

IN THE SUPREME COURT OF THE  
STATE OF CALIFORNIA

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**Lockheed Martin Corporation, et al.**  
*Petitioners and Defendants*

v.

**Superior Court of the State of California, For the County of San  
Bernardino  
West District – Rancho Cucamonga**  
*Respondent*

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**Roslyn Carrillo, individually and on behalf of all  
others similarly situated, et al.**  
*Plaintiffs and Real Parties In Interest*

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*From a Decision from The Court of Appeal, Fourth Appellate District,  
Division Two  
Case Nos. E205064, E025163, E025181*

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**BRIEF OF *AMICI CURIAE*  
BRUCE AMES, MARCIA ANGELL,  
LEONARD HAMILTON, RONALD HART,  
JOSHUA LEDERBERG, SALLY SATEL,  
DIMITRI TRICHOPOULOS, JAMES WATSON,  
and RICHARD WILSON  
IN SUPPORT OF PETITIONERS AND DEFENDANTS**

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## SUMMARY OF ARGUMENT

The Court of Appeal properly vacated vacating the certification of a proposed class which is estimated to include most of the residents of the City of Redlands over a forty-year period. The class was proposed for purposes of deciding whether the expense of medical monitoring of all members of the class should be borne by the defendants.

*Amici* believe that the trial court failed to consider how the numerous individual issues essential to establishing a right to medical monitoring under the facts of this case could be resolved on a class basis.

The proposed class includes persons, who, over a forty-year period, may have lived in the defined area for as little as six months, and who may have been to exposed to various chemicals in a city water supply. The exposure of each putative class member varies greatly, depending on numerous individual factors, including, *inter alia*, the length of residence in the defined area (which may have varied from six months to 40 years), the usage of city drinking water during the period, the medical condition of each class member prior to any exposure, or subsequently incurred independent of exposure to the city drinking water.

Plaintiffs seek to create an unspecified medical monitoring program on a classwide basis, despite numerous individual issues relating to exposure, personal characteristics and lifestyle factors.

This Court recognized in *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1125 (1988), that "personal injury mass-tort class-action claims can rarely meet the community of interest requirement in that each member's right to recover depends on facts peculiar to each particular case." As for medical monitoring, this Court held in *Potter v. Firestone Tire & Rubber Co.*, 6 Cal. 4th 965, 1009 (1993), that a party cannot recover for medical monitoring damages unless he or she has suffered harm in the form of a medical need for monitoring beyond what was already required for that individual. That proof raises the same individual issues of exposure and pre-existing medical condition that predominate in personal injury actions.

No class can be certified unless Plaintiffs meet their burden of proving that there is a "community of interest" among the class members. This means that Plaintiffs must

prove that each of the elements of the claims asserted on behalf of proposed class members and relevant defenses are capable of common proof. In this case the proof required under *Potter* raises at least four individual issues:

- The severity of the exposure. Plaintiffs' own expert testified that the actual dose of any class member will be determined based on a variety of individual considerations including "residence time or time spent in an area; sources of fluid; work loads; age; gender; body surface area; personal habits and style; patterning and conditioning, whether you're one who walks around drinking water all the time

or not, and this is  
very much a  
conditioned kind  
of thing."  
(Vol. 33,  
Tab 103,  
pages 8203-05  
(Teitelbaum  
Depo. at 137:23-  
138:6 and  
138:14-139:6))

- Whether the proposed medical monitoring is already needed by the individual class member as a result of his or her medical history or personal lifestyle, exposure to other chemicals in the home or in the workplace, etc.;

## ARGUMENT

### I.

#### **THERE IS AN INSUFFICIENT COMMUNITY OF INTEREST AMONG THE CLASS MEMBERS TO SUPPORT CLASS CERTIFICATION BECAUSE OF THE PREDOMINANCE OF INDIVIDUAL ISSUES**

##### **A. The Trial Court Failed Properly to Consider the Individual and Common Issues To Be Tried.**

"A class action is appropriate only when there exists a 'sufficient community of interest' in 'common questions of law and fact' so that proceeding in the class action form will result in 'substantial benefits both to the litigants and to the court.'" *Hamwi v. Citinational-Buckeye Inv. Co.*, 72 Cal. App. 3d 462, 471 (1977) (citation omitted); *see also Linder v. Thrifty Oil*, 23 Cal. 4th 429 (2000).<sup>1</sup> In making this determination, a trial court must conclude that the "issues that may be jointly tried," when compared with those "requiring separate adjudication," are "sufficiently numerous and substantial to make the class action advantageous." *Hamwi*, 72 Cal. App. 3d at 471 (citation omitted).

