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ATTACHMENT A

A 1980 REASSESSMENT OF THE HEALTH HAZARDS OF LOW-LEVEL IONIZING RADIATION

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Abstract

A decade ago the risks of leukemia from exposures to low levels of ionizing radiation were estimated by linear extrapolation from data on persons exposed to much higher levels. In recent years, however, a number of scientific studies have reported excess risks where the data was on persons actually exposed to low-level radiation. The new findings are incompatible with the estimates based on the Linear Hypothesis although these estimates continue to be used in public health. Fifteen studies involving low-level nuclear radiation and ten studies involving diagnostic radiation are listed and briefly described. Most of these studies have positive qualitative findings but a few also have quantitative estimates of risk such as doubling doses. The qualitative findings would be extremely unlikely at the estimated exposure levels (which represent average exposures well under 5 rads or rems) if the extrapolative estimate of over 100 rads of the Federal Interagency Task Force Report were correct. The quantitative estimates from the data on persons exposed to low-level radiation give doubling doses in the vicinity of 5 rads and are also incompatible with the extrapolative estimates. The failure of the Linear Hypothesis to fit the new facts seems to reflect a greater efficiency-per-rad in producing genetic damage for the low-dose range than for the high-dose range.

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1. INTRODUCTION: THE REASSESSMENT OF RISKS IN 1980

The assessment of the health hazards of low-level ionizing radiation is not an altogether simple task but the job is much easier now in 1980 than it was in 1970 or 1960.

One reason why it is easier today is that there have been major scientific advances in our understanding of the causes of human cancer, in the area of carcinogenesis, in the past 20 years. Despite the impression created by the traditional mystique of cancer research, the fact is that we now know the immediate cause of radiation-induced cancers and probably all human cancers. The first event in the long evolutionary biological process that ends with death from leukemia or other cancer is the occurrence of a biochemical lesion or a break-point in the complex chemical structure of the DNA in the genetic material of a human cell. This break-point may be inherited from a parent as genetic damage, or it may be produced by radiation, chemicals, or biological materials in the environment. We now know that this genetic degradation is the cause of cancer.

It is informative to compare the controversy over low-level radiation hazards in 1980 with the controversy over the health hazards of cigarettes that began in 1950. Our epidemiological studies in the 1950's were met with flat denials that cigarettes cause cancer or could possibly cause cancer. Today, however, there is no argument about whether radiation can cause cancer. Everyone agrees that higher levels of exposure, such as therapeutic medical x-rays, can and do cause

leukemia and cancer. In 1960 it was argued on the basis of a threshold theory that low-level radiation was harmless. However, by 1970 the first National Academy of Sciences report (1) on the biological effects of ionizing radiation ("BEIR I") recognized that there were some effects at low-levels. The question then was: How much of an effect is there? This is still the question in 1980. It might be noted that this is a quantitative rather than a qualitative question.

Perhaps the simplest way to put the question in terms that everyone can understand is to introduce the easily-grasped technical concept of a doubling dose. Now all of us are exposed to background levels of radiation and possibly other carcinogens that can produce the break-points in the DNA that result in leukemia. Depending on demographic factors such as age or sex there is a certain risk of leukemia from these background exposures. If an additional dose of radiation is given to the individual, there is an additional risk of leukemia. When the dose comes from medical x-rays, it is generally measured in units called rads. When it comes from nuclear radiation, the amount is given in rems. For present purposes, rads and rems are roughly interchangeable. The dose (in either units) that will double the background risk of leukemia is called the doubling dose.

The most crucial question in the 1980 reassessment of radiation hazards can therefore be put as follows: What is the doubling dose for leukemia in men?

One might ask: How is the doubling dose related to official standards such as the permissible levels set by the Nuclear Regulatory Commission for exposures of nuclear workers? The current NRC standard is five rem per year so the relationship is easy to see. If, for instance, the doubling dose is less than five rem then the current standard is much too high and the NRC is permitting a dangerous exposure. No other carcinogen is permitted at levels close to a doubling dose for cancer in humans. On the other hand, if the doubling dose were over 100 rem, then the NRC standard would be defensible.

One might also ask: Why focus on leukemia instead of some other disease? We can and do consider other cancers and other diseases. However, there are three strong scientific reasons for the focus on leukemia. First, leukemia is generally acknowledged to be a radiogenic disease. Second, it is often our earliest warning, since it can start occurring in around seven years whereas the solid cancers tend to take twenty years. Third, it is probably our clearest indicator of genetic damage and therefore other health risks can be predicted from the leukemia risks. Leukemia is, of course, a serious health hazard in its own right, but it is particularly important as our best early warning system for other hazards.

2. THE RIVAL RISK HYPOTHESES: THREE THEORIES OF LOW LEVEL RISKS

Putting the question in the form "What is the doubling dose for leukemia?" allows a relatively clear and simple statement of the

three hypotheses that are involved in the current controversy. The doubling dose can be calculated from the relationship between, say, dose in rems and relative risk of leukemia for a given dose, from what is generally called a dosage response curve. The rival hypotheses can be represented as three curves on the graph for the dosage response curve. The three theoretical curves are shown in Figure 1.

INSERT FIGURE 1

The three rival theories are shown as curves A, B, and C in Figure 1. They are:

(A) The original Threshold Hypothesis which was probably the most popular view in 1960 and which supported the official doctrine that "Low-level radiation is harmless". This curve is the heavy dotted line that turns sharply downward at some level well above one rad. According to this theory there would be no risk at dosages below the point where the curve intercepts the horizontal or x-axis.

(B) The Linear Hypothesis which was probably the most popular view in 1970. It is the theory adopted in the 1972 BEIR report and in the 1979 update which takes the same approach. This curve is a solid straight line in Figure 1. When the dosage response curve plots excess radiation (in addition to background) versus excess risk of leukemia, the straight line should go through the point where the x-axis and y-axis intercept. The Linear Hypothesis is an irreplaceable assumption

for all of the estimates in the BEIR report since the actual data is on persons exposed to higher dosages of radiation, generally over 100 rads. Linear extrapolation must be used to estimate the risks at the low levels, generally under five rads, which are the critical levels for the public health problems from both nuclear and medical radiation.

