

MEMORIAL SLOAN-KETTERING CANCER CENTER

1275 YORK AVENUE, NEW YORK, NEW YORK 10021



October 8, 1980

L206

The Honorable Hugh L. Carey
and Members of the New York State Legislature
State House
Albany, New York

Dear Governor Carey and Members of the New York State Legislature:

This letter transmits the report of the Panel to Review Scientific Studies and the Development of Public Policy on Problems Resulting from Hazardous Wastes. This Panel was created by Executive Order on June 4, 1980.

In fulfillment of its charge the Panel reviewed studies conducted under a variety of auspices, including the New York State Department of Health, the U.S. Environmental Protection Agency and private investigators. As a result of this review, the Panel has concluded that there has been no demonstration of acute health effects linked to exposure to hazardous wastes at the Love Canal site. The Panel has also concluded that chronic effects of hazardous wastes exposure at Love Canal have neither been established or ruled out as yet, in a scientifically rigorous manner. The studies conducted in the past two years have been inconclusive in demonstrating long term health effects due to hazardous wastes exposure.

The Panel finds that the continued uncertainty regarding chronic health effects is related to several factors:

- Inadequate research designs for health effects studies particularly regarding chromosome damage and informal surveys of the Love Canal residents.
- The inevitable necessity of time required for longitudinal prospective studies and complex retrospective studies concerning long term exposures to hazardous wastes.
- Inadequate intergovernmental coordination and cooperation in the design and implementation of health effects studies.

Many of the events of the past two years have fueled rather than resolved public anxiety and questions regarding the possible health effects of hazardous wastes of Love Canal. The design, implementation

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and release of the EPA chromosome study has not only damaged the credibility of science but exacerbated any future attempts to determine whether and to what degree, the health of the Love Canal area residents has been affected. The Panel's recommendations attempt to assure that the circumstances which have resulted in inadequate science will not be repeated. It may be too late to remedy the mistakes of the Love Canal experience; but there remains an opportunity to avoid a repetition of such mistakes in the future.

I extend my appreciation to the members of the Panel for their high level of participation and commitment within a compressed time frame in completing this effort. I wish also to recognize the complete cooperation of State agencies and other organizations and individuals in supplying study materials to the Panel.

Respectfully,

A handwritten signature in cursive script, appearing to read "Lewis Thomas".

Lewis Thomas, M.D.
Chairman

REPORT OF THE GOVERNOR'S PANEL TO
REVIEW SCIENTIFIC STUDIES AND THE
DEVELOPMENT OF PUBLIC POLICY ON
PROBLEMS RESULTING FROM HAZARDOUS
WASTES

Members of the Panel:

Lewis Thomas, M.D., Chairman
Saul J. Farber, M.D., Secretary
Richard A. Doherty, M.D.
Attallah Kappas, M.D.
Arthur A. Upton, M.D.

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I. INTRODUCTION

A. Panel Creation and Charge

On June 4, 1980, Governor Hugh L. Carey signed an Executive Order establishing a panel to review scientific studies and the development of public policy on problems resulting from hazardous wastes in New York State. The panel was specifically charged to review and evaluate medical and scientific data related to the Love Canal site developed by State agencies, Federal agencies and private investigators. The panel was further charged to review and comment upon the proper relationship between State and Federal agencies and the proper use of medical and scientific data in the development of public policy in the areas of environmental protection and public health. A complete text of the Executive Order is presented in Appendix A.

The circumstances surrounding the creation of the panel are well known to the informed public. The entire chronology of events regarding the Lovel Canal site have been reported in the local and national media, often daily. The possible health effects of toxic substances on the population proximate to the Love Canal have received particular attention. Indeed, the publication of studies on health effects and subsequent criticisms of these studies in the media have created more uncertainty than understanding on potential health problems for both the public and government officials. The number of Federal, State and private investigators and the range of studies previously conducted and in progress have also contributed to public and governmental confusion as to the responsibility of appropriate agencies. The inadequate coordination of study designs and procedures to insure meaningful findings concerning health effects has exacerbated the problems faced by decision makers in responding to this situation.

Lastly, the panel, in consideration of its charge, recognized that the Lovel Canal problem and that of hazardous wastes in general are but an example of the range of issues requiring clarity in scientific knowledge and advice which face the State and Federal governments.

B. Membership

The panel appointees represented varied backgrounds in the medical sciences:

Lewis Thomas, M.D., Chancellor Chairman
Memorial Sloan-Kettering Cancer
Center

Saul J. Farber, M.D., Dean Secretary
School of Medicine
New York University Medical Center

Richard A. Doherty, M.D.
Associate Professor, Pediatrics,
Genetics, Obstetrics and Radiation
Biology/Biophysics
University of Rochester Medical Center

Attallah Kappas, M.D.
Physician-in-Chief
Rockefeller University Hospital

Arthur C. Upton, M.D., Chairman
Department of Environmental Medicine
New York University Medical Center

C. Panel Meetings and Procedures

This panel held meetings on June 5, June 13, July 2 and July 21, 1980. Upon an initial discussion of the charge and a method of procedure, the panel initiated requests to identify and receive reports and studies related to the health effects of hazardous wastes at the Love Canal site. Panel requests were made to the U.S. Environmental Protection Agency, the Center for Disease Control, the National Institute of Environmental Health Sciences, the Hooker Chemical and

Plastics Corporation, Dr. Beverly Paigen, Ph.D. (Roswell Park Memorial Cancer Institute), Dr. Stephen Barron, M.D. (SUNY at Buffalo Medical School) and the Love Canal Homeowners Association. All studies conducted by the New York State Department of Health were also made available to the panel. Pertinent studies and reports identified by the panel are enumerated in Appendix B.

Subsequent meetings of the panel were devoted to reviews of specific studies on health effects and to the chronology and events surrounding the Love Canal situation related to planning and coordination of health studies and Federal-State relationships.

Section II and III of this report detail the panel's findings on health studies completed to date and planned for the future. Section IV provides the observations and recommendations of the panel regarding future State policy development.

II. REVIEW OF THE LOVE CANAL PROBLEM

The condition of chemical pollution in the Love Canal area became a matter of national public concern in the Spring of 1978, followed by the publication by the New York State Department of Health of a brochure entitled "Love Canal - Public Health Time Bomb" in September 1978. The language employed in this report was strong indeed: the situation was an "environmental nightmare", capable of causing "profound and devastating effects", constituting a condition of "great and imminent peril".

The Love Canal - Public Health Time Bomb publication was a special report to the Governor and Legislature which described the chronology of State actions and findings culminating in the declaration of the existence of an emergency by the then Commissioner of Health, Robert P. Whalen, M.D. This declaration in

August 1978 was made pursuant to P.H.L. Section 1388 which had been enacted by the Legislature in June 1978.

The Panel understands that the declaration of an emergency by the Commissioner of Health was a requisite to insure adequate jurisdiction and resources for governmental response to the Love Canal situation; it was also in support of an application to the Federal government for a declaration of a national disaster, which would make available additional resources. The Panel also understands that a finding of "great and imminent peril" was a statutory requirement of Section 1388.

With this rhetorical setting of the stage, it might reasonably have been predicted that a concerted, coordinated and intensively organized series in Federal-State scientific studies would have followed, laying out the problem in all its dimensions and providing a solid base of data as a foundation for public policy in coping with the problem.

Something went wrong, however, and now, two years after the printing of "Love Canal - Public Health Time Bomb", we face almost the same set of urgent questions as were posed at the first recognition of the problem, and we have almost no clear-cut, unequivocal answers.

In the view of this Panel, what went wrong was not that the problem was neglected or put to one side; an immense amount of hard work was performed by a large number of qualified investigators from State and Federal agencies. In addition, there has been much effort put into this problem by groups of well-intentioned private individuals including certain studies lacking in scientific design and skill.

