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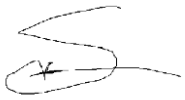

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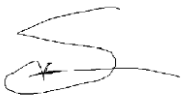

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Taking up Bioethical Responsibility?

The role of Global Bioethics in the Social Responsibility of Pharmaceutical Corporations operating in Developing Countries

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Abstract

Today, bioethics is challenged due to the consequences of globalisation. While traditionally being focused on sensitive national issues, bioethics is currently confronted with international problems related to global health, global inequality and the increasing operations of the pharmaceutical industry in developing countries. For these reasons the Universal Declaration on Bioethics and Human Rights is trying to get bioethics to a next level by defining broad principles and including the pharmaceutical industry in its scope.

This thesis will explore if the new more broad and global bioethics can adopt a bigger role in the corporate social responsibility of the pharmaceutical industry. This is done by looking at the response of the pharmaceutical industry towards the bioethical concerns about the affordability of medicines, the research on neglected diseases and clinical trials with human subjects. These concerns are already addressed by human rights and the right to health in specific. If bioethics wants to play a role in the corporate social responsibility of pharmaceutical corporations it needs to search for its added value in comparison to the rights based approach that the pharmaceutical industry has adopted.

Keywords: Bioethics, the Universal Declaration of Bioethics and Human Rights, the International Committee on Bioethics, Pharmaceutical Corporations, Access to Medicines, the Right to Health, Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.

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Introduction

'*In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.'*

- Millennium Development Goal target 8.E

Big pharmaceutical corporations all around the world carry a lot of responsibility as their business policies influence directly and indirectly life and death of persons in need of medicines, especially in the developing countries. Almost two billion people lack access to essential medicines. Improving access to essential medicines could save 10 million lives each year.[1] The most pressing concerns are about the affordability of medicines, the research and development for neglected diseases and clinical trials with human subjects. Making these ethically heavy weighting decisions is not easy and pharmaceutical corporations are many times heavily criticized for the handling of these issues. While healthcare is in most cases seen as a part of the public responsibilities of a state, the delivery of the products which enable healthcare, like medical equipment and medicines, are arranged by private corporations. While the healthcare policies of democratic states are open to public scrutiny, the ethical choices of a private pharmaceutical corporation lack democratic control. It is for that reason that it is important for the pharmaceutical industry to adopt ethical sound business policies.

Although bioethics is traditionally seen as being concentrated on sensitive national issues as abortion, cloning, genetics and euthanasia, it is increasingly concerned with global problems which relate to the ethics of biology and the life sciences. The International Bioethics Committee (IBC) of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) is on the forefront in broadening and globalising bioethics. Its biggest step towards that goal has been the creation of the Universal Declaration of Bioethics and Human Rights. The ethical concerns regarding the presence of pharmaceutical corporations in the developing countries fall within the

[1] United Nations General Assembly, Annex to the right to health, A/63/263, 11 August 2008, Preambular para. A.

scope of that declaration. The declaration has created the broadest view of bioethics, by adopting fifteen underlying principles.

While bioethics slowly enters the debate about these concerns, the discipline has to ask itself which role it wants to have and more importantly can have within the social responsibility of pharmaceutical corporations. The ability to play a role at all in the area of the pharmaceutical corporation's responsibility towards the access to essential medicine is linked to the presence of human rights, especially the right to health, as it covers the same concern. The discipline of bioethics needs to have an added value in comparison with human rights in order to be taken seriously by pharmaceutical corporations. It is hard to do as the rights based approach to currently applied to the access to essential medicine is seen as positive due to its empowerment of the rights-holders (the persons needing medicine) and the strengthening of the capacity of the duty-barriers. Normally the duty barrier is a State, however the responsibility of pharmaceutical corporations is increasingly emphasised. The former Special Rapporteur on the right to the highest standard of health spend considerable energy on the inclusion of pharmaceutical corporations by having consultations with pharmaceutical corporations and designing Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines.

Due to the amount of effort the World Health Organisation, the Special Rapporteur on the right to the highest standard of health and other stakeholders put in putting pharmaceutical corporations into the rights based approach towards the ethical problems it is confronted with, there is little chance that the discipline of bioethics can get attention of the pharmaceutical industry on its own. There is a need for global bioethics to adopt the human rights discourse in order to be relevant for corporations to adopt bioethical concerns.

The main research question therefore is: what is the role of global bioethics in the social responsibility of pharmaceutical corporations in developing countries?

This thesis advances in seven chapters to answer this question. After explaining the methodology of this thesis, the origin of bioethics is explained. This is done in order to

understand the recent change of a national orientated bioethics towards a global bioethics. In the third chapter global bioethics will be defined. The Universal Declaration on Bioethics and Human Rights (UDBHR) of the IBC will guide this definition and will explain the new scope of global bioethics, which includes the pharmaceutical corporations.

The fourth chapter will introduce the leading human rights based approach towards the right to health. It will show that this approach is dominant in the international field, as important governmental and non-governmental organisations have adopted it. Human Rights are seen as the best tool to create change.

The fifth section will introduce three concerns regarding pharmaceuticals activities in the developing world. These are, the use of human subjects in clinical trails, the affordability of medicines and the research and development of medicines for neglected diseases. These three concerns will make the topics concerning the social responsibility of pharmaceutical corporations more explicit and practically understandable.

The sixth chapter will look how the pharmaceutical industry is reacting on these three concerns by systemically scrutinising their corporate social responsibility reports. Within this chapter the thesis will explore if there are any references towards bioethics or medical ethics within these documents. The concern regarding the use of human subjects in clinical trials in developing countries is expected to have clear references to bioethics as it is has been at the centre of the discipline since the start. The other two concerns are related to the right to essential medicines, which makes it unlikely that bioethics is mentioned in connection to that part of the pharmaceutical corporation's social responsibility. The two topics will nevertheless be discussed, but then rather in the language of a rights based approach to health instead of referring to bioethics. The same chapter will discuss why global bioethics is not mentioned in the corporate social responsibility documents of the pharmaceutical industry. This relates to the dominance of the language of human rights in the field of access to essential medicines and the more detailed and concrete guidelines it shapes for pharmaceutical corporations.

In the seventh and last chapter a SWOT analysis is made about bioethics as envisioned by the Universal Declaration of Bioethics and Human rights. This is done to look at the competitive advantage it has in relation to the human rights based approach.

This thesis will argue that although bioethics is not explicitly mentioned in the documents concerning social responsibility of pharmaceutical corporations, it does have a role to play. This thesis will argue that, the role of bioethics is at the forefront of the debate of social responsibility of pharmaceutical corporations, it should make ethical analyses of emerging global concerns, especially when it concerns technical, medical issues. These analyses can then, when there is international consensus, be turned into authoritative interpretations of human rights. Using the language of human rights is essential in these matters as a rights based approach is very effective in creating change.

For the purpose of this article, corporate social responsibility is defined as 'the continuing commitment by business to behave ethically and contribute to economic development while improving the quality of life of the workforce and their families as well as the local community and society at large.'[2] The United Nations maintains the view that business have a responsibility to respect human rights, which is set out UN Guiding Principles on Business and Human Rights, which was endorsed unanimously in the United Nations Human Rights Council in 2011. Furthermore, the UN special rapporteur on the right to health created 'human rights guidelines for pharmaceutical companies in relation to access to medicines' to make the social responsibility of pharmaceutical more clear and precise.[3]

To come up with a definition of Bioethics is notoriously difficult. The UDBHR has not clarified the term as there was no international consensus on it. Although definitions appeared in earlier drafts, it has been left out in the final version.[4] The changing and different meanings of the word bioethics will be introduced in the second chapter of this thesis.

[2] World Business Council for Sustainable Development, Corporate social responsibility: making good business sense, 2000, at http://research.dnv.com/csr/PW_Tools/PWD/1/00/L/1-00-L-2001-01-0/lib2001/WBCSD_Making_Good_Business_Sense.pdf (consulted on 10 July 2013), p. 10.
[3] United Nations General Assembly, Annex to the right to health, A/63/263, 11 August 2008.
[4] Langlois, 2008, p. 42.

1. Methodology

This thesis focuses itself on the role of bioethics in the corporate social responsibility of Pharmaceutical Corporation in the developing world. In order to make scientific sound conclusions about the role of bioethics in this area a mixture of methods is used.

In the following chapter, an historical perspective is used to describe the changes bioethics underwent to become what it is currently. At the start the definition will be given of bioethics, which is rather broad and can be used for the activities of bioethics on a global scale. Thereafter, the history of bioethics will be shown, which is important for the understanding of the field of study. Primary and secondary sources will be used to describe the involvement from an oath, to the start of medical ethics toward a global enterprise.

The third chapter will analyse the impact bioethics has on a global level. As global bioethics is a fairly new phenomenon, it seemed necessary to explain the main actors and documents on the international level. Chosen is to focus on the International Bioethics Committee (IBC) of UNESCO and the Universal Declaration of Bioethics and Human Rights (UDBHR) as the main pillars for the internationalisation of bioethics. This is done as it is the most authoritative organ of global bioethics, because it truly represents over 190 countries and the UDBHR is the only universal governmental document on bioethics. The UDBHR includes corporations in its scope and is therefore useful when talking about pharmaceutical companies.

The fourth chapter will analyse, with primary and secondary sources, the influence of the right to health and the human rights based approach to health. This is the dominant way of going about global health concerns, also relating to pharmaceutical corporations.

After the introduction to global bioethics, three global bioethical and human rights concerns will be introduced, as this thesis is too limited to take into account all relevant issues in connection with bioethics and pharmaceutical corporations. These can be seen as small case studies to create a practical application of the UDBHR on relevant

concerns regarding the social responsibility of pharmaceutical corporations. The three concerns will be introduced and the responsibility of pharmaceutical corporations towards these concerns will be explained.

Following the introduction of these concerns, social responsibility documents of pharmaceutical corporations will be scrutinised. This will happen in a mini-meta analysis of a sample of five big multinational pharmaceutical corporations, which are very active in the field of social responsibility, especially in relation to the access of essential medicine. To target these early adapters of social responsibility policies, one can see if global bioethics is present in the documentation. Eight questions will be asked relating to the previously mentioned three concerns and the role of bioethics. Within the chapter the research design will be more concretely discussed. Due to the sample of five pharmaceutical corporations it is not possible to derive generalisations of the research, one should see this therefore as an illustration.

The last chapter will analyse the results of the above described qualitative research. The lack of mentioning of bioethics in the documentation will be explained by the success of a rights based approach in order to create a change in policies. A strength, weakness, opportunities, and threats (SWOT) analysis will be made. This is a commonly used method in the corporate world to identify the competitive advantage of a firm. In this case the competitive advantage of global bioethics in relation to human rights will be discovered.

Limitations

This thesis will not try to solve the highly complex problems the area of global public health is coping with. It will also not mingle in the discussion which kind of policies pharmaceutical corporations have to adopt to behave more socially responsible. It will merely discuss the role global bioethics can and is playing in the social responsibility of pharmaceutical corporations. This thesis does hold the premise that human rights and global bioethics are positive influences on the discussion about how to fill in the social responsibility of pharmaceutical corporations.

Furthermore, this thesis solely focuses on the global level of bioethics. For these reasons documents and discussions on a regional or national level are not taken into

account. The choice has been made to focus on the UDBHR rather than on regional texts, as for example the Convention for Bioethics of the Council of Europe.

2. History of Bio-ethics

The past four decades have witnessed the emergence and remarkable success of the fields of bioethics and medical humanities.[5] Due to the increasing globalisation of health problems and the economic globalisation in connection with the pharmaceutical corporations, bioethics has over the years been broadening and internationalising its view and methods. In the early years of this century this resulted in international agreements and organisations. The international face of bioethics is currently shaped by IBC's UDBHR of 2005.

In order to understand the change from the Hippocratic oath towards an international document, this part is devoted in analysing the way bioethics developed towards an international discipline. Emphasis will be put on the drivers of change, which created the existence of the discipline which was coined bioethics. The discipline came to existence due to different incentives in the 1970's. Currently other incentives are present, which can create an equally big change within the discipline. Bioethics has a developing definition and the development of gigantic pharmaceutical corporations and the increasing importance of global interdisciplinary problems connected with life sciences in a world full of inequalities, can create a new urgency for a more international focus of the discipline.

