BORDEN INC
990 KINGSMILL PARKWAY
COLUMBUS, OHIO 43229



ALFRED S. CUMMIN, Ph.D.
VICE PRESIDENT
SCIENCE AND TECHNOLOGY

July 2, 1985

Robert N. Jones, M.D.
Professor of Medicine
Tulane Medical Center
Department of Medicine
Pulmonary Diseases Section
1700 Perdido Street
New Orleans, Louisiana 70112

Dear Dr. Jones:

Thank you for your letter of June 20, 1985 together with your protocol for your "Gulf States Chemical Industry Study: Respiratory Effects of Exposure to Irritant Gases and Vapors."

Your envisioned program is certainly interesting, fundamental in nature and should be of some interest to the chemical industry, including companies who are not necessarily located in the "Gulf States."

I would, therefore, suggest that you submit your proposed program to the CMA (Chemical Manufacturers Association), Mr. Robert Roland, President, 2501 M Street, N.W., Washington, DC 20037.

I believe this would be of help to you in obtaining general funding for your proposal (especially since it appears to be of a continuing nature) without being dependent on the evaluation of your protocol by a number of individual chemical companies.

Yours sincerely,

A. S. Cummin

A. S. Cummin
Vice President,
Science & Technology

ASC:cac

bcc: Mr. R. Ventres
Mr. A. D'Amato
Mr. W. Kocher
Mr. J. Dames

Sackler
7-1-85

from the desk of – DR. A. S. CUMMIN

6/27/85

To Toshio Mekaru
Norm Brusk

1. What do you think of this study?

2. What are the pros and cons of our participating?

3. What do you recommend?

A. S. Cummin

No Herbicide evidence?
1 Nuts, weeds
2 reduce but limited
balanced for area Industry
3 [illegible]
4 N.O SM
5 ~~50~~ 1 mile Insecticide
½ mile N.O SM

Tulane Medical Center

Department of Medicine
Pulmonary Diseases Section
1700 Perdido Street
New Orleans, Louisiana 70112
(504) 588-5265

June 20, 1985

RECEIVED
JUN 25 1985
DR. A. S. CUMMIN

Dr. Alfred S. Cummin
Vice President, Science and Technology
Borden, Inc.
990 Kingsmill Parkway
Columbus, Ohio 43229

Mr. Anthony S. D'Amato
President, Chemical Division
Borden, Inc.
One Clark Street
North Andover, Massachusetts 01845

RE: Proposed research

Gentlemen:

John Dames suggested that you are the appropriate recipients of the enclosed materials. He also relayed some of your initial questions.

We will have a better idea about the number of corporations that might be willing to participate after we see the initial responses to the enclosures. We will probably approach twelve to twenty corporations. We hope to obtain baseline assessments on about 10,000 workers. The chief response variables of interest are short and long-term changes in lung function, and supplemental data such as medical history, respiratory symptoms, and changes in the chest x-ray. The study design precludes examination of questions about potential carcinogenicity, or non-respiratory toxic effects. We will seek total funding by the National Institutes of Health.

Hans Weill or I would be glad to answer questions about the proposed study. We ask only for a prompt decision as to whether we may present a more comprehensive and detailed explanation of what is proposed, perhaps in a forum attended by representatives of a number of potential corporate participants.

Very truly yours,

Robert N. Jones, M.D.
Professor of Medicine

RNJ/kar

Tulane Medical Center
Department of Medicine
Pulmonary Diseases Section
1700 Perdido Street
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(504) 588-5265

June 20, 1985

Dr. Alfred S. Cummin, Vice President-Science and Technology
Borden, Inc.
990 Kingsmill Parkway
Columbus, Ohio 43229

Dear Dr. Cummin:

I am writing to elicit your interest and participation in a proposed major study of the potential long-term respiratory effects which could result from single, high level or recurrent moderate/low level exposures to irritant gases or chemical vapors. Enclosed is a draft outline summarizing the research approach that I and my colleagues believe will answer many of the unresolved scientific issues.

While worldwide attention has been directed to acute irritant gas exposures by the Bhopal disaster, our experience indicates that accidental exposures of varying intensity occur episodically in manufacturing and distribution. We are frequently asked to perform medical evaluations in cases of putative chemical lung injury. Conclusions are often tentative because of the very limited scientific data base and the lack of objective assessment of health status before exposure.

As you may know, I direct an interdisciplinary research unit which has had wide experience in the investigation of the health consequences of various potentially injurious workplace inhalants, including irritant gases and vapors. We are in the planning phase of the renewal proposal of our large Specialized Center of Research NIH grant (for a fourth five-year cycle). We believe that the time is right to focus research effort on the important scientific questions relating to chemically-induced lung injury.

The potential for irritant chemical and gas exposures is industry-wide and the study will require a population of substantial size in a variety of chemical environments. I am therefore contacting a number of large chemical manufacturers who have facilities in this geographic region with the hope that a high level of interest in collaborating in this endeavor will result.

The NIH center grant renewal process is well underway and the time available for obtaining industry access and participation is limited to the next couple of months. The entire cost of this project will be included in the grant budget. I would respectfully ask that you give review of this proposal at the appropriate levels of your management the needed high priority. I anticipate that further and more detailed exploration would likely be in the form of personal communication with me, which I welcome at a time and place of your convenience.

I look forward to your reactions to this proposal.

