IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

JANET SCHUBERT,

Plaintiff,

vs.

GENZYME CORPORATION, ET AL.,

Defendants.

MEMORANDUM DECISION AND ORDER

Case No. 2:12CV587DAK

Judge Dale A. Kimball

This matter is before the court on Defendant Genzyme Corporation's Motion for Judgment on the Pleadings Regarding Plaintiff's Claim for Negligent Manufacturing. Genzyme seeks an order dismissing Plaintiff Janet Schubert's negligent manufacturing claim to the extent that it claims a duty to manufacture a pharmaceutical in quantities sufficient to meet market demand. On July 18, 2013, the court held a hearing on the motion. At the hearing, Plaintiff was represented by Jeffrey D. Eisenberg, and Genzyme was represented by Richard E. Mrazik and Katherine Venti. The court took the matter under advisement.[1] The court has considered carefully the memoranda submitted by the parties, as well as the law and facts relating to the

[1] The case is also before the court on Plaintiff's Motion for Leave to Amend the Complaint, which was filed after the Motion for Judgment on the Pleadings was briefed and heard. As such, the motion to amend was filed while the motion for judgment on the pleadings was pending. The motion to amend is taken under advisement on the briefs and denied without prejudice as discussed below.

motion. Now being fully advised, the court renders the following Memorandum Decision and Order.

BACKGROUND

This is a product liability/medical malpractice case arising out of a shortage of the medication, Fabrazyme®, manufactured by Genzyme. Plaintiff Janet Schubert, the widow of Dr. William Schubert, alleges that the shortage caused her husband's death.

In 2005, Dr. Schubert was diagnosed with Fabry Disease and began taking Fabrazyme. Fabry Disease is caused by a faulty or missing enzyme needed to metabolize lipids. Fabrazyme is an enzyme replacement treatment for Fabry Disease. From the time of his diagnosis until sometime in late 2009, Dr. Schubert received the FDA approved dose of Fabrazyme every two weeks.

In June 2009, Plaintiff alleges that Genzyme "negligently allowed a virus contamination in the manufacturing facility where Genzyme makes Fabrazyme, which led to a shortage of the drug, and which resulted in Genzyme not meeting demand of Fabrazyme to Fabry Disease patients." Third Am. Compl. ¶ 22. In November 2009, the shortage worsened when the FDA discovered additional contamination in some Fabrazyme and production of the drug was further limited.

Plaintiff contends that "[d]ue to this shortage, Genzyme began arbitrarily rationing Fabrazyme towards the end of 2009. Although patients under the age of 18 continued to receive their treatment as scheduled, older patients received as much as a 70% reduction in dose." *Id.* Plaintiff further alleges that "Genzyme's rationing scheme was undertaken despite [its] knowledge that less than full dosage would not be effective and many patients would suffer

catastrophic health deterioration and even death." *Id.* ¶ 23. Plaintiff's Complaint alleges that Dr. Schubert's health condition began to decline shortly after he began treatment with the reduced dose in late 2009.

Dr. Schubert learned that a Canadian bioequivalent drug, Replagal, could be obtained through a compassionate exception from the FDA. After some alleged delays that Plaintiff attributes to Dr. Schubert's treating physician, Dr. Schubert eventually obtained the FDA exception and began taking Replagal. However, Plaintiff alleges that "the delay in obtaining the proper dosage of the medication proved fatal and ultimately caused Dr. Schubert's death." *Id.* ¶ 30. Dr. Schubert died on March 6, 2010.

