COMMENTARY: ETHICAL ISSUES OF CURRENT HEALTH-PROTECTION POLICIES ON LOW-DOSE IONIZING RADIATION

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Running Head: Ethical issues of current policies

ABSTRACT

The linear no-threshold (LNT) model of ionizing-radiation-induced cancer is based on the assumption that every radiation dose increment constitutes increased cancer risk for humans. The risk is hypothesized to increase linearly as the total dose increases. While this model is the basis for radiation safety regulations, its scientific validity has been questioned and debated for many decades. The recent memorandum of the International Commission on Radiological Protection admits that the LNT-model predictions at low doses are "speculative, unproven, undetectable and 'phantom'." Moreover, numerous experimental, ecological, and epidemiological studies show that low doses of sparsely-ionizing or sparsely-ionizing plus highly-ionizing radiation may be beneficial to human health (hormesis/adaptive response). The present LNT-model-based regulations impose excessive costs on the society. For example, the median-cost medical program is 5000 times more cost-efficient in saving lives than controlling radiation emissions. There are also lives lost: e.g., following Fukushima accident, more than 1000 disaster-related yet non-radiogenic premature deaths were officially registered among the population evacuated due to radiation concerns. Additional negative impacts of LNT-model-inspired radiophobia include: refusal of some patients to undergo potentially life-saving medical imaging; discouragement of the study of low-dose radiation therapies; motivation for radiological terrorism and promotion of nuclear proliferation.

Key Words: low-dose radiation, risk, hormesis, adaptive response

With the linear no-threshold (LNT) model of radiation-induced cancers it is assumed that each ionizing radiation dose increment, no matter how small, constitutes an increase in the cancer risk to humans. The risk is assumed to increase linearly as total dose increases, with an adjustment made to the slope of the dose-response curve for the reduced risk at lower dose rates. Typically, the slope is scaled down by a factor of 2 for very low dose rates (e.g. for Fukushima down-winders) in comparison to the slope for high dose rates (e.g. Hiroshima and Nagasaki).

Where mixtures of different radiations are involved (e.g., alpha, beta, and gamma), special *radiation weighting factors* (RWFs) are used to obtain a weighted dose named *equivalent dose*. RWF values are based on relative biological effectiveness (RBE) and vary from 1 (X, beta, gamma) to 20 (alpha). The RBE values come from animal and in vitro studies and vary a lot for different conditions. Where different organs are involved, *tissue weighting factors* are also used, which relate to differing tissue sensitivities; the resulting overall dose assigned to an individual applies to the whole body and is called *effective dose*. Effective dose has the following property: if e.g., only the lung is irradiated and the risk of lung cancer is 0.01, then the effective dose is the hypothetical uniform gamma-ray dose to the total body that results in the same risk (0.01) of cancer, when all cancer types are considered. The partitioning of the risk between cancer types is based on LNT and assigned uncertain tissue weighting factors.

Both equivalent dose and effective dose are expressed in units of sievert (Sv). Small effective doses on average (e.g., 0.1 mSv = 0.0001 Sv) to each member of a large population (e.g., 1 million persons downwind of Fukushima) are added to obtain a large collective dose (e.g., 0.1 millisievert × 1 million persons = 100,000 person-millisieverts), a hypothetical value which is then multiplied by a risk coefficient to predict hypothetical cancer cases or cancer deaths for the population. It is important to recognize that the risk coefficient makes sense and both equivalent dose and effective dose are directly related to cancer risk only when dose-response relationships of interest are of the LNT type. Thus, collective dose is a LNT-hypothesis-related hypothetical value.

The LNT model in a more complex form (e.g., weighted average of absolute and relative risk forms) is presently relied on for cancer risk assessment. The LNT model is also relied on by regulatory agencies, and as such it has become the basis for radiation safety regulations. Moreover, the LNT model is widely accepted by the general public. However, the scientific validity of this model has never been proven and has been seriously questioned and debated for many decades (Taylor 1980; Feinendegen 1991; Jaworowski 1999; Tanooka 2001; Sakai *et al.* 2003; Scott 2008; Tubiana *et al.* 2009; Cuttler 2010; Fornalski and Dobrzyński 2010; Sanders 2010; Feinendegen *et al*. 2013). The absence of scientific consensus has always been officially acknowledged, including by the US Congress Office of Technology Assessment (OTA 1979). The recent memorandum of the ICRP (International Commission on Radiological Protection) Task Group (Gonzalez *et al.* 2013) states that:

> "*While* ***prudent for radiological protection****, the LNT model is not universally accepted as biological truth, and its influence and inappropriate use to attribute health effects to low dose exposure situations is often ignored...*
>
> ***Speculative, unproven, undetectable and 'phantom' numbers*** *are obtained by multiplying the nominal risk coefficients by an estimate of the collective dose received by a huge number of individuals theoretically incurring very tiny doses*

that are hypothesized from radioactive substances released into the environment." (Highlights are by the authors).

Thus, the Task Group of the ICRP, one of the main bodies promoting the LNT model, admits that LNT predictions at low doses (up to 100 mSv) are "*speculative, unproven, undetectable and 'phantom'*," raising the reasonable wonder how such a model can be "*prudent for radiological protection*" and be justifiably used in low-dose radiation risk assessment. The supporters of the LNT model claim that its use is "conservative" and should be continued until the model is proven to be untrue. They claim that in the field of safety every risk factor should be considered hazardous until proven safe, like every firearm should be considered loaded until proven unloaded. The case of radiation protection is quite different, as discussed below.