*Amici* submit that from a scientific perspective, in this case there is an overwhelming predominance of individual over common issues. *See, e.g. Kennedy v. Baxter Healthcare Corp.*, 43 Cal. App. 4th 799, 810 (1996) (citing *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1123 (1998)). This Court has endorsed a long-standing principle, relied upon by the Court of Appeal here, that "a class action cannot be maintained where each member's right to recover depends on facts peculiar to his case." *Kennedy*, 43 Cal. App. 4th at 799.<sup>2</sup> *Amici* believe that the trial court failed to consider how the numerous individual issues essential to establishing a right to medical monitoring in this case, including the extent and severity of exposure and the individualized need and benefit

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<sup>1</sup> Section 382 of the Code of Civil Procedure authorizes class suits in California when "the question is one of common or general interest, of many persons, or when the parties are numerous, and it is impracticable to bring them all before the court."

<sup>2</sup> *See, e.g., Silva v. Block*, 49 Cal. App. 4th 345, 351 (1996); *Kennedy v. Baxter*, 43 Cal. App. 4th 799, 809 (1996); *Clausing v. San Francisco Unified Sch. Dist.*, 221 Cal. App. 3d 1224 (1990); *Osborne v. Subaru of Am., Inc.*, 198 Cal. App. 3d 646 (1988).

from medical monitoring in light of an individual's pre-existing medical condition, could be resolved in a class action.

B. The Individual Issues Raised In The Claim For Medical Monitoring Under *Potter* Are Integral To The Creation Of The Remedy And Cannot Be Avoided To Accommodate Class Treatment

Any consideration of class certification in this case must begin the elements of proof required by *Potter*.

In *Potter*, four individuals who lived near the landfill discovered that their drinking water wells were contaminated with toxic chemicals that had escaped from the landfill. Although plaintiffs had suffered no illnesses as a result of their exposure to chemicals in their drinking water, they sued for negligence in causing them an increased risk of illness. The trial court found that the defendant had negligently contaminated plaintiffs' drinking water and awarded damages to plaintiffs for future medical monitoring costs. The Court of Appeal reversed the awards for medical monitoring costs because plaintiffs failed to establish that cancer was reasonably certain to occur, 6 Cal. 4th at 979, but this Court reversed, holding that "the cost of medical monitoring is a compensable item of damages where the proofs demonstrate, through reliable medical expert testimony, that the need for future monitoring is a reasonably certain consequence of a plaintiff's toxic exposure and that the recommended monitoring is reasonable." *Id.* at 1009. This Court reasoned that "recovery for medical monitoring costs is supported by a number of sound public policy considerations," including "an important public health interest in fostering access to medical testing[;]" the "deterrence value" of making persons who release toxic chemicals into the environment pay for the consequences of their conduct; preventing or mitigating the effects of future illnesses; and "it would be inequitable for an individual wrongfully exposed to dangerous toxins . . . to have to pay the expense of medical monitoring when such intervention is clearly reasonable and necessary." *Id.* at 1008. This Court made it clear, however, that these public policy considerations do not allow recovery "solely upon proof of an exposure to toxic chemicals; rather, there must be a further showing that the need for monitoring is a reasonably certain consequence of the exposure." *Id.* at 1006.

In *Potter* this Court summarized the criteria for a toxic exposure plaintiff to recover medical monitoring costs "...if the evidence establishes the necessity, as a direct consequence of the exposure at issue, for specific monitoring beyond that which an individual should pursue as a matter of general good sense and foresight." *Potter*, 6 Cal. 4th at 1009 n.27. This requirement exists because an asymptomatic plaintiff exposed to potential toxins suffers "injury" only if the particular exposure to that individual requires additional monitoring. The "substantial evidentiary burdens" imposed on a plaintiff seeking medical monitoring (*Potter*, 6 Cal. 4th at 1009) represent an attempt to reconcile the recognition of a remedy for asymptomatic individuals with the fundamental principle that negligent conduct that does not cause damage does not create a cause of action in tort. *Budd v. Nixen*, 6 Cal. 3d 195, 200 (1971).

The proof of causation required by *Potter* focuses on individualized issues, because the medical monitoring an individual should have pursued absent the toxic exposure can only be determined after evaluating that person's prior and current medical conditions and personal risk of contracting a disease that warrants monitoring. As *Potter* explained:

Even if a defendant negligently exposes a smoker to toxins that significantly increase the smoker's risk of cancer, that defendant is not liable for reasonably certain future medical monitoring costs unless the recommended monitoring calls for tests or examinations that are in addition to or different from the type of monitoring that the smoker should prudently undertake regardless of the subsequent toxic exposure.

*Id.* at 1012 n.31 (emphasis added).

The four of the "five factors" in *Potter* emphasize individual issues:

- (1) the significance and extent of the plaintiffs' exposure to chemicals;
- (2) the toxicity of the chemicals;
- (3) the relative increase in the chance of onset of disease in the exposed plaintiff as a result of the exposure, when compared to (a) the plaintiff's chances of developing the disease had he or she not been exposed, and (b)

- the chances of the members of the public at large of developing the disease;
- (4) the seriousness of the disease for which the plaintiff is at risk; and
  - (5) the clinical value of early detection and diagnosis.

*Id.* at 1009. Of these five, only factor (2) can be said to be common to the putative class.

*Potter* requires consideration of the *actual* exposure of each person seeking medical monitoring and the *actual* potential effect.<sup>3</sup> Even Plaintiffs' experts acknowledged that the "outcome of the exposure is determined by many factors including the dose" (Vol. 3, Tab 19, page 518 (Teitelbaum Decl. at 24:9-10)), *i.e.*, the risk of disease may increase as the dose increases. (Vol. 14, Tab 33, pages 3384, 3387-88 and 3391 (Guzelian Decl. at ¶¶ 42, 50, and 56)). Given the number of chemicals, the uncertainty of the use of the "safe dose" in the class definition, the variety of diseases purportedly implicated, individuals' other environmental, occupational or lifestyle exposures to toxic substances, and the variety of individual health preconditions involved, the issue of whether a particular person received a dose in excess of a safe dose is directly relevant to whether that individual can establish the right to recover medical monitoring expenses.

In this context, *amici* have considered whether, from a scientific perspective, there is enough similarity between the plaintiffs to justify their being legally called a "class" for the purposes of this case. They obviously all live within the defined geographic area. That would be sufficient only if it could be proven that something about living in this area could cause discernible medical problems. But that does not seem to be the case. We see nothing in the record to suggest that the people living in the defined area were exposed to either TCE or perchlorate at a high enough level to cause cancer.<sup>4</sup> There is, of course,

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<sup>3</sup> Plaintiffs apparently will seek only to establish exposure at the level set forth in class notice, generally the MCL (Maximum Contaminant Level), or "safe" (not unsafe) dose. The uncontroverted evidence was that the MCL and the PAL (Provisional Action Limit) relied upon by Plaintiffs as the threshold exposure are conservative regulatory standards and levels of contamination many times above them are considered safe. (Vol. 33, Tab 103, pages 8227-28 and 8236-37 (Guzelian Decl. at ¶¶ 56-57 and 73-74)).

<sup>4</sup> *Amici* believe that it will be useful for the court to understand the system that has evolved in the medical and public health communities to discover whether or not a disease has a cause.

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The procedure is one of making postulates, often little more than inspired guesses, and asking whether or not the postulate fits the facts. This is not appreciably different from the procedure in any other scientific endeavor. For a study of diseases, the procedure follows a series of steps. At each stage the postulate is examined more carefully, and the data may reject it. In mankind's endeavor to improve public health, there is no shame in making postulates that turn out to be wrong; but for the procedure to work society must admit when the postulate does not work. Moreover for the procedure to work, society must be patient, and not take draconian or punitive action when the postulate remains unproven.

