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WINDSOR MINERALS INC. P.O. Box 680 Windsor, Vermont 05089

NIOSH SPONSORED TALC STUDY

INTRODUCTION:

Corporate representation relating to the NIOSH sponsored talc study now underway in Vermont has included representatives from Baby Products, Analytical Research and Windsor Minerals. Functional activities included monitoring and directing "in house" activities and acting in a educational and advisory capacity to provide NIOSH and Harvard School of Public Health with a realistic study plan.

The result of these activities has created a minimal risk to our corporate talc commitment and has further provided the opportunities to strengthen the foundations of this commitment.

At the present time we can predict with a high level certainty the specific risks involved and provide adequate defenses against these risks. We can further,responsibly predict the outcome of the study, and even influence the conclusions by way of directional suggestions involving the subjective interpretations of the study groups.

This writer now recognizes that the judgment and decision making responsibility of this team has reached its limits. The responsibilities and consequences of applying the alternatives we have provided, must now be implemented by those in higher management who have the vantage point of long term perspectives of the realistic consequences of a particular decision.

CONCLUSIONS:

The conclusions and results derived from the medical and environmental studies will show little or no epidemiological effects relating mineral dust exposures to the workers of Windsor Minerals. Likewise the analytical aspects involving TEM and X-ray diffraction studies will confirm what we have already related to NIOSH and can substantiate with vast quantities of data. The other Vermont companies will not fare nearly as well.

The corporate risks and defenses based upon the scientific details of this study are covered in great depth in the pages that follow. They ultimately define the corporate risks at every step, provide knowledgeable outcome assertions and define the strategic decisions that must be faced. The salient areas and questions which must be brought to attention are outlined below.

1. Medical risks of negative findings in X-ray and dynamic pulmonary studies are greatest in the other Vermont talc companies. Knowing there are similarities in the geology and geography of these companies to Windsor's operations raises the following decision requiring questions.



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a) What effect will this have on the corporate use of Vermont talc?

b) What effort and in what directions do we proceed to provide our Baby Powder and Industrial Materials with the protection they deserve?

c) Do our efforts to provide this protection conflict with corporate or moral philosophies?

2. Environmental and analytical study outcomes are well defined as are the related risks and defenses. Within the framework of little or no medical risks as previously discussed, and including the NIOSH study objectives of defining the respirable related health effects of pure talc and generic "talc", requires decisions concerning the following:

a) Do we alter the properties of Baby Powder to meet changing health perceptives?

b) How do we strengthen our industrial markets?

c) What are our obligations to provide purified talc to other manufacturers for consumer markets?

d) Do we utilize a favorable study conclusion for future protective purposes or do we exploit the marketing potential involved and how does this interact with (c) above?

3. Mortality studies will not be applicable to Windsor Minerals due to its relatively small and short occupational existence. The other companies will probably show no increased tumor mortality but will indicate increased respiratory related mortality.

Our credibility will allow us to minimize the increased respiratory morbidity and mortality in the other companies on the basis of sound scientific and rational arguments. These are covered in depth at a later point. Since our primary corporate commitment is to health care I must ask:

1. Whether a company with no such concerns will respect and return our aid,or will they exploit our influence in the form of profiteering which may involve mining undesirable ore bodies; improper ventilation; etc., etc.; neglecting to consider a follow up study in five years?

2. If the above is a reality,will we be stirring up a hornets' nest again?

The previous statement serves as an antecedent to the detailed scientific support and strategic considerations which follow. The total document will stand as reference for those individuals and

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groups who will later participate in the study and provide the guidelines to maintain future direction as the study progresses.

Vernon Zeitz

VZ:ab

VERNON ZEITZ
MANAGER, RESEARCH &
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NIOSH Sponsored Talc Study - Strategies and defenses relating to the study in progress and terminal conclusions upon completion.

