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Research Paper

Socio-ethical Issues in Nanomedicine Research

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Abstract
The promises made by the advent of nanotechnology are immense. As the science and technology of nanomedicine speed ahead, ethics and the regulations are struggling to keep up. It is important to address these socio-economic, ethical and risks issues proactively to avoid any untoward consequences to the environment and human health. Currently, the research spotlight is solely on the development of new drug delivery system; with little focus on toxicity and safety studies of nanomaterials. As the use of nanomaterials in nanomedicine increases, questions of social justice, socio-economic equality and concept of "access to new forms of healthcare to all" become an important subject of discussion for the public and scientific community.
Keywords: *Nanotechnology, Nano-Medicine, Ethics, Socio-Economics impact, Emerging technology.*

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I. Introduction

In recent years, the nanoscale phenomena have generated big appeal, ambition, curiosity and expected to have a significant and dominant role in just about every aspect of the economy. (M. E. Ludeña, 2008). The literature on nanotechnology shows the impressive growth of this field. It is predicted that nanotechnology has potential to fetch high competitive advantage to the firms (Canton, 1999; Shapira, 2011).

Nanotechnology and Biotechnology are undoubtedly the two most revolutionary and prospective technologies of the present era. With the convergence of these two technologies emerged a new convergent technology "Nanobiotechnology". Nanobiotechnology has garnered much enthusiasm and anticipation of great economic and social benefits through novel innovations from the technology, especially in the field of healthcare. Nanomedicine, an offshoot of nanobiotechnology, speaks of a very specific medical mediation at the molecular scale for therapeutic means such as in the treatment of diseases or fixing damaged tissues, such as bone, muscle, or nerve. The application of nanotechnology to human healthcare offers numerous potential pathways and very promising possibilities to improve medical diagnosis and therapy and even to regenerate tissues and organs. It can provide personalised yet more affordable healthcare while at the same time offering an improved quality of life for everyone.

New technologies raise inordinate expectations of new openings and an excited, faster and cheaper accessibility of technology and products. Still, in case of emerging technologies advances are accompanied by qualms about what unforeseen or untoward effects might arise out of those technologies. Those effects may take years or even decades to surface and become clear but when they do, they can even outweigh the benefits from that technology.

Issues in Nanomedicine Research

Nanomedicine research is an increasingly energetic and exciting field of science across the world. Scientists around the world are keen to understand the role of nanomedicine in detecting changes and problems at the molecular and cellular levels and diagnosis which can dramatically increase survival rates and improved prognosis. The conventional high-technology medicines largely count on the use of sophisticated and expensive medical tools, minimally-invasive devices and implants. while nanomedicine is much more focused on nanoscale interactions within individual cells or individual biomolecules As science and technology continue to advance, so do the ethical, social, economic and legal concerns and implications, surrounding these developments. Many scholars have observed that scientific research and development that is shaped and conditioned by, its social and cultural contexts or vice versa. There is a vast literature on several issues surrounding the development of nanomedicine research.

The systematic exploration of social and ethical issues of nanotechnology started a few years ago. It has been widely recognized that there is a need to address social and ethical issues of nanotechnology in addition to scientific, economic and political issues [e.g. European Commission 2004, 2005]. Owing to the nascent stage of nanotechnology development, these are mainly debated about possible social and ethical issues for nanotechnology in general.

1. Socio-Ethical Issues

Nanotechnology offers great promise for medicine, but much of this still lies in the future. This future angle has made nanotechnologies susceptible to the current zeitgeist of over claiming in science, be it the potential benefits or harm. Given to the difficulties in foresight of breakthrough technologies, there are always constant fears about how the technology will turn out, especially when the technology has a direct impact on human health and environment. Nanotechnology is poised to add a new dimension to the bio (human) and non-bio (machine) interface such as brain chips or implants, which eventually raises new ethical issues of privacy, informed consent and equity which are very specific to nanomedicine. Ethical and social debates on nanomedicine are quite different from earlier revolutionary technology which also had bio & non-bio interface like Genetically Modified (GM) food or Information Communication Technology (ICT).

