PLAINTIFF'S EXHIBIT

SWB-61

# Comments on "Projections of Asbestos-Related Disease, 1980-2000 - A.M. Walker"

Laboratory Report

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## Introduction

For purposes of public health and medical surveillance planning, and for consideration of research priorities, it is useful to have reliable estimates of asbestos-associated disease incidence anticipated in the next 4 or 5 decades. Our Laboratory has prepared such estimates;[1] [2] as have others.[3] [4]

A new estimate has recently been offered.[5] These projections of asbestos-related disease, 1980-2009, by Alexander M. Walker for Epidemiology Resources, Inc. constitute an unusual document. In line with others, Walker estimates the amount of current asbestos disease using available data on mesothelioma incidence. The procedure involves some uncertainties and some subjective judgments, but these can be evaluated and their correctness ascertained. He then undertakes a unique calculation. Projections for asbestos disease for the entire United States are made for the 1990's and early part of the twenty-first century, based on uncertain estimates of the number of workers exposed prior to 1955 and data on age and time of onset of employment of 77 individuals employed in an unidentified "asbestos-using industry" after 1955. These estimates of future disease cannot be directly evaluated because of the unavailability of basic data. However, they can be compared to other estimates and the sources of differences identified.

## Review of the methodology for estimates of future malignant disease

Walker ultimately relates all projections of asbestos disease to the incidence of mesothelioma currently identified in the United States. Here, he first estimates the number of mesothelioma cases in the United States, 1975-1979, from data available from the Surveillance, Epidemiology and End Results (SEER) program[6] and the percentage of such cases that may have had an asbestos exposure. This provides him with a number for current mesothelioma cases with past asbestos exposure. Data on 278 recently deceased mesothelioma cases in Johns-Manville's litigation files provide information on the distribution of ages and years of first exposure to

asbestos. Using current models of the time course of mesothelioma, he then estimates the exposed population necessary to produce the currently estimated asbestos mesothelioma cases. In these calculations, various adjustments were made to existing data and these directly influenced the estimates of current mortality attributable to asbestos.

Future asbestos disease depends very much on the number of individuals that were employed in industries and occupations with asbestos exposure since World War II. To obtain such an estimate, Walker relied heavily upon an unidentified survey, conducted by individuals named Elrick and Lavidge, who reported the distribution of ages of workers at first entry into an "asbestos using industry." This survey identified 214 individuals who had worked in this industry from before 1930 to 1979. Noteworthy was the fact that only 79 were aware of actual exposure to asbestos dust. No information was given as to the nature of the industry nor was the source of the data provided. Of significance for judging the validity of estimates of future asbestos mortality, only 77 of the individuals were employed subsequent to 1955. The procedure for estimating future disease among individuals exposed to asbestos subsequent to 1955 in all industries and occupations utilized this distribution of times of entry into the work force. The pre-1955 and post-1955 asbestos employment estimated from this survey were adjusted to the pre-1955 population based on current mesothelioma incidence. Walker further assumed that subsequent to 1960 there was a significant reduction of workplace asbestos exposure and reduced the estimated workforce (and, thus, its exposure) by arbitrary amounts ranging from 10% in 1960-64, 50% in 1965-69, 75% in 1970-74, to 100% in 1975-79.

The incidence of lung cancer was then estimated using the workforce as derived above, assumptions on the relative exposure of workers (taken to be one-half that of insulators on average), and data on the time course of lung cancer as related to asbestos exposure and age.

## Analysis of Current Mesothelioma in Cases Related to Asbestos Exposure

### Task 1A: Number of mesothelioma cases in the United States, 1975-1979.

The number of mesothelioma cases in the United States, 1975-79, was directly calculated from the incidence rates in the SEER program, 1973-1978 and the 1977 U.S. male population. This led to an estimate that 854 mesothelioma cases would have occurred in males under age 79. This number was adjusted to account for several factors:

1. The SEER data spanned the years 1973-1978 with a midpoint year of 1975 1/2. To obtain a 1977 incidence figure, the above value was increased to account for the 10% annual increase seen between the years of the Third National Cancer Survey (TNCS) and the 1973-1978 SEER data. This correction is an appropriate one.

2. The second adjustment was to reduce the estimate obtained from the SEER data by 12% because Seattle and San Francisco, two large World War II shipbuilding areas, were included in the SEER program and these were felt to contribute to an overstatement of the mesothelioma rates. This correction appears to be an inappropriate one. Extensive population mobility would rapidly reduce the effects of any disproportionate World War II exposure in Seattle and San Francisco. However, if one attributes all of the excess mortality seen in Seattle, San Francisco and Hawaii to shipbuilding and removes it from consideration, the 1973-78 age standardized incidence for white males would drop only 15%, from 9.3 to $7.9/10^6$. Since shipbuilding occurred on all sea coasts, one could only reduce the Seattle-San Francisco excess in SEER by the over-representation of shipbuilding in those areas during World War II. Information is available from U.S. Maritime Commission data for commercial shipyards that allows this to be estimated.[7] Puget Sound and San Francisco Bay yards accounted for 18% of the dead weight ship tonnage produced by all commercial yards during World War II. This is to be com-

pared with the 10% representation of the national population by SEER. Thus, the shipbuilding correction should be 15% x (0.18-0.10)/0.18 = 6%.

While a slight overestimate may result from inclusion of Seattle and San Francisco in SEER, an underestimate is likely because of omission of large urban and industrial areas, regions in which considerable asbestos was used in thermal insulation in high-rise buildings, chemical plants, refineries, power plants, etc. We feel this under-representation is at least equal to the 6% over-representation of shipbuilding, and, thus, would not correct for either factor.

3. A third adjustment of 10% is made in the SEER data for under-reporting of mesothelioma cases. This estimate may be somewhat low, although not greatly so. From a review of the pathology data available on the 175 mesothelioma cases in the Selikoff survey of insulation workers,[8] it was found that pathological review by Drs. Suzuki, Kannerstein and/or Churg altered the initial pathological diagnosis in 2 of 63 cases of pleural mesothelioma (3.2%) and 42 of 112 cases of peritoneal mesothelioma (37.5%). (Errors on the certificate of death diagnoses were much greater than the above; seventy-one of the 175 death certificates did not list mesothelioma as the underlying cause of death.) Eight cases that were listed as mesothelioma on certificate of death had pathological findings that indicated another cause of death. In all cases these initial pathological observations were verified. As the pathological diagnosis of mesothelioma in non-insulation workers might be expected to be poorer, at a minimum the SEER would miss about 5% of pleural cases and 50% of peritoneal cases. This would mean an underestimate in the total number of cases of from 15% to 20%.

4. One slight downward adjustment to Walker's data might be made. He applied white male incidence rates for mesothelioma to the total U.S. population. The SEER data suggest that the incidence

in nonwhites is less than in whites. The correct [illegible] 5.4% if the full difference were correct. (The 1973-78 SEER white male incidence is $9.3/10^6$, that of all males is $8.8/10^6$).

However, diagnosis of mesothelioma in blacks is likely to be significantly poorer than in whites so a correction of perhaps 3% is more appropriate. On the other hand, Walker did not explicitly include occupational deaths in women. We will consider these later.

5. One further adjustment should be made to the data of Walker. He considered only deaths through age 79; an additional 8.4% occurred in individuals 80 or older.

Thus, the actual number of 1977 mesothelioma cases in the United States is better represented by a value -

$$854 \times 1.15 \times 0.97 \times 1.084/0.825 = 1252$$

or at 28.5% more than Walker estimated. This difference, however, is relatively minor and would not be of major concern were it not compounded by more egregious errors.

Task 1B: The Fraction of Mesothelioma Cases with a Documented History of Asbestos Exposure

Walker estimates that only 54% of the male mesothelioma cases had a definite or possible history of exposure, with approximately 20% of the total cases having a "heavy exposure." This value is arrived at by some average of the percentage of cases with asbestos exposure identified from death certificate occupational records or interviews in various studies conducted between 1968 and 1978 in North America and before 1964 in London. The 54% is a misrepresentation of what the data would suggest for the 1977 period of time. Table 1 shows the proportion of mesothelioma cases with asbestos exposure as determined by interview in four North American studies. The data have been adjusted to the year 1977 from the midyear of the survey to account for the increasing percentage of deaths that would be occupational in recent years. In this adjustment it was assumed that all of the increases in male rates during the 1970's were occupationally

related and that all of the residue not reported as occupational in any survey were not occupationally related. The average of the adjusted percentage is 74%.

This adjusted percentage represents an underestimate of any occupational contribution as many interviewees (sometimes distant next of kin) would be unaware of a decedent's occupational exposure (thirty or forty years before). Further, even the decedent may have been unaware of the exposure (cf., the Elrick and Lavidge survey). Our analysis of exposures to asbestos[2] demonstrates that there is very high short-term turnover in industrial employment. Thus, many jobs with short-term asbestos exposure could easily be missed by an interviewer. The difficulty of obtaining an accurate occupational work history, even from the worker involved, is well described by Cochrane and Webster.[9] Parenthetically, they documented an asbestos exposure in 106 of 107 South African mesothelioma cases, when the history was obtained from the patients themselves. Not all 106 documented cases, however, were occupational; environmental exposures contributed some cases.