The developing definition of bioethics

Before delving into the history of bioethics, it is essential to grasp what bioethics is about. One of the most authoritative definitions is found in the Encyclopaedia of Bioethics of 1995, written by Warren Thomas Reich. He starts of by mentioning the etymology of the word bioethics, which is derived from the Greek words bios (life) and ethike (ethics).[6] It is important to note that, in this regard ethics does not solely refer to the rules, customs and beliefs of a society; it also 'names the scholarly effort to articulate and analyse those rules, customs and beliefs.'[7] Reich continuous to describe bioethics as 'the systematic study of the moral dimensions – including moral vision,

[5] Reich & McCullough, 1999, p.1.
[6] Reich (a), 1995, p. xix.
[7] Jonsen, 1998, p. 6.

decision, conduct, and policies – of the life sciences and healthcare, employing a variety of ethical methodologies in an interdisciplinary setting'.[8] The scope of Bioethics is described in the Encyclopaedia as encompassing 'the broad terrain of the moral problems of the life sciences, ordinarily taken to encompass medicine, biology, and some important aspects of the environmental, population and social sciences. The traditional domain of medical ethics would be included within this array, accompanied now by many other topics and problems.'[9]

At the core of American bioethics are the classical four principles of bioethics: respect for autonomy, beneficence, non-maleficence, and justice.[10] In the European bioethics the principles of autonomy, dignity, integrity and vulnerability are at its core.[11] The International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organisation created the Universal Declaration on Bioethics and Human Rights, which introduces a list of 15 principles, which are important to bioethics on a global scale. These principles are: human dignity and human rights, benefit and harm, autonomy and individual responsibility, consent, persons without the capacity to consent, respect for human vulnerability and personal integrity, privacy and confidentiality, equality, justice and equity, non-discrimination and non-stigmatization, respect for cultural diversity and pluralism, solidarity and cooperation, social responsibility and health, sharing of benefits, protecting future generations and protection of the environment, the biosphere and biodiversity.[12] As this thesis will focus on global bioethics, the latter principles will be taken into account.

In chapter 3 of this book the different views on the scope of bioethics will be discussed. It is fair to say that the definition of bioethics started of more narrow and is increasingly becoming broader, encompassing more and more themes. Global bioethics, which will be discussed further in chapter 3 of this thesis, makes use of the broad definition to create an international acceptable explanation of bioethics, which is connected to human rights. The three concerns, which will be introduced in the next part

[8] Reich (a), 1995, p. xxi.
[9] Ibidem, p. 250.
[10] Gillon, 1994.
[11] Rendtorff, 2002, p. 235.
[12] Article 3 till Article 17 of the Universal Declaration of Bioethics and Human Rights.

of the thesis are topics which are interesting to study from the viewpoint of global bioethics and human rights.

From medical ethics towards Bioethics

To understand the development of bioethics towards its usage, it is important to look at the roots of bioethics and the goals which one tried to reach with bringing this discipline to life. Part of the motivation to start bioethics include the disbelief in self-regulation and the increasing complexity of medicines and other health related instruments and activities.

From oath to ethics

Before the introduction of the discipline of bioethics, ethics were already present in the field of medicine.[13] Many scholars point back at 400 BCE when the Hippocratic Oath was written in Ancient Greece.[14] This oath has often been used for medical students to may strengthen a doctor's determination to behave in an ethical way in extreme situations.[15] It is hard to argue that the Hippocratic Oath has have had fundamental importance in the ethics of medicines during 2400 years. Historians argue that the Hippocratic Oath was of little importance at the time of writing, might not even reflect the ethics at the time and is probably not even written by Hippocratic. The oath disappeared during the time of the Roman Empire, only to be rediscovered by Medieval church scholars. Only as recent as the eighteenth century the oath started to play a role in graduation ceremonies in Europe and the United States. Today, 98% of American medical students still swears an oath, often an adaptation of the Hippocratic Oath.[16]

Around the same time the first steps began to make the public involved in ethical consideration of the field of medicine. The first laying open of the field of medicine occurred in the work of the eighteenth-century Scottish physician and philosopher John

[13] There are multiple ancient sources concerning medical ethics and deontology, such as 'The Laws of Hammurabi' (Ancient Babylon, 18th century B. C.), 'About the physician', 'The Oath' and 'The Law' by Hippocrates, (Ancient Greece, 5-4 centuries B. C.) and 'The Book of Life' (India, 5-4 centuries B.C.).
[14] Miles, 2005, p.3.
[15] Gillon, 2000, pp. 83-84.
[16] Sritharan, et al, 2001, p. 1440.

Gregory, who set out to create a profession of medicine in a true moral sense of a fiduciary profession by making medicine accountable for its scientific and moral quality. In 1767 he gave lectures about medical ethics at the University of Edinburgh.[17] He compiled these lectures and published them in 1772, under the title *Lectures on the Duties and Qualifications of a Physician*. Translations into German (1778), French (1787), and Italian (1789) followed shortly after.

Gregory lived in times wherein doctors were not familiar with code of ethics. The Scotsman was of the opinion that physicians were putting monetary interest before the patient, there was a different of treatment between the low-born and the high-born and the physician was generally 'hard hearted, focused on themselves to the exclusion of the needs of their patients'.[18] As a result he created a view of medical ethics, which is based on sympathy. His major concern was the ethics which physicians applied to their work.[19]

Following on the writings of Gregory, Thomas Percival (1740-1804) wrote the first professional ethics guide to physicians and firstly coined the term medical ethics.[20] He started being engaged in medical ethics after he was invited to head a committee which drafted rules of conduct for a hospital which closed, because of disagreement among the staff.[21] He then continued writing on the topic and was convinced that caring for the sick, the most important part of the profession of a physician or surgeon, should be in the centre of the profession. He put more emphasis on acting collectively and making codes of the entire profession, rather than talking about the personal ethics of a single doctor.

Although, some describe his book, *Medical Ethics or, a code of Institutes and Precepts adapted to the Professional Conduct of Physicians and Surgeons* (1803), as a

[17] McCullough, 1998, p. 173
[18] Ibidem 82.
[19] Ibidem.
[20] Percival, 1803.
[21] Baker & Emanuel, 2000. p. 13

gentleman's code,[22] the American Medical Association based its own code of ethical principles on his writings in 1847.[23]

History of Pharmaceutical Corporations

Having briefly delved into the world of medical ethics of about 200 years ago, we can conclude that the creation of medical ethics occurred because of the unsatisfactory ethical behaviour of doctors. Both John Gregory and Thomas Percival were led by the ethical flaws of some physicians, and saw the need for ethical guidance. Halfway the 19th century the American Medical Association started to incorporate the guidelines as a code to the guilt of medical practitioners.

One can also observe that the central concern to Medical Ethics was the physician and the surgeon. Although Percival devotes a chapter in his *Medical Ethics* to the relationship with pharmacists, the makers of medicines during these times did not get attention for the ones ethically concerned with the art of healing.[24] This is also not surprising given the grand importance of doctors at the time and the early innocent stages of pharmaceutical research and production. The latter argument can be well illustrated by the example of the discovery of chloroform by Sir James Young Simpson.[25] He discovered the anaesthetic qualities of chloroform by trying it out on himself and his friends in the night of 4 November 1847. After administering himself chloroform, he found himself on the floor, passed out of the new substance. That made him realise that this method could surpass ether, the previously used anaesthetic. Out of joy and curiosity he administered it many times to himself, his friends and a niece that same night.[26]

This way of discovering medicine was not out of the ordinary in the 19th Century. Although the common law started to accept the need of human experimentation and the vital role of patient's consent with that research, in most cases before the Second World War, the research of new pharmaceutical products continued

[22] Davis, 2003, p. 244.
[23] American Medical Association, History of AMA Ethics, at http://www.ama-assn.org/ama/pub/about-ama/our-history/history-ama-ethics.page? (consulted on 10-2013)
[24] Percival, 1849, p. 9.
[25] Rothman, 2003, p. 21.
[26] Gordon, 2010, p. 108.

on a small scale, with a limited amount of human research subjects. Most of the time the experimentation started at the home of the physician and the human guinea pigs were limited to the body of the investigator, his family, friends or neighbours.[27]

Although, in the early 1900's the personal link with the research subject was replaced by physicians experimenting on patients, research maintained a small scale endeavour. While some researchers started to place the experimental gains above the wellbeing of the patient and were discovering the ethical limits of experimentation, it was only during the Second World War, the world of medicine and pharmaceutical research started to change. The changing nature of the practicing of medicine also created new ethical questions and different kind of healthcare professionals, like big pharmaceutical corporations. These changes also created a shift in the thinking about medical ethics and made bioethics into existence.

The emergence of Bioethics

In the same way Gregory and Percival were unsatisfied with the ethical standards of their time, there was an enormous outcry about the lack of ethical medical standards used in the Second World War and also after it. This thesis is too short to delve into the cruelties of the Nazi human experiments[28] and the unethical experimentation on the side of the Allies.[29]. However it has to be noted that in the Nuremberg Military Tribunals, twenty-three defendants were accused of having been involved in Nazi human experimentation and mass murder under the guise of euthanasia. The judges of the so called 'Doctor's trial', created a nonbinding set of principles. This Nuremberg Code has never fully been translated into a national law or adopted as part of a code of ethics of a medical association. However it is fair to say that the code influenced medical ethics and human rights on a universal scale. Important to manage in this regard is that Article 1 of the Nuremberg code created the international recognized basic requirement of consent, which is articulated in international law in Article 7 of the United Nations International Covenant on Civil and Political Rights

[27] Rothman, 2003, p.21
[28] See, Annas & Grodin, 1992.
[29] Rothman, p. 30.

(1966)[30]. It is important to state that this proves the entanglement of human rights and bioethics was created at the start of the human rights movement. It is in this code where the medical ethics and the protection of human rights merged first.[31]

Post World War II

Although the atrocities in the field of medical ethics and especially human experimentation was universally known because of its total lack of ethics, the wakeup call to medical ethics did arrive yet. While human rights where of core concern of the United Nations, and the never-again-thinking of 'barbarous acts which have outraged the conscience of mankind'[32], the direct translation into what some call a paradigm shift from medical ethics to bioethics took an additional 25 years.[33] Only in the 1970's the term bioethics started to be used and the discipline started to grow in size and importance. The cause of this rise in bioethics can be explained by two main factors, the unethical behaviour of medical personnel and the rapid technological advancements in medicine.

Unethical Experimentation

Even after the sanctioning of the Nazi human experimentation in the Second World War, American researchers ran their laboratories free of external constraint, like laws or ethical bodies. The only ones they were responsible to for conducting human experiments, was their own individual conscience.[34] This inward-looking world of medical research and the paternalistic tradition in medical practice was reason for Henry Beechers[35] and Jay Katz[36] to write articles about the unethical use of human subjects.[37]

[30] Article 7 of the ICCPR, No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.
[31] Shuster, 1997, pp. 1436-1440.
[32] United Nations, Human Rights Declaration, 1948, preambular para. 2.
[33] Almeida & Schramm, 1999, p. 15.
[34] Rothman, 2003, p. 69.
[35] See, Beecher, 1966. In that article he talked about the frequency of unethical procedures in clinical research and names 22 studies, which were unethical.
[36] See, Katz, 1972. He created a historical overview of abuses in scientific experimentation on human beings.
[37] Brandt, Bioethics: Then and Now, at http://www.bucklin.org/bioethics-history.htm (consulted on 10 July 2013)

Rapid changes in medical science

As explained earlier, in the 19th century the practice of medicine did almost not use any instruments. [38] However, after World War II, 'explosive advances occurred almost simultaneously' in the area of medicine.[39] This relates to chances to the improvement and discovery of pharmaceuticals, but also in public healthcare.

In the United States the amount of hospital admissions per year increased from 146.500 in 1873 to over 29 million in the late 1960's. Also the amount of hospital beds soared in the US, from 400.000 in 1909 to 1.5 million in 1973. In the United Kingdom the amount of hospital beds per thousand inhabitants doubled in between 1860 to 1940. [40] This was caused mainly by the creation of government funding for healthcare. Additionally the costs of healthcare started rising towards 17.9% of the GDP in the US, while being around 3.5% to 7% in most African countries.[41] Practicing physicians were no longer alone part of the healthcare community, nowadays physicians are just a small amount of employees in the healthcare centre. In the United States only one in fifteen of persons working in the healthcare sector is a practising physician.[42] In this research was done in unethical on some human subjects and the industrialisation of medicine for them to be used on the battlefield started. It is there where the first multinational pharmaceutical firms started to exist and the ethical problems with it started.

Coining the term Bioethics

As mentioned above, the new ethical questions in the area of medicine due to the rapid developing technology and the idea, which Archer describes as 'dehumanizing technologism'[43], the idea that the development of medical science is above all, created the right setting for bioethics to establish itself. More and more scientists started to understand that the system to ethically scrutinise the field of medicine did not prevent the unethical situations, which Henry Beechers and Jay Katz described, from happening.

[38] Porter, 1999, p. 341.
[39] Bordley & McGehee, 1976., p. ix.
[40] Porter, 1999, p.334
[41] World Health Organisation, Health Financing, at http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html (consulted on 10 July 2013).
[42] Porter, 1999, p.334
[43] Archer, 1996, p.22.

