Rel:12/01/2006 HOUSTON COUNTY HEALTH CARE V. WILLIAMS Rel:01/12/2007 AS MODIFIED ON DENIAL OF REHEARING

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SUPREME COURT OF ALABAMA

OCTOBER TERM, 2006-2007

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Houston County Health Care Authority d/b/a Southeast Alabama Medical Center d/b/a Dothan Surgery Center

v.

Cynthia Williams and Regina Clevenger

Appeal from Houston Circuit Court (CV-01-440)

HARWOOD, Justice.¹

¹This case was originally assigned to another Justice on this Court; it was reassigned to Justice Harwood on May 10, 2006.

Houston County Health Care Authority d/b/a Southeast Alabama Medical Center d/b/a Dothan Surgery Center ("SAMC") appeals pursuant to Ala. Code 1975, § 6-5-642, from the order of the Houston Circuit Court certifying a class action in a lawsuit pending against SAMC. We vacate the classcertification order and remand the case for further proceedings consistent with this opinion.

Background Facts

SAMC operates an ambulatory-surgery center ("the center") in Dothan. Two plastic surgeons, Dr. Dwight Baker and Dr. Richard McClintock, frequently performed cosmetic breast augmentation ("CBA") procedures at the center between May 1998 and August 2001 using saline-filled silicone breast implants. Until January 31, 2001, they each used the "open bowl" technique to fill the breast-implant shells with saline. As explained in a March 12, 2002, report (hereinafter "the CDC report") prepared by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services ("the CDC"):

"In the 'open bowl' technique, an empty, sterile plastic bowl was placed on the instrument tray before the woman arrived in the OR [operating room]. The circulating nurse (or assistant) then took a

bottle of saline for irrigation out of the warming cabinet (across the hall from OR-2) ... and poured the saline into the bowl. The saline in the bowl was exposed to the air and environment. After the woman arrived in the OR 5-55 minutes later, she was prepped and anesthetized. A tissue pocket then was created in the right glandular and muscular tissue for the implant.

"....

"The scrub nurse removed the breast implant from sterile packaging ...[,] attached its the manufacturer's filling tube to the diaphragm valve in the silicone shell ... [,] used a 60-ml syringe to draw-up saline from the open bowl and injected the saline into the implant via a filling tube. ... The scrub nurse detached the syringe from the filling tube, repeated the procedure, and removed any trapped air bubbles. Next, the surgeon placed the implant (filled with 120 m. of saline) into the tissue pocket. More saline was drawn up by the scrub nurse and injected into the [implant] by the assistant until the desired shape and size were achieved. A similar pocket was created on the left side, and the procedure repeated for the other implant."

On December 21, 2000, Dr. Baker removed an implant from the right breast of a patient in whom he had inserted bilateral implants at SAMC's surgery center on August 10, 2000. The patient had developed chronic inflammation in her right breast resulting in capsular contracture. Upon removing the right implant, Dr. Baker noticed an abnormal black sediment in it. The material was cultured and found to be

Curvularia spp., a soil fungus that produces airborne spores and can thus become present elsewhere in the environment.² The patient's left implant was not removed.

On January 26, 2001, Lori Faust, another patient in whom Dr. Baker had surgically placed implants at the center on September 12, 2000, returned to him complaining of swelling and intense pain in her right breast. He surgically explored the breast that day and found inflammation evidencing an early infection; when he removed the implant he noticed many particles of black residue in the implant itself. Curvularia was cultured from the residue in the implant, but not from the inflamed breast tissue. Dr. Baker elected to remove not only the right implant but also the left implant; the fluid in the left implant was clear, without any evidence of residue, and there was no inflammation or other sign of infection in the left breast.

After this second discovery of Curvularia-contaminated implant saline, Dr. Baker and Dr. McClintock discontinued their use of the "open bowl" technique; Dr. Baker began using

²"Curvularia spp." designates species of the genus Curvularia. <u>Stedman's Medical Dictionary</u> 439, 1659 (Lippincott Williams & Wilkins 2000).

a "closed system," whereby the saline was transferred from the bottle into the implant without any exposure to the air, and Dr. McClintock began covering the bowl of saline with a sterile drape.³

Dr. Baker presented the Faust implant-contamination case to SAMC's infection-control committee on February 6, 2001. The committee instituted a quality-assurance investigation that month, obtaining in the process fungal cultures from the air vents in the surgery center. The cultures were negative for Curvularia. On May 29, July 12, and July 19, 2001, respectively, Dr. Baker removed both implants from three women for whom he had performed bilateral CBAs at the center on August 31, June 1, and July 8, 2000, respectively.⁴ The removals ("explantations") were performed for reasons unrelated to any symptoms of breast discomfort or any signs of possible infection. As a purely incidental finding at each explantation, Dr. Baker discovered abnormal residue in one of

³In April 2001 Dr. Baker transferred his practice to another surgery center, and in June 2001 Dr. McClintock retired from practice.

⁴On June 22, 2001, Faust sued SAMC and McGahan Medical Corporation, the manufacturer of her implants, in the Houston Circuit Court.

the two implants removed. When cultured, that residue was identified as Curvularia. All the women made a full recovery from their explantations without any signs or symptoms of fungal infection. (For convenience, these five cases of known Curvularia-implant contamination will be referred to as "the original five.")

The infection-control committee contacted the CDC on July 16, 2001, and, after a necessary liaison was established through the appropriate local and state health officials, the CDC was invited on July 20 to assist in an epidemiologic investigation to identify the source and risk factors of the Curvularia contamination. CDC personnel arrived at the surgery center on July 24 and began an on-site investigation, which concluded with an "exit interview" with SAMC staff on August 8. The CDC report comprises 15 pages of single-spaced typewritten text and five attachments. The CDC noted that Dr. Baker had performed the CBAs for all the original five. Ιt determined that he had performed four of those CBAs in operating room 2 ("OR-2") of the center's four operating rooms and that each of those procedures had lasted longer than the average of the 228 CBAs identified by the CDC as having been

performed at the center during the "study period" selected by the CDC: May 1 through September 30, 2000. (As noted, the CBAs for the original five were performed within that time period.)