Step 1 -- An observant physician sees a disease or ailment that he has not seen before and makes a postulate about a possible cause. This by itself is merely an anecdote. Then the physician might write about his observation in a medical journal, encouraging other physicians to look for the same combination of circumstances.

Step 2a -- A number of other physicians realize that they have seen the same disease, and maybe they have a similar combination of circumstances lending verisimilitude to the first physician's postulate. An energetic physician might make a simple patient survey to see whether the incidence of the disease in question appeared to be increased in any particular group. That seems to have been done in this case using a patient survey rather than by a detailed study. It is important to recognize that even after this corroboration the postulate is still only a collection of anecdotes and NOT a scientific study. However, the collection of anecdotes might convince some scientist and or public health authority to study the matter in more detail. This has been done in this case also.

Step 2b -- Simultaneously with looking at the cases of cancer, a diligent public health expert will also use his imagination to see whether there is any particular exposure - to infectious disease or to chemical pollutant, and to see whether there is any information about that disease or pollutant to suggest the direction a careful study might take. In this case the fact that small amounts of perchlorate had entered the water accidentally should lead, and did lead, scientists to study the question of whether perchlorate could have caused disease. It is unquestioned that at high doses perchlorate is toxic. Above a chronic dose of 2 mg/day it inhibits the uptake of iodine and this could be adverse for the thyroid. [Lamm paper in press] It seems also that there are small amounts of trichloroethylene (TCE) in the water. Again it is unquestioned that at high doses TCE is acutely toxic to the liver. It also has been shown to produce cancer in some (but not all) species of laboratory animals. But TCE has never been shown to cause cancer even in people who were moderately highly exposed. TCE is NOT listed as a human carcinogen in any of the usual compilations (International Agency for Research on Cancer, Environmental Protection Agency etc.).

Step 3 -- A careful study has been done by Dr. John Morgan (J. Morgan, "Comparison of Observed and Expected Number of New Cases in the Twelve Census Tracts Encompassing Redlands, 1988-1994" (June 4 1996 and update

a possibility that one or more individuals within the putative class was accidentally exposed to much higher levels of TCE or perchlorate than the average, and high enough to cause acute disease. But that very unusual high exposure would have to be

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dated December 29, 1998) [need name of journal in which this paper was published]. He compared the Standard Incidence Ratios (the ratio of cancers seen in the Redlands area to that expected based upon the average incidence in the state) for various years for all cancers and for particular cancers. This study was reviewed in the context of this case by Dr. Patricia Buffler (*See Declaration in Support of Lockheed Martin Corporation's and Highland Supply Corporation's Opposition to Plaintiffs' Motion to Certify by Patricia Buffler Ph.D.*) Their conclusions are that the overall cancer rate was not increased and the slight (+10%) increase in the cancer that might be relevant to high percholate exposure -- thyroid cancer -- was well within statistical sampling error.

Steps 4 and 5 -- The existence of an elevated Standard Incidence Ratio (SIR) would still not be proof of causation. If society is convinced that the elevated SIR is troubling, it could provide funds for a careful epidemiologist to go further. He would firstly carry out a Case Control Study in which patients with the disease (thyroid cancer) are matched with a control group of people with similar backgrounds, including dietary and smoking habits. Still more convincing would be a cohort study in which a cohort (group) of people are followed to see whether or not they develop the disease. In this case there is no indication from the SIR that these would be interesting studies and they have not been done.

Step 6 -- Once there is proof of an increase in cancer rate then society must decide what to do. The most obvious step is to remove the exposure that is believed to cause the increase. If such removal is easy and cheap, and only to the extent that such if removal is cheap and easy society may well decide to act in this way before steps 4 and 5 are carried out and convincing proof is available.

