IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

LISA GAYLE BUTLER and DAVID A. HOLLAND, individually and as personal Representatives of the ESTATE OF MATY GAYLE HOLLAND, deceased.	§	
Plaintiffs,	§	
v.	§	CIVIL ACTION NO. H-18-898
JUNO THERAPEUTICS, INC.	§	
Defendant.	§	

MEMORANDUM AND ORDER

Maty Gayle Holland died in 2016, at age 19. She had battled leukemia off and on for six years before she died. She died less than two months after starting to participate in a clinical trial of a drug for FDA approval. (Docket Entry No. 41). After her death, Holland's parents, Lisa Gayle Butler and David A. Holland, individually and as estate representatives, sued the drug manufacturer, Juno Therapeutics, Inc., in March 2018. (Docket Entry No. 1). In October, the plaintiffs filed an amended complaint, and Juno moved to dismiss. (Docket Entry Nos. 41, 43). The plaintiffs responded, Juno replied, and the parties supplemented their briefs on the plaintiffs' fraud allegations and on Juno's learned-intermediary doctrine defense. (Docket Entry Nos. 46, 48, 56–60, 62-1). The court heard oral argument on the motion to dismiss.

Based on the pleadings; the motion, response, and reply; the supplemental briefing; counsels' arguments at the motion hearing; and the applicable law, the court denies the motion to dismiss. (Docket Entry No. 43). The reasons for this decision are detailed below.

I. Background

In 2010, Holland, then 13-years old, was diagnosed with acute lymphoblastic leukemia. (Docket Entry No. 41 at ¶ 49). Conventional chemotherapy led to remission by the time she entered high school, but the cancer returned during her freshman year of college. (*Id.* at ¶¶ 49–50). Chemotherapy initially seemed to work, but further rounds did not lead to remission. (*Id.* at ¶ 50). In May 2016, Holland, then 19-years old, joined Juno's Phase II JCAR015 ROCKET Trial. (*Id.* at ¶¶ 52, 57). In June, a week after her first infusion of the trial drug, JCAR015, Holland died. (*Id.* at ¶¶ 76, 80).

A. The FDA Approval Process

The Food and Drug Administration must approve New Drug Applications before a manufacturer may market a drug. 21 U.S.C. § 355(b)(1). The FDA requires three clinical trial phases to show that the drug is efficacious and safe, consistent with the Food, Drug and Cosmetic Act of 1938 before a manufacturer can submit a New Drug Application. *Id.* § 355(i), (b)(1).

Phase I studies "determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and[] . . . early evidence on effectiveness." 21 C.F.R. § 312.21(a). Phase II studies "include[] controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." *Id.* § 312.21(b). Phase III studies involve "expanded controlled and uncontrolled trials . . . . performed after preliminary evidence suggesting effectiveness of the drug has been obtained." *Id.* at § 312.21(c). They give new data on the drug's efficacy and safety and help inform physician labeling. *Id.*

Clinical-trial sponsors must submit an Investigational New Drug Application to the FDA to begin a clinical trial. 21 U.S.C. § 355(i); 21 C.F.R. § 312.20. Sponsors must select medical investigators for the trial and ensure that the investigations are conducted properly and that the "FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug." *Id.* § 312.50. If the three-phase clinical trial is successful in showing the drug's safety and efficacy, the sponsor may file a New Drug Application that specifies the conditions the drug will treat and in what dose. (*See* Docket Entry No. 41 at ¶¶ 19–23); *see* 21 U.S.C. § 355(b)(1); 21 C.F.R. §§ 314.50(d)(5).

Before an investigation or clinical trials begin, a sponsor must provide "each participating clinical investigator an investigator brochure," 21 C.F.R. § 312.55(a), containing "[a] brief description of the drug substance and the formulation," "[a] summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans," "[a] summary of the pharmacokinetics and biological disposition of the drug in animals and, if known, in humans," "[a] summary of information relating to safety and effectiveness in humans obtained from prior clinical studies," and "[a] description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and of precautions or special monitoring to be done as part of the investigational use of the drug." 21 C.F.R. § 312.23(a)(5). The sponsor has an ongoing responsibility to "keep each participating investigator informed of new observations discovered by or reported to the sponsor on the drug, particularly with respect to adverse effects and safe use. . . . Important safety information is required to be relayed to investigators." *Id.* § 312.55(b).

Testing new drugs on people, even people with few options, is fraught with ethical issues. Those are amplified when the patient is young. The regulations address the ethical concerns by

requiring informed consent after the risks are properly disclosed. "[N]o investigator may involve a human being as a subject in research . . . unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." *Id.* § 50.20. Disclosures required for legally effective informed consent include, among other things, "[a] description of any reasonably foreseeable risks or discomforts to the subject" and, "[f]or research involving more than minimal risk . . . and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained." *Id.* § 50.25(a)(2), (6).

One critical issue in this case is whether Juno adequately disclosed the risks to Holland to satisfy the requirements for legally sufficient informed consent. Another issue is whether the fact that Juno paid the JCAR015 ROCKET Trial investigator to conduct the Trial vitiates the learned-intermediary doctrine. These and other issues raised by the motion to dismiss and response are analyzed below.

B. Juno Therapeutics and JCAR015

Juno Therapeutics develops biopharmaceutical "cellular immunotherapies" for treating cancer. (Docket Entry No. 41 at ¶ 1). Juno specializes in treatments that collect, modify, and use a patient's own T cells to treat that patient's cancer. (*Id.*). The most advanced of these treatments is CAR-T therapy. (*Id.*).

Juno sponsors clinical trials to test its products. (*Id.*). Juno has three "CD19 Product Candidates, JCAR014, JCAR015, and JCAR017. All "use a chimeric antigen receptor" or "CAR" to target the CD19 protein found on the surface of the malignant white blood cells that cause B-cell leukemia and lymphoma. (*Id.*). The CAR-T therapy using these products begins with leukapheresis, or harvesting of the patient's own white blood cells. (*Id.* at ¶ 15). Once harvested,

the T cells are "selected and activated," and "gene sequences for the CAR construct are transferred into the T cell DNA using a viral vector." (*Id.*). This process creates receptors on the T-cell surface that, once infused back into the patient's body, allow the T cells to recognize and attack the CD19 protein on the cancer cells. (*Id.* at ¶ 14). The number of modified cells is then expanded to the proper dose. (*Id.* at ¶ 15). The patient receives chemotherapy to deplete the existing T cells and allow the modified cells to grow. (*Id.* at ¶ 16). The last step is to infuse the patient with the genetically engineered T cells. (*Id.* at ¶ 17).

The FDA has not yet approved any of Juno's CD19 product candidates. None of its CD19 products has made it past a Phase II clinical trial. (*Id.* at ¶ 2).

Juno competes with other biotech companies to enroll patients in clinical drug trials so that it can be the first to the market with a CAR-T immunotherapy that makes it through the FDA approval process. (*Id.* at ¶ 3). Juno used a "fast to market strategy" for JCAR015 and designated the JCAR015 Phase II trial as a "ROCKET Trial." (*Id.*). In its 2015 Annual Report, Juno stated that it planned to seek regulatory approval for JCAR015 as early as 2017. (*Id.*). The Annual Report warned of delay if Juno had trouble enrolling patients in its clinical trials and identified the treatment-related side effects as a possible barrier to enrollment. (*Id.* at ¶¶ 4,5).

In January 2007, the Memorial Sloan Kettering Cancer Center in New York sponsored an Investigational New Drug Application for Juno's JCAR015. (*Id.* at ¶ 31). The Phase I clinical trial began in January 2010 and was expected to end in January 2017. Early results showed that JCAR015 had serious risks. (*Id.* at ¶¶ 31–33). In its 2015 Annual Report, Juno acknowledged side effects ranging from "minor reactions to death," including severe neurotoxicity severe

cytokine release syndrome.[1] (*Id.* at ¶¶ 6, 33). Both neurotoxicity and severe cytokine release syndrome require "ICU level care" and can be fatal. (*Id.* at ¶¶ 28, 35).

The FDA placed the JCAR015 ROCKET Trial on hold after two patients died in 2014. (*Id.* at ¶ 36). The FDA removed the hold after Juno made several changes to the Phase I protocol. (*Id.*) According to Juno's 2015 Annual Report, 52% of the patients in the Trial with acute lympoblastic leukemia suffered from either severe cytokine release syndrome or severe neurotoxicity. (*Id.* at ¶ 38). In the "morphologic patient population" of the patients with more than 5% lymphoblasts in their bone marrow, 84% suffered from either severe cytokine release syndrome or severe neurotoxicity. (*Id.* at ¶ 39). Juno stated in 2015 that besides the severe cytokine release syndrome or severe neurotoxicity, "JCAR015 has been generally well tolerated." (*Id.* at ¶ 41).

Juno provided its ROCKET Trial investigators with both an Investigator's Brochure and a sample informed consent form. Both were required, and both were intended, to explain the risks and side effects associated with JCAR015. (*Id.* at ¶ 26). The ROCKET Trial's informed consent form listed as "common" side effects those occurring in more than 20% of patients. But the form did not list either neurotoxicity or severe cytokine release syndrome among the common side effects. (*Id.* at ¶ 40). Even though the Phase I Trial was not scheduled to end until January 2017, Juno advanced to a Phase II trial on August 21, 2015. (*Id.* at ¶ 42). Juno stated in its 2015 Annual

[1] The plaintiffs explain that severe neurotoxicity is the result of exposure to a substance that causes a reaction in the nervous system and can result in confusion, speech loss, brain swelling, and seizures. (Docket Entry No. 41 at ¶ 35). Severe cytokine release syndrome is caused by a rapid release of cytokines from T cells into the bloodstream. T cells normally release cytokines to stimulate and direct immune responses and severe cytokine release syndrome occurs when too many cytokines are released too rapidly. Symptoms can range from mild fever, nausea, fatigue, and low blood pressure, to seizures, hallucinations, and loss of coordination. Although the syndrome can be managed in many patients, in extreme cases, patients have to be placed on a ventilator and can die. *See generally* Daniel W. Lee *et al.*, *Current Concepts in the Diagnosis and Management of Cytokine Release Syndrome*, 124 BLOOD 188 (2014).

Report that the ROCKET Trial "could support accelerated U.S. regulatory approval as early as 2017." (*Id.*).

Another Juno drug in clinical trials, JCAR014, was similar enough to JCAR015 for Juno to cite data from the JCAR014 trials in analyzing the JCAR015 Trials, including the ROCKET Trial. (*Id.* at ¶¶ 43, 47). JCAR014 and JCAR015 require the same chemotherapy treatments before the infusions and target the same CD19 proteins. (*Id.* at ¶ 44). JCAR014 caused severe cytokine release syndrome in 23% of acute lymphoblastic leukemia patients and severe neurotoxicity in 50% of those patients. (*Id.* at ¶ 45). Six patients, including 3 acute lymphoblastic leukemia patients, died from those two side effects during the JCAR014 trial. (*Id.* at ¶ 46). The plaintiffs point out that Juno's 2015 Annual Report showed that 11 of the 20 patients in the JCAR014 trial who received the cyclophosphamide and fludarabine drug combination experienced severe cytokine release syndrome or severe neurotoxicity; 35% experienced severe neurotoxicity. (*Id.* at ¶ 48). None of the 12 patients who received only cyclophosphamide experienced severe cytokine release syndrome, and only 17% of those patients experienced severe neurotoxicity. (*Id.*).

Juno acknowledged the potentially deadly side effects of its CD19 product candidates, including JCAR015, in various media. Its 2015 Annual Report explained that the "use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent." (*Id.* at ¶¶ 6, 27). The Annual Report stated that Juno had "seen severe neurotoxicity . . . in some cases leading to death, in a number of patients . . . using each of JCAR015, JCAR017, and JCAR014." (*Id.* at ¶ 27 (emphasis omitted)). In a different lawsuit brought under the federal securities laws, Juno acknowledged in a pleading that "Car-T therapy can have serious and deadly side effects, including severe neurotoxicity that can damage the brain and cause cerebral edemas and death." (*Id.* at ¶ 28

(emphasis omitted)). The plaintiffs allege that "Juno's knowledge of such risks is also evidenced by various papers and presentations that it, its officers, employees, agents, and researchers working on its clinical trials, published in various publications or presented to various conferences and meetings." (*Id.* at ¶ 29).