(C) From a public health standpoint the worst possible curve is the one which arises with what might be called a Genetic Degradation Hypothesis. This curve is the light dotted line that bends off above the straight line at the lower doses. It will be argued that this is the hypothesis that fits the facts that are available in 1980. We now have information on leukemia risks in groups which were actually exposed to low-level radiation. Hence, estimates of risk can now be made directly from the data without the strong assumption of the Linear Hypothesis.

The difference between the three rival hypotheses can be expressed very simply in terms of the notion of excess risk-per-rad. The Linear Hypothesis assumes that there is a constant risk-per-rad--the risk being the same at high doses as at low doses. The Threshold Hypothesis assumes that the risk per rad is less (or vanishes entirely) at low doses. The Genetic Degradation Hypothesis assumes that the risk per rad is greater at low doses than at high doses. The rationale for this hypothesis is that at low doses, chances are that there will be one break-point produced or none at all. At high doses, however, multiple break-points are produced. This heavy damage blocks the

cellular reproduction needed to produce the cancer. It therefore "wastes" the break-points and results in a lower risk per rad at higher doses.

3. TESTING THE HYPOTHESES: QUALITATIVE TESTS

Modern science began with the Galilean Rule: A theory must fit the facts. So the first step in the 1980 reassessment of radiation risks is to determine how well each of the three rival theories fits the epidemiological facts that are now available. In principle, the best test would be a quantitative one: A dosage response curve for the range around five rads would be constructed from actual data on persons exposed to radiation in this range and this actual curve compared directly with the theoretical curve. This will be done in a later section. However, the quantitative tests are more complicated, and we may start with the simpler qualitative tests of the three hypotheses.

The reason that qualitative tests are feasible here is that there is an enormous difference between the estimates from the Linear Hypothesis and the estimates from the Genetic Degradation Hypothesis. The latter, as will be seen later, gives an estimate of the doubling dose that is probably less than five rads (25). The official estimates, such as those in the latest Federal Interagency Task Force Report (2), puts the doubling dose at over 100 rads. With one estimate more than 20 times another, even a qualitative approach can indicate which estimate fits the facts and which does not. The Threshold Hypothesis is easily

distinguished from both other hypotheses since it implies an infinite doubling dose at low doses.

If the doubling dose were over 100 rads or if it were infinite, then the effects of doses between 100 millirads and 10 rads, in what will be called the one rad range, would be negligible. My testimony of March 6, 1979, to the Senate Government Affairs Subcommittee on Energy, Nuclear Proliferation, and Federal Services in Washington, D.C. (3), began by noting this point:

"Three years ago it was widely believed by the self-styled radiation protection community that it would be impossible to detect any health effects in studies of people exposed to dosages in the one rad range. At that time, Tom Mancuso and I were the only ones doing large-scale epidemiological studies to look at these hazards. Two years ago I predicted that if scientists would only try to look at populations with exposures in the one rad range they would find, as we did, that there are serious health hazards. Since that time more than half a dozen new studies have looked at what happened to persons exposed to nuclear radiation in the one rad range and have reported positive results. These are the studies that I want to try to put together.

In ten minutes I cannot hope to go into details on all the studies, the criticisms of these studies that have been made by the members of the radiation protection community who wrote the interagency report, or the answers to these criticisms. Very briefly, there are three kinds of studies of nuclear radiation hazards at the one rad

level. The first kind deals with persons who were exposed to fallout from the nuclear weapons testing of the cold war era. This includes studies of the servicemen at Big Smoky and other tests. There are also the after-effects on adults and children in the areas of Utah downwind from the tests. The second kind study involves occupational exposures. This includes studies of the workers at the Hanford reprocessing plant and at the Portsmouth Naval Shipyard. The third class of study involves exposures to nuclear wastes such as the uranium tailings or releases from power plants. Depending on what is counted, there are now between half a dozen and a dozen positive reports of hazards to persons exposed to nuclear radiation in the one rad range. It is virtually impossible that they are all false alarms."

This testimony involved an early draft of the Interagency Report, commonly called the Libassi Report, but the bibliography of the final version (2) will be used here.

More specifically, the final version of the Libassi Report cites five references for the hazards of nuclear radiation from fallout if thyroid cancer is also considered (4-8). However, this list only includes publications in the technical literature. It omits the reports on fallout from Dr. Ernest Sternglass and others even when they appear in a Congressional report (9). It omits media reports entirely, for instance the reports on the marines at Nagasaki (10). The coverage of hazards to workers at nuclear installations is better and seven references with positive results are cited (11-16). There are three positive

reports on hazards of nuclear wastes or emissions or areas of high natural radiation (17-19), but none of the studies of populations in the vicinity of nuclear power plants (20) are cited. The Rocky Flats and uranium tailings hazards are given only cursory mention. Despite the omissions, it can be seen that there are well over a dozen positive studies which were cited in the Libassi Report, disparaged, and then disregarded.

There are eleven reports of positive findings for diagnostic x-rays cited (21-31), all of which find excess leukemia among patients exposed to this low-level radiation. A negative study of occupational hazards of radiologists is cited (32) but not the positive studies. An important study of the children of radiologists (33) is omitted as are some important diagnostic x-ray studies (34).

One might wonder why in 1980 there are so many positive studies on groups exposed to low-level radiation when in 1960 or 1970 there were so few. Basically what has happened is this: Time is running out on both the Threshold Hypothesis and the Linear Hypothesis. The nuclear exposures started in the 1950's and 1960's but due to the long latent period for the malignant diseases the health effects are only now coming to light.

These are the qualitative facts. How well do the three rival theories fit the facts? The long list of positive reports cited above are about what would be expected if the Genetic Degradation Hypothesis were correct and the doubling dose for leukemia was less than 5 rads.

