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A 'Shocking' Claim Of Design Defect

Law360, New York (March 26, 2012, 1:32 PM ET) -- Today we bring you a split decision tossing out a failure-to-warn claim because the doctor didn't read the warnings at all, but allowing the plaintiff to continue on his design defect claim, despite the doctor having done exactly what the warning warned against.

Makes us think of that song from Mary Poppins — a spoonful of sugar makes the medicine go down. Well, we're still gagging a bit on the design defect decision, but at least the dismissal of the failure-to-warn claim is helping to satisfy our sweet tooth.

Johnson v. Medtronic Inc., 2012 Mo. App. LEXIS 294 (Mar. 6, 2012) involved an allegedly defective defibrillator and a doctor who everyone agrees acted well below the standard of care.

But before we get to the doctor, a quick tutorial on defibrillators. Most of us associate defibrillators with shocking a patient suffering from cardiac arrest — picture almost any episode from any medical drama that has ever been on television — a life-threatening emergency situation. That patient would be suffering from ventricular fibrillation and a defibrillator would be used to administer a nonsynchronized shock.

On the other hand, plaintiff here suffered from recurring atrial fibrillation, a nonemergent heart-rhythm disorder. During an acute episode of atrial fibrillation, a defibrillator is sometimes used to shock the heart back into normal rhythm. This is accomplished by administering a synchronized shock. Id. at *4-5.

Now let's turn to some of the factual highlights — or lowlights — of this case. Plaintiff presented to the emergency room in atrial fibrillation, which the attending cardiologist decided to treat with electric cardioversion. Id. at *3. Plaintiff, based on his knowledge of his recurrent condition, confirmed with the cardiologist that he would use a biphasic defibrillator and the cardiologist agreed. Id. at *3-4.

The cardiologist then proceeded to use a monophasic defibrillator. Id. at *4. For the initial shock, the cardiologist selected the synchronous mode on the defibrillator to administer a synchronized shock. When the initial shock was unsuccessful, the cardiologist administered a second shock, but this time he did not select the synchronous mode on the defibrillator.

Because the defibrillator had automatically reset itself to asynchronous mode, the second shock was a nonsynchronized shock that sent the plaintiff into cardiac arrest. The cardiologist applied 12 more unsuccessful shocks from the monophasic defibrillator before switching to a biphasic defibrillator, which successfully cardioverted the plaintiff's heart on the first attempt. Id. at *7-8.

The alleged defect was the fact that the defibrillator "automatically reverted to the asynchronous mode after each synchronized shock and required the user to then select the synchronous mode for each synchronized shock." Id. at *10. Presumably, this is so the device is ready to be used in emergency, cardiac arrest situations.

So, if that's the defect, let's look at the warnings.

The defibrillator came with an instruction manual that stated: "If synchronized cardioversion needs to be re-attempted, press sync again, device automatically returns to the asynchronous mode after each synchronized discharge." Id. at *5. There was also a label on the device itself which specifically stated: "Push SYNCH for each synchronized attempt." Id. at *6. In addition, when the device was in synchronous mode, its monitor displayed a green light reading "SYNCH." Id.

We think the failure to warn inquiry could have ended here, but the doctor's testimony went even further:

- He admitted he'd never read the instruction manual or the instructions affixed to the device;
- He admitted that had he read them, he would have understood them and could have followed them;
- He admitted that had he read them, he presumably would have followed them. Id. at *9.

The court sums it up nicely:

> "With this backdrop, then, it is undisputed that [the cardiologist] used the [defibrillator] without regard to the instruction manual and the instruction label on the machine and, thus, [defendant's] alleged failure to warn or alleged inadequate warning was not the proximate cause of [plaintiff's] injuries." Id. at *20.

That was the sweet part of the decision.

Unfortunately, we have to swallow a little castor oil, too. To recap, we have a doctor who not only used the wrong device, but used it incorrectly because he failed to read any of the warnings or instructions accompanying the device and plaintiff's alleged injury was supposedly caused by the very danger about which defendant warned.

Given these facts, we have to say we are much more enamored of the trial court's decision on design defect — defendant "was not required to manufacture and market a foolproof device." Id. at *11 (quotation marks omitted).

While the Missouri Court of Appeals said it agreed with that statement, it didn't agree with the trial court's conclusion that "the use of the [defibrillator] by a trained medical practitioner in violation of the standard of care could not constitute a reasonably anticipated use by [defendant]." Id. (quotation marks omitted).

Rather, the appellate court reasoned:

> "We recognize that [the cardiologist's] actions in this case were contrary to the instructions provided by [defendant], both on a label on the defibrillator and in its instruction manual. However, the fact that a particular use of a product is contrary to the manufacturer's instructions does not, per se, establish that the use could not be anticipated." Id. at *32-33.

But it was anticipated and that's why it was warned about. The court's reasoning and conclusion seem to fly in the face of the learned intermediary doctrine, which it clearly relies on to dismiss the failure-to-warn claim. It seems undisputed that a defibrillator is an unavoidably unsafe product — it uses electricity to shock the heart into rhythm.

For that reason, it is only to be used by trained professionals, professionals who know about the difference between and consequences of administering the wrong type of shock. Professionals who are warned, in more than one way, about how to properly use the defibrillator.

While we agree with the court that there are instances where perhaps a design defect claim is viable where a manufacturer "chooses to warn of the danger (even admittedly adequately warn) rather than preclude the danger by design." Id. at *34.

We also agree that such a claim is more appropriate in the context of the court's stated example of a "lawn mower designed without a guard or deflector plate," id., and not a medical device used incorrectly by a negligent physician who ignored every warning and instruction offered by the manufacturer.

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