



Shell Oil Company
Interoffice Memorandum

PLAINTIFF'S EXHIBIT

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SUBJECT: Shell Extended Medical Surveillance - Current Status and Proposal for the Future

Enclosed please find a copy of a revised discussion of Shell extended medical surveillance. It includes a proposal for extension of asbestos SMSP participant follow-up into retirement (as is already occurring at certain Shell locations) as well as similar follow-up for retirees from the Silica and Man-Made Mineral Fibers SMSP's. Your review and comments would be greatly appreciated by February 28, 1992.

Thank you for your attention to this matter.

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Enclosure

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SHELL EXTENDED MEDICAL SURVEILLANCE - CURRENT STATUS 1991
AND PROPOSAL FOR THE FUTURE

Background

In 1981, the Shell Data Evaluation and Prioritization Team (D.E.P.T.) task force reviewed each substance covered by a specific Shell Medical Surveillance Program (SMSP) to determine whether or not any of the programs should be extended to include employees after retirement (Enclosure I). As a result of that review, eight substances were considered to be potential candidates for such a program. Two substances were recommended by D.E.P.T. for initial implementation. Both were chosen because of their potential carcinogenicity and because the amount of human data regarding the two substances was considered incomplete. The two substances chosen by D.E.P.T. were vinyl chloride monomer (VCM) and epichlorohydrin (ECH). VCM was later dropped from consideration when it was learned that most cases of angiosarcoma of the liver related to VCM exposure are diagnosed before the age of 65 and that no effective intervention was possible. A modified program was developed and implemented for ECH. Each ECH examination participant was offered a single examination five years after retirement. Only a small number of individuals were eligible for this program (less than 15 per year) and no adverse health effects linked to ECH were identified as a result of the program. In 1989, at the end of five years, that program ceased.

In 1985, a medical surveillance program was begun at Wood River, Illinois which included both active employees and retired employees living in the vicinity of the Wood River Manufacturing Complex (WRMC). This program was location specific and was developed in response to Shell mortality studies which had identified an excess of deaths due to leukemia in WRMC employees and retirees. The leukemia excess could not be associated with any specific time period, chemical exposure, or work area. This surveillance program has been well received by the location and has resulted in the early diagnosis of many highly treatable nonmalignant conditions. It has not found an unusual number of leukemia cases and has provided valuable reassurance that there is not an epidemic of hidden leukemia in active Wood River employees. It has found a possible increased number of cases of myelodysplasia (MDS), a

condition which frequently progresses to leukemia, in elderly retirees (average age = 76). MDS is known to be more common in the elderly. It is not clear at this time whether the apparent increase in MDS cases seen is due to a real increase in cases or to more comprehensive medical follow-up.

Since the early 1980s, the Shell Martinez Manufacturing Complex has had an asbestos medical surveillance program that includes medical surveillance of retirees with any signs or symptoms of asbestos related conditions at the time of retirement. Union bargaining was involved in this decision. The program has been well received by employees at Martinez and has allowed continued follow-up and counselling of retirees with asbestos-related disease. It has helped assure that affected individuals have received pulmonary and optimal medical management.

In the mid-1980s, the Shell Deer Park Manufacturing Complex medical director identified approximately 20 retiring employees with medical findings compatible with past asbestos exposure and, with Corporate Medical approval, arranged for continued postretirement medical follow-up of this group. Late last year, Westhollow Research Center requested and received approval for medical follow-up after retirement of a few employees who had asbestos-related medical findings.

The individual programs created have been effective. They have, however, created a situation in which certain Shell locations are providing a greater degree of medical follow-up for possible occupationally related diseases than other Shell locations. This, in turn, has led Corporate Medical to consider the whole issue of extended medical surveillance again and to seek a more integrated and consistent companywide approach for the future.

Relevance of 1981 D.E.P.T. Criteria

The technical factors developed by D.E.P.T. on which to evaluate potential candidates for an extended medical surveillance (EMS) program are just as relevant now as in 1981. These are:

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- A. The carcinogenic potency or other chronic toxicity of the chemical (the more toxic, the greater the potential need for an EMS program).
- B. The frequency/duration of exposure of Shell employees (the more frequent and longer duration, the greater the potential need).
- C. The route of exposure to Shell employees.
- D. The exposure levels of Shell employees.
- E. The latency period (time from exposure to development of disease).
- F. The extent and quality of existing epidemiologic data.
- G. The number of Shell employees affected (a factor only of importance if the rationale for a program is to provide additional epidemiologic data).

A factor not considered in 1981 is the presence of known, effective, early intervention to either reverse or control the disease process. Given these factors, Shell Corporate Medical has reviewed the existing SMSP examinations to determine which might be considered for a companywide extended medical surveillance program.