Unlike GM or stem cell research; issues in nanomedicine are more complex and stem out of a plethora of concerns related to dignity, safety, individual and social ethics, public policy, the economy, societal debates, economic, political and ethical concerns, legal issues, these issues may sound separated, yet in reality they are interrelated in multifaceted ways and need to be properly addressed if nanomedicine is to be used in a way which is ethically sound, democratically discussed and humble to citizens' rights (Commission, 2007). The ethical principles at stake in nanomedicine form part of several different ethical theories (Ebbesen, 2006) and this study will merge them to highlight and bring forth key concepts

- **Non-instrumentalisation**: The ethical requirement of not using individuals merely as a means or guinea pig for experimentation or commercial exploit but always as an end of their own (Fliesler, 2014).
- **Privacy:** The ethical principle of not invading or infringing a person's right to privacy.
- **Non-discrimination**: It is likely that nanomedicine products will also be very expensive when they will initially hit the market and that nanomedicine may create health-based national and international inequalities even worse. There are concerns over the affordability of nanomedicine and here comes the ethical principle of non-discrimination; People deserve equal treatment unless there are ample reasons that justify differential treatment procedures. It is a widely accepted principle in common that primarily relates to the distribution of healthcare resources (Resnik, 2007).
- **Informed Consent**: The ethical principle that patients should not be exposed to treatment or research without their free and informed consent obtained and until they are told about all the unforeseen risks involved but the question is How is it possible to give information about future research balances and to make a realistic risk assessment in view of the many unknowns and the complexities?
- **Equity**: The ethical principle that everybody should have fair access and right to use the benefits stemming out of new or old knowledge base.
- **Justice**: The enabling nature of nanotechnology makes some issues very critical. Nanomedicine enabled enhancement of body functions to raise similar issues as performance-enhancing drugs in sports do (UNESCO, 2006).
- **The Precautionary Principle**: This principle entails the moral duty of continuous risk assessment with regard to the not fully foreseeable impact of new technologies as in the case of ICT implants in the human body.

2. Issues of Toxicity and Safety

Significant apprehensions have been shown by experts and public bodies about unforeseen uncertain and distinctive toxicities from ENPs. Two chief concerns are; the first dearth of standardized protocols on nanomedicine and second the uncertainties about the fate of nanoparticles in the body. For first concern, there are no specific laws or mechanisms in place for oversight of nanomedicine the regulatory agencies continue to treat nanoproducts as substantially equivalent ("bioequivalent") to their bulk counterparts (Bawa, 2011), which is a farcical situation being novelty is the main feature of nanomedicines A well-known and notoriously famous case of Clinical Trial Phase-I study of a drug molecule '*TGN 1412 (CD 28 MAB)'* is a perfect example of an absence of a standardized risk assessment knowledge base for nanomedicine. *TGN 1412 (CD 28 MAB)* intended to treat *Rheumatoid Arthritis* and *Lymphatic Leukemia* was to be administered to six healthy volunteers intravenously and within half an hour of administration, all six volunteers developed severe life-threatening adverse effects. Hence it was concluded that in case of nanomedicine in-vivo results cannot be trusted or extrapolated for trials involving humans and more work is need to be done to reduce the risk associated with nanomedicine based clinical trials (Attarwala, 2010) (O'Mathuna, 2009). The second concerns hold its validity

in the very uniqueness of nanoparticles, the very reason which makes nanoparticles so promising; the uncertainties about the properties and behaviour of nanoparticles. Nanoparticles can generate an immune response, are able to cross the blood-brain barrier and potential to attack and damage CNS or can cause tissue toxicity if not properly eliminated (Johnson, 2009). A number of toxicological responses of nanomedicine based on in-vivo studies are reported such as hypersensitivity reactions, element-specific toxicity and generation of reactive oxygen species causing lipid peroxidation leading to inflammation. (Chan, 2007)

3. Environmental Risks

National Science Foundation (NSF) and Environmental Protection Agency (EPA) have raised serious concerns over potential harms of nanomaterials on the environment and the worries reported and raised by social scientists and civil society (Dreher, 2004). ENMs by-product from industrial production is most protruding nano pollution, other pathways would be consumer products, biological excretion, and destruction of nanoparticle-containing infrastructure (Wright, 2011) Mechanisms are symptomatic of that those nano pollutants or ENMs would mainly be disposed in water and air and through water or inhalation can cause respiratory disorders and affect the health of individuals (Litton, 2007; Prabhala, 2012)