The chronology of Love Canal events clearly demonstrates early and frequent consultation by the State with the Federal government on the subject of health effects studies. The record indicates just as clearly that that an articulated and coordinated Federal and State approach was not achieved and has not been achieved to date. For example, a 1978 State request for funding of health effects studies, including chromosomal studies, was rejected by the U.S. Environmental Protection Agency, while that agency later undertook to fund a limited and controversial study of chromosomal damage almost two years later, without the participation or consultation of the New York State Department of Health. A central flaw in all this work was its almost total lack of coordination, and an appalling absence of communication among the various groups of scientists involved. There did not emerge at any point in the

past two years anything like a master plan for assembling the kinds of information required for analyzing and comprehending the problem.

With the absence of a coordinated plan there was also the absence of an understanding by both the public and government officials of the nature and limitations of past or anticipated scientific inquiries. A demonstration of health effects due to chronic exposure of multiple hazardous chemicals is an exceedingly complex scientific problem. There appears to have been little understanding at the outset of the nature of the requisite clinical and epidemiological inquiries, the length of time necessarily associated with these studies, and most importantly, the expected outcomes of the studies.

The net result is today's state of ambiguity around the most important and urgent question concerning the public health: Has the health of the people residing in the polluted zones at Love Canal been damaged and if so, in what ways? Are there reasons to fear further damage in the form of disease states within this population in the years to come?

Meanwhile, because of this ambiguity, the people most directly affected by the conditions at Love Canal have been subjected to more than two

years of the most intense anxiety and fear. In the absence of clear-cut, authoritative answers, many of the residents have come to believe that their health is in fact irreversibly damaged, that they are at future risk of cancer, congenital malformations in their offspring, and an increased incidence of miscarriages and abortions. At the same time, adding to their anguish, the investments made by homeowners in their property have lost all or nearly all of their original value, with no kind of assurance that the value will ever return.

This Panel recognizes that there was a reason for the State Health Department's initial announcement of "Public Health Time Bomb", but not a good enough reason. There ought to be a better mechanism for convincing the Federal government that a certifiable disaster area exists, in order to obtain Federal funds, than to arouse such fears of imminent peril as swept through the Love Canal area in this case. A better mechanism might have been found if effective Federal/State consultations had been launched promptly when the problem was first recognized. It may be that the atmosphere of public near-hysteria which was created in mid-1978 contributed to the failure on the part of public health agencies to put together an appropriately orderly, deliberative

and systematic investigation of the situation.

This Panel acknowledges that the Love Canal problem was something quite new, a situation not encountered before by public health agencies. In the past, instances of environmental pollution emerged as sudden, acute episodes, usually derived from a single industrial source, with readily discernible and quantifiable health hazards. Love Canal, in contrast, represented the chronic contamination of a whole community's living space, extending back over a period of decades, and most complex of all, involving not one but scores of different chemicals seeping through the earth and into households all at once. No book of rules exists for handling this kind of problem, but from now on it is obvious that rules will have to be formulated.

The panel believes that its most useful function, at this stage of events, is to make several recommendations for consideration by the Governor which may assure a more orderly course of scientific inquiry in the specific case of Love Canal, and for the future in the event that comparable events occur in other parts of the State. In short, what should have taken place, beginning in mid-1978, particularly with respect to the role of the State Health Department and its relationship to other specialized

scientific resources within New York State, what should have been the role of Federal agencies in this affair, and what should come next?

III. THE QUESTION OF HEALTH HAZARD

It is clear enough from the available data that no acute cases of intoxication by chemical pollutants have been observed within any part of the Love Canal community, "wet" or "dry". That is, no clusters of cases of acute liver disease, or kidney disease, or pulmonary manifestations, or hemolytic anemia or agranulocytosis, and certainly no peripheral or central nervous system syndromes. Whatever else may be going on, there has not been a sufficient concentration of toxic material to produce overt illness attributable to poisoning.

This was clear enough from the outset. The real worry for the community, and for the Health Department, was about more chronic forms of disease, with long-term hazards to health. The two hazards uppermost in the minds of the Love Canal residents are, and have been for

the past two years, the risk of cancer and the risk of reproductive abnormalities.

To date, the questions remain unsettled. There are on the record three reports bearing on the problem of chronic disease, each of which has become the basis for widespread publicity and compounding apprehension within Love Canal Community. These are (1) the EPA-sponsored cytogenetics study, (2) the peripheral nerve-conduction study by Dr. Steven Barron and associates, and (3) the epidemiological study of pregnancy disorders, birth defects and related illnesses by Dr. Beverly Paigen.

A. The EPA-Sponsored Cytogenetics Study

In retrospect, this study represents a paradigm of administrative ineptitude, with all the defects to be expected when one governmental agency undertakes work in a highly sensitive area without knowledge, consultation or prior review by another agency with heavy responsibilities for the same problem.

It is known that certain chemical toxins can produce abnormalities in the structure of chromosomes, which can then be visualized in cultured leukocytes taken from the circulating blood. The technique for such examinations is well recognized, although the health significance of chromosomal abnormalities in cultured leukocytes remains uncertain; various degrees of breakage and deformity of the chromosomes are seen in certain

transient virus infections, and a certain number of abnormalities are seen as background in populations of entirely normal people. The test may be a useful method for surveying populations, but it is of questionable significance when applied to individuals or small groups. It is without value unless the subjects being tested are matched by a control group of similar people. Moreover, the technique is complex and exacting, requiring highly skilled technicians for its performance and highly specialized professionals for the appraisal of results. In our present state of knowledge, chromosomal analysis is by no means to be regarded as a routine procedure in public health practice.

In January 1980, the Biogenics Corporation of Houston, under a contract with EPA, carried out a cytogenetic study of Love Canal residents. Blood specimens were obtained from 36 individuals residing in the most severely affected area and transferred to a tissue culture laboratory for culture and further treatment. The chromosomes in 11 of the 36 were regarded as abnormal, on the basis of what were regarded as chromosomes breaks, chromatid breaks and "supernumerary acentric fragments". Subsequently, a formal report was presented by Biogenics to EPA. in which the following statement was made:

...,"It appears that the chemical exposures at Love Canal may be responsible for much of the apparent increase in the observed cytogenetic aberrations and that the Love Canal residents are at an increased risk of neoplastic disease, of having spontaneous abortions, and of having children with birth defects". Following this sentence, a mildly qualifying statement is made: "...However, in the absence of a contemporary control population, prudence must be exerted in the interpretation of such results".

The Biogenics report was made public soon after being submitted to EPA, and received the widest possible coverage in the press and on television. The public was given the strong impression that the Love Canal pollution was endangering the survival of all contacts and their offspring. During the next few weeks the Biogenics report was reviewed by several groups of experts in the field of cytogenetics, with expressions of doubt that the reported results were of significance. These were particularly critical of the techniques employed, the lack of controls, and the possibly artifactual nature of the "super-numerary acentric fragments". The controversy continues with charges of incompetence and irresponsibility being made against the Biogenics laboratory and countercharges by the laboratory of bias and prejudice on the part of its critics. An extensive

review of the matter was published in Science, June 13, 1980, implying that the Biogenics study had been badly botched and misinterpreted, but in the August 15 issue of the same journal a letter appeared from Dr. Marguery Shaw, a well recognized cytogeneticist at the University of Texas in Houston, stating that she had reviewed the slides on which the Biogenics report was based and had confirmed, in all essential details, the Biogenics Laboratory findings. (see Appendix C) The whole affair has assumed the dimensions of a major and still unsettled scientific controversy, and meanwhile, once again, the Love Canal residents are left with even deeper causes for worry and fear.

The Panel agrees with those who have criticized the Biogenics study on technical grounds, but feels even more strongly that such a poorly designed investigation as this one should not have been launched in the first place. With so much at stake for the residents involved, to have set up experiments that lead to public conclusions of such magnitude, without prior review of the protocol by qualified uninvolved peer scientists, and without any after-the-fact, independent review by competent scientists before release of the results, was a disservice to the citizens most intimately concerned and, as well, to the public at large. The damage done by this EPA effort is perhaps beyond

mending; many of the Love Canal residents have by now become so distrustful of governmental agencies and their scientific reliability that they are unwilling to believe anything except the worst of news about themselves.

