2014

A "Duty" to Continue Selling Medicines

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American Journal of Law & Medicine, 40 (2014): 330-392

A "Duty" to Continue Selling Medicines

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[†] © William M. Janssen. Professor of Law, Charleston School of Law. This Article expands on a chapter written for TOP 20 FOOD AND DRUG CASES OF 2013 & CASES TO WATCH, 2014 (FDLI 2014). The author thanks Gregory J. Wartman, Michael Levin-Epstein, and the Food and Drug Law Institute for that opportunity. The author also thanks James M. Beck, Esq. and the various blind reviewers who participated in the peer-review of the submitted draft; the final version reflects their much appreciated recommendations.

With disappointing frequency, shortages occur in the supply of prescription pharmaceuticals. Sometimes, those shortages persist for months (even years), and can implicate the only known medicine to treat a life-threatening medical condition. Sometimes, those shortages may also be due to avoidably negligent decisions in manufacture. Twice in the past two years, seriously ill patients—confronting just such medicine supply shortages—have resorted to the courts, demanding a judicial remedy for negligently caused supply interruptions to critically needed medicines. In doing so, they have asserted a bold litigating position: the law ought to impose upon drug manufacturers a legal duty to continue selling their medicines. In other words, once a pharmaceutical manufacturer enters a medicine market, it is obligated by law to remain there and preserve perpetually its medicine's supply. This claim of compelled-access-to-pharmaceuticals pushes to the very frontier of drug law in America.

This Article begins by tracing the two cases (one in Utah, the other in Florida) that confronted these creative compelled-access-to-medicines arguments. Earlier cases, resolving a distinctive but thematically similar compelled-access argument in the context of experimental drugs, are introduced as well. The discussion explains how each claim lost in court. The Article next performs an independent survey of a wide range of legal theories—in constitutional principle, enacted law, regulatory law, and case law—that could be cited as alternative potential sources for imposing a duty on manufacturers to continue selling their drugs. It demonstrates that none is likely to be a credible source for that duty. Finally, the Article examines the competing policy considerations that would be implicated by "inventing" such a duty, finds that a judicial invention is unwise, but offers a potential statutory amendment designed to strike a sound balance between the legitimate proprietary and autonomy interests of manufacturers and the health and survival interests of critically ill patients.

I. INTRODUCTION

The Panic of 1983 reached its climax in late December. With the winter holiday season bearing ever closer, citizens across the Nation were overwrought. Long lines formed in the wee hours of the morning as the anxious braved the winter cold to queue up in the dark. Spontaneous telephone chains emerged, as neighbors called out to one another with gathered (or inferred) reconnaissance. The evening TV news broadcasted stories of brawls in the aisles and terror in the parking lots. Fistfights and hoarding were commonplace. The phone in most parented homes was never far from reach, as nerve-wracked adults waited for the word that would launch them off the family room sofa, dashing out to the car, and careening down the road towards some unassuming shopping center: Cabbage Patch Kids had been spotted.

The culprits of this frenzy were cuddly, all-fabric toy dolls, invented by a 21-year-old art student and later mass-produced by Coleco in 1982.[1] They became the singular have-to-have toy the next Christmas. So crazed was the country, that the

[1] *See* Megan Angelo, *12 Things You Never Knew About Cabbage Patch Kids*, GLAMOUR (Nov. 12, 2013), http://www.glamour.com/entertainment/blogs/obsessed/2013/11/cabbage-patch-kids-facts.html.

Cabbage Patch Kids made it on the December 12, 1983 cover of *Newsweek* magazine with the splashy caption, "What a Doll!"[2] In the years that followed, students of economics and consumer behavior would devote all manner of academic energy to exploring the curious phenomenon of "scarcity marketing" and the psychological dynamics in demand-building from a suppressed supply.[3] But back at Christmas 1983, the "panic" triggered by this toy shortage seemed much less academic. Though entertaining to chuckling spectators standing off from the fray in the distance, it was all too real for desperate parents, hell-bent on ensuring their children's happy walk to the tree that approaching Christmas morning. For them, the hunt for a Cabbage Patch Kid seemed like a life-or-death mission.[4]

What if it really had been?

The cute and now legendary tale of the Cabbage Patch Kids craze grows far darker when a supply shortage imperils something more serious than plush toys. Such was the case in 2009 and 2010 when an enzyme replacement therapy, essential to treating a rare but devastating illness, fell into dangerously short supply.[5] What if the maker of that therapy could have done better to protect the integrity of its product supply? What if the supply interruption could be traced back to careless behavior and poor production judgments? What if the product in depleted supply was critical to sustaining human life, and its interruption turned a loving spouse into a widow?

These were the accusations leveled by a woman in Idaho against the biologics company that had produced her late husband's enzyme therapy. She brought a lawsuit contending that tort law imposed upon that company a duty to exercise reasonable care to ensure that its inventory of enzyme replacement medicine would not be interrupted (or, if it was, that the supply be swiftly repaired).[6] She alleged, in short, that drug manufacturers ought to have a civil duty to sell, and continue selling, their medicine products to all needy patients.[7] It is a remarkable contention, and one that presses to the very frontier of pharmaceutical law in America.

This Article explores the contention that medicine makers ought to be held legally responsible, in tort or otherwise, for carelessly caused interruptions in the supply of medicines. Part I of this Article discusses the several litigations that have introduced this argument into contemporary law. Part II examines, claim by claim, various legal principles that might be candidates for the source of such a legal "duty" to be imposed on medicine manufacturers. Finally, Part III considers the wisdom of inventing such a "duty" if none is found elsewhere, the competing policy

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[2] *Id.* A Christmas later, the panic was still in full bloom. *See Cabbage Patch Kids Shortage Will Continue*, SCHENECTADY GAZETTE (Dec. 27, 1984), http://news.google.com/newspapers?nid=1917&dat=19841227&id=FBEhAAAAIBAJ&sjid=HHQFAAAAIBAJ&pg=4058,2816568.

[3] *See* Russ Pitts, Op-Ed., *The Wii Shortage, and Other Disasters of Toy Economics*, ESCAPIST (Nov. 19, 2007, 6:00 PM), http://www.escapistmagazine.com/articles/view/editorials/op-ed/2650-The-Wii-Shortage-and-other-Disasters-of-Toy-Economics. The dynamics are even more fascinating when the "shortage" is contrived. *See* Alyssa Gregory, *Scarcity Marketing: Use the Fear of Shortage to Sell More*, SITEPOINT (Jan. 28, 2010), http://www.sitepoint.com/scarcity-marketing.

[4] Some of the stories were just plain remarkable. There's the Kansas City postman who flew to London to buy one, a group of Wisconsin residents who waited outside in a cold stadium because a local radio personality had jokingly promised a delivery "drop" from overflying B-29 bombers, and the Texas shopper who "hung onto her doll despite another woman's purse strap wrapped around her throat." Jerry Adler et al., *Oh, You Beautiful Dolls!*, NEWSWEEK, Dec. 12, 1983, at 78-79.

[5] *See* Schubert v. Genzyme Corp. (*Schubert I*), No. 2:12-cv-00587-DAK, 2013 WL 4776286, at *1 (D. Utah Sept. 4, 2013).

[6] *Id.* at *2.

[7] *See id.*

considerations weighing on that invention, and a statutory solution that may bridge the various interests in a manner that could offer fresh solutions to this recurring dilemma of drug supply shortages.

II. ALLEGING A "DUTY" TO CONTINUE SELLING MEDICINES

The existence of a legal duty on the part of pharmaceutical manufacturers to continue selling their medicines received its most fulsome airing in a Salt Lake City lawsuit brought by an Idaho widow in March 2012.[8] Her complaint was filed, amended three times, tested on a motion to dismiss, and then revisited on a motion for reconsideration.[9]

But this plaintiff's contention in Utah, though novel, was not wholly unprecedented. At about the same time, lawyers in Florida were raising a similar claim on behalf of a Pinellas County woman. That case was also litigated in the trial court, appealed to the federal court of appeals, and denied review by the United States Supreme Court.[10]

Along the way, lawyers in various other jurisdictions have been pressing similar claims on behalf of clinical drug trial participants who sought continued access to experimental drugs after their clinical trials (and access to the experimental therapies) terminated.[11] All of these litigations champion one common theme: medicine manufacturers ought to have a legal duty to keep manufacturing and selling their goods.

What emerges from this body of case precedent is a captivating tale of tragically ill patients innovating with fascinatingly crafted arguments in support of bold claims that a private commercial actor owes them, as buyers, a duty to sell. It is a riveting tale well worth recounting in depth.

A. DR. SCHUBERT AND CONTINUED ACCESS TO FABRAZYME

1. Dr. Schubert's Story

Dr. William Schubert was an obstetrician and gynecologist practicing medicine in southeastern Idaho until his death in March 2010 at the age of 63.[12] By reported accounts, he was a father of seven, a stepfather to three, and the compassionate deliverer of nearly 6,500 babies during his career.[13] About six years prior to his death, Dr. Schubert was diagnosed with Fabry Disease, a rare, inherited, life-threatening medical condition caused by the malfunctioning of an enzyme essential to metabolize lipids.[14] It is estimated that the disease afflicts 1 in 40,000 to 60,000 males, and less frequently in females,[15] or about 5,000 to 10,000 people.[16]

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[8] *Id*. at *1.

[9] *Id. See also* Third Amended Complaint and Jury Demand ¶ 10, *Schubert I*, 2012 WL 11883868.

[10] *See* Lacognata v. Hospira, Inc., No. 8:12-cv-822-T-30TGW, 2012 WL 6962884 (M.D. Fla. July 2, 2012).

[11] *See infra* Part II(C).

[12] *See William Schubert*, MEMORIAL SOLUTIONS, http://www.memorialsolutions.com/sitemaker/sites/coloni1/obit.cgi?user=179238Shubert (last visited Sept. 19, 2014).

[13] *Id.*

[14] *See* Third Amended Complaint and Jury Demand, *supra* note 9, ¶ 20. More specifically, Fabry Disease results from a cellular buildup of globotriaosylceramide, a particular type of fat, which progressively affects many parts of the body and can lead to kidney damage, heart attack, and stroke. The disease is believed to be caused by mutations in the GLA gene, which alters the structure and function of a certain enzyme responsible for breaking down those globotriaosylceramide fats, which in

To treat his Fabry Disease, Dr. Schubert was prescribed Fabrazyme, an enzyme replacement therapy. This substance is classified as a "biologic" (or "biological product") because, unlike more conventional drugs which have a known structure and are chemically synthesized, biological therapies are complex mixtures, usually isolated from human, animal, or microorganism sources, and may be composed of sugars, proteins, nucleic acids, or living material like cells and tissues.[17] Producing biologics is often a complex process, with unique manufacturing challenges—including susceptibility to microbial contamination.[18] Nonetheless, "biologics" may also "represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available."[19] Fabrazyme was evaluated and approved as a "biologic".[20] Manufactured by Genzyme Corporation at its plant in Allston, Massachusetts, Fabrazyme is prepared using recombinant DNA technology in a Chinese Hamster Ovary mammalian cell expression system to create a recombinant human replacement enzyme having the same amino acid sequence as the native enzyme.[21]

During most of the time Dr. Schubert was treating with Fabrazyme, this Genzyme product was the only enzyme replacement therapy approved in the United States for Fabry Disease.[22] Because (presumably) so few patients treat with Fabrazyme (fewer than 1,000 patients in 2010) and because the product preparation technology is so lengthy and complex,[23] the therapy was exceptionally expensive—about $200,000 per year.[24] Nonetheless, with little other choice, Dr. Schubert and his wife downsized to a smaller home in order to afford their insurance premiums for the Fabrazyme treatments (nearly $4,000 per month).[25] Once his biweekly intravenous treatments of Fabrazyme began, Dr. Schubert "thrived"[26] with "improved" health.[27]

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turn allows the globotriaosylceramide fats to accumulate throughout the body and especially in cells lining blood vessels, the kidneys, the heart, and the nervous system. *See Fabry Disease*, GENETICS HOME REFERENCE, http://ghr.nlm.nih.gov/condition/fabry-disease (last updated Feb. 2012).

[15] *Fabry Disease*, *supra* note 14.

[16] *See* Christine McConville, *Faults Co. Over Factory Woes, Effect of Drug Limits on Husband*, BOS. HERALD, Apr. 22, 2010, at 026.

[17] *See What Are "Biologics" Questions and Answers*, FDA, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm (last updated Apr. 14, 2009) ("Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.").

[18] *See id.*

[19] *Id.*

[20] *Fabrazyme Approval Letter 4/24/03*, FDA, *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm128159.htm (last updated Apr. 30, 2003).

[21] *See* GENZYME CORP., FABRAZYME FULL PRESCRIBING INFORMATION 2, *available at* http://www.fabrazyme.com/hcp/pi/fz_us_hc_pi.pdf (last visited Sept. 19, 2014).

[22] *See* Press Release, FDA, Genzyme Has Announced a Drug Shortage, http://www.fda.gov/downloads/drugs/drugsafety/drugshortages/ucm187056.pdf (last visited Sept. 19, 2014).

[23] *See How Fabrazyme Is Made*, GENZYME CORP., http://www.fabrazyme.com/patient/product/fz_us_pt_pd_made.asp (last visited Sept. 19, 2014).

[24] *See* Andrew Pollack, *Genzyme Drug Shortage Leaves Users Feeling Betrayed*, N.Y. TIMES (Apr. 15, 2010), http://www.nytimes.com/2010/04/16/business/16genzyme.html?pagewanted=all&_r=0.

[25] *Id.*

[26] McConville, *supra* note 16.

[27] Pollack, *supra* note 24.

Given the small patient populations this and its other enzyme replacement therapies treat, the manufacturer came to know most of its Fabrazyme patients by name.[28] Indeed, patients often turned to the manufacturer's case workers to assist them in finding funding for their prescriptions.[29] This unusual patient-manufacturer intimacy, along with the life-sustaining importance of the product it sold, left Genzyme with, in the words of its chief executive, an "enormous humility."[30] That humility was put to the test in 2009.

A short while earlier, the manufacturer had tasked its same Massachusetts production facility that made Fabrazyme to also produce Myozyme, a different therapy used to treat Pompe's disease, a condition that largely affects infants.[31] That decision evidently left less space available in the facility to produce and store Fabrazyme inventory.[32] When a viral contamination struck the facility in June 2009, global shortages of the company's enzyme replacement products followed.[33] Five months later, a Food and Drug Administration (FDA) inspection of the production plant uncovered tiny pieces of steel, rubber, and fiber contaminating certain of the medicines.[34] Four months after that, the plant was hit by a power failure.[35] This dizzying confluence of events—viral contamination, production contaminations, and power failure, all impacting the time-intensive manufacture of a delicate human enzyme product at the only plant in the world where the only producer in the world made the critical, life-sustaining treatment—proved catastrophic.

Faced with this inventory shortage, the manufacturer began rationing the enzyme therapy medicine, providing some patients with only 30% of their prescribed dosages.[36] Shortly after beginning his own reduced-dosage therapy, Dr. Schubert's health deteriorated rapidly.[37] In reply to Mrs. Schubert's pleas for increased dosage, Genzyme made an accelerated delivery of one dose in February 2010.[38] At the same time, Mrs. Schubert urgently pressed for special access to a new, as-yet unapproved bioequivalent drug from Canada.[39] Although this access was eventually granted, the approval came too late. Dr. Schubert died from Fabry Disease in the first week of March 2010.[40] Before succumbing, he had urged his wife: "You need to tell this story; this is horrible. There are just too many things that fell down."[41]

Genzyme disputed that the Fabrazyme shortages were directly responsible for Dr. Schubert's death, but acknowledged that the company had let its patients down.[42]

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[28] *See id.*

[29] *See id.*

[30] *Id.*

[31] *See* McConville, *supra* note 16.

[32] *Id.*

[33] *Id.* Evidently, viral contaminations in biotechnology factories that use living cells to make medicines are not unusual events. *See* Pollack, *supra* note 24.

[34] *See* McConville, *supra* note 16.

[35] *Id*.

[36] *See* Pollack, *supra* note 24.

[37] *Id*.

[38] *Id.*

[39] *See id*.; *Schubert I*, 2013 WL 4776286, at *1.

[40] Pollack, *supra* note 24.

[41] *Id*.

[42] *See id*. Among its defenses, Genzyme contended that "[r]educed dosing affects each patient differently," and that the company "had no way of knowing how patients would respond to reduced treatments." McConville, *supra* note 16. In any event, it appears that severe patient consequences—like the one Dr. Schubert endured—were uncommon. *See* Pollack, *supra* note 24 ("Even doctors and patient advocates say that while many patients have experienced increased and sometimes intense pain

"We saved thousands of babies" by producing the Pompe's disease drug Myozyme at the manufacturing facility, the company's senior official noted, "and we made that decision in the absence of really calculating that a virus could hit the plant and take up inventory."[43] "Many patients' lives were saved. . . . Given that we had never had a virus before, it was probably an understandable decision. But it was a high price to pay."[44] In May 2010, Genzyme entered into a consent decree with FDA pursuant to which it agreed to rectify manufacturing quality violations at its Massachusetts production plant and to a disgorgement of $175 million in unlawful profits from sales of plant-manufactured products.[45] FDA inspections charged that inadequate manufacturing systems had resulted in "production delays" and "critical shortages of medically necessary products to consumers."[46] The shipping of Fabrazyme did not resume until March 2012, more than two years after the shortage had begun.[47]

2. Mrs. Schubert's Claims

Two years later, Mrs. Schubert filed a wrongful death action against Genzyme (and others) in state court in Salt Lake County, Utah.[48] The case was subsequently removed to federal district court.[49] As amended, Mrs. Schubert's complaint proposed to hold Genzyme accountable for her husband's death under theories in negligence, strict liability, breach of express warranties, and breach of the implied warranty of both merchantability and fitness for a particular use.[50] Among the negligence claims Mrs. Schubert asserted were carelessness in:

- [R]estricting and/or consenting to a restriction of administrating Fabrazyme® at a dose that is below the FDA approved use of 1 mg/kg body weight infused every two weeks . . .
- [S]elling Fabrazyme® contaminated with glass, rubber, and steel particles . . .

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and fatigue since the shortage began, more serious medical complications have been rarer."); s*ee also* Sheri Qualters, *Judge Skeptical of Pharmaceutical-Rationing Lawsuit*, NAT'L L.J. (Jan. 15, 2014) ("A Boston federal judge criticized the pleadings in two unusual purported class actions against Genzyme Corp. over its rationing of the drug Fabrazyme, complaining that just one of more than 70 plaintiffs appears to have a valid claim. . . . [The judge] repeatedly contended that none of the plaintiffs had claimed a specific injury. 'It doesn't get better by aggregating a bunch of individuals, none of whom said they suffered a particular harm,' he said.").

[43] McConville, *supra* note 16.

[44] Pollack, *supra* note 24.

[45] *See* Press Release, FDA, Genzyme Corp. Signs Consent Decree to Correct Violations at Allston, Mass., Manufacturing Plant and Give Up $175 Million in Profits (May 24, 2010), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm213212.htm.

[46] *Id.*

[47] *Genzyme Begins Shipping Fabrazyme from Newly Approved Framingham Manufacturing Plant*, BUS. WIRE (Mar. 1, 2012, 8:30 AM), http://www.businesswire.com/news/home/20120301005875/en/Genzyme-Begins-Shipping-Fabrazyme-Newly-Approved-Framingham#.U_IbU2OZ3Zs.

[48] *See* Complaint and Jury Demand, Shubert v. Genzyme Corp., No. 120901550 (Utah Dist. Ct. Mar. 2, 2012). Among the other defendants Mrs. Schubert had originally sued were Sanofi, which purchased Genzyme in April 2011 and succeeded to its product line; Sanofi-Aventis U.S. LLC; and Mount Sinai School of Medicine, the patent holder and sole licensee of Fabrazyme. *Id.* In subsequent amendments, Mrs. Schubert added various Utah healthcare providers for failing to properly, swiftly seek a compassionate use exemption to enable her husband to access the unapproved Canadian drug. *See* Third Amended Complaint and Jury Demand, *supra* note 9.

[49] *See* Defendant Genzyme Corp.'s Notice of Removal, *Schubert I*, No. 2:12-cv-00587 (D. Utah Sept. 4, 2013), 2012 WL 4924848.

[50] *See* Third Amended Complaint and Jury Demand, *supra* note 9, ¶¶ 34-64.

- [Failing] to give adequate and complete warnings of the known or knowable dangers involved in the use of Fabrazyme® at a reduced dose as required by FDA regulations . . .
- [U]nreasonably 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 . . .
- [F]ailing to provide or require proper and/or adequate reserves of unadulterated Fabrazyme® in order to prevent or mitigate manufacturing errors . . .
- [F]ailing to provide or license a second source of manufacture for Fabrazyme® in order to prevent or mitigate life-threatening supply chain disruptions . . .
- [O]therwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.[51]

Many of Mrs. Schubert's claims presented as typical drug and device claims often do—defects in manufacturing, failure to abide by good manufacturing procedures, weak quality assurance oversights, failure to warn, and unauthorized deviations from an approved indication in a manner that renders the medicine mislabeled and misbranded. Although each of these raised heart-wrenchingly serious allegations from Mrs. Schubert's perspective, none charted an especially novel or audacious new path in the law.

Save one. Along with her familiar, run-of-the-mill product liability claims, Mrs. Schubert also included the provocative allegation, novel in the annals of pharmaceutical law, that Genzyme had a tort duty to maintain an uninterrupted supply of the product her husband wanted to buy—in other words, that this medicine manufacturer had a legal duty, enforceable in an American civil court, to continue selling its products to those who wanted to buy them, or face tort liability if it stopped.[52] As the district judge framed it in considering Genzyme's motion for judgment on the pleadings, the contention was that drug companies have "a duty to manufacture a pharmaceutical in quantities sufficient to meet market demand."[53] Or, stated another way, that there may not —must not—be Cabbage Patch Kid shortages with medicines.

Genzyme challenged Mrs. Schubert's argument with a narrow motion for judgment on the pleadings. After answering Mrs. Schubert's complaint,[54] Genzyme argued in a crisp eight pages that the threshold element of negligence theory—the existence of an enforceable legal duty—was absent in Mrs. Schubert's contention, and that the company was, therefore, entitled to judgment as a matter of law on her

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[51] *Id.* ¶ 36. (bullet points added).

[52] *See* Defendant Genzyme Corp.'s Motion for Judgment on the Pleadings Regarding Plaintiff's Claim for Negligent Manufacturing at 3, *Schubert I*, No. 2:12-cv-00587 [hereinafter Judgment on the Pleadings].

[53] *Schubert I*, 2013 WL 4776286, at *1. The operative complaint had framed it similarly: "The Product Defendants owed a duty to Decedent and other persons who they know, or should have known relied upon Fabrazyme as a life-saving drug, to use reasonable care to ensure a continued supply in therapeutic doses." Third Amended Complaint and Jury Demand, *supra* note 9, ¶ 43.

[54] The manufacturer pleaded, as its third defense, that it "owed no duty and breached no duty to Plaintiff or to any person whose alleged damage, loss, or injury purports to be a basis for claims in this action." Defendant Genzyme Corp.'s Answer to Third Amended Complaint at 13, *Schubert I*, No. 2:12-cv-00587.

novel negligent medicine supply interruption claim.[55] The company offered: "Plaintiff's negligent manufacturing claim is based upon Genzyme's alleged failure to do that which it had no legal duty to do – manufacture enough Fabrazyme for every patient that wants it. No such duty exists in any statute, any contract, or in Utah's common law."[56]

Mrs. Schubert responded that Utah precedent supported the duty she advocated imposing upon Genzyme, reasoning that she was accusing the manufacturer of an affirmative act of misconduct, not a mere omission.[57] She insisted that the company "owed a duty of care to act reasonably in its supply and manufacture of Fabrazyme."[58]

The Salt Lake City federal district court rejected Mrs. Schubert's argument. It ruled: "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."[59] The rationale the court offered in its ruling was instructive.

3. Mrs. Schubert's Claim Is Rejected

The district court crafted its ruling carefully. To the extent Mrs. Schubert's argument was properly understood as contending that the manufacturer's decision to supply a reduced dose of Fabrazyme unwittingly exposed her husband to greater dangers than taking no medicine at all, or that the manufacturer failed to impart proper warnings about treating with a reduced dose, that claim could survive past the pleadings stage.[60] However, to the extent Mrs. Schubert's contention was more properly understood as faulting the manufacturer for failing to supply enough Fabrazyme to meet market demand, that claim failed for want of a legal duty.[61]

The district court then turned to threshold principles of tort law.

The State of Utah abides by a familiarly traditional approach to the tort of negligence. That tort is, the Utah Supreme Court had taught, "the failure to do what a reasonable and prudent person would have done under the circumstances, or doing what such person under such circumstances would not have done. The fault may be in acting or omitting to act."[62] The court had itemized the four showings that must be

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[55] *See* Judgment on the Pleadings*, supra* note 52.

[56] *Id.* at 3.

[57] *See* Memorandum in Opposition to Defendant Genzyme Corp.'s Motion for Judgment on the Pleadings Regarding Plaintiff's Claim for Negligent Manufacturing at 8, *Schubert I*, No. 2:12-cv-00587-DAK [hereinafter Memorandum in Opposition].

[58] *Id.*; *see also id.* at 6 (citing Jeffs v. West, 275 P.3d 228 (Utah 2012)).

[59] *Schubert I*, 2013 WL 4776286, at *7.

