

# Ethical Issues in Nanomedicine

F. Graur<sup>1,2</sup>, R. Elisei<sup>1</sup>, A. Szasz<sup>1</sup>, H.C. Neagos<sup>1,2</sup>, A. Muresan<sup>1</sup>, L. Furcea<sup>1,2</sup>, I. Neagoe<sup>2</sup>,  
C. Braicu<sup>2</sup>, G. Katona<sup>3</sup>, and M. Diudea<sup>3</sup>

<sup>1</sup> Surgical Clinic III, Cluj-Napoca, Cluj, Romania

<sup>2</sup> "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca, Cluj, Romania

<sup>3</sup> Babes-Bolyai University, Cluj-Napoca, Cluj, Romania

**Abstract**— Nanomedicine is a top developing domain. However, there are neither sound rules, nor a proper legislation that might regulate the ethics in this domain. Here we discuss the main topics pertaining to the ethics in nanomedicine at this time. From issues such as equity and discrimination, to profound modifications of the human body, far beyond the limit of human and non-human, there are many ethical aspects that can give rise to conflicting opinions.

**Keywords**— ethics, nanomedicine, nanotechnology.

## I. INTRODUCTION

Developing technologies that combine several areas have been constantly growing in recent years. Technologies that use nanostructures, nanotechnologies, are about to revolutionize the healthcare system in the near future.

Nanostructures will be able to act at molecular levels unattainable until now, revolutionizing medical therapies and therapeutic protocols. Nanotechnology and research in this area have experienced an extremely quick development in recent years, enjoying a very generous grant. Nanotechnology was able to break through the existing barriers across multiple disciplines and to become a multidisciplinary science which combines not only physical sciences, chemistry and engineering, but also molecular biology research and other healthcare segments.

## II. BACKGROUND

In the next decades nanotechnologies will revolutionize the healthcare system and the practice of medicine. There are drug delivery nanoparticles already in use, testing or development, and they will make it possible for us to reach targets such as chemotherapy, nanowiring for brain activity monitoring, nanoscaffolds for neural tissue repair and nanofiber brain implants. [1]

Nanomedicine refers to that side of the healthcare system that uses nanodrugs, which constitute a heterogeneous group of drugs that display, in general, unique properties, due to their nanoscale dimensions (nanometer to micron),

many of these properties being fundamentally different from those of their macroscopic analogues.[2]

We will examine the development of nanotechnology and debate on the ethical issues to be considered when developing prudent policies regarding nanotechnologies.[1] The specific ethical regulations regarding nanomedicine should take into account all the ethical issues pertaining to human dignity, such as privacy, non-discrimination, informed consent, equity, etc. [3]

## III. EQUITY AND NONDISCRIMINATION

Ever since the idea came out, nanotechnology research has been enjoying an astounding development in many areas. The greatest progress and development was achieved by the pharmaceutical companies in drug delivery, domain which is already yielding significant results. Today, drug delivery covers over 78% of global sales in nanomedicine. At the moment, a new level of nanomedicine is in research, thanks to advances in pharmacogenetics and pharmacogenomics: the drug delivery system research was specifically targeted, this thrusting into limelight the concept of personalized medicine. [2] All this research is being done by the greatest pharmaceutical companies worldwide. In 2006 an amount of over 12.4 billion USD was spent, globally, by corporations, governments and venture capitalists, with 13% more than the one spent in 2005 and the amounts are increasing every year.[4] Specialists forecast that the nanotechnology pharmaceutical applications market will be around 18 billion dollars per year.[5] Even a cursory glance at the 2007 report will lead us to the conclusion that the US demand for nanomedical products will rise to over 53 billion US dollars in 2011 and to 110 billion in 2016.[6] Due to the fact that nanomedical products are extremely expensive, as the investors have to cover their investments, the nanomedical products market is expanding only in developed countries like the USA or Western European Countries. In developing countries, like those from Eastern Europe, the governments and the people cannot afford the nanomedical products. Thus, the following question arises: how ethical is it to implement very expensive nanomedical

therapies for patients and medical systems? This situation is creating a gap between the state of the health care system in developed countries and that of the health care system in developing countries. Moreover, an increasing number of specialists are emigrating to Western European Countries to have access to new nanotechnologies in the medical care system. [7] This will ultimately lead to a lack of specialists in developing countries and to poor medical care and assistance for the people who live there.