Various features of the physical plant of the surgery center immediately adjacent to one or more of the operating rooms were considered likely contributors to fungal growth and the spread of fungal spores, including moisture sources and variances in air-current distribution. Two of the operating rooms, including OR-2, were found to have negative air pressure, contrary to the established standard requiring that operating rooms have positive air pressure. As a consequence, when the door to each of those two operating rooms was opened, air from the adjacent corridor was drawn in.⁵ The final staging area for the saline bottles before they were delivered into an operating room was the warming cabinet located only six feet immediately across the corridor from the door to OR-This cabinet was opened 60-70 times a day and had never 2. been cleaned. Curvularia was isolated from the nasal mucus of

⁵If positive air pressure had been maintained, interior air would have been pushed out into the corridor when the door was opened.

35 percent of the center's staff, including Dr. Baker and the nurse who had assisted him in the CBAs for four of the original five. No Curvularia was isolated from Dr. McClintock's nasal mucus.

The CDC report concluded that "[t]he saline used to fill the silicone shells probably was contaminated while sitting in an open bowl before and during the procedure in the OR." It noted that "OR-2 and duration of time in the OR were associated with an increased risk of acquiring Curvularia spp. contamination of implanted [implants]." The CDC advanced the following hypothesis as to how the implant contamination had occurred:

"The source of the fungal spores could have been the ambient air of the OR, [Dr. Baker], [his regular nurse assistant], or other culture positive personnel, or the surface of the saline bottle. А likely scenario to explain the contamination is that the moist sheetrock ceiling in the sterile supply room provided favorable growth conditions for fungi, including Curvularia spp. Fungal spores, via air currents, dust, or water droplets, then settled from the ceiling onto the surface of the saline bottles stored directly under the water-damaged ceiling. The contaminated saline bottles then were placed into the warming cabinet, where the constant opening and closing of the cabinet door resulted in air drafts laden with fungal spores. The air-borne fungal spores then were then drawn into OR-2 which was at negative pressure and located directly opposite the warming cabinet. This scenario would

explain why women who had their surgical procedure in OR-2 were at increased risk of [having a Curvularia contaminated implant].

"One of [the original five] was operated on in OR-1. Curvularia spp. could have been dislodged from the surface of the saline bottle as the saline was being poured into the open bowl. It is plausible that [the nurse assistant] or [Dr. Baker] shed [a species of Curvularia], although it was not possible to establish linkage to either on epidemiologic evidence."

The CDC noted that as of the time of the CDC report, 17 other women who had undergone bilateral CBAs at the center later had explantations for various reasons, and the saline in their implants had been found in every instance to be clear and uncontaminated. The CDC also noted that the time frame of the CBAs of the original five overlapped the time when a new air-handling system had been installed at the center and was also a time of the year of greater relative humidity.

The CDC report concluded with a reiteration of the recommendations it had shared with SAMC personnel at its August 8, 2001, exit interview. It recommended that only a "closed system" be used to fill breast implants; that the center be closed for all further surgery until its airhandling system had been properly balanced, airflow direction adjusted, and moisture-control problems corrected; and that

all women who had undergone a CBA using the open-bowl technique between April 1, 2000, and January 31, 2001, be notified that they might be at risk of having implants contaminated with Curvularia. The CDC explained that at the time of the exit interview, it had suggested a beginning date of May 1 for notification, but on November 15 had suggested moving that date back to April 1 in order to afford a "twomonth buffer before the earliest operation date for one of [the original five]." The January 31, 2001, "cutoff" date was chosen because Dr. Baker and Dr. McClintock had by then stopped using the open-bowl method. SAMC had already ceased admitting patients to the center on August 29, 2001; it did not reopen the center until extensive renovations and remediations had been accomplished.

Responsive to the CDC's exit-interview recommendation, as revised on November 15, SAMC sent identical letters on December 5 to the 384 women who had undergone open-bowl CBA surgery at the center during the time frame specified by the CDC. The letter read:

"We are contacting you to notify you about a problem we identified with some saline-filled breast implants used during the time period when your breast augmentation surgery took place at [the

center]. Women who underwent breast augmentation procedures with saline-filled implants at [the center] during the period between April 1, 2000 and January 31, 2001 may potentially be at risk for having a fungal contaminant in the saline within their implants. We have conducted a formal evaluation of the problem with the assistance of the [CDC].

"While the majority of the women who had these implants have had no symptoms or problems due to the contaminant, the potential for an infection or inflammatory reaction increases and exists if any leakage from the implant occurs. As of this time, we know of only one patient who has developed a medical problem as a direct result of the fungal contaminant, and this was a localized inflammatory reaction or infection in the breast. The symptoms of such an inflammatory reaction or infection would include breast tenderness, hardness to the touch, redness, or pain in the breast.

"It is important that you contact Dr. Dwight Baker's office at [local and long-distance telephone numbers provided]. An appointment will be made for you to meet with Dr. Baker so that he can evaluate your potential risks in connection with this fungal contaminant and the options available to you. Arrangements have been made so that this appointment will be provided to you at no cost. This number should be contacted whether you were Dr. Baker's surgical patient or Dr. McClintock's surgical patient."

The Litigation

Faust sued SAMC and McGahan Medical Corporation, the alleged manufacturer of the implant shells, on June 22, 2001.⁶

⁶A <u>pro tanto</u> settlement between the plaintiffs and McGahan eliminated it from the case, and its temporary involvement in

She filed a third amendment to her complaint on February 26, 2002, for the purpose of adding Cynthia Williams, Regina Clevenger, and Wanda DeShazo as plaintiffs and recasting the complaint into 15 numbered counts.⁷ Williams averred that Dr. Baker had performed a bilateral CBA on her at the center on October 4, 2000, and that, after she received SAMC's December 5, 2001, letter, she arranged to have her implants removed on December 26, 2001. She averred further that subsequent microbiological examination revealed that the saline within one of her removed implants was contaminated with a fungus. Clevenger stated that Dr. Baker performed a bilateral CBA on that she likewise had received a copy of the December 5, 2001, letter.

Against SAMC the plaintiffs asserted claims labeled "breach of implied warranty"; "medical malpractice"; "AEMLD," i.e., a claim under the Alabama Extended Manufacturer's Liability Doctrine for allegedly providing defective products

the litigation is not relevant to the issues hereinafter discussed.