[60] *Id.* at *6. Indeed, when Mrs. Schubert, in her briefing, attempted to recolor her argument as a defective design or defective warning claim (premised on the alleged non-therapeutic effect of a reduced dose Fabrazyme regimen), the court quickly agreed that such a claim survived a pleading attack. *See id.* at *5-6 ("[T]o the extent that Plaintiff claims that the lowered dosage of the medication was more harmful [than] receiving no medication . . . . 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."). Those more traditional claims survived through the pleadings stage (and, indeed, had not even been challenged by Genzyme in its motion). *See* Judgment on the Pleadings, *supra* note 52 at 2 n.1 ("Through this motion, Genzyme is not seeking a dismissal of Plaintiff's negligent failure to warn claim, but focuses solely on a dismissal as a matter of law of Plaintiff's claim of negligent manufacturing.").

[61] *Schubert I*, 2013 WL 4776286, at *6.; s*ee also id.* at *7 ("Plaintiff's negligence claim is dismissed to the extent that it is based on a shortage of Fabrazyme.").

[62] Meese v. Brigham Young Univ., 639 P.2d 720, 723 (Utah 1981) (footnote omitted).

made to prevail in a negligence lawsuit: "(1) a duty of reasonable care owed by the defendant to plaintiff; (2) a breach of that duty; (3) the causation, both actually and proximately, of injury; and (4) the suffering of damages by the plaintiff."[63] Thus, the starting block for negligence in Utah (like in nearly all other American jurisdictions) is proof that a duty of care was owed.[64]

Genzyme's motion for judgment on the pleadings took issue with this threshold element of the tort. Mrs. Schubert had insisted that the manufacturer owed such a duty of care to all those "who relied on Fabrazyme as a life-saving drug to use reasonable care to ensure a continued supply."[65] Genzyme demurred that no such duty was owed.[66] Determining who was right on this duty issue, explained the presiding federal judge, "is a question of law for the court."[67]

The court found no Utah authority squarely confronting and resolving the question Mrs. Schubert had framed.[68] But the court found Mrs. Schubert's citation to a recent Utah Supreme Court ruling instructive. In that case, *Jeffs v. West,*[69] the court considered the case of a husband who, while treating on certain medicines prescribed by a nurse practitioner, had shot and killed his wife. The couple's children brought suit, charging that the nurse practitioner owed them a duty of care, which she had breached by her allegedly negligent prescriptions.[70] The court ruled that a duty of care was owed the children, and reversed the pre-answer dismissal of their lawsuit.[71] In doing so, the court adopted a framework of factors relevant in discerning whether a duty of care exists between a plaintiff and a defendant:

> (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.[72]

Not all factors merited equal weight, taught the court. Instead, the first factor—affirmative act or mere omission—is the most important. "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."[73] That pivotal difference will trigger, in turn, the second factor, relationship between the parties: "[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

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[63] Williams v. Melby, 699 P.2d 723, 726 (Utah 1985) (citations omitted).

[64] *See generally* DAVID G. OWEN, PRODUCTS LIABILITY LAW 62 (2d ed. 2008) ("[Duty serves] as the foundational element of a negligence claim, [and] provides the front door to recovery for the principal cause of action in the law of torts: Every negligence claim must pass through the 'duty portal' that bounds the scope of tort recovery for accidental harm.").

[65] *Schubert I*, 2013 WL 4776286, *at* *2 (quoting Third Amended Complaint and Jury Demand, *supra* note 9, ¶ 43).

[66] *Id.*

[67] *Id.*

[68] *See id.* at *3 ("There is no Utah case law addressing the duty of a drug manufacturer to supply the market with sufficient quantities of its product.").

[69] 275 P.3d 228 (Utah 2012).

[70] *See id.* at 228.

[71] *Id.* at 230.

[72] *Id.*

[73] *Id.* at 231.

contrast, generally implicates a duty only in cases of special legal relationships."[74] The federal district court in Mrs. Schubert's case summarized the dispositive importance of these first two factors concisely: "generally, a special relationship is required to impose a duty in situations of nonfeasance."[75] The Utah Supreme Court relegated the remaining three factors (foreseeability and likelihood of injury, cost-bearing, general policy considerations) to "minus" factors—that is, they could be invoked "to eliminate a duty that would otherwise exist."[76]

Adopting this framework as the analytical structure for its decision, the federal court turned to consider whether Mrs. Schubert's allegations of negligent supply interruption presented a claim of negligence-by-affirmative-act or negligence-by-mere-omission. If the former, proving a special relationship between Mrs. Schubert and the manufacturer would be unnecessary and the imposition of a duty of care would be likely; if the latter, a special relationship would be essential to preserving the lawsuit and, without it, no duty of care would exist.[77] Moreover, only if these first two factors counseled in favor of finding a duty of care to exist would the final three "minus" factors even come into play at all.[78]

In testing for affirmative-act or mere-omission, the federal court found one further point of guidance in the *Jeffs* opinion. The supreme court had emphasized there that the legal question of duty or no-duty "must be determined as a matter of law and on a categorical basis for the given class of tort claims,' [and] not [by] a fact-specific case-by-case approach."[79] Thus, on the nurse practitioner negligent prescription theory posed to the court in *Jeffs*, "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."[80]

Predictably, the parties appreciated the near-dispositive importance of this affirmative-act or mere-omission dichotomy, and their briefing mirrored their partisan perspectives. Genzyme contended that its failure to supply sufficient Fabrazyme volumes was a failure to act (i.e., a mere omission or nonfeasance).[81] Conversely, Mrs. Schubert argued that the shortage was an affirmative act (*i.e.*, misfeasance) because it resulted from Genzyme's own affirmatively careless conduct.[82]

The federal court sided with Genzyme.[83] Mrs. Schubert's negligent supply interruption theory, the court held, was an allegation of nonfeasance (mere omission), not one of misfeasance (affirmative act).[84] The court reached its conclusion by first rejecting Mrs. Schubert's reasoning that the *cause* of the Fabrazyme shortage bore on the threshold question of legal duty.[85] The reasons prompting the shortage may or may not have been neglectful or careless, but those reasons would not help discern whether avoiding product shortages—considered categorically—was an owed duty at all.[86] In effect, paraphrasing the Utah Supreme

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[74] *Schubert I*, 2013 WL 4776286, at *4 (quoting *Jeffs*, 275 P.2d at 231).
[75] *Id.*
[76] *Jeffs*, 275 P.2d at 230.
[77] *See Schubert I*, 2013 WL 4776286, at *4.
[78] *See id.*
[79] *Id.* (quoting *Jeffs*, 275 P.2d at 234) (internal quotation marks omitted).
[80] *Id.* (quoting *Jeffs*, 275 P.2d at 235).
[81] *See id.* at *3.
[82] *See id.*
[83] *Id.* at *5.
[84] *Id.* at *3.
[85] *Id.*
[86] *Id.* at *4-5.

Court's assessment in *Jeffs*, the court was duty-bound instead to consider medicine manufacturers as a class, negligent medicine supply interruptions in general, and the full range of injuries that could follow in this class of cases.[87]

This distinction proved decisive: the critical issue for the court was not how negligently the medicine shortage might have been created, but instead whether the medicine shortage qualified as an affirmative act or not. Refocusing on the shortage as "act" or "omission" led the court to its conclusion: "under Utah negligence law, [the manufacturer's] failure to meet market demand for a drug is nonfeasance."[88] The court explained that the "harm" Mrs. Schubert was alleging was "the shortage of the medication," and a shortage of supply "is an act of nonfeasance."[89]

Having ruled that Mrs. Schubert's negligent supply interruption claim accused the manufacturer of a mere omission rather than an affirmative act, the court next examined whether a special relationship existed between Mrs. Schubert and the manufacturer. As noted earlier, "[w]hile acts of misfeasance typically carry a duty of care, nonfeasance generally implicates a duty only in cases of special legal relationships."[90] Examples of such special relationships, surveyed the court, included the relationships between common carriers and their passengers, innkeepers and their guests, landowners and their invitees, and custodians and their charges.[91] Disposing of this second factor was swift, since "[p]laintiff d[id] not allege nor argue that a special relationship existed."[92]

Next, the court considered the final three factors—the "minus" factors of foreseeability and likelihood of injury, cost bearing, and general policy considerations. None of the three would have become germane to the analysis unless the court had first found that the initial two factors counseled in favor of imposing a duty on Genzyme.[93] Nonetheless, the court explained that it, too, would examine the remaining factors because "even if Genzyme's failure to produce sufficient quantities of Fabrazyme was deemed to be an affirmative act of misfeasance . . . public policy considerations would weigh heavily against finding a duty."[94]

Mrs. Schubert gave two reasons why public policy would be well served by recognizing her negligent supply interruption claim. First, she contended that such production is required under the Bayh-Dole Act, which contemplates that federally funded inventions must be made "reasonably accessible to the public."[95] Second, she insisted that "it is imperative that when companies undertake the responsibility of manufacturing a drug that they do so safely."[96] Neither argument convinced the court.

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[87] *See id.* at *5.

[88] *Id.*

[89] *Id.* at *6. In a somewhat disorienting closing thought, the court pronounced that "Genzyme should not be penalized for producing as much of the product as it could." *Id.* Disorienting, because the rational corollary of that pronouncement was, in point of fact, at least the thematic position Mrs. Schubert was advocating—that Genzyme ought to be penalized (or at least held to account) for producing *less* of the product than it could, *and than it would have, had they operated their medicine production operation more carefully*.

[90] *Schubert I*, 2013 WL 4776286, at *5.

[91] *Id.*

[92] *Id.*

[93] *Id.* at *7 ("[T]he *Jeffs* Court recognized [that the remaining factors] are relevant to determining whether there is a duty when an affirmative act occurred.").

[94] *Id.* at *6.

[95] Memorandum in Opposition, *supra* note 57, at 10 (discussing the Bayh-Dole Act, codified at 35 U.S.C. §§ 200-12 (2012)).

[96] *Schubert I,* 2013 WL 4776286, at *6.

The court disagreed with Mrs. Schubert's research into federal law. The court could find nothing there that imposes upon a pharmaceutical manufacturer "a duty to continue manufacturing"—even though "[p]harmaceutical manufacturing is heavily regulated by federal law."[97] Federal law did impose on manufacturers the obligation to report manufacturing interruptions and discontinuances, and did authorize the "marching in" of the federal government to license others to pursue for practical advantage a federally funded invention when an inventor has proven unable to do so.[98] But nowhere in federal law could the court find a "statutory duty placed on a manufacturer to ensure a continued supply of any given pharmaceutical,"[99] nor a "federal law requiring a manufacturer to produce amounts sufficient to meet all potential demand."[100] The fact that no such obligation has ever been imposed by Congress, notwithstanding the comprehensive federal regulatory scheme already on the books, counseled the court towards caution. "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."[101]

Additionally, the court was persuaded that ample policy considerations tilted against imposing a tort duty on manufacturers to avoid medicine supply interruptions. Such a tort duty would, explained the court, "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."[102] Those burdens, reasoned the court, would, rather than align with public policy, compete with it by "creat[ing] an enormous disincentive for potential providers of pharmaceuticals from entering the market in the first place and could stifle development of new therapies."[103]

Next, the court determined that imposing this tort duty was unnecessary, since pharmaceutical manufacturers are already well incentivized to avoid medicine supply interruptions. "[C]onsistently meeting demand" allows manufacturers to remain on good terms with doctors, hospitals, and distributors.[104] Meeting customer demand also maintains purchaser relationships and secures the business interest of achieving profitability.[105]

The court also seemed to accept the inevitability of some medicine shortages, and their occurrence quite apart from manufacturer neglect. "There are technical challenges posed by producing biologic therapies. These cannot always be controlled despite a company's best efforts."[106] The numerous drug shortages that had imperiled the Nation's healthcare system just in the preceding two years gave the court still further pause: "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."[107] These challenges inherent in the manufacturing of pharmaceuticals (and especially biologics) deeply influenced the

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[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.* at *7.
[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] *Id.*

court's opinion. "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."[108]

Finally, the court noted that the only other jurisdiction to have considered the question Mrs. Schubert posed—the recognition of a tort duty to continue to supply medicines—was the federal district court in central Florida (discussed in the section that follows), and it had summarily rejected the contention.[109]

Accordingly, mindful of the extraordinary extension in Utah law Mrs. Schubert had sought, informed by the absence of local or national authority favorable to her cause, convinced that the more relaxed "mere-omission" standard applied, and persuaded of the heavy tilt of public policy against her position, the court granted Genzyme's motion for judgment on the pleadings. As instructed in *Jeffs*, the court reached a categorical, non-fact-bound answer to the question of whether the law of torts imposes on manufacturers of medicines a duty to avoid supply interruptions of life-sustaining products. It does not.[110]

B. MS. LACOGNATA AND CONTINUED ACCESS TO AQUASOL A

The litigants in Mrs. Schubert's lawsuit against Genzyme cited the Florida federal court's decision in *Lacognata v. Hospira, Inc.*[111] as an important precedent that ought to have been either informing to (Genzyme's position) or distinguished by (Mrs. Schubert's position) the Utah court. Although the facts in *Lacognata* differed in several respects from Mrs. Schubert's dispute, a legally enforceable obligation to continue selling medicines was a featured contention there as well.

1. Jennifer Lacognata's Story

Jennifer Lacognata suffered from short-bowel syndrome, an unusual complication following weight-loss surgery she had recently undergone, and became unable to absorb vitamin A in her diet.[112] Vitamin A is essential for vision, is involved in immune function and reproduction, and plays a critical role in the

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[108] *Id.*

[109] *Id.* at *3 (citing Lacognata v. Hospira, Inc., No. 8:12-cv-822-T-30TGW, 2012 WL 6962884, at *2 (M.D. Fla. July 2, 2012) ("There is no authority that supports Plaintiff's argument that a drug manufacturer . . . has a duty to continue supplying a patient with a drug it knows the patient relies upon for his or her medical health.")).

[110] On a subsequent motion to reconsider or, alternatively, to certify the question over to the Utah Supreme Court, the district court denied relief. The court found that it had not misapprehended Mrs. Schubert's contentions, but instead had painstakingly preserved her right to press on under traditional defective design, manufacture, and warning theories. Schubert v. Genzyme Corp. (*Schubert II*), No. 2:12-cv-00587-DAK, 2013 WL 6809143, at *1-2 (D. Utah Dec. 20, 2013). Similarly, because the court understood its ruling to constitute a straightforward application of the very prior Utah precedent Mrs. Schubert had argued to be controlling, the court found no cause to trouble the Utah Supreme Court for a certification. *Id.* at *2.

[111] No. 8:12-cv-822-T-30TGW, *aff'd*, 521 F. App'x 866 (11th Cir. 2013).

[112] *See* Petition for Writ of Certiorari at 4, Lacognata v. Hospira, Inc., 134 S.Ct. 458 (2013) (No. 13-305); *see also* Katie Thomas, *Drug Shortages Persist in the U.S., Harming Care*, N.Y. TIMES (Nov. 16, 2012), http://www.nytimes.com/2012/11/17/business/drug-shortages-are-becoming-persistent-in-us.html?pagewanted=all&_r=0 (describing Jennifer Lacognata's side effects from her weight loss surgery).

normal functioning of the heart, lungs, kidneys, and other organs.[113] Rare in developed countries, a prolonged deficiency in vitamin A can cause dry eye, night blindness, total blindness, skin disorders, infections, diarrhea, and lung disorders.[114] To treat her vitamin A deficiency, Mrs. Lacognata was prescribed Aquasol A, an injectable vitamin A palmitate manufactured by Hospira.[115] She was, however, unable to fill her prescription because of a global shortage of this drug.[116] Unfortunately, she had no FDA-approved alternative source for injectable vitamin A; Hospira was the world's only manufacturer of the drug.[117] This product shortage began in November 2010, and persisted through late May 2014, with no anticipated availability date supplied by the company.[118] In the meantime, Mrs. Lacognata developed "debilitating night blindness, skin lesions, and other health problems."[119] Her attorney recounted a bleak situation:

> Mrs. Lacognata has become legally blind, has been terminated from her job, has been terminated from private insurance care, and has been placed on Social Security and Medicaid. She will likely die from the vitamin A deficiency. She is forty-three years old with two young children.[120]

In 2012, Mrs. Lacognata sued Hospira, blaming the worldwide shortage of Aquasol A on poor and avoidable business decisions the manufacturer had made.[121] Specifically, she contended that the shortage had been caused by Hospira's decision to switch production facilities for the manufacture of Aquasol A without first bringing a new, substitute manufacturing plant on line and without first ensuring a sufficient reserve inventory of the drug to mitigate potential production delays.[122] The delay in Aquasol A production thereafter persisted, continued Mrs. Lacognata, because the company prioritized the manufacture of certain of its other products ahead of restoring the manufacture of Aquasol A.[123]

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[113] *See* George Ansstas et al., *Vitamin A Deficiency*, MEDSCAPE (June 11, 2014), http://emedicine.medscape.com/article/126004-overview; *Vitamin A: Fact Sheet for Health Professionals*, NAT'L INSTS. HEALTH, http://ods.od.nih.gov/factsheets/VitaminA-HealthProfessional (last updated June 5, 2013).

[114] *Drugs and Supplements: Vitamin A (Retinol)*, MAYO CLINIC, http://www.mayoclinic.org/drugs-supplements/vitamin-a/background/hrb-20060201 (last updated Nov. 1, 2013).

[115] Petition for Writ of Certiorari, *supra* note 112, at 4.

[116] *See* Complaint ¶¶ 37-41, *Lacognata*, No. 8:12-cv-822-T-30TGW, 2012 WL 1312173.

[117] *Id.* ¶ 11; *see also Vitamin A Injection*, AM. SOC'Y HEALTH SYS. PHARMACISTS (Aug. 13, 2014), http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=704 ("Hospira is the sole manufacturer of vitamin A injection.").

[118] *See* Complaint, *supra* note 116, ¶¶ 16-17; s*ee also Current and Resolved Drug Shortages and Discontinuations Reported to FDA: Vitamin A Palmitate (Aquasol A),* FDA, http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Vitamin%20A%20Palmitate%20(Aquasol%20A)%20Injection&st=r&tab=tabs-4 (last updated Sept. 8, 2014) [hereinafter *Current and Resolved Drug Shortages*]; *Vitamin A Injection*, *supra* note 117 ("Hospira has Aquasol A injection on back order and the company cannot estimate a release date.").

[119] Thomas, *supra* note 112.

[120] Petition for Writ of Certiorari, *supra* note 112, at 5.

[121] *See* Complaint, *supra* note 116, ¶¶ 69-70.

[122] *Id.* ¶¶ 18-20, 53-54.

[123] *Id.* ¶¶ 43, 55-56; s*ee also* Thomas, *supra* note 112 ("Hospira has temporarily stopped selling Aquasol A after it decided to move manufacturing of the product from an outside company to one of its plants. The company recently decided to abort the plan, citing complex technical challenges, and now has a deal with another company to begin making the vitamin. . . . A company spokeswoman said Hospira recognized the critical need for Aquasol A and was 'working diligently' to return it to the market, but declined to provide an estimate of when.").

2. The Lacognata Lawsuit and Ruling

Mrs. Lacognata's class action lawsuit charged Hospira with negligence, negligence per se, tortious interference with both a business relationship and a physician/patient relationship, and breach of implied contract.[124] The negligence count was premised on an alleged breach of the duty Hospira "owed . . . to foreseeable users of Aquasol A . . . to provide sufficient quantities of Aquasol A to the marketplace to meet the demand of said foreseeable users," by:

- [F]ailing to take reasonable steps to avoid and prevent a shortage of Aquasol A when it transferred manufacturing facilities;
- [F]ailing to take reasonable steps to maintain inventories and capital sufficient to mitigate foreseeable manufacturing shortages;
- [A]ffirmatively representing that the shortage would be ended by specific dates that Defendant knew or should have known were false;
- [D]iscontinuing the manufacture of Aquasol A at its first facility before bringing the second facility on line[;]
- [F]ailing to provide or license a second source of manufacture for Aquasol A in order to prevent or mitigate life-threatening supply chain disruptions; and
- [I]n otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.[125]

The complaint's negligence per se count was based on Hospira's withdrawal of interstate access to Aquasol A without first seeking approval from FDA under its New Drug Application license and in affirmative breach of that license, which, Mrs. Lacognata contended, "does not give permission for companies to withdraw treatment access from interstate commerce."[126]

The tortious interference count charged that Hospira's Aquasol A shortage intentionally and without justification interfered with physician-patient relationships by denying to patients the benefits of that relationship as a consequence of the company's "direct, self-serving and malicious actions made in bad faith"—namely, the implementation of an inadequate plan to combat supply disruptions, the refusal to honor lawfully authorized medical prescriptions, and the deprioritization of the drug's manufacture in preference to others.[127]

Finally, the breach of implied contract count was grounded in Hospira's failure to honor its pledge to return Aquasol A to the market by September 2011.[128]

Hospira moved to dismiss the complaint, characterizing the claim as an "unprecedented legal theory" that had been "shoe horn[ed] . . . into various run-of-the-mill state law tort and contract causes of action."[129] Hospira framed the dispute this way: "[The] claim, in sum, is that a prescription drug manufacturer has a legal duty to manufacture and supply the market with sufficient product so long as there is a consumer who needs it. But, there is no Florida authority (or authority from any

[124] Complaint, *supra* note 116.
[125] *Id.* ¶¶ 69-70 (bullet points added).
[126] *Id.* ¶ 74(c).
[127] *Id.* ¶¶ 78-80.
[128] *Id.* ¶¶ 39, 84-86.
[129] Defendant Hospira, Inc.'s Motion to Dismiss Plaintiffs' Complaint for Failure to State a Claim & Incorporated Memorandum of Law in Support at 1-2, Lacognata v. Hospira, Inc., No. 8:12-cv-822-T-30TGW, 2012 WL 6962884 (M.D. Fla. July 2, 2012), 2012 WL 11875420.

state for that matter) supporting that novel proposition."[130] Moreover, Hospira cited the complaint for the concession that "Plaintiff's physician had not even prescribed Aquasol A for her as of the time Hospira stopped selling it,"[131] noting that the supply disruption could therefore not have been directed intentionally or maliciously at Mrs. Lacognata.[132]

Mrs. Lacognata opposed the motion, arguing that it was "Hospira's conduct (and no one else's)" that had placed Aquasol A patients at a foreseeable risk of harm by "negligently transferr[ing] manufacturing facilities without properly securing the supply chain of Aquasol A" and "by negligently undertaking a safety program" through an "inadequate stockpile" of the drug and "otherwise deprioritizing remediation" of the patients' injuries.[133] Mrs. Lacognata equivocated as to whether Hospira had "a general duty to 'manufacture' or 'supply' Aquasol A in [a] competitive marketplace," but reasoned that such a duty had certainly arisen from Hospira's status as the sole global supplier of this pharmaceutical: "Hospira has a specific legal duty to exercise reasonable care to prevent the foreseeable harms flowing from its decisions to temporarily cease production *especially* where it has absolute monopoly power. As such a monopolist must exercise far more care than manufacturers in a competitive market."[134]

The trial court agreed with Hospira on all points. First, the court dismissed Mrs. Lacognata's negligence claim in a Spartan four sentences, observing that "[t]here 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 that it knows the patient relies upon for his or her medical health," and, resolved the court, "[i]t is not this Court's role to dramatically expand Florida law as Plaintiff seeks."[135] Second, the court, with similar expedition, rejected the negligence per se claim in four sentences, explaining that the FDA regulation on which Mrs. Lacognata relied obliges a manufacturer merely to notify FDA of its voluntary product withdrawals, not to continue supplying its products. And, in any event, local precedent rejected the contention that this regulation could support a negligence per se claim at common law.[136] Third, the court dismissed the tortious interference claim, finding "no authority for the proposition that a manufacturer commits an 'intentional and unjustified' interference with the patient/physician relationship by failing to supply sufficient quantities of a medication prescribed during the course of that relationship."[137] Finally, the court ruled against the implied contract claim, noting that local law enforces such promises only if made on definite terms, and that Mrs. Lacognata's allegation "that Hospira told her that Aquasol A would be backordered until September 2011 . . . hardly amounts to a promise with definite terms."[138] The court was also unpersuaded by her asserted detrimental change in position, since she had not alleged, for example, that she had somehow surrendered an opportunity for

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[130] *Id.* at 2.
[131] *Id.* at 5.
[132] *Id.* at 13.
[133] Plaintiff's Brief in Opposition to Defendant Hospira's Motion to Dismiss at 2, *Lacognata*, No. 8:12-cv-822-T-30TGW, 2012 WL 11875409 [hereinafter Plaintiff's Brief in Opposition to Hospira].
[134] *Id.* at 5.
[135] *Lacognata*, 2012 WL 6962884, at *2.
[136] *Id.*
[137] *Id.* at *3.
[138] *Id.*

another treatment option in reliance on the September 2011 date.[139] Having dismissed Mrs. Lacognata's case in its entirety, the trial court closed the file.[140]

Mrs. Lacognata appealed to the United States Court of Appeals for the Eleventh Circuit, which summarily affirmed the trial court's dismissal just two days after hearing oral arguments.[141] In a per curiam ruling, the Eleventh Circuit announced curtly that it was affirming "based on the reasons stated in the district court's order."[142]

Finally, Mrs. Lacognata sought review before the United States Supreme Court. In her petition for a writ of certiorari, she pitched that the courts below had ruled errantly in holding "that FDA licensees do not have a duty to honor State-issued prescriptions for drugs under the Food, Drug, and Cosmetics Act despite foreseeable and preventable catastrophic injuries being caused by such refusals."[143] She anchored her position on Hospira's status both as an FDA licensee and as the sole global supplier of Aquasol A: "Under the Eleventh Circuit's decision, sole source FDA-licensees can intentionally withdraw the market supply 'temporarily' or delay remediation of current shortages without consequence."[144] As a result, Mrs. Lacognata explained that her only avenue for injectable vitamin A was the market for veterinary products (where injectable vitamin A is available for "corn-fed cattle to prevent dietary vitamin A deficiency because corn does not contain enough vitamin A to sustain healthy livestock").[145] Such recourse is dangerous, she pleaded, "because [veterinary drugs] may be unsafe, unsanitary, and ineffective for human use," and difficult to access, because "her doctors and pharmacists would necessarily violate the law and ethics by substituting potentially dangerous veterinary vitamin A for Hospira's product, Aquasol A."[146] In any event, she pressed, "[t]he purpose of the Food, Drug, and Cosmetics Act is to protect consumers from unregulated markets, not to force patients into using them."[147]

Mrs. Lacognata's petition was filed on September 5, 2013.[148] Eight days later, Hospira, Inc. waived its right of response.[149] The petition was distributed to the Justices on September 25, was listed for Conference on October 11, and denied on October 15.[150] As of August 2014, Aquasol A—though still listed in shortage—had resumed shipping.[151]

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[139] *See id*.