They would be extremely unlikely if the Linear Hypothesis were correct. They would be impossible if the Threshold Hypothesis were correct. Or putting it another way: In accordance with the Galilean Rule that a theory must fit the facts, the Threshold Hypothesis would have to be completely rejected and the Linear Hypothesis almost as strongly rejected on the basis of these facts. This does not absolutely prove the Genetic Degradation Hypothesis but it makes it the only tenable hypothesis of the three.

4. TEST OF THE THEORIES: A QUALITATIVE EXAMPLE

This brief survey will not attempt to review all of the dozen or more of studies that now show positive effects in groups exposed in the one rad range. Instead it will focus on one such study which, characteristically, has been reported in the media rather than in a scientific journal. As I noted in a letter to Health Physics (35), the report appeared in the New York Times for June 17, 1979:

"Under the headline 'Study Casts Doubt on A-Test Fears' was a report from the Defense Nuclear Agency that retrospective reconstruction of the troop exercises at Big Smoky gave an estimated mean exposure of 970 millirems--'less than a third the exposure now permitted nuclear workers over three months'. The implication was that this 'could help determine the Government's liability in veterans' claims' and, as the headline suggest, minimize the pay out. The underlying notion here was that 970 millirem was too small a dose to have any serious health

consequences, the same thing some health physicists have been saying for many years.

In the same news story, it is noted that studies of leukemia in the troops at Big Smoky by the Center for Disease Control found 'about double the statistical expectation'. The significance of this result is in no way changed by the dosimetry estimate. If exposure to about one rem produces a doubled risk of leukemia, the inference that would be drawn by any competent professional concerned with protecting the public health and safety (or by any non-professional with common sense) is that the doubling dose for leukemia is probably under the five rem per year currently permitted for nuclear workers by the NRC. Instead of 'Casting Doubt on A-Test Fears' this result suggests that the current NRC levels do not protect nuclear workers and may not protect the public either."

The CDC study is rather strong evidence in its own right and even the Libassi Report (2) admits "an expected incidence of between two and four cases" of leukemia from the radiation as statistical impossibility with a 100 rad or an infinite doubling dose. However, these nuclear radiation studies are what might be called "fragile" statistically when considered <u>separately</u>. In other words, unless a first-rate statistical analysis is used, the hazards may be missed. A poor analysis can easily cover up the positive effects. The reason for this fragility is that, on one hand there are a relatively small number of leukemias and, on the other hand, <u>conservative</u> assumptions in

calculating expectations can easily negate effects of borderline statistical significance. This makes it easy to "discredit" the positive findings. As I noted in my 1979 Senate testimony (3):

"The radiation protection community has used a divide and conquer strategy to deny or discredit these reports, treating each as if it is separate and unrelated and attacking each in turn. The main thrust of the criticisms is that the numbers of leukemias or cancers in the critical series that give positive findings is generally small. The numbers range from 6 in the Portsmouth Shipyard study (with one expected) to 32 in the Utah children(with 13 expected). It is argued that this is too few to be sure of the hazard. It is also claimed that even if there was a hazard, the casualties would be unimportant and not worth worrying about. The attitude of the radiation protection community has been that we should take a few civilian casualties for the sake of nuclear power or nuclear deterrents."

While it is relatively easy to fault the qualitative results of each study and relatively hard to argue that any one study is conclusive, the cumulative evidence cited in these more than 20 references, all of which show excess risks of leukemia or other diseases among persons exposed to doses of ionizing radiation in the one rad range, is not so easy to shake. Even if the chances of spurious positive results in any study were as high as 50-50, the chances that all of the results are spurious would be far less than one in a thousand.

It has been argued that the types of radiation and circumstances of exposure are different in each of the nine different studies so that evidence cannot be combined. However, all of the studies involve the same critical event--the production of a break-point in the DNA of human genetic material. Hence, all of them are directly relevant to the question of whether or not there is an appreciable risk of genetic damage occurring at low doses of radiation. All provide positive evidence of such damage.

5. TESTING THE THEORIES: QUANTITATIVE ANALYSIS

While there are numerous epidemiological studies which provide qualitative evidence of serious hazards at low levels of ionizing radiation, there are fewer that provide quantitative results. The main reason for this is the relatively large number of leukemia cases needed for a quantitative analysis. Leukemia is such a rare disease that even if risks are doubled or tripled there will only be a handful of cases in most studies. Quantitative studies are also much more demanding with respect to the design of the study, the methodologies used in collecting the data, and the amount of detailed and verified information on each person. The two main quantitative studies are those of Mancuso, Stewart, and Kneale on the Hanford workers (11-13), and those of Bross, Ball, Natarajan, Falen, et al on the Tri-State Survey (21-25).

The kind of extensive and detailed data that is needed for quantitative studies is illustrated by Table 1. Table 1 shows the

observed numbers of men in the Tri-State Survey who were 65 years or older tabulated by three factors. One factor was a report of non-lymphatic leukemia or no leukemia. The second factor was a report of heart disease or no heart disease. The third factor was the dosage of medical x-rays estimated in rads from verified reports of exposures. The table also shows expected numbers which are numbers predicted under a Genetic Degradation Hypothesis. Similar tables can be constructed for men 15-44 and 45-64 years of age (25).

INSERT TABLE 1

An inspection of Table 1 indicates some of the strengths of the Tri-State Survey data for quantitative analysis. There are more than 100 leukemia cases in this one table. For purposes of comparison, there are also 68 "controls" without leukemia. These are not the "pick-up" controls that are so often used in epidemiological studies. The controls are persons in a stratified random sample of households in the general population that was carried out concurrently with the leukemia survey. Random samples are ideal (but too expensive for most epidemiological studies) and they allow further methodological refinements such as "double-blind" interviewing. In other words, the person interviewed in the household was told only that this was a health survey while the interviewer was given an address and not told whether it was a leukemic or a random sample household. Other precautions were

taken to avoid interviewer biases such as validation of all reports of x-rays against hospital or other records.

