



A-BOMBS, BEARS AND CORRUPTED SCIENCE

Reassessing radiation safety

Edward Calabrese and Mikko Paunio

With a foreword by Lord Lilley

The Global Warming Policy Foundation

GWPF Essay 12

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Contents

Foreword by Lord Lilley	vi
About the authors	viii
Precaution and Assumption and the Deceits of Corrupted Science	1
Edward J. Calabrese	
Introduction	1
Prelude	1
How the LNT assumption came to be	2
BEARS and BEIR	6
The LNT's downfall	9
Conclusions	9
A final thought	11
Black Rain and the Fall of the LNT Hypothesis	13
Mikko Paunio	
Summary	13
The Life Span Study	13
The LNT and overregulation	15
The fall of the LSS	16
Conclusions	17

Foreword

By Lord Lilley

You can have ‘too much of a good thing’. But can you have ‘too little of a bad thing’? Professor Calabrese has shown that a great many things that are damaging in large quantities may – in small doses, below a certain threshold – do no harm or even be beneficial. It seems that very small doses of potentially damaging substances can stimulate the repair and protection mechanisms that our bodies have evolved to help us survive.

But for radiation, it has been conventionally assumed by most regulatory authorities that there is no minimum threshold, let alone any ‘hormesis’ – that is, any beneficial effect – from exposure to levels of radiation a little higher than the natural background level.

Consequently, safety rules are based on the assumption that the slightest exposure to radiation is cumulative over time. This imposes huge costs on any activity involving nuclear radiation, most especially civil nuclear power. This is immensely important for any country seriously intending to remove fossil fuels from its power sector. The intermittent nature of most renewables makes a reliable baseload essential, which generally means nuclear. Yet the costs of nuclear power have been ramped up by attempts to eliminate even the remotest risk to the slightest exposure to radiation.

Of course, it is essential that nuclear power stations are absolutely safe. Happily the nuclear industry worldwide has by far the best record of any source of electricity. Even when the Fukushima reactor was impacted by a tsunami, there were no deaths from radiation, although many were drowned.

In his paper, Professor Calabrese argues that the assumption that there is no lower threshold, and that the effect of low levels of radiation could be calculated by linear extrapolation from high-level impacts, was adopted as an article of faith almost from the time of the Manhattan Project, in defiance of evidence that that was not the case.

Subsequently, the linear no-threshold (LNT) assumption gained apparent empirical endorsement from analysis of the Life Span Study (LSS) of survivors of the Hiroshima and Nagasaki atomic bombs. However, as Dr Paunio shows, that study faces major challenges, not least because it ignores the effects of nuclear fallout and secondary radiation.

However, the regulatory authorities have stuck rigidly to the LNT theory and seem unwilling to take on board evidence that contradicts it.

The importance of this behaviour goes beyond its impact on the costs of nuclear power. It shows that even scientists are human! They are reluctant to change their minds and to abandon familiar beliefs. As Max Planck said: ‘A new scientific truth does not advance by convincing its opponents but...one funeral at a time. This is especially true if the established belief generates ongoing research grants or sustains a cherished ideology. It should be remembered that the initial thrust of environmentalism (when it emerged as an ideology rather than a simple love of creation) was anti-nuclear, not anti-fossil fuels. And, many environmentalists remain as hostile to nuclear energy as to fossil fuels – though decarbonisation will depend on nuclear power.

Yet the scientific method is based on a willingness to abandon even the most long-held theory if it conflicts with the facts. As Richard Feynman said: ‘It doesn’t matter how beautiful your theory is, it doesn’t matter how smart you are. If it doesn’t agree with experiment, it’s wrong.’

The lesson of the sorry saga recounted in these two papers applies not just to the nuclear field but to all areas of science that are politicised or where access to grants is crucial. It is

that we should put our faith in the scientific method, not in scientists – if they withhold data, ignore inconvenient facts and cannot replicate their experiments.

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Precaution and Assumption and the Deceits of Corrupted Science

Edward J. Calabrese

Introduction

The adoption of the so-called 'linear no-threshold assumption' (hereafter LNT), which is used to estimate cancer risks in the low-dose zone, was due to a series of difficult-to-comprehend errors, deceptions and purposeful scientific misconduct by a relatively small group of strategically placed scientific elites in the United States. These individuals included Nobel Prize winners and other high achievers in the field of radiation genetics, who not only thought they were saving humanity from the harmful consequences of all things nuclear, but were equally concerned with ensuring that grant funding to support their research would never end. While their duplicitous actions have been hidden from view for 70 years, their story has unravelled in recent years in a series of painstaking investigations of newly uncovered scientific reports, personal letters, internal memos and other materials.

These factual errors and misrepresentations were enveloped and advanced by the error-making experts to ensure the LNT assumption's adoption across the globe. Regulators then never looked back, never thought they might be wrong or considered that they might have been misled.

The LNT assumption subsequently led to the wholesale overregulation of the nuclear industry, playing as it did on fears that permeated society at all levels. These fears lead to vast protests, delays in plant construction, massive cost increases, cancellation of newly proposed plants, and the rather rapid strangulation of the nuclear industry, despite ever growing societal energy needs and emerging political, regulatory and scientific concerns over increases in atmospheric carbon dioxide. The story I tell will show that the LNT theory lacked a proper scientific foundation, that science needs to be self-correcting and that it is time to reconsider nuclear regulation.

Prelude

A number of years ago I attended a conference at which a researcher showed the results of exposing mice to ionising radiation at levels about 60 times greater than background throughout their lives.¹ Since all public health authorities and regulatory agencies have long claimed that any exposure to radiation is potentially harmful, increasing risks of developing numerous types of cancer and other diseases, I was quite surprised to see that the mice treated with the radiation their entire lives, then the equivalent of elderly people, looked

¹ The particular mice used were predisposed to develop diabetes later in life.

remarkably healthy, showing a wonderfully shining coat of fur. They seemed to be in the prime of their adult life. However, their counterparts in the experiment, the mice that had not received the radiation treatment (i.e. the so-called control group), looked unhealthy, very haggard, skinny, with very little fur, and that patchy and dull. In fact, the control group mice reminded me of my dad during the final months of his life. He died at nearly 95 years of age, after a well-lived life, but he looked terribly worn, just like the control group mice.