[140] *Id.* at *4.

[141] Lacognita v. Hospira, Inc., 521 F. App'x 866, 866 (11th Cir. 2013).

[142] *Id.*.

[143] Petition for Writ of Certiorari, *supra* note 112, at 3.

[144] *Id.*

[145] *Id.* at 5 n.1; s*ee also* Igor Kossov, *Supreme Court Asked To Weigh Hospira Drug-Shortage Suit*, LAW360 (Sept. 17, 2013), http://www.law360.com/articles/472711/supreme-court-asked-to-weigh-hospira-drug-shortage-suit (quoting Mrs. Lacognata's counsel as saying "[y]ou can get injectable vitamins from veterinary markets. Cattle require vitamin A injections when they're fed corn. So when cows have a vitamin deficiency, they are treated for it, but U.S. citizens can't be.").

[146] Petition for Writ of Certiorari, *supra* note 112, at 5.

[147] *Id.* at 13.

[148] *Id.*

[149] Waiver of Right of Respondent Hospira, Inc. to Respond, Lacognita v. Hospira, Inc., 134 S.Ct. 458 (2013) (13-305).

[150] *See* Lacognata v. Hospira, Inc., 521 F. App'x 866 (11th Cir. 2013), *cert. denied*, 134 S.Ct. 458 (13-305); Docket No. 13-305, *Lacognita*, 134 S.Ct. 458 (2013) (showing the sequence of events leading up to the denial of certiorari).

[151] *Current and Resolved Drug Shortages*, *supra* note 118.

C. CLINICAL TRIAL PATIENTS AND CONTINUED ACCESS TO EXPERIMENTAL DRUGS

Both Mrs. Schubert and Mrs. Lacognata had pressed the courts to impose upon their respective drug manufacturers a judicially-created duty to avoid negligent interruptions in the supply of FDA-approved medications. That argument was pioneered by these two litigants in Utah and Florida, but the theory of a judicial recourse for denied drug access had been explored years earlier in the context of experimental, unapproved new drugs. For years, study participants in clinical trials of investigational medicines had sought relief from the courts when their trials ended and access to the testing drug had terminated. The body of case law that emerges is instructive in many respects, though concededly those disputes present a somewhat different legal quandary given their peculiar factual circumstances.

1. The Experimental Drug Landscape

Experimental (or "investigational") drugs are medicines that are in the process of being tested for their safety and effectiveness, and either have not yet been approved at all by FDA or are federally approved for some uses but are being investigated for new uses.[152] As FDA explains it, patients typically seek access to these sorts of still-under-testing medicines for two reasons: they are suffering from a serious illness and traditional, FDA-approved therapies are not working or are causing unacceptably severe side effects, or they have come to learn about promising early testing results and want to hear more.[153] Access to medicines during their safety and effectiveness testing periods is restricted by FDA because these drugs "may pose unknown risks to patients and we do not know if [they are] effective."[154] Nevertheless, for critically ill patients, especially those with frightful near-term prognoses, waiting out the safety and effectiveness testing period may not be possible. For those patients, however serious the unknown risks might ultimately prove to be, an investigational medicine may represent the only viable pathway to improved health (or survival), and the risks of the testing drug—albeit unknown—would likely be enthusiastically accepted in the exchange.[155]

FDA has established two avenues for lawful patient treatment with experimental medicines. First, a patient can seek enrollment as a participant in the medicine's clinical testing process itself, and, through that access, possibly receive the testing drug.[156] Second, the manufacturer of the drug can volunteer to provide the testing

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[152] *See For Consumers: Access to Investigational Drugs*, FDA, http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/accesstoinvestigationaldrugs/default.htm (last updated Feb. 2, 2014).

[153] *See id.*

[154] *Id.; For Consumers: Access to Investigational Drugs Outside of a Clinical Trial (Expanded Access)*, FDA, http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/AccesstoInvestigationalDrugs/ucm176098.htm (last updated July 16, 2014) ("[I]nvestigational drugs have not yet been approved by the FDA as safe and effective. They may be effective in the treatment of a condition, or they may not. They also may have unexpected serious side effects. It is important for you to consider the possible risks if you are interested in seeking access to an investigational drug.").

[155] *Cf.* Abigail Alliance for Better Access to Dev'l. Drugs v. von Eschenbach, 495 F.3d 695, 700 (D.C. Cir. 2007) (responding to FDA's concern that "most experimental cancer drugs 'have potentially lethal toxicity, with potentially large effects on a patient's remaining quality of life,'" advocacy group posited that terminally ill patients "are typically willing to assume risks"); Abney v. Amgen, Inc., No. 5:05-CV-254-JMH, 2005 WL 1630154, at *11 (E.D. Ky. July 8, 2005) ("Plaintiffs state that they are willing to take all the adverse risks of GDNF," which manufacturer feared could be substantial.) *aff'd*, 443 F.3d 540 (6th Cir. 2006).

[156] *See For Consumers: Access to Investigational Drugs Outside of a Clinical Trial (Expanded Access)*, *supra* note 154 ("Patients may be eligible to receive an investigational drug as a participant in

drug (albeit unapproved either entirely or for this particular use) to an individual patient or intermediate-sized patient populations, and then seek FDA approval to do so.[157] This process, known colloquially as "compassionate use" access,[158] is regulated heavily by FDA. It is, for example, only available to patients suffering from a serious[159] or immediately life-threatening[160] health condition, and only under certain circumstances, where: no "comparable or satisfactory alternative therapy to diagnose, monitor, or treat" the condition exists; the potential benefit to the affected patients justifies the potential risks; those potential risks are not unreasonable in the context of the treatment; and the use "will not interfere with the initiation, conduct, or completion of clinical investigations . . . or otherwise compromise the potential development of the expanded access use."[161] Moreover, this expanded access imposes an array of additional obligations on the supplying manufacturer, including the obligation to file a detailed expanded access submission with FDA[162] and its obligation to implement appropriate patient safeguards.[163]

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a clinical trial."); *Compassionate Drug Use*, AM. CANCER SOC'Y, http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/compassionate-drug-use (last updated July 9, 2013) ("The simplest way to get an unapproved drug is through a clinical trial."). Even participation in the drug testing process, however, does not ensure access to the medicine itself. Human clinical studies are ordinarily controlled by having only portions of the study participants receive the experimental medicine while others receive a different therapy or a placebo. *See Clinical Research Versus Medical Treatment*, FDA, http://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/ucm20041761.htm (last updated Sept. 15, 2014).

[157] *See For Consumers: Access to Investigational Drugs Outside of a Clinical Trial (Expanded Access), supra* note 154 ("FDA regulations allow access to investigational drugs for treatment purposes on a case-by-case basis for an individual patient, or for intermediate-size groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial. They also permit expanded access for large groups of patients who do not have other treatment options available, once more is known about the safety and potential effectiveness of a drug from ongoing or completed clinical trials."); *see also* 21 C.F.R. § 312.310 (2013) (authorizing use with individual patients, including on an emergency basis); *id.* § 312.315 (authorizing use with intermediate-size patient populations).

[158] *See* Suthers v. Amgen Inc. (*Suthers I*), 372 F. Supp. 2d 416, 423 n.6 (S.D.N.Y. 2005) ("'Compassionate use' is the phrase sometimes used to describe FDA permission to distribute experimental drugs to a specific category of patients in 'extraordinary circumstances.'"). *See generally Compassionate Drug Use*, *supra* note 156 ("Medical professionals use the term 'compassionate use' to refer to the treatment of a seriously ill patient using a new, unapproved drug when no other treatments are available. . . . Drugs that are being tested but have not yet been approved by the US Food and Drug Administration (FDA) are called *investigational* drugs. These drugs are generally available only to people who are taking part in a clinical trial (a research study that is testing the drug). Being able to use one of these drugs when you are not in a clinical trial has many names, but is most commonly referred to as *compassionate use*.").

[159] FDA defines "serious disease or condition" as one "associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one." 21 C.F.R. § 312.300(b) (2013).

[160] FDA defines "i*mmediately life-threatening disease or condition" as* "a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment." *Id.*

[161] *See id.* § 312.305(a)

[162] *See id.* § 312.305(b). Though detailed written submissions are ordinarily required of the supplying manufacturer, FDA permits patient access to experimental drugs on an emergency basis, which can begin even without a written submission and upon telephonic authorization from an FDA reviewing official. *Id.* § 312.310(d).

[163] *Id.* § 312.305(c)

Importantly, nothing in the federal drug laws obligates a medicines manufacturer to agree to supply patients with access to experimental drugs.[164] Indeed, various reasons might convince a manufacturer to refuse a patient such compassionate use access. First, the manufacturer may become persuaded, through the clinical trial data and analysis (or otherwise), that the drug's safety or efficacy profile renders it likely too dangerous or suspect to be administered.[165] Second, the production of the testing drug may prove challenging, causing the manufacturer to make only those quantities of the drug necessary for the clinical testing process itself.[166] Third, the production of the testing drug may be expensive, which might also limit the manufactured volumes to test-quantities only.[167] Fourth, whatever quantities of drugs were produced may have been consumed or become otherwise unavailable because they have been committed to different uses.[168] Fifth, in addition to the often byzantine path of paperwork and approvals needed to facilitate compassionate use drug access, the manufacturer may also confront internal policies and parameters that constrain its grants of access.[169] Sixth, even if compassionate use access is granted, the costs of the experimental drug itself, or the costs of administration and patient monitoring, may not be absorbed fully (or at all) by the supplying manufacturer and those expenses may prove to be prohibitive to the affected patients, rendering actual drug access illusory.[170] Seventh, the manufacturer

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[164] *See* FDA, GUIDANCE FOR INDUSTRY: EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE—QS & AS 10-11 (2013), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf ("Q20. Can FDA require a company to provide expanded access to its drug if FDA authorizes the expanded access? A20. No, FDA cannot compel a company to provide expanded access to its drug. When a company provides expanded access to its drug, it is doing so voluntarily."); *Compassionate Drug Use, supra* note 156 ("[T]here's no way to force the drug company to supply the drug."); *For Consumers: Access to Investigational Drugs Outside of a Clinical Trial (Expanded Access)*, *supra* note 154 ("Manufacturers may not always be willing or able to provide access to a drug outside of their clinical trials. . . . Companies are not required to make their drug available through expanded access, or to make more of a drug for that purpose.").

[165] *See* Abney v. Amgen, Inc., 443 F.3d 540, 544-45 (6th Cir. 2006) (recounting scientific concerns expressed by experimental drug's manufacturer to justify termination of all clinical use of the product); *Suthers I*, 372 F. Supp. 2d 416, 418-19 (S.D.N.Y. 2005) ("Amgen terminated the second study when it discovered that the GDNF treatment produced antibodies that potentially neutralized the human body's naturally produced GDNF and risked worsening a patient's condition. It also received test data indicating that administration of GDNF in primates caused neurotoxic responses, and in humans yielded no statistically significant results over a placebo.").

[166] *See For Consumers: Access to Investigational Drugs Outside of a Clinical Trial (Expanded Access)*, *supra* note 154 ("Companies manufacture investigational drugs for the purpose of testing them in clinical trials, since that is the most effective and efficient way to determine whether the drugs work, and whether they are safe to use. . . . Sometimes, even when an expanded access program has been established, there may not be enough of a drug available for all patients requesting access.").

[167] *See id.* ("Investigational drugs are expensive to manufacture."); *Compassionate Drug Use*, *supra* note 156 ("There may be very limited amounts of the drug, and producing extra medicine for people who are not in clinical trials can be costly for the drug company, especially when there's a chance the drug might never be approved.").

[168] *See* Cacchillo v. Insmed, Inc., 638 F.3d 401, 403 (2d Cir. 2011) (noting manufacturer's position that IPLEX is no longer produced, only limited stores of IPLEX remain and, according to Ismed, all remaining IPLEX has been committed to patients with amyotrophic lateral sclerosis").

[169] *See Compassionate Drug Use*, *supra* note 156 ("Getting the drug through expanded access programs (if one is offered by the drug company) or single-patient compassionate use is possible for some people. But going through all the steps needed to get single-patient compassionate use of an unapproved drug can be frustrating and take a lot of time. For instance, drug companies have different policies and processes.").

[170] *See id.* ("Another big problem is cost. Some drug companies will supply the drug for free, but others charge patients. Most insurance companies will not pay for investigational drugs. There may

may have made a simple, unvarnished business-judgment assessment, concluding that the commercial return on the product is outpaced by the costs of development and production.[171]

Patients who succeed in navigating this treacherous and perhaps lonely[172] journey are likely to plot along a gamut of reactions, from disappointment with the therapeutic results of the experimental drug to elation upon receiving genuine health improvement.[173] For those fortunate patients falling in the latter category, continued access to what might be, for them, a true "miracle drug" (and their last hope) is a first order of business. The manufacturer's decision to terminate clinical access to the testing drug understandably confounds that expectation and, occasionally, triggers lawsuits pressing for resumption of access to the drug.

Case decisions in this category are qualitatively different in some respects from the complaints challenging access to FDA-approved medicines, like those pressed by Mrs. Schubert in Utah and Mrs. Lacognata in Florida. For example, participants in clinical trials for new medicines are required to sign written consent forms which, as a matter of contract law, may explicitly set out such matters as the logistics of drug access during the trial itself and after the trial concludes, and even the supplier's policies on later compassionate use availability.[174] Similar provisions regarding post-

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also be other costs, such as the clinic's cost of giving the drug and monitoring your response, that might not be covered by your health insurance.").

[171] This, in fact, was a contention pressed in litigation against one such manufacturer. *See* Abney v. Amgen, Inc., 443 F.3d 540, 545 (6th Cir. 2006) ("The plaintiffs assert that Amgen's reasons for ending the study were financial rather than safety and efficacy. They allege that because of the prolonged time it took Amgen to develop a delivery method for GDNF, Amgen has little time left before its patent on the drug expires. Moreover, based on the invasive means of delivering the drug, only those with severe Parkinson's disease would use the drug, leading to less profit. Finally, GDNF has a short shelf life and thus Amgen would constantly be required to produce new proteins. The plaintiffs claim that all of these considerations led Amgen to conclude that it was financially untenable to bring the drug to market and thus Amgen terminated the study. Amgen vehemently disputes the plaintiffs' claims.").

[172] The precise number of actual patients treated through compassionate use access to experimental pharmaceuticals is elusive. *See Compassionate Drug Use*, *supra* note 156 ("[D]espite these hurdles, compassionate drug use does happen. Because actual use is not well-documented, there are no numbers or statistics on how often it's done, who's doing it, or how well it's working for patients.").

[173] *See*, *e.g.*, *Abney,* 443 F.3d at 544 ("The plaintiffs contend that after GDNF was administered, they experienced marked physical, cognitive, and emotional improvement."); Cacchillo v. Insamed Inc., 833 F. Supp. 2d 218, 224 (N.D.N.Y. 2011) (noting that through "Mrs. Cacchillo's participation in the [trial] . . . she experienced a near total recovery of her day-to-day functionality without suffering any side effects. Where she had once been able to withstand only a few minutes of light activity, had been unable to keep her chin from her chest without assistance, and could not dress herself, by October 2008, Mrs. Cacchillo was able to spend a day shopping, manipulate buttons and zippers, and walk with her head up."); *Suthers I*, 372 F. Supp. 2d 416, 418 (S.D.N.Y. 2005) (noting that plaintiffs viewed their treatment on the experimental drug "as greatly relieving their symptoms. The medical researcher supervising their participation reports that Mr. Suther [sic] was able to walk up to two miles a day and Ms. Martin was able to walk and run and had an improved sense of smell and greater control over facial muscles").

[174] *Cf.* Cacchillo v. Insmed, Inc., 638 F.3d 401, 406 (2d Cir. 2011) ("Cacchillo's claims hinge on Insmed's alleged promise to support Cacchillo's compassionate use application. Yet, Cacchillo has no evidence that such an agreement existed beyond her own vague recollection."); s*ee*, *e.g., Informed Consent Template for Cancer Treatment Trials*, NAT'L CANCER INST. (Aug. 12, 2011), *available at* http://www.cancer.gov/clinicaltrials/conducting/nci-ic-template-august-2011 (noting that supplier "will supply" the testing drug "at no charge while you take part in this study" and, "[e]ven though it probably won't happen, it is possible that the manufacturer may not continue to provide the" drug "for some reason," and, were that to occur, "[y]ou might be able to get the [drug] from the manufacturer or your pharmacy but you or your insurance company may have to pay for it," or "[i]f there is no [drug] available at all, no one will be able to get more and the study would close").

study access to the testing medicines may appear in the language of the agreement between the drug manufacturer and those conducting the clinical study.[175] Even in clinical study agreements which do not expressly set forth prospective drug access policies, the foreclosing impact of contract law is likely still to be felt through integration clauses that renounce unambiguously the existence of any promise other than ones set forth directly in writing.[176] Moreover, each clinical study is governed by its own contractual terms, and manufacturers may behave differently, study to study, as circumstances dictate.[177] For all of these reasons, the clinical trial participant case law is distinct. Nonetheless, the nature of the arguments raised and the reasoning of the adjudicating tribunals are informing.

2. The Experimental Drug Rulings

a. Parkinson's Disease Patients

Two tribunals, in New York[178] and Kentucky (later the Sixth Circuit),[179] considered the complaints of a series of Parkinson's Disease patients who, at the close of their participation in clinical trials to test an experimental glial-derived neurotrophic factor ("GDNF"), litigated their rights against Amgen (the manufacturer) to continue receiving that testing drug.

Parkinson's Disease is a chronic, degenerative disorder of the central nervous system that afflicts 1 in 100 persons over the age of 60—an estimated five million people globally.[180] The condition results in tremors, shaking, slow movement,

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[175] *See, e.g., Abney*, 443 F.3d at 547 n.5 (noting that Amgen had no duty to provide the testing drug to plaintiffs because "the Informed Consent Document allows Amgen to terminate the study for scientific reasons, which is at least arguably what occurred in this case"); Vinion v. Amgen, Inc., No. CV-03-202-M-DWM, 2004 WL 6057351, at *3 (D. Mont. Aug. 30, 2004) (noting that agreement between drug company and investigators provided: "At the termination of the study, Immunex shall direct the Investigator, at the sole direction of Immunex, to dispose of or return to Immunex all unused Study Drug").

[176] *See, e.g.*, *Abney*, 443 F.3d at 547 (noting that there were "no other documents that create a contractually enforceable duty for Amgen to continue to provide GDNF to the plaintiffs"); *Vinion*, 2004 WL 6057351, at *3 (reciting the contract's integration clause—"[t]his written Agreement constitutes the entire agreement between the parties, and no terms or understandings not contained in this Agreement shall be valid or binding unless contained in writing and signed by both parties"—and the no-conflicting-agreements clause covenanted by the study investigator, and then ruling: "The contract includes no term that agrees to provide Enbrel after the study, and in fact, states that drug shipments will be discontinued and extra drugs will be returned to Immunex. This contract creates no duty between Immunex and Plaintiffs and could have created no impression in Dr. Whitehouse, who signed it, that some oral agreement outside the four corners of the document bound Immunex to continue to provide Enbrel. Any possible oral agreement . . . would have to be between Hayes as an agent of Immunex and Whitehouse. However, the written contract would supplant it and contains no promise of drugs").

[177] *See*, *e.g.*, Vinion v. Amgen Inc., 272 F. App'x 582, 584 (9th Cir. 2008) ("That the Companies were inconsistent in extending post-study drugs to participants in different studies has no bearing on whether the Companies' conduct towards Appellants left them with the reasonable belief that Dr. Whitehouse was the Companies' agent.").

[178] *See* Suthers v. Amgen Inc. (*Suthers II*), 441 F. Supp. 2d 478, 482-88 (S.D.N.Y. 2006) (granting defendant's motion to dismiss); *Suthers I*, 372 F. Supp. 2d at 417 (denying plaintiffs' motion for preliminary injunction).

[179] Abney v. Amgen, Inc., No. 5:05-CV-254-JMH, 2005 WL 1630154 at *1 (E.D. Ky. July 8, 2005) (denying plaintiff's motion for preliminary injunction), *aff'd*, 443 F.3d 540 (6th Cir. 2006).

[180] *See Abney*, 443 F.3d at 542; *Parkinson's Diagnosis Questions*, MICHAEL J. FOX FOUND. FOR PARKINSON'S RES., https://www.michaeljfox.org/understanding-parkinsons/i-have-got-what.php (last visited Sept. 19, 2014). The disease is named after James Parkinson, an English doctor who lived and practiced medicine in London, and in 1817 published *An Essay on the Shaking Palsy*, which first

muscle stiffness, and muscle rigidity.[181] Conventional treatment regimens are largely palliative, replacing dopamine to help mask the disease's symptoms; none of those regimens arrest the loss of dopamine-producing neurons or otherwise effect a cure.[182] The experimental GDNF drug, however, held the early promise of doing what no other Parkinson's treatment offered: protecting and restoring the body's dopamine-producing neurons.[183]

Among the challenges of this drug was the need to deliver it effectively into the brain. The selected method was direct infusion, achieved by implanting a GDNF-filled pump into the patient's abdomen, through which catheters snake up through the patient's cheek, neck, and head to deliver the drug directly into the targeted area of the brain.[184] Early "open-label" clinical studies of GDNF using this delivery method produced encouraging results, and the manufacturer proceeded to more elaborate clinical testing.[185] That further testing, however, produced mixed outcomes, with some patients subjectively reporting "dramatic improvement" while other markers suggested far more modest success.[186] However, the manufacturer grew especially worried as two medical concerns emerged: first, some study participants were developing antibodies that neutralized the GDNF and threatened their bodies' own natural volumes of GDNF (especially concerning as medical science does not know what function naturally-occurring GDNF performs in the human body, though it may be a crucial one); and second, long-term toxicology studies revealed the development of brain lesions in primates.[187]

This confluence of data prompted the manufacturer to terminate further clinical study of GDNF, against the wishes of the study participants, the principal study investigators, and the participating physicians[188] When patients approached the manufacturer for compassionate use access to this drug—which, in their judgment, was offering meaningful medical benefits—the company turned to an external expert panel of three bioethicists and five Parkinson's Disease specialists for advice.[189] By a 7-1 vote, the panel recommended terminating use of the drug.[190] The company followed this guidance, and denied compassionate use access.[191]

In litigation, the patients in both New York and Kentucky contended that the manufacturer had a legal obligation to continue supplying them with GDNF.

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characterized the symptoms of the condition. *See* Patrick A. Lewis, *James Parkinson: The Man Behind the Shaking Palsy*, 2 J. PARKINSON'S DISEASE 181 (2012). The disease results from the loss of certain brain cells which produce dopamine, "a chemical messenger responsible for transmitting signals within the brain that allow for coordination of movement. Loss of dopamine causes neurons to fire without normal control, leaving patients less able to direct or control their movement." *Parkinson's Diagnosis Questions*, *supra*. The specific cause of the condition remains unknown, though research suggests a combination of genetic and environmental factors are the culprits. *Id.*

[181] *See Abney*, 443 F.3d at 542.

[182] *Id.* at 542-43.

[183] *Id.*; *Suthers I*, 372 F. Supp. 2d at 418.

[184] *Abney*, 443 F.3d at 543.

[185] *Id.* A study is considered "open-label" when the participants in the clinical study are aware of the drug and that they are receiving it. *See id.*

[186] *Id.* at 543-44.

[187] *See id.* at 544 ("More worrisome to Amgen, however, was that the antibodies could attack naturally occurring GDNF in the body. While it is unclear what naturally occurring GDNF does, animal studies have shown that an absence of GDNF during development causes irreversible damage to vital organs.").

[188] *See id.* at 544-45.

[189] *See id.* at 545.

[190] *Id.*

[191] *Id.*

Specifically, they argued that such a duty arose by contract, by promissory estoppel, and by the company's position as a fiduciary to the Parkinson's patients.[192] Rejecting the manufacturer's conclusion that GDNF was proven unsafe during the clinical studies, the patients insisted the company's decision to terminate was motivated by baser motives: that the drug's long development time had left too small a remaining period of patent exclusivity, that the invasive delivery method for the drug would relegate its use to a much smaller population of potential consumers, and that the product's short shelf-life would impose a heavy manufacturing burden.[193] In sum, the patients complained "that Amgen's reasons for ending the study were financial rather than safety and efficacy."[194]

In New York, the trial court first denied the patients their requested preliminary injunction and then granted the defendant's motion to dismiss. On the injunction, the court first found no likelihood of success on the merits of the patients' claim that the drug manufacturer had "[given] up the right to terminate the trials in its unfettered discretion."[195] The court held that both the contract and promissory estoppel claims failed for want of evidence of an enforceable promise.[196] That the company invited the clinical trial patients to participate in an expensive scientific investigation did not, reasoned the court, morph into an assurance of a continued supply of the testing drug:

> It is not illogical for a [clinical trial] participant to assume that a company that has invested hundreds of millions of dollars to acquire the rights to a therapeutic treatment, and then spent millions more to test it, would want to bring the treatment to market if safe and effective. But that is a far cry from establishing a contract by which Amgen bargained away the freedom to terminate the research trials in its sole discretion.[197]

On the final claim, the court found no forum authority recognizing a fiduciary relationship between a clinical trial sponsor and its study participants.[198] Nor was the court receptive to the soundness of such a fiduciary relationship argument: the duty owed by clinical researchers is to the successful completion of the study, not the health improvement of any particular patient.[199] "The fiduciary duty envisioned by the plaintiffs," concluded the court, "would presumably mean that if it were in a study participant's best interests to continue a clinical study, then the sponsoring company would be without power to terminate it without risking a finding of breach."[200] For such a result, the court had no stomach.

