

# The Mismeasure of Radiation

*Debunking the Flawed Science that Low-dose Radiation May Cause Cancer; In Fact, It May Even be Beneficial*

BY JEFFRY A. SIEGEL AND CHARLES W. PENNINGTON

DOES RADIATION CAUSE CANCER? IT DEPENDS ON THE dose. What dose? There's no question that ionizing radiation at high doses can cause cancer, but there are no data to support this connection at low doses. We are literally bathed every second of every day in such low-dose radiation due to natural background radiation, exposures that vary annually from a few mGy (mGy is milligray, a unit of ionizing radiation dose in the International System of Units). There is an average exposure of 3 mGy in the U.S. to 260 mGy on the rest of the planet depending upon where one lives. For comparison, a computed tomography (CT) medical imaging scan is about 10 mGy. Irrespective of the level of background or other low-dose exposure to a given population, no associated health effects have been documented to date anywhere in the world. Nevertheless, for more than 50 years, the linear no-threshold hypothesis (LNT) has been a tenet of industrial, radiological, and medical scientific thought and practice.<sup>1</sup> This hypothesis is used for cancer risk estimation from exposure to ionizing radiation all the way down to zero dose.

The LNT is based on observed effects at high radiation doses, with unobserved, low-dose effects being extrapolated by modeling linearly downward, meaning that the proven consequence of *high* doses has simply been assumed to apply even near zero dose, *with no threshold below which radiation is harmless*. Hence it predicts some level of cancer at *all* doses.

The problem with this hypothesis is that the body responds differently to radiation at high v. low doses, as proven in many studies: high-dose responses are associated with extensive damage while at low doses the body eliminates the damage through a variety of protective mechanisms, evolved in humans from eons of living in a world bathed in slowly delivered but sometimes high-dose natural radiation. Importantly, low dose radiation-induced

carcinogenesis has never been demonstrated by empirical evidence. Yet, the LNT has resulted in the development, implementation, and application of global regulations, policies and recommendations from government regulators and industry advisory bodies for rigorous control of both actual and potential exposures to low-dose ionizing radiation (LDIR) generated by selected industries and practices for both workers and the general public. Dropping atomic bombs over the Japanese cities of Hiroshima and Nagasaki allowed for the testing of the LNT with respect to carcinogenic mortality of human beings from radiation exposure, including LDIR. Such research was undertaken shortly after the war with the formation of the Atomic Bomb Casualty Commission, soon succeeded by the Radiation Effects Research Foundation (RERF) in Japan (<http://www.rerf.jp>), in cooperation with the United States. The RERF's Life Span Study (LSS) is used to promote the LNT for dose-response data involving acute dosages received by populations proximate to weapon detonation and age/sex-adjusted cancer mortality of these populations. The LSS cohort of A-bomb survivors is the single most important data base—the “gold standard”—for estimating radiation effects in humans.<sup>2</sup>

Based mainly on LSS data, a committee of the National Academy of Sciences in 2006 concluded that: “current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of radiation-induced solid cancers in humans.”<sup>2</sup> The National Academy of Sciences committee defined “low dose” as a dose less than 100 mGy or a dose rate less than 0.1 mGy/min over months or a lifetime, but the Committee did not conclude that the LNT is correct nor rule out the possibility of a threshold, below which radiation is harmless. However, the French Academy

of Sciences Report in 2005 reached very different conclusions.<sup>3</sup> Doubts were raised about the validity of using the LNTH to estimate carcinogenic risks at doses below 100 mGy, recognizing the abundant evidence for radiation adaptive response in terms of protection and lack of evidence for harm below this dose level.

This paper examines the initial LNTH formulation, its LSS database developments and its acceptance as “good science” with respect to the carcinogenicity of LDIR. It then addresses the defense of using the LNTH as merely a simple, conservative, and helpful algorithm in protecting the public. The findings herein show that the early work by the founders and developers of the LNTH’s application to LDIR genetic and carcinogenic effects, by the organizations applying the LNTH to the Hiroshima and Nagasaki datasets on carcinogenic effects, and by the scientific community’s review of that research at the time represent some of the greatest scientific failures of the 20th century.<sup>4-7</sup> The paper subsequently shows application of the LNTH within regulations and standards is not conservative, and its derived policies are not necessarily protective, if current global experience is used as a standard for protection.<sup>8</sup> Further, the LNTH only enables a “risk” assessment and does not consider any LDIR effect that may be beneficial, a documented effect resulting from the body’s adaptive response to putative LDIR damage.<sup>9</sup> The LNTH may thus be seen to be its own antithesis, the linear no-threshold hyperbole, a tool for badly exaggerating LDIR risk and actual effect, thereby advancing radiophobia.

