Defect Allegations Insufficient in Drug Case

October 17, 2011 by Sean Wajert

We may be accustomed to talking about whether a product was "defective" and, as counsel for defendant sellers, working hard to show that the product contained no "defect." Earlier this month came a decision reminding us that, in some contexts, a defect, even one that caused the injury, may not be all plaintiffs need to allege and prove. Mills v. Bristol-Myers Squibb Co., No. 11-00968 (D. Ariz., 10/7/11).

Plaintiff was prescribed Clopidogrel (branded as "Plavix") for the treatment of peripheral vascular disease. Two years later, plaintiff initiated this action alleging that the drug caused excessive rectal bleeding. The court dismissed, and plaintiff eventually sought leave to file a Second Amended Complaint. Defendants argued that leave to amend should be denied as futile. And the court agreed.

The interesting part of the opinion for our readers is the discussion of strict products liability, premised on two theories: design defect and failure to warn. (Plaintiff also premised her negligence claim on these theories.) For plaintiff to prevail under both theories she had to show that the product left the defendants' hands in a defective condition, the defect rendered the product unreasonably dangerous, and the defect was a proximate cause of plaintiff's injuries. Sw Pet Prods., Inc. v. Koch Indus., Inc., 273 F. Supp. 2d. 1041, 1051 (D. Ariz. 2003).

Plaintiff alleged that Plavix was allegedly defective when ingested along with aspirin by people who have peripheral vascular disease, and that the defect caused her injury. So there you have it. But wait... simply pleading a defect is not enough. To prevail on a design defect claim in Arizona, a plaintiff must also show that the defective product is unreasonably dangerous. Although plaintiff's design defect claim was apparently pled pursuant to the Restatement (Second) of Torts § 402(a), the federal court concluded that Arizona would now use the Restatement (Third) of Torts, particularly its definition of an unreasonably safe prescription drug or medical device in a design defect claim. Section 6(c) of the Third Restatement, noted the court, declares that a prescription drug or medical device is unreasonably unsafe due to defective design only if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for *any class* of patients.

Here, although plaintiff alleged that no reasonable health-care provider would prescribe Plavix for plaintiff knowing of the alleged risks to Caucasian patients who genetically are poor metabolizers of Plavix, and who are diagnosed with peripheral vascular disease and concomitantly ingest aspirin, nowhere did the plaintiff allege that Plavix would not be prescribed for any class of patients.

And arguably even under a traditional risk/benefit analysis used to determine whether a product is unreasonably dangerous based on the Restatement (Second) of Torts, plaintiff's

pleading did not state a plausible claim. Although detailed factual allegations are not necessary in pleadings, "labels and conclusions" are insufficient. Bell Atlantic Corp v. Twombly, 550 U.S. 544, 555 (2007). And that's what she offered on risk benefit elements.

As to the warning claim, plaintiff needed to allege, then show, that had a proper warning been given, the injury would not have happened. See Gosewisch v. Am. Honda Motor Co., Inc., 153 Ariz. 400, 403, 737 P.2d 376, 379 (1987) (superseded by statute on other grounds). Here, plaintiff averred only on information and belief that her doctor would not have prescribed Plavix had he known of its true risks for patients like plaintiff. But the court noted that plaintiff could simply have contacted her physician to determine the facts, which were not solely in the control of defendants. She did not do so, and her allegations thus fell short.