Months later, the court considered, and granted, the manufacturer's motion to dismiss. Retracing its earlier logic from the injunction proceeding, the court ruled that the breach of contract, promissory estoppel, and fiduciary breach counts were

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[192] *See* Abney v. Amgen, Inc., No. 5:05-CV-254-JMH, 2005 WL 1630154, at *3 (E.D. Ky. July 8, 2005) (considering no additional counts of negligence, good faith and fair dealing, or unfair trade practices ruling on the motion), *aff'd*, 443 F.3d 540, 545 (6th Cir. 2006); *Suthers I*, 372 F. Supp. 2d 416, 419 (S.D.N.Y. 2005).

[193] *See Abney*, 443 F.3d at 545.

[194] *Id.*

[195] *Suthers I*, 372 F. Supp. 2d at 430.

[196] *Id.* at 423-26.

[197] *Id.* at 425.

[198] *Id.* at 426.

[199] *See id.* at 427 & n.9.

[200] *Id.* at 428.

deficient.[201] The patients' three remaining counts met a similar fate. No breach of the covenant of good faith and fair dealing could be found where the actor behaves "in its own self-interest consistent with its rights under a contract."[202] No negligence claim could succeed because a "gratuitous actor", having once begun to render aid, is only liable for stopping if the actor thereby places the victim in a worse position than had aid never been begun. And according to the pleadings, "[t]here is no allegation that these plaintiffs were worse off than their pre-GDNF baseline because of the administration and withdrawal of GDNF."[203] Moreover, the applicable negligence measure of damages—"the difference between what [the patients'] condition would have been if GDNF had never been administered as compared to what it is having received GDNF but having had it withdrawn"—could not be "fairly read" into the complaint.[204] Lastly, a count of deceptive business practices under New York law failed because the patients lacked the necessary predicate status as statutory "consumer" victims.[205]

In Kentucky, similar patients pressing similarly pleaded allegations filed a similar motion for a preliminary injunction. There, too, the trial court found no likelihood of success on the merits. The court ruled that no contractual promise to continue supplying the drug was made to the patients, that the promissory estoppel claim failed for the same reason, and that no fiduciary relationship arose between the clinical trial sponsor and the trial participants.[206] The court further ruled that the equivocal study results defeated the patients' allegation of irreparable harm,[207] that those same results as well as the specter of the company's uncontainable liability suggested a meaningful harm to the defendant,[208] and that the public interest disfavored the awarding of relief.[209] On this closing point, the court reasoned:

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[201] *Suthers II*, 441 F. Supp. 2d 478, 482-88 (S.D.N.Y. 2005). In this later opinion, the court embellished its reasons for rejecting a fiduciary relationship between investigator and subject: "The goal of the drug trial is to add to the body of information concerning the tested drug. Those who selflessly brave the risks stand to benefit a broader population by helping to prove or disprove the safety and efficacy of a drug. Any benefit to the participant is incidental." *Id.* at 488 (footnote omitted).

[202] *Id.* at 485.

[203] *Id.* at 489-90. There was, the court acknowledged, the matter of the invasiveness of the surgically-implanted GDNF delivery method, but this fact was found to fail the "gratuitous actor" liability analysis because the patients each gave their informed consent aware that they might never actually receive GDNF. *Id.* at 490.

[204] *Id.*

[205] *Id.* at 490-91.

[206] Abney v. Amgen, Inc., No. 5:05-CV-254-JMH, 2005 WL 1630154, at *5-10 (E.D. Ky. July 8, 2005), *aff'd*, 443 F.3d 540 (6th Cir. 2006).

[207] *Id.* at *11 ("While the plaintiffs introduced evidence that GDNF may be safe and effective, the defendant also introduced equally sound, scientific evidence to the contrary. As such, it is unclear whether the plaintiffs would benefit from continued treatment, much less be irreparably harmed in the event an injunction does not issue.").

[208] *See id.* ("[I]n the face of credible scientific evidence of possible adverse effects, the Court finds that the defendant might well suffer irreparable harm if an injunction was entered because of the possibility of future liability.").

[209] *Id. at *12* ("Although the Court personally understands the devastation Parkinson's disease brings to the lives of those who have the disease (my late father suffered from it) and the plaintiffs' immense desire for a cure, the public interest would not be furthered by ordering a clinical trial sponsor to provide unapproved and potentially dangerous drugs to clinical trial participants.").

> Granting an injunction and forcing a trial sponsor to provide drugs it–and the FDA–find unsafe, because other experts find the drugs safe and effective, would discourage sponsors from financially supporting human clinical trials. This is true because sponsors would have to continue to make and provide drugs that are potentially dangerous.[210]

On appeal, a panel of the Sixth Circuit affirmed in an opinion largely tracking the district court's reasoning.[211]

b. Duchenne Muscular Dystrophy Patients

Two other litigations, another in New York (later in the Second Circuit)[212] and one in New Jersey (later in the Third Circuit),[213] examined claims by muscular dystrophy patients seeking post-clinical trial access to two different experimental medicines. As had the Parkinson's Disease courts, these tribunals likewise rejected the plaintiffs' claims to continued drug access.

The earlier litigation involved a claim by a teenage boy—Jacob Gunvalson—suffering from Duchenne Muscular Dystrophy (DMD).[214] DMD is a genetic disorder principally afflicting young males, marked by progressive muscle weakness and degeneration, and caused by the absence of a particular protein helpful to keeping muscle cells intact.[215] Symptoms of the disease emerge during early childhood and, though historically life expectancies were very brief, patients with the condition commonly now survive into their thirties or later.[216] The condition has no known cure, and treatment regimens are palliative.[217]

In 2006, Jacob's mother sought her son's participation in clinical trials for an experimental drug known as PTC-124.[218] Evidently, she was well known to the drug's manufacturer through her prominence as a lobbyist for federal DMD funding (and had, at least once, stayed as a guest overnight in the company vice president's home).[219] She contended that company representatives discouraged her from enrolling her son in an early clinical trial on the assurance that he would be able to be treated with the experimental drug at some later date.[220] Claiming reliance on this assurance, Jacob's mother did not enter Jacob into those clinical trials. Later, when an expanded clinical trial for the drug began, Jacob was denied participation as

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[210] *Id*.

[211] *See* Abney v. Amgen, Inc., 443 F.3d 540 (6th Cir. 2006).

[212] *See* Cacchillo v. Insmed, Inc., 638 F.3d 401 (2d Cir. 2011) (affirming denial of preliminary injunction); Cacchillo v. Insmed, Inc., Civ. No. 1:10-CV-01199 (TJM/RFT), 2013 WL 62220 (N.D.N.Y. Feb. 19, 2013) (granting summary judgment), *aff'd*, 551 F. App'x 592 (2d Cir. 2014); Cacchillo v. Insmed, Inc., 833 F. Supp. 2d 218 (N.D.N.Y. 2011) (granting in part and denying in part motion to dismiss).

[213] *See* Gunvalson v. PTC Therapeutics, Inc., Civ. No. 08-3559 (WJM), 2008 WL 4003377 (D.N.J. Aug. 21, 2008) (granting preliminary injunction), *vacated*, 303 F. App'x 128 (3d Cir. 2008).

[214] *See id*.

[215] *See Duchenne Muscular Dystrophy: Overview*, MUSCULAR DYSTROPHY ASS'N, http://mda.org/disease/duchenne-muscular-dystrophy/overview (last visited Sept. 19, 2014). More specifically, DMD is due to an absence of the protein *dystrophin, which causes muscle cells to become fragile and easily damaged*. *Id.* The disease "was first described by the French neurologist Guillaume Benjamin Amand Duchenne in the 1860s," but it was not until the mid 1980s that "researchers identified a particular gene on the X chromosome that, when flawed (mutated), leads to DMD." *Id.*

[216] *Id.*

[217] *See Duchenne Muscular Dystrophy*, MEDLINEPLUS, http://www.nlm.nih.gov/medlineplus/ency/article/000705.htm (last updated Feb. 3, 2014).

[218] *Gunvalson*, 2008 WL 4003377, at *1.

[219] *Id.* at *4.

[220] *Id.* at *1.

ineligible, and a subsequent petition to the company for compassionate use access to the drug was refused.[221] At this point, Jacob and his mother sued the company for access to the drug, claiming promissory estoppel, fraud, and negligent misrepresentation.[222]

On a subsequent motion for a preliminary injunction to compel the drug access, the trial court ruled in Jacob's favor. The court found that Jacob was likely to succeed by proving that the company was promissorily estopped from refusing drug access, that denial would cause him irreparable harm from the progression of his disease, that any burden on the company occasioned by the need for their approval submissions to FDA "is trivial compared to the potential harm to Jacob without the medication," and that "the public has an interest in the provision of possibly life-saving experimental drugs to terminally ill persons, as evidenced by the FDA's enactment of the compassionate use exception."[223]

Although the trial court granted Jacob his requested injunction, it steered a cautious path. The court emphasized the "unique situation" implicated by the special, personally familiar relationship between Jacob's mother and the company, and then expressed its "[strong] doubts that many–if any–other parents of DMD children [had] this kind of relationship with [the drug's manufacturer]."[224] The court cautioned that its "ruling today should not in any way suggest that [the manufacturer] has a general obligation to provide PTC-124–or any experimental drug–to sick persons."[225]

On appeal, a panel of the Third Circuit reversed, faulting the trial judge for wrongly concluding that the drug-availability statements the Gunvalson family ascribed to the company possessed the specificity and clarity necessary to support a promissory estoppel claim. To the contrary, they did not.[226] In closing, the Third Circuit offered this sentiment:

> As we explained in open court following oral argument, we are sympathetic to the plight of Jacob and his family. Similarly, we are moved by the Gunvalsons' heroic efforts on behalf of their son and others afflicted with this devastating disease. Nevertheless, we are constrained by the law to conclude that the Gunvalsons cannot demonstrate either a clear and definitive promise or detrimental reliance, requirements for a promissory estoppel claim.[227]

c. Type 1 Myotonic Muscular Dystrophy Patients

The New York litigation involved a patient suffering from a different category of the disease, Type 1 Myotonic Muscular Dystrophy (MMD1).[228] This type of

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[221] *Id.* at *1-2.
[222] *Id.* at *2.
[223] *Id.* at *3-5.
[224] *Id.* at *5.
[225] *Id.*
[226] *See* Gunvalson v. PTC Therapeutics, Inc., 303 F. App'x 128, 130 (3d Cir. 2008) ("The promises the Gunvalsons assert that [the manufacturer] and its officers made to them lack the requisite specificity and clarity required to succeed under the theory of promissory estoppel. . . . [The alleged statements] fail as a clear and definite promise because [they] assert[] nothing conclusive about Jacob's participation in future trials or his access to PTC-124.").
[227] *Id.*
[228] *See* Cacchillo v. Insmed, Inc., 638 F.3d 401 (2d Cir. 2011) (affirming denial of preliminary injunction); Cacchillo v. Insmed, Inc., Civ. No. 1:10-CV-01199 (TJM/RFT), 2013 WL 62220 (N.D.N.Y. Feb. 19, 2013) (granting summary judgment), *aff'd*, 551 F. App'x 592, (2d Cir. 2014);

muscular dystrophy is linked to a particular gene abnormality.[229] The condition is characterized by progressive muscle degeneration, weakness and shrinkage of muscle tissue, abnormal heart rhythm and heart muscle weakening, breathing muscle weakening, gastrointestinal tract abnormalities, and other symptoms.[230] Like DMD, this MMD1 type of muscular dystrophy knows no current cure and is treated symptomatically.[231]

Angeline Cacchillo suffered from MMD1 and came to learn that a Virginia pharmaceutical company had undertaken clinical trials to explore whether its drug, IPLEX, which was FDA-approved for other indications, could also prove beneficial in treating MMD1.[232] Mrs. Cacchillo enrolled in clinical studies of IPLEX, and seemed to experience meaningful health benefits from treatment with the drug.[233] As the trial's end approached, Mrs. Cacchillo sought continued access to the drug under the compassionate use exception, but was refused; instead, she learned that the manufacturer was "unconvinced" by the clinical trial data, was terminating the study with MMD1 patients, was "immediately ceasing the supply of IPLEX to any new patients," and "would not be initiating any further clinical trials of IPLEX at that time."[234]

Mrs. Cacchillo sued the drug manufacturer in a lawsuit pressing nine causes of action. The trial judge dismissed several of those claims early. A federal civil rights act count was dismissed when the court ruled that the drug company had acted privately, without involvement of a government agency, in declining Mrs. Cacchillo's continued access to the drug.[235] An intentional infliction of emotional distress count was dismissed after the court held that company's denial following its review of the clinical study data did not rise to the requisite level of outrageousness needed to support that claim.[236] A count for negligent assumption of duty was denied because the court found no allegations that the drug access refusal "enhanced the risk that Plaintiff faced, created a new risk, or induced Plaintiff to forego some other unidentified, unknown, or unproven opportunity to avoid risk."[237] No breach of fiduciary duty claim was permitted since the court found that the manufacturer's administration and monitoring of IPLEX effects during the clinical trials gave rise to a fiduciary relationship.[238] Finally, the court dismissed the negligence and unjust

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Cacchillo v. Insmed, Inc., 833 F. Supp. 2d 218 (N.D.N.Y. 2011) (granting in part and denying in part motion to dismiss).

[229] Specifically, "a gene on chromosome 19 called DMPK contains an abnormally expanded section" which, in turn, "appear[s] to have many complex effects on various cellular processes." *Myotonic Muscular Dystrophy: Overview*, MUSCULAR DYSTROPHY ASS'N, http://mda.org/disease/myotonic-muscular-dystrophy/overview (last visited Sept. 19, 2014).

[230] *See id.*

[231] *Myotonic Muscular Dystrophy: Medical Management*, MUSCULAR DYSTROPHY ASS'N, http://mda.org/disease/myotonic-muscular-dystrophy/medical-management (last visited Sept. 19, 2014).

[232] *Cacchillo*, 2013 WL 622220, at *1. The drug IPLEX is "a combination of two substances: human insulin-like growth factor 1 (IGF-1) and human insulin-like growth factor-binding protein-3 (rhIGFBP-3) . . . a unique drug engineered as a synthetic replacement for hormones and proteins which are not produced by individuals afflicted with neuromuscular disorders like MMD1." *Id.* at *1 n.3.

[233] *Id.* at *4, *10.

[234] *Id.* at *10-11.

[235] Cacchillo v. Insmed, Inc., 833 F. Supp. 2d 218, 233-34 (N.D.N.Y. 2011).

[236] *Id.* at 238-39.

[237] *Id.* at 239.

[238] *Id.* at 240.

enrichment counts as lacking the necessary pleading plausibility to persist in the litigation.[239]

Later, the court granted summary judgment, terminating Mrs. Cacchillo's remaining contract, fraud, and negligent misrepresentation counts, and thereby closing the litigation. In entering judgment on the contract count, the court ruled that the terms of the agreement that Mrs. Cacchillo purported to exist between herself and the manufacturer "were not definite enough to constitute an enforceable promise"; that the manner by which the company was to supply the drug was "uncertain"; that the open-ended term of the claimed agreement was not reduced to a writing as the applicable statute of frauds required, and that Mrs. Cacchillo's "unilateral understanding" of the company's obligation was "insufficient to form the basis of an agreement."[240] Similarly, the court's summary judgment on the fraud count rested on the lack of evidence that any statements made by the manufacturer were false, or,if false, were made with a then-present intent not to perform. In any event, because the evidence showed that Mrs. Cacchillo's decision to participate in the early clinical trials "was not dependent on any statements made by [the manufacturer] about post-trial compassionate use of IPLEX, she cannot establish reliance as a matter of law."[241] Finally, judgment on the negligent misrepresentation count was entered because the alleged misrepresented information was not "factual in nature," but instead "promises of future conduct" that could not, under controlling law, support the claim.[242]

d. Asbestosis Patients

In Montana, a district court (and later the Ninth Circuit) examined whether two participants in a clinical trial for an experimental asbestosis drug were entitled to a continued free supply of the medicine once the study terminated.[243] Like the litigations brought by both the Parkinson's patients and the two groups of muscular dystrophy patients, these patients' claims failed.

Asbestosis is a chronic lung disease brought on by prolonged inhalation exposure to fibers of asbestos, a natural mineral product that was, historically, used in certain building materials, including insulation.[244] The disease is marked by lung tissue scarring and shortness of breath, with symptoms appearing only years after the asbestos fiber exposure.[245] No treatment to reverse the lung scarring effects is known; current treatment is limited to slowing the disease's progression and providing symptom relief.[246]

The drug Enbrel is an existing, FDA-approved medicine for use by patients suffering from moderately to severely active rheumatoid arthritis, and for whom

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[239] *Id.* at 240-41.

[240] Cacchillo v. Insmed, Inc., Civ. No. 1:10-CV-01199 (TJM/RFT), 2013 WL 622220, at *13-15 (N.D.N.Y. Feb. 19, 2013), *aff'd*, 551 F. App'x 592 (2d Cir. 2014).

[241] *Id.* at *15-18.

[242] *Id.* at *18.

[243] Vinion v. Amgen, Inc., No. CV 03-202-M-DWM, 2005 WL 6763338 (D. Mont. Nov. 9, 2005), *aff'd*, 272 F. App'x 582 (9th Cir. 2008); Vinion v. Amgen, Inc., No. CV 03-202-M-DWM, 2004 WL 6057351, at *1 (D. Mont. Aug. 30, 2004) (granting in part and denying in part motion to dismiss).

[244] *Diseases and Conditions: Asbestosis Definition*, MAYO CLINIC (Jan. 2, 2014), http://www.mayoclinic.org/diseases-conditions/asbestosis/basics/definition/con-20019671.

[245] *Id.*

[246] *Diseases and Conditions: Asbestosis Treatment and Drugs*, MAYO CLINIC (Jan. 2, 2014), http://www.mayoclinic.org/diseases-conditions/asbestosis/basics/treatment/con-20019671.

certain other antirheumatic drugs have proven inadequate.[247] The drug's manufacturer launched a clinical trial to study whether Enbrel could have an additional use in helping manage asbestosis. Two asbestos patients, Patrick Vinion and Clayton Riddle, participated in that clinical trial upon, they claimed, the manufacturer's promise that, if Enbrel proved effective in managing their asbestos symptoms, they would be provided free Enbrel when the study concluded.[248] The drug company denied the existence of any such agreement, and argued that to the extent that any such promise was made by the doctor conducting the clinical trial, he was unauthorized to make it.[249] The two patients filed an eight-count complaint to obtain what they alleged to be the benefit of the bargain they had struck.[250]

In a factual nuance distinct from the claims pressed by the Parkinson's and muscular dystrophy patients, the patients in the Montana litigation had continuous, uninterrupted access to the medicine at issue; Enbrel was lawfully on the market (albeit approved for a different use), and these patients' physicians were lawfully entitled to write prescriptions to secure continued treatment on the drug.[251] The fight in Montana was not to the access itself, but to access without charge.

Preliminarily, the trial judge dismissed the patients' breach of contract count, ruling that the pleaded allegations contended only that the conducting doctor (and not the drug's manufacturer) had made assurances of free Enbrel.[252] The judge also dismissed plaintiffs' claim for violation of the Montana consumer protection statute, holding that participants in a clinical drug study were not "consumers" within the meaning of this law and that such participants fell outside the scope of the persons for whom the law was enacted.[253] The judge, however, decided not to dismiss the remaining counts on a motion to dismiss.[254]

Those counts could not survive a later motion for summary judgment, however. Each of them (negligence, negligent misrepresentation, intentional misrepresentation, negligent infliction of emotional distress, intentional infliction of emotional distress, and loss of consortium) was terminated on summary judgment.[255] The court found that the uncontroverted deposition testimony of the central witnesses disproved any free-of-charge Enbrel promise, and the consent form that the plaintiffs signed contained no assurance of continued drug access.[256] Moreover, the record belied the plaintiffs' contention that the doctor conducting the clinical trial was the actual or ostensible agent of the drug manufacturer, or otherwise had the legal right to bind the manufacturer to a free-of-charge supply promise.[257] Consequently, because there was no evidence supporting a free-medicine promise,

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[247] *Etanercept Product Approval Information: Licensing Action 12/2/98*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm080536.htm (last updated Oct. 29, 2009).

[248] *Vinion*, 2004 WL 6057351, at *1.

[249] *Id.*

[250] *Id*.

[251] Vinion v. Amgen, Inc., No. CV 03-202-M-DWM, 2005 WL 6763338, at *4 (D. Mont. Nov. 9, 2005) ("Because Enbrel is available to the Plaintiffs, albeit at a cost, they can only show they have been damaged if they can show that Defendants breached a promise to provide the drug *free of charge*."), *aff'd*, 272 F. App'x 582 (9th Cir. 2008).

[252] *Id.* at *3-4.

[253] *Id.* at *4.

[254] *Id.* at *4-5.

[255] *Id.*, at *7.

[256] *Id.* at *1-6.

[257] *See id.* at *6-7.

the court ruled that the plaintiffs had failed to show that the drug manufacturer owed them a duty to supply Enbrel at no charge.[258]

On appeal, a divided panel of the Ninth Circuit affirmed: "Although we have sympathy for Appellants, the law is not on their side."[259]

e. Patients Suing FDA

Litigating access to unapproved, experimental medicine products that are still undergoing testing is not always a fight simply against the drug's manufacturer. Occasionally, the litigation target is the regulator itself. Those cases—where patients seek to force FDA's hand—often employ creative strategies and claim-framing that may inform the litigation options available against manufacturers. Two leading cases are illustrative.

In *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*,[260] an organization of terminally ill patients and their advocates posited that the federal regulatory safety and effectiveness assessment processes were too lengthy, especially given that the "risk-benefit tradeoff facing patients who are terminally ill and who have no other treatment options" is different.[261] The Abigail Alliance petitioned FDA to issue new regulations allowing experimental drug sponsors to market their medicines after the completion of early clinical testing, at least in certain circumstances.[262] When FDA refused the request, the Alliance sued, arguing that the court should recognize a substantive due process right in terminally ill patients to access to experimental drugs.[263]

To acknowledge such a constitutional right, courts must ordinarily find the posited right to be a "fundamental" one, "objectively" and "deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [the right] were sacrificed."[264] The District of Columbia Circuit rejected that a "fundamental" right of the terminally ill to experimental drugs exists. The court reasoned that the Nation's "history and tradition" confirms instead a "long expressed interest in drug regulation," and that FDA's constraints on experimental products are "entirely consistent with our

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[258] *Id.* at *7.

[259] Vinion v. Amgen, Inc., 272 F. App'x 582, 583 (9th Cir. 2008). The majority agreed with the trial judge that the written documents imparted no promise of free medicine at the conclusion of the clinical trial, that the evidence showed no direct promise by the manufacturer, and that the doctor conducting the study was not shown to be the manufacturer's actual or apparent agent. *Id.* at 584-85. The dissenting judge would have found that the evidence left an open question whether a jury could fairly decide that the doctor qualified as an "implied agent" of the manufacturer sufficient to commit the company to a free-of-charge supply of Enbrel. *Id.* at 585-87 (Fletcher, J., dissenting).

[260] Abigail Alliance for Better Access to Dev'l. Drugs v. von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007). The Abigail Alliance was begun in Virginia in March 2001 by Abigail Burroughs, her family, and her supporters when, at the age of 21, she ran out of conventional options to battle her cancer, and she pressed to obtain access to two new drugs to aid in her fight. Although Abigail died in June 2001, her parents and supporters have continued to advocate for expanded access by terminally ill patients to experimental medicines. *See* Frank Burroughs, *Our Story*, ABIGAIL ALLIANCE, http://www.abigail-alliance.org/story.php (last visited Sept. 19, 2014).

[261] *Abigail Alliance*, 495 F.3d at 699.

[262] *Id.* Phase I testing gathers some data on an experimental drug's effectiveness, but the primary focus of Phase I inquiries is whether the drug is safe enough to continue clinically testing it. *See id.* at 698.

[263] *See id.* at 701-02.

[264] *Id.* at 702 (quoting Washington v. Glucksberg, 521 U.S. 702, 720-21 (1997) (ruling that state law forbidding the causing or aiding in suicide did not offend the Due Process Clause)).

historical tradition of prohibiting the sale of unsafe drugs."[265] The court also discounted Abigail Alliance's insistence that the country's common law tradition supported its view. The court concluded that neither the common law doctrine of necessity, intentional interference with rescue, or self-defense aided the Alliance's argument.[266] Consequently, the court found that no "fundamental" constitutional right to terminally ill patient access to experimental drugs existed.[267]

That conclusion, then, relegated Abigail Alliance to proving that FDA's refusal to accelerate access by the terminally ill to experimental drugs failed the Constitution's rational basis scrutiny, a proof the court found the Alliance could not carry.[268] FDA, the court ruled, had a rational basis for insisting on "a scientifically and medically acceptable level of knowledge about the risks and benefits" of an experimental drug.[269] Although the court sent the Alliance away without relief, the court pointed the Alliance to the legislature as the more appropriate venue for their petition:

> The Alliance's arguments about morality, quality of life, and acceptable levels of medical risk are certainly ones that can be aired in the democratic branches, without injecting the courts into unknown questions of science and medicine. Our Nation's history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so.[270]

The opinion in *Abigail Alliance* proved convincing to an Ohio district judge confronting similar arguments in *CareToLive v. von Eschenbach*, decided a few months later.[271] In *CareToLive*, a similar association of cancer patients and their supporters brought suit against FDA to force immediate access to Provenge, a biological treatment for a certain type of metastatic prostate cancer.[272] FDA had declined to approve Provenge pending further submissions.[273] As in *Abigail Alliance*, the plaintiffs in *CareToLive* invited the court to recognize their substantive due process "right to survive," or, as they more elaborately expressed it, the

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[265] *Id.* at 703-06.

