



The Age of Nano-Pharmaceutics: Promise or Catastrophe

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Editorial

The world is rapidly changing. If we look back 10 or 20 years ago, we can see the pace at which technology and science has influencing our lives, culture, and reality. The images that we understood as children now hold no meaning to the generation that is entering universities today. Just hand a teenager a cassette tape and they are clueless as to what it is. The medical field is not exempt to these influences. Medical devices and tools that were once commonplace in research labs or clinical settings have become forgotten relics. I fear that just as the memory of tools and devices have failed to be transferred to this current generation, the knowledge, wisdom and understanding of scientific principles and the lessons learned will soon be forgotten in pursuit of the next scientific discovery.

Nanotechnology has become a hot topic within many research fields. The potential applications of nanotechnology are infinite and hold great promise if the industry lives up to its hype. However, there is a very disturbing trend within this burgeoning field that must be addressed as we continue forward in developing nanotechnological applications. A meeting held in Triangle Park North Carolina in the fall of 2009 is a great introduction to this trend. Present at this meeting were consumer advocates, government regulators, and industrial scientists. They had assembled to examine the potential safety of nano-scale titanium dioxide. Dr. Gary Ginsburg, a toxicologist from the Yale School of Public Health and the University Of Connecticut School Of Community Medicine, stated. "The horse has already left the barn, it's already out there. In this case, the environment is the Guinea pig. All we can do at this point is really try to do a good job of seeing what is getting into the human ecology" [1].

His viewpoint provides us with an understanding that the field of nano safety is lagging far behind nano technological developments and its associated science. This inversion of understanding concerning nano safety is of great concern in the application of nano pharmaceuticals. As engineered nanoparticles, nano-composites, and other nano-applications continue to move forward at a fast-pace, it is likely that the pace of development will surpass our understanding of nano safety, which could spell a potential catastrophe. Simple questions regarding long-term nano material exposure limits and toxicological effects have yet to be fully elucidated.

As far back as the 1950's, nanomaterials have been in use. In the 1990's nanomaterials became commonly used in household products [1]. Yet today, with almost 30 years of nanomaterial use we have very little understanding of the true biological, environmental, or global effects of nanomaterials. In America and Europe, agencies have already sounded a warning bell to implement strategies to better evaluate nano material safety. However, even with this warning, the development of approved models, standardized screening protocols, and classification standards for the evaluation of nano material safety is decades behind the current industrialization and commercial utilization of nano material. As we move forward in evaluating the toxicity and safety of nanomaterials the requirement for a detailed characterization of all the physico-chemical properties is vitally important [2].

Within the field of nanomaterial science is the newly developed field of nanopharmaceutics. Today we can truly say the advent of the age of nanopharmaceuticals is upon us. A simple Google search of the term will return over 46,000 results. There are symposiums regarding nanopharmaceuticals and journals devoted to this topic. However, are we any closer to understanding the safety of nanopharmaceuticals than we are the safety of the nanomaterials within commercialized products?

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The very nature of nanomaterials gives rise to the greatness of their potential. The properties of the bulk compound are no longer the properties of the nano compound with the same composition. What was deemed safe as a bulk compound may be toxic as a nano material. Nanomaterials of the same composition but different size and shape hold different physiochemical properties. These altered properties give nanomaterials characteristics that hold amazing potential and a broad range of applications.

We are on the verge of a new frontier, one of nano proportions, and the tools we once used are limited in their ability to evaluate this nano-frontier. Nonetheless, the scientific principles utilized for centuries, founded on solid logical reasoning, are vitally important to tapping into the vast potential of the world of nano pharmaceuticals. Our ability to detect, monitor, or quantify nanopharmaceuticals within a biological system is relatively nonexistent. Bio-persistence, bioaccumulation, drug interactions, bio-clearance, drug half-life, long-term side effects, lifetime exposure limits, lifetime drug interactions due to bio-persistence and bioaccumulation, as well as environmental effects of bio-cleared compounds and disposal of unused nanopharmaceutical compounds are just some of the variables that must be considered with regards to safety concerning nanopharmaceuticals.

With the wide range of potential held within the nanopharmaceutical industry, we know the impact of nanopharmaceuticals will change the world. The applications of these compounds are limitless. One thing we must keep in mind as we move towards this amazing future is that the cost of discovery is more than just the investment in their development. If we fail to initiate an integrated nano safety protocol for nanopharmaceutical development the end result of nanopharmaceuticals could leave a catastrophic impact on the world. This is too high a cost to pay.

Nanosafety protocols cannot wait until they are mandated by a government regulatory organization, or a law implemented by a government body. We as the developers of nano pharmaceuticals must take in hand the task of insuring our products are safe by implementing the age-old scientific principle - *primum non nocere* "first, to do no harm". We must approach this task with the knowledge that each nanopharmaceutical compound has its own unique physiological, biological, environmental and ecological effects due to the wide variety of properties at the nano scale. This requires that extensive characterization, classification, and individualized studies for each nanopharmaceutical be performed. Standardized toxicological screening protocols must be developed to properly screen nanopharmaceuticals as a class of drugs. As the nanopharmaceutical industry moves forward these protocols will and must dynamically change as our knowledge increases. We must take the leadership role and hold scientific principles above that of profit and realize the onus of promise or catastrophe is upon our shoulders.

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