UNPUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

ALLISON A. MURPHY, a minor, by Rita and John Murphy, as Parents and Next Friends,
Plaintiff-Appellant,

and

RITA MURPHY, individually; JOHN MURPHY, individually,
Plaintiffs,

v.

PLAYTEX FAMILY PRODUCTS CORPORATION,
Defendant-Appellee.

No. 02-1110

Appeal from the United States District Court
for the District of Maryland, at Greenbelt.
Andre M. Davis, District Judge.
(CA-00-3664-AMD)

Argued: May 7, 2003

Decided: June 26, 2003

Before WILKINS, Chief Judge, and WILKINSON and MOTZ, Circuit Judges.

Affirmed by unpublished per curiam opinion.

COUNSEL

ARGUED: Lloyd David Inglehart, Columbia, Maryland, for Appellant. William H. Robinson, Jr., WRIGHT, ROBINSON, OSTHIMER

& TATUM, Washington, D.C., for Appellee. **ON BRIEF:** Terrence M.R. Zic, WRIGHT, ROBINSON, OSTHIMER & TATUM, Washington, D.C.; C. Ervin Reid, WRIGHT, ROBINSON, OSTHIMER & TATUM, Richmond, Virginia, for Appellee.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

OPINION

PER CURIAM:

Plaintiff Allison Murphy sued Playtex Products, Inc., after contracting toxic shock syndrome while using Playtex brand tampons. The district court found that Murphy's state law claims relating to the failure of Playtex to adequately warn her of the dangers of using tampons were preempted by federal regulation in the field. Additionally, the district court found that her design defect claims failed as a matter of law. We agree with the district court and dismiss all counts.

I.

Plaintiff Allison Murphy suffered from toxic shock syndrome ("TSS") in January 1998 while using Playtex tampons. After her bout with TSS, Murphy, along with her parents as next friends, filed this action against Playtex alleging negligence, strict liability, breach of express warranty, and breach of implied warranty under Maryland law, as well as violation of the Maryland Consumer Protection Act. Murphy sought restitution and punitive damages based on Playtex's failure to adequately warn her of the risk of TSS associated with tampon use and Playtex's alleged negligent use of rayon fiber instead of cotton fiber in the manufacture of its tampons.

TSS is a rare but potentially life-threatening illness caused by the bacterium staphylococcus aureus. The disease is most commonly linked to the use of high absorbency tampons in young women.

The risk of contracting TSS from tampons has been recognized by the United States Food and Drug Administration ("FDA") for over twenty years. In light of this risk, the FDA has promulgated regulations for the manufacture and distribution of tampons. Playtex prints the mandated federal warning about TSS in three spots on its packaging. Because higher absorbency tampons are more likely to cause TSS, Playtex also prints the range of absorbency of its tampons in five spots on the tampon packaging. Each box of Playtex tampons also contains an insert with a warning about TSS and detailed information about the symptoms of TSS and ways to decrease the risk of getting TSS.

When the FDA first promulgated these regulations in 1982, FDA researchers reviewed extensive amounts of material on the relation of TSS to tampon use. The researchers concluded that although tampon use was associated with TSS, tampons were not in themselves dangerous. Moreover, these researchers found that no particular tampon fiber or ingredient increased the risk of TSS. During its review of tampon regulations in 1988 and 1989, the FDA again found that "none of the comments favoring ingredient labeling cited, discussed, or submitted any data showing an association between any particular ingredient and any risk to health." In 1989, the Center for Disease Control ("CDC") concurred that no particular composition of tampons affected the risk of contracting TSS.

Based on this information, Playtex moved for summary judgment on all claims. Specifically, Playtex contended that Murphy's failure to warn claims were preempted by § 360k(a) of the Federal Devices Act, which requires the labeling of tampon packages, and that her other claims were insufficient under Maryland law. On December 19, 2001, the district court granted Playtex's motion for summary judgment. *Murphy v. Playtex Family Prod.*, 176 F. Supp. 2d 473 (D. Md. 2001). Murphy now appeals.