[266] *See id.* at 706-10.

[267] *Id.* at 711 ("[W]e conclude that the Alliance has not provided evidence of a right to procure and use experimental drugs that is deeply rooted in our Nation's history and traditions. To the contrary, our Nation's history evidences increasing regulation of drugs as both the ability of government to address these risks has increased and the risks associated with drugs have become apparent. Similarly, our legal traditions of allowing a necessity defense, prohibiting intentional interference with rescue, and recognizing a right of self-defense cannot justify creating a constitutional right to assume any level of risk without regard to the scientific and medical judgment expressed through the clinical testing process.").

[268] *See id.* at 712.

[269] *Id.* at 712-13.

[270] *Id.* at 713.

[271] CareToLive v. Eschenbach, 525 F. Supp. 2d 938 (S.D. Ohio 2007).

[272] *Id.* at 943 ("Provenge uses a patient's own cells to prepare a final product designed for infusion back into the patient's bloodstream to activate his or her immune system against the cancer cells. Provenge is referred to as an active cellular immunotherapy, designed to elicit a patient's specific immune response to a target antigen expressed in prostate cancer tissue, *i.e.*, to train a patient's immune system to recognize cancer cells and to fight them. Because it is designed to act in this manner, Provenge is a vaccine and thus a 'biological product' subject to FDA regulation under the [Public Health Service Act]."). See *supra* note 17 for a general introduction to "biologics" and biological products.

[273] *CareToLive*, 525 F. Supp. 2d at 958 (citations omitted).

"fundamental right of late stage cancer patients in consultation with their doctors, who have no reasonable alternative treatments available and when their only alternative to treatment is death without hope . . . to [have] access to a treatment that has been substantially proven to be effective and which has been demonstrated to be safe."[274]

The court declined, ruling that no such fundamental liberty interest exists.[275] The longstanding commitment to drug regulation in the United States belied the surmise that this "right to survive" through access to experimental drugs was "deeply rooted in this Nation's history and tradition," nor could the court fathom how "a right inextricably entangled with the details of shifting administrative regulations" could ever so qualify.[276] Moreover, because no such liberty right was recognized, the plaintiffs' procedural due process[277] and equal protection[278] claims failed as well.

III. SOURCES OF A "DUTY" TO CONTINUE SELLING MEDICINES

Plaintiffs have proved quite inventive in postulating why a "duty" ought to exist for pharmaceutical manufacturers to continue supplying their medicines to patients. Mrs. Schubert in Utah and Mrs. Lacognata in Florida have added new chapters to this endeavor, extending it (for the first time) to FDA-approved medicines facing product shortages. The various litigation strategies are a veritable march through tort and contract law theory, implicating common law principles that have long remained buried in those dusty volumes of the Restatement of the Law where few dare to venture. Neither the court in Utah nor the court in Florida provided this effort any encouragement.[279] The labor of the experimental drug clinical trial plaintiffs shows the same lack of success, as they, too, journeyed to the outer reaches of constitutional law, statutory law, and common law for relief. The paths staked in these various litigations illustrate how the current state of the law resists a snug fit with this type of "duty."

Over time, these litigations have explored ten different candidates as the possible source of a duty to continue supplying medicines. None has proven successful. An independent assessment of these ten potential analytical sources for a litigation remedy tends toward the same conclusion. Existing law, however creatively repackaged, does not impose upon pharmaceutical manufacturers a "duty" to keep selling their medicines.

A. CURRENT FEDERAL PHARMACEUTICAL LAWS

The most probable source of any legal duty imposed on medicine manufacturers to avoid supply interruptions and to continue selling their medicines is federal law. "The pharmaceutical drug industry has been heavily regulated [by federal law] since

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[274] *Id.* at 964-65.
[275] *Id.* at 965-66.
[276] *Id.*
[277] *Id.* at 966-67. The court reasoned that only the FDA Commissioner's decision triggers a procedural due process entitlement, and plaintiffs' allegations related to events that preceded the Commissioner's involvement. *See id.*
[278] *Id.* at 967-68. The court added that the proffered unlawful classification—that men, elderly men, and African Americans are "disproportionately affected" by this certain type of cancer—could not support an equal protection claim. *See id.*
[279] *Schubert I*, No. 2:12-CV-00587-DAK, 2013 WL 4776286 (D. Utah Sept. 4, 2013); Lacognata v. Hospira, Inc., No. 8:12-cv-822-T-30TGW, 2012 WL 6962884 (M.D. Fla. July 2, 2012).

1906," with a web of laws that today constitutes a "comprehensive regulatory regime."[280] If a duty to keep selling exists, somewhere within that sprawling body of law would seem its most likely source. In none of the litigations summarized above, however, did any court unearth such an obligation.

The requirement that any new drug be approved prior to distribution is readily found.[281] Other laws appear plainly. The new drug laws, for example, authorize FDA to withdraw,[282] or encourage the manufacturer's voluntary withdrawal[283] of, a drug's approval under certain circumstances. Those laws also permit FDA to withdraw a drug's approval upon the applicant's own request.[284] Where that applicant is the medicine's sole manufacturer, and the drug is "life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition," the laws impose on the applicant a further obligation to notify FDA in writing at least six months prior to the medicine's temporary or permanent discontinuance.[285] (If that length of prior notice is not possible, the applicant is allowed to make that notification "as soon as possible."[286]) Upon receiving notice of such a temporary or permanent discontinuance, FDA is authorized to expedite review of certain new drug applications or expedite facility inspections or reinspections, if doing so "could help mitigate or prevent [a medicine] shortage."[287] Drug withdrawals from sale must be followed up, within fifteen days, by a report to FDA supplying various information concerning the withdrawn drug.[288] On that report, "[i]t is requested but not required that the reason for withdrawal of the drug product from sale be included."[289] Finally, these laws permit, and sometimes require, FDA to independently determine whether a drug's voluntary withdrawal was due to safety or effectiveness concerns.[290]

Fairly read, these federal laws do not appear in any respect to bar a medicine manufacturer from ceasing to sell its drugs. On the contrary, the laws seem to anticipate just that, and then set in place procedures to be followed once such a

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[280] Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2676 (2011); s*ee* Kragor v. Takeda Pharm. Am., Inc., 702 F.3d 1304, 1307 (11th Cir. 2012) (commenting that "the pharmaceutical industry is heavily regulated by the federal government"); *see generally* William M. Janssen, *A Historical Perspective on Off-Label Medicine: From Regulation, Promotion, and the First Amendment to the Next Frontiers*, *in* OFF-LABEL COMMUNICATIONS: A GUIDE TO SALES & MARKETING COMPLIANCE 6 (Mark Carlisle Levy ed., 4th ed. 2012) ("[T]he reach of federal regulation has grown exponentially. By 1938, even with the arrival of the new FDCA, the entirety of the statute devoted to medical products encompassed a mere five pages. By 2012, the page count had soared to more than 750 pages (more than 5,000 pages if one includes case law annotations), and FDA's own regulations now span nine volumes in the Code of Federal Regulations, encompassing just under 4,400 pages of additional federal law.").

[281] *See* 21 U.S.C. § 355(a) (2012) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.").

[282] *See id*. § 355(e).

[283] *See* 21 C.F.R. § 314.150(d) (2014).

[284] *See id.* § 314.150(c).

[285] 21 U.S.C. § 356c; 21 C.F.R. § 314.81(b)(iii); *see also id.* § 314.81(b)(iii)(d) ("Discontinuance means any interruption in manufacturing of a drug product described in paragraph (b)(3)(iii)(a) of this section for sale in the United States that could lead to a potential disruption in supply of the drug product, whether the interruption is intended to be temporary or permanent.").

[286] 21 U.S.C. § 356c(b)(2).

[287] *Id.* § 356c(g).

[288] 21 C.F.R. § 314.81(b)(iv).

[289] *Id.* § 314.81(b)(iv)(a)(4).

[290] *See id.* § 314.81(b)(iii); (b)(iii)(d) ("Discontinuance means any interruption in manufacturing of a drug product described in paragraph (b)(3)(iii)(a) of this section for sale in the United States that could lead to a potential disruption in supply of the drug product, whether the interruption is intended to be temporary or permanent.").

cessation occurs.[291] Both Mrs. Schubert and Mrs. Lacognata argued that federal law forbade their drug manufacturers from refusing to supply the medicines.[292] After checking, neither court found such an obligation grounded in enacted federal law.[293] An independent review of those laws supports that conclusion.

Even were the federal pharmaceutical laws susceptible to such a reading, a further obstacle would stand in the way of a patient using them in civil litigation. The federal pharmaceutical laws permit only the federal government to sue to vindicate those legal mandates; no private right of action exists.[294]

For much the same reason, the intimation that the federal patent laws can offer a compelled-access remedy is also unlikely to succeed. Mrs. Schubert, for example, had argued that the manufacturer of her husband's medicine was liable in negligence "for non-use of the invention by banning the publicly funded invention from being given in therapeutic doses to Fabry Disease patients."[295] She is correct that a federal agency that funds an invention may "march-in" to take back the invention's license and re-grant it to another if the person or entity entitled to make use of the invention "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use" or to "alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[296] Like the federal pharmaceutical laws, however, this "march-in" provision grants rights to the federal government and its agencies, but nowhere purports to invest citizens with private rights to sue.[297] More telling still, it appears that no federal agency has ever exercised its own "march-in" authority;[298]

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[291] *See* Collagenex Pharm., Inc. v. Thompson, Civ. No. 03-1405(RMC), 2003 WL 21697344, at *2 (D.D.C. July 22, 2003) ("After an NDA [New Drug Application] is awarded, the holder may voluntarily withdraw the drug from sale. FDA then moves the drug to the Discontinued Drug List to provide notice that it has been withdrawn.").

[292] *See* Memorandum in Opposition, *supra* note 57, at 10 (noting Schubert's argument); Plaintiff's Brief in Opposition to Hospira, *supra* note 133, at 14-15 (noting Lacognata's argument).

[293] *See Schubert I*, No. 2:12-CV-587DAK, 2013 WL 4776286, at *6 (D. Utah Sept. 4, 2013) ("Pharmaceutical marketing 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."); Lacognata v. Hospira, Inc., No. 8:12-CV-822-T-30TGW, 2012 WL 6962884, at *2 (M.D. Fla. July 2, 2012) ("[T]he FDA regulation Plaintiff relies on does not require a manufacturer to obtain FDA approval to stop supplying a prescription product to the market; it merely states that after a manufacturer has voluntarily withdrawn a product from the market, the FDA may investigate the reasons for the withdrawal.").

[294] *See*, *e.g.*, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."); Allergan, Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350, 1354 (Fed. Cir. 2013) ("[T]he FDCA . . . does not itself allow a private right of action."); Morris v. PLIVA, Inc., 713 F.3d 774, 778 (5th Cir. 2013) ("[T]he Federal Food, Drug, and Cosmetic Act . . . provides no private right of action for these violations."); Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) ("[N]o private right of action exists for a violation of the FDCA."); *In re* Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 788–89 (3d Cir. 1999) ("It is well settled . . . that the FDCA creates no private right of action."); Bailey v. Johnson, 48 F.3d 965, 968 (6th Cir. 1995) ("Considering the FDCA's legislative history as set out above, we are compelled to conclude that Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA.").

[295] *Schubert I*, 2013 WL 4776286, at *2.

[296] 35 U.S.C. § 203(a)(1) (2012).

[297] *Id.* § 203(a) (providing that "the Federal agency under whose funding agreement the subject invention was made shall have the right" to march-in).

[298] *See* Carik v. U.S. Dep't of Health & Human Servs., No. 12-272 (BAH), 2013 WL 6189313, at *13 (D.D.C. Nov. 27, 2013) (quoting, with apparent approval, defendant's contention on the point).

indeed, a "march-in" petition for this very biologic—Fabrazyme—was considered and denied by the National Institutes of Health.[299]

For all of these reasons, it is unlikely that current federal statutory or regulatory law supports imposing a "duty" on manufacturers to continue selling medicines.

B. SUBSTANTIVE DUE PROCESS

As the fountain of protection for many personal liberties, the Constitution has been cited as a potential source for a "right to survive" or "right to save one's life," an enshrinement that could implicate so fundamental a personal liberty interest that its encroachment by a medicine manufacturer might entitle a plaintiff to a remedy under the Reconstitution Civil Rights Act of 1871.[300] Neither Mrs. Schubert nor Mrs. Lacognata pressed such an argument, and when experimental drug patients attempted it, they were turned away.[301]

Many impediments greet such a contention. The Supreme Court has had a controversial past in its struggle to give meaning to the doctrine of substantive due process, a principle that forbids certain governmental actions, "regardless of the fairness of the procedures used to implement them . . . [so as] to prevent governmental power from being 'used for purposes of oppression.'"[302] Consequently, the Court now admonishes great restraint and "the utmost care whenever we are asked to break new ground in this field" because the "guideposts for responsible decision-making in this unchartered area are scarce and open-ended."[303] The concern, mulled the Court, is to guard against "the liberty protected by the Due Process Clause [being] subtly transformed into the policy preferences of the Members of this Court."[304]

Consequently, to prevail on a substantive due process claim, litigants must establish as a threshold matter that the liberty interest sought to be vindicated—here, the right to compel access to a medicine—is "deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty," and, further, that the interest is capable of careful description.[305] Litigants have, to date, most often foundered on the first inquiry.[306] The courts that have considered the issue have

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[299] NAT'L INSTS. OF HEALTH, DETERMINATION IN THE CASE OF FABRAZYME MANUFACTURED BY GENZYME CORPORATION, *available at* https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf (last visited Sept. 19, 2014).

[300] 42 U.S.C. § 1983 (2012) ("Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable.").

[301] *See* Abigail Alliance for Better Access to Dev'l. Drugs v. von Eschenbach, 495 F.3d 695, 701-14 (D.C. Cir. 2007); Cacchillo v. Insmed, Inc., 833 F. Supp. 2d 218, 233-34 (N.D.N.Y. 2011); CareToLive v. von Eschenbach, 525 F. Supp. 2d 952, 964-66 (S.D. Ohio 2007).

[302] Daniels v. Williams, 474 U.S. 327, 331 (1986). See JOHN E. NOWAK ET AL., CONSTITUTIONAL LAW 425- 52 (2d ed. 1983) for a narrative of the Court's substantive due process precedent.

[303] Collins v. City of Harker Heights, 503 U.S. 115, 125 (1992).

[304] Washington v. Glucksberg, 521 U.S. 702, 720 (1997).

[305] *Id.* at 720-21.

[306] *See Abigail Alliance*, 495 F.3d at 711 ("[W]e conclude that the Alliance has not provided evidence of a right to procure and use experimental drugs that is deeply rooted in our Nation's history and traditions."); *CareToLive*, 525 F. Supp. at 965 ("Plaintiff's substantive due process claim must . . . fail because Plaintiff cannot demonstrate that the asserted liberty interest is fundamental.").

found that, contrary to a national history and tradition of unrestricted access to pharmaceuticals, the historical record recounts instead a pattern of aggressive regulatory oversight and sharply constrained access to drugs.[307]

Moreover, the guarantee of substantive due process is a safeguard against untoward action by (or fairly attributable to) the government.[308] Although a private actor's conduct could, in an appropriate context, trigger a substantive due process constitutional violation, to do so it must be "fairly attributable to the State."[309] This, in turn, requires that the private actor's conduct cause a deprivation through "the exercise of some right or privilege created by the State or by a rule of conduct imposed by the State or by a person for whom the State is responsible," and that the private actor "may fairly be said to be a state actor" because "he is a state official, because he has acted together with or has obtained significant aid from state officials, or because his conduct is otherwise chargeable to the State."[310] Absent such a limit on liability, cautioned the Court, "private parties could face constitutional litigation whenever they seek to rely on some state rule governing their interactions with the community surrounding them."[311]

Here, too, drug-access litigants have failed. Neither FDA nor other governmental entities are typically implicated in the private actor's decision *not* to supply medicines (especially in a manufacturing shortage circumstance), nor is the patient's claimed injury (denial of medicine access) caused by the regulator's conduct or decision-making.[312] To the contrary, in most drug supply interruption scenarios one might envision, the decision to interrupt a supply of medicines is entirely one made by the private actor (or as a necessary consequence of external circumstances—like viral contaminations, power failures, and the like—over which FDA had no control).[313] Indeed, an FDA-approved medicine's supply interruption

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[307] *See Abigail Alliance*, 495 F.3d at 701-07; *CareToLive*, 525 F. Supp. 2d at 964-66.

[308] 42 U.S.C. § 1983 (2012) (forbidding deprivations accomplished "under color of any" state law)*; see also* United States v. Classic, 313 U.S. 299, 326 (1941) ("Misuse of power, possessed by virtue of state law and made possible only because the wrongdoer is clothed with the authority of state law, is action taken 'under color of' state law.").

[309] Lugar v. Edmondson Oil Co., 457 U.S. 922, 937 (1982); s*ee id.* at 936-37 ("As a matter of substantive constitutional law the state-action requirement reflects judicial recognition of the fact that 'most rights secured by the Constitution are protected only against infringement by governments' . . . . [The Court affirms] the essential dichotomy set forth in [the Fourteenth] Amendment between deprivation by the State, subject to scrutiny under its provisions, and private conduct, `however discriminatory or wrongful,' against which the Fourteenth Amendment offers no shield. Careful adherence to the 'state action' requirement preserves an area of individual freedom by limiting the reach of federal law and federal judicial power. It also avoids imposing on the State, its agencies or officials, responsibility for conduct for which they cannot fairly be blamed. A major consequence is to require the courts to respect the limits of their own power as directed against state governments and private interests. Whether this is good or bad policy, it is a fundamental fact of our political order.") (citations omitted).

[310] *Id.* at 937.

[311] *Id.*

[312] *Cf.* Carik v. U.S. Dep't of Health & Human Servs., No. 12-272 (BAH), 2013 WL 6189313, at *13 (D.D.C. Nov. 27, 2013) ("[T]he actions of private pharmaceutical companies are not fairly attributable to the defendants because '[e]ven extensive regulation by the government does not transform the actions of the regulated entity into those of the government,' and because '[m]ere approval of or acquiescence in the initiatives of a private party is not sufficient to justify holding the [government] responsible for those initiatives.'") (citations omitted).

[313] *See generally* S.F. Arts & Athletics, Inc. v. U.S. Olympic Comm. & Int'l Olympic Comm., 483 U.S. 522, 544 (1987) (citing Blum v. Yaretsky, 457 U.S. 991, 1011 (1982) ("The Government may subsidize private entities without assuming constitutional responsibility for their actions.")).

decision, when made, likely clashes with, rather than advances, the national health policy objectives FDA is charged with pursuing.[314]

This precise barrier defeated Mrs. Cacchillo's federal constitutional claim to her muscular dystrophy medicine.[315] The court there wrote that "[it] is not enough . . . for a plaintiff to plead state involvement in *some activity* of the institution alleged to have inflicted injury upon a plaintiff; rather, the plaintiff must allege that the state was involved with *the activity that caused the injury* giving rise to the action."[316] Therefore, because Mrs. Cacchillo made no allegation "that any federal or state agency or actor had any involvement in Insmed's decision to decline its support for [her] compassionate use application," the court concluded that "there is no plausible basis upon which to find state or federal action sufficient to support" a constitutional injury.[317]

These impediments—the lack of a constitutionally recognizable liberty interest in uninterrupted medicine access and the lack of causal involvement by government in the access interruption—portends poorly for a successful substantive due process claim by patients against medicine manufacturers. This constitutional guarantee is unlikely to be a source for a "duty" on drug makers to continue selling their medicines.

C. CONVENTIONAL PRODUCTS LIABILITY THEORY

Prototypical products liability law is similarly unlikely to be the wellspring from which a "duty" to continue selling medicines will come. Classically litigated, products liability theory is formulated to mediate personal and property losses caused by *encountering* a product that contained a defect in its design, defect in its manufacture, or defect in its warnings or instructions.[318] Liability grounded on an absence of such an encounter turns products theory on its head.

Design defects are "hazards lurking in a product's engineering or scientific conception that may reasonably be avoided by a different design or formula."[319]

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[314] *See* Valerie Jensen et al., *FDA's Role in Responding to Drug Shortages*, 59 AM. J. HEALTH SYS. PHARMACY 1423, 1424-25 (2002).

[315] *See* Cacchillo v. Insmed, Inc., 833 F. Supp. 2d 218 (N.D.N.Y. 2011).

[316] *Id.* at 234 (quoting Sybalski v. Indep. Grp. Home Living Program, Inc., 546 F.3d 255, 257-58 (2d Cir. 2008)); *see also id.* at 234 n.15 ("The question is not whether the decision to establish the [private entity] was state action, but rather whether the [private entity's] decision to sanction [plaintiffs] may be 'fairly attributable' to the [g]overnment.") (citation omitted).

[317] *Id.* at 234.

[318] *See*, *e.g.*, Evans v. Lorillard Tobacco Co., 990 N.E.2d 997, 1010 (Mass. 2013) ("A product may be defective and unreasonably dangerous because of a manufacturing defect, a design defect, or a warning defect, that is, a failure reasonably to warn of the product's foreseeable risks of harm."); Rabon-Willimack v. Robert Mondavi Corp., 905 N.Y.S.2d 190, 192 (App. Div. 2010) ("A product may be defective because of a mistake in the manufacturing process resulting in a manufacturing flaw, because of an improper, defective design, or because the manufacturer failed to provide adequate warnings regarding the use of the product."); Watson v. Ford Motor Co., 699 S.E.2d 169, 174 (S.C. 2010) ("For the sake of context, there are three defects a plaintiff in a products liability lawsuit can allege: 1) a manufacturing defect, 2) a warning defect, and 3) a design defect."); *see also* Mercer Mut. Ins. Co. v. Proudman, 933 A.2d 967, 969 (N.J. Super. App. Div. 2007) (noting legislature's codification of case law, "leaving 'intact' the three theories, specifically defective manufacture, defective design, and defective warnings, by which a manufacturer or seller may be held strictly liable for harm caused by a product.").

[319] OWEN, *supra* note 64, at 344; *see*, *e.g.*, Branham v. Ford Motor Co., 701 S.E.2d 5, 16 (S.C. 2010) ("[I]n a product liability design defect action, the plaintiff . . . will be required to point to a design flaw in the product and show how his alternative design would have prevented the product from being unreasonably dangerous.").

Lying "at the heart of products liability law," design liability "rests fundamentally on the premise that manufacturers are fairly held to answer in courts for the basic safety of their products' designs."[320]

Manufacturing defects are "unintended physical irregularities that occur during the production process,"[321] resulting in a "flawed condition" of the product which "may lead to its failure during use, to an accident, and possibly to an injury to the user or another."[322] Considered a "first pillar of modern products liability law," it is "now quite settled" that "manufacturers and other suppliers are liable for injuries caused by manufacturing defects in products that they sell."[323]

Warning defects are "the absence[s] of information needed by users to avoid product hazards."[324] These "informational obligations" are two-fold: the duty "to inform buyers and users of hidden dangers in a product" (the warning duty) and the duty "to inform buyers on how to avoid a product's dangers in order to use it safely" (the instruction duty).[325] When a user is injured by a product "because such danger or safety information was not provided, the manufacturer is subject to liability for the harm."[326]

Each of these three classic products claims necessarily contemplates that the product at issue will have contained an actual defect that rendered the product, upon its encounter with the litigating plaintiff, in a "condition unreasonably dangerous to the user."[327] More simply stated, plaintiffs will be arguing that the product that injured them (or otherwise caused them a loss) would not have done so had it been more properly designed, more properly manufactured, or more properly warned about. At their irreducible core, then, these claims all hinge on an injury (or loss) suffered *by exposure to* the allegedly defective product. This, in turn, presupposes that the product at issue has, in point of fact, been sold to or otherwise conveyed to the litigating plaintiff, thereby facilitating the injurious encounter which brings him or her to court in the first place.[328] In other words, the import of conventional products liability theory is holding product sellers and suppliers accountable for

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[320] OWEN, *supra* note 64, at 495.

[321] *Id.* at 344.

[322] *Id.* at 447; s*ee*, *e.g.*, iLight Techs. Inc. v. Clutch City Sports & Entm't, L.P., 414 S.W.3d 842, 846 (Tex. App. 2013) ("A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous. A plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff's injuries.") (citations omitted).

[323] OWEN, *supra* note 64, at 447.

[324] *Id.* at 345; *see*, *e.g.*, Chavez v. Glock, Inc., 144 Cal. Rptr. 3d 326, 343 (Ct. App. 2012) ("Generally speaking, manufacturers have a duty to warn consumers about the hazards inherent in their products. The requirement's purpose is to inform consumers about a product's hazards or faults of which they are unaware, so that they can refrain from using the product altogether or evade the danger by careful use.") (citations omitted).

[325] OWEN, *supra* note 64, at 584.

[326] *Id.* at 581.