A change was necessary, and the change, was called bioethics, which covers more than medical ethics. Since its origins in the early seventies, bioethicists have become 'a necessary supplement to the imperatives of political decision making' in many countries by acting as a broker between society, politicians and the medical profession.[44]

Warren Thomas Reich describes the origin of the word bioethics in the early 1970's as a bilocated birth. Both Van Rensselaer Potter, at the University of Wisconsin, and André Hellegers, at Georgetown University, came up with the word almost simultaneously.[45] The discipline tried to break with the traditional medical ethics, which focused around doctor-patient relationships. Topics as demographic growth, the regulation of birth, environmental preservation, the quality of life of future generations, relations between rich and poor countries, are part of bioethics and not of medical ethics.[46]

Potter wrote down the words bioethics first in his 1971 book, Bioethics, A Bridge to the Future. He defined bioethics broadly, as 'a new discipline that combines biological knowledge with a knowledge of human value systems.... I chose bio- to represent biological knowledge, the science of living systems; and I chose -ethics to represent knowledge of human value systems'.[47] He eventually selected the term global bioethics and this became the title of his second book.[48] Next to that he published a series of articles on his vision of bioethics as a bridge between the sciences and the humanities in the service of world-wide human health, and a protected environment.[49]

While Potter saw bioethics as a new discipline combining life science and philosophy, the Georgetown view of Hellegers regarded it as a branch of applied ethics.[50] According to the more dominant vision of Hellegers, the emphasis on the clinical component should remain, but the way to go about ethical issues had to be more

[44] Rose, 2007, p 97.
[45] Reich, 1995 (b), p. 19. However, Sas maintains in his article of 2007 that the German theologian Fritz Jahr used the term Bio-Ethik already in 1927. He did that with the intention to establish a new academic discipline, based on an ethical approach to issues concerning human beings and the environment. See, Sass, 2007.
[46] Cascais, 2007, p. 4.
[47] Potter, 1971, p. 2.
[48] Whitehouse, 2003, p. W28.
[49] Harvard Square Library, Van Rensselaer Potter: Global Bioethics 1911-2001, at http://www.harvardsquarelibrary.org/unitarians/potter.html (consulted on 11 July 2013).
[50] Cooter, 2004, p. 1749.

interdisciplinary.[51] Hellegers' narrow view of bioethics together with the principalsism from the Kennedy Institute of Ethics dominated the discipline, because the dilemmas that were labelled bioethical at Georgetown were of greater interest to physicians, the public, and policymakers than were the environmental concerns raised by Potter.[52] Hellegers view was that medical ethics had to be broader understood and was not an internal concern of doctors among each other anymore, but part of a societal discussion.[53]

However, with bioethics entering into the international level, a shift is noticeable towards a broader view of bioethics, which comes closer to Potter's original definition. Reich defines bioethics in this global sense as the 'ethics of the life sciences and health care'[54]. This understanding of bioethics means that bioethics goes beyond ethical issues in medicine to include ethical issues in public health, population concerns, genetics, environmental health, reproductive practices and technologies, animal health and welfare, and the like.[55] The growing interest in global health care ethics, disparities with respect to medical access and health outcomes, concerns about equity and distributive justice regarding new and emerging technologies, collaborative community-engaged research, and public health ethics are signs that bioethics is becoming more responsive to a more global vision of health-care ethics.[56]

[51] Reich, 1999, p. 25.
[52] Evans, 2000, p. 31.
[53] Ten Have, 2010, p. 71-73.
[54] Reich,W. T. 1995.The word "bioethics":The struggle over its earliest meanings.Kennedy Inst Ethics J 5(1):19–34, p 30.
[55] Ross, 2010, p. 452.
[56] Ibidem

3. Global Bioethics: adopting a Broad View

In the previous chapter the origins of bioethics out of medical ethics and as a reaction on rapid changes in the medical world and unethical behaviour, mostly in the area of clinical trials with human subjects, was clarified. In this chapter, the focus will be on the current view of bioethics and its interaction with globalization. According to the World Health Organisation, 'the prospects for future health depend to an increasing—but as yet uncertain—extent on the processes of globalisation'.[57] Due to globalisation, the problems the world is facing are increasingly tackled on a global scale, instead of in every particular country. Failing public health in one country can create increasing risks for infectious diseases to spread all over the world, as was exemplified by the SARS outbreak in 2003, the Bird flu and the Mexican flu.

More importantly in our case is the effect of economic globalisation on pharmaceutical corporations, which are trading, producing, researching and developing all over the world. While mostly based in the developed world, the influence of these gigantic corporations is far reaching, especially in developing nations. How does bioethics react on the switch from traditional national ethical problems related to physicians and public health, to the ethics of an international corporate influence on health?

Another question which will be dealt with in this chapter is related to the paradox of a globalising discipline, specialised in national discussions about ethics. In other words, bioethics is striving for a global approach, but the field 'is characterised by the multiplicity of religious convictions, historical references, philosophical systems and medical practices'.[58] It is even possible to create an international accepted version of something as culturally depended as bioethics?

[57] McMichael & Beaglehole, 2000, p. 498.
[58] Byk, C., Bioethics: Between Universalism and Globalisation, at http://www.iales.org/doc_anglais/Bioethics,%20between%20universalism%20and%20globalisation.pdf (consulted on 10 July 2013)

Globalisation and Global Bioethics

Globalisation also reached the area of bioethics; it is no longer possible for the discipline to hide from international challenges. It is the task of global bioethics to envisage solutions to ethical problems of technology and medicine which are faced by people all over the world. The challenge is that the solutions should transcend national borders and cultures. The relevance of global bioethics is obvious with respect to for example international research ethics, global vaccine initiatives and global health equity. According to Peter Singer, the founder of the International Association of Bioethics, almost any debate in medical ethics today must give consideration to global implications.[59]

The International Bioethics Committee (BIC) of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) supports the global bioethics perspective. The international organisation in the field of bioethics argued that it felt a 'necessity of setting universal ethical guidelines covering all issues raised in the field of bioethics and the need to promote the emergence of shared values'.[60] The debate in bioethics covers two concerns: '(a) the moral values that actually guide the behaviour of individuals and communities and (b) the moral values and priorities that should guide public policies at various levels on these issues. In this context, a truly urgent and universal issue is benefit-sharing and equal access to the advances of science and technology for all humanity.'[61]

International bioethical organisations and codifications

The interest in global bioethics is also confirmed by the increasing international activities of non-governmental[62] and governmental organisations on bioethics. Also international representation of physicians and pharmaceutical corporations are also

[59] Singer, 2000, p. 284.
[60] UNESCO, Universal Declaration on Bioethics and Human Rights, at http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/ (consulted on 10 July 2013).
[61] SHS/EST/02/CIB-9/5 (Rev. 3), 13 June 2003, p. 3, para. 11.
[62] Especially the British based Nuffield Council on Bioethics is active in getting bioethics on the international field, see Nuffield Council on Bioethics, Broadening bioethics: clinical ethics, public health and global health, at http://www.nuffieldbioethics.org/video/broadening-bioethics-clinical-ethics-public-health-and-global-health (consulted on 11 July 2013).

involved in influencing bioethics on a global level. These organisations are all interested in creating, shaping and influencing bioethical codes, guidelines, declarations, etc.. Bioethics has the need to be enforced through ethical codes, professional bodies, licensing boards, ethics committees, and a set of regulations, rules and laws.[63] The living proof of the existence of a thriving global bioethics environment is in these organisations and codifications of bioethical issues. The International Bioethics Committee and its Universal Declaration on Bioethics and Human Rights, will be at the centre of this part, as it is the first universal governmental agreement on the principles of bioethics.

The scope of bioethics in international codes and guidelines

Ethical codes of the medical associations in the field of bioethics are mostly focused on clinical trials involving human subjects. The most important is the Declaration of Helsinki (1964) of the World Medical Association (WMA). The World Medical Association, which represents physicians worldwide, created this voluntary code for its members, but it is more than that. Over the years the code has have been incorporated other 'international and national instruments, guidelines, laws, regulations, and other non-binding texts on human subjects research.'[64] It is seen as the most widely accepted guidance worldwide on this theme. [65] The WMA also created other global policy statements, but the scope stays limited. The focus of the WMA is with medical ethics, which is only a small part of bioethics. The approaching global bioethics has a wider scope than medical ethics and addresses issues which are less technical and medical, but more socially orientated. These include overcoming 'global inequities that are almost impossible to remedy'.[66]

The Council for International Organizations of Medical Sciences (CIOMS) introduced another voluntary code on medical trails involving human subjects, namely

[63] Hussein, 2009.
[64] Human & Fluss, The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspectives, 2001, at http://www.wma.net/en/20activities/10ethics/10helsinki/draft_historical_contemporary_perspectives.pdf (consulted on 10 July 2013)
[65] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2226192/
[66] Macpherson, 2007, p. 588.

the International Ethical Guidelines for Biomedical Research Involving Human Subjects of 1992. This is also a highly appreciated guideline on the same topic as the Helsinki declaration. It demonstrations the limited scope of the highly praised ethical guidelines as the ethics of human subject research have been part of medical ethics for many years. The broad scope which is adopted by the UDBHR is nowhere to be found in the codes of the federations.

The broad scope of the International Bioethics Committee and the Universal Declaration on Bioethics and Human Rights

Excluding the European Union's and Council of Europe's regional efforts relating to bioethics, the International Bioethics Programme of UNESCO is the most important international governmental meeting point, solely for the purposes of bioethics. The programme is part of UNESCO's Division of the Ethics of Science and Technology in the Social and Human Sciences Sector and was established in 1993. It exists out of two components, namely the International Bioethics Committee, Intergovernmental Bioethics Committee (IGBC). While the IBC is composed of 36 independent experts, the IGBC counts 36 representatives of Member States. Both of the committees are advisory bodies and cooperate with each other in order to advice, recommend and make proposals on issues of bioethics. These recommendations, proposals and advices are then submitted to the Director-General, in order to be considered by UNESCO's governing bodies.[67] Also part of the academic community of bioethics acknowledges the importance of the IBC. Michael Yesley stated about the meeting of the IBC he attended that it 'was an opportunity to witness several ongoing transitions in bioethics: from a philosophical to a legal orientation, from national to international standards, and from professional to political policymaking.'[68]

While, the IGBC, was established 5 years after the IBC and is meant to examine the advice and recommendation of the IBC at least every two year, the work of the IBC is more intensive. The IBC's objectives are the following:

[67] UNESCO, About the Bioethics Programme, at http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/about-bioethics/ (consulted on 10 July 2012).
[68] Yesley, 2005, p. 8.

'1. To promote reflection on the ethical and legal issues raised by research in the life sciences and their applications.

2. To encourage the exchange of ideas and information.

3. To encourage action to heighten awareness among the general public, specialized groups and public and private decision-makers involved in bioethics.

4. To co-operate with the international governmental and non-governmental organizations concerned by the issues raised in the field of bioethics as well as with the national and regional bioethics committees and similar bodies.

5. To contribute to the dissemination of the principles set out in the UNESCO Declarations in the field of bioethics, and to the further examination of issues raised by their applications and by the evolution of the technologies in question.'[69]

Interesting to note is that the cooperation, mentioned in point four does not explicitly mention corporations. However, the objectives do include the cooperation with non-governmental organisations, which can mean that be the organisations which represents the pharmaceutical industry. The UN does not define the term precisely, however it is commonly accepted that business and trade associations fall within the scope of the definition.[70] One way or another, the focus of the IBC is more with public policies than with the possibility of advising and guiding ethical policies for corporations.

The main achievement of the IBC is the creation of an international declaration that represents the universal principles of bioethics and human rights, the Universal Declaration on Bioethics and Human Rights (UDBHR).[71] According to Henk ten Have, director of UNESCO's Division of Ethics of Science and Technology at the time of the creation of the declaration, the document originated out of the concern of a lack of bioethical guidelines in developing countries and the fact that only fifty of the more

[69] UNESCO, International Bioethics Committee (IBC), at http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/ (consulted on 10 July 2013).
[70] Martens, 2002, pp. 273-274.
[71] Global Governance Watch, International Bioethics Committee Seeks to Make Civil Society Responsible for Health, at http://www.globalgovernancewatch.org/spotlight_on_sovereignty/international-bioethics-committee-seeks-to-make-civil-society-responsible-for-health (consulted on 10 July 2013).

than hundred ninety United Nations (UN) member states have national bioethics committees.[72]

As the title of the declaration already reveals, human rights are incorporated in the document. This incorporation was caused due to the influence of developing nations in the negotiations. There was a political need to connect bioethics with human rights in order to 'give it more clout' as Ten Have said.[73] Michael Yesley states that the movement to merge bioethics and human rights was captured in one quote of an Argentinean representative during the negotiations on the declaration, who said 'referring to bioethics without human rights is not bioethics.' [74] Later in this chapter, the relationship between human rights and bioethics will be further explained.

The declaration is a non-binding document, and serves as a commitment for Member States of the UN and the international community to respect and apply the fundamental principles of bioethics, which are defined in the declaration.[75] The document is meant to be the bioethical equivalent of the Universal Declaration of Human Rights. The declaration was forced to commit itself to the articulation of principles, rather than specific topics, as the latter would be impossible due to the lack of consensus. Therefore the declaration exists out of fifteen international principles of bioethics (article 3 to article 17).[76]Some are centred on the individual, others on the community and the last focus is on the world as a whole. It is concerned mainly with the ethical impact of medicine, science and technology on humans, but also touches on environmental and animal ethics. This means that it choses for a broader approach of Potter rather than the classic more limited approach to bioethics from Helleger.[77]

The scope of the UDBHR, although primarily addressed to Member States, includes the 'guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private', as noted in Article 1 paragraph 2 of the UDBHR. Also in the definition of the aims of Article 2 of the UDBHR,

[72] Wolinsky, 2006, p. 356.
[73] Ibidem, p. 354.
[74] Ibidem, p. 355.
[75] UNESCO, Universal Declaration on Bioethics and Human Rights, at http://unesdoc.unesco.org/images/0014/001461/146180E.pdf (consulted on 10 July 2013).
[76] ten Have, 2010, pp.73-74.
[77] Ibidem.

pharmaceutical corporations are included, as it is the aim of the UDBHR 'to guide the actions of individuals, groups, communities, institutions and corporations, public and private.' Article 21 on transnational practices also includes pharmaceutical corporations as it describes that 'states, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.'