It is useful to put any suggested action in perspective by comparing it with the actions society takes in similar circumstances with different postulated causes. Here it is important to remember that, with very few exceptions, the cancers caused by external agents and pollutants are not distinguishable in themselves from those cancers that have a natural cause. One can compare any proposed action or cure for a cancer that is postulated to have been caused by an external agent with the actions normally taken to cope with cancer. In particular one can compare what "medical monitoring" or cancer screening, is recommended by physicians and is effective. Cancer screening, by way of mammograms, is highly recommended for older women, but in general there is little in the way of screening for most cancers. [If it were proven (which it has not been) that there was an increase in cancer rate of 10% and increase in medical monitoring of 10% might be justified, but it would be hard to argue logically for more. *Do we really want to say this? How do you measure an "increase in medical monitoring" as a percentage?*]

individually established, and would mean that that individual was distinct from the rest of the people in the "class area."

Occupational and residential epidemiologic studies fail to show any significant, specific, strong or consistent pattern of association between TCE and any form of cancer. For example, reviews by the International Agency for Research and Cancer (IARC) show, for all cancer combined, that men exposed to TCE have about a 10% *lower* cancer mortality rate than does the comparable general population. Nor did the IARC find any significant association with the forms of cancer (cancer of the liver/biliary tract and lymphomas) that might be posited, on the basis of animal studies, as possible targets for human carcinogenesis by TCE. The available epidemiologic evidence on TCE and cancer in human beings actually is reasonably consistent to the effect that TCE is not a human carcinogen.<sup>5</sup> In evaluating the association between possible exposure to a

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<sup>5</sup> The evaluation and interpretation of epidemiologic studies in terms of causality involves the consideration of many factors. The most common set of these factors make up the "Hill criteria". These criteria were first used in 1964 in *Smoking and Health* in the US Surgeon General's report. They were subsequently modified and codified by Sir A. Bradford Hill (1965). The Hill criteria, or guidelines, for assessing causality can be summarized as follows:

- (a) Consistency. A consistent association is one that is seen in most studies.
- (b) Specificity. The exposure is associated with only one or a few diseases.
- (c) Strength. Associations with high SMRs are more likely to be causal.
- (d) Dose-Response Relationship. The higher the exposure, the greater the frequency of disease.
- (e) Coherence. The association is consistent with findings from other sciences and has biological credibility.
- (f) Temporal Relationship. In order to be causal, an exposure must occur before the occurrence of the disease of interest.
- (g) Statistical Significance. Statistically significant associations are more likely to be causal than are those which are not significant. However, a statistically significant association may not reflect causality and a non-significant association may.

In judging whether an association between an exposure and a disease is causal, the Hill criteria ordinarily are an important part of the process. Irrespective of the method used to judge causality, or the lack thereof, objective scientific information rather than subjective personal experience must form the basis of the judgment. Further, because it is common in epidemiology for there to be considerable variation in the presence and strength of association among studies, information must be presented from all of them in order to arrive at the most defensible interpretation. Therefore, it is not accepted scientific practice to include only studies that are consistent (or not consistent) with an association between a chemical and a disease.

chemical and the occurrence of cancer, it is standard epidemiologic practice to be as specific as possible. Thus, diseases are defined narrowly rather than broadly, and an effort is made to evaluate a specific exposure in relation to a specific disease. While there are instances in which one exposure causes several diseases, and in which one disease has several causes, understanding of etiology develops from the evaluation of individual exposures in relation to individual diseases.

In 1995, a Working Group of the International Agency for Research on Cancer made the following evaluation of *TCE*:

(a) There is limited evidence in humans for the carcinogenicity of trichloroethylene.

(b) Trichloroethylene is probably carcinogenic to humans (Group 2A).

In interpreting the meaning of category 2A the word "probably" should not be taken literally to mean at least 51% likely. This is so because the IARC evaluation is a subjective judgement and not a quantitative assessment. And, as Weiss (1996b) has pointed out, there is a major ambiguity in the IARC classification criteria that allows considerable variation in the strength and nature of the evidence that may be used to place a chemical in category 2A.