Until July 2016, Juno's clinical tests for its CAR-T therapy drugs used a chemotherapy drug cocktail of cyclophosphamide and fludarabine. (*Id.* at ¶ 16). After three patients died in July 2016, Juno stopped using that drug combination. (*Id.*).

C. Holland's Involvement in the JCAR015 ROCKET Trial

Holland's regular oncologist suggested that CAR-T immunotherapy might be a treatment option after her lymphoblast levels fell below 0.1% after several rounds of chemotherapy. (*Id.* at ¶¶ 50–51). Holland was referred to a pediatric oncologist at the M.D. Anderson Cancer Center, Dr. Michael E. Rytting. Holland and her parents met with Dr. Rytting to discuss CAR-T options in May 2016. (*Id.* at ¶¶ 51–52). Dr. Rytting told them that Holland could be a candidate for Juno's Phase II JCAR015 ROCKET Trial. (*Id.* at ¶ 52).

Dr. William Wierda was the Study Chair for the ROCKET Trial at M.D. Anderson and the investigator responsible for administering the treatments to participants, including Holland. (*Id.* at ¶ 53). The plaintiffs emphasize that "[t]here were no alternative drugs for Dr. Wierda to choose from for the ROCKET Trial" and that he could prescribe only JCAR015 for that Trial. (*Id.*). Juno paid Dr. Wierda for serving as the investigator for the JCAR015 ROCKET Trial at M.D. Anderson. The informed consent form disclosed Dr. Wierda's financial relationship with Juno as "significant" and the plaintiffs allege that Dr. Wierda "was not a prescribing physician." (*Id.*). Dr. Wierda also received compensation for consulting and research for other drug companies, including two of Juno's CAR-T competitors. (*Id.*).

The M.D. Anderson leukemia team, which included Dr. Wierda, reviewed Holland's case in May 2016. (*Id.* at ¶ 54). The team approved her participation in the JCAR015 ROCKET Trial on May 10. (*Id.*). On May 16, 2016, Holland and her mother met with Dr. Wierda to discuss the ROCKET Trial. (*Id.* at ¶ 55). Dr. Wierda explained that Holland was eligible for the Trial and noted the successful remission rates of CAR-T immunotherapy trials. (*Id.*). The plaintiffs allege that "Dr. Wierda did not discuss any risks or side effects to participants in the ROCKET Trial during this meeting." (*Id.*). Dr. Wierda did explain the prescreening process and answered other questions. (*Id.*).

Holland and her mother then met with Virginia Bayer, the lead clinical research nurse for the ROCKET Trial at M.D. Anderson. (*Id.* at ¶ 56). Dr. Wierda was not present. (*Id*. at ¶ 58). Bayer reported to Dr. Wierda and was responsible for "guiding participants through the informed consent process, collecting data for the trial, managing the clinical and operational aspects of the clinical trial protocol, ensuring that participants [met] protocol goals, and providing information to both participants and . . . Dr. Wierda." (*Id.*). Bayer explained the informed consent form to Holland and her mother during this meeting, and Holland signed it.[2] (*Id.* at ¶ 57). The plaintiffs allege that Holland was not given a copy of the form, signed or blank. They also allege that neither Bayer nor the content of the consent form revealed "the significant known risks to patients in the ROCKET Trial of suffering from severe neurotoxicity, severe cytokine release syndrome, or cerebral edema, leading to death, after their infusion with JCAR015." (*Id.*).

Federal regulations require clinical trial sponsors to inform participants of reasonably known risks through investigators, such as Dr. Wierda. The FDA does not approve any informed consent forms. Instead, the investigators' or sponsor's institutional review boards must approve

[2] The parties dispute whether Juno supplied the informed consent form that Holland signed. (*See* Docket Entry No. 43 at 30).

the forms used in a clinical trial. (*Id.* at ¶ 60 n.38). The plaintiffs do not allege what institutional review board approved the consent form Holland signed or who comprised that board.

Juno provided its investigators with information on the JCAR015 ROCKET Trial risks in its Investigator's Brochure. (*Id.* at ¶ 60). The FDA requires an Investigator's Brochure to include "pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans," as well as information on the possible risks, side effects, and safety of the drug being tested. (*Id.* at ¶ 24 (citing 21 C.F.R. §§ 312.25(a)(5), 312.55)). Juno released the most recent version of the ROCKET Trial Investigator's Brochure on October 27, 2015. (*Id.* at ¶ 60). Neither Holland nor her family was given a copy of the Brochure before Holland agreed to participate in the Trial. (*Id.*).

Nothing in the ROCKET Trial informed consent form disclosed the known risks of severe neurotoxicity or severe cytokine release syndrome. The form stated that it listed "commonly occurring side effects" and "rare but serious side effects." (*Id.* at ¶ 61). Juno defined "common" side effects as those occurring in more than 20% of patients. (*Id.* at ¶ 40). Data from the JCAR014 trials had shown that 20% of patients suffered from severe cytokine release syndrome and 35% suffered from severe neurotoxicity. (*Id.* at ¶ 48). The plaintiffs allege that because Juno used "JCAR014 trial data to provide insight[s]" into CAR therapy, that data is also relevant to the JCAR015 ROCKET Trial. (*Id.* at ¶ 43). The plaintiffs allege that Juno should have specifically and prominently listed severe neurotoxicity and severe cytokine release syndrome as "common" side effects of JCAR015. (*Id.* at ¶ 61).

The informed consent form stated that JCAR015 was an in early study phase and that the side effects were not well known. (*Id.* at ¶ 62). According to the plaintiffs, the form had no information about the patients who had died soon after their infusions, including deaths from

severe neurotoxicity or severe cytokine release syndrome. (*Id.*). Nor did the form disclose the increased risk of these severe side effects in "morphologic" patients, or the increased risk among patients receiving the cyclophosphamide and fludarabine drug combination. (*Id.* at ¶¶ 64–65). The form also did not disclose that Holland fit into both categories. (*See id.* at ¶ 75). The form did not explain what medical treatments might be options in the event of side effects or other injury, as required for studies with more than a minimal risk. (*Id.* at ¶ 66). Juno did disclose information about these known side effects, risks, and deaths in its annual reports and other literature and presentations, but provided none of those to Dr. Wierda's team to give to potential patients. (*Id.* at ¶ 62).

Holland signed the informed consent form. She spent the next four days completing pre-screening, testing, and having her white blood cells harvested for modification in a lab. (*Id.* at ¶ 57, 59). Shortly after Holland signed the informed consent form in May 2016, the first JCAR015 ROCKET Trial patient died from severe cytokine release syndrome and severe neurotoxicity. (*Id.* at ¶ 68). Eleven days later, Juno published a press release about the JCAR015 ROCKET Trial's successful findings. (*Id.* at ¶ 69). The press release did not mention the recent death or any of the deaths from Phase I. (*Id.*).

In June 2016, Bayer contacted Holland and her family to tell them that a "new safety concern" had arisen and that the JCAR015 ROCKET Trial was on hold until patients could review a new informed consent form. (*Id.* at ¶ 71). Bayer explained that Dr. Wierda would provide more details, but that Holland and others whose T cells were already harvested would be permitted to continue the Trial "once the new informed consent form was ready." (*Id.*).

On June 15, Dr. Wierda met with Holland and her mother and told them that a patient had recently died from a high fever and cerebral edema within 24 hours of receiving the JCAR015

Trial infusion. (*Id*. at ¶ 72). Dr. Wierda explained that the cerebral edema could have been reversed if the patient had immediately received steroids, which did not occur because the patient had a high fever that could have led to T-cell suppression. (*Id.*). Dr. Wierda explained that a new informed consent form with the recent deaths was not available. (*Id.*). He assured Holland and her family that Holland would do fine continuing the Trial. He also made clear that if she developed a high fever, he would administer steroids promptly. (*Id.*).

Juno did not update the Investigator's Brochure after the May 2016 death and before Holland's JCAR015 infusion. (*Id.* at ¶ 74). Holland did not receive an updated informed consent. (*Id.*). According to the plaintiffs, Dr. Wierda's information was wrong and "creat[ed] the false impression that the deadly side effects were reversible." (*Id.*). The plaintiffs allege that Dr. Wierda's assurances "play[ed] a significant role in [Holland] initially agreeing to participate in the ROCKET Trial [and] . . . in preventing [Holland] from declining to continue in the trial following the May death." (*Id.*).

Holland continued the prescreening and testing on June 15, 2016. (*Id.* at ¶ 75). The tests showed high lymphoblast levels, placing her in the high-risk category for developing severe neurotoxicity or severe cytokine release syndrome. (*Id.*). Neither she nor her family were given this information. (*Id.*). The next day, Holland started the preconditioning chemotherapy at M.D. Anderson, receiving the cyclophosphamide and fludarabine drug combination. (*Id.* at ¶ 76). On June 23, she received the infusion of genetically modified CAR-T cells. (*Id.* at ¶ 77). On June 27, she developed a fever of 103.5 degrees, and the next day she developed severe neurotoxicity. (*Id.*). On June 29, Dr. Wierda told Holland's parents that neurotoxicity is common and reversible, but, that afternoon, Holland began having continuous seizures and was moved to the intensive care unit. (*Id.* at ¶ 78).

On June 30, one week after the infusion, nurses informed Holland's parents that she had developed cerebral edema. (*Id.* at ¶ 79). A CAT scan showed it to be irreversible. (*Id.*). Dr. Wierda told Holland's parents that he thought the edema was caused by the addition of fludarabine to the chemotherapy. (*Id.*). Holland's ventilator was turned off and she died the same day. (*Id.* at ¶ 80). Her death certificate stated the cause of death as severe cerebral edema, status epilepticus, and cytokine release syndrome. (*Id.*)

Another JCAR015 ROCKET Trial patient died the same week. (*Id.* at ¶ 82). On July 7, Juno publicly announced the three deaths since May, including Holland's. (*Id.*). Juno also corrected misstatements about the number of deaths stated in previously filed SEC documents. (*Id.*). The FDA again put the Trial on hold. It removed the hold once Juno removed the fludarabine from the chemotherapy treatments and prepared a new informed consent form. (*Id.*).

In November 2016, two more JCAR015 ROCKET Trial patients died. (*Id.* at ¶ 83). This time, Juno voluntarily put the Trial on hold, pending an investigation. Juno terminated all JCAR015 Trials in March 2017. (*Id.*). At least seven patients had died during the JCAR015 Phase I and II Trials, and at least six patients had died during the JCAR014 Trials. (*Id.*). Of the JCAR015 ROCKET Trial Phase II participants, 52% suffered severe neurotoxicity and 21% suffered severe cytokine release syndrome. (*Id*. at ¶ 84).

Juno issued its investigation's findings in 2017 that the severe cytokine release syndrome and severe neurotoxicity experienced in the JCAR015 ROCKET Trial were caused by "early and rapid modified CAR-T cell expansion" combined with a rise in interleukin-15 levels. (*Id.* at ¶ 85). The report stated that at least one patient-specific factor contributed to the deaths from these side effects. (*Id.* at ¶ 86). Patients with certain gene signatures were reported to experience greater toxicity, "including all five patients who died." (*Id.*). The plaintiffs allege that the report was

"botched," pointing out that Holland did not have this gene signature and that at least seven participants, not five, had died during the Phase I and Phase II JCAR015 Trials. (*Id.*).

The plaintiffs allege that had Holland or her parents known of the risks of the JCAR015 ROCKET Trial, she would not have participated. (*Id.* at ¶ 87). They assert that Juno did not give Holland the opportunity to give legally effective informed consent. (*Id.*).

E. The Claims

The plaintiffs assert seven claims against Juno in the amended complaint: (1) wrongful death and survival under Texas Civil Practice and Remedies Code §§ 71.002, 71.021; (2) strict products liability; (3) fraud and fraudulent concealment; (4) negligence; (5) negligent marketing; (6) negligent misrepresentation; and (7) breach of warranty. The plaintiffs have voluntarily dismissed their previously asserted design-defect claims. (Docket Entry No. 58).

