Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Negligent Undertaking Liability Only Goes So Far

By **Michelle Yeary, Dechert LLP**

Michelle Yeary

Law360, New York (May 1, 2017, 12:49 PM EDT) -- When this author hears "negligent undertaking," my mind does not automatically turn to products liability – but rather to pre-teen children. Pre-teen children are at the age where they are asked (actually required) to "undertake" more and more duties and responsibilities. But often these duties are undertaken in a rather haphazard or lackadaisical way that some might say rises to the level of negligence.

Dishes with food left on them put back in the cabinet. Wet laundry left in the dryer for more than a day. And as for cleaning up after the dog, well, enough said. And as one of the two arbiters of whether such pre-teens have failed to act in good faith, I admit to guilt in an expanding definition of what constitutes negligent undertaking.

The New Jersey courts fortunately have stricter and more precise guidelines than mood and level of tolerance on any given day to guide them, and those rules led them to dismiss plaintiff's negligent undertaking claim in Nelson v. Biogen Inc., 2017 WL 1382910 (D.N.J. Apr. 17, 2017).

The product at issue is Tysabri, a drug used to treat multiple sclerosis. Patients who test positive for anti-JC virus antibodies were shown to be at an increased for developing a certain brain infection with use of the drug. Id. at *1. The plaintiff contracted the infection after being treated with the drug for three years.

It is worth pointing out some of the procedural history here to understand that his was a bit of a hail-Mary by the plaintiff. The plaintiff's initial and first amended complaints contained a claim for negligence that was dismissed because in New Jersey the sole remedy for products liability is the New Jersey Product Liability Act (NJPLA). Id. at *2.

All products liability claims, except express warranty, are subsumed by the Act. So the plaintiff's second amended complaint alleged design defect and failure to warn under the NJPLA. The defendants moved to dismiss the design defect claim as preempted, and the plaintiff withdrew the claim before the court could rule on the motion. Id.

Which left the plaintiff with only a failure to warn claim in his third amended complaint. After two years of discovery, the plaintiff moved to amend his complaint for a fourth time, this time to add a negligent undertaking claim.

The basis for the claim, argued the plaintiff, was that the defendants had entered into a licensing agreement with the National Institutes of Health to allow the defendants to use the NIH's JC virus antibody assay to develop the assay for commercial use. The assay would allow doctors to test for the antibodies to determine if their patients were at an increased risk for the brain infection. Id.

The licensing agreement was entered into in 2006 and the defendants released their JC virus antibody assay in 2012. The plaintiff alleges that when the defendants entered into the licensing agreement, they were voluntarily undertaking the duty to develop the assay and that they failed to do so in a reasonable and timely manner. Id. at *3.

First, the court held that this negligent claim, like the negligence claim in the plaintiff's original complaint, was preempted by the exclusivity of the NJPLA. The plaintiff argued that negligent undertaking was different than other negligence claims, because it is not based on a pre-existing duty. Not only did the plaintiff have no New Jersey or other authority for this argument, it is a distinction without merit.

As the court pointed out, "the application of the NJPLA is not premised on the timing of the duties incurred." Id. at *4. Further, most duties (unlike those in my household) are at some point voluntarily assumed. "For example, before Defendants decided to develop, market, and sell Tysabri, they had no duty to do so. Once Defendants voluntarily decided to produce Tysabri, they then had a duty to act with reasonable care in doing so." Id. Negligent undertaking is precluded by the NJPLA.

Second, the court found it would be an unprecedented expansion of liability to use negligent undertaking to create third-party negligence obligations to non-parties to the license, or indeed to any contract. The plaintiff cited no cases in which a party who agreed to a license was held liable for negligent undertaking. Id. at *5.

Acknowledging significant policy concerns, the court suggested that the more appropriate way to address issues of the type raised by the plaintiff would be to deal with them specifically in the contract. The NIH could have included a time limit by when the defendants should have developed the assay or the license would be revoked. Id.

Further, the plaintiff failed to allege an essential element of negligent undertaking — reliance. Id. at *6. The plaintiff alleged that his status as a third-party beneficiary to the license agreement satisfied the reliance requirement, but he cited no authority for that proposition. So, closely adhering to the Erie doctrine, the court concluded that "If the courts of New Jersey believe that such an extension is appropriate, then they are in a better position to expand their own common law in the first instance." Id.

This means the plaintiff is back to his third amended complaint — failure to warn only. There is good precedent on the adequacy of the Tysabri warnings and on Wyeth v. Levine preemption.

And precedent has much more bearing in the courtroom than in the laundry room — where when prior rulings are cited to the judges they can be summarily ignored with a simple “that was then, and I’ve changed my mind.”

Michelle Hart Yeary is counsel at Dechert LLP with extensive experience in product liability litigation, including the defense of mass torts in federal multidistrict litigation and coordinated state court proceedings. She is a regular contributor to the Drug & Device Law blog.