Another estimate can be obtained by comparing the age standardized mesothelioma rates in men and women in the TNCS and SEER programs where crude differences between the male and female rates in these programs would suggest that the contribution of asbestos in the male rates is at least 70%. As some occupational mesotheliomas occur among women, the percentage of occupationally related mesotheliomas among men estimated by this procedure would be even higher.

Considering the underreporting of asbestos exposure in interviews it is reasonable to assume that at least 80% of male cases are occupational. This increases the current occupational mesothelioma estimates of Walker by 48%. Coupled with his previous understatement of the U.S. mesothelioma cases in males, the number in the 1975-1979 quinquennium is at least 5,000 (80% of 6,250), not 2,630 (54% of 4,870). Females would contribute about another 250-500 cases. Walker understates the occupational asbestos mesothelioma mortality in 1977 by a factor of two.

In one sense, the uncertainties of the percentage of mesotheliomas attributed to occupational exposure to asbestos in 1977 are relatively unimportant. In that year the age standardized mesothelioma mortality for white males was $9.3/10^6$. In 1980 it had risen to $16/10^6$ (R. R. Connelly, personal communication) with all of the increase likely to be asbestos related. This raises the percentage of current occupational cases to about 90%. This 1980 value also points to the error of the Walker estimates. He projected 3,200 cases for the quinquennium 1980-1984, a 22% increase over 1975-1979. The observed 1980 value for white males is already 50% above the observed average for the 1975-1979 years and in excess of 1,500 per year (see below).

The procedure for estimating an "insulator-equivalent" population exposure to asbestos from current mesothelioma incidence, and the age and year of onset of 278 Johns-Manville cases is a proper one. It is limited, of course, by the small number of cases (278) which provide the age and year of onset data for the calculation. Unfortunately, it is not possible to verify the calculations because the basic data were not provided in the report. However, it is important to note that the procedure used by Walker does not give information on the actual population exposed or on the distribution of exposures in the population. These are important parameters in the assessment of various surveillance options that may be considered. Further, they are also extremely important in estimating the number of asbestos related lung cancers compared to those expected in exposed populations, as was noted by Walker.

Estimates of Future Mesothelioma

As mentioned in the preface, Walker's estimates of future mesothelioma hinge upon the distribution of times of first asbestos work for 77 individuals employed subsequent to 1955 in an "asbestos using industry." The absurdity of using such a data base for a projection into the twenty-first century is clearly evident. Firstly, it is statistically unreliable. Secondly, it does not account for employment in the major asbestos using industries in that period of time, construction and maintenance. Instead of a contracting work force as was suggested in Table 8 of the Walker

report, the construction industry was expanding, with an increasing number of individuals exposed to asbestos. Thirdly, during the years 1958-1972 the spraying of asbestos was commonly done for fireproofing buildings and led to significant on-site contamination with an entire construction work force being exposed to increasing quantities of asbestos dust. This sprayed-on asbestos, parenthetically, now in place in a variety of public buildings, adds further exposure to current and future building maintenance activities.

Dr. Walker has not taken into account the lesson learned in recent years: that the majority of asbestos disease occurs among individuals in the product use area rather than in manufacturing. Here, heavy intermittent exposures continued until the early 1970's during the installation of asbestos in power plants, ships, factories, high-rise buildings, refineries, chemical plants etc. Unless one identifies the individuals exposed in these industries, any projections of future disease have little relevance.

Comparison of Walker estimates with those of others and with TNCS or SEER.

As described above, the use of data from an unknown "asbestos-using industry" provides the basis for estimating asbestos disease from post-1955 exposures. The limitation of basing estimates of disease for the next 50 years on dates of hire of 77 men over 25 years is obvious. What may be less obvious is the great importance of choice of industry. Consider the differences in results if the "asbestos-using industry" had been the manufacture of steam locomotives which ceased in 1955, on the one hand, or on the other hand, the sprayed-asbestos insulation industry which received approval for the use of such materials in fireproofing only in 1958.

