Supreme Judicial Court of Massachusetts, Middlesex.

**Florence VASSALLO & another [FN1]**

FN1. Her husband, Vincent Vassallo. The complaint, and other papers in the trial court, use the pseudonyms Jane and John Doe to describe the plaintiffs. We see no reason to refer to the plaintiffs by way of pseudonyms in this opinion.

v.

**BAXTER HEALTHCARE CORPORATION & another. [FN2]**

FN2. Baxter International, Inc.

Argued May 5, 1998.
Decided July 16, 1998.

Woman who had received silicone breast implants sued successors in interest to manufacturer of implants, asserting claims of negligent design, negligent product warnings, breach of implied warranty of merchantability, and under consumer protection statute. The Superior Court Department, Middlesex County, Margot Botsford, J., entered judgment on jury verdict for woman on negligence and breach of warranty claims, and entered separate memorandum of decision on consumer protection claim, but did not award damages on consumer protection claim. After application for direct appellate review was granted, the Supreme Judicial Court, Greaney, J., held that: (1) opinion testimony of expert witnesses was properly admitted; (2) industry research on silicone implants, including materials prepared after woman received implants, was admissible with respect to issue of characteristics of gel used; (3) evidence of complaints received by manufacturer after woman received implants was admissible; (4) manufacturer not be held liable under implied warranty of merchantability for failure to warn or provide instructions about risks that were not reasonably foreseeable at time of sale, or could not have been discovered through reasonable testing, abrogating *Hayes*, 391 Mass. 407, 462 N.E.2d 273, and *Simmons*, 413 Mass. 205, 596 N.E.2d 318; and (5) court's finding of violation of consumer protection statute, and decision not to award damages, were supported by evidence.

Affirmed.

West Headnotes

**[1] Appeal and Error ⚿204(2)**
30k204(2)

**[1] Appeal and Error ⚿205**
30k205

**[1] Appeal and Error ⚿898**
30k898

On record where objections are properly preserved, reviewing court may examine trial judge's decision to admit or exclude certain scientific expert evidence on de novo basis, but where party who has lost evidentiary ruling preserves only limited basis for review, reviewing court ordinarily examines only that basis, consistent with established principle governing appellate review in civil cases that issues not properly raised in trial court will not be considered on appeal.

**[2] Evidence ⚿555.10**
157k555.10

Causation opinions of expert witnesses regarding effects of silicone breast implants were scientifically valid, and were admissible in products liability action, notwithstanding lack of classical epidemiological studies; both witnesses possessed knowledge, skill, and experience to qualify as experts in their fields, and had conducted research, published in peer reviewed journals on related topics, and treated hundreds of women with silicone gel breast implants in their clinical practices.

**[3] Evidence ⚿555.10**
157k555.10

**[3] Evidence ⚿557**
157k557

Opinion testimony of physician regarding degradation of silicone in human body, which was based on his own in vitro and in vivo research on effects of silicone in body, internal studies by manufacturer of silicone implants, and other studies in field, was admissible in products liability action against manufacturer of silicone breast implants.

**[4] Evidence ⚿555.4(5)**
157k555.4(5)

Expert witnesses in products liability action against

manufacturer of silicone breast implants could not testify on direct examination regarding out-of-court opinions of other scientists, in absence of some specific exception to hearsay rule.

**[5] Evidence ⚷555.4(1)**
157k555.4(1)

Expert witness may base opinion on facts or data not in evidence if the facts or data are independently admissible, and are a permissible basis for expert to consider in formulating an opinion.

**[6] Evidence ⚷556**
157k556

Testimony of expert witnesses for manufacturer of silicone breast implants about specifics of published literature published after plaintiff received implants, including results of consensus development conference on silicone gel breast implants, was hearsay with no independent basis for admission.

**[7] Products Liability ⚷81.1**
313Ak81.1

Trial court did not abuse its discretion in ruling that literature on silicone gel which was published after date on which plaintiff received silicone breast implants was irrelevant in products liability action with respect to issue of whether manufacturer had notice of problems related to plaintiff's implants.

**[8] Evidence ⚷351**
157k351

Internal studies performed by manufacturer of silicone gel used in breast implants were scientific studies containing primarily factual data, and were admissible under exception to hearsay rule as business records providing evidence concerning characteristics of gel used in implants, in products liability action by implant recipient against implant manufacturer. M.G.L.A. c. 233, § 78.

**[9] Evidence ⚷351**
157k351

Internal studies performed by manufacturer of silicone gel used in breast implants, which were prepared after plaintiff had received implants, were admissible as business records providing evidence concerning characteristics of gel used in implants in products liability action against implant manufacturer, where gel composition did not change during years following implementation. M.G.L.A. c. 233, § 78.

**[10] Evidence ⚷155(5)**
157k155(5)

Curative admissibility doctrine is only applicable to allow admission of otherwise improper evidence if original evidence being rebutted was improperly admitted.

**[11] Evidence ⚷141**
157k141

Evidence of complaints regarding silicone breast implants which were received by manufacturer following date on which products liability plaintiff received her implants were admissible to show notice to manufacturer of specific problems experienced by purchasers and users, and were relevant to issue of manufacturer's continuing duty to warn of risks discovered after plaintiff's implants were manufactured.

**[12] Evidence ⚷141**
157k141

Evidence of complaints made to manufacturer of silicone breast implants on year-by-year basis, with appropriate cautionary instruction to jury that the complaints were not admitted for truth of what they said, but for jury's consideration of what manufacturer was being told and was learning about its product, was admissible in products liability action as evidence of notice to manufacturer of defects in integrity of its product, about which it had failed to warn.

**[13] Products Liability ⚷13**
313Ak13

**[13] Products Liability ⚷81.1**
313Ak81.1

Evidence of manufacturer's failure to adequately test product is relevant to claims of design, manufacturing, or warning defects, but does not furnish separate, independent basis for liability. Restatement (Second) of Torts § 402A.

**[14] Products Liability ⚷81.1**
313Ak81.1

Jury may consider product testing by manufacturer in

evaluating products liability claim based on design defect.

**[15] Appeal and Error ⚿1071.1(7)**
30k1071.1(7)

Any error by judge in determining that manufacturer of silicone breast implants had inadequately tested implants was harmless, where judge had independent bases upon which to find negligence, and violation of consumer protection statute, on part of manufacturer. M.G.L.A. c. 93A, §§ 2(a), 9.

**[16] Sales ⚿284(1)**
343k284(1)

Manufacturer may not be held liable under implied warranty of merchantability for failure to warn or provide instructions about risks that were not reasonably foreseeable at time of sale, or could not have been discovered by way of reasonable testing prior to marketing product; abrogating *Hayes v. Ariens Co.*, 391 Mass. 407, 413, 462 N.E.2d 273; *Simmons v. Monarch Mach. Tool Co.*, 413 Mass. 205, 596 N.E.2d 318.

**[17] Products Liability ⚿9**
313Ak9

**[17] Products Liability ⚿14**
313Ak14

Product manufacturer is held to standard of knowledge of an expert in the appropriate field, and is subject to continuing duty to warn, at least purchasers, of risks discovered following sale of product at issue.

