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RESEARCH SUMMARY

REGULATION UNDER UNCERTAINTY
Use of the Linear No-Threshold Model in Chemical and Radiation Exposure

The catastrophic consequences of events such as the Hiroshima and Nagasaki bombings have made the harmful health effects of exposure to high doses of radiation abundantly clear. But what about exposure to low doses of radiation—for example, radiation from X-rays and CT scans? For decades, government regulators have used a risk assessment model known as the linear no-threshold (LNT) model to inform their rulemaking. This model presumes that low-dose exposure to chemicals and radiation is always harmful. In fact, according to the model, there is no threshold to toxicity—exposure to even a single molecule results in proportional and irreversible harm. This implies that setting regulatory standards to ever lower exposure levels will always appear desirable, especially when cost considerations are ignored.

Relying on updated research and incorporating lessons from economic theory, a new study for the Mercatus Center at George Mason University explains why using the LNT model as the default risk assessment model is inadequate at best and harmful to public health at worst. Regulatory agencies should consider alternative risk assessment models when investigating the risks and benefits of low-level exposure to chemicals and radiation.

To read the study in its entirety and learn more about its authors, Dima Yazji Shamoun, Edward Calabrese, Richard A. Williams, and James Broughel, see "Regulation under Uncertainty: Use of the Linear No-Threshold Model in Chemical and Radiation Exposure."

BACKGROUND

The National Academy of Sciences endorsed the use of the LNT model for radiation 60 years ago. In the decades that followed, the model came to be adopted as the default risk assessment model by regulatory agencies in the United States and throughout the world. Although LNT was initially applied to radiation, it came to be used for hundreds of chemicals and pollutants as well. Today,

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the LNT model underlies much of the healthcare and environmental regulation that exists in the United States as agencies drive exposure to lower and lower levels.

METHODOLOGY

Several decades of risk research provide a basis for evaluating the LNT model's validity. Evidence comes from the areas of DNA repair, preconditioning, and adaptive responses in biology:

- *LNT validation.* It takes thousands of subjects to identify small responses and infrequent events that result from low-dose exposure to stressors. Therefore, the LNT model typically relies on studies in which a population was exposed to high doses of a toxic substance.
- *Hormesis.* Another model, known as hormesis, has shown that while high doses of a substance such as radiation or a carcinogen may be harmful, low doses of the same substance can actually be beneficial, even decreasing the risk that a subject will develop cancer.
- *DNA repair, preconditioning, and adaptive responses in biology*. When the LNT model was adopted for radiation, many scientists believed that a single change to DNA could cause cancer and irreversible damage. We now know that DNA mutation only happens when a large number of molecules are affected. Furthermore, several types of cells can repair mutated DNA. Organisms have even been found to adapt to low doses of environmental "stressors" like pollutants and chemicals. For instance, low doses of X-rays have been shown to initiate an anti-inflammatory response and treat pneumonia, and low-dose radiation has been found to induce a protective effect against kidney damage in diabetic patients.

KEY FINDINGS

- *The LNT model should not be the default model used for characterizing public health risks.* Following the recommendations of the National Research Council, regulators should select the model that is best supported by the scientific evidence given the type of risk evaluated. In cases where the evidence is inconclusive, multiple models, including a threshold or a hormetic model, should be harmonized through a model uncertainty framework and incorporated into decision-making.
- *The LNT model causes regulators to continually overestimate risk (although by varying degrees), which upsets the careful balancing required when risk managers consider countervailing risks.* Though the LNT model is supposed to be a "better safe than sorry" approach, policy decisions based on overestimating one risk could lead to worse public health outcomes owing to risk-risk and health-health tradeoffs. Overestimation of risk could also encourage regulators to set tolerance levels below any optimal hormetic level of exposure with respect to public health.

CONCLUSION

Advances in the science of risk, along with insights from tradeoff analysis in economics, demonstrate that the linear no-threshold model should be reevaluated as the default model for cancer risk assessment. Rather than intentional overestimation of risk—which may lead to unintended consequences and worse public health outcomes—the weight of the scientific evidence should be the tiebreaker when selecting models to inform policy. When science cannot definitively adjudicate between models, formal model uncertainty analysis becomes indispensable to adequate risk-based regulatory decision-making.