Summary and Objectives

One objective of this document is to stimulate poignant considerations of the NIOSH sponsored Vermont talc study as applied to our corporate involvement. Structured within this statement are the following:

1. Pertinent history of this study.

2. Statements of fact and theory which should be incorporated into our thinking for protective and strategic purposes.

3. Responsible accurate prediction of the scientifically based conclusions of the study.

4. Corporate protection against unexpected findings.

5. Discussions concerning the means whereby this study and the resulting conclusions can be utilized to strengthen our present scientific and financial position in the talc industry which lead to the possibilities and questions which follow:

   a) Halting the erosion of confidence in our talc based products resulting from crusading health advocates who rely on extrapolation and guesses as opposed to scientific evidence.

   b) Development of strong offensive opportunities through our having a government issued statement as a basis for support.

   c) Will there be corporate involvement with, or independence from the other Vermont talc producers?

   d) How do our present products rate in terms of the health related aspects of this study, based on a viewpoint which incorporates the most recent concepts and technology involving respirable materials?

Concurrent with the detailed treatment which follows, and as a consequence of the obvious complexities inherent within a statement of this nature, a development outline is provided to both maintain and identify the objectivity of the presentation, and the reader's perspective, while being enveloped by the voluminous content of this document.

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DEVELOPMENT OUTLINE

Section 1

I. Opening Statement.

II. Historical perspective of strategy development.

III. Foundations for defensive position and future strategic development.

A. Nomenclature and talc definition.

B. "Respirable" particle definition.

1. environmental model and measurements.

2. true respirable dose response.

C. Asbestos induced tumor development (prevailing theory).

1. prerequisite properties (dimensional).

2. penetrability.

3. irritability upon penetration.

D. "Nuisance" dust concept invalid.

E. Low respirability of platy minerals.

F. Total access to information.

G. Qualified sources of talc for J&J.

Section 2 Outline of NIOSH Study Model (Table 1).

Section 3 Data and present information sources available to study.

A. Comparative pulmonary function data - Table 2.

B. Green survey - Attachments 1 and 2.

C. Rubino Mortality Study - Attachment 3.

D. Detection of Ventilatory Abnormalities in talc workers - Attachment 4.

E. McCrone Ore Reports - Attachment 5.

F. McCrone Report - Argonaut Ore Body - Attachment 6.

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G. Windsor Environmental Sampling - Attachment 7.

H. J&J Analytic Results - George Lee - Attachment 8.

I. Sivertson Data - George Lee - Attachment 9.

J. NIOSH letter - Attachment 10.

Section 4 Outcome Strategy Outline.

I. Statement of Predicted Outcome.

II. Medical Study.

A. Positive Aspects.

B. Negative Aspects.

C. Conclusions.

D. Risk Level and Defenses.

E. Strategic Considerations.

III. Environmental Study.

A. Positive Aspects.

B. Negative Aspects.

C. Conclusions.

D. Risk Level and Defenses.

E. Strategic Considerations.

IV. Analytical Study.

A. Positive Aspects.

B. Negative Aspects.

C. Conclusion.

D. Risk Level and Defenses.

E. Strategic Considerations.

F. Comments.

V. Mortality Study.

A. Speculative Comments Only.

B. Defensive Position.

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SECTION 1

I. Opening statement:

It is an acknowledged fact that in recent years a great deal of adverse publicity has been directed at "talc". Personal contacts with physicians and consumers leads me to believe, that both our Baby Powder and industrial markets are endangered through future erosion of sales resulting from a loss of confidence associated with the health risks assigned to "talc".

This writer believes, that our prior corporate involvement in the way of doing battle with federal, academic and consumer health groups have had little effect in the world of the physician and consumer to counteract the above.

As both an optimist and a pragmatist, it is my belief the NIOSH sponsored talc study represents our first and, possibly, last opportunity to halt the increasing negativism that is being directed at our corporate involvement with "talc" and at "talc" per se.

As a consequence of these beliefs, and what I am led to believe to be a strong corporate commitment to talc, I feel it essential to prepare a statement encompassing the present study, its outcome, and the strategic position and decisions with which we will be faced.

The readers of this should fully recognize, that the development and application of the strategies posed by this writer stand as a singular approach, from a singular position, in an attempt to successfully resolve a problem whose magnitude and degrees of freedom exceed the capabilities of any individual. The underlying purpose of what follows is to stimulate, either through reader agreement or disagreement, perspectives which will enhance and strengthen our position with respect to both the present NIOSH sponsored talc study and our future in talc related activities.

