New pharmaceutical technologies usher in significant changes to liability laws

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As more pharmaceutical manufacturers introduce digital components to their products, the industry is beginning to consider long-term implications around liability issues.

As the line between products and services in health care continues to blur, traditional notions of product liability are coming into focus. Gina Rodriguez, trial lawyer in Hogan Lovells' Denver office, and Lauren Colton, Hogan Lovells' Head of Global Products practice, say that as pharmaceutical manufacturers continue to develop new and novel health care technologies, with an eye on providing further benefit to patients, they should also closely consider potential future risks as laws around liability continue to move into unchartered territory.

"We're entering an era where delivery modes for pharmaceutical products are rapidly increasing the amount of direct interaction between drug manufacturers and patients," says Colton. "Product liability law has not yet caught up with the advent of new and novel technologies like health monitoring devices and internet-connected drug delivery systems."

With these direct-to-consumer technologies often providing the type of health care oversight traditionally within the realm of providers, Rodriguez says companies may be at increased risk for future types of liability. "What were once viewed as health care products are becoming more and more like consumer products," says Rodriguez. "[These products] signal a major change in responsibility for manufacturers." She sites drug adherence as an example of a potential liability issue. "Let's say a manufacturer provides a medical mobile application that reminds patients to take their drugs. If the app stops working, does the company face liability for the failure to provide a prescription notification? These are the big-picture questions we're tackling."

The potential for civil liabilities is also a concern. "Patient support programs have received attention recently because they are a new model of patient-pharmaceutical company interaction," says Colton. "Companies have to be careful not to engage in activities that could be viewed as the corporate practice of medicine, which is illegal in a number of jurisdictions. There's a real concern that these patient interaction programs could be opening companies to new types of civil liabilities, such as professional malpractice."

Rodriguez and Colton both urge pharmaceutical companies to think about how additions to their product line can put them at risk, and to lean on their legal teams to help navigate what will continue to be uncertain legal waters. "These are really exciting times," says Colton. "The pace of

innovation is like nothing that I've ever seen in my lifetime. But for medical companies, it is also a time when they need to be vigilant about protecting themselves. The instinct is to consider product liability litigators only if you need to, but we really hope that clients understand… early consultation is becoming more and more critical to protect them from litigation down the road."

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