[327] Branham v. Ford Motor Co., 701 S.E.2d 5, 8 (S.C. 2010); *see*, *e.g.*, Rohde v. Smiths Med., 165 P.3d 433, 437 (Wyo. 2007); UTAH CODE ANN. § 78B–6-703 (LexisNexis 2008).

[328] *See*, *e.g.*, CONN. GEN. STAT. §§ 52-572m(a)-n(a) (2013) (authorizing product liability actions against a "product seller", defined as "any person or entity, including a manufacturer, wholesaler, distributor or retailer who is engaged in the business of selling such products whether the sale is for resale or for use or consumption"); Rabon-Willimack v. Robert Mondavi Corp., 905 N.Y.S.2d 190, 192 (App. Div. 2010) (permitting parties "injured as a result of a defective product" to "seek relief against the product manufacturer or others in the chain of distribution if the defect was a substantial factor in causing the injury"); *see also* Escola v. Coca Cola Bottling Co., 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring) ("[T]he manufacturer is responsible for an injury caused by such an article to any person who comes in lawful contact with it.").

injuries caused when *contact with* their products' defects, existing at the moment of sale, causes injury or loss.[329]

This model is ill-suited as a source for a "duty" on a manufacturer to continue selling medicines. In a supply-interruption context, there is no encounter between the manufacturer's product and the plaintiff. Indeed, it is this very *absence* of an encounter that forms the gravamen of the complaint. The patient's allegation isn't that the product is defective (in design, manufacture, or warning), but that the product's attributes are quite to the contrary highly desirable, useful, and (at least at this point in the contention) safe.[330] The manufacturer's claimed misdeed is not an errant supplying of a defective product—what classic products liability theory aims to vindicate. Rather, the misdeed is the errant failure to supply a non-defective product to someone who wanted to, but was refused the right to, encounter it. The very essence of products liability theory is missing. In short, none of the foundational requisites for conventional products liability will exist in a claim a supply-interruption patient is likely to bring. Accordingly, conventional products law is not a probable source for this "duty".

D. CONTRACT, QUASI CONTRACT, AND WARRANTY LAW

Litigants have also attempted to ground a right to continued drug access on common law contract and warranty theories. The framing of such claims is illustrative as to why contract and warranty theory, too, are unlikely to represent credible sources for a "duty" on manufacturers to keep selling.

A claim of breach of express contract was pressed by the asbestosis experimental drug patients in *Vinion v. Amgen, Inc.*, where the plaintiffs alleged that, as participants in the clinical drug trial, they were assured of continued access to Enbrel.[331] Similarly, the Parkinson's patients in *Abney v. Amgen, Inc.*[332] and *Suthers v. Amgen Inc.*[333] alleged that, in accordance with the terms of a written informed consent form, the manufacturer committed to providing them with post-trial access to GDNF. Likewise, the muscular dystrophy patient in *Cacchillo v. Insmed Inc.* contended that the manufacturer induced her to participate in a clinical trial to study the drug IPLEX with the false promise of assisting her in obtaining compassionate use access to the drug after the trial had closed.[334] None of those contract claims survived.

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[329] *See* OWEN, *supra* note 64, at 3 ("Operating *ex post*, after a product accident has occurred, [products liability law] rules define the legal responsibility of sellers and other commercial transferors of products for damages resulting from product defects and misrepresentations about a product's safety or performance capabilities."); *see also* RESTATEMENT (SECOND) OF TORTS § 402 A cmt. c (1965) ("[T]he justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it."); *cf. id.* at cmt. f ("The rule stated in this section applies to any person engaged in the business of selling products for use or consumption.").

[330] *See*, *e.g.*, *Suthers II*, 441 F. Supp. 2d 478, 488-89 (S.D.N.Y. 2006) ("There is no claim that the product was negligently designed or manufactured or that the defendant failed to exercise reasonable care in warning plaintiffs. Rather, plaintiffs view the drug as beneficial and desire to continue to receive the benefits.").

[331] Vinion v. Amgen, Inc., No. CV 03-202-M-DWM, 2004 WL 6057351, at *1, *3-4 (D. Mont. Aug. 30, 2004).

[332] Abney v. Amgen, Inc., 443 F.3d 540, 544, 547-49 (6th Cir. 2006).

[333] *Suthers I*, 372 F. Supp. 2d 416, 419 (S.D.N.Y. 2005).

[334] Cacchillo v. Insmed Inc., Civ. No. 1:10-CV-01199 (TJM/RFT), 2013 WL 622220, at *4 (N.D.N.Y. Feb. 19, 2013), *aff'd*, 551 F. App'x 592 (2d Cir. 2014).

The necessary predicate for success on these claims—as with any express contract claim—is, of course, the existence of a legally enforceable promise.[335] Thus, to support a contract-based duty to avoid shortages or supply interruptions, a contract—an affirmative *promise*—must have committed the manufacturer to a continued, uninterrupted patient supply of the drug at issue. Contracting parties can agree freely on such terms as they may choose,[336] and it is certainly not impossible that a medicine manufacturer could draw up a contract committing to continuously supplying a patient with uninterrupted access to a drug. Not impossible, but as this case law bears out, certainly improbable.[337]

Furthermore, what a patient understood a manufacturer's commitment to be, no matter how emotionally compelling that conclusion might be, is never solely dispositive on contract formation. It is now generally clear that "unilateral understandings of one party, no matter how subjectively reasonable, are insufficient to form the basis of a contractual promise."[338] What instead, the patient will be obligated to show are the terms of an agreement sufficiently definite to constitute an enforceable promise, a standard that vague, imprecise ruminations or intimations cannot meet.[339] Moreover, if the claimed promise was not reduced to writing, the allegation may also run aground on statute of frauds principles.[340]

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[335] *See*, *e.g.*, McCaskey v. Cal. State Auto. Ass'n, 118 Cal. Rptr. 3d 34, 42 (Ct. App. 2010) ("[A] breach of contract ordinarily occurs upon the promisor's *failure to render the* promised *performance.*"); Baysden v. Hitchcock, 553 N.W.2d 901, 903 (Iowa Ct. App. 1996) ("A breach of contract occurs where a promisor, who had promised to do a certain act or make a specific payment, fails to do so when the time for doing such act or making such payment has occurred."); Townewest Homeowners Ass'n v. Warner Commc'n Inc., 826 S.W.2d 638, 640 (Tex. App. 1992) ("[A] breach of contract occurs when a party fails or refuses to do something he has promised to do.") (citation omitted).

[336] *See*, *e.g.*, Kernz v. J.L. French Corp., 667 N.W.2d 751, 755 (Wis. Ct. App. 2003) ("The ultimate aim of all contract interpretation is to ascertain the intent of the parties. . . . When the terms of a contract are plain and unambiguous, we will construe the contract as it stands.") (citations omitted).

[337] *See Cacchillo*, 2013 WL 622220, at *15 ("There are insufficient facts indicating an agreement between Plaintiff and Defendant that, no matter the results of the trial, Plaintiff would receive IPLEX after the clinical trial."); *Suthers II*, 441 F. Supp. 2d 478, 484 (S.D.N.Y. 2006) ("[T]he text of the Informed Consent negates the existence of a contractual promise to supply 'GDNF indefinitely' as alleged in the body of the complaint.") (footnote omitted); Abney v. Amgen, Inc., No. 5:05-CV-254-JMH, 2005 WL 1630154, at *5-8 (E.D. Ky. July 8, 2005) (ruling that no contract had been created between the patients and the manufacturer, and even if one had, "the Court finds that the language of the document supports Amgen's ability to terminate the study for scientific reasons"), *aff'd*, 443 F.3d 540 (6th Cir. 2006); Vinion v. Amgen, Inc., No. CV 03-202-M-DWM, 2004 WL 6057351, at *3-4 (D. Mont. Aug. 30, 2004) (finding no support for the existence of any contract between the patients and the manufacturer, and even had there been one, "[t]here is nothing in this form that would lead a signatory to understand that following the study, the drugs would be provided free of cost").

[338] *See Cacchillo*, 2013 WL 622220, at *14 (citation omitted); *accord Suthers I*, 372 F. Supp. 2d 416, 424 (S.D.N.Y. 2005) ("It is a basic principle of contract law that the unilateral understandings of one party, no matter how subjectively reasonable, are insufficient to form the basis of a contractual promise.") (citation omitted); *see also* Irons v. Cmty. State Bank, 461 N.W.2d 849, 856-57 (Iowa Ct. App. 1990) (observing that "unilateral expectations and understandings do not create a contract"); State v. Carson, 243 P.3d 73, 76 n.2 (Or. Ct. App. 2010) (reaffirming "the core principle of the objective theory of contracts that a party's unilateral and subjective understanding of a contract's effect is immaterial") (citation omitted).

[339] *See Cacchillo*, 2013 WL 622220, at *14 (assuming even that website postings and other statements could constitute an "offer," "the terms of the purported agreement were not definite enough to constitute an enforceable promise" because "[t]he duration of Defendant's purported obligation was unclear;" thus, "[n]o reasonable fact finder could find that an agreement was reached on this essential term").

[340] *See id.* at *15 (finding statute of frauds violation with alleged continued-supply agreement, because the agreement could not be performed within one year and was not reduced to writing).

Allegations of promissory estoppel have proven similarly unavailing for continued-access claims. The common law generally enforces promises made, even in the absence of consideration, if they are reasonably and detrimentally relied upon by the promisee.[341] Such was the claim asserted by Mrs. Lacognata in Florida[342] and Jacob Gunvalson in New Jersey.[343] Mrs. Lacognata contended that her manufacturer had breached an implied contract when, after representing to her that Aquasol A would be backordered until September 2011, it failed to provide her with Aquasol A in September 2011.[344] Jacob alleged that his manufacturer had promised him access to the experimental drug PTC-124, prompting him to forego enrolling in a clinical study to otherwise obtain access to that drug.[345]

Neither claim prevailed. Both courts found that the asserted promises (critical for sustaining any promissory estoppel claim) lacked the required specificity, clarity, and conclusiveness to be enforced.[346] Thus, the same essential missing element that doomed the express breach of contract claims—an enforceable promise—defeated the promissory estoppel contentions.

One final observation about Jacob Gunvalson's litigation merits mention. Although later reversed by the Third Circuit, Jacob's claim had originally succeeded before the trial judge, at least to the extent of a grant of preliminary injunctive relief.[347] Even there, though, the trial judge took great pains to avoid the impression that his ruling stood as any broad precedent. In the judge's opinion, Jacob should prevail, but only because his mother's special access and intimacy with the drug manufacturer through her role as a prominent patient advocate had placed the promise-making event in a "unique situation."[348] "The Court strongly doubts," continued the opinion, "that many – if any – other parents of DMD children have this kind of relationship with PTC (or other drug companies)."[349] Indeed, the judge explained that he "believes PTC's claim that it normally takes care to refrain from promising any parent access to PTC 124 and that it attempted to do so in this

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[341] *See*, *e.g.*, Gunvalson v. PTC Therapeutics, Inc., Civ. No. 08-3559, 2008 WL 4003377, at *3 (D.N.J. Aug. 21, 2008) ("Promises without consideration are enforceable if the promisee reasonably relied on them to his detriment."), *vacated*, 303 F. App'x 128 (3d Cir. 2008). *See generally* Garcia v. World Savings, FSB, 183 Cal. App 4th 1031, 1040-41 (Ct. App. 2010) ("The doctrine of promissory estoppel make[s] a promise binding under certain circumstances, without consideration in the usual sense of something bargained for and given in exchange. Under this doctrine a promisor is bound when he should reasonably expect a substantial change of position, either by act or forbearance, in reliance on his promise, if injustice can be avoided only by its enforcement. The vital principle is that he who by his language or conduct leads another to do what he would not otherwise have done shall not subject such person to loss or injury by disappointing the expectations upon which he acted.") (citations omitted) (internal quotation marks omitted).

[342] *See* Lacognata v. Hospira, Inc., No. 8:12-cv-822-T-30TGW, 2012 WL 6962884, at *3 (M.D. Fla. July 2, 2012), *aff'd*, 521 F. App'x 866 (11th Cir. 2013).

[343] *See Gunvalson*, 2008 WL 4003377, at *2-3.

[344] *See* Complaint, *supra* note 116, ¶¶ 39, 84-88.

[345] *See Gunvalson*, 2008 WL 4003377, at *1.

[346] *See Lacognata*, 2012 WL 6962884, at *3 ("Plaintiff alleges that Hospira told her that Aquasol A would be backordered until September 2011. This hardly amounts to a promise with definite terms."); Gunvalson v. PTC Therapeutics, Inc., 303 F. App'x 128, 130 (3d Cir. 2008) ("The promises the Gunvalsons assert that PTC and its officers made to them lack the requisite specificity and clarity required to succeed under the theory of promissory estoppel. . . . [The alleged promissory statements] by PTC officers fail as a clear and definite promise because it asserts nothing conclusive about Jacob's participation in future trials or his access to PTC 124.").

[347] *See Gunvalson*, 2008 WL 4003377, at *2-3 ("Here, it is reasonably likely that PTC promised Plaintiffs to provide Jacob with PTC124, causing them to forgo enrolling him in the initial Phase 2a trials to their detriment, as Jacob is foreclosed from entering the current clinical trials as a result.").

[348] *Id.* at *5.

[349] *Id.*

case."[350] Nonetheless, the judge "also [found] that Plaintiffs' unusually close relationship with PTC likely muddied this otherwise clear message."[351] Then, with a forebodingly worded closing admonition, the judge cautioned: "Thus, the Court's ruling today should not in any way suggest that PTC has a general obligation to provide PTC 124–or any experimental drug–to sick persons. Indeed, the Court appreciates that sound scientific and medicinal practices may disfavor a drug company from doing so."[352] The judge's sentiment could hardly be clearer: Jacob wins here, but only because of extraordinarily peculiar circumstances unique to him and his family; no other patient should expect the same result.

Finally, in her complaint against Genzyme Corporation, Mrs. Schubert alleged that the manufacturer had breached an express warranty, an implied warranty of merchantability, and an implied warranty of fitness for a particular purpose by selling her husband reduced doses of Fabrazyme when, at those reduced volumes, the medicine was not therapeutic in treating his disease.[353] It is telling that the drug manufacturer did *not* attack this claim in its motion to dismiss.[354] Such claims are highly promise-specific. They contend that the manufacturer's act of *supplying* a partial dose implied that the *as-supplied* dose was not merchantable or fit because the reduced dose rendered it non-therapeutic, and thus the *supplying* of the partial-dose of the medicine was actionable. Whatever fate such a claim may meet in the course of Mrs. Schubert's litigation, this much is plain: the claim is not one vindicating a "duty" to supply something, but rather a fairly traditional "duty" to avoid supplying something improper.

The lesson from this journey through continued-access claims pressed under contract theory tends to confirm that the source of a broad "duty" to avoid interrupting a supply of medicines is unlikely to be grounded in contract. True, manufacturers could make promises to patients, enforceable in contract theory, that a supply of medicine will never be interrupted, and, if made, such promises are subject to being enforced. As this review makes plain, such promises are unlikely. Or, in the belief expressed by Jacob Gunvalson's judge, manufacturers are far more prone to "take[] care to refrain from promising any . . . access to" medicines.[355] Mindful of the meticulously enforced requirement that agreements be definite, clear, and conclusive to support a legal remedy, it seems very improbable that a contractually enforceable "duty" to continue selling medicines will arise from some non-specific, penumbral-like ether emanating from the law of promises.

E. COMMON LAW DUTY TO INITIATE A RESCUE

The common law does not generally impose a duty to attempt a rescue of someone known to be in danger.[356] This principle is understood to apply "irrespective of the gravity of the danger to which the other is subjected and the

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[350] *Id.*
[351] *Id.*
[352] *Id.*
[353] *See* Third Amended Complaint and Jury Demand, *supra* note 9, ¶ 52-64.
[354] *See* Judgment on the Pleadings, *supra* note 52, at 2 n.1 (confirming expressly that the only allegation in the complaint under attack was negligent manufacturing).
[355] *Gunvalson*, 2008 WL 4003377, at *5.
[356] *See* RESTATEMENT (SECOND) OF TORTS § 314 (1965) ("The fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action.").

insignificance of the trouble, effort, or expense of giving him aid or protection."[357] Indeed, the principle is said to apply even when the actor's failure to act "is due to a desire that the other shall be harmed."[358] Although the principle has been decried "as revolting to any moral sense," it "thus far . . . remain[s] the law."[359]

The principle recognizes two caveats. First, it applies "only where the peril in which the actor knows that the other is placed is not due to any active force which is under the actor's control;" if it is, then "his failure to control it is treated as though he were actively directing it."[360] The Restatement offers this illustration:

> A, a factory owner, sees B, a young child or a blind man who has wandered into his factory, about to approach a piece of moving machinery. A is negligent if he permits the machinery to continue in motion when by the exercise of reasonable care he could stop it before B comes in contact with it.[361]

Second, it does not apply when a special relationship exists between the actor and the person in need of rescue (such as common carrier to passengers, innkeeper to guests, possessor of land to invitees, and legal or voluntary custodian to charges), which imposes independently a duty to aid.[362]

Mrs. Lacognata argued, at least implicitly, that both these caveats triggered a tort duty on the part of Hospira to continue to supply her with Aquasol A.[363] She reasoned that the manufacturer's conduct "(and no one else's) placed [her] at a foreseeable risk of harm when Hospira negligently transferred manufacturing facilities without properly securing the supply chain of Aquasol A and . . . by creating an inadequate stockpile and otherwise deprioritizing remediation of the injuries to" her.[364] Hospira, she insisted, "was not a bystander to the Aquasol A shortage because Hospira's conduct (not someone else's) created the zone of

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[357] *Id.* at § 314 cmt. c. *See generally id.* at illus. 1 ("A sees B, a blind man, about to step into the street in front of an approaching automobile. A could prevent B from so doing by a word or touch without delaying his own progress. A does not do so, and B is run over and hurt. A is under no duty to prevent B from stepping into the street, and is not liable to B.").

[358] *Id.* at § 314 cmt. e. *See generally id.* at illus. 4 ("A, a strong swimmer, sees B, against whom he entertains an unreasonable hatred, floundering in deep water and obviously unable to swim. Knowing B's identity, he turns away. A is not liable to B.").

[359] *Id.* at § 314 cmt. c.

[360] *Id.* at § 314 cmt. d.; *see*, *e.g.*, Rasnick v. Krishna Hospitality, Inc., 713 S.E.2d 835, 837 (Ga. 2011) ("[T]he general principle [is] that, 'a person is under no duty to rescue another from a situation of peril which the former has not caused'") (citation omitted); Estate of Cilley v. Lane, 985 A.2d 481, 485 (Me. 2009) ("Maine law does not impose a general obligation to protect others from harm not created by the actor. The fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action.") (citations omitted) (internal quotation marks omitted); Seebold v. Prison Health Servs., Inc., 57 A.3d 1232, 1246 (Pa. 2012) (noting that generally "there is no duty to protect or rescue someone who is at risk on account of circumstances the defendant had no role in creating").

[361] RESTATEMENT (SECOND) OF TORTS § 314 cmt. d, illus. 2 (1965).

[362] *See id.* § 314 A (1965); *see also* Grimes v. Hettinger, 566 S.W.2d 769, 775 (Ky. Ct. App. 1978) ("[A] duty to aid one in peril has been imposed when a special relationship exists between the parties.").

[363] The court in Mrs. Schubert's case in Utah also considered these caveats, and particularly the second—special relationship. In dismissing Mrs. Schubert's negligence claim, the court found that she had neither alleged nor argued the point. *Schubert I*, No. 2:12-CV-00587-DAK, 2013 WL 4776286, at *5 (D. Utah Sept. 4, 2013).

[364] Plaintiff's Brief in Opposition to Hospira, *supra* note 133, at 2.

risk."[365] Thus, "because Hospira's conduct placed the Plaintiffs at a foreseeable risk for injury, it also had a duty to exercise care."[366]

The court blithely dismissed this proposition. "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 that it knows the patient relies upon for his or her medical health."[367] The court did not further explain its reasoning, but a fair assumption may be that the court rejected the notion that a drug manufacturer places a patient in a duty-inducing "peril" when it interrupts a medicine supply that could help abate the medical condition from which that patient suffers.[368] More particularly, in this line of thought, the "peril" in which the patients find themselves is caused by the underlying medical condition itself, not by the availability or unavailability of the manufacturer's medicines. Had the medicine been unavailable for other reasons (such as, for example, because it had never been invented), the "peril" confronting the patients would be no different.[369] Consequently, the first caveat—peril creation—is not implicated.

On other occasions, courts weighing continued-access claims have similarly rejected the contention that a medicine supplier owes a special relationship to those patients for whom the medicine may benefit. For example, the Sixth Circuit rejected the Parkinson's patients' argument that the drug company owed a "fiduciary duty to ameliorate their pain and treat their illness with the best medicine available."[370] The court there reasoned that nothing in the evidentiary record established that the drug company had covenanted to act primarily for the benefit of the clinical study patients: "While benefiting the plaintiffs could arguably be described as one of [the] reasons [for sponsoring the clinical trial], there is nothing to suggest that the parties agreed that this would be the primary reason for Amgen's sponsorship of the study."[371] Other courts have reached similar conclusions in separate compelled-access litigations.[372] In general, it seems fairly settled that most ordinary, arms-

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[365] *Id.* at 5.

[366] *Id.*

[367] Lacognata v. Hospira, Inc., No. 8:12-cv-822-T-30TGW, 2012 WL 6962884, at *2 (M.D. Fla. July 2, 2012), *aff'd*, 521 F. App'x 866 (11th Cir. 2013).

[368] This was, after all, how Mrs. Lacognata understood Hospira to be arguing. *See* Plaintiff's Brief in Opposition to Hospira, *supra* note 133, at 4-5 (noting that Hospira was "impliedly arguing that Hospira did not create the situation wherein vitamin A deficient patients would be placed at risk").

[369] Some support for this conclusion already exists in the law of rescue. In *Rasnick v. Krishna Hospitality, Inc.*, 713 S.E.2d 835 (Ga. 2011), the Georgia Supreme Court confronted the question of whether the duty on innkeepers to protect guests from "peril" extended not merely to external (criminal menaces) and internal (smoke inhalation) risks, but to preexisting, guest-specific risks (like their own health vulnerabilities) as well. The court ruled that such a duty did not exist: "[C]ontrary to [plaintiff's] argument, the alleged negligence in her suit cannot be credibly cast as a condition of the premises or akin to a premises hazard like a smoke-filled building. Because any risk or problem stemming from a medical condition unrelated to and not caused by the guest's stay at the facility is not internal *to the premises* but rather *internal to the guest.*" *Id.* at 837-38.

[370] Abney v. Amgen, Inc., 443 F.3d 540, 550 (6th Cir. 2006).

[371] *Id.*

[372] *See*, *e.g.*, Cacchillo v. Insmed Inc., 833 F. Supp. 2d 218, 240 (N.D.N.Y. 2011) ("Here, there was no fiduciary duty on Defendant's part to administer and monitor the effects of IPLEX during the clinical trial . . . and there are insufficient facts plausibly demonstrating that Insmed had a fiduciary duty relative to any treatment Plaintiff would or could receive after the clinical trial concluded."); *Suthers I*, 372 F. Supp. 2d 416, 426-27, 429 (S.D.N.Y. 2005) (holding that "fiduciary duties do not arise solely because one party has expertise that is superior to another," and to find a fiduciary duty on the part of the study sponsor "would presumably mean that if it were in a study participant's best interests to continue a clinical study, then the sponsoring company would be without power to terminate it without risking a finding of breach"); *cf. Suthers II*, 441 F. Supp. 2d 478, 485 (S.D.N.Y.

length commercial relationships between a goods or services supplier and its customer are not fiduciary ones.[373]

Consequently, it appears that the common law duty to initiate a rescue is not a probable source for a "duty" on a manufacturer to continue selling its medicines.

F. COMMON LAW DUTY TO CONTINUE A RESCUE ONCE INITIATED

The law likewise does not generally impose upon one who, without obligation, initiates a rescue, a new duty to continue to perform the rescue now begun. "The fact that the actor gratuitously starts in or aids another does not necessarily require him to continue his services. He is not required to continue them indefinitely, or even until he has done everything in his power to aid and protect the other."[374] In fact, so long as the actor's gratuitous attempts at rescue have not placed the person in a worse position than he or she was before, "[t]he actor may normally abandon his efforts at any time."[375] The actor's motives for ceasing the rescue "are immaterial," and the actor is not required "to justify his failure to continue the services by proving a privilege to do so;" in fact, the actor "may without liability discontinue the services through mere caprice, or because of personal dislike or enmity toward the other."[376]

Thus, having once begun to supply a life-sustaining or health-improving medicine, the law of rescue could impose upon a manufacturer the duty to continue that supply only if the cessation of the supply would place the consuming patients at an increased risk of harm. Notably, in making the increased-harm calculus, the courts "compare the risk of harm resulting from the negligence to that existing before, not during, the undertaking."[377] The critical inquiry under rescue theory, then, is not whether patients having benefited from the drug are worse off after having the drug later denied them, but whether being denied the drug places those patients in a worse position than they were before they ever began treating on the drug.[378] Presumably, that must be an unusual case; no continued-access litigant seems ever to have had the factual record to press that claim.[379] For this reason,

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2006) ("Plaintiffs have no support for the broad proposition that an entity violates the implied covenant of good faith and fair dealing by acting in its own self-interest consistent with its rights under a contract.").

[373] *See* Kim v. Sumitomo Bank, 21 Cal. Rptr. 2d 834, 836 (Ct. App. 1993) (finding no fiduciary relationship between bank and its loan customers); Trident Indus. Prods. Corp. v. Am. Nat'l Bank & Trust Co., N.A., 501 N.E.2d 273, 280 (Ill. App. Ct. 1986) (finding no fiduciary relationship between bank and creditor).

