15-P-1272 Appeals Court

LESLIE NIEDNER, administratrix,[1] vs. ORTHO-McNEIL PHARMACEUTICAL, INC., & others.[2]

No. 15-P-1272.

Suffolk. May 5, 2016. - September 21, 2016.

Present: Cypher, Blake, & Henry, JJ.

Negligence, Duty to warn, Pharmaceutical manufacturer, Design, Defective product, Manufacturer. Contract, Warranty. Warranty. Negligence, Misrepresentation. Consumer Protection Act, Unfair or deceptive act. Conscious Pain and Suffering. Practice, Civil, Summary judgment.

Civil action commenced in the Superior Court Department on September 21, 2010.

The case was heard by Heidi E. Brieger, J., on a motion for summary judgment.

Roopal P. Luhana, of New York, for the plaintiff.
Susan M. Sharko, of New Jersey, for Ortho-McNeil Pharmaceutical, Inc., and others.

[1] Of the estate of Adrianna Duffy.

[2] Johnson & Johnson; Johnson & Johnson Pharmaceutical Research and Development, LLC (formerly known as R.W. Johnson Pharmaceutical Research Institute); and Sara M. Nelson.

BLAKE, J. Adrianna Duffy was a seventeen year old college student when she collapsed in her dormitory room and died of a pulmonary embolism. Duffy's mother, Leslie Niedner, as administratrix of Duffy's estate, filed a complaint against the defendants, Ortho-McNeil Pharmaceutical, Inc.; Johnson & Johnson; and Johnson & Johnson Pharmaceutical Research and Development, LLC (collectively, J & J), alleging multiple causes of action relating to J & J's birth control product, Ortho Evra.[3] Following a hearing on J & J's motion for summary judgment, a judge of the Superior Court allowed the motion and ordered the dismissal of the complaint in its entirety. We affirm.

Background. The following undisputed facts are taken from the summary judgment record. Sara M. Nelson of the Massachusetts General Hospital Chelsea Healthcare Clinic was Duffy's pediatrician from about October of 2004, until her death in 2009. In July, 2008, Duffy, accompanied by Niedner, met with Nelson to discuss birth control options. Nelson recommended and prescribed an oral birth control pill. The prescription was filled in July, August, and September of 2008. Duffy also used

[3] Defendant Sara M. Nelson, Duffy's pediatrician, entered into a stipulation with the other parties that Nelson would be dismissed from the case. Whether the dismissal is with or without prejudice depends on the outcome of this appeal.

condoms when she was sexually active. At some point thereafter, Duffy discontinued her use of oral birth control pills.

In June, 2009, Duffy decided that she needed a backup birth control method, again, in addition to condoms. She and Niedner met with Nelson on June 23, 2009, to discuss Duffy's options. Duffy asked Nelson about the Ortho Evra patch (patch), as she wanted an easy and simple method of birth control. The patch prevents pregnancy by transferring synthetic forms of the hormones estrogen and progestin through the skin. Unlike oral birth control pills, which must be taken at the same time each day, the patch is applied to the skin once per week for three weeks, followed by a fourth patch-free week.

Nelson prescribed the patch for Duffy at that meeting. As she had when she prescribed oral birth control pills, Nelson informed Duffy and Niedner of the risks associated with using the patch, including that all hormonal contraceptives come with a risk of suffering blood clots.[4] When the prescription was filled by Walgreens pharmacy (pharmacy), the package included an insert prepared by J & J (the manufacturer), as well as a leaflet from the pharmacy, both of which set forth the risks associated with use of the patch, including the risks of stroke,

[4] Nelson testified at her deposition that she was aware of one study that suggested that the risk of clotting was potentially double in users of the patch as compared to users of oral contraceptives.

heart attack, and blood clots. Approximately three months after Duffy began using the patch, she died from a massive bilateral pulmonary embolus.