II. Historical Perspectives of Strategy Development:

The present strategic position, as will be related, was the result of a tedious trial and error involvement with NIOSH and Harvard.

Initial meetings generated mutual attitudes of fear, mistrust, and animosity. From our vantage point, the study groups (i.e. NIOSH and HSPH) continuously referred to terminology involving causative agents, pulmonary morbidity, etc. Our perceptions indicated an unwillingness on their part to relate or respond to the realities of our operations. Among points of concern were the following:

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1. ore body variations, both Vermont and domestic U.S.

2. dramatic improvements in the working environments resulting from changes in mining methodology and improving technology.

3. unclear organizational responsibilities within the study groups.

4. poorly structured explanations concerning the purpose of the study and objectives relating to the outcome.

5. A lack of objectivity which we had previously encountered with other government agencies and academic groups.

It was later discovered that our perceptions were for the most part correct. The reasons, however, were found to be the result of a singular lack of knowledge concerning both the mineralogy of "talc" and the industrial realities of its mining and subsequent conversion to products and the uses of these products. There were many misconceptions contained within their study plan; the most prominent being that of the extreme purity of the Vermont talcs in their natural state.

The only alternative at this point was to generate a strong educational effort to provide the basis for a study conducted in an atmosphere of knowledgeable and sound science.

Numerous preliminary meetings were held involving both Harvard and NIOSH on the pretense of protocol reviews; while in reality were structured as a "crash course" in ultramafic and serpentine mineralogy, including lectures on geochemistry directed at the metamorphic pathways, through which talc, and its accessory minerals are formed. Emphasis was placed upon the interaction between the geo chemical precursors and the geological conditions surrounding the transformations leading to, and explaining, the large number of differing "talc" ore bodies which are known to exist today.

A great deal of effort was expended by representatives of both Windsor Minerals and Johnson and Johnson to develop defensive and offensive opportunities through this approach, which relied upon low keyed but highly persuasive intellectual arguments. The process was extremely effective and allowed the subtle development of a strong strategic position with respect to this study and, if properly utilized, will have far reaching, positive long term corporate implications.

III. Strategic foundations:

The following represents in detail a number of cogent points, which are statements of fact or theory from NIOSH, which should provide the protective and the possible offensive mechanism to

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further our corporate involvement in talc, and to this study in particular.

A. Nomenclature and talc definition

The word talc is used loosely to describe a wide variety of minerals ranging from essentially pure talc ($Mg_3Si_4O_{10}(OH)_2$), to materials having no talc content whatsoever. The resulting confusion has led to unproven and, most probably, erroneous health statements directed at the specific mineral talc as best exemplified by Windsor's Grade 66 cosmetic talc. This study will be directed at clarifying and distinguishing the health related effects, if any, resulting from pure talc exposures, as opposed to the non-talc constituents.

NIOSH agrees the word and symptomology describing "talcosis" is probably a misnomer as the dust exposures relating to the symptons were primarily amphiboles, carbonates, and silica, with minimal talc exposures.

B. "Respirable" Particle Definition

A "respirable particle" is defined physiologically as a particle which penetrates the deep lung, i.e., past the ciliated epithelial linings into the alveolar spaces. This study will utilize technology which, at best, is a poor model of the lung. Both Harvard and NIOSH acknowledge the difficulty and dangers in oversimplifying the environmental exposure measurements and are very much aware that the factors of size, shape, charge, density, and chemistry will effect a particle's aerodynamic properties. These factors will be taken into consideration in attempting to describe, in a responsible manner, the relationship of a respirable dose response to measured pulmonary effects, if such a relationship does exist.

C. Carcinogenic properties of Asbestos

The etiology of chrysotile asbestos induced tumor development as presently accepted by NIOSH, does not relate its toxicity or carcinogenic potential to either its chemical composition ($Mg_3Si_2O_5(OH)_4$), trace metal components or absorbed surface contaminants, as has been proposed in the past. These theories have been dispelled on the basis of finding a number of materials having similar carcinogenic potential, but differing widely in their chemistry, ultrastructure, and sources of occurrence. This effect has been observed in materials such as anthophyllite, crocidolite, mineral wool, fiberglass, etc., and the tumor potential of these materials has been attributed solely to properties associated with their fibrous nature.