### **In the Beginning...**

First came Muller, Stern and others in the 1920s to 1940s who, based on irradiating fruit flies with X-rays, birthed the concept of the LNTH of radiation mutagenesis.<sup>10-12</sup> This was misguided, at best, because only high doses delivered at extremely high dose rates were used. Despite their own admitted need to observationally validate the extrapolation down to zero dose resulting from the LNTH<sup>5</sup>, it was only assumed that such linear extrapolation was valid. The hypothesis was only validated for doses in the 250-500 mGy range delivered acutely over very short periods. Importantly, Muller and Mott-Smith reported in 1930<sup>4</sup> that natural background radiation produced 1/1000 of the gene mutations predicted, based on linear extrapolations from responses observed at high doses, essentially disproving their own LNTH years before it was even conceived. In addition, the data obtained by

Spencer and Stern in 1948<sup>5</sup> and Uphoff and Stern<sup>7</sup> in 1949 indicated a strong dose rate effect at a total dose of 500 mGy, i.e., as the dose rate was decreased (for the same total dose), the mutation rate decreased as well, indicating strong evidence of the existence of a threshold.<sup>13</sup> These extremely important findings were either discounted or missed by the investigators and scientific community of the day; if they had been appreciated, as they should have been by 1949, it is highly likely that the LNTH would not have survived its birth, as it was a linear threshold, not a linear no-threshold, dose-response relationship that was demonstrated. To be clear, this is not a matter of opinion; rather, the conclusions here are firmly rooted in the researchers’ own cited publications and are, thus, irrefutable from a scientific perspective.

The application of the LNTH to radiation carcinogenesis soon followed, most notably resulting from the work of Edward Lewis using very premature data from the Hiroshima and Nagasaki detonations. Lewis’ analyses, published in *Science* in 1957,<sup>14</sup> led to the highly controversial conclusion that a no-harm threshold was not apparent; i.e., the dose-response at low doses was linear with no threshold, supporting the LNTH. However, the scientific community’s reaction to Lewis’ conclusion supporting the LNTH was mostly negative, and Lewis became embroiled in controversy. Whether a threshold exists for cancer risk assessment remains hotly debated, but it is the accepted dogma used by regulators all around the world, as well as by various scientific advisory bodies, which brings us to RERF’s LSS of the A-bomb survivors.

### **The Rules of Boxing**

The use of models to explain the dose-response relationship of LDIR and cancer mortality should reflect the actual physical processes (rules) occurring in the range of data under consideration, herein called “the box.” If the rules change, so will the resulting pattern of the data, such that some data (e.g., low-dose data on the order of less than 200 mGy) belong in one box, while the higher dose data fall into a different box where different rules apply. The problem is that if one believes all the data fall under one set of rules when they do not, one will wrongly sort the data into a single box. The model constructed based on the best fit of those data will not be accurate at low doses. Researchers often present data using sophisticated statistical methods that inappropriately force all observations into a single large box, like forcing the “foot into the glass

slipper.” However, what happens in the high dose box must stay in the high dose box, and the same is true for the low dose box because the interaction of tissue and radiation, and thus the rules, are different. But when the LNTH is presumed (i.e., one big box fits all), the rules of boxing are violated, assuring linearity using modeling that camouflages or mis-models actual data at low doses, precluding any chance of uncovering a threshold.