4. Enhancement Vs Therapy: Nanomedicine Affordability & Nano-divide

Fairness is one of the key doctrines of biomedical ethics and this very principle is at the heart of debates over societal implications of nanomedicine. Accessibility, availability and affordability of nanomedicine form the core of the social issues related to nanomedicine Many experts have already warned against a possible "nano-divide"; term implies that there will be winners who have access to nanomedicine and losers who don't have (Invernizzi & Foladori, 2005; Baird, 2004). The economically weaker section may not be able to afford expensive sophisticated nanomedicine innovation thus might leg behind further (J., 2006). The use of growth hormones in paediatrics, plastic and cosmetic surgery, doping in sports, or genetic engineering are all examples of drug and technology-based enhancements (Farah, et al., 2004). There are various reasons for social scientists to find unnecessary enhancement morally incorrect. The first reason is, enhancement can lead to unfair competition Enhancements can aid people acquiring a competitive edge in sports, work and other aspects of life. Enhancement therapies designed for disabled people is a very longed-for and highly appreciated option but the question of justice comes when a healthy person goes for those enhancements becomes super strong or intelligent and now having an unfair benefit over somebody with a normal body or mind. Second, enhancement can also worsen existing socioeconomic inequalities if only the rich people can afford enhancements and passes their advantages to their generations then the rich will get richer while poor will stay poor. Third, enhancement can lead to discrimination or bias against people who are not enhanced and thus leading to great social inequality (Rothman, 2003)

5. Transhumanism

Inspired by science fiction, Transhumanism or human mechanization is actually finding its way into our lives. It's a radical new approach to future-oriented thinking that is based on the premise that the human species in its current form does not represent the end our development but its beginning. World Transhumanist Association defines transhumanism as *"The intellectual and cultural movement that affirms the possibility and desirability of fundamentally improving the human condition through applied reason, especially by developing and making widely available technologies to eliminate ageing and greatly enhance human intellectual, physical, and psychological capacities".* (The World Transhumanists Association). Prostheses, plastic surgery, intensive use of telecommunications, the cosmopolitan outlook, the globetrotter lifestyle, androgyny, assisted reproduction, the absence of religious beliefs, and a rejection of traditional family value are considered as signs of transhumanism. The major objection to transhumanism is: It's dehumanizing; assaults the societal structure and attacks the very essence of being human by robing ethical and moral threads. There is a fundamental difference between improving the human health on one hand and radically modifying the human genetic makeup on the other hand. It is the later phenomena Francis Fukuyama and other critics of transhumanism are against and opposing to and not only that but transhumanism also poses some other very serious issues such as privileged few are having control and access to those futuristic technologies and can use for some nefarious purposes like the military misuses. An ecological misbalance and wastage of resources is also a point of concern (Transhumanism, 2014; Smith, 2011; Bostrom, 2003).

6. Risks in an uncertain science

"*I know that I know nothing,"* when Socrates said that he might not have thought how pragmatic, relevant yet ironic his words going to become in modern times. The era of nanotechnology has revived and reminded us the importance of great words of wisdom. David Garland, in the chapter *"The Rise of Risk"* quotes the distinguished sociologist Anthony Giddens as how he most often likes to begin public lectures by posing

different versions of the following question to his audience: "What do the following have in common? Mad cow disease, the troubles of Lloyds Insurance, the Nick Leeson affair [at Barings Bank], genetically modified crops, global warming, the notion that red wine is good for you and anxieties about declining sperm counts?" (Garland, 2003). The answer, of course, is that they are all about risk and how risk has become a multifaceted entity; affecting and extending to our social, political and economic dialogue and it puts forward the argument that the risks are in fact increasing due to technology, science and industrialization rather being wilted by them (Jarvis, 2007). However Giddens is not alone here and we are increasingly finding words on understanding, coping and managing risks, for instance; Francis Fukuyama (Fukuyama, 2003), Ulrich Beck (Beck, 1992; Ecological Enlightenment: Essays on the Politics of the Risk Society, 1991; Democracy without Enemies, 1998; World Risk society, 1999), or Peter L. Bernstein's successful attempt to understand the societal entangling and embedment of risk in "against the gods". Nevertheless, the common thread which emerges out of all these writings is that how technology and science are shaping our lives, creating risks and not deliberates penalties for the environment, our health and the overall well-being of mankind.

