**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ALABAMA**
**Southern Division**

In re:
SILICONE GEL BREAST IMPLANT
PRODUCTS LIABILITY LITIGATION
(MDL 926)

HEIDI LINDSEY, et al.,
Plaintiffs,

-vs.-

DOW CORNING CORP., et al.,
Defendants.

Master File No. CV 92-P-10000-S

Civil Action No. CV 94-P-11558-S

**OPINION (Corrected)**
**(Approval of Settlement)**

In April 1994, the court provisionally certified the Lindsey action (CV 94-P-11558-S) under Rule 23(b)(3) as a class action for settlement purposes and gave preliminary and conditional approval to a proposed $4,225,070,000 class settlement, reputed to be the largest such settlement ever. Detailed information concerning the settlement, including all of the items required under Rule 23(c)(2), as well as a form for requesting exclusion from the class, was sent by first-class mail to each person, domestic[1] and foreign, identified as possibly a breast-implant recipient. Written objections and comments from class members and others have been received and reviewed. At hearings held on August 18, 19, and 22, 1994, the court heard oral comments from all persons--regardless of whether they had legal standing to be heard or had timely requested permission--who wished to speak in favor of or in opposition to the proposed settlement. The matter was taken under submission at the conclusion of these hearings on August 22, 1994. After considering all issues and concerns presented, the court concludes that the proposed settlement, with certain clarifications and minor modifications described in this Opinion, including a redefinition of the class, should be approved.

Even its proponents do not claim this settlement is perfect or without problems. In approving the settlement, the court is heeding the admonition of Voltaire, which has been often repeated and rephrased during the hearing process: "The best is the enemy of the good."

## TIMING AND NATURE OF SETTLEMENT

This is not a settlement hastily proposed at the outset of litigation before significant discovery and without the insights afforded from presentation of evidence at a trial. Breast implant litigation began more than fifteen years ago, and about a dozen cases have been tried to verdict in different federal and state courts. The deluge of new filings of cases that began in early 1992 has resulted in massive discovery efforts, involving the production and review of millions of pages of documents and the taking of hundreds of depositions.

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1 In this opinion, the court may, for convenience, use the term "domestic" to refer to class members or claimants who are not Foreign Claimants as that term was defined in the Settlement Notice and has been refined in later Orders.

Extensive, arms-length, non-collusive, good-faith settlement negotiations were conducted over many months, even as counsel continued just as vigorously and thoroughly to prepare for potential trial of the thousands of cases already filed or expected in the future.

On the other hand, neither can this settlement be evaluated on the basis of a closed set of data from which all claims can be measured with precision or confidence. Scientific inquiries into possible linkage between breast-implantations and a variety of serious diseases and medical conditions are ongoing and will likely continue for many years. Thousands of class members have serious physical conditions they attribute to their implants. Thousands of others do not have, and may never or only many years later experience, any problems associated with their implants. Some want their implants removed immediately; some want to keep their implants in place, at least for the time being. Verdicts in the cases thus far tried have been mixed, some favorable to the defendants and some favorable to the plaintiffs. While these cases are useful in understanding the dynamics, cost, and length of trial and in considering possible settlement values, they do not provide a reliable basis for any statistical extrapolation or prediction as to outcomes of trials in the many different factual and legal settings these claims involve.

In proposing a settlement in the face of these uncertainties, the parties are recognizing that (1) the defendants' resources are not unlimited, and would be reduced, to the potential detriment of claimants, by the huge costs incurred in litigation over the coming years;[2] (2) thousands of claimants cannot afford to wait their turn in the judicial queues; and (3) the federal and state court systems will not be able to resolve promptly all breast implant cases without a substantial reduction in the number of cases now pending or expected. Almost 10,000 such cases, many with multiple plaintiffs, are now pending in this court, with almost as many in state courts around the country. Some implant cases have also been filed in other countries.

The terms of this complex settlement, as described in detail in the Settlement Notice with its attachments and as refined in Orders No. 15-20, will not be repeated or summarized in this Opinion except as needed when discussing particular issues. What perhaps should be noted is that--in the effort to provide a fair and workable procedure for resolving thousands of claims on an optional basis--the settlement contains many

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2 Indeed, some have questioned whether the defendants' resources are sufficient to make the $4,225,070,000 payments that may be required under the settlement. After substantial investigation, Plaintiffs' Settlement Class Counsel have stipulated that adequate financial assurances have been given by the various Settling Defendants under Section XIV of the Settlement Agreement with respect to their ability to make these payments. Based on these stipulations, and after conducting an appropriate in camera review, the court has found these assurances to be satisfactory. However, it should be noted that at least some defendants might be unable to make the required payments under the settlement if the cost of defending and responding to adverse judgments outside the settlement becomes too great; this will depend not only on how many cases by opt-outs they must defend but also on how quickly those cases are brought to trial.

innovative provisions not found in traditional class action settlements. These features include a program for receiving claims over a 30-year period and for payments that do not depend on the amount of contributions or financial resources of the defendant that supplied the particular claimant's implants; a simplified claims procedure that does not involve adversarial proceedings or require examinations by court-appointed physicians; the initial identification of certain diseases and medical conditions for which substantial amounts--as much as $1,400,000 net after attorneys' fees--would be paid to class members who have or in the 30-year period develop such conditions, without requiring proof of causation; additional compensation should a recipient's condition or disability worsen during that period; a method for adding to this list other diseases or medical conditions (including ones affecting children of implant recipients) if justified by scientific research; procedures for later additional opt-out rights should defendants' settlement contributions prove to be inadequate to pay the full amount of the projected settlement benefits for these diseases and conditions; the protection of claimants against excessive attorney's fees or administrative expenses through a special fund and mechanism for determining and paying those fees and expenses; and the establishment of a series of special funds to provide compensation or reimbursement for medical evaluations, removal of implants, implant ruptures, and other injuries not covered under the disease compensation program, to provide for emergency situations, and to correct for inequities among class members under other parts of the settlement.

## NOTICE

As indicated, the settlement notice package--which included a cover letter; a Synopsis; the detailed 26-page Settlement Notice; a Question-and-Answer booklet; and forms to register, submit a claim under the Disease Compensation Program, or opt out--has been mailed by first-class mail to every person, foreign and domestic, identified as possibly a breast-implant recipient. In excess of 380,000 packages have been mailed thus far. These mailings, which began in April 1994, have continued and will continue as new names and addresses become known. In addition to the written communications, telephone answering services, using both ordinary and toll-free numbers, have been established. Thousands of telephonic inquiries have been answered by attorneys acting for the Plaintiffs' Settlement Committee and by attorneys specially employed in a Claims Assistance Office. Additional information has been disseminated by the many support groups that provide assistance to implant recipients and their families.

There has been almost no criticism directed to the form and content of the settlement notice package[3] or to the extensive additional efforts to provide information about the proposed settlement to those putative class members who have made known their

3 The objection has been raised that the settlement package was not translated into Spanish. The short-form notice, summarizing key points and highlighting important dates, was, however, translated into Spanish and 9 other languages, as well as into a few additional dialects or variants.

potential interest. Indeed, the efforts to provide information to such persons must be viewed as among the most extensive and complete ever undertaken. While some delays were experienced initially--either because of some early problems in the telephone service used to record names and addresses of persons requesting a copy of the settlement package or in the "turn-around" time for mailing the package after such requests were received--these were resolved, and the court has accepted late opt-outs that were possibly the result of such delays. Recognizing both the additional time it took many foreign claimants to request and receive the settlement notices and the "super" opt-out rights that would later be available to them, the court continued to accept all exclusions from foreign claimants even up to the date of the hearings.

The major complaint about the notice program is made by foreign claimants and centers on the court-approved program designed to provide "short-form" or otherwise abbreviated information concerning the settlement. This program included the expenditure of over two million dollars in the United States for advertisements in newspapers, in magazines, and on television, and for distribution of audiotapes for radio transmission, but did not provide paid advertisements outside the United States. Some foreign claimants, emphasizing this disparity in paid advertising, challenge the notice program as insufficient under the Constitution or Rule 23.

In analyzing these criticisms, the proper focus is not the differences between domestic and foreign notice, but the adequacy of the notice program outside the United States, with emphasis on the consequences of failure to be exposed to notice. Several factors deserve mention.

First, it should be stressed that the primary purpose of this part of the notice program was not to give the required notice. Rather, it was to solicit name-address information about the persons to whom the settlement notice package could be mailed. These claimant-identification efforts were approved by the court--notwithstanding the large expense, which would reduce funds available for distribution to class members--in order to supplement the list of approximately 80,000 putative class members available from other known sources (e.g., lists obtained from defendants, plaintiffs, and non-parties, including health-care providers). The settlement package was mailed to every foreign class member identified through any of these means, as well as to each domestic class member.

Second, unlike some latent toxic-tort cases, this notice did not have to serve the purpose of informing members of the public about whether they might have claims. With rare exceptions, persons would know whether they were breast-implant recipients. While much more information about the settlement was provided, the key portions were designed to alert such persons to the existence of the proposed class settlement and of various means to obtain more detailed information concerning their rights and options under the settlement.