**[18] Courts ⚿100(1)**
106k100(1)

Standard under which defendant may not be held liable under implied warranty of merchantability for failure to warn or provide instructions about risks that were not reasonably foreseeable at time of sale, or could not have been discovered by way of reasonable testing prior to marketing of product, applies to all claims on which final judgment was not been entered, or as to which appeal is pending or appeal period has not expired, at time of decision establishing standard, and to all claims on which action is commenced after release of opinion establishing standard.

**[19] Consumer Protection ⚿39**
92Hk39

Evidence supported judge's findings that manufacturer of silicone breast implants had violated consumer protection statute. M.G.L.A. c. 93A, §§ 2(a), 9.

**[20] Consumer Protection ⚿40**
92Hk40

Trial judge could properly decline to assess additional compensatory damages on claim asserted under consumer protection statute against manufacturer of silicone breast implants on basis that such an assessment would duplicate jury's award of damages on products liability claim against manufacturer. M.G.L.A. c. 93A, §§ 2(a), 9.

****912 *3** David R. Venderbush, Los Angeles, CA (Harry T. Daniels, Boston, with him) for defendants.

Fredric L. Ellis, Belmont (Edward D. Rapacki, with him), for plaintiffs.

Hugh F. Young, Jr., Reston, VA, and David R. Geiger, Boston, for Associated Industries of Massachusetts & others, amici curiae, submitted a brief.

Before WILKINS, C.J., and ABRAMS, LYNCH, GREANEY and MARSHALL, JJ.

GREANEY, Justice.

In this products liability case, the plaintiff Florence Vassallo claimed that the defendants, Baxter Healthcare Corporation and Baxter International, Inc., were liable to her for damages because silicone breast implants, manufactured by a predecessor company to the defendants (Heyer-Schulte Corporation), that had been implanted in her were negligently designed, accompanied by negligent product warnings, and breached the implied warranty of merchantability, with the consequence that she was injured. The plaintiff Vincent Vassallo claimed a loss of consortium. The plaintiffs also asserted a claim for violation of G.L. c. 93A, §§ 2(*a*) and 9.

A jury in the Superior Court heard the negligence and breach of warranty claims, returned verdicts (in response to special questions) on those claims in favor of the plaintiffs, and assessed damages. The judge entered a separate memorandum of decision on the G.L. c. 93A claim in which she found the

defendants liable for a violation of that statute. The judge concluded that the defendants' conduct was not knowing or wilful, determined that an assessment of additional compensatory damages would duplicate the damages determined by the jury, and awarded the plaintiffs their reasonable attorney's fees and costs. The defendants appealed from the judgment, and we allowed their application for direct appellate review.

We conclude that the determinations of liability as to the negligence and G.L. c. 93A claims are correct, and the judgment can be affirmed on this basis. As a result, we need not consider the defendants' arguments concerning the warranty findings.

We conclude, however, that we should change our products liability law to conform to the clear majority rule regarding what has to be shown to recover in a breach of warranty claim ***4** for failure to warn of risks associated with a product, and we do so in Part 3 of this opinion.

The jury could have based their verdicts on the following evidence. In February, 1977, at the age of forty-eight, Mrs. Vassallo underwent breast implantation surgery. The silicone gel breast implants that Mrs. Vassallo received were manufactured by Heyer-Schulte Corporation in October, 1976. Through a series of corporate transactions, the defendants assumed responsibility for breast implant products manufactured by Heyer-Schulte.

In 1992, Mrs. Vassallo underwent a mammogram after complaining of chest pains that extended up under her left armpit. The mammogram revealed that her breast implants possibly had ruptured. The silicone gel implants were subsequently removed in April, 1993, and were replaced with saline implants. During the course of the explant surgery, the surgeon noted severe, permanent scarring of Mrs. Vassallo's pectoral muscles which she attributed to the silicone gel. The implants themselves were encapsulated in scar tissue with multiple nodules of silicone granulomas. Dissection of the scar ****913** tissue capsules revealed that the left implant had ruptured, releasing free silicone gel, while the right implant was intact, but had several pinholes through which silicone gel could escape.

The plaintiff's pathology expert, Dr. Douglas Shanklin, indicated that, based on the cellular responses shown in the pathology slides of Mrs. Vassallo's breast tissue taken at the time of explant, the rupture had been longstanding, perhaps for several years. According to Dr. Shanklin, Mrs. Vassallo's pathology slides showed silicone granulomas, giant cells, lymphocytes, and macrophages, all of which indicated a chronic immunological and inflammatory reaction to the silicone implants. Dr. Shanklin also identified deposits of silica and lymphocytic vasculitis, which, he testified, were evidence that Mrs. Vassallo suffered from an autoimmune disease caused by the silicone gel.

Doctor Christopher Batich, professor of materials science and engineering at the University of Florida, testified for the plaintiffs on the effects of silicone in the body. He discussed animal studies that demonstrated migration of silicone to various organs both from ruptured gel implants and after intramuscular injection of "radio-labeled" liquid silicone. Doctor Batich also discussed the mechanism by which silicone can degrade to ***5** low molecular weight materials in the body, [FN3] and explained that the use of silicone gel in breast implants was unreasonably dangerous "[b]ecause the material can get out of the implant, it can break up into small particles, it can travel through the body, and it can undergo chemical transformation into things that have biochemical effects."

> FN3. Doctor Batich discussed a Dow Corning study that showed that silicone is metabolized in the human body by the process of demetholation (removal of methyl groups) to form silica. Doctor Batich also discussed his own research and Dow Corning animal studies in which exposure of silica to water resulted in the formation of silenol, which was found to be extremely toxic in rats, with damage to the central nervous system, liver, and blood vessels.

Doctor Bruce Freundlich, chief of rheumatology at Graduate Hospital in Philadelphia and an associate professor of medicine at the University of Pennsylvania, indicated that silicone gel breast implants can cause atypical connective tissue disease with a variety of symptoms that can include joint pain, dry eyes and mouth, difficulty sleeping leading to chronic fatigue, breast pain, fever, reduced sensation in the hands and feet, hair loss, itching, problems swallowing, and heartburn. Doctor Freundlich also offered his opinion that Mrs. Vassallo was suffering from atypical autoimmune disease, based on a review of her medical records and a physical examination that revealed the

following symptoms: "tobacco pouch mouth," or a tightening of the face around the mouth, which has been associated with scleroderma or mixed connective tissue disease; puffy fingers; an ulceration on one finger; thickening of the skin on her face and neck; telangiectasia, or small red blood vessels, of the nose; hyperreflexia; nocturnal myophonic jerking; dry eyes; elevated levels of antinuclear antibodies and IGA immunoglobin antibodies [FN4]; numbness and tingling in her hands; chronic fatigue; hair loss; difficulty swallowing; and problems with memory loss. According to Dr. Freundlich, Mrs. Vassallo's problems were related to her exposure to silicone gel, and her future was "guarded."