Speaking informally, the basic idea of the mathematical model for the Genetic Degradation Hypothesis that was used here to calculate the expectations is this: The x-ray produces genetic degradation, break-points in the DNA of genetic material of the human cells. This concept leads, in turn, to what can be called a Co-occurrence Hypothesis. In other words if a clone of defective cells develops, the breakpoint is likely to have a spectrum of health effects rather than the single effect of producing leukemia. This is because we are dealing with non-specific break-points and the actual biological end result of putting this misinformation into the genetic code is likely to be a loss or reduction of some enzyme. As Dr. B.N. Ames has noted, "Damage to DNA appears to be the major cause of most cancers and genetic birth defects, and it may contribute to aging and heart disease." (36)

Such a deficiency, in turn, affects the operations of the complicated host defense system in a variety of ways. One result may be impairment of the feedback controls for the white cell system and clinical symptoms of leukemia. Another result may be difficulties with the circulatory system and clinical symptoms of heart disease. Thus one cause, a given break-point, can therefore produce more than one effect. In this data, we are looking at co-occurrence of two effects, heart disease and leukemia.

The results of the use of the Co-occurrence model are shown in Figure 2 which gives the percentage increase in the risk of leukemia by average trunk dose in rads. It should be noted that most of the intervals do not intersect the x-axis even at the lowest dosages studied. In other words, there is evidence of some excess risk of leukemia even at one rad. This shows that the Threshold Hypothesis is flatly contradicted by the facts. The Linear Hypothesis for a 100 rad doubling dose is shown in Figure 2. Note that the line falls below the lower limit of the confidence intervals at the lower doses. The line shows why linear extrapolation from high-dose data seriously underestimates the low-level risk. Therefore the Linear Hypothesis does not fit the facts either. By a process of elimination, the Genetic Degradation Hypothesis and a doubling dose around five rads is the only theory which fits the facts.

INSERT FIGURE 2

6. QUANTITATIVE ESTIMATES OF DOUBLING DOSE

The mathematical model that successfully predicted the Tri-State Survey data in Table 1 and gave the dosage response curve in Figure 2 can be readily extended to provide a relatively precise estimate of the doubling dose for non-lymphatic leukemia in men. In Figure 2, each estimate of the "percent increase in the risk of leukemia" is separately determined by the data for a given age and dosage category.

If an additional parameter is introduced, the doubling dose, then the simple mathematical relationship between this parameter and the original parameters of the model permits the calculation of the expectations for the entire body of data. Providing that there is a coherent dosage-response pattern to the overall data, the numerical value of the doubling dose that minimizes the total Chi-Square will predict (or explain) the whole of the data.

The Minimum Chi-Square procedure that has just been described in words can be reduced to algorithmic form (e.g., to a completely mechanical procedure) that can then be programmed on an electronic computer. Details are given elsewhere (37). When this has been done, the basic data can be typed in at a terminal, a button pushed, and an estimate of the doubling dose will be printed out that is determined solely by the data and is uncontaminated by opinions, expert or otherwise. This has in fact been carried out and the results are shown in Figure 3. On the x-axis of Figure 3 are different values of the doubling dose parameter and on the y-axis the corresponding values of Chi-Square. The estimate of doubling dose and its confidence interval can be read off directly from Figure 3.

INSERT FIGURE 3

Two curves are shown in Figure 3. The solid curve shows the push-button results for all 13 age-dosage categories. The dotted curve

shows the corresponding results obtained by omitting the most divergent category. The horizontal lines indicate the critical level for the confidence intervals (e.g., the minimum Chi-Square plus the 95% tabular value for one degree of freedom). The intersection of the horizontal line with the corresponding curve for Chi-Square is shown by arrows and gives the confidence limits on the estimates. Thus for the full data the minimum occurs for a doubling dose of about five rads and the confidence interval is 3.6 to 7.6 rads. For the dotted curve the estimate is 3.3 rads and the interval from 2.2 to 4.4 rads.

There are now other estimates of doubling dose which serve to einforce the Tri-State Survey results. The Mancuso, Stewart, and Kneale studies of Hanford find excess blood cancers although they do not find excess leukemia, for reasons probably related to the small number of cases. For the blood cancers, the doubling dose reported in Vienna was 3.6 rem (12). The Hanford data also provides estimates of doubling doses for solid tumors such as breast cancer in women and lung cancer in men. These values are higher than for the blood cancer but are generally in the 5 to 10 rem range.

Dr. Thomas Najarian and Dr. Theodore Colton have redone their original study using the badge doses for the individual workers that were finally released by the Portsmouth Naval Shipyard. As reported in congressional testimony (38), they have largely confirmed their original findings by what amounts to an independent study. The excess risks of blood cancers and of leukemia are double or triple the expected values

but the overall cancer risks are about what would be expected. From the average exposures (39), it is possible to make rough estimates of the doubling dose. These turn out to be about 3.5 rem for both blood cancers and leukemias. So it seems fair to say that all of the quantitative estimates of doubling dose that are based on data on persons actually exposed to low-level radiation are in agreement that the doubling dose for leukemia is probably less than the five rem exposure that the Nuclear Regulatory Commission currently permits for nuclear workers each year.

7. IMPLICATIONS FOR PROTECTING THE PUBLIC HEALTH

On the basis of present facts, the best 1980 estimate for the doubling dose for leukemia (or for blood cancers) would seem to be about 3.5 rads or rems. However, in view of the historical trends in the estimates of risks from ionizing radiation, the present estimate should be viewed with some caution. The hazards have consistently been underestimated and the estimates have been drastically revised every generation. Improvements in the data or the biostatistical techniques for analyzing the data might well result in the lowering of the estimate of the doubling dose to 1.0 rad or less. Hence in cost-benefit evaluations for the deployment of new radiological technology the 3.5 rad estimate should be regarded as a minimum cost.