On October 29, 2010, Niedner filed her first amended complaint alleging that Duffy's use of the patch had caused her death, and that J & J was liable for breach of warranty (under theories of design defect, failure to warn, and manufacturing defect), breach of express warranty, negligence, fraudulent concealment, conscious pain and suffering, and violating the consumer protection act, G. L. c. 93A.[5] The complaint centers on Niedner's failure to warn claim, which is based on her allegation that she and Duffy were not told that the risk of suffering a blood clot is significantly increased with use of the patch as compared to an oral contraceptive. Put another way, Niedner's complaint is focused on the comparative risk of developing blood clots, not the risk of developing blood clots in and of itself. J & J moved for summary judgment, arguing that the risks of using the patch, including the increased risk of blood clots, were adequately disclosed, and that Niedner's remaining causes of action fail as a matter of law for lack of evidence. The judge agreed and allowed the motion. After

[5] An additional count alleged professional negligence as to Nelson only.

judgment entered, this appeal followed. Additional facts will be set forth as necessary.

Discussion. 1. Standard of review. "We review a grant of summary judgment de novo to determine 'whether, viewing the evidence in the light most favorable to the nonmoving party, all material facts have been established and the moving party is entitled to a judgment as a matter of law.'" Juliano v. Simpson, 461 Mass. 527, 529-530 (2012), quoting from Augat, Inc. v. Liberty Mut. Ins. Co., 410 Mass. 117, 120 (1991). See Mass.R.Civ.P. 56(c), as amended, 436 Mass. 1404 (2002). "The moving party bears the burden of affirmatively demonstrating the absence of a triable issue." Lev v. Beverly Enterprises-Mass., Inc., 457 Mass. 234, 237 (2010). "Conclusory statements, general denials, and factual allegations not based on personal knowledge [are] insufficient to avoid summary judgment." Madsen v. Erwin, 395 Mass. 715, 721 (1985), quoting from Olympic Jr., Inc. v. David Crystal, Inc., 463 F.2d 1141, 1146 (3d Cir. 1972).

2. Duty to warn. Ordinarily, a manufacturer of a product with known dangers has a duty to warn consumers who will foreseeably come in contact with, and be endangered by, the product of those dangers. H. P. Hood & Sons v. Ford Motor Co., 370 Mass. 69, 75 (1976). When communication with a consumer is unreasonable, however, the "manufacturer may be absolved from blame because of a justified reliance upon . . . a middleman."

MacDonald v. Ortho Pharmaceutical Corp., 394 Mass. 131, 135 (1985), quoting from Carter v. Yardley & Co., 319 Mass. 92, 99 (1946). Under this "learned intermediary rule," a drug manufacturer's duty to warn is generally discharged by providing physicians with an adequate warning about any risks associated with its prescription drug products. Id. at 136, quoting from McEwen v. Ortho Pharmaceutical Corp., 270 Or. 375, 386-387 (1974) ("the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, [although] the manufacturer is directly liable to the patient for a breach of such duty"). "The rationale underlying the prescription drug rule is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly." Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992) (applying Massachusetts law).

In MacDonald, the Supreme Judicial Court created a narrow exception to the learned intermediary rule, holding that a manufacturer of oral contraceptives was "not justified in relying on warnings to the medical profession to satisfy its common law duty to warn," but also had a duty to directly warn the consumer about the risks of taking birth control. Id. at 138. The court noted several factors that set birth control

pills apart from other prescription drugs, such as "the heightened participation of patients in decisions relating to use of 'the pill'; . . . the limited participation of the physician," and that less medical supervision is provided as compared with other prescription drugs. Ibid. The court also found significant that Federal regulations require that manufacturers of oral contraceptives warn consumers directly of their risks. Ibid. Because the patch is a hormonal birth control product, like the birth control pills at issue in MacDonald, the court's holding in that case controls here. Accordingly, J & J had a duty to directly warn Duffy of the risks associated with use of the patch.

