Through past decades, materials engineered into nanotechnology have moved from an exotic research pursuit to inclusion in hundreds of mainstream consumer products. Engineered nanomaterials markets exceed billions of dollars annually with rapid expansion. Specialized nanoparticle chemistries (e.g., metals, ceramics, and carbon allotropes) are produced in metric tons annually for commercial ventures. Two basic types of human nanomaterials exposures are generally considered: deliberate (i.e., medical or therapeutic administrations), and inadvertent or non-deliberate (i.e., environmental, occupational, consumer, food-derived). Many medical innovations under assessment now claim benefits from nanotechnology, most using nanoparticles as functional building blocks. Drug delivery systems by their very nature are prime for such use: several polymer nanophase formulations are approved for human use, and dozens more nano-therapeutics are in clinical trials. Medical imaging and diagnostic systems using nanotechnology are also abundant, some marketed, most in testing. Nonetheless, less sophisticated consumer nano-based products dominate current nanotechnology applications. With entry of engineered nanomaterials and products into nearly every aspect of life come increasing calls for prudent assessment of new safety and exposure risks. Human exposure to environmental non-engineered, natural sources of nanomaterials is by far the most significant. By contrast, deliberate exposure to human-made nanosystems is a relatively recent phenomenon, yet substantial enough to warrant clear safety or hazard assessments. Every possible result is now published for a given nanomaterial in biological tests: from "overt toxicity" to "no observable toxicity". Hence, a classic "cup is either half-full or half-empty" analogy with regard to nanotechnology's promise exists. Significantly, exaggerated commercial benefit forecasts for nanotechnologies are offset by equally extreme, adverse 'doomsday' human health impact scenarios. Reality exists somewhere in between. Safety, efficacy and toxicity of nanomaterials in both deliberate and inadvertent human exposures has yet to be determined. Dosimetry, metrics, and analytical detection are difficult for most materials at the nanoscale in complex biological systems.

The compelling challenge is to develop reliable predictive biological and biomedical assays that utilize simple, inexpensive in vitro formats to understand how nanomaterials move through the ecosystem, the food chain, and the human body. Currently, assays are not sensitive enough to detect nanomaterials at suitable levels, or discern effects of their size, shape, chemistry, environmental history, or aggregation state on any biological effect. Importantly, in vivo animal models are fraught with their own issues in terms of faithful duplication of many human conditions, translations of exposure or dosing, and responses to nanomaterials in various forms and routes of exposures. Therefore the literature is very confusing in its current state, without a clear consensus. The important correlation between in vitro assay and in vivo outcomes, including predictive modeling for human responses (both good and bad) is currently missing.

General References: