Legal Opinion Letter

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PHARMACIST'S CRIME SHOULDN'T EXPOSE BUSINESSES TO LIABILITY

by
Thomas P. Redick

The boundaries of product liability have generally stopped short of holding companies liable for the unforeseen, intervening third party fraud. Dean Prosser has cautioned tort law duty is not coextensive with foreseeability, and that intervening intentional torts are generally not be foreseeable enough to give rise to a duty to intervene. *Prosser on Torts* at 303 (5th Ed. 1984), Dobbs, LAW OF TORTS (2000).

In the context of pharmacy fraud, however, a recent trial court decision in a pharmacy fraud case may have extended forseeability too far. In an unpublished trial court decision in *Hayes v. Courtney Pharmacy Inc.*, (Mo. Cir. Ct. Case No. 96885), the Circuit Court for Jackson County, Missouri held that a pharmaceutical company could be alleged to have a duty to oversee the criminal activities of a pharmacist who deliberately diluted chemotherapy drugs, rendering them ineffective. Holding Eli Lilly potentially liable for the conduct of a pharmacist that kept most of their drug from reaching the end user is unprecedented; as a remedy for fraud, it may prove to be a hazard to health of consumers.

The apparent basis for the court's decision, on a motion to dismiss for failure to state a claim, was plaintiff's allegation that the defendant pharmaceutical company, Eli Lilly, should have been able to detect the criminal actions of the pharmacist merely by matching up the discrepancies in amounts ordered and used for a particular number of patients. This "foreseeability" would allow the case to proceed to trial, defeating a motion to dismiss for failure to state a claim.

The *Hayes* decision came in a high-profile pharmacy fraud case, where Robert Courtney, a pharmacist, was sued and lost a $2.25 billion verdict on October 10, 2002. Eli Lilly was dragged into this vortex of fraud when plaintiff's attorneys attempted to tar Eli Lilly with the same brush used on the fraudulent pharmacist. In denying a motion to dismiss, however, the court may have opened up new vistas of potential liability for drug companies.

The decision holding that Eli Lilly had a duty to monitor Mr. Courtney is worth a critical review, because this novel tort theory represents a policy decision by a lone trial court that should be challenged in future cases. The actual practices of pharmaceutical companies and their control make it difficult, if not impossible, for them to monitor pharmacy fraud for the following reasons. First, there should be no duty to supervise *licensed* providers who are already subject to state oversight by a competent, independent board.

Thomas P. Redick is a partner in the St. Louis law firm Gallop, Johnson & Neuman, L.C.

Second, *privacy* interests of patients may also preclude monitoring of their records by a distant corporation (Health care providers are obliged to maintain secrecy of HIV-positive status, genetic information and other issues). Third, pharmaceutical companies do not sell directly to doctors or pharmacists, so monitoring gaps would emerge. Fourth, coordination with monitoring between manufacturers and independent wholesalers (whose customers lists are confidential business information) would trigger legal complications. Finally, any system for detecting such fraud could presumably be subverted by those clever fraudulent pharmacists seeking to cover their tracks. Pharmacy oversight is not conducive to control by a pharmaceutical "big brother" wielding new information technology tools.

Fortunately, the *Hayes* case settled before trial and will not have any impact on the case law that makes up precedent (i.e., reported decisions). It is merely one state court decision that will be lost among myriad published appellate pharmaceutical cases. As long as this decision is not repeated in other jurisdictions and factual settings, it may remain a lone aberration. At some point in the future, however, another trial court might see an arguable factual basis for recognizing a duty to use more advanced pharmacy fraud detection systems in the pharmaceutical industry. Even with such advances, however, there will be strong policy grounds for maintaining local licensing boards to prevent such fraud from occurring.

Product liability has generally allowed manufacturers to assume that intentional misuse (*e.g.*, deliberately flicking one's Bic around gasoline pumps to get a rise out of a friend) will not lead to comparative fault of the manufacturer. *See Meadows v. Friedman R.R. Salvage Warehouse*, 655 S.W.2d 718, 720 (Mo. App. 1983) (duty to protect against intentional criminal conduct, assault on railroad property, is "not determined by the foreseeability of a criminal act" but by the ability of defendant to take "measures to guard against it" and "the relationship involved"). Duties to seek out rare instances of pharmacy fraud — one needle in a thousand haystacks of transactions — cannot be imposed merely based on the foreseeability of criminal conduct.

It is important to the future of pharmaceutical innovation that the *Hayes* decision remains an aberration. There has to be a limit to the amount of intentional misuse that merits the monitoring of misconduct. Case law has distorted product warning labels in various industries to the point of comedy, with warnings that serve primarily as jokes circulated via e-mail (e.g., Underarm deodorant warning: "Do not spray in eyes"; a prescription of sleeping pills warning: "May cause drowsiness"; the novelty rock garden saying, "Eating rocks may lead to broken teeth"; and the stroller warning: "remove child before folding"). Each of these silly warnings probably has a history — a case where someone actually did the idiotic thing in the warning.

It is not humorous, however, when duties to monitor conduct are extended beyond what is possible or practical for pharmaceutical companies to accomplish, as occurred in the *Hayes* decision. The excess attention to preventing misuse and fraud could in the context of pharmaceuticals lead to the sunset of many useful products that cannot be designed without the unsafe alternative use.

There may a lesson in the *Hayes* case, however, for careful drug pharmaceutical companies and various other manufacturers who rely upon both learned intermediaries and electronic data tracking the activities of these intermediaries. In the age of information technology, the mere *capability* of analyzing data to detect fraud on the part of learned intermediaries may lead to potential liability for failing to interpret the warning signs. At least one court has now held that these patterns can permit a plaintiff to appear before a jury to resolve the question of whether the company "should have known" of the fraudulent practice.

Given this trend, counsel advising pharmaceutical companies on liability avoidance should be cautious in approaching any proposed monitoring systems that might intrude upon privacy rights. Industry counsel should keep in mind the steady evolution of information technology and legal precedent, and share information about pending cases involving detection of third party misconduct in the sale of pharmaceuticals.

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