⁷DeShazo was subsequently dismissed on her own motion, and her temporary involvement with the action is irrelevant to the issues now before the Court. She claimed a fungal infection associated with foot surgery performed at the center on June 1, 2001, by a third surgeon.

unreasonably dangerous for the use for which they were intended; "premises liability"; "duty to warn"; "suppression"; "res ipsa loquitur"; and "class action complaint," seeking certification of their action as a class action. In that final claim, the plaintiffs asserted that the questions of law and fact common to the class included "whether SAMC's' conduct constituted outrageous conduct which caused plaintiffs and the class members to suffer severe and genuine emotional distress, including a reasonable fear of developing life-threatening and debilitating disease." The "class action complaint" also sought "equitable relief in the form of a Court-ordered and supervised medical monitoring program, funded by defendants to assist Plaintiffs and the Class Members in early detection and treatment of illnesses caused by their exposure to the various fungi." Thereafter, DeShazo and Faust filed motions asking that their claims against the defendants be severed and that the class action be dismissed as to them, with Williams and Clevenger to continue to serve as representative plaintiffs for the class action. The circuit court granted those motions on August 27, 2002, and the case proceeded with only Williams

and Clevenger as named plaintiffs and putative class representatives.

The Law Applicable to Class Actions

"In order to obtain class certification, [the plaintiffs] must establish all of the criteria set forth in Rule 23(a), [Ala. R. Civ. P.,] and at least one of the criteria set forth in Rule 23(b). <u>Ex</u> parte AmSouth Bancorporation, 717 So. 2d 357, 362 (Ala. 1998). Rule 23(a) provides:

"'(a) Prerequisites to a Class Action. One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.'

"Rule 23(b) provides, in pertinent part:

"'(b) Class Actions Maintainable. An action may be maintained as a class action if the prerequisites of subdivision (a) are satisfied, and in addition:

"'....

"'(3) the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a

class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of of the class members in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of claims in the particular the forum; (D) the difficulties likely to be encountered in the management of a class action.'

"In reviewing a class-certification order, this Court looks to see whether the trial court exceeded its discretion in entering the order; however, we review de novo the question whether the trial court applied the correct legal standard in reaching its decision. <u>Reynolds Metals Co. v. Hill</u>, 825 So. 2d 100, 104 (Ala. 2002).

"'We note that an abuse of discretion in certifying a class action may be predicated upon a showing by the party seeking to have the class-certification order set aside that "the party seeking class action certification failed to carry the burden of producing sufficient evidence to satisfy the requirements of Rule 23." <u>Ex parte</u> <u>Green Tree Fin. Corp.</u>, 684 So. 2d 1302, 1307 (Ala. 1996). Thus, we must consider the sufficiency of the evidence submitted by the plaintiff customers.' "Compass Bank v. Snow, 823 So. 2d 667, 672 (Ala. 2001). If [the plaintiffs] failed to meet the evidentiary burden as required by Rule 23, then the trial court exceeded its discretion in certifying a class action. <u>Smart Professional Photocopy Corp. v.</u> Childers-Sims, 850 So. 2d 1245, 1248 (Ala. 2002).

"As noted above, Rule 23(b)(3) requires a finding that 'questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.' This requirement '"tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation."' Reynolds Metals, 825 So. 2d at 104 (quoting Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 623, 117 S.Ct. 2231, 689 (1997)). In 138 L.Ed.2d making this determination, '[c]ourts examine the substantive law applicable to the claims and determine whether the plaintiffs presented sufficient proof that common questions of law or fact predominate over individual claims.' Voyager Ins. Cos. v. Whitson, 867 So. 2d 1065, 1071 (Ala. 2003). 'When individual issues predominate over the common claims, manageability of the action as a class is not possible.' Voyager Ins., 867 So. 2d at 1077. Therefore, this Court must determine whether [the plaintiffs] presented sufficient evidence that common questions of law or fact predominate over individual issues as to each of [the plaintiffs'] claims."

University Fed. Credit Union v. Grayson, 878 So. 2d 280, 285-

86 (Ala. 2003).

Section 6-5-641(e), Ala. Code 1975, provides, in pertinent part, as follows:

"When deciding whether a requested class is to be certified, the court shall determine, by employing a rigorous analysis, if the party or parties requesting class certification have proved its or their entitlement to class certification under Ala. R. Civ. P. 23. The burden of coming forward with such proof shall at all times be on the party or parties seeking certification, and if such proof shall not have been adduced, the court shall not order certification of the class. In making this determination, the court shall analyze all factors required by Ala. R. Civ. P. 23 for certification of a class and shall not order certification unless all such factors shall have been established."

This Court has explained:

"In determining whether the questions of law or fact common to the class members predominate over those questions that affect only individual class members, the court must initially identify the substantive law applicable to the case and identify the proof that will be necessary to establish the claim. <u>Alabama v. Blue Bird Body Co.</u>, 573 F.2d 309, 316 (5th Cir. 1978). This consideration is particularly important in cases where one or more of the claims will require proof of subjective factors"

Ex parte Green Tree Fin. Corp., 723 So. 2d 6, 9 (Ala. 1998).

"We have held that the necessity of individualized testimonies from each class member to prove an essential element of the cause of action defeats class certification. <u>Reynolds Metals Co. v. Hill</u>, 825 So. 2d 100 (Ala. 2002); <u>Compass Bank v. Snow</u>, [823 So. 2d 667 (Ala. 2001)]."

Smart Prof'l Photocopy Corp. v. Childers-Sims, 850 So. 2d

1245, 1249 (Ala. 2002).

"The mandate to identify the 'substantive law applicable to the case' requires more than a simple statement of which state's law governs; the trial court is required to identify the elements of the claims to be certified and to discuss, in the context of the class-certification criteria, the proof the plaintiffs must present to establish each of those elements. It is only by specifically discussing the elements of each claim in the context of the Rule 23 criteria that the trial court may determine whether the plaintiffs can establish the 23(a) 23(b) elements Rule and of class certification. See e.g., Mann [v. GTE Mobilnet of Birmingham Inc., 730 So. 2d 150, 152 (Ala.1999)]; Ex parte Green Tree Fin. Corp., 723 So. 2d 6 [(Ala. 1998)]."

<u>Bill Heard Chevrolet Co. v. Thomas</u>, 819 So. 2d 34, 41-42 (Ala. 2001).

In connection with the plaintiffs' burden to demonstrate that class certification is proper, "[t]he trial court may not merely rely on assurances of counsel that any problems with predominance or superiority ... can be overcome." <u>Ex parte</u> <u>Green Tree Fin. Corp</u>. 723 So. 2d at 10. "'If serious manageability problems exists, it is no answer to say that they will be resolved later in some unexplained or uncertain manner.'" <u>Compass Bank v. Snow</u>, 823 So. 2d 667, 675 (Ala. 2001) (quoting with approval an unpublished order issued by a federal district judge in a case involving claims virtually identical to those asserted in <u>Snow</u>).