* It is a pity that this matter was so badly handled. There was no good reason why the responsible authorities in EPA could not have consulted beforehand with their counterparts in the New York State DOH, and enlisted the advice and close participation of outside consultants with international reputations in the field of cytogenetics, and then mapped out a thorough, careful and scientifically valid approach to the question of chromosome injury.

There is now no question that a proper cytogenetics study is urgently needed. The Panel does not know whether the degree of chromosomal injury claimed in the Biogenics Laboratory study, even if confirmed, is in itself a reason for alarmed predicitions concerning cancer or congenital defects - indeed, similar chromosomal abnormalities are characteristically observed in other circumstances (measles, for example) without known sequelae. However, the mere fact that the chromosomal damage is real - if it is - means that the residents of Love Canal are being biologically affected by something in their environment, and this observation - if confirmed - would greatly weaken the position, taken by some, that the only ill-effects suffered by this population are psychological.

B. The Nerve-Conduction Study

A reliable and precise technology exists for the determination of the conduction velocity in various peripheral nerves, sufficiently sensitive to detect nerve damage before the development of subjective symptoms. It has proved useful in the early detection of neuropathy in diabetes, and in a variety of nerve injuries caused by toxins.

A study of a small number of Love Canal residents was undertaken in the spring of 1980 by Dr. Steven Barron, a neurologist at the State University in Buffalo, and a copy of Dr. Barron's report has been made available to the Panel.

The results of this study were essentially negative. No statistically significant difference was detected between the conduction velocity in 35 Love Canal residents and a matched control group of 20 residents of other areas. However, the author stated in his conclusion that there were "trends within the data of non-significant slowing of sensory conduction velocity" in the ulnar and sural nerves, raising the possibility that further studies involving larger numbers of subjects might indeed turn out to be positive. This report will be presented at the September meeting of the American Association of Electromyography and Electrodiagnosis in Philadelphia,

and there is little doubt that the public interpretation of the results will be that another ambiguity has emerged from incomplete scientific inquiry into the Love Canal problem, and that the residents are threatened by still another type of health disaster.

The conduction study would need to be repeated in a much larger group of residents and under highly controlled circumstances before any serious conclusions can be reached. This is the major conclusion reached by Dr. Barron in his report. The weakness of the study lies in its inadequacy of scale, and in the elusive meaning of the terms "trends within data" and "non-significant slowing". The study illustrates the plain fact that small-scale "pilot" experiments are not appropriate for problems as large as that of Love Canal, and equivocal or ambiguous observations under these circumstances are likely to do more harm than good.

C. The Epidemiologic Study by Beverly Paigen, Ph.D.

Dr. Paigen, consultant to the Love Canal Homeowner's Association since early 1978, is a Cancer Research Scientist at Roswell Park Memorial Institute in Buffalo. On March 21, 1979, she presented an extensive report on the health problems in Love Canal residents in testimony before the House Subcommittee on Oversight

Investigations. Copies of that testimony have been made available to the Panel.

Although Dr. Paigen is to be commended as a private citizen for undertaking on her own an extremely difficult and complex task, her report falls far short of the mark as an exercise in epidemiology. She believes fervently that her observations prove the existence of multiple disease states directly attributable to chemical pollution, but her data cannot be taken as scientific evidence for her conclusions. The study is based on largely anecdotal information provided by questionnaires submitted to a narrowly selected group of residents. There are no adequate control groups, the illnesses cited as caused by chemical pollution were not medically validated; in her comparison of the health problems of people living in the "wet" and "dry" areas no cognizance is taken of the age differences between the two groups, and the statistical methods used for analysis of the data are open to question.

The Panel finds the Paigen report literally impossible to interpret. It cannot be taken seriously as a piece of sound epidemiologic research, but it does have the impact of polemic. Obviously, the questions raised by Dr. Paigen must now be answered, specifically and as soon as possible, but this will

entail a much more elaborate epidemiologic study. Such studies, we understand, are presently being conducted by the New York State Department of Health.

D. State Health Department Studies

In summary, the State Health Department began its efforts with a gas chromatographic survey of the chemical composition of eight sumps from the area most affected, followed by tests of air samples from the basements of approximately 700 houses, demonstrating the presence of toluene, chlorobenzene, chloroform, trichlorethylene and other volatile organic materials in the sump materials and, at low levels, in some of the air samples. Later in 1978, low levels of dioxin were found in soil from a construction pit. These studies were continued through 1979 and 1980, with testing and, analyses still in progress.

Meanwhile, epidemiologic investigations of the residents of the area were begun in June 1978 aimed primarily at determining whether reproductive abnormalities (excess miscarriages, birth defects, low birth weights) existed at levels higher than normal. The results of the latter studies were and remain inconclusive, owing in part to the relatively small population available for study and the absence

of a comparable, matched population of controls with which to compare the figures. The investigators (Vianna et al, Dept. of Health) thought there might be some increase in miscarriages and infants with low birth weight, but the data cannot be taken as more than suggestive. No cases of chloracne were found, and there appeared to be no excess of cases of cancer, asthma, epilepsy, liver disease or hematologic abnormalities.

During the summary of 1978, approximately 4000 blood specimens were obtained at 12 clinics held in the area, with essentially negative results except for a few instances of elevated enzymes employed for liver function tests, at levels of equivocal significance. In August 1978, 5000 soil samples from 700 houses were taken for chemical analysis, with results (still incomplete) similar to earlier soil studies in the area. A radioactivity survey was completed in September 1978 with essentially negative results. Over a six month period in 1978-79, medical examinations were performed on 112 construction workers employed in excavation work at the Love Canal site; apart from a few cases of transient dermatitis no disease states were encountered which seemed work-associated. At the present time a retrospective study of cancer incidence among residents of Love Canal census tract, dating back to 1950, is in progress.

F. Future Health Studies

1. Center for Disease Control, United States Public Health Service (CDC).

The CDC has initiated medical examinations for any Love Canal area residents who wish them. The Panel is extremely concerned that the purpose of this program be critically scrutinized. These examinations, if undertaken outside a carefully designed research protocol, may contribute to the clinical and epidemiological questions which must be addressed.

Over the next year, CDC will conduct an epidemiological study comparing findings in selected Love Canal residents with findings in matched individuals not from Love Canal. This study will include testing for possible chromosome abnormalities, neurological assessments and other clinical and laboratory tests.

2. National Academy of Science.

The National Academy of Science proposed to conduct a study focusing on the complex problems associated with the assessment of the possible impact on human health from industrial wastes. This project will begin in September 1980 and end in August 1982. The study will address scientific strategies and methods by which incidents such as the Love Canal can be investigated and data from them interpreted. The Panel

feels that the review by the National Academy of Sciences will help to put the nationwide problem of industrial wastes and possible health consequences into perspective.

3. New York State Department of Health.

Epidemiologic studies in progress focus on determining the occurrence of cancer and adverse pregnancy outcomes in over 900 families who lived in the Canal area and moved away prior to June 1978. This will take two years to complete. Later this year results will be available on comparisons of cancer and adverse pregnancy outcomes in the Love Canal census tracts with other census tracts of similar socioeconomic level. In the laboratory, a large number of soil samples are yet to be tested. Teratologic and pathologic effects of Love Canal soil and air above soil are being studied in rats. The Panel feels that these studies should continue, but all of them should have the benefit of external review by expert scientists in the fields involved.

IV. RECOMMENDATIONS

The Love Canal dilemma is perhaps the most complex public health problem to confront New York State in many decades, and it demands for its appraisal and ultimate solution an array of scientific disciplines well beyond the scope of conventional medical or public health practice: it contains intricate problems for toxicology, oncology, industrial hygiene, genetics, developmental biology, psychology, economics, organic chemistry, physics and geology, to name only a partial list.