These seven claims are based on the theory that Juno knew of the risks and side effects and failed to disclose them to Holland and her parents. (*Id.* at ¶¶ 91, 95, 97, 102–06). The plaintiffs allege that had Holland known about the high rates of severe neurotoxicity and severe cytokine release syndrome, she would not have participated in the JCAR015 ROCKET Trial and "would not have died from severe neurotoxicity and severe cytokine release syndrome." (*Id.* at ¶¶ 91, 95, 97). They allege that Juno had a duty to use reasonable care in disclosing the known risks and effects of JCAR015 and that Juno breached that duty by failing to disclose or to warn. (*Id*. at ¶¶ 102–04). They argue that the applicable standard of care required compliance with FDA regulations that plaintiffs allege Juno did not meet because of its deficient informed consent and risk disclosures. (*Id.*). The plaintiffs further allege that Juno negligently misrepresented JCAR015's known fatal side effects and risks, providing false information about the risks of participating in the JCAR015 ROCKET Trial. (*Id.* at ¶ 105). Finally, they allege that the informed

consent form expressly affirmed the safety of receiving JCAR015 in the ROCKET Trial, and that Holland and her parents relied on these statements in agreeing to participate. They allege that Juno breached its duty of care by failing to disclose the ROCKET Trial's dangers. (*Id.* at ¶ 106).

Juno moves to dismiss the plaintiffs' amended complaint for failure to state a plausible claim. (Docket Entry No. 43). Each argument and response is considered below.

II. The Legal Standard

Rule 12(b)(6) requires dismissal if a plaintiff fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). Rule 12(b)(6) must be read in conjunction with Rule 8's requirement of a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). A complaint must contain "only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Rule 8 "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556).

To withstand a Rule 12(b)(6) motion, a "complaint must allege 'more than labels and conclusions,'" and "a formulaic recitation of the elements of a cause of action will not do." *Norris v. Hearst Tr.*, 500 F.3d 454, 464 (5th Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (alteration in original) (quoting *Twombly*, 550 U.S. at 557). "[A] complaint

'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief—including factual allegations that when assumed to be true 'raise a right to relief above the speculative level.'" *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). "Conversely, when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Id.* (quotation marks and alteration omitted).

In considering a motion to dismiss under Rule 12(b)(6), "a district court must limit itself to the contents of the pleadings, including attachments." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000). Documents "attache[d] to a motion to dismiss are considered part of the pleadings, if they are referred to in the plaintiff's complaint and are central to [the] claim." *Id.* at 498–99 (quoting *Venture Assocs. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993)). The court may also "take judicial notice of matters of public record." *Norris*, 500 F.3d at 461 n.9.

When a plaintiff's complaint fails to state a claim, the court should generally give the plaintiff a chance to amend under Rule 15(a) before dismissing the action with prejudice, unless it is clear that to do so would be futile. *See Carroll v. Fort James Corp.*, 470 F.3d 1171, 1175 (5th Cir. 2006) ("[Rule 15(a)] evinces a bias in favor of granting leave to amend." (quotation omitted)); *Great Plains Tr. Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002) ("[D]istrict courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."). A court may deny a motion to amend as futile if an amended complaint would fail to state a claim upon

which relief could be granted. *Pervasive Software Inc. v. Lexware GmbH & Co.*, 688 F.3d 214, 232 (5th Cir. 2012). Whether to grant or deny leave to amend "is entrusted to the sound discretion of the district court." *Id.*

Each claim and the sufficiency of the pleading are analyzed below.

III. Design Defect

The plaintiffs' amended complaint asserts defective-design claims against Juno. (Docket Entry No. 41 at ¶¶ 96–100, 103; *see id.* at ¶¶ 91, 95). The plaintiffs have informed the court that they are nonsuiting "their design defect claims, including claims related to the ROCKET Trial protocol." (Docket Entry No. 58). The plaintiffs' remaining claims are "solely based on marketing defects [and] failure to warn." (*Id.*).

Juno's motion to dismiss the plaintiffs' claims for defective design is denied as moot.

IV. Failure to Warn

The plaintiffs' remaining claims turn on Juno's alleged failure to warn Holland and her parents about the dangers of the JCAR015 experimental therapy in the JCAR015 ROCKET Trial. Juno argues that the strict liability, fraud, negligence, and breach of warranty claims all depend on the allegation that Holland's informed consent was inadequate because Juno either misrepresented or omitted information on severe neurotoxicity and severe cytokine release. (*See* Docket Entry No. 43 at 15). Texas law treats these claims as alleging a failure to warn. *Cf. Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008) (strict liability, negligence, misrepresentation, and breach of warranty claims are essentially failure to warn claims), *aff'd*, 321 F. App'x. 350 (5th Cir. 2009); *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 710 (E.D. Tex. 1997) (similar claims against a drug manufacturer were based on allegations of the manufacturer's failure to warn), *aff'd*, 165 F.3d 374 (5th Cir. 1999). The plaintiffs' strict liability, negligence, and breach

of warranty claims are best analyzed as failure to warn claims; the fraud claims are considered separately.

Juno argues that the failure to warn claims should be dismissed because it had "no legal duty to warn Ms. Holland directly," and it "did not author, approve, or obtain the Informed Consent from Ms. Holland." (Docket Entry No. 48 at 15). Juno contends that distributing the Investigator's Brochure satisfied its duty to warn the ROCKET Trial investigators and through them met its duty to warn patients. (*See id.*). Juno also argues that it is entitled to dismissal because the learned-intermediary doctrine applies and there is a statutory presumption of non-liability for it as a pharmaceutical manufacturer. (*Id.* at 22).

A. The Learned-Intermediary Doctrine

One issue is whether and how the learned-intermediary doctrine applies in the context of a clinical trial of an experimental drug. "Under Texas law, a manufacturer must instruct consumers as to the safe use of its product and warn consumers of the dangers of which it has actual or constructive knowledge at the time the product is sold." *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010) (citing *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984)). The learned-intermediary doctrine shields prescription-drug manufacturers from liability when a plaintiff sues for failure to warn of a drug's effects. *Id.* "The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn consumers." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207 (5th Cir. 2008). Because it is the prescribing physician who evaluates the risks and benefits of available drugs for a particular patient, and because that physician is best able to pass on warnings from the manufacturer and to supervise the drug's use, *id.*, "the manufacturer's or supplier's duty to warn end users of the dangerous propensities of its product is limited to providing an adequate warning to an

intermediary, who then assumes the duty to pass the necessary warnings on to the end users." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 154 (Tex. 2012) (citations omitted). As long as the manufacturer sufficiently warns the prescribing or treating physician—the learned intermediary—the manufacturer is not liable for failures to warn the ultimate consumer. *Ackermann*, 526 F.3d at 207.

The doctrine is not an affirmative defense. *Id.* Instead, it makes the manufacturer liable for failing to warn the prescribing physician, but shields that manufacturer from liability if the physician then fails to convey the warnings to the patient. *Id.*; *see also Centocor*, 372 S.W.3d at 153–54 ("It is firmly established in Texas that whether a duty exists is ordinarily a legal matter for the court to decide.").

Juno argues that it had no duty to warn Holland or her parents based on the learned-intermediary doctrine, barring the claims. (Docket Entry No. 43 at 15–21). According to Juno, the M.D. Anderson leukemia team served as the learned intermediary because it approved Holland's participation in the ROCKET Trial after receiving the Investigator's Brochure, which included information on the risks of the treatment protocol. (*See id.* at 20–21). The plaintiffs respond that the learned-intermediary doctrine cannot apply in the clinical-trial context because the traditional physician-patient relationship that justifies the doctrine is not present. (Docket Entry No. 46 at 14–15). They argue that when, as here, the treating physician is being paid by the manufacturer, added reasons undermine the doctrine. The plaintiffs argue that even if the doctrine does apply, they have sufficiently alleged the inadequacy of Juno's warnings in the Investigator's Brochure and M.D. Anderson's informed consent form to withstand dismissal. (*Id.* at 8–11; Docket Entry No. 60 at 4–8).

When the learned-intermediary doctrine applies, "a plaintiff must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury." *Ackermann*, 526 F.3d at 208. "In other words, '[u]nder Texas law, a plaintiff who complains that a prescription drug warning is inadequate must also show that the alleged inadequacy caused her doctor to prescribe the drug for her.'" *Id.* (quoting *McNeil v. Wyeth*, 462 F.3d 364, 372 (5th Cir. 2006)). When a manufacturer adequately warns a physician of a drug's risks, or a physician otherwise knew the risks when prescribing the product, the inadequacy of the manufacturer's warning did not cause the injury and the learned-intermediary doctrine prevents recovering from the manufacturer. *Id.* A plaintiff alleging reliance on an inadequate manufacturer's warning must also show that an adequate manufacturer's warning would have changed the physician's prescription choice. *Id.* (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)). In the prescription-drug context, a warning that "specifically mentions the circumstances complained of . . . is adequate as a matter of law.'" *McNeil*, 462 F.3d at 368 (quoting *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied)). Otherwise, the adequacy of the warning is a fact question for the jury. *Id.*

Both persuasive and precedential case law suggests that applying the learned-intermediary doctrine to the clinical drug trial context administered by investigative teams—as opposed to the typical treating physician's prescription of an FDA-approved drug—is at least premature at the pleadings stage. And even if these pleadings support applying the doctrine, the allegations as to the warning, the JCAR015 ROCKET Trial, and the physicians' involvement in the Trial, raise substantial questions requiring a more complete record to decide whether Juno's warning to the alleged learned intermediary was adequate and whether it removed any duty to warn Holland.

1. The Learned-Intermediary Doctrine in the Clinical-Trial Context

According to the plaintiffs, the learned-intermediary doctrine does not apply in the experimental-drug context. (*See* Docket Entry No. 46 at 6; Docket Entry No. 25 at 11–18). Instead, the doctrine applies only to FDA-approved drugs, not to experimental drugs administered in clinical trials. (Docket Entry No. 25 at 12). The plaintiffs argue that cases applying the doctrine refer to "prescription drug manufacturer[s]" and to "intermediaries who prescribe the drug," not to manufacturers of drugs that are in trials and cannot be prescribed, and not to the clinical investigators running those trials. (*Id.* at 12 (emphasis omitted)). The plaintiffs contend that JCAR015 was not a "prescription drug" because the FDA had not approved it for marketing, and that Dr. Wierda was not a physician who "prescribed" the drug to Holland. (*Id.*).

Whether the doctrine applies to clinical trials depends, in part, on how similar clinical trials are to the situations in which the learned-intermediary doctrine's application is firmly established. There are four common justifications for the doctrine. *See, e.g.*, Lars Noah, *This is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 891–92 (2009). First, manufacturer liability intrudes on the physician-patient relationship, which creates judicial second-guessing of medical judgments. *Id.* at 891 (citing *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984)). Second, physicians are better situated than drug manufacturers to warn patients about risks and must do so to obtain informed consent. *Id.* (citing *Brooks*, 750 F.2d at 1232 ("[T]he question turns on who is in a better position to disclose risks."); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 357 (Ill. 1996) ("[P]rescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs.")). Third, it is impractical to require drug manufacturers to communicate directly with patients. *Id.* (citing *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130–31 (9th Cir. 1968)

("[I]t is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning.")). Fourth, because risk information is complex and manufacturers are unaware of each patient's situation and ability to understand, manufacturers are not as well positioned as prescribing physicians to explain the risks to lay patients. *Id.* (citing *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) ("[T]he information regarding risks is often too technical for a patient to make a reasonable choice"); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1290 (E.D. Mich. 1991) ("As with other prescription drugs, patients are unlikely to understand technical medical information regarding the nature and propensities of oral contraceptives.")).

The Texas Supreme Court has explained that it adopted the learned-intermediary doctrine because "prescription drugs are complex and vary in effect, depending on the unique circumstances of an individual user, and for this reason, patients can obtain them only through a prescribing physician." *Centocor*, 372 S.W.3d at 154 (citing *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)); *see also Ackermann*, 526 F.3d at 207 ("Under the doctrine, a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use. . . . If the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided. Accordingly, the doctrine excuses a drug manufacturer 'from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers.'" (citation omitted) (quoting *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467–68 (5th Cir. 1999))). But "when the warning to the intermediary is inadequate or

misleading, the manufacturer remains liable for injuries sustained by the ultimate user." *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 592 (Tex. 1986).