"If a named plaintiff has not been injured by the wrong alleged in the complaint, then no case or controversy is presented and the plaintiff has no standing to sue either on his own behalf or on behalf of a class." <u>Ex parte Prudential</u> <u>Ins. Co. of America</u>, 721 So. 2d 1135, 1137 (Ala. 1998). This Court has noted that

"'[t]he definition of a class cannot be so broad that it includes persons without standing to bring the action on their <u>own behalf</u>. Each class member must have standing to bring the suit <u>in his own</u> <u>right</u>.' <u>Slaughter v. Levine</u>, 598 F. Supp. 1035, 1041 (D.Minn. 1984) (emphasis added), aff'd, 801 F.2d 288 (8th Cir. 1986), <u>rev'd sub nom</u>. on other grounds, <u>Gardebring v. Jenkins</u>, 485 U.S. 415, 108 S.Ct. 1306, 99 L.Ed.2d 515 (1988); see also <u>Rios v. Marshall</u>, 100 F.R.D. 395, 407 (S.D.N.Y. 1983) ('class definition ... should be limited to those individuals who were adversely affected by the practices of which the named plaintiffs complain')."

Ex parte Central Bank of the South, 675 So. 2d 403, 406-07 (Ala. 1996). "There would be no reason to certify a class on a claim that is not viable." <u>Mutual Sav. Life Ins. Co. v.</u> <u>James River Corp. of Virginia</u>, 716 So. 2d 1172, 1180 (Ala. 1998).

The Class-Certification Hearing

At the class-certification hearing convened on October 14, 2002, the plaintiffs presented expert testimony from Dr.

Stephen Moser, an associate professor of pathology and associate director of the diagnostic microbiology laboratory at the University of Alabama at Birmingham ("UAB") Health System; Dr. Bayard Tynes, an internist and professor of medicine and infectious diseases at UAB; and Dr. Paul Howard, an associate clinical professor of plastic surgery at UAB. Williams and Clevenger also testified, and they introduced the deposition of Dr. Baker. Additionally, the plaintiffs introduced "every deposition that has been taken" by either introduced over 140 side, and the parties exhibits, contributing to the voluminous record in this appeal. SAMC presented expert testimony from Dr. Trish Perl, an associate professor of medicine in infectious diseases and a hospital epidemiologist at Johns Hopkins Hospital in Baltimore, and Dr. Ronald Nichols, a professor of surgery and microbiologist at Tulane Medical School in New Orleans, with special expertise in surgical infection control.

Dr. Baker testified that he had used the "open bowl" method from the time he arrived at the center in January 1999 until he began using a closed system after January 31, 2001. He acknowledged that microscopic fungal spores in the air in

an operating room could have gotten into the saline in the open bowl. He had used equally all four operating rooms at the center. At the time of his June 1, 2002, deposition, he had performed 143 explantations on returning patients. All removed implants had been clear and apparently uncontaminated except for the second implant removed from one of the original five; it, like her first explanted implant, contained black particles in the saline. He further testified, and the other experts concurred, that the only way to determine whether fungal contamination is present in an implant is to remove the implant for examination.

By the time of the class-certification hearing, more women who had had CBAs at the center had elected to have their implants removed. The CDC had tested all the implants and provided culture reports reflecting that only the second implant Dr. Baker had removed from one of the original five had tested positive for Curvularia. Out of a total of over 180 sets of implants removed following SAMC's December 5 notification letter and sent to the CDC for testing, all had tested negative for Curvularia except the second implant from one of the original five.

Moser, retained by counsel for the plaintiffs, Dr. conducted an inspection of the center on September 18, 2001. By then it had been closed for several weeks, and operating rooms 1, 2, and 3 had undergone extensive demolition. In the report Dr. Moser submitted following the inspection, he noted that because of the demolition, the center at the time of his inspection was "heavily contaminated with dust," precluding "meaningful quantitative counts of airborne fungi." Dr. Moser did observe extensive evidence of mold contamination and "[t]he presence of moisture on sheetrock [indicated] that this might be a longer-term problem." Based on the details provided by the CDC report and other information available to him, he believed that conditions conducive to fungal growth were "more than likely consistent throughout [the time from 1998 until the center was closed] and the probability of exposure would be high." Dr. Moser opined that "during that period of time it would be highly probable that organisms were in the environment and potentially could have exposed people in that environment." He acknowledged that the amount of fungi in the air to which patients might be exposed would differ according to the date and duration of the surgery, how

long the saline sat in the open bowl, the amount of saline injected, and the humidity condition of the time of year. He also recognized that a woman undergoing a CBA in OR-2 would be at greater risk of exposure than if the CBA had been performed in another operating room. Dr. Moser's definition of exposure was "whether or not the fungus was probably present in the environment at the time"; he explained that "the conditions, whether they be periodic or not, over this period of time favored that exposure." As to whether that created any risk to a particular patient, or what that risk would be, Dr. Moser indicated, "you need to ask the physicians." Dr. Moser explained further that even if a fungal spore was present in implant saline when it was inserted, it might not "persist" and grow.

Dr. Tynes testified that the moisture problems at the center and "high humidity problems" were conducive to mold growth and that the negative pressure in two of the operating rooms meant that there was "a higher degree of outside organisms coming into the operating room rather than having a sterile condition inside and pushing these to the outside." He believed that all the patients were "potentially exposed"

to fungal spores, although the more recent CDC data "shows that there are maybe less than we thought there might be initially." He agreed that a patient whose CBA had been performed in OR-2 was at greater risk for Curvularia; that the identity of the surgeon who did the CBA was a risk factor; and that the duration of the surgery and how long the saline bowl was left open were also risk factors. Dr. Tynes explained that sooner or later all breast implants will leak. He testified that breast-implant Curvularia could cause serious health consequences if a leak occurs, but it is also possible for Curvularia-contaminated saline to leak out of a breast implant and cause no health problems. The CDC report, introduced at the class-certification hearing, stated that if breast implants

"remain intact, the risk of local or disseminated disease should be minimal. However, the incidence of [implant] deflation through leakage is estimated to be 1% to 4% per year for the first 10 years. ... The relative high leakage rate of [implants] is Curvularia concerning because spp. or other pathogens may escape during leakage and result in local soft tissue infection or disseminated disease."