Third, substantial efforts, costing several hundred thousand dollars, were in fact undertaken to provide potential claimants outside the United States with the needed information. Details are outlined in the affidavits and supplemental materials and exhibits provided by APCO Associates, Inc., and Diana Pendleton. The program included extensive distribution of a court-approved "short-form" notice translated into 10 foreign languages and into additional dialects or variants; press conferences and press releases directed to world-wide media, with press kits sent to media in 24 countries; insertion of information onto a world-wide interactive computer network; distribution of translated letters from the court, with additional enclosures, to national health ministries and to national and regional medical associations in many countries; distribution of these materials to 54 United States Ambassadors and to the Ambassadors to the United States from these countries; transmission of translated news releases to over 1,500 media outlets outside the United States, including 29 television stations. As had been hoped, many of the media outlets and governmental/medical/consumer groups in turn took steps to disseminate this information to potential class members in their countries.

A criticism by some foreign claimants is that implants were distributed by American manufacturers in countries in addition to the 24 in which the more extensive notification efforts were undertaken. Most of the implants distributed outside the United States were sent to these 24 countries. It is clear, moreover, that notice of the settlement (and of the mailing and telephone locations for obtaining information about the settlement) has reached putative class members in more than just these 24 countries, as is indicated by the fact that settlement packages have been sent to, or registration and exclusion forms received from, persons in more than 65 countries to date.

Fourth, in evaluating the adequacy of the notice program outside the United States as well as any justification for differences in domestic and foreign notice, it is critical to understand the differences in potential consequences upon the two groups of a failure to receive notice of the settlement. Domestic class members who do not learn of the settlement and consequently do not register or opt out by the 1994 deadlines face the loss of their rights to sue in courts in their own country and retain only the right, which may be of little value, to become late registrants under the settlement. On the other hand, foreign claimants who, not learning of the American settlement, fail to register by the December 1st deadline retain all rights to proceed in the courts of their own country. Given this fundamental difference in the consequences of failure to receive notice, a strong argument can be made that a claimant-identification program outside the United States would not have even been required.

The court finds and concludes that, under these circumstances, the notice program, with all its components, satisfies constitutional requirements and, in the words of Rule 23, constitutes "the best notice practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort." Rule 23 does not require the most extensive notice possible, particularly when additional expenditures will reduce

the amount to be paid to class members.

## SUPPORT BY CLASS MEMBERS

While approval of a proposed class settlement is not a matter to be decided by a plebescite, the views of putative class members are certainly relevant and entitled to great weight. One may gauge the extent of support or opposition in this case by looking to such matters as the written submissions, the statements made during the hearing, and the number of opt-outs and early registrations.

Two general conclusions can be drawn: First, virtually all domestic class members--at least after they understand that the court has no power to order the defendants to contribute larger amounts to the settlement or to make major revisions in the terms of the settlement--want the settlement to be approved, and without delay. Second, while virtually all foreign claimants believe the proposed settlement inequitably treats foreign claimants in relation to domestic claimants, thousands of them do, at least if certain changes are made, want the settlement to be approved so they can participate, subject to their rights to opt out at a later date. Opposition to the settlement is most significant among putative class members in Australia and Canada, though even in those countries there are many wanting an opportunity to participate subject to their future opt-out rights.

The settlement notice package informed putative class members about their right to submit objections and comments respecting the proposed settlement.[4] It also advised them that there was no need to submit comments if they supported the settlement and, indeed, that the court would assume that persons favored approval of the settlement if they did not opt out or submit any comment. (See Q42 in the "Questions-and-Answers.") Not surprisingly in light of this advice, most of the comments submitted did contain various criticisms of the proposed settlement. What was not expected and is perhaps more significant is the relative paucity of negative comments--less than 1/3 of 1% of those to whom notices were sent and only slightly more than 1% of those who have already registered under the settlement. Although considered by the court as similar to "amicus" submissions, many of these were from persons who opted out of the settlement or were mailed after the June 17th deadline. Most of these criticisms, moreover, reflect a misunderstanding about the court's powers--erroneously believing that the court could order major changes in the proposed settlement, such as requiring the defendants to pay greater amounts into the settlement fund.

Given the purpose of the hearing, it is likewise not surprising that a majority of the oral presentations to the court were critical of various aspects of the proposed settlement. What is most significant is that, once understanding the limitations and constraints on the

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4 The "short-form" notices also advised putative class members of their opportunity to submit objections or comments.

court's powers in considering the proposed settlement, only a very few--indeed, only two of the domestic class members--asked the court to reject the settlement. Even among those speaking for foreign class members, most were calling for the court to use whatever powers it had to reduce perceived inequities between foreign and domestic members, rather than to reject the settlement.

Some indication of the broad support for the settlement is given by the number of early registrations. By the start of the hearing, more than 90,000 persons had already registered with the Claims Office even though the settlement had not yet been approved by the court and more than three months remained before the December 1, 1994, registration date. Tens of thousands of additional registrations could be expected by December 1, with many to be submitted, along with claim forms and supporting medical documentation, by September 16 for consideration under the Current Disease Compensation Program. There have been few registrations by foreign claimants, no doubt due in large measure to the criticisms and requests for changes being advanced by their counsel.

Two points may be made about the number of persons electing to opt out of the settlement class: (1) In absolute terms, the number of opt-outs--approximately 7,800 persons in the United States and approximately 6,500 persons outside the United States--is substantial, and indeed raises the specter that one or more defendants may elect to withdraw from the settlement in view of the risks and costs of potential litigation with these claimants. (2) In relative terms, the number of opt-outs is a small fraction --less than 5%-- of the total number of persons identified as putative class members, and may be viewed as surprisingly low considering the extensive public discussions of the settlement and the fact that so many thousands already have employed attorneys and indeed have actions pending.

It would be a mistake, however, to assume that persons opting out want the settlement to be disapproved. Yes, most[5] elected to opt out because they believed they could recover more through individual litigation than under the settlement. But most also, when informed, would understand that the settlement will serve their best interests by reducing the court congestion that could long delay judicial resolution of their individual lawsuits and by enabling the defendants to remain sufficiently viable economically as to be able to respond in damages if found liable in those lawsuits. Indeed, after the figures were released regarding the number of opt-outs, many--realizing that with so many opt-outs an early judicial resolution of their claim was unlikely, and reevaluating the benefits provided under the settlement, including the potential for later opting out--have withdrawn their exclusion and rejoined the settlement class. This trend is likely to continue for several weeks, not only by domestic claimants, but also by foreign claimants as they learn of the changes being made for their benefit.

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5 Based on a review of the opt-out forms, it appears that some returned the form in error or because of a misunderstanding of their rights and that others did so because of a personal aversion to participation in any form of legal proceeding.

## OBJECTIONS BY CLASS MEMBERS

While, as indicated, objections and criticisms were submitted by only a minute portion of the putative class, these comments nevertheless have been given serious attention by the court. Some raise questions that merit discussion in this Opinion.

At the outset, it should be emphasized that the court is not called upon to decide the merits of the claims made on behalf of the class members or to decide whether, or to what extent, the defendants are liable to all or any of the class members. Rather, the court has been presented with an agreement between the parties for possible settlement of claims. It cannot rewrite the essential provisions of that agreement, but rather must decide whether to approve or disapprove that agreement. It cannot, for example, order the defendants to pay more money into the settlement or change the basic provisions for distribution of those proceeds as agreed to by the parties and submitted to the class members. There are, however, some details of the settlement that are within the court's power to modify at this time, as well as some that would be subject to being addressed by the court during the 30-year period for implementing the settlement. Moreover, there may be some changes to which the parties would, after having heard the comments of class members, agree and which would not require another class notification and hearing process.

### Adequacy

Perhaps the most serious question relates to the "adequacy" of the Disease Compensation Program. While only a few challenge the adequacy of the amounts shown in the Schedule of Benefits,[6] many are concerned that the defendants' contributions to the Disease Compensation Program--up to $2,715,070,000--will not be sufficient to pay benefits at the levels shown in the Schedule. More particularly, they believe the defendants' contributions to the "Current Disease" portion of this program--$1,200,000,000--will only be enough to make payments to these initial claimants at a fraction of the amounts shown in the Schedule. This potential can be demonstrated through simple mathematical calculations under various hypotheses. For example, even if all eligible Current Disease claimants were in the lowest level on the Schedule ($105,000), this level would be reduced by 50% if there were as many as 23,000 such persons.

Currently no one has reliable data to determine how many class members satisfy the symptom and disability criteria to qualify at this time under the Current Disease Compensation Program, much less to predict how many will meet those criteria during the 30-year life of the Ongoing Disease Compensation Program. The defendants may be correct in their belief--or hope--that the number of persons having the requisite symptoms

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6 These amounts are to be viewed as offers to compromise and settle disputed claims. Obviously many class members believe that larger amounts would be awarded if the claims were pursued successfully in litigation.

and disabilities to qualify under the Disease Compensation Program will not be so large as to cause any reduction in the scheduled benefit levels or at most only a small reduction that, indeed, might be remedied through additional negotiations.[7] If, however, as many believe, there are tens of thousands of persons who will qualify at varying benefit levels under the Current Disease Compensation Program, the reductions in scheduled benefits are likely to be so significant that a large number of class members would elect at that point to opt out and in turn the defendants would withdraw from the settlement.

The court's guess is that the $1.2 billion to be paid into the Current Disease Compensation Program will not be enough to pay all approved claims at 100% of the amounts shown on the Schedule. But the court cannot even hazard a guess as to whether such a reduction in benefits--often referred to as "ratcheting"--would be so large that it could not be remedied through further negotiations of the parties or would result in massive opt-outs from the settlement.