The 1980 scientific evidence on radiation risks indicates that these risks are more than 30 times greater than official estimates

made in 1979. This drastic revision in the risk estimates should in theory require major changes in the way in which radiation technology is currently deployed and used. In practice, however, the standards set by the Nuclear Regulatory Commission and other official agencies or by the quasi-official organizations (e.g. ICRP, NCRP) reflect the state of the art in the technologies rather than health statistics. Unfortunately, this situation is not likely to be changed by the current scientific evidence on health hazards.

Perhaps public and judicial awareness that compliance with the present standards does not adequately protect the health and safety of nuclear workers or of the general public may compel changes in the present promiscuous and sometimes dangerous uses of radiation technologies. Litigation involving low-level radiation exposures is rapidly increasing in the United States. Lawsuits involving compensation, malpractice, or environmental protection may eventually make it unprofitable to misuse radiation technologies even if the official standards continue to permit such abuses.

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37. Bross IDJ, Natarajan N: Cumulative Genetic Damage in Children Exposed to Preconception and Intrauterine Radiation. Investigative Radiology, in press.

38. Colton T, Najarian T: Results of Second PNS Study. Testimony Before the Subcommittee on Health and Scientific Research. June 19, 1979.

39. Colton T: Letter to Bross, July 19, 1979.

Table 1

Observed and Expected Numbers of Men Over 65 Years (Tri-State Survey) by Disease Status (Non-Lymphatic Leukemia, Heart Disease) and Number of Rads

Less than 1 rad		Heart Disease	No Heart Disease
Leukemia	Observed	9	14
	Expected	8.27	17.43
No Leukemia	Observed	5	17
	Expected	4.98	17.92
1-5 rads		Heart Disease	No Heart Disease
Leukemia	Observed	9	19
	Expected	9.35	17.43
No Leukemia	Observed	4	17
	Expected	4.88	16.98
5-10 rads		Heart Disease	No Heart Disease
Leukemia	Observed	7	9
	Expected	6.56	12.38
No Leukemia	Observed	5	10
	Expected	3.47	12.14
10-20 rads		Heart Disease	No Heart Disease
Leukemia	Observed	10	13
	Expected	11.76	11.68
No Leukemia	Observed	4	4
	Expected	2.74	6.62
20 rads or more		Heart Disease	No Heart Disease
Leukemia	Observed	5	6
	Expected	6.40	4.66
No Leukemia	Observed	1	1
	Expected	0.93	1.15

LEGENDS FOR FIGURES

Figure 1: Three Theoretic Hypotheses for the Shape of the Dosage Response Curve for Ionizing Radiation

Figure 2: Confidence Intervals of the Percentage Increase in Excess Leukemia Risk by Average Trunk Dose (Rads) and Age (solid bars, 65+; short dash, 46-64; long dash, under 45). Theoretic Lines for Doubling Doses of 5 and 100 Rads shown for Comparison.

Figure 3: Minimum Chi-Square Estimation Procedure for Doubling Dose for Non-Lymphatic Leukemia in Men for Range 0-9 Rads.

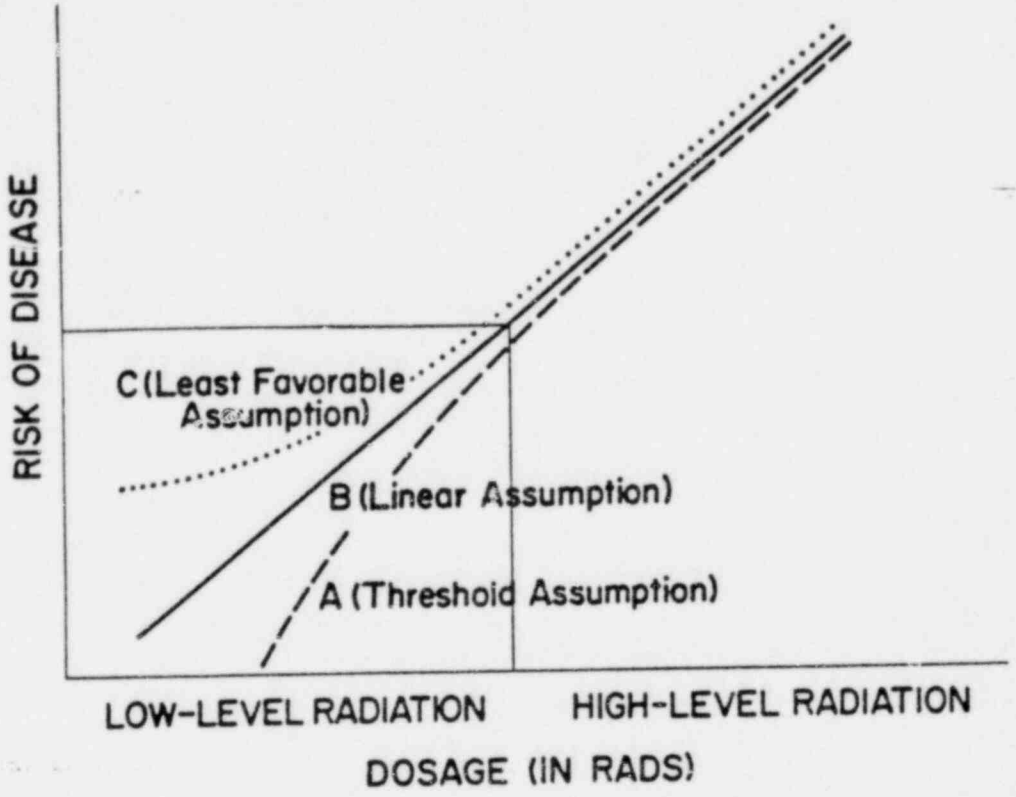
RISK OF DISEASE
C (Least Favorable Assumption)
B (Linear Assumption)
A (Threshoid Assumption)
LOW-LEVEL RADIATION
HIGH-LEVEL RADIATION
DOSAGE (IN RADS)