It is also true of course that the hazards posed by long-stored chemical wastes are a national problem, and therefore a matter of interest and responsibility for several Federal agencies as well as for the Department of Health. But Love Canal is, first of all, a New York State problem, and it has now become a genuine

emergency for psychological and socioeconomic reasons as well as for reasons of public health.

The Panel believes that there is a great need at the present time for new administrative mechanisms to be set in place by the State for centralizing and coordinating the planning of all scientific activities relating to Love Canal. This responsibility should be centered, operationally, in the Department of Health and the strongest possible measures taken to ensure that Federal agencies are obligated to interact and collaborate with the Department of Health on every aspect of this problem. It cannot be considered sensible for a Federal agency, as has already been the case with various EPA efforts, to bypass a State agency in direct approach to citizens of the State, and to engage in investigations on such citizens without consultation and communication with the State administration.

Much of the anxiety caused for the Love Canal residents might well have been averted if a single Federal-State group had evolved early in the history of this situation and if public pronouncements were made only by this group and limited to the exactitudes permitted by the current state of scientific knowledge. Nowhere for example have we seen a proper qualification of the meaning of toxicological find-

ings in terms of the vast uncertainties of host responses. Evidence of chemical pollution is disturbing in an absolute sense; but in the face of the reality - which prevails in a vast number of settings other than the Love Canal area - the issues are those of actual, definable damage, of remedy to the extent that current knowledge permits, and of prevention in the future. The scientific evidence, incomplete though it is, reveals no state of population damage justifying the terms "imminent peril" and "profound and devastating effects". The promise of "remedy" implicit in the pronouncements of the EPA in this situation is illusory since neither the quantitative nor the qualitative aspects of the possible risks are known. And the manner in which prevention of situations like that enveloping the population and area surrounding the Love Canal can be prevented in the future remains yet unclear.

All these dimensions to the Love Canal problem could have been better handled by a joint Federal-State effort working through the Department of Health and including among its responsibilities not only the scientific investigations appropriate to the situation but also the educational efforts deserved by the public and demanded by the uncertainties of the body of knowledge in this type of pollution situation.

The public deserves no less than the facts as we know them concerning environment-host interactions, even if those facts constitute an incomplete body of knowledge and even if they reveal the limitations of the science of this field at the present time. The clear absence of acute damage to the Love Canal residents does not preclude a degree, perhaps, of damage over the very long term - but even here no working group can speak with that certainty which has characterized various pronouncements about this situation and has directly increased the intense anxiety of the Love Canal population.

A. Federal Role

The events surrounding the Love Canal demonstrate the need for the assignment of a lead Federal agency to direct all Federal involvement in health effects studies of hazardous wastes. The Panel recommends that either the Center for Disease Control or the National Institute for Environmental Health Sciences be so assigned. The Environmental Protection Agency has not demonstrated the capacity to design and implement health effects studies in a scientifically rigorous manner.

The Panel further recommends that the Federal lead agency be the single point of Federal decision-

making on the design and implementation of health effects studies regardless of source of Federal financing.

The Panel recommends, given the jurisdictional responsibility of the State public health authorities in these matters, that no Federal sponsorship of health effects studies either directly or by contract be undertaken without at least the consent, and preferably the active participation, of a State public health authority.

B. Federal/State Relationships

The Panel recommends that a specific and detailed protocol for coordination of health effects studies and other related health concerns regarding hazardous wastes sites be developed between the New York State Department of Health and the Federal government lead agency.

The Panel recommends that no health effects study of State or Federal sponsorship be initiated without a rigorous peer review of study design, methodology, and procedures similar to reviews conducted by the National Institutes of Health.

The Panel further recommends that non-governmental sponsors and investigators of health effects of hazardous wastes also seek out the highest caliber peer review of research proposals prior to implementation.

C. New York State

The Love Canal problem is an paradigmatic example of government decision-making at the outer bound of scientific knowledge. With a literally exponential growth in information and awareness concerning environmental contaminants and human health has also come a greater appreciation of the limitations of what we can know with certainty. Dialogues of hazardous wastes, air pollution, water quality, nuclear wastes and other environmental problems now center on such imponderable and ambiguous subjects as risk assessment, acceptable levels of voluntary and involuntary risk, and benefit/cost analysis. While the Panel believes it is important to improve public awareness of the current limitations of science with respect to environmental hazards, the critical failure in the past two years has been the inconclusiveness of studies carried out to date. Where improvements in public and decision-maker understanding might have been achieved, only further questions and debates on scientific credibility have been the result.

The recommendations proposed above should improve the quality of scientific investigation and governmental coordination necessary to answer the question posed earlier in this report, that is, has the health

of the people residing in the polluted zones at Love Canal been damaged and in what ways.

We recommend the creation by the Governor of a Scientific Advisory Panel, composed perhaps of 10 to 15 scientists, representing expertise in all of the technical disciplines involved in the Love Canal problem. This should not be an ad hoc committee with the charge to look into the matter and then to emerge with quick questions and answers. This kind of environmental health problem is not going to be solved easily or quickly, nor will it go away in time, nor will Love Canal be the only such problem confronting the State in the years ahead. There is need for a standing Panel, responsible to the Governor, capable of working with the Department of Health and other State bodies to form working groups of other scientists outside the committee, and authorized to draw upon the extraordinary scientific talent and resources which are available within the State in the public system and in the private universities, medical schools and research institutes of New York.

We suggest that the mode of operation of the Scientific Advisory Panel be patterned after that of the President's Science Advisory Committee (PSAC) which functioned with great value to the country from

the time of its inception in the Truman administration until its termination by the Nixon administration.

We recommend that the Advisory Panel be given access to all material bearing on the Love Canal problem, that it carry a particular responsibility for reviewing and advising on all new scientific studies while they are in the planning stage, and that it examine all reports (or, where necessary, obtain reviews by subpanels of its own creation) before they are issued as public documents by the State or any collaborating Federal agency. The Advisory Panel would also keep itself closely informed, perhaps through the personal involvement of its chairman or staff, concerning any new studies at Love Canal by Federal agencies or their contractors, including the proposed studies by the National Academy of Sciences and the CDC.

If, as we would expect, this Panel were to be made up of distinguished and nationally eminent members, the problems now posed by multiple agencies within Federal and State systems undertaking independent and sometimes uncoordinated research activities would diminish. Furthermore, it might be hoped that new ideas would emerge within the Committee for approaching the scientific problems represented in the Love Canal situation, and also those similar problems not yet

recognized elsewhere in the State but which surely will occur in the future.

It is our intention that the Scientific Advisory Panel supplement rather than supplant the mandates of existing Advisory Councils or the operating responsibilities of Executive Department agencies. We therefore recommend that the proposed special Panel be organized within the Governor's Health Advisory Council. This organizational placement would not only be efficient but also take advantage of the broader health policy advice available from that body.

We believe the special Panel will provide a needed organizational focus for advice on government decisions affecting a wide range of environmental problems with potential health effects. We also expect that this special Panel might provide a resource for advice to the Governor on a broader range of scientific questions facing State government.

APPENDIX A



No. 102

EXECUTIVE ORDER

ESTABLISHING A PANEL TO REVIEW
SCIENTIFIC STUDIES AND THE
DEVELOPMENT OF PUBLIC POLICY
ON PROBLEMS RESULTING FROM
HAZARDOUS WASTES

In light of recent conflicting and confusing reports of scientific findings at Love Canal, public policy decisions affecting the residents of that area have been made more difficult.