The presentation of the mouse study raised many questions. What was it about the radiation treatment that led these mice to appear so healthy? Could it have been a mistake, or an April Fool's joke, and that the treatment and control groups were really reversed? The data were so inconsistent with nearly everything that I had been taught and read over multiple decades that they did not make any sense. Yet I knew the research team and the lead presenter; they had a long record of substantial research achievement. Thus I knew that the data they presented was not a joke but was real and believable. Furthermore, the investigator said that in other experiments they had conducted, different types of mice showed the same dramatic, positive responses compared to the unexposed control groups. So the findings were not only reproducible but generalisable as well.

I got a copy of the paper and pictures of the healthy looking treated mice and the unhealthy looking control group and began to try to figure out what was wrong with this story. The key question for me was how this dose of radiation caused these clearly beneficial effects. I also wondered about the control mice and why they looked so unhealthy. In fact, the control group was living the so-called good life: eating healthy food, drinking good water, and not being exposed to any harmful substances. And yet these animals looked terrible. So, what was harming them and how was the radiation treatment slowing down the aging process in the exposed mice?

This presentation had challenged my long-held beliefs about radiation effects and dose-response in the field of toxicology and human risk assessment. Chemical carcinogens and ionising radiation are believed to present risks down to a single molecule, or ionisation in the case of radiation. In fact, prior to the conference, I had written numerous books on toxicology and risk assessment, and had always been supportive of this idea. But this one little picture of some mice was turning my career beliefs upside down. In fact it strongly suggested that the dose of radiation given to the mice was having a fundamentally *positive* response on key medical and health endpoints.

Yet the idea that any dose of chemical carcinogen or ionising radiation, no matter how low, has the potential to cause cancer and shorten our lives has become a core societal belief. We live as if it were true. The effects have been felt across society, and in many aspects of life. In particular, regulators have imposed progressively lower and even extreme, ultra-low exposure limits to chemicals and ionising radiation, imposing enormous costs on society, creating unjustified fear of radiation in the public, and also suppressing the beneficial uses of radiation.

But now I was beginning to have my doubts. And my desire to get to the truth of this question began in earnest.

How the LNT assumption came to be

So how did the scientific community and society in general come to believe that any dose of chemical carcinogens and ionising radiation, no matter how low, presented a risk to society? It turns out that this belief is now about 90 years old, with the credit or blame be-

ing mostly given to a Nobel Prize recipient from the USA by the name of Hermann Joseph Muller. Professor Muller, who lived from 1890 to 1967, became famous for claiming to be the first to demonstrate that environmental agents such as ionising radiation could induce gene mutations. He did this in his laboratory at the University of Texas at Austin, in the late fall of 1926, using the fruit fly as his research model. Many people had tried to induce mutations in various organisms since about 1910 but no one had succeeded prior to Muller. These researchers were not actually interested in cancer, but were trying to determine the mechanism by which evolution occurred. Muller's apparent success opened the floodgates of research into this area, and led, two decades later, to his being awarded the 1946 Nobel Prize for Medicine.

It did not take Muller very long after his initial famous experiments to expand his perspectives to address the medical and public health implications of X-ray treatment on humans and what this could mean for their health. While he had demonstrated X-ray induced mutation, his experiments involved delivery of very high doses, so he could not make any definitive statement about the nature of the response at the lower radiation doses that people receive in daily life. The next research step was therefore to better define the dose response, and Muller asked two students to do so independently, again using fruit flies. Both found that the gene mutation response was linear or proportional to the dose, although both were still using very high doses of radiation compared to background radiation levels: hundreds of thousands to millions of times greater.

Based on these two studies, Muller concluded that there was a linear dose response. But he also made a big leap: he concluded that this linear response would continue all the way down to very low doses; in fact right down to a single photon, something so small that it could not be measured. He was therefore entering into the domain of extrapolation biology, where one goes far beyond the data and makes predictions. It is somewhat similar to weather forecasters who make long-range predictions, such as how much snow Boston will experience two winters from now.

Muller's assertion was highly speculative, but he became very emphatic about this possibility, claiming to have established that it was a definite biological principle. He called it the 'Proportionality Rule', and it was from this statement, made in 1930, that the modern linear no-threshold (LNT) dose response model was derived.

Even though Muller had proclaimed his new Proportionality Rule, it did not have much success in being accepted within the biomedical community. In fact, it was only taken seriously by those within Muller's own field of radiation genetics. The field of medicine at that time was wedded to the threshold dose response model – the idea that there was some lower limit of dose at which the response dropped to zero – and scientists working in the area offered up considerable resistance to Proportionality Rule. Muller, however, was able to link his dose response idea with the theories of some leading physicists, who provided a potential mechanism by which the Proportionality Rule might operate. This work transformed it into something called the linear single-hit dose response model.

Despite Muller's meteoric rise to fame in the scientific world, his work was challenged by some leading contemporary radiation geneticists, such as Lewis Stadler from the University of Missouri, who claimed that Muller had not induced gene mutations at all. What he really produced, Stadler claimed, were massive gene deletions. He said that these resulted in altered chromosomal inheritance and in clearly visible changes across generations. In other words, the genetic changes that Muller had reported were mostly the result of grossly damaged and restructured chromosomes, and not small gene mutations at all.

As a result of the mounting success of Stadler's criticism, Muller chose a different research approach to prove that linearity was correct. To accomplish this goal he had to reinvent himself, testing which dose-response theory could best explain the occurrence of radiation-induced mutation. It actually was pretty simple in retrospect. There were two possibilities. If the linear no-threshold model applied, then mutation damage would progressively accumulate, and would be explained by the total dose received. The alternative was the threshold model, which implied that there was some level of radiation exposure below which the body could repair the damage. If this were the case, then the mutation damage would depend on the dose *rate*; that is, how much radiation was received per unit time.

Muller directed a study to try to prove his point in the later part of the 1930s. The work was performed in Scotland, again with fruit flies, at the University of Edinburgh, by a graduate student named Ray-Chaudhuri, and the results supported Muller's belief in total dose being the key driver and therefore in low-dose linearity being the likely effect. However, the study had multiple limitations,² some of them serious, preventing any firm general conclusion from being drawn.