Dr. Howard testified that breast implants leak at the rate of 1 to 2 percent per year and that the chance of an

implant rupturing after 8 to 10 years is probably greater than 50 percent. Dr. Howard therefore tells all his patients that they should have their implants replaced at that point in time. He has never used the open-bowl technique in performing a CBA. According to Dr. Howard, a woman having a CBA in an operating room contaminated by fungus would "probably be okay" if nothing was placed in her body that was contaminated with the fungus, but if the open-bowl technique was selected by the surgeon, "I would say [contamination is] more likely." An implant is not contaminated just because there is fungus in the air; contamination occurs only if the fungus ends up in the implant. Dr. Howard testified that a decision to use the open-bowl technique is the surgeon's, but that the standard of care would dictate that the surgeon follow the manufacturer's instruction on use of the silicone implant, which usually recommends a closed system for the saline. A contaminated implant creates the possibility of future inflammation or infection, but, based on the latest CDC test results on the removed implants, Dr. Howard placed the risk of Curvularia infection at less than two percent.

SAMC's two expert witnesses likewise viewed the risk of Curvularia contamination for any particular patient as quite low, in light of the negative test results reported by the CDC. Dr. Nichols characterized the risk for infection as "very, very, a very low," believing it to be less than one percent. Dr. Perl testified that "the risk of contamination [of a proposed class member] is extremely low, although I will admit that it probably varies from patient to patient." Given that only one of the six known cases of implant fungal contamination involved possible infection, Dr. Perl calculated the risk of infection for the class members to be .25 to .5 percent.

Williams testified that after she received SAMC's letter she went to see Dr. Baker, and he recommended that she have her implants taken out and tested, explaining that there was no other way to determine if fungal contamination was present in them. He told her that SAMC would pay for the explantation. Because of the mistrust Williams had by then developed for Dr. Baker and SAMC, she elected to have her implants removed by another surgeon in Dothan on December 26, 2001, at her own expense. The removal surgery cost Williams

\$3,200. Williams testified concerning her emotional upset after she received SAMC's letter and the financial hardship imposed on her by the cost of the explantation surgery. Apparently, her removed implants were not sent to the CDC but rather were turned over to Dr. Moser. He testified that he tested them and found a fungus present in the left implant but not in the right one. He was unable to determine the type of fungus involved because it was "a sterile isolate"; he could classify it only as some sort of fungus, "a mold," and he could not rule out the possibility that it was Curvularia.

Clevenger testified that she telephoned Dr. Baker's office after she had received SAMC's notification letter, and Dr. Baker's office arranged a conference call between Clevenger and Dr. McClintock. He advised her that it would be in her best interest to have her implants removed and replaced and that he would have Dr. Baker call her back, but she never heard from Dr. Baker. As of the date of the hearing, she had not had her implants removed, although she testified that she wanted to have that done eventually. She knew that SAMC would pay for the procedure if she had Dr. Baker perform the explantation at the center, but she no longer trusted him or

SAMC, and she wanted to have the procedure done in her hometown of Macon, Georgia. At the time of the hearing, however, she did not have the money to pay for the surgery. She testified that she has not yet experienced any signs or symptoms of any problems with her breasts.

The Class-Certification Order

On March 12, 2003, the trial court entered its classcertification order, certifying a class composed of "[a]ll women who underwent breast augmentation at [the center] with saline breast implants (not pre-filled from the manufacturer) between April 1, 2000, and January 31, 2001." After reciting the factual background of the case, the court discussed application to the facts of the various requirements of Rule 23(a) and (b), Ala. R. Civ. P., discussing in turn "numerosity," "commonality," "typicality," "adequacy," and finally "predominance" and "superiority." With respect to predominance, the court declared:

"An exposure type mass tort is 'particularly appropriate' for class action treatment.¹³ In this particular matter it is the view of the Court that the question of predominance requires an analysis as to whether questions of law and fact regarding liability predominate over questions of law and fact as to the individual class members' damages. Counsel for Plaintiffs outlined a number of

liability issues common to all members of the class. Among those issues, which are compelling to the Court, are the cause of the fungus, the exposure to the fungus, the source of the fungus, matters involving informed consent, the use of the open bowl method, the same filling method, and the same storage of the saline at the Center. The court would add to this list that all class members used just two physicians at one facility. Also all were exposed during roughly the same time period as the women whose contaminated implants were removed. Ιn addition to these common facts, the questions of law regarding liability are the same with all of the class.

"Even in questions of damages the law would be the same with each member of the class. In the event the jury determines liability, factual issues of damages will vary from member to member; however, issues of non-compensatory damages will be fairly common to all members of the class. For example, the question of lost income, if any, will vary from member to member;¹⁴ however, should the jury award mental anguish or punitive damages, many common issues of law and fact would be involved.

"¹³<u>Ex parte Russell Corp.</u>, 703 So. 2d 953 (Ala. 1997).

"¹⁴On the other hand, present medical expenses of the large majority of the subclass who have had their explants removed have already been absorbed by [SAMC] thus obviating a jury determination of these amounts."

With respect to the introductory sentence of this section of the trial court's order, we note the following: This Court's opinion in <u>Ex parte Russell Corp.</u>, which the trial

court cites as authority, although vacating the order certifying the class, does contain the statement that the facts and issues involved in that case "make it particularly appropriate for class relief." 703 So. 2d at 965. That statement was clearly dictum, as the special writing of Justice Houston, joined by Chief Justice Hooper, points out. 703 So. 2d at 966 (Houston, J., concurring in the result). Of the seven Justices participating in the case, only the author of the opinion and two other Justices approved the statement. So. 2d at 968 (Cook, J., dissenting, joined by Shores, 703 J.). Therefore, as this Court later pointed out in Regions Bank v. Lee, 905 So. 2d 765, 771 n. 5 (Ala. 2004): "[T]he law [on the adequacy issue] as stated in <u>Russell</u> is not binding on this Court."

The class-certification order in the instant case certified the entire action for class-action treatment without discussing, or discriminating among, the various claims involved, much less the elements of those claims. The court did state that "because Plaintiffs seek monetary damages, the requirements of Rule 23(b) must be established. This subsection requires a showing of predominance and

superiority." Obviously, the court's reference related specifically to Rule 23(b)(3).