While the IARC has placed *TCE* in its category 2A, the National Toxicology Program (NTP) of the United States has a different view. The NTP categorizes a chemical compound either as a "known" carcinogen for human beings or as "reasonably . . . anticipated to be a human carcinogen". In fact, the NTP has placed *TCE* on neither list. (*US Department of Health and Human Services, 1998*).

A careful study has been done by Dr. John Morgan (J. Morgan, "Comparison of Observed and Expected Number of New Cases in the Twelve Census Tracts Encompassing Redlands, 1988-1994" (June 4, 1996 and update dated December 29, 1998) [\*\*\* need name of journal in which this paper was published]. He compared the Standard Incidence Ratios (the ratio of cancers seen in the Redlands area to that expected based upon the average incidence in the state) for various years for all cancers and for particular cancers.

In the absence of statistical association it is not reasonable even to entertain the question of a causal relationship. The most likely interpretation of all of the available data is that exposure to *TCE* does not cause cancer in human beings.

Medical monitoring, or, more properly, "screening"<sup>6</sup> is a reasonable approach to cancer control only in some limited populations and only for a limited number of cancers. Screening is used as part of a disease control program for the presumptive identification of preclinical disease in a group of apparently healthy persons. It is based on the use of procedures or tests that can be applied safely, rapidly and economically. If properly designed and employed, a screening program may distinguish between persons who have and who do not have a particular disease. Persons identified as disease suspects must then be subjected to diagnostic tests and examinations of a more sophisticated, complex and specific nature to establish or exclude a diagnosis.

There are five prerequisites that are generally accepted in the scientific and public health communities as necessary for implementing screening programs. They should apply to any specific program proposed by plaintiffs in this case. They are:

- (i) The prevalence (frequency) of cases of the preclinical disease being sought should be high among the persons who are actually screened.
- (ii) The disease should be sufficiently serious to warrant the effort, cost and possible adverse effects of the program.
- (iii) Eliciting evidence of the preclinical disease must be achievable with a test that is safe, simple, inexpensive and unobjectionable to the screenees.
- (iv) The evidence sought should indicate a high probability that the disease is present, and similarly, absence of the evidence should signify the near-certainty that the disease is absent.

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<sup>6</sup> "Screening" is use of a relatively simple, inexpensive test to a large number of asymptomatic persons in order to classify them as likely or unlikely to have the disease that is the object of the screen. In outcome terms, the objective of screening for a particular disease is to reduce the morbidity and mortality from that disease among the persons screened. Screening is a combined medical-public health practice conducted at the level of the individual and among the well.

(v) Treatment of the disease at the screen-detected stage should be easier and more effective than treatment given when the disease ordinarily would be symptom-diagnosed. Medical monitoring generally is an expensive and ineffective approach to cancer control. For cancer screening to have any reasonable chance of success a set of recognized guidelines for screening programs should be met. The guidelines should require that one use a sensitive, specific screening test in a high-risk population for the detection of a serious cancer whose treatment can be greatly enhanced by early detection.

No form of cancer to which TCE might even be considered to be related has been successfully screened for. *Amici* are not aware of any recognized screening test for such conditions as liver or biliary tract cancer or for any of the lymphomas. We are not aware of any recognized method for "residential screening" nor are we aware of any instance in which screening for an exposure (as opposed to a disease) has led to any individual or public health benefit. Moreover, medical monitoring may actually increase morbidity and even mortality in some populations.

It is the understanding of *amici* that the plaintiffs in this case consider that they should be screened for a variety of conditions including, most prominently, one or more cancers or precancerous states allegedly caused by their exposures to TCE. The most fundamental consideration, of course, is that TCE is not known to cause any form of cancer and certainly none for which, to my knowledge, screening ever has been advocated. In fact, it appears to us unlikely that any such test or series of tests or program could be recommended on any scientific or public health basis. If, hypothetically, low level exposure to TCE, such as some plaintiffs may have experienced, causes liver cancer, we would then ask: (i) Is the risk of liver cancer among the TCE-exposed plaintiffs high enough to warrant screening? (ii) Is there a good liver cancer screening test available? (iii) What are the sensitivity, specificity and potential adverse side effects of such a test? (iv) What will be the favorable and unfavorable impacts of early detection of liver cancer, if it occurs, on any individual? Based on my experience and knowledge I would suggest that the answers to these questions and to others that reasonably may be

asked would argue persuasively against the conduct of a screening program for liver cancer.