> FN4. An antibody is an "immune or protective protein ... evoked in man or other animals by an antigen." Stedman's Medical Dictionary 94 (25th ed.1990).

Doctor Eric Gershwin, chief of the division of rheumatology, immunology, and allergy at the University of California at Davis School of Medicine, discussed his own clinical research, and internal Dow Corning studies, to support his conclusion that silicone gel acts as an adjuvant to stimulate the body's immune ***6** system. [FN5] Based on his research and treatment of more than 700 women with silicone gel breast implants, Dr. Gershwin stated that there is a unique constellation of symptoms seen in approximately five per cent of women with silicone breast implants, and that these symptoms, taken together, constitute an atypical autoimmune disease. Doctor Gershwin also reviewed Mrs. Vassallo's ****914** medical records and concluded that her symptoms were consistent with this atypical autoimmune disease and were caused by her ruptured silicone gel breast implant.

> FN5. An adjuvant is defined in immunology as "a vehicle used to enhance antigenicity." Stedman's Medical Dictionary 28 (25th ed.1990).

There was also extensive testimony as to knowledge, attributable to the defendants, of the risks of silicone gel breast implants up to the time of Mrs. Vassallo's implant surgery in 1977. According to Heyer-Schulte's own internal correspondence, the company was aware of a "Talk Paper," issued by the United States Food and Drug Administration in 1976, that documented migration to the brain, lungs, and heart, and death following injections of liquid silicone into the human body. In 1976, Heyer-Schulte received a report of an animal study, partially funded by Heyer-Schulte and conducted using miniature silicone gel implants supplied by Heyer-Schulte, that documented migration of gel from ruptured implants to the surrounding connective tissues and local inflammatory responses with fibroblastic activity and giant cell formation. The authors of the study stated: "The present tendency by manufacturers of breast implants towards ever thinner envelopes and a filler that is getting further away from gel and closer to silicone liquid must be looked at in the light of these experimental findings, and the question must be asked whether the possible advantages of these changes outweigh the disadvantages." Heyer-Schulte was also aware that some of their implants were rupturing, having received 129 complaints of ruptured gel implants in 1976. In fact, the president of Heyer- Schulte had written in 1975 that "[p]resently, mammary implants have been designed to be increasingly fragile in response to plastic surgeons' demand for softness, realistic feel and mobility." As a result, Heyer-Schulte knew that its implants were "not consistent as far as durability or destructibility is concerned." The encapsulation of the implant, and the viscous nature of the silicone gel, made it difficult to detect that a rupture had occurred, allowing the silicone to leak ***7** into the body for long periods before explantation. By 1975, Heyer-Schulte also knew that, even without a rupture of the implant shell, the silicone gel could leak (known as "gel bleed") through to the exterior surface of the implant and possibly produce "detrimental effect[s]" in the body.

Despite this knowledge of the possible adverse long-term consequences of leaking silicone in the body, Heyer-Schulte conducted few animal, and no clinical, studies to document the safety and efficacy of its silicone gel implants. When Heyer-Schulte began using silicone gel manufactured by Dow Corning in 1976, they relied primarily on the animal testing conducted by Dow Corning, despite the observations of a Heyer-Schulte scientist that "the data ... [did] not answer questions concerning migration," and "was lacking in quality and left many questions unanswered." Heyer-Schulte did conduct toxicity testing on the Dow Corning gel; the gel passed the seven-day and thirty-day toxicity tests, but failed the ninety-day toxicity test based on the microscopic tissue evaluation that showed considerably greater fibrous tissue reaction and inflammation to the silicone gel than to the control material. There is no indication in the record that Heyer-Schulte ever repeated this ninety-day toxicity test, and the

company continued to use the Dow Corning gel in the manufacture of their silicone gel breast implants.

Heyer-Schulte did furnish warnings to physicians concerning their silicone gel implants in a product insert data sheet (PIDS). The 1976 version of the PIDS that accompanied Mrs. Vassallo's implants included warnings that the implant shell could be easily cut or ruptured by excessive stresses, and that Heyer-Schulte could not guarantee gel containment in the case of a rupture. The warnings did not address the issue of gel bleed, the fact that a rupture could result from normal stresses and could persist undetected for a significant time period, or the consequences of gel migration in the body. The PIDS also contained a list of potential complications associated with breast implants, but this list did not address the risks of chronic inflammation, permanent tissue scarring, or possible effects on the immune system. Proposed revisions to the PIDS, which would have included "a warning to the effect that uncontained silicone gel may have untoward consequences," and complications of "migration of the silicone, with mild to severe ****915** consequences, including reduction of breast size and absorption of the silicone by the blood ***8** and lymph systems, resulting in damage to the liver and kidneys," were rejected by Heyer-Schulte's president in March, 1976. The president did issue a letter to doctors dated August 23, 1976, which stated that "[i]f a shell is torn[ ] with time and normal stresses the gel will migrate," and that "mild inflammation and polynuclear giant cell response characterized as mild foreign body reaction" had been associated with the silicone gel implants. Once again, this letter did not completely address the potential effects of silicone migration on the body's immune system. Mrs. Vassallo stated that, if she had known that the implants could cause permanent scarring, chronic inflammation, and problems with her immune system, she would not have gone ahead with the implantation procedure. We now turn to the issues appropriate for discussion.

1. The defendants filed three motions in limine to exclude the testimony of the plaintiffs' experts, Drs. Gershwin, Freundlich, and Batich. As to Dr. Gershwin's anticipated testimony, the defendants' motion sought to exclude his opinions that "silicone breast implants cause disease and that plaintiff['s] breast implants cause[d] her alleged illness." As to Dr. Freundlich's expert testimony, the defendants' motion sought to exclude his opinions that "(1) silicone can cause an atypical connective tissue disease in some women; (2) plaintiff['s] illness may be classified as an undifferentiated connective tissue disease; and (3) ... [the plaintiff's] disease is related to her silicone gel breast implants." As to Dr. Batich's anticipated testimony, the defendants' motion sought to exclude opinions "about what silicone does in the human body." Each motion put forth a number of grounds as to why the expected opinions by the plaintiffs' experts should be excluded. [FN6] The plaintiffs filed a detailed opposition to the defendants' motions. Together, the defendants' motions, and the plaintiffs' opposition, placed before the judge considerable documentary and other materials. The record prepared on the motions included references to medical and scientific publications, affidavits expressing the views of experts, and the transcript of a four-day evidentiary hearing, ***9** held in the United States District Court for the District of Oregon, [FN7] pursuant to the *Daubert* decisions, [FN8] on defense motions in limine in several consolidated products liability actions to exclude expert testimony offered by the plaintiffs on causation issues relating to alleged injuries claimed from silicone breast implants.

FN6. For example, the defendants' motion in limine argued, as to Dr. Gershwin, that he was not qualified to testify on the alleged degradation of silicone; that his methodologies were not scientific (because, according to the motion, he behaves like a litigation advocate, not a scientist, his testimony is unreliable, and he reached his conclusions by unscientific means); and that his testimony did not meet the legal requirements for expert testimony in a Massachusetts courtroom.