In order to evaluate the validity of such reports and to provide the Governor and the Legislature with guidance for proper use of medical and scientific data in connection with the handling of chemically contaminated areas, I, Hugh L. Carey, Governor of the State of New York, by virtue of the authority vested in me by the Constitution and laws of the State of New York do hereby appoint a Panel To Review Scientific Studies and the Development of Public Policy on Problems Resulting From Hazardous Wastes and request this panel to submit a report to the Governor and the Legislature at the earliest possible time.

In preparing its report, the panel shall:

- Review and evaluate medical and scientific data and studies prepared by or at the request of the State Departments of Health and Environmental Conservation in connection with Love Canal, and the methodology used in compiling such data and preparing such studies.
- Review and evaluate medical and scientific data and studies prepared by or at the request of the Federal government in connection with Love Canal, with specific reference to studies relating to genetic damage conducted at the request of the Federal Environmental Protection Agency, and the methodology used in compiling such data and preparing such studies.
- Review and evaluate medical and scientific data and studies relating to Love Canal compiled or prepared by any other agency, group or organization.
- Review available data concerning other known chemically contaminated areas in the State.

- Review and comment upon the proper relationship between State and federal agencies in local health emergencies such as that at Love Canal.
- Review and comment upon the proper use of medical and scientific data in the development of public policy in the areas of environmental protection and public health.
- Review and comment upon the current state of scientific knowledge regarding the effects of chemicals on the environment and public health.

The Governor shall appoint the members of the panel and shall designate a chairman. The members shall receive no salary but shall be reimbursed for reasonable and necessary expenses incurred in the performance of their duties.

I hereby direct all State agencies to assist and cooperate fully with the panel and to provide the panel with all available data necessary to the completion of its tasks and I urge federal agencies and other bodies who have collected data at Love Canal to cooperate fully with the panel.

G I V E N under my hand and the
Privy Seal of the State at
the Capitol in the City of
Albany this fourth day of
June in the year of our
Lord one thousand nine hundred
eighty.

BY THE GOVERNOR

Secretary to the Governor

APPENDIX B

Love Canal Studies by the New York State Department of Health
June 1980

<u>Investigator</u> <u>Date of Report</u>	<u>Title</u>	<u>Results and Comments</u>
1. Whalen RP et al September 1978	Love Canal - Public Health Time Bomb	Descriptive account to the Governor and Legislature. Copies were available to the public.
2. Vianna NJ et al May 1980 Draft	Adverse pregnancy outcomes in the Love Canal area	Epidemiologic study of residents living near the Canal in June 1978. Study shows suggestive increases in miscarriages and percent low birth weight, but the numbers of persons available for study and the inability to establish their real exposure make it uncertain to what extent these adverse effects can be attributed to chemical wastes. News release of this study on June 24, 1980. No instances of chloracne and no excess of cancer, asthma or epilepsy were found among these area residents.
3. Vianna NJ and Fitzpatrick JE Summer 1978	Blood counts and tests of liver functions.	Twelve clinics were held and about 4,000 blood specimens collected. Blood counts were not unusual. No clinical evidence of liver disease. Some persons were reported as having abnormal liver tests which diminished after relocation.
4. Kim S et al February 1978	Gas chromatography/mass spectrometric analysis of a composite sample of 8 sumps from Ring 1 houses.	Sumps contained toluene, chlorobenzene, di-, tri-, tetra- and pentachlorobenzene and other compounds.
5. Kim S et al June-Dec. 1978	Home basement air testing for 7 "marker" chemicals by gas chromatography. Approx. 700 houses tested.	Chloroform, benzene, trichloroethylene, toluene, tetrachloroethylene, chlorobenzene and chlorotoluene found in low levels in some basements. Results influenced by air flux through houses and solvents stored in basements by homeowners.
Kim S et al March 1978	Soil samples tested for Lindane	Lindane found

<u>Investigator</u> <u>Date of Report</u>	<u>Title</u>	<u>Results and Comments</u>
7. Kim S et al October 1978	Leachate from construction pit tested for dioxin	Dioxin Found
8. Division of Laboratories and Research, Cornell University Remote Sensing Group August 1978	Infrared aerial photography	Low lying areas (swales) noted which intersect the Canal and indicate the possibility of preferential drainage paths for leachate.
9. Kim S et al Feb.-Aug. 1979 Laboratory testing and analysis still in progress	Soil sampling of 700 houses with 5,000 soil samples collected. 1,000 samples from transect. 50 samples from storm sewers. Soil samples from beneath school playground.	Extensive contamination with toxic chemicals of soil near the Canal documented. Attempts to define leachate migration inconclusive. Preliminary data suggest swales not conducting leachate outside Ring 1. Traces of lindane and dioxin found beneath school playground.
10. Matuszek JM September 1978	Radiological survey of ambient (background) levels and soil samples.	Report indicates no serious radiologic health hazard.
Department of Health, including Roswell Park Employees Clinic Oct. 1978 - Mar. 1979 Further monitoring of workers planned.	Medical examinations of 112 construction workers from Canal remedial construction project.	8 skin related conditions noted. Similar number with elevated liver function tests before and after Canal work.
12. Pierce GJ September 1979	Examination of various forms of plant life.	No abnormalities found.
13. McMartin D Aug. 1978 - Sept. 1979	Autopsies of 3 dogs, 1 blackbird, 2 gulls	No histopathologic lesions that could definitely be ascribed to toxic chemicals.
14. Kaminsky LS et al In progress	Teratologic and pathologic effects of Love Canal soil and air above soil on rats	In progress. Earlier Department study showed that large doses of chemical wastes affected mice livers and kidneys.
15. Janerich DT et al In progress	Diagnosis or death from cancers among Love Canal census tract residents, 1950-79.	In progress.

<u>Investigator ate of Report</u>	<u>Title</u>	<u>Results and Comments</u>
16. Greenwald P et al In progress	Comparison of adverse pregnancy outcomes of Love Canal census tract to other tracts of similar socioeconomic level.	In progress.
17. Vianna NJ et al In progress	Retrospective study of cancer in former Canal residents.	In progress. 975 families who lived in the Canal area and moved away prior to June 1978 have been identified.

Love Canal Studies by the United States Environmental Protection Agency
June 1980

(Note that these studies were provided to the Panel by the State Health Department)

Contractor or
Investigator,
Date of Report

Title

Results and Comments

- | <u>Contractor or Investigator,
Date of Report</u> | <u>Title</u> | <u>Results and Comments</u> |
|--|--|---|
| 1. E.D. Pellizzari
Research Triangle
Park on Contract
for EPA
April 24, 1978 | Improvement of Methodologies
for the collection and
analysis of carcinogenic
vapors. Monthly technical
progress report number 7. | Household basement air samples
found to contain toxic chemicals. |
| 2. F.C. Hart Associates
on Contract for
EPA
July 28, 1978 Draft
Aug. 18, 1978 Second
Phase report | Analysis of a groundwater
contamination incident
in Niagara Falls, New York | Some contamination with chlorinated
hydrocarbons found outside 1st
ring. |
| 3. D. Picciano
Biogenics Corp.
on Contract for
EPA
May 14, 1980 | Pilot Cytogenic Study
of the Residents of
Love Canal, New York | 36 residents examined. High
frequency of "supernumerary
acentric chromosomes" and other
chromosome abnormalities reported. |
| 4. Research Triangle
Park on Contract
for EPA | Preliminary tables. Test-
ing of drinking water, human
blood samples, indoor air
samples and human breath
for halogenated compounds. | No final report received. |

Other Studies Reviewed

1. Report of Pilot Project: Nerve Conduction Determinations at "Love Canal",
Niagara Falls, New York; Stephen A. Barron, M.D., Department of Neurology, School
of Medicine State University of New York at Buffalo, Buffalo, New York.
2. Beverly Paigen, Ph.D., Roswell Park Memorial Institute, Buffalo, New York; testimony
to the U.S. House of Representatives Subcommittee on Oversight and Investigations,
March 21, 1979.