II.

Murphy first argues that the district court erred in finding her state law failure to warn claims preempted by § 360k(a) of the Federal Devices Act. Preemption is appropriate, however, where a plaintiff seeks to impose labeling requirements which are "different from, or

in addition to," specific regulations promulgated by the FDA. *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 328 (4th Cir. 1996). Therefore, the district court was correct to find that Murphy's state law failure to warn claims, no matter how they were framed, were preempted by the extensive federal regulation in the field.

The FDA has promulgated specific regulations mandating the substantive content of TSS warnings on tampon boxes. *See* 21 C.F.R. § 801.430. While not every federal regulation will preempt state law claims, preemption will be found when it is clear that "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996). In this case, the regulations at issue are "not only device-specific (tampons), but also disease-specific (TSS)." *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740 (9th Cir. 1997). Thus, it is clear that the federal regulators considered exactly the risk that Murphy was exposed to and determined how best to warn consumers of this risk through product labeling.

Moreover, other courts faced with similar cases have specifically held that federal labeling requirements for tampons preempt state law warning claims. *See Papike*, 107 F.3d at 740; *Nat'l Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994); *Moore v. Kimberly-Clarke Corp.*, 867 F.2d 243 (5th Cir. 1989). We agree with these courts and thus find that the district court correctly determined that "plaintiffs' failure to warn claims, including plaintiffs' Consumer Protection Act claim, are expressly preempted by the requirements of 21 C.F.R. § 801.430."* *Murphy*, 176 F. Supp. 2d at 483.

*Murphy also argues that summary judgment was inappropriate because her negligent manufacture claims "were not preempted by 360k(a) to the extent that such claims rested on allegations that the manufacturer negligently failed to comply with the duties equal to, or substantially identical to, requirements imposed under Federal law by the FDCA." Murphy does not actually allege, however, that Playtex does not comply with the labeling regulations. Indeed, Murphy explicitly conceded that the tampon box contained several warnings as required by the FDA. This claim is therefore without merit.

III.

Murphy next argues that the district court erred in dismissing her design defect claims. The district court found that these claims were insufficient as a matter of law. *Murphy*, 176 F. Supp. 2d at 487. Because Murphy's evidence fails to raise an issue of triable fact under either test utilized by the Maryland courts, we affirm the district court's grant of summary judgment.

The elements of proof for a design defect claim under Maryland law are the same whether the claim is for strict liability, negligence, or breach of warranty, all of which Murphy alleges. *Watson v. Sunbeam Corp.*, 816 F. Supp. 384, 387 n.3 (D. Md. 1993). In order to recover on a product defect claim, a plaintiff must prove that a defect which renders the product unreasonably dangerous might arise from the design of the product, a deficiency in its manufacture, or from the absence or inadequacy of any instructions or warnings as to its safe and appropriate use. *Simpson v. Standard Container Co.*, 527 A.2d 1337, 1339-40 (Md. Ct. Spec. App. 1987). In other words, Murphy must show that Playtex acted unreasonably when, knowing the risk inherent in its product, it nonetheless put the product on the market. *Ziegler v. Kawasaki Heavy Indus., Ltd.*, 539 A.2d 701, 705 (Md. Ct. Spec. App. 1988).

Maryland courts have applied both a risk/utility test and a consumer expectation test for determining whether a product is unreasonably dangerous due to a design defect. Murphy argues that Playtex's choice of rayon fiber instead of cotton fiber for its tampons is unreasonable under either test. We address each theory in turn.

A.

Maryland courts applying a risk/utility test focus on "whether the benefits of a product outweigh the dangers of its design." *Tannenbaum v. Yale Materials Handling Corp*, 38 F. Supp. 2d 425, 430 (D. Md. 1999). Murphy contends that she has proffered sufficient evidence to establish a prima facie case under the risk/utility test.

