



CHEMICAL MANUFACTURERS ASSOCIATION

October 31, 1995

Christian Seigneur, Ph.D.
General Manager
ENSR
1420 Harbor Bay Parkway
Suite 160
Alameda, CA 94502

Dear Dr. Seigneur:

On July 31, you sent me a proposed letter agreement seeking to alter ENSR's obligations under the March 31, 1995 letter agreement between ENSR and CMA regarding the transfer from ENSR to Applied Epidemiology, Inc. ("AEI") of raw data from the CMA vinyl chloride epidemiology study. On August 17, I asked you to expedite the preparation and delivery to AEI of a sanitized copy of the master tape from the vinyl chloride study. On September 1, I provided a detailed response to your proposed July 31 letter agreement and again requested your assistance in expediting the transfer of data to AEI pursuant to the March 31 agreement between ENSR and CMA.

To date you have not responded to my September 1 letter. On September 9, Dr. Donald Whorton sent a letter to Dr. Ken Mundt at AEI enclosing a tape that contains some information from the master tape from the vinyl chloride study, along with a memorandum summarizing the information on that tape. While we appreciate Dr. Whorton's efforts to expedite the process of transferring data to AEI, I must correct several points in his letter and relate the problems that AEI has encountered in trying to use the data that Dr. Whorton forwarded.

First, the only file content information provided was a cursory listing of the files on the tape. It did not include the kind of documentation necessary to interpret and use the encoded data. Without variable labels or coding keys, AEI has no means to understand the contents of those files. In addition, many of those files are currently in formats that cannot be read outside of the system in which they were originally used. Even if those files are converted to readable formats and contain descriptions of the variables used, it will probably be time-consuming and expensive to use them, without the benefit of the manuals or other documentation that normally accompany such data tapes.

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Second, approximately 1000 death certificates still have not been received by AEI: 829 from the previous vinyl chloride update, and up to 200 from the original study. While it is possible to replace certificates for deaths occurring after 1979 -- albeit at unanticipated and unnecessary added cost and delay* -- certificates for deaths occurring prior to 1979 may be much more difficult or even impossible to replace. As Dr. Mundt explained in the enclosed response of September 25 to Dr. Whorton, the missing death certificates are critical to AEI's ability to complete the vinyl chloride update, not to mention an invaluable archive from a scientific and financial perspective. Moreover, the data tape that ENSR transferred to AEI on September 9 is not an adequate substitute for those missing death certificates because, as you know, all death certificate information on that tape has been blocked.

Our agreement obligates ENSR to "transfer all of the records from the Vinyl Chloride study in ENSR's possession to CMA." As noted in my September 1 letter, we had previously been informed by ENSR that: "All of the data have been transferred from EHA to ENSR as part of the purchase of EHA by ENSR. The data are easily retrievable for a further update." Now Dr. Whorton tells us that the data are not so easy to retrieve, and in fact, may not be retrievable at all.

ENSR's representations that it had, and could easily retrieve, the data from the earlier vinyl chloride study and update formed the basis for our March 31 agreement. CMA also relied on those representations when it devoted considerable time and expense to obtaining permission from a large number of states for ENSR to transfer death certificates and/or confidential death-related information to AEI and CMA. Finally, and most importantly, CMA relied on those representations when it entered into a contract with AEI to update the vinyl chloride study for the period 1982-92. Pursuant to that agreement, AEI was to have received all relevant study materials and data by May 1, 1995. As of November 1, the delay will reach six months. During this time AEI has been paying staff to process the data expected from ENSR.

Due to ENSR's delay in transferring data and materials, the only study milestone that AEI has been able to complete so far is the preparation of a

* Just replacing the 829 death certificates from the previous vinyl chloride update will cost \$10 per certificate, or \$8,290, without considering personnel time and related expenses.

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peer-reviewed protocol. According to AEI, that effort represents at most a two-month personnel effort, leaving a four-month period of unanticipated staffing costs. As the monthly payroll for the study is \$10,237, the total cost of the four-month delay amounts to \$40,948. If AEI seeks to recover this cost from CMA, CMA will look to ENSR for indemnification.

In addition, the records that ENSR has transferred to AEI have been incomplete and disorganized. Most of the approximately 100 bankers' boxes of paper records, files and computer tapes that AEI has received were neither labeled nor accompanied by a catalogue or inventory. In addition, many of the boxes contained materials unrelated to the current study (including computer tapes), and others contained records which could not be identified, as no master listing of the study cohort has yet been provided. AEI estimates that approximately \$10,000 beyond that budgeted will be required to organize the materials received, sort out the unrelated records, and create an accurate inventory. Again, CMA will look to ENSR for indemnification.

Finally, AEI has the right to terminate its agreement with CMA to update the study if delays exceed six months. In this event, CMA will look to ENSR for compensation for the damage it suffers.

As I noted in my previous letter, the update of the vinyl chloride study will be an important contribution to the scientific understanding of the health effects associated with exposure to vinyl chloride. We trust that you share our commitment to the successful completion of this project.

I request that you respond to this letter and my September 1 letter as soon as possible. If we do not receive a detailed written response by November 15, I will turn this matter over to our legal counsel for full enforcement of CMA's rights, with instructions to pursue all legal remedies.

Sincerely,



Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel

Enclosure

cc: Donald Whorton, M.D.

CMA 115251

**APPLIED
EPIDEMIOLOGY
INC.**



September 25, 1995

Donald Whorton, M.D.
M. Donald Whorton, M.D., Inc.
1135 Atlantic Avenue
Alameda, CA 94501

Dear Don:

Thank you for sending a copy of the master tape (without death certificate information post 1982), which we received on Friday. As a correction to Nancy Gordon's memo to you dated September 13, 1995, all death certificate information was blocked, instead of blocking only that from the 6 or 8 states with confidentiality agreements remaining, to expedite transfer of the bulk of data to us. We trust that as soon as all states grant releases, you will forward the remaining data, or withhold information only for states not granting a release.

We will begin reading the contents of the tape immediately; however, it appears that no documentation of the files was sent to us with the tape. We would have expected to receive at least standard directories (including data audit trails) and coding manuals. As you probably know, re-creating documentation is time consuming, and may lead to errors. Please send as soon as possible any such documentation which might exist.

We also hope that the lost death certificates will be located and transferred as our agreements with the states allow, as these represent an important factor in our ability to complete the update since 1982, and a valuable resource, both from a scientific and financial perspective. So, although we should be freed from the present log jam and able to proceed with parts of the study update, we still anticipate receiving from you substantial materials produced during the previous update.

Finally, please note that our street address is Suite #90, 479 West Street, Amherst, MA 01002. We appreciate all your efforts to facilitate the transfer of the study materials, and urge you to call if we may be of any assistance.

Sincerely yours,

Kenneth A. Mundt, Ph.D.

cc: Dr. Shah
Dr. Ramlow

P.O. BOX 2424 • AMHERST, MA 01004



(413) 256-3556 • FAX (413) 256-3503

CMA 115252