The need for bioethical advancement for developing countries is one of the major priorities of the document. Serra, a consultant for UNESCO's Ethics Education Program, argues that the inclusion of social responsibility (article 14 of the UDBHR), including access to healthcare and essential medicines, is an example of an innovation which is helpful for developing countries.[78]

One of the big concerns regarding the globalisation of bioethics is the maintenance of cultural diversity of bioethics in a uniform document. Discussing the 'core moral disputes regarding matters of life and death, from abortion and euthanasia to the allocation of scarce medical resources, remain as points of cultural conflict, thus placing bioethics at the centre of the culture wars.'[79] As said before, the UDBHR committed itself to the articulation of principles, rather than specific topics. Article 12 of the UNBHR contains the principle 'respect for cultural diversity and pluralism'. This way the UNBHR fosters the many different cultures and views of bioethics and of topics of bioethics.[80]

UN Inter-Agency Committee on Bioethics

In March 2003, the UN Inter-Agency Committee on Bioethics was established in order to promote coordination and cooperation among different UN agencies, which are active in the field of bioethics, including its human rights aspects. The Committee meets at least once a year. The U.N. agency members of this committee are listed below:

Food and Agriculture Organization (FAO)

[78] Benatar, 2006, p. 18.
[79] Engelhardt, Jr. p. 31.
[80] ten Have & Jean, 2009, p. 1999

International Labor Organization (ILO)
Office of the U.N. High Commissioner on Human Rights (UNHCHR)
U.N. Educational, Scientific, and Cultural Organization (UNESCO)
World Intellectual Property Organization (WIPO)
World Health Organization (WHO)

Other international organizations are Associate Members, like the Council of Europe, the European Commission, the Organization for Economic Cooperation and Development (OECD), and the Arab League Educational, Cultural and Scientific Organization (ALECSO). The establishment of such an interdisciplinary international committee is a sign that global bioethics is increasingly important in many different policy areas.[81]

[81] ten Have, 2006, p. 337.

4. A Rights Based approach to Global Health

> '*i. Pharmaceutical companies, including innovator, generic and biotechnology companies, have human rights responsibilities in relation to access to medicines*'[82]

This is stated in the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines. Also the International Federation of Pharmaceutical Manufacturers & Associations, the representatives of the pharmaceutical industry on the global level, acknowledge that in the developing world 'multi-stakeholder initiatives have proven to be the most efficient and effective way of improving health status'.[83] How come that in this case, next to the classic responsible actor, the state, the corporate side of medicine also has a role to play in the problems relating to health in the developing world?

Millennium Development Goals and the right to health

Global health concerns are not only addressed in the area of bioethics. Human Rights and the Millennium Development Goals (MDG) also cover this discipline. MDG target 8E,' In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries,' and MDG 6,'combat hiv/aids, malaria and other diseases'. These two aspects of the MDG are giving a push to the United Nations and other international organisations and non-governmental organisations to focus on the right to health.

The United Nations claims that human rights are the basis to achieve the MDGs.[84] For these MDGs regarding global health the human right to health is of main importance. This right is noted in the third preambular paragraph of the Constitution of the World Health Organisation, article 25 of the Universal Declaration of Human Rights, article 11 of the International Covenant on Economic, Social, and Cultural

[82] A/63/263, 11 August 2008, preamble paragraph i, p. 15.
[83] International Federation of Pharmaceutical Manufacturers & Associations, About Access, at http://www.ifpma.org/global-health/ (consulted on 10 July 2013).
[84] Office of the High Commissioner for Human Rights, Human Rights are the basis for achieving the MDGs, at http://www.ohchr.org/EN/Issues/MDG/Pages/FoundationforEngagement.aspx (consulted on 10 July 2013).

Rights (ICESCR), Article 12 of the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) ; article 24 of the Convention on the Rights of the Child (CRC); and article 25 of the Convention on the Rights of Persons with Disabilities.

The most authoritative source of the interpretation of the right to health is General Comment No. 14 of the Committee on Economic, Social and Cultural Rights. It states that 'every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.'[85] It includes the availability, accessibility (including the four dimensions: non-discrimination, physical accessibility, affordability and information accessability) acceptability and quality of public healthcare.[86]

Human rights however are only legally binding towards states, as they are classically seen as the duty barriers of human rights. A state is responsible for regulating 'the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others.'[87] This means that the right to health is not directly applicable to non-state actors such as pharmaceutical corporations, but that the State is responsible to adopt 'all measurers necessary' in in order to prevent pharmaceutical corporations from infringing the right to health of third parties.[88]

The Human Rights Council (HRC) creates the mandate of the Special Rapporteur on the enjoyment of the highest attainable standard of physical and mental health. In 2007 he was requested by the HRC to 'to submit proposals that could help the realization of the health-related Millennium Development Goals'.[89] On the basis of MDG target 8E the special rapporteur consulted with pharmaceutical corporations[90] and

[85] Committee on Economic, Social and Cultural Rights, General Comment No. 14, E/C.12/2000/4, 11 August 2000, para. 1.
[86] Ibidem, para. 12.
[87] Ibidem, para 51.
[88] Ibidem.
[89] Human Rights Council, Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/6/29, 14 December 2007.
[90] This included an official visit to GlaxoSmithKlein, a pharmaceutical multinational, see. United Nations General United Nations General Assembly, the right to health, A/63/263, 11 August 2008, para 2.

created human rights guidelines for pharmaceutical companies.[91] These guidelines are very precise and assign various tasks on the pharmaceutical corporations.

One of the responsibilities that pharmaceutical companies have to take according to the guidelines is the adoption of 'a human rights policy statement which expressly recognises the importance of human rights generally and the right to the highest attainable standard of health in particular.'[92] Furthermore, the guidelines also ask from the company to 'publish a a comprehensive annual report, including qualitative and quantitative information, enabling an assessment of the company's policies, programmes, projects and other activities that bear upon access to medicines.'[93] These kinds of reports will be used in the research in chapter six of this thesis. Furthermore, the guidelines give in 12 pages a comprehensive overview of the human rights responsibility pharmaceutical corporations have towards access to medicine. The topics touched upon are: Disadvantaged individuals, communities and populations, transparency, management monitoring and accountability, corruption, public policy influence, advocacy and lobbying, quality, clinical trials, neglected diseases, patents and licensing, pricing, discounting and donations, ethical promotion and marketing, public private partnerships, and associations of pharmaceutical companies.

Another important player on global health is the World Health Organisation (WHO). Its Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), is concerned with the prices of medicine and the research for neglected diseases and takes the pharmaceutical corporations into account, however it does not refer to bioethics, but only to human rights and the millennium development goals.[94] Mainly the World Health Organisation takes a human rights based approach and only uses the term bioethics in connection to research involving human subjects.

Human Rights Based Approach

[91] Ibidem, appendix.
[92] Ibidem, para. 1.
[93] Ibidem, para 13.
[94] See, World Health Organisation, Public Health, at, http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf (consulted on 10 July 2013)

A human rights based approach is the preferable approach to take to development according to the United Nations. It is defined as 'A human rights-based approach is a conceptual framework for the process of human development that is normatively based on international human rights standards and operationally directed to promoting and protecting human rights.'[95] The approach goes beyond charity and focuses on rights-holders and duty-bearers. Normally the duty barrier is a State, however the responsibility of pharmaceutical corporations is increasingly emphasised. The difference between the State's and the pharmaceutical corporation's role as a duty barrier is that State's have the legal obligation to carry out human rights and pharmaceutical corporations have the social responsibility to do so, as international human rights are not binding towards corporations.

Health professionals' practice, typically governed by ethical codes, may benefit from human rights guidelines, clients' or communities' human rights are threatened.[96] Activities supporting accountability could range across a wide spectrum, from public critiques to litigation, although they are usually in an adversarial mode. Rarely do public servants and governments welcome being held to account - after all, who would want to be viewed as a human rights violator?[97]

[95] Office of the United Nations High Commissioner for Human Rights, Frequently Asked Questions on a Human Rights-Based Approach to Development Cooperation, at http://www.ohchr.org/Documents/Publications/FAQen.pdf, (consulted on 10 July 2013), p. 15.
[96] London, 2008, p. 65.
[97] Ibidem, p.70.

5. Three essential bioethical and human rights concerns regarding the Pharmaceutical Corporations operating in the Developing World

Due to the enormous technological, scientific and economic changes in the latter half of the twentieth century, many pharmaceutical companies have grown as enormous multinational corporations. Economic globalisation created transnational corporations which are located in countries around the world. Anderson and Cavanagh found in 2000 that of the 100 largest economies in the world, 51 are corporations; only 49 are countries.[98] The pharmaceutical world is no exception. Pfizer for example is the biggest pharmaceutical company and 37th biggest company of the world in 2013.[99] Its revenue of USD$58.99 billion is more than the GDP of Mozambique and Senegal combined.[100] All the revenues of the top 10 pharmaceutical corporations (USD$454,59 billion[101]), which represent over one third of the entire pharmaceutical market,[102] is about twenty times as much as the GDP of Zambia.[103] Together they employ 864.875 persons, twice as many people as there are living in Brunei.[104] In short, the pharmaceutical corporations are powerful players. It is also predicted that it stays that way, as it is predicted that North and South America, Europe and Japan will continue to account for a full 85% of the global pharmaceuticals market well into the 21st century. Furthermore, pharmaceutical companies currently spend one-third of all sales revenue on marketing their products, roughly twice what they spend on research and development.[105]

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[98] This is based on a comparison of corporate sales and country GDPs, Anderson & Cavanagh, 2000.
[99] Forbes, Pfizer, at http://www.forbes.com/companies/pfizer/ (consulted on 10 July 2013).
[100] CIA The World Factbook, Country Comparison: GDP, at https://www.cia.gov/library/publications/the-world-factbook/rankorder/2001rank.html / (consulted on 10 July 2013).
[101] Forbes, The World's Biggest Public Companies, at http://www.forbes.com/global2000/list/ (consulted on 10 July 2013).
[102] World Health Organisation, Pharmaceutical Industry, at http://www.who.int/trade/glossary/story073/en/ (consulted on 10 July 2013).
[103] CIA The World Factbook, Country Comparison: GDP, at https://www.cia.gov/library/publications/the-world-factbook/rankorder/2001rank.html / (consulted on 10 July 2013).
[104] CIA The World Factbook, Country Comparison: Population, at https://www.cia.gov/library/publications/the-world-factbook/rankorder/2119rank.html/ (consulted on 10 July 2013).
[105] World Health Organisation, Pharmaceutical Industry, at http://www.who.int/trade/glossary/story073/en/ (consulted on 10 July 2013).

According to the WTO there exists 'an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way'.[106] Roy Porter, describing the history of medicine, observes that there is a paradox in medicine, whereas the capabilities and the know-how of pharmaceuticals seems to develop fast and endlessly, the unfulfilled health requirements of impoverished societies remains existent. Medicine is the greatest benefit to mankind, but there has to be work done for the benefit to be practically accessible and usable in an ethical way for humankind as a whole.[107]

Pharmaceutical corporations are mostly criticized on several problems with an ethical dimension in their operations in the developing world. Underneath you will find a non-exhaustive list of three problematic topics which will be discussed in this thesis. These issues are: clinical trials with human subjects; the affordability of medicine; and research and development for neglected diseases. These topics are urgent, important and best described in the current academic literature. This focus is necessary due to the limitations of the length of this thesis. The decision to focus on the three below mentioned problems is taken with due regard to the other issues which are in no sense less problematic.[108]

Clinical trials with human subjects

The unethical aspects of testing new drugs in clinical trials in developing countries is romanticized and made popular in the book and subsequent movie adaption of the book 'the Constant Gardener'. This is based on the true story of clinical trials of Pfizer in Kano, Nigeria, in 1996. In this case Pfizer tested a drug on 100 children, which was not authorized by the Nigerian authorities and lacked the consent of the parents and

[106] Ibid
[107] Porter, 1999, p13.
[108] Other topics which are also important ethical concerns for the pharmaceutical industry include, but are not limited to: biopiracy, private public partnerships, workplace health and safety, transparency, public policy influence, advocacy and lobbying, cultural differences, appropriate use of medicine.

children. Five children died after taking the unapproved drug.[109] After several law suits, Pfizer agreed to a USD$75 million out of court settlement for all the victims.[110]