In the short term, these new medical technologies will be out of reach for many people of lower socioeconomic status or for those in developing countries, because the price of the new products will be really high until the original patents on them expire and the respective generic products arrive on the market. However, in the future there is a possible scenario where only the rich have access to novel treatments, while the poor are denied even the knowledge of their diseases.[2] On the other hand, issues such as biopiracy, intellectual property theft and greed of the multinationals have been proffered as reasons for the unavailability of essential drugs to the poorest and neediest people in the world. Moreover, the Western companies make efforts to keep the prices high by continually citing the need to reward the innovation as a justification for stronger patent laws; that makes them spend more on reformulating preexisting drugs than on innovations.[8]

There is a fear regarding the future “nano-device” society, the divide between the rich and the poor being likely to expand because of expensive nanomedical drug treatments and huge implants prices.[9]

The massive investments in nanomedicine areas and the research and development in nanotechnology, as well as the lack of policy related to research funding and to educational programs have caused nanoethics to lag behind, and we should not have allowed this to happen.[10]

#### IV. TREATMENT VERSUS ENHANCEMENT

The boundary between enhancement and therapy is rather relative, because both are based on the concept of the “normal”, which is also very relative. Consequently, the following question arises: when should the novel medical procedure or treatment be considered therapy and when should it be viewed as enhancement? An answer to this question is needed because the novel medical procedures, therapy and diagnosis methods can be used to enhance the human body or mind.[2] It is difficult even for the scientists to draw a clear-cut line between therapy and enhancement.[11] On the other hand, Norm Daniels argues that any intervention designed to restore and preserve a species-typical level of functioning for an individual should count

as therapy [12] and the rest as enhancement, while Eric Juengst states that therapy is health related, aimed at pathologies which compromise health, whilst enhancement aims at improvements which are not health related.[13]

All the science fiction scenarios of today are getting closer and closer to reality due to the novel technology which is creating nanoscale devices that can be inserted into the human body for diagnosis, treatment or enhancement. Here comes the ethical problem regarding the distinction between therapy and enhancement. In the case of the invention of an artificial oxygen boost red blood cell – called respirocyte – which holds a reservoir of oxygen, the question above will definitely arise.[14] These cells could help heart attack victims to survive and would allow their heart to continue breathing oxygen from these artificial cells until the emergency team can offer them proper medical treatment. But, at the same time, these cells could be used by an athlete to enhance his body and boost his performance.[15] How ethical and moral is it to use these cells for enhancement?

As regards the nano-chip implants, there may also appear some ethical issues, such as hybrid humans, which will be on the interface of human and machine. Nano-chip brain implants may lead to the “Lego set mentality” [16] of “Nanomed-human beings”. There is also the ethical issue of affecting the human brain with these nanochip brain implants which may go beyond the healing purpose and impact on the preservation of human identity [9], this being one of the ethical principles pertaining to human dignity that we mentioned above.

#### V. TOXICITY AND BIOCOMPATIBILITY OF NANOSTRUCTURES

The most highly developed sector of nanomedicine is the nanodrug delivery and therapy system, which uses a wide range of materials to deliver active agents to different parts of the human body. The behavior of nanomaterials is often unpredictable, because they may behave differently in vivo as compared to in vitro: nanoparticles can disintegrate into smaller particles that are toxic to the human body, or they may aggregate into larger particles as well.[17] Because of that, it is ethically desirable to design short- and long-term studies to determine whether nanomedicines really are more effective and safer for humans than conventional drugs. Nevertheless, when trying to run those trials, there may appear some other difficulties, such as problems with comprehension and with understanding as regards the informed consent, given the complexity of nanotechnologies. Moreover, the long-term effects of using nanomedicines still are, to this day, largely unknown.[2]

To ensure that the new drugs can be used safely by the people, nanomedicine companies should be required to conduct long-term studies on nanomedical products following their introduction on the market: post-marketing surveillance or Phase IV studies. But this type of studies is poorly practiced because they are not required by current laws. Although it is clear that new regulations should be introduced, this is to be done with care, so as to prevent over-regulating tendencies, because those would have a chilling effect on research, development, commercialization efforts and fair access of the public to nanomedicines.[18]

## VI. INFORMED CONSENT

Nanotechnology risks communication problems between the promoters of the study and the subjects participating in the research; therefore, conflicts with the public opinion are often a difficult challenge. Applicable laws and ethical rules require investigators to inform potential subjects or their legal representatives of the study's objectives, of the procedures to be performed, of the benefits, of the risks the participants may be subject to during the study, of the alternatives that they have, of the privacy protection that they are offered and of any additional information that the subject needs in order to decide whether or not to take part in the study.[19] The participants most often underestimate the risks to which they subject themselves by taking part in such a study, and are likely to overestimate the benefits.[20] During the study of nanomaterials, investigators must inform subjects of the possible existence of risks that may not be obvious at that particular time.[21]