Juno reasons that because the doctrine is based on the physician-patient relationship and because that relationship remains at the center of a clinical trial, the doctrine applies. Juno points to the *Centocor* court's explanation that "[a]s a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient." (Docket Entry No. 43 at 16 (quoting *Centocor*, 372 S.W.3d at 159)). Juno contends that this understanding of the doctrine applies "to investigational drugs, as the prescribing physician is still the one best suited to make decisions about treatment of a specific patient." (*Id.*). The plaintiffs respond that the reasons for the learned-intermediary doctrine in the prescription-drug context do not apply in the clinical-trial context because the physician-patient relationship is not the same. (Docket Entry No. 25 at 13–14; Docket Entry No. 46 at 10–13). In the clinical-trial context, the plaintiffs argue, a patient does not have the ongoing relationship with the investigator that characterizes a patient's relationship with her treating physician. (Docket Entry No. 25 at 14).

i. Cases in the Southern District of Texas

Two recent decisions in the Southern District of Texas cast doubt on whether the learned-intermediary doctrine applies in clinical trials.[3] In *Rodriguez v. Gilead Sciences, Inc.*, No. 2:14-

[3] Juno directs the court's attention to several out-of-state cases. (Docket Entry No. 43 at 16 n.4). For example, in *Wholey v. Amgen, Inc.*, 165 A.D.3d 458 (N.Y. App. Div. 2018), the New York appellate court explained that "[a]s the sponsors of a clinical trial, defendants owed no duty to plaintiff . . . , an enrollee in the trial" and modified the lower court's ruling to grant the drug manufacturer's motion to dismiss for the plaintiffs' failure to warn claims. *Id.* at 458. Juno points out four cases—a 2001 decision by the U.S. District Court for the District of Kansas, a 1991 Ohio state court decision, a 1978 Arizona state court decision, and a 2000 U.S. District Court for the Southern District of California decision—to support its claim that "the learned-intermediary doctrine applies equally to investigational drugs." (Docket Entry No. 43 at 16 n.4 (citing *Kernke v. The Menninger Clinic, Inc.*, 173 F. Supp. 2d 1117, 1122 (D. Kan. 2001) (summary judgment granted to drug manufacturer in a wrongful death action based on a death during a Phase II clinical study because the court concluded that the manufacturer provided adequate warnings to investigators in the investigator's brochure); *Tracy v. Merrell Dow Pharma. Inc.*, 569 N.E.2d 875, 880 (Ohio 1991) ("We have found no cases distinguishing between investigational drugs and FDA-approved

CV-324, 2015 WL 236621 (S.D. Tex. Jan. 16, 2015) (Ramos, J.), the court considered a damages suit for a permanent heart injury sustained in a clinical trial for an experimental hepatitis C treatment. As here, the plaintiff alleged that because the drug manufacturer wanted to be the first into the market, it concealed the risks of the drug under investigation to avoid discouraging participants and to speed up the clinical trial and approval. *Id.* at *1. The defendant drug manufacturer asserted that it owed no duty to warn the plaintiff because, under the learned-intermediary doctrine, the duty to warn ran only to the physician handling the clinical trial, who it alleged had full knowledge of the risks. *Id.* at *4.

The *Rodriguez* court explained the reasons for the doctrine in the pharmaceutical context:

> [c]entral to the learned intermediary doctrine in the pharmaceutical context is a prescribing physician acting in the best interests of the patient through a physician-patient relationship. Rodriguez has pled that Dr. Lawitz [the investigator] was not a "prescribing physician" and was not acting within a physician-patient relationship during the clinical study but was rather an extension of Gilead, incentivized to act as a drug marketer rather than as a treating physician.

Id. at *5 (citations omitted).

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drugs when applying the learned-intermediary rule . . . . The use of investigational drugs may, of course, require greater warning and more physician supervision, but the status of the drug with the FDA does not alter the relationship between drug and patient."); *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) ("In the case of prescription drugs (and especially for investigational drugs, which can be prescribed only by selected investigators) the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the prescribing physician.")); *id.* at 19 n.8 (citing *Little v. Depuy Motech, Inc.*, No. 96-CV-0393-L-JAH, 2000 WL 1519962, at *8–9 (S.D. Cal. 2000) (applying the learned-intermediary doctrine and explaining that the physician's role as a paid investigator for a medical device "further support[ed] a finding that [the physician] knew about the risks associated" with the device))). Juno overstates the persuasive value of these precedents. For example, while the District of Kansas applied the doctrine to a clinical trial in *Kernke*, it did so without analyzing whether the doctrine applies to non-FDA approved investigational drugs. *Kernke*, 173 F. Supp. 2d at 1121. Additionally, each of the cases Juno offers applied the doctrine after the motion-to-dismiss stage. *Id.* at 1120–21 (applying the learned-intermediary doctrine at the summary judgment stage); *Tracy*, 569 N.E.2d at 878 (evaluating the adequacy of jury instructions on the learned-intermediary doctrine); *Gaston*, 588 P.2d at 332 (considering an appeal based on jury instructions on the learned-intermediary doctrine); *Little*, 2000 WL 1519962, at *8 (applying the learned-intermediary doctrine at the summary judgment stage). These cases do not significantly support Juno's assertion that, as a matter of law, the learned-intermediary doctrine precludes the plaintiffs' failure to warn claims at the motion-to-dismiss stage.

The *Rodriguez* court also distinguished the case law applying the doctrine to drugs givin in clinical trials. *Id.* at *5–6. It distinguished *Kernke v. The Menninger Clinic Inc.*, 173 F. Supp. 2d 1117 (D. Kan. 2001), because that case was decided at the summary judgment stage, not on the pleadings, and it was undisputed in *Kernke* that "the clinical investigators were acting as prescribing physicians." *Rodriguez*, 2015 WL 236621, at *5. The *Rodriguez* court distinguished *Tracy v. Merrell Dow Pharmaceuticals Inc.*, 569 N.E.2d 875 (Ohio 1991), because it dealt with a post-trial challenge to a jury instruction on the learned-intermediary doctrine and with the sufficiency of the evidence to support the jury's finding that the relationship between the investigating physicians and the patient supported applying the doctrine. *Rodriguez*, 2015 WL 236621, at *5 (citing *Tracy*, 569 N.E.2d at 878–79). The *Rodriguez* court distinguished *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978), because that case also considered the issue after a merits trial, examining whether there was sufficient evidence that the warnings had been inadequate. The *Gaston* court did not address whether the investigating physician was or was not a "prescribing" physician. *Rodriguez*, 2015 WL 236621, at *5 (citing *Gaston*, 588 P.2d at 340). Finally, the *Rodriguez* court distinguished *Little v. Depuy Motech, Inc.*, No. 96CV0393-L JAH, 2000 WL 1519962, *8–9 (S.D. Cal. June 14, 2000), which held at the summary judgment stage that the physician's role as an investigator in the manufacturer's clinical trial did not impair his independent medical judgment. *Id.* The *Rodriguez* court noted that because these cases were decided "only at an evidentiary phase," and because the application of the learned-intermediary doctrine in the clinical-trial context often "is a question of fact, subject to determination on the basis of evidence," dismissal at the pleading stage would be inappropriate. *Id.* at *6.

The *Rodriguez* court followed *Murthy v. Abbott Laboratories*, 847 F. Supp. 2d 958 (S.D. Tex. 2012) (Ellison, J.), denying the motion to dismiss in favor of considering the issue at summary

judgment with more evidence in the record. *Rodriguez*, 2015 WL 236621, at *5–6; *see also In re DePuy Orthopaedics, Inc*., No. 3:11-MD-2244-K, 2016 WL 6268090, at *6 (N.D. Tex. Jan. 5, 2016) (denying summary judgment because "the learned intermediary doctrine does not apply when a manufacturer compensates a physician or incentivizes him or her to use its product" and there were factual disputes material to deciding the objectivity and the independent medical judgment of the physician); *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2015 WL 1909859, at *9 (E.D. La. Apr. 21, 2015) (denying summary judgment when the plaintiff raised genuine factual disputes as to the physician's alleged biases, but noting that "case law indicates that mere evidence of a consulting relationship between a doctor and a drug manufacturer is not sufficient to prove that the doctor failed to exercise independent judgment when prescribing the drug in question").

In *Murthy*, the plaintiff participated in a clinical trial of an FDA-approved drug for treating rheumatoid arthritis. 847 F. Supp. 2d at 964. The plaintiff's treating rheumatologist was also the investigator for the clinical trial, and he was paid by the drug manufacturer. *Id.* Before the plaintiff began the treatment, she signed an informed consent form the physician provided her. *Id.* The plaintiff participated in the trial for a year before she was diagnosed with B-cell lymphoma, which she alleged was a known but undisclosed side effect of the treatment. *Id.* When the plaintiff sued the drug manufacturer, the manufacturer moved to dismiss based on the learned-intermediary doctrine. *Id.* at 967. The court denied the motion, concluding that it was inappropriate to grant a motion to dismiss based on the learned-intermediary doctrine. *Id.* at 972. The *Murthy* court explained its reasons:

> The learned intermediary doctrine is premised on the assumption that "the physician understands the potential dangers involved in the use of a given drug and, as the prescriber, stands between the drug and the ultimate consumer." Under the doctrine, "it is assumed that a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use." In

> other words, the choice the prescribing physician "makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative."

Id. at 968 (citations omitted). The court stated that it would consider the issue on a fuller record, after discovery and on a summary judgment motion or at trial. *Id.* at 971.

The *Murthy* court considered the other exceptions to the learned-intermediary doctrine, not involving clinical trials of non-FDA-approved drugs. The exceptions included whether it was reasonably foreseeable that the drugs would be distributed without an individualized patient assessment, *id.* (citing *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1277 (5th Cir. 1974)); direct marketing to consumers, *id.* (citing *Perez v. Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999)); or any prophylactic administration, such as vaccinations administered for overseas travel, *id.* (citing *Samuels v. Am. Cyanamid Co.*, 495 N.Y.S.2d 1006 (N.Y. Sup. 1985)).

The *Murthy* court also considered cases that declined to find an exception to the doctrine. *See id.* at 968–70. The *Murthy* court noted that the Fifth Circuit had recently expressed skepticism that a Texas court would adopt an exception to the doctrine for overpromotion, that is, promoting a drug for a non-FDA approved purpose. *Id.* at 970 (citing *Ebel v. Eli Lilly & Co.*, 321 F. App'x 350, 356 (5th Cir. 2009)). "The central theme, consistent among all of the cases finding an exception to the learned[-]intermediate doctrine, is that the physician-patient relationship is not the same as in typical treatment scenarios." *Murthy*, 847 F. Supp. 2d at 970 (quoting Jeffrey J. Wiseman, *Another Factor in the "Decisional Calculus": The Learned Intermediary Doctrine, the Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. REV. 993, 1007 (2001)).

The *Murthy* court concluded that the physician-patient relationship in that case differed from the usual treatment relationship in two critical ways: the manufacturer directly marketed the drug to the patient through a promotional video, and the manufacturer had compensated the

plaintiff's physician for administering the drug. *Id.* Because the Texas Supreme Court had not addressed those circumstances, the *Murthy* court made an *Erie* guess based on the justifications for the learned-intermediary doctrine. *Id.* at 970–71. The court opined that the Texas Supreme Court would apply an exception to the doctrine because it is based on the physician exercising independent medical judgment about, and having direct communications with, the patient. *Id.* at 971. The defendant in *Murthy* had circumvented that physician-patient relationship by disseminating the promotional video to the patient and compensating the physician for his role in administering the drug. *Id.* The compensation undermined the doctrine's assumption that the physician has made an independent judgment in the patient's best interests, free of any incentive to choose a particular drug. *Id.* The *Murthy* court cited studies showing that gifts or other compensation from drug companies influenced medical professionals' decisions in treating their patients, and that conflicts of interest arose when physicians benefitted from enrolling their patients in clinical trials. *Id.* at 971–72. The court reasoned that a physician who receives compensation from a drug company is no longer standing between the drug company and the patient as an independent intermediary. The physician is instead aligned with the drug company's interests.[4] *Id.* at 972. The *Murthy* court concluded that if the legal duty rested on the drug manufacturer, dismissal at the pleadings stage was premature. *Id*. Whether the physician's compensation undermined the learned-intermediary doctrine was a case-specific question that required a fuller record, available at summary judgment or trial. *Id.*

[4] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998), § 6 cmt. b ("[I]n certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly."); *see also id.* § 6(d)(2) ("A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: . . . the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.").