Many news agencies[111], NGOs[112], and academics[113] are concerned about the way that pharmaceutical corporations are conducting research with human subjects in developing nations. Around 30% of the studies on http://clinicaltrails.gov has been indicated to be in developing nations.[114] This means that the process of globalization also reached pharmaceutical clinical trials. Countries like India, China, South-Africa and Brazil are becoming more and more bases for clinical research, due to the increasing bureaucracy and costs of research with human subjects in the United States and Western Europe.[115] A first-rate academic medical centre in India charges approximately USD$1,500 to USD$2,000 per case report, less than one tenth the cost at a second-tier centre in the United States.[116] It is also interesting to note that the Indian government receives an estimated income of USD$1.7 billion in 2010, when 2 million Indians are estimated to have taken part in clinical trials.[117] Also the reporting of study results of clinical trials conducted in developing countries and published in academic journals has been increasing.[118]

The source of the concern of the shift of clinical trials to developing nations is the safeguarding of the ethics. Developing countries do not have many control mechanisms

[109] Washinton Post, Panel Faults Pfizer in '96 Clinical Trial in Nigeria, 2006, at http://www.washingtonpost.com/wp-dyn/content/article/2006/05/06/AR2006050601338.html
[110] Reuters, Nigerian claimants collect first Pfizer suit payout , 2011, at http://www.reuters.com/article/2011/08/11/nigeria-pfizer-idUSL6E7JB25Q20110811. (consulted on 10 July 2013).
[111] See for example, BBC, Have India's Poor become human guinea pigs?, 2012, at http://www.bbc.co.uk/news/magazine-20136654 (consulted on 10 July 2013) and Spiegel International, Drug Companies perform medical tests in developing countries, 2013, at http://www.spiegel.de/international/world/drug-companies-perform-medical-tests-in-developing-countries-a-899798.html (consulted on 10 July 2013).
[112] See for example, Nuffield Council on Bioethics, Research in Developing Countries, 2005, at http://www.nuffieldbioethics.org/research-developing-countries-follow (consulted on 10 July 2013) and Doctors Without Borders, Clinical Trials in Africa: Ethical Research Needed on Diseases, 2007, at http://www.doctorswithoutborders.org/news/article.cfm?id=2066 (consulted on 10 July 2013).
[113] See, Emanuel, et al., 2004 and Béréterbide & Hirsch, 2008.
[114] U.S. National Institutes of Health, Map of All Studies in ClinicalTrials.gov, at http://clinicaltrials.gov/ct2/search/map (consulted on 10 July 2013).
[115] Glickman, et al., 2009.
[116] Garnier, 2008, p. 75.
[117] Global Medicine, Clinical trials in developing countries, at http://globalmedicine.nl/issues/issue-5/clinical-trials-in-developing-countries-2/ (consulted on 10 July 2013).
[118] Glickman, et al., 2009.

in place for checking the ethics of clinical trials with human subjects and the human subjects themselves are seen as vulnerable. The International Bioethics Committee of UNESCO describes two important aspects causing the vulnerability of human subjects in developing nations. Firstly, 'the personal, economic or socio-political situation of potential research participants may render them vulnerable to exploitation'. A high illiteracy rate and sparse public healthcare services create a uniquely sensitive environment for vulnerable individuals.[119] Secondly, vulnerability increases due to 'the 'therapeutic misconception'. That means that persons may agree to participate in research with the false belief that there may be some benefit for them. In areas where healthcare services are not available or up to standards, as in developing countries, this misconception is more likely to occur. [120]

Next to the vulnerability of the human subject, the lack of resources, time, and space of the government to assess and inspect the ethics of a clinical trial is a cause of concern. In one study, only 25% researchers surveyed in developing countries reported that their research had been reviewed by a local institutional review board or health ministry.[121] In many countries of the African Region, national ethics and scientific review committees as well as national regulatory authorities require strengthening according to the World Health Organisation.[122] More broadly speaking, there is a lack ethics committees in the developing world who can monitor, study the conduct and follow-up effectively.[123]

The development of ethical standards for research with human subjects is one of the oldest issues within bioethics and goes to the core of the discipline. There are a handful of international documents, which articulate ethical standards regarding research of

[119] Karlberg & Speers, Reviewing Clinical Trials: Guide for the Ethics Committee, 2010, at http://www.pfizer.com/files/research/research_clinical_trials/ethics_committee_guide.pdf, (consulted on 10 July 2013), p. 75.
[120] UNESCO, The Principle of Respect for Human Vulnerability and Personal Integrity, 2013, at http://unesdoc.unesco.org/images/0021/002194/219494E.pdf (consulted on 10 July 2013) p. 16.
[121] Hyder, et al, 2004, p. 69
[122] World Health Organisation, Vaccine Regulations, at http://www.afro.who.int/en/clusters-a-programmes/vrg.html (consulted on 10 July 2013).
[123] Tornieporth, 2002, p. 54.

human subjects.[124] Mainly international research ethics require not merely that research risks are reasonable in relation to potential benefits, but also that they respond to the health needs of the population being studied. This is because, according to the principles of beneficence and justice, only research that is responsive to these needs can offer relevant benefits to the population.[125] This relates to the principles of benefit and harm, autonomy and individual responsibility and consent as stated in in article 4 to article 7 of the UDBHR.

It is important to note that 'free consent to medical or scientific experimentation' is also vastly rooted in the field of human rights, as it is part of Article 7 of the International Covenant on Civil and Political Rights.[126] However, the Human Rights Committee expressed its concern in 1992 in General Comment 20 on Article 7 about that specific aspect of the Article 7. It states that 'the reports of States parties generally contain little information on this point. More attention should be given to the need and means to ensure observance of this provision.'[127]

Next to the negligence of the article the article also presents a high threshold for medical experimentation to fall under article 7. It is important that the article does not rules out legitimate scientific and medical practices. Therefore it appears that only experiments that are seen as torture or cruel, inhuman or degrading treatment by nature are within the scope of Article 7. The World Organisation Against torture is of the opinion that other experiments which fall below this threshold are not included.[128] It seems, that bioethics is therefore of great importance for the experiments, which fall below the threshold.

The affordability of medicine

[124] See, Nuremberg Code, Helsinki Declaration, International Conference on Harmonization – Guideline for Good Clinical Practice & CIOMS International Ethical Guidelines.
[125] National Bioethics Advisory Commission, 2001, p. 8
[126] Article 7. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.
[127] Human Rights Committee, General comment No. 20., HRI/GEN/1/Rev.9 (Vol. I), 2008, p. 200, par. 7.
[128] World Organisation Against Torture, 2006, p. 173.

Expenditure on medicines accounts for a major proportion of health costs in developing countries. This means that access to treatment is heavily dependent on the availability of affordable medicines.[129] Doctors Without Bothers claims in its 2013 report about Antiretroviral drugs for HIV patients that, although the competition of generic manufactures of certain medicines makes the price drop substantially[130], the patent protected newer drugs are still extremely high priced.[131]

On the other side, the industry is characterized by high fixed costs for the research and development and low variable costs for the production of the medicine.[132] It is estimated that the development of a major drug costs over USD $1 billion and requires as long as 10 years to be introduced into the market.[133] Therefore, the corporation, with responsibilities towards their investors, also has the duty to make profit, like a healthy private corporation, in order to invest in the research and development of other new medicine. There are two well-known options to lower the price of medicine: differential pricing and patents.

Differential pricing is 'the adaptation of prices charged by the seller to the purchasing power of governments and households in different countries'.[134] This means that the pharmaceutical industry can establish a higher price for developed countries than for developing nations. There are some technical difficulties with differential pricing, the major one being parallel imports. This means that richer countries import the cheaper priced medicine from developing nations. This way of trading is called parallel, because it takes place outside and parallel with the distribution network that the

[129] World Health Organisation, Access to Medicines, at http://www.who.int/trade/glossary/story002/en/ (consulted on 10 July 2013)
[130] For example Brazil and China used the treat of compulsory licencing to obtain price reductions and voluntary licenses to manufacture generic medicine. See, Bloomberg, Brazil Pushes Merck, Pfizer to Cut Drug Costs Amid WTO talks, 28 August 2003, at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a_804W5JtnZc (consulted on 10 July 2013); Knowledge Ecology International, Recent example of the use of compulsory licenses on patents, 2007, at http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf (consulted on 10 July 2013)
[131] Doctors Without Borders, 2013, p. 27.
[132] Outterson, 2004, p. 201.
[133] Adams & Brantner, 2010, p. 141.
[134] World Health Organisation, Report of the Workshop on Differential Pricing & Financing of Essential Drugs, 2001, at http://apps.who.int/medicinedocs/en/d/Jh2951e/1.html (consulted on 10 July 2013).

pharmaceutical company maintains, while the drugs are similar.[135] Furthermore, there are discussions about the place of middle-income countries in the differential pricing debate and about the price the wealthy inhabitants of developing nations have to pay. Nonetheless differential pricing remains one of the most valuable instruments to create sustainable low prices for developing nations.

The second part of the pricing debate centres around patents. A patent gives a patent holder the right to exclude others from making, using or selling the invention. This right is created to reward the intellectual effort and work and compensates for the expenses for the research and experimentation leading up to the invention.[136] In the case of Patent protection has to last at least 20 years from the date the patent application was filed.[137]

Under Trade-Related Aspects of Intellectual Property Rights (TRIPS) rules of the World Trade Organisation (WTO), a voluntary licence is required if an entity other than the patent holder wants to market the patented product. However, in the case of a national emergency, extreme urgency, or public non-commercial use, the need for a voluntary licence can be waived and a compulsory licence issued by a judicial or administrative authority can be granted. In Doha, the WTO came to the agreement that countries could break patents in the interests of public health, it states that 'the TRIPS Agreement does not and should not prevent Members (of the WTO) from taking measures to protect public health.'[138] The Doha declaration also created the possibility for a developing country, which does not have the capacity to manufacture the medicine, to import it from another country[139].

However, developing countries have increasingly been pressured by developed states, mainly the United States, to accept TRIPS-plus clauses, in which increased

[135] World Intellectual Property Organisation, at http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm (consulted on 10 July 2013).
[136] World Intellectual Property Organisation, International Exhaustion and Parallel Importation , at http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf, (consulted on 10 July 2013), p. 17, par. 2.3.
[137] World Trade Organisation, fact sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions, at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (consulted on 10 July 2013), article 33.
[138] World Health Organisation, the Doha Declaration on the Trips Agreement and Public Health, at http://www.who.int/medicines/areas/policy/doha_declaration/en/ (consulted on 10 July 2013).
[139] 't Hoen, 2002, p. 34.

restrictions are imposed as part of bilateral free-trade agreements.[140] Furthermore, pharmaceutical corporations are discontented with states putting their patents aside in the name of public health and make it difficult for states to issue compulsory licences. This is exemplified by the many court cases the pharmaceutical industry started against the countries wherein compulsory licenses were used. Many of these lawsuits are very unpopular and puts the pharmaceutical industry in a bad corporate light. [141]

The right to health also includes the accessibility of essential medicines. In this case it is the 'economic accessibility' or differently put, the affordability of health, including medicines. General Comment No. 14 of the Committee on Economic, Social and Cultural Rights, regarding the right to health, puts the emphasis on the importance of the inclusion socially disadvantaged groups. Furthermore, the general comment states that poorer households should not be disproportionately burdened with health expenses as compared to richer households, supporting the idea of price differentiation.[142]

This concern is not a classical bioethical concern, as it has little to do with medical ethics, but rather with the wider aspects of bioethics, an unjust system which needs to be challenged in order to be ethical. Article 14, regarding social responsibility and health, of the UDBHR significantly broadens the agenda of bioethics and covers this concern. The IBC addresses the pharmaceutical industry in particular to take up social responsibility, which includes different aspects. Under the UDBHR a socially responsible company should have policies on access to treatment for developing countries which include the five priorities of pricing, patent, joint public private initiatives, research and development and the appropriate use of drugs. The IBC sadly concludes that instead of taking the ethical responsibility to define policies on access to

[140] Oxfam, Patents versus Patients : Five years after the Doha Declaration, at http://www.oxfam.org/sites/www.oxfam.org/files/Patents%20vs.%20Patients.pdf (consulted on 10 July 2013), p. 2.
[141] Examples of these law suits are the recent one in India and South-Africa, see Intellectual Property Watch, India's First Compulsory License Upheld, But Legal Fight Likely To Continue, 2013, at http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/ (consulted on 10 July 2013); Inter Press Service, Drug Companies Drop Lawsuit Against Governmen, at http://www.ipsnews.net/2001/04/health-south-africa-drug-companies-drop-lawsuit-against-government/ (consulted on 10 July 2013).
[142] Committee on Economic, Social and Cultural Rights, General Comment No. 14, E/C.12/2000/4, 11 August 2000, para. 12(b).

treatment, the involvement of corporations have been limited to charitable undertakings.[143]

The recent draft report of the IBC on the principle of non-discrimination and non-stigmatization (article 11 of the UDBHR) also mentions the concern of pricing and patents in the context of 'persistent problems'. Furthermore, the report gives positive examples of the use of TRIPS flexibilities by governments in the case of antiretroviral for HIV.[144] It is therefore fair to say that the IBC is deeply concerned with this matter and tries to put it to the center of the global bioethical debate.