It is thus useful to compare the estimates for current and future mesothelioma derived by Walker with other estimates and with currently observed data. In the first section, it was shown that the 1973-76 average white male mesothelioma incidence of $9.3/10^6$ corresponded to approximately 856 x 0.97 x 1.084/0.825 = 1,083 cases in males (1,252 in 1977). It was estimated that at least 80% would be occupationally related in 1977. On

that basis the non-occupational rate would be $2.1/10^6$. In the analysis that follows, we will consider this rate to have remained constant since 1968, the first year of the TNCS. It is undoubtedly an overestimate, particularly in earlier years when diagnosis would be somewhat poorer. Table 2 lists the observed white male rates for the years of the TNCS and SEER[6] along with the estimate of occupational mesotheliomas they imply. The relationship used was $9.3/10^6$ = 1,088 U.S. male cases which takes account of mesothelioma in blacks, underdiagnosis of cases, and inclusion of individuals over age 79. Also shown are correction for non-occupational cases, conservatively estimated to be 20% in 1977, and for occupational cases in women, conservatively estimated to be 5% of the male cases. The annual number of mesothelioma cases are listed in column 5 and are also plotted in Figure 1 along with the projections of Walker[5] and of Nicholson, Perkel and Selikoff.[2] In contrast to Walker, our projections were based on estimates of the populations exposed to asbestos and of the risk present in various exposed groups. It was not based on SEER data. Thus, concordance with SEER data serves as a validity check.

The most dramatic feature of Figure 1 is the rapid increase in the cases of mesothelioma attributed to asbestos. Part of this increase may be due to better diagnosis in the more recent years of the SEER program but such an effect would be small (10-20%, perhaps). If the percentage of non-occupational mesotheliomas is less, the rise would be less steep but still much greater than estimated by Walker (and by us, as well). The dotted line between 1970 and 1980 shows the effect of considering 90% of cases to occupational in 1977 and a 20% improvement in diagnosis to have occurred between 1970 and 1980. Conversely, if the non-occupational cases are a greater proportion of the total, the SEER values would lie somewhat lower, but the trend with time would be even steeper. The other notable feature of Figure 2 is that Walker estimated only 35% of the cases actually seen in 1980. The underestimates will increase significantly in future years as a result of his significant understatement of the population exposed and his underestimate of exposure since 1955. By 2005 his estimates are only 18% of ours. Further, from a comparison of the trend of SEER cases with time, it would appear that even our estimates in the year 2005 are likely to be an understatement. It should be noted, however, that the

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current steep increase of mesothelioma with time implies a continued rise for at least a decade or two. The long time span over which mesotheliomas are seen from given exposure circumstances precludes any sharp alterations in incidence rates or trends.

Lung Cancer Mortality

The population estimated from current mesothelioma cases (understated by at least a factor of two) and the "asbestos-using industry" employment data were used to project lung cancer cases. The number of current and future cases was estimated using the fact that asbestos exposure leads to an increased relative risk of lung cancer proportional to exposure which is applied to general population mortality data. This was adjusted by a factor to account for selection effects.[1] [2] The procedure is roughly correct, except that the correction factor was related to time since 1979, not to 35 years from first exposure or after age 60. The results, however, are most in error because of the previously described inadequacies in estimating the number of occupational mesothelioma cases (which served as a basis for estimating the population currently at risk) and the population believed to be at risk subsequent to 1955.

Figure 2 displays the lung cancer mortality estimates of Walker[5] compared with ours.[2] Walker's estimates are about 83% of ours in 1980 but only 14% in 2005. His much steeper decline can be attributed largely to the above misestimates of the population at risk. The more rapid decline in Walker's lung cancer cases relative to those he estimates for mesothelioma is the result of applying an arbitrary reduction in relative risk after 1979.

Cancer of other sites

In addition to lung cancer and mesothelioma, the rates of cancer of the larynx, pharynx-buccal cavity, esophagus, stomach, colon-rectum, and kidney are each elevated significantly in some exposed populations compared with rates expected in the general population.[8] Cancer rates at other sites are also elevated, butare not of statistical significance for

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an individual site. However, the excess of all these "other cancers" is significant at the $p < 0.0001$ level. None of these gastronintestinal or other cancers were considered by Walker. Overall, the asbestos-related excess of these other sites is about 25% of the excess observed in lung cancer.

Asbestosis projections

The data used by Walker for projecting the prevalence of asbestosis are also fraught with difficulties. He utilized a variety of procedures to obtain the estimate of asbestosis cases in the United States. In one, he uses British data which suggest that approximately 28% of mesothelioma cases have diagnosable asbestosis, coupled with the uncertain evidence that individuals with asbestosis have a mortality of about 0.005/year. The estimate of the current number of asbestotics was then estimated by taking 28% of the mesothelioma deaths/yr (those that had asbestosis) and dividing by the mortality rate for mesothelioma among asbestotics (0.005/year). This led to an estimate of about 55,000 men with fairly severe asbestosis and the percentage of deaths from asbestosis among individuals who are asbestotic to obtain similar estimates. Walker then arbitrarily assumed that there would be little development of asbestosis subsequent to 1985.