Juno seeks to distinguish both *Rodriguez* and *Murthy* as "founded on an ultimately inaccurate guess by the federal courts as to where Texas law was headed." (Docket Entry No. 43 at 19). Juno argues that *Murthy* "was not singularly focused on the compensation of the doctor in declining to apply the learned-intermediary doctrine," but also on the drug company's direct-to-consumer advertising. (*Id.* (citing *Murthy*, 847 F. Supp. 2d at 971)). Juno concludes that "[t]he *Rodriguez* court merely followed the *Murthy* court," making it unpersuasive as well. (*Id.* at 20 (citing *Rodriguez*, 2015 WL 236621, at *6)).

Juno's argument is an insufficient basis for dismissal. The *Murthy* court denied the manufacturer's motion to dismiss because a fuller record as to the facts of the physician's compensation and its effect was necessary. *Murthy*, 847 F. Supp. 2d at 973. The opinion carefully explained why it was inappropriate to dismiss the plaintiff's failure to warn claims based on the learned-intermediary doctrine without considering "the factual circumstances surrounding the compensation of Murthy's physician in order to evaluate whether application of the learned intermediary doctrine is appropriate." *Id.* at 972.

ii. The Texas Supreme Court and *Centocor*

Neither Texas nor other states provide clear guidance on applying the learned-intermediary doctrine to clinical trials of non-FDA approved drugs in experimental phases. *Murthy* relied in part on a Texas appellate case, *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476 (Tex. App.—Corpus Christi 2010). *Centocor*, since decided by the Texas Supreme Court, considered whether the doctrine applied in a prescription-drug context. *Centocor* did not, however, involve an experimental drug administered in a clinical trial. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012).

The plaintiff in *Centocor* had Crohn's disease. Many procedures over the years had achieved only limited success. *Id.* at 143–44. After a "flare" in the disease, the patient sought treatment from a physician who told her that her options were steroids or a Remicade infusion. *Id.* at 144. The plaintiff agreed to the infusion. Remicade was a relatively new but FDA-approved drug for treating Crohn's disease and rheumatoid arthritis. *Id.* A known side effect was a drug-induced form of the autoimmune disorder, lupus, including the joint pain and swelling that lupus often involves. *Id.* at 146. The physician who prescribed the Remicade infusions referred the patient to another physician for treatment. *Id.* The treating physician was not the prescribing physician and did not discuss the Remicade-infusion risks with the patient. *Id.* at 146–47. A nurse working with the treating physician took the patient's history and did discuss side effects of the infusion with her. *Id.* at 147. After the patient started the first infusion, the nurse showed her an informational video about Remicade and the infusion process, produced and provided by the drug manufacturer. *Id.* The plaintiff experienced improvements in her Crohn's disease after the infusions, but she also began experiencing severe arthritis-like joint pain and swelling pain. *Id.* at 148–49. After consulting a rheumatologist, the plaintiff was prescribed additional Remicade infusions to treat the arthritis pain. She received 14 additional infusions over the next 18 months. *Id.* Each infusion provided temporary pain relief. *Id.* at 149. Eventually, it became clear that the plaintiff's joint pain and swelling were from a drug-induced lupus-like syndrome caused by the Remicade, not by Crohn's disease or rheumatoid arthritis. *Id.* at 149–50.

A trial resulted in a jury verdict for the plaintiff. The drug manufacturer appealed, arguing that the learned-intermediary doctrine precluded recovery because its warning to the prescribing physician was adequate and the manufacturer had no duty to warn the plaintiff. *Id.* at 151. In affirming the trial court, the Texas court of appeals adopted a "direct-to-consumer" advertising

exception to the learned-intermediary doctrine. The exception applied because the drug manufacturer had directly marketed the infusions to the patient through the informational video, which had misrepresented the drug's risks. *Id.* at 152. The drug company appealed to the Texas Supreme Court, arguing, in part that it was error to create an advertising exception to the learned-intermediary doctrine because direct-to-consumer advertising "does not threaten the physician-patient relationship, but helps educate consumers about available medications . . . ." *Id.* at 154.

The Texas Supreme Court concluded that a direct-to-consumer advertising exception did not apply, but limited the holding to on the facts before it. *Id.* at 162. The court reviewed the learned-intermediary doctrine, reiterating that the rationale for the doctrine is the unique role of health-care professionals who have the expertise and are in a position to assess the risks and benefits of a specific drug for a specific patient. *Id.* at 157. The court confirmed that the doctrine applies to prescription-drug products-liability cases:

> [b]ecause patients can obtain prescription drugs only through their prescribing physician or another authorized intermediary and because the "learned intermediary" is best suited to weigh the patient's individual needs in conjunction with the risks and benefits of the prescription drug, we are in agreement with the overwhelming majority of other courts that have considered the learned intermediary doctrine and hold that, within the physician-patient relationship, the learned intermediary doctrine applies and generally limits the drug manufacturer's duty to warn to the prescribing physician.

Id. at 159.

The Texas Supreme Court considered the exceptions to the learned-intermediary doctrine in light of changes to the pharmaceutical drug market since the doctrine's inception. Both the *Restatement* and the courts had recognized limited exceptions to the doctrine, including mass inoculations, oral contraceptives, and contraceptive devices. *Id.* at 159 n.18. The most recent exception, the court noted, was the "direct to consumer advertising" or "mass marketing" exception, which a few courts had recognized but more courts had declined to recognize. *Id.* at

160. Considering only the facts of the case and Texas law, the court held that the "direct to consumer advertising" exception did not apply to those facts. *Id.* at 162 ("We acknowledge that some situations may require exceptions to the learned[-]intermediary doctrine, but without deciding whether Texas law should recognize a DTC advertising exception when a prescription drug manufacturer distributes intentionally misleading information directly to patients or prospective patients, we hold that, based on the facts of this case, no exception applies.").

As noted, the court limited its decision to the facts before it, stating:

> [w]ithout deciding whether Texas law should recognize any of the other exceptions to the learned[-]intermediary doctrine, we find no reason to adopt an exception where the physician-patient relationship existed, the pharmaceutical company provided a warning to the patient's prescribing doctors that included the side effect of which the patient complains, and the patient had already visited with her prescribing physician and decided to take the drug before she saw the informational video at issue.

Id. at 164. The court did not foreclose recognizing more exceptions to the doctrine in future cases presenting different facts. The opinion reinforced the *Murthy* court's reasoning that the question is whether "the physician-patient relationship existed" in the first place. *Id.*

The facts here differ significantly from those considered in *Centocor*. If a patient sees direct-to-consumer advertising from the manufacturer, but takes the prescription drug only after an independent evaluation by her physician, the physician does not materially differ from the neutral, independent learned intermediary that the doctrine recognizes. By contrast, when the physician is compensated by the manufacturer of the drug she is prescribing to the patient, or otherwise aligns her incentives with the drug manufacturer, she may no longer act as a neutral, independent learned intermediary. *Centocor* does not foreclose finding an exception to the learned-intermediary doctrine here, but instead supports it. The physician may still have a professional obligation to act in the patient's best interests, but, as the *Murthy* court noted, the physician's interactions with the drug manufacturer fare so significant so as to overcome the

presumption that the physician's relationship to her patient ensures an independent, individualized assessment of that patient's best interests directly communicated to the patient. *Murthy*, 847 F. Supp. 2d at 972.

The *Centocor* court also considered the duty owed to the plaintiff by a nonprescribing physician, finding that none existed:

> [d]espite the intricate web of modern healthcare providers and treatments, the bedrock of our healthcare system is the physician-patient relationship, and the ultimate decision for any treatment rests with the prescribing physician and the patient. As a matter of both necessity and practicality, the duty to warn the patient of the potential risks and possible alternatives to any prescribed course of action rests with the prescribing physician.

372 S.W.3d at 166. Although the court considered the issue as it applied to a situation in which one physician had prescribed the treatment and then referred the patient to another physician to perform it, the same principle applies when a physician is acting outside the traditional physician-patient relationship.

The parties devote considerable time to debating who was the learned intermediary in the JCAR015 ROCKET Trial. "[I]n Texas, even when a physician makes no individualized judgment in prescribing and administering a prescription drug, [the learned-intermediary] doctrine has been applied as long as a physician-patient relationship is in existence." *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 92 (Tex. App.—Texarkana 2000, no pet.). The question is whether a patient's relationship to the investigators and the other physicians involved in the clinical trial created a "physician-patient relationship."

Juno does not disagree that Dr. Wierda was not in a traditional physician-patient relationship with Holland. Instead, Juno emphasizes that a group of physicians, the M.D. Anderson leukemia team, was involved in deciding whether Holland could and should participate

in the trial. Juno argues that this team collectively served as the learned intermediary between Juno and Holland. (Docket Entry No. 56 at 2).

While Juno is correct that *Centocor* did not recognize exceptions to the learned-intermediary doctrine, the court did not address the doctrine's application to clinical trials. *Centocor* bolsters *Murthy*'s reasoning that the traditional physician-patient relationship could be compromised by the clinical-trial incentives of paying the investigator heading the team. Both *Centocor* and *Murthy* emphasize the centrality of the traditional physician-patient relationship, including the importance of structural assurances that independent prescription decisions based on each specific patients' medical needs will occur. *See Murthy*, 847 F. Supp. 2d at 971; *Centocor*, 372 S.W.3d at 166; *see also* Wiseman, 52 S.C. L. REV. at 1007 ("The central theme, consistent among all of the cases finding an exception to the learned intermediate doctrine, is that the physician-patient relationship is not the same as in typical treatment scenarios."). While *Centocor* shows the strength of the doctrine in the normal prescription-drug context, it does not decisively answer whether this court should apply the doctrine in this clinical-trial context involving a lead investigator or the treatment team who was paid to run the trial.

The plaintiffs point to factual allegations justifying applying the learned-intermediary doctrine exceptions discussed in *Murthy* and *Centocor* to the JCAR015 ROCKET Trial. They allege that their clinical-trial participants do not have a traditional physician-patient relationship with the Trial investigators. Participants such as Holland do not choose the physician who would administer the Trial. The plaintiffs allege that while a traditional physician-patient relationship is "highly personal and individualized," a trial investigator will not develop a similarly close relationship with participants. (Docket Entry No. 46 at 14). The plaintiffs allege that the financial relationship between Dr. Wierda and Juno and that Dr. Wierda's role in "tout[ing] the positive

aspects of the ROCKET Trial . . . . played a critical role in preventing [Holland] from declining to continue in the trial." (Docket Entry No. 41 at ¶¶ 55–56, 74). The plaintiffs allege and argue that because Dr. Wierda was compensated for his role as the JCAR015 ROCKET Trial lead investigator at M.D. Anderson, he was not in the type of physician-patient relationship with Trial participants, including Holland, that the learned-intermediary doctrine is intended to protect. The plaintiffs also note that in a clinical trial, the investigator does not weigh the risks and benefits of different drugs or treatments, but instead focuses primarily or only on the experimental drug. (*See* Docket Entry No. 41 at ¶ 53 ("There were no alternate available drugs for Dr. Wierda to choose from for the ROCKET Trial, but only one—JCAR015.")).

Juno responds that the factual allegations do not support applying the doctrine because its policy rationales are not present in the experimental-drug clinical-trial context. Juno argues that Holland's involvement in the JCAR015 ROCKET Trial was the decision of "a team of investigators and other medical professionals," including her oncologist. (Docket Entry No. 43 at 20 (citing Docket Entry No. 41 at ¶ 51)). Because there were many "intermediaries" who Juno did not compensate involved in the decision to enroll Holland in the Trial, Juno argues that Dr. Wierda's financial relationship with Juno does not sufficiently change the physician-patient relationships to justify applying an exception to the learned-intermediary doctrine. (*Id.* at 20–21). Juno warns that recognizing an exception to the learned-intermediary doctrine here "would amount to a *per se* rule that the learned-intermediary doctrine can never apply to clinical trials . . . . remov[ing] from the equation the 'medical expert, the prescribing physician [who] can take into account the propensities of the drug, as well as the susceptibilities of his patient.'" (Docket Entry No. 43 at 21 (quoting *Centocor*, 372 S.W.3d at 159)).

