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NO DUTY-TO-WARN EXCEPTION

Marketing of prescription drugs blurs the line

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A general and universally accepted rule of product liability law is that a company that markets goods must warn foreseeable ultimate users of the dangers inherent in its products. Where prescription drugs are concerned, however, the manufacturer's duty to warn is limited to an obligation to inform not the patient, but rather the prescribing physician of the potential side effects that may result from taking the drug.

The Illinois Supreme Court has stated that this special standard for prescription drugs is an "understandable" exception to the duty to warn based on the purported differences between prescription drugs and any other consumer goods. According to the court, prescription drugs are generally complex medicines and the prescribing physician, as a medical expert, is in the best position to take into account the properties and effects of the drug as well as the susceptibilities of her patient. It is her task to weigh the risks and benefits of any drug against its potential dangers.

The drug manufacturer is thus required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer. This doctrine rests almost completely on the assumption that the choices physicians make are "informed" and utilize "individualized medical judgment," free from improper influence or manipulation.

Prescription drug makers, however, have always marketed their drugs to just health-care professionals. In the 1980s and early 1990s, manufacturers began to market their products directly to consumers through both print and broadcast media ads. By definition, marketing involves the process of "promoting" and "selling" products and is utilized to influence behavior by creating impressions, often subliminally, and exploiting emotion. It is not evidence-based and it often does not even involve facts.

A recently-settled whistleblower lawsuit against Novartis Pharmaceuticals illustrates the disconnect between the learned intermediary theory and reality. The lawsuit was filed by former employee, Oswald Bilotta, who began working as a sales representative for Novartis in 1999. As Mr. Bilotta told Gretchen Morgenson of NBC News, when he started, Novartis and its sales reps were focused almost exclusively on providing information about the company's products but by the mid-2000s, the focus became much more about "incentivizing."

One of industry's common physician incentives is known as a speaker program and during this time period, Novartis began supercharging its program. According to the U.S. attorney for the Southern District of New York, over a decade, Novartis spent hundreds of millions of dollars on its speaker programs, which included speaker fees or honoraria, top-shelf liquor, and exorbitant meals.

The "lectures" were held at luxury restaurants in New York City, Chicago, Miami and San Francisco. Over the decade covered by the False Claims Act complaint, one doctor received more than $320,000 in honoraria and wrote more than 8,000 prescriptions for Novartis drugs. The subjects at many of these "conferences" were well-known drugs that had been on the market for years. Often no one even mentioned the drug, much less provided relevant information about it.

"They wanted to have the veneer of conveying medical knowledge," Mr. Bilotta told NBC. "But how much education on these old drugs do you need? I'd be stunned if 10% of the programs were legitimate."

According to the Department of Justice, Novartis repeatedly hosted the same doctors at speaker programs for the same drugs. One example includes more than 19,235 physicians who attended a Novartis program with the exact same title three or more times in a six-month period. In Rockford, Novartis held 124 speaker programs over eight years with the same 10 doctors attending — and that group or a subset were the only people attending. Novartis paid one of the doctors to "speak" at 102 of the events. According to DOJ, these and other promotional programs were "…nothing more than a means to provide bribes to doctors."

One of the exceptions to the Illinois version of the learned intermediary doctrine is triggered when a manufacturer fails to adequately warn the prescribing physician about side effects or other potential dangers of a drug because if the physician does not have accurate information, her prescribing decision cannot be "informed." But Mr. Bilotta's lawsuit illustrates how frequently prescribing behavior can be influenced by marketing, regardless of the facts. If a doctor's choice of prescription is influenced — consciously or unconsciously — by marketing, how can that decision be "learned?" And if marketing does not influence prescribing behavior, why does big pharma spend billions on it?

Perhaps it's time to rethink the pharmaceutical industry's special exemption from the duty to warn. It's been abused for far too long. CL

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