Discussion

In attacking the class-certification order, SAMC challenges the trial court's findings as to all the Rule 23(a) and (b) requirements save "commonality." We focus on the Rule 23(b)(3) requirements of "predominance" and "superiority."⁸

As pointed out earlier, in order properly to perform the predominance inquiry, a court must examine the substantive law applicable to the various claims asserted in the case and identify the elements of those claims, giving consideration to the proof that the plaintiffs must present to establish each

⁸In connection with its challenge to the "adequacy" of the class representatives, SAMC seeks to have this Court order that the record be supplemented pursuant to Rule 10(f), Ala. R. App. P., to include materials generated in Faust's severed action subsequent to both the class-certification order and the date the appeal was taken in this case. We deny SAMC's motion in that regard, agreeing with the plaintiffs that Rule 10(f) does not allow, under the circumstances of this appeal, for the addition to the record on appeal of matters not before the trial court when it entered its decision on class certification. Cowen v. M.S. Enters., Inc., 642 So. 2d 453, 454-55 (Ala. 1994); Richburg v. Cromwell, 428 So. 2d 621, 622 (Ala. 1983); Williams v. City of Northport, 557 So. 2d 1272, 1273 (Ala. Civ. App. 1989). As to the basis of the adequacy challenge otherwise, we find the principles expressed in Regions Bank v. Lee, supra, sufficient to show that the trial court did not exceed its discretion in rejecting, on the record before it, the arguments SAMC advanced.

element. In the process, the court must be mindful that "the necessity of individualized testimony from each class member to prove an essential element of the cause of action defeats class certification." <u>Smart Prof'l Photocopy Corp.</u>, 850 So. 2d at 1249. See also <u>State Fire & Cas. Co. v. Evans</u>, [Ms. 1021370, June 16, 2006] ____ So. 2d ____ (Ala. 2006). Because we find that one or more essential elements of the majority of the claims involved in this case will require individualized testimony, we need discuss only those particular elements in our analysis.

Because the plaintiffs allege a "medical injury" arising in the context of their patient-hospital relationship as the basis for each of their claims, see <u>Ex parte Addiction &</u> <u>Mental Health Servs., Inc.</u>, [Ms. 1041820, July 7, 2006] ____ So. 2d ____ (Ala. 2006), all the claims are governed by the Alabama Medical Liability Act of 1987, § 6-5-540 et seq., Ala. Code 1975 ("the AMLA"). <u>Collins v. Ashurst</u>, 821 So. 2d 173 (Ala. 2001); and <u>Mock v. Allen</u>, 783 So. 2d 828 (Ala. 2000). This includes claims under the Alabama Extended Manufacturer's Liability Doctrine ("the AEMLD"), claims alleging fraud, and claims alleging lack of informed consent. Mock, supra.

"In any action for injury or damages or wrongful death, whether in contract or in tort, against a health care provider for breach of the standard of care, the plaintiff shall have the burden of proving by substantial evidence that the health care provider failed to exercise such reasonable care, skill, and diligence as other similarly situated health care providers in the same general line of practice ordinarily have and exercise in a like case."

§ 6-5-548(a). A hospital is a health-care provider under the AMLA. § 6-5-542(1). In addition, to prove causation with respect to any of their claims, the plaintiffs must prove by substantial evidence that the acts or omissions of SAMC "probably caused" their injuries. <u>Shanes v. Kiser</u>, 729 So. 2d 319 (Ala. 1999); <u>McAffee v. Baptist Med. Ctr.</u>, 641 So. 2d 265 (Ala. 1994).

In their brief to this Court, the plaintiffs assert that "[i]n this particular case, the exposure is the injury." (Plaintiffs' brief, p. 42.) We disagree. Under current Alabama caselaw, mere exposure to a hazardous substance resulting in no present manifestation of physical injury is not actionable under the AMLA where the exposure has increased only minimally the exposed person's chance of developing a serious physical disease and that person has suffered only mental anguish. <u>Thomas v. BSE Indus. Contractors, Inc.</u>, 624

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So. 2d 1041 (Ala. 1993); <u>Hinton v. Monsanto Co.</u>, 813 So. 2d 827 (Ala. 2001); and Southern Bakeries, Inc. v. Knipp, 852 So. 2d 712 (Ala. 2002). In Pfizer, Inc. v. Farsian, 682 So. 2d 405 (Ala. 1996), a plaintiff attempting to proceed on a theory fraudulent suppression of information relating to a of preexisting history of component failures in a heart valve, resulting in numerous deaths, could not recover damages based solely on the risk that his heart valve might one day fail, when he could not prove that the valve was not then working properly. This Court held that, whether viewed in terms of the law as it relates to fraud or as it relates to product liability, the heart-valve recipient's "concern that his heart valve, which is presently functioning normally, could later malfunction is not an injury recognized by Alabama law." 682 So. 2d at 407. A person exposed to a known hazardous substance but not claiming a present physical injury or illness as a result may not recover as damages the costs of medical monitoring. Hinton, supra. "Opening the courts generally for compensation for fear of future disease would be a dramatic change in the law and could engender significant unforeseen and unforeseeable consequences; awarding such

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compensation is better left to the Legislature." <u>Southern</u> <u>Bakeries</u>, 852 So. 2d at 718. The plaintiffs do not argue on appeal that we should overrule or depart from this precedent.

Under this Court's previous holdings, therefore, those proposed members of the class who have not undertaken explantations and who have no signs of any infection or other adverse effects have not suffered a legal injury. Their only present detriment would be the fear arising from the possibility that when put in place, one or both of their implants contained saline that had been exposed to Curvularia which might have developed into Curvularia spores, contamination, which might survive within the implant and eventually escape its confines, which might then result in an infection. As the evidence at the class-certification hearing demonstrated, the level of such fear would vary from patient to patient; some could be expected to take a stoic view and, based on the very low statistical risk shown to be involved, have little apprehension about their individual situation. We do not denigrate the fear of future complications entertained by any woman electing thus far to forgo explantation. We simply recognize that under existing precedent, that fear does

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not constitute a present legal injury and is not actionable, where no other present injury can be demonstrated.

Clevenger, the representative of patients who have not either of their breast implants removed, had has not experienced any signs of infection or other complications that might be thought attributable to Curvularia contamination. No evidence was introduced to suggest that any of the class members who have not undergone explantations have experienced any symptoms of adverse effects. Accordingly, this subset of patients, and Clevenger as their representative, have suffered no actual injury and thus lack standing to maintain this action. Ex parte Prudential Ins. Co. of America, supra; Mutual Sav. Life Ins. Co., supra; and Ex parte Central Bank of the South, supra. Consequently, the class-certification order must be vacated as to them.