Many courts outside Texas have been reluctant to find an exception to the doctrine in the clinical trial context, even when a financial relationship between manufacturer and investigator may mean that "the physician is not independent of the manufacturer" and is no longer "well-positioned to evaluate the risk-benefit information the manufacturer provides." Kate Greenwood, *Physician Conflicts of Interest in Court: Beyond the "Independent Physician" Litigation Heuristic*, 30 GA. ST. U.L. REV. 759, 790 (2014). The Fourth Circuit concluded in *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999), a physician working as a consultant for a manufacturer that is "an employee of [the manufacturer] or so closely related to [the manufacturer] that [the physician] could not exercise independent professional judgment" may require an exception to the doctrine. *Id.* at 163. The Fourth Circuit held that while the physician in *Talley* was a "consultant to [the manufacturer] Danek . . . assisting in efforts to secure FDA approval" and "received an annual consulting fee of $250,000, a travel budget, research funds, and 25,000 shares of stock in Danek," the learned-intermediary doctrine still applied because the financial relationship did not interfere with the physician's independent medical judgment. *Id.* at 157, 165.

Other courts have reached similar conclusions, including the California Superior Court, which noted that while "payment for research is a widespread practice . . . the court was unable to find a case where a physician who was paid for research was considered to have abrogated his or her role of learned intermediary." Greenwood, 30 GA. ST. U.L. REV. at 793 (quoting Ruling on Plaintiff's Motion for Directed Verdict on Defendant's Learned Intermediary Doctrine Defense, *In re Vioxx Cases*, No. JCCP 4247, 2006 WL 630592 (Cal. Super. Ct. Dec. 19, 2006)). All these cases, however, either dismissed the plaintiffs' claims at the summary judgment stage, suggesting that dismissing claims against a drug manufacturer with an alleged financial relationship to the prescribing physician in the clinical-trial context at the pleadings stage is premature, or allowed

the case to proceed to trial with a jury instruction on the doctrine. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596, 06-cv-3456, 2010 WL 348276 (E.D.N.Y. Jan. 22, 2010) (granting summary judgment and applying the learned-intermediary doctrine when a physician "conducted paid research" and "served as a paid speaker" for the drug manufacturer); *Tracy*, 569 N.E.2d at 876, 879 (the trial court correctly instructed the jury on the learned-intermediary doctrine because, while the defendant, Merrell Dow, paid the plaintiffs' physician for each participant the physician enrolled in the clinical trial of an anti-smoking drug, there was no evidence that the physician was "an employee of Merrell Dow or . . . was acting under the control of Merrell Dow").

Texas courts have not ruled on the impact of a financial relationship between a prescribing physician and the drug manufacturer on the application of the learned-intermediary doctrine, or on the doctrine's application in the clinical-trial context. *Centocor* addressed only direct-to-consumer advertising in reaffirming the reasons for the learned-intermediary doctrine. The fact that Texas law is uncertain makes it even more important to resolve the learned-intermediary doctrine issue here on the basis of a fuller record, either on summary judgment or at trial.

2. Whether Juno's Warnings Were Adequate

Even if the court determined that the learned-intermediary doctrine applies in this context, the allegations reveal significant factual disputes that would make dismissal of the plaintiffs' claims premature. When the doctrine applies, "if the warning to the intermediary is inadequate or misleading, then the manufacturer remains liable for injuries sustained by the ultimate user." *Centocor*, 372 S.W.3d at 170; *see also Wholey v. Amgen, Inc.*, 165 A.D.3d 458, 459 (N.Y. App. Div. 2018) ("The learned intermediary doctrine does not compel dismissal of the claims that the drug's warning labels were insufficient, since the claims are premised not on defendants' failure

to warn plaintiff directly but on their failure to provide proper warnings to her prescribing medical professionals.").

Juno does not dispute that it owed a duty to provide adequate warnings to Dr. Wierda and the M.D. Anderson leukemia team. (Docket Entry No. 43 at 16). Juno argues that it fulfilled that duty when it provided an adequate warning of the risks of the JCAR015 ROCKET Trial. (*Id.* at 17). The plaintiffs allege that the warnings that Juno gave to Dr. Wierda and the M.D. Anderson clinical trial team were inadequate and misleading.

The facts alleged are that Holland saw her regular oncologist, Dr. Patel, who told her about CAR-T immunotherapy and suggested she see Dr. Rytting at M.D. Anderson. Dr. Rytting told Holland about the JCAR015 ROCKET Trial administered by Dr. Wierda. While Juno argues that it was a team of physicians who "prescribed" Holland's participation in the JCAR015 ROCKET Trial, the amended complaint alleges that her decision to participate was based on her interactions with Dr. Wierda, making him the learned intermediary, if the doctrine applies.

Dr. Wierda was not Holland's regular physician. The plaintiffs allege facts showing that Dr. Wierda's financial interest in the JCAR015 ROCKET Trial meant that his relationship with Holland was not a traditional physician-patient relationship. The plaintiffs argue that the reasoning in *Murthy* and *Rodriguez* applies to make the learned-intermediary doctrine inapplicable on these facts. Juno responds that the financial relationship between Dr. Wierda and Juno does not eliminate the physician-patient relationship, emphasizing that the allegations about the M.D. Anderson team involved in "prescribing" the JCAR015 ROCKET Trial to Holland shows careful and objective consideration.

Juno argues that the plaintiffs' allegations show that the "learned intermediary" was the M.D. Anderson leukemia team led by Dr. Wierda. According to Juno, the team was warned about

the risks of JCAR015 in the Investigator's Brochure. (*See* Docket Entry No. 43 at 17 (citing Docket Entry No. 41 at ¶ 26)); Docket Entry No. 56 at 1–2). Juno argues that in the Brochure, it "specifically warned" Dr. Wierda and the team "of the risks and consequences of developing severe cytokine release syndrome ("sCRS") and neurotoxicity." (Docket Entry No. 43 at 17; *see also* Docket Entry No. 56 at 2). "Dr. Wierda was further advised (and it is undisputed that he, in turn, advised Ms. Holland) of the death of a clinical trial patient who had developed life-threatening side effects of CRS and neurotoxicity after his JCAR015 infusion." (*Id.* at 17–18 (citing Docket Entry No. 41 at ¶ 68, 72)).

Juno has submitted the informed consent form for the M.D. Anderson JCAR015 ROCKET Trial. (Docket Entry No. 43-1). Juno disputes that it provided this form to M.D. Anderson. (Docket Entry No. 43 at 30 ("Juno did not approve or provide the Informed Consent document to Ms. Holland.")). The form lists numerous possible side effects of the treatment and states that "cytokine release syndrome (such as flu-like symptoms and/or shortness of breath)" is among them. (*Id.* at 14). The form does not list the incidence rate or the likelihood of death from this side effect.

The plaintiffs point to several deficiencies in the JCAR015 ROCKET Trial informed consent form. (*See* Docket Entry No. 25 at 17–22). The plaintiffs argue that the form did not mention severe cytokine release syndrome or severe neurotoxicity, but merely described benighn sounding "flu-like symptoms," despite the fact that Juno's 2015 Annual Report stated that the severe versions are listed as "notable side effects" of JCAR015. (Docket Entry No. 41 at ¶ 61). To the extent that the informed consent form mentions "cytokine release syndrome," it does not identify it as severe and minimizes the risk. (*Id.* at ¶ 61 n.40). They also argue that the informed consent form failed to disclose any risk of cerebral edema. (*Id.*).

The plaintiffs point to the informed consent form statement that "[t]his is an early study of JCAR015, so the side effects are not well known." (*Id.* at ¶ 62). This statement, they argue, was false when made because Juno's other literature and reports state that the side effects of JCAR015 were well known and the trial had gone on for more than six years. (*Id.*). According to the plaintiffs, the informed consent form should have clearly listed both severe neurotoxicity and severe cytokine release syndrome as "common" side effects and, in addition, disclosed the increased risk of death for "morphologic" patients who, like Holland, have more than 5% lymphoblasts in their bones. (*Id.* at ¶ 64). Because the consent form warned of a much lower risk, the warning was both misleading and ineffective. (*Id.* at ¶ 66).

The plaintiffs also note that the informed consent form did not mention the higher incidence of either severe neurotoxicity or severe cytokine release syndrome among patients receiving the cyclophosphamide and fludarabine drug combination. (*Id.* at ¶ 65). The plaintiffs acknowledge that the Investigator's Brochure contains more information than the informed consent form and allege that neither was regularly updated with recent critical information. (*See id.* at ¶ 74).

Juno does not substantially engage with this part of the plaintiffs' argument. Juno instead emphasizes the amended complaint allegation that "Dr. Wierda was not a conduit for any warnings of the deadly risks of JCAR015 from Juno to [Holland]." (Docket Entry No. 43 at 21 (quoting Docket Entry No. 41 at ¶ 58)). But relying entirely on the Investigator's Brochure does not resolve the pleading sufficiency. "Merely mentioning in the label the condition of which the plaintiff complains . . . is not necessarily sufficient for a finding of adequacy of [a warning] as a matter of law, at least where the plaintiff's contention is not that the warning is inadequate because her condition was not mentioned, but that the label is misleading as to the risk level for developing the condition." *Murthy*, 847 F. Supp. 2d at 968 (citing *McNeil*, 462 F.3d at 368). "Indeed, '[w]arning

the learned intermediary of a much lower risk than the actual risk could render the warning not just misleading, but ineffective.'" *Id.* (quoting *McNeil*, 462 F.3d at 368). If a manufacturer presents a risk as unlikely or fails to identify the likelihood of the risk, and gives data to support the occurrence rate it describes, "that number must be within a certain degree of accuracy." *Id.* (quoting *McNeil*, 462 F.3d at 368).

Based on the facts alleged, the plaintiffs have stated a claim for failure to warn. The plaintiffs have alleged facts supporting a plausible inference that the warnings in the informed consent form were inadequate. *See Monk v. Wyeth Pharms., Inc.*, No. SA-15-CV-1273-XR, 2017 WL 2063008, at *7 (W.D. Tex. May 11, 2017) ("Whether those warnings were in fact adequate—such that the learned intermediary doctrine would shield Defendants from liability—can be considered at the summary judgment phase after the parties have conducted discovery on the issue.").

The Investigator's Brochure contains more information than the informed consent form. (*See* Docket Entry No. 43-2). This could be fatal to the plaintiffs' claims if the court determines that the learned-intermediary doctrine applies and if the Brochure's warnings to Dr. Wierda and the M.D. Anderson team adequately addressed the side effects that led to Holland's death. But the plaintiffs have pleaded sufficient facts to state a claim for relief that the Brochure also presented inadequate warning and risk disclosures, making summary judgment or trial the appropriate stage to resolve these issues.

B. The Presumption of Non-Liability Under Texas Law

Juno moves to dismiss the failure to warn claims on the separate ground of the statutory presumption under Texas law that pharmaceutical manufacturers are not liable for injuries caused by inadequate warnings if those warnings were approved by the FDA. (Docket Entry No. 43 at 22

(citing TEX. CIV. PRAC. & REM. CODE § 82.007)). The plaintiffs respond that Juno misapplies the statute, misstates the FDA process, and relies on inapposite authority. (Docket Entry No. 46 at 17).

Section 82.007 states:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act . . . .

TEX. CIV. PRAC. & REM. CODE § 82.007(a)(1). Section 82.007 lists ways for a plaintiff to rebut the presumption of nonliability. *Id.* at 82.007(b).

Juno argues that because the Federal Food Drug and Cosmetic Act "provides for FDA approval for the distribution of investigational new drug products in clinical trials," § 82.007 covers the plaintiffs' claims. (Docket Entry No. 43 at 22-23). Juno explains that the Investigator's Brochure provided the warnings required by the FDA regulations. (*Id.* at 23 (citing 21 C.F.R. §§ 312.23(5))). Juno cites the *Murthy* court's statement that "[s]ection 82.007 expressly precludes liability unless Plaintiffs can rebut the presumption by establishing one of four statutory exceptions." (*Id.* (citing *Murthy*, 847 F. Supp. 2d at 976–77)). Juno argues that because the amended complaint does not allege facts that show any exception, the failure to warn claims must be dismissed. *Id.*

The plaintiffs respond and allege that § 82.007 applies only when both the drug and the warning were approved by the FDA; neither JCAR015 nor the Juno-provided informed consent form were FDA approved. (Docket Entry No. 46 at 17; Docket Entry No. 25 at 22–25). The

plaintiffs also argue that this part of *Murthy* is inapposite because that case addressed an FDA-approved drug and a "post-approval" clinical trial. (Docket Entry No. 25 at 24).