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It is presently believed that the carcinogenic potential of a fiber is lost if it can be biologically encapsulated and effectively removed from pulmonary tissue.

The tumor potential of a fiber is strongly related to its dimensional properties of length and diameter. It is felt that long ($>$ 5-10 microns), thin ($<$ 1.0 micron) fibers present the greatest hazard. Fibers less than 1.0 micron in length are most probably cleared and do not pose a true carcinogenic potential.

D. Nuisance dust

The present concept of a nuisance dust is rapidly falling out of favor. Recent evidence shows that any material when respired at a sufficient level gives rise to pulmonary morbidity. The extent of the damage will depend primarily on the quantity and nature of the respired materials. This is exemplified by recent findings of excessive damage in the lungs of worker exposures to seemingly innocuous, readily metabolized materials such as starch (baker's) and carbonate dust (marble workers).

E. Respirability of platy materials

Environmental sampling by Harvard and NIOSH, using their hydroclone based air sampler, has shown platy talc to have a low value of respirability with respect to other mineral forms.

F. Access to information

The medical and epidemiological aspects of this study will be supported by the best available technology through the assurances of a system of checks and balances, whereby all involved groups will have access to all information accumulated pertaining to this study. Subsequent review and comment by the individual companies, and their consultants, will mean objectivity in data treatment, interpretation and any conclusions reached by the study groups.

G. Qualified domestic sources of talc for use by Johnson & Johnson.

NIOSH and Harvard are aware that there is only one presently qualified domestic source for J&J Baby Powders. They were given explanations involving unique plate structure, minimal quantities of undesirable minerals, beneficiation expertise, etc. We attempted to and, in fact, created a mystique around our talc involvement through our operations and factual knowledge.

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SECTION 2 TABLE 1

NIOSH Study Model (Outline)

I. Medical Study (HSPH)
   - A. MRC questionnaire
   - B. Physical examination
   - C. Chest X-rays
   - D. Pulmonary function test

II. Environmental Study (predominantly HSPH)
   - A. Mass respirable sampling (Cyclone)
     - 1. Analytical support
       - a) Gravimetric mass exposure det'mn
       - b) Fiber counts (microscopy-light, SEM)
       - c) Silica det'mn(I.R. spectroscopy)
       - d) X-ray diffraction
   - B. Reconstruction of previous environment
     - 1. Impinger vs. mass respirable sampler
       - a) Correlation attempt

III. Analytical Study (Predominantly NIOSH and Contractors)
   - A. Bulk analysis - sample splitting
     - 1. X-ray - quantitative mineralogical analysis
     - 2. Asbestiform analysis
       - a) TEM morphology
       - b) Electron diffraction patterns
     - 3. Wet analysis
       - a) Quartz

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IV. Mortality Study

A. Records (past payroll)

1. Name

2. Social Security No. IRS obtain info as to living or dead and last or present address

3. Starting Date

4. Termination date

B. Mortality analysis for causal relationship

V. Conclusions

A. Will separate by Co. for analysis

B. Will analyze industry as whole

C. Will attempt explanations if biological effects are seen

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SECTION 3

Data and present information sources available to study for outcome prediction and strategy development.

A. Comparative pulmonary function data - Table 2

B. Green Survey - Attachment 1 & 2

C. Rubino Mortality Study Attachment 3

D. Detection of ventilatory abnormalities in talc workers - Attachment 4

E. McCrone Report - 6 months' analysis of weekly ore composites from all mined ore bodies - Attachment 5

F. McCrone report - Argonaut ore body - Attachment 6

G. Windsor environmental sampling - Attachment 7

H. J&J Analytical results - Attachment 8

I. Sivertson data - Attachment 9

J. NIOSH letter - Attachment 10

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SECTION 4 Outcome Strategy Outline

I. Certainty statement

The terminal data obtained by the study groups involved is for the most part within our possession. Referring back to Sections 2 and 3 show that we have adequate information to predict with a high degree of certainty the following portions of the NIOSH study model (Table 1):

I. Medical Study

II. Environmental Study

III. Analytical Study

However confident we may feel about the ultimate outcome, we must still approach each area as a possible risk, and develop the predicted conclusions and logical sequential relationships which follow, on the basis of priority alternatives. Proceeding in this fashion creates multiple pathways for maneuverability, if needed and provides the degree of freedom necessary for the corporate defense against any subjective inclusion by the involved study groups.