Evaluation of EMS Potential of Current SMSPs

Of the current 15 SMSP examinations that are substance specific, only a handful might qualify for an EMS program on the basis of long latency, high toxicity, and sufficient potential exposure. For all 15, the argument could be made that more extensive epidemiology data would be desirable. Quickly rejected from further consideration at this time are the SMSP examinations for:

- A. Epichlorohydrin (ECH) - rejected due to lack of benefit of previous program.

- B. Ethylene Dibromide (EDB) - rejected due to uncertain long term toxicity; low exposure levels in Shell.
- C. Formaldehyde - rejected due to lack of exposure in Shell.
- D. Hexamethylphosphoramide (HMPA) - rejected due to absence of specific human adverse health effect; no longer used in Shell.
- E. Isopropyl Alcohol (IPA) - rejected due to low risk for adverse health effect; lack of effective intervention; Shell no longer uses strong acid process.
- F. Lead - rejected due to fact that majority of adverse health effects are primarily acute rather than chronic (occur at time of exposure rather than many years later).
- G. Multiple Chemicals (Laboratory Workers) - rejected due to no single substance or outcome.
- H. Pesticides - rejected due to no known specific chronic outcome.
- I. Propane Sultone - rejected due to no known specific chronic outcome; no longer used in Shell.
- J. Vinyl Chloride Monomer (VCM) - rejected due to fact that most effects occur in active rather than retired personnel; no longer produced by Shell.

There are five SMSP examinations for which medical rationale is available and where the existence of an EMS program might be expected to be of benefit to Shell retirees as well as to the company. Employees have been or still are occupationally exposed; the long term chronic health effects are of a potentially sufficiently serious nature; early treatment and intervention may offer improved quality of life; and onset of disease is likely to occur or progress after retirement.

The issue of using an EMS program to further knowledge of a disease process and extend the epidemiology is also important, but in most cases, secondary to assuring appropriate medical follow-up of individuals at risk of developing an occupational disease. Epidemiology is enhanced only with much higher participation rates than such a program is likely to achieve. Better understanding of the natural history of a disease process, however, can be gained from even relatively low participation rates (60% participation was projected in 1981, and this is likely to be high, given the Wood River EMS participation rate for retirees of somewhat less than 50%).

Regular examination of individuals in a recognized risk group in a standardized manner and with specialty follow-up when indicated can provide a higher level of medical care and earlier recognition and treatment of problems than individual care by a personal physician untrained in occupational medicine and not seeing similar individuals. As with the SMSP examination, the EMS examination is an adjunct to care by the individual's personal physician and would be designed to assist the personal physician, not replace the personal physician.

The five programs for which an EMS program might be medically considered are:

- A. Asbestos - Long term chronic effects take many years to develop and are more likely to produce clinical disease after retirement than before. The severity of adverse health effects is high, and effects include lung cancer, mesothelioma, and progressive pulmonary disease (asbestosis). The number of exposed employees within Shell is high. In 1988, for all of Shell, 1295 asbestos examinations were performed and there were 325 living retirees who had previously participated in the asbestos examination program while active employees. Regular medical follow-up, counselling, and early treatment can mitigate the effects of asbestos-related disease. Such follow-up may also help in the early detection of lung cancer, but this is less certain. The goal of an asbestos EMS program would be to assure appropriate medical follow-up. Because employees with medical findings suggestive of asbestos-related

effects are far more likely to have their condition progress and to develop complications than those without such findings, the frequency of examination could be based on the presence or absence of such medical findings. Yearly examination would be recommended for all retirees with possible asbestos-related findings; those without such findings would be offered an every three year examination.

- B. Benzene - Long term chronic effects may take many years to develop. Leukemia is the best known chronic toxic outcome, although the possibility of other lymphohematopoietic neoplasms and blood dyscrasias has also been raised by some studies. Against an EMS program is the lack of efficacy of medical surveillance of active employees to either detect leukemia or to identify early changes associated with the development of leukemia. Recent advances in treatment hold promise for early intervention at a preleukemia stage if it can be identified. However, detection still remains a problem. An EMS for benzene at this time is of questionable benefit, but revisit may be indicated in the future as medical treatment advances and as a more complete picture of the effectiveness of follow-up of WRMC employees for possible leukemia (not benzene exposure) emerges.
- C. Ethylene Oxide - The long term chronic effects are uncertain, but may include leukemia, stomach cancer, and neurological impairment. Many of the same arguments as noted for benzene apply here. The number of employees potentially exposed is also small within Shell--in 1988 there were 184 active employees in the program and 8 retirees had previously been in the program while active employees.
- D. Man-Made Mineral Fibers (MMMF) }
 E. Silica } These two are considered together and should perhaps be considered with asbestos as well. Long term chronic effects include the possibility of lung cancer and progressive lung disease. Retirees are as likely, or more likely, to develop clinical disease. Treatment at an early stage can help mitigate at least some aspects of the disease. Many of the same individuals previously

exposed to asbestos are now exposed to man-made mineral fibers. The total number in both programs is small--30 active employees in the silica SMSP in 1988 with 11 retirees who as active employees had participated; less than 50 active employees have been enrolled in the MMMF program since its initiation in 1989. Medical follow-up and management of cases is very similar to that for asbestos. Combining these two plus asbestos into an EMS program for substances which produce chronic occupationally induced pulmonary disease would seem reasonable.