FIGURE 1

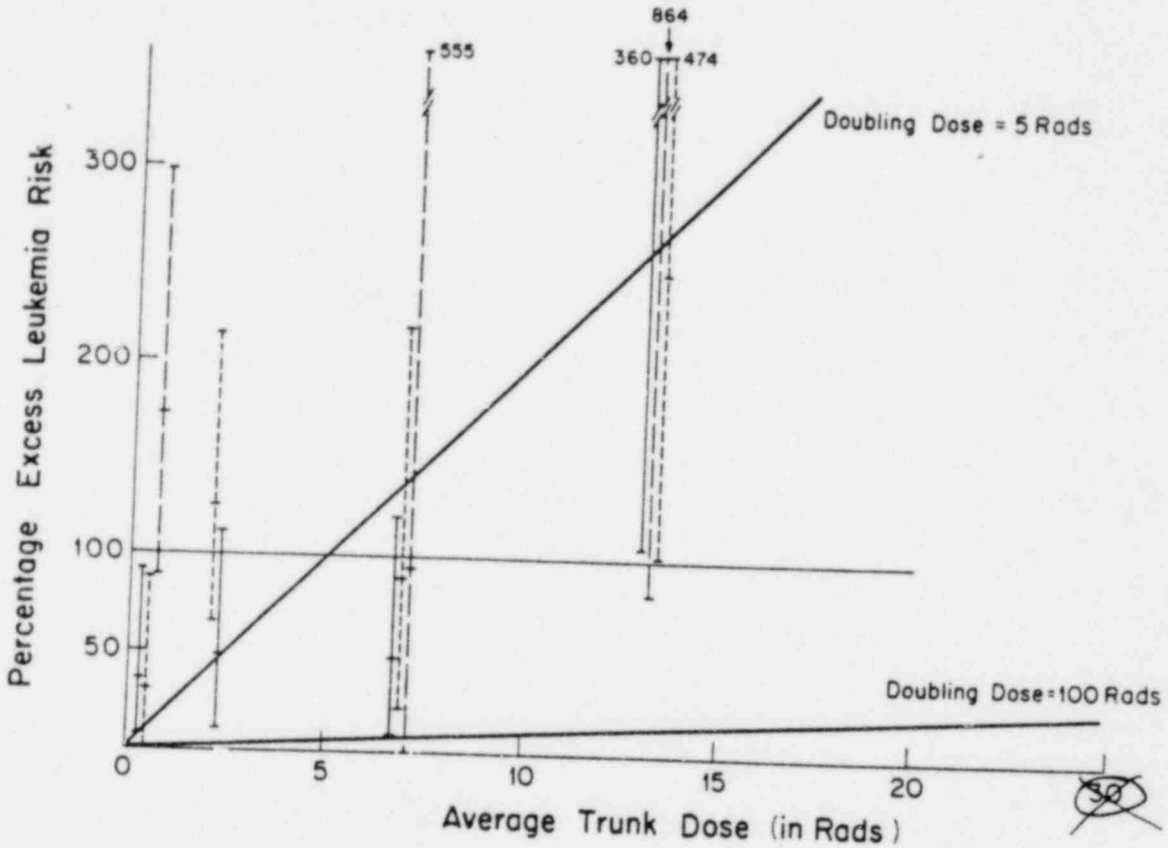
864
555
360
474
Doubling Dose = 5 Rads
Doubling Dose = 100 Rads
Percentage Excess Leukemia Risk
300
200
100
50
0
5
10
15
20
30
Average Trunk Dose (in Rads)

FIGURE 2

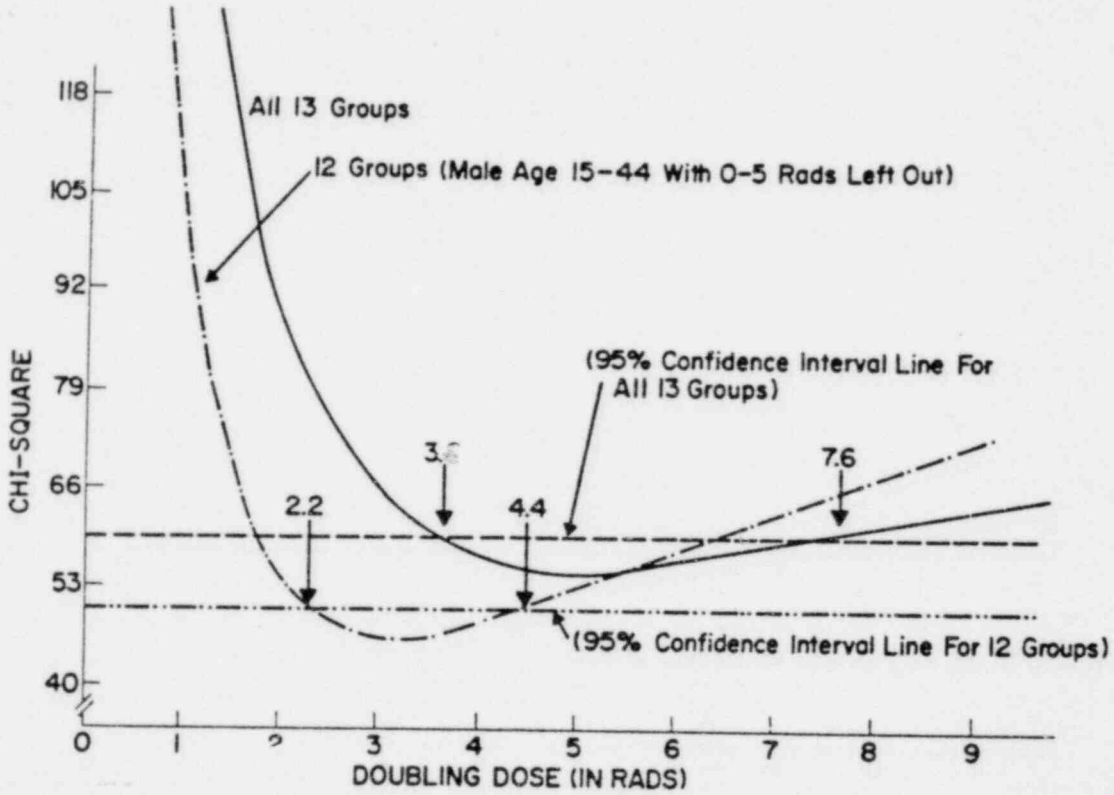
All 13 Groups
12 Groups (Male Age 15–44 With 0–5 Rads Left Out)
(95% Confidence Interval Line For All 13 Groups)
(95% Confidence Interval Line For 12 Groups)
CHI-SQUARE
118
105
92
79
66
53
40
2.2
3.
4.4
7.6
0
1
2
3
4
5
6
7
8
9
DOUBLING DOSE (IN RADS)