3. Adequacy of the warning. The box containing the patches purchased by Duffy contained an insert entitled "DETAILED PATIENT LABELING." The insert explains how to use the patch and the risks associated with its use, and informs consumers that they should consult their physician to discuss the information contained in the insert. Both Duffy and Niedner read the insert for the patches Duffy purchased. Neither Duffy, nor Niedner, consulted Nelson concerning the patch after she prescribed it. The relevant portions of the insert, as reviewed by Duffy and Niedner, are as follows:

"DESCRIPTION

"The contraceptive patch ORTHO EVRA® is a thin, beige, plastic patch that sticks to the skin. The sticky part of the patch contains the following hormones: norelgestromin (progestin) and ethinyl estradiol (estrogen). These hormones are absorbed continuously through the skin and into the bloodstream. On average, the amount of estrogen delivered through the skin produces estrogen exposure that is higher than the exposure when taking a birth control pill containing 35 micrograms of estrogen" (emphasis supplied). . . .

"INTRODUCTION
"Any woman who considers using the contraceptive patch ORTHO EVRA® should understand the benefits and risks of using this form of birth control. This leaflet will give you much of the information you will need to make this decision and will also help you determine if you are at risk of developing any serious side effects. It will tell you how to use the contraceptive patch properly so that it will be as effective as possible. However, this leaflet is not a replacement for a careful discussion between you and your health care professional. You should discuss the information provided in this leaflet with him or her, both when you first start using the contraceptive patch ORTHO EVRA® and during your revisits. . . .

"OTHER CONSIDERATIONS BEFORE USING ORTHO EVRA®
"Hormones from ORTHO EVRA® get into the blood stream and are processed by the body differently than hormones from birth control pills. You will be exposed to about 60% more estrogen if you use ORTHO EVRA® than if you use a typical birth control pill containing 35 micrograms of estrogen. In general, increased estrogen may increase the risk of side effects." (Emphasis in original.)

"The risk of venous thromboembolic events (blood clots in the legs and/or the lungs) may be increased with ORTHO EVRA® use compared with use of birth control pills. Studies examined the risk of these serious blood clots in women who used either ORTHO EVRA® or birth control pills containing one of two progestins (levonorgestrel or norgestimate) and 30-35 micrograms of estrogen. Results of these studies ranged from an approximate doubling of risk of serious blood clots to no increase in risk in women using ORTHO EVRA® compared to women using birth control pills" (emphasis supplied).

> "You should discuss this possible increased risk with your healthcare professional before using ORTHO EVRA®. Call your healthcare professional immediately if any of the adverse side effects listed under 'WARNING SIGNALS' occur while you are using ORTHO EVRA®. . . .
>
> "RISKS OF USING HORMONAL CONTRACEPTIVES, INCLUDING ORTHO EVRA® . . . .
>
> "1. Risk of Developing Blood Clots
> "Blood clots and blockage of blood vessels that can cause death or serious disability are some of the most serious side effects of using hormonal contraceptives, including the ORTHO EVRA® contraceptive patch. In particular, a clot in the legs can cause thrombophlebitis, and a clot that travels to the lungs can cause sudden blocking of the vessel carrying blood to the lungs. . . .
>
> "The risk of venous thromboembolic disease (blood clots in the legs and/or the lungs) may be increased with ORTHO EVRA® compared with that of oral contraceptives containing norgestimate and 35 mcg of estrogen (see the earlier Section OTHER CONSIDERATIONS BEFORE USING ORTHO EVRA®). You should discuss this possible increased risk with your healthcare professional before using ORTHO EVRA®. Call your healthcare professional immediately should any of the adverse effects listed under 'WARNING SIGNALS' occur while you are using ORTHO EVRA®." (Emphasis supplied.)

Here, it is undisputed that Duffy developed blood clots in her lungs. This is a risk expressly set forth in the insert, where it is described in no less than four places. The greater dose of estrogen, and the corresponding increased risk of adverse events, such as blood clots, also is clearly stated in plain language. The insert also cautions that it is not a replacement for careful discussion between the patient and her healthcare professional and that these discussions should take place when the patient first uses the patch and during the

patient's revisits. As a matter of law, the insert adequately warned both Niedner and Duffy of the increased risk of developing blood clots that could result in death, as compared to the risks associated with the birth control pill, in terms understandable to a lay person. See MacDonald, 394 Mass. at 140, quoting from Restatement (Second) of Torts § 328B(d) and comment g (1965) ("A court may, as a matter of law, determine 'whether the defendant has confirmed to [the common law duty to warn] standard'").