The plaintiffs are correct that § 82.007 is inapplicable and that *Murthy*'s reasoning on § 82.007 does not inform this analysis. In *Murthy*, the FDA had already approved both the drug and the package insert containing the warnings. *See Murthy*, 847 F. Supp. 2d at 964. Here, the FDA has approved neither the drug nor the informed consent form; the JCAR015 ROCKET Trial was still in the experimental stage when Holland decided to and did participate.

The plaintiffs cite *Rodriguez*, which addressed § 82.007 and a non-FDA approved drug. (Docket Entry No. 25 at 25). The *Rodriguez* plaintiff made the same argument the plaintiffs make, that § 82.007 does not apply to pre-FDA-approved clinical trials because the drug is not a "product approved" by the FDA. *Rodriguez*, 2015 WL 236621, at *6. The *Rodriguez* court observed that the statute "would indicate that any approval by the FDA, acting pursuant to the Act, would create the non-liability presumption." *Id.* at *6. The court noted that "in explaining the requirements for an 'investigational new drug' clinical trial, the regulation speaks in terms of authorizations rather than approvals," but declined to decide whether an "approval" differed from an "authorization." *Id.* at *7 (citing 21 C.F.R. § 312). The court denied the motion to dismiss to consider the § 82.007 issue on a more complete record, with "evidence of precisely what materials were provided to the FDA and whether the warnings on which [the drug company] relie[d] were 'approved.'" *Id.*

Juno presents no persuasive basis to distinguish the *Rodriguez* approach. The court defers the nonliability presumption issue until summary judgment.

C. The Negligence-Based Claims

Juno argues that the plaintiffs have failed to plead facts to support their negligence-based claims. First, Juno argues, for the same reasons discussed above, that it owed no duty to warn

Holland directly. (Docket Entry No. 43 at 17). Second, Juno argues that the plaintiffs' negligent-marketing claim fails because Juno satisfied its duty to warn through the Investigator's Brochure. (*Id.* at 26–27). Finally, Juno argues that the plaintiffs fail to state a claim for negligent misrepresentation because they fail to allege specific representations Juno made that were false. (*Id.* at 27–28).

1. Whether Juno Owed a Duty to Holland

The first argument is based on the learned-intermediary doctrine. The plaintiffs have sufficiently pleaded facts that the learned-intermediary doctrine may not apply to the JCAR015 ROCKET Trial. If the doctrine does not apply, Juno would have a duty to warn Holland. These allegations survive a motion to dismiss.

Juno also argues that federal regulations place the responsibility to obtain informed consent on the clinical-trial investigator, not on the manufacturer. (Docket Entry No. 43 at 26). The plaintiffs agree. (Docket Entry No. 25 at 25). The plaintiffs' argument is that while federal regulations define the trial "sponsor" as responsible for clinical investigations, and the investigators as responsible for the clinical-trial participants, those regulations do not absolve sponsors from ensuring that participants are adequately warned and informed. (*Id.*); *see, e.g.*, 21 C.F.R. § 312.50 ("Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. Additional specific responsibilities of sponsors are described elsewhere in this part.").

For example, federal regulations require that "[b]efore the investigation begins, a sponsor . . . shall give each participating clinical investigator an investigator brochure containing the information." 21 C.F.R. § 312.55(a). In addition, "[t]he sponsor shall, as the overall investigation proceeds, keep each participating investigator informed of new observations discovered by or reported to the sponsor on the drug, particularly with respect to adverse effects and safe use." § 312.55(b). The regulations impose responsibilities on the sponsors, separate and apart from those imposed on the investigators, including to provide information that may be necessary to generating complete, accurate, and updated informed consent documents.

The plaintiffs argue that "there is no authority for the proposition that such regulations placing duties on investigators extinguish any common law tort duties to the clinical trial participants." (Docket Entry No. 25 at 27); *see Wildman v. Medtronic*, 874 F.3d 862 (5th Cir. 2017) (state-law breach-of-warranty claims were not preempted by the FDA regulatory scheme); *Wydermyer v. Janssen Pharms., Inc.*, No. 6:16-CV-01000-RWS-KNM, 2017 WL 3836143 (E.D. Tex. July 19, 2017) (denying a motion to dismiss state-law negligent-misrepresentation and fraud claims as parallel to the FDA regulation violations alleged).

The plaintiffs cite *Zeman v. Williams*, No. 11-10204, 2014 WL 3058298 (D. Mass. July 7, 2014), a case involving a clinical trial for a Parkinson's disease treatment. In *Zane,* the plaintiffs sued the clinical-trial sponsor—the equivalent of Juno—for negligence, breach of warranty, and loss of consortium. *Id.* at *1. The plaintiffs alleged that the sponsor breached a common-law duty to the trial participants when the sponsor had drafted and approved the clinical-trial protocol and the allegedly inadequate informed consent form. *Id.* The sponsor moved to dismiss, making arguments similar to those Juno makes here. *See id.* at *2–3. The court denied the motion to dismiss the negligence claims, explaining that:

> [b]oth the investigator and the sponsor have responsibilities under the regulations regarding obtaining a subject's informed consent. . . . It is certainly true that the investigator has a major, if not the major, role in obtaining a properly informed consent. But that does not foreclose the possibility that some other persons, including particularly the trial's sponsor, might also have a responsibility to help assure that the investigator actually gets a properly informed consent. After all, even under the "learned intermediary" rule, a pharmaceutical company will not be held liable to injury to a patient only if it has given adequate information to the intermediary physician so the physician can adequately inform the patient. If the investigator fails to inform a subject about some substantial risk because the sponsor has failed adequately to inform the investigator about the risk, the sponsor may be liable in tort.

Id. at *3 (citations and emphasis omitted). *Zeman* suggests that a drug manufacturer may owe a duty to both the investigator and to the patients enrolled in the trial to disclose the risks and obtain informed consent. Juno, arguing that its only duty was to the investigators, provides precedent emphasizing the importance of limiting a drug manufacturer's liability. (*See* Docket Entry No. 43 at 25–26 (citing *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006); *Wholey*, 2018 WL 4866993, at *1; *Kernke*, 173 F. Supp. 2d at 1124)). But these cases do not show that, as a matter of law, a manufacturer has no duty to the clinical-trial participants.

The plaintiffs have sufficiently pleaded a common-law duty at this stage to withstand dismissal.

2. Negligent Marketing

A negligent-marketing claim requires the plaintiffs to establish "1) a duty by the defendant to act according to an applicable standard of care; 2) a breach of the applicable standard of care; 3) an injury; and 4) a causal connection between the breach of care and the injury." *Perez v. Goodyear Tire & Rubber Co.*, No. 4-14-00620-CV, 2016 WL 1464768, at *9 (Tex. App.—San Antonio Apr. 13, 2016, no pet.).

Juno again argues that it owed no duty to Holland and that the plaintiffs pleaded no facts to support their conclusory allegation that Juno failed to give adequate warnings to its investigators

in the Investigator's Brochure. (Docket Entry No. 43 at 26). The plaintiffs have sufficiently pleaded facts showing that Juno may also have owed Holland a duty to warn of the drug's risks. Juno argues that because the plaintiffs admit that the Investigator's Brochure disclosed the risks of participation in the JCAR015 ROCKET Trial, the plaintiffs' allegations are insufficient. (*Id.* at 27). This argument fails to take into account that the amended complaint does allege that the Brochure was insufficient, including that it was not updated with information about the patient deaths occurring during the Trial. (Docket Entry No. 41 at ¶¶ 73–74).

The plaintiffs have sufficiently pleaded a common-law duty, and a breach of that duty, to withstand dismissal on the pleadings.

3. Negligent Misrepresentation

"The elements of a cause of action for negligent misrepresentation are: (1) the representation is made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest; (2) the defendant supplies 'false information' for the guidance of others in their business; (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the information; and (4) the plaintiff suffers pecuniary loss by justifiably relying on the representation." *Allied Vista, Inc. v. Holt*, 987 S.W.2d 138, 141 (Tex. App.—Houston [14th Dist.] 1999, pet. denied) (citing *Fed. Land Bank Ass'n v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991)). The false information requires a "misstatement of existing fact, not a promise of future conduct." *Id.* (emphasis omitted).

Juno argues that the plaintiffs fail to adequately allege a specific misrepresentation, a needed to state a plausible claim. (Docket Entry No. 43 at 27–28). Juno contends that because the plaintiffs allege and argue that the informed consent form contained allegedly false information that encouraged Holland's participation in the JCAR015 ROCKET Trial, and because that

informed consent form was prepared by the investigators and not by Juno, the plaintiffs have not pleaded any specific misrepresentations by Juno. (*Id.* at 28). But Juno allegedly provided M.D. Anderson a sample form, and the extent to which the M.D. Anderson investigators modified or added risk disclosures from Juno's Investigator's Brochure and the accuracy of that Investigator's Brochure following the May 2017 JCAR015 ROCKET Trial death is in dispute.

The plaintiffs' ability to bring a negligent misrepresentation claim in a personal injury action is unclear under Texas law. The *Restatement (Second) of Torts* recognizes two categories of negligent misrepresentation. Under § 552B, a plaintiff must show that the defendant negligently supplied false information in the course of his business, that his intent was to influence the plaintiff's business decisions, and that the advice caused monetary loss. *See* RESTATEMENT (SECOND) OF TORTS § 552B (1977). Under § 311, a plaintiff may bring a claim for negligent misrepresentation when a defendant negligently offers false information that results in the plaintiff's physical harm. RESTATEMENT (SECOND) OF TORTS § 311. A negligent-misrepresentation claim under § 311 does not require showing that the defendant intended to influence the plaintiff's business decisions or that the harm was a monetary loss. Texas courts have not explicitly adopted § 311, but the courts have signaled that they will consider nonpecuniary loss in a negligent-misrepresentation claim. *See Roberts v. Zev Techs., Inc.*, No. 1:15-cv-309 RP, 2015 WL 7454688, at *5 (W.D. Tex. Nov. 23, 2015) (citing *Golden Spread Council, Inc. # 562 of the BSA v. Akins*, 926 S.W.2d 287, 295 (Tex. 1996) (Enoch, J., concurring in part and dissenting in part) (criticizing the majority for coming close to adopting § 311 without doing so explicitly, and explaining that "this Court has refused to recognize the tort of negligent misrepresentation for a non-pecuniary injury. . . . And as recently as last year, when called to do so, we did not."). Texas Supreme Court has stated that "[a] party may recover for negligent misrepresentations involving a

risk of physical harm only if actual physical harm results." *D.S.A., Inc. v. Hillsboro Indep. Sch. Dist.*, 973 S.W.2d 662, 664 (Tex. 1998) (per curiam) (citing RESTATEMENT (SECOND) OF TORTS § 311 (1965)).

In *Hillsboro*, the Texas Supreme Court concluded that the plaintiff's negligent misrepresentation claim failed for lack of the independent injury required under Texas law. *Id.* at 663 (citing RESTATEMENT (SECOND) OF TORTS § 552B). "Negligent misrepresentation implicates only the duty of care in supplying commercial information; honesty or good faith is no defense, as it is to a claim for fraudulent misrepresentation." *Id.* (emphasis omitted). The plaintiff in *Hillsboro* sought only benefit-of-the-bargain damages and failed to allege an additional injury. The court rejected the plaintiff's exemplary damages claim, explaining that:

> the court of appeals erroneously sustained [the plaintiff's]'s gross negligence recovery on the theory that [the defendant], by inducing [the plaintiff] to build a school without adequate supervision, imposed an extreme risk of harm on third parties—the children who eventually occupied the building. A party may recover for negligent misrepresentations involving a risk of physical harm only if actual physical harm results. *See* RESTATEMENT (SECOND) OF TORTS § 311 (1965). As there is no evidence that any children were *actually* harmed or that any of the other hypothetical dangers the court of appeals cited actually materialized, [the plaintiff] is not entitled to exemplary damages.

Id. at 664 (emphasis in original). The parties did not cite, and the court did not find, other cases allowing recovery for negligent misrepresentation claims resulting in physical harm, or Texas cases stating that Texas has adopted § 311. While dicta in *Hillsboro* and *Golden Spread* indicate that Texas endorses the theory, Texas cases on negligent misrepresentation overwhelmingly apply the § 552B definition, which requires a business-related misrepresentation and a pecuniary loss. Neither is present here.