[374] RESTATEMENT (SECOND) OF TORTS § 323 cmt. c (1965).

[375] *Id. See generally* Beers v. Corp. of President of Church of Jesus Christ of Latter-day Saints, 316 P.3d 92, 100 (Idaho 2013) ("When a party assumes a duty by voluntarily performing an act that the party had no duty to perform, the duty that arises is limited to the duty actually assumed. Thus, merely because a party acts once does not mean that party is forever duty-bound to act in a similar fashion. A beach-goer may assume a duty to rescue a drowning swimmer in a non-negligent manner by undertaking to do so, but that same beach-goer has no obligation to rescue anyone else.") (citation omitted) (internal quotation marks omitted).

[376] RESTATEMENT (SECOND) OF TORTS § 323 cmt. c (1965).

[377] Entex, A Div. of Noram Energy Corp. v. Gonzalez, 94 S.W.3d 1, 9 (Tex. App. 2002). *See generally* RESTATEMENT (SECOND) OF TORTS § 323 cmt. c (1965) (recognizing rescue liability when "the actor's assistance has put the other a worse position than he was before").

[378] *Cf. Suthers II*, 441 F. Supp. 2d 478, 490 (S.D.N.Y. 2006) ("Fairly read in context, the complaint alleges that GDNF ameliorates the symptoms of Parkinson's disease and when the drug is withdrawn the symptoms return. . . . There is no allegation that these plaintiffs were worse off than their pre-GDNF baseline because of the administration and withdrawal of GDNF.").

[379] One group of patients might have tried, however. In the Parkinson's patients litigations, the drug at issue (GDNF) was delivered to the brain through a surgical implantation of a pump and

common law rescue theory is unlikely to represent a source for imposing a "duty" to continue selling medicines.

G. COMMON LAW DUTY TO AVOID A NEGLIGENT RESCUE

A corollary rescue principle is the common law obligation that one who, voluntarily or for compensation, embarks upon a rescue is obliged to perform that rescue in a non-negligent manner, and will be held answerable for a negligent rescue if that negligence either increases the risk of harm to the victim or the victim detrimentally relies on the rescue then begun.[380]

As discussed above, because increased-harm is measured at a point before any medicine is supplied, it would be the unusual case that a patient is worse off (for rescue liability purposes) after having started the drug than he or she would have been had the drug never been used at all.[381] This is, of course, not to suggest that patients always benefit from medicines, or that they don't sometimes have reactions to the medicines that degrade their health even further. Neither is true. But in the former instance, those patients likely are not litigating for continued access to the drug; in the latter instance, those patients absolutely are not litigating for such access.

To prove a detrimental reliance under this rescue theory, a patient would have to demonstrate that he or she foreswore an opportunity for an alternative medical benefit in reliance on the assurance of continued supply of the drug at issue.[382] This, too, is an unlikely liability scenario. If there is an alternative to the medicine the patient wants, then compelled-access litigation would be unnecessary. If there is no alternative medicine, then the elements needed for negligent rescue are never triggered. This corollary to the rescue theory similarly does not seem a strong candidate as the source of a "duty" to continue selling medicines.

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catheter system, and that invasive installation procedure, along with whatever associated complications might have arisen, "amounts to the type of worsening that would give rise to liability in negligence." *Suthers II*, 441 F. Supp. 2d at 490. However, because the patients understood the installation logistics and signed a proper informed consent to the procedure, no duty to continue to provide the medication was triggered. "Any harm caused by the surgical implantation," reasoned the court, "arises from participation in the research trial and not from the administration and withdrawal of GDNF." *Id.* at 490.

[380] *See* RESTATEMENT (SECOND) OF TORTS § 323 (1965). A companion principle imposes similar liability when a failure to render services to another causes foreseeable harm to a third-party. *See id.* § 324A (1965); *id.* § 323 cmt. a ("The rule stated in this Section parallels the one stated in § 323, as to the liability of the actor to the one to whom he has undertaken to render services. This Section deals with the liability to third persons."). Third-party liability is understood to follow when the actor's failure to exercise reasonable care increases the risk of harm to the third-party, undertakes to perform a duty already owed, or causes the third-party to detrimentally rely. *Id.* § 323(a)-(c). This context would seem to be once-removed from the actual purported relationship between a drug manufacturer and its customers.

[381] *See supra* notes 379-80.

[382] *See* RESTATEMENT (SECOND) OF TORTS § 323 cmt. c (1965) ("Where, however, the actor's assistance has put the other a worse position than he was before . . . because the other, in reliance upon the undertaking, has been induced to forego other opportunities of obtaining assistance, the actor is not free to discontinue his services where a reasonable man would not do so.").

H. COMMON LAW DUTY TO AVOID INTERFERING WITH A RESCUE

The common law also imposes liability on an actor who intentionally or negligently interferes with another's efforts to perform a rescue.[383] As framed by the Second Restatement of Torts, an actor can tortiously prevent a third person's attempts to rescue "by injuring or destroying the usefulness of a thing which the third person is using to give aid or by otherwise preventing him from using it."[384] Mrs. Lacognata argued that just such an interference occurred with her access to Aquasol A. Specifically, she contended that her physicians were engaged in her rescue, doing so through the writing of prescription scripts for her purchase of Aquasol A, but that the drug's manufacturer had interfered with that rescue by refusing to honor her prescription because of the drug's supply interruption.[385]

Several challenges await any patient aspiring to invoke this adaptation of common law rescue theory. First, many jurisdictions have not adopted this tort principle at all; consequently, it remains unclear whether the principle would even be theoretically available in the particular jurisdiction where a patient is litigating.[386] Second, although the case law construing and applying this principle is thin, the type of "prevention" required to implicate this tort is ordinarily "active intervention," rather than passive inaction, and that intervention must alter, impede, or completely thwart the rescuing efforts of the rescuing actor.[387] Third, that "intervention" must be something more than a mere "refusal to allow one's property to be commandeered, even for a good purpose," because "[i]f the English words 'prevent' and 'interfere' still mean anything, they necessarily convey the notion of some sort of affirmative action, not just refusal to turn one's property over to someone else."[388] Fourth, for the tort to apply, the victim must be in real, imminent threat of bodily harm.[389] Fifth,

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[383] *See id.* § 326 (1965) ("One who intentionally prevents a third person from giving to another aid necessary to prevent physical harm to him, is subject to liability for physical harm caused to the other by the absence of the aid which he has prevented the third person from giving."); *id.* § 327 ("One who knows or has reason to know that a third person is giving or is ready to give to another aid necessary to prevent physical harm to him, and negligently prevents or disables the third person from giving such aid, is subject to liability for physical harm caused to the other by the absence of the aid which he has prevented the third party from giving.").

[384] *Id.* ch. 12, topic 8, scope note.

[385] Complaint, *supra* note 116, ¶¶ 78-82. In the experimental drug context, the Abigail Alliance had offered a somewhat similar contention, also rejected by the court. *See* Abigail Alliance for Better Access to Dev'l. Drugs v. von Eschenbach, 495 F.3d 695, 708 (D.C. Cir. 2007) ("The Alliance next invokes the tort of intentional interference with lifesaving efforts, which the Restatement of Torts defines as 'intentionally prevent[ing] a third person from giving to another aid *necessary* to his bodily security.' But that is not this case. The Alliance seeks access to drugs that are experimental and have not been shown to be safe, let alone effective at (or "necessary" for) prolonging life.") (citations omitted).

[386] *See*, *e.g.*, Moses v. Bridgeman, 139 S.W.3d 503, 501-11 (Ark. 2003) (noting that Arkansas courts have not adopted Sections 326 and 327 of the Second Restatement of Torts); Spierer v. Rossman, No. 1:13–cv–00991–TWP–TAB, 2013 WL 6817233, at *8 (S.D. Ind. Dec. 23, 2013) (noting the same in Indiana); Keesee v. Freeman, 772 S.W.2d 663, 668 (Mo. Ct. App. 1989) (noting the same in Missouri); State v. Lisa, 945 A.2d 690, 691 (N.J. 2008) (noting the same in New Jersey).

[387] Gomes v. Commercial Union Ins. Co., 783 A.2d 462, 469 (Conn. 2001); *see also* Eric J. v. Betty M., 90 Cal. Rptr. 2d 549, 560 (Ct. App. 1999) (holding that the terms "prevent" and "interfere" "necessarily convey the notion of some sort of affirmative action").

[388] *Eric J.,* 90 Cal. Rptr. 2d at 560.

[389] *See* Ambros-Marcial v. United States, 377 F.Supp.2d 767, 777 (D. Ariz. 2005) ("[T]he danger to the victim must be imminent."); *Gomes*, 783 A.2d at 469 (necessitating a showing of "a real and immediate threat of bodily harm); *Keesee*, 772 S.W.2d at 668 (same).

the law will not treat a decision not to begin a rescue as a tortious "prevention" or "interference" with rescue.[390]

In a compelled-access lawsuit, the "intervention" with the prescribing physician's script-writing rescue that Mrs. Lacognata alleged is a passive failure to supply, rather than an active interference.[391] To view it otherwise would be to accept that one who attempts to rescue has a lawful right to count on the affirmative assistance of another, independent non-rescuer, whose failure to oblige the request qualifies as tortious interference. Neither the Restatement nor the construing case law seems to validate that reasoning. If any analogy from the case law is apt, it is more likely to be the commandeering of another's property, "even for a good purpose," and that behavior was found to fall outside the scope of the tort.[392]

Because the case law applying this tortious interference principle is so under-developed nationally, a sound prediction about its usefulness is impossible. But the language of the Restatement and the theoretical direction of those few cases construing it to date discourage the conclusion that a "duty" to continue supplying medicine will be found here.

I. COMMON LAW DOCTRINES OF "NECESSITY" AND SELF-DEFENSE

In the *Abigail Alliance* litigation, the plaintiffs cited both the common law doctrines of necessity and self-defense to the District of Columbia Circuit as support for their contention that denying the terminally ill access to experimental drugs was inconsistent with the Nation's legal tradition.[393] Neither defense is traditionally understood as a "claim;" instead, both are recognized as impediments to a criminal prosecution.[394] For this reason, the District of Columbia Circuit was perplexed about

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[390] *See* Miller v. Arnal Corp., 632 P.2d 987, 994 (Ariz. Ct. App. 1981) ("In this case one group of corporate employees, the ski patrol, decided to attempt a rescue. A higher-ranking corporate employee . . . told the patrol members that they could not undertake the rescue as they had planned. The effect was that the corporation as an entity decided, through the interactions of its employees, not to begin a rescue. The corporation cannot be held liable for interfering with a rescue attempt, because it chose not to make any attempt. As discussed above, there is no duty to rescue an endangered stranger. Thus there is no basis upon which to hold appellee liable for interfering with or preventing a rescue attempt."); *Keesee*, 772 S.W.2d at 668 (noting that the tort applies "only when there is a real and immediate threat of bodily harm and active intervention by the defendant to thwart the efforts of a rescuer").

[391] The Second Restatement's illustrations tend to corroborate this conclusion. The Restatement authors posit this example of intentional interference: "A prevents the fire department from using a fireplug in front of A's premises for the purpose of putting out a fire in B's house. This A does under an unfounded claim that he is entitled to the entire supply of water from the plug. In consequence, the fire department is unable to put out the fire and B, while carefully attempting to rescue from his house some valuable chattels, is injured. A is subject to liability to B." RESTATEMENT (SECOND) OF TORTS § 326 cmt. a, illus. 1 (1965) (noting the intentional prevention of assistance). They also posit this example of negligent interference: "The engineer of the A Railway Company knows that there is a fire on B's premises, but negligently runs over a fire hose which a fire department is using to extinguish the fire. As a result the fire, which would have been extinguished had the fire hose not been injured, spreads and B is burned while reasonably trying to rescuer valuable chattels from his house. The A Railway Company is subject to liability to B for his injuries." *Id.* § 327 cmt. 1, illus. 1 (describing negligently preventing assistance). Both examples feature a positive act by the defendant that defeats another actor's attempts at rescue.

[392] *Eric J.*, 90 Cal. Rptr. 2d at 560.

[393] Abigail Alliance for Better Access to Dev'l. Drugs v. von Eschenbach, 495 F.3d 695, 707-08 (D.C. Cir. 2007).

[394] *See* People v. Pepper, 48 Cal. Rptr. 2d 877, 880 (Ct. App. 1996) (discussing theory and elements of criminal defense of necessity); State v. Watson, 449 S.E.2d 694, 701-02 (N.C. 1994) (discussing theory and elements of criminal self-defense).

how these doctrines would aid a compelled-access claim,[395] surmising only that the argument served as some type of invitation for the judiciary, embracing reasoning from these doctrines, to enter a coercive civil order forcing drug manufacturers to vindicate their "medical necessity" and/or entitlement to "medical self-defense."[396] Weighing that logic, the District of Columbia Circuit was unmoved.

The defense of necessity conjures the image of Victor Hugo's memorable plight of Jean Valjean against the zealous French criminal authorities over the value of bread stolen to feed his sister's starving family.[397] Alas, as Valjean learned, the law has never embraced this defense with much vigor.[398] The throwing of male passengers overboard can still be prosecuted even though the act was intended to prevent a lifeboat of women and children from capsizing,[399] the killing of one shipwreck survivor could be prosecuted notwithstanding that the act was intended to provide his flesh as food to save two other shipwrecked sailors from starving,[400] and Jean Valjean could still be incarcerated for years for bread theft even though his sister's son had food to survive.

Where applicable, the defense of necessity requires the showing that a criminal law was violated

> (1) to prevent a significant evil, (2) with no adequate alternative, (3) without creating a greater danger than the one avoided, (4) with a good faith belief in the necessity, (5) with such belief being objectively reasonable, and (6) under circumstances in which [the violator] did not substantially contribute to the emergency.[401]

The defense, however, is not available where it is "at odds with the terms of" statutory law[402] or would otherwise "overrule a value judgment already determined

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[395] *Abigail Alliance*, 495 F.3d at 708 (D.C. Cir. 2007) ("The Alliance offers, however, little detail about how necessity would apply to its case.").

[396] *Id.* ("[W]ould terminally ill patients have a right to force drug companies to provide them with experimental drugs?").

[397] "There lived a man named Jean Valjean / He stole some bread to save his sister's son / For nineteen winters served his time / In sweat he washed away his crime." ALAIN BOUBLIL ET AL., *Valjean's Confession, on* LES MISÉRABLES (1985).

[398] *See generally* United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 490 (2001) ("Even at common law, the defense of necessity was somewhat controversial.").

[399] *See* United States v. Holmes, 26 F. Cas. 360 (C.C.E.D. Pa. 1842) (No. 15,383).

[400] *See* Regina v. Dudley & Stephens, 14 Q.B.D. 273 (1884).

[401] People v. Pepper, 48 Cal. Rptr. 2d 877, 880 (Ct. App. 1996); s*ee also* State v. Shed, 828 So.2d 124, 129 (La. Ct. App. 2002) ("'Necessity,' when raised as a defense to the illegal possession of a firearm, entails proof that the threat of force by another is imminent and apparent, and that the person threatened has no reasonable alternative but to possess the firearm."); State v. Shotton, 458 A.2d 1105, 1106 (Vt. 1983) ("(1) there must be a situation of emergency arising without fault on the part of the actor concerned; (2) this emergency must be so imminent and compelling as to raise a reasonable expectation of harm, either directly to the actor or upon those he was protecting; (3) this emergency must present no reasonable opportunity to avoid the injury without doing the criminal act; and (4) the injury impending from the emergency must be of sufficient seriousness to outmeasure the criminal wrong."). *See generally Oakland Cannabis Buyers' Coop*., 532 U.S. at 490 ("A necessity defense 'traditionally covered the situation where physical forces beyond the actor's control rendered illegal conduct the lesser of two evils.'"); Stephen S. Schwartz, *Is There A Common Law Necessity Defense in Federal Criminal Law?*, 75 U. CHI. L. REV. 1259 (2008).

[402] *Oakland Cannabis Buyers' Coop*., 532 U.S. at 491 ("We need not decide, however, whether necessity can ever be a defense when the federal statute does not expressly provide for it. In this case, to resolve the question presented, we need only recognize that a medical necessity exception for marijuana is at odds with the terms of the Controlled Substances Act.").

by the legislature."[403] Those elements alone, the District of Columbia Circuit ruled, defeated the Abigail Alliance's compelled-access argument.[404] Congress, through enactment of the federal pharmaceutical laws, barred general access to experimental drugs and, instead, prescribed how they may be studied and used.[405] The resulting legislative scheme constraining pharmaceutical access as a matter of national policy thereby foreclosed the availability of a common law necessity doctrine.[406] In effect, the legislature had already set the balance on access that the patients would have the judiciary reconfigure, and the courts would not intrude into those policy judgments reached by a separate branch of government.

A similar result could be expected in a non-experimental drug access dispute. There, too, Congress has prescribed the conditions under which a manufacturer may supply its medicines, and no federal supply obligation has been imposed.[407] An invitation for a judicial reconfiguration of that value balance, invoking an offensive necessity defense, is likely to be perceived as a similar policy encroachment.

Likewise, the criminal doctrine of self-defense is unlikely to prove useful to a compelled access claim. This doctrine justifies a criminal defendant, who is threatened with force, in responding with defensive force.[408] But that exertion of defensive force must be necessary. As one court wrote:

> Thus if the threat to the defendant is only that of harm to his person on some future occasion, so that there is no need for an immediate response and, indeed, some opportunity to seek less drastic means of avoiding that harm, an immediate use of force in self-defense would not be justified.[409]

The doctrine thus presupposes the presence of an aggressive, forcible, affirmative attack on the victim, and the moderated use by the victim of only that amount of defensive force necessary to repel that attack.[410] While compelled-access litigants might very reasonably feel otherwise, the elements of this common law criminal defense do not fit snugly within the context of a medicine manufacturer refusing passively to continue selling its medicines. Extending this defensive

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[403] Abigail Alliance for Better Access to Dev'l. Drugs v. von Eschenbach, 495 F.3d 695, 708 (D.C. Cir. 2007); *see also Oakland Cannabis Buyers' Coop*., 532 U.S. at 484 ("Under any conception of legal necessity, one principle is clear: The defense cannot succeed when the legislature itself has made a 'determination of values.'") (citation omitted).

[404] *Abigail Alliance*, 495 F.3d at 708.

[405] *See id. See generally* United States v. Schoon, 971 F.2d 193, 195 (9th Cir. 1991) (noting that necessity defense cannot be involved in the context of civil disobedience, where criminal defendant is merely protesting policy judgments deemed to be unjust); United States v. Kabat, 797 F.2d 580, 591 (8th Cir. 1986) ("The necessity defense was never intended to excuse criminal activity by those who disagree with the decisions and policies of the lawmaking branches of government . . . .").

[406] *Abigail Alliance*, 495 F.3d at 708.

[407] *Id.* at 698.

[408] *See* WAYNE R. LAFAVE, CRIMINAL LAW 471-72 (5th ed. 2010).

[409] *Id.* at 472. *See generally* People v. White, 687 N.E.2d 1179, 1181 (Ill. Ct. App. 1997) ("The elements of self-defense are (1) that unlawful force is threatened against a person; (2) that the person threatened is not the aggressor; (3) that the danger of harm is imminent; and (4) that the use of force was necessary.") (citation omitted).

[410] *See* Graham v. Commonwealth, 525 S.E.2d 567, 572 (Va. Ct. App. 2000) ("Self-defense . . . is a defense to an act of violence that repels violence directed at the defendant."); *see also* Hollowell v. State, 707 N.E.2d 1014, 1021 (Ind. Ct. App. 1999) ("Where a person has used more force than necessary to repel an attack the right to self-defense is extinguished, and the ultimate result is that the victim then becomes the perpetrator.") (citation omitted); State v. Barnd, 619 N.E.2d 518, 521 (Ohio Ct. App. 1993) ("Self-defense presumes intentional, willful use of force to repel force or escape force.") (citation omitted).

criminal law doctrine successfully into an offensive civil platform for continued drug access seems untenable.

J. SUI GENERIS TORT

The practical unavailability of so many other potential candidates for legal theories may explain why Mrs. Schubert and Mrs. Lacognata were well served by endeavoring to craft sui generis tort claims as their leading litigation arguments. Mrs. Schubert had argued that the State of Utah ought to impose a continued-access duty on Genzyme Corporation because the injury inflicted on her husband by the shortage of Fabrazyme was both foreseeable and caused by the company's affirmative, tortious conduct.[411] Mrs. Lacognata had contended that the State of Florida ought to impose a continued-access duty on Hospira. because she sustained her injury while in a zone of injury foreseeable to the company.[412] Neither court, however, was convinced and neither recognized such sui generis duties.

The court in Utah acknowledged the possibility that unique circumstances could give rise to a legal duty, but emphasized how heavily controlling local precedent, in finding such a duty to exist, had weighed the parties' special relationship to one another and the affirmative (rather than passive) nature of the alleged misconduct.[413] The latter distinction carries a formidable heritage. In 1965, the American Law Institution embraced the same distinction as categorically pivotal in duty analysis:

> In general, anyone who does an affirmative act is under a duty to others to exercise the care of a reasonable man to protect them against an unreasonable risk of harm to them arising out of the act. The duties of one who merely omits to act are more restricted, and in general are confined to situations where there is a special relation between the actor and the other which gives rise to the duty.[414]

No special relationship was alleged or argued by Mrs. Schubert,[415] so the principal focus of the court's inquiry was relegated to whether a medicine supply interruption, which was allegedly caused and then tolerated to persist by the manufacturer's negligence in production, was an affirmative act or a passive one. As the court explained: "[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."[416]

Mrs. Schubert had argued that Genzyme Corporation was affirmatively negligent because it had made intentional, conscious decisions that she asserted were

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[411] *See* Memorandum in Opposition, *supra* note 57, at 1 ("Defendant Genzyme owed a duty when it decided to manufacture and supply the market with Fabrazyme. Utah law makes it very clear that when a party takes affirmative actions (as opposed to merely omissions), they [sic] owe a duty to exercise reasonable care in effectuating those actions.").

[412] *See* Plaintiff's Brief in Opposition to Hospira, *supra* note 133, at 4 ("While Hospira's actions are not explicitly cataloged or listed, Hospira's actions meet the test for creation of a legal duty existing under Florida negligence law, which is creating a 'zone of foreseeable injury' to the Plaintiffs.").

[413] *See Schubert I*, No. 2:12-CV-00587-DAK, 2013 WL 4776286, at *3-4 (D. Utah Sept. 4, 2013) (citing and applying factors from *Jeffs v. West*, 275 P.2d 228 (Utah 2012)).

[414] RESTATEMENT (SECOND) OF TORTS § 302 cmt. a (1965).

[415] *See Schubert I*, 2013 WL 4776286, at *5.

[416] *Id.* at *4 (quoting *Jeffs*, 275 P.2d at 231).

negligent (e.g., shifting Fabrazyme production operations to a different facility before that facility was actually ready to go on-line, not stockpiling supplies of Fabrazyme).[417] The court rejected this construction.[418] Mrs. Schubert's focus on the reasons for the shortage was misguided. The reasons prompting the shortage may or may not have been neglectful or careless ones, but those reasons would not bear on the operative question of whether the shortage itself—considered categorically—was an affirmative act or a failure to act.[419] Here, the court sided with the manufacturer: the "harm" Mrs. Schubert was alleging was "the shortage of the medication," and a shortage of supply "is an act of nonfeasance."[420] Since a sui generis Utah duty could arise only upon a showing of either a special relationship or the performance of an affirmative act, this last ruling doomed that portion of Mrs. Schubert's negligence count.[421]

This line dividing affirmative action/misfeasance from passive omission/nonfeasance has not always proven easy to discern.[422] Still, this distinction remains "deeply rooted" in tort.[423] Scholars surmise that the reason for the distinction may "lie in the fact that by 'misfeasance' the defendant has created a new risk of harm to the plaintiff, while by 'nonfeasance' he has at least made his situation no worse, and has merely failed to benefit him by interfering in his affairs."[424]

In the realm of liability arising from products, this reasoning is classically borne true. The Buick Motor Company was held liable to Donald MacPherson, for example, not because it "was a manufacturer of finished automobiles," but rather because "it was not at liberty to put the finished product on the market without subjecting the component parts to ordinary and simple tests" that would have detected their imperfections.[425] Likewise, Yuba Power Products was not liable to William Greenman because it manufactured the Shopsmith combination power tool, but rather because it "place[d] [that article] on the market, knowing that it [was] to be used without inspection for defects, [and then] prove[d] to have a defect that

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[417] *Id.* at *2.

[418] *Id.* at *4-5.

[419] *See id.*

[420] *Id.* at *6.

[421] Apart from her claim that the manufacturer owed her husband a duty to avoid medicine supply interruptions, Mrs. Schubert had also argued that the manufacturer's decision to supply the medicine in partial-dose units—while allegedly knowing that the partial dose would prove non-therapeutic—was a further affirmative act of negligence, supporting an additional claim for recovery. The court agreed that this latter claim, alleging the actual supplying of a defective product, could survive the manufacturer's motion to dismiss. *See id.* ("[T]o the extent that Plaintiff claims that the lowered dosage of the medication was more harmful [than] 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.").

[422] *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 374 (5th ed. 1984) ("In theory the difference between the two is fairly clear; but in practice it is not always easy to draw the line and say whether conduct is active or passive.").

[423] *Id.* at 373.

[424] *Id.* Just as in Utah, the law generally does not impose liability upon nonfeasance absent "some definite relation between the parties, of such a character that social policy justifies the imposition of a duty to act." *Id.* at 374. *See generally id.* at 375 ("The question appears to be essentially one of whether the defendant has gone so far in what he has actually done, and has got himself into such a relation with the plaintiff, that he has begun to affect the interests of the plaintiff adversely, as distinguished from merely failing to a confer a benefit upon him.").

