NOTICE: Decisions issued by the Appeals Court pursuant to its rule 1:28 are primarily addressed to the parties and, therefore, may not fully address the facts of the case or the panel's decisional rationale. Moreover, rule 1:28 decisions are not circulated to the entire court and, therefore, represent only the views of the panel that decided the case. A summary decision pursuant to rule 1:28, issued after February 25, 2008, may be cited for its persuasive value but, because of the limitations noted above, not as binding precedent.

COMMONWEALTH OF MASSACHUSETTS APPEALS COURT

BILLIE ALLEN *vs.* BOSTON SCIENTIFIC CORP. & another. [FN1]

12-P-1578

MEMORANDUM AND ORDER PURSUANT TO RULE 1:28

The plaintiff, Billie Allen, appeals from a judgment dismissing her first amended complaint (complaint) [FN2] for failure to state a claim on which relief can be granted under Mass.R.Civ.P. 12(b)(6), 365 Mass. 754 (1974). The plaintiff's complaint alleges actions for breach of warranty, negligence, failure to warn, and deceptive trade practices under the Massachusetts Consumer Protection Act, G. L. c. 93A, § 2. The defendants, Boston Scientific Corp. (Boston Scientific) and American Medical Systems, Inc. (AMS), prevailed on their motions to dismiss because the motion judge determined that Allen had not pleaded sufficient facts to 'nudge her claims across the line from conceivable to plausible.' We reverse. In reviewing the allowance of a motion to dismiss under rule 12(b)(6), 'we examine the same pleadings as the motion judge and therefore proceed de novo.' *Dartmouth v. Greater New Bedford Regional Vocational Technical High Sch. Dist.,* 461 Mass. 366, 373 (2012). See *Greenleaf Arms Realty Trust I, LLC v. New Boston Fund, Inc.,* 81 Mass. App. Ct. 282, 288 (2012).

Background. The following facts are alleged in the plaintiff's complaint. On April 23, 2008, Allen was implanted with AMS's Perigee device. On November 5, 2008, she was implanted with Boston Scientific's Monarc and Pinnacle devices. The devices are designed for women who suffer from stress urinary incontinence (SUI) and pelvic organ prolapse (POP) as a result of weakening or damage caused to the walls of the vagina. The plaintiff suffers from both SUI and POP, and the devices were implanted to treat these conditions. The defendants marketed their devices as safer and more successful than other surgical options, and as a quicker and more efficient way to correct SUI or POP.

As alleged in the plaintiff's complaint, the devices contain a monofilament, polypropylene mesh; due to the presence of this mesh, the devices are biologically incompatible with the uses for which they are intended. The devices have a propensity to erode and can cause chronic infections, vaginal scarring, severe pain, and other complications. In support of these assertions, Allen states that, on October 20, 2008, the Food and Drug Administration (FDA) issued a public health notification describing over 1,000 adverse events that were reported over a three-year period related to vaginal sling implants. AMS and Boston Scientific are manufacturers of the devices that were the subject of this notification. Neither Boston Scientific nor AMS notified physicians or patients of the reported adverse events, or of the devices' biological incompatibility, their propensity to erode, the rate and manner of erosion, the risk of chronic infections resulting from their implantation, the risk of vaginal scarring, the risk of recurrent severe pelvic pain, or the overall severity of complications.

Finally, Allen claims that she has suffered serious bodily injuries, including recurrent pelvic

pain, and that she has undergone multiple surgeries and revisionary procedures as a result of having the devices implanted. These types of complications are among those specifically identified in the 2008 FDA notification.

Discussion. In reviewing the dismissal of a complaint for failure to state a claim on which relief can be granted, we take as true the allegations of the complaint, as well as such inferences as may be drawn therefrom in the plaintiff's favor. *Chokel v. Genzyme Corp.,* 449 Mass. 272, 273 (2007). *Golchin v. Liberty Mut. Ins. Co.,* 460 Mass. 222, 223 (2011), *S. C.,* 466 Mass. 156 (2013). The complaint must be sufficient to 'raise a right to relief above the speculative level.' *Iannacchino v. Ford Motor Co.,* 451 Mass. 623, 636 (2008), quoting from *Bell Atl. Corp.* v. *Twombly,* 550 U.S. 544, 555 (2008) (*Twombly*). However, the plaintiff's burden at this time is not one of probability; rather, she must show only that her claims are facially plausible. See *Twombly,* 550 U.S. at 556; *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009). Thus, the ultimate inquiry is whether the plaintiff has alleged such facts, adequately detailed, so as to plausibly suggest an entitlement to relief. See *Greenleaf Arms Realty Trust I, LLC v. New Boston Fund, Inc.,* 81 Mass. App. Ct. at 288; *Cameron Painting, Inc.* v. *University of Mass.,* 83 Mass. App. Ct. 345, 347 (2013).

As described above, the plaintiff has detailed a number of factual allegations that, taken as a whole, plausibly suggest that she has suffered injuries as a result of the defendants' defective products, negligence, and/or unfair or deceptive practices. Allen has alleged, amongst other things, that she was implanted with three devices that were marketed as a safer alternative to other products and procedures on the market; that these products contained a mesh component that has a tendency to erode, thereby causing severe complications; that the defendants did not provide either her or her physicians with any warnings as to the products' propensity to erode; and that, after these devices were implanted, she experienced recurrent pain and has since undergone multiple revisionary surgeries. These statements, which we must take as true, are sufficient at this stage to plausibly suggest that Allen is entitled to relief on the claims she has asserted.

The defendants make much of the fact that the plaintiff's complaint contains a number of legal conclusions. Putting such conclusions aside, the complaint details a number of facts that support the plaintiff's claims and raise her right to relief above the speculative level. *Iannacchino v. Ford Motor Co.,* 451 Mass. at 636, citing *Twombly,* 550 U.S. at 555. We conclude that the complaint is sufficient to plausibly suggest an entitlement to relief. Accordingly, we reverse the judgment dismissing the plaintiff's first amended complaint.

Judgment reversed.

By the Court (Kafker, Trainor & Maldonado, JJ.),

Entered: October 9, 2013.

FN1. American Medical Systems, Inc.

FN2. The complaint at issue on this appeal is the plaintiff's first amended complaint, which was filed after the motion judge allowed the defendants' motions to dismiss the original complaint with leave to amend.

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