The plaintiffs argue that Texas law adopts § 311, citing cases from the Northern District of Texas and the Texas Supreme Court. (Docket Entry No. 25 at 31–32). *Staples v. Merck & Co.*, 270 F. Supp. 2d 833 (N.D. Tex. 2003), relied on one intermediate appellate court case to conclude

that Texas has adopted § 311. *See id.* at 840 (citing *EDCO Prod., Inc. v. Hernandez*, 794 S.W.2d 69 (Tex. App.—San Antonio 1990, writ denied)). The intermediate appellate court decision, *EDCO Products*, was decided before the Texas Supreme Court issued *Council, Inc. # 562 of the BSA v. Akins*, 926 S.W.2d 287 (Tex. 1996), which stated that Texas had not explicitly adopted a nonpecuniary injury theory for negligent misrepresentation claims. *See id.* at 295 (Tex. 1996) (Enoch, J., concurring in part and dissenting in part). Because it is unclear that Texas courts have, or have not, adopted § 311, the court examines whether the negligent-misrepresentation claim is subject to dismissal on other grounds.

Juno argues that the court should dismiss the negligent-misrepresentation claim because the plaintiffs fail to specify what misrepresentations were made and fail to meet the Rule 9(b) heightened pleading requirements. (Docket Entry No. 43 at 28); *see Lone Star Fund V (US), LP v. Barclays Bank PLC*, 594 F.3d 383, 387 n.3 (5th Cir. 2010) ("Rule 9(b) does apply. '[T]his court has applied the heightened pleading requirements when the parties have not urged a separate focus on the negligent misrepresentation claims' such as when 'fraud and negligent misrepresentation claims are based on the same set of alleged facts.'"); *see also McCall v. Genentech, Inc.*, No. 3:10-CV-1747-B, 2011 WL 2312280, at *3 (N.D. Tex. June 9, 2011) ("When claims for fraud and negligent misrepresentation are based on the same set of alleged facts, Rule 9(b)'s heightened pleading standard applies."). "In the Fifth Circuit, the Rule 9(b) standard requires 'specificity as to the statements (or omissions) considered to be fraudulent, the speaker, when and why the statements were made, and an explanation of why they were fraudulent.'" *Id.* (quoting *Plotkin v. IP Axess, Inc.*, 407 F.3d 690, 696 (5th Cir. 2005)).

The plaintiffs have satisfied this pleading standard. They allege that Juno's omissions and statements about the severity and prevalence of the JCAR015 side effects were untrue; that Juno

made the statements or omissions in the informed consent form provided to the investigators; and that the statements and omissions were fraudulent because the severity and prevalence of certain side effects—severe neurotoxicity and severe cytokine release syndrome—was significantly higher than represented, especially among the high-risk groups that included Holland.

To the extent that Texas law allows negligent-misrepresentation claims based on personal injury, the plaintiffs have met the heightened pleading requirement. The parties may raise the issue of whether Texas law recognizes § 311 at the summary judgment stage, when the relevant facts are better developed and the applicable law more fully briefed.

D. The Fraud and Fraudulent Concealment Claims

"To state a claim of fraud by misrepresentation under Texas law, a plaintiff must sufficiently allege (1) a [material] misrepresentation that (2) the speaker knew to be false or made recklessly (3) with the intention to induce the plaintiff's reliance, followed by (4) actual and justifiable reliance (5) causing injury." *Rio Grande Royalty Co., Inc. v. Energy Transfer Partners, L.P.*, 620 F.3d 465, 468 (5th Cir. 2010) (citing *Ernst & Young, L.L.P. v. Pac. Mut. Life Ins. Co.*, 51 S.W.3d 573, 577 (Tex. 2001)). In addition, fraud claims must comply with the particularity requirements of Rule 9(b).

The plaintiffs allege a single count for both fraud and fraudulent concealment. Under Texas law, fraudulent concealment "applies when a defendant makes fraudulent misrepresentations or, if under a duty to disclose, conceals facts from the plaintiff and thereby prevents the plaintiff from discovering the cause of action against the defendant." *Avance v. Kerr-McGee Chem. LLC*, No. 5:04CV209, 2006 WL 3909715, at *3 (E.D. Tex. Dec. 18, 2006); *see also Earle v. Ratliff*, 998 S.W.2d 882, 887 (Tex. 1999) (describing fraudulent concealment as an equitable doctrine providing a defense against limitations.); 50 TEX. JUR. LIMITATIONS OF ACTIONS

§ 119 ("Fraudulent concealment is not an independent cause of action but, rather, is an equitable doctrine that provides an affirmative defense to statutes of limitations estops the defendant from relying on the statute of limitations.").

The doctrine serves the same purpose as the discovery rule, to toll the statute of limitations or defer accrual of the cause of action. *See, e.g., S.V. v. R.V.*, 933 S.W.2d 1, 6 (Tex. 1996). It is an affirmative defense to a statute of limitations defense, not a stand-alone cause of action. 50 TEX. JUR. LIMITATIONS OF ACTIONS § 119; *see also BP Am. Prod. Co. v. Marshall*, 342 S.W.3d 59, 67–69 (Tex. 2011); *Doe v. St. Stephen's Episcopal Sch.*, 382 F. App'x 386 (5th Cir. 2010) (addressing the fraudulent-concealment doctrine to suspend the running of the statute of limitations).

However, the plaintiffs have pleaded sufficient facts to proceed on their fraud claim. They allege that Juno, through the informed consent form, materially misrepresented the severity and prevalence of the side effects of JCAR015. The plaintiffs sufficiently allege that Juno had provided M.D. Anderson an informed consent form that lacked the requisite warnings. (*See* Docket Entry No. 41 at ¶¶ 26, 40, 60–67). Juno argues that it did not approve or provide the informed consent form, but whether the investigators changed the informed consent form in a material way, or adopted a form identical to the sample informed consent form Juno provided, cannot be resolved on the pleadings. The same is true for Juno's argument that it did not approve the informed consent forms. (*See* Docket Entry No. 43 at 29–30). The plaintiffs also allege that Juno did not update the Investigator's Brochure to reflect the JCAR015 ROCKET Trial death in May, leading to inaccurate warnings given to Holland through the informed consent. (Docket Entry No. 41 at ¶ 74). Based on the alleged facts in the amended complaint, Juno provided the model informed consent form to the investigators, implicitly approving that form. (Docket Entry No. 41 at ¶ 26). The allegations

contrasting the information in the informed consent form with the information in Juno's annual reports and highlighting the failure to update the Investigator's Brochure sufficiently pleads a fraud claim.

E. The Breach of Warranty Claim

The plaintiffs bring a breach-of-express-warranty claim for the information contained in the informed consent form, which they allege affirmatively misrepresented the risks of serious side effects. (Docket Entry No. 41 at ¶ 106). Juno argues that the claim fails because "Juno made no statement to Ms. Holland" and "was not a party to" the informed consent form the M.D. Anderson investigators gave to Holland. (Docket Entry No. 43 at 30).

A breach of an express warranty claim in Texas requires a plaintiff to prove: "(1) an express affirmation of fact or promise by the seller relating to the goods; (2) that such affirmation of fact or promise became a part of the basis of the bargain; (3) that the plaintiff relied upon said affirmation of fact or promise; (4) that the goods failed to comply with the affirmations of fact or promise; (5) that the plaintiff was injured by such failure of the product to comply with the express warranty; and (6) that such failure was the proximate cause of plaintiff's injury." *Massa v. Genentech, Inc.*, No. H-11-70, 2012 WL 956192, at *9 (S.D. Tex. Mar. 19, 2012) (quoting *Morris v. Adolph Coors Co.*, 735 S.W.2d 578, 587 (Tex. App.—Fort Worth 1987)).

The plaintiffs have sufficiently alleged the facts necessary to state a plausible claim. Generally, breach-of-warranty claims are subject to the learned-intermediary doctrine. *Gonzalez v. Bayer Healthcare Servs.*, 930 F. Supp. 2d 808, 818 (S.D. Tex. 2013). Because the plaintiffs have sufficiently alleged that the learned-intermediary doctrine does not apply, the claim for breach of warranty survives dismissal.

F. Exemplary Damages

The plaintiffs seek exemplary damages, alleging that Juno's acts were intentional, knowing, malicious, wanton, willful, and in conscious disregard of Holland's rights. The plaintiffs cite Texas Civil Practice & Remedy Code §§ 41.003(a) and 71.009, as well as § 32.46 of the Texas Penal Code, to argue that the statutory cap on exemplary damages does not apply.

"Under section 41.003, exemplary damages cannot be awarded without a finding, by clear and convincing evidence, of fraud, malice, or gross negligence." *Signal Peak Enters. of Tex., Inc. v. Bettina Invs., Inc.*, 138 S.W.3d 915, 927 (Tex. App.—Dallas 2004, pet. struck). In a wrongful death case, exemplary damages are available "when the death is caused by the willful act or omission or gross negligence of the defendant." *Callis v. Union Carbide Chem. & Plastics Corp.*, 932 F. Supp. 168, 169 n.2 (S.D. Tex. 1996) (quoting TEX. CIV. PRAC. & REM. CODE ANN. § 71.009 (Vernon 1986)). Section 32.46 of the TEXAS PENAL CODE states: "A person commits an offense if, with intent to defraud or harm any person, he, by deception . . . (a) causes another to sign or execute any document affecting property or service or the pecuniary interest of any person."

Juno argues that the plaintiffs' claims for exemplary damages should be stricken because exemplary damages are a remedy, not a cause of action. The Texas Supreme Court has held that exemplary damages are not an independent cause of action "where no cause of action for compensatory damages otherwise exists." *Travelers Indem. Co. of Ill. v. Fuller*, 892 S.W.2d 848, 849 (Tex. 1995). The plaintiffs have successfully pleaded several causes of action for compensatory damages, which permits them to prove that they also are entitled to exemplary damages.

Juno also argues that Article XVI, § 26 of the Texas Constitution prohibits parents from recovering punitive damages on wrongful death claims for their children. (Docket Entry No. 43

at 31). The plaintiffs agree. (Docket Entry No. 25 at 35). The plaintiffs admit that they cannot recover exemplary damages for wrongful death, but they argue that they can recover under the Texas Survival Statute, relying on *Flock v. Scripto-Tokai Corp.*, No. H-00-3794, 2001 WL 34111723, at *22 (S.D. Tex. Nov. 19, 2001).

In *Flock*, the court considered this same issue, explaining that "[u]nder Article XVI, § 26 of the Texas Constitution, parents of a deceased child are not entitled to recover exemplary damages arising out of the wrongful death of their child; only the 'surviving husband, widow, heirs of his or her body, or such of them as there may be' are permitted to recover such damages." *Id.* at *22 (citing TEX. CONST. art. XVI, § 26; *Hofer v. Lavender*, 679 S.W.2d 470, 475–76 (Tex. 1984)). As the plaintiffs argue, "[t]he Supreme Court of Texas has held . . . that parents may recover exemplary damages when bringing an action on behalf of their deceased child under the Texas Survival Statute." *Id.* (citing *Hofer*, 679 S.W.2d at 476).

Juno argues that because exemplary damages under the Texas Survival Statute must be brought under § 41.003, the court should strike the claim under § 71.009. (Docket Entry No. 43 at 32). Juno argues that the plaintiffs have not alleged "facts demonstrating that Juno acted with malice" or gross negligence, which is required under § 41.003. While the court strikes the claim for exemplary damages under § 71.009, the plaintiffs have sufficiently pleaded facts that could show that Juno was grossly negligent based on its alleged awareness of JCAR015's dangerousness and its alleged failure to properly warn. The court dismisses the claim under § 71.009, but not the claim in its entirety. Because the plaintiffs have sufficiently stated a fraud claim, there is no basis on which to strike the exemplary-damages claim.

IV. Conclusion

For the reasons set out in detail above, the court denies Juno's motion to dismiss except as to the plaintiffs' claim for exemplary damages under Texas Civil Practice & Remedy Code § 71.009. (Docket Entry No. 43).

SIGNED on June 21, 2019, at Houston, Texas.

Lee H. Rosenthal
Chief United States District Judge