A Duty To Sell Life-Saving Medicine?

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William M. Janssen, *A "Duty" To Continue Selling Medicines*, 40 **Am. J. of Law & Med.** 330 (2014), available at SSRN.

Imagine that you have a rare, life-threatening medical condition. You are prescribed a drug that is critical to your survival. You thrive on the prescribed drug and your health improves significantly. However, only one company manufacturers this drug. Unfortunately, due to contamination during the production process, the manufacturer experiences inventory shortages. As a result, you cannot get prescriptions filled as ordered by your doctor, and your health deteriorates rapidly. Does the drug company have a legal duty to continue selling you the prescribed medicine? And, if the manufacturer's negligence caused the inventory shortage, can you sue the company for tort-based damages? Professor William M. Janssen tackles these intriguing questions in his recent article, *A "Duty" To Continue Selling Medicines*.

I was fascinated by the dilemma that Janssen lays out in his article. He begins his exploration of the legal duty question with a compelling and heart-wrenching tale. In 2004, a Salt Lake City man was diagnosed with a rare, life-threatening disease, but he thrived after receiving a biological enzyme replacement therapy. In 2010, however, the biologic manufacturer reduced its inventory in order to make space available to produce a different therapy. At around the same time, a virus struck the manufacturing facility, contaminating the product, and in addition, the biologic was somehow contaminated during the production process with tiny pieces of steel, rubber, and fiber. These events led to a shortage of the drug, and the Utah patient received only 70% of his prescribed dosage. When he died, his widow brought suit alleging that the manufacturer failed to use reasonable care to ensure an adequate supply of the biologic. Her claim failed in court based on the finding that the manufacturer had no legal duty to continue to supply the drug. Specifically, the Utah court rejected the widow's argument that the manufacturer engaged in affirmative wrongdoing by allowing the biologic to become contaminated by the virus, and thereby creating a drug shortage. Rather, the court found that the alleged medicine shortage was merely a failure to act (nonfeasance), and therefore, tort law did not provide a remedy.

After presenting a few of these case scenarios, the article surveys a wide range of theories—from statutory pharmaceutical laws to federal constitutional law—that could be considered potential sources for legal claims. Of particular interest, Janssen considers a variety of tort principles including the no-duty-to-rescue doctrine. An exception to the no-duty-to-rescue rule provides, however, that a person responsible for an instrumentality must render aid if the instrumentality causes harm, even if there's no fault. Janssen situates this hornbook doctrine in the medicine shortage context: Arguably, the drug manufacturer's inadequate supply is an instrumentality of harm, regardless of any fault. Janssen, however, concludes that this exception does not apply because the patient's harm is not caused by the drug shortfall, but rather by the underlying medical condition.

Janssen next considers the corollary rescue principle that one who undertakes a rescue must do so non-negligently. Liability may attach if the rescuer abandons his attempt in a manner detrimental to the injured party. But Janssen rejects this theory on the ground that the drug shortfall did not place the plaintiff in a worse position than where he was before beginning treatment. Still, perhaps the loss-of-

chance doctrine could apply here, and compensate the plaintiff for his reduced chance of survival without the drug. Although Janssen does not directly address this theory, his analysis implicitly rejects it. In examining the common law duty to avoid interfering with a rescue, Janssen concludes that the manufacturer's failure to supply adequate amounts of the drug should be considered passive inaction, not the "active intervention" required by the no-duty-to-rescue doctrine (P. 378), or presumably, the affirmative misconduct required under the loss-of-chance doctrine.

Given the lack of a viable legal theory under current doctrine, Janssen explores whether tort law should be extended to provide a remedy for these patients. On the one hand, imposing a duty to supply life-saving drugs on drug manufacturers could encourage them to take risk-reduction precautions. Perhaps supply interruptions could be avoided or minimized if drug manufacturers faced tort liability. Likewise, it would seem that drug manufacturers are in the best position to absorb the costs of injury. Yet on the other hand, such liability could stifle research and development, especially where, as in the cases discussed, the drugs serve a very small population.

Trying to balance these competing policy concerns, Janssen recommends a regulatory solution that would avoid the drug shortfall in the first place. The first step of this solution would place responsibility on the manufacturer to submit a "realistic proposal" to the FDA, "supported by appropriate commitments and resources," to resolve the shortage. (P. 390.) Alternatively, the manufacturer could enter into a license agreement with a substitute manufacturer to resolve the shortage. Where the original manufacturer fails to "satisfy [the FDA] that a reasonable proposal is in place to resolve the shortage," Janssen proposes empowering the FDA to license an alternative drug manufacturer. (*Id.*) The goal, then, would be to fix the supply interruption and also to incentivize the original manufacturer to remedy the shortfall as quickly as possible.

Janssen's article is well worth reading. He calls attention to an important social problem and his conclusion highlights the inability of tort law to address all of society's injuries. One hopes to see more work on this topic.

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