FIGURE 3

ATTACHMENT B

WHY THE CANCER RISK-PER-RAD IS MAXIMIZED AT LOW DOSES

While at first it might seem surprising that the risk of cancer and other manifestations of genetic damage will be greater on a per-rad basis for low doses extended over a long period of time than for high doses given in a short period, there is now little scientific question that this is actually the case.

This means that the proposed venting of radioactive gases from the Three Mile Island containment in small amounts over a longer period of time is not any safer for those living in the TMI area than an accidental loss of containment of the same amount of radiation. Spreading out a given total dose minimizes the short-term biological effects but actually maximizes the much more serious long-term effects which involve genetic damage.

There is a simple scientific explanation of why the effects are maximized by repeated low-dose exposures. We now know that the immediate cause of radiation-induced cancers is the production of a break-point or damage to the complex biochemical structure of the DNA of human genetic material. As Dr. B.N. Ames recently reported in Science, 204(4393):587-593, 1979:

"Damage to DNA appears to be the major cause of most cancers and genetic birth defects, and it may contribute to aging and heart disease."

There are two steps in the causation of cancer. First, the production of the break-point by the ionizing radiation. Second, the reproduction of this misinformation by cloning of the damaged cell. The misinformation must be reproduced many millions of times before the effects can be seen clinically. This is why low-level radiation effects are subtle and occur many years after the actual exposure.

At low levels of ionizing radiation it is unlikely that there will be a single break point produced in a given cell and extremely unlikely that there will be more than one. However, at high levels of radiation two or more break-points may occur. This heavier damage is likely to be "wasted" for the production of cancer since it may block the reproduction of the damaged cell. In effect, the cancer is caused and cured at the same time.

Because the break-points produced at high doses are "wasted" so far as the production of cancer is concerned, the risk of cancer on a per-rad basis is less at high doses than at low doses. This is not a theoretical point because in the data from the Rochester epidemic of breast cancer produced by high doses of x-ray given for post-partum mastitis this can be seen from the dosage-response curve (JNCI, 60(4): 727-728, 1978). My invited lecture at Heidelberg cites more than 20 scientific reports that support this finding on efficiency of genetic damage per rad.

Hence, the proposed venting of radioactive gases at TMI will not be safe and will actually result in the maximum risk of genetic damage and cancer for the population downwind from the containment.

Irwin D.J. Bross, Ph.D.
Director of Biostatistics
Roswell Park Memorial Institute
666 Elm Street
Buffalo, N.Y. 14263

ATTACHMENT C

Dear

A few months ago, the American public breathed a sigh of relief--the danger from the Three Mile Accident was over. This now seems to have been premature. An August 14, 1979 news story from AP (copy enclosed) suggests that mismanagement by General Public Utilities may result in far greater hazards from the nuclear waste disposal than from the original accident.

The situation is as follows:

1. The plant was damaged beyond repair but GPU is determined to cover up this fact.

2. The only technology now available for disposal of this plant that will permit adequate protection of the public and the workers is entombment. My letter to Dr. Kemeny on this point is enclosed.

3. Any other technology would require disposal of the radioactive wastes by venting into air, dumping into the river, or transport of large amounts of such material by truck or other means. Any or all of these will expose workers and the public to dosages of radioactivity which will result in far more deaths and disabilities than the original accident.

4. Testimony in New Jersey involving inclusion of entombment costs in the current utility rates illustrates that even if a nuclear power plant is shut down when it is intact and functioning, there is at present no better technology for disposal available than entombment. The Bechtel report involves "paper" technology, methods that have never been previously used or tested or applied on the large-scale operations required here. Clean up of the present shambles is clearly a job which is several orders of magnitude more difficult than clean up of an intact installation. The Bechtel report is the same kind of technical-sounding claptrap that the DOE subcontractors produced on the West Valley clean up. (See enclosed note on lying with Mickey Mouse arithmetic).

5. I suspect that the purpose of this scheme is to stall action indefinitely by exploiting the almost automatic environmentalist reaction. What with environmental impact statements, the litigation could go on for years. It could take 5 years before it is finally admitted that the installation will have to be entombed. In the meantime with the decision in limbo, the Three Mile Island installation would continue as a passive threat to the public health and safety. If there were dumping, it will be an active threat.

6. In view of the continuing and deliberate mismanagement by General Public Utilities, it is essential that the Presidential Commission, or Congress, or both, consider the nuclear waste disposal problem that resulted from the Three Mile Island accident as well as the accident itself. I believe that the federal and state agencies should advise GPU to start to develop plans for entombment as an alternative to the Bechtel report. The decision-making on waste disposal should be taken away from GPU since the utility is completely unqualified for this task.

A critical factor in all this (although it is not so evident) is the new research on the health hazards of low-level ionizing radiation that shows that the NRC permissible levels are in fact dangerous levels. The 5 rem dose to workers permitted each year is probably more than a doubling dose for leukemia and genetic damage and other health problems. Thus, even if the clean-up is in compliance with present standards, the exposures during the clean-up and after its theoretical completion would produce heavy mortality and morbidity among the workers. It would also endanger the general population down-wind or down-stream from the dumping or on the routes used in transport of radioactive materials.