FN7. *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387 (D.Or.1996).

FN8. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir.), cert. denied, 516 U.S. 869, 116 S.Ct. 189, 133 L.Ed.2d 126 (1995).

The judge held a nonevidentiary pretrial hearing on the defense motions in limine. Although the defendants' counsel initially argued that an evidentiary hearing should be held on the three motions, similar to the hearing conducted in the Federal District Court in Oregon, they abandoned that position during the hearing and maintained, as to the testimony of Drs. Gershwin and Freundlich, that their causation opinions could be admitted at trial

only if "classical epidemiological studies" existed to support their causation conclusions. [FN9] On this point, counsel for the parties indicated that their respective positions could be resolved on the conflicting materials submitted by each side concerning the relatively narrow issue whether classical **916 epidemiological studies were a necessary predicate to the opinions expected to be offered by Drs. Gershwin and Freundlich. As to the anticipated testimony of Dr. Batich (and to a part of Dr. Gershwin's testimony), the defendants' trial counsel argued, primarily, that the testimony was unreliable because experts supplying data for Dr. Batich's conclusions had relied on certain studies involving the breakdown of silicone which had used, in the defendants' opinion, a scientifically questionable technique called nuclear magnetic resonance spectography (NMRS). [FN10] Once again, as had been done before, the parties left *10 the judge to decide the issue on the paper record without a separate evidentiary hearing.

FN9. Epidemiology is "[t]he study of the relationships between the various factors that determine the frequency and distribution of diseases in human and other animal populations." Stedman's Medical Dictionary 522 (25th ed.1990). To date, no epidemiological studies on the subject of silicone gel breast implants have definitively established a causal link between exposure to these implants and development of atypical connective tissue disease.

FN10. According to expert testimony at the *Daubert* hearing held by the Federal District Court in Oregon, nuclear magnetic resonance spectroscopy (NMRS) is "a technique for deciding the structure of molecules." The defendants argued that Dr. Batich's testimony concerning the degradation of silicone to silica in the body would be based on the NMRS testing of Dr. Leoncio Garrido, and that Dr. Garrido's work was not reliable because another scientist, Dr. Peter Macdonald, was not able to reproduce Dr. Garrido's findings.

The judge did not rule on the motions in limine at the conclusion of the pretrial hearing. The judge's final rulings were made at the trial, when each of the three plaintiffs' experts offered their opinions. At trial, the defendants' counsel objected to opinions elicited from Drs. Freundlich and Gershwin as to whether "silicone gel breast implants can cause an atypical connective tissue disease in someone." At this critical point, in response to a direct question asked by the judge, the defendants' counsel specified that their objection was based solely on the ground previously advanced at the pretrial hearing on the motions in limine that the opinions to be put before the jury by Drs. Gershwin and Freundlich were inadmissible "without epidemiologic studies." The judge ruled on the precise objection then made as follows: "Given that that's the ground, given the record that we have here on the motion[s] in limine, I'll deny the motion[s]."

With respect to Dr. Batich's testimony at trial, the defendants' counsel made only the argument, referred to above, that his testimony was inadmissible because he had relied on studies using the NMRS technique. The judge overruled the objection to Dr. Batich's testimony, stating that, on the basis of the record developed at the Federal District Court hearing in Oregon, including the testimony of a court-appointed independent expert in chemistry, "there is a sufficient basis to accept Dr. Batich's testimony, including any reliance on the [disputed NMRS] experiments and articles to satisfy a standard ... of reliability." The judge left the defendants' criticism of Dr. Batich's testimony for cross-examination.

The defendants make a wide assortment of arguments on appeal that the three challenged expert opinions, to use the caption headings in their appellate brief, did not meet "the *Frye* Test of General Acceptance in the Scientific Community," [FN11] that the "Medical Community Does Not Accept Plaintiffs' Experts' Conclusions," and that "Other of the *Lanigan* / *Daubert* Factors Do Not Support the Trial Court's Denial of [the Defendants'] *11 *Lanigan* Motions." [FN12] We need not consider any of the defendants' arguments for the reasons now discussed.

FN11. *Frye v. United States,* 293 F. 1013 (D.C.Cir.1923). Under the *Frye* test, expert testimony based on scientific knowledge is admissible only if it is generally accepted by the relevant scientific community.

FN12. *Commonwealth v. Lanigan,* 419 Mass. 15, 26, 641 N.E.2d 1342 (1994) (*Lanigan* ), in which we adopted the general principles expressed in the Federal *Daubert* decisions, note 8, *supra,* that the scientific reliability and validity of evidence may be established using factors derived from a variety of scientific principles in addition to, or in lieu of, general acceptance in the relevant scientific community (*Frye* test, note 11, *supra* ).

The defendants did not press for an evidentiary hearing on their motions in limine (and they do not

argue now that they should have had one). The defense was content, as the trial approached, to have the judge consider and decide their contentions on the record placed before her (which was primarily a paper record), and the defense limited its objection to a single point in the case of each expert. The particular point was reiterated at the crucial moments in the trial when **917 the judge was called on to make a final ruling on the motions in limine.

[1] On a record where objections are properly preserved, we may examine, on a de novo basis, a trial judge's decision made pursuant to the standards set forth in *Commonwealth v. Lanigan,* 419 Mass. 15, 641 N.E.2d 1342 (1994) (*Lanigan* ), to admit or exclude certain scientific expert evidence. *Commonwealth v. Vao Sok,* 425 Mass. 787, 797, 683 N.E.2d 671 (1997). Where, however, the party who has lost the evidentiary ruling preserves only a limited basis for review, we ordinarily examine only that basis, consistent with the established principle governing appellate review in civil cases that issues not properly raised in the trial court will not be considered on appeal. This principle was stated by Justice Quirico, writing for the Appeals Court in *Commonwealth v. Olson,* 24 Mass.App.Ct. 539, 544, 510 N.E.2d 787 (1987), as follows:

> "A lawyer cannot try a case on one theory and then, having lost on that theory, argue before an appellate court about alleged issues which might have been, but were not, raised at the trial. That is true whether or not the trial lawyer and the appellate lawyer are the same person, and whether or not they are in any way associated. The appeal must be based on what took place at the trial, not on anything which is presented for the first time before an appellate court."

See *Huber v. Huber,* 408 Mass. 495, 497, 561 N.E.2d 863 (1990); *Fishman v. Brooks,* 396 Mass. 643, 649, 487 N.E.2d 1377 (1986); *Kagan v. Levenson,* 334 Mass. 100, 107, 134 N.E.2d 415 (1956). *12 See also *Commonwealth v. Shea,* 401 Mass. 731, 740, 519 N.E.2d 1283 (1988) (defendant failed to renew objection when evidence sought to be suppressed was introduced at trial); *Commonwealth v. Gabbidon,* 398 Mass. 1, 7, 494 N.E.2d 1317 (1986) (filing of motion in limine to prevent the introduction of evidence does not, by itself, preserve appellate rights); *Freyermuth v. Lutfy,* 376 Mass. 612, 616, 382 N.E.2d 1059 (1978) ("The consequence of the failure to object is to waive the objection to the testimony").