The dose-response data from the LSS population during the period 1958-1998 has been reported on the RERF website (<http://www.refr.jp>) and by Preston et al. to be consistent with the LNTH down to zero dose.<sup>15</sup> But if the low dose data are examined in their own box, i.e., if only the dose-response box for the data points ranging from 0 to 200 mGy are plotted, these data do not follow any obvious relationship, let alone a linear one.<sup>9</sup> Linearity at low doses does not exist; rather, it is forced into existence by modeling the high-dose extrapolation based on the LNTH. If only the low-dose data were known and analyzed, it is inescapable that the LNTH is incorrect.<sup>9</sup> Furthermore, a no-harm or benefit-inducing threshold is rendered invisible by the preconceived assumption that none exists—a self-fulfilling prophecy. If no such initial assumption is made and an unconstrained fit is used, the data force the display of a threshold. As has previously been demonstrated, a linear function, whether generated based on the low-dose data box only (thinking “outside the box”) or based on a single box encompassing the entire dose-response curve (thinking “inside the box”), does not describe these low-dose data. Therefore, the universal LNTH-rule does not apply to low-dose data.

A recent update to these LSS data (1950-2003) reported by Ozasa et al.<sup>16</sup> for the RERF indicated dose-responses for cancer mortality at low doses that are more consistent with a linear quadratic model because significant upward curvature was exhibited. Excess relative risk (ERR) for solid cancer mortality was plotted versus radiation dose. There was significant variability in the ERR, with some values being negative (showing a benefit), casting further doubt on the shape of the dose-response at low doses. Further, our analyses of the raw data presented in the 3 lowest dosage categories in Table 9 of the Ozasa et al. paper, indicate 315 solid cancer deaths per 100,000 person years at doses <0.5 mGy, 319 such deaths at doses in the range of 0.5 to 100 mGy, and 348 deaths within the 100 to 200 mGy range. The uncertainty associated

with 315 deaths at the 95% confidence level is  $\pm 35$ , (meaning plus or minus 35 deaths) so the differences of 4 and 33 deaths are insignificant with high confidence, even if “massaged” by a linear ERR model. Ozasa et al.<sup>16</sup> reported the lowest dose range with no significant ERR for all solid cancer mortality was 0 to 180 mGy with an estimated ERR of 0.43 (95% CI: -0.0047, 0.91,  $P=0.052$ ). (Note:  $ERR = (R-B)/B$  where R and B are solid cancer mortality rates for radiated and baseline cohorts; therefore, ERR values <1 signify a finding of no increased solid cancer mortality in any individual who had been irradiated within this low dose range.) With Ozasa et al. admitting no difference in solid cancer mortality demonstrated up to at least 180 mGy in the atomic bomb survivor population, any incremental 10-mGy exposure due to, for example, a CT scan should not be feared, since it cannot be associated with any radiation-caused solid cancer deaths.

The ERRs estimated by Ozasa et al. may even be too high, and a reanalysis of the Ozasa data by Doss in 2013<sup>17</sup> indicated a beneficial (cancer preventive) effect at low doses. Further reanalysis of the LSS cohort of A-bomb survivors using a non-parametric statistical procedure by Sasaki et al.<sup>18</sup> in 2014 has exhibited a threshold at low dose (<0.2 Gv or 200 mGy) manifesting as negative ERRs, again consistent with a radiation-induced benefit.

The observed threshold and negative ERRs are in agreement with experimental evidence of adaptive protection against cancer (e.g., anti-oxidant production, apoptosis, boosting immune system, and repair of DNA double-strand breaks) at low doses.<sup>9</sup> Thus, the traditional and historical mechanistic description of radiation-induced cancer, whereby double strand breaks lead to chromosome aberrations that inevitably lead to cancer, has been demonstrated to be false. A large body of evidence indicates low-dose radiation has the opposite effect of high-dose radiation (or, stated differently, what happens at high doses stays at high doses). The action mechanisms have been shown to be unique for low-dose radiation exposure; processes activated by low doses are related to protective responses, whereas high-dose responses are associated with extensive damage (cell killing, tissue disruption, and inflammatory diseases). Since different rules apply to high and low doses, a linear extrapolation from high-dose data down to zero dose (i.e., the use of one big box) is scientifically unjustified and simply wrong.

Based on revisions to, and reanalyses of, the atomic bomb survivor data since the National

Academy of Sciences report in 2006, these data do not support the LNTH, but rather the linear threshold dose-response relationship with a threshold of about 200 mGy.<sup>9</sup> Below this linear threshold, the data are consistent with either no harm or benefit from low-dose radiation exposure.