Determining the type of tests necessary to detect cancer in all persons who have lived in the geographic area defined in the plaintiffs' class designation would require intense and individualized study of each person by qualified physicians to determine the nature of testing indicated for each. It is impractical and inadvisable to apply all possible tests for cancer on a common basis to all persons who have lived in the geographic area defined by plaintiffs.<sup>7</sup>

In our view, a screening program as sought by the plaintiffs in this case is not indicated, would not serve any useful purpose and is not practicable or desirable for cancer or any health effect which plaintiffs contend has been or may be caused in the future by chemical exposure.

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<sup>7</sup> Apparently, the "condition" for which screening is sought by plaintiffs is "all disease" (cancer and other) caused by chemical exposures originating from groundwater allegedly contaminated by the defendants. However, there is no screening test which is inclusive of diseases caused by chemical exposure. Nor is there any test for "cancer". Cancer is a general term for all malignant processes affecting any organ. There is no general screening test for all cancer, only tests for specific cancers of specific organs, such as cancer of the breast, colon or cervix. Furthermore, utilizing all known screening tests to screen for cancer at as many sites as possible is inappropriate for a general population. Attempting to discover preclinical cancer at all sites requires differing tests, many of which are invasive and specific to the site and type of cancer which is being investigated. Because some of the tests used to detect cancer are invasive, one would not apply such tests uniformly to all members of the population. Any screening test for cancer will produce false positive results. That is, some persons who do not actually have cancer will react positively to the test and would then be subjected unnecessarily to invasive diagnostic procedures such as endoscopy or biopsy. Most cancer tests produce one to five percent of such false positives results, that is, 10-50 persons out of each 1,000 screened would be subjected to traumatic and unpleasant procedures in an effort to find non-existent cancers.

## **II. Determining Whether a Particular Exposure Has Sufficiently Increased the Risk of an Individual to Justify Additional Medical Monitoring Beyond is an Individualized Inquiry**

In *Potter*, one of the "evidentiary burdens" a claimant seeking medical monitoring damages must bear is that the plaintiff demonstrate "the relative increase in the chance of onset of disease in the exposed plaintiff as a result of the exposure, when compared to (a) the plaintiff's chances of developing the disease had he or she not been exposed, and (b) the chances of the members of the public at large of developing the disease." *Potter*, 6 Cal. 4th at 1005. "[T]here is no question that a defendant ought not to be liable for medical monitoring of a plaintiff's preexisting condition that is unaffected by a subsequent toxic exposure negligently caused by the defendant," but only for "increased or different monitoring of the preexisting condition . . . where necessitated as a direct result of the subsequent exposure." *Id.* In *Gutierrez v. Cassiar Mining Corp.*, 64 Cal. App. 4th 148 (1998), the court reversed a jury verdict awarding medical monitoring damages based on the trial court's failure to instruct the jury that a defendant is not liable for medical monitoring for pre-existing conditions, unless "additional or different tests are necessitated as a result of the toxic exposure caused by the defendant." *Id.* at 153.

The analysis and comparison of both pre-existing risk and pre-existing need are inherently individualistic in this case, given the wide range of chemicals involved and the potential diseases asserted. The Court of Appeal in *Gutierrez* recognized that *Potter* dictates that "the plaintiff must bear alone any amount of [the cost of medical monitoring] which his or her preexisting conditions would already require." *Id.* at 156.

From an epidemiologic perspective, there are four areas in which the plaintiffs in this litigation could be dissimilar from one another and which variation would probably bear on the issue of "commonality" in considering the appropriateness of class certification: 1) variation in exposure to TCE; 2) variation in internalization of TCE; 3) variation in susceptibility to TCE; and 4) variation in experienced relative risk. When these four major sources of variation are combined, any individual's exposure to TCE and

his or her risk of any particular cancer would vary widely. The putative plaintiffs are not a homogeneous group in this regard.

In addition, any statements about TCE and cancer risk, whether in connection with causation or class certification, relate only to a hypothetical risk. No sanctioning body, including particularly the IARC<sup>8</sup> or the U.S. National Toxicology Program<sup>9</sup>, considers TCE a known or established human carcinogen. Both Plaintiffs' and Defendants' experts agree that the actual susceptibility to disease, *i.e.*, the risk, of a person exposed to a dosage of a chemical is affected by his or her age, gender and a variety of circumstances. (Vol. 1, Tab 9, page 237 (Dahlgren Decl. at ¶ 26);<sup>10</sup> Vol. 3, Tab 19, page 518 (Teitelbaum Decl. at 24:9-17)). As stated by Daniel Teitelbaum, M.D., one of Plaintiffs' experts:

The outcome of the exposure [to a chemical], however, is determined by many factors including the dose, and the genetic makeup of the target individual. Other factors, which include age, gender, nutritional status, adaptation and acclimatization to the Redlands geographic and climatologic factors, lifestyle issues and more, determine which disease

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<sup>8</sup> In 1995, a Working Group of the International Agency for Research on Cancer made the following evaluation of TCE:

- (a) There is limited evidence in humans for the carcinogenicity of trichloroethylene.
- (b) Trichloroethylene is probably carcinogenic to humans (Group 2A).

However, in interpreting the meaning of category 2A the word "probably" should not be taken literally to mean at least 51% likely. The IARC evaluation is a subjective judgement and not a quantitative assessment. There is a major ambiguity in the IARC classification criteria that allows considerable variation in the strength and nature of the evidence that may be used to place a chemical in category 2A. [See Weiss \*\*\*]

<sup>9</sup> The National Toxicology Program categorizes a chemical compound either as a "known" carcinogen for human beings or as "reasonably . . . anticipated to be a human carcinogen". The NTP has placed TCE on neither list. (see *US Department of Health and Human Services, 1998*).

<sup>10</sup> Dr. Dahlgren was expressly "asked to assume that there is a clinically significant exposure to these chemicals among members of a group that is geographically defined as residing within Redlands," and he was not asked whether an exposure meeting the class definition constituted a "clinically significant exposure." (Vol. 1, Tab 9, page 231 (Dahlgren Decl. at ¶ 9)). Dr. Teitelbaum apparently made the same assumption as Dr. Dahlgren. \*\*\*

occurs in which person, and at what time of life, and in what body location.

(Vol. 3, Tab 19, page 518 (Teitelbaum Decl. at 24:9-14); *see also* Vol. 14, Tab 33, page 3368 (Guzelian Decl. at ¶ 7) ("justification of an opinion to recommend medical monitoring requires a quantitative analysis of the tests to be employed, the diseases to be screened for, and the available treatments for these conditions appropriately integrated into each particular individual's medical care program taking notice of such individual factors as their age, gender, medical and psychological history, and various lifestyle and familial risk factors"))).

While Dr. Dahlgren states that "[s]pecial testing of high-risk groups is good medicine." (Vol. 1, Tab 9, page 240 (Dahlgren Decl. at ¶ 33)) and further states that "[a]ll physicians recommend that persons at increased risk of a specific health problem should be seen by a physician regularly for check-ups," *Id.*, he concedes that membership in a "high risk" group depends many factors, including other environmental exposures, work history, genetic susceptibility, and lifestyle choices such as smoking and drinking, to name a few.

**CONCLUSION**

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## CERTIFICATE OF SERVICE BY MAIL

I, Barbara Tarentino , declare as follows:

I am employed by Atlantic Legal Foundation, in the City, County and State of New York; I am over the age of eighteen years and am not a party to this action; my business address is 205 East 42nd Street, New York, NY 10017, in said City, County and State. On December \_\_\_\_\_, 2000, I served the within BRIEF OF AMICI CURIAE by placing a true copy thereof in an envelope addressed to each of the persons named and at the address shown on the attached service list.

I certify under penalty of perjury that the foregoing is true and correct, that the foregoing document was printed on recycled paper, and that this Certificate of Service was executed by me on December \_\_\_\_\_, 2000, at New York, New York.

---

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