7. Nanomedicine development and risks

The very character that makes nanotechnology so attractive is also the reason for apprehensions that is the footing of nanotechnologies rests on nanomaterials that possess unusual physicochemical properties, there is growing evidence that the manufacture, use and disposal of some nanoproducts might present potential risks as much as they do pose benefits. The structure (size and shape) and its altered features and greater reactivity of certain nanomaterials can enhance exposure potential and cause and stimulate unusual or adverse responses, they can pose larger 'real hazard potential' over conventional chemicals (Maynard, 2007). Another concern is that existing risk assessment, management or regulatory frameworks may not be adequate to address nanotechnology risks given that they are tailored for conventional chemicals (Grobe, 2008).

II. Conclusion:

Nanomedicine is a global business enterprise impacting universities, startups and boardrooms of big pharma alike. Industry and governments are clearly beginning to envision nanomedicine's enormous potential. As long as government expenditure encourages facile technology transfer to the private sector, nanomedicine will eventually blossom as a source of corporate investment and revenue. Will nanomedicine transform our industrial base and have a dramatic impact on healthcare and our long-term quality of life? As envisioned here, applications of nanomedicine hold out a wealth of promise, given the many applications in drug delivery, diagnostics, detection, discovery, sensing and imaging. However, nanomedicine has been so enthusiastically promoted that the hype and expectations may far exceed reality, especially given the immense lag time between R&D and the appearance of commercially-viable products in the marketplace. Therefore, for nanomedicine to truly become a global megatrend, this hype must be separated from reality.
It is also important to ensure that advances in medical care due to nanotechnology do not come at the expense of fairness, safety or basic understanding of what it means to be a healthy human being. The changes that nanomedicine is likely to bring about should be addressed and managed through strategic planning and ethical analysis. As scientific advances occur, the responsible development of nanomedicine requires that societal and ethical concerns be addressed. Even if many of these issues are not new or unique, it will still be essential to address these questions and arrive at justifiable answers for them. Initially, some of the important ethical concerns will continue to focus on risk assessment and environmental management. Later on, classic ethical questions regarding social justice, privacy, confidentiality, long-term risks versus benefits and human enhancement are certain to arise. Eventually, novel ethical issues and unforeseen dilemmas will emerge as the field advances further and intercept other areas of biomedical research, including genomics, personalized medicine, bioinformatics and neurobiology.
There is also great concern today over the environmental issues, health risks and safety of many nanotechnologies and nanomedicines. There have been dire warnings concerning the risks inherent in some of these technologies. Regulatory agencies like the FDA are struggling to formulate an appropriate set of guidelines, a difficult task given the current level of uncertainty.
We argue that time to consolidate these discoveries is essential. The history of science is replete with technological innovations that moved from the laboratory to the marketplace, only to precipitate grievous consequences once they were widely disseminated. Classic examples include pesticides, atmospheric CO2, atmospheric fluorocarbons, radioisotopes and thalidomide. Today, the stakes are much higher. Repercussions (real and imagined) may be rapidly forthcoming and blame will be assigned through the courts, which is generally not the most effective route to the truth. However, current fears about self-replicating nanobots, the potential toxic effects of nanoparticles and the calls for strict regulatory oversight or a nanotech moratorium, will eventually give way to intelligent public dialogue on the realistic impact of nanotechnology and nanomedicine. Government and industry must pay greater attention to emerging public concerns of

nanomedicine (environmental, ethical, societal and health issues) in order to prevent any public backlash. In the end, acceptance of nanomedicine will largely depend upon trust in government oversight of ethically sound R&D and commercialization. Only then will the public be more engaged in and aware of nanomedicine, leading to its wider adoption in society.

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