APPENDIX C

Love Canal: False Alarm Caused by Botched Study

In the opinion of many experts, the chromosome damage study ordered by the EPA has close to zero scientific significance

The much-publicized study of chromosome damage among residents of Love Canal has been discredited. The most recent attack was by a panel convened by the Environmental Protection Agency (EPA) on 27 May, which concluded that the study has virtually no value and cannot be salvaged. The report was meant to be legal, not scientific, evidence for the Justice Department in its suit against Hooker Chemical. Tragically, the EPA has ended up by needlessly terrifying the Love Canal residents.

Love Canal has for several years been "a neighborhood of fear," says New York Governor Carey. Residents have been increasingly alarmed by reports that the toxic wastes buried in the area may be causing cancer, miscarriages, birth defects, and seizures.

The latest episode in the saga of Love Canal began on 17 May. On that day the EPA released a report saying that Love Canal residents may have damaged chromosomes and might therefore be at an increased risk of developing cancer or having children with birth defects.

The residents reacted emotionally to the EPA report, with nearly hysterical demands that they be evacuated from the area. "It [the EPA report] was one more frightening, scary thing and we couldn't take it any more," says Lois Gibbs, head of the Love Canal Homeowners Association. On 21 May, President Carter declared a state of emergency at Love Canal, clearing the way for the relocation of about 2500 residents, at a cost to the federal government of \$3 million to \$5 million.

Barbara Blum, deputy EPA administrator, announced the relocation at an EPA news conference. But she was careful not to attribute the move to the report on chromosome damage. "This action is being taken in recognition of the cumulative evidence of exposure to toxic wastes . . . and of mounting evidence of resulting health effects," she said. In fact, the chromosome study had just been severely criticized by a panel of experts who reviewed it for the Department of Health and Human Services

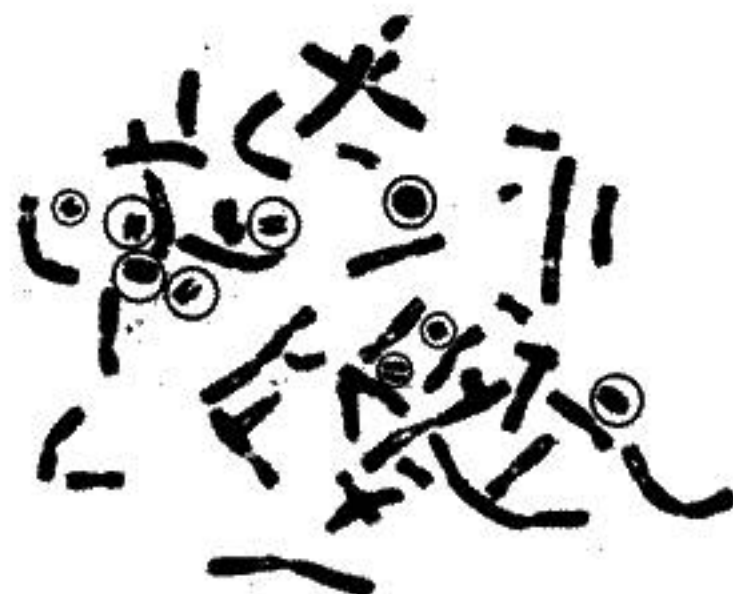
(HHS). Serious questions were raised about whether the study shows anything at all about the residents' chromosomes and why the EPA conducted such a study in the first place.

The EPA has reason to be interested in Love Canal. It is suing the Hooker Chemical and Plastics Corporation (now owned by Occidental Petroleum) for \$124.5 million, charging it with dumping

certainly time for well-designed medical and epidemiological studies to be conducted at Love Canal.

The EPA study, however, was not well designed. It was not even meant to be scientific, according to Stephen Gage, assistant administrator for research and development at EPA. "This [the study] was a small fishing expedition. The Justice Department asked us to undertake it

Chromosome damage. Ring chromosomes and chromosomal fragments, which are two forms of damage, are circled. [Source: L. Atkins, Massachusetts General Hospital]



toxic chemical wastes at Love Canal and at three other sites in the Niagara Falls area. From 1947 to 1952 Hooker dumped 21,800 tons of chemicals at Love Canal, but it contends that it disposed of these wastes in full accordance with environmental regulations at that time. In 1953 Hooker sold the Love Canal dump site to the Niagara School Board for \$1 with a deed disclaiming responsibility for any injuries that might result from the buried wastes. In addition to building a school on the dump site, the school board sold the remaining land to developers, who built houses there.

Over the past decade, toxic chemicals have been leaching from the land into the homes and schools on the site. Last year, the EPA said that four suspected carcinogens were found in air samples near the contaminated area. Residents have complained that they are ill and that they have unusually high frequencies of cancer, miscarriages, and birth defects. These effects have been difficult to document, but many scientists believe it is

in connection with our suit against Hooker," he says.

The difficulties with the EPA study were first brought to light when HHS asked a panel of eight scientists, three of whom are cytogeneticists, to review it. The scientists had seen the written report and had serious reservations about it. But they felt that they needed to see the data before coming to any final conclusions.

The data were in the hands of Dante Picciano, who conducted the study under an EPA contract and who works for the Biogenics Corporation in Houston. Charles Carter, scientific director of the National Institute of Environmental Health Sciences and chairman of the HHS panel, spoke to the EPA about seeing the data and was given the impression that if the panel members went to Houston, the data would be available and they could speak to Picciano.

On the night of 19 May, the HHS panel flew to Houston. When they arrived, however, they learned that Picciano

would neither speak to them nor release his data unless he could place a person of his choosing on the panel. Carter negotiated well into the night with HHS officials and with the Biogenics Corporation over whether Picciano's demand should be met and, if so, who would be an ac-

ceptable addition to the panel. Finally, the Biogenics Corporation insisted that Jack Killian, a controversial figure in the field of cytogenetics, be a member of the HHS panel.

At this point, says Carter, negotiations ceased and the panel members went

home. Killian was completely unacceptable to the panel because he had been Picciano's collaborator in a previous highly disputed study of chromosome damage among workers at Dow Chemical Company. The HHS panel, Carter reports, questioned whether Killian might also have some association with Biogenics. Picciano says he sees nothing wrong with insisting that Killian be a member of the HHS panel. "I think it is a normal procedure in a scientific review to appoint someone or object to someone on the team," he explains.

Unable to see Picciano's data, the HHS panel was forced to rely on his written report. On 21 May, HHS released the panel's assessment of the report and its conclusion that the study "provides inadequate basis for any scientific or medical inferences from the data (even of a tentative or preliminary nature) concerning exposure to mutagenic substances because of residence in the Love Canal area."

The three cytogeneticists on the HHS panel were Sheldon Wolff of the University of California at San Francisco, Arthur Bloom of Columbia University, and Michael Bender of Brookhaven National Laboratory. All agree that the most glaring deficiency of the study was its lack of simultaneous controls and that, for this reason alone, the results are meaningless.

Everyone has some amount of chromosome damage, which may be caused by viral infections, medical or dental x-rays, or exposure to chemicals, to sunlight, or to certain medications. It is thus extremely important that the cells of a suspect population be compared to those of a control population to see if the suspect population has, on the average, excessive chromosomal aberrations. The controls should be closely matched to the exposed subjects in terms of age, sex, medical history, and geographic area because all of these factors can affect the numbers of aberrations. Since cells are grown in the laboratory before they are examined for chromosome damage and laboratory conditions can affect the number of chromosomal aberrations, the controls and test cells should be cultured at the same time. In addition, Bloom stresses, the person assessing the aberrations should not know which cells are from the exposed population and which from the controls. "This is a very subjective science," he says.

Rather than following this prescription for a well-controlled study, Picciano compared the chromosomes of the Love Canal population to those of a population that he had studied earlier and that, he

Chromosome Damage: What It Is, What It Means

Chromosome damage is an important test of whether people have been exposed to toxic chemicals. But the test is hard to interpret. Some damage occurs naturally because of such things as colds, flu, x-rays, and sunlight, and damage also increases as a person ages. People who have come into contact with a toxic substance, however, may have more damage than a comparable group that has not been so exposed.