In approving the settlement in the face of these serious risks and uncertainties, the court is doing so primarily because of the so-called second opt-out right. Under terms of the settlement, all registered class members not opting out in the initial period will be given another right to opt out if funds paid into the Current Disease Compensation Program are insufficient to pay eligible domestic[8] claimants the full amount of benefits shown on the Schedule. After being notified of the amount of the potential reduction in payment levels, all such persons--not just those who had submitted Current Disease claims--would be able to remove themselves from the settlement class without any penalty. They would then have full rights to institute and pursue litigation against all Settling Defendants and Released Parties, including any rights to seek punitive or multiple damages, and any applicable statutes of limitation or repose would have been suspended during the time they were members of the class.

Through this unusual procedure, it will be possible to obtain the missing information many say is critical in assessing the fairness and adequacy of the settlement; namely, information about the number of breast-implant recipients suffering from various diseases and medical conditions allegedly caused by those implants. Class members then will have an option to exclude themselves from the settlement class. In short, before class members face the loss of any rights relating to individual litigation, they will be advised of both the maximum and the minimum amounts payable under the Disease Compensation Program to current claimants. The provisions for Current Disease claims and for a second opt-out, in combination, provide a sufficient response to the concerns of those who have

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7 Under III.C.2.a(4)(a) of the Settlement Agreement, counsel for the plaintiffs and settling defendants are obligated, if there is a potential reduction in scheduled benefits under the Current Disease Compensation Program, to meet and discuss in good faith possible methods and options to reduce potential opt-outs.

8 There are even greater second opt-out rights for foreign claimants, which will be discussed later in this Opinion.

suggested that the court delay approval of the settlement until reliable data can be obtained about the medical conditions of implant-recipients.

It should be recognized that, if there is a reduction and second opt-out period, some delay--perhaps six months or so--in pursuing individual litigation will have been suffered by those who elect to opt out at that time, or indeed by all class members should the defendants withdraw because of the number of opt-outs. The court concludes, however, that, notwithstanding the risk of such delays, it is in the interest of the class as a whole to give the settlement the chance to succeed. Those who are convinced the settlement is doomed to fail have had, of course, the right to opt out during the initial period in order to pursue their individual claims.

Disease Compensation Program

In addition to concerns about funding of the Disease Compensation Program, discussed above, some have criticized various features of the Program itself, the Schedule of Benefits (or grid), and the Disease Schedule attached as Exhibit D to the Settlement Notice.

The most frequently expressed criticisms of the program relate to the omission of cancer--particularly breast cancer--from the list of covered diseses and the omission of children's illnesses that some attribute to the mother's implant. Many have requested that the court modify the Program to add these and other diseases and illnesses to those covered under the Current Disease Compensation Program.

As earlier indicated, the court is limited in its power to alter the agreement reached by the parties. The court is clearly precluded at this time from adding other diseases and conditions to the Schedule of Benefits or the Disease Schedule because the parties have agreed to a procedure for considering such additions. Under the agreement, a new disease or condition can be added by the court to the Ongoing Disease Compensation Program during its 30-year period, but only after a determination by a 5-person court-appointed Medical Panel that the then-existing medical and scientific evidence demonstrates that the disease or condition is caused by breast implants. The agreement expressly provides that this procedure would govern the potential addition of children's illnesses.

There can be no guarantee, of course, that any illnesses will be added to the Disease Schedule under this procedure, for even if on-going scientific research should indicate that breast implants can be a cause of some disease, the court would still have to consider whether to authorize inclusion of the disease under the Disease Compensation Program, which provides benefits without requiring proof of causation.[9] Recognizing that inclusion

9 The court is frankly skeptical that any disease with a high incidence rate in the general population, such as breast cancer, could be added to the Disease Schedule, unless the scientific evidence not only demonstrated that breast-implants could be a cause of the disease but also

of new diseases is problematic at best, the settlement has, through the initial opt-out period, provided a means for implant recipients to pursue through the tort system a claim that they suffer from a serious disease which they believe was caused by a breast-implant but which is not included in the Disease Schedule. With respect to claims of injury to children from their mother's breast implant, the agreement provides an opt-out right, protected against statutes of limitation, until the later of two years after attaining their majority or after manifesting symptoms of the illness claimed to be the result of the mother's implant. The dissatisfaction and objections of those with illnesses not covered under the Disease Compensation Program, while certainly understandable, do not constitute a basis for the court's rejecting the settlement. It should be noted that, in developing criteria for distributions under the Designated Fund III-V, it may be appropriate to give some consideration to particular conditions, such as disfigurement, not included as a covered disease under the Disease Compensation Program.

A few have criticized the Schedule of Benefits for its treatment of implant recipients with multiple diseases or conditions covered under the Disease Schedule, e.g., both lupus and atypical connective tissue disease. A claimant with multiple diseases or conditions covered under the Disease Schedule is to be paid based upon the disease, severity level, and onset age that would provide the greatest payment.[10] The critics of these provisions argue that in litigation a claimant with multiple covered diseases would be compensated for all the diseases, or at least in a greater amount than if she suffered from only the most serious disease, and that the Disease Schedule should similarly provide increased compensation for multiple diseases. While it certainly would have been rational and fair for the Disease Compensation Program to have been structered in that manner, the approach agreed to by the parties--which the court is without power to change--is also rational and fair, particularly since the few class members in that situation were given the right to opt out if they believed it was in their best interest to pursue their multiple-disease claims in separate litigation.

Deadline To Submit Claims Under Current Disease Compensation Program

Many have asked for an extension of the September 16, 1994, deadline for submitting claims and supporting documentation under the Current Disease Compensation Program. The principal reasons for an extension relate to the time it has taken for many class members to receive the settlement notice and understand their rights, and the difficulties many class members have experienced in obtaining medical examinations to support such claims. These problems are most pronounced with respect to foreign claimants, many of whom face the additional burden of having medical reports translated

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indicated particular symptoms or etiological criteria for determining that a particular person's disease was likely caused by an implant.

10 The agreement also provides that a claimant paid for one condition, who later develops a condition (or severity level) for which a larger amount is provided under the Schedule, would receive an additional payment based on the difference between the two amounts.

into English.

While, unlike many other requests for changes in the terms of the settlement, the court does have the power to grant such an extension, the decision is not a simple one. Many other class members oppose this request because any extension is likely to result in an equal delay--or perhaps a longer delay due to the increased number of claims--in reviewing claims; in determining the extent, if any, of a reduction in projected benefits under the Current Disease Compensation Program; and in making payments to claimants, some of whom may be in desperate need of funds. Moreover, the inability of a class member to meet this deadline does not mean that the person is prevented from participating in the Disease Compensation Program; rather, such a claim, when submitted after the deadline, would be processed under the Ongoing Disease Compensation Program, which may provide the same level of benefits as for current claimants.

On the other hand, there are certainly disadvantages to a class member who could qualify as a current claimant but whose claim is processed under the Ongoing Disease Compensation Program. First, there could be a significant delay between the time for payments under the Current Disease Compensation Program and for payments of Ongoing Claims, even in the first year of the latter program. Second, there is the possibility that, because of the interrelationship between the defendants' funding obligations under the Ongoing Disease Compensation Program and the amounts payable under that program, Ongoing Claimants could be paid less--or over a longer period--than similarly situated Current Claimants.[11]

On balance, the court concludes that a modest additional grace period should be allowed for class members to submit to the Claims Office the medical documentation required for current claims under paragraph 27(b) of the Settlement Notice--until October 17, 1994, for domestic claimants and until December 1, 1994, for foreign claimants. The court is not extending the deadline for submitting a complete and signed Claim form (postmarked by September 16, 1994). All class members submitting Current Claims are urged to submit their medical documentation by September 16 if they can possibly do so. Claims submitted by the September 16th deadline are, if the required documentation is submitted by the October 17th or December 1st deadlines, to be processed by the Claims Office in the same manner as for other timely claims. As for documented claims submitted before September 16, if there are minor deficiencies in the supporting medical documentation, such claimants are to be notified by the Claims Administrator of the deficiencies and are to be given 30 days to provide the additional information needed. The Claims Administrator shall give such notices as soon as practical after the October 17th and December 1st dates, but the court vacates any prior directives imposing on the Claims Administrator a specific time period in which to give "deficiency" notices.

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11 While, in such circumstances, adversely affected Ongoing Claimants would have additional opt-out rights, there are some restrictions on these rights, such as precluding claims for punitive and multiple damages.

Opt-out Rights

As mentioned earlier, the court has been accepting exclusions postmarked after the deadlines[12] for all foreign claimants and, on a minimal showing of cause, for domestic claimants, and has also been allowing persons to withdraw their exclusions in order to rejoin the settlement class. Because of the effect on the defendants' decisions whether to withdraw from the settlement due to the number of opt-outs--decisions that are to be made by September 9, 1994--the court will scrutinize very carefully any new requests to be excluded and allow such exclusions only on a showing of compelling circumstances. Also, because of the potential effect on allocation and distribution of benefits under both the Disease Compensation Program and the Designated Funds, the court would expect final membership in the settlement class (subject to any later opt-out rights allowed under the settlement) to be fixed on the basis of materials submitted by December 1, 1994.

The agreement and settlement notice provide that, if a breast-implant recipient withdraws from the settlement class, this automatically excludes her family members and personal representatives from the settlement class. This is an appropriate provision as it relates to any derivative claims or similar claims that are based on the implant recipient's injury or death. The parties, however, are agreed that claims by children of an implant recipient for their own personal injury or death resulting from their mother's implant should be treated differently; namely, by allowing the child to remain in the settlement class with respect to such personal claims (subject to the extended special opt-out rights) even if the mother excludes herself from the settlement class. This change is approved by the court and will be effected by changing paragraph (b)(6) of the class definition.

