Sooner or Later, There Will (Likely) be Litigation

By Ron Hedges

With new technology comes new opportunities… as well as the potential for litigation. Take 3D implanted devices for example. Implanted devices are commonplace in healthcare. These devices can accomplish a range of tasks, such as deliver timed dosages of drugs, monitor heart activity, and serve as templates for cell growth. Three-dimensional digital scanning technology now offers a new source of implants. It was also inevitable that there would be some type of litigation over an implanted 3D device. And it happened in the United States District Court for the Northern District of California.

In *Buckley v. Align Technology, Inc.*, a case filed in the United States District Court for the Northern District of California, the individual plaintiff brought an action against the defendant manufacturer of 3D digital products intended to treat the misalignment of teeth. The plaintiff alleged that the defendant misrepresented the performance of the products and sought to represent a class of consumers. The defendant made a motion to dismiss, which the court granted, concluding that the plaintiff had failed to identify any false or fraudulent statement made to her by the manufacturer.

The court also held that, to the extent that the plaintiff alleged that the manufacturer had failed to warn her of any dangerous side effects, her claim was barred by the "learned intermediary doctrine." Under this doctrine, any duty to warn by a manufacturer runs to a medical professional rather than a patient when the professional prescribes to a patient. In *Buckley,* the challenged products had been prescribed to the plaintiff by a dentist. Finally, the court rejected the argument that the plaintiff was entitled to some type of refund from the manufacturer.

What does all this mean? First, whenever a healthcare provider takes advantage of a new technology, the provider should appreciate that there will be the potential for litigation that involves the technology. For better or for worse, that is the reality of a society that prides itself on the availability of judicial remedies for harm. Second, existing law should provide a template within which the new technology will "fit" and be evaluated. That is the genius of our judicial system. Really, it is.

As a post script to this post, a reminder for those readers who follow legal developments: On December 1st amendments to the Federal Rules of Civil Procedure will become effective. I reviewed these amendments in an article that appeared in the October 2014 issue of *Journal of AHIMA*. In the next column I will share my thoughts on what the amendments might or might not accomplish.

***Editor's note: The views expressed in this column are those of the author alone and should not be interpreted otherwise or as advice.*

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