HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

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Roger Coates
IRPA Past-President

Subject: Response to comments on the recent release of the documentary series entitled "Historical Foundations on the Linear No-Threshold Dose Response Model for Cancer Risk Assessment."

Dear Roger,

Thank you for the thoughtful response and comments on the "History of the LNT" videos. I hope you will continue to make time to finish watching all the videos. I agree with your statement about Dr. Calabrese being relaxed, confident and a fluent performer with an amazing ability to recall details. He did this over two days with no knowledge of how the interview would occur. It's truly remarkable how he is able to bring history to life with such accuracy. It's also a sad history, in my opinion, which reflects poorly on the scientific community – mostly within the American scientific community.

I appreciate your willingness to express your reservations on how effective this will be to influence the international RP community. I would like to address your three points that supported your reservations.

Comment 1: *The videos focus on internal US decision-making, with little or no reference to what was happening in the rest of the world, which also moved towards the adoption of LNT as the basis for the system of protection. Whilst this is perhaps understandable from an HPS perspective, it devalues its contribution to the international debate on the future of the system of protection.*

Response: These videos are the beginning of what we hope to be several series of videos on the historical evolution of the LNT model. "To understand a science, it is necessary to know its history" (*Positive Philosophy).* Much of the history starts in the U.S. and Dr. Calabrese is the most published author in the world on this topic, so it seemed appropriate to start with his take based on his nearly 50 years of research experience. That said, there are some international perspectives discussed in Episode 6 with Hermann Muller's work with German physicists that resulted in the birth of the LNT single-hit theory. Episode 11 presents how the British had a similar panel and that they reviewed the Neel study of atomic bomb survivors, whereas the U.S. committee did not. Episode 15 expands on the reports prepared by the U.S. and British committees and summarizes the confrontation between Neel and Muller during an international

World Health Organization conference in Copenhagen, Demark. That exchange led several British scientists to take sides. Many sided with Neel. Perhaps you were not able to review these later episodes but I thought I would note these specific examples where international engagement occurred within the video series.

While there may be more that can be said about the international community's role in selecting the LNT for radiation protection (RP), I can assure you that the HPS intent was never to devalue the contribution to the international debate on the future of the system of protection. On the contrary, I hope this encourages the international community to conduct a similar dive into their history, provide source documents, and produce a transparent product for the world to see as we all engage in the debate on the future of the system of protection. If you are willing to provide documents or be interviewed as part of our continuing efforts, I would be happy to coordinate an interview with yourself or others you believe can present the history and provide original documents to support your or their interpretation of the events that led to the adoption of the LNT model.

Comment 2: *The video series essentially focusses on US science and decision-making up to the mid-70s, mainly ending with the BEIR 1 report in 1972. Whilst the later video episodes discuss events up to around 2015, the focus is still on the relevance of the science underpinning the BEIR 1972 report, and in particular on the reported studies by one group (Russell and colleagues) on one topic (mice studies). The presentations are therefore largely silent on the development of the international scientific perspective for the last 50 years or more. This is a major drawback in terms of the video series making a useful contribution to the debate on the future of the system of protection.*

Response: The historical events that are presented in these videos establish the foundation upon which the LNT model was established for RP purposes, especially in the United States. The United States is the largest member of the International Radiation Protection Association (IRPA) and our history should be a significant contribution to the international discussion regarding the continued use of LNT for RP purposes – especially in the low dose region (e.g., several to 100s x background dose rates). The HPS position statements on radiation risk in these low-dose environments are consistent with the international community. Applying the LNT model to determine environmental clean-up levels based on potential risks is one of the central problems with reliance on the LNT model. Other problems are observed within the medical community and nuclear power industry.

Even the international community agrees that estimating risks at levels at or near background is inappropriate – yet the US Environmental Protection Agency (EPA) does exactly this while the international community does not. Perhaps that may be why IRPA continues to rely on the LNT for RP purposes – because it does not apply it for environmental cleanup purposes.
There are many examples that can illustrate this but I'll only mention one. The Po-210 cleanup levels following the murder of Alexander Litvinenko in London were based on a 1 mSv dose, roughly equivalent to 10 Bq per square centimeter (fixed contamination). This is essentially a dose-based criteria that is not derived from the LNT model. It essentially represents a threshold model. The U.S. EPA cleanup policy, based on the LNT model with an acceptable excess cancer

risk of 1 in a million, results in a cleanup value of 0.000525 Bq per square centimeter (surface preliminary remediation goal for settled dust). There is at least a 19,000 fold difference between the UK and US cleanup numbers and the only reason for it is due to a US policy that relies on the LNT model and uses it in a manner that is inappropriate and recognized as such by the international RP community.

Naturally, these videos primarily focused on the historical events in the US, many of which occurred before the mid-1970s. The 1972 report and the failure to correct the record after learning about the cluster errors discovered by Paul Selby (Episode 21) resulted in the US EPA maintaining the LNT model for RP purposes. Had these corrections been part of the BEIR committee discussion, it is quite possible that a return to the threshold model may have occurred based on scientific data. Since that time, the US EPA acknowledges that the continued use of the LNT model is based on a policy decision and is not based on science. A policy decision by any government agency should be discussed during the debate on the future of the system of protection – for many of the reasons noted in the recent IRPA position paper on reasonableness in the optimization of radiation protection. While we cannot control government policy decisions, we can certainly comment on the scientific robustness of such policies.