Nonetheless, this study set the stage for a major LNT test, during the Manhattan Project when the US developed the atom bomb. This second study aimed to describe the effects of radiation on the genes and chromosomes of mice and fruit flies. However, the mouse study, which used about 400,000 animals, frustratingly failed to yield any usable data. This meant that the estimate of the possible risk of birth defects in future generations of humans had to be based on the fruit-fly data – hardly a representative model.

The study was conducted at the University of Rochester in New York State under the direction of Professor Curt Stern, with the assistance of Muller, then at Amherst College. While the project was far more advanced than the efforts of Ray-Chaudhuri, it too would fall victim to technical problems: inadequate control of temperature, problems with the calibration of the X-ray machine, the improper combining of multiple dosage groups in the low dose zone, amongst others. While these limitations would be obvious to even the non-specialist, Stern and others simply ignored them, since the acute dosing phase of the study had yielded the hoped for linear response. However, the hopes for a linearity confirmation were dashed by Ernest Caspari, one of Stern's students, who found that at a low dose rate the mutations either did not occur or were repaired soon after being induced. Stern's reaction to the new, yet disturbing data was to refuse to accept them, claiming that there must have been an error and it most likely was due to the fact that the control values were simply erratic, being too high.

The big experiment for genetic mutation at the Manhattan Project, therefore, did not come out as hoped for or expected. However, Caspari did not simply accept the conclusion of Stern, but turned to the scientific literature, finding multiple papers that proved that his control group was behaving normally and that Stern's criticism was unsupported. As a result, Stern backed off, but he had not given up.

His next step would become a turning point in risk assessment history. Stern decided that he had to 'save LNT' and so, when he and Caspari wrote their paper, they used the discussion section to tell the readers not to accept or use Caspari's problematic study until it could be determined why it did not support the earlier acute exposure work. The two men

² The Ray-Chaudhuri study had a number of important design and execution limitations, such as limited sample size, quality control issues, changes of models during the experiment, lack of documentation of essential methods, major statistical errors and failure to collect critical information on female fertility, sex ratios, age of males and other parameters.

fully understood that this scientific dispute would not be easily resolved, because the two studies had at least 25 major methodological differences between them; in fact, in the 70 years since then, no-one has ever tried.

Stern sent the manuscript to Muller on 6 November, 1946, with all the data of Caspari, showing support for a threshold dose response, rather than a linear one. Muller soon wrote back indicating that these data created a serious problem for the LNT theory and that the study needed to be repeated, hopefully to show that the original data of Caspari should not be accepted. This actually was the right thing to do, as all studies need to be replicated, often more than once. Yet Muller offered no criticism of the Caspari study. Indeed, two months later, he said that Caspari was a strong researcher and that he could not be critical of him.

Despite the fact that Muller had seen the data of Caspari, recognised that it seriously challenged the LNT theory, but could not find fault with it, he proclaimed in his Nobel Prize lecture the following month that the threshold model was in effect dead and should be replaced with the LNT model. In other words, he chose to hide what he knew, telling the audience that a threshold model was not even a possibility, when in fact he had just told Stern that he needed to spend an entire year to replicate the Caspari report. In effect, Muller deliberately deceived his audience in an effort to manipulate them into accepting his ideological perspective.

As a result of the Muller recommendation, Stern set forth to do the needed replication. However, problems occurred once again. They started at the end of World War II, when his experienced colleagues, Warren Spencer and Ernest Caspari, moved on from the Manhattan Project to academic positions, to be replaced by an inexperienced Masters student, Delta Uphoff.

In her first attempt to replicate part of Caspari's work, Uphoff obtained control group problems herself, but this time they were real. Her control group values were registering at about 40% lower than the historical control values, as well as those of the Caspari control group. Stern wrote in his subsequent report to the US Atomic Energy Commission that the data were uninterpretable, with problems being most likely due to investigator bias. This was a very remarkably candid statement, yet it did not identify who specifically was being blamed for the bias, how such bias arose and whether it affected other experiments.

With the first experiment of Uphoff deemed problematic, the second experiment was then found to have the same problem, with the control group again showing a value about 40% below the historical control. The third attempt finally got the control group response 'right' but the data for the radiation treatments were several fold more extreme than even predicted by the LNT model. At that point the fruit fly study at Rochester had become what appeared to be an abject failure. So what would Stern do next to save the LNT single-hit model?

It is important to understand that the written statements of Stern claiming failed studies and a biased research team were classified by the US government. They could not be read by the scientific community, reporters or the general public. This gave Stern the opportunity to be creative with his scientific deviousness. His strategy for saving the LNT model involved breathing new life into the failed experiments of Uphoff. He did this by now considering all her experiments as valid and having no methodological, procedural or biasing issues. This decision was made without sharing his prior written judgements with scientific community; that is, without explaining how a study that was considered invalid a year before was now acceptable and the reasons for the change of opinion. However, since only very few people would have known of the classified material he had a clear road ahead.

Stern then used his contacts at *Science* journal to arrange to publish the results from the five experiments – Spencer's, Caspari's, and the three by Uphoff. The paper was only a brief note, and did not include the methods and materials, or all the necessary back up data and related information; in the text, he and Uphoff pledged to write a more comprehensive paper and to provide the necessary experimental details, although they never did. It is likely that Stern worked out this arrangement with Bentley Glass, his former student who had just become an editor at *Science*. Since Glass was an expert in the area of radiation genetics it is highly likely that he would have influenced the successful publication of that paper.

In the note, Stern not only resuscitated the invalid research of Uphoff, he also failed to list a long string of weaknesses of the Spencer study while trying to highlight purported limitations in the Caspari study that had in fact long been shown to be nothing of the kind. Thus, the Manhattan Project mutation study, under the direction of Stern and with the consulting guidance of Muller, delivered the LNT concept to the federal government and the scientific community.