The agreement and settlement notice also provide that family members cannot exclude themselves from the settlement class as to these derivative claims (e.g., loss of consortium, loss of services, etc.) if the implant recipient remains in the class. The reason for this restriction is obvious--the defendants would be unwilling to make a settlement with an implant recipient that could be as much as $1,400,000 if they would still be subject to potentially large expenditures of time and money in litigation with the recipient's spouse involving most of the issues that litigation with the implant recipient would entail. The objection has been raised by a few spouses that this is unfair, particularly since they are not assured of any additional payments under the settlement for their claims.[13]

The court rejects the argument that it should disapprove the settlement unless, as has been done in a few class action settlements, some of the settlement funds are set aside to pay these derivative claims. Given the large number of potential derivative claims--probably over half of the existing lawsuits have been brought by a wife and husband--any

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12 The original deadline of June 17, 1994, was extended for some class members until July 1, 1994.

13 It is possible that distributions from Fund V might recognize, to some degree, derivative claims of spouses in particularly compelling circumstances.

such diversion, to be meaningful, would involve a substantial reduction in the amounts payable to the implant recipients themselves and would result in expensive and time-consuming administrative reviews.[14] The approach of this settlement--treating the amounts offered as payments to settle both the direct and the derivative claims--is a fair and reasonable approach. If the amount offered is not considered by the wife and husband as adequate to compensate for both types of claims, they could have elected--and may again have the option--to exclude themselves from the settlement class. Should the wife and husband disagree as to whether to exclude themselves from the settlement, it is appropriate in the context of this litigation for that decision to be made by the wife. The special problems presented in a proposed class action such as this should be viewed as justifying the court's exercise of equitable powers in these circumstances, notwithstanding an arguable interference with the rights of a husband.

Special Problems Regarding Foreign Claimants

"Foreign Claimants" are identified under the terms of the Settlement Agreement and implementing Orders and Notices of the Court as those class members who, as of April 1, 1994, were neither citizens nor permanent resident aliens of the United States and whose breast-implants had all been implanted outside the United States. As earlier indicated, relatively few foreign claimants have thus far registered with the Claims Office, and it appears that, of the foreign claimants with notice of the settlement, a relatively high percentage have either criticized the settlement as unfair or have opted out of the settlement class. Some of their objections--relating to notice and the time for opting out or filing claims--have already been discussed and, at least in part, been ameliorated through changes in the settlement.

Various objections have been raised by foreign claimants, including the fact that all seven named plaintiffs in the Lindsey case are domestic claimants, that none of the attorneys on the Plaintiffs' Negotiating Committee had clients who are foreign claimants, and that the question of providing opportunities for foreign claimants to participate in the proposed settlement was initiated by a defendant rather than the Plaintiffs' Negotiating Committee. The fundamental objection raised by foreign claimants relates, however, to the disparity in potential benefits afforded foreign claimants as compared to domestic claimants--particularly, the 3% "cap" under the Disease Compensation Program, the reduction in Scheduled Benefits for foreign claimants under that program, and the exclusion of foreign claimants from participation under Designated Funds I-V.

In and of itself, the lack of foreign claimants from the list of named plaintiffs in Lindsey or from those who were clients of counsel on the Plaintiffs' Negotiating Committee is not necessarily fatal to certification of the class and approval of the

14 State laws differ not only as to the elements of recoverable damages in derivative claims, but also as to whether a husband may initiate or pursue a derivative claim separate from his wife's claim or after the wife's claim has been settled.

settlement, even in the face of differences in treatment under the settlement. To impose such a requirement would mean that there must be representative or represented claimants who fit each of the 60 categories on the Schedule of Benefits--and perhaps also in other possible categories that arguably should have, but were not, treated as meriting special classification in the Schedule--as well as representative or represented claimants having all the various combinations of characteristics that might produce different distributions from the Designated Funds. The number of persons needed to satisfy a standard based on permutation of these various factors would become so numerous as to justify a separate class action for the representative claimants.

In deciding whether the requirements of Rule 23(a) are satisfied, the court must use a more flexible standard tailored to the factual and legal context of the particular action sought to be maintained as a class action. When a settlement is proposed with respect to a class in which there are differences in the circumstances of different class members, the critical inquiry should not be based on some narrow reading of Rule 23(a), but on whether the terms of the proposed settlement make fundamentally unfair distinctions among class members or fail to make distinctions that, as a matter of fundamental fairness, should have been made among class members.

There are substantial differences between the benefits afforded to foreign and to domestic class members under the settlement. Most significant are the provisions for adjusting benefits payable to foreign claimants under the Disease Compensation Program in light of potential compensation available to such persons in the country where the implantation was performed, for a 3% "cap" on the funds to be paid to foreign claimants under that program, and for excluding foreign claimants from benefits under Designated Funds I-V. In combination if not singly, these disparities have generated understandable protests from foreign claimants that they are being treated unfairly. These objections are not taken lightly by the court, particularly in view of the absence of direct participation by representatives of foreign claimants in the negotiation process. The proffered rationale and justification for these disparities involve both legal and pragmatic considerations.

The parties responsible for this settlement believe--and the court agrees--that the settlement value of tort claims that can be pursued in federal or state courts in the United States is generally greater than the settlement value of such claims if pursued in judicial and administrative tribunals in at least most other countries. This should not be understood as in any way disparaging the tort systems in those countries; rather, it simply recognizes the practical effect on settlement values of such differences as the manner for resolving tort claims (including rights to trial by jury in the United States), the elements and measures of recoverable damages (including, in many jurisdictions in the United States, the opportunity for punitive or multiple damages), the standards and procedures for offering expert testimony, the actions and findings of governmental regulatory bodies with respect to breast implants, and the extent of governmentally-supported healthcare systems.

The parties also believe--and the court agrees--that the reduction in settlement value of claims by foreign claimants is not wholly eliminated by the possibility that such claimants might institute lawsuits in federal and state courts in the United States. These plaintiffs would have to overcome defendants' arguments based on the doctrine of forum non conveniens and, even if successful, could still face choice-of-law problems that might result in less favorable rules than domestic plaintiffs would enjoy. The Settling Defendants believe that they could prevail in these arguments, at least in most circumstances, and Plaintiff's Settlement Counsel, while reluctant to make any statements that could adversely affect members of the class represented by them, acknowledge that these can be serious concerns for foreign claimants attempting to litigate in the United States. Of course, the additional expense and difficulties in conducting litigation in a country where the plaintiff and perhaps critical witnesses do not live may make litigation in the United States impractical and unrealistic for many foreign claimants.

These considerations do justify some disparity in the amounts to be paid to domestic and foreign claimants under the Disease Compensation Program. Indeed, most of those representing foreign claimants acknowledge--albeit unenthusiastically--that some reduction in the Schedule of Benefits for their clients would be understandable and acceptable. Even so, they would complain about the lack of any standards or criteria for paying foreign claimants--the Settlement Notice merely says that the portion of funds in this Program set aside for foreign claimants will be allocated "by the Court, after consulting with the Claims Administrator and Settlement Class Counsel, in a manner that takes into account the types of compensable injuries and the amount of compensation typically awarded for similar injuries in the country where the implantation was performed." There is no indication whether this allocation would be based on the Schedule of Benefits or even whether compensation would be paid for the same diseases and conditions specified in the Disease Schedule--and, of course, the reference to the Court's consulting with Settlement Class Counsel is hardly reassuring to foreign claimants. There is even a question whether the court might further limit foreign claimants to less than this 3%.

The Court concludes that, in fairness, the following modifications should be, and are hereby, made with respect to the method and procedure for determining, subject to availability of funds, the amounts payable to foreign claimants under the Disease Compensation Program: (1) Payments will be made to them for the same diseases and conditions described in the Disease Schedule, including any future additions. (2) The projected benefits to foreign claimants will be based on a percentage of the amounts listed in the Schedule of Benefits for domestic claimants having the same disease or condition, severity level, and age at onset. (3) These percentages will be fixed, in advance of the announcement of the second opt-out right, on a country-by-country basis that takes into account the types of compensable injuries and amount of compensation typically awarded for such injuries in those countries, but with a possible increase in this percentage for claimants who are parties in pending litigation in the United States and can demonstrate they are probably not subject to the objection of forum non conveniens. (4) The grid

amounts for each country will be at least 40% of that for domestic claimants, and may be as high as 90% of those amounts. (5) In determining these percentages, the Court will consult with the Claims Administrator and with persons active in the representation of foreign claimants, selected by the court based on recommendations of members of the Foreign Plaintiffs Subcommittee.

These modifications do not, however, answer the second concern and objection voiced by foreign claimants; namely, that relating to the "3% cap." Under the agreement--and this is something the court cannot change--the amounts payable to foreign claimants under the Disease Compensation Program are not to exceed 3% of the funds paid into that Program. Those who negotiated the settlement have candidly acknowledged that this limitation was based not on any empirical study, but rather on pragmatic considerations. In short, recognizing that a total of $2,715,070,000 would be paid into the Program, how much of this should be set aside for foreign claimants to enable offers of settlement that would be acceptable to many of them, while not so depleting the funds available for domestic claimants as to make the settlement offer unacceptable to too many of them? The 3% figure was ultimately viewed by the parties as not so large as to result in offers of settlement unacceptable to too many domestic claimants. Whether and to what extent--in light of the smaller percentage of foreign class members who were expected to participate in the settlement, or in light of the reduced benefit levels resulting from consideration of the tort system in their own country--this 3% cap would result in any further reduction in benefits payable to foreign claimants could not and cannot now be known, and, of course, depends in large measure on how many foreign claimants register and file claims under the settlement.