Murphy's sole evidence is contained in the affidavits of designated experts Philip M. Tierno, Ph.D. and Bruce A. Hanna, Ph.D. Both are

microbiologists who have collaborated in conducting unblinded test tube experiments allegedly proving that tampons made with cotton fiber present less risk of TSS than tampons with rayon fiber. Both scientists have conceded in deposition testimony, however, that tampon-associated TSS will occur regardless of what fiber is used. They have also conceded that no other scientists have corroborated their views and that their work has not been verified by epidemiological studies of any sort. *Murphy*, 176 F. Supp. 2d at 477.

In fact, significant research done in published, peer-reviewed scientific studies has refuted their conclusions. Every other study done in the field has indicated that no greater quantity of TSST-1, the toxin that causes TSS, is produced in the presence of rayon fibers than in the presence of cotton fibers. These studies have been replicated both in the laboratory and in animal testing and are also consistent with the conclusions reached by the FDA and CDC. *Murphy*, 176 F. Supp. 2d at 477-78.

Faced with this overwhelming scientific evidence, at least two other circuits have already found that the unproven opinions of Tierno and Hannah were insufficient to create a genuine issue of material fact as to the risks associated with rayon tampons. *See Haddix v. Playtex Family Prods. Corp.*, 138 F.3d 681, 685-86 (7th Cir. 1998); *Papike*, 107 F.3d at 743. The district court, citing to these opinions, found that Murphy could not "establish by a preponderance of the evidence to a reasonable jury a necessary element of [her] case — that Playtex acted unreasonably in designing or manufacturing tampons with rayon fiber." *Murphy*, 176 F. Supp. 2d at 493. We agree that Murphy failed to show that the risks inherent in marketing rayon tampons outweighed the benefit to consumers. Therefore her case cannot survive summary judgment on a risk/utility analysis.

B.

The consumer expectations test "focuses on what a buyer/user of a product would properly expect that the product would be suited for." *Tannenbaum*, 38 F. Supp. 2d at 430. Using this test, Maryland courts have found that a product is unreasonably dangerous if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge

common to the community as to its characteristics." *Phipps v. General Motors Corp.*, 363 A.2d 955, 959 (Md. 1976). Murphy argues that Playtex tampons were dangerous beyond the expectations of the average consumer because the warnings on the package did not sufficiently convey the dangers of using high absorbency tampons.

Since January 1987, Playtex has printed a TSS warning statement in three separate locations on the outside of each box of Playtex tampons. The alert reads as follows:

> ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

Playtex also includes on the outside of each box the range of absorbency available in different tampons. Printed next to this absorbency range is a statement that consumers should "[s]elect the minimum absorbency needed to control your menstrual flow in order to reduce the risk of getting TSS." All Playtex tampon packages also include a package insert concerning TSS which is printed in bold face block and bridged across the top of the tampons. The FDA has never found that this packaging does not comply with the mandatory federal TSS warning requirements.

The mandated warnings on each box of Playtex tampons clearly set forth the risk of acquiring TSS through the use of tampons. Murphy testified that she had read the TSS alert statement on the outside of the tampon package prior to her illness and that she was aware of the risk of TSS from tampon use. Murphy was further aware that Playtex tampons come in different absorbencies and that she should use the minimum absorbency that she needed. *Murphy*, 176 F. Supp. 2d at 482.

The district court found that "[u]nder such circumstances, an ordinary consumer would expect to be exposed to the risk of TSS associated with Tampon use" and that allowing Murphy's claim to go forward on a consumer expectation theory would allow "the anomalous circumstance that a consumer is entitled to expect a product to perform more safely than its government mandated warnings indicate." *Murphy*, 176 F. Supp. 2d at 488 (internal citations omitted).

The district court concluded that as a matter of law the tampons manufactured by Playtex were not dangerous to an extent beyond that which would be contemplated by the ordinary consumer because Playtex fully complied with federal labeling requirements. *Id.* We agree and therefore find that Murphy cannot prevail on a consumer expectation theory.

IV.

For the foregoing reasons, the judgment of the district court is

AFFIRMED.