### **A Conservative Approach or an Unsafe Practice?**

Given that most LNTH advocates endorse its use in regulations and standards, it should come as no surprise that many politicians, media outlets, consumer-interest and public advocacy organizations widely practice fear-mongering about radiation with the public at large by ignoring the fact that the LNTH is unproven and widely disputed. The media picks this issue regularly using the “if we scare, we care” principle to bolster readership. Indeed, the application of the LNTH for LDIR risk assessment results in misguided public policies that have engendered deep-seated radiophobia, producing significant loss of human life, major psychological injury and huge economic costs to regions and nations.

Siegel and Welch observed that overestimating radiation risks using the LNTH may be worse than underestimating them.<sup>9</sup> For example, the fear produced by publicly advancing acceptance of the LNTH with theoretical and unproven threats to public health resulted in unnecessary loss of life due to traumatic forced evacuations, suicides, and unneeded abortions after the Fukushima and Chernobyl nuclear accidents. Fear of radiation after the Fukushima event has likely been more harmful than the radiation itself, as official figures indicate more than 1600 deaths were a direct result of the forced evacuations; evacuation orders still in effect after 4 years as reported in *The Japan Times* are simply unconscionable.<sup>19</sup> Many of these needless “disaster-policy-driven deaths” were caused by fear of radiation resulting from policies imposed to reduce LNTH-projections of cancer mortality. Approximately 150,000 people in Fukushima prefecture were mandatorily evacuated to avoid 12-25 mGy radiation exposure in the most affected regions and 1-10 mGy to all other residents for the first year.<sup>20</sup> In a recent study published in 2015, these doses were generally larger than the reported actual yearly doses estimated.<sup>21</sup> According to the United Nations Scientific Committee on the Effects of Atomic Radiation in 2013, “Radiation exposure following the nuclear accident at Fukushima-Daiichi did not cause any immediate health effects. It is unlikely to

be able to attribute any health effects in the future among the general public and the vast majority of workers.”<sup>22</sup>

The situation in the three countries surrounding Chernobyl is far worse, with its mental health impact being the largest public health problem resulting from the accident.<sup>23</sup> Most of the public’s suffering results from groundless fear of LDIR, as inculcated through LNTH-based regulations and policies.

Tens of thousands of people surrounding Chernobyl live in a depressed state, convinced radiation will shorten their lives. Seven million people live on welfare, psychologically incapable of being socially productive. Over the 20 years following the accident, Belarus, the Russian Federation, and the Ukraine spent hundreds of billions of dollars on public benefit programs and recovery.<sup>24</sup>

Voluntary abortions and suicide rates increased following the accident due to radiophobia,<sup>24</sup> despite there being no data to support LDIR-induced genetic effects, no demonstrated increase in solid cancers or leukemia from LDIR, and no proof of other non-malignant disorders due to LDIR.<sup>25</sup> And while some analyses indicate that the Chernobyl accident was responsible for increased thyroid cancer in children and adolescents, many valid criticisms remain indicating other mechanisms, e.g., mass screenings, overdiagnosis, and registration of unirradiated persons as victims, not radiation exposure, may be likely causes of increased childhood thyroid cancer claims.<sup>26</sup>

Chernobyl’s first responders and cleanup personnel have also been studied. The Estonian cleanup workers, for example, received an average radiation dose of approximately 100 mGy (a low dose, but certainly higher than the average dose received by other Estonian males). However, even though this dose is equivalent to that received from 10 CT scans, the study report concludes: “after a quarter century of follow-up of the Estonian cohort... there is an increased risk of alcohol-related cancers and of suicide. No definite indication of health effects directly attributable to radiation exposure was found.” Similar reports exist for Chernobyl workers from other areas.

Chernobyl and Fukushima impacts of LNTH-indoctrination of the public are clear evidence that LNTH-derived policy is as unsafe a practice as shouting fire in a crowded theater. Forced evacuations are the rule, causing unthinkable disruptions in people’s lives and significant loss of life due to radiophobia, rather than allowing sheltering-in-place, since this option is thought to cause theoretical and

imaginary LNTH-based cancer deaths in 20-30 years. Experience has shown far more actual deaths resulting from poorly planned and executed evacuations than from LNTH-based projections, evacuations that are unnecessary because the LNTH-based threat is false.

Looking at broader applications of the LNTH, risk is related to probability that an effect will occur, whereas the effect (i.e., harm, no harm, or benefit) is the outcome of concern. International Commission on Radiological Protection (an international organization for guidance on radiation protection) recommendations imply that risks may be inferred for prospective assessment of radiation exposure situations, but such inferences should not be automatically interpreted as meaning that effects will be revealed by retrospective assessment.<sup>27</sup> According to a 2013 Memorandum of this Commission's Task Group 84, following exposure to radiation doses below about 100 mGy, an increase of cancer has not been convincingly or consistently observed in epidemiological or experimental studies and will probably never be observed because of overwhelming statistical and biasing factors.<sup>28</sup> Since LNTH-derived increased cancer risk estimates at low doses cannot be validated by observed effects, the hypothesis should be rejected. Nevertheless, theoretical cancer deaths after LDIR exposure obtained by inappropriate calculations based on the LNTH and misuse of the collective dose concept are often postulated. Yet, any risks—if they did result in any harmful effects—would be so small that they would fall within the noise of spontaneous cancer morbidity and mortality of unexposed people. Thus, while increased radiation-induced cancer risks at low doses are often derived using the LNTH, these risks are purely mathematical fiction based only on an unvalidated hypothesis and its theoretical model. Harmful effects are far less than unlikely, with no harm or a benefit the more likely outcome.

### Conclusions

This paper has focused on the LNTH's lack of substance and science in its application to LDIR and cancer mortality. The published research on the LNTH by its founders shows that the data and their analyses were flawed and that there was neither theoretical nor testing bases to justify its acceptance, even as a risk predictor, let alone an effect predictor, for carcinogenesis from LDIR; in fact, the linear threshold, not the linear no-threshold, dose-response relationship was demonstrated. The "gold standard" data source for dose v. cancer mor-

tality, derived from the RERF LSS studies, shows that the LNTH is invalid at low doses and that there is a threshold, indicating a cancer-preventative effect for LDIR. This helps explain why no epidemiological studies have ever demonstrated a causal relationship between low-dose radiation exposure and carcinogenesis. Paracelsus, a 16th century Renaissance physician, took an anti-LNTH stance long before it was even known or fashionable to do so when he said, "Poison is in everything, and no thing is without poison. The dosage makes it either a poison or a remedy."

Application of the LNTH and its dull-witted usage by media and governments that builds fear of LDIR have harmed many millions of innocent people who were near a nuclear event or who may have refused to undergo a medical radiological imaging examination to diagnose a medical condition. Such application has also endangered whole industries, the economic foundations of complete regions of countries, and even entire countries' economic well-being. Belarus, the Russian Federation, the Ukraine, and, now, Japan are suffering from the radiophobia that has been taught and enforced by the application of the LNTH by governments, regulators, and advisory bodies for far too long.

This paper has shown that the LNTH is truly its antithesis, a very large linear no-threshold hyperbole, that greatly exaggerates not only the risk, but also the effect of LDIR, producing fear of radiation and resulting in almost immeasurable harm to the public. Governments, industries, and advisory bodies need to rid themselves of their historically-baseless and scientifically unfounded lucubration on the LNTH and pursue the linear threshold relationship that is supported by science, in the interest of the public's well-being. Is it not obvious that the Sorcerer's Apprentice is running a global organization concerned mostly with the business of preserving radiophobia, and that something substantial and dispositive for stopping this fear mongering must be done soon? Hasn't the LNTH been a hypothesis long enough, providing no evidence over about 70 years that LDIR increases cancer mortality? It is time for science to arrive at summary judgment that the LNTH is flawed—based on the merits presented herein—so that a purposeful defenestration of the LNTH may proceed with all due haste. This change would allow radiation risk assessment using the demonstrated linear threshold relationship regarding LDIR and carcinogenic mortality, alleviating suffering, and abating a needless public fear. No hypothetical harm, no fallacious fear. **S**

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