In recognition of the additional uncertainties confronting foreign claimants, provisions were included in the settlement to afford all registering foreign class members a guaranteed second right to opt out after the amounts payable to foreign claimants under the Current Disease Compensation Program were determined--that is, after applying the 3% cap. This second opt-out right has been clarified to assure that foreign claimants opting out at such time would have not only any rights to pursue claims in their own country, but also whatever rights they might have--with benefit of a suspension of statutes of limitation--to pursue litigation in the United States. Foreign claimants unwilling to remain class members with this uncertainty, of course, had the opportunity to exclude themselves during the first opt-out period, and some 6,500 elected to do so. Those who had no interest either in the settlement or in pursuing litigation in the United States did not have to do anything--for, by taking no action whatsoever in this settlement, they would still have the right to pursue claims in their own courts. Those, however, having some interest in the settlement depending upon what ultimately was offered to them, could register, file current claims if qualified, and then make their decision whether to remain in the settlement after the amounts potentially payable became known.

There is the distinct possibility that the combination of a country-based reduction

and a 3% cap will result in such a disparity between benefits payable to domestic and foreign claimants under the Disease Compensation Program as to be unacceptable to most foreign claimants. The court has seriously considered whether the proper course of action would be simply to eliminate all foreign claimants from the class and reduce the defendants' contributions by the amount subject to being paid to such claimants. It is clear, however, that many foreign claimants, notwithstanding their feelings of discrimination, want the opportunity to be in the class so as to make their decisions when they know the potential benefit levels. The court is reluctant to shut the door completely to such persons.

Although troubled by the claims of discrimination between groups of class members, the court concludes that it should approve at this point the proposed 3% "set aside" for foreign claimants with the following modifications: (1) The 3% should be not merely a "cap," but indeed a true set aside for the benefit of foreign claimants. That is, 3% of the amounts to be paid into the Disease Compensation Program should, and will, be set aside (together with the net earnings on such funds) for the benefit of foreign claimants in subsequent years of the program unless and until the court determines, upon a review of claims and registrations, that further separation of funds is not necessary to protect the interests of foreign class members in the future years of the program. (2) If the 3% limitation would in any year have the effect of reducing amounts payable to them, foreign claimants would be given at that time the election either to opt-out of the settlement or to have the portion of their claims not payable because of this limitation carried over to the following year or years for inclusion and payment as Ongoing Claims of foreign class members. To eliminate or minimize the amount of such potential reductions, Settling Defendants are authorized to agree to accelerate the payment of the 3% of the payments due from them in later years for foreign claimants without having to agree to a similar acceleration of payments on behalf of domestic claimants. (3) The Settling Defendants will not include, in measuring the statute of limitations or repose in any action brought inside or outside the United States by a foreign claimant who registers but later opts out of this settlement, the period of time between the filing of the Lindsey action and 30 days after the date such foreign claimants opts out.

The third major objection by foreign claimants is that, with respect to benefits under Designated Funds I-V, they are not merely limited to 3% of the funds contributed by the defendants but totally excluded. Some justification for exclusion from Fund I and II can be offered--that through government programs in many foreign countries class members may be able to secure, without additional personal expense, medical examinations for diagnosis of problems possibly related to breast implants or for removal of breast implants. Upon analysis, however, this rationale must be rejected, for Funds I and II provide compensation only for expenses not subject to reimbursement through insurance and such governmental programs. The court concludes that, subject to the same type of 3% set-aside as in the Disease Compensation Program, foreign claimants should, and will, be eligible to participate in distributions under Funds I-V in the same manner as for domestic claimants. As with the Disease Compensation Program, this 3% will be set aside and preserved for the

benefit of foreign claimants unless and until the court determines, upon a review of claims and registrations, that further separation of funds is not necessary to protect the interests of foreign class members in the future years of the program. The court has been advised that this modification of their agreement would be acceptable to Plaintiffs' Negotiating Committee and the Settling Defendants. Although this modification will diminish somewhat the potential benefits of domestic class members under the settlement, the amount--representing less that 4/10 of 1% of the settlement funds to be paid by defendants--is really de minimis with respect to domestic claimants, and does not require renotification of the class members, particularly since they were advised of the court's broad powers and discretion with respect to distributions under Funds I-V.

As previously mentioned, many foreign claimants have complained that none of the Settlment Class Counsel have clients who are foreign class members. Exercising the power earlier reserved, the court, after consulting with members of the Foreign Plaintiffs Subcommittee, will designate during December 1994 an additional attorney having such clients to serve in this capacity with the other attorneys already designated. In deciding to make this appointment, the court is not indicating any dissatisfaction with the work of the Settlement Class Counsel; indeed, they have performed their responsibilities with great skill, dedication, and integrity. Rather, the court believes that Settlement Class Counsel will benefit from having among their number an attorney with this perspective. Such participation should be particularly helpful should there be additional negotiations under Section III.C.2.a(4)(a) of the Settlement Agreement to consider methods for reducing the number of potential opt-outs due to a "ratcheting" of Scheduled Benefits.

The court understands that, with these various changes, representatives of foreign claimants from most countries believe the proposed settlement, though not perfect, is acceptable and provides potentially significant benefits to their clients, subject to the right to opt out after determination of benefit levels for foreign claimants under the Disease Compensation Program.

Nevertheless, it appears that a substantial proportion of implant recipients in Australia and in the Canadian provinces of Ontario and Quebec do not believe the settlement, even with these modifications, provides a satisfactory basis for resolving their claims. The most intense and unyielding objections to this proposed settlement, even as possible changes were being discussed, came from counsel representing clients in those locations. Almost 80% of the foreign claimants who have opted out of the settlement are from Australia or those Canadian provinces. There are perhaps as many as 4,000 Australian and Canadian citizens who are already parties in lawsuits pending in state and federal courts in the United States, and who believe they can defeat motions based on forum non conveniens.

There are additional breast implant cases pending in courts in Australia and Canada, and counsel representing such persons argue that potential tort recoveries in those countries

would be comparable to those in this country. It is also significant that Australia and the Canadian provinces of Ontario and Quebec have statutes permitting class or group actions comparable to our Rule 23. Indeed, class actions have already been requested and certified in Ontario, requests for class actions are pending in Quebec, and a group action was pending in Australia at the time of the settlement hearing in this case, though it was at least temporarily discontinued on August 29, 1994.[15] The classes certified in Ontario are limited to persons who reside or are domiciled in Ontario or had an implant in Ontario, and the class definitions proposed in Quebec and Australia likewise have contained similar geographic limitations.

Maintenance of a class action under Rule 23(b)(3) is conditioned upon a finding that "a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Two of the four matters listed in the Rule as pertinent to this finding are "(A) the interest of members of the class in individually controlling the prosecution or defense of separate actions" and "(B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class." In this case, even in the context of a proposed class settlement, these criteria are not met with respect to foreign claimants from Australia or the two Canadian provinces, and the class definition will be modified to exclude them from the settlement class.[16] Some of these persons may be class members in the Mentor Settlement Class or be entitled to share in the trust funds set aside in bankruptcy court for claimants of the Bioplasty defendants; exclusion from the Lindsey class will not have the effect of excluding such persons from the Mentor Settlement Class or prevent them from participating in the distribution of such settlement and trust funds.[17]

It is clear, however, that some of those so excluded would find the terms of the settlement, as amended, acceptable and would like to participate in the settlement, subject to their later rights to opt out. The parties are agreeable to a method--which the court approves--by which such persons, on a purely voluntary and individual basis and waiving any objections to terms of the settlement, can elect to become members of the settlement class. In redefining the class, provisions will be included to allow such voluntary opting into the settlement class by affirmatively so electing by December 1, 1994.

## BAR ORDER

15 This voluntary discontinuance was without prejudice to the rights of the representative parties to reinstitute representative proceedings if Australian breast implant recipients are excluded from the Lindsey class.

16 The redefinition does not exclude those Australian and Canadian residents who--because they are United States citizens or received a breast implant in the United States--would be treated under the settlement in the same manner as other domestic claimants. The settlement class in this case and the classes formed in Ontario would also overlap with respect to citizens or resident aliens of the United States who have received a breast implant in Ontario.

17 At a subsequent date the court will establish procedures relating to possible claims against the Mentor and Bioplasty funds by persons who are excluded from or opt out of the Lindsey class.

The settlement, of course, precludes further claims by class members against the Settling Defendants and Released Parties. It does not, however, preclude class members from instituting or pursuing breast-implant litigation against others--hospitals, doctors, and non-settling manufacturers and suppliers--who have not joined in the settlement. The Settling Defendants are understandably concerned that, in addition to the $4.225 billion being paid by them in the settlement, they could be exposed to liability for still further amounts under theories of indemnification or contribution asserted by defendants in those cases. As in other similar class settlements, the Settling Defendants have, as a condition to agreeing to the settlement, insisted on protection against such claims. This protection is contained in Sections IX and XII.5 of the Settlement Agreement, which purport to bar claims against the Settling Defendants and Released Parties by such non-settling defendants seeking through indemnification or contribution to recover in whole or in part amounts that such persons may be called upon to pay to class members.

The basic problem with the bar order is obvious: it would affect potential rights of persons and entities who have not agreed to it and who are not even parties in the Lindsey action. Adhering to the teaching contained in other cases in which this problem has arisen, the court has invited these non-parties to comment on or object to the proposed bar order. Several have done so, some through motions to intervene.[18] After considering their arguments,[19] the court concludes that, with some modifications and clarifications, the provisions of the settlement with respect to the bar order are fair and reasonable, and can and should be approved.

First and perhaps most significantly, this approval shall not be viewed as precluding such non-settling defendants from taking advantage of any rights of setoff or credit, or similar rights to limit or reduce claims by class members, otherwise available to them have under applicable state laws based on payments made to or for the benefit of class members under this settlement. The settlement agreement is hereby deemed modified to the extent it may otherwise be read as denying such rights.

Second, these provisions bar only actions--whether based on contribution, indemnity, or other similar theories of law--in which such non-settling defendants might seek to recover from the Settling Defendants or Released Parties for liability of such non-settling defendants to class members for breast- implant related injuries or for expenses incurred in defending against such actions or claims. Approval of the settlement does not

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18 The motion to intervene filed by Koken Co., Ltd., may be viewed as untimely, having been postmarked after the June 17th deadline. However, it is not clear that this deadline would have applied to non-parties, and the court has elected to treat the motion as timely.

19 They do not deny that the settlement, at least indirectly, is likely to be of great benefit to them. They expect that not many class members who have named them as additional defendants will pursue these claims after settling with the "major" defendants. While unhappy with any diminution in their rights, they do not really want the settlement to fail.

bar claims by such a non-settling defendant based on a contract between the non-settling defendant and a Settling Defendant that explicitly provides for contribution or indemnification; nor does it bar any independent claims relating to other disputes between such non-settling defendants and the Settling Defendants and Released Parties.

Third, by seeking and obtaining this bar, the Settling Defendants and Released Parties shall likewise be precluded from making similar claims against such non-settling defendants for reimbursement, indemnification, subrogation, contribution, or the like for money paid by them under the settlement. In short, the bar is a mutual bar. It may be noted that the agreement similarly precludes such claims as between or among the Settling Defendants.

Fourth, the bar order does not affect any claims between or among the Settling Defendants, Released Parties, and non-settling defendants for contribution or indemnification relating to claims made by persons who are not members of the settlement class or who opt out of the settlement class.

Fifth, the provisions of the settlement extending the statute of limitations and statute of repose for class members do not apply to claims of class members against the non-settling defendants.

Sixth, a Settling Defendant that withdraws from the Settlement pursuant to Section V of the Agreement or is determined to be in Final Default under Section XIII of the Agreement shall be treated, for purposes of the bar order, in the same manner as a manufacturer, supplier, or health-care provider that was not a party to this settlement, with the exception, however, that, should 3M Corporation so withdraw, it would nevertheless retain full rights of indemnity and contribution regarding the INAMED entities in any claim against 3M outside this Settlement.

With the above modifications, the court finds and concludes that the bar order is essential to the settlement, is fair and equitable, is supported by adequate consideration, and is within the court's powers even though these other manufacturers, suppliers, and health-care providers have not agreed to the order or been named in parties in the Lindsey action. *See In re U.S. Oil and Gas Litigation*, 967 F.2d 489, 496 (11th Cir. 1992), and *In re Jiffy Lube Securities Litigation*, 927 F.2d 155, 158-60 (4th Cir 1991).

The motions to intervene filed on behalf of Porex Technologies Corp., Koken Co., Ltd., General Electric Company, and the Scotfoam entities are denied.[20] It should be understood that, if an issue relating to the bar order should arise in subsequent litigation, these non-settling defendants, having been denied intervention, would be entitled to argue

20 If another party should appeal to attack the modifications in the bar order made for the benefit of the non-settling defendants, these motions to intervene would be reconsidered to enable such persons to defend such changes as appellees.

against any preclusive effect under the doctrine set forth in *Martin v. Wilkes*, 490 U.S. 755 (1989). The merits of that argument would, of course, be determined at that time by the court in which it is raised.

## SUBROGATION

Following the preliminary approval of the proposed settlement on April 1, 1994, a number of insurers, trusts, and governmental agencies filed motions to intervene in order to assert purported rights of subrogation or claims for reimbursement based upon past or future payment of medical expenses or provision of medical services to class members, and to object to certain provisions in the settlement that might adversely affect those rights. In Order No. 20, signed July 22, 1994, the court denied these motions as premature, without prejudice to resubmission at an appropriate time after (and in the event) the proposed settlement should become final and effective. This issue merits discussion in this Opinion, particularly since the basis for this ruling involves some modification or clarification of the settlement agreement and since a similar motion has been filed by four Canadian Provinces and a motion for reconsideration has been filed by one of the earlier movants.[21]

At the outset, it should be noted that any ambiguity in the class definition giving rise to the possibility that such health-care providers would themselves be class members under paragraph 1(a)(3) of Order No. 15 has been clarified in Order No. 20. While this paragraph of the class definition does provide for inclusion of persons and entities having claims against the Settling Defendants they may assert "independently or derivatively because of their personal relationship" with other class members, it was not intended to include, and does not include, persons and entities simply having claims for subrogation or for reimbursement.

The settlement agreement contains several provisions intended by the parties to maximize the benefits class members would receive by eliminating or reducing the extent settlement funds would be paid to such health-care providers. Some of these provisions can be, and are, approved by the court; others cannot be, and are not, approved.

The provisions relating to Designated Funds I and II (relating to medical expenses for diagnoses, evaluation, and explantation), as contained in the Settlement Agreement and as refined in the Settlement Notice, limit distributions from those funds to "unreimbursed" medical costs--"*i.e.*, costs neither reimbursed nor paid by a third party (*e.g.*, a private insurance company, Medicare, or Medicaid)." While health-care providers would, understandably, prefer there be no such limitation, they cannot insist that settlement funds be used for such purposes.[22]"You would be eligible to participate [under Fund I and II] without

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21 JHE Enterprises, Inc. filed a motion for reconsideration on August 17, 1994, alternatively seeking a certification under 28 U.S.C. § 1292(b).

22 Although language in the Settlement Agreement or Settlement Notice may be read as

regard to whether the [uninsured medical] expenses are paid by you or your attorney or are still unpaid. It is contemplated, however, that the procedures will provide that amounts approved under these Funds are paid to the proper person -- to you if you paid the expenses, to your attorney if paid by such person, or to your doctor if the bill is still unpaid."

These provisions also call for class members receiving payments under these Funds to assign their rights against third parties to the Settlement Fund, which could then seek reimbursement as assignee. In approving these provisions for assignment, the court is not in any way determining whether such third-parties would have any liability to the Fund as assignee after payments have been made to class members. Many of the would-be intervenors have pointed to provisions in their contracts or in statutes and regulations that make them responsible only as payers of last resort, and the availability of such defenses is unimpaired by the Settlement Agreement.

The parties have, however, overreached in attempting, primarily in Section III.G of their agreement, to preclude all subrogation claims not only against the Settling Defendants but also against the settlement fund and class members receiving benefits under the Settlement. While it is proper to preclude further claims against the Settling Defendants by such subrogation claimants--who have not demonstrated that the proposed settlement should be disapproved as inadequate--nevertheless these claimants cannot be deprived at this time, without their consent and without an opportunity to present their claims, of such rights they may have to pursue and perhaps intercept, in whole or in part, the benefits that may become payable to individual members of the class. The court's approval of this settlement should not be understood as approving those provisions or as denying such potential subrogation rights.

What rights, if any, different subrogation claimants may have is a matter yet to be determined. These questions may depend not only on the particular contracts or statutes under which these claims are made, but also on the particular law to be applied.[23] These claims will also necessarily depend upon a determination of the benefits payable to particular members of the class.

To delve into these difficult issues at this time--before the defendants' "walk-away" decisions or the outcome of any appellate proceedings are known, and before any determination of potential benefits to class members has been made--is premature and involves potentially wasteful expenditures of time and money. In denying these motions to intervene on the basis of timeliness, the court did so not because they came too late, but because they are too early. The court will consider these issues at a later time, before any

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permitting payments from these Funds only directly to the class member herself, the court in the supplemental Questions-and-Answers approved by Order No. 18 clarified the situation:

23 In earlier presentations, Settlement Class Counsel have argued that most, if not all, subrogation claims could be defeated. The court has not ruled on the merits of these arguments or the contrary arguments by subrogation claimants.

distributions (other than perhaps emergency distributions under Fund V) are made, and hopefully on the basis of motions that in some appropriate manner identify the persons on whose behalf subrogation claimants have paid medical expenses, rather than simply assert a general claim against the class.

For the reasons indicated, the motion to intervene by the four Canadian Provinces is denied as premature without prejudice to later resubmission, and the motion for reconsideration by JHE Enterprises is denied.

## WITHDRAWAL BY A DEFENDANT

Section V.C. of the Settlement Agreement contains provisions describing the effect that withdrawal by a settling defendant would have on the rights of class members. As a matter of clarification, a class member whose breast implants were all manufactured by a settling defendant that withdraws from the settlement (or by a withdrawing defendant and a non-settling defendant) will be treated as no longer a class member. Such a person (and her family members and legal representatives with derivative claims) would have the same rights to proceed against the withdrawing defendant, the other settling defendants, and released parties as if her initial right to withdraw from the class extended to such date and she had thereupon opted out of the class.

## REQUESTS FOR REDEFINITION OF CLASS

The court is denying a request to expand the settlement class by eliminating paragraph (b)(3) of the class definition, which excludes certain persons who before June 17, 1994, settled with a Settling Defendant. However, this exclusion only applies if the person has provided a "general release" of claims related to breast implants. It does not preclude class membership unless the terms of the release are sufficiently broad to preclude claims not merely against the defendant with whom the settlement was entered, but also against other Settling Defendants participating in this settlement. If a release is not so inclusive, the consequence will not be to bar the person from membership in the settlement class, but rather to reduce benefits otherwise payable to such person under the settlement by the amount of the prior settlement.

The court is also denying a request to expand the settlement class by eliminating paragraph (b)(4), which excludes certain persons who before June 17, 1994, have had a judgment, after a trial on the merits, entered on a breast implant claim in favor of a Settling Defendant. However, this exclusion applies only if such a judgement is "final." If a timely post-judgment motion or direct appeal from an adverse judgment is pending, such a person is not precluded from membership in the settlement class, though, by remaining in the class, she would be precluded from pursuing the motion or appeal and should take steps to cause the motion or appeal to be withdrawn.

## MISCELLANEOUS MOTIONS

The court will now address a series of motions relating to the proposed settlement that were filed on behalf of putative class members before the commencement of the hearings. While several of these were postmarked after the June 17th deadline, the court's rulings are not based on untimeliness.[24]

(1) On April 18, 1994, Lewis Saul and Charles Wolfson filed a motion to intervene on behalf of Diane Matheson, Catherine McNeill, and Barbara Living, identified in the motion as residents of Canada, Australia, and New Zealand, respectively, and as "Foreign Claimants" under the initial class definition, seeking to intervene to present and preserve objections relating to disparities in the treatment of Foreign Claimants under the settlement. Accepting these allegations as correct[25] and understanding that Matheson neither resides nor is domiciled in Ontario or Quebec, the court grants the motion as it relates to Matheson and Living. The motion is denied as it relates to McNeill inasmuch as she is not a member of the class as redefined.

(2) On May 23, 1994, Silber, Perlman & Bruegger and Slater & Gordon filed a motion to intervene on behalf of certain individuals identified in the motion as Australian citizens, as parties in two cases pending in state courts in Texas, and as "Foreign Claimants" under the initial class definition. Supplements to this motion were filed on May 24, 1994, and June 24, 1994. Under the class, as redefined, these movants are not members of the class and accordingly the motion, as supplemented, is denied.[26]

(3) On June 17, 1994, Lawrence W. Schonbrun filed a motion to intervene on behalf of Ellen Saravis, identified as a class member--apparently a citizen of the United States--who seeks to intervene to present and preserve her objection that class members are not sufficiently protected against the possibility of excessive attorney's fees being paid from the settlement funds. Accepting these allegations as correct,[27] the court grants the

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24 On August 26, 1994, after all matters relating to the settlement were taken under submission, Silber, Perlman & Bruegger and Slater & Gordon filed a motion to intervene on behalf of certain individuals identified in the motion as citizens of New Zealand and as "Foreign Claimants" under the initial class definition, seeking to intervene to present and preserve objections relating to disparities in the treatment of Foreign Claimants under the settlement, together with a companion motion asking to adopt on their behalf objections previously made by other foreign claimants. These motions are denied as untimely. It may be noted that intervention is being allowed on behalf of a New Zealand resident represented by other counsel.

25 The court assumes that the individuals had a breast implant before June 1, 1993, and are not excluded from class membership under paragraphs (b)(1)-(4) of the revised class definition.

26 In addition, several of the movants--Elizabeth Goudge, Sandra Simpson, Christine Kendrick-Hardway, Astid Beath, Elaine Lapins, and Barbara Nicholson--have filed with the court elections to be excluded from the class.

27 See footnote 25.

motion for intervention of Saravis with respect to this objection. The court does note, however, that it has not at this time approved 25%--or, indeed, any percentage or amount--as attorney's fees, and that Saravis' concerns will more properly be addressed when the court considers guidelines for making claims against Designated Fund VI or when applications for fees are in fact submitted and reviewed. At such time Saravis will, by virtue of this intervention, have standing to challenge such procedures and applications.

(4) On June 17, 1994,[28] Lewis Saul mailed to the court a motion to intervene on behalf of Margaret K. A. Hunter and Maureen Upjohn, identified in the motion as Foreign Claimants under the initial class definition, seeking to intervene to present and preserve objections relating to disparities in the treatment of Foreign Claimants under the settlement. Accepting these allegations as correct and further understanding that they reside and are domiciled in New Zealand, the court grants the motion.

(5) On June 17, 1994,[29] Lewis Saul mailed to the court a motion to intervene on behalf of Edward L. Bilyeu, identified in the motion or the accompanying affidavit as a resident of Pennsylvania and as the spouse of a breast-implant recipient class member who has not opted out, seeking to intervene to present and preserve objections that the proposed settlement does not provide any special benefits to him in addition to benefits that may be payable to his wife, and does not permit him to opt-out of the settlement to pursue derivative claims if his wife remains in the settlement. Intervention is hereby granted, but, for the reasons earlier discussed, the objections are denied. Under the circumstances, however, the court grants an additional period of 30 days in which his wife may elect to exclude herself and her husband from the class.

(6) On June 20, 1994, Johnson & Dylewski filed a motion to intervene on behalf of Consumentenbond and five individuals identified in the motion as residents of the Netherlands who are "Foreign Claimants" under the initial class definition and who seek to intervene to present and preserve objections relating to disparities in the treatment of Foreign Claimants under the settlement. Accepting these allegations as correct,[30] the court grants the motion as it relates to the five class members--Grietje Van Gelderen, Anna Maria Catherina Beriere, Johanna Maria Josepha Liduina Govaart, Cahterina Johanna Maria Granneman-Van Der Werff, and Wilhelmina Geralda Helena Helbig-Pruyn. Although the motion is denied as it relates to intervention by Consumentenbond as a organization, Consumetenbond will be permitted to continue to represent the interests of the five individual class-member intervenors.

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28 The court either did not receive or misplaced this motion. However, counsel has certified that the motion was mailed to the court and to liaison counsel on June 17, 1994. Accepting these assertions as correct and noting that the motion was called to the attention of the court during the hearing, the court has accepted a copy of the motion sent after the hearing and treated it as timely.

29 See footnote 28.

30 See footnote 25.

(7) On July 8, 1994, Silber, Perlman & Bruegger and Slater & Gordon filed a motion on behalf of certain named Australian women who, under the initial class definition, were "Foreign Claimants", requesting that an order be entered directing that all settlement funds be paid into the registry of court and that no settlement funds be distributed until all appellate challenges to the settlement and class certification are exhausted. Since, under the redefinition of the class, the movants are no longer class members, they have no standing to present this motion. Were the court to address the merits of the motion, however, it would deny the motion for the following reasons: (A) the only payments to be made by defendants prior to disposition of any appeals are the "Preliminary Payments" that were made in April 1994, (B) these "Preliminary Payments" are and will remain under the control and supervision of the court, and (C) distributions from the "Preliminary Payments" may be made only with court approval, are limited to administrative matters (e.g., costs of notice, establishment of Claims Office and Claims Assistance Office, etc.), and would be chargeable against Designated Fund VI. This motion is denied.

(8) On August 2, 1994, Robles and Gonzales filed two motions seeking to add a special disease/condition as a separate covered disease/condition on the Disease Compensation Schedule. One motion was filed on behalf of Pat Holt and others similarly situated respecting cancer; the other was filed on behalf of Kim Lyons and others similarly situated relating to deformity or disfigurement. The court has no authority to modify the terms of the settlement agreement in the manner requested and accordingly must deny these motions. However, the settlement establishes a mechanism by which additional diseases/conditions--whether these or others--might be added to the Disease Schedule under the Ongoing Disease Compensation Program. Moreover, the standards for distribution of Designated Funds III, IV, and V--yet to be written--might give recognition to special conditions or disabilities not currently on the Disease Schedule. The denial, therefore, of these two motions is without prejudice to the issue of whether these or other conditions might be added to the Ongoing Disease Compensation Program at a later time or taken into account in the distribution of Designated Funds.

(9) On August 15, 1994, Cashman & Partners filed a motion to intervene on behalf of Andrea Kannane, Rhonda Driver-Parks, and Betty Grogan, identified in the motion as Australian residents who would be "Foreign Claimants" under the initial class definition. Under the class as redefined, however, these persons are not class members and the motion is accordingly denied.

## SUMMARY

The court has made a few modifications to the settlement agreement that either appear to be within the court's power or are believed to be acceptable to the parties, the major ones being a grace period for filing supporting medical documentation for current

claims and certain revisions affecting foreign claimants, including clarification and improvement of potential benefits under the Disease Compensation Program, providing potential benefits under Designated Funds I-V, and redefining the class to exclude--but with provisions for purely voluntary participation--residents of Australia and the Canadian Provinces of Ontario and Quebec.

The court finds that, with these changes--

(1) the proposed settlement is a good-faith, arms-length, and non-collusive compromise and settlement of disputed claims;

(2) the proposed settlement is, from the standpoint of the class members, fair, reasonable, adequate, and in their best interests; and

(3) the proposed settlement is, from the standpoint of the defendants, a fair and reasonable compromise of each Settling Defendant's potential liabilities and legal obligations regarding claims for bodily injury or death from breast implants, which have been agreed to by defendants only after extensive negotiations conducted with the assistance of three independent persons appointed by the court, and which imposes a legal obligation upon such defendants to make the payments at the times, in the amounts, and in the manner specified in Exhibit D to the Settlement Agreement and Exhibit C to the Settlement Notice. The allocation of payments as between Designated Funds I-VI and the Disease Compensation Program does not alter the fact that the total amount to be paid by each defendant reflects that defendant's reasonable settlement of compensatory bodily injury claims.[31]

Concurrently with this Opinion, the court is signing and entering a Final Order and Judgment that incorporates as appropriate the terms of the settlement as approved. This judgment is expressly made a final judgment under Rule 54(b), with the time for appeal commencing this date. If any Settling Defendant seeks to exercise its option to withdraw from the settlement, it should do so by means of a motion under Rule 59 filed by September 9, 1994. Any contention by Settlement Class Counsel or a Settling Defendant that the court's modifications are unacceptable and beyond the court's power should likewise be presented by a motion under Rule 59.

This the 1st day of September, 1994.

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31 The court has been informed that the liability insurance carriers and reinsurers for each of the defendants were notified of the terms of the settlement, of the hearings to consider approval of the settlement, and of the court's announcements that it would welcome the views of such insurers. No carriers appeared to oppose the settlement as being an improper or excessive settlement by their insured.

/s/ Sam C. Pointer, Jr.
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION(MDL 926)HEIDI LINDSEY, et al.,
Plaintiffs, -vs.-DOW CORNING CORP., et al.,
Defendants.

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Master File No. CV 92-P-10000-SCivil
Action No. CV 94-P-11558-S

FINAL ORDER AND JUDGMENT (Corrected)

In accordance with the findings and conclusions contained in the Opinion filed herewith, the Settlement Agreement[32]--with the modifications made in prior orders, in the

32 The Settlement Agreement means not only the initial settlement agreement filed on March 19, 1994, with its Exhibits, but also the supplemental agreements or addendums later filed with

Opinion, and in this Order--is determined to have been entered into in good faith, to be non-collusive, to be reasonable, fair, and adequate, to be in the best interests of the class, and therefore is approved. Based on, subject to, and incorporating such provisions, it is hereby ORDERED and ADJUDGED as follows:

1. Heidi Lindsey and the other designated Representative Plaintiffs under Order No. 15 shall have and recover for themselves and other members of the plaintiffs' class:

(a) from Dow Corning Corporation the sum of $2,018,740,000.00;

(b) from Baxter Healthcare Corp. and Baxter International, Inc., the sum of $555,790,000.00;

(c) from Medical Engineering Corporation and Bristol-Myers Squibb Co. the sum of $1,154,290,000.00;

(d) from Minnesota Mining & Manufacturing Co. the sum of $325,000,000.00;

(e) from Applied Silicone Corporation the sum of $250,000.00;

(f) from Wilshire Technologies, Inc., the sum of $8,000,000.00;

(g) from Union Carbide Corporation the sum of $138,000,000.00; and

(h) from McGhan Medical Corp. the sum of $25,000,000.00.

2. The provisional certification of the class for settlement purposes, with certain modifications, is confirmed.

(a) Except as provided in (b), the class on whose behalf this judgment is entered consists of--

(1) all persons, wherever located, who have been implanted before June 1, 1993, with one or more breast implants (whether or not already or later removed), with respect to any claim against a Settling Defendant or Released Party for their own personal injury or death that may be asserted as due in whole or part to any breast implant;

(2) every child, wherever located, born before April 1, 1994, whose natural mother is a person described in subparagraph (1) above and who was born after the date his or her mother had a breast implant, with respect to any claim against a Settling Defendant or Released Party for his or her own personal injury or death that may be asserted as due in whole or part to his or her mother's having had a breast implant; and

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respect to Union Carbide Corporation, Union Carbide Chemicals and Plastics Company, Inc., INAMED; 3M; Applied Silicone; Wilshire Foam Products, Inc.; Wilshire Advanced Materials, Inc., and Wilshire Technologies, Inc.

(3) all persons or entities (including estates, representatives, spouses, children, relatives, and "significant others"), wherever located, with respect to any claim against a Settling Defendant or Released Party that they may assert independently or derivatively because of their personal relationship to a person described in subparagraph (1) or (2) above.

(b) Excluded from the class are the following:

(1) breast-implant recipients all of whose breast implants can be identified as manufactured or distributed by Porex Medical Technologies Corp., Koken Co., Ltd., or other foreign manufacturers not listed in Exhibit A or B to the Settlement Notice;

(2) breast-implant recipients who, as of April 1, 1994, were not citizens or permanent resident aliens of the United States if all of their breast implantations were performed outside the United States and--

(A) they have received any compensation for breast implant injuries or expenses from a Settling Defendant under the laws or procedures of another country; or

(B) they as of April 1, 1994, resided or were domiciled in Australia, or resided or had received a breast-implant in either the Province of Ontario or the Province of Quebec, Canada, except that such persons may, on an individual and purely 'opt-in' basis, become voluntary 'Foreign Claimant' members of the settlement class. To opt in, such persons must file a Registration Form with the Claims Administrator, P. O. Box 56666, Houston, Texas, USA, 77256, postmarked no later than December 1, 1994. By voluntarily opting in through this registration, such persons--

(i) will be deemed to waive any objections and to accept the general terms of the settlement applicable to Foreign Claimants, and

(ii) will have all rights and benefits accorded to Foreign Claimants, including the right to opt out after the court determines the projected amounts payable to Foreign Claimants under the Disease Compensation Schedule. If an opting-in Foreign Claimant should later elect such opt-out right, the Settling Defendants will be precluded from asserting in a defense based on a statute of limitations, statute of repose, or similar proscription the period of time from January 24, 1992, to the date that is 30 days after such person elects to opt-out of the class.

(3) breast-implant recipients who, before June 17, 1994, shall have separately settled with a Settling Defendant, providing a general release of claims related to breast implants, unless (A) they were not represented by counsel in such settlement and the settlement involved a payment of less than

$15,000 or (B) they demonstrate by clear and convincing evidence that their settlement was induced by a Settling Defendant's fraud;

(4) breast-implant recipients who, before June 17, 1994, shall have obtained and collected a judgment against a Settling Defendant on a breast-implant claim or, after a trial on the merits, shall have had a final judgment entered against them on a breast-implant claim in favor of a Settling Defendant;

(5) breast-implant recipients who (during the "First Opt Out" period) elect to exclude themselves from the Settlement Class by return of a completed Exclusion Form, received or postmarked no later than June 17, 1994, or whose Exclusion Form, though received or postmarked after that date, is accepted by the Court as timely; and

(6) any person or entity described in paragraph 2(a)(3) whose status as a class member depends on class membership of a recipient excluded under paragraphs 2(b)(1) through 2(b)(5).

(c) As used in this Order and Judgment, the terms "Settling Defendants" and "Released Parties" mean those persons and entities listed or described in Schedules A and B to the Settlement Notice.

(d) A list of persons excluding themselves from the class will, in order to protect privacy interests to the extent possible, be maintained under seal by the court, with the identity of such persons subject to disclosure only to the extent necessary to protect the rights of the various parties (such as to determine whether a person is precluded from instituting or maintaining some other action).

3. Except as otherwise provided in the terms of settlement as approved by the court:

(a) the Settling Defendants and Released Parties are forever released from any and all claims which any member of the class had, has, or may have in the future against any of such persons and entities with respect to any existing or future claim, known or unknown, accrued or unaccrued, for personal injury or death that may be asserted as due in whole or part to any breast implant;

(b) each member of the class is barred and permanently enjoined from instituting, asserting, or prosecuting against any of the Settling Defendants or Released Parties in any pending or future action in any federal or state court in this country, or in any court or tribunal in any other country, any and all claims which such individual had, has, or may have in the future against any of such persons and entities with respect to any existing or future claim, known or unknown, accrued or unaccrued, for personal injury or death that may be asserted as due in whole or part to any breast implant;

(c) other persons and entities, not parties to the settlement agreement,

against whom members of the class may assert claims for breast-implant related injuries or death are barred from making claims for contribution or indemnification against the Settling Defendants and Released Parties to the extent described in the accompanying Opinion, but are not precluded from asserting any rights to set-off, credit, or reduction that may be allowed under applicable state law; and

(d) other persons and entities, not parties to the settlement agreement, who may have claims for subrogation or reimbursement arising from payment of medical expenses or providing medical services to class members, are barred from making such claims against the Settling Defendants and Released Parties, but are not by this judgment precluded from subsequently attempting to institute or pursue such claims against the settlement fund or class members.

4. Costs are taxed against the settlement funds paid by the defendants.

5. Under Fed. R. Civ. P. 54(b), the court expressly determines that there is no just reason for delay and expressly directs that this judgment, upon filing in CV 94-P-11558-S, be deemed as a final judgment with respect to all claims by members of the class against the defendants herein with respect to breast-implant related injuries or death.

6. Without deferring or delaying the finality of this order and judgment, this court retains exclusive, general, and continuing jurisdiction as needed or appropriate in order to administer, supervise, implement, interpret, or enforce the settlement, including the investment, conservation, protection, allocation, and distribution of the settlement funds.

This the 1st day of September, 1994.

/s/ Sam C. Pointer, Jr.
United States District Judge