[425] MacPherson v. Buick Motor Co., 111 N.E. 1050, 1055 (N.Y. 1916) (citations omitted).

cause[d] injury to a human being."[426] In neither case did the existence of the owed duty hinge on the reasons for those products' failures; instead, the owed duty arose because the manufacturer had performed the positive act of supplying.

Creative advocacy notwithstanding, it appears that the Utah court's reasoning here represents the more faithful application of the affirmative act/passive omission distinction. A shortage of a product is an omission or nonfeasance (a failure to act), irrespective of the array of affirmative forces which aligned to bring about that shortage.

The Florida court in Mrs. Lacognata's case did not elaborate on the basis of its rejection of her negligence theory, but, like Utah, Florida also recognizes the distinction in its law between negligent actions and negligent omissions.[427] Even under the "zone of risk" formulation Mrs. Lacognata advanced, "[t]he law does not require persons to protect others from danger, unless such persons themselves created the danger."[428] Here, the danger Mrs. Lacognata confronted was from her tragic medical condition, and it was that illness that placed her in a "zone of risk." The fact that her drug's manufacturer realized that some action on its part could prove necessary for her aid "does not of itself impose upon [the manufacturer] a duty to take such action."[429] As in Utah, the Florida law of duty did not support sui generis liability.

III. INVENTING A "DUTY" TO CONTINUE SELLING MEDICINES

> Last thing I remember, I was running for the door.
> I had to find the passage back, to the place I was before.
> "Relax," said the night man, "We are programmed to receive.
> You can check-out any time you like, but you can never leave."[430]
>
> Eagles, Hotel California

This foraging through the law has demonstrated that recognized and settled legal principles are unlikely to provide a source for a "duty" imposed on medicine manufacturers to avoid interruptions in the supply of their products. Indeed, one might fairly conclude that this tale of this journey has confirmed much the contrary, that manufacturers have no legal duty to continue selling medicines. But should they?

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[426] Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 900 (Cal. 1963).

[427] *See* Estate of Johnson *ex rel.* Johnson v. Badger Acquisition of Tampa LLC, 983 So.2d 1175, 1183-84 (Fla. Dist. Ct. App. 2008) ("Allegations of a negligent omission to act do not create a duty for a party where the risk was put in place by another.").

[428] Thompson v. Baniqued, 741 So.2d 629, 631 (Fla. Dist. Ct. App. 1999); *see also id.* (quoting from Section 314 of the Second Restatement of Torts that "[t]he fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action"); *cf.* Jaworski v. Kiernan, 696 A.2d 332, 336 (Conn. 1997) ("A simple conclusion that the harm to the plaintiff was foreseeable, however, cannot by itself mandate a determination that a legal duty exists. Many harms are quite literally 'foreseeable,' yet for pragmatic reasons, no recovery is allowed.") (citations omitted).

[429] *Baniqued*, 741 So.2d at 631 (quoting from Section 314 of the Second Restatement of Torts that "[t]he fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action") (citations omitted).

[430] EAGLES, *Hotel California, on* HOTEL CALIFORNIA (Asylum Records 1977).

Were these manufacturers selling the Cabbage Patch Kids cuddly fabric toy dolls, the answer would almost certainly be a resounding "no." Actually, the answer might be a bit stronger than that, maybe an angry "no" or even a *they-ought-to-be-sanctioned-for-litigating-that* "no." Does that answer change if the product is, say, windshield wipers? Suppose a new brand of car accepts only a certain model of wiper blades, and at the moment, everyone is sold out of that type. If a driver is injured in the rain from obscured vision because she just plain couldn't buy replacement blades anywhere, is the blade manufacturer liable for her wrecked car? Her injured foot? The bus full of dead commuters whom she hit? What about a new cell phone? As we have all learned, there seems to be a not-so-cottage industry in the making of brand-specific power cords for charging each new model of phone. What if, because of one manufacturer's cord shortage, a parent's dead battery prevents him from summoning timely aid for his choking child? Is there liability for that shortage?

The question, then, devolves down to whether a particular line of products—here, medicines, and their unique capacity to alleviate human frailty, suffering, and death—ought to command a different answer. In the context of a right to the compelled access to medicines, this is indeed a perplexing twist. But, in many ways, it is little more than the most recent wrinkle on a quest that is as old as tort law itself. When should civil liability lie?

In one of the earliest surviving negligence decisions, the English King's Bench ruled in 1466 in *The Thorns Case* that the cutting of one's own trees on one's own property can still expose an actor to a claim in trespass if, should the cuttings fall onto a neighbor's land, that neighbor's crops are trampled when the cuttings are retrieved.[431] Nearly a quarter-millennium later, Professor Wigmore would pronounce that little had changed in the foundational principle of tort law that liability follows upon an act that causes injury to another because "the doer of a deed was responsible whether he acted innocently or inadvertently, because he was the doer."[432] A consequence of *acting* is always the possibility of *intruding*, and in that intrusion—to another's person, property, rights, or privileges—liability may loom.

But policing the boundary set by tort law has grown increasingly more complicated over time. Mrs. Palsgraf lost her lawsuit against the Long Island Railroad because the law of negligence would not tolerate a recovery. "Negligence, like risk, is thus a term of relation," taught Judge Cardozo. He continued, "[n]egligence in the abstract, apart from things related, is surely not a tort, if indeed it is understandable at all . . . . Negligence is not a tort unless it results in the commission of a wrong, and the commission of a wrong imports the violation of a right . . . ."[433] Nor could the charterer of steamships look to tort law to remedy malfunctioning turbines because, explained Justice Blackmun, "a manufacturer in a commercial relationship has no duty under either a negligence or strict products-

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[431] Hull v. Orange, Y.B. Mich. 6 Ed. 4, f. 7, pl. 18 (1466), *reprinted in* C. H. S. FIFOOT, HISTORY AND SOURCES OF THE COMMON LAW: TORT AND CONTRACT 195, 196 (1949) (quoting Justice Littleton: "If a man suffers damage, it is right that he be recompensed . . . . [F]or the law is all one in great things and in small; and so, according to the amount of the trespass, it is proper that he should make amends."); *id.* (quoting Chief Justice Choke: "[W]hen the principal thing is not lawful, then the thing which depends upon it is not lawful. For when he cut the thorns and they fell on to my land, this falling was not lawful, and then his coming to take them away was not lawful. As to what has been said that they fell *ipso invito*, this is not a good plea; but he should have said that he could not do it in any other manner or that he did all that was in his power to keep them out; otherwise he shall pay damages.").

[432] John H. Wigmore, *Responsibility for Tortious Acts: Its History*, 7 HARV. L. REV. 315, 317 (1894).

[433] Palsgraf v. Long Island R.R. Co., 162 N.E. 99, 101 (N.Y. 1928).

liability theory to prevent a product from injuring itself," lest "contract law . . . drown in a sea of tort."[434] Likewise, a tragically impaired child could find no recompense in tort law for that child's "wrongful life," wrote the South Carolina Supreme Court, because such a claim does not "present an ordinary tort case," because "it is difficult, if not impossible, to apply a traditional duty-breach-causation-damages analysis to it," because it implicates "formidable theological and philosophical issues," and because "being born with a naturally occurring defect or impairment does not constitute a legally cognizable injury" under the law.[435] Discerning where this tort boundary lies has proven to be quite confounding.

In fixing this elusive boundary line, a rule compelling manufacturers to continue selling their medicines interjects a numbing array of policy considerations. The law might, for example, aspire that the specter of such liability will broadly prompt manufacturers to be more motivated to protect their product supply from interruption.[436] Or the law might hope more specifically to incentivize superior manufacturing care, more attention to factory maintenance and hygienics, and greater redundancies to mitigate any product supply interruptions, were they to occur.[437] The law might also perceive this new liability as an insurance policy of sorts, ensuring that the party best able to absorb the costs of injury and loss is held to do so, in order to avoid that loss falling on a party with lesser means and abilities.[438] Or the law might just endeavor to use this liability to achieve broader, national healthcare policy objectives by ensuring that those who have an ability to mitigate illness and disease are obliged to do so.[439]

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[434] East River S.S. Corp. v. Transamerica Delaval, Inc., 476 U.S. 858, 871, 866 (1986).

[435] Willis v. Wu, 607 S.E.2d 63, 71 (S.C. 2004).

[436] *See* Escola v. Coca Cola Bottling Co., 150 P.2d 436, 440-41 (Cal. 1944) (Traynor, J., concurring) ("It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot."); *see also* KEETON ET AL., *supra* note 422, at 25 ("The 'prophylactic' factor of preventing future harm has been quite important in the field of torts. The courts are concerned not only with compensation of the victim, but with admonition of the wrongdoer.").

[437] *See generally Escola*, 150 P.2d at 440-41 ("Even if there is no negligence . . . public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. . . . It is to the public interest to discourage the marketing of products having defects that are a menace to the public.").

[438] *See* Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 901 (Cal. 1963) ("The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves."); *Escola*, 150 P.2d at 441 ("Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business."); RESTATEMENT (SECOND) OF TORTS § 402 A cmt. c (1965) (noting as justification for strict liability "that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained"); KEETON ET AL., *supra* note 422, at 24 ("Another factor the courts have considered in weighing the interests before them is the relative ability of the respective parties to bear a loss which must necessarily fall upon one or the other, at least initially.").

[439] *See generally* Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 69 (D.D.C. 1998) ("There are few, if any, more important functions performed by any regulatory agency than the function . . . [of] ensuring that when a citizen takes a prescription drug, that individual has absolute assurance that the product is safe and effective for the condition for which his physician has prescribed it."), *amended by*, 36 F. Supp. 2d 16 (D.D.C. 1999), *vacated in part*, 202 F.3d 331 (D.C. Cir. 2000); Exec. Order No. 13,588, 76 Fed. Reg. 68295 (Oct. 31, 2011) ("Shortages of pharmaceutical drugs pose a serious and growing threat to public health."); FDA, REPORT TO CONGRESS – FIRST ANNUAL REPORT ON DRUG SHORTAGES FOR CALENDAR YEAR 2013 at 10 (Feb. 5, 2014) [hereinafter FDA FIRST ANNUAL REPORT], *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/

The same compelled access requirement might, however, stand at cross-purposes to some of the very goals the law intends to achieve. A compelled access standard might not meaningfully enhance a manufacturer's motivation to protect its product supply; indeed, as the court in Mrs. Schubert's case mused, pharmaceutical companies would seem to be already quite highly motivated "to meet demand in order to be profitable and maintain customers," and to preserve "good relationships and a good reputation with doctors, hospitals, and distributors"—the essential conduits to the consuming patient populations—"by consistently meeting demand" for prescription drugs.[440] Moreover, an absence from the market—even a temporary one—entices a medicine maker's competitors to swoop in and steal the patient's business (if market competition presently exists), or encourages new competitor entry from those who may be attracted to the supply vacuum and FDA's promise of expedited treatment.[441] One is challenged to imagine how a legal mandate to continue to supply drugs would improve the supply-preservation motivations that these incumbent commercial forces already exert.

More worrisome to the court in Utah was the possibility that imposing such liability would shrink, not expand, the availability of critical medicines. "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."[442] That court dismissed so "onerous" a rule as "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."[443] This concern may be particularly apt in the case of delicate biologics, like human enzymes produced through recombinant DNA technologies, where the drug production costs are high and the available patient population to be treated is small.[444] As the *Schubert* court acknowledged, "[t]here are technical challenges posed by producing biologic therapies" which "cannot always be controlled despite a company's best efforts."[445] Markets such as these may prove especially sensitive to new legal standards that add to production complications that are already costly and problematic, producing even greater volatility in medicine availability. Given all these factual variables, the practical operation of such a compelled-access rule might result in unpredictable poor outcomes, which also ill-serves the law.[446] In any event, products liability has never been "absolute,"[447] nor have the merits of cost-spreading theory ever given

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UCM384892.pdf ("Drug shortages remain a significant public health issue in the United States and a top priority for FDA.").

[440] *Schubert I*, No. 2:12-CV-00587-DAK, 2013 WL 4776286, at *7 (D. Utah Sept. 4, 2013).

[441] *See* 21 U.S.C. § 356c(g) (2012) (noting that upon receiving notice of a temporary or permanent discontinuance, FDA is authorized to expedite review of certain new drug applications or expedite facility inspections or reinspections, if doing so "could help mitigate or prevent [a medicine] shortage").

[442] *Schubert I*, 2013 WL 4776286, at *7.

[443] *Id.*

[444] *See id.*

[445] *Id.*

[446] *See* Horst v. Deere & Co., 769 N.W.2d 536, 551 (Wis. 2009) ("One of the basic requirements of a coherent legal test is that it offer a framework for analyzing claims that provides some measure of predictability. Predictability is important in the law because it allows citizens and businesses to shape their behavior accordingly.") (citation omitted).

[447] *See*, *e.g.*, Chotin Transp., Inc. v. United States, 819 F.2d 1342, 1351 n.5 (6th Cir. 1987) (en banc) ("[S]trict liability in a products liability case does not impose absolute liability."); O'Neil v. Crane Co., 266 P.3d 987, 1005 (Cal. 2012) ("From its inception . . . strict liability has never been, and is not now, absolute liability. As has been repeatedly expressed, under strict liability the manufacturer

courts warrant for its rote application in a market-driven economy.[448] A rule compelling a manufacturer to keep selling medicines, then, is troubling.

What, then, of Mrs. Schubert's husband and Mrs. Lacognata, and the many others who suffer serious, life-threatening, and potentially life-ending risks as a consequence of what might have been avoidable medicine supply interruptions? In the environment of serious competing policy concerns, what is the law to do?

A half-century ago, Judge Breitel writing for the New York Court of Appeals counseled:

> While it may seem that there should be a remedy for every wrong, this is an ideal limited perforce by the realities of this world. Every injury has ramifying consequences, like the ripplings of the waters, without end. The problem for the law is to limit the legal consequences of wrongs to a controllable degree.[449]

Balancing those competing concerns could be a proper undertaking for the judiciary; surely, the history of the law demonstrates the fitness of courts to craft legal remedies to meet new challenges.[450] Here, though, the sprawling prevalence of federal pharmaceutical laws, the innumerable competing forces bearing on these products as articles circulating in a highly-competitive market economy, the irreducible importance of a safe, reliable, and accessible medicine supply, the very real human suffering inaccessible medicines can cause, the need for a vibrant incenting of medical product innovation and invention, and the tremendous practical risks accompanying missteps in setting the proper legal balance on the compelled-access question, all counsel otherwise. A very thoughtful answer to this thicket is necessary, one that meets—as nearly as possible—all the competing policy considerations the complex issue implicates. The source of that answer should be a legislative one.

Congress has moved in part, enacting the statute that requires early manufacturer notification of medicine supply interruptions and discontinuances, and that invests FDA with authority to expedite approvals that might mitigate or prevent drug shortages.[451] According to FDA, the result of these new provisions and an increased agency focus has been the prevention of 140 new drug shortages in the

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does not thereby become the insurer of the safety of the product's user.") (citations omitted); Korando v. Uniroyal Goodrich Tire Co., 637 N.E.2d 1020, 1024 (III. 1994) ("Strict products liability is not a doctrine of absolute liability; the manufacturer of a product is not an absolute insurer.").

[448] *See* Cafazzo v. Cent. Med. Health Servs., Inc., 668 A.2d 521, 526 (Pa. 1995) ("To assign liability for no reason other than the ability to pay damages is inconsistent with our jurisprudence.") (citation omitted).

[449] Tobin v. Grossman, 249 N.E.2d 419, 424 (N.Y. 1969). *See generally* KEETON ET AL., *supra* note 422, at 6 (describing the endeavor of tort law as "to strike some reasonable balance between the plaintiff's claim to protection against damage and the defendant's claim to freedom of action for defendant's own ends, and those of society . . . .").

[450] *See*, *e.g.*, Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 901 (Cal. 1963) ("Although in these cases strict liability has usually been based on the theory of an express or implied warranty running from the manufacturer to the plaintiff, the abandonment of the requirement of a contract between them, the recognition that the liability is not assumed by agreement but imposed by law . . . and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products . . . make clear that the liability is not one governed by the law of contract warranties *but by the law of strict liability in tort*.") (emphasis added); MacPherson v. Buick Motor Co., 111 N.E. 1050, 1053 (N.Y. 1916) ("[T]he presence of a known danger, attendant upon a known use, makes vigilance a duty. We have put aside the notion that the duty to safeguard life and limb, when the consequences of negligence may be foreseen, grows out of contract and nothing else. We have put the source of the obligation where it ought to be. *We have put its source in the* law.") (emphasis added).

[451] 21 U.S.C. § 356c (2012).

first nine months of 2013 and the reduction of new drug shortages from 117 in 2012 to 38 in 2013.[452]

Nonetheless, Mrs. Schubert's husband has since passed away (unnecessarily, she claims, due to limited Fabrazyme availability), and Mrs. Lacognata waited some three years for the resumption of the long-suspended production of Aquasol A.[453] To be sure, the drug shortage trend line has improved, thanks to Congress, FDA, and cooperation from the pharmaceutical industry. But the law has yet to introduce the one solution necessary to best protect against drug shortages: a viable system for alternative sourcing to provide a replacement supply. Until that objective is successfully tackled, the forebodingly unacceptable risk of medicine shortages will persist.

IV. A STATUTORY PROPOSAL FOR ENHANCED MARKET INCENTIVIZATION OF ALTERNATE SOURCING

Congress has acted. In 2012, it directed manufacturers to promptly report a permanent discontinuance or meaningful disruption in the supply of drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition.[454] Congress also empowered FDA to expedite the review of replacement drug approvals and facility inspections.[455] Both are sound additions to the statutory and regulatory regimes, but neither endeavors to proactively establish new pathways for reliable access to alternative sourcing (at least not beyond the proactive nature of an expedited review of submissions by others). Yet, if a fair and viable system for alternative sourcing could be installed, it would hold dual promise—providing an actual, pragmatic fix for supply interruptions and creating new commercial incentives on the incumbent source to speed along the remedy for supply interruptions that occur.

But "fair" is the watchword for any sound alternative sourcing statutory program. As the National Institutes of Health took pains to recount in denying a "march-in" solution for the Fabry disease patient community, "Genzyme made substantial investments in the development of Fabrazyme."[456] It is, perhaps, an understatement of monumental proportion. In the crafting and commercialization of biologics, manufacturers often tread at the very outer edge of science and medicine. These pioneering ventures are unquestionably costly when measured by any metric (by financial impact, personnel deployments, institutional focus, lost opportunity costs, and others). Any credible alternative sourcing statutory framework must respect that investment of treasure and genius, and, in the quest for shortage remediation, must balance it acceptably in such a manner that avoids disincentivizing future innovation and invention. Of course, such a framework must also protect the original manufacturer from liability to those who are consuming its medicine in the form manufactured by someone else. It is a mighty challenge.

I propose a balance through an amendment of Congress' *Discontinuance or Interruption in the Production of Life-Saving Drugs* statute, to rework current Section 356c(g),[457] in a manner that empowers FDA to (a) erect timetables for

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[452] FDA FIRST ANNUAL REPORT, *supra* note 439, at 10.
[453] *See supra* notes 48, 116 and accompanying text.
[454] 21 U.S.C. § 356c(a) (2012). *See generally supra* notes 256-61 and accompanying text.
[455] *See id.* at § 356c(g).
[456] NAT'L INSTS. OF HEALTH, *supra* note 299, at 6.
[457] 21 U.S.C. § 356c(g) (2012) (emphasis added to reflect my proposed additions).

remedying a critical drug shortage, (b) invite a manufacturer facing a shortage to design, within that timetable, an internal or external solution for the shortage, and (c) license an alternative supplier under such terms that offer a credible commercial motivation for external participation yet protects the ultimate investment of the incumbent supplier. As amended, new Section 356c(g) could read:

> (g) Agency Authority to Respond to Drug Shortages
>
> If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary may **take one or more of the following actions**—
>
> (1) expedite the review of a supplement to a new drug application submitted under section 355(b) of this title, an abbreviated new drug application submitted under section 355(j) of this title, or a supplement to such an application submitted under section 355(j) of this title that could help mitigate or prevent such shortage; or
>
> (2) expedite an inspection or reinspection of an establishment that could help mitigate or prevent such drug shortage; or
>
> **(3a) for those drugs for which the manufacturer is the sole supplier and which represent a medical benefit potential that is meaningfully superior to any alternative drug therapy then approved and reasonably available (hereinafter "Section (g) Manufacturer"), require that manufacturer to supply the Secretary with a realistic proposal, supported by appropriate commitments and resources, to resolve the shortage within [x] days, or, alternatively, to supply the Secretary with a licensing arrangement with a responsible substitute manufacturer, satisfactory to the Secretary, by which the Section (g) Manufacturer has coordinated through a reasonable proposal, supported by appropriate commitments and resources, to resolve the shortage within [x] days.**
>
> **(3b) Should the Secretary invoke the procedures set forth in paragraph (3a) above, and should the Section (g) Manufacturer fail to satisfy the Secretary that a reasonable proposal is in place to resolve the shortage within [x] days, the Secretary shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder, to grant a license to a designee of the Secretary to manufacture the subject drug in a manner that resolves the shortage within [x] days of the Secretary's direction. Thereafter, the designee shall have the exclusive right to manufacture and distribute the subject drug, without direct or indirect competition from the original manufacturer, for a period of up to [x] months, after which the Section (g) Manufacturer may resume the manufacture and distribution of the subject drug, without loss to the right of the Secretary's designee to continue to manufacture and distribute the subject drug as well.**

(3c) Should the Secretary grant a license to a designee as provided in paragraph (3b) above, the Section (g) Manufacturer shall not be liable under any federal or State law for any injury or loss sustained by any consumer from using the drug manufactured by the Secretary's designee.

This proposal endeavors to strike a sound balance among the many competing interests implicated by a compelled access law.

First, it respects the manufacturer's free market autonomy by not imposing any new, legally enforceable obligations on the manufacturer to continue selling a medicine it has no interest, for whatever reason, in producing. Under this law, manufacturers are free to enter and leave a particular drug marketplace without legal sanction.

Second, it respects the manufacturer's right to pursue private, non-governmental paths for resolving persistent drug shortages for a product the manufacturer intends not to abandon.

Third, before government intervention, it permits FDA sensible discretion to determine that a particular drug shortage is unavoidable, that no substitute supplier is likely to be better able to resolve the shortage, or that everything reasonably appropriate is being done to remediate the shortage.

Fourth, for those drug shortages, FDA would have the authority to facilitate the drug's supply through an alternative manufacturer. This authority would exist only with respect to a shortage: (a) that is persistent; (b) where the manufacturer is the sole supplier; (c) where the medicine is life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery; (d) where the medicine qualifies as a product that represents a medical benefit with a potential meaningfully superior to that offered by any alternative drug therapy then approved and reasonably available; and (e) where the manufacturer is shown to be unable or unwilling to supply the drug within a reasonable time period or arrange for a responsible surrogate to supply the drug within a reasonable time period. That new manufacturer, in turn, would gain a reasonable incentive to remedy the drug shortage by obtaining a period of exclusivity, free from competition by the original manufacturer. The original manufacturer, although debarred for a period of time from competing with the new manufacturer, would be able to re-enter the market and resume production and distribution of its drug after a reasonable return-on-investment period for the new manufacturer.

Fifth, it protects the original manufacturer from liability for injuries and losses incurred through the use of a product made by the Secretary's designee, and not by the original manufacturer. In this way, the original manufacturer who has been affirmatively displaced by the Secretary (at least for a period of time) is not exposed to "innovator liability" and other claims for products manufactured by its successor.[458]

All told, this proposal would invest FDA with a formidable new power to resolve persistent shortages of critical medicines. The specter of that power adds a

[458] *Cf.* Wyeth, Inc. v. Weeks, No. 1:10-cv-602, 2014 WL 4055813 (Ala. Aug. 15, 2014) (ruling that brand name manufacturer could, under certain conditions, be liable under Alabama law for injuries caused to a patient using a generic manufacturer's version of the medicine); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Ct. App. 2008) (holding the same under California law); Kellogg v. Wyeth, Inc., 762 F. Supp. 2d 694 (D. Vt. 2010) (holding the same under Vermont law).

new incentive for manufacturers to "fish-or-cut-bait" in shortage situations. Yet that power must be foresworn by FDA if the manufacturer desires to and develops a reasonable plan to remedy the shortage, and, if exercised, the power incorporates business incentives to encourage new suppliers to help abate critical medicine shortages.

This proposal has three further advantages. It avoids entangling the law in an unpredictable, judicially created tort scheme where the more sensible remedy is a legislative one. It confirms, unambiguously, that medicine manufacturers have no legal duty to continue selling medicines when they want to stop. And it affords a new chance for an alternate path for critical medicines to reach the seriously ill. In sum, it is a further step in the right direction.

V. CONCLUSION

No one is reported as having died from a shortage of Cabbage Patch Kids, Christmas morning disappointment notwithstanding. But all products are not equal in the roles they play in our contemporary, complex free-market economy. This Article has explored the challenge of recurring interruptions in the supply of critical medicines, and has found that the existing legal remedies are unlikely to impose on drug manufacturers a "duty" to keep selling. Nor should the law. That outcome would compete far too fundamentally with the essential premise of the American free enterprise system. Nonetheless, that liberty ought not to come at the cost of human lives and human suffering if a sensible balance can be struck that provides those seriously ill with the medicines they need and yet respects the ownership interests and autonomy of the entities that invent and supply those medicines. A proposed amendment to Congress's recent statutory framework for drug shortages holds the promise of achieving just that.