Sincerely yours,

Hans Weill, M.D.
Schlieder Foundation
Professor of Pulmonary Medicine

HW/kar

BOR 007968

GULF STATES CHEMICAL INDUSTRY STUDY:
RESPIRATORY EFFECTS OF EXPOSURES TO IRRITANT GASES AND VAPORS

PURPOSE

The study is designed to determine the risk (if any) of long-term lung injury from single high or recurrent lower level exposures to irritant gases and chemical vapors, as encountered in the chemical manufacturing industry.

RATIONALE

Few data are available to estimate the risk of chronic respiratory effects resulting from accidental high level exposures or recurrent long-term lower level exposures to irritant gas emissions. Worldwide attention has been directed to the issue of short-term, high level exposures by the recent catastrophic events in Bhopal, India. In addition to the increased concern for chemical plant workers and surrounding populations, the consequences of this disaster have been far reaching. Major chemical producers have undertaken comprehensive review of safety procedures and the U.S. Congress has initiated inquiries and legislation which are intended to minimize the risk of a similar disaster in the United States. The potential for protracted and expensive litigation, avoided only if a negotiated settlement is effected, is obvious, and this is in turn likely to influence future litigation risk in this industry.

From a scientific standpoint, massive accidental exposures of this magnitude are not likely to provide answers to many of the important questions about possible long-term effects of such exposures. For example, what is the likelihood of long-term effects in survivors, and what governs the risk of an adverse outcome? Accurate assessment of residual effects of acute exposures requires surveillance of a large work force, with appropriate baseline measurements that can be compared to data obtained following any accidental high level exposure. These pre-exposure measurements are precisely what is lacking in civil disasters.

That accidental exposures of varying intensity occur is known as the result of frequent requests for medical evaluation of workers who have had putative exposures and have claimed long-term respiratory symptoms. In most cases these exposures did not result in a severe acute illness requiring hospitalization, but evaluation of the extent of injury is hampered because of the absence of standardized, high quality pre-exposure assessment of respiratory health.

This study will also address the issue of whether the long-term, intermittent, lower level exposures that occur in this industry contribute to the risk or severity of chronic airways obstruction (CAO). Current methods of longitudinal population study will allow analysis of the effect of several risk factors (e.g., smoking and allergy, in addition to the chemical exposures) in accelerated decline of lung function, a reliable predictor of eventual disabling CAO. While there has been an increasing data base on "industrial bronchitis" and occupationally-induced air flow limitation resulting from particulate exposures, essentially no comparable information is available for occupational groups exposed to gases and vapors.

APPROACH TO THE STUDY

This proposed study will be included as a major component of the competitive renewal application for the fourth five-year cycle of the Tulane Pulmonary Specialized Center of Research (SCOR). If approved and funded by the National Institutes of Health (NIH), the research will begin on December 1, 1986.

The study will depend on access to a large multi-plant chemical manufacturing cohort that can be placed under long-term surveillance. Carefully selected, limited and non-invasive observations of the study population will be obtained jointly by the SCOR investigators and company medical personnel. The anticipated health measurements will not be likely to require more worker time than current health surveillance procedures. Baseline and longitudinal data will be analyzed to provide information regarding the central scientific questions: (1) what are the long-term respiratory effects, and their determinants, of single exposures to irritant gases, and (2) does recurrent exposure to lower levels of these materials constitute a risk factor for the development of CAO?

In addition to highly standardized measurement of ventilatory function, using computerized spirometry and telecommunications, questionnaire data, and chest radiographs, newer non-invasive methods for measuring acute lung injury will be selected (e.g., products of connective tissue damage, perhaps measured in the blood and/or urine) and correlated with other biological and environmental data. A specific aim is to follow the subsequent respiratory course of any worker exposed accidently to an irritant gas or vapor, and to compare this experience with his/her baseline data and with relevant measures of respiratory health in co-workers who have not had such exposures.

Monitoring of workers sustaining a single moderate/high level exposure for the development of non-specific bronchial hyperresponsiveness (NSBHR) will provide insight into an issue recently raised, that concerning the likelihood of such an exposed worker developing asthma.

The longitudinal data set will provide the basis for assessment of any low level chemical exposure-related contribution to CAO. Techniques for such longitudinal analysis are well developed, can take into account such confounding factors as smoking and pre-existing disease, and have proven to be of predictive value in clinically significant CAO. Further refinement of statistical approaches to the analysis of longitudinal data will be undertaken.

SPECIFIC ADVANTAGES TO INDUSTRY

- The development of a scientific data base that will facilitate the assessment of alleged chemically-induced respiratory injury, particularly in those instances involving a claim of long-term or permanent respiratory effects.

- Assessment of possible gas- or chemical vapor-specific differences in the potential for inducing chronic lung/airways effects in exposed workers.

- Availability, to the participating companies, of fully standardized and validated measurements of employees' pulmonary function, using "state of the art" equipment supplied by the research center and maintained in the plant.

- Baseline or "pre-exposure" data for comparison in the event of moderate/high level exposure in the study population, allowing valid judgement to be made about the possibility of any exposure-related respiratory consequences.

- Study direction and performance by a highly experienced and credible inter-disciplinary research group. This group has been engaged in the investigation of health effects in workers exposed to mineral and organic dusts, and irritant gases and vapors, for two decades, and is geographically proximate to a heavy concentration of chemical manufacturing facilities.

- Research funding by the National Heart, Lung and Blood Institute of the National Institutes of Health, through the SCOR program. This is the thirteenth year of the Tulane Pulmonary SCOR, the only such program exclusively devoted to the study of occupational and environmental lung disease.

- The multi-company, multi-plant nature of the study will avoid undue focus on one corporation, facility, or chemical.