It is difficult to judge the validity of the procedure of estimating the number of current asbestotics. The British data on the percentage of heavily exposed mesothelioma cases may not be relevant to the United States. Further, the mesothelioma mortality among asbestotics of 0.005 is very uncertain. The greatest problem with his estimate is the assumption that no new cases will develop after 1985. This is clearly wrong. To a first approximation, they should develop at a rate approximately proportional to new cases of mesothelioma. The proportionality constant is difficult to estimate accurately. It can be approximated by considering the deaths (from all causes) among 55,000 asbestotics alive in 1977. This assumes that the new cases in 1977 are roughly equal to those that are dying (a steady state hypothesis and one that understates the situation). The number of deaths from 55,000 would be about 3,000-5,000/year, only slightly less than the number of mesothelioma cases. Thus the proportion-

ality constant is about 1. The pool of heavily exposed asbestotics is likely to increase until at least 1990 and decline thereafter faster than mesothelioma mortality.

The above analysis is concerned with heavily exposed workers having an age specific total mortality 2-3 times expected. The problem of asbestosis among lesser exposed individuals is not considered. Many individuals, not at risk of death from asbestosis, will have X-ray abnormalities and, perhaps also, some pulmonary dysfunction. No estimate is made of the number of such workers nor of their requirements for medical care and surveillance.

Summary

Little public health guidance can be expected from the Walker evaluation of anticipated incidence of asbestos-associated disease, 1980-2009. In part, this reflects idiosyncratic selection of reported information, often not accessible in available literature, as well as omission of significant populations at risk. Of most significance, the calculations by Walker provide a serious underestimate of disease associated with past asbestos exposure. The underestimate for cancer mortality in current years is about a factor of 2, but by the year 2000 would appear to be low by at least a factor of 5. These underestimates occur for the following reasons:

1. Incidence of mesothelioma in national reporting programs (TNCS and SEER) is utilized as an index for incidence of current asbestos associated disease. It is therefore disadvantageous that a number of adjustments made to the reported data were inappropriate, leading to an underestimate of approximately 25% in the number of recent mesothelioma cases in the United States. This is compounded by a sharp underestimate of the proportion of these cases attributed to previous asbestos exposure, resulting in an understatement of current disease by a factor of 2.

2. Walker's estimates of future mesothelioma hinge upon the distribution of times of first asbestos work for 77 individuals first employed between 1955 and 1979 in an "asbestos using industry." No information was provided concerning the nature of the industry or the source of the data. The extraordinary weakness in using such a data base is clearly evident. Firstly, it is statistically unreliable. Secondly, and of most importance, it does not take account of the major sources of asbestos exposure in that period of time, the expanding construction and maintenance industries (witness the omission by Walker of asbestos spraying exposure in the construction industry 1958-1972, where virtually the entire construction workforce was exposed to considerable amounts of asbestos). Thirdly, estimates made from this scant population base were further compromised by an inappropriate, unsubstantiated exposure reduction to those estimated to be employed. Walker failed to acknowledge the major lesson learned in recent years - that most asbestos disease occurs with asbestos use rather than in manufacturing. Unless individuals in these industries are identified, projections of future disease have little relevance.

3. Estimates of future lung cancer mortality were affected by the above limitations. Moreover, a reduction in risk, seen in long-term exposed populations over the age of 60 or after 35 years from first employment, was applied to all exposed individuals after 1979, leading to the virtual elimination of lung cancer as a disease of concern after the year 2000.

4. For public health and medical surveillance planning, it is important to know not only the incidence of fairly severe asbestosis, sufficient to produce an age-specific total mortality 2-3 times expected, but also the number of individuals exposed to asbestos at levels below such heavy exposures. Many individuals with exposures of lesser intensity will nevertheless have X-ray abnormalities and some will have disability of various degrees. No estimate is made of the number of such workers. This may exceed the total number of cases of all other asbestos disease. It is therefore disadvantageous that it was omitted.

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Table 1

Proportion of mesothelioma cases with asbestos exposure history

| Reference | Region; subjects | Source of data | Proportion of cases with asbestos exposure (%) | | Adjusted to 1977 |
|---|---|---|---|---|---|
| Peto et al[10] | Los Angeles 1974-1978, males | Case or close relative interview | 69/91[a] | 76% | 78% |
| Vianna et al[11] | New York State high incidence counties, 1968-78 | Patient or first degree relative interview | 17/31[b] | 55% | 72% |
| Tagnon et al[12] | Coastal Virginia 1972-78, white males | Patient or next of kin interview | 43/56 | 77% | 81% |
| McDonald et al[13] | All Canada (emphasis on Québec) 1968-70 | Relatives and friends interviews | 31/69[c] | 45% | 74% |

[a]Excludes those for whom interviewee was unsure of work history.