Just to make sure that there was no backtracking, Muller would go on to publish several further papers claiming that Uphoff's studies were valid and that Caspari's work could not be trusted because of an aberrantly high control group reading. However, the scientific record has established just the opposite to be true. Although Muller probably never thought that his correspondence with Stern during the Uphoff research period would be discovered, it shows him unequivocally stating that Uphoff's findings were the aberrant and unreliable ones while he strongly agreed with the Caspari data. Muller and Stern were twisted in the lies and deceptions they used in their quest to save the LNT single-hit theory.

BEARS and BEIR

The longstanding debate over LNT and the threshold model would come to a head in the mid-1950s at the height of the Cold War, with atmospheric testing of nuclear weapons and growing radionuclide contamination becoming a political and public health concern. In early 1955, the Rockefeller Foundation approached President Eisenhower with the idea of supporting a National Academy of Sciences (NAS) study into radiation and its many possible societal impacts. The work of the Biological Effects of Atomic Radiation (BEAR I) committee began in the fall of 1955, with completion targeted for June the following year. The foundation would have considerable influence on the work, as the president of the NAS, Detlev Bronk, was also president of the Rockefeller Institute for Medical Sciences.

Perhaps the key decision in the entire process was the creation of a separate Genetics Panel. In earlier national and international advisory committees, genetics had always been part of the purview of the Medical Panel, and while radiation geneticists had been actively represented, any attempts to gain endorsement of the LNT model had always been overruled. However, this time Bronk would ensure a different outcome. Firstly, he selected Warren Weaver, a long-time director of research at the Rockefeller Foundation, to chair the panel. The two men were able to fill the panel with supporters of the LNT theory; Weaver knew them all very well and understood their attitudes to radiation, public health and dose response. More importantly, through his role at Rockefeller, he also controlled grant funding for most of them. The result was that he and Bronk exerted substantial influence over the panel, an entirely unethical situation.

When the Genetics Panel met, there was no debate over the nature of the dose response. The panel was hard-wired into the LNT model. In fact, rather than debating the relative mer-

its of the threshold and LNT models, member Tracy Sonneborn, a colleague of Muller at the University of Indiana, read the equivalent of the radiation geneticist credo into the official transcripts, without interruption or subsequent debate. The radiation geneticist credo was actually pretty clear and direct: mutation damage induced by ionising radiation was irreparable, irreversible, and cumulative, all leading to a linear dose response. For this group of scientists the issue was not only clear, it seemed to be 'settled science'.

Even though the panel was supposed to meet periodically for the next nine months, the key issue – that of the nature of the dose response – was settled without debate or controversy. In fact, this created a problem for Weaver as there was really very little left for the panel to do. He therefore created an 'assignment' for the geneticists. Each of them was to estimate the number of birth defects due to a certain level of gonadal radiation over the next ten generations for the US population, which then numbered about 160 million people. They were given a month to get the assignment in, providing their methodology and damage estimates. All the responses were to be sent to James Crow, a panel member, who would organise the data for distribution to the entire panel. Three of the twelve geneticist members refused to do the assignment, claiming that it was a foolish and impossible task, with simply too much uncertainty; they said that any estimates could not be defended and therefore were not useful and were entirely misleading.

Nine members did turn in assessments to Crow. Unfortunately, these revealed that they had very little idea how to carry out the work and had very little confidence in their estimates. The figures they submitted differed wildly, which got Crow worried: he knew that if these uncertainties were exposed, the scientific community and the general public would not have any confidence in their public health recommendations. He determined that the public and the scientific community should be kept in the dark about the truth of the situation.

On his own, Crow removed the three assessments that added most to the massive group uncertainty: he knocked out estimates based on bacteria and humans, retaining only those based on studies on mice and fruit flies. This was a decision that he was not authorized to take. However, based on the transcripts of the meetings and other communications, the panel members mostly had no objections to what he did. The exception was Professor James Neel of the University of Michigan, who claimed that Crow's actions were scientifically wrong and led to a biased report.

In fact, even after eliminating so many of the responses, there was still too much uncertainty, with the dose response found by the remaining six experts varying 750-fold. So, when the panel wrote their report in the journal *Science*, they claimed that the range of variation was only 100-fold. The data thus show that the authors of this *Science* paper – that is, the entire Genetics Panel – falsified the research record on two major points: removing the inconvenient results and misrepresenting the uncertainty range of the estimates. To ensure that they would not be 'caught', the panel refused to share information on how they estimated risks with the scientific community. In fact, when formally challenged to provide documentation to support their positions on the LNT model and related questions, they refused to do so, a decision that was okayed by President Bronk, who thus made himself complicit in the fraud.

The BEAR I Committee Genetics Panel report made national headlines, with front-page stories appearing in major outlets such as the *New York Times* and *Washington Post*. The Rockefeller Foundation ensured that the report was sent to all public libraries in the US. Arrangements were made for Congressional hearings in order to further push the acceptance of the LNT theory. Other influential groups, such as the National Committee for Radiation

Protection and Measurement³ (NCRPM), were waiting for the Genetics Panel report in order to move their own risk assessment agendas along. Although the Genetics Panel report only covered the effect of radiation on mature spermatozoa, which lack DNA repair capabilities, the NCRPM decided to generalize the recommendations to somatic cells – those that form the rest of the body – which have a range of ways to fix damaged genetic material. In this way the committee extended the LNT concept from birth defects to cancer risk assessment, although any cancer risk predictions based on it would have been very wrong, and inappropriate for public policy. Furthermore, the NCRPM's decision was made in the absence of any supporting animal-model study, making it highly questionable. But the flaws in the NCRPM process were either missed, not appreciated, or ignored in scientific and government regulatory circles, allowing the LNT theory to become accepted as a major plank of cancer risk assessment.

However, unlike the BEAR I Genetics Panel, the NCRPM was not dominated by advocates for the LNT theory. This led to debate, conflicts, and in the end some compromise. The compromise was that when the NCRPM adopted the LNT model, it did so based upon the concept of the Precautionary Principle, with an accompanying statement to indicate that it had not been shown whether the LNT assumption was valid or not. This was far different from the actions of the BEAR I Genetics Panel, which was adamant that its science was correct and that all genetic damage was irreversible, irreparable and cumulative. Nevertheless, the LNT perspective had won the day.