Excess damage in a population may have some meaning but on an individual basis it does not. On the average, a population with damaged chromosomes may have more cancer and more birth defects than otherwise expected, but the individuals in the population whose chromosomes are damaged are not necessarily those who will suffer these ill effects. Chromosome damage is just an indicator, a sign that the population may have been exposed to something that damages DNA. Many of the substances that cause chromosomal aberrations are also thought to cause cancer and birth defects. But the white blood cells sampled for a test of chromosome damage are not themselves likely to give rise to cancer, and they cannot contribute to birth defects because they are neither sperm nor egg cells.

The assessment of chromosome damage is as much an art as a science. White blood cells must be carefully cultured, then stained and examined under the microscope. The 46 chromosomes in a human cell can be individually identified by their characteristic shapes and sizes. If there is damage, it often appears as breaks and deletions or as rings, which are formed from chromosome fragments. Cells with damaged chromosomes usually die or repair the damage.

Although the chromosomes are the carriers of genes, almost never can specific chromosomal aberrations be associated with specific birth defects or cancer. One exception is Down's syndrome, in which individuals inherit an extra chromosome 21 and this extra chromosome shows up in all their cells. But most genetic defects and most DNA damage that may lead to cancer involve submicroscopic changes in DNA and quite often do not lead to physical changes in the chromosomes. There is only indirect evidence associating chromosome damage with birth defects and cancer.

Perhaps the best evidence correlating damaged chromosomes with an increased incidence of cancer comes from the survivors of Hiroshima and Nagasaki. They had a significant amount of chromosome damage, which was directly related to the dose of radiation they had received. Moreover, the more radiation they were exposed to, the greater their incidence of cancer. But even in that population, those with the greatest amount of chromosome damage were not necessarily those who got cancer.

Among the Hiroshima and Nagasaki survivors, there was no statistically significant increase in birth defects and miscarriages. Ionizing radiation is known to cause birth defects and miscarriages, but the normal rate of these incidents is so high that it is very hard to show a significant increase, especially in a small population, according to Jean French of the Center for Disease Control. Nearly 11 percent of all children born have genetic defects, and as many as 50 percent of all pregnancies are estimated to end in a spontaneous abortion.

"It's a scary thing to tell people they have chromosome breaks," says Arthur Bloom of Columbia University. "But the breaks are by no means a harbinger of cancer or birth defects."—GINA BARI KOLATA

said, had no known exposure to toxic chemicals. Picciano agrees that simultaneous controls are desirable, as does Beverley Paigen of Roswell Park Memorial Institute. Paigen selected the Love Canal residents whose blood was sampled and helped design the chromosome study. But Picciano and Paigen disagree on why there were no simultaneous controls, although both blame the EPA.

According to Picciano, because the EPA wanted the study done so quickly there was no time to select simultaneous controls. (The study was begun in January and completed in May.) Paigen says that she had already chosen appropriate control subjects before the study began but the EPA ruled them out because it did not want to spend much money. (The study cost \$10,000.) Chuck Morgan of EPA says the agency cannot comment on why the study had no simultaneous controls because "this is an enforcement investigation."

Picciano, Paigen, and Gage say that even though the lack of simultaneous controls is a flaw, the study nonetheless does provide evidence that some Love Canal residents may have excessive chromosome damage. The residents did not differ significantly in the types of aberrations observed in the control groups. But, Gage explains, they did have a highly unusual sort of damage, something Picciano calls "supernumerary acentric chromosomes." Picciano claims that 8 of 36 Love Canal residents had this sort of damage and none of the controls did. He estimates, "from my own experience," that such aberrations should normally occur in only 1 out of 100 individuals.

The cytogeneticists on the HHS panel, however, say that the term supernumerary acentric chromosomes is not a standard one and they are not sure what Picciano was seeing. Since he refuses to show them his slides, there is no way for them to know what, if anything, he saw. The cytogeneticists have other criticisms of Picciano's methodology and would also like to see data on how the Love Canal residents were selected for testing.

The mystery of the supernumerary acentric chromosomes has now been solved by an EPA-sponsored panel. Reacting to the severe criticisms of the chromosome study, the EPA asked Roy Albert of New York University to organize a panel to review the study's data. The panel met on 27 May. Sidney Green and Peter Voytek of the EPA sat in on the session. The panel members were provided with photocopies of the photographs of the chromosome preparations so they could look for the supernumerary acentric chromosomes.

But when the EPA panel looked at the data, they saw nothing that could by any stretch of the imagination be called supernumerary acentric chromosomes. Even worse, sources say, the panel found that Picciano himself was inconsistent in what he called supernumerary acentric chromosomes. One time, for example, it was a chromosome 1 that had broken in half. Another time, it was another sort of break. The EPA panel concluded that there was no evidence that the Love Canal residents had excessive chromosome abnormalities and that supernumerary acentric chromosomes exist only in the mind of Picciano.

Considering the irredeemable flaws in the EPA study, a number of cytogeneticists have been asking why Picciano was asked to do it. Gage says that Picciano had done other consulting work for the agency in the past and that he is very experienced in assessing chromosome damage. But Picciano's dispute with Dow Chemical is well known and has caused the HHS panel members, at least, to wonder why a less controversial scientist was not chosen.

Picciano and Killian resigned from Dow Chemical after that company refused to release their study on chromosome damage in Dow workers exposed to benzene. Using the same group of historical controls that was used for the Love Canal study, Picciano and Killian concluded that the benzene workers had excessive chromosomal aberrations. Dow questioned the study on grounds similar to those raised by the HHS panel who reviewed the Love Canal study. The company says it then redid the benzene study with simultaneous controls and found no evidence of chromosomal aberrations in the benzene workers.

Perry Gehring, director of health and environmental sciences for Dow Chemical, is vehement about the scientific problems with Picciano and Killian's benzene study. "If Picciano used the same controls in the Love Canal study as in the benzene study then I assure you there are no controls," he says. Gehring claims that Picciano and Killian selectively removed from their control group cells with unusually large numbers of aberrations. Picciano, told of this charge, laughed and said, "Did I do that? I don't remember doing that."

Gehring says that Dow reevaluated Picciano and Killian's slides of chromosomal aberrations in the benzene workers and also sent the slides to an outside consultant for evaluation. A number of the aberrations allegedly seen by Picciano and Killian could not be substantiated, according to Gehring. Pic-



Love Canal children seek evacuation.

ciano, however, says his only disagreement with Dow was on the level of the workers' exposure to benzene.

After leaving Dow, Picciano worked for a time at the Occupational Health and Safety Administration (OSHA). He gave OSHA his study of the Dow benzene workers and, 2 years ago, OSHA submitted the study as evidence at a hearing to reduce the allowable exposure of workers to benzene. The Manufacturing Chemists Association asked James H. Jandel, a hematologist at Harvard Medical School, to take a look at the data. Jandel agreed and requested that his colleague Peter Tishler, a cytogeneticist, comment as well. Neither Jandel nor Tishler thought the study was scientifically adequate. "I was very unimpressed," says Tishler. Among their numerous criticisms were the lack of concurrent controls and the failure to use modern staining techniques, which are also criticisms of the Love Canal study made by the HHS panel. "The sloppy way in which this [the benzene study] was handled is offensive to me," says Jandel. The court decided to stay the request for lower allowable benzene exposure levels.

Picciano, Paigen, and the EPA say the significance of the Love Canal study has been blown out of all proportion. It was only meant to be a pilot study to show whether a larger and more scientific study is warranted. And the preliminary evidence from the Love Canal study convinces them that a larger study is worthwhile.

The critics of the Love Canal study, on the other hand, explain that it is illogical to say that an unscientific study can provide evidence of anything. And they say that the tragedy of the situation is that the Love Canal residents are the ones to suffer.

