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TITLE: Linear No-Threshold Model and Standards for Protection Against Radiation

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From: Lu, Alan [mailto:ALu@USChamber.com]
Sent: Thursday, November 19, 2015 4:41 PM
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Subject: [External_Sender] Docket Nos. PRM-20-28, PRM-20-29, and PRM-20-30; NRC-2015-0057

Please see the attached comments from the U.S. Chamber of Commerce on the Petition for Rulemaking, Linear No-Threshold Model and Standards for Protection Against Radiation in Docket Nos. PRM-20-28, PRM-20-29, and PRM-20-30; NRC-2015-0057 (Federal Register Volume 80, Number 120, Tuesday, June 23, 2015). These comments were also filed on Regulations.gov today.

Thank you,

Alan Lu

-

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November 19, 2015

VIA ELECTRONIC FILING AND ELECTRONIC MAIL

The Honorable Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852
ATTN: Rulemakings and Adjudications Staff

**Re: Docket Nos. PRM-20-28, PRM-20-29, and PRM-20-30;
NRC-2015-0057; Linear No-Threshold Model and
Standards for Protection Against Radiation; Federal
Register Vol.80, No.120 (Tuesday, June 23, 2015)**

Dear Ms. Vietti-Cook:

The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and dedicated to promoting, protecting, and defending America's free enterprise system. Many of the Chamber's members are adversely affected by the reliance by federal agencies on the "linear no-threshold" (LNT) model and the extremely conservative effect the model has on estimated risk. Moreover, the LNT model exaggerates the estimated benefits of excessively stringent regulatory standards. Given longstanding concerns about the suitability of the LNT model as a default for regulatory decision-making, the Chamber strongly supports the changes to application of the LNT model sought in the three petitions for rulemaking referenced above.

Background

The Chamber's review of the record concerning the use of the LNT model by federal agencies persuades us that the unquestioning use of the LNT model for low-level exposures to radiation needs to be reevaluated. Recent evidence indicates that while the LNT model is adequate for higher radiation doses, it may not be accurate in the low dose range.¹

The relationship between dose and response can be illustrated by dose-response (D-R) curves. As shown in Fig. 1 below, the threshold D-R curve illustrates that there are doses below which no effects occur. If this dose-response curve were for the common drug **aspirin**, the beneficial and adverse effects at progressively higher doses would follow the pattern of heart-protective, analgesia, ringing ears, temporary deafness, dizziness, hyperactivity, seizures, coma and death.²

It is also well-established that low doses of many chemicals can produce a variety of protective effects (i.e., adaptive responses). As illustrated in Fig. 1, this phenomenon, characterized by J- or U-shaped dose-response curves, is called **hormesis**.³ This is a well-studied phenomenon, in which approximately 40% of chemicals produce generally favorable biological responses to low exposures with higher-level exposures exhibiting toxicity.⁴

Similarly, radiation hormesis is a phenomenon in which low doses of ionizing radiation can be beneficial, stimulating the activation of repair mechanisms and other adaptive responses that protect against adverse effects not activated in the absence of ionizing radiation.⁵

¹ DOE Low Dose Radiation Program; <http://lowdose.energy.gov/>.

² R. Golden, "A Laypersons History of the Linear No-Threshold (LNT) Model and Related Issues" (April 2014) (hereinafter "*LNT History*"), available upon request from the U.S. Chamber of Commerce, Environment, Technology and Regulatory Affairs Division.

³ *Id.*

⁴ *Id.*

⁵ *Id.*

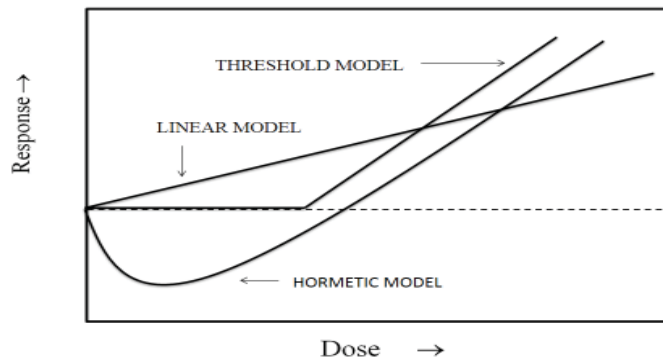


Figure 1. *Threshold, hormetic and linear dose-response curves.*

By far the most conservative dose-response relationship is the linear no threshold (LNT) model.⁶ As illustrated in Fig. 1, this is where the dose-response curve (regardless of whether there are supporting data) is assumed to start at zero dose so, by definition, there is no dose without an adverse effect.⁷ The LNT dose-response model is the major regulatory driver for cancer (and increasingly non-cancer effects as well) used by some federal agencies for risk assessment purposes.⁸ As shown in Fig. 1, the overarching “scientific” tenet of the LNT is that the only exposure (i.e., dose) without any risk is zero.

Radiation and the LNT Model

The origins of the LNT date back to the late 1920s, based primarily on x-ray induced mutations in fruit flies, the standard animal model used at that time.⁹ In 1927, the geneticist Hermann Muller conducted experiments with fruit flies that were exposed to various doses of x-rays with the results showing that the lowest dose tested (equivalent to a dose of over 1,000 chest x-rays delivered in under four minutes) caused mutations in male fruit fly gonads.¹⁰ These experiments set in motion additional work by other scientists, in addition to Muller, who were interested in determining dose-response relationships between x-rays and mutations.¹¹

⁶ *LNT History* at 2.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

Subsequently, numerous similar studies in fruit flies were published, with mixed findings. Some studies showed clear thresholds while others indicated linearity, mostly depending on the number of x-ray doses used. Muller linked the concept of a single “hit” to linearity as well.¹²

A 1948 study by Curt Stern and Ernst Caspari supported a threshold dose-response for ionizing radiation on male fruit fly germ cells.¹³ This latter study was important because it dealt with a lifetime (i.e., chronic) exposure at the lowest dose rates yet evaluated.¹⁴ Significantly, modern studies with *Drosophila* (fruit flies) clearly demonstrate not only thresholds for radiation-induced mutation, but protective effects (i.e., radiation hormesis) at low doses.¹⁵

Department of Energy (DOE) Low Dose Radiation Research Program

In 1998, funding was appropriated to establish the Department of Energy’s Low Dose Radiation Research Program.¹⁶ The goal was to move radiation research into the 21st century with the new tools and methods now available. This is because radiation-induced cancer risk is still predominantly based on the extrapolation of data from atomic bomb survivors.¹⁷ Substantial data from the Low Dose Program encompasses some 730 papers on radiation-induced mutation and cancer show thresholds for these effects *in vivo*.¹⁸ The collective results from DOE (plus other substantial data on radiation & chemicals) demonstrate the LNT does

¹² According to Dr. Golden, “Muller’s first (of three) experiments actually showed evidence of a threshold. The second experiment could have supported linearity, but had only two doses. The third experiment lacked a control group. Support for linearity was demonstrated in experiments by two of Muller’s students after his initial finding and the data were published without his name on the papers.” *LNT History* at footnote 1.

¹³ *LNT History* at footnote 3.

¹⁴ Dr. E. Calabrese obtained several thousand pages of declassified data and other correspondence from the Manhattan Project as well as from the American Philosophical Association and the University of Indiana library. This included substantial correspondence between H. Muller, C. Stern, E. Caspari and other radiation geneticists. *LNT History* at 3.

¹⁵ Ogura et al. (2009). Reduction in Mutation Frequency by Very Low-Dose Gamma Irradiation of *Drosophila melanogaster* Germ Cells. *Rad. Res.* 171(1):1-8; Koana et al. 2010. A U-Shaped Dose-Response Relationship between X Radiation and Sex-Linked Recessive Lethal Mutation in Male Germ Cells of *Drosophila*. *Rad. Res.* 174(1):46-51; Koana et al. 2007. Reduction of Background Mutations by Low-Dose X Irradiation of *Drosophila* Spermatocytes at a Low Dose Rate. *Rad. Res.* 167(2):217-221. *LNT History* at footnote 4.

¹⁶ See DOE Low Dose Radiation Program; <http://lowdose.energy.gov/>.