Plaintiff, individually and as personal representative of Dr. Schubert's heirs, brought this lawsuit, asserting claims against Genzyme for negligence, strict liability, and breach of express and implied warranties. The only cause of action at issue in the present motion is the negligence cause of action. Plaintiff alleges that Genzyme owed a duty to Dr. Schubert to "use reasonable care to ensure a continued supply in therapeutic doses." Plaintiff further alleges that Genzyme is liable in negligence

> for restricting and/or consenting to a restriction of administering Fabrazyme at a dose that is below the FDA approved use of 1 mg/kg body weight infused every two weeks; for selling Fabrazyme contaminated with glass, rubber, and steel particles; for failure to give adequate and complete warnings of the known or knowable dangers involved in the use of Fabrazyme at reduced dose as required by FDA regulations; for unreasonably using a publicly funded invention by restricting administration to below the FDA approved dose and for non-use of the invention by banning the publicly funded invention from being given in therapeutic doses to Fabry Disease patients; for failure to provide or require proper and/or adequate reserves of unadulterated Fabrazyme in order to prevent or mitigate manufacturing errors; for

> failing to provide or license a second course of manufacture for Fabrazyme in order to prevent or mitigate life-threatening supply chain disruption; and in otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.

Id. ¶ 36. Genzyme does not move to dismiss the negligent failure to warn portion of this cause of action. Genzyme's present motion deals only with the portions of this cause of action alleging negligence in supplying enough Fabrazyme to meet market demand, referred to by Genzyme as Plaintiff's negligent manufacturing claim.

DISCUSSION

Genzyme moves for judgment on the pleadings, asserting that Plaintiff's negligent manufacturing claim fails as a matter of law because Genzyme has no duty to manufacture Fabrazyme in sufficient supply for any or all users. To state a claim for negligence under Utah law, a plaintiff must assert that (1) defendant owes plaintiff a duty of reasonable care, (2) defendant breached that duty, (3) the breach caused plaintiff's injury, and (4) plaintiff suffered damages. *Williams v. Melby*, 699 P.2d 723, 726 (Utah 1985).

Genzyme argues that, as a matter of law, Plaintiff cannot establish a duty of care owed by Genzyme to Plaintiff with respect to manufacturing enough Fabrazyme to meet all market demand. Plaintiff alleges that Genzyme "owed a duty to Dr. Schubert and other persons who they knew or should have known relied on Fabrazyme as a life-saving drug to use reasonable care to ensure a continued supply." *Id.* ¶ 43. Whether a duty of care exists is a question of law for the court.

The only other court to address whether a drug manufacturer has a duty to manufacture sufficient supplies of a pharmaceutical ruled that there is no such duty. *Lacognata, et al. v.*

Hospira Inc., 2012 WL 6962884, *2 (M.D. Fla. July 2, 2012). In *Lacognata*, the plaintiff suffered from a Vitamin A deficiency that prevented her from absorbing Vitamin A, which can cause blindness and other adverse effects. *Id.* at *1. The plaintiff sued the manufacturer of Aquasol A, a prescription form of injectable Vitamin A, alleging that the manufacturer had a legal duty to continue supplying the drug to patients who needed the drug and it was negligent in creating a global shortage of the drug. *Id.* at *2. The manufacturer was the only manufacturer of the drug and it exited the market entirely. *Id.* The court disagreed with the plaintiff: "There is no authority that supports Plaintiff's argument that a drug manufacturer, like Hospira, has a duty to continue supplying a patient with a drug it knows the patient relies upon for his or her medical health." *Id.* (noting it is not "court's role to dramatically expand Florida law as Plaintiff seeks").

Similarly, Genzyme argues that Utah law does not impose upon manufacturers a duty to ensure a continued supply of their product for all potential users. Plaintiff, however, contends that *Lacognata* is factually distinguishable and Utah case law discussing duty demonstrates that Genzyme owes Plaintiff a duty.

There is no Utah case law addressing the duty of a drug manufacturer to supply the market with sufficient quantities of its product. However, Plaintiff relies heavily on the Utah Supreme Court's general discussion of a party's legal duty of care in *Jeffs v. West*, 275 P.2d 228 (Utah 2012). In *Jeffs*, a nurse had prescribed a patient at least six medications. *Id.* at 229-230. While these medications were in the patient's system, the patient shot and killed his wife. *Id.* at 230. The couple's children filed suit against the nurse alleging negligence in the prescription of the medications that allegedly caused the patient's violent outburst and his wife's death. *Id.* The district court dismissed the cause of action, concluding that the nurse owed no duty of care to the

children because no patient-health care provider relationship existed between the nurse and children. *Id.* The Utah Supreme Court reversed, holding that healthcare providers have a legal duty to nonpatients to exercise reasonable care in prescribing medications to patients who pose a risk of injury to third parties. *Id.*

In *Jeffs*, the Utah Supreme Court recognized that its previous cases have identified several factors relevant to determining whether a defendant owes a duty to a plaintiff: "(1) whether the defendant's allegedly tortious conduct consists of an affirmative act or merely an omission; (2) the legal relationship of the parties; (3) the foreseeability or likelihood of injury; (4) public policy as to which party can best bear the loss occasioned by the injury; and (5) other general policy considerations." *Id.* at 230 (citations omitted).

With respect to the five factors, the court stated that "[n]ot every factor is created equal." *Id.* "The long-recognized distinction between acts and omissions–or misfeasance and nonfeasance–makes a critical difference and is perhaps the most fundamental factor courts consider when evaluating duty." *Id.* at 231. The court recognized that "[a]cts of misfeasance, or 'active misconduct working positive injury to others' typically carry a duty of care," whereas "[n]onfeasance–'passive inaction, a failure to take positive steps to benefit others, or to protect them from harm not created by any wrongful act of the defendant'–by contrast, generally implicates a duty only in cases of special legal relationships." *Id.*

"'In almost every instance, an act carries with it a potential duty and resulting legal accountability for that act. By contrast, an omission or failure to act can generally give rise to liability only in the presence of some external circumstance–a special relationship.'" *Id.* (quoting *Webb v. University of Utah*, 2005 UT 80, ¶ 10, 125 P.3d 906). Thus, generally, a special

relationship is required to impose a duty in situations of nonfeasance. *Id.*

The *Jeffs* court distinguished cases where the healthcare provider was alleged to have negligently released a patient or failed in preventing the patient from escaping from the hospital because such cases involved nonfeasance or a failure to act by the healthcare provider. *Id.* at 233. In contrast, in *Jeffs*, the court found that prescribing the medications was an affirmative act and a special relationship did not need to underlie the nurse's duty to the patient's children. *Id.*

The *Jeffs* court also emphasized that "duty must be determined as a matter of law and on a categorical basis for a given class of tort claims," not a fact-specific case-by case approach. *Id.* at 234. "Rather, the duty analysis considers healthcare providers as a class, negligent prescription of medication in general, and the full range of injuries that could result in this class of cases." *Id.* at 235.

In the present case, the parties disagree as to whether Genzyme's alleged conduct constitutes misfeasance or nonfeasance. Genzyme argues that a failure to supply enough product is an act of omission and, therefore, nonfeasance. Whereas Plaintiff argues that the alleged conduct was affirmative misfeasance because Genzyme's actions caused the shortage. In determining whether there is a duty to supply the market with sufficient quantities of a product, Genzyme contends that the reason for the shortage is irrelevant. However, Plaintiff asserts that Genzyme negligently caused its product to become contaminated, which reduced the supply.

Utah cases on duty support Genzyme's position that the reason for the shortage is irrelevant to the court's determination as to whether Genzyme owes Plaintiff a duty. In *Higgins v. Salt Lake County*, 855 P.2d 231 (Utah 1993), the court identified the first issue on appeal as: "assuming that defendants may have failed to use reasonable care in treating, supervising,

diagnosing, and not committing" a mental health patient with a history of violence, "did defendants owe a duty to" the family of a child stabbed by the patient. *Id.* at 235. This framing of the issue demonstrates that possible negligent acts causing the patient to be out in the public did not create a duty between the parties.

In *Rollins v. Petersen*, 813 P.2d 1156 (Utah 1991), the court analyzed whether the Utah State Hospital had a duty to protect the decedent from a patient known to be dangerous. *Id*. at 1158-59. The patient had been diagnosed as mentally ill, admitted to the hospital several times for violent behavior, most recently admitted for stabbing a roommate, and had a history of escaping from the hospital on at least two other occasions. *Id.* at 1158. On the date in question, the patient walked out of the facility, despite his assignment in a locked ward, and found an unattended automobile on a nearby street, which he stole. *Id.* He later lost control of the car on the freeway, causing a head-on collision with another vehicle and killing decedent. *Id.*

In *Rollins*, the decedent's heirs asked the court to impose a duty on the hospital to protect the public at large from allegedly dangerous persons in custody. *Id.* at 1161. But the court declined to find such a duty, stating that "if these custodians owed a duty to every member of the public for any harm done by a person under their control, the broad potential for liability could effectively cripple these programs." *Id.* The court also found that there was no evidence that the patient had not set himself apart in terms of dangerousness and the decedent was not in a distinct group at risk. *Id.* at 1162. Therefore, the court found that the hospital had no duty to the decedent. *Id.*

In determining whether the hospital owed the plaintiffs a duty, the *Rollins* court did not address whether the hospital was negligent in any specific aspects that enabled the patient to

walk away from the facility. And, the *Jeffs* case referred to the *Rollins* case as a "straightforward nonfeasance case." 275 P.2d at 232. Similarly, in this case, the court concludes that under Utah negligence law, Schubert's failure to meet market demand for a drug is nonfeasance.

While acts of misfeasance typically carry a duty of care, nonfeasance generally implicates a duty only in cases of special legal relationships. *Jeffs*, 275 P.3d at 231. Special relationships "generally arise when one assumes responsibility for another's safety or deprives another of his or her normal opportunities for self-protection." *Webb*, 125 P.3d at 909. Examples of special relationships include "common carrier to its passenger, innkeeper and guest, landowner and invitees to his land, and one who takes custody of another." *Id.* Plaintiff does not allege nor argue that a special relationship existed between Genzyme and Dr. Schubert.

Plaintiff, however, also argues that Genzyme engaged in an affirmative act of misfeasance when it decided to continue supplying the market with Fabrazyme at a dose below the FDA approved dosage, knowing that the reduced dose would result in harm to users. Plaintiff contends that *Lacognata* is distinguishable because the drug manufacturer ceased production altogether. Plaintiff argues that failing to supply the market with any product is an act of omission, but supplying the market with less than the FDA required amount is an affirmative act.

To the extent that Plaintiff is asserting that Dr. Schubert was harmed by not receiving the full dose, the analysis is the same. The court finds no legal or factual distinction between this case and *Lacognata.* In other words, the court finds no distinction between the duty of a company that exits the market altogether and a company that does supply enough product to meet full market demand. In both instances, the harm is the shortage of the medication and it is an act

of nonfeasance. Genzyme should not be penalized for producing as much of the product as it could.

However, to the extent that Plaintiff claims that the lowered dosage of the medication was more harmful that receiving no medication, there is a distinction between the cases and Plaintiff's claim survives at the pleading stage. Plaintiff alleges that Genzyme knew a reduced dosage of the medication would be more harmful than no medication. Whether there is support for this allegation will need to be proven or rebutted through discovery and/or trial.

Because Plaintiff asserts that the shortage of supply was an affirmative act instead of nonfeasance, Plaintiff analyzes the remaining factors of foreseeability and public policy, which the *Jeffs* court recognized are relevant to determining whether there is a duty when an affirmative act occurred. As to general policy considerations, Plaintiff argues that this factor weighs in favor of finding a duty because it is imperative that when companies undertake the responsibility of manufacturing a drug that they do so safely. Genzyme is the only company that is allowed to manufacture and distribute Fabrazyme in the United States and Plaintiff contends that the Bayh-Dole Act requires Genzyme to make Fabrazyme "reasonably accessible to the public." 35 U.S.C. § 200(b)(5).

However, even if Genzyme's failure to produce sufficient quantities of Fabrazyme was deemed to be an affirmative act of misfeasance, the court finds that public policy considerations would weigh heavily against finding a duty. "A court's conclusion that duty does or does not exist is an expression of the sum total of those considerations of policy which lead the law to say that the plaintiff is [or is not] entitled to protection." *Webb*, 125 P.3d at 909.

Pharmaceutical manufacturing is heavily regulated by federal law and there is no statutory

duty placed on a manufacturer to ensure a continued supply of any given pharmaceutical. Federal regulations require a manufacturer to report an interruption or discontinuance to the FDA, but there is no regulation imposing a duty to continue manufacturing. *See* 21 C.F.R. § 314.81(b)(3). In addition, the Bayh-Dole Act does not require specific levels of production. Rather than requiring a manufacturer to produce a sufficient amount of a product, the Bayh-Dole Act provides a procedure by which a license to produce an invention arising from federally supported research or development can be granted to others if (1) the contractor or assignee has not take, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention; or (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees. *See* 30 U.S.C. § 203 (the "March-In Provision").

There is no federal law requiring a manufacturer to produce amounts sufficient to meet all potential demand. In such a heavily regulated industry, if such a duty was deemed necessary, the governing regulators would have imposed it. Moreover, it is more appropriate for such governing regulators to create such a duty than for this court to do so.

The court agrees with Genzyme that important policy considerations underlie the lack of a duty to manufacture a drug in quantities sufficient to meet all market demand. Imposing such a duty would prevent a manufacturer from ever ceasing production, require it to predict all potential demand, and further require it to maintain large stockpiles to prevent any shortages in case of production problems. Such an onerous rule is contrary to public policy because it creates an enormous disincentive for potential providers of pharmaceuticals from entering the market in the first place and could stifle development of new therapies. There are already strong incentives

for pharmaceutical companies to supply drugs to all who may need them. There is also an incentive to maintain good relationships and a good reputation with doctors, hospitals, and distributors by consistently meeting demand. From a business perspective, it is in the company's best interest to meet demand in order to be profitable and maintain customers. Despite these strong incentives to meet supply, a variety of factors can cause a company not to meet demand. There are technical challenges posed by producing biologic therapies. These cannot always be controlled despite a company's best efforts. The FDA reported 178 drug shortages in 2010 and 251 drug shortages in 2011. The court need look no further than the seasonal flu vaccine to find an example of a potentially life-saving therapy being routinely rationed among different patient populations. In light of the unavoidable nature of manufacturing and supply issues, a rule requiring manufacturers to forever supply a therapeutic or preventative treatment to everyone who is or may be prescribed it, regardless of the cost or feasibility of doing so, would create a significant disincentive to manufacturers that is against the public interest.

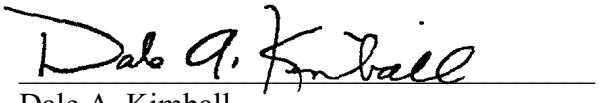
Plaintiff's claim that Genzyme has a duty to meet all market demand for Fabrazyme would assert liability on a theory never before recognized in Utah. The court declines to expand Utah law in such a way. Genzyme's failure to produce enough Fabrazyme is an omission that does not give rise to a duty under Utah or federal law. Accordingly, Plaintiff's negligence claim is dismissed to the extent that it is based on a shortage of Fabrazyme. To the extent that Plaintiff alleges that the drug obtained by Dr. Schubert was harmful in its reduced dosage, contaminated, or faulty, this is a typical products liability action and that portion of the negligence claim survives.

CONCLUSION

For the reasons stated above, Defendants' Motion for Judgment on the Pleadings is GRANTED. Plaintiff's Motion for Leave to File an Amended Complaint is DENIED without prejudice. To the extent that the motion to amend relates to clarifying claims based on a shortage of Fabrazyme, the motion is moot. However, Plaintiff may resubmit the motion with respect to other allegations and claims at issue in the Complaint.

Dated this 4th day of September, 2013.

BY THE COURT:



Dale A. Kimball,
United States District Judge