One of the original five, Faust, has removed herself from this action. The other four, with the exception of the one who had her second implant removed following issuance of the SAMC notification letter, had no knowledge or apprehension of the potential for a fungal contamination before it was detected in one of their removed implants. They did not

undergo their explantations as a result of any awareness of the potential for Curvularia contamination. Only one of those other three may have experienced some difficulty as a result of the contamination of one of her implants. The CDC report states that "they all made a full recovery." As explained, they cannot recover simply for a fear they may have that their exposure to Curvularia may cause problems in the future. Moreover, their small number would clearly not satisfy the subclass "numerosity" requirement of Rule 23(a)(1), i.e., that "the class is so numerous that joinder of all members is impracticable." See Cox v. American Cast Iron Co., 784 F.2d 1546, 1553 (11th Cir. 1986) ("As the trial judge who originally certified the class pointed out, citing 3B Moore's Federal Practice ¶ 23.05[1] at n. 7 (1978), while there is no fixed numerosity rule, 'generally less than twenty-one is inadequate, more than forty adequate, with numbers between varying according to other factors.'"). When a subclass is created out of a class, the subclass must itself be treated as a class for the purpose of Rule 23, and must independently meet all the requirements of Rule 23 for maintenance of a class action. Johnson v. American Credit Co.

<u>of Georgia</u>, 581 F.2d 526 (5th Cir. 1978); <u>LaBauve v. Olin</u> <u>Corp.</u>, 231 F.R.D. 632 (S.D. Ala. 2005); <u>Pickett v. IBP, Inc.</u>, 197 F.R.D. 510 (M.D. Ala. 2000); <u>Woodward v. Nor-Am Chem. Co.</u>, (No. Civ. A. 94-0780-CB-C, May 16, 1996)(S.D. Ala. 1996)(not reported in F. Supp.).

Thus, the three women who had the explantations before they reviewed the notification letter from SAMC and who had the explantations for reasons unrelated to any fear or symptoms of Curvularia contamination and who have made a full recovery without any known complications are not eligible for subclass certification. Even if their demonstrated implant contamination should be recognized as a present injury and their claims could be merged with those of the larger cohort of women who underwent explantation following receipt of the notification letter, class certification would still be inappropriate, for the reasons hereinafter explained.

Those patients who underwent explantations following receipt of the notification letter have experienced an actual injury by virtue of undergoing that surgery, even in those instances where SAMC paid for it. SAMC makes no claim that the decision by any of those women to have her implants

removed was in any way unreasonable. The evidence from Dr. Baker, Williams, and Clevenger was to the effect that Dr. Baker recommended such removal, and several of the other experts who testified would recommend removal of the implants to every patient. The detriment to these patients is the explantation surgery, independent of any contamination or fear of infection. Therefore, any woman undergoing explantation surgery as a result of receiving the notification letter would have standing to bring an action, and Williams is representative of this group.

Accordingly, we look to see if those plaintiffs with standing carried their burden of proving that, with respect to this potential class, common questions of law or fact predominate over individual issues. To that end, we consider the elements of certain of the claims included within the certified class action. To prove their claim specifically labeled as one for medical malpractice, <u>as well as</u> all of their other differently denominated claims, the plaintiffs must prove a breach of the standard of care. See, e.g., Ala. Code 1975, § 6-5-548(a). Any breach of the standard of care would be a function of the evolving conditions existing at the

center at a particular point during the course of the time frame in the class-certification order. Individualized proof would therefore be required to establish that a breach of the standard of care had occurred as of the date of any particular patient's CBA.

To prove their AEMLD claim, the plaintiffs must prove that they suffered injury from a Curvularia-contaminated implant provided by SAMC. See Skelton v. Druid City Hosp. Bd., 459 So. 2d 818 (Ala. 1984). They must prove that at least one of the implants inserted in their breasts was "in a defective condition unreasonably dangerous" to the plaintiff at the time of implantation and that she probably suffered injury as a result. Casrell v. Altec Indus., Inc., 335 So. 2d 128, 132 (Ala. 1976). For any individual patient to show that inserted "a defective condition her implant was in unreasonably dangerous" to her and that she probably suffered injury as a result, she will have to present individualized proof concerning the condition of her implant and its effect All of the members of this potential class of on her. patients have had their implants removed and the contents cultured, and only the second implant removed from one of the

original five was found to have any fungal contamination. The very low risk of actual contamination agreed upon by the experts at the class-certification hearing precludes any reliance upon an assumption that mere exposure to the varying conditions of the ambient air in the operating room probably led to contamination for any given patient. Actual defective condition of the implants must therefore be proved for each individual patient.

To prove her interrelated claims of premises liability and duty to warn of the condition of the premises, each plaintiff would have to show by substantial evidence either that the center was not kept in a reasonably safe condition at the time of her CBA or that SAMC failed to warn her of a danger of which it knew or ought to have known at the time of her surgery. <u>Mills v. Bruno's, Inc.</u> 641 So. 2d 777 (Ala. 1994). SAMC's actual knowledge over the course of the time frame specified by the class-certification order of a possible problem of fungal contamination at the center, its eventual actual knowledge of the detected presence of fungal contamination, and what SAMC should have known as information came to its attention over the course of that time frame were

not static. What SAMC knew or should have known varied along the entire course of that time line. Thus, individualized inquiry will be required to determine whether SAMC failed to keep its premises in a reasonably safe condition at any given point in time and whether it knew or ought to have known of conditions potentiating fungal growth, or actual fungal growth, and ought to have warned its patients accordingly.

The count of the complaint captioned "suppression" asserts that SAMC "actively suppressed and concealed" from the plaintiffs "known dangers presented by the fungal contamination of its premises and operating rooms," withholding dissemination of information that would have warned the plaintiffs of the risks associated with the contamination. As thus pleaded, and as the plaintiffs acknowledge in their brief, to establish their suppression claim, the plaintiffs must prove that SAMC had actual knowledge of the fungal contamination. See also State Farm Fire & Cas. Co. v. Slade, 747 So. 2d 293, 323-24 (Ala. 1999). Thus, the plaintiffs will need to prove what SAMC actually knew at different points along the evolving course of the time line in the class-certification order. Additionally, a

plaintiff in a suppression case must prove that she was induced to act by her reasonable reliance on the state of affairs as it appeared in the absence of the suppressed information (<u>Voyager Ins. Co. v. Whitson</u>, 867 So. 2d 1065, 1074 (Ala. 2003); <u>Ex parte Household Retail Servs., Inc.</u>, 744 So. 2d 871, 879 (Ala. 1999)) and that she suffered an <u>actual</u> injury <u>as a result</u> of the suppression. <u>Southern Bakeries</u>, 852 So. 2d at 716.

"When fraudulent suppression is at issue, the trial court 'must examine the facts to determine whether the defendant had a duty to disclose.' <u>Ex parte</u> <u>Government Employees Ins. Co.</u>, 729 So. 2d [299] at 305 [(Ala. 1999)]. 'The impact of this law ... on the class certification decision, is fatal.' <u>Mack</u> [v. <u>General Motors Acceptance Corp.]</u>, 169 F.R.D. [671] at 677 [(M.D. Ala. 1996)]."

<u>Regions Bank v. Lee</u>, 905 So. 2d at 774. "Whether the [defendants] had a duty to disclose and breached that duty as to any of the [plaintiffs] are also individual issues that are inappropriate for class certification." <u>Compass Bank v. Snow</u>, 823 So. 2d at 674. Again, what SAMC actually knew about the dangers of fungal contamination of its premises and, consequently, what duty it had to disclose information to the patients at the center, would have been different at different points in time along the time line in the class-certification

order. Thus, "the trial court would be forced to make a detailed inquiry as to each and every class member to determine whether [SAMC] owed that member a duty to disclose and whether [SAMC] had induced each individual to act." University Fed. Credit Union v. Grayson, 878 So. 2d at 289. Because of the need for such a constellation of individualized proofs, suppression cases are rarely, if ever, eligible for class-action treatment. <u>Regions Bank</u>, supra; <u>Grayson</u>, supra; <u>Voyager Ins. Cos.</u>, supra; <u>Compass Bank</u>, supra; <u>Ex parte Household Retail Servs.</u>, Inc., supra; and <u>Ex parte Government Employees Ins. Co.</u>, supra.

The plaintiffs have otherwise insinuated into the classaction-certification proceedings claims of "lack of informed consent" and "outrageous conduct." To sustain a claim of outrageous conduct, each particular plaintiff will need to show, as an essential element of the cause of action, that her level of emotional distress meets the level of extreme emotional distress for which an action for the tort of outrage will lie. <u>Thomas v. BSE Indus. Contractors</u>, 624 So. 2d at 1045.

To prove lack of informed consent, each patient will need to establish what disclosure of information is required by the standard of care applicable to a hospital, establish what she was in fact told, and prove that had she been given certain inappropriately withheld information she would not have submitted to the medical treatment in question. Craig v. Borcicky, 557 So. 2d 1253 (Ala. 1990). Although Dr. Baker testified in his deposition that in advance of performing a CBA he provided the patient with certain prepared materials and generally discussed the risks associated with the surgery in the same manner each time, he also testified he would try to answer any individual questions a patient might have. The claim in this case, however, is that SAMC failed to obtain the informed consent it independently was obliged to obtain and evidence concerning what discussions there was no its personnel routinely had with patients. For the reasons already explained, what information SAMC should have included in any informed-consent disclosure would have varied over the course of time according to the level of knowledge it had by then acquired concerning fungal contamination of the center. Likewise, individualized inquiry would need to be made

concerning the effect appropriate disclosure would have had on the decision-making process of a particular patient. The requirement for individualized inquiry into the state of mind of each plaintiff makes the claim inappropriate for class certification. <u>Funliner of Alabama, LLC v. Pickard</u>, 873 So. 2d 198, 211 (Ala. 2003). See also <u>Avis Rent-a-Car Sys., Inc.</u> v. Heilman, 876 So. 2d 1111, 1123 (Ala. 2003).

The plaintiffs seek to recover for each patient in the proposed class damages for mental anguish and emotional suffering and punitive damages.

"Under Alabama law, recovery of damages for emotional distress requires individualized proof. See <u>Kmart Corp. v. Kyles</u>, 723 So. 2d 572 (Ala. 1998). For this reason, class certification of claims seeking damages for emotional distress is inappropriate. See <u>Allison v. Citqo Pet. Corp.</u>, 151 F.3d [402] at 417 [(5th Cir. 1998)]."

Funliner, 873 So. 2d at 210.

Individualized proof also would be required to prove the costs of explantation for any patient who elected not to have Dr. Baker perform the explantation at the center; the costs of any replacement augmentation; the loss of time and income associated with the explantation and the associated

convalescence; and any disfigurement or cosmetic detriment resulting from the explantation surgery.

Punitive damages in this case would have to relate to, and therefore require time-correlated proof of, what SAMC knew or should have known about fungal contamination at any given point in time and consciously or deliberately withheld oppressively, fraudulently, wantonly, or maliciously. Ala. Code 1975, § 6-11-20.

Given this array of individualized inquiries that necessarily must be undertaken in the trial of this action as comprehensively certified by the trial court, it is clear that the plaintiffs did not carry their burden under Rule 23(b)(3) of proving, among other things, that questions of law or fact common to the class members predominate over questions applicable only to individual class members. Similarly, the plaintiffs have failed to sustain their Rule 23(b)(3) burden of proving that class-action treatment of this entire case would be superior to any other method for the fair and efficient adjudication of the controversy. "When individual issues predominate over the common claims, manageability of the action as a class is not possible," and the plaintiffs'

claims "fail to meet the superiority requirement of Rule 23(b)(3)." <u>Voyager Ins. Co.</u>, 867 So. 2d at 1077. "Because individual issues predominate over the common claims, manageability difficulties render the claims unfit for class certification." <u>Smart Prof'l Photocopy</u>, 850 So. 2d at 1252.

Because, as noted, we deal with the certified action as an entirety, there having been no separation and analysis of the various claims and their elements in the classcertification order, we do not now undertake to investigate whether any of the claims not discussed above might properly be susceptible to class-action treatment. "We conclude that the trial court is in a better position to determine whether, based on the facts of this case and this Court's conclusion that individual issues of fact exists as to the fraudulentsuppression claim" and the other identified claims, "class certification is proper as to [any remaining] claims." Regions Bank v. Lee, 905 So. 2d at 776 n. 11.

Conclusion

Because, as to a majority of the claims certified for class-action treatment, the plaintiffs failed to carry their burden of proving their entitlement to class certification

under Rule 23(b)(3), the trial court erred in certifying the class. We therefore vacate the class-certification order and remand this case for further proceedings consistent with this opinion.

ORDER VACATED AND CAUSE REMANDED.

Nabers, C.J., and See, Lyons, Woodall, Stuart, Smith, Bolin, and Parker, JJ., concur.