty of Good Faith.**

AstraZeneca contends Dressen’s claim for Breach of the Implied Duty of Good Faith is barred by the PREP Act and “meritless.”<sup>125</sup> Because the Implied Duty of Good Faith is “one species of breach of contract,”<sup>126</sup> the court concludes that PREP Act immunity does not extend to claims for breach of this duty. In support of its contention that Dressen’s claim for breach of the Implied Duty of Good Faith is “meritless,” AstraZeneca relies on caselaw noting that the duty “cannot be read to establish new, independent rights or duties . . . nor create rights or duties inconsistent with express contractual terms.”<sup>127</sup> AstraZeneca does not proffer any argument as to which rights or duties Dressen seeks to create or establish that are inconsistent with the ICF—only that she asserts “an amorphous, unbounded right to recovery from AstraZeneca.”<sup>128</sup> While Dressen may or may not be entitled to the full extent of damages she seeks, Dressen simply alleges AstraZeneca acted with “unconscionable delay” in fulfilling contractual obligations, despite her repeated queries as to when the obligations would be performed.<sup>129</sup> Nowhere does she create a right or duty that does not exist in the contract by virtue of invoking the covenant of good faith and fair dealing.

Accepting as true Dressen’s allegations set forth in the Complaint, she has plausibly pleaded facts sufficient to show AstraZeneca “intentionally or purposely. . . destroy[ed] or

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<sup>125</sup> *Motion to Dismiss* at 22–23.

<sup>126</sup> *Ole Mexican Foods Inc. v. J & W Distribution LLC*, 549 P.3d 663, 673 (Utah Ct. App. 2024).

<sup>127</sup> *Motion to Dismiss* at 24.

<sup>128</sup> *Id.*

<sup>129</sup> *Opposition* at 16.

injure[d] [Dressen's] right to receive the fruits of the contract.”<sup>130</sup> The court reserves judgment on whether the ICF should be construed as an insurance contract because Dressen has plausibly satisfied the general standard for breach of the Implied Duty of Good Faith, and any future characterization of the ICF's genre of contract will be assessed after further briefing as it relates to the type and extent of damages available to Dressen.

### CONCLUSION

For the foregoing reasons, AstraZeneca's Motion to dismiss is DENIED.<sup>131</sup>

SO ORDERED this 4th day of November 2024.

BY THE COURT:



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ROBERT J. SHELBY  
Chief United States District Judge

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<sup>130</sup> *Vander Veur v. Groove Entm't Techs.*, 452 P.3d 1173 (Utah 2019); see *Complaint* ¶¶ 107–31; 147–58 (detailing Dressen's numerous attempts to secure payment from Velocity and AstraZeneca).

<sup>131</sup> Dkt. 24.