

Contrasting nanomedicine claims versus human clinical performance: why such disconnects?

David W. Grainger, Ph.D.

Departments of Biomedical Engineering, and of Pharmaceutics and Pharmaceutical Chemistry
University of Utah, Salt Lake City, UT 84112 USA
email: david.grainger@utah.edu

Thousands of publications to date claim evidence for nanomedicine anti-tumor drug delivery efficacy in cell and animal models of cancer. A few of these materials, particles or therapies are approved for human use. Sufficient global human clinical records are now published that allow meta-analyses of human effectiveness for limited nanomedicines. Few nanomedicines to date exhibit enhanced clinical anti-cancer effectiveness compared to free drug (clinical standard of care). Therefore, nanomedicines have yet to deliver much of their anticipated therapeutic value to patients, despite much hype and their increased costs. I will examine some case studies for nanomedicines now in clinical use and even commercialized. Scientific research credibility, lack of in vitro-in vivo correlations, and exaggeration of preclinical outcomes for nanomedicines are increasingly questioned by all stakeholders: political representatives, industrial and academic scientific peers, physicians patients, citizens and taxpayers. Erosion of this collective research support base must be stopped for research programs in advanced therapeutics and biomaterials to continue. Pressures in academic publishing as a common global academic performance indicator may be one important factor driving this inequality. Nevertheless, evidence supporting improved cancer treatments through applications of nanotechnology are largely unfounded by human experiences to date. Due to the costs to society and to industry for validating experimental nanomedicine designs that fail to produce human therapeutic progress, we must redouble efforts to (1) improve in vitro-in vivo validations, (2) examine differing biodistributions of nanomaterials in animal models versus humans, (3) better match drugs and their delivery systems to address disease sites, and (4) reduce the exaggeration in reporting preclinical model results that fail to translate to human use.