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Scale of Health: Indices of Safety and Efficacy in the Evolving Environment of Nanoparticle Toxicology

Abstract \*

The interdependent relationship between pharmacology and toxicology is fundamental to the concepts of efficacy and safety of both nano-enabled drugs and nanoparticle systems. The traditional concept of establishing efficacious and tolerated doses to define a 'therapeutic window' appears simplistic in the context of an exponentially increasing database on molecular mechanisms and cell biology that inform our understanding of homeostasis. Recent advances in nanomedicine illustrate the convergence of efficacy and safety considerations that are central to establishing a clear pathway for regulatory review. The following overview considers biological responses to the administration of nanoparticles and the scale of balanced (i.e. within a range that might be considered 'normal') to unbalanced (i.e. abnormal responses associated with health and disease). Considering complex phenomena that impact health or disease as continuous rather than discrete processes may be the first area in which society may benefit from large biological data sets. Integration of knowledge obtained from specific pathways and their correlation with irreversible phenomena will aid in the understanding of future interventions - either therapeutic or preventative.

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