[2] The judge properly concluded that the causation opinions of Drs. Gershwin and Freundlich could be admitted in the absence of classical epidemiological studies. Both witnesses possessed the knowledge, skill, and experience to qualify as experts in their fields, having conducted research, published in peer reviewed journals on silicone related topics, and treated hundreds of women with silicone gel breast implants in their clinical practices. At the *Daubert* hearing held by the Federal District Court in Oregon, the transcript of which was included in the record before the judge, Dr. Gershwin described the bases for his opinion that silicone gel breast implants cause disease in women as including animal studies and controlled, blinded, clinical studies showing stimulation of the immune system by silicone; animal studies showing migration of the silicone; clinical studies showing local complications of silicone, including chronic inflammation; and the differential diagnosis method of identifying a patient's symptoms as being among those associated with silicone gel breast implants and eliminating any other causes for these symptoms. Although there was conflicting testimony at the Oregon hearing as to the necessity of epidemiological data to establish causation of a disease, the judge appears to have accepted the testimony of an expert epidemiologist that, in the absence of epidemiology, it is "sound science ... to rely on case reports, clinical studies, in vivo tests, [and] animal tests." [FN13] The judge may also have relied on the affidavit of the plaintiffs' epidemiological expert, Dr. David S. Egilman, who identified several examples in which disease causation has been established based on animal and clinical case studies alone to demonstrate that "doctors utilize epidemiological data as one tool among many."

> FN13. Although epidemiological studies have been conducted to investigate the associations between silicone breast implants and various diseases, none of these studies has addressed the disease at issue in this trial, namely, atypical connective tissue disease.

*13 The judge's decision, that the plaintiffs' evidence of general causation (specifically the testimony of Drs. Gershwin and Freundlich) was scientifically valid despite the absence of **918 supporting epidemiological data, is consistent with decisions by other courts. See *Benedi v. McNeil-P.P.C., Inc.,* 66 F.3d 1378, 1384 (4th Cir.1995) (holding that epidemiological studies were not necessary to provide causal link between acetaminophen and liver damage in a person who regularly consumed alcohol, because the methodology underlying the expert's conclusion was

sound); *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124 (9th Cir.1994), cert. denied, 513 U.S. 1082, 115 S.Ct. 734, 130 L.Ed.2d 637 (1995) (upholding the District Court's decision to admit plaintiff's expert testimony regarding causal link between plaintiff's silicone gel breast implants and her mixed connective tissue disease, because the "experts based their opinions on the types of scientific data and ... techniques relied upon by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data to review"); *Jennings v. Baxter Healthcare Corp.*, 152 Or.App. 421, 437, 954 P.2d 829 (1998) (concluding that the trial court did not err in allowing testimony as to silicone-related disorders based on animal research and clinical experience using the differential diagnosis technique). Contrast In re Breast Implant Litig., Master File No. 96-S-9620 (D. Colo. June 3, 1998) (excluding expert testimony regarding causal link between silicone gel implants and autoimmune or systemic disease); *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387 (D.Or.1996) (excluding all testimony concerning a causal link between atypical connective tissue diseases and silicone gel implants as not based on accepted scientific testimony and not admissible under *Daubert* ); *Kelley v. American Heyer-Schulte Corp.*, 957 F.Supp. 873 (W.D.Tex.1997) (excluding expert testimony by plaintiff's epidemiologist and rheumatologist regarding a causal link between plaintiff's implants and her symptoms of Sjogren's Syndrome). Based on our review of the trial record, we cannot say that the judge erred in allowing the opinions of Drs. Gershwin and Freundlich as to causation in the absence of supporting epidemiological data. We emphasize that the relevant issue was the scientific validity of the methods relied on by the experts to form their conclusions. See *Commonwealth v. Lanigan, supra* at 25, 641 N.E.2d 1342. Challenges to the conclusions themselves go to the weight, not the admissibility, of the evidence, see *Commonwealth v. Gomes*, 403 Mass. 258, 273, 526 N.E.2d 1270 (1988), ***14** and the defendants were given ample opportunity to challenge these conclusions through cross-examination and the direct testimony of their own expert witnesses.

[3] The judge also had a basis for concluding that the opinion of Dr. Batich on the degradation of silicone in the human body should be admitted. Doctor Batich's testimony was based on his own in vitro and in vivo research on the effects of silicone in the body, internal studies conducted by Dow Corning, and the NMRS studies conducted by Dr. Leoncio Garrido, see note 10, *supra*. Doctor Batich's opinion was also supported by the testimony of Dr. Shanklin, who observed silica, a by-product of silicone degradation, in the tissue samples removed from Mrs. Vassallo at the time of explant. Doctor Shanklin's testimony preceded the judge's ruling on the defendants' motion in limine with respect to Dr. Batich, and was received without objection. The only basis for the defense motion in limine preserved for appeal was the scientific validity of Dr. Garrido's NMRS study. [FN14] This issue had been discussed in detail at the *Daubert* hearing, held by the Federal District Court in Oregon, by expert witnesses who both opposed and supported the scientific reliability of Dr. Garrido's research. In addition to the transcript of that hearing, the judge had before her the draft report of the independent chemistry expert appointed to review the ****919** testimony in the Oregon hearing, Dr. Ronald McClard, who concluded that, although Drs. Garrido and Macdonald (who conducted similar research) reached different results in their studies, "[Dr.] Garrido's claimed observations of [silicone] in the NMR is supported by scientifically valid reasoning and methodology ... and are clearly relevant to the matter at hand." The judge stated that she relied on both the transcript of the Oregon hearing and the report of Dr. McClard in ruling that Dr. Batich's testimony was sufficiently reliable to satisfy the applicable standard for ***15** admissibility. Given the conclusion of Dr. McClard, we cannot say that the judge erred in denying the defense motion in limine with respect to Dr. Batich.

> FN14. The following colloquy was held between the judge and defense counsel immediately prior to the ruling on the defense motion in limine with respect to Dr. Batich:
> THE JUDGE: "In connection with the Defendants' Motion in Limine concerning his [Dr. Batich's] testimony, I think as [defense counsel] has articulated, that the focus of the motion is the defendants' contention that the testimony that Dr. Batich would give is not reliable insofar as it is based on Dr. Batich's review of the Garrido experiments, and NMR results, is that correct ... ?" DEFENSE COUNSEL: "Reliance, your Honor."
> THE JUDGE: "Yes. It's based on that he relies upon that."

