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Nanomedicine: Economic Prospect and Public Safety Leanne Lai^{1*}, Tram Nguyen¹, Alexander Ting², Tianzhi Yang³ and Shuhua Bai³

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The National Institutes of Health Roadmap for Medical Research envision that nanotechnology will begin yielding significant medical benefits within the next ten years [1]. The emerging trend of nanomedicine commonly associates with engineered nanoparticles in the context of drug delivery methods, diagnostic imagining tools and medical device applications. Especially, the field of nanoscale drug delivery system is progressing to a higher level as this trend is thriving on global pharmaceutical markets. Nowadays, nanotechnology scientists have successfully developed many new forms of the pharmaceutical products for cancer treatment, hepatitis, infectious diseases, anesthetics/analgesics, cardiovascular disorders, inflammatory/immune disorders, endocrine/exocrine disorders, degenerative disorders, and others [2]. Many believe that nanomedicine will make a significant impact on current practice of medicine and enhance patients quality of life.

As public demands for new drug developments have been increasing while the "number of new drugs approved per billion US dollars spent on research and development has decreased by half for every nine years since 1950" [3]. Pharmaceutical industries are facing challenge to invent effective products to publics while sustaining profitability. In fact, FDA approvals have been continuously reducing, with merely 21 FDA new drug approvals in 2010 [4]. Thus, nanomedicine has the inevitable potential and capacity to not only provides advanced therapeutic options to patients, but also anticipates commercial potential to pharmaceutical industries. According to BCC research market forecasting, the global nanomedicine market reached \$63.8 billion in 2010 and \$72.8 billion in 2011. At this rate, it is expected to increase to \$130.9 billion by 2016 [5]. With evolving nanomedicine discoveries, the economic prospect is promising. One strategy used by the drug industry to extend the drug's patent life in their most lucrative years is to reformulate, or regenerate, the drug. Pharmaceuticals may take advantage of this reformulation concept by reinventing Drug Delivery Systems (DDS) to enhance the lifetime of drugs in the body by using liposomes and polymer micelles. Thus, with nanomedicine emerging, the importance of reformulation has been redefined. Applying state-of-the-art nanotechnology drug delivery system may soon become the main focus for research and development due to the cost effective opportunities that it will create for industries. In addition to pharmaceutical industries, government agents and research institutes have also contribute to this hype. For example, the US National Institutes of Health established "Nanomedicine Initiative" in 2005 with a national network of eight Nanomedicine Development Centers for two major goals: 1) understand how the biological machinery inside living cells is built and operates at the nanoscale and, 2) use this information to reengineer these structures, develop new technologies that could be applied to treating diseases, and/or leverage the new knowledge to focus work directly on translational studies to treat a disease or repair damaged tissue [1].

Despite nanomedicines being highly desirable due to their ability, they may also pose a threat against patient's health if used without proper assessment. A worldwide challenge that scientists are facing in this emerging field of nanomedicine is to develop an appropriate guideline for the safety and efficacy use of nanoparticles. This has become such a challenge due to the limited information and inadequate data that has been collected on nanomedicine. Thus, it is significant to understand nanotoxicology, in which Oberdorster has defined as the "adverse effects of engineered nanoparticles on living organism and ecosystem" [6]. As the definition implied some of the main concerns in nanotoxicology focus on nanoparticles pharmacokinetics/pharmacodynamics properties and how they are degraded in our environment. The complexity of these nanoparticles interaction in the body depends on their different characteristics, such as size, shape, surface area, solubility, crystallinity, portal of entry and aggregation. These complications are of also worrisome to society in that nanomedicine waste may cause environmental damage in the long term.

Uncertainties do not end with the concern of the potential threats of nanotoxicology. In fact, it serves as one of the culprit reasons for the need to create regulatory standards that are specific for nanomedicine. With the development of these advancing innovative drugs, the U.S. Food and Drug Administration (FDA) will be responsible for overseeing and controlling regulations for these nanoparticles that will function as drug delivery, diagnostic imaging and medical devices. The FDA has recognized that nanoparticles exhibit special characteristics that have safety concerns of their own and cannot be compared with their larger molecular counterparts. Hence, the agency has gathered a team called the nanotechnology task force to work towards establishing a regulation for this practice. Their objective is to come up with a "comprehensive nanospecific regulation, new standards or nanomaterial toxicity testing, classification of nanomaterials as new substances and mandatory labeling of nanomaterials and nanoproducts" [7]. Until a standard national guideline has been created, the FDA plans to evaluate the safety and efficacy of a product by using a case by case method.

The development of nanomedicine cannot be too accentuated on its hurdles with technical challenges as well as its battles with public safety. Given the needs for revolutionizing the way diseases are managed, the further challenge and/or opportunity for nanomedicine is to continuously discover advanced, safe, and cost-effective therapeutic products to society.

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