Research and development for neglected diseases

Pharmaceutical corporations are private enterprises with a responsibility towards the shareholders to make profit. Therefore pharmaceutical companies do not make business decisions which are only ethically desirable, but financially irresponsible. This is especially the case for 'neglected diseases' and 'poverty-related diseases', the group of diseases which does not have an effective, affordable, or easy to use drug treatment.[145] The patients of those diseases are not few in number, but they located in low-income countries and therefore too poor to pay for the drugs.[146] The pharmaceutical industry therefore does not want to invest in the research and development of drugs of these diseases as it is too costly and risky to invest in low-return neglected diseases.[147]

Because of the absence of market incentives, there is a lack of new tools, diagnostics, drugs and vaccines for these diseases and research has been under-funded or neglected. Of the 1,556 new drugs approved between 1975 and 2004, only 21 (1.3%) were specifically developed for tropical diseases and tuberculosis, even though these

[143] UNESCO, Report of the International Bioethics Committee of UNESCO on Social Responsibility and Health, 2010, at http://unesdoc.unesco.org/images/0018/001878/187899E.pdf (consulted on 10 July 2013), para. 64-65.
[144] UNESCO, Draft Report of the IBC on the Principle of Non-discrimination and Non-stigmatization, 2013, at http://unesdoc.unesco.org/images/0022/002211/221196E.pdf (consulted on 10 July 2013) pp. 7-8.
[145] The World Health Organisation gives an overview of the 17 diseases it recognises as neglected tropical diseases, see: World Health Organisation, Neglected tropical diseases, at http://www.who.int/neglected_diseases/diseases/en/ (Consulted on 10 July 2013).
[146] Outterson, 2004, p. 212.
[147] Yamey, 2002, pp. 2-3.

diseases account for 11.4% of the global disease burden.[148] New numbers show that of the 850 new therapies and vaccines approved by the US Food and Drug Administration, the European Medicines Agency and other agencies between 2000 and 2011, 37 focused on neglected diseases, and just four of those were new chemical entities.[149] Public and private initiatives have tried to overcome this market limitation through incentive packages and public-private partnerships.[150] Private-sector research obligations should be explored, and a public-sector not-for-profit research and development capacity promoted.[151]

As with the previous concern about pricing, the UDBHR connected to this topic through article 14, regarding social responsibility and health, and article 11, regarding discrimination and stigmatisation. In both reports about these two articles the IBC expresses its concern about the The generalized lack of interest on the part of industry in research geared to the development of new vaccines and drugs to treat tropical diseases and ailments typical of the poor could be explained by the high cost of research and the small or negative profit margins to be expected.[152] It is recognized that lack of access to medicines for economic reasons is a clear case of discrimination, contravening the provisions of Article 2 of the Universal Declaration of Human Rights and Articles 11 and 14 of the Universal Declaration on Bioethics and Human Rights.[153] Again, similar to the concerns about pricing, the research and development side of pharmaceutical corporations is put as an important topic within global bioethics.

Nonetheless, the World Health Organisation chooses for a rights based approach towards neglected diseases.[154] It puts the right to health in in the centre of its 'Global

[148] Drugs for Neglected Diseases Initiative, Diseases & Projects, at http://www.dndi.org/diseases-projects/diseases.html (consulted on 10 July 2013).
[149] Willyard, 2013, p. 2.
[150] Trouiller, et al, 2002, p. 2188.
[151] Ibidem, p. 2188.
[152] UNESCO, Report of the International Bioethics Committee of UNESCO on Social Responsibility and Health, 2010, at http://unesdoc.unesco.org/images/0018/001878/187899E.pdf, para. 66
[153] UNESCO, Draft Report of the IBC on the Principle of Non-discrimination and Non-stigmatization, 2013, at http://unesdoc.unesco.org/images/0022/002211/221196E.pdf (consulted on 10 July 2013), para. 4.12.
[154] World Health Organisation, A Human Rights-Based Approach to Neglected Tropical Diseases, at http://www.who.int/hhr/activities/NTD%20information%20sheet%20-%20English.pdf (consulted on 10 July 2013), p. 2.

Plan to Combat Neglected Tropical Diseases'.[155] A human rights-based approach requires that the interventions and processes in response to neglected tropical diseases are guided by human rights principles, such as participation, non-discrimination and accountability.[156]

The three concerns in the context of the UDBHR

In the Report of the IBC called 'the Possibility of Elaborating a Universal Instrument on Bioethics', several themes were mentioned which could be of interest to mention for an basic universal instrument of bioethics, which later would be called the Universal Declaration on Bioethics and Human Rights. The preparatory documents refer explicitly in paragraph 24 to 26 to the research involving human subject. It specifically mentions the concerns of the exploitation of human subject in clinical trials in developing nations. Furthermore, in the chapter of 'Healthcare', another concern, namely the inequality between the access to medicine for rich and poor is seen as having immense ethical significance. The issue of parallel importation, generic medicine and compulsory licencing are explicitly mentioned in paragraph 18 of 'the Possibility of Elaborating a Universal Instrument on Bioethics'. Furthermore, the concern related to the pricing of medicine, intellectually property rights, is also deemed important in global bioethics according to the preparatory document from the IBC, as it is mentioned in paragraphs 27, 28, 29.[157]

While our third concern, neglected diseases of the developing countries, is not explicitly mentioned in the preparatory documents, in IBC's 'Draft Report of the IBC on the Principle of Non-discrimination and Non-stigmatization' it is unambiguously referred to. Neglected tropical diseases is listed as one of the three major persistent problems in that document. It is referred to in the draft report in the context of access to medication.[158]

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[155] World Health Organisation, Global Plan to Combat Neglected Tropical Diseases: 2008-2015, at http://whqlibdoc.who.int/hq/2007/who_cds_ntd_2007.3_eng.pdf (consulted on 10 July 2013), p. 7.
[156] World Health Organisation, A Human Rights-Based Approach to Neglected Tropical Diseases, at http://www.who.int/hhr/activities/NTD%20information%20sheet%20-%20English.pdf (consulted on 10 July 2013), p. 2.
[157] Ibidem, paras 27-29.
[158] SHS/EGC/IBC-20/13/2, 10 June 2013, p. 2.

It is safe to conclude that there is an interest in global bioethics due to globalisation and that our three concerns are taken up seriously by the discipline on a global level. According to Article 2 of the UDBHR it is its aim 'to guide the actions of individuals, groups, communities, institutions and corporations, public and private.' Is the engagement of the IBC towards these three topics enough to guide the actions of the pharmaceutical corporations? The following chapter will demonstrate the role of bioethics in the social responsibility documents of pharmaceutical corporations, the documents guide the actions of the company, something the IBC would be happy to influence.

6. The role of bioethics in the social responsibility reports of pharmaceutical corporations

This chapter will focus on the pharmaceutical corporation's social responsibility and the role that bioethics is playing in that. Previously this thesis developed the idea that, due to globalisation of health problems and the economic globalisation's effect on the exponential growth and power of the pharmaceutical industry, bioethics was developing into a universal phenomenon. The International Bioethics Committee makes reports based on the UDBHR which addresses the pharmaceutical industry. On the hand of the previously introduced bioethical and human rights concerns, this chapter will demonstrate the role that pharmaceutical corporations give to bioethics in their corporate social responsibility documents. It is interesting to see if they join the bandwagon of the expanding field of bioethics or if they focus more on the classical definition, which is narrower and closer to medical ethics.

It is expected that pharmaceutical corporations at least point to bioethics in relation to our previously introduced concern about clinical trials with human subjects. This relationship with bioethics would fit in both the wide and narrow definition of bioethics. The ethics of research on human subjects has been a primary concern of medical ethics and bioethics since the Second World War. Furthermore, the human rights dimension of this technical and specific issue is slim.

The other two concerns, the concern around the prices of medicine and the concern regarding neglected diseases are more related to the right to health and the access to essential medicine. The recent efforts of the former special rapporteur to include the pharmaceutical industry by creating specific guidelines for them, is expected to have more effect on the pharmaceutical industry than the introduction of the fifteen principles in the UDBHR. Furthermore, the lack of coordination with the World Health Organisation makes it unlikely that the UDBHR will find an entry to the

If this hypothesis is correct, it will demonstrate that the UDBHR and the IBC does not have a firm grip on the pharmaceutical industry. The area of bioethics which will create attention of the pharmaceutical industry are found in the gaps human rights has, especially in issues which are technical and need special medical awareness. The

question is then; does global bioethics as expressed in the UDBHR still have additional value for the pharmaceutical industry? Is it sufficient for bioethics to stay behind the scenes and concentrate on academic debates of these kinds, influencing human rights and therefore influencing the pharmaceutical industry indirectly? The latter questions will be answered in the following chapter.

The research design

To find out if the above written hypothesis holds, an analysis of the role of bioethics in the corporate social responsibility documents will be made. The five best scoring corporations of the 'Access to Medicine Index' are selected as the sample for the research. The Access to Medicine Index exists out of a ranking of the twenty largest pharmaceutical corporations.[159] The rationale behind choosing these corporations consists out of two parts. Firstly, taking these multinational pharmaceutical corporations assures that they are operating in the developing world and big enough to have an impact on the access to medicine in that area. Secondly, by being among the five best scoring pharmaceutical corporations in the Access to Medicine Index displays the willingness of a corporation to adapts its corporate policies towards a more ethical way of doing business. One can expect that they are the early adaptors in the field of social responsibility.

In the Access to Medicine Index of 2012 the following five pharmaceutical corporations scored the highest, from the number one to the number five of the index:

1. GlaxoSmithKline plc
2. Johnson & Johnson
3. Sanofi
4. Merck & Co. Inc.
5. Gilead Sciences

Furthermore, there are two type of sources used which will be scrutinised. Firstly it is the own documentation regarding social responsibility. These documents are

[159] See, http://www.accesstomedicineindex.org/ (consulted on 10 July 2013)

found on the website of the pharmaceutical corporation and are often called 'annual social responsibility report' or alternatively 'sustainability report'. In these documents the corporation itself explains their view on its social responsibility and their activities around certain topics. These documents can be compiled together or there are reports on specific topics.The second type of source is the company profile of the ten of the Access to Medicine Index of 2012. These profiles are compiled with the cooperation of the pharmaceutical industry and focuses on 7 technical areas.[160] These areas are: philanthropy, capability advancement, patents, pricing, research and development, public policy and management. Additionally the country profile focuses on four strategic pillars: innovation, performance, transparency and commitments. Our three bioethical and human rights concerns as listed in the precious chapter are represented in this report. The technical areas called pricing and patents are connected our affordability concern. Both the clinical trials with human subjects concern and the neglected diseases concern are discussed in the chapter of research and development in the company profile.

The above mentioned documents will be used as sources to answer the following fifteen questions, which will lead to the grand answer of the role of bioethics within corporate social responsibility of the pharmaceutical industry.

1. Does the corporation have public accessible documents outlining its corporate social responsibility approach?

2. Does it mention the concept of human rights?

3. Does it mention the concept of bioethics or medical ethics?

4. Does it mention the concern about clinical trails in the developing world?

5. Does it mention the concern about affordability?

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6. Does it mention the concern about the R&D for neglected diseases?

7. Does it mention the declaration of Helsinki, the Universal Declaration of Bioethics and Human Rights and/or any other bioethical code?

8. Does it mention any human rights documents?

These questions can all be answered with yes and no. When answered with a yes or no answer the type of questions 'when yes, how does it look like?' and 'When no, why not' will be addressed too. The answers of the latter type of questions is called 'extra information' in this study. For the questions 5, 6 and 7 the extra information part will describe if the concerns are met with a human rights approach or does it put the concern in a bioethical context.

Results

The answers on the above mentioned questions have been put into table and will be discussed underneath question per question.

1. Does the corporation have public accessible documents outlining its corporate social responsibility approach?

Corporation Name	Answer	Extra Information
GlaxoSmithKline plc	Yes	*The names of the documents which are which are taken into account are*:[161] Corporate Responsibility Report 2012[162]; GSK Human Rights Statement[163]; Clinical Trials in the Developing World;[164]

[161] Excluding the Company Profile of the Access to Medicine Index of 2012, which are available for all ten pharmaceutical corporations.
[162] Glaxo Smith Kline, Corporate Responsibility Report 2012, at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/cr-report-2012/gsk-cr-2012-report.pdf (consulted on 10 July 2013).