Phyllis Whitenight, a Love Canal homeowner, was a subject in Picciano's study and was one of those found to have supernumerary acentric chromosomes. Her reaction to the study and its critics is that the government is trying to whitewash some very scary data. Whitenight had breast cancer nearly 5 years ago but the cancer had not spread and she says she was given no chemotherapy or radiation treatments following her mastec-

tomy. Until the chromosome report, she had thought her prognosis was good. "Now the fear comes back," she says.

Gibbs, speaking for the Love Canal Homeowners Association, says Picciano's report "is very frightening to the residents." She believes it indicates that the residents are at risk for cancer, birth defects, and miscarriages. The HHS review of the data, she says, is seen by the residents as "almost an attempt to sabotage the report." The residents think the government is trying to adjust the figures and minimize the risk by criticizing the study. "It scared the hell out of the residents when the government reacted [to Picciano's report] by moving people out," Gibbs remarks.

In the view of several critics, the EPA made an incredible blunder by releasing such a poorly conducted study. Far from aiding its case against Hooker, the agency may have hurt it. "If there's anything to bring joy to the heart of Hooker, it's a discussion in the public press that questions the validity of the EPA data and the interpretation of it," says one federal administrator. The EPA may also have damaged its credibility in the scientific community. "I for one will never believe anything the EPA says or releases again unless it has been peer reviewed," says Ernest Hook, of the New York State Health Department and a member of the HHS panel.

—GINA BARI KOLATA

Letters

Love Canal Chromosome Study

I have had the opportunity to examine the photographs of chromosomes in 151 metaphase spreads (and 111 accompanying karyotypes) from short-term lymphocyte cultures of Love Canal residents prepared by Dante Picciano, scientific director of the Biogenics Corporation, for the Environmental Protection Agency (EPA). In addition, I have examined 200 dividing cells under the microscope from four previously unscored slides prepared for the study. Picciano's report to EPA was sharply criticized in Gina Bari Kolata's article "Love Canal: False alarm caused by botched study" (News and Comment, 13 June, p. 1239).

I would like to comment on four of the controversial issues that have arisen from Picciano's pilot study. These are (i) the quality of the cytogenetic preparations, (ii) the cytogenetic interpretation of the abnormalities reported, (iii) the lack of simultaneous controls, and (iv) the biological significance of chromosomal abnormalities in terms of health effects such as cancer and birth defects. A detailed report of my observations will be sent to EPA and will be published in the *Mammalian Chromosome Newsletter*.

Although Picciano and I both live in Houston, I had never met him until 12 June 1980. I was in Australia and New Zealand from 9 May until 1 June and was unaware of the Love Canal chromosome study until I returned home. At that time Picciano offered to make the photographs and slides available to me for review.

Quality of cytogenetic preparations. I subjectively classified the quality of the photographs I examined from Picciano's 36 subjects, with 83 percent scored as good to excellent and 17 percent fair to poor. This is in contrast to the EPA-sponsored panel report (Roy Aibert, chairman) which states that the quality of the Xerox copies of photographs of metaphase spreads which they examined was fair or poor. Most of the chromosomes I examined did *not* exhibit overcontraction due to excess Colcemid exposure. None of the cells showed the se-

vere chromosome damage commonly seen in cultures exposed to clastogenic agents *in vitro*.

Cytogenetic interpretation. Cytogeneticists are aware of differences among observers in scoring chromosomal abnormalities. I tended to score many abnormalities as "chromatid gaps" that were scored by Picciano as "chromatid breaks." I also scored fewer "chromosome breaks" than Picciano. Nevertheless, our agreement was remarkable about other unstable abnormalities (Table 1).

Kolata states (p. 1241), "[t]he EPA panel concluded that . . . supernumerary acentric chromosomes exist only in the mind of Picciano." Because of this damning statement I wish to report my observations of Picciano's photographs containing abnormalities which I recorded as "long acentric fragments." Among 15 cells, all of which were karyotyped, I found 28 acentric fragments. Eight of these fragments were as long as the long arm of a No. 2 chromosome while nine were *longer* than any chromosome arm of the human complement. The latter could not result from a simple chromosome break. Unless they were chromosomes with centromere inactivation or premature separation of the centromere, they must represent some form of breakage and reunion. Without C-banding and G-banding the derivation of these objects remains unsettled. In nine of the 15 cells there was significant chromosomal material present in addition to the normal diploid complement, and in two other cells extra material was probably pres-

ent. This was observed in cells from both males and females. Among the 200 cells examined under the microscope I scored three additional long acentric fragments.

In my experience, long acentric fragments are very rarely seen in normal individuals. I could find no cytogenetic surveys in which they were separately categorized and commented upon. However, there are at least two photographs published in the literature in which long acentric fragments appear (1). I cannot agree that supernumerary acentric fragments are a figment of Picciano's imagination.

Rings and chromatid interchanges are also rare in normal individuals. Court-Brown *et al.* reported (2) that *no* rings were observed in any preparations from their random sample. They examined 12,264 cells, of which 8,983 were cultured for between 65 and 75 hours, compared to 9,102 cells examined by Picciano. German (3) reported two quadriradial configurations in cells from 49 clinically normal individuals studied, but one of those appeared in a nonradioactive cell from a culture that had been exposed to tritiated thymidine.

The lack of simultaneous controls. The results are neither positive nor negative because of absence of contemporary controls. I find it difficult to understand why the EPA panel stated flatly that the absence of simultaneous controls was a very serious deficiency of the study and then stated that Picciano's results were considered to be well within normal limits. Were they trying to say that the study is a "false alarm" or that it is "botched" because their own conclusions are different from Picciano's, even though both used historical controls?

I believe that a sensibly designed, controlled, collaborative study should be undertaken as soon as possible. Further, I suggest that the cytogenetics community attempt to design a study that would be acceptable *in advance*, considering all of the possible parameters, such as culture conditions, intraobserver consistency, interobserver differences, suitable control groups, appropriate staining procedures, number of cells per individual and number of individuals to be scored, number of laboratories, and blind scoring of subjects and controls. Until a consensus is reached concerning a research protocol and the interpretation of possible results, it is a waste of time to gather more data that cause anxiety and anguish among the Love Canal residents. Cytogeneticists could perform a useful service by designing chromosome studies of humans exposed to toxic chemicals. Undoubtedly many studies will be request-

Table 1.

Unstable chromosome abnormalities	Picciano (No.)	Shaw (No.)
Dicentrics	1	1
Chromatid interchange (triradial figure)	1	1
Rings	5	3 definite; 3 possible
Acentric "double minutes"	0	2
Long acentric fragments	14	28

ed in the future by government, industry, exposed populations, special interest groups, and others. Expert advice from statisticians and epidemiologists would be necessary for developing an acceptable research design.

Biological significance. It is difficult for the lay person to understand uncertainties in science, yet it is imperative that scientists attempt to educate the nonscientist concerning the problems which arise when extrapolating from laboratory data to an assessment of risk in human populations. Stochastic events that occur after exposure to mutagens, clastogens, carcinogens, and teratogens are not easy to explain. Chromosome damage is only one indicator in a series of poorly understood biological events that occur randomly in cells (and therefore in individuals) as a result of an external environmental insult. We cannot equate a ring chromosome in a lymphocyte with a cleft palate in an offspring. We should recognize our ignorance and uncertainties and try to help the regulators as well as the human subjects to appreciate the concept of probabilities rather than certainties. In our democratic society, perhaps we will decide that 500,000 deaths per year is an acceptable price for toxic chemicals in our environment, just as we have decided that 50,000 traffic deaths per year is an acceptable price for automobile travel. On the other hand we may decide that 5000 deaths per year is an unacceptable price for toxic chemicals. The scientists should provide the data and interpret the results: the public should decide.

MARGERY W. SHAW

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3. J. German, *Science* 144, 298 (1964).