Finally, I respectfully disagree with your characterization of these historical documentary videos as a "major drawback" in terms of making a useful contribution to the debate on the future of the system of protection. I believe knowing the history of how we arrived to our current understanding will help us make better decisions moving forward. We cannot and should not dismiss this history simply because it does meet an unknown threshold of criteria for inclusion into the debate.

Comment 3: *It is fully accepted that major policy decisions should not be based on, or dominated by, the scientific output of a single group of scientists. It is recognised that certain biases or omissions, either unconscious or deliberate, have the potential to impact presented views. Hence major policy decisions should always be based wherever possible on multiple scientific inputs. This point is well made in the videos. However, one corollary of this perspective is that the HPS itself is in danger of falling into the same trap, in that the current series is totally reliant on the views of a single scientist who may well also be susceptible to biases and omissions.*

Response: You bring up a good point about relying on the views of a single scientist who may be susceptible to biases and omissions. Dr. Calabrese was selected because he is the most published author in this field. I asked him to present his research while agreeing to be on camera and be willing to answer any challenge by our interviewer, Barbara Hamrick, an HPS Past-President, Certified Health Physicist, and Attorney. He did this interview without knowledge of the questions or how the process would evolve. Months after the interview, I challenged Dr. Calabrese to provide hard documentation for every statement that might be considered controversial to an objective viewer. We also had a team of reviewers provide feedback on every episode to ensure it was as fair and objective as possible. This process was necessary to ensure a transparent pursuit of the truth behind the historical evolution of the LNT model. While this story was told by one person, the history and associated documentation were produced by several

Nobel Laureates and many other scientists, private, and government organizations. Therefore, these videos reveal more than just one person's views, thus effectively eliminating the potential for bias. Further, if others can identify source documents to counter those presented, then we will revise these episodes as appropriate.

We do plan to continue this series with more videos and I welcome your suggestions to include more people who are willing and able to provide source documents supporting their perspectives on the science behind the application of the LNT model. As a scientific organization, we recognized that government policies and regulations may not always be consistent with the latest science for many reasons. However, it is our mission and responsibility to stay focused on the scientific basis for understanding risks from radiation and other exposures. Your suggestion to review NCRP Commentary 27 and the recent UNSCEAR 2020/2021 Report on the Biological Mechanisms for the Inference of Cancer Risks from Low-Dose and Lose Dose-Rate Radiation will certainly be part of our next effort.

I would like to clarify a point regarding your suggestion that the HPS emphasizes the view that an assumption of LNT means that "there is no safe level of radiation" conflates the concept of "safe" with "no risk". This position should be attributed to Dr. Muller and not the HPS. During his Noble Prize speech, he stated "*…They leave, we believe, no escape from the conclusion that there is no threshold dose…*" (Episode 8). This belief was repeated by many others throughout history. That message ultimately was interpreted as there is no safe level of radiation and many governments have implemented policies based on this belief. While I agree with your statement that the RP profession must more clearly communicate what is "safe" vs. what is "no risk", continued reliance on the LNT-based approach only re-enforces the public doubts and fears associated with radiation exposures. Suffice to say, I believe that the RP community must withdraw from an LNT-based approach and begin to educate the public on the scientific basis for doing so. A more informed public will lead to less fear and better decision-making regarding risks. More people will be willing to get necessary medical exposures, environmental cleanups will cost less which leaves billions of dollars to be spent on real public health issues, and the nuclear power industry can build more economically-sound power plants that also reduce carbon emissions.

We do agree on the need to focus on the decision-making process, especially for using common sense. Our perspectives differ though on the timing to focus the debate on shape of the dose response curve and if there is a risk at these very very low doses. The ICRP is reviewing the entire system of radiation protection now – so the timing is perfect. I also believe science should drive our decisions which includes a perspective that there is a real possibility of beneficial effects at these very very low doses. Tens of thousands of peer-review papers support the concept of hormesis in this dose range. Your paper in the JRP is a great summary for a path forward supporting a threshold model approach. I believe it's not possible to incorporate your recommendations while continuing adhere to the LNT-based system of RP.

Finally, these videos were produced, in part, because of IRPA's engagement with the ICRP effort to review the entire system of RP. We support that effort and are in general agreement with just about everything stated in the IRPA Perspective on Reasonableness, except for the continued

reliance on the LNT-approach for RP purposes. I will work with IRPA leadership to seek a broader dialogue on this issue and hope these videos will be shared with our other associate members so they can become more familiar with history. I feel that your statement that IRPA may judge not to use resources to engage more directly in the specific LNT debate would be another way to censure scientific debate. I hope that the contributions from the HPS, which represents the largest member within IRPA, are fairly considered and shared with the full membership and that we can continue to improve the system of RP.

I truly appreciate your opinion and candor. We have the same objective to strengthen and improve the system of RP for the betterment of humans and the environment. I feel that if we can stay focused on the science behind these efforts, we will find ourselves in complete agreement.

Warm Regards
John Cardarelli II,