Johnson & Johnson	Yes	*The names of the documents which are which are taken into account are*: 2012 Citizenship & Sustainability Report[165]; Johnson & Johnson Statement on Human Rights.[166]
Sanofi	Yes	*The names of the documents which are which are taken into account are*: Corporate Social Responsibility 2012[167]; Human Rights Factsheet[168];
Merck & Co. Inc.	Yes	*The names of the documents which are which are taken into account are*: Corporate Responsibility Report 2011.[169]
Gilead Sciences	No	*The names of the documents which are which are taken into account are*: Only the Company profile of the Access to Medicine Index[170]

2. Does it mention the concept of human rights?

Corporation Name	**Answer**	**Extra Information**

[163] Glaxo Smith Kline, GSK Human Rights Statement, 2012, available at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/Human_Rights_Statement.pdf, (consulted on 10 July 2013).
[164] Glaxo Smith Klein, Clinical Trials in the Developing World, 2011, available at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/GSK-on-clinical-trials-in-the-developing-world.pdf (consulted on 10 July 2013).
[165] Johnson & Johnson, Annual Report 2012, at http://www.jnj.com/sites/default/files/pdf/2012-JNJ-Citizenship-Sustainability-ANNUAL-REPORT-June2013-FINAL062413.pdf (consulted on 10 July 2013).
[166] Johnson & Johnson, Statement on Human Rights, at http://www.jnj.com/about-jnj/our-citizenship/accountable-business-practices/johnson-and-johnson-statement-on-human-rights-2?&pageNo=1 (consulted on 10 July 2013).
[167] Sanofi, 2012 Report Corporate Social Responsibility, at http://en.sanofi.com/Images/32419_CSR_Report_2012_v3.pdf (consulted on 10 July 2013).
[168] Sanofi, Human Rights, http://en.sanofi.com/csr/download_center/download.aspx?file=Human_Rights_Sanofi_May_2013.pdf (consulted on 10 July 2013).
[169] Merck & Co. Corporate Responsibility Report 2011, at http://www.merckresponsibility.com/downloads/MRK_Report_Builder_Full_120824.pdf (consulted on 10 July 2013).
[170] Access to Medicine Index, Company Profile: Gilead Sciences, at http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/company/downloads/company_profile_access_to_medicine_index_2012_27nov12_final_gilead.pdf (consulted on 10 July 2013).

GlaxoSmithKline plc	Yes	It states in its Human Rights Statement that: 'businesses have a role to play in safeguarding human rights; we support and are committed to upholding the Universal Declaration of Human Rights and the core labour standards set out by the International Labour Organisation. GSK is also a signatory to the UN Global Compact.'[171]
Johnson & Johnson	Yes	Furthering Human Rights is one of the goals described in the annual report.[172] The right to health care is mentioned in the human rights statement.[173]
Sanofi	Yes	It refers to all 21 human rights in its human rights policy statement. 'Sanofi has adopted an ambitious and holistic approach based on initiatives to progress in order to ensure that human rights are soundly integrated throughout all the Group's operations'.[174]
Merck & Co. Inc.	Yes	Merck & Co. has a commitment to protecting and promoting fundamental human rights.[175]
Gilead Sciences	No	

3. Does it mention the concept of bioethics or medical ethics?

Corporation Name	**Answer**	**Extra Information**
GlaxoSmithKline plc	No	The only mentioning of ethics is made in the context of the marketing of medicines[176]
Johnson & Johnson	Yes	It refers to bioethics in the context of clinical research; animal testing; stem cell research; nanotechnology; biotechnology; Xenotransplantation.
Sanofi	Yes	Sanofi has a bioethics Committee since 2010, which is limited to its research strategy.[177]

[171] Glaxo Smith Kline, GSK Human Rights Statement, 2012, available at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/Human_Rights_Statement.pdf, (consulted on 10 July 2013).
[172] Johnson & Johnson, Annual Report 2012, at http://www.jnj.com/sites/default/files/pdf/2012-JNJ-Citizenship-Sustainability-ANNUAL-REPORT-June2013-FINAL062413.pdf (consulted on 10 July 2013)., p. 5
[173] Johnson & Johnson, Statement on Human Rights, at http://www.jnj.com/about-jnj/our-citizenship/accountable-business-practices/johnson-and-johnson-statement-on-human-rights-2?&pageNo=1 (consulted on 10 July 2013).
[174] Sanofi, 2012 Report Corporate Social Responsibility, at http://en.sanofi.com/Images/32419_CSR_Report_2012_v3.pdf (consulted on 10 July 2013), p. 1.
[175] Merck & Co. Corporate Responsibility Report 2011, at http://www.merckresponsibility.com/downloads/MRK_Report_Builder_Full_120824.pdf (consulted on 10 July 2013). p. 18.
[176] Glaxo Smith Kline, Corporate Responsibility Report 2012, at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/cr-report-2012/gsk-cr-2012-report.pdf (consulted on 10 July 2013), p. 36.

Merck & Co. Inc.	No	No mentioning of either of the two.
Gilead Sciences	No	

4. Does it mention the concern about clinical trials in the developing world?

Corporation Name	Answer	Extra Information
GlaxoSmithKline plc	Yes	'GSK-sponsored clinical trials world-wide are conducted according to the same fundamental ethical principles. The studies meet international and national regulatory and legislative requirements.'[178] It uses public position statements to make its vision clear.[179]
Johnson & Johnson	No	Although it mentions the ethics behind clinical trials, it does not provide for extra information about their efforts in the developing world.
Sanofi	Yes	Sanofi assesses the vulnerability of human subjects in resource poor settings. This is done in the context of bioethics. [180]
Merck & Co. Inc.	No	Although it mentions the ethics behind clinical trials, it does not provide for extra information about their efforts in the developing world.
Gilead Sciences	No	Although it mentions the ethics behind clinical trials, it does not provide for extra information about their efforts in the developing world.

5. Does it mention the concern about affordability?

Corporation Name	Answer	Extra Information
GlaxoSmithKline plc	Yes	It spells out their achievements in flexible prising and the establishment of an Developing Countries and Market Access operating unit[181].
Johnson & Johnson	Yes	It mentions the Millennium Development Goals in this context;
Sanofi	Yes	It refers to differential pricing, but without a bioethics or

[177] Sanofi, 2012 Report Corporate Social Responsibility, at http://en.sanofi.com/Images/32419_CSR_Report_2012_v3.pdf (consulted on 10 July 2013), p 39.
[178] Glaxo Smith Klein, 2011.
[179] Access to Medicine Index 2012, Country Profile of GlaxoSmithKline plc, 2012, at http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/company/downloads/company_profile_access_to_medicine_index_2012_03122012_final_gsk.pdf (consulted on 10 July 2013), p. 6.
[180] Sanofi, 2012 Report Corporate Social Responsibility, at http://en.sanofi.com/Images/32419_CSR_Report_2012_v3.pdf (consulted on 10 July 2013), p. 39.
[181] Glaxo Smith Kline, Corporate Responsibility Report 2012, at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/cr-report-2012/gsk-cr-2012-report.pdf (consulted on 10 July 2013), p. 18.

		human rights context.
Merck & Co. Inc.	Yes	We respect the right to health for all people and work toward expanding access to care.
Gilead Sciences	Yes	It is seen as a best practise for patens and pricing, but without a bioethics or human rights context.[182]

6. Does it mention the concern about the R&D for neglected diseases?

Corporation Name	**Answer**	**Extra Information**
GlaxoSmithKline plc	Yes	It does not refer to bioethics or human rights norms, but to nongovernmental initiatives such as the London Declaration.[183]
Johnson & Johnson	Yes	It refers to the concern about neglected diseases as an objective to advance global health. Human rights nor bioethics is mentioned in this context.[184]
Sanofi		It does not refer to bioethics or human rights norms, but to nongovernmental initiatives such as the London Declaration.[185]
Merck & Co. Inc.	Yes	Merck & Co. understands that the role of the pharmaceutical industry in respecting and promoting health as a human right is complex. 'We believe that our most basic role is our core activity of discovering, developing and delivering medicines and vaccines to address unmet medical needs.'[186]
Gilead Sciences	No	Below average performance, no cures in pipeline for neglected diseases.[187]

[182] Access to Medicine Index, Company Profile: Gilead Sciences, at http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/company/downloads/company_profile_access_to_medicine_index_2012_27nov12_final_gilead.pdf (consulted on 10 July 2013), p. 9-13.
[183] Glaxo Smith Kline, Corporate Responsibility Report 2012, at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/cr-report-2012/gsk-cr-2012-report.pdf (consulted on 10 July 2013), p. 24.
[184] Johnson & Johnson, Annual Report 2012, at http://www.jnj.com/sites/default/files/pdf/2012-JNJ-Citizenship-Sustainability-ANNUAL-REPORT-June2013-FINAL062413.pdf (consulted on 10 July 2013), p. 14
[185] Sanofi, 2012 Report Corporate Social Responsibility, at http://en.sanofi.com/Images/32419_CSR_Report_2012_v3.pdf (consulted on 10 July 2013), pp. 4 & 12
[186] Merck & Co. Corporate Responsibility Report 2011, at http://www.merckresponsibility.com/downloads/MRK_Report_Builder_Full_120824.pdf (consulted on 10 July 2013). p. 32.
[187] Access to Medicine Index, Company Profile: Gilead Sciences, at http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/company/downloads/company_profile_access_to_medicine_index_2012_27nov12_final_gilead.pdf (consulted on 10 July 2013), p. 7.

7. Does it mention the Declaration of Helsinki, the Universal Declaration of Bioethics and Human Rights or any other bioethical codes?

Corporation Name	Answer	Extra Information
GlaxoSmithKline plc	Yes	It only refers to the Helsinki Declaration and to the International Conference on Harmonization Good Clinical Practices guidelines.[188]
Johnson & Johnson	Yes	It only refers to the Declaration of Helsinki and the Belmont Report.[189]
Sanofi	No	It does not refer to international standards.
Merck & Co. Inc.	Yes	the Declaration of Helsinki, the International Conference on Harmonization Good Clinical Practices guidelines, and the 1997 UNESCO Declaration on the Human Genome and Human Rights.[190]
Gilead Sciences	Yes	It mentions the Declaration of Helsinki.[191]

8. Does it mention any human rights documentation?

Corporation Name	Answer	Extra Information
GlaxoSmithKline plc	Yes	UN Declaration of human rights, the UN Guiding Principles on Business and Human Rights. Additionally GlaxoSmithKline is a signatory to the UN Global Compact.[192]
Johnson & Johnson	Yes	UN Declaration of Human Rights, The International Covenant on Civil and Political Rights and The International Covenant on Economic, Social and Cultural Rights.[193]
Sanofi	Yes	UN Declaration of human rights, the UN Guiding

[188] Glaxo Smith Kline, Corporate Responsibility Report 2012, at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/cr-report-2012/gsk-cr-2012-report.pdf (consulted on 10 July 2013), p. 41.
[189] Johnson & Johnson, Annual Report 2012, at http://www.jnj.com/sites/default/files/pdf/2012-JNJ-Citizenship-Sustainability-ANNUAL-REPORT-June2013-FINAL062413.pdf (consulted on 10 July 2013), p. 23.
[190] Merck & Co. Corporate Responsibility Report 2011, at http://www.merckresponsibility.com/downloads/MRK_Report_Builder_Full_120824.pdf (consulted on 10 July 2013). p. 23.
[191] Access to Medicine Index, Company Profile: Gilead Sciences, at http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/company/downloads/company_profile_access_to_medicine_index_2012_27nov12_final_gilead.pdf (consulted on 10 July 2013), p. 8.
[192] Glaxo Smith Kline, Corporate Responsibility Report 2012, at http://www.gsk.com/content/dam/gsk/globals/documents/pdf/corporateresponsibility/cr-report-2012/gsk-cr-2012-report.pdf (consulted on 10 July 2013), p. 36.
[193] Johnson & Johnson, Statement on Human Rights, at http://www.jnj.com/about-jnj/our-citizenship/accountable-business-practices/johnson-and-johnson-statement-on-human-rights-2?&pageNo=1 (consulted on 10 July 2013).

		Principles on Business and Human Rights, International Covenant on Economic, Social and Cultural Rights, and the UN Guiding Principles on Business and Human Rights. Additionally Sanofi is a signatory to the UN Global Compact.[194]
Merck & Co. Inc.	Yes	United Nations Global Compact and as defined in the United Nations Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights[195]
Gilead Sciences	No	

Analysis of results

Although the results of this research cannot be generalised due to its low external validity, because of the small amount of pharmaceutical corporations, it does not counter the hypothesis that a broadly defined global bioethics is not adopted in the social responsibility documents of pharmaceutical corporations

All but one pharmaceutical corporation publish their social responsibility reports online and many of them have a specific human rights policy statement. Showing the importance of the human rights based approach. This emphasis on human rights is also illustrated by the mentioning of the concept of human rights and referring to basic human rights documents in all the social responsibility reports which are published online.

In contrast, the discipline of bioethics is only literally mentioned infrequently in these reports. Although the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practices guidelines are mentioned are frequently mentioned by the pharmaceutical companies, the UDBHR is not mentioned at all. Furthermore, the concept of bioethics is mentioned only in its traditional narrow definition as it relates to clinical research with human subjects only.

[194] Sanofi, Human Rights, http://en.sanofi.com/csr/download_center/download.aspx?file=Human_Rights_Sanofi_May_2013.pdf (consulted on 10 July 2013), p. 1.
[195] Merck & Co. Corporate Responsibility Report 2011, at http://www.merckresponsibility.com/downloads/MRK_Report_Builder_Full_120824.pdf (consulted on 10 July 2013). p. 28.

Furthermore, only Merck refers to the right to health and human rights in relation to the concerns of affordability and the research and development of neglected diseases. The other documents are mostly attentive of these problems, but do not mention the bioethical or human rights responsibility it originates from. Sanofi is the only one who puts a bioethical assesses the vulnerability of human subjects in resource poor settings in its reports. Although it refers to bioethics, it refers to bioethics in the narrow kind of the word, rather than in the broad bioethics envisioned by the UDBHR.