It is hoped that the following outline will serve as a directional guide, illuminating the intricacies involved, and the necessity for well planned, thoughtful decisions in what I project to be a long and lucrative future involving talc.

II. Medical Study*

A. Positive Aspects

1. Green paper (Attachments 1 & 2).
Windsor employees exhibit superior pulmonary against control population.

2. Theriault paper (Attachment 4)
Windsor employees (Industry C Pg. 5) have greatest percentage of "above group".

3. Table 2 - non smoking talc workers have best age and height corrected pulmonary functions when compared to normal population and marble workers (Vermont).

4. Chest X-rays - (Personal communication with Dr. Green (UVM).

a) Windsor employees have same incidence of rounded opacities as control (6½%).

* Refer to numbered attachment in Section 3.

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b) Windsor employees have 50% lower incidence of irregular opacities.

5. Sivertson data - ? expected positive findings with respect to W.M.

B. Negative Aspects

1. Green paper (Attch. 1 & 2) - Windsor employees exhibit greater sputum production than control.

2. Theriault paper (Attch. 4) - Talc workers show relatively large regressive volumes associated with smoking.

C. Conclusions

1. Most reasonable conclusion is that Windsor employees show no negative dose response as a result of reasonable exposures. It makes use of good ventilatory practices and the respirable dusts to which they are exposed are relatively innocuous.

The workers in the other companies are probably exposed to higher concentrations of dust and consequently show greater regressive pulmonary changes.

2. Windsor employees have better age, height corrected pulmonary functions as a result of higher quality ore differences. This is reflected in X-ray and pulmonary tests.

D. Risk Level - & Defenses

A. Risk very low in Windsor Minerals

B. Risk higher in EMTAL and V. Talc.

D. Defenses could be based upon

1. Unknown health effects of contaminants.

a) Chlorite, pentlandite

b) Carbonates (marble workers)

2. Distinction between pure talc and talc ores.

3. Fineness of mine dust vs. products (Grade 36 - coarse).

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4. Distinction between companies.

5. Sputum production is expected to be higher in dusty industries.

6. Higher smoking regressive constants can be due to

   a) workers not admitting how many cigarettes smoked per day.

   b) synergism between dust and smoke.

E. Comments

It is highly doubtful whether any defensive posture need be taken based upon present data and knowledge.

F. Strategic Considerations

1. How to best use positive statement as to relative innocuosness of dust.

   a) Windsor Minerals - industrial materials

   b) J&J - baby powders

2. Explaining pulmonary function differences between Vermont companies.

   Possible: a) exposure levels (higher)
   b) " " (longer)
   c) mineral differences

   - non talc contaminants
   - differences in talc (plate size & shape)

3. Long term considerations

   a) Do we help other Vermont talc companies if their medical results are considerably lower than ours?

   b) Is it better for strategic purposes to isolate Windsor Minerals from other Vermont talc companies, or to isolate Vermont talc companies from other domestic suppliers?

   c) Do we use a positive statement for merely defensive purposes or will we use it offensively in the future? If so, how?

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III. Environmental Study

A. Positive Aspects

1. Low talc respirability - (Section 1-III-E).

2. Windsor respirable sampling shows reasonable level of dust (Sec. 3-G).

3. No detectable silica levels (Section 3-F).

B. Negative Aspects

1. Fiber counts - light microscopy;poor method.

2. Reconstruction of past environment (may be positive or negative depending on results).

C. Conclusions:

Present dust levels are not excessive, however there is sufficient respirable dust to disavow statement that dust levels are too low for conclusive indication of minimal health effect.