Conclusion

Thus at this time, the only SMSP program in which an EMS program makes medical sense on the basis of current diagnosis and treatment is asbestos or a combined asbestos/MMMF/silica EMS program to medically follow-up employees who retire from these programs. Offering more frequent follow-up to individuals with medical examination findings at the time of retirement or last examination would be less costly and would focus on the highest risk group. Less frequent medical follow-up of those without findings would assure that such individuals still have the opportunity to have a periodic assessment of their status. Total annual expected participation of those with medical findings where perhaps an 80% response is possible would be roughly 30 per year Shell-wide. Every three year participation of those without medical findings with a 50-60% response rate would be roughly 50 per year.

Corporate Medical is of the opinion that at those locations where follow-up of retirees with possibly asbestos-related medical findings has occurred, the programs have been well received and of benefit to employees and to the company. Extension to other locations with asbestos, silica, or MMMF examination programs would be favored. The following protocol is proposed for use by those locations which do not already have such a program.

EXPANDED MEDICAL SURVEILLANCE PROGRAM FOR RETIREES
FROM ASBESTOS, SILICA, OR MMMF SMSPs
(EMS - ASM)

I. Entrance Criteria

- A. Retirees who actively participated in the Shell Medical Surveillance Programs for Asbestos, Silica, or MMMF while at Shell and who experienced potential for exposure to asbestos, silica, or MMMF on an intermittent or regular basis in more than one year.
- B. Any retiree with documented asbestos, silica, or MMMF-related disease.

II. Exit Criteria: None

III. Medical Evaluation Schedule and Protocol

- A. Frequency of examination is determined by presence or absence of signs and symptoms of asbestos, silica, or MMMF-related disease at time of most recent previous surveillance examination.
 - 1. For those whose termination SMSP examination or most recent EMS examination found evidence of possible or probable asbestos, silica, or MMMF-related disease, an annual examination should be offered.
 - 2. For those whose termination SMSP examination or most recent EMS examination found no evidence of exposure-related disease, an examination every three years shall be offered.
- B. Examination Content - This examination should be specifically targeted to the pulmonary, cardiovascular, and gastrointestinal systems.

Forms to be used are the following:

1. S-11100 (Rev. 7-90) Confidential Medical History
2. S-22324 (Rev. 10-89) Smoking and Supplemental Medical History
3. S-11102 (Rev. 9-90) Medical Exam Report-Confidential
4. S-1118-2 Periodic Medical Questionnaire-Asbestos
5. S-12972 (Rev. 11-86) ILO Pulmonary Surveillance Worksheet

Examination shall include:

1. Medical history as per forms noted above
2. Chest X-ray (PA only) with clinical interpretation and B-reading. Right and left anterior oblique X-rays should be included every three years.
3. Pulmonary function testing: FVC, FEV₁, and calculated FEV₁: FVC ratio.
4. Physical examination by a physician directed to the pulmonary, cardiovascular, and gastrointestinal systems.
5. Rectal examination
6. Stool test for occult blood
7. Resting EKG
8. Counseling by the physician concerning the combined effect of smoking and exposure to asbestos, silica, possibly MMF on the development of lung cancer.

This examination should be coded as EMS-ASM EXAM.

IV. Alert Limits

- A. Any evidence of possible exposure-related disease, e.g., asbestos, silicosis, lung fibrosis, lung cancer, mesothelioma.
- B. Chest X-ray with evidence of possible exposure-related lesion such as pleural thickening or pleural plaques, interstitial fibrosis, or tumor.

- C. Loss of pulmonary FVC or FEV_1 , of greater than 80% from past best effort (on last exam), or decrease of more than 6% in the FEV_1/FVC . Tests with such changes should be repeated in two (2) weeks.
- D. Persistently abnormal pulmonary function tests.

These alert limits indicate the point at which referral to a pulmonary specialist should be seriously considered. A positive occult blood in stool test should be referred to the individual's personal physician.

V. Records

- A. Please forward one copy of all exam and consultation records to Corporate Medical with EMS-ASM EXAM clearly marked in the upper right corner of each document face sheet.

VI. Important. Notify Corporate Medical of any:

1. Diagnosis of exposure-related disease.
2. Any referral to a specialist for evaluation of possible exposure-related disease.

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