Niedner nevertheless claims the holding in MacDonald compels a reversal of the summary judgment in favor of J & J because the insert failed to warn that the patch "delivers a variable and unreasonably dangerous amount of estrogen, up to 56 micrograms, directly to the bloodstream, unlike any contraceptive on the market and, as a result, it is twice as likely to cause a fatal blood clot." In MacDonald, supra at 134, the plaintiff suffered a stroke. The manufacturer in that case, however, did not expressly warn of "stroke," but only of fatal blood clots that could lodge in the lungs or the brain. Id. at 132-133. The court upheld a jury's determination that the warning was insufficient because it failed to include the word "stroke." Id. at 141. Here, the insert was abundant in its warning of the possibility of blood clots in the lungs that could lead to death, including the outcome of one study that

showed a doubling of the risk of serious blood clots as compared to oral contraceptives. Unlike in MacDonald, the insert here did not omit language that would have been more understandable to an average user. Rather, as we have noted, the warnings were plain, numerous, and comprehensive.

4. Design defect. For a product to be defective, it must be "'made according to an unreasonably dangerous design' and does not meet a consumer's reasonable expectation as to its safety." Everett v. Bucky Warren, Inc., 376 Mass. 280, 290 (1978), quoting from Prosser, Torts § 99, at 659 (4th ed. 1971). The focus of the claim must be on the design itself, not on the manufacturer's conduct, and it requires proof of the existence of a safer alternative design. Id. at 290-291. See Evans v. Lorillard Tobacco Co., 465 Mass. 411, 428 (2013). Here, Niedner contends that oral contraceptives, which are taken daily, are a feasible and safer alternative design to the patch, which is applied once per week for three weeks, with the fourth week being patch-free. While both products are hormonal contraceptives that prevent pregnancy, the difference in the drug delivery method, each of which has its own advantages and disadvantages, makes the pill fundamentally different from the patch. See id. at 431 ("[I]n a case where the allegedly defective product is a cigarette, the reasonable alternative design must also be a cigarette"). See also Restatement (Third)

of Torts: Products Liability § 2 illustration 9, at 26-27 (1998). As such, one cannot serve as a safer alternative for the other.

5. Manufacturing defect. A manufacturer of a product that is dangerous due to a lack of reasonable care in its manufacture or inspection owes a legal duty to those who will foreseeably come into contact with it to use reasonable care to prevent injury to those persons. Carter v. Yardley & Co., 319 Mass. at 96. The proper inquiry is "whether the deviation from the design rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes." Back v. Wickes Corp., 375 Mass. 633, 641 (1978). The summary judgment record is devoid of any evidence that the specific patch used by Duffy was manufactured differently, or deviated in any respect from its intended design.[6]

6. Remaining claims. Niedner's remaining claims are likewise unsupported by the record and require little analysis. No breach of express warranty occurred because the risks associated with use of the patch were clearly explained in the insert, and J & J made no representations or specific promises to Niedner or Duffy other than those contained therein. See G. L. c. 106, § 2-313(1)(a). Because Niedner has failed to

[6] Niedner does not contend that the patch was ineffective for the purpose of birth control. Indeed, there is no evidence that Duffy became pregnant.

demonstrate that the insert was inaccurate, false, or deceptive, her c. 93A and negligent misrepresentation claims also fail. See G. L. c. 93A, § 2; Fox v. F & J Gattozzi Corp., 41 Mass. App. Ct. 581, 587-588 (1996).[7]

Finally, recovery for a decedent's conscious pain and suffering requires "cognizable proof beyond mere surmise." Heng Or v. Edwards, 62 Mass. App. Ct. 475, 492 (2004). Because the summary judgment record contains no evidence to support this claim beyond Niedner's unsupported contention that sudden death from blood clots would cause such suffering, it also fails.

Judgment affirmed.

[7] Massachusetts does not recognize an independent claim for fraudulent concealment. Rather, G. L. c. 260, § 12, tolls the statute of limitations for a cause of action if an alleged wrongdoer concealed its existence through some affirmative act done with the intent to deceive. The statute has no application here. See Hays v. Ellrich, 471 Mass. 592, 601-602 (2015).