D. Risk Level & Defenses

1. All risks lie in mininterpretation of data, e.g. optical microscopy, X-ray.

2. Defenses - Section 1-III C, B, F
- Section 2-E, F. G

3. Reconstruction of past environment is virtually impossible for the following reasons:

a) Very little relationship between mass respirable sampling vs. total particle count.

b) Changing drilling methods changed dust particle size distribution.

c) Early work by USBM did not size particles (count only).

4. Specific mineral talc ($Mg_3Si_4O_{10}(OH)_2$) has inherent low respirability due to shape, size, etc.

E. Strategic Considerations

1. Relating to medical study, and lower respirability of talc than other minerals,should add a degree of certainty to safety of our industrial talcs.

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2. Since pure talc has a relatively large AED (cyclone measurements), a realistic defense can be structured for Baby Powder based on the fact that it can't be dangerous if it doesn't reach deep lung tissue.

3. If our materials show a lower, concentration corrected, respirable content than EMTAL or V.T. Co., what considerations will, or should, be given to these facts by our management? (Section 4, II-E-3).

4. How can a clear,positive statement by Harvard concerning low respirable content and safety of our industrial minerals and purified talc be used in future?

   a) marketing?

   b) P.R. to physician and consumer?

IV. Analytical Study (NIOSH)

A. Positive Aspects

1. Distinguishing Vermont ores from New York and California based on X-ray (platy talcs vs. tremolitic).

2. Definition and distinction between pure talc and generic "talc".

3. Positive statements from a Government agency hold weight with other Government agencies.

B. Negative Aspects

1. Finding undesirable minerals at low levels (TEM).

2. Misinterpretation of X-ray.

C. Conclusions

1. NIOSH will provide a document or report establishing TLV's based on Medical and Environmental Study. Ultimately Vermont industrial products will have higher TLV's than N.Y. or California Talc.

2. They will distinguish mineral talc from word "talc".

3. They will accept any data from J&J which is meaningful with respect to health aspects of pure talc.

4. They may classify Windsor talcs as "safer" than other Vermont talcs through establishing higher TLV's - (See Rubber Worker Morbidity Study).

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D. Risk Level and Defenses:

1. Risk of finding low levels of undesirable materials in ores may be adequately defended by the following:

a) Sect. 1-III-C & F.

b) Relate to positive findings in Sect. 4-II-C
Sect. 4-III-C

c) Undesirable minerals must also be found in air samples.

d) Relate to data in following
Section 3-E, F, H

2. Defenses and present data minimize effect of any negative findings.

D. Strategic Considerations:

1. See conclusions above. What consideration should be applied to these conclusions if they are, in fact, realized.

F. Comments:

The potential of finding anything anywhere at any time if one looks hard enough, is certainly a reality. Our greatest effort should be directed at this area.

V. Mortality Study

A. Speculative comments: This area poses the greatest risk to Windsor Minerals since we have no inkling of what the mortality tables of Vermont talc workers resembles. This writer doubts that a carcinogenic-latency period will be found.

B. Defensive Positions:

1. Rubino Mortality Study - differentiate pure talc from mineral mix.

2. Increased tumor worker mortality (not likely) can be result of other respirable irritants resulting from

a) unclear occupation exposure apart from talc industry.

b) materials heretofore unclassified as hazardous found in ores, e.g., chlorite pentlandite, biotite, etc.

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3. Increased respiratory but non-tumor related mortality can be result of

   a) excessive dust exposures before implementation of dust controls. (Early exposures were probably 30-50 times present levels.) One can apply Section 1-3-D.

   b) poorly defined early smoking history - e.g. Camels-no filters-were #1 selling cigarettes.

   c) uncertain mineral exposures in early mine environments.

C. Conclusions:

It is doubtful whether a mortality study could be conducted to have statistical meaning in today's work environments. The lack of finding any epidemiological mortality in early talc workers will be extremely significant in that these exposures represent worst case conditions.

Negative findings in the Vermont study will have very little relevance to Windsor Minerals or to J&J, due to the short duration of our operations and the small number of individuals who would be categorized as fitting into the cohort based on duration of exposure, latency period and work history.

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