Numerous studies (experimental, epidemiological, and ecological) have shown that low doses of ionizing radiation can be beneficial to health (Feinendegen *et al.* 2004; Jaworowski 2008; Tubiana *et al.* 2009; Sanders 2010; Thompson 2011). For example, in an epidemiological study of cancer among nuclear industry workers, the rate of cancer mortality (as well as overall mortality) among the workers was substantially lower than in the reference population (Sponsler and Cameron 2005). In an epidemiological study of lung cancer association with residential radon exposure, low doses of radiation were found to prevent the occurrence of some lung cancers (Thompson 2011). Also, the healing properties of radon from spas have been utilized for centuries before people heard the word "radiation" and radon treatment is widely accepted by both the medical community and patients in Europe (Erickson 2007). Radon therapy is also popular in Japan and to a lesser extent in the United States. The lack of popularity in the United States appears to relate at least in part to the claim by the U. S. Environmental Protection Agency that residential radon causes thousands of lung cancer deaths annually among U. S. citizens.

The low-dose radiation benefits mentioned above and numerous others (Mitsunobu *et al.* 2003; Boreham *et al.* 2007; Lacoste-Colin *et al.* 2007; Liu 2007; Cohen 2008; Nakatsukasa *et al.* 2008; Scott 2008, 2011; Scott *et al.* 2008; Sanders 2010, Thompson 2011; Doss 2012; Sanders 2012; Scott and Dobrzyński 2012; Ulsh 2012; Calabrese 2013; Feinendegen *et al.* 2013; Nomura *et al.* 2013) comprise emerging scientific support for the application of radiation hormesis/adaptive response for a variety of health benefits.

The present LNT-based regulations impose excessive costs to the society, effectively leading to loss, rather than saving, of life. For example:

- According to the researchers from the Harvard School of Public Health (Graham 1995), spending $100,000,000 per year on controlling radiation emissions might save 1 life-year per year, if the LNT model were valid, while life-saving medical program median cost is $19,000 per life-year saved. Another study concluded that costs of radiation protection are about 5000 times higher than the cost of protection of workers from all other and much more probable events (Inhaber 2001).
- At Chernobyl and Fukushima, compulsory relocation (ordered by the authorities on the basis of ICRP recommendations which are based on the LNT model predictions) led to social destruction, which caused significant emotional/psychological problems and life-shortening. After Fukushima alone, more than 1000 non-radiogenic disaster-related premature deaths were officially registered among the evacuated population during the first year after the accident (Saji 2013). If not evacuated, these people would

have received low doses of radiation that would have led, according to the LNT model, to shortening of life expectancy by less than one week (Socol *et al.* 2013) – while even this estimation is "speculative, unproven, undetectable and ‘phantom’" according to the above-mentioned ICRP Task Group memorandum.

There are additional aspects of human cost because of the LNT model and the associated radiophobia – an irrational fear of radiation hazards:

- "*Predictions of hypothetical cancer incidence and deaths ... cause some patients and parents to refuse medical imaging procedures, placing them at substantial risk by not receiving the clinical benefits of the prescribed procedures*" (AAPM 2011).
- Present policy significantly dissuades the study of low-dose radiation therapies for beneficial effects in medicine, whereas animal studies have shown potential for treatment of diseases for which presently no treatments are available, e.g., treatment of Alzheimer's disease using low-dose radiation (Wei *et al.* 2012).
- After Chernobyl, there were more than 100,000 unnecessary abortions of pregnancies among females that received negligible radiation doses (or no dose at all) associated with the reactor accident (Ketchum 1987).
- Finally, unrelated to medical treatment but related to ethics, radiophobia contributes to motivating radiological terrorism and promoting nuclear proliferation (Socol *et al.* 2013).

In light of the above we suggest that the scientific community address these questions:

1. Can the LNT model, whose predictions are "speculative, unproven, undetectable and ‘phantom’", be "prudent for radiological protection" and “accurate for low-dose-risk estimation”?
2. Doesn’t the high human cost of LNT-model-based policy necessitate serious reconsideration of this policy?
3. Should the present approval procedure for using low-dose radiation in medical research/treatment be eased in cases of cancer, autoimmune disease, diabetes, bronchial asthma, Parkinson's, Alzheimer's and other presently-incurable diseases associated with major suffering?
4. Should the medical community attend to debunking radiophobia by *explaining the evidence against the LNT model*?
5. Should bio-medical research of low-dose radiation be given a priority in order to resolve the existing controversy about negative/zero/positive carcinogenic effect?

Note: This paper is an adaptation of a letter recently submitted to the Israeli Bioethics Commission by some of the authors (Yehoshua Socol, Ludwik Dobrzyński, Mohan Doss, Ludwig E. Feinendegen, Marek K. Janiak, Charles L. Sanders, Brant Ulsh, Alexander Vaiserman). All authors of this paper are members of **S**cientists for **A**ccurate **R**adiation **I**nformation (**SARI**) whose mission is *to help prevent unnecessary, radiation-phobia-related deaths, morbidity, and injuries associated with nuclear/radiological emergencies through countering phobia-promoting* *misinformation spread by alarmists via the news and other media including journal publications*.

DISCLAIMER: This paper represents the professional opinions of the authors, and does not necessarily represent the views of their affiliated institutions.

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