## VII. BOUNDARY BETWEEN LIVING AND NON-LIVING

When we start using nanomaterials in medicine, some fundamental questions about human nature and human enhancement are bound to arise.[22] One such question refers to how many implantable nanodevices it would take for a person to no longer be considered a human being.[2] Such questions spring to mind when one imagines futuristic scenarios about our nanomedical future: the "nanofuture". The conventional boundary between living and non-living is blurred in these scenarios, because, due to the socio-economic inequity, unfair competition and discriminations might raise some other ethical issues. We can consider, for instance, exactly who is eligible for enhancement and who is not. Should military people and athletes be considered morally eligible to have some parts of their bodies enhanced to increase their body performance, whilst other people should not?[2]

## VIII. HYPERDIAGNOSIS AND HYPER THERAPY

In a medical future where a single chip will be able to check every other second if there are some abnormalities in the body cells or fluids and in the blood flow, and also to detect any mutation on the gene level, there arises the question of what a disease actually implies. Is it enough to detect an individual defective cell or a minor abnormal change in the blood chemistry to set up a diagnostic? In this context, we have to reconsider what the syntagm "healthy person" means and what the phrase "a person who has a disease" refers to, as well as how far, how deep to molecular level, we should go when establishing a diagnosis. This new kind of nanodevices, or nanochips (lab on a chip) which can detect almost any abnormality in the human body, from the blood chemistry to the ability to detect a single cancerous cell, cannot only diagnose current illnesses or diseases, but can also analyze the DNA for diseases that may appear in the future.[23] These nanochips can generate panic, increased anxiety and fear about illness, being thus likely to cause psychosocial harm. What is more, these nanodevices, which are real repositories of medical information about the health status of any one of us, must not be accessible to insurance companies, because, if they are, the harm such devices may cause will outweigh their potential benefits.[2] Consequently, inevitable ethical issues arise, issues concerning the patient's right to know, right not to know and duty to know, which are inherent to the principle of autonomy.[24] On the other hand, nanochip implants which monitor a person's health raise serious privacy concerns, for instance in what regards those who monitor the information from the chip, those who have access to all this information, and whether or not these chips may be used for other purposes than the medical ones, purposes such as enhancement, for example.[25] Nanomedicine aims to provide all the relevant medical information regarding the patient, including the prevision of malignant tumors for example, by means of this "lab-on-a-chip", which is able not only to read the human genetic code, but also to issue forecasts about the medical future of the patient.[16]

## IX. RESPONSIBILITY

In the nanomedical era, fast diagnoses and speedy treatment possibilities will be common. What if this leads to mistaken diagnoses and inappropriate treatment for diseases that, maybe, do not actually exist in a certain patient's case? How far should we trust the new discoveries in nanomedicine? What if there appear on the market instruments for a nanomedical entire body scan that may provide diagnostics and treatment, but which could be bought by people as

easily as the blood pressure measure instruments used today? The problem is that people will avoid going to the doctor if they are able to buy “their personal nanomedical doctor”, due to the fear and high costs of medical assistance and treatment, and of medical insurance. [2]

There is also the question regarding the doctors’ responsibility, which might be shifting away from the doctors to the patients, as the medicine of the future will be minimally invasive and will increase the patients’ autonomy by reducing the amount of personal interaction.[25]

## X. CONCLUSION

As Ferrari et. al. conclude, we should not take our concerns to the extreme by over-analyzing nanomedicine ethical issues: “the greatest risk in nanomedicine may well be in letting our concerns paralyze our action and not taking advantage of the full, revolutionary potential that nanotechnology in medicine can offer humankind” [26].

The future innovations in nanomedicine should be analyzed from an ethical, political and social point of view. The most important thing for a proactive analysis of the new nanotechnologies is to make sure that the proper authorities discover and debate, from as early as the project phase, the ethical issues that can appear. In order for this to become reality, a very tight collaboration is required between those who are developing the novel nanotechnologies and the ethics specialists. This is the only way to ensure that the nanomedical technologies will get the ethical and social acceptance of the people. [27]

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Author: Graur Florin  
 Institute: University of Medicine and Pharmacy Cluj-Napoca  
 Street: Croitorilor 19-21  
 City: Cluj  
 Country: Romania  
 Email: [graurf@yahoo.com](mailto:graurf@yahoo.com)