Despite the apparent technological complications the situation here is as simple as 1,2,3. One, there is (according to recent measurements) enough radioactivity loose at this site to kill a lot of people. Two, with entombment the radioactivity stays on site. Three, with any other plan the radioactivity has to be dumped somewhere and any attempt to do this can kill both workers and the public. Clearly, no dumping whatever should be allowed until there is a final decision on disposal since there can be no excuse for unnecessarily jeopardizing human health and safety.

Very sincerely yours,

Irwin D.J. Bross, Ph.D.
Director of Biostatistics

IDJB/mak

Attachments: (1) AP News Story (8/14/79)
(2) Letter to Dr. John Kemeny (07/30/79)
(3) "How to Lie With Mathematics"

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

Irwin D. J. Bross, Jr., Ph.D.
Director of Biostatistics
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14263

JAN 21 REC'D

Dear Dr. Bross:

I am writing in response to your letters of August 16 and October 4, 1979, to Dr. Parsont regarding your concerns about Three Mile Island. Dr. Parsont requested that I respond to your suggestion that entombment is the only technology that will permit adequate protection of the public and the workers. I regret that this answer to your letters has been delayed.

First, with regard to the best method of dealing with Three Mile Island, Unit 2. No decision has been made as to whether to recover and restart the plant or to decommission it, nor has the licensee submitted any proposals to the NRC in this regard.

Secondly, with regard to your suggestion of entombment. It appears to me that there are a number of items which must be accomplished whether the plant is recovered and returned to service or decommissioned. For example, in either case the reactor fuel must be removed from the reactor vessel, put in a safe configuration, stored on site or shipped off site for disposal. There are several reasons why these actions have to be performed. First, heat generation (approximately 250 kilowatts at present) is continuing in the reactor core due to the radioactive decay of fission products in the fuel material. This heat must be removed. Secondly, current NRC regulations do not allow a licensee to leave a reactor core in place without adequate safeguards. That is, the plant could not be entombed without providing for long-term cooling of the reactor core and adequate safeguards; therefore, the fuel in the reactor vessel must be removed.

In order to remove the fuel, the reactor building must be made accessible for long-term occupancy by the on-site personnel. To permit long-term occupancy of the reactor building, the contaminated water and air in this building must be removed and the building must be decontaminated. Commitments to specific clean-up choices have not yet been made. On November 21, 1979, the Commission issued a Statement of Policy and Notice of Intent to Prepare a Programmatic Environmental Impact Statement directing the NRC staff to prepare a programmatic environmental impact statement on the decontamination and disposal of radioactive wastes resulting from the March 28, 1979, accident at Three Mile Island, Unit 2; a copy of this statement is enclosed for your information This programmatic environmental impact statement will focus on the environmental issues and alternatives associated with the performance of these clean-up activities.

I trust this response has addressed your concerns about entombment of the Three Mile Island, Unit 2, facility.

Sincerely,

Richard H. Vollmer, Director
Three Mile Island Support

Enclosure:
Statement of Policy and Notice
of Intent to Prepare a
Programmatic Environmental
Impact Statement dated
November 21, 1979

Irwin D.J. Bross, Ph.D.
Director of Biostatistics
Roswell Park Memorial Institute
666 Elm Street
Buffalo, N.Y. 14263

February 1, 1980

Richard H. Vollmer, Director
Three Mile Island Support
United States
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Vollmer:

Thank you for your letter of January 18, 1980, commenting on the entombment option for the damaged installation at Three Mile Island and enclosing a notice of intent for an environmental impact statement dated 21 November 1979.

I can't believe that you mean what your letter says, so I will try to continue this dialogue. For one thing, what you say seems to contradict the last paragraph of the notice.

As I read you, you say in effect: We have rules and regulations that an installation must be neat and tidy before we would permit entombment. To follow these rules we will have to take the radioactivity now in the containment (where it is not harming anyone) and vent it into the atmosphere or dump it into the river (where it will be a serious hazard to the health and safety of the public). We are going to put workers into the containment (where the radioactivity will still be at dangerously high levels after dumping) to tidy things up so that we can, in the end, decide what to do (and probably end up entombing the whole thing). In other words, we are determined to [illegible] by the book even if this means we end up with the same concrete mausoleum and, in the process, we waste hundreds of millions of dollars and kill or harm the workers and the citizens of at least three states.

I can't believe it.

The Three Mile Island accident did not go "by the book" and NRC and DOE and everyone else have got to consider solutions which are not in the book. I take your point about heat generation. However, this simply means that there must be a self-contained cooling system (e.g. a piping system) in the concrete for this purpose. As a child in the early 1930's at Boulder Dam, I saw this technology (which is really a part of the process of putting in the concrete). True, there may

have to be additional heat-exchangers here to get the concrete to set properly, but apart from the current NRC regulations (which I hope can be modified to save a few hundred lives) there is no reason to remove the fuel rods. Entombment would be ample protection against this immobilized radioactivity.

My basic points are:

(1) As long as the radioactivity is immobilized in concrete inside the containment it won't hurt anyone. On the other hand, if it is dumped it will vitiate the whole point of the expensive containment and will produce an environmental disaster.

(2) The entombment can be done remote--by machines and not men. Hence, the system can be put in place without serious exposure to workers and at a fraction of the cost of "going by the book".

(3) This NRC offhand dismissal of what should have been the first option considered hardly indicates that clean-up would be "done consistently with the public health and safety, and with awareness of the choices ahead". Instead it shows a "regulatory mentality" which is determined to "go by the book" when the book needs to be rewritten.

From DOE I would expect this (see my enclosed Draft Environmental Impact Statement for the West Valley clean-up). I was hoping for more from NRC. I did, at least, get a coherent and organized statement from you (which I probably wouldn't have received from DOE) so there is at least a basis for dialogue. What I would like to hear from you is that NRC would consider and at least get a preliminary feasibility study on the entombment option (even if it means changing some regulations). I believe Congress would help you if new laws are needed for the changes.

Very sincerely yours,

Irwin D.J. Bross, Ph.D.
Director of Biostatistics

IDJB/mak
Enc.