The decision of the NCRPM was a key turning point, and would prepare the way for a second BEAR Committee (BEAR II) to consider cancer risk in 1960. Back in 1956, this task had been handed to the committee's Medical Panel, which had defaulted to the old standby, the threshold dose response model. However, in 1960, cancer risk was considered by both the Medical and the Genetics Panels. Surprisingly, the Medical Panel now changed its judgement, even though the panel members were essentially the same as before. In their reports, both panels used nearly the same wording, both claiming that the uncertainties were simply too great, and estimates of cancer risks at low doses could not be reliably made. This position was actually similar to that of the NCRPM; it just didn't make the NCRPM's subsequent leap to acceptance of the LNT model via the use of the Precautionary Principle.

It is important to note that these LNT evaluative groups made their judgements and recommendations based on newly emerging data from the atomic blasts in Japan, which suggested a linear dose response for leukemia. However, the data was debatable and the questions over its reliability had not been resolved at that time. Furthermore, in late 1958, William Russell and colleagues at Oak Ridge National Laboratories had demonstrated that the radiation geneticist mantra of irreversible, irreparable and cumulative damage was wrong: mutational damage *could* be efficiently repaired, and such damage was best predicted by dose rate rather than total dose, contradicting Muller's long-time view.

Despite limited supportive and even contradictory data, the LNT model and its justification via the Precautionary Principle remained the dominant perspective on radiation cancer risk throughout the 1960s. But then, in 1970, the newly created US Environmental Protection Agency (EPA) asked the NAS to advise them on cancer risk from low doses of ionising radiation. In their 1972 final report, the NAS Committee on the Biological Effects of Ionizing Radiation (BEIR I) recommended the adoption of the LNT model but also dispensed with

³ It should be noted that Jim Crow of the Genetics Panel was also a member of the NCRPM committee, giving him two bites at the LNT apple.

the Precautionary Principle as a justification. In fact, they had reviewed in detail the work of the earlier BEAR I panel (somehow ignoring BEAR II and the NCRPM). Their decision to drop the Precautionary Principle probably came about because the EPA wanted to protect its planned nationwide cancer risk assessment program from accusations of being driven by fearmongering rather than science.

The BEIR I report was considered a great success since it had not only transitioned from dependence upon the fruit fly model of Muller to a mammalian one, but also now shifted the debate away from birth defects caused by radiation and on to cancer. This was necessary since the Japanese epidemiological studies of the effects of radiation from the atomic bombs had been consistently, yet surprisingly, negative on the question of birth defects, despite the broad spectrum of exposures.

By 1975, the EPA had formally acknowledged the acceptance of the LNT recommendation of the BEIR I report, claiming that it was founded on the results of the massive studies on mammalian gene mutation led by William Russell and his wife Liane. Most epidemiological experiments fail to detect effects at low dose, possibly affected by the occurrence of considerable variability in a highly heterogeneous human population; they typically fail to detect risks that are less than twice the background risk. The Russell studies, however, were on a different scale, involving experiments on nearly two million mice, an effort that will likely never be repeated. As a result they have become a gold standard in the field, and they were a key element in the EPA decision to accept the LNT model, not only for radiation-induced cancers but also for chemical-induced ones, since these are driven by genetic mutation too.

The LNT's downfall

LNT was the generally accepted view until very recently. Then, in 1995, Paul B. Selby, a former graduate student of Russell, and a long-time genetics researcher at Oakridge National Laboratories, discovered significant irregularities in the Russell control group database. This led to a major investigation, which confirmed that the Russell control group had major errors. Both the Russells and Selby published their own views on the corrections required in the peer-reviewed scientific literature. But the new cancer incidence figure for the control group suggested by the Russells was indistinguishable from the rate for the group exposed to low doses of radiation, which would imply that there was indeed a threshold effect. Moreover, the rate suggested by Selby was even higher than the rate in the group that had received low radiation doses. This would imply a hormetic effect - in other words that the radiation was somewhat beneficial. Either way, the LNT hypothesis seemed to be falsified.

The scientific differences between Selby and the Russells involved serious attempts to correct the critical scientific errors that led to the LNT model. Unfortunately, their dispute was highly technical and esoteric in nature, and thus has not been widely discussed or considered outside the specialist literature. However, it is clearly of critical importance to the way in which cancer risk is regulated around the world. The present author has therefore attempted to make a wider audience aware of the importance of Selby's discoveries, paving the way to a new assessment of the risks of ionising radiation.

Conclusions

So what does this all mean? This is a story of how the LNT model for cancer risk assessment came to be and how it came to rule the regulatory world. This occurred because of mis-

takes, ideological bias, scientific misconduct by leading scientists – including a Nobel Prize winner – and a failure of the scientific community and regulatory agencies to do their job. This is especially true for agencies like the EPA who base their standards on the LNT model and who have responsibility to the public to do a competent job. Cancer risk assessment around the world is still based on flawed science and deliberate misrepresentations of the scientific record. These flaws waste vast amounts of public moneys, threaten the health of the population and mislead the courts on numerous public health and toxic tort judgments.

The story reveals several important issues, which have the potential to significantly impact global health and economies:

Science is failing to self-correct This paper has revealed that the LNT assumption was based on the false premise that Muller produced gene mutations; this error provided a 'legitimate' foundation for acceptance of the LNT single-hit model. It also showed how ideologically motivated scientists at the highest levels, including in the NAS, worked to ensure the acceptance of the LNT model in the face of substantial contrary data. This objective even led Muller to deceive the audience during his Nobel Prize lecture. Despite the documentation of the corrupt basis of the historical and scientific foundations of the LNT model, regulatory agencies worldwide have not acknowledged that the key foundational basis of their programs for carcinogens, including ionizing radiation, are seriously flawed. Science-based organisations acknowledge errors, correct them, and then make the necessary improvements. But this is not the *modus operandi* of governmental regulatory agencies as far as the LNT model is concerned. Why is this the case? Most questions of decision-making are best understood by considering the interests of the group making such decisions. So, why would regulatory agencies ignore the serious historical and scientific flaws of their principal regulatory cancer risk assessment paradigm, unless it was in their interests to perpetuate a dishonest paradigm? Perhaps exaggeration of risks and misrepresentations of the scientific record provide job security.

Self-interest science and the LNT model It is often said that one should follow the money trail to determine intention. In the environmental domain, much is made of who is funding a study and possibility of conflicts of interest. However, the issue of a study's funding is deeper and more insidious than just the interests of its financial backers. During my work on this paper, I obtained correspondence that revealed that several members of the BEAR I and II Genetics Panels felt that it would be a good idea to exaggerate the risks of ionising radiation, so as to frighten the public, politicians, and media, and to encourage the flow of grant funding. This is a type of dishonesty that is found across the scientific community (and in society in general), but is not reported and is nearly impossible to detect. Academics need continuous large-scale research funding, so it is not hard to imagine that many of their public statements and grant proposals contain such dishonest exaggeration. This can have a negative impact on societal beliefs, education, the proper allocation of resources, and the adoption of public policies and legislation. Thus, while it is legitimate to want to know the identity of funding sources, it is also important to dig deeper and to ferret out what may be an even more significant abuse of the scientific process: exaggerations and misrepresentations made to enhance the possibility of grant funding. Such exaggerations in the quest for public monies should become the object of professional ethics reviews at university and governmental levels. However, this is very much like asking the fox to guard the chickens.

The Precautionary Principle: be careful what you wish for Society has adopted a Precautionary Principle that claims that lower exposure to environmental stresses, including

toxic chemicals and ionising radiation, is always better. This concept has been incorporated into many governmental regulations, imposing considerable costs in the absence of any demonstrable gain. While 'lower is always better' sounds good, the toxicological reality is that the underlying premise of the Precautionary Principle is false. Over the last 30 years there has been a revolution in our understanding of dose response. It is now clear that at low doses essentially all environmental stressors of a physical and chemical nature induce adaptive responses that enhance biological resilience, protecting cells, organs, and organisms. This brings us neatly back to the conference I described at the opening of this paper: the control mice, unhealthy and haggard and near to death, and the radiation-treated group, strikingly healthy, with shiny and full body fur. They would ultimately outlive the controls by about 30%. This elegant yet simple experiment discredits not only the LNT model, but also the misguided Precautionary Principle, both of which find themselves decoupled from scientific understanding. Dose response is at the heart of toxicology, risk assessment, and public health, and it is necessary for the scientific community to finally self-correct and follow the data rather than ideology and, in so doing, better serve society and the needs of public health.

A final thought

On 16 March 1994, the Pulitzer Prize winning author Jon Franklin addressed the annual meeting of the US Society of Toxicology in Dallas, Texas, on the topic of 'Poisons of the Mind'. His concluding statement showed a striking parallel between the societal responsibilities of the media and toxicologists. He wrote:

The Supreme Court has said to my profession that freedom of speech does not give it the right to shout 'fire' in a crowded theater. Now I say to yours that panic is a kind of poison and that untruths, like arsenic, are cumulative. Exaggerations collect into little lies, which pool together with silence and uncorrected hyperbole to, in time, become mythologies that spawn the hysteria that, like the venom of the krait, decouple everything and produce chaos and death.

And so as you conduct your business here, and as you go back to your laboratories at home, I would ask you to remember that the most important resource we have is not the environment, or the well-being of our people. It is rather a civilization that *values* the environment and its citizens. And I would remind you as well that human history admits to greater dangers than you can titrate in your laboratories.

Let me close with a warning from Frederick Nietzsche, the patron philosopher both of the Nazis and, in more modern times, those who oppose science.

'Whoever fights monsters,' he said, 'should see to it that in the process he does not become a monster. And when you look long into the abyss, the abyss also looks into you.'

We want clean air. We want clean water. We want to rid our environment of poisons. But in our quest for material purity we must never forget for an instant that there are poisons, too, of the mind.

Black Rain and the Fall of the LNT Hypothesis

Mikko Paunio

Summary

The adoption of the linear no-threshold (LNT) model for the risk posed by ionising radiation has had significant adverse societal, economic and environmental consequences. As a result, Germany and Japan are to abandon nuclear power and the long-awaited nuclear renaissance has been thwarted. Overregulation has led to delays and skyrocketing costs.

This paper discusses the Japanese Life Span Study (LSS) of Hiroshima and Nagasaki survivors, which is a key scientific finding supporting the LNT model. It has recently been discovered that the papers that emerged from the study failed to consider the effects of nuclear fallout and secondary radiation, and thus the modest increase in cancers observed among the survivors was actually the result of much higher radiation doses than previously thought. This suggests that small radiation doses are much less dangerous than was believed, and indeed the new results seem to confirm other studies that have suggested that small doses are actually somewhat beneficial.

It is the hope of this author that science and sound argument – not ideology – will prevail when radiation regulation is written in the future.

The Life Span Study

The dropping of the Hiroshima and Nagasaki bombs in August 1945 was, unsurprisingly, pivotal in forming ideas about nuclear energy and ionising radiation ('radioactivity'). The horrific images taken at the time created a strong link in the popular consciousness between radioactivity and harm to human beings. This link was then reinforced, first by the peace movement of the 1960s and later by the nascent environmental movement. Greenpeace, it should be remembered, started out as a campaign against underground nuclear bomb tests in Alaska. The green movement quickly moved on from campaigns against nuclear weapons to campaigns against civil nuclear energy, with their efforts gaining significant momentum from three nuclear power plant accidents: Three Mile Island (1979), Chernobyl (1986) and Fukushima (2011).

In fact, the myths and falsehoods reach right back to 1945. Contrary to common belief, ionising radiation did not have a central role in the immediate acute health effects of the atomic bombings,⁴ causing no more than 7% of the acute deaths in Hiroshima and Nagasaki. In fact, the initial blast and the flash of electromagnetic energy killed most of the victims and

⁴ http://www.atomicarchive.com/Docs/MED/med_chp10.shtml.

caused most of the injuries.^{4,5} There is a wry comment in the Federation of US Scientists' webpage describing the basic characteristics of contemporary nuclear weapons:

With larger weapons, above 50 Kt, blast and thermal effects are so much greater in importance that prompt radiation effects can be ignored.⁶

Most if not all nuclear warheads today belong to this category.

However, there was another set of myths around the nuclear bombs that had a much more important effect, and one that is still with us today. It arose out of the work of the Japanese Life Span Study (LSS), an examination of the so-called *hibakusha*: the survivors of the atomic bomb blasts. The LSS tracked the medical histories of the *hibakusha* after recruitment to the study from soon after the end of the war, comparing them to those not in the city at the time of the blasts (known as 'NICs') who were considered to have had little or no exposure. The short-term exposures to gamma radiation of participants were estimated from data collected in Nevada after nuclear weapons tests. With figures for the radiation exposures and mortality in hand, it was then possible to construct a mathematical model to describe the relationship between the two datasets. The model chosen was essentially a straight line – a linear model – although it seemed to overpredict mortality at low exposures. In other words, the model used suggested that even low doses of radiation were dangerous – there was no 'threshold' below which radiation exposures were harmless – but the mortality figures were telling a different story.

This then was the so-called linear no-threshold (LNT) model, which is the subject of the papers in this volume. The poor match to experimental data at low exposures has been the source of considerable criticism over the years. One recent paper called the LNT model a 'failed fiction'.⁷ Nevertheless, the criticisms went unheeded and the LSS has become a key pillar of support for the LNT.

The LNT was important ammunition for the green movement, who worked hard to spread the idea that even if a nuclear bomb blast didn't get you, eventually you would die from the effects of ionising radiation. In 1987, I was hired as a medical and public health researcher by the Finnish Prime Minister's office to assess the public health impact of different primary energy sources and the role of energy supply in meeting our economic development and social needs. While in this post, green activists bombarded me with anti-nuclear literature, full of bizarre claims about the risks of ionising radiation. For example, it was said that the scientific literature showed that the dose-response curve of ionising radiation was supralinear – in other words that low-dose radiation exposure was especially dangerous. Nothing of the sort has ever been shown. Another strange claim, widely disseminated in Germany in the 1980s, was that European forests were dying within 100 km of nuclear power plants due to low-level ionising radiation releases.

One of the gravest examples of this reckless propaganda comes from the long campaign against the UK's Sellafield nuclear reprocessing facility in the 1990s. Greenpeace took out a newspaper advert claiming that 2000 people would die as a result of the site's operations over the following 10 years. The claim was accompanied by an image of a hydrocephalus-affected child said to be a victim of nuclear weapons testing in Kazakhstan. The advertise-

⁵ Harada T. Nuclear flash burns: A review and consideration. *Burns Open* 2 (2018) 1–7.

⁶ Chapter 3. Effects of Nuclear Explosions – Section I – General <https://fas.org/nuke/guide/usa/doctrine/dofm8-9/1ch3.htm#s3>.

⁷ Pennington CW, Siegel JA. The linear no-threshold model of low-dose radiogenic cancer: a failed fiction. *Dose-Response* 2019; 1-10.

ment was banned, but not before the disinformation had spread far and wide. There are many similar examples.

The LNT and overregulation

The LNT hypothesis was propelled to the centre of public policy by the fearmongering campaigns of the greens, and the result was the development of the central principle of nuclear regulation – the idea that nuclear exposures should be kept ‘as low as reasonably achievable’. This has led to extraordinary over-regulation around the world, and to the stifling of the nuclear energy industry in most countries. The following examples give a flavour of some of the impacts:

Indoor radon In 2013 the EU set a legally binding standard for airborne radon levels in all European Union buildings outside the workplace.⁸ Radon is a radioactive gas that seeps out of the ground and is concentrated inside buildings. It has been suggested that radon causes lung cancer at low levels,⁹ but such claims are hard to prove. Even at high concentrations, there is only a small increase in cancer risk, so extrapolations to low concentrations using the LNT model are scientifically controversial. Indeed, most cases of lung cancer in Finland involve radon exposures below levels at which the state would demand action. It is true, however, that radon – at least in higher exposure levels – does increase the risk of developing lung cancer among smokers – there appears to be an additive effect. However, efforts to lower radon levels in homes have made little difference to exposures, so reducing lung cancer risk is best addressed by smoking cessation. The EU standard on radon is therefore likely to be expensive and ineffective.

Medical bureaucracy The 2013 directive also requires that when health insurance companies ask patients to undergo diagnostic procedures that involve radiological exposures, a variety of bureaucratic hoops need to be jumped through to ensure that patients are aware of the ‘risks’. As we have seen, these risks do not appear to exist.

Human exposure limits A variety of activities might expose the public to ionising radiation, for example CT scans or use of radioisotopes in industry, and these all require licensing by national authorities. The EU has said that annual radiation exposures from such activities must not exceed 1 milliseivert (mSv), and has therefore stipulated that individual licensees must ensure a maximum public exposure of 0.1 mSv. To put these figures in perspective, people living in Cornwall, where the rocks are radioactive, receive an average annual dose of 6.9 mSv,¹⁰ or possibly even more.¹¹ It is officially estimated that 100,000 Finns receive annual radiation doses of over 20 mSv from radon, and thousands have annual exposures of the order of hundreds of millisieverts. Yet after the Fukushima tsunami, people were evacuated because they were expected to receive a radiation dose that would exceed 20 mSv over the following year. It is now well documented that the death toll that resulted from the evacuation far exceeded any possible harms from the radiation dose.¹²

⁸ Article 74 in 59/2013/Euratom/.

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/16538937>.

¹⁰ <https://www.gov.uk/government/publications/ionising-radiation-dose-comparisons/ionising-radiation-dose-comparisons>.

¹¹ The new ICRP biokinetic model suggests around 14 mSv.

¹² Sutou S. *Fukushima Nuclear Accident: Global Implications, Long-Term Health Effects and Ecological Consequences*. Nova Science, 2015.

Radiation in the food chain The EU prescribes allowable levels of radioactivity in food. It asks what level of radioactivity in food would cause an annual radiation exposure equal to the 1 mSv human exposure limit, as discussed in the last paragraph, on an assumption that 10% of food consumption was radioactive.¹³ A radiation leak could in theory lead to large amounts of food (or animal feed) being taken out of the food supply and having to be disposed of at great cost. Now we know that the LNT theory is crumbling, it can be seen that there is little risk. The irony is that even if the LNT theory were correct, the risks are very small at low levels.¹⁴

Regulation of NORM Naturally occurring radioactive material (NORM) is now an important issue in many industries, including many related to energy production: NORMs are found in coal ash, mining wastes, and in flowback water from the oil and gas industry. There are strict regulations for transport and disposal of NORMs, as well as strict reporting requirements. If low-level radiation is harmless, then this is unnecessary.

Licences for everything Licensing of any activity involving radioactive materials takes place on an extraordinary scale. In particular, the main licensing procedures in nuclear facilities are very demanding. Sometimes there are multiple regulators to satisfy, and hundreds of different licences to be applied for. It is little wonder that building a new nuclear power station takes so long.

Overengineering In a variety of industries, equipment or components are required to be of nuclear grade and to be tested and certified to a much higher level than normal. They can thus end up a hundred times more expensive than the standard industrial grade equivalents.

It is hard to overstate the cultural, socioeconomic and adverse environmental consequences of the ill-informed fears of low-dose radiation. One important example is the decisions of Germany and Japan to abandon nuclear energy. Even Finland, despite a steady programme of building new nuclear capacity, is feeling the pressure. There has been a profound effect on nuclear programmes around in the world, resulting in delays and skyrocketing costs. As just one example, the Olkiluoto 3 reactor – a large 1650 MW French design – is currently scheduled to start operating some time this summer, over ten years late, and with costs three times the original budget.

The fall of the LSS

In recent years, two devastating blows have been struck at the LNT hypothesis. The first is discussed by Ed Calabrese in the first paper in this volume. The second discovery came from a Japanese researcher named Shizuyo Sutou, who discovered a major flaw in the LSS study. As noted above, the radiation exposures of the *hibakusha* were estimated from experiments conducted in Nevada. However, it is well documented that in Hiroshima and Nagasaki, so-called 'black rain' brought large amounts of airborne radiation – fallout – to ground, thus delivering a secondary radiation exposure, which affected not only those afflicted by the primary radiation exposure – the *hibakusha* – but also those living outside the city who sub-

¹³ https://ec.europa.eu/commission/presscorner/detail/en/MEMO_11_215.

¹⁴ Grant et al. (2017) Solid cancer incidence among the life span study of atomic bomb survivors: 1958–2009. *Radiation Research*; 187(5): 513–537.

sequently visited the epicentre.^{15,16} There was nothing like this in the Nevada desert. This meant that the LSS study had effectively only considered primary radiation exposures and so the real radiation doses received, both by the 'non-exposed' NICs and by the *hibakusha* inside the city, were much higher than previously thought. This finding is therefore a direct challenge to the scientific status quo: the modest increases in solid tumour rates observed amongst the *hibakusha* compared to controls were actually based on relatively large radiation exposures. As Sutou put it:

Taking the residual radiation into account, the exposure doses of *hibakusha* and 'in-the-city-control' people were largely underestimated; thus, the cancer risk for subjects involved in the LSS has, accordingly, been largely overestimated. Thus, the LNT hypothesis has lost its basis. The title of my article is 'Tremendous human, social, and economic losses caused by obstinate application of the failed linear no-threshold model.' In the face of this misconception, I recently felt obliged to encourage the Fukushima people not to fear radiation.¹⁵

There is even evidence that people could benefit from low doses of ionising radiation – a so-called hormesis effect.¹⁷

Conclusions

The dramatic findings of Sutou and a growing body of critical reviews¹⁸ have delivered serious, and possibly terminal, damage to the LNT hypothesis. It now seems likely that low doses of ionising radiation are harmless, and possibly even beneficial. It seems that the public has been on the receiving end of a campaign of disinformation. With electricity prices rising across the western world and concern over climate change showing no sign of abating, it is undoubtedly time to reconsider the role the LNT plays in nuclear regulation and to think anew about what the real risks of nuclear are.

¹⁵ Sutou S. Rediscovery of an old article reporting that the area around the epicenter in Hiroshima was heavily contaminated with residual radiation, indicating that exposure doses of A-bomb survivors were largely underestimated. *J Radiat Res.* 2017; 58(5): 745–754.

¹⁶ Sutou S. Black rain in Hiroshima: a critique to the Life Span Study of A-bomb survivors, basis of the linear no-threshold model. *Genes Environ* 2020; 42: 1.

¹⁷ See discussion in Ed Calabrese's paper in this volume.

¹⁸ See, for example, Shibamoto Y, Nakamura H. Overview of biological, epidemiological, and clinical evidence of radiation hormesis. *International Journal of Molecular Sciences* 2018; 19: 2387. Ulsch BA. A critical evaluation of the NCRP COMMENTARY 27 endorsement of the linear no-threshold model of radiation effects. *Environmental Research* (2018); 167: 472–487. Pennington CW, Siegel JA. The linear no-threshold model of low-dose radiogenic cancer: a failed fiction. *Dose-Response* 2019; 1-10.

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Our main focus is to analyse global warming policies and their economic and other implications. Our aim is to provide the most robust and reliable economic analysis and advice. Above all we seek to inform the media, politicians and the public, in a newsworthy way, on the subject in general and on the misinformation to which they are all too frequently being subjected at the present time.

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1	Nigel Lawson	The Trouble With Climate Change
2	Peter Lee	Ethics and Climate Change Policy
3	Matt Ridley	The Climate Wars and the Damage to Science
4	Richard Lindzen	Global Warming and the Irrelevance of Science
5	Clive James	Mass Death Dies Hard
6	Garth Paltridge	Four Questions on Climate Change
7	Guus Berkhout	Climate Thinking: Broadening the Horizons
8	Robert Lyman	Transition to Reality: The Prospects for Rapid Decarbonisation
9	Ruth Lea	Five Essays on Climate Policy
10	John Constable	The Fatal Attraction of a Post-Covid Green New Deal
11	Michael Kelly	Electrifying the UK and the Want of Engineering
12	Calabrese and Paunio	A-Bombs, Bears and Corrupted Science

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