In view of the narrow issue before us, we need not decide whether, as argued by the plaintiffs, the opinions of their experts fall within those cases which accept expert testimony based on personal

observations, clinical experience, or generally accepted scientific techniques without application of the possibly more rigorous analysis set out in *Lanigan, supra,* [FN15] or whether, as argued by the defendants, the opinions require detailed consideration under *Lanigan* for determination of their inherent scientific reliability. We note, however, that the Federal courts (and other State courts) have taken the latter view and have conducted inquiries under the *Daubert* decisions (or the particular State counterpart). See, e.g., *Hall v. Baxter Healthcare Corp., supra; In re Breast Implant Cases,* 942 F.Supp. 958 (E. & S.D.N.Y.1996); *Jennings v. Baxter Healthcare Corp., supra.* We also point out as well that a national panel of experts has been appointed pursuant to Fed.R.Evid. 706 to try to arrive at a consensus concerning the admissibility of expert testimony of the type involved in this case. See *Hall v. Baxter Healthcare Corp., supra* at 1394. The report of this rule 706 panel may resolve the controversy surrounding claims of atypical connective tissue disease related to silicone breast implants.

FN15. See, e.g., *Commonwealth v. Gordon,* 422 Mass. 816, 842, 666 N.E.2d 122 (1996) (opinion based on eight years' experience with non- specific ortho-tolodine testing); *Commonwealth v. Avellar,* 416 Mass. 409, 417-418, 622 N.E.2d 625 (1993) (pediatrician's opinion that child victim's father exhibited inappropriate grief response at hospital); *Commonwealth v. Ghee,* 414 Mass. 313, 320, 607 N.E.2d 1005 (1993) (opinions based on physical comparisons of fingerprint photographs and die lines on plastic bags); *Commonwealth v. Cifizzari,* 397 Mass. 560, 569, 492 N.E.2d 357 (1986) (opinion that bite marks matched defendant's dental impression). The plaintiffs urge that a *Lanigan* analysis is only required when the proffered scientific evidence suggests a "mystic infallibility" or may usurp the jury's role as fact finder. See, e.g., *Commonwealth v. Rosier,* 425 Mass. 807, 813-814, 685 N.E.2d 739 (1997) (polymerase chain reaction [PCR]based DNA testing at STR loci); *Commonwealth v. Vao Sok,* 425 Mass. 787, 796-803, 683 N.E.2d 671 (1997) (PCR-based DNA testing at DQA1 and PM loci); *Commonwealth v. Sands,* 424 Mass. 184, 185-188, 675 N.E.2d 370 (1997) (Horizontal Gaze Nystagmus [HGN] testing); *Commonwealth v. Mendes,* 406 Mass. 201, 205-211, 547 N.E.2d 35 (1989) (polygraphy).

2. We next discuss the other issues argued as a basis for a new trial by the defendants.

[4][5] (a) The judge properly prevented the defendants' experts (as well as the plaintiffs' experts) from testifying on direct examination to the out- of-court opinions of other scientists in the ***16** absence of some specific exception to the hearsay rule (none was shown). The judge followed our established rule. *Grant v. Lewis/Boyle, Inc.,* 408 Mass. 269, 273, 557 N.E.2d 1136 (1990). Her ruling conformed with our decision in *Department of Youth Servs. v. A Juvenile,* 398 Mass. 516, 531, 499 N.E.2d 812 (1986), in which we declined to adopt Proposed Mass. R. Evid. 703 (the equivalent of Fed.R.Evid. 703), and instead, took "a modest step by permitting an expert to base an opinion on facts or data not in evidence if the facts or data are independently admissible and are a permissible basis for an expert to consider in formulating an opinion." See *Commonwealth v. Waite,* 422 Mass. 792, 803, 665 N.E.2d 982 (1996) ("When an expert provides the jury with an opinion regarding the facts of the case, that opinion must rest on a proper basis, else inadmissible evidence might enter in the guise of expert opinion"). There is nothing in *Commonwealth v. Lanigan, supra,* that casts doubt on, or suggests the need to reconsider, this rule. The judge correctly ruled that the defendants could use scientific ****920** studies and literature in cross-examination of the plaintiffs' experts. [FN16]

FN16. The defendants did, in fact, do this on several occasions, using epidemiological and other studies from the literature that favored the defense during the cross-examinations of Drs. Freundlich, Gershwin, and Pierre J. Blais.

(b) There was no error in the judge's rulings on certain items of evidence pertaining to the issue of notice to Heyer-Schulte of the safety of the gel implants. The defendants claim that they were prejudiced by the judge's rulings allowing the plaintiffs to introduce product complaints and Dow Corning studies that postdated Mrs. Vassallo's implants, while preventing the defendants from introducing documents allegedly reporting on implant safety assessments post-1977. The record does not support the defendants' contentions.

[6][7] First, the judge properly prohibited the defendants from asking their experts about the specifics of post-1977 published literature, including the results of a 1982 consensus development conference on silicone gel breast implants, because this testimony was hearsay with no independent basis for admission. See *Grant v. Lewis/Boyle, Inc.,*

*supra.* The judge did not abuse her discretion in ruling that the post-1977 silicone gel published literature was irrelevant on the issue of notice to Heyer-Schulte of problems related to Mrs. Vassallo's implants. This ruling was equally enforced against both the plaintiffs and the defendants.

[8][9][10] ***17** Second, the internal Dow Corning studies were admissible on grounds other than notice, that is, as business records providing evidence concerning the characteristics of the silicone gel used in Mrs. Vassallo's implants. Post-1977 Dow Corning studies remained admissible on these grounds because the gel composition did not change during these later years. The defendants took advantage of the ruling allowing post-1977 Dow Corning studies by introducing in evidence a 1986 Dow Corning study that favored their case. The defendants' reliance on the "curative admissibility doctrine" to justify this action is misplaced; this doctrine is only applicable if the original evidence being rebutted was improperly admitted, which is not the case here. See *Commonwealth v. Ruffen,* 399 Mass. 811, 813-814, 507 N.E.2d 684 (1987).

[11] Third, the defendants never objected to any testimony concerning post-1977 complaints, and again, took advantage of this evidence to ask their materials expert, Dr. Donald Uhlmann, about the number of rupture complaints received from physicians from 1974 to 1990 for implants manufactured in 1976. The defendants did object to sending post-1977 complaints to the jury during a discussion of the exhibits after the close of testimony. At that point, the judge properly ruled that the post-1977 complaints were admissible to show notice to Heyer-Schulte of specific problems experienced by purchasers and users of their silicone gel implants and were relevant to the issue of Heyer-Schulte's continuing duty to warn of risks discovered after the product at issue had been manufactured. See *doCanto v. Ametek, Inc.,* 367 Mass. 776, 784-785, 328 N.E.2d 873 (1975).

[12] (c) The judge properly allowed the plaintiffs to introduce evidence of complaints made to Heyer-Schulte on a year-by-year basis with an appropriate cautionary instruction to the jury that the complaints were "not admitted for the truth of what the complaints say," but for the jury's "consideration of what Heyer-Schulte was being told and was learning about its product." The complaints of substantially similar defects and consequences were admissible as evidence of notice to Heyer-Schulte of defects in the integrity of its product about which it had failed to warn. See *Burnham v. Mark IV Homes, Inc.,* 387 Mass. 575, 585, 441 N.E.2d 1027 (1982); *H.P. Hood & Sons v. Ford Motor Co.,* 370 Mass. 69, 75, 345 N.E.2d 683 (1976).

Moreover, the defendants' contention that the plaintiffs were allowed to present "undifferentiated boxes of complaints without any foundational showing that the products or grievances ***18** at issue were related to Mrs. Vassallo's" is not supported by the record. Prior to submitting the complaints to the jury, those concerning the single lumen gel ****921** implants were identified separately from the double lumen implants, which contained both gel and saline, and all complaints were categorized by year and type of problem (i.e., rupture, migration, and tissue reaction). Complaints concerning the double lumen implants were relevant with respect to rupture, because the shells of these implants were made of the same silicone material as the gel implants. The judge gave a limiting instruction to the jury that complaints concerning the types of implants other than the gel implant received by Mrs. Vassallo were only relevant insofar as notice of problems with the implant shell. This limiting instruction was sufficient to overcome any prejudice complained of by the defendants.

(d) There was no error in the admission of internal Dow Corning research documents concerning silicone. As previously discussed, these studies were admissible as business records, see G.L. c. 233, § 78 , providing evidence concerning the characteristics of the silicone gel used in Mrs. Vassallo's implants, and both parties took advantage of the judge's ruling. At trial, the defendants concurred that the studies were Dow Corning business records, but maintained that they were still inadmissible hearsay. The defendants now offer the specific argument that the Dow Corning studies were inadmissible as business records because they largely contained opinions. See *Julian v. Randazzo,* 380 Mass. 391, 393, 403 N.E.2d 931 (1980) (police report, comprising investigating officer's opinion and recommendation, not admissible); *Burke v. Memorial Hosp.,* 29 Mass.App.Ct. 948, 949, 558 N.E.2d 1146 (1990) ("Opinions contained in business records are not admissible unless they fall within some other exception to the hearsay rule"). However, the Dow Corning studies can be distinguished from the cases offered by the defendants. The police report in *Julian, supra* at 394, 403 N.E.2d 931, was "second-level" hearsay, consisting of information gained by

interviewing other police officers and bystander witnesses. The records offered in *Burke, supra* at 950, 558 N.E.2d 1146, were employee performance evaluations that, "by their very nature consisted almost entirely of judgmental evaluations and opinions." By contrast, the Dow Corning documents were scientific studies containing primarily factual data. While these studies may also have contained opinions regarding the authors' interpretations of the data, the ***19** defendants' objections were to the studies as a whole. No request was made to strike or exclude those portions containing inadmissible opinions. The defendants' motion was, therefore, overbroad as including competent evidence relevant to the composition and physiological effects of the silicone gel used in Mrs. Vassallo's implants. See *Griffin v. General Motors Corp.*, 380 Mass. 362, 365, 403 N.E.2d 402 (1980).

[13][14][15] (e) The defendants correctly point out that evidence of failure adequately to test a product is relevant to claims of design, manufacturing, or warning defects, but does not furnish a separate, independent basis for liability. See J.R. Nolan & L.J. Sartorio, Tort Law §§ 292-295 (2d ed. 1989 & 1998 Supp.); Restatement (Second) of Torts § 402A (1965). The judge's instruction that the jury could consider product testing in evaluating the design defect claim was not in error. However, the defendants argue that the judge based her findings of negligence and breach of warranty in connection with the G.L. c. 93A decision in part on inadequate testing when, as contended by the defendants, there was no evidence that additional testing would have disclosed otherwise unknown information affecting the design of the product or the provision of warnings. See *Mason v. General Motors Corp.*, 397 Mass. 183, 192, 490 N.E.2d 437 (1986) (failure to test not relevant absent a showing that useful information would have been derived from test). Regardless of whether additional testing performed by Heyer-Schulte would have revealed additional risks associated with the silicone gel implants, any error committed by the judge related to the issue of testing was non-prejudicial as the judge had independent bases to find negligence and a violation of G.L. c. 93A.

3. The evidence warrants the jury's findings (and their verdicts) on the negligence claims, and the defendants' arguments seeking judgment in their favor or a new trial on the negligence claims have been considered ****922** and rejected. No issue is raised as to the amount of damages awarded.

[16] Because the plaintiffs' recoveries can be upheld on the jury's findings of negligence, we need not address the defendants' claims of error concerning the breach of warranty count. We take this opportunity, however, to consider the defendants' argument that we should change our products liability law concerning the implied warranty of merchantability from what is stated in *Hayes v. Ariens Co.*, 391 Mass. 407, 413, 462 N.E.2d 273 (1984), and that the law should be reformulated to adopt a "state of the art" standard ***20** that conditions a manufacturer's liability on actual or constructive knowledge of the risks.

Our current law, regarding the duty to warn under the implied warranty of merchantability, presumes that a manufacturer was fully informed of all risks associated with the product at issue, regardless of the state of the art at the time of the sale, and amounts to strict liability for failure to warn of these risks. See *Simmons v. Monarch Mach. Tool Co.*, 413 Mass. 205, 207-208 n. 3, 596 N.E.2d 318 (1992); *Hayes, supra.* This rule has been justified by the public policy that a defective product, "unreasonably dangerous due to lack of adequate warning[s], [is] not fit for the ordinary purposes for which [it is] used regardless of the absence of fault on [a defendant's] part." *Id.*

At trial, the defendants requested a jury instruction that a manufacturer need only warn of risks "known or reasonably knowable in light of the generally accepted scientific knowledge available at the time of the manufacture and distribution of the device." The judge declined this request, and instead gave an instruction using language taken almost verbatim from that in *Hayes, supra.* While the judge's instruction was a correct statement of our law, we recognize that we are among a distinct minority of States that applies a hindsight analysis to the duty to warn. [FN17]

> FN17. The Reporters' Note to the Restatement (Third) of Torts: Products Liability § 2(c) comment m, at 106 (1998), lists four States taking the position that a manufacturer is charged with a duty to warn of risks without regard to whether the manufacturer knew or reasonably should have known of the risks, including Massachusetts; Hawaii, see *In re Haw. Fed. Asbestos Cases*, 960 F.2d 806 (9th Cir.1992) (applying Hawaii law); Pennsylvania, see *Dambacher v. Mallis*, 336 Pa.Super. 22, 485 A.2d 408 (1984); Washington, see *Ayers v. Johnson & Johnson Baby Prods. Co.*, 117 Wash.2d 747, 818 P.2d 1337 (1991).