[b]Excludes indirect exposure (e.g. family member of an exposed person).

[c]Includes "possible" exposure as well.

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Table 2

Estimates of occupational mesothelioma based on TNCS* and SEER* data

Mesothelioma incidence /$10^6$

| | SEER or TNCS age adjusted white male rates[a] | Corrections for "background" cases (-2.1) | 5% addition for direct occupational cases in women | Occupational mesothelioma cases[c] |
|---|---|---|---|---|
| 1969-71 | 5.5 | 3.4 | 3.6 | 421 |
| 1973 | 6.6 | 4.5 | 4.7 | 550 |
| 1974 | 9.3 | 7.2 | 7.6 | 889 |
| 1975 | 9.3 | 7.2 | 7.6 | 889 |
| 1976 | 9.4 | 7.3 | 7.7 | 901 |
| 1977 | 8.5 | 6.4 | 6.7 | 784 |
| 1978 | 12.3[b] | 10.2 | 10.7 | 1252 |
| 1979 | 13[b] | 10.9 | 11.4 | 1334 |
| 1980 | 16[b] | 13.9 | 14.6 | 1708 |

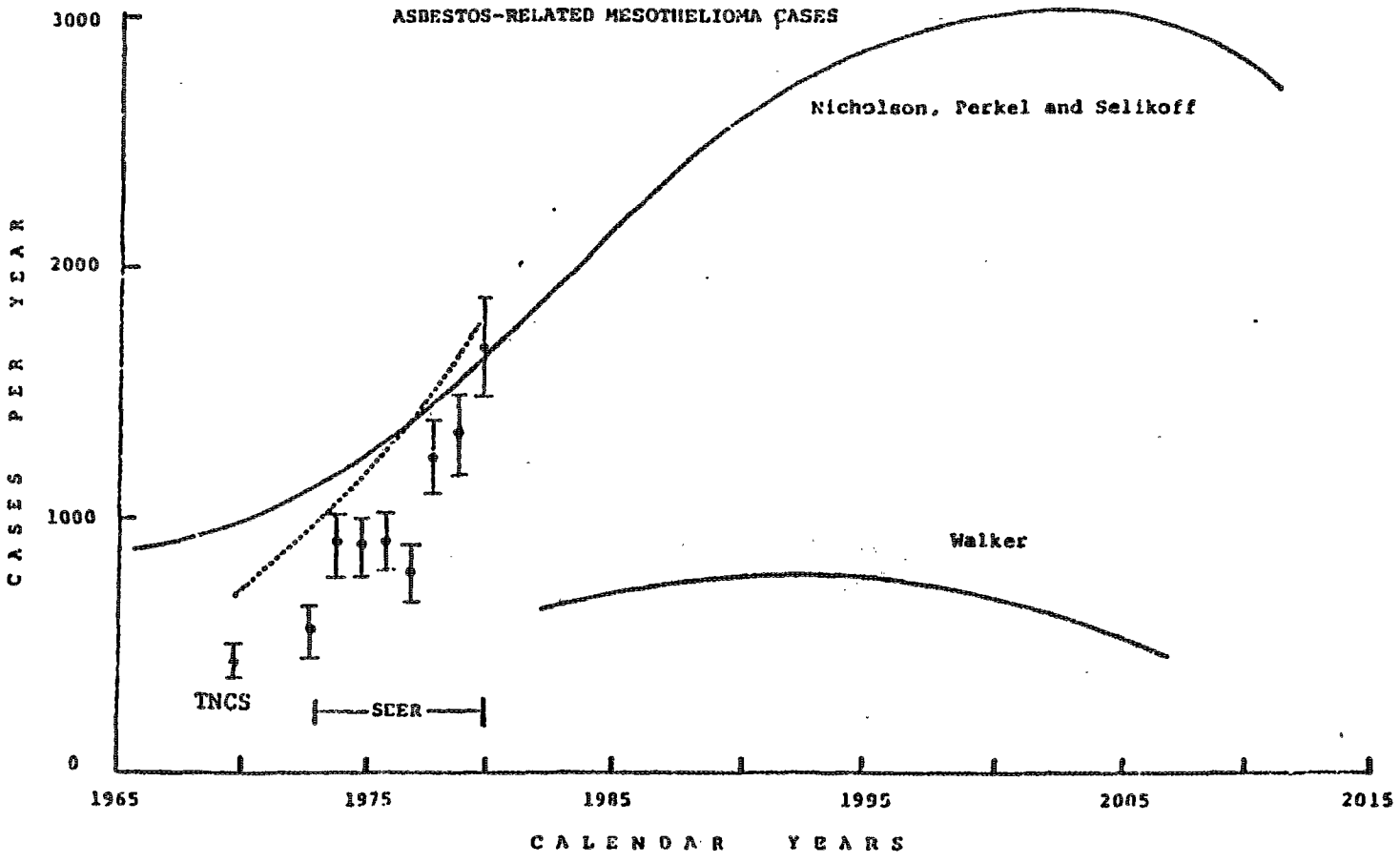
[a] From Ref. 6

[b] Date furnished by R.R. Connelley, personal communication.

[c] Obtained using the relationship $9.3/10^6$ = 1088 cases in all males. This corrects for inclusion of nonwhites (3%) for under diagnosis of mesothelioma (17.5%), and for inclusion of deaths over 79 (8.4%).

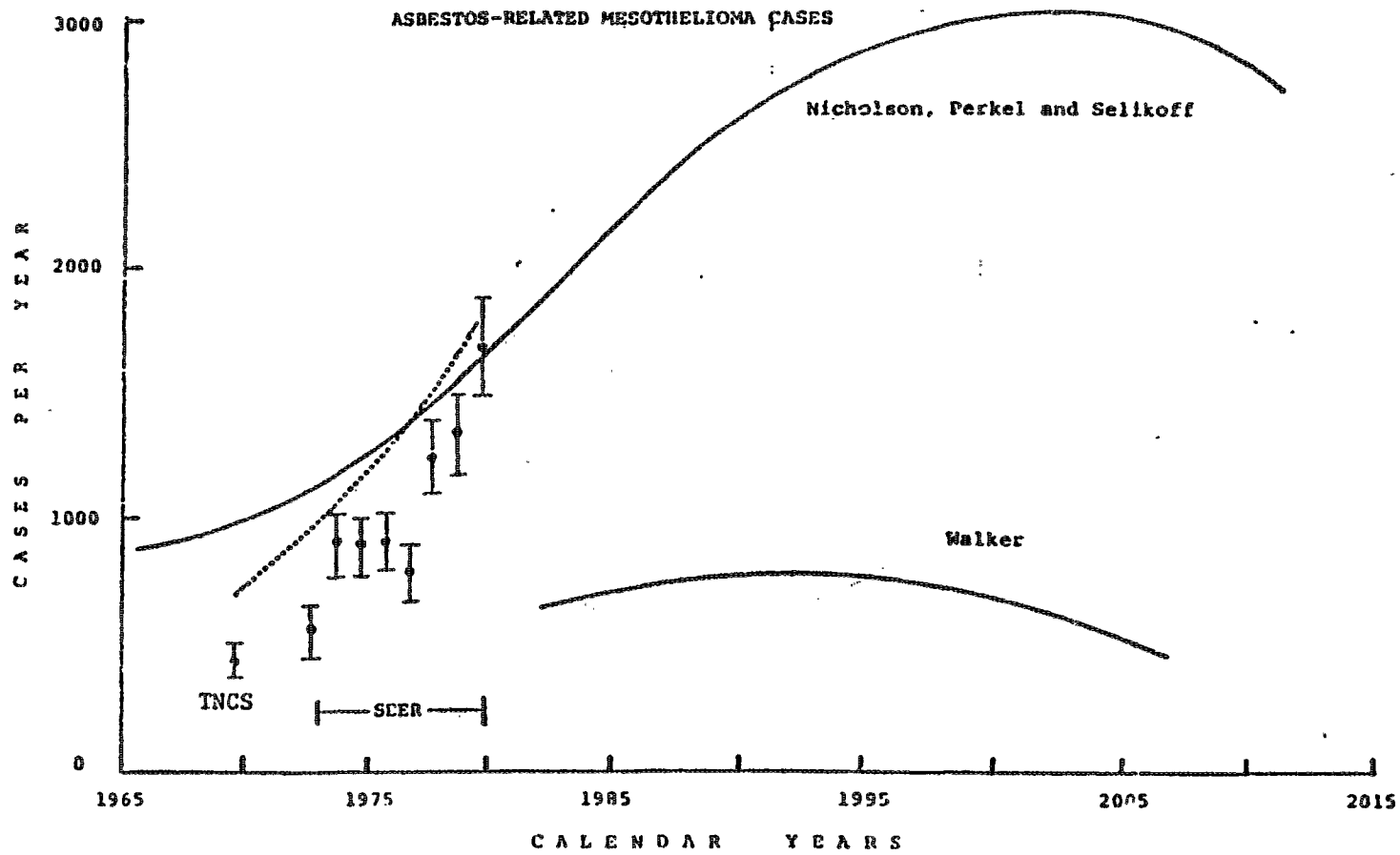
* TNCS = Third National Cancer Survey; SEER = Surveillance, Epidemiology and End Results program, National Cancer Institute, Bethesda, Md.