In short, the hypothesis is confirmed by the research on five pharmaceutical corporations. The human rights approach has a much more stringent grip on the social responsibility of pharmaceutical corporations. While the basic human rights documents are explicitly mentioned in all the reports, the, what supposed to be, bioethical counterpart of the United Nations Declaration of Human Rights is not mentioned at all.

This makes one wonder what the role of bioethics, as mentioned in the UDBHR, should be in the social responsibility of pharmaceutical corporations, when the rights based approach is deeply integrated in its core. The following chapter will explorer the competitive advantage of bioethics by using the method of a SWOT analysis.

7. The competitive advantage of Global Bioethics

Having seen that bioethics as defined by the UDBHR is not able to be integrated in the social responsibility documents of the pharmaceutical corporations, bioethics should look towards itself and think what their place can be, based on their weaknesses and strengths. While the UDBHR includes human rights, the human rights based approach towards the right to health is firmly established that it can also pose a threat to the relevance to the discipline of bioethics. The dominance of human rights in influential international organisations and non-governmental organisations is hard to replace by a new developing discipline of global bioethics. The UDBHR is a document based on compromises, which makes it a collection of principles, which often miss the interpretation of their practical meaning.

This chapter will apply a SWOT (strengths, weaknesses, opportunities and threats) analysis on the discipline of bioethics as it is envisaged by the UDBHR. The Joint Research Centre of the European Commission describes the SWOT analyses as a useful tool to improve the competitiveness of a company, region or country.[196] However a SWOT analysis can do the same for a discipline which struggles with its place among other disciplines.[197]

A SWOT analysis consists out of two main parts, the internal factors and external factors that have an impact on the development of the organisation and in this case the discipline. The internal factors consists out of strengths and weakness of the organisation, while the external factors list threats and opportunities by analysing the environment the discipline is located in. The environment in this case is the one of a human rights approach dominance. In order to strategically develop and to create a competitive advantage, the discipline should match their strengths with the opportunities and overcome weaknesses and ward of threats. [198]

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[196] The European Commission Joint Research Centre, SWOT Analysis, at http://forlearn.jrc.ec.europa.eu/guide/2_scoping/meth_swot-analysis.htm#Who_for (consulted on 10 July 2013)
[197] Blayney, 2008, p. 53.
[198] The European Commission Joint Research Centre, SWOT Analysis, at http://forlearn.jrc.ec.europa.eu/guide/2_scoping/meth_swot-analysis.htm#Who_for (consulted on 10 July 2013).

This SWOT analysis will display the strengths and focal points of the discipline, where it excels over a human rights based approach. The hypothesis is that bioethics is broader and more specialised on complicated, technical medical issues. However, it misses the obligatory nature and the adaption in different international organisations and non-governmental organisations. BIC itself and the view BIC has on bioethics is fairly unknown. One of the most promising opportunities is to adopt the language of human rights, as it is increasingly seen as the dominant language of international organisations. However, bioethics should focus more on new approaching issues in the area of the ethics of the life sciences and biology, especially the more technical and medical ethical concerns.

The strengths

1. The broadness of the discipline.

'The UDBHR has the broadest scope of any other bioethics document that existed before.'[199] The broadness of the discipline of bioethics that the UDBHR envisions makes it possible for bioethics to take a holistic approach to problems. While human rights scholars have to get their mandate from international human rights. The bioethicist can reflect on the ethics of any problem that life sciences and biology throw at it. This way no limitations are posed on the ethical reflection of new problems. The technological developments and changes due to globalisation keep challenging ethicists to form opinions and debates on topics which human rights could not anticipate.

2. Expertise in medical and technical areas

Bioethicists have more knowledge about specific medical and technical areas than human rights scholars. Due to their academic background, as many are medical doctors, and their experience in the field of life sciences and biology. One of these areas is

[199] Benatar, 2006, p. 18.

research with human subjects, others are for example cloning, xenotransplantation and eugenics.

3. Constructing the foundations of new rights

Due to its wide definition and various methods, bioethics is quick with creating moral viewpoints and ideas about emerging issues. It can make codes and guidelines quicker than human rights can pass legislation through the General Assembly of the United Nations. These discussions, codes and guidelines can be seen as the start of laws, even human rights laws. In this way bioethics can influence human rights, by being the first to open the discussion on emerging problems at the intersection of the ethics with life sciences and biology.

The weaknesses

1. Lack of knowledge and authority of the UNDBHR

Even practitioners in the field are not aware of the existence of the UNDBHR.[200] Although the document is out since 2005, it still ' has achieved little attention, and few are likely to aspire to its ideals'. [201] The IBC is not a well-known institution as the human rights council of the UN is. Their actions do not reach as far and are not carried out by different organisations of the UN. The language of human rights has been an integral peace of international organisations and non-governmental organisations alike. The language of bioethics has not gotten that far, because its steps on the international stage are still new.

2. No practical guidance

[200] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2226192/
[201] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2652798/

It has been said about the UNBHR that it offers no 'practical guidance'[202] Due to the concessions which are made in order to gain consensus on the document, the view on bioethics has been explained by broad principles. These principles are broad in order to gain consensus, but are hard to put into practical use. The uncertainty of the consequences of the use of these principles comes from the fact that they have not been interpreted and made specific yet. A system like the authoritative interpretation of human rights by general comments is missing.

3. Young document

Global bioethics is 'the attempt to agree on fundamental conditions for human flourishing and to secure them for all … [I]t is a task that cannot be achieved by one generation.' [203] The document is still very new, as it was created this century. The Human Rights Declaration of 1948 was also not popular from the start. The popularity of human rights only started in the 1970's, two decades later after the introduction of the declaration.[204] With time the authority, the knowledge and the practical use of the document will improve.

The opportunities

1. Adopting the *lingua franca* of the international community

For international governmental organisations and nongovernmental organizations (NGOs), such as Amnesty International, Global Lawyers and Physicians, and Doctors without Borders 'human rights has become a kind of moral–political Esperanto.'[205] It has been accepted as the 'language of international ethics' and is now becoming 'the lingua franca of the new global bioethics.'[206] This discourse created a universally shared

[202] Ibidem.
[203] Ibidem.
[204] Moyn, 2010, p. 4.
[205] Santos, 2002, p. 282.
[206] Arras & Fenton, 2009, p. 27.

framework for addressing ethical problems. Bioethics has to adopt this language in order to make a point on the international stage. Reasoning from human rights articles in connection with bioethics, makes the discipline more interesting for above described parties. However, one has to take into account that human rights statements are 'declarations of what is obligatory', while 'bioethics documents are frequently exploratory or speculative in nature, arguing about what may or may not be permissible or necessary.'[207]

2. Making use of the human rights based institutions

When adopting the language of human rights, bioethics can 'enjoy the political support of a worldwide network of influential international organizations'.[208] There is an institutional framework in use for human rights. National and international organisations are used to adopt human rights documents and put them as a priority in their values. Bioethics can enter more doors of more organisations, increasing its influence when it knows how to connect to these organisations. Now bioethicists are more seen as working from their ivory tower and discussing among each other, rather than advocating through organisations and pushing for change, like human rights.

The threats

1. Bioethics is too political

Behaving on an international level and wanting to create change through international governmental organisations like the United Nations, politics have to be practised. The influence of politicians on the UDBHR has made the document a shadow of what it could be. The document wants to be seen as a powerful international consensus about bioethical issues. However by having to create a consensus for political reasons, the

[207] Wolinsky, 2006, p. 356.
[208] Arras & Fenton, 2009, p. 27.

power of the document declines. Diplomatic language starts to be used and 'many countries would feel that a stronger statement is necessary.'[209]

2. Bioethics will be subsumed by human rights

Udo Schuklenk, is not so positive about the increasing merger of bioethics and human rights. About the UDBHR he states that, 'the United Nations being the United Nations, human rights is the end-all of anything to do with ethics. So the result was that any other approach to ethical thinking was basically taken out of the document.'[210] Faunce also states that 'norms previously considered within the sole province of bioethics and medical ethics' are now taken over by international human rights law.[211]

It is therefore important that when bioethics takes over the discourse of human rights, it does not lose its own identity of philosophical reasoning from different angles. The involvement with human rights should not make bioethics a discipline with a single view of international morality, the one of human rights. Bioethics should actually challenge.

The SWOT-analysis shows that the strength of the new Global Bioethics is in its broadness and the quick way of reacting. The ethical philosophical discussion before the construction of a right should be the focus of bioethics. Furthermore, the technical and medical knowledge about many changes in the life sciences is only vested within bioethics. Although, bioethics wants to expand from these technical issues to social issues, bioethics should not lose this part of its discipline.

Due to the recent publication of the UDBHR it is still a document which needs to be interpreted to make the principles more clear. Furthermore, it lacks attention from other organisations. The IBC has to involve different stakeholders in the process of the clarification of the articles, to attract more attention to the document.

Furthermore, the new global bioethics which is developing, should adopt the language of human rights, but not its practises. It should stay on a philosophical level

[209] Wolinsky, 2006, p. 355.
[210] Wolinsky, 2006, p 356.
[211] Santos, Faunce, 2005.

and have ethical discussions with different viewpoints. However, one can relate these discussions to the rights, in order to free ride on the available institutions and interest which human rights gathered over decades.

The inclusion of the UDBHR into the social responsibility of the pharmaceutical corporations will stay marginal due to the broadness of the principles. Only where bioethics can fill the gaps of human rights regarding medical issues, which are too specialised and technical for human rights, bioethical principles and codes can flow into the social responsibility of pharmaceutical corporations. In this regards human rights trump bioethical principles.

Conclusion

Currently we can definitely not speak from a tentative 'bioethical responsibility' of pharmaceutical corporations operating in the developing world. Although bioethics has a role to play in the corporate responsibility it is not comparable to the role human rights is taking in the debate. In the case of new, technical medical innovations, like eugenics and cloning, where no societal consensus is reached up on yet, does bioethics play a big role. Bioethics also plays a big role in the field of clinical trials with human subjects. However, the social side of medicine, which is created due to inequalities in the delivery of health, because of prices and lack of research is covered by human rights. The Universal Declaration of Human Rights has been approved sixty years earlier than the Universal Declaration of Bioethics and Human Rights. Now it is seen as 'the way' to go about change in an international setting. The emphasis of a human rights based approach in many organisations, makes the new global bioethics stand alone. To link itself with human rights and go along with the rights based approach is possible, however, bioethics needs to hold on to its competitive advantage. It complements human rights in being more philosophical and better at home in the life sciences. It is ideal for topics where human rights did not delved in yet.

In short, this thesis developed an overview of the change of focus within bioethics. Starting of with a gentleman's code for physicians and ending with a global discipline which is searching for a holistic approach to the crossing of ethical problems with the life sciences and biology. Globalisation and technical advancements create new concerns for bioethics. The concerns about global health and the increasing power of pharmaceutical corporations are part of the need of bioethics to leave its national home and try it on the international stage. The same way as bioethics evolved out of medical ethics, global bioethics starts to evolve from bioethics.

The biggest devotee of global bioethics is the International Committee on Bioethics of UNESCO. It pushes global bioethics to the broadest point of its definition with the Universal Declaration on Bioethics and Human Rights. This is the first political document of bioethics and is supposed to be the base of future global bioethics. It mainly consists of fifteen principles, which were introduced as a way to create

consensus among the different State's. The result is that a consensus is reached, but that the power of the document is lost. The principles are not precise enough to build up on, it needs interpretation and experience to see how these principles develop. The interesting part is that the document also takes corporations in its scope. The goal is to influence corporations to abide by the principles. The International Bioethics Committee has already created documents which talk about the responsibility of the pharmaceutical corporations on certain issues, like the vulnerability of human subjects of developing nations, the affordability of medicines and the need for research and development on neglected diseases.

Human rights and mainly the right to health, also take up these above mentioned concerns. The special rapporteur is consulting with pharmaceutical corporations about possible solutions for these concerns and others. These consultations resulted in the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines. These guidelines are based on a human rights approach to global health, are precise and developed with consultation of the pharmaceutical industry. Furthermore, the rights bases approach is endorsed by other United Nations organs and by the biggest policy scrutinisers of the pharmaceutical industry, non-governmental organisations, like doctors without borders.

It is therefore not surprising that only a little bit of bioethics was found next to a bunch of human rights in the corporate social responsibility reports of several pharmaceutical corporations. Bioethics was only named into connection with classical issues as eugenics, xenotransplantation and the bioethical codes regarding human subjects in clinical trials. While the Universal Declaration of Bioethics and Human Rights was not named once, almost every corporate social responsibility report named the Universal Declaration of Human Rights.

The SWOT-analysis points out that it is necessary for the discipline of bioethics to take over the international language of ethics, the one of human rights. This way it can free ride on the name and fame of human rights. However, bioethics should remain pluralistic, broad and on top of the newest developments in the area of the life sciences.

In conclusion, the role of bioethics in the corporate social responsibility of pharmaceutical corporations is small, but not unimportant. In order to be better

established on the international stage bioethics needs to obtain the human rights discourse.

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