The majority of States, either by case law or by statute, follow the principle expressed in Restatement (Second) of Torts § 402A comment j (1965), which states that "the seller is required to give warning against [a danger], if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the ... danger." See, e.g., M.F. Daller, Product Liability Desk Reference--a Fifty-State Compendium (1996 ed.); Annot., *Strict Products Liability: Liability for Failure to Warn as Dependent on Defendant's Knowledge of Danger*, 33 A.L.R.4th 368, 377 (1984 & 1997 Supp.); Restatement (Third) of Torts: Products Liability, Reporters' Note to comment m, at 104 (1998) ("An overwhelming ***21** majority of jurisdictions supports the proposition that a manufacturer has a duty to warn only of risks that were known or should have been known to a reasonable person"). At least three jurisdictions that previously applied strict liability to the duty to warn in a products liability claim have reversed themselves, either by statute or by decision, and now require knowledge, or reasonable knowability as a component of such a claim. See *Fibreboard Corp. v. Fenton*, 845 P.2d 1168, 1172-1173 (Colo.1993); *Feldman v. Lederle Labs.*, 97 N.J. 429, 455, 479 A.2d 374 (1984); La.Rev.Stat. Ann. § 9:2800.59(B) (West 1997). The change in the law of New Jersey is particularly relevant, because we relied in part on New Jersey law in formulating the strict liability standard expressed in the *Hayes* decision. See *Hayes, supra* at 413, 462 N.E.2d 273, citing *Beshada v. Johns-Manville Prods. Corp.*, 90 N.J. 191, 202-207, 447 A.2d 539 (1982).

The thin judicial support for a hindsight approach to the duty to warn is easily explained. The goal of the law is to induce conduct that is capable of being performed. This goal is not advanced by imposing liability ****923** for failure to warn of risks that were not capable of being known. See Henderson, Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, 65 N.Y.U. L.Rev. 265, 274 & n. 32 (1990).

The Restatement (Third) of Torts: Products Liability § 2(c) (1998), recently approved by the American Law Institute, reaffirms the principle expressed in Restatement (Second) of Torts, *supra* at § 402A comment j, by stating that a product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings ... and the omission of the instructions or warnings renders the product not reasonably safe." The rationale behind the principle is explained by stating that "[u]nforeseeable risks arising from foreseeable product use ... by definition cannot specifically be warned against." Restatement (Third) of Torts: Products Liability, *supra* at § 2 comment m, at 34. However, comment m also clarifies the manufacturer's duty "to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing ***22** would reveal. A seller is charged with knowledge of what reasonable testing would reveal." *Id.* [FN18]

> FN18. Several respected legal scholars, many of whom were advisors to the Restatement (Second) of Torts, Reporters to the Restatement (Third) of Torts formulation of the principles of product liability, or both, have concluded that liability for a failure to warn should not be imposed without a showing that a defendant knew or should have known of the alleged risk at the time the product was sold. See, e.g., Owen, Defectiveness Restated: Exploding the "Strict" Products Liability Myth, 1996 U. Ill. L.Rev. 743, 782-784; Henderson, Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, 65 N.Y.U. L.Rev. 265, 273-280 (1990); Wade, Symposium: The Passage of Time: The Implications for Product Liability: On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing, 58 N.Y.U. L.Rev. 734, 760 (1983).

We have stated that liability under the implied warranty of merchantability in Massachusetts is "congruent in nearly all respects with the principles expressed in Restatement (Second) of Torts § 402A." *Commonwealth v. Johnson Insulation*, 425 Mass. 650, 653-654, 682 N.E.2d 1323 (1997), quoting *Back v. Wickes Corp.*, 375 Mass. 633, 640, 378 N.E.2d 964 (1978). The main difference has been our application of a hindsight approach to the duty to warn of (and to provide adequate instructions regarding) risks associated with a product. We recognize that this approach has received substantial criticism in the literature, see note 18, *supra*, and, in fact, has not been uniformly applied by Massachusetts State and Federal courts. See, e.g., *Boston v. United States Gypsum Co.*, 37 Mass.App.Ct. 253, 261-262, 638 N.E.2d 1387 (1994) (noting, but not addressing, jury instruction that for a breach of warranty claim, the "duty to warn extends only to such dangers or defects about which the manufacturer either actually knew ... [or] which it reasonably should have known"); *Welch v. Keene Corp.*, 31 Mass.App.Ct. 157, 163 & n. 2, 575

N.E.2d 766 (1991) (noting that, for a breach of warranty claim, "a manufacturer has a duty to warn only as to those dangers about which the manufacturer actually knew or about which it reasonably should have known"); *Kotler v. American Tobacco Co.,* 926 F.2d 1217, 1231-1232 (1st Cir.1990), vacated on other grounds, 505 U.S. 1215, 112 S.Ct. 3019, 120 L.Ed.2d 891 (1992) (same); *Anderson v. Owens-Illinois, Inc.,* 799 F.2d 1, 4 (1st Cir.1986) (same); *Wasylow v. Glock, Inc.,* 975 F.Supp. 370, 378 (D.Mass.1996) (same).

[17][18] In recognition of the clear judicial trend regarding the duty to warn in products liability cases, and the principles stated in Restatement (Third) of Torts: Products Liability, *supra* at § 2(c) ***23** and comment m, we hereby revise our law to state that a defendant will not be held liable under an implied warranty of merchantability for failure to warn or provide instructions about risks that were not reasonably foreseeable at the time of sale or could not have been discovered by way of reasonable testing prior to marketing the product. A manufacturer will be held to the standard of knowledge of an expert in the appropriate field, and will remain subject to a continuing duty to warn (at least purchasers) of risks discovered following the sale of the product at ****924** issue. In accordance with the usual rule governing retroactivity in this type of action, the standard just expressed will apply to all claims on which a final judgment has not been entered, or as to which an appeal is pending or the appeal period has not expired, and to all claims on which an action is commenced after the release of this opinion. See *McCarthy v. Litton Indus., Inc.,* 410 Mass. 15, 25-26, 570 N.E.2d 1008 (1991); *Payton v. Abbott Labs,* 386 Mass. 540, 568-570, 437 N.E.2d 171 (1982). [FN19]

FN19. As previously stated, the jury's verdict on the negligence count precludes the defendants from benefiting from this change in the warranty law. See *Hayes v. Ariens Co.,* 391 Mass. 407, 410, 462 N.E.2d 273 (1984) (defendant cannot be found negligent without also breaching implied warranty of merchantability). Moreover, the jury appear to have found that the defendants did have actual or constructive knowledge of risks associated with the silicone breast implants that were not contained in any warnings issued with the product.

[19][20] 4. The judge made detailed findings of fact to support her rulings that G.L. c. 93A had been violated. The judge's findings are not clearly erroneous, her legal conclusions are sound, and, having found no error in the trial, we reject the defendants' argument that the G.L. c. 93A decision cannot stand. The judge could properly decline to assess additional compensatory damages on the G.L. c. 93A claim because such an assessment would duplicate the jury's award of damages. See *Calimlim v. Foreign Car Ctr., Inc.,* 392 Mass. 228, 235, 467 N.E.2d 443 (1984). The fact that Mr. Vassallo was not included in the demand letter sent under G.L. c. 93A, § 9, caused the defendants no prejudice because the award of attorney's fees and costs would, in any event, be attributable in its entirety to Mrs. Vassallo's G.L. c. 93A claim.

5. The judgments are affirmed. The plaintiffs may apply to a single justice of this court for an award of appellate attorney's fees and costs pursuant to G.L. c. 93A, § 9(4), and *Yorke Mgt. v. Castro,* 406 Mass. 17, 19-20, 546 N.E.2d 342 (1989).

*So ordered.*

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