Figure 1



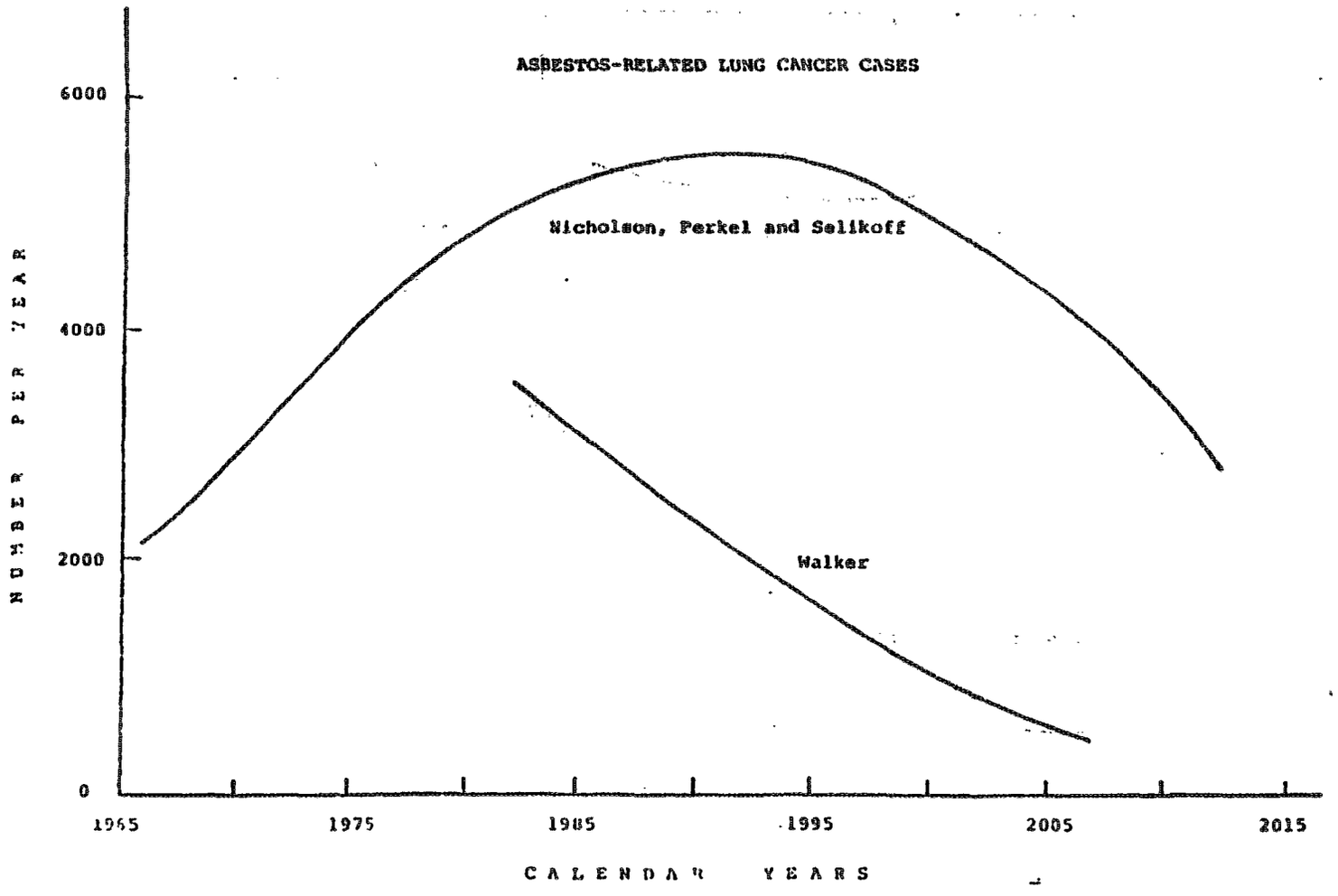

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Figure 1




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Figure 2




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