¹⁷ *LNT History* at 4.

¹⁸ *Id.*

not conform to the newest experimental data developed using modern toxicological tools and is an “*artificial construct*” that needs replacement.¹⁹

In addition, a February 28, 2014) letter to advisory bodies signed by 24 members and associate members of Scientists for Accurate Radiation Information,²⁰ a group familiar with the radiation data, is critical of the LNT as used for radiation risk assessment.²¹ As summarized in this letter, “*Considering the overwhelming amount of data that supports the validity of low dose radiation adaptive protection and the resultant **invalidation of the LNT model**, we urge you to recognize this publicly with a declaration and recommend to governments that they discontinue the use of the LNT model for radiation safety purposes, supplanting it with a threshold model.*”²²

Reality vs. LNT-Driven Cancer Risks

Federal agencies rely on the LNT not only to calculate risks but also to estimate benefits. A striking example of LNT-driven distortion concerns the Environmental Protection Agency’s projected cancer risks from exposure to formaldehyde. Because formaldehyde is a naturally occurring chemical in all living organisms—including humans—small amounts are exhaled in every breath (i.e., low parts per billion; ppb). Nevertheless, based on the LNT model the low ppb formaldehyde exhaled in every breath poses an unacceptable risk of cancer.²³ If true, this would imply that simply having a conversation with someone would be a cancer risk for both parties!

In the late 1970’s EPA estimated, based on the LNT model, that the then-current exposures to DDT, dieldrin, and aflatoxin (all liver carcinogens in rodents) were responsible for 153,000 liver cancers/year in the U.S., despite the fact that there were only about 7,000-8,000 liver cancers/year from **all** sources of exposure.²⁴

¹⁹ See DOE Low Dose Radiation Program; <http://lowdose.energy.gov/>.

²⁰ <http://radiationeffects.org/>.

²¹ *LNT History* at 4-5.

²² *Id.* (emphasis added).

²³ *LNT History* at 9.

²⁴ *Id.*

Economic consequences of the LNT model

Because the LNT model produces inflated estimates of cancer and non-cancer risk, decisionmakers are often misled into selecting unnecessarily costly and burdensome regulatory approaches that yield no greater safety than less-stringent alternatives.²⁵ Government-owned facilities containing small amount of very low-level radioactive materials, for example, may not need to be addressed the same way that a facility with higher-level materials must be. Billions of dollars of taxpayer funds may be wasted to meet LNT-driven standards for managing low-level radioactive materials. The LNT model's continued unquestioning use in low-level radiation situations must be critically assessed and reevaluated, on at least a case by case basis.

Conclusion

The LNT model for cancer risk assessment was understandably adopted due to precautionary considerations, for radiation in 1956. In the intervening years, however, as knowledge of mechanisms and modes of action for cancer causation have advanced, the rationale for continued reliance on the LNT model for low-level radiation has disappeared.

High quality *in vivo* and *in vitro* empirical data supporting threshold and hormetic dose-response relationships exist for radiation.²⁶ By contrast, DOE's Low Dose Radiation Program has suggested that the LNT model "may not be an accurate reflection of radiation risk."²⁷

For all of the foregoing reasons, the Chamber urges the Nuclear Regulatory Commission to **grant** the three petitions for rulemaking referenced above and make the appropriate regulatory changes regarding application of the LNT model to low-level exposures to ionizing radiation.

²⁵ See M. Honeycutt, "The Impact of the Use of the Linear No-Threshold Model in the EPA and Regulatory Arena" (August 1, 2013) .

²⁶ *LNT History* at 9.

²⁷ DOE Low Dose Radiation Program; <http://lowdose.energy.gov/>, A.L. Brooks, "A History of the United States Department of Energy (DOE) Low Dose Radiation Research Program: 1998-2008" (Review Draft) at 126.

The Chamber appreciates your consideration of our comments. If you have any questions, please contact me at (202) 463-5533 or wkovacs@uschamber.com.

Sincerely,

A handwritten signature in black ink, appearing to read "William L. Kovacs". The signature is